ASSESSING HEALTH CARE NEED FOR PROSTATECTOMY

by

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Abstract

This thesis describes a study that estimated the health care need for prostatectomy in a typical district of 250,000, among men who have both the appropriate indications for treatment and who would choose treatment if offered. It established the appropriate indications for prostatectomy using a literature review and a nominal group type consensus panel consisting of 6 urologists and 3 general practitioners. These were expressed in terms of different combinations of type of retention, type and severity of symptoms, and level of comorbidity. A 2-stage community survey of 2000 men aged 55 and over randomly selected from 8 general practices, using postal questionnaires, was conducted in North West Thames health region. The surveys collected information about: (1) self-reported frequency and severity of lower urinary tract symptoms; (2) the impact of these symptoms on daily activities and on health status; (3) the advice-seeking behaviour of men with symptoms and consequent action of GPs and urologists; and (4) patient preference for treatment. These results were combined to estimate the number of prostatectomies required in a typical district.

The overall response rate was 66% (initial survey=78%, follow-up survey=84%). 20% of men reported moderate or severe lower urinary tract symptoms. Of these, 28% found their symptoms to be a medium or big problem and that, depending on the activity, between 9% and 39% experienced interference with their daily activities. Health status, as measured by either the Nottingham Health Profile or the SF-36, worsened as symptom severity increased. Forty five per cent of men with symptoms had seen their general practitioner for their symptoms. Of these, 62% were referred on to a urologist, of which the majority (71%) were offered, and accepted surgery. When presented with details and information on the risks and benefits of prostatectomy, a substantial proportion (22%) of men with lower urinary tract

symptoms, reported that they would probably, or definitely, refuse treatment, while a 47% of men were unsure. The estimate of required number of prostatectomies in a district with a population of 250,000 ranged from 225 to 4329 depending on the level of appropriateness, symptom severity and preference adopted. The decision about which estimate to use in purchasing prostatectomy for lower urinary tract symptoms must be made by local authorities.

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Chapter 1 - Introduction

A consequence of the 1990 reform of the National Health Service is that health authorities must now assess the health needs of their populations and purchase appropriate care to meet these needs (1). There is little detailed information on the need for health care, (ie. the number of people in the population who would benefit from treatment) because: it is difficult to identify those people with appropriate indications for treatment in the population; little is known about the acceptability of many interventions to individuals; and it may be difficult to relate the prevalence of those with appropriate indications to the annual need for treatment.

Benign prostatic hyperplasia (BPH) is the commonest cause of lower urinary tract symptoms affecting middle-aged and elderly men. The provision of treatment for these symptoms has become of increasing interest to health service purchasers because there is evidence that they are more common than previously thought (2). In addition new forms of treatment are becoming widely available, although their effectiveness is still being evaluated and prostatectomy remains the treatment of choice (3-8). Knowledge of the prevalence of lower urinary tract symptoms and their impact on men form the basis of the four measures required by those involved in the planning and provision of services for BPH: 1) the number of men in the population experiencing urinary symptoms that bother them (felt need); 2) the number of men with symptoms who seek treatment (demand); 3) the number of men considered by general practitioners and surgeons to be in need of treatment, based both on men's urinary symptoms and on clinical findings (normative need); and 4) whether individuals choose to receive treatment after being presented with information about interventions and their risks and benefits. Assessing the health care need for prostatectomy should be based on these measures, but little information is available.

1.1 How many men in the community have lower urinary tract symptoms?

Detailed information on the prevalence and severity of symptoms is scarce and estimates vary widely. In general health surveys of men over the age of 65, between 16% and 40% report having either urinary symptoms or having had a previous prostatectomy, or both [Spain - 16%; USA - 25%; Israel 40%] (9-11). A household survey undertaken in Michigan in 1983-84 found that 35% of men over the age of 60 had one or more symptoms of prostatism (12). A review of general practice case notes in the United Kingdom (U.K.) suggested that 6% of men over the age of 60 had undisclosed "marked prostatism", based on the presence of four urinary symptoms, and a further 14% had "mild prostatism", with three symptoms (13). In a questionnaire administered to men over the age of 60 who attended a health screening clinic in the U.K., 18% reported five or more urinary symptoms (14). A recent population-based study, defining BPH using a combination of urinary symptoms, flow rates, and prostatic size, reported a prevalence among Scottish men aged 40 to 79 of 253 per 1000 (2). A virtually identical study of 2,119 men aged 40-79 in Minnesota found that prostatism rose from 26% in the 40-49 age group to 46% in the 70+ group, higher than the prevalence found in the Scottish study (15).

Little is known about the impact, in terms of bothersomeness and health status, that urinary symptoms have on men in the community. The only data from a representative sample of the general population in the U.K. (the Scottish study mentioned above) found that 77% of men with BPH, reported at least one bothersome urinary symptom compared with 47.2% of men who did not have the condition and that the relative difference increased as the reported number of urinary symptoms increased (16). These men were more likely than men without symptoms to have less 'general well-being'(17) and to experience interference in their activities of daily living

such as: limiting fluids before travel (7.5%) or bedtime (10.3%), inability to drive for 2 hours (5.7%), not having enough sleep (7.4%), limiting visits to places without toilets (7.9), limiting playing sports (2.7%) and limiting visits to cinema, theatre, church etc. (3.3%) (16). A study that compared the results of two similar studies in Scotland and the U.S.A. concluded that although there were differences in the prevalence of urinary symptoms (more men in Minnesota reported greater frequency and more bother) the impact of symptoms on interference in daily activities was the same (18).

1.2 Do men with symptoms seek health care?

There is little evidence about the extent to which men seek medical advice for their urinary symptoms, and what factors determine their behaviour. The only study that examined this, found that a third of otherwise healthy men in Denmark, with frequency, post-micturition dribbling, and a weak stream, believed that their symptoms did not justify seeking treatment (19).

1.3 What are the appropriate indications for prostatectomy?

Patients proceeding to prostatectomy commonly present with acute retention, chronic retention or a complex of lower urinary tract symptoms that include hesitancy, poor flow, terminal dribbling, frequency, feeling of fullness, urgency and nocturia (20). A review of published reports suggests only limited agreement about the appropriate indications for prostatectomy. For example, while some authors state that acute retention, in the absence of detrusor failure or neuropathic obstruction, is an absolute indication (21), others argue in favour of conservative treatment for those who can void successfully after a period of catheter drainage (22,23). A urologist in Scotland reported that acute retention was the only indication for which he would perform a prostatectomy (24). A recent study of the practice behaviour of urologists concluded

that consensus about appropriate practice has yet to be achieved (25).

The range of clinical opinion about the appropriateness of surgery is reflected by wide variation in prostatectomy rates both between and within countries (26). Reported prostatectomy rates in western countries vary considerably, from 60 to 368 per 100,000 (27-30). The standardized prostatectomy ratio adjusted for age and private sector contribution varies in English regions from 77 to 144 (England=100) (29,31). There is little evidence that the variation results from differences in the prevalence of BPH, but rather, from the supply of surgical services, including the availability of surgeons and their judgment of the clinical appropriateness of surgery (30,32,33).

There is further controversy about whether to treat lower urinary tract symptoms or to treat clinical measures of obstruction and whether to perform surgery early to avoid the greater risk when the patient grows older or to limit surgery to those patients with symptoms significantly affecting their quality of life (33). These arguments have assumed greater importance following the publication of reports casting doubt on previous beliefs about the level of risk associated with transurethral resection of the prostate (TURP)(3) and claims that up to 75% of TURPs performed in the United States may be inappropriate (34).

1.4 Do men want treatment?

Even after being offered treatment, men may not wish to accept it. In a British study, 30% of 107 men with 'minimal symptoms' on a waiting list for prostatectomy declined surgery after being reassured about the natural history of prostatic obstruction (35). An American study to validate a quality of life questionnaire among men awaiting prostatectomy was forced to exclude 37 men (55%) when they elected not to have

surgery (36). An initiative to clear a waiting list for prostatectomy in the U.K. reported that 38 (16.4%) declined urological surgery, although the authors did not provide a detailed breakdown to permit identification of those awaiting prostatectomy (37). In another Danish study, 11 men out of 72 (15%) who were referred for surgery refused treatment because they did not perceive their symptoms to be severe enough (38). Preliminary results from studies in the United Kingdom and the United States of symptomatic men considering prostatectomy suggest that many choose to decline surgery after viewing an interactive video disc that provides information on the risks and benefits of treatment (39,40).

As part of the American Health Care Policy and Research (AHCPR) review of clinical practice guidelines for the treatment of BPH, a panel conducted two preference analyses (7). The first panel presented non-urologist physicians and Ph.D. medical researchers over the age of 60 with symptom severity scenarios and asked them to rank treatment outcomes in order of importance. The second surveyed actual patients with mild, moderate and severe symptoms. In both groups, most patients with mild symptoms chose 'watchful waiting', those with moderate symptoms showed a wide range of preferences, and those with severe symptoms chose surgery (7).

1.5 Conclusion

The health care need for prostatectomy has not been assessed adequately because there is insufficient information about: 1) the prevalence and severity of lower urinary tract symptoms; 2) whether men with symptoms seek treatment; 3) the appropriate indications for prostatectomy; and 4) whether prostatectomy is acceptable to men with the appropriate indications. The purpose of this thesis is to estimate the number of men in a typical district who would benefit from having a prostatectomy and who

would accept treatment if offered it. The following two chapters will: 1) review the literature on health care needs assessment; 2) review the methodological issues relevant to assessing the need for prostatectomy; and 3) present a plan of the thesis.

Chapter 2 - Health care needs assessment

Introduction

A need for health care has been defined as 'the ability of an individual to benefit from health care and exists where he or she has a condition for which there is an effective and acceptable intervention' (41). The definition emphasizes the 'benefit arising from the intervention', which can be curative, preventive or palliative. Benefit depends on the effectiveness of care and is achieved through a change in health status (42). In theory and in practice, there are many difficulties in assessing health care need. These arise because different disciplines bring their own perspectives to need and because the terms need, demand and use are often used interchangeably and incorrectly to equate use and demand to need. This chapter will: 1) explain the recent interest in needs assessment in the U.K.; 2) outline several concepts of need; 3) distinguish between need, demand and use; 4) describe the different approaches to needs assessment; and 5) propose a model for assessing health care need.

2.1 Recent background to needs assessment in the U.K.

In 1988 and 1989, the government published two important white papers on health which resulted in a major restructuring of the NHS. The first of these, Public Health in England (the Acheson Report), called for strengthening traditional public health interventions and recommended that district health authorities make their planning and management decisions on the basis of epidemiological assessments of the population (43). The Acheson report was followed by Working for Patients, published in 1989, that created an internal market for health care within the NHS (1). The internal market, dividing the provision of health care into purchaser and provider organisations, came into effect on April 1st, 1991. Health authorities and general practitioners holding their own budgets became responsible for purchasing health care

from providers, which included hospitals managed directly by health authorities and others that opted for managerial autonomy within the NHS. The reforms arising from Working for Patients require purchasers of health care to negotiate contracts with providers in order to ensure that the delivery of health care meets the health care needs of the population. The government believes that the reforms will enable the NHS to provide a higher quality service to those who need it in an effective and efficient way. Working for Patients clearly stated:

> District health authorities can then concentrate on ensuring that the health care needs of the population for which they are responsible are met; that there are effective services for the prevention and control of disease and the promotion of health; that their population has access to a comprehensive range of high quality, value for money services (1).

The idea of assessing the health needs of the population is not recent. There have been several attempts to measure the need for and evaluation of, health services (44). In 1957, Morris proposed an 'epidemiology of health services' and cautioned that assessing need as a basis for health planning was a formidable exercise (45). In 1975, the Resource Allocation Working Party (RAWP) was established in an attempt to allocate health care resources to regions in Britain according to need (46). However, they had no direct measure of need and were forced to use standardized mortality ratios (SMRs) as an indirect measure of health, rather than health care need. A review undertaken to explore the use of hospital utilisation data as an alternative to using SMRs as part of the RAWP formula found that hospital utilisation data were a poor measure of need because they provided no indication of the appropriateness of different rates of hospital use among socio-economic groups, or of the distribution of unmet need needs in the population (47). In addition the allocation formula reflected existing pattern of supply of hospital services. Subsequently, more sophisticated models have been constructed, using two-stage least squares

regression, in an attempt to separate supply factors from need (48).

Aside from the specific factors in the U.K., there are several more general reasons for the current interest in using needs assessment in the planning and provision of health care. Increasing costs and demands in all industrialised countries have forced governments to examine and reform their health systems. Increasing evidence of variations in rates of clinical interventions has led to questions about the provision of many forms of treatment (49,50). Politicians and managers have drawn attention to many treatments shown to be harmful or inefficacious, or not demonstrated to be beneficial (51,52). Purchasers of health care are interested in these findings because they suggest that treatments are either being withheld or provided inappropriately. This will be 1) expensive for the purchaser, 2) harmful to patients from whom treatment is withheld; or 3) harmful to patients who are treated unnecessarily. The necessity to rationalise expenditures coupled with the knowledge that some interventions may be ineffective, has stimulated the government to create a situation for health authorities and general practitioners to purchase care that is both effective and for which there is a demonstrated need in its population.

Since the publication of Working For Patients in 1989, a number of publications about needs assessment have appeared (53-57). In general, these papers, written by public health physicians, managers, planners, academics and clinicians, began to propose methods for, and discuss some of the pitfalls of health care needs assessment. To clarify the Department of Health's position, the NHS Management Executive published a discussion paper in 1991 identifying three levels of health needs assessment: corporate, comparative and epidemiologic/economic (58). The paper advocated a pragmatic approach that would facilitate decision making in the short term. This

approach combined corporate needs assessment (the opinions of specialists and GPs) and comparative needs assessment (the comparison of service provision with other areas) to provide an achievable 'needs agenda' for many district health authorities. Subsequently, the NHS Management Executive commissioned a series of reviews summarizing existing knowledge about incidence, prevalence and effectiveness (59).

2.2 Concepts of health care need

There is considerable confusion about the definition of health care need. First, there is a difference between the health care need of an individual (of interest to individuals and to carers), and the sum of these needs in the population (of interest to purchasers and providers of health care). The health care need representing the aggregate need for health care in a population is the focus of this discussion. Secondly, there is a distinction between the need for health, and the need for health care. It is well recognized that health implies much more than the absence of disease and is influenced by factors outside of the health sector such as education, income level, environment. By comparison, health care refers to a specific intervention, offered with the aim of improving an individual's health status. An aggregate health care need may be said to exist where a population has the ability to benefit from an intervention. This health care need has been termed a 'health care requirement' as distinct from health needs, or the neediness of the population as used by the nineteenth century social reformers (55). It has been argued that the confusion between these meanings has been responsible for the lack of interest in determining the level of need for particular health care interventions (55).

A further problem has arisen as a result of the different disciplines that have been involved in assessing need, including epidemiology, health economics, health services research and sociology. There have been few attempts to bring these groups together. Epidemiologists are interested in measuring the distribution and determinants of health in the population. Consequently, their activities have traditionally been directed towards describing the incidence and prevalence of disease in the population rather than measuring the number of individuals in a population who could benefit from treatment.

An economic approach to assessing health care need is based on the principle that resources are scarce, and that some health needs can be shown to be greater than others by using measures of relative benefit such as quality-adjusted-life-years (QALYs). The implicit assumption of the health economic approach is that priorities can be set to maximize benefit within available resources. It has been argued that economic needs assessment can determine a threshold level for treatment or services, below which funding would be unavailable (60), although others have countered that the use of priority setting is not needs assessment, but rather follows from it (61,62), as it must be based on evidence that the intervention studied can bring about benefits to the target group. A well publicised attempt, in Oregon, to generate a set of health care priorities using cost-benefit analyses has proved unworkable (63).

A framework developed by a sociologist has been often used to distinguish different types of social need (64). The framework is comprised of four different types of need: normative, felt, expressed and comparative. Normative needs are identified by experts or professionals and are often defined in terms of standards or thresholds.

Comparative need, or the comparison of needs between groups in the population, defined on the basis of area of residence, gender or social class, is based on the assumption that different areas require similar provision of services, reflecting equal need relative to each other. Felt need is need that is perceived by individuals. Expressed need, or demand, is a felt need expressed as a demand for a service.

Although this classification is useful in distinguishing different aspects of needs, its use in assessing the need for health care is limited. Normative needs assessment, on its own, is of little use in identifying the need for health care for several reasons: 1) professionals may disagree about appropriate standards; 2) standards may change over time as new knowledge about interventions becomes known; and 3) it does not consider the population distribution of health care needs. Information about the effectiveness and appropriateness of the intervention, if explicit, is usually determined from literature reviews or by clinical consensus. Comparative need is confounded by other explanations for differences in rates between areas, such as supply factors (number of beds or surgeons, or differences in clinical practice) (47,48). The definition of comparative need often contains the implicit assumption that the higher rate is correct, which may be untrue. Felt need is a poor measure of the need for health care because individual's perception of their own health is affected by their own values and knowledge. Individuals differ in their expectations of health and in their knowledge about the benefits of treatment. Illness behaviour varies between personalities and cultures. The need for health care may not be recognized by individuals if they are asymptomatic. Finally, these four categories of need are not mutually exclusive and different combinations are possible. For example, a need for a service may be normatively defined (recognized by professionals), felt (perceived by individuals) but not expressed (individuals do not seek treatment).

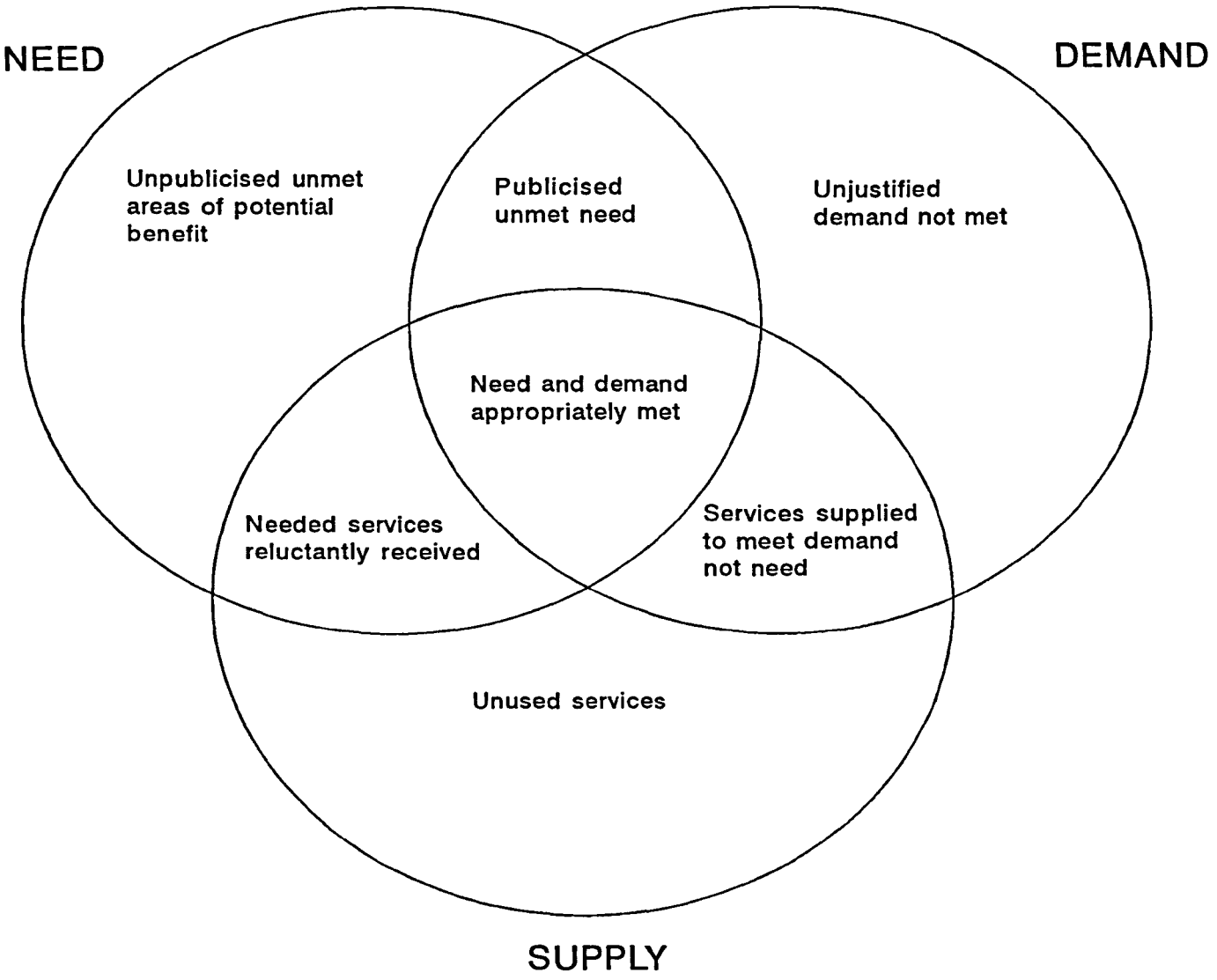
2.3 Need, demand and use

Further confusion over the use of the term 'need' has arisen because the terms need, demand and use are often used incorrectly. They are distinguished as follows: need is what people can benefit from, demand is what people ask for, and use is what people obtain (56). Thus the demand for health care occurs when an individual perceives their health status to warrant lay or formal health care. If the carer judges that the individual will benefit from care, then the demand for care is translated into the use of health care. The differences between need and demand can arise from differences in illness behaviour and those between demand and use arise from differences in clinical judgment. Measures of demand and use are often incorrectly equated with need. Figure 2.1 illustrates the relationship between need, demand and use. Measures of need should be free of the influence of supply or availability of care (thus population based) and should reflect contemporary population characteristics rather than historical ones.

2.4 Measuring health care needs

The variety of approaches to measurement of health care needs reflects the confusion surrounding the definitions used. They depend on which approach to need is being considered. Thus they can include: epidemiology, demography, effectiveness of services, quality of services, comparative analysis with other districts or regions, consumer's views of services, a corporate review, which takes account of the interests of local people, general practitioners, providers, clinicians, other agencies, the regional health authorities and the NHS executive. Health care 'needs' have been measured both directly and indirectly (65). Direct measures have included: health care utilisation data, case registries and population reports of morbidity. Indirect measures have included socio-demographic characteristics, measures of deprivation and

Figure 2.1 The relationship between need, demand and use.



measures of mortality. Data sources for assessing health care need include: 1) health indicators; 2) existing utilisation data; 3) waiting lists as a measure of expressed demand; and 4) surveys (66).

2.4.1 Health indicators

Health indicators include routinely collected data such as mortality rates or morbidity rates from disease registers. Their application to assessing health care need is limited because the data: 1) measures health (or lack of it), not health care need; 2) mortality data reflects the experience of people who have already died and are thus of largely historic relevance; and 3) does not account for health problems that people do not seek care for. Methodological problems include errors arising from misdiagnosis, incomplete death certification and classification, and coding errors.

2.4.2 Existing utilisation data

Utilisation data are derived from routinely collected statistics from hospital or from primary care. Need derived from hospital utilisation is biased because it is heavily dependent on existing levels of supply of services and historical patterns of care (47). Supply factors, such as the number of beds or the number of physicians, and access to care, are an important determinant of the utilisation of these services. In addition, needs assessments based on utilisation data assumes that the existing level of service provision does not change over time and that the existing service is both appropriate and comprehensive. Health care needs assessment based on utilisation data relies on historical patterns of care which may have become entrenched and may be of little value to local needs. An example of this is the high density of hospitals in inner London, when most of the population now live outside London. Data are also subject to varying levels of inaccuracy (67). A further problem arises from the

exclusion of data from the private sector (68,69). It has been estimated that routine information sources cover only 80 per cent of elective surgery conducted in England and Wales and there are systematic regional differences (31).

Where no local utilisation data are available, needs assessment may be modelled by applying age-sex-specific utilisation rates from elsewhere to local population characteristics, using epidemiological data from elsewhere. In addition to suffering from the same limitations as above, modelling health care needs on the basis of demographic characteristics also assumes that the characteristics in the population used as the basis for assessing need are the same - this assumption may be untrue.

2.4.3 Waiting lists as measure of demand

The demand for health care, reflecting both felt and expressed need, is usually measured by using waiting lists to estimate health care need. Waiting lists do not reflect the true need for treatment for several reasons. First, they are notoriously inaccurate. Close examination of lists for surgery showed that 40% of those on the list had either: died, migrated, got better, already been treated or did not want an operation (70). Waiting lists do not consider the severity and urgency of an individual's condition requiring treatment. In addition, health professionals may be uncertain about the appropriate treatment and use the waiting list as a way to ration care (71).

2.4.4 Prevalence surveys as a measure of need

It is now generally agreed that the most accurate method of assessing the need for health care in a population is by a community based survey measuring the prevalence of certain conditions in individuals (59,61). Health care needs derived from local survey data are directly relevant to the local population. Local surveys allow the

investigator to determine thresholds for need, if there is agreement about who will benefit from treatment. Nevertheless, there are still problems. Surveys do not always ask questions pertinent to clarifying true need. It may be difficult to develop an operational definition of a condition that can be measured simply. Only well-defined conditions that can be determined by a questionnaire are amenable to survey methods. Those requiring more invasive examinations for diagnosis will be costly and raise ethical issues. The results are often biased due to methodological limitations such as sampling errors, reporting and non-response bias and problems of reliability and validity of the instrument used. The need for health care determined from a survey only provides information about prevalent need and does not tell us about one about what to do once the backlog has been cleared. New treatments emerge and thresholds for treatment change. The rapid change in technology combined with the time required to undertake research means that the results of needs-based research may be dated by the time they are published.

2.5 NHS Management Executive needs assessment

In recognition that health authorities will not have either the skills or resources to assess all of the health care needs of their populations, the NHS Management Executive commissioned a number of epidemiologically-based needs assessments (formerly known as Project 26) (59). The purpose of these reviews was to summarise the health care needs of a typical district, for a specific disease and to compile the best available information on the incidence and prevalence of a particular disease and information on the effectiveness of the service. A two volume compendium of reviews has just been published for seven conditions (diabetes mellitus, renal disease, stroke, coronary heart disease, respiratory disease, lung cancer and colorectal cancer), six elective surgical procedures (hernia repair, varicose vein treatment, prostatectomy for

BPH, total hip replacement, total knee replacement, and cataract surgery) 5 mental health topics (adult mental illness, dementia, learning disabilities, alcohol and drug abuse), infertility and community child health services (59). These diseases and services currently reflect approximately one third of health spending, and were selected because they were either: high cost, high volume, high morbidity or high mortality (59).

The underlying basis of the epidemiologically based needs assessment reviews were that they be 'disease driven', and that their focus be on the incidence and prevalence of disease in the population, and on the effectiveness of care (72). Each assessment was required to follow a detailed protocol that included: 1) estimates of the size of the problem, 2) a summary of the available services, 3) a review of the effectiveness and cost-effectiveness of the services, 4) the development of models of care based on this information and 5) the identification of outcome measures, targets and information requirements, and research priorities. In a paper outlining their experience of managing the project, Stevens and Raftery reported that they had difficulty in measuring the level of current services primarily due to problems in obtaining accurate data and in defining models of care, such as prevention, treatment, care and rehabilitation (72).

In addition to these difficulties, the reviews did not examine: 1) the appropriateness of the indications for treatment; and 2) no consideration was given to patient preference for treatment. The extent of these problems will depend on the condition or service under consideration. The suggestion that corporate or comparative needs assessments (also known as marginal needs assessments) are adequate does not recognize that corporate self-interest groups will have an interest in promoting

supplier demand. The suggestion that an economic approach should be coupled with an epidemiologically based needs assessment does not recognize the crucial distinction between the two. Although it has been argued that needs can be determined from an economic perspective (60,73), these arguments do not distinguish between a true need for health care that exists in the population regardless of the costs of a treatment, and priorities for various treatments derived from societal values. In addition to the NHS initiative, a number of other publications by other groups are beginning to appear. These include assessing the needs of the elderly (74) and those with visual disability (75). Many other topics for needs assessments are recorded by the Needs Network, a register of individuals and organisations involved in assessing health care needs in the U.K. established by the Institute of Public and Environmental Health at the University of Birmingham (76).

2.6 Towards a model for assessing health care need

There is emerging agreement about the best way to assess the health care need or the requirements for specific interventions (61,77-79). The first step is to reach consensus, based on the best available evidence, about the appropriate indications for the intervention. This should include a review of the published scientific literature and, where the evidence is incomplete or conflicting, a panel of people with expertise and/or a legitimate interest in the topic to discuss the appropriate indications for treatment. The second step is to estimate the population prevalence of individuals with appropriate indications. The final step is to determine which individuals with clinically appropriate indications actually want the intervention in question. Despite the importance of this kind of research, relatively little of it has been undertaken.

The need for hip replacement is one of few attempts to assess true need with a prevalence survey (80). Individuals with symptoms of hip disease in a defined population were identified in two stages - initial screening and detailed follow-up of possible cases. The threshold for treatment was defined as the lowest level of symptoms, using validated scores, found among those on a waiting list for hip replacement. When the results were used to estimate the required number of operations in England and Wales, the figure derived was less than half of the actual number of operations performed in 1978 (81). This study highlighted the importance of identifying explicit thresholds and considering that the prevalence of symptoms may over-estimate the need for treatment as it may include individuals who are unfit for surgery.

2.7 Summary

The recent NHS reforms have given district purchasing authorities the responsibility for assessing the health needs of their populations. A recent series of epidemiologically based needs assessment reviews was inadequate because; few were based on studies of the prevalence of disease in defined local populations; there was little information on the appropriateness of the indications for treatment; and it did not consider the acceptability of the treatment to patient. Health care needs assessments must incorporate these steps if they are to be of value to purchasers of health care.

Chapter 3 - Rationale for examining prostatectomy

Introduction

Prostatectomy to remove obstruction of the urethra arising from benign prostatic hyperplasia (BPH) is one of the commonest elective surgical procedures, accounting for 42,000 operations in the U.K. in 1989/90 (82). Information on the prevalence of BPH and on the indications for treatment is hindered by confusion over the definition of BPH and debate about the relative importance of clinical measures of obstruction and patient-perceived measures of symptom severity, health status and quality of life. These problems are compounded by the poorly understood natural history of BPH. This chapter reviews the literature relevant to assessing the need for prostatectomy for BPH and consists of the following sections: 1) a definition of BPH; 2) indications for treatment; 3) effectiveness of treatment; 4) alternative treatments; and 5) previous work that sought to assess the need for prostatectomy in the U.K. Finally, it presents the aims and objectives of the thesis.

3.1 Definition of BPH

Benign prostatic hyperplasia (BPH) is an adenomatous growth of the prostate gland, surrounding the urethra at the outlet of the bladder, that gradually obstructs the urethra leading to difficulty in urinating. The consequences of an untreated obstruction may include: progressively severe obstructive and irritative symptoms, episodes of acute retention, and chronic urinary retention predisposing to bladder and renal damage (83).

Confusion exists over the use of the term BPH. The terms benign prostatic hypertrophy (increase in the size of cells) and benign prostatic hyperplasia (increase in the production of cells) are used interchangeably. Strictly speaking, the latter is the

correct term as it correctly describes the underlying pathology. Although both are descriptions of the histology of an enlarged prostate gland, they are often used as a term to describe the symptoms associated with obstruction. The expressions 'prostatism' and 'symptoms of benign prostatic hyperplasia' have also been used to describe these symptoms. A recent editorial advocated the use of the term 'lower urinary tract symptoms' (84) because 1) the same urinary symptoms also occur in women, despite the impossibility of their having an enlarged prostate; 2) there is poor correlation between urinary symptoms and prostatic enlargement; and 3) possibly up to 35% of men with symptoms do not have obstruction (8). Urologists often define BPH on the basis of clinical measures of obstruction such as uroflometry, postvoid residual urine, and pressure-flow studies. The definition of BPH may be considered in terms of three overlapping concepts: 1) histological evidence of benign prostatic hyperplasia; 2) lower urinary tract symptoms; and 3) clinical evidence of obstruction.

3.2 Indications for treatment

Most men who seek treatment do so either because of an episode of acute retention or because their symptoms bother them and interfere with their daily activities. Lower urinary tract symptoms include hesitancy, poor flow, terminal dribbling, frequency, feeling of fullness, urgency and nocturia (20). In a prospective study of men undergoing prostatectomy, there were 3 principal diagnostic categories: 35% patients were symptomatic only, 37% had chronic retention (with or without a history of acute retention and/or symptoms) as defined by their surgeon and 28% had a history of acute retention (with or without symptoms) (85). Seventy seven per cent of these patients had more than one indication. Routine investigations are conducted to rule out other possible causes of symptoms. These include a detailed medical history (to check for haematuria, urinary tract infection, diabetes, nervous system disease or

medication), a physical examination including a digital rectal examination, urinalysis using either a dipstick test or by examining the spun sediment (to rule out urinary tract infection or haematuria) and measurement of serum creatinine (to rule out renal insufficiency) (7).

The absolute indications for prostatectomy are difficult to define (33). A review of published reports suggests only limited agreement about the appropriate indications for prostatectomy. There is complete agreement about the need for surgery in the presence of chronic retention, though a lack of consensus as to the definition of the condition. While some authors state that acute retention, in the absence of detrusor failure or neuropathic obstruction, is an absolute indication (21), others argue in favour of conservative treatment for those who can void successfully after a period of catheter drainage (22,23). Yet a urologist in Scotland reported that acute retention was the only indication for which he would perform a prostatectomy (24). A recent study of the clinical practice of urologists concluded that consensus about appropriate practice has yet to be achieved (25). Some of this difficulty arises from the debate about whether to treat symptoms or urological measures of obstruction.

3.2.1 Symptoms

Symptoms are often thought to be due to either the direct effects of obstruction on urinary flow [obstructive symptoms: hesitancy, poor flow, dribbling, fullness], or to secondary changes in bladder function [irritative symptoms: frequency, urgency, nocturia, dysuria], although there is little evidence to support the usefulness of this distinction (33). It has been suggested that obstructive symptoms be referred to as 'voiding symptoms' and that irritative symptoms, should be referred to as 'filling symptoms' (84), although there is no agreement over which particular symptoms are

associated with BPH.

In general symptom measures have been developed by urologists and have not been fully evaluated in patients and men without symptoms (82). Two main symptom scoring systems have been developed in the U.S.A. to measure symptoms (86). With the first, the Madsen-Iversen index, patients are interviewed about the quality of their urinary stream, straining to void, hesitancy, intermittency, bladder emptying, stress incontinence or postvoid dribbling, urgency, frequency and nocturia. Symptoms are graded on a scale from 0 to 4 and a total score of 27 calculated by summing individual symptom scores. This index is derived from a questionnaire completed by the clinician rather than the patient and thus is inappropriate for survey purposes.

The widely used Boyarsky index considers the severity of nocturia, frequency, hesitancy, intermittency, terminal dribbling, urgency, impairment in size and force of stream, dysuria, and sensation of incomplete voiding. Symptoms are graded on a scale from 0 to 3 and a total score of 27 calculated by summing individual symptom scores. The items consist only of a list of symptoms being measured, rather than defining the question asked. The scoring is inconsistent; for some items the first point is 'no symptoms', for others, 'symptoms less than 20% of the time'.

To overcome the limitations of these methods the American Urological Association formed a measurement committee to develop a symptom index and quality of life questionnaire to provide a measure of outcome for the treatment of BPH (87). A 73-item pilot questionnaire was administered to patients with a clinical diagnosis of BPH, and to younger control patients without urinary symptoms drawn from general practice. Individual symptom questions were correlated with an overall question about

bother. Those that were highly correlated (incomplete emptying, frequency, intermittency, urgency, weak stream, hesitancy and nocturia) were tested further for internal consistency, and test-retest reliability. An index of these symptoms was developed by summing the individual scores. This index was highly correlated (r=0.78) with patients' global rating of their urinary problems and with comparable elements of the Madsen-Iversen (r=0.85) and Boyarsky (r=0.93) indices (88).

The seven questions were then modified based on comments from subjects and the 7 item index re-validated in 107 patients with clinically diagnosed BPH and 49 controls. Each item response ranged from 'not at all' to 'almost always', on a scale from 0 to 5. These items were then summed to produce an overall symptom score ranging from 0 to 35. The results of the second validation study found high internal consistency (Cronbach's alpha = 0.86) and high test-retest reliability (r = 0.92). The scores were highly correlated with subjects global ratings of their urinary symptoms and the index was able to distinguish BPH patients from control subjects. Finally, the sensitivity of the index was examined by administering it to 27 men immediately before prostatectomy and 1 month after. The scores dropped from a mean of 17.6 to 7.1.

The results of the validation studies were compared with how bothered patients were by their symptoms, in order to create three severity categories: none/mild [0-7], moderate [8-19], and severe [20-35]. The committee noted however, that these categories were somewhat arbitrary, and that descriptions of ranges of scores should be tailored to the purpose for which they are being used.

The AUA symptom score has recently been adopted by the World Health Organization

(89) and recommended for use by the U.S. Department of Health and Human Services (7). It is now referred to as the International Prostate Symptom Score (IPSS) and consists of a self-administered 7-item questionnaire about symptoms where item responses range from 'not at all' to 'almost always' (87). The index, the sum of the 7 items, can then be divided into 3 categories of symptom severity: none/mild [0-7], moderate [8-19] and severe [20-35].

3.2.2 Urological measures

The decision to offer treatment is based on a combination of urinary symptoms and the results of clinical investigations. There is controversy about the relative importance of symptoms and outflow obstruction defined by urodynamic tests which determine the functional and anatomic status of the bladder and urethra. These tests include uroflometry (measurement of urinary flowrate during micturition), postvoid residual urine (urine remaining in the bladder following micturition) and pressure flow studies (measurement of pressure in bladder during voiding). Two other investigations, cystometry (measurement of bladder capacity & presence of detrusor contractions), and imaging (intravenous urography) are not recommended (7).

3.2.2.1 Uroflometry

Flow rates include the peak flowrate (Q_{max}) and average flowrate (Q_{ave}). Results of studies that correlate these measures with symptom severity are conflicting. Some studies have demonstrated a relationship between symptoms and low flow rates or high urethral resistance (90-92), while others found a poor correlation (91,93-97). A current surgical textbook advocates the use of urodynamics (98) even though studies have concluded that measurements of urinary flow are not associated with symptoms or with the outcomes of prostatectomy (25,26,95,99-104). Possible reasons for the

conflicting results include: discrepancies between manual and automatic measurements, and that although Q_{max} decreases with age and voided volume, no age or volume correction factor is used (7). Flowrates could not distinguish between obstruction and detrusor instability as the cause of a low Q_{max} (7). Studies that have examined the value of uroflow to predict the outcome of prostatectomy have shown symptom improvement in men with a Q_{max} of less than 10 ml/s (105). Frimodt-Moller found no association between symptoms and outflow obstruction as defined by urodynamics and concluded that urodynamics were of no help in either confirming a clinical impression or identifying parameters that might alter diagnosis or treatment (95). Support for the view that uroflowmetry is not an aid for decision making comes from a recent study in the UK that found that urodynamic studies were conducted in only 26% in patients (106) and the AHCPR clinical guidelines recommend their use as optional only (7).

3.2.2.2 Postvoid residual urine

Postvoid residual urine (PVR) refers to the volume of urine left in the bladder following emptying and is commonly measured using urethral in-and-out catheterization or by ultrasound. Bruskewitz found that there was no correlation between PVR and urodynamic findings, and symptoms (107). Residual urine may originate from other causes than outflow obstruction and some patients with severe obstruction may present with no PVR (108). No study has reported a positive correlation between pre-operative residual urine and post-operative outcome (33). It has been suggested that the PVR should be carried out for men who have selected a non-surgical intervention such as watchful waiting or medical treatment (7).

3.2.2.3 Pressure flow studies

Pressure flow studies distinguish between those who have a low Q_{max} resulting from obstruction and those who have bladder detrusor instability, by measuring the pressure of the bladder during voiding. The measure is the difference between the intra-abdominal pressure and the intravesical pressure (P_{det}) and if it exceeds 100 cm during peak flow, then there is evidence of urethral obstruction. Evidence supporting the use of pressure flow studies is conflicting. A study that examined outcomes in terms of both P_{det} and Q_{max} and symptom assessment found that a urethral resistance cutoff value 0.6 ml/sec was not predictive of success in terms of $Q_{max,}$ detrusor pressure, resistance, or symptoms (97). Furthermore, men who were dissatisfied with the outcome of prostatectomy were incorrectly classified pre-operatively on the basis of urological testing (105).

A recent study examining the correlation between AUA symptom scores and both uroflow rate and prostate size in 198 men presenting to urologists, found no correlation, although it did show significant correlations with a 3-item general health index, 3-item activity index and a 5-item mental health index (109). The authors concluded that AUA symptom index is more precise than any of the commonly used physiological measures (109). Bruskewitz found that symptom scores and urodynamic studies were poorly correlated in 46 patients undergoing prostatectomy and concluded that symptoms were a better predictor of post-operative outcome (97).

Those who favour urodynamics point out the non-specificity of symptom scores, as indicated by similar results of their application in women, for whom prostatic obstruction is an impossibility (110-112). Second, if there is a suspicion of detrusor instability indicated by frequency, urgency and urge incontinence, then pressure flow

studies may be important in order to avoid unnecessary and inappropriate surgery (113). Given that most surgery is carried out to improve quality of life, which is highly correlated with symptom severity (16,17,114), the presence of urinary symptoms is the main factor that should be taken into consideration in the decision to offer treatment unless it can be shown that other measures will accurately predict patients who will benefit. The AHCPR clinical guidelines suggest that uroflometry, postvoid residual urine and pressure-flow studies be considered as optional tests after the initial evaluation has shown these men to have moderate to severe urinary symptoms based on the AUA symptom score.

In summary, the AUA symptom index should not be used as the only way of diagnosing BPH in individual patients because the symptoms are not specific for BPH (ie urinary tract infection, neurogenic bladder dysfunction, urethral stricture and prostate cancer). When these causes have been ruled out, the AUA symptom index is appropriate for use in treatment, planning and in the measurement of outcomes of the symptoms characteristic of BPH. At a population level, however, this is less of a problem as the other causes of urinary symptoms are much less common than BPH.

3.4 Effectiveness of prostatectomy

In order to assess the need for health care it is necessary to demonstrate the benefit of the intervention in question through effectiveness studies. Effectiveness is studied by examining outcomes following treatment. Commonly used measures of outcome are: mortality, complications, symptom change, general health status, quality of life and re-operation. This section examines the effectiveness of prostatectomy from data derived from: 1) case series which follow patients for up to one year; 2) longitudinal administrative data bases with follow-up of mortality, further illness episodes and re-

operation rates; and 3) randomised clinical trials that have compared the outcomes of TURP with open prostatectomy. The following section refers exclusively to the outcomes of TURP.

3.4.1 Mortality

Published case-series from several different countries suggest that 90 day post-operative mortality rates range from 1% to 9% (25,28,115-123). The age-adjusted cumulative risk of dying obtained from population-based studies within 90 days was found to be 1% and 4% in two studies (122,124). In-hospital mortality rates are of little relevance as sixty per cent of deaths within 90 days occur after discharge from hospital (125). A meta-analysis incorporating the results of 150 studies and reflecting a sample of 50,000 patients determined that the mean 90 day mortality was 1.5% [95% confidence interval 1.3-1.7] (113). Mortality increases with increasing length of time after surgery. Roos and colleagues have reported that the risk of death in three different countries [Canada, Denmark and the U.K.] increased from 10% at 1 year to 50% at 8 years (115,125,126). Different investigators may use different inclusion criteria for patients (selection bias), and results are more likely to be reported if they demonstrate an improvement on previous case-series.

The extent to which deaths are associated with TURP is uncertain. Results of comparing post-operative death rates with mortality in the general population are conflicting. In Rochester, Minnesota, average annual mortality rates over a 6 year period following prostatectomy were not statistically different from the rates of men who had not undergone prostatectomy (28). Similar results were obtained in the U.K. (20). In contrast, a study in men between the ages of 65 and 69 undergoing prostatectomy had more than twice the expected mortality rate compared with age-

matched men who had not undergone prostatectomy (26). There are considerable differences in the mortality achieved by different hospitals. There appears to be an association with hospital size in the U.S.A. (125). Compared with hospitals of 300 beds, the relative risk of death is 1.51 [95% CI, 1.01-2.27] in hospitals of 150-300 beds and 1.79 (95% CI, 1.24-2.59) in hospitals of under 150 beds. Studies which examined mortality were based on linking routine hospital data with national mortality records; although the use of routine hospital data must be interpreted with caution because of their limitations which include: incompleteness, inaccurate coding and misdiagnosis (127), difficulties in identifying deaths following discharge (128), and failure to adjust for case-mix (129). In summary, the 90 day mortality associated with TURP is around 1.5%.

3.4.2 Complications

The incidence of post-operative complications prior to discharge has been reported as about 18% to 23% (20,25,116,130). A meta-analysis reported that 'general complications' will develop in 6% - 32% following surgery (113). Problems arise in measuring the prevalence of complications because: definitions differ; severity is dependent on who reports the symptoms; and there is variation in the length of followup after surgery. The most common complications of prostatectomy are bleeding, urinary retention, urinary infection, incontinence and impotence. The incidence of complications depends partly on whether the surgeon or the patient is the source of the information; patients report complications more often than surgeons (101).

3.4.2.1 Bleeding

Widespread differences in the reporting of bleeding following prostatectomy can be attributed to differences in the definition of bleeding. Bleeding requiring transfusion has been reported in 3% - 4% of cases prior to discharge, although surgeons are likely to differ in their tendency to transfuse (120,131). Bleeding leading to clot retention was found in 11% before discharge (20). Most patients (90%) reported some post-operative bleeding, but only 14% saw their general practitioner and only 1% required readmission (20). In two studies, 2.3% - 5.8% of patients required re-hospitalization because of bleeding (28,124).

3.4.2.2 Urinary retention

Between 15% and 19% of patients reported one or more episodes of urinary retention due to blood clots within 3 months of surgery (102). In two studies, 4% - 5% developed retention serious enough to require hospitalization following surgery (20,28). Five years post-discharge, 19% of patients reported the 'sensation of retention' (103).

3.4.2.3 Infection

Urinary tract infection (UTI) is a commonly reported complication of prostatectomy. Reported rates following surgery vary from 2% - 20% (20,100,102,120,116), reflecting how a UTI was defined - the low rate of 2% referred to UTI confirmed by bacteriological culture.

3.4.2.4 Incontinence

Thirty eight per cent reported incontinence 3 weeks after discharge (20). One year after surgery, studies have reported between 1% and 20% (95,100,102,103,119,120)

and 3% after 5 years. A meta-analysis of 150 studies combining the results from 50,000 patients, reported the long-term prevalence of incontinence was 0.8% [95% CI, 0.6%-1.2%] (113).

3.4.2.5 Sexual problems

Sexual problems such as erectile impotence or retrograde ejaculation are reported following surgery. Of men who were able to have an erection before surgery, 5% reported that they were unable to have an erection 3, 6, and 12 months after surgery (102,131). A study in Germany reported that surgery had no significant effect on the prevalence of impotence (104). A meta-analysis of 150 studies combining the results from 50,000 patients suggested that 3.4% [95% CI, 3.3 - 3.5] will develop erectile impotence (113). Between 50% and 93% of men reported retrograde ejaculation (103,121). Thirty four percent of sexually active men reported that the operation had made their sex life worse (121). It has recently been suggested that the increase in sexual dysfunction is related to age, and a recently published prospective study supports the view that impotence following TURP is no more common than in men who receive no treatment (7).

3.4.2.6 Urethral strictures

The occurrence of stricture is a recognised complication of transurethral surgery. Stricture after surgery occurs in 0.6% - 0.8% of cases (100,120,121). Stricture that was serious enough to require regular intermittent dilatation or a urethroplasty ranged from 1.2% to 7% one year after discharge (100,124). Between 3.9% and 4.6% had a stricture serious enough to have dilatation within 5 years of discharge.

3.4.2.7 Cardio-vascular complications

The occurrence of pulmonary embolism as a result of deep vein thrombosis has been reported in two case-series as 0.1% and 0.4% (120,132).

3.4.2.8 Perforation of the prostatic capsule

Perforations that were large enough to be noticed and serious enough to warrant drainage have been reported in 0.4% - 0.5% of patients undergoing TURP (120,132).

3.4.3 Change in symptoms

A number of studies have assessed change in symptoms using symptom scoring indices, where ordinal scales for symptoms obtained by a questionnaire are combined into a single measure. Following prostatectomy, the proportion of men who reported an improvement in symptoms ranged from 70% to 90% (20,102,113,120,121,133-140). These studies are summarised in Table 3.1. The extent of improvement is related to: pre-operative severity; at what time following surgery that symptom severity is reported, differences in the patient perceptions of severity, and patient expectations (141). After one year, 93% of severely symptomatic and 79% of those with moderate symptoms experienced improvement in a symptom index (102). Seventy two per cent reported that they passed water more easily, between 5 and 8 years following their operation (121). Nevertheless, a small percentage (5%) of patients reported a worsening of symptoms, and 7% of those with severe symptoms reported no improvement (102). Further, it has been estimated that symptoms improve spontaneously in 50% of men between the ages of 45 and 80 without treatment, and 31% will experience an improvement in their symptoms within 5 years of having presented with symptoms of BPH (99). However, until further studies of natural history are undertaken, the true remission rate remains uncertain.

Table 3.1 Summary of results of studies examining symptom improvement 12 months following transurethral resection of the prostate.

Study (ref)	Year	Design	N	Measure	Degree of improvement
Singh (120)	1973	case-series	804	patient opinion	97% 'very good' or 'improved'
Chilton (100)	1978	case-series	1,004	patient opinion	92% 'cured' or 'better'
Meyhoff (134)	1986	RCT	75	symptom index	90% improvement
Dorflinger (137)	1987	RCT	38	Madsen-Iversen index	95% improvement
Larsen (138)	1987	RCT	37	Madsen-Iversen index	94% improvement
Malone (121)	1988	case-series	184	6 items	80% asymptomatic
Fowler (102)	1988	cohort	263	5-item symptom index	79% (moderate symptoms), 93% (severe symptoms) improved
Kadow (142)	1988	RCT	38	symptom index	71% improvement
Nielsen (135)	1988	RCT	49	frequency	78% improvement
Lepor (133)	1990	cohort	32	Boyarsky index	84% voiding symptoms significantly improved
Doll (20)	1992	cohort	388	7-item symptom index	90% improvement
Soonawalla (136)	1992	RCT	220	subjective improvement	90% improvement
Kabalin (139)	1993	RCT	12	AUA index	83% improvement
Dahlstrand (140)	1993	RCT	40	Madsen-Iversen	'significant improvement'
AHCPR guidelines (7)	1994	meta-analysis	4,945	'quantitative'	88% median probability for improvement

3.4.4 General health status

The Nottingham Health Profile (NHP) has been used to assess self-perceived health status in a cohort of 388 men at 3,6, and 12 months following surgery (114). Sixty per cent of those with a health problem prior to operation reported an improvement a year after surgery. Patients experienced improvement for all dimensions of health status, most notably sleeping, although those with more severe symptoms showed greater improvement than those with moderate symptoms (114).

3.4.5 Quality of life

A series of 263 patients in Maine, were interviewed about their quality of life before and after prostatectomy, using 3 standard indices: an activity index, a mental health index and a general health index (102). Twelve months following surgery, quality of life had improved only in those patients who had reported severe symptoms (and especially those with a history of acute retention) before surgery. Modelling has been used to predict that immediate surgery for a 70 year old man with moderate symptoms would result in a loss of 1 month in life expectancy, and a net benefit of 3 quality-adjusted life months (143). In a prospective series of 100 patients, quality of life improved significantly, although the authors did not provide information about how they measured quality of life (104).

3.4.6 Re-operation

Re-operation rates vary depending on the type of study; case-series may report lower rates because of selection and reporting biases, and shorter length of, or incomplete, follow-up. One study reported a two year cumulative probability of a repeat operation of 3% (144). The probability of having a repeat prostatectomy increases with length of follow-up. At 6 months, reported rates vary from 1% to 9%

(20,25,28,103,113,115,120). The eight year cumulative re-operation rate is 12% - 20% (115,124,125,145,146). A study using decision analysis with American data suggested that a 70 year old man undergoing prostatectomy for moderate symptoms but with no evidence of chronic retention had a cumulative probability of at least one further operation during his lifetime of 21% (143). In a case series of 2015 cases, 12% reported a previous TURP (130).

3.5 Alternative treatments

A number of alternative treatments for lower urinary tract symptoms for BPH are available. These include: watchful waiting, operation (TURP, transurethral incision of the prostate (TUIP), open prostatectomy), medical treatment (alpha blockers, alpha reductase inhibitors, hormonal manipulation), and non-invasive procedures (balloon dilation, hyperthermia, thermal therapy, laser prostatectomy, prostatic stents). These are all under investigation (7). The evidence about effectiveness, in terms of long-term improvement in symptoms, is limited because these treatments are too recent for their to be long term follow-up of outcomes. Furthermore, data that does exist, has often failed to assess the response of symptoms to treatment.

Watchful waiting is a widely used term but one that is poorly defined. The patient receives no intervention and is monitored by his physician, although there appears to be little consensus about how active the monitoring should be and when it should be abandoned in favour of treatment. It is based on the observation that up to 50% of men with untreated 'prostatism' will experience an improvement in their symptoms (99).

Transurethral incision of the prostate (TUIP) involves making an incision in the

prostate and prostate capsule using an instrument passed through the urethra. It is more commonly used with smaller prostates. In an open prostatectomy, a suprapubic or perineal incision is made and the inner portion of the prostate gland is excised. Balloon dilatation is a procedure where a balloon is placed in the urethra in the location of the obstruction and inflated to displace the obstructing tissue.

Medical treatments include alpha-adrenergic receptor blockers which cause the relaxation of the smooth muscle of the prostate and bladder neck, and 5-alpha reductase inhibitors which prevent the conversion of testosterone to dihydrotestosterone, resulting in some shrinking in the size of the prostate.

A number of other surgical approaches have been used, and are undergoing further evaluation. These include prostatic stents (a tube of specially treated wire is placed endoscopically into the prostatic urethra and left there), hyperthermia (a probe is inserted into the urethra or rectum and microwaves are generated to heat the prostate), and lasers.

In preparing the AHCPR clinical guidelines, the BPH panel prepared a comparison of the percentage of patients experiencing changes in globally assessed BPH symptom status following treatment. These results should be interpreted cautiously because the studies that report on alpha-blockers and balloon dilatation examined few patients, and because of differences in the way that symptom improvement is reported (eg. some report the presence or absence of change, while others measure the extent of symptom change). There is little evidence about the long-term improvement in symptoms. Furthermore, there has not been a randomized trial that directly compares the results of these different treatments with TURP, and until such time as there is,

no definitive statements can be made about the relative efficacy of these alternative treatments.

Following an exhaustive review, U.S. clinical practice guidelines recommended that: patients with mild symptoms (AUA symptom index score less than 7) be followed with a strategy of watchful waiting; patients with moderate symptoms (AUA score greater than or equal to 8) be given information about the benefits and harms of watchful waiting, medical therapies, balloon dilation and surgery (7). Most surgeons believe prostatectomy is the treatment of choice for lower urinary tract symptoms (3-6,8) and it remains the most widely used treatment in both the U.K. (147) and in the U.S.A. (116). However, the use of 5-alpha reductase inhibitors is increasing rapidly although this and associated marketing techniques used, have generated considerable controversy (148). The U.S. guidelines advocate that once, the patient has decided to choose surgery, then the choice of specific procedure (TURP, open or TUIP) should be left to the surgeon (7).

3.6 Previous work related to assessing need for prostatectomy

An epidemiologically based needs assessment for prostatectomy for BPH commissioned by the Department of Health was based on 3 types of evidence: 1) epidemiological and utilisation data; 2) evaluation studies; and 3) economic analyses (82). Data were taken from existing information sources and publications in order to determine the required annual level of provision of prostatectomy for each district. The authors highlighted the difficulties of using prevalence data to assess need for prostatectomy: 1) existing information was primarily about the distribution of prostate size rather than about symptoms; 2) symptoms of BPH may often revert spontaneously without treatment; and 3) no information exists about the acceptability

of the surgery to the patient. The review estimated that 250 men over the age of 55, were likely to be referred for treatment per year in a typical district of 250,000 people, although this figure was acknowledged by the authors to be an approximation due to several shortcomings (82). The limitations included: 1) the absence of consensus about the appropriate indications for treatment; 2) prevalence estimates of BPH were derived from published sources of questionable validity, and 3) patient preference for treatment was not taken into consideration. The authors emphasized that there was a wide range of benefits for patients with different degrees of severity. They concluded with the recommendation that more research be directed towards the perceptions and experience of men with BPH, to investigate the reasons for their willingness or unwillingness to tolerate their urinary symptoms, and to establish a process to involve patients in decisions about treatments (82).

3.7 Summary & plan of thesis

The recent NHS reforms have highlighted the role of assessing the need for health care in the population. The need for prostatectomy, a surgical treatment shown to benefit men with moderate or severe urinary symptoms, has not been adequately determined because: 1) there is a lack of consensus about the appropriate indications for treatment; 2) data on the prevalence and incidence of the symptoms of BPH in the population are lacking; and 3) there is little information about the acceptability of prostatectomy to men with symptoms. Despite the emergence of treatment alternatives for men with urinary symptoms, prostatectomy is the preferred treatment and results in the highest proportion of men experiencing improved symptoms, and the greatest improvement in symptoms. Nevertheless, there are risks associated with the procedure. TURP is associated with post-operative mortality rates of approximately 1.5%. The main complications of surgery include: bleeding, infection, incontinence, sexual dysfunction, and strictures.

The **aims** of this thesis are:

1. to determine the appropriate indications for transurethral resection of the prostate for BPH.

2. to measure the prevalence and severity of lower urinary tract symptoms in men aged 55 and over.

3. to determine: (1) the extent to which lower urinary tract symptoms affect the daily activities and health status; and (2) whether men with lower urinary tract symptoms would choose treatment.

4. to estimate of the health care need for prostatectomy in a typical district with a population of 250,000.

The **objectives** of this thesis are:

1. to use a consensus panel of urologists and general practitioners to determine the appropriate indications for prostatectomy.

2. to conduct a survey of men aged 55 and over, in North West Thames health region.

3. to conduct a follow-up survey of men who reported mild, moderate or severe urinary symptoms.

Chapter 4 - Methods

Introduction

This chapter describes the methods used to assess the health care need for prostatectomy, including the nominal group technique to determine appropriateness and the two surveys employed. The first section describes the consensus panel, including the preparation of the background material, the selection of the panellists, the conduct of the panel and the analysis of the panel results. Second, the initial survey is described, including the selection of the sample, the questionnaire, the case-note review, and the scoring of comorbidity, retention and symptom severity. Third, the second survey is described, including the selection of the second sample, the follow-up questionnaire (both the NHP and the SF-36 versions), the scoring of patient preference and the investigation of response bias. Fourth, the methods used to estimate the number of prostatectomies required in a district are described. Finally, details of data handling and analysis are presented.

4.1 Consensus panel

A study of the prevalence of individuals with appropriate indications for treatment requires that an agreed case definition be developed, based on the best available evidence about appropriateness of the treatment in question. Ideally, such a definition would be derived from the results of large, high quality randomised controlled trials that relate specific indications to treatment outcomes. These would incorporate outcomes that are relevant to the patient and are sufficiently generalisable, both in terms of patients included and treatment settings. Unfortunately, in many areas of health care, such trials have not been conducted.

Where such evidence does not exist, but where smaller and perhaps less generalisable randomised controlled trials are available, the next best alternative is generally believed to be a systematic review, using meta-analysis to combine the results of these trials. This technique is being increasingly used to provide overviews of evidence and to resolve inconsistencies in the results of published studies. A meta-analysis was not possible here due to a lack of relevant trials. Although there were some observational studies and a few small trials of particular therapies for lower urinary tract symptoms, they were of limited value in determining the indications for prostatectomy because the results were not representative of those for whom treatment might be considered and many were conducted in "centres of excellence", which may be atypical (149).

An alternative approach where the information required for meta-analysis is lacking is formal consensus development, although it has been subject to relatively little research and is accepted to have many limitations. It enables the experience of those with expertise or a legitimate interest in the topic to bring together their ideas in a formal and structured way, along with the available evidence. It explicitly recognises that disagreement and uncertainty may remain at the end of the process. The use of consensus development in the health care field has been used to examine issues in health service organisation, definition of professional roles, design of educational programmes, long-term projections of need for care for particular client groups and development of criteria for appropriateness of interventions (150).

This formal structure, involving explicit incorporation of the available evidence, is felt to be an improvement, at least in process terms, on the alternatives such as committees in which a few individuals may dominate the discussion and in which

evidence may be suppressed. Moreover, individuals are often unready to retract long-held and publicly stated opinions in open committees, even when these have proven to be false. Committee decisions are also subject to influences as diverse as the size of the committee, the extent of discussion, time constraints, seating positions, and the presence or absence of rules of procedure (151).

One approach, the nominal group method, has been increasingly used in recent years in health services research. It consists of two rounds where panellists rate their agreement with a series of statements, discuss them and then reconsider their initial ratings in view of the distribution of initial scores and subsequent discussion. The process was developed in the U.S.A. in the 1960s and has been applied to problems in social service, education, other areas of government activity and industry (152). It is the method used most frequently to identify agreed indications for a particular surgical or medical intervention based on the judgement of panellists, informed by a detailed literature review and their clinical judgement, where the evidence is conflicting or missing (153). The leading proponent of this method has been the RAND corporation in the U.S.A..

In the U.K., the nominal group method has been used less extensively but its applications have included: coronary angiography (154), coronary artery bypass grafting (154), cholecystectomy (155) and total hip replacement (156). Other work has examined the out-of-hours work of junior doctors (157-161), the use of diagnostic tests out of hours (162), the work of house officers (163) and the avoidance of emergency hospital admissions (164).

4.1.1 Literature review

A review of the literature on the epidemiology of BPH, methods of treatment, indications and outcome of prostatectomy was performed. Initially, MEDLINE was searched for the following medical subject headings (MeSH): prostatectomy, symptoms, standards, statistics and numerical data, and utilisation (165). The search covered the years 1983 to 1991 and included papers in all languages. The review was supplemented by examination of major textbooks, follow-up of additional references quoted in the papers located, and personal communication with other investigators known to be conducting research on this topic, both in the U.K. and the U.S.A. In total, 175 papers were reviewed, of which eighty-two were included in the literature review [Appendix A1].

4.1.2 Selection of panel

The panel was composed of 5 consultant urologists, one senior registrar in urology and 3 general practitioners. In forming the panel, 13 consultant urologists in the North West Thames health region and 15 general practitioners, selected on the basis of previously expressed interest in the topic, were approached and asked to participate. The final selection of the panel was based on availability to attend the discussion panel. The urologists on the panel represented teaching and non-teaching hospitals, as well as urban and rural districts. It was decided to limit the panel to medically qualified individuals. This is consistent with the approach taken with previous panels examining appropriateness in the U.K. but it inevitably leads to the development of a medical case definition.

There is clearly a need for incorporating the views of health consumers but there are two ways of doing so. In this case, the panel was established to identify those men

to whom urologists would offer surgery rather than those who would accept it. The issue of patient views was tackled primarily by seeking information on treatment preference at a later stage in the study from those with possible indications for surgery. If it had been desired to incorporate the views of patients at this stage, a further obstacle would have been the absence of experience in how best to do this. With a relatively small panel, there is a danger that one or two patients, potential patients, or their representatives would be marginalised by the medical participants. There is also a real problem in identifying such individuals and assessing their representativeness, although to some extent the selection of general practitioners poses a similar problem.

In the first round, panel members were sent the literature review and a questionnaire (developed from the literature review and with advice from a consultant urologist), that asked them to rate the appropriateness of potential indications for TURP [Appendix A2]. The indications were grouped into four categories of retention (acute, chronic, acute on chronic, and no retention), with differing types and levels of symptoms and different levels of comorbidity.

4.1.3 Definition of indications

Chronic retention was defined as a post-void residual volume of 400 ml or greater, on the basis of advice from the panel. Symptoms were classified as irritative (frequency, nocturia and dysuria), obstructive (hesitancy, poor flow, dribbling and feeling of fullness) or a combination of both irritative and obstructive. Levels of symptom severity were categorized as none (symptoms never occur), mild (symptoms present occasionally or nocturia occurs once per night), moderate (symptoms present about half the time or nocturia occurs 2 - 3 times per night) and severe (symptoms present

most or all of the time or nocturia occurs 4 or more times per night). Life expectancy was used as proxy measure of comorbidity. High comorbidity was defined as life expectancy of less than a year, medium comorbidity as at least a year but less than five years and low comorbidity as five years or more. The raters were guided by these examples: less than 1 year = inoperable cancer with secondaries, 1 to 4 years = chronic obstructive airway disease with dyspnoea on moderate exertion; angina on moderate exertion, and 5 or more = no co-morbidity, hypertension controlled by treatment, osteoarthrosis. It was assumed that there was no pre-operative evidence of prostatic cancer and that patients were fit enough to undergo general or spinal anaesthetic. Other forms of treatment such as drug therapy or stents were assumed to be available, so that if they were appropriate as first line therapy, TURP was deemed to be inappropriate.

Each combination of these four factors (type of retention, type of symptoms, severity of symptoms and comorbidity) was taken to describe a category of patient. For example, one such category might represent patients in acute retention with mild obstructive symptoms and low comorbidity. If symptom severity was 'none', further breakdown by symptom type was not applicable, and if there were no retention and no symptoms, further breakdown by comorbidity was not applicable. On this basis a total of 118 unique patient categories were assessed.

4.1.4 Scoring of appropriateness

Appropriateness was scored using a 9 point scale, in which 1 indicated that the risk of TURP always outweighed the benefits and so surgery was always inappropriate, and 9 indicated that the benefits of TURP always outweighed the risks and so surgery was always appropriate. A score of 5 indicated that the risks and benefits were equal.

After completing and returning the questionnaire, panellists attended a structured meeting at which they were presented with a summary of the first round responses to the questionnaire showing the median and the range of scores. Each patient category, where there was disagreement, was discussed in turn, followed by the opportunity for panellists to reconsider their previous responses. The discussion enabled panellists both to clarify their interpretation of the indication and to discuss areas of genuine controversy. This final rating was used in the analysis.

Agreement was defined as when, after discarding the single highest and lowest ratings, the ratings of the seven remaining panel members fell within a 3 point range. Panellists were judged to have disagreed if, after discarding the highest and lowest ratings, at least one rating fell in the 1-3 range and at least one rating in the 7-9 range. Categories about which there was neither agreement nor disagreement were classified as partial agreement. For patient categories about which the panel agreed, surgery was judged to be inappropriate if the median rating fell between 1-3 and appropriate if the median rating fell between 7-9. A rating of 4-6 was judged to be equivocal. This is the system used in the RAND consensus conferences and other studies undertaken previously in the U.K. (153,155,163).

4.2 Initial survey

4.2.1 Selection of sample

A cross-sectional population survey of the prevalence of urinary symptoms in men aged 55 and over was carried out in North West Thames region. This age group was selected on the basis of the results of a study in the Oxford and North West Thames regions in which more than 99% of men undergoing prostatectomy were aged 55 or more (20). Initially thirty general practices were selected randomly from all practices

in North West Thames region and invited to participate. The fifteen practices that expressed an interest in the study were sent further information and the panel literature review. Seven practices withdrew at this stage. The remaining eight practices were distributed throughout the region and included inner city, suburban and rural practices. These practices were asked to provide a list of all men aged 55 years and over. In total, 3716 men were identified, with the number of men in each practice ranging from 143 to 1180. With the exception of the smallest practice, where the entire list was used, 265 men were randomly sampled from the whole of each practice's list to create a database of 2000 names and addresses. This number was chosen to yield 95% confidence intervals of ±1.5% if the true prevalence of moderate or severe symptoms was around 25%.

4.2.2 Urinary symptom questionnaire

A two page questionnaire [Appendix A3], together with a personally addressed covering letter [Appendix A4] signed by the individual's general practitioner and the author, and a stamped, addressed envelope for reply, was sent to each man. Non-respondents were sent a reminder letter and a second questionnaire one month later. The questionnaire sought information about the men's socio-demographic characteristics [age, ethnicity and proxy measures for income (housing tenure and car ownership] and about any urinary symptoms they had experienced over the preceding month. Questions on urinary symptoms were taken from the American Urological Association (AUA) symptom index (87), with some minor modifications to the wording of the questions to make them more appropriate for a British population. For example, the AUA question on fullness 'Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?' was changed to 'In the past month, how often did you feel that your bladder did not empty

fully after urinating?'. A pilot version of the questionnaire, sent to 30 men selected from a general practice in North East Thames region, achieved a response rate of 80% and led to minor modifications in the layout of the questions. For comparison, population estimates and demographic information for residents of North West Thames region were obtained from the 1991 census (166). Ethical approval was sought and obtained from the relevant district ethics committees.

4.2.3 Case-note review for non-response bias

To investigate the possible effects of response bias, general practice case notes from 100 randomly selected non-respondents were compared with the case notes of 100 randomly selected respondents. Information taken from these case notes included age, history of urinary symptoms, previous prostate surgery, and medical history. Reasons for the unavailability of any case-notes, such as the patient having died or moved away, were recorded.

4.2.4 Scoring of symptom severity

A symptom index, ranging from 0 to 30, was calculated by summing the scores of six urinary symptoms (fullness, frequency, intermittency, urgency, poor flow and hesitancy) where each symptom was assigned one of the following values: never=0, hardly ever=1, less than half the time=2, about half the time=3, more than half the time=4 and almost always=5. The symptom index was categorized into five levels of severity; none [0], very mild [1], mild [2-9], moderate [10-18] and severe [19-30]. These cutoff points were consistent with those used in a cohort study of men undergoing prostatectomy in Oxford and North West Thames region (167) and with the definitions used in the consensus panel where 'none' and 'very mild' symptoms were grouped together. Responders were also asked about how bothersome any

trouble with urinating had been in the preceding month, with possible responses on a five point scale: no problem, very small problem, small problem, medium problem and big problem.

4.1.5 Definition of retention

An episode of acute retention was defined as respondents reporting a previous episode of ever being blocked up completely so that they were unable to urinate. The presence of chronic retention, defined to be post-void residual urine of > 400 mls, could not be determined from a postal questionnaire.

4.1.6 Scoring of comorbidity

To measure comorbidity respondents were asked the open-ended question 'do you have any other health conditions that affect the way you feel, or the things that you can do at this time?' Their responses were then reviewed independently by two doctors and rated on the basis of life expectancy on a scale of 1 to 3 [1=less than 1 years, 2=2-4 years, and 3=greater than 5 years]. The raters were guided by the examples used in the consensus panel discussion. As with levels of urinary symptoms, these categories were designed in order to be consistent with those used by the consensus panel. Where there were disagreements between raters, the higher rating (ie. a longer life expectancy) was used. Where the respondent's life expectancy, as determined from the life table for England and Wales 1989-91 (168) on the basis of age alone, was lower than the comorbidity rating, the life table value was used.

4.3 Follow-up survey

4.3.1 Selection of second sample

The 516 (34.9%) men in the initial survey who reported a symptom score of 7 or more and /or a history of acute retention, were sent a second questionnaire 6 weeks later that sought information about the impact of lower urinary tract symptoms on their health status, behaviour and preference for treatment. To avoid unnecessary distress to families, a list of these men was sent to all GP practices beforehand, in order to ensure that any men had not died since the initial survey.

4.3.2 Follow-up questionnaire

A seven page questionnaire [Appendix A5] was sent together with a personal covering letter [Appendix A6] from the individual's GP and a stamped, addressed envelope for reply. All non-respondents were sent a reminder letter and a second questionnaire one month later. Interference in daily activities was determined by asking whether men: worried about needing a toilet or wetting self in public, avoided using a toilet, were embarrassed about using a toilet often or limited the amount they drank. Participants were asked whether they had sought advice for their urinary symptoms and from who, whether they had visited their GP or urologist, and what had been the results of these consultations. Health status was measured using one of two standard instruments: the Nottingham Health Profile (NHP) or the SF-36. Each version of the questionnaire was randomly allocated to half the sample.

4.3.2.1 Nottingham Health Profile

The Nottingham Health Profile is a valid and reliable self-administered questionnaire, widely used in the UK (169). Respondents were asked to agree or disagree with 38 statements about their health; eg. 'I find it painful to change position', 'I feel I am a

burden to people'. Using the methods recommended by the creators of the NHP, all item responses were weighted and combined into 6 dimensions [energy (3 items), pain (8 items), emotional reactions (9 items), sleep (5 items), social isolation (5 items) and physical mobility (8 items)]. Possible scores ranged from 0 (perfect health) to 100 (poor health) (169). The use of weights is suggested if the study is confined to the UK, for use in comparing results with other studies (169). It was hypothesized *a priori* that emotional reactions, sleep and social isolation would be affected by lower urinary tract symptoms, but that the other dimensions would not.

4.3.2 MOS 36-Item Short Form Health Survey

The SF-36 was developed for the Medical Outcomes Study and by the RAND corporation in the U.S.A. (170), and adapted for use in the UK by the Medical Care Research Unit at the University of Sheffield (171). There is considerable evidence as to its reliability and validity in the U.K. (171-173). It consists of 36 items. Where applicable, item responses were transformed so that all 36 items were scored from 0 - 5. A higher score indicates better health. Item scores were then combined into eight different dimensions of health as recommended [Appendix A7](174). Four dimensions relate to general health status: physical functioning (10 items), mental health (5 items), energy/vitality (4 items) and general health perceptions (5 items). Three relate to general quality of life: limitations due to physical role problems (4 items), social functioning (2 items), and limitations due to emotional role problems (3 items). One relates to both health status and quality of life: pain (2 items). Where item scores were missing, they were imputed by taking the average of other items in the relevant health dimension. Out of a possible 7812 responses (36 items, 217 questionnaires), 387 (5%) answers were missing. It was hypothesized that social functioning, vitality and mental health would be significantly affected by urinary

symptoms, and that general health perceptions would be affected to a lesser extent.

The availability of published NHP scores in 388 men undergoing prostatectomy (114) allowed for a comparison of health status in the sample at similar symptom severity scores. Similarly, health status as measured by the SF-36 were compared with published population norms (172).

4.3.3 Patient preference for treatment

In order to discover whether men would accept treatment or not, participants were presented with currently available evidence about the outcome of treatment and a simple description of the procedure. The information was worded was as follows: 'The most common treatment for urinary problems caused by enlargement of the prostate gland is surgery. This involves passing an instrument like a small telescope up the penis to clear the blockage. It usually involves a hospital stay of about 8 days. About 80% of men experience an improvement in their symptoms following surgery, about 15% are unchanged and 5% worse off. Some men will also have difficulty getting an erection after surgery. In addition, about 10% have complications, such as bleeding, infections and leakage of urine, which normally clear up within a few weeks. If your urinary symptoms were found to be due to an enlarged prostate and you were offered surgery for it, feeling the way you do now, would you choose to have it?' Respondents were asked to score their preference on a scale of 0-5 [0=definitely want, 1=probably want, 2=not sure, inclined to yes, 3=not sure but inclined to no, 4=probably don't want, 5=definitely don't want.

4.3.4 Investigation of response bias

To investigate the possible effects of response bias in the follow-up survey, the 85

(16%) non-respondents were compared with the respondents in terms of age, severity of symptoms, previous surgery and acute retention, using data from the initial survey.

4.4 Estimating need

The prevalence of appropriate indications [the results of the consensus panel and the results of the initial population survey], were combined with information on patient wants [the results of the follow-up survey] to calculate: 1) the age-specific rates of those with mild (symptom score less than 10), moderate (score 10-18) or severe (score 19-30) urinary symptoms; 2) the age-specific rates of those with the appropriate indications for prostatectomy; and 3) the age-specific rates of those for whom prostatectomy was indicated and who would accept treatment if offered. These rates were then applied to the age-specific population estimates from North West Thames region obtained from the 1991 census (166), to predict the prevalent need in a population of 250,000. This population was selected to represent the catchment population of a typical district hospital. Prevalent rates per 1000 were calculated with 95% confidence intervals. Sensitivity analyses were undertaken to investigate the effect of varying the definitions of 'appropriate' and 'wanted' by altering the symptom severity threshold, the level of agreement required of the panel, and the level of certainty about surgery required of the patient (Table 4.1). In addition, rates were calculated, based on the actual behaviour of those men who had already been offered surgery by their urologist. Data on prevalent need was used to estimate the incident need, based on a number of assumptions about current utilization, remission rates, operative risk, and differing risks of developing symptoms. Details of the model are presented in Appendix A8.

Table 4.1. Combination of definitions used in the sensitivity analysis.

Symptom severity	Level of agreement	Patient preference
Mild, moderate, severe		
	Agreement	
		definitely want
		definitely or probably want
		definitely or probably want, or inclined to yes
	Agreement + Equivocal	
		definitely want
		definitely or probably want
		definitely or probably want, or inclined to yes
	Based on action of those offered surgery	
Moderate, severe		
	Agreement	
		definitely want
		definitely or probably want
		definitely or probably want, or inclined to yes
	Based on action of those offered surgery	
Severe		
	Agreement	
		definitely want
		definitely or probably want
		definitely or probably want, or inclined to yes
	Based on action of those offered surgery	

4.5 Data processing and analysis

Data from the consensus panel and both surveys was manually entered by a professional data-entry clerk, into a database using a data-entry program written in Paradox (175). The data was then transferred to a mainframe computer with a CMS operating system for analysis. The lists of patient names and addresses provided by the general practitioners were entered and converted into an ASCII file using an optical scanner, and maintained in a Wordperfect (176) mail-merge list. Each individual was assigned a unique identifying number which allowed for the merging of the files containing the results of the initial survey with those of the follow-up survey. One variable from each data record was compared with the corresponding response on the questionnaires in order to ensure that the data had been entered accurately. All computer print-outs were closely examined for unexpected results or

unusual findings. All errors were corrected before the data were analyzed.

Data analysis consisted of frequency distributions. Confidence intervals for proportions were calculated at the 95% level using the method of Fleiss (177). The significance of observed differences was calculated using chi-squared statistics (178). Wilcoxon matched-pairs signed-ranks were calculated to test for a change in bothersomeness and frequency. A chi-squared approximation, the Kruskal-Wallis test was used to test the relationship between SF-36 dimension scores and symptom status. All analyses were conducted using procedures written in SAS (178).

Chapter 5 - Results

Introduction

This chapter reports the results of: (1) the consensus panel that considered the appropriate indications for prostatectomy; (2) the initial survey of 2000 men in North West Thames; (3) the follow-up survey that measured the impact of men's mild, moderate or severe lower urinary tract symptoms on their health status and choice of treatment; and (4) estimates of need in a typical district.

5.1 Results of the consensus panel

The panel was held at the London School of Hygiene and Tropical medicine over the course of an afternoon. Participants were given a lunch and travelling expenses were reimbursed. GPs were also paid at locum rates for their time. One of the invited consultants did not attend, although this possibility had been anticipated. The panel was chaired by a senior lecturer in public health medicine. After an introductory explanation, participants discussed each item on the questionnaire.

The panel discussion was lively with all members contributing and very little clear disagreement. The main findings of the consensus panel were: (1) the panel attached little importance to mild symptoms; (2) history of urinary retention, the severity of urinary symptoms and the degree of comorbidity were given roughly equal weight by the panel; and (3) while a history of acute retention was important, the type of retention was less so, although acute-on-chronic retention was a stronger indication than either acute or chronic retention alone. Where there was agreement, there was no difference in the appropriateness of treatment for either chronic retention or no retention in terms of symptom severity and level of comorbidity. The panel confirmed that comorbidity does play a part in determining appropriateness, despite the view of

some that it is unimportant because prostatectomy can be done under spinal anaesthesia.

The panel did not consider that surgery was necessarily appropriate in patients with a history of acute retention, although there is a large group of these patients in whom surgery will sometimes be appropriate. There was some discussion about 'trial without catheter' and one panellist reported that urologists disagree about the 'evidence' about the length of trial, and another said 'if there is a consensus about trial without catheter - it depends on results in terms of their symptoms'.

Some panellists felt that the exercise had involved an artificial distinction between obstructive and irritative symptoms which was seldom made in practice, whereas others expressed the view that prostatectomy should be performed for obstructive symptoms but not for irritative symptoms, because irritative symptoms were caused by detrusor instability rather than an enlarged prostate. One urologist said 'patients don't come through the door and say "I can't pee fast or it takes a long time to start", rather they have frequency, nocturia and dysuria' and another urologist said 'you don't do a prostatectomy for irritative symptoms only for obstructive symptoms and the patient doesn't present with 400 mls residual urine, he presents with symptoms'.

The panel debated about distinguishing chronic retention from no retention because virtually all people have incomplete emptying of the bladder and men have severe chronic retention with no symptoms. One urologist noted that with chronic retention with significant obstruction, surgery was performed to remove the obstruction, regardless of irritative symptoms, in order to protect the bladder. Another urologist said 'irritative symptoms in chronic retention are due to a full bladder not an enlarged

prostate'.

Finally, all participants stated that they had enjoyed the exercise and felt they had benefitted from the discussion. One GP said "As a GP I came to learn, I have', and another said 'I am going to refer more and my urologist isn't going to thank me'. One urologist commented 'by the time I finished the questionnaire, I wondered what on earth I'm doing this operation for'.

The panel reached agreement on 67% of the patient categories (Table 5.1), with 45% appropriate for surgery, 17% inappropriate, and 5% equivocal. Clear disagreement occurred in only 6%. The patient categories for which surgery was considered appropriate, unclear or inappropriate are summarised in Figure 5.1, in which no distinction is made between the type of symptoms. Ratings for each item are presented in Appendix A9. In general, surgery is indicated for chronic retention or acute retention if symptoms are severe, or if symptoms are moderate and life expectancy is greater than five years. Acute on chronic retention is an indication for surgery regardless of symptom severity, if life expectancy is greater than one year. For patients with neither acute nor chronic retention, surgery is indicated for patients with severe symptoms, or moderate symptoms and a life expectancy of greater than five years. Surgery is inappropriate for chronic and acute retention if symptoms are non-existent or mild, and life expectancy is less than 1 year, and for those without retention and with only mild symptoms. Although the panel felt that surgery was appropriate for men with mild symptoms, no comorbidity and no retention, at similar levels of symptom severity and comorbidity, the panel felt equivocal about men with acute retention. Further details of the consensus panel have been published and may be found in Appendix A10.

Figure 5.1 Indications for prostatectomy

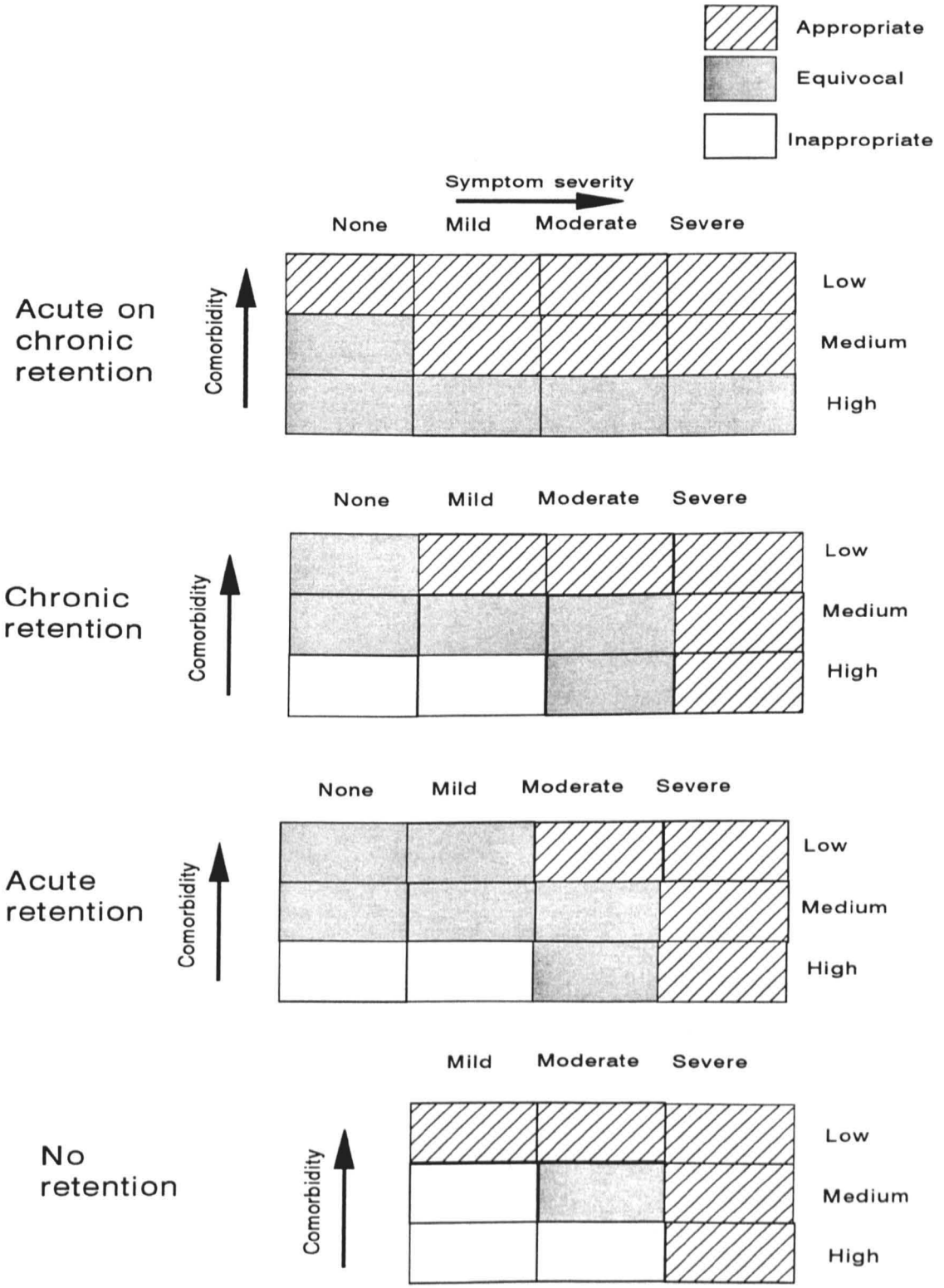


Table 5.1 **Final ratings of indications for transurethral resection of the prostate by the panel.**

	Yes	(%)
Agreement	79	(67)
Appropriate	53	(45)
Equivocal	6	(5)
Inappropriate	20	(17)
Partial agreement	32	(27)
Disagreement	7	(6)
Total	118	(100)

5.2 Results of the initial survey

5.2.1 Characteristics of the sample

Of the 2000 men that were sent a questionnaire, 21 had died and 74 were unknown at the address in the general practice records, so that the final study population was 1905 (Table 5.2). The response rate following the first mailing was 64%, rising to 78% (1480 returned questionnaires) following a postal reminder. The age-structure of those responding was similar to that of all men living in North West Thames region, except for those in the 55 to 59 age group, who appeared to be under-represented in our sample (Table 5.3). Responders were more likely to be white than would be expected from the male population in this age group.

Table 5.2 **Response rates to the initial survey.**

	N	(%)
Responded	1480	(74)
Not returned	405	(21)
Returned without response	20	(1)
Not known at address or moved	74	(4)
Died	21	(1)
Total	2000	(100)

Response rate among valid responders (1480/1905) is 78%

Table 5.3. **Demographic characteristics of responders, urinary symptom prevalence survey, North West Thames region, 1992.**

	Sample (%)		Population (%)	
Age group				
55-59 Years	275	(19)	89,073	(24)
60-64 Years	322	(22)	80,261	(22)
65-69 Years	298	(21)	68,962	(19)
70-74 Years	236	(16)	51,837	(14)
75-79 Years	157	(11)	41,059	(11)
80-84 Years	104	(7)	23,932	(6)
85+ Years	51	(4)	13,437	(4)
Total	1,443	(100)	368,561	(100)
Ethnicity (> 55 years)				
White	1,389	(97)	345,756	(92)
Non-white	40	(3)	30,829	(8)
Total	1,429	(100)	376,585	(100)

(1) Missing data are not included in column totals.
(2) Population estimates for NWTRHA are taken OPCS 1991 Census, County Monitors

The comparison of sub-samples of responders and non-responders found no difference in mean age (70 vs. 71 years). Apparent non-responders included 8% that had either died, moved or the general practitioner had no evidence of having the medical record (Table 5.4). In addition, for 2% of responders and 11% of non-

responders, although there was evidence that a record existed, these records could not be located. Comparison of the medical records available revealed that responders were more likely to have undergone previous prostate surgery (7% vs. 1%; $p<0.05$), but there was no significant difference in the histories of their reported urinary symptoms.

Table 5.4 **Characteristics of responders and non-responders, urinary symptom prevalence survey, North West Thames region, 1992.**

	Responders		Non-responders		SE
	N	(%)	N	(%)	
Status					
On GP list	98	(98)	81	(81)	4.17**
Deceased/moved/ghost	0	(0)	8	(8)	2.71**
Notes not found	2	(2)	11	(11)	3.43**
Total	100	(100)	100	(100)	
Urinary symptoms					
No urinary symptoms	79	(81)	72	(89)	5.33
Previous prostate surgery	7	(7)	1	(1)	2.80*
Urinary symptoms	5	(5)	4	(5)	3.92
Urinary symptom, referral	4	(4)	2	(2)	2.50
Other urology	3	(3)	2	(2)	2.31
Total	98	(100)	81	(100)	

SE = Standard error of the difference

* $p < 0.05$
** $p < 0.01$

5.2.2 Prevalence and severity of symptoms

The distribution of each urinary symptom by level of severity is shown in Figure 5.2. While most men report that they never, or hardly ever, experience these symptoms, a substantial percentage of men experienced urinary symptoms more than 'hardly ever': some did not feel that their bladder emptied fully after urinating (21%); some often had to go again within 2 hours of urinating (37%); some stopped and started when they urinated (22%); some found it difficult to postpone urinating (22%); some had a weak stream (24%); and some had to push and strain to start urinating (10%). The distribution of the Symptom Index is also strongly skewed to the left (Figure 5.3); few men experience high composite symptom scores. On categorising the data, 20.8% report no symptoms, 10.4% very mild symptoms and 48.5% mild symptoms (Table 5.5). The overall proportion of men with moderate/severe symptoms was 20.4%. This increased from 16.2% in those aged 50 to 59 to a plateau of between 20% and 25% in those aged between 65 and 79 years. It then fell to 11.9% in those over the age of 85.

Table 5.5. *Frequency distribution of symptom severity* **by age group, men aged 55 and over, North West Thames region, 1992.**

Age group (years)	Symptom severity: None %	Very mild %	Mild %	Moderate %	Severe %	Moderate & Severe combined	95% CIs
55-59 (n=272)	21.0	11.8	51.1	12.8	3.3	16.2	12.1 to 20.8
60-64 (n=310)	23.2	11.0	46.6	15.8	3.6	19.4	15.2 to 23.9
65-69 (n=287)	22.0	10.5	46.7	17.1	3.8	20.9	16.4 to 25.8
70-74 (n=228)	18.9	9.7	45.8	16.7	9.2	25.9	20.4 to 31.7
75-79 (n=148)	20.3	7.4	52.0	14.9	5.4	20.3	14.3 to 27.1
80-84 (n=94)	12.8	10.6	51.1	19.2	6.4	25.5	17.3 to 34.6
85+ (n=42)	23.8	9.5	54.7	11.9	0	11.9	4.5 to 23.5
Total (n=1381)	20.8	10.4	48.5	15.6	4.8	20.4	18.3 to 22.5

N=1480, 99 missing; percentages have been rounded.
CIs= Confidence Intervals

Figure 5.2. Distribution of urinary symptoms, men aged 55 and over, North West Thames, 1992.

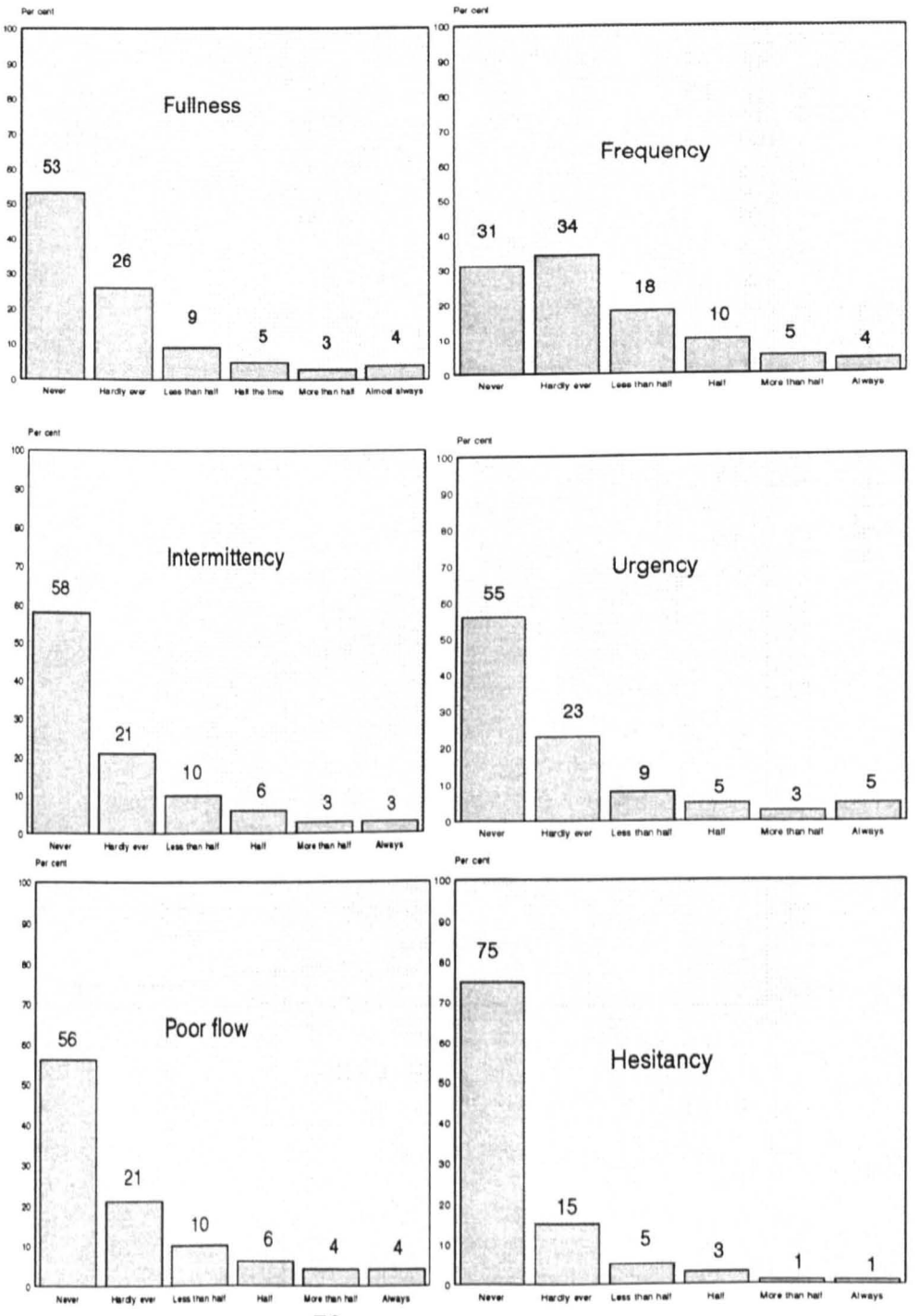
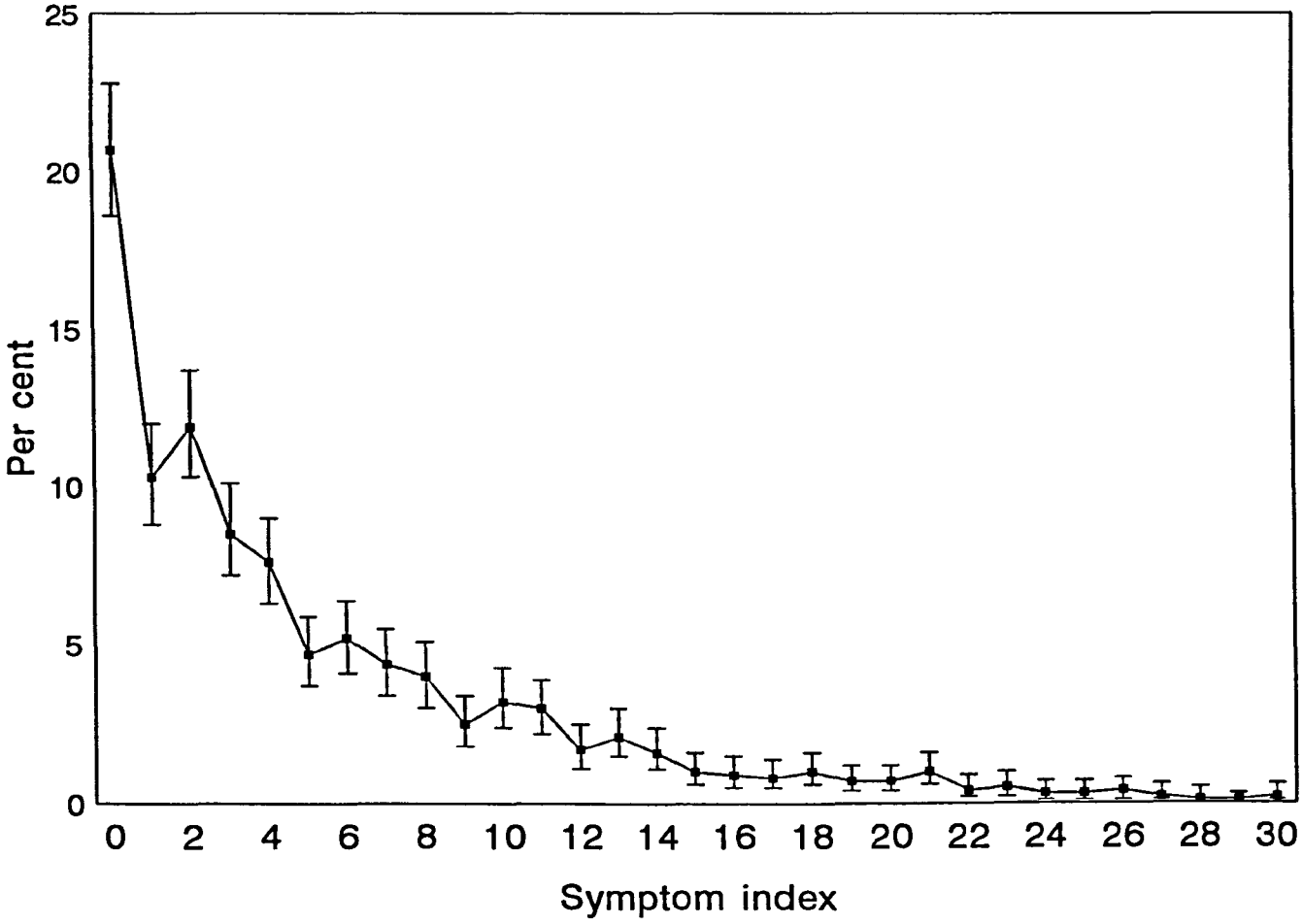


Figure 5.3. Distribution of Symptom Index, (95% confidence intervals), men aged 55 and over, North West Thames region, 1992.



5.2.3 Impact of symptoms

The extent to which men were bothered by their symptoms increased significantly with increasing symptom severity (Table 5.6). Of those with mild symptoms, only 0.5% felt they were a medium or big problem; this increased to 15.9% of those with moderate symptoms and 66.2% of those with severe symptoms. Of those with mild symptoms, 2.8% reported interference in their daily activities most or all of the time (Table 5.7). This increased to 17.9% for those with severe symptoms. When asked about spending the rest of their life with their current symptoms, 43.1% of men with moderate or severe symptoms reported they would feel unhappy or terrible (Table 5.8). This proportion varied by symptom severity from 3.5% of those with very mild symptoms to 76.4% with moderate symptoms.

Table 5.6. **Frequency distribution of bothersomeness by symptom severity, men aged 55 and over, North West Thames region, 1992.**

	Symptom severity							
Bothersomeness	None %	Very mild %	Mild %	Moderate %	Severe %	Moderate & severe combined	Total	95% CIs
No problem	99.0	97.3	73.7	20.5	5.9	17.0	70.0	12.9 to 21.6
Very small problem	1.0	2.7	20.8	34.9	4.4	27.6	16.2	22.5 to 32.9
Small problem	0	0	4.9	28.8	23.5	27.6	7.9	22.5 to 32.9
Medium problem	0	0	0.6	14.0	44.1	21.2	4.5	16.7 to 26.1
Big problem	0	0	0	1.9	22.1	6.7	1.4	4.2 to 10.0
Total	n=293	n=146	n=690	n=215	n=68	n=283	n=1412	

N=1480, 68 missing; percentages have been rounded.
CIs= Confidence intervals

Table 5.7. **Frequency distribution of interference in daily activities by symptom severity, men over the age of 55, North West Thames region, 1992.**

Interference in daily activities	Symptom severity: None %	Very mild %	Mild %	Moderate %	Severe %	Moderate & Severe combined	Total (%)	95% CIs
Never	99.0	100	92.8	71.6	35.8	63.1	88.1	57.2 to 68.4
Some of the time	1.1	0	6.9	25.6	46.3	30.5	10.4	25.2 to 35.9
Most of the time	0	0	0.4	2.8	13.4	5.3	1.3	3.1 to 8.4
All of the time	0	0	0	0	4.5	1.1	0.2	0.3 to 2.8
Total	n=287	n=145	n=685	n=215	n=67	n=282	n=1399	

N=1480, 81 missing; percentages have been rounded.
CIs= Confidence intervals

Table 5.8. **Frequency distribution of perception of future by symptom severity, men over the age of 55, North West Thames region, 1992.**

Perception of future	Symptom severity: None %	Very mild %	Mild %	Moderate %	Severe %	Moderate & Severe combined	Total	95% CIs
Delighted	75.3	59.9	27.1	1.4	0	1.1	35.0	0.3 to 2.8
Pleased	20.9	33.1	45.9	22.8	4.4	18.4	33.8	14.1 to 23.1
Not bothered	3.9	7.0	22.9	43.3	19.1	37.5	20.4	31.9 to 43.0
Unhappy	0	0	4.1	30.2	63.2	38.2	9.9	32.5 to 43.8
Terrible	0	0	0	2.3	13.2	4.9	1.0	2.8 to 7.9
Total	n=283	n=142	n=677	n=215	n=68	n=283	n=1385	

N=1480, 95 missing; percentages have been rounded.
CIs= Confidence intervals

5.2.4 Previous prostate surgery and other urological symptoms

The prevalence of urinary symptoms is dependent on previous prostatectomy rates and the effectiveness of this surgery. One hundred and sixty four (12%) of men reported having undergone previous prostate surgery. To allow for the different numbers of men at risk of having first-time surgery, the probability of having first-time surgery when in each age group was calculated by dividing the number of men who had surgery when in each age group by the number of men that had reached that age group (Table 5.9). The probability of having surgery (derived by subtracting the

number of years reported since surgery from their current age) when under 50 years of age was only 0.1% and increased to 8% in the age group 75 to 79. This is equivalent to a doubling in the probability of having surgery every five years. Because there are fewer men in older age groups, this gives a different picture from that seen in urological practice. Almost half (45.7%) the men who had undergone surgery were aged between 60 and 69.

Table 5.9. **Experience of prostate surgery, men over the age of 55, North West Thames region, 1992.**

Age group (years)	Sample population having reached or exceeded age group	Number of men having surgery within age category N	(%)	% probability of having surgery	Current age of men with previous surgery N	(%)	Current % of having had previous surgery by age
< 50	1443	2	(1.3)	0.1			
50-54	1443	8	(5.2)	0.6			
55-59	1443	17	(11.1)	1.2	7	(4.3)	0.5
60-64	1168	34	(22.2)	2.9	17	(10.4)	1.5
65-69	846	36	(23.5)	4.3	31	(18.9)	3.7
70-74	548	21	(13.7)	3.8	32	(19.5)	5.8
75-79	312	25	(16.3)	8.0	34	(20.7)	10.9
80-84	155	8	(5.2)	5.2	26	(15.9)	16.8
85+	51	2	(1.3)	3.9	17	(10.4)	33.3
Total		153	(100)		164	(100)	

N=169 with previous surgery; missing age at previous surgery=16, missing current age=5

Of the 156 (6%) of men who reported a previous episode of acute retention, only 38.5% had undergone surgery (Table 5.10). 8% percent of men reported a previous urinary tract infection. When asked about urinary incontinence, 7.5% leaked enough urine to be embarrassed, and 0.8% needed to wear pads.

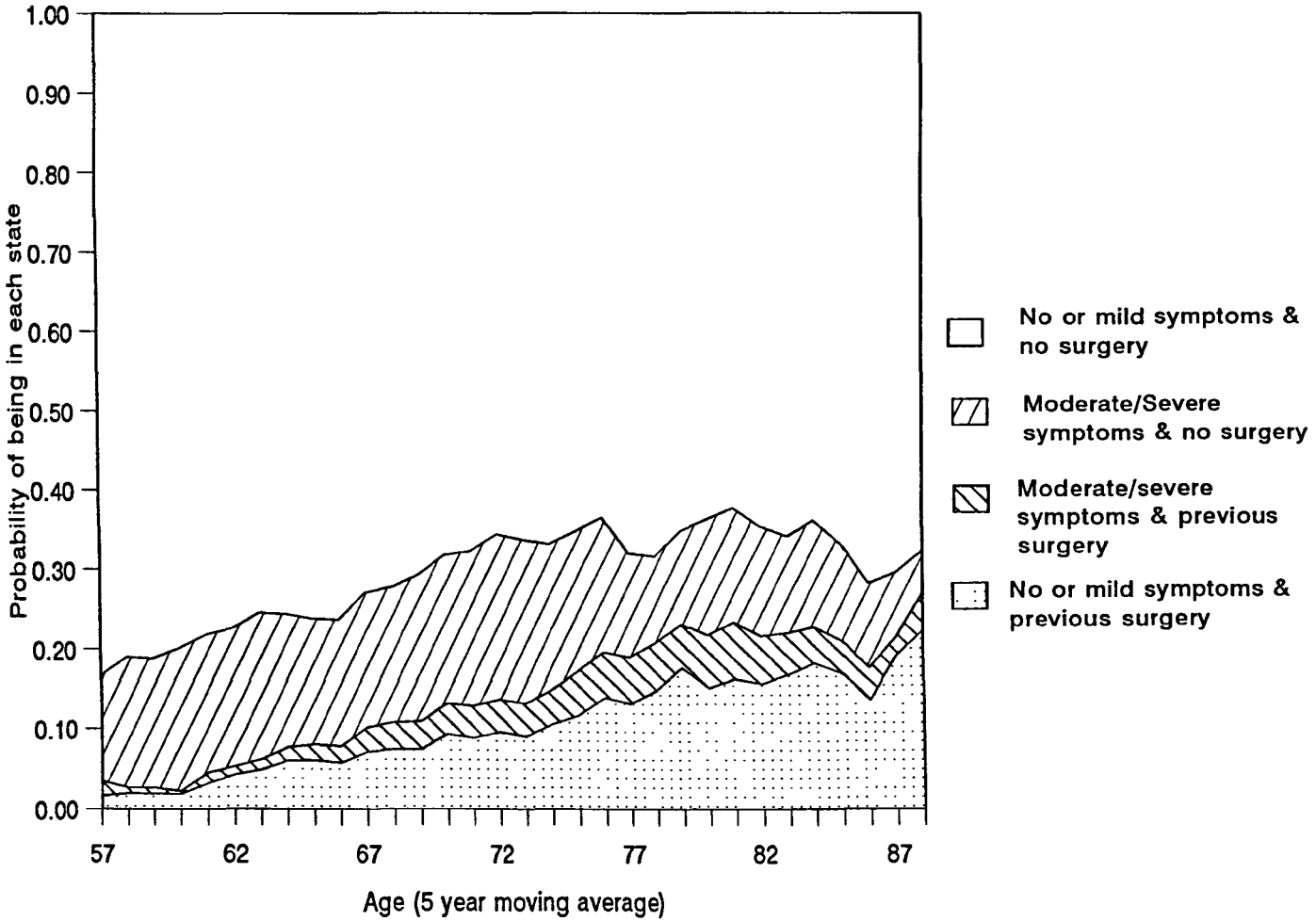
Table 5.10. **Distribution of previous surgery by acute retention, men aged 55 and over, North West Thames region, 1992.**

		Previous surgery		
		Yes	No	Total
Acute retention	Yes	60 (38.5)	96 (61.5)	156 (100)
	No	24 (1.9)	1239 (98.1)	1263 (100)
	Total	84 (5.9)	1335 (94.1)	1419

5.2.5 Summary

The current pattern of urinary symptoms among men aged 55 and over and the urological response to them is best illustrated by combining the data on the prevalence of men with a history of prostate surgery (Table 5.9) and the prevalence of urinary symptoms (Table 5.5). Figure 5.4 shows the proportions of men in each age group in each of the following states: (a) no or mild symptoms and no previous surgery; (b) moderate/severe symptoms but no previous surgery; (c) previous surgery with no current moderate/severe symptoms; and (d) previous surgery and current symptoms. The percentage of men having either moderate or severe symptoms or a history of previous prostate surgery, or both increased from 17% at age 57 to 38% at age 81. The percentage of men with moderate/severe symptoms who have not had prostate surgery increases until the age of 73 and then appears to decrease. Of men who have had prostatectomy, the percentage with recurrence or persistence of moderate or severe symptoms appears to remain relatively constant across the age range, at about 30%.

Figure 5.4 Age-specific probabilities of moderate/severe symptoms and previous prostate surgery, North West Thames region, 1992.



5.3 Results of the follow-up survey

5.3.1 Characteristics of the sample

Of the 516 men who were sent a questionnaire (34.9% of the original sample), 8 had died and 3 had moved, so that the final study population was 505 (Table 5.11). 72 questionnaires were not returned and a further 13 questionnaires were returned without response, so that the response rate was 83.2% (420/505). A comparison of non-responders and responders showed little difference in mean age (69.5 vs. 67.1 years). Responders were significantly more likely to have moderate or severe symptoms (Table 5.12). Responders were also more likely to have had previous prostate surgery, and to have experienced an episode of acute retention, although these differences were not significant. In total, 420 men with a symptom score or 7 or more, or a history of acute retention were included in the analysis.

Table 5.11 Response rates to the follow-up survey, North West Thames region, 1992.

	N	%
Responded	420*	(81)
Not returned	72	(14)
Returned without response	13	(3)
Not known at address or moved	3	(1)
Died	8	(2)
Total	516	(100)

* Response rate among valid responders 420/505 = 83.2%

Response rate for: Nottingham Health Profile 221/258 = 85.7%, SF-36 217/258 = 84.1%

Table 5.12. **Characteristics of responders and non-responders to the follow-up survey, North West Thames region, 1992.**

	Responders		Non-responders		SE
	N	%	N	%	
Symptom severity					
Mild	181	43.1	76	89.4	4.12**
Moderate	185	44.0	5	8.2	3.84**
Severe	54	12.9	2	2.4	2.3
Total	420		85		
Previous prostate surgery					
Yes	77	18.4	9	10.6	3.84**
No	342	81.6	74	89.4	
Total	419		85		
Missing=1					
Acute retention					
Yes	53	13.0	6	7.2	3.44**
No	355	87.0	77	92.8	
Total	408		74		
Missing=12					

SE= Standard error of the difference
** $p < 0.01$

To test the extent to which men's urinary problems may have changed between the initial survey (from which their Symptom Index scores were derived) and the follow-up survey (from which patient preference was determined), questions on bothersomeness and frequency of urination were included in both. The results of a Wilcoxon matched-pairs signed rank test confirmed that there had been no significant change in the extent of bothersomeness of symptoms (Z=-0.12, p=0.905). However, there was a slight, but statistically significant, decrease in the severity of frequency of urination between the two surveys (z=-3.02, p=.0025). The median score of 2 remained the same, while the mean score decreased from 2.2 to 2.1.

5.3.2 Impact of urinary symptoms on daily activities

The distribution of the impact of severe symptoms on daily activities is shown in Figure 5.5. While, the majority of men did not find that their symptoms interfered with their activities, substantial percentages of men were affected in some aspects more often than 'hardly ever': some worried about needing a toilet (18%), some worried about wetting themselves in public (23%), some avoided using public toilets due to difficulty starting to urinate (38%), some were embarrassed about having to use the toilet often (36%) and some limited the amount they drank (57%). In contrast, men with mild symptoms reported little interference with their activities - the proportion ranged from 3% who worried about wetting themselves in public to 16% who limited the amount they drank. Overall, 90% of men reported interference with at least one of these activities.

5.3.3 Association with health status

NHP scores by symptom severity are presented in Table 5.13. The median NHP scores increased (ie. health worsened) as symptom severity increased for energy, emotional reactions and physical mobility. The Spearman's correlation coefficients for these dimensions were statistically significant ($p<0.01$). Although the median score for sleep remained constant at 13 across the symptom severity categories, the Spearman correlation coefficient was significant ($p=0.005$). The median values were 0 (perfect health) for all other dimensions. The most striking finding was that the changes in median values, affecting energy, emotional reactions and physical mobility, occurred between moderate and severity categories. This was inconsistent with the view of the panel that moderate and severe symptoms should be treated in the same way.

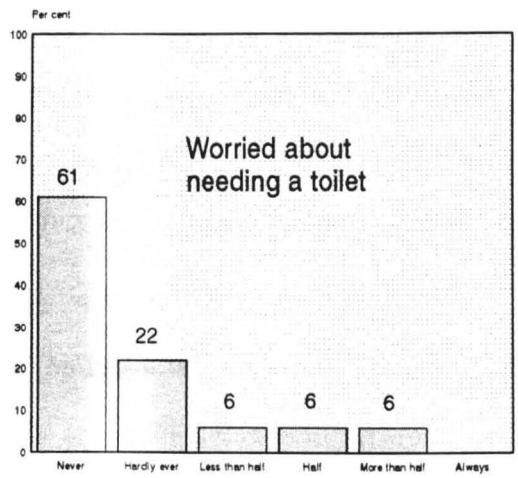
Table 5.13. Median Nottingham Health Profile scores by symptom severity, among men aged 55 and over in a population sample, interquartile range, North West Thames region, 1992.

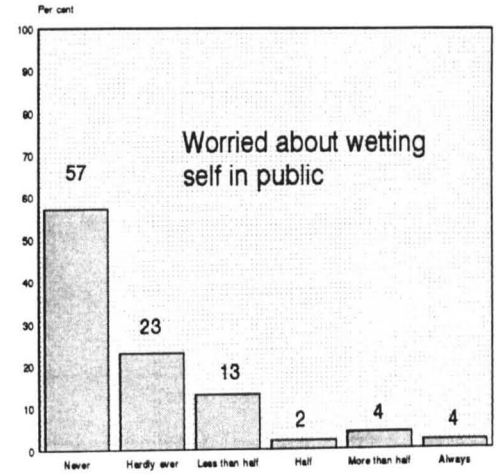
	Mild			Moderate			Severe				
	N	Median	range	N	Median	range	N	median	range	Spearmans correlation coefficient	p
Energy	76	0	[0 -24]	88	0	[0 - 24]	29	24	[0 - 63]	0.19	0.007
Pain	71	0	[0 - 0]	83	0	[0 - 0]	30	0	[0 - 13]	0.12	0.104
Emotional reactions	70	0	[0 - 7]	85	0	[0 - 10]	30	10	[0 - 24]	0.22	0.002
Sleep	75	13	[0 - 16]	83	13	[0 - 34]	31	13	[0 - 38]	0.20	0.005
Social isolation	73	0	[0 - 0]	88	0	[0 - 0]	31	0	[0 - 0]	0.06	0.374
Physical mobility	70	0	[0 - 0]	89	0	[0 - 9]	30	11	[0 - 22]	0.22	0.002

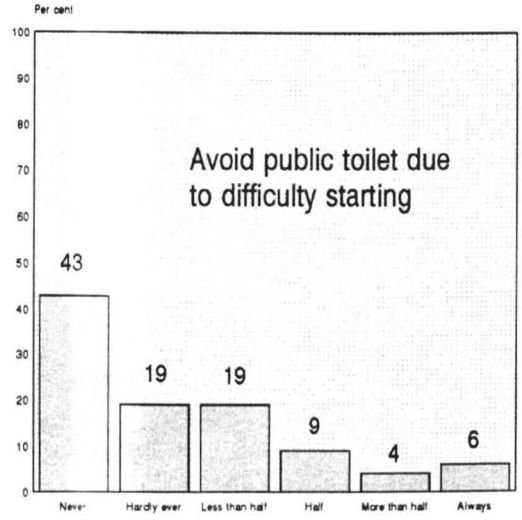
Table 5.14. Median SF-36 scores, interquartile range, by symptom severity, men aged 55 and over (n=205), North West Thames region, 1992.

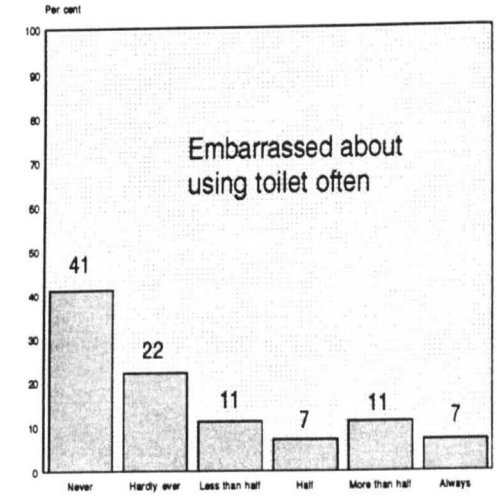
	Mild			Moderate			Severe				
	N	Median	range	N	Median	range	N	Median	range	Spearmans correlation coefficient	p
Physical Functioning	87	85	60-95	81	85	55-95	18	75	44-95	-.990	0.073
Physical Role	85	100	50-100	75	75	25-100	18	88	0-100	-.193	0.009
Bodily Pain	93	84	62-100	85	84	41-100	20	62	50-100	-.123	0.080
General Health Perceptions	89	72	59-75	81	62	79-77	18	62	47-82	-.206	0.004
Vitality	90	60	50-76	85	60	45-75	20	58	50-69	-.209	0.003
Social Functioning	94	100	75-100	85	100	63-100	19	75	0-100	-.212	0.002
Emotional Role	87	100	33-100	76	100	33-100	19	100	0-100	-.107	0.147
Mental Health	93	84	72-92	85	76	60-88	20	74	54-91	-.269	0.0001

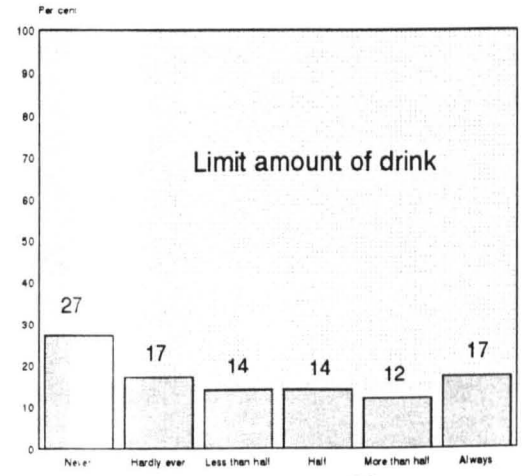
Figure 5.5 Interference with activities, men aged 55 and over with severe urinary symptoms, North West Thames, 1992.











Median SF-36 scores by symptom severity are presented in Table 5.14. For most dimensions health status decreased as symptom severity increased from mild to severe. The exceptions were emotional role and vitality where there was little difference between men with moderate and with severe symptoms. The dimensions for which there was a statistically significant ($p<0.01$) decrease in scores with increasing symptom severity were physical role, social functioning, mental health, and general health perceptions. As with the NHP, the greatest changes in the medians occurred between moderate and severe, with relatively little difference in median values between mild and moderate symptoms.

5.3.4 Association with bothersomeness

Median NHP scores by bothersomeness are presented in Table 5.15. Median scores for emotional reactions increased as the reported 'bothersomeness' of symptoms increased ($p=0.004$). Statistically significant relationships were also observed for sleep ($p=0.019$) and pain ($p=0.045$). Median SF-36 scores by bothersomeness are presented in Table 5.16. The association between health status and bothersomeness was more marked than for symptom score, with highly significant associations and higher correlation coefficients for each dimension.

Table 5.15. Median NHP scores, interquartile range, by 'bothersomeness', men aged 55 and over, North West Thames region, 1992.

	No or 'very small' problem			Small problem			Medium or big problem			Spearmans correlation coefficient	p
	N	Median	range	N	Median	range	N	Median	range		
Energy	138	0	[0-24]	40	0	[0-0]	30	24	[0-63]	0.06	0.390
Pain	127	0	[0-0]	40	0	[0-0]	29	0	[0-15]	0.14	0.045
Emotional reactions	129	0	[0-0]	40	0	[0-10]	29	10	[0-41]	0.20	0.004
Sleep	133	13	[0-29]	40	13	[0-44]	29	13	[0-34]	0.17	0.019
Social isolation	135	0	[0-0]	39	0	[0-0]	30	0	[0-22]	0.08	0.251
Physical mobility	132	0	[0-10]	41	0	[0-11]	30	0	[0-22]	0.10	0.173

Table 5.16. Median SF-36 scores, interquartile range, by 'bothersomeness', men aged 55 and over (n=217), North West Thames region, 1992.

	No or 'very small' problem			Small problem			Medium or big problem			Spearmans correlation coefficient	p
	N	Median	range	N	Median	range	N	Median	range		
Physical Functioning	131	85	[55-95]	44	75	[60-90]	25	85	[45-95]	-0.18	0.0103
Physical Role	129	100	[67-100]	39	50	[33-100]	26	100	[0-100]	-0.25	0.0004
Bodily Pain	144	84	[62-100]	44	62	[41-92]	28	62	[41-100]	-0.22	0.0009
General Health Perceptions	137	72	[57-82]	41	60	[47-77]	25	57	[47-72]	-0.24	0.0004
Vitality	141	65	[50-80]	42	53	[45-70]	28	53	[48-60]	-0.24	0.0004
Social Functioning	145	100	[75-100]	44	75	[50-100]	27	88	[50-100]	-0.32	0.0001
Emotional Role	133	100	[50-100]	39	67	[0-100]	26	67	[0-100]	-0.24	0.0006
Mental Health	144	84	[72-92]	42	71	[52-84]	28	68	[52-86]	-0.30	0.0001

5.3.5 Comparison with men undergoing prostatectomy and in the general population

A comparison of median NHP scores in men with urinary symptoms with men undergoing prostatectomy is shown in Table 5.17. There was no significant difference in symptom score between men undergoing surgery (median=10) and men in the population with moderate or severe urinary symptoms (median=0, Mann-Whitney=-0.55, p=0.58). A relatively high proportion of NHP scores were 0 for men in the population with symptoms and the surgical cohort (Table 5.17). In all dimensions other than energy, the percentage of men with scores greater than zero was greater for those men undergoing surgery (5.18). The differences reached statistical significance for 3 dimensions: emotional reactions (p=0.004), pain (p=0.004), and energy (p=0.032).

A comparison of mean SF-36 scores in men with urinary symptoms with published population norms is shown in Table 5.19. Men with moderate and severe symptoms reported worse health than the general population. These differences were statistically significant for all dimensions except physical functioning. The smaller group whose symptoms were bothersome to the extent of being a medium or big problem had a greater relative general health status for all dimensions. Comparison with published age-adjusted SF-36 mean scores with other conditions in the general population revealed that, in general, men with moderate and severe symptoms reported worse scores than people with varicose veins, but better scores than those with low back pain, menorrhagia, and suspected peptic ulcer (Figure 5.6).

Table 5.17. **Median and interquartile ranges for the Nottingham Health Profile in men with moderate or severe symptoms in a cohort of men before prostatectomy in Oxford and North West Thames, 1988, and a population sample from North West Thames, 1992.**

	Surgical cohort			Population sample		
	N	Median	Range	N	Median	Range
Energy	220	0	[0-24]	238	0	[0-24]
Pain	218	0	[0-13]	234	0	[0-13]
Emotional reactions	219	10	[0-30]	236	8	[0-27]
Sleep	221	13	[13-44]	240	13	[13-36]
Social isolation	220	0	[0-16]	234	0	[0-05]
Physical mobility	218	0	[0-22]	235	0	[0-22]

Source: Doll HA et al. Patient perceived health status before and up to 12 months after TURP for benign prostatic hypertrophy. Soc Sci Med 1993; 37:115-22.

Table 5.18. **Proportion of cases with scores greater than zero among men with moderate or severe lower urinary tract symptoms either undergoing prostate surgery or in the population.**

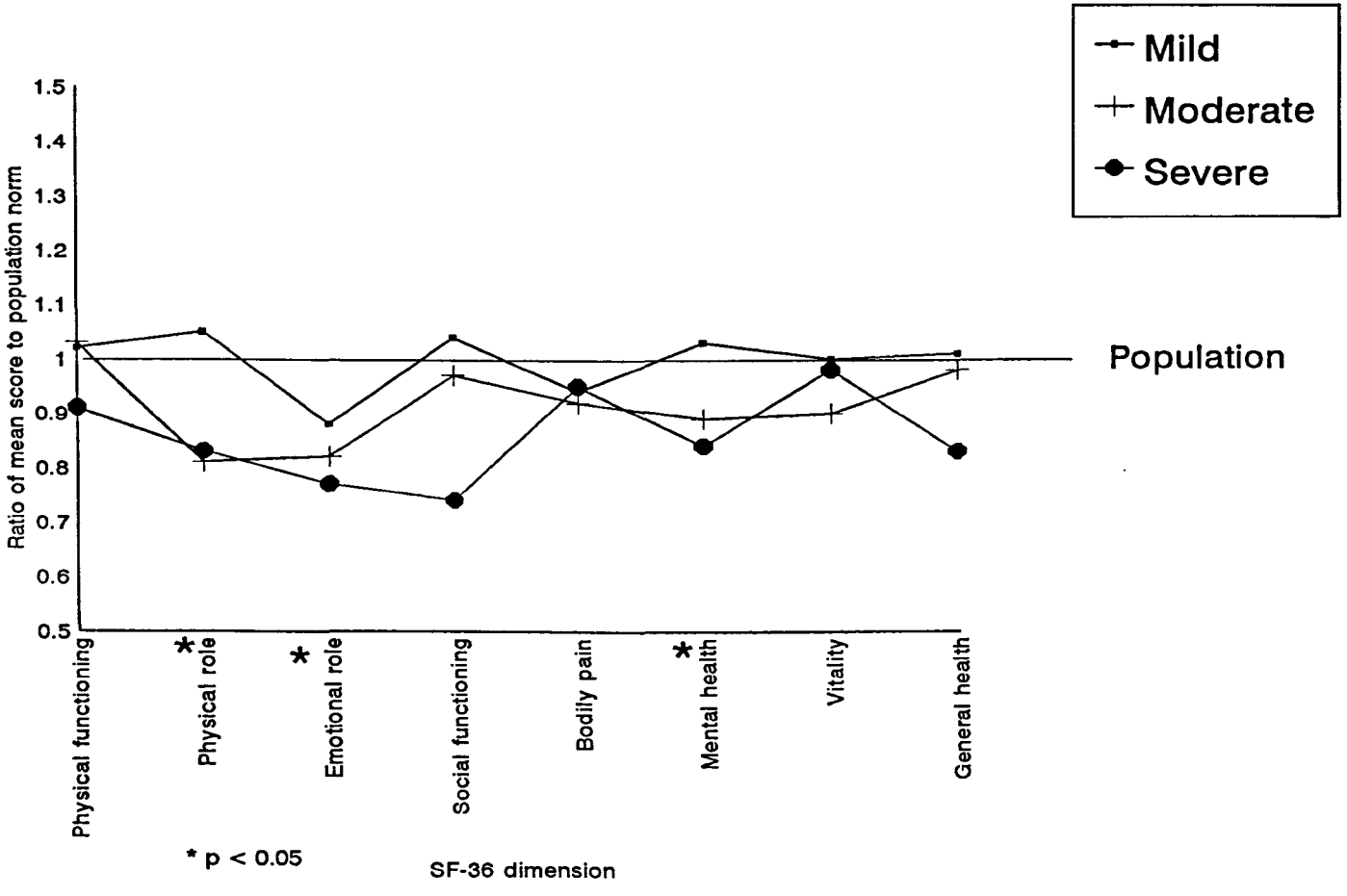
	Energy (% > 0) 95% CI	Pain (% > 0) 95% CI	Emotional reactions (% > 0) 95% CI	Sleep (% > 0) 95% CI	Social isolation (% > 0) 95% CI	Physical mobility (% > 0) 95% CI
Men undergoing surgery with	32.0 [25.9 - 8.2]	41.5 [34.9 - 47.9]	57.8 [50.9 - 63.9]	76.9 [70.7 - 81.8]	25.6 [20.0 - 31.5]	42.9 [36.2 - 49.3]
Men in the population	40.2 [31.3 - 48.8]	21.2 [14.3 - 29.2]	34.8 [26.3 - 43.4]	57.1 [66.7 - 74.3]	16.9 [10.9 - 24.3]	32.8 [24.6 - 41.2]
Wilcox p value	0.032	0.004	0.0004	0.07	0.322	0.153

Table 5.19. **Comparison of SF-36 scores in men aged 55-65 with moderate & severe urinary symptoms, North West Thames region, with healthy men aged 55-64 in Oxford Regional Health Authority area, 1991-92.**

	Moderate & severe symptoms N	Mean	[95% CIs]	Healthy population norms N	Mean	[95% CIs]	Difference	p
Physical Functioning	39	81.5	[75.3 - 87.7]	619	80.9	[79.2 - 82.6]	0.6	0.5596
Physical Role	37	65.5	[51.2 - 79.8]	619	80.2	[77.5 - 82.9]	-14.7	0.0071
Emotional Role	37	70.3	[57.0 - 83.6]	619	86.6	[84.3 - 88.9]	-16.3	0.0006
Social Functioning	38	81.4	[72.9 - 89.9]	619	87.5	[85.8 - 89.2]	-6.1	0.0495
Bodily Pain	39	72.8	[65.7 - 80.4]	619	79.0	[77.6 - 80.4]	-6.2	0.0158
Mental Health	39	68.5	[60.8 - 76.2]	619	78.0	[76.4 - 79.6]	-9.5	0.0026
Vitality	39	57.6	[51.6 - 63.6]	619	63.2	[61.3 - 65.1]	-5.6	0.0735
General Health Perceptions	38	61.0	[53.0 - 69.0]	619	68.5	[66.8 - 70.2]	-7.5	0.0179

Source of population norms: Jenkinson C, Wright L, Coulter A. Quality of life measurement in health care: A review of measures, and population norms for the UK SF-36. Health Services Research Unit, Department of Public Health and Primary Care, University of Oxford, 1993.

Figure 5.6. Ratio of mean SF-36 scores, for three categories of symptom severity, to population mean, men aged 55-64, for North West Thames region, 1992.



5.3.6 Advice-seeking behaviour

The pattern of the advice-seeking behaviour of men with symptoms is shown in Table 5.20. About half the men (51.7%) had not sought any advice for their symptoms; this behaviour was more common among those with mild (56.9%) or moderate (51.9%) symptoms than among those with severe symptoms (33.3%). Of those seeking advice, the principal source was their GP (89% of those with moderate symptoms, 97% of those with severe symptoms). The percentage of men who sought advice from their GP about their symptoms increased from 40.3% of those with mild symptoms to 64.8% with severe symptoms.

Table 5.20. **Source of advice used by men with symptoms, by symptom severity, men aged 55 and over, North West Thames region, 1992.**

	Symptom severity				
	Mild %	**Moderate %**	**Severe %**	**Total %**	**95% CIs**
No advice	56.9	51.9	33.3	51.7	56.8 to 56.3
Relatives	2.0	1.1	1.9	1.7	0.7 to 3.2
Friends	1.0	3.2	0	1.7	0.7 to 3.2
Nurse	0	1.1	0	0.5	0.1 to 1.5
GP	40.3	42.7	64.8	44.6	39.7 to 49.2
Total	n=181	n=185	n=54	n=420	

CIs= Confidence intervals

5.3.7 Action of GPs and Urologists

Of the 187 men who had consulted their GP, 21.1% were reassured, 16.6% were prescribed medication, and 62.3% were referred to a surgeon (Table 5.21). The decision to refer for consultant opinion was independent of symptom severity [mild (62.3%), moderate (63.5%) and severe (60.0%)]. Of the 109 men who were referred, 9 were still waiting to see their surgeon. The majority (71.4%) had been offered and

accepted surgery (Table 5.22). Of the remainder, 15 had been reassured, 4 had been prescribed medication and 7 had been offered and declined surgery. Again, the decision to offer treatment was independent of symptom severity although the numbers in each group were small.

Table 5.21. **Action taken by GP, by symptom severity, for men aged 55 and over who consulted their GP [n=187], North West Thames region, 1992.**

	Symptom severity				
	Mild %	Moderate %	Severe %	Total %	95% CIs
Reassured	17.4	25.4	20.0	21.1	15.5 to 27.5
Prescribed	20.2	11.3	20.8	16.6	11.6 to 22.5
Referral	62.3	63.4	60.0	62.3	54.6 to 68.9
Total	n=69	n=71	n=35	n=175	

CIs= Confidence intervals
Missing=12

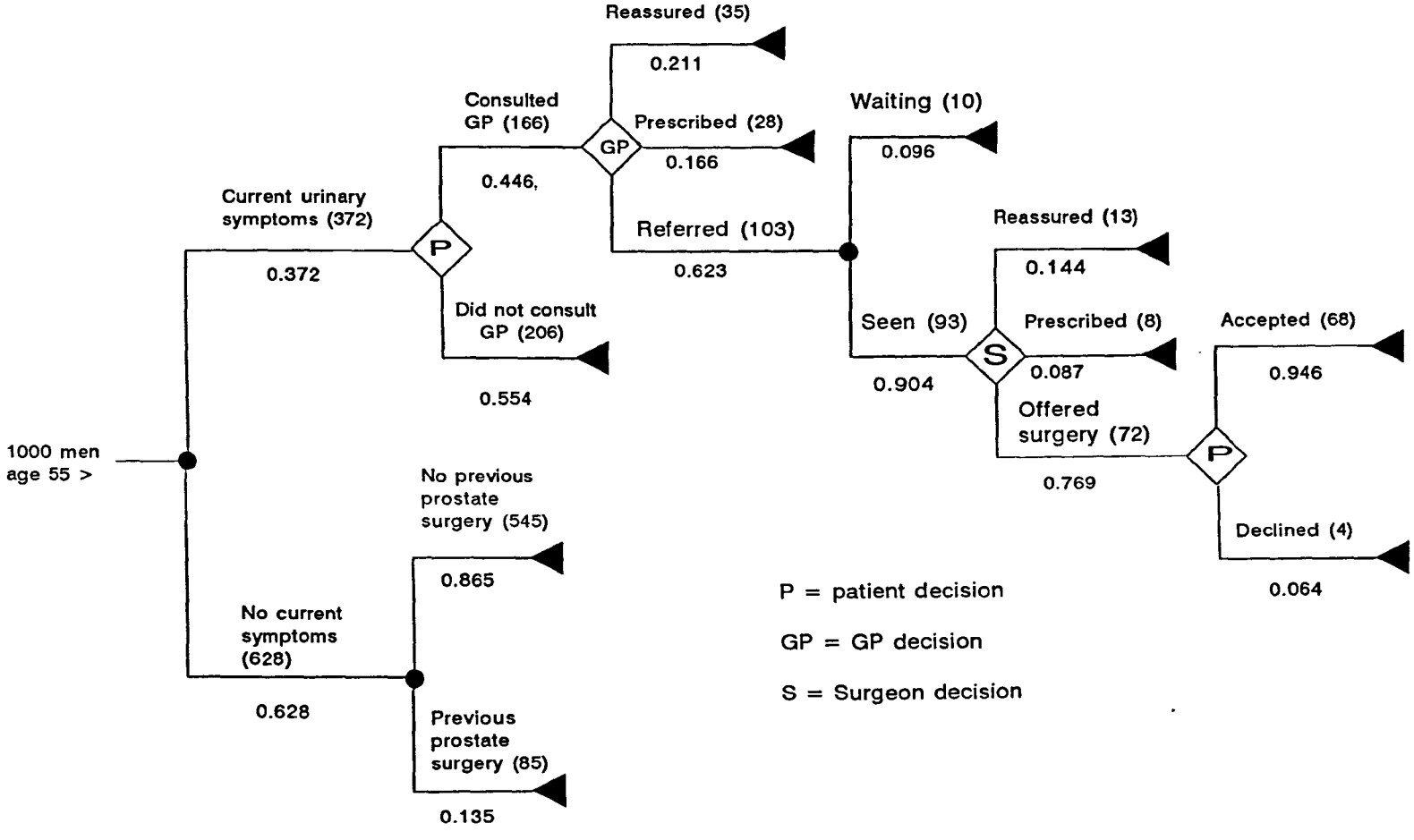
Table 5.22. **Action taken by urologist or surgeon, by symptom severity, for men aged 55 and over who had consulted a urologist [n=100], North West Thames, 1992.**

	Symptom severity				
	Mild %	Moderate %	Severe %	Total %	95% CIs
Reassured	10.3	20.0	23.5	16.5	9.8 to 24.8
Prescribed	0	11.4	0	4.4	1.4 to 10.0
Declined surgery	10.3	5.7	5.9	7.7	3.4 to 14.3
Accepted surgery	79.5	62.9	70.6	71.4	60.9 to 79.2
Total	n=39	n=35	n=17	n=91	

CIs= Confidence intervals
Missing=9; Still waiting to see urologist=9

The health care sought by men with urinary symptoms and the response of GPs and urologists have been summarised in a decision tree (Figure 5.7) that provides a model of the effect of each of the factors described earlier in a population of 1000 men aged 55 and over.

Figure 5.7. Decision tree for men with mild, moderate and severe urinary symptoms, North West Thames region, 1992.



5.3.8 Patient preference for treatment

Table 5.23 shows the distribution of patient preference for treatment by symptom severity. At their current level of symptoms, 30.6% of men would definitely or probably choose to have a prostatectomy, while 22.1%. would probably or definitely not want treatment. Nearly half of men (47.3%) were unsure what they would choose, although more men were inclined to have the operation than not (32.0% vs. 15.3%). Overall, men were more likely to choose surgery (62.6% vs. 37.4%). The proportion of men choosing surgery was not significantly related to symptom severity, a history of previous prostate surgery or of an episode of acute retention (Table 5.24).

Table 5.23. **Patient preference for treatment, by symptom severity, for men aged 55 and over who had not seen a urologist [n=315], North West Thames, 1992.**

	Symptom severity				
	Mild %	**Moderate %**	**Severe %**	**Total %**	**95% CIs**
Definitely want	13.9	17.2	25.8	16.7	12.7 to 21.3
Probably want	14.8	14.1	19.7	13.9	10.2 to 18.2
Not sure, inclined to yes	32.0	32.8	29.0	32.1	26.7 to 37.5
Not sure, inclined to no	13.9	16.4	16.1	15.3	11.4 to 19.8
Probably don't want	8.2	6.3	12.9	7.8	5.1 to 11.4
Definitely don't want	17.2	13.3	6.5	14.2	10.5 to 18.6
Total	n=122	n=128	n=31	n=281	

Missing=34; Table excludes those not seen by their urologist

Table 5.24. **Distribution of choice, by symptom severity, previous surgery, acute retention, men aged 55 and over who had not seen a urologist [n=315], North West Thames region, 1992.**

	Choosing Prostatectomy N	%	95% CIs [Low - High]
Symptom severity			
Mild	74	(60.7)	[51.4 - 68.5]
Moderate	82	(64.1)	[55.1 - 71.5]
Severe	20	(64.5)	[45.4 - 77.6]
Total	176	(62.6)	[56.7 - 67.9]
Missing=34, Mantel-Haenszel X^2=0.15, p=0.70			
Previous surgery			
Yes	10	(71.4)	[42.0 - 86.0]
No	166	(62.4)	[56.3 - 67.8]
Total	176	(62.9)	[56.9 - 68.1]
Missing=35, X^2=0.46, p=0.50			
Acute retention			
Yes	15	(68.2)	[45.1 - 82.0]
No	155	(61.3)	[54.9 - 66.9]
Total	170	(61.8)	[55.8 - 67.2]
Missing=41, X^2=0.41, p=0.52			

A separate analysis was undertaken of only those men who expressed a firm view about surgery (i.e that they definitely or probably would or would not choose it). In this group, men who had consulted their GP were more likely to have indicated that they definitely or probably would choose surgery (63, 71.6%) than those who did not consult their GP (64, 57.1%). Although this difference was small, it was statistically significant (chi-squared = 4.4, p=0.035).

5.4 Estimating need

The age-specific prevalence rates for those with appropriate indications who would choose surgery increased from 58.8 per 1000 in the 55-59 age group to 201.8 per 1000 in the 70-74 age group, before declining to 190.5 per 1000 in the over 85 year olds (Table 5.25). When these rates were applied to men over the age of 55 in a typical district of 250,000, the prevalent need for prostatectomy was 4295. This figure dropped to 2664 if men with mild symptoms were excluded from the calculation of the rates (Table 5.26) and to 741 if only those men with severe symptoms were considered (Table 5.27). The effects of the sensitivity analyses are shown in Table 5.28. The central estimate of prevalent need [based on men with moderate or severe symptoms who probably or definitely would want surgery and had indications which the panel viewed unequivocally as appropriate, was 1405. Although this estimate was consistent with the panel's ratings, inspection of the relationship between symptom level and health status (Section 5.3.3) suggests that it may be more suitable to consider men with severe symptoms separately. Accordingly, the estimate was reduced to 225 by considering only those men with severe symptoms who would definitely want surgery. This figure was 4329 if men with mild symptoms, men who were only inclined to want surgery, and indications about which the panel members were equivocal, were included.

Modelling incident need involved the matching of modelled age-specific incremental incidence rates to the observed prevalence rates found in the survey, using a process of fitting curves to the observed data. The results suggest that in a population containing 35,000 men aged between 50 and 90 (a typical figure for a catchment population of 250,000) there would be 400 to 500 new cases of men with moderate or severe lower urinary tract symptoms, who would probably or definitely choose

surgery. The model is described in detail in Appendix A8.

Table 5.25. Age-specific prevalence rates per 1000, mild, moderate & severe symptoms, appropriate indications, and chosen, 95% confidence intervals, and prevalent need in a district with a population of 250,000, men aged 55 and over, North West Thames region, 1992.

Age group	Sample N	Current symptoms N	Rate	[95% CIs]	Appropriate N	Rate	[95% CIs]	Appropriate & Chosen N	Rate	[95% CIs]	Population men > 55	Need N
55-59	272	66	242.6	[193.8 - 295.0]	59	216.9	[170.4 - 267.7]	16	58.8	[35.1 - 91.2]	6,254	368
60-64	310	84	271.0	[223.0 - 321.3]	79	254.8	[208.0 - 304.5]	56	180.6	[140.4 - 225.6]	5,636	1018
65-69	287	90	313.6	[261.0 - 367.6]	75	261.3	[212.3 - 313.2]	53	184.7	[142.5 - 231.7]	4,842	894
70-74	228	73	320.2	[261.0 - 381.0]	65	285.1	[228.4 - 344.6]	46	201.8	[152.9 - 256.2]	3,640	735
75-79	148	59	398.6	[320.1 - 475.7]	47	317.6	[244.9 - 392.9]	39	263.5	[196.2 - 336.2]	2,883	760
80-84	94	32	340.4	[247.8 - 435.3]	25	266.0	[182.5 - 357.5]	19	202.1	[129.0 - 288.4]	1,680	340
85+	42	12	285.7	[162.3 - 423.2]	8	190.5	[91.4 - 319.6]	8	190.5	[91.4 - 319.6]	943	180
Total	1381	416	301.2	[277.3 - 325.6]	358	259.2	[236.5 - 282.6]	237	171.6	[152.3 - 192.0]		4295

Table 5.26. Age-specific prevalence rates per 1000, moderate & severe symptoms, appropriate indications, and chosen, 95% confidence intervals, and prevalent need in a typical district with a population of 250,000, men aged 55 and over, North West Thames region, 1992.

Age group	Sample N	Current symptoms N	Rate	[95% CIs]	Appropriate N	Rate	[95% CIs]	Appropriate & Chosen N	Rate	[95% CIs]	Population men > 55	Need N
55-59	272	35	128.7	[92.4 - 171.7]	33	121.3	[86.1 - 163.4]	9	33.1	[16.2 - 59.3]	6,254	207
60-64	310	49	158.1	[120.2 - 201.1]	49	158.1	[120.2 - 201.2]	36	116.1	[83.7 - 154.8]	5,636	654
65-69	287	56	195.1	[151.9 - 243.0]	52	181.2	[139.4 - 228.0]	37	128.9	[93.5 - 170.7]	4,842	624
70-74	228	48	210.5	[160.7 - 265.7]	45	197.4	[149.0 - 251.5]	32	140.4	[99.3 - 189.0]	3,640	511
75-79	148	26	175.7	[120.0 - 241.2]	22	148.6	[97.5 - 211.0]	18	121.6	[75.6 - 180.2]	2,883	351
80-84	94	19	202.1	[129.0 - 288.4]	18	191.5	[120.4 - 276.6]	14	148.9	[86.7 - 228.5]	1,680	250
85+	42	4	95.2	[31.0 - 205.5]	3	71.4	[18.6 - 174.2]	3	71.4	[18.6 - 174.2]	943	67
Total	1381	237	171.6	[152.3 - 192.0]	222	160.8	[142.0 - 180.7]	149	107.9	[92.3 - 125.0]		2664

Table 5.27. Age-specific prevalence rates per 1000, severe symptoms, appropriate indications, and chosen, 95% confidence intervals, and prevalent need in a typical district with a population of 250,000, men aged 55 and over, North West Thames region, 1992.

Age group	Sample N	Current symptoms N	Rate	[95% CIs]	Appropriate N	Rate	[95% CIs]	Appropriate & Chosen N	Rate	[95% CIs]	Population men > 55	Need N
55-59	272	8	29.4	[13.7 - 54.6]	8	29.4	[13.7 - 54.6]	6	22.1	[9.0 - 44.8]	6,254	138
60-64	310	8	25.8	[12.0 - 48.0]	8	25.8	[12.0 - 48.0]	6	19.4	[7.9 - 39.4]	5,636	109
65-69	287	9	31.4	[15.4 - 56.3]	9	31.4	[15.4 - 56.3]	6	20.9	[8.5 - 42.5]	4,842	101
70-74	228	16	70.2	[42.0 - 108.3]	16	70.2	[42.0 - 108.3]	13	57.0	[32.0 - 92.4]	3,640	207
75-79	148	7	47.3	[20.9 - 90.0]	7	47.3	[20.9 - 90.0]	5	33.8	[12.5 - 92.1]	2,883	97
80-84	94	5	53.2	[19.7 - 111.5]	5	53.2	[19.7 - 111.5]	5	53.2	[19.7 - 111.5]	1,680	89
85+	42	0	0		0	0		0	0		943	0
Total	1381	53	38.4	[29.1 - 49.5]	53	38.4	[29.1 - 49.5]	41	29.7	[21.7 - 39.6]		741

Table 5.28. **Sensitivity analyses for the prevalent need for prostatectomy, in a typical district of 250,000, North West Thames, 1992.**

Symptom[1] severity	Level of[2] agreement	Patient[3] preference	N	Rate per 1000	Need (N)
Mild, moderate, severe (symptom score 7 - 30)					
	Agreement				
		definitely want	67	48.5	1242
		definitely or probably want	107	77.5	2005
		definitely or probably want, or inclined to yes	211	152.8	3954
	Agreement + Equivocal				
		definitely want	78	56.5	1462
		definitely or probably want	122	88.3	2285
		definitely or probably want, or inclined to yes	231	167.3	4329
	Based on action of those offered surgery[4]		169	122.5	3170
Moderate, severe (symptom score 10 - 30)					
	Agreement				
		definitely want	49	35.5	919
		definitely or probably want	75	54.3	1405
		definitely or probably want, or inclined to yes	137	99.2	2567
	Based on action of those offered surgery		97	70.3	1819
Severe (symptom score 19 - 30)					
	Agreement				
		definitely want	12	8.7	225
		definitely or probably want	15	10.9	282
		definitely or probably want, or inclined to yes	21	15.2	393
	Based on action of those offered surgery		29	21.0	543

[1] Symptom severity measured in initial survey

[2] Level of agreement from consensus panel

[3] Patient preference measured in follow-up survey

[4] 65 men in the sample had been offered and accepted surgery for their symptoms

Chapter 6 - Discussion

Introduction

This study has estimated the population prevalence and incidence of British men with appropriate indications who would want surgery for BPH. It is one of the few health care needs assessments undertaken to inform the purchasing process in the reformed NHS. This chapter summarizes the results of the study and considers the limitations of the methods used. The results are interpreted with respect to other relevant research. Finally, the implications of the study, both in terms of further research and policy are presented.

6.1 Summary of results

The main findings of the consensus panel were: 1) the panel attached little importance to mild symptoms; 2) history of urinary retention, the severity of urinary symptoms and the degree of comorbidity were given roughly equal weight by the panel; and 3) while a history of acute retention was important, the type of retention was less so, although acute-on-chronic retention was a stronger indication than either acute or chronic retention alone.

The initial survey described the prevalence and severity of urinary symptoms in British men aged 55 and over. Although most men reported no urinary symptoms, 20% reported moderate or severe symptoms. Of these, only 28% found their symptoms a medium or big problem. Thirty seven per cent of those with moderate or severe symptoms experienced interference with their daily activities at least some of the time, and 43% would be unhappy at the prospect of a future with their symptoms continuing at their current level.

Although, the majority of men with moderate or severe symptoms reported no interference in their daily activities, a substantial proportion reported that their activities were limited more than 'hardly ever'. Some aspects of health status and quality of life measured by both the Nottingham Health Profile (energy, emotional reactions and physical mobility) and the SF-36 (physical role, social functioning, mental health and general health perceptions) deteriorated with increasing symptom severity. Men with moderate or severe symptoms reported worse health, as measured by the SF-36, than men of similar age in the population, especially for physical role, emotional role and mental health.

Slightly fewer than half (45%) of men with symptoms reported that they had consulted their general practitioner, of whom the majority (62%) were referred to a surgeon, and of these the majority (71%) reported that they were offered and accepted surgery. However a substantial proportion (22%) of men said that they would choose to accept their symptoms and forego surgery, and a further 47% were unsure whether or not to go for surgery.

The best estimate of prevalent need for prostatectomy in a typical district of 250,000 among men who (a) have appropriate indications as defined by a consensus panel, and (b) would choose treatment if offered was 1405, but sensitivity analyses suggest that the figure could range from 225 to 4329, depending on the threshold for intervention adopted. The results of modelling incident need, corresponding to this prevalence, suggest that in a population containing 35,000 men aged between 50 and 90 (a typical figure for a catchment population of 250,000), there may be around 400 to 500 new cases with moderate or severe urinary symptoms per year who would choose to have surgery.

6.2 Limitations of methods

Before any conclusions may be drawn, the problems associated with undertaking health care needs assessments and the resulting limitations must be considered. This section discusses the limitations of: 1) developing an agreed case-definition; 2) consensus methods; 3) those associated with survey methods including bias, and problems of reliability and validity of the instrument used; and 4) inferring incidence from prevalence.

6.2.1 Developing an agreed case definition

The clinical decision to offer treatment is generally based on a combination of urinary symptoms and the results of urological investigations such as flow rates and residual volume. Currently there is debate in the urological literature about the relative importance of symptoms and urological measures, and several studies have shown a poor correlation between them (92,93,109,179). The panel members were equivocal about whether asymptomatic chronic retention (defined by them as post-void residual urine of greater than 400 mls) was an indication for surgery. This could not be detected in the population using a questionnaire. For practical purposes, its prevalence was assumed to be zero, because only 2% of the members of a group of 388 men in North West Thames & Oxford regions undergoing prostatectomy, had chronic retention without also reporting some symptoms (20), and analysis of unpublished data on 227 men in a community survey in Scotland that used transrectal ultrasonography found no asymptomatic men with a post-void residual urine of greater than 200 mls (2). Given that most surgery is carried out to improve quality of life, which is highly correlated with symptom severity (16,17,114), the presence of urinary symptoms was considered to be the most important factor in determining need for surgery in a population.

Ideally, indications for treatment would be based on high-quality evaluative research relating pre-intervention test results and symptoms to outcome, measured in terms of improvement in symptoms and quality of life, from men in a wide range of age/symptom level combinations. Such evidence is not available for prostatectomy; randomised clinical trials often exclude patients who have less well defined symptoms, have comorbidity or are older. Those RCTs that have examined symptomatic improvement in men undergoing TURP or open prostatectomy are of limited use, because they use different definitions of symptoms, and follow-up is only up to one year. In addition, neither symptoms nor urinary flow rates have strong power in predicting outcomes. Several observational studies of men undergoing prostatectomy were available, but it was still necessary to combine available research results with opinion from a consensus panel.

6.2.2 Limitations of consensus methods

A review of the literature on the management of lower urinary tract symptoms in men showed that there was little evidence about the effectiveness of treatment for men with differing types and severity of symptoms and, specifically, there were no relevant randomised controlled trials. This precluded the use of a meta-analysis. Consequently, to develop an agreed case definition, a method was required that used the limited evidence available optimally. Four possible alternatives were considered. These were: a committee, a delphi technique, a consensus development conference, and a nominal group.

The use of a simple committee was rejected for several reasons. First, there is evidence that committees are often dominated by one individual or by a coalition representing vested interests. This was seen as a potential problem because of the

mix of urologists and general practitioners. Second, the decisions made are susceptible to many factors extraneous to the topic of discussion. For example, increasing group size promotes more extreme positions, side by side seating promotes greater polarisation than face-to-face seating, limiting discussion time and tight rules of procedure promote compromise (151). Third, the traditional committee format does not enable explicit rating of the potential indications for treatment and prior identification of extreme positions.

The delphi technique is more appropriate to situations where there is little or no evidence. It typically involves two postal questionnaires, where participants rate their responses to specific questions and incorporates feedback of the first round results to inform the second round. It is primarily a means of measuring rather than developing consensus as it does not incorporate a method for resolving misunderstandings and definitional issues. The importance of this is the subject of debate in the literature. It has been argued that the absence of discussion forces an artificial consensus and weakens the validity of the conclusions (180), although in practical terms, the difference is slight (181). In contrast, others believe that there are no significant advantages in a meeting based approach (182,183). In establishing the appropriate indications for prostatectomy, it was felt that a meeting could provide additional qualitative information on the factors underlying disagreement. It was for this reason that a delphi technique was rejected.

Consensus development conferences, consist of a jury that considers the evidence of both expert and lay individuals. The jury then reaches a decision and releases a consensus statement. This would have been a viable alternative although it does not incorporate a means for explicitly addressing all of the possible combinations of

indications and thus may have been less useful in identifying areas of residual uncertainty. It was not used here because it because of the considerable time required by the participants (typically 2 days and an overnight stay) and its resulting prohibitive expense.

Having rejected the alternatives, a nominal group consensus panel was selected. The methods adopted were described in section 4.1. Despite their use in the health field, consensus development methods have been the subject of little rigorous evaluative research, especially when compared with the work on the dynamics of committees. Some has, however, been conducted in the areas of behavioural science and forecasting (181,184).

Consensus methods, in particular Delphi, have been described as methods of 'last resort' (185) with defenders warning against overselling the methods and suggesting that they should be regarded more as methods for structuring group communication than as a means for providing answers. There is clearly a danger that the fact that these approaches have a prescribed method and are often used to generate quantitative estimates may lead the casual observer to place greater reliance on their results than might be warranted. Unless findings can be tested against observed data, it is uncertain that the methods have produced the correct answer.

It has been argued that the delphi method fails to meet the standards normally set for scientific methods (180). The criticisms are based on the past poor quality studies rather than fundamental critiques of the method, eg. poor questionnaire design, inadequate testing of reliability and validity of methods, and the methods of defining and selecting experts. It is also argued that the method forces consensus and is

weakened by not allowing participants to discuss issues.

In this study, there are several limitations to consensus methods that need to be remembered. First, there is a potential bias in the selection of the panellists. The extent to which the panel reflected the views of other urologists and general practitioners is uncertain and could only be ascertained by repeating the process with a different group. Although it has been shown that doctors who are willing to participate in expert panels are representative of their colleagues in terms of measurable demographic, educational and employment variables (186), the exact composition of a panel can effect the results obtained (187). In this study, all the panel members came from one health region, in which the prostatectomy rate was 23% lower than the national average in 1985 (29). It may well be that a panel consisting of consultants from other regions would have given different results. It has been suggested that urologists from other regions would have placed greater importance on urinary flow-rates than symptoms (188).

Second, it is unclear how far stated opinions correspond to actual clinical practice. This question could only be answered by a detailed study of the patients seen and treated by panel members. In practice some of the combinations of signs, symptoms and comorbidity that the panel were asked to consider may be very rare. This may explain the one anomaly in the results of the panel. The indications defined as appropriate by the panel were generally consistent with each other, with the exception of men with mild symptoms and low comorbidity, for which the panel felt equivocal about whether surgery was appropriate for men with acute retention. The panel were not given an opportunity to re-score on the basis of the final results as shown in Figure 5.1. If they had done so, they might have identified this apparent anomaly and

re-scored accordingly. It is, however, reassuring that out of 45 cells, there was only one obvious inconsistency.

Several approaches to aggregating the results of nominal group type consensus panels have been described (153). Four definitions of agreement have been proposed: 1) A9S - all nine of the ratings fell within a single 3-point region - 1 to 3, 4 to 6, 6 to 9; 2) A9R - all nine of the ratings fell within any 3-point range; 3) A7S - after discarding one extreme high and one extreme low rating, the remaining seven ratings all fell within a single 3-point region - 1 to 3, 4 to 6, 7 to 9; and 4) - A7R after discarding one extreme high and one extreme low rating, the remaining seven ratings all fell within any 3 point range. Disagreement can be defined in the same way. In this study, the relaxed definitions A7R and D7R were used. There is no clearly preferred approach. It has been suggested that A7R can be used where unanimity is not essential. As this study sought to identify areas for which there was a broad degree of agreement, not necessarily unanimity, it was decided to use A7R. The effect of using a stricter definition (eg. AS9) would have decreased the extent of agreement.

Fourthly, the ratings of a panel are dependent on the definitions used. As in many areas of clinical work, terms in everyday use are used differently by different clinicians. Although there was some uncertainty among a few of the panellists at first, agreed definitions were developed and used as a basis for the second round, in some cases leading to modification of earlier scores. It is unknown to what extent panellists made use of the literature review that had been provided, although most stated that they had found it helpful.

Finally, the existence of a consensus does not in itself mean the consensus view is

correct and there is a danger that the nominal group process will arrive at collective ignorance rather than wisdom. As such it is not a replacement either for rigorous scientific reviews of published literature or for research, but rather a means of identifying current medical opinion and areas of disagreement. Unless these findings can be tested against observed data, we can not be sure that these the method has produced the correct answer. Ideally indications for surgery should be based on high quality evaluative studies that relate patient characteristics and clinical outcome. Such studies, whether experimental or non-experimental are beginning to become available.

6.2.3 Survey methods

If a set of indications can be established, the next step is to assess their prevalence in the population. Surveys are subject to sampling and response bias. Those responding to the initial survey may not have been fully representative of the general population. Men in the 55 to 59 age group were under-represented compared with the general population.

Second, those who do not respond to surveys may differ in some way from those who do. From the examination of case notes, 8% of men who did not respond had died, moved or had no general practice medical records. This suggests that the true response rate may have been as high as 80%. Non-responders did not differ from responders in terms of their history or lower urinary tract symptoms as recorded in general practice records, although they were less likely to have had previous prostate surgery. However, those who responded to the follow-up survey were more likely to report symptoms than those who did not. This suggests that the number of men seeking and receiving treatment may have been slightly overestimated.

There was a six week gap between the initial surgery and the follow-up survey in which patient preference, health status and quality of life was measured. Could the symptom severity have altered between the two surveys? There was no significant change in the 'bothersomeness' of symptoms, which is highly correlated with symptom severity (87), and no change in the median score for frequency of urination. There was a slight decrease in the mean score for frequency of urination (2.2 to 2.1), which could be explained by regression towards the mean, a statistical phenomenon in which, if a follow-up sample is chosen on the basis of extreme scores, their retest scores will tend to be closer to the population mean than the initial scores. As the difference was of little clinical significance (2.2 to 2.1), the time gap between the collection of data on symptom severity and on health status probably did not introduce any significant bias.

6.2.4 Reliability and validity of questions

The way the questions were phrased could bias the results. Where possible, questions with known reliability and validity were used; these included questions on lower urinary tract symptoms, and health status. The question about patient choice was designed specifically for this study.

6.2.4.1 Lower urinary tract symptoms

The index used to measure urinary symptoms was similar to the American Urological Association symptom index, which has been extensively tested and has been shown to be internally consistent and have good test-retest reliability, as judged by Pearson correlation coefficients (87). The index used here differed from the AUA index in two respects. Firstly the wording of the questions was modified slightly to make them clearer to U.K. responders in response to comments during the pilot survey. For

example, the AUA question on fullness 'Over the past month or so, how often have you had the sensation of not emptying your bladder completely after you finished urinating?' was changed to 'In the past month, how often did you feel that your bladder did not empty fully after urinating?'. Although these changes were minor, and probably did not affect reliability and validity, in retrospect, it would have been better to have left them as they were.

Secondly, the question on nocturia mistakenly used daytime frequency response categories, rather than night-time categories. This resulted in nocturia categories that were too crude to use (times per night = 1-3, 4-5, 6-7, 8-9, 10-11, 12 or more). Consequently, nocturia was excluded from the calculation of the symptom index so that it ranged from 0-30 rather than 0-35. It is unlikely that this had a significant effect on the results because: 1) nocturia has many other causes, such as cardio-vascular disease and the person's fluid intake before going to bed; 2) nocturia is the symptom that responds least well to prostatectomy (155); and 3) in a validation study of the AUA index, the highest inter-symptom correlation was between nocturia and frequency and frequency was already included in the index. To examine the consequences of omitting nocturia from the initial analysis of the first questionnaire, a 7-item index was calculated for the 420 men who received the follow-up survey. This was accomplished by adding the nocturia result from the second questionnaire to the 6-item index derived from the initial questionnaire. The total score for the 7 item index was re-scaled to give values that ranged from 0 to 30. When the 2 indices were compared there was little difference in the proportion of men in each severity category (mild 43.1% vs. 45.1%), moderate (44.0% vs. 42.7%) and severe (12.9% vs. 12.1%). These differences were not statistically significant.

Symptom severity categories were derived from cutoff points used in a previous study (167). The use of different cutoffs would have important implications for the numbers of individuals in each category. For example, moderate or severe symptoms were defined as a symptom index score of greater than 9, giving a prevalence in the male population aged 55 and over of 204 per 1000. Reduction of the threshold to 8 would result in a prevalence of 227 per 1000; a threshold of 11 would result in a prevalence of 170 per 1000. Since the survey was undertaken, American guidelines have been published using a lower threshold. Had this been available at the time, it would have been used.

Although the categories of symptom severity (mild, moderate and severe) used in the consensus panel were similar to those used in the prevalence survey, they were not equivalent. In the panel, participants used their own subjective definitions of these categories, while in the survey, the severity categories corresponded to those of the AUA symptom index. In retrospect, it might have been better to present the AUA symptom categories to the panel as an example. This question could only be examined by a detailed study that compared the subjective assessment of a clinician using these categories of severity, with the symptom categories in patients derived from the AUA symptom index.

6.2.4.2 Health status and quality of life

The Nottingham Health Profile has been extensively tested and shown to be both reliable and valid in a variety of contexts (169). It has been shown to be sensitive to changes in health status following prostatectomy (189). However, it is not recommended that the NHP be used on the general population, or for those with relatively mild medical conditions because most of a sample with low disability will

score zero, which makes it unsuitable for comparative purposes (169).

The SF-36, an increasingly used measure of generic health status, has also been tested for its reliability and validity (171-173). While the internal consistency of the SF-36 has been shown to be good, the test-retest reliability remains uncertain (190). The SF-36 has been criticised because it does not include sleep (191), which is often an important factor for men with urinary symptoms. The interpretation of the SF-36 is confined to younger age groups because there are no published norms for those over the age of 65 (172).

6.2.4.3 Patient preference

The question about patient preference was developed specifically for this study and has not been tested for its reliability and validity, in particular its power to predict the decision that a man will take in practice. Nevertheless, it was discussed extensively with researchers who have considerable experience in questionnaire design. It was decided not to include information on possible post-operative mortality in the question about patient choice because the risk is small (1.5%) and because it might unnecessarily frighten men. Similarly, although retrograde ejaculation is a reported complication, it was considered to be another form of sexual dysfunction, and information about difficulties in getting an erection was already included. Furthermore, it was difficult to come up with a simple but accurate and comprehensible form of wording that described this complication.

Most of the published work about patient preferences has been applied to choices for specific treatment alternatives in cancer patients (192) [especially breast cancer (193,194)], women undergoing abortion (195), rheumatic disease (196),

cardiovascular risk management (197), and hypothetical lung cancer in ambulatory patients with chronic conditions (198). The studies typically examine tradeoffs between quality of life and life expectancy, which use econometric methods such as standard gamble and time tradeoffs (199).

These methods are subject to many biases, arising from their underlying assumption that people make rational choices in situations of uncertainty. The evidence that this assumption is not always true has been reviewed at length (200,201). In brief, the potential biases include: social desirability, in which respondents give answers they feel will be welcomed, although it is unclear whether this is context dependent or reflecting an underlying trait of individuals (202); acquiesence or 'yea-saying', in which respondents tend to answer positively regardless of the question (203); biases that relate to the construction of scales or range of choices such as end aversion, positive skews, and halo effects (200); and framing, in which the formulation of the choices influences the decisions taken, probably because many people are risk averse when gain is involved and risk takers where loss is a possibility (204,205,198). They have also been criticised on the basis of low levels of test-retest reliability (206), and for the way that utility values are assigned to different health states (207). The approaches are quite complex and it has been have noted that they should be administered by a trained interviewer, making them unsuitable for this study (200).

It was unclear whether the considerable additional investment that would have been required could have been justified on the basis of the current state of knowledge of methods for assessing patient preference. The constraints of the question used in this survey are apparent but a better alternative was not obvious and it was felt necessary to obtain some measure of patient preference, even though it had many limitations.

This work does, however, highlight the need for much more methodological research in this complex but important area.

The probabilities of specific outcomes in the description of the procedure relates to the total population of patients undergoing prostatectomy regardless of symptom level. Ideally, the information for each level of symptom severity would be specific to the situation of each respondent. This was not done because information was not available for many outcomes by level of symptom severity. Quantification of lower urinary tract symptoms by symptom severity is relatively new and little relevant outcomes research has been published. The information on outcomes provided on the question on patient choice was primarily derived from two studies. A cohort of 263 men found that the relative improvement in symptom severity was 93% in the severe category and 79% in those with moderate symptoms. 80% of men with mild pre-operative symptoms reported either no change or an improvement within 12 months of surgery (102).

In another study conducted in men undergoing prostatectomy in North West Thames and Oxford regions, the relative improvement in symptom severity was: severe (96%), moderate (90%) (20). Eighty percent was chosen as a conservative estimate for the probability in symptom improvement for those with moderate or severe symptoms. However, this figure did not apply to those with mild symptoms, of only whom only 18% reported symptom improvement 12 months following surgery (20). Consequently, the estimate of patient preference in this group was misleading. Nevertheless, the proportion of those in each choice category was consistent with the expected trend by symptom severity, ie. the relative proportions of those who definitely wanted surgery increased from mild to severe, and decreased for those who definitely didn't

want surgery. Second, the inclusion of information by three levels of symptom severity (mild, moderate & severe) would have made the question relatively complex to understand and could have contributed to more responders leaving the question unanswered.

In retrospect, the question could have been tailored to the symptom severity of each individual, as determined from the first questionnaire, despite the limitations of the evidence upon which to base this process. This raises the question which is unresolved, of how closely to match the probabilities of differing outcomes. A compromise would have been to have three questionnaires for those with mild, moderate or severe symptoms. This would have added to the complexity of the process of questionnaire distribution, although it would not have been insurmountable. This issue should be addressed by others seeking to assess need in this way.

6.2.4 Inferring incidence from prevalence

Once the level of prevalent need in the population has been established, the next step is to estimate the level of incident need. In view of the number of variables involved, it was necessary to construct a model to do this [Appendix A8]. The model was quite complex, but even so, a number of potentially desirable features were left out. For example, no distinction was made between moderate and severe symptoms, and it was not possible to take symptom duration directly into account. Instead, the probability of surgery depended on age, which provides only a proxy indicator of severity and duration.

In addition to these limitations, many combinations of assumptions were possible and the confidence intervals around the observed rates were wide, so that many scenarios

could provide adequate fits to the prevalence curves. Thus it is difficult to know which assumptions are tenable and which are not. First, a very steep rise in incident need between the ages of 55 and 59, remaining more or less constant thereafter, was a necessary feature of any plausible scenario. Second, the results were sensitive to candidate withdrawal rates. They were not sensitive to post-surgical relapse rates, which is fortunate because the assumptions about the pattern of post-surgical relapse were arguably some of the least well-founded. Third, it was not possible to reproduce the observed prevalence curve with any precision without introducing a high risk group. This was modelled by creating two cohorts at birth, with the annual increment in incidence rate in the high risk group a fixed multiple of that for the low risk group. There are many other ways this could have been done, and in reality one might expect not two but many groups, and a spectrum of risks. In using this model, two groups provided a better fit than a single homogenous population, and the best fits were associated with a relatively small high-risk group at a very substantially increased risk.

6.3 Interpretation of the results

6.3.1 Prevalence of lower urinary tract symptoms

It has been suggested that there is a large proportion of men in the British population with undiagnosed but symptomatic prostatism (2). This study supports this view. The only other study on the prevalence of urinary symptoms in men in the U.K. has been reported by Garraway et. al. They reported a prevalence among men aged 40-79 years of 104 per 1000 (16). These figures referred to men with a symptom score of at least 11 out of a possible 48 points (eight symptoms each with a maximum score of six). An equivalent cut-point in this study, 7 out of 30, would produce a prevalence of 292 per 1000. However, some important methodological differences between the

two studies remain. In the study by Garraway, the men were younger (over 50% were under 55 years), 9% of men in the study population were excluded and the response rate was lower (only 64% (16) compared with 78%). All of these might explain why they obtained a lower estimate of prevalence. These factors could therefore reconcile these results with theirs.

The finding that 61.5% of men with a history of acute retention had not undergone surgery indicates that the view that this is an almost absolute indication for surgery (208) is no longer held. This finding is consistent with the views of the consensus panel on the appropriate indications for prostatectomy. Furthermore, some men who recovered from an episode of acute retention subsequently had only minor symptoms. This is consistent with an emerging theory that the condition may have a different aetiology from BPH, perhaps involving vascular events in the prostate.

These results and evidence from other studies suggest that prostatism begins to develop in some men under the age of 50. The sample was chosen on the basis of evidence that prostatectomy was almost never performed on men under the age of 55 (20). The relatively high prevalence of moderate or severe symptoms among men in the 55 to 59 age group indicates that future studies should include younger men. This is consistent with the population based survey by Garraway that described the onset of urinary symptoms among men in their forties (2) and a review of autopsy data by Berry et. al. suggesting the first changes in prostatic weight appear in men as young as under 30 (209). From the age of 55 until the early seventies, the percentage of men with moderate or severe symptoms who have not had surgery increases slowly from 15% to 20%, decreasing thereafter. A few individuals have surgery under 50, but the probability of surgery only exceeds 1% in the 55 to 59 age

group. Thereafter it increases steadily. This leads to a progressive increase in the number of men who have had surgery by the age of 85. Of those who have had surgery, the proportion who have residual or recurring symptoms is roughly constant. The figure of about a third in this study is higher than that found in two cohort studies of men undergoing surgery (102,167) but both followed up patients for only one year. Some of the men in our survey had surgery up to 10 years previously.

These results suggest that lower urinary tract symptoms shown by the prevalence of either symptoms or a past history of prostatic surgery, increases steadily throughout middle and old age, with the first signs appearing below the age of 55 and with almost 40% of men having been affected by the age of 80. After 80, the prevalence of lower urinary tract symptoms does not increase further, and may actually decrease. These findings may occur by chance because there were only 29 men over the age of 80 in our sample with moderate or severe symptoms, but if true, there are three possible explanations. The first is that some cases of BPH resolve spontaneously. This has been suggested by other authors and seems to be a view held by many urologists, although there is no strong empirical supporting evidence (210).

Second, most of those men who are going to suffer from lower urinary tract symptoms begin to do so by the time they reach 80, and that the population contains subgroups with varying susceptibilities to the disease, with those reaching 80 without having developed symptoms likely to remain in this state. Some support for this hypothesis comes from a review of series of autopsy data that suggested that at least 10% of men have no histological evidence of BPH by the time they reach the ninth decade (209). The third possibility is that men suffering from lower urinary tract symptoms have a reduced life expectancy, leading to selection out of the population in this age

group. If the last of these is true, it could be due to either the effects of the disease or the complications of treatment. This explanation is consistent with the results of the study by Wennberg et. al. that suggested that transurethral prostatectomy was associated with an increase in mortality compared with men not undergoing surgery (125). If any of these suggestions, or a combination thereof, are true there are important implications for urology research and practice, especially as new therapies designed to prevent the development of lower urinary tract symptoms become available. For example, it would be useful to compare the characteristics of those men who do and do not suffer from BPH, including for example, differences in androgen responsiveness.

6.3.2 Impact of symptoms on general health status and quality of life

Although 20.4% of men have moderate or severe symptoms, this does not reflect the degree of concern that they express. Only 6% of men report that their symptoms are a medium or big problem and 2% report that they interfere with their daily activities all or most of the time. In contrast, 11% feel unhappy or terrible about the prospect of a future with their current level of symptoms, indicating a difference between the extent to which men are affected at present and how they would like to be in the future. A possible explanation for this is that men are able to cope with their existing level of symptoms but feel that they will be unable to do so in the future as they become older and more infirm.

This study measured the extent to which lower urinary tract symptoms affect general health status and quality of life using the NHP and the SF-36. Measures of lower urinary tract dysfunction can be considered within the impairment - disability - handicap model, in which impairment describes an anatomical or physiological defect,

disability reflects the limitations to an individual's activities resulting from the impairment, and handicap describes the extent to which the environment obstructs or supports the individual in leading a normal life with the disability. In the case of lower urinary tract disease, a decreased rate of urinary flow can be considered as an impairment, symptom scores are disease-specific measures of disability, as are the NHP-Part 1 and some components of the SF-36; the NHP-Part II and the remaining components of the SF-36 are measures of handicap. The factors influencing each step in this set of interactions explain the imperfect correlation between each of the measures and demonstrates that factors that related to the individuals' expectation and environment, as well as clinical factors, must be taken into account in the decision to offer surgery.

In this study, both the NHP and the SF-36 performed as expected: the health status of men worsened as the severity of their lower urinary tract symptoms increased. The energy, emotional reactions and physical mobility dimensions of the NHP were associated with increasing symptoms severity, as were the social function, mental health, physical role and general health dimensions of the SF-36.

These findings are consistent with results in the U.S.A. that have found that worry and embarrassment about urinary symptoms were associated with increasing AUA frequency and bother scores (211) and that men with heightened bother were more anxious and had lower general psychological well-being that those without (211). The results with the SF-36 are consistent with a study in the U.S.A that compared mean SF-36 scores in men with: no, occasional (up to twice a night) and frequent (3 or more times) nocturia. It found significant differences in scores on the dimensions of physical functioning, role limitations due to emotional problems due to pain (212).

It was possible to compare median NHP scores in the survey with those of men undergoing prostatectomy. The proportion of men undergoing prostatectomy and who had median NHP scores greater than 0, was higher than men in the population-based sample. This suggests that, for a given level of symptoms, the impact of symptoms, the patients quality of life influences the decision to seek treatment. This is intuitive, although few studies have shown it. It is also consistent with the decision to seek treatment, which is affected by the person's physical, sociological and psychological environment. This has been demonstrated previously in the U.K. in a comparison of men with BPH being treated in the public sector with those treated privately (213).

It was also possible to compare mean SF-36 scores with recently published population norms. On the evidence presented here, it appears that, men with moderate or severe symptoms are less affected on most dimensions of general health status and quality of life than people with low back pain, menorrhagia or suspected peptic ulcer, but more affected than those with varicose veins. However, this crude comparison obscures both the need to take into account the threshold for inclusion of each group, defined in terms of a disease specific measure, and the extent to which men with a particular level of symptoms are bothered by them and how they impinge on their quality of life. In addition, this analysis should be treated with caution as the use of means may not be appropriate because the distribution of item scores is strongly skewed. Surprisingly, median SF-36 scores for the population were unavailable.

The NHP and SF-36 provided a reasonably valid and robust method for measuring the general health status of men with urinary symptoms. They responded in predictable ways to the presence and severity of urinary symptoms. However, some

unexpected responses were found and these, together with the absence of an explicit measure of sleep disturbance in the SF-36, and the high number of men with perfect health (ie 0 for NHP and 100 for the SF-36) suggest that alone, they may not be sufficiently sensitive for the detailed assessment of men with urinary symptoms. They may nonetheless provide a basis for comparing the health of such men with other groups of potential patients and could be used in making comparisons of the likely gain in health status that might be achieved following treatment.

6.3.3 Illness-related behaviour

Few men in this survey reported seeking advice from relatives, friends or the practice nurse for their symptoms. This may be because they believe that lay carers and nurses have little to offer for urinary problems or it may reflect under-reporting; having received advice from family or friends to see their GP, they only reported that they saw a GP. It is also possible that there is some reporting bias because they view these sources of advice in a less formal way. It has been estimated that 25% to 75% of symptoms are dealt with by patients themselves or friends and family (181,182) and that the decision to consult a GP is dependent on the influence of advisers, the effectiveness of self-care and the need for information (183). Many men may consider their urinary symptoms as part of the normal aging process and thus do not consider their condition worthy of consulting their GP. The findings in this study are consistent with those of a study in Denmark that found that men aged 70 and over with voiding difficulties did not consult a doctor for their urinary symptoms (184).

Although, men are more likely to visit their GP as their symptoms worsened, the decision of the GPs to refer appears to be independent of symptom severity. This study confirms the important gatekeeper function of general practitioners: half of the

men who went to see their GP had not been referred to a surgeon. This is consistent with research on the referral decision that shows that a wide variety of factors, and not just the patient's condition are important (167). Semi-structured interviews with family physicians in Canada found that of non-medical factors in the decision to refer, patient wishes were the most important (186). Difficulties with travel, access to a consultant, and family wishes also influenced the decision (186). The effect of these factors in this study is unknown.

Some men were prescribed medication for their urinary symptoms, either by their GP (16.6%) or their urologist (7.9%) despite a lack of any definitive evidence of the efficacy of such treatments and the recommendation that prostatectomy is still the treatment of choice for BPH (3-7,147). During the period of the study, Finasteride (Proscar®), was being marketed and some men may have been prescribed it as participants in studies to evaluate the drug.

6.3.4 Patient preference

Thirteen per cent of responders did not answer this question and, of those who did answer, 45.2% were unsure whether they would choose surgery. It is not known whether their uncertainty arose from the wording of the question, insufficient information being provided, or from the difficulties in deciding about treatment. It is likely that some have what has been termed an 'external locus of control' and would transfer the decision to treat to the surgeon. A study of 55 men undergoing prostatectomy who were questioned about their opinion on informed consent found that 54% (25/46) trusted their doctor to do the right thing and did not think detailed explanation was important (171).

As part of the preparation of the AHCPR guidelines, 53 patients with mild, moderate or severe symptoms judged by the AUA symptom score, were presented with a booklet that listed the important outcomes of four treatments (watchful waiting, TURP, alpha-blocker therapy and balloon dilation)(7). The results showed that a similar proportion of patients with mild symptoms reported that they would choose TURP (30% in U.S patients vs. 29% in the survey). More U.S. patients with moderate (40% vs. 31%) or severe symptoms (75% vs. 46%) said that they would choose surgery. However, important distinctions exist between the two studies. The American preference analysis consisted of men whose symptoms bothered them to the extent that they sought care for their symptoms. In addition, the American were presented with other treatment choices, whereas the men in the survey were only asked whether or not they would choose TURP.

Although men in the survey reported that they would definitely or probably choose treatment, it is unknown whether their attitude towards treatment would correspond to their actual behaviour. Published research relates to patient preference for treatment alternatives, as part of the patient-physician interaction, rather than about the provision of information by questionnaire as a basis for decisions about treatment preference.

6.3.5 Sensitivity analyses

A range of values of prevalent need were presented depending on combination of symptom severity, level of comorbidity, extent of agreement about appropriateness and degree of individual preference. It was decided to include the group of men with mild symptoms in the sensitivity analysis despite the fact that men with mild symptoms are less likely to benefit from treatment, the enormous cost implications of treating

4329 men, and that the AHCPR guidelines advocate that men with mild symptoms be followed with a strategy of 'watchful waiting'(7). This was because men with mild symptoms were considered by the consensus panel and panellists felt that surgery was appropriate in men with mild symptoms, low comorbidity and no retention. This group is likely to represent a large portion of men in the community and many men in this category reported that they would probably or definitely want a prostatectomy. It is important that the estimate should be used with caution. The decision about which estimate of need commissioning agencies on which to base their purchasing decisions must be left to local authorities.

Although this estimate was consistent with the panel's ratings, inspection of the relationship between symptom level and health status (Section 5.3.3) suggests that it may be more suitable to consider men with severe symptoms separately. Accordingly, the estimate was reduced to 225 if only those men with severe symptoms who would definitely want surgery were considered. This figure rose to 4329 if men with mild symptoms, men who were only inclined to want surgery, and indications about which the panel members were equivocal, were included. The decision about which estimate of need, commissioning agencies use, should be a matter for local discussion

6.3.6 Application of the results to purchasing

In Britain, prostatectomy for BPH was the subject of one of a series of needs assessments commissioned by the NHS Management Executive based on existing epidemiological and utilisation data, evaluation studies, and economic analyses (72). It estimated that the number of prostatectomies in a typical district of 250,000 was 179 per year (82), rather lower than the existing level of provision of approximately

220 (based on National Hospital Episode data for 1989/90). The report concluded that 'either the definition of clinical BPH bears little relation to the requirement for surgery or there is a huge pool of need not being satisfied'.

The underlying rationale for assessing local health care needs is to allow local authorities to purchase appropriate care to meet local needs. Purchasing may be thought of as a way of both increasing the effectiveness of health care and saving costs. The existence of information about health care need for a given procedure is only the first step in ensuring that local populations receive appropriate treatment. The results of this study raise several issues relevant to purchasing.

The first step in using information from needs assessment to inform the purchasing process is to examine existing provision of services in order to find out if health care is already being provided at levels which meet the health needs of their population. This may require extensive cooperation with local providers because despite some recent improvements, routine data in the NHS is still notoriously unreliable (67). Furthermore, the contract minimum dataset provides little information about the appropriateness of the specific treatments being provided. As up to 20% of prostatectomies are performed in private hospitals (31), it is essential to obtain data from the private sector, an issue that has received very little attention so far (68).

Another possible application is the development of referral guidelines, although the difficulties involved in their development and implementation, should not be underestimated. This is because there is a lack of research-based evidence and a genuine uncertainty about the appropriateness of many interventions. Second, for guidelines to be locally acceptable, there is a need for local ownership which must

involve extensive discussion with local GPs, FHSAs and providers. Guidelines may be unhelpful in the case of patients with multiple conditions or unclear diagnosis, if patients fall outside of the study populations upon whom the research evidence is taken, such as the exclusion of the elderly and women from studies of cardio-vascular disease. Comprehensive effectiveness reviews for many conditions are currently unavailable, although the U.K. Clearing House on Health Outcomes will publish an effectiveness bulletin for prostatectomy in 1995. Nevertheless, the existence of guidelines does not ensure that they will be used. If clear and acceptable guidelines are available, then the issue arises about how purchasers are to ensure that they are being met. Currently, it is unclear how purchasers will monitor providers' adherence to guidelines, especially when they are constrained by the lack of meaningful information (187).

Third, a question remains about whether purchasing authorities have the resources to conduct all of these activities. The purchasing function is still underdeveloped in many commissioning agencies. Many services are purchased through block contracts by specialty, and consequently do not consider specific conditions or treatments. It has been suggested that purchasing agencies require the following skills: public health medicine, finance, contracting, health services evaluation, information technology, communications and public relations (188). Staff with formal training or expertise in all of these areas may be in short supply. When the potential number of conditions that purchasing authorities should provide services for is considered, the amount of time and resources required to follow through the results of health care needs assessment, is considerable.

Finally there is the dilemma raised by issues of resource allocation and priority

setting. The results in this study and other research which examined the need for services for people with visual disabilities (75) suggest that there may be a considerable volume of unmet need for common procedures. It is possible that purchasing authorities could be faced with high unmet needs for many treatments with demonstrated effectiveness. It is unclear how purchasers are to resolve the dilemmas that could arise from the need to allocate scarce resources and how to include the views of public. An attempt to include the public in establishing health care priorities, the Oregon experiment, proved unworkable (63).

This study supports the view that there is a volume of unmet need for prostatectomy, but offers a range of possible values for prevalent need contingent on indications and patients' attitudes to surgery. Which figure to apply in purchasing must be a matter for local policy and priorities. Although the higher prevalence estimates would support greatly increased provision of urological services for a limited period, the need for surgery would stabilise at the incidence level once the backlog had been cleared. It is uncertain how long it would take to work off the backlog at different rates of surgery. In principle a model could be built to explore this question, but it would need to be a dynamic one because, as this study has shown, general practitioners may respond to perceived increases in availability of treatment with higher levels of referral, and thus maintain waiting times near their current levels.

A number of alternative medical and surgical treatments are becoming available. Although they are thought of as substitutes for prostatectomy, in practice there is growing evidence that they are additive, being used on men with symptoms below the threshold currently used by individual surgeons. This rapid change in technology combined with the time required to undertake research means that research results

can lose much of their relevance by the time they are published. This is not yet the case for this study, because of the absence of evidence of the effectiveness of alternative treatments, but this may not last for much longer.

6.4 Implications of findings

6.4.1 Further research

This study has identified a number of areas of potential further research. Some of these have been raised by the review of the literature and others arise directly from the findings of this study.

A review of the literature identified a number of gaps of knowledge. First, although there is good evidence on the outcomes of TURP, there is little information about the outcomes of emerging alternative treatments, despite their use by many GPs and urologists, and aggressive marketing techniques by drug companies of medical therapy. More research is under way to study the long term benefits of these different treatments, but there is an urgent need for randomised control trials that compare the outcome of TURP with other surgery (open, microwave, laser), medical treatments and watchful waiting. The last of these would have to be defined explicitly in order to distinguish it from 'no treatment'. A further issue relates to what measures of outcome will be used, given the lack of concordance between symptoms and urinary flow. As drug treatment may need to be continued for many years, what is the most appropriate time at which to measure outcomes? The AUA symptom index, measures of generic health status, such as the NHP or SF-36, and quality of life measures should be included to determine which patients would be more likely to benefit from treatment. These studies would also have to consider that men with symptoms often spontaneously remit, and the possibility that men modify their behaviour, ie, limit the

amount that they drink.

Despite continued uncertainty about the effectiveness of treatment for BPH, urologists in Britain have been reluctant to participate in a randomised controlled trial comparing transurethral resection of the prostate with open surgery, medical treatments and watchful waiting. Other issues arise. Are the treatments to be seen as a substitute for TURP among patients currently offered treatment? Is it envisaged that they will be offered to patients with less severe disease than those currently being treatment? If two treatments are shown to have the same effectiveness, then economic arguments may become more important.

There is considerable debate about the relationship between symptoms, urological measures, and autopsy evidence of BPH. It has been suggested that lower urinary tract symptoms can arise from either, obstruction or detrusor instability, and that symptom scores are unable to distinguish between the two. Large scale studies to distinguish which men are most likely to benefit on the basis of these measures are needed. Results of the Royal College of Surgeons of England Regional Prostatectomy Audit may be able to answer some of these questions.

Little is known about the natural history of BPH, although three points should be considered in future studies. From this study it is clear that lower urinary tract symptoms begin to occur to some men under the age of 55. Future prevalence studies should include men over the age of 40. It is clear from the autopsy evidence and the findings from this study that some men may not develop the lower urinary tract symptoms of BPH and modelling of incident need required an assumption that there was a low-risk and a high-risk group. If this assumption is true, then a case-

control study could elucidate the reasons for this difference. Androgen responsiveness or other genetic factors may help to explain aetiology.

This study found that some men are more willing to tolerate their lower urinary tract symptoms, than others. Further qualitative research should examine the factors that determine patient perceptions of disease. These could be explained by individual values to health and whether or not individuals health-related behaviour follows an external or internal 'locus of control'. These factors will differ between individuals. In particular, much more work is required to explore the wide variation in scores using both instruments on men with severe symptoms, with some men apparently relatively unaffected but others affected severely.

Similarly, there was a difference with regards to whether men sought treatment for symptoms and whether or not they would choose surgery. The extent to whether men eventually receive treatment is complex, and is influenced by: their health-related values, the willingness to accept risk, and the doctor-patient interaction. A related question is what happens to men who do not seek treatment. A follow-up survey of men with symptoms could discover the extent to which symptoms remit, or whether their symptoms develop to the point where they develop acute retention, which requires an emergency admission to hospital.

The provision of outcomes information and the question on patient choice, by survey is new. Further work needs to be done to test the reliability and validity of providing information, and to explore ways of providing complex information on treatment outcomes by questionnaire. This could be accomplished by detailed qualitative work or a follow-up survey which compares the reported preference for treatment with their

actual behaviour if offered treatment. Further work is needed to examine the relationship between characteristics of the doctor, the patient and their interaction.

6.4.2 Implications for policy

This study was conducted in order to provide information to inform purchasing. The next step would be to work with a purchasing authority in order to determine the usefulness of the results of this study in informing local strategy for urological services. This work is in progress, in close cooperation with a local purchasing authority. There are two applications.

First, the estimated incident need identified in this study is being compared with existing utilisation data from NHS and private hospitals in order to find out whether current provision is congruent with local needs. As a first step, all episodes with a recorded diagnosis of BPH or a procedure of prostatectomy have been extracted from the local minimum data-set. It had been planned to augment this with information from private hospitals, but they were not all willing to cooperate. Consequently, the estimates of NHS provision have been inflated based upon the estimated contribution of the private sector of prostatectomy (31). The results of such study do not tell us about the appropriateness of care, however, as this could only be accomplished with a detailed history from each patient undergoing prostatectomy.

Second, referral guidelines are being developed as an aid for general practitioners in treating patients with lower urinary tract symptoms. The feasibility of introducing treatment thresholds based on the AUA symptom index into GP surgeries is being explored. These guidelines are likely to take the form of a decision tree, based on the results of physical examination and symptom scores. Ideally, this process would also

include provision of information about the procedure and involve patients in the decision whether to be referred to a urologist. The AHCPR clinical practice guidelines and the results of this study provide a starting point for the development of local guidelines. The development of guidelines must include local input from GPs and urologists, for it to succeed.

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APPROPRIATENESS OF TRANSURETHRAL RESECTION OF THE PROSTATE

A Review of the Literature

March, 1992

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Chapter 1 - Introduction

Prostatectomy for benign prostatic hypertrophy (BPH) is a common operation for men that has been performed since the turn of the century (1). It has been estimated that the probability of a 40 year old man having this surgery before he reaches 80 is one in ten in the U.K. and one in three in the U.S.A. (2,3). Prostatectomy is performed in order to improve quality of life and to prevent mortality, morbidity by reducing symptoms. Over 90% of operations are performed by the transurethral route. However concern has recently been expressed about the indications for and outcome of TURP. Wide variations in the rates of surgery arise because there is no clear agreement about appropriate indications. Urologists often disagree about whether individual patients should undergo surgery (4,5,6). It has been suggested that 75% of prostatectomies performed in the U.S.A. are inappropriate and if these operations were avoided $US 2-3 billion could be saved annually (7). In addition, a recent study suggested mortality following TURP, may be significantly higher than that following open operation (8). After a brief account of BPH, this paper will review the literature on the indications for and outcome of TURP.

1.1 Definition of benign prostatic hyperplasia

Benign prostatic hyperplasia (BPH) is a adenomatous growth of the prostate gland that gradually obstructs the urethra leading to difficulty in urinating. The consequences of an untreated obstruction include: chronic urinary retention predisposing to bladder and renal damage; episodes of acute retention; and progressively severe obstructive and irritative symptoms (9). There is sometimes confusion about the use of the term BPH: some authors use BPH to describe the pathological process while others use it to describe the symptoms associated with the process.

1.2 Natural History of BPH

The prevalence of enlarged prostate estimated from digital rectal examination and the reporting of obstructive symptoms increases with age (10). The benign growth of the prostate or a hypertrophy of muscles at the neck of the bladder, or a combination of both leads to the obstruction. It is probable that the pathogenesis of prostatic hyperplasia starts at the age of 30 (autopsy prevalence of 8%) and increases steadily so that by the age of 70 the prevalence of BPH has reached 70% (11). While symptoms associated with BPH are persistent in most cases, in 25% to 30% of men, urinary symptoms resolve spontaneously (12).

1.3 Etiology

Risk factors that have been associated with the development of BPH include: increasing age (10,11,13,14,), non-smoking (13,14), and ethnicity [higher in Africans, American Blacks, Jews, Welsh; lower in Asians] (2,14,15,16,17,18). Two studies that have examined the relationship between BPH and socio-economic status have produced contradictory results (14,20). Other suggested risk factors include coffee consumption, diet [milk, yellow and green vegetables], sexual activity, leanness, high urine alkalinity, a history of renal x-rays, and tuberculosis (13,14,19). BPH never develops in men who have been castrated early in life, and indeed castration used to be recommended as a treatment for obstructive uropathy (21).

1.4 Epidemiology

The epidemiology of BPH has been studied using a variety of data sources: autopsies, studies of the prevalence of symptoms in populations, operation rates, and the prevalence of prostatectomy.

1.4.1 Autopsy studies

A meta-analysis of 1075 autopsies from 5 independent studies found that 61% of males over the age of 40 have pathological evidence of BPH (11). The frequency of nodular hyperplasia was 42%, 71%, 82% and 88% in men aged 51-60, 61-70, 71-80 and 81-85 years old, respectively (11).

1.4.2 Prevalence surveys

Surveys have examined either the prevalence of prostatic symptoms or enlargement of the prostate. A community survey of the health status of 217 men aged 65 and over in Israel found that 40% of men reported having undergone prostatectomy or suffered probable BPH on the basis of symptoms (frequency, nocturia, weak stream, dribbling) (23). Another study of men over the age of 65 living in Iowa found that the age-adjusted prevalence of those who responded positively to a question on prostate symptoms was between 22% and 32% (24). A recent study of prostate size among men aged 40-79 years living in Scotland, using ultrasound reported that the prevalence of BPH, defined as a prostate gland greater than 20 g, was 253 per 1000 (25). Prostate size was not correlated with symptoms.

1.4.3 Operation Rates

Annual age-adjusted prostatectomy rates in Western countries range from 60 per 100,000 to 368 per 100,000 (26,27,28,29,30). In general these rates are more than twice as high in North America than in England and Wales, and Denmark(30).

1.4.4 Prevalence of prostatectomy

Longitudinal studies measuring the prevalence of prostatectomy for BPH in American men belonging to a prepaid health care plan reported rates of 129 per 1000 in men over the age of 40 [Kaiser Permanente 1972-1990] and 55 per 1000 in men over the age of 50 [Veterans Administration Normative Aging Study 1968-90] (13,31).

Chapter 2) Indications

Benign prostatic hyperplasia commonly presents in one or more of three ways: a complex of obstructive and irritative urinary symptoms [hesitancy, poor flow, terminal dribbling, frequency, feeling of fullness, dysuria and nocturia], chronic retention and acute retention. In a recent study, about one third of patients were symptomatic, one third had evidence of chronic retention (with or without a history of acute retention and/or symptoms) and one third had a history of acute retention (with or without symptoms) (32). There is considerable uncertainty about the appropriate indications for prostatectomy because there has been little research relating outcomes of treatment to indications. This section will review the available evidence.

2.1 History and Urinary Symptoms

Symptoms are generally regarded as either obstructive [hesitancy, poor flow, dribbling, a feeling of fullness] or irritative [frequency, nocturia and dysuria]. In studies, four commonly used symptom scoring systems [Madsen-Iversen, Boyarsky, Fowler and the American Urological Association Measurement Committee] have been used in the U.S.A. to assess the severity of symptoms (33). These indices consist of a number of questions on the frequency and severity of symptoms. Irritative symptoms may be idiopathic or secondary to BPH, although there is conflicting evidence about this (5). Symptoms are difficult to standardise and depend on subjective reports which will differ between individuals (34).

2.2 Chronic Retention

Chronic urinary retention may be defined incomplete emptying of the bladder and is distinguished from acute retention by the absence of pain. Symptoms include: recurrent urinary tract infection, residual urine after micturition, overflow incontinence,

bladder damage and eventually symptoms of renal failure. In one series of 388 patients undergoing surgery for chronic retention, all had either a history of acute retention or obstructive or irritative symptoms (32).

2.3 Acute Retention

The presenting features of acute retention are: abdominal pain, a full bladder, and a continued inability to urinate. Acute retention is generally considered to be an absolute indication for prostatectomy in the absence of detrusor failure or neuropathic obstruction (35). Fifty eight to seventy per cent of patients presenting with acute retention had another episode of retention within one week in a trial without catheter (36,37). In two reports, 28% to 34% of prostatectomies were performed for acute retention (38,39). In contrast, others have argued that acute retention is not an absolute indication for prostatectomy, as it can often be explained by prostatic infarction. Men who are able to void successfully after a period of catheter drainage has allowed post-infarction oedema to resolve are eligible for conservative treatment with regular follow-up, providing there is no evidence of chronic retention (40,41). It has been argued that this is also true for acute retention precipitated by bed rest, diuresis or anticholinergic drugs (42).

2.4 Examination

2.4.1 Abdominal examination

Abdominal examination will provide evidence of incomplete emptying of the bladder. The bladder is palpated for fullness and pain may be evidence of infection.

2.4.2 Digital Rectal Examination

Digital rectal examination is not predictive either of the extent of obstruction, symptoms, or post-operative outcomes (43,44,45). Thus an enlarged prostate in itself is not an indication for an operation. The usefulness of digital rectal examination lies in its ability to distinguish prostatic cancer from BPH due to its texture. It is believed that an enlarged prostate from BPH will exhibit a symmetrical and smooth, rubbery character; prostatic cancer will exhibit more of a hard, craggy mass (44).

2.5 Investigations

Routine pre-operative investigations include blood pressure and tests for haemoglobin, blood urea and serum creatinine. As many patients are elderly, a chest x-ray and ECG will usually be performed. A mid-stream urine will be collected and cultured for evidence of infection. Serum acid phosphatase levels may be measured to exclude the possibility of prostatic cancer, although because these levels may be high in the absence of cancer, they are of limited use. Some patients also undergo imaging (radiography or ultrasound) and pre-operative urodynamic studies to provide more evidence about the nature and effect of the obstruction.

2.5.1 Imaging

Imaging is performed to find residual urine, upper tract dilatation and bladder stones. Residual volume is evidence of painless retention. However, residual urine may originate from other causes than outflow obstruction and some patients with severe obstruction may present with no post-residual urine (46). Residual volume is not correlated well with symptoms, results of urodynamic studies, cystoscopy and post-operative outcome (5,47). No study has reported

a positive correlation between pre-operative residual urine and post-operative outcome (5). Routine intravenous urograms are not recommended because it has no advantage over abdominal radiology and ultrasonography (25,48,49). It is however, indicated for haematuria (5).

2.5.2 Urodynamic Studies

There is controversy surrounding the use of urodynamic assessment prior to prostatectomy (5). A current surgical textbook advocates the use of urodynamics (44) even though studies have concluded that measurements of urinary flow are not associated with symptoms or with the outcomes of prostatectomy (12,34,50,51,52,53,54,55,56). A recent study in the UK found that urodynamic studies were conducted in only 26% in patients (57). If there is a suspicion of detrusor instability evidenced by frequency, urgency and urge incontinence, then pressure flow studies may be important in order to avoid the unnecessary inappropriate surgery (48).

2.5.3 Cystometry

Cystometry to measure detrusor contractions of the bladder (which may explain irritative symptoms in some patients) was unable to predict those with detrusor contractions following surgery (50,58). In a recent review of the indications for prostatectomy it was stated that cystometry did not identify patients who would benefit from surgery (5).

2.6 Age

Although there is an independent effect of age on mortality, advanced age does not appear to be a contra-indication to prostatectomy. A case-series of men over the age

of 90 who underwent prostatectomy has been reported (59). Investigators in Germany concluded that age was not a determinant of the frequency of peri-operative complications (60).

2.7 Co-morbidity

The contra-indications for prostatectomy are few. Poor physical condition of patients need not preclude surgery (44). Co-morbidity may be measured in terms of the operative anaesthetic risk during the operation, or by life expectancy. The risks associated with a general anaesthetic can be avoided by using a spinal anaesthetic although spinal anaesthesia is associated with its own risks, especially for those patients who are on anti-coagulants. A study examining the effect of comorbidities on outcome was unable to identify subgroups of patients more likely to suffer complications because of their comorbidities (60). However, patients hospitalized with high risk diagnoses in the year before surgery have been found to have an increased relative risk of death: 1.46 [95% CI, 1.14-1.87] for those hospitalised 6 months prior to surgery and 1.54 [95% CI, 1.13-2.10] among those hospitalised 7 - 12 months prior to surgery (8,61).

2.7.1 Cardiovascular disease

For patients with a recent myocardial infarction (MI) or stroke, it is claimed that prostatectomy should be delayed by 6 months but no evidence is given (44). A past history of MI more than 6 months previously is not claimed to be a contra-indication. Following a stroke, an assessment should be undertaken to exclude neuropathic obstruction (44). Patients on digitalis have a relative risk of death of 1.4 [95% CI, 1.1-1.78] (8).

2.7.2 Chronic Obstructive Lung Disease

Severe bronchitis and emphysema are not thought to be contra-indications for prostatectomy providing a careful pre-operative assessment has taken place (44).

2.8 Timing of Surgery

The attitude of surgeons to the timing of surgery is another area of potential disagreement. There are two conflicting views; a preventive approach that argues that prostatectomy should be performed early in the course of BPH to avoid the elevated risks of surgery associated with advancing age, and a quality of life theory that argues that in the absence of actual or impending renal dysfunction, surgery should only be performed to produce improvements in symptoms status or quality of life (62). The quality of life theory argues that eventual prostatectomy is not inevitable and suggests that watchful waiting is the appropriate management. Early surgery also increases the probability of a repeat operation.

2.9 Summary

There appear to be three main indications for TURP; chronic retention, acute retention and symptoms. Digital examination appears to be of little use except to aid in the differential diagnosis of cancer. There is little evidence to support the use of urograms and imaging. Symptom scoring systems are useful to monitor outcome but are rarely used. There is no firm evidence of contra-indications for TURP.

Chapter 3 - Treatments

Treatments for BPH may be classified broadly as either surgical or medical. In general, the surgical approach attempts to remove the obstruction and the medical approach tries to shrink or relax the smooth muscle of the prostate gland. The most commonly used treatment for BPH is prostatectomy (63). A recent editorial in the Journal of the American Medical Association stated that it was unlikely that medical therapies would replace prostatectomy as the standard treatment for BPH (7).

3.1 Surgical

3.1.1 Transurethral Resection of the Prostate (TURP)

The standard treatment for BPH is transurethral resection of the prostate. A resectoscope is passed along the urethra and either a cold punch or hot loop is used to resect the obstructing tissue from the lumen of the urethra. TURP accounts for 90-95 percent of prostatectomies performed in the U.S.A. under Medicare and at least 95% in the UK (8,64,65).

3.1.2 Open

A suprapubic or retropubic incision is made and the adenoma is excised. One textbook of surgery advises open prostatectomy if the prostate gland is greater than 100 g (44).

3.1.3 Urethral Stenting

A tube woven out of specially treated wire is placed endoscopically into the urethra and left there. Often stents are used for patients who are unfit for prostatectomy. Stents are being evaluated at a number of centres in Europe

and by the Federal Drug Administration (FDA) of the U.S.A. (66).

3.1.4 Hyperthermia

A probe is inserted into the urethra or rectum and microwaves are generated to heat the prostate to a temperature no greater than 44°C (less than the level where necrosis occurs). A variation of this approach uses alternate cooling and heating of the prostate. Repeated treatments are usually necessary (66).

3.1.5 Cryo-surgery

A cryoprobe is inserted into the urethra and the obstructive tissue is frozen into an iceball. The necrotic tissue is then voided naturally - in some circumstances, the tissue must be resected. Cryo-surgery is used for those who are unfit for surgical intervention (66).

3.1.6 Balloon Dilatation

A balloon is placed in the urethra in the location of the obstruction and inflated to displace the obstructing tissue. The success of this procedure is uncertain; some centres report favourably, while others report little long-term benefit. It has been extensively evaluated and been found that the effects are temporary - symptoms often return within a year (66).

3.1.7 Laser

Several centres are evaluating the use of lasers that originate from a balloon inflated in the obstructive tissue. Laser treatment of BPH is still in the early stages of development (66).

3.1.8 Other

A number of other treatments have been suggested as possible treatments for BPH; they include high intensity focused ultrasound, high energy shock wave treatment, and pyrotherapy (66).

3.2 Medical

Although pharmacological agents have been successful in reducing the size of the prostate and relieving symptoms of obstruction, many individuals do not respond to medical treatment and a recent review article concluded that non-operative management of BPH was unlikely to challenge prostatectomy as the preferred treatment (21).

3.2.1 Alpha-adrenergic Blockers

Alpha-adrenergic blockers cause the relaxation of the smooth muscle of the prostate and bladder neck (21).

3.2.2 Hormonal

The use of hormonal treatments for BPH rests on the observation that men who have been castrated or lack testosterone never develop BPH. Consequently treatments have been tried which inhibit the binding effect of these hormones resulting in a shrinkage of the prostate gland, although there are unpleasant adverse effects (21).

3.2.3 Proscar

Proscar is 5-α reductase inhibitor that prevents the conversion of testosterone to dihydrotestosterone that is associated with the growth of the prostate. The

results of one clinical trial of Proscar are inconclusive (7).

Chapter 4 - Outcomes of TURP

Outcomes research is a way of answering the basic question of whether patients benefit from surgery. Commonly used measures of outcome are: mortality, complications, symptom change, general health status, quality of life, and reoperation. The data reported here are derived from (a) case series or longitudinal administrative databases with followup of mortality, further illness episodes and reoperation rates, and (b) prospective cohort studies which follow patients for up to one year. The following sections refer exclusively to TURP.

4.1 Mortality

Published case-series from several different countries suggest that 90 day post-operative mortality rates range from 1% - 9% (8,28,38,39,59,64,67,68,69,60,71,72). The age-adjusted cumulative risk of dying obtained from population-based studies within 90 days was found to be 1% and 4% in two studies (60,73). In-hospital mortality rates are of little relevance as sixty per cent of deaths within 90 days occur after discharge from hospital (72). A meta-analysis incorporating the results of 150 studies and reflecting a sample of 50,000 patients determined that the 90 day mortality was 1.5% [95% confidence interval (CI), 1.3 - 1.7] (44). Mortality increases with increasing length of time after surgery. Roos and colleagues have reported that the risk of death in three different countries [Canada, Denmark and the U.K.] increase from 10% at 1 year to 50% at 8 years (8,72,75). The higher rates observed in population studies may arise in part from selection bias that is a recognised feature of case-series. Different investigators may use different inclusion criteria for patients and results are more likely to be reported if they demonstrate an improvement on previous case-series. The extent to which deaths are associated with TURP is uncertain. Results of the comparison of post-operative death rates with mortality in the

general population are conflicting. In Rochester, Minnesota average annual mortality rates over a 6 year period following prostatectomy were not statistically different from the rates of men who had not undergone prostatectomy (28). Similar results were obtained in the U.K. (39). In contrast, a study in men between the ages of 65 and 69 undergoing prostatectomy had more than twice the expected mortality rate compared with age-matched men who had not undergone prostatectomy (76). There are considerable differences in the mortality achieved by different hospitals. There appears to be an association with hospital size in the USA (72). Compared with hospitals of over 300 beds, the relative risk of death is 1.51 (95% CI, 1.01-2.27) in hospitals of 150-300 beds and 1.79 (95% CI, 1.24-2.59) in hospitals of under 150 beds. In summary, the 90 day mortality associated with TURP is around 1.5%.

4.2 Complications

The incidence of post-operative complications prior to discharge has been reported as about 18% to 23% (38,39,62,70). A meta-analysis reported that 'general complications' will develop in 6% - 32% [95% CI] following surgery (74). Problems arise in measuring the prevalence of complications because: definitions differ; severity is dependent on who reports the symptoms; and on the length of time following surgery. The most common complications of prostatectomy are bleeding, urinary retention, urinary infection, incontinence, and impotence. The incidence of complications depends partly on whether the surgeon or the patient is the source of information; patients report complications more than surgeons (77).

4.2.1 Bleeding

Widespread differences in the reporting of bleeding following prostatectomy can be attributed to differences in the definition of bleeding. Bleeding requiring

transfusion has been reported in 3% - 4% of cases prior to discharge (38,68). Bleeding leading to clot retention was found in 11% before discharge (39). Most patients (90%) reported some post-operative bleeding, but only 14% saw their GP and only 1% required readmission (39). In two studies, 2.3% - 5.8% of patients required re-hospitalization because of bleeding (28,73).

4.2.2 Urinary Retention

Between 15% and 19% of patients reported one or more episodes of urinary retention due to blood clots within 3 months of discharge from hospital (78). In two studies, 4% - 5% of patients developed retention serious enough to require hospitalization following surgery (28,39). Five years post-discharge, 19% of patients reported the 'sensation of retention' (79).

4.2.3 Infection

Urinary tract infection (UTI) is a commonly reported complication of prostatectomy. Reported rates following surgery vary from 2% - 20% (38,39,65,68,78). In general these rates are high; the low rate of 2% refers to UTI confirmed by culture in one study.

4.2.4 Incontinence

Thirty eight percent reported incontinence 3 weeks after discharge (39). This had fallen to between 1% - 20% (50,65,67,68,78,79) one year after surgery and to 3% at 5 years later (79). A meta-analysis reported the long-term prevalence of incontinence was 0.8% [95% CI, 0.6%-1.2%] (74).

4.2.5 Sexual Problems

Sexual problems such as erectile impotence or retrograde ejaculation are reported following surgery. Of men who were able to have an erection before surgery, 5% report that they were unable to have an erection 3, 6, and 12 months after surgery (39,78). In contrast, a study in Germany reported that surgery had no significant effect on the prevalence of impotence (80). A meta-analysis suggested that 3.4% - [95% CI, 3.3 - 3.5] will develop impotence (74). Between 50% and 93% percent of men reported retrograde ejaculation (69,79). Thirty four percent of sexually active men reported that the operation had made their sex life worse (69).

4.2.6 Strictures

The occurrence of stricture is a complication of surgery. Temporary stricture after surgery occurs in 0.6 - 0.8% (65,68,69). Stricture that was serious enough to require regular intermittent dilatation or a urethroplasty ranged from 1.2% - 7% one year after discharge (65,73). Those patients 3.9% - 4.6% serious enough to have dilatation at within 5 years from discharge (76,79).

4.2.7 Deep Vein Thrombosis

The occurrence of pulmonary embolism as a result of deep vein thrombosis has been reported in two case-series as 0.1% - 0.4% (65,68).

4.2.8 Perforation

Perforations that were large enough to be noticed and serious enough to warrant drainage have been reported in 0.4% - 0.5% of patients undergoing

TURP (65,68).

4.3 Symptoms

A number of studies have assessed changes in post-operative symptoms using symptom scoring indices, where ordinal scales for symptoms obtained by a questionnaire are combined into a single measure. Following prostatectomy, the proportion of men who reported an improvement in symptoms ranged from 70% - 90% (39,51,52,53,65,68,69,74,79). The extent of improvement is related to: pre-operative severity; when the symptoms are reported; and differences in the patient perceptions of severity. After a year, 93% of severely symptomatic and 79% of those with moderate symptoms experienced improvement in a symptom index (78). Seventy two per cent reported that they passed water more easily, between 5 and 8 years following their operation (69). Nevertheless, a small percentage (5%) of patients reported a worsening of symptoms, and 7% of those with severe symptoms reported no improvement (78). Further, it is estimated that symptoms will improve spontaneously in 50% of elderly men with no treatment, and 31% will experience an improvement in their symptoms within 5 years of having presented with symptoms of BPH (12). Generally, obstructive symptoms appear to respond better to TURP than irritative ones (61).

4.4 Health Status

The Nottingham Health Profile was used to assess self-perceived health status in a cohort of 388 men at 3, 6 and 12 months following surgery (32). Sixty per cent of those with a health problem prior to operation reported an improvement a year after surgery. Patients experienced improvement for all health problems and activities of daily living; the most notable change was for sleeping (32).

4.5 Quality of Life

A series of 263 patients in Maine, were interviewed about their quality of life before and after prostatectomy (78). Twelve months following surgery, quality of life had improved only in those patients who had reported severe symptoms (and especially those with a history of acute retention) before surgery. Markov modelling has been used to predict that immediate surgery for a 70 year old man with moderate symptoms would result in a loss of 1 month in life expectancy, and a net benefit of 3 quality-adjusted life months (42). However the latter figure is sensitive to the weighting used for different health states. In a prospective series of 100 patients, quality of life improved significantly (80).

4.6 Reoperation

Reoperation rates vary depending on the type of study; case-series will report lower rates because of selection and reporting biases, and the length of followup. One study reported a two year cumulative probability of a repeat operation of 3% (81).The probability of having a repeat prostatectomy increases with length of followup. At 6 months reported rates vary from 1% to 9% (8,28,62,65,68,72,74). The eight year cumulative reoperation rate is 12% - 20% (8,53,72,73,82). A study using decision analysis with American data suggested that a 70 year old man undergoing prostatectomy for moderate symptoms but with no evidence of chronic retention had a cumulative probability of at least one further operation during his lifetime of 21% (42). In a case series of 2015 cases, 12% reported a previous transurethral prostatectomy (70).

4.7 Summary

TURP appears to be associated with post-operative mortality rates of 1% - 9%; and these rates increase with increasing length of time following surgery. The main complications of surgery include: bleeding, infection, incontinence, sexual problems, strictures, deep vein thrombosis and perforation. Symptoms improve for most men undergoing TURP.

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Appendix A2 - Consensus panel questionnaire

Appropriateness of TURP

Consensus Panel Exercise

The purpose of this exercise is to rate the appropriateness of various indications for TURP, taking into account severity of symptoms and levels of comorbidity.

Assumptions

We would like you to assume that patients have: a) no pre-operative evidence of prostatic cancer, and b) are fit enough to undergo at least a spinal anaesthetic.

Co-morbidity can be a factor in the decision to operate. We have chosen to use life expectancy as an indicator of co-morbidity. Examples of patients at each level of co-morbidity might be as follows.

Less than 1 year	inoperable cancer with secondaries
1 - 4 years	COAD with dyspnoea on moderate exertion; angina on moderate exertion
5 or more	no co-morbidity, hypertension controlled by treatment, osteoarthrosis

Task:

Please rate the appropriateness of chronic retention, acute retention, both chronic and acute retention or no retention as indications for TURP for each level of severity, and for each level of co-morbidity.

1 = prostatectomy is never indicated
9 = prostatectomy is always indicated

Symptom definition

Irritative symptoms include:	frequency, nocturia and dysuria
Obstructive symptoms include:	hesitancy, poor flow, dribbling and a feeling of fullness

None	Symptoms never occur.
Mild	Symptoms occur occasionally or nocturia occurs once per night
Moderate	Symptoms occur about half the time or nocturia occurs 2 - 3 times per night
Severe	Symptoms occur most or all of the time or nocturia occurs 4 or more times per night.

Indications for prostatectomy

A - Chronic retention: TURP is indicated for patients with chronic retention (but not acute) and there are:

Irritative Symptoms

	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Obstructive Symptoms

	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Combination of Irritative and Obstructive Symptoms

	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Indications for prostatectomy

B - Acute retention: TURP is indicated for patients with acute retention (but not chronic) and there are:

Irritative Symptoms	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Obstructive Symptoms	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Combination of Irritative and Obstructive Symptoms	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Indications for prostatectomy

C - Acute and Chronic retention: TURP is indicated for patients with acute and chronic retention and there are:

Irritative Symptoms

Comorbidity (years of life expectancy)

	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Obstructive Symptoms

Comorbidity (years of life expectancy)

	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Combination of Irritative and Obstructive Symptoms

Comorbidity (years of life expectancy)

	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Indications for prostatectomy

D - No retention: TURP is indicated for patients with no retention (but not acute) and there are:

Irritative Symptoms

	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Obstructive Symptoms

	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

Combination of Irritative and Obstructive Symptoms

	Comorbidity (years of life expectancy)		
	High (less than 1)	Medium (1 - 4)	Low (more than 5)
None	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Mild	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Moderate	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9
Severe	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9

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Men's Urinary Symptom Questionnaire

Please circle one number for each question that best describes your experience over the past month.

		Never 0%	Hardly ever 1-19%	Less than half the time 20-39%	About half the time 40-59%	More than half the time 60-79%	Almost always 80-100%
1.	In the past month, how often did you feel that your bladder did not empty fully after urinating?	0	1	2	3	4	5
2.	In the past month, how often did you have to 'go again' within 2 hours of urinating?	0	1	2	3	4	5
3.	In the past month, how often did you stop and start several times when you urinated?	0	1	2	3	4	5
4.	In the past month, how often have you found it difficult to postpone urinating?	0	1	2	3	4	5
5.	In the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
6.	In the past month, how often have you had to push or strain to start urinating?	0	1	2	3	4	5

		Times per night					
		1-3	4-5	6-7	8-9	10-11	12 or more
7.	In the past month, how many times did you get out of bed at night to urinate?	0	1	2	3	4	5

		No problem	Very small problem	Small problem	Medium problem	Big problem
8.	Overall, how bothersome has any trouble with urinating been during the past month?	0	1	2	3	4

		Rarely or never	Enough to embarrass me	Had to wear a pad to stay dry
9.	Over the past month, have you had any leakage of urine?	0	1	2

10. If you were to spend the rest of your life with your current urinary condition, how would you feel about it?

Delighted	Pleased	Not bothered either way	Unhappy	Terrible
0	1	2	3	4

11. In the past month, how much of the time has any urinary problem kept you from doing the kinds of things you would usually do?

Never	Some of the time	Most of the time	All of the time
0	1	2	3

12. Has your prostate condition **ever** caused you to be blocked up completely so that you could not urinate at all?

Yes	No
1	2

13. Have you ever had prostate surgery? Yes No

If so, when ? _____ 1 2

14. Have you been prescribed any antibiotic tablets for urine infection by your doctor **within the last two years?**

Yes	No
1	2

15. Do you have any other health conditions that affect the way you feel or the things that you can do at this time?

a _____ b _____ c_____

16. Date of Birth _____ day _____ month _____ year

17. Which situation best describes how you and your household occupy your accommodation?

Buying the property through mortgage or loan	Owning the property	Rented Privately	Rented from local authority
1	2	3	4

18. How many cars or vans are normally available for use by you or members of your household?

None	One	Two	Three or more
0	1	2	3

19. How would you define your ethnic background?

White	Black Caribbean	Black African	Black Other	Indian	Pakistani	Bangladeshi	Chinese	Other (specify)
1	2	3	4	5	6	7	8	_____

Thank-you very much for your help. Please return the completed questionnaire in the envelope provided.

Appendix A4 - Covering letter to the initial survey

DRS JONES KARAME HESLOP BAKER AND TAINE
BROOK END SURGERY
POTTON, SANDY, BEDS
SG19 2QS
TEL POTTON 260 340

[address here]

Dear [name here],

We are writing to ask you to participate in a study being conducted by the London School of Hygiene and Tropical Medicine. The study will find how many men in the community have trouble with their prostate that leads to difficulties urinating. The results will be important for planning health services.

The questionnaire should take you less than 5 minutes to complete and your name and answers will remain strictly confidential. If you have any specific questions about the study please contact either of us.

Please return the completed questionnaire in the envelope provide. Thank-you for your help

Sincerely yours

Dr M A Karame

Duncan Hunter
Research Fellow
Health Services Research Unit
London School of Hygiene and
Tropical Medicine
071 927 2258

London School of Hygiene and Tropical Medicine
(University of London)

Men's Urinary Symptom Questionnaire

Please circle one answer for each question that best describes your experience over the past month.

		Never 0%	Hardly ever 1-19%	Less than half the time 20-39%	About half the time 40-59%	More than half the time 60-79%	Almost always 80-100%
1.	In the past month, how often did you have to 'go again' within 2 hours of urinating?	0	1	2	3	4	5
2.	How often did you avoid some activity (eg. going out with friends, shopping etc.) because you are worried about needing a toilet?	0	1	2	3	4	5
3.	How often do you avoid some activity because you are worried about wetting yourself in public?	0	1	2	3	4	5
4.	How often do you avoid using public toilets because you may have difficulty starting to urinate?	0	1	2	3	4	5
5.	How often are you embarrassed about having to use the toilet often?	0	1	2	3	4	5
6.	How often do you limit the amount you drink because of any urinary symptom you might experience?	0	1	2	3	4	5

		Times per night					
		None	1	2	3	4	5 or more
7.	In the past month, how many times did you get out of bed at night to urinate?						

		No problem	Very small problem	Small problem	Medium problem	Big problem
8.	Overall, how bothersome has any trouble with urinating been during the past month?	0	1	2	3	4

9. In general, compared to other persons of your age, would you say that your health is:

Excellent	Very Good	Good	Fair	Poor
0	1	2	3	4

10. Overall, how long would you say you have had your urinary symptoms?

Less than a year	1 - 2 years	3 - 4 years	5 - 9 years	10 or more years
0	1	2	3	4

We would now like to know about anything you've done about your urinary symptoms.

11. Have you sought advice from any of the following? Tick more than 1 if necessary

relatives [ ]

friends [ ]

chemist [ ]

nurse [ ]

GP [ ] if yes, please answer Question 12.

12. If you have spoken to your GP, what happened?

I was offered reassurance [ ]

I was prescribed pills [ ]

I was referred to a hospital [ ] if yes, please answer Question 13. surgeon or urologist

13. If you were referred to a hospital surgeon or urologist, what happened?,

I am still waiting to be seen [ ]

I did not attend [ ]

I was offered reassurance [ ]

I was prescribed pills [ ]

I was offered surgery but declined [ ]

I was offered surgery and accepted [ ]

The Nottingham Health Profile

Listed below are some problems people may have in their daily life. Look down the list and put a tick in the box under yes for any problem you have at the moment. Tick the box under no for any problem you do not have. Please answer every question. If you are not sure whether to say yes or no, tick whichever answer you think is more true at the moment.

	Yes	No
I'm tired all the time	[ ]	[ ]
I have pain at night	[ ]	[ ]
Things are getting me down	[ ]	[ ]

	Yes	No
I have unbearable pain	[ ]	[ ]
I take tablets to help me sleep	[ ]	[ ]
I've forgotten what its like to enjoy myself	[ ]	[ ]

	Yes	No
I'm feeling on edge	[ ]	[ ]
I find it painful to change position	[ ]	[ ]
I feel lonely	[ ]	[ ]

	Yes	No
I can only walk about indoors	[ ]	[ ]
I find it hard to bend	[ ]	[ ]
Everything is an effort	[ ]	[ ]

	Yes	No
I'm waking in the early hours of the morning	[ ]	[ ]
I'm unable to walk at all	[ ]	[ ]
I'm finding it hard to make contact with people	[ ]	[ ]

	Yes	No
The days seem to drag	[ ]	[ ]
I have trouble getting up and down the stairs or steps	[ ]	[ ]
I find it hard to reach for things	[ ]	[ ]

Remember if your are not sure whether to answer yes or no to a problem tick whichever answer you think is <u>more true</u> at the moment

	Yes	No
I'm in pain when I walk	[ ]	[ ]
I lose my temper easily these days	[ ]	[ ]
I feel there is nobody I'm close to	[ ]	[ ]

	Yes	No
I lie awake most of the night	[ ]	[ ]
I feel as if I'm losing control	[ ]	[ ]
I'm in pain when I'm standing	[ ]	[ ]

	Yes	No
I find it hard to dress myself	[ ]	[ ]
I soon run out of energy	[ ]	[ ]
I find it hard to stand for long (eg. at the kitchen sink, waiting for a bus)	[ ]	[ ]

	Yes	No
I'm in constant pain	[ ]	[ ]
It takes me a long time to get to sleep	[ ]	[ ]
I feel I am a burden to people	[ ]	[ ]

	Yes	No
Worry is keeping me awake at night	[ ]	[ ]
I feel that life is not worth living	[ ]	[ ]
I sleep badly at night	[ ]	[ ]

	Yes	No
I find it hard to get on with people	[ ]	[ ]
I need help to walk about outside (eg. a walking aid or someone to support me)	[ ]	[ ]
I'm in pain when going up & down stairs or steps	[ ]	[ ]

	Yes	No
I wake up feeling depressed	[ ]	[ ]
I'm in pain when I'm sitting	[ ]	[ ]

Now we would like you to think about the activities in your life which may be affected by health problems.

In the list below, tick yes for each activity in your life which is being affected by your state of health. Tick no for each activity which is not being affected, or which does not apply to you.

Is your present state of health causing problems with your ...

	Yes	No
Job of work (that is paid employment)	[ ]	[ ]
Looking after the home (Examples: cleaning & cooking, repairs, odd jobs around the home)	[ ]	[ ]
Social life (Examples: going out, seeing friends, going to the pub etc.)	[ ]	[ ]
Home life (That is: relationships with other people in your home)	[ ]	[ ]
Sex life	[ ]	[ ]
Interests and hobbies (Examples: sports, arts and crafts, do-it-yourself etc.)	[ ]	[ ]
Holidays (Examples: summer or winter holidays, weekends away etc.)	[ ]	[ ]

The SF-36 Health Status Questionnaire

The following questions ask for your view about your health, how you fell and how well you are able to do your usual activities. If you are unsure about how to answer any question, please give the best answer you can and make any comments in the space available after question 10. Please tick one

1. In general would you say your health is:

Excellent	[ ]
Very good	[ ]
Good	[ ]
Fair	[ ]
Poor	[ ]

2. Compared to one year ago, how would you rate your health in general now?

Much better than one year ago	[ ]
Somewhat better than one year ago	[ ]
About the same	[ ]
Somewhat worse than one year ago	[ ]
Much worse now than one year ago	[ ]

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so how much?

Please tick one box on each line

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a.	vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	[ ]	[ ]	[ ]
b.	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	[ ]	[ ]	[ ]
c.	Lifting or carrying groceries	[ ]	[ ]	[ ]
d.	Climbing several flights of stairs	[ ]	[ ]	[ ]
e.	Climbing one flight of stairs	[ ]	[ ]	[ ]
f.	Bending, kneeling or stooping	[ ]	[ ]	[ ]
g.	Walking more than a mile	[ ]	[ ]	[ ]
h.	Walking half a mile	[ ]	[ ]	[ ]
i.	Walking 100 yards	[ ]	[ ]	[ ]
j.	Bathing and dressing yourself	[ ]	[ ]	[ ]

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Answer Yes or No to each question

	YES	NO
a. Cut down on the amount of time, you spent on work or other activities	[ ]	[ ]
b. Accomplished less than you would like	[ ]	[ ]
c. Were limited in the kind of work or other activities	[ ]	[ ]
d. Had difficulty performing the work or other activities (eg. it took extra effort)	[ ]	[ ]

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Answer Yes or No to each question

	YES	NO
a. Cut down on the amount of time you spent on work or other activities	[ ]	[ ]
b. Accomplished less than you would like	[ ]	[ ]
c. Didn't do work or other activities as carefully as usual	[ ]	[ ]

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

Please tick one

Not at all [ ]
Slightly [ ]
Moderately [ ]
Quite a bit [ ]
Extremely [ ]

7. How much bodily pain have you had during the past 4 weeks?

None [ ]
Very mild [ ]
Mild [ ]
Moderate [ ]
Severe [ ]
Very severe [ ]

8. During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?

Not at all	[ ]
Slightly	[ ]
Moderately	[ ]
Quite a bit	[ ]
Extremely	[ ]

YOUR FEELINGS

9. These questions are about how you feel and how things have been with your during the past month, (for each question, please indicate the one answer that comes closest to the way you have been feeling)

Please tick one box on each line

How much time during the past month:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. did you feel full of life?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
b. Have you been a very nervous person?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
c. Have you felt so down in the dumps that nothing could cheer you up?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
d. Have you felt calm and peaceful?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
e. Did you have a lot of energy?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
f. Have you felt downhearted and low?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
g. Did you feel worn out?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
h. Have you been a happy person?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
i. Did you feel tired?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]
j. Has your health limited your social activities (like visiting friends or close relatives)?	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

HEALTH IN GENERAL

10. Please choose the answer that best describes how true or false each of the following statements is for you?

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
a. I seem to get ill more easily than other people	[ ]	[ ]	[ ]	[ ]	[ ]
b. I am as healthy as anybody I know	[ ]	[ ]	[ ]	[ ]	[ ]
c. I expect my health to get worse	[ ]	[ ]	[ ]	[ ]	[ ]
d. My health is excellent	[ ]	[ ]	[ ]	[ ]	[ ]

Comments

Choice of treatment

The most common treatment for urinary problems caused by enlargement of the prostate gland is surgery. This involves passing an instrument like a small telescope up the penis to clear the blockage. It usually involves a hospital stay of about 8 days. About 80% of men experience an improvement in their symptoms following surgery, about 15% are unchanged and 5% worse off. Some men will also have difficulty getting an erection after surgery. In addition, about 10% have complications, such as bleeding, infections and leakage of urine, which normally clear up within a few weeks.

If your urinary symptoms were found to be due to an enlarged prostate and you were offered surgery for it, feeling the way you do now, would you choose to have it?

definitely want	probably want	not sure but inclined to yes	not sure but inclined to no	probably don't want	definitely don't want
0	1	2	3	4	5

Thank you very much for your help. Please return the completed questionnaire in the envelope provided.

Appendix A6 - Covering letter to the follow-up survey

Dr. Helen M. Murphy
Dr. N. Elizabeth Lee

The Surgery 2 Hanway Place London W1P 9DF
Telephone: 071-323-0760

[address here]

Dear [name here],

Thank you for returning out recent questionnaire about urinary symptoms. For the final part of this project, we are sending a more detailed questionnaire to those who reported symptoms. The purpose of the second questionnaire is to learn about the effect that urinary symptoms may have on your quality of life.

We would be very grateful if you took about ten minutes to complete the enclosed questionnaire and return it in the envelope provide. Your name and answers will remain strictly confidential.

If you have any further questions about the study or would like to receive the results of the survey, please contact either of us. Thank-you in advance for your help.

Sincerely yours,

Dr. N. Elizabeth Lee
The Surgery 2 Hanway Place
London W1P 9DF
Tel: 071 323 0760

Duncan Hunter
Research Fellow
London School of Hygiene and
Tropical Medicine
071-927-2258

Appendix A7 - Data checks of SF-36 scores

Formal scoring checks are recommended for the SF-36. After items have been recoded the correlations should be positive in direction and substantial in magnitude (0.30 or higher). The following table presents the correlation between each scale and the component items.

Scale	Item	Correlation coefficient
Physical functioning	3a	0.65
	3b	0.84
	3c	0.82
	3d	0.83
	3e	0.86
	3f	0.78
	3g	0.84
	3h	0.85
	3i	0.79
	3j	0.72
Physical role	4a	0.87
	4b	0.86
	4c	0.91
	4d	0.87
Bodily pain	7	1.0
	8	1.0
General health	1	0.83
	11a	0.65
	11b	0.80
	11c	0.64
	11d	0.81
Vitality	9a	0.84
	9e	0.82
	9g	0.79
	9i	0.76
Social functioning	6	0.87
	10	0.92
Emotional role	5a	0.89
	5b	0.90
	5c	0.86
Mental health	9b	0.75
	9c	0.85
	9d	0.82
	9f	0.81
	9h	0.78

Appendix A8 - Modelling incident need

The model was developed by Colin Sanderson.

Methods

Data on prevalence from the survey were used to estimate the incidence of men with moderate or severe urinary symptoms who would probably or definitely want surgery if offered it ('candidates for surgery'). A multiple decrement life-table model for men aged 0 to 89 was constructed with the following 'states': never a candidate for surgery; currently a candidate for surgery; no longer a candidate as a result of surgery; candidature withdrawn (due to symptom remission or change of mind about wanting surgery); and dead. The overall mortality experience of the population was defined by the life table for North West Thames region (178). The model was Markovian in the sense that probabilities of moving from one state to another depended only on age and the two states involved, and not on any 'history'. Thus for candidate for surgery, the probability of having surgery in any one year was dependent on age rather than, for example, duration of symptoms. (These probabilities were set to match the observed age-specific rates for prostatectomy in the region.) Also it was assumed that, following surgery, all patients had their symptoms relieved in the short term, but that there was a constant probability of relapse during each year of life thereafter. The model allowed for the division of the cohort into two groups with different risks of developing symptoms for which surgery was wanted. It was assumed that within a risk group, the incremental incidence (defined in Table 1, with other model parameters would not decrease with increasing age).

Output consisted of age-prevalence curves that could be matched to the observed data, together with figures for cumulative withdrawal and cumulative post-operative

rates. Root-mean-square measures of absolute error in the predicted numbers of candidates for surgery in five-year bands in a population of 250,000 indicated goodness of fit. Using different sets of structural assumptions and age-specific incremental incidence rates, a process of trial and error was used to reproduce the observed prevalence curves.

Results

The first scenario reported here (Table A9.1 and Figure A9.1) involves a simple set of assumptions consistent with what is currently known. There was no high-risk group. The lifetime rate of candidate withdrawal for the cohort was set at 40% (7) and the lifetime post-surgical relapse rate was set at 15%. These were reproduced by the model by setting the annual withdrawal rate for all current candidates for surgery to 6.7% per year and the relapse rate to 1.8% per year. To provide a reasonable match to the observed prevalence curves, it was necessary for incidence rates to increase very sharply in men aged between 50 and 59, and for there to be no material increase with age thereafter.

Although the results of scenario 1 lie within the confidence intervals of the observed prevalence curve, it was not possible under this set of assumptions to reproduce the sharpness of the rise in prevalence from 55-59 at the same time as the flattening after the age of 60, and so a high-risk group was introduced. With p as the proportion of the cohort in the high risk group and r as the 'risk' or incremental incidence ratio as defined in Table A10.1, a variety of combinations of p and r were tried. In general, values of p around 10% and values of r around 20-50 (eg scenario 2 with p = 10% and r = 50: Table A10.2, Figure A10.2) provided better fits than values of p around 25-50% and values of r around 2-5 (eg scenario 3 with p = 50% and r = 3: Table

A10.2). In addition scenario 2 involved a relative risk of mortality of 2 in the high risk group. The sensitivity of the incidence to the assumed candidature withdrawal rate is shown by scenario 4, which is similar to scenario 2 but with a rate of 25% rather than 40% (Table A10.2).

The results of this modelling exercise suggest that in a population containing 35,000 men aged between 50 and 90 (a typical figure for a catchment population of 250,000) there would be 400 to 500 new cases of men with moderate or severe urinary symptoms per year, who would probably or definitely choose to have surgery.

Table A9.1. Parameters used in the model to estimate incident need.

Base incremental incidence rate	for each year of life, the increment in the proportion of the unaffected population who become candidates for surgery, either in the whole population or in the low risk group
Surgical rate	the proportion of candidates for surgery that have surgery during the year, for different age groups
Operative risk	the excess death rate amongst those having surgery in the year following their operation
Post-operative relapse	the proportion of current non-symptomatic post-surgery cases that develop symptoms in the following year
Withdrawal rate	the proportion of candidates for surgery at the beginning of the year who were no longer candidates at the end of the year
Risk fraction, p	the proportion of the initial cohort that falls into the high risk group
Relative incremental risk for high risk group, r	the ratio of the incremental risk of becoming a candidate for surgery in the high risk group to the base incremental rate
Risk lead period for high risk group	for example, if the annual increment in incidence in the low-risk group is 0.4% in those aged 55-59, a 5-year lead period - but relative incremental risk of 1 - would imply that the increment in the high risk group was 0.4% in those aged 50-54
Relative risk of mortality in high risk group	the ratio of age-specific mortalities in the high and low risk groups

Table A9.2. Results from life-table model

	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Base incremental incidence rate				
0-49	.0000	.0000	.0000	.0000
50-54	.0020	.0002	.0016	.0002
55-59	.0028	.0028	.0015	.0024
60+	.0000	.0004	.0000	.0003
High risk group				
proportion in group	0	10%	50%	10%
relative incremental risk	-	50	2	50
relative risk of mortality	-	2	1	2
Lifetime candidate withdrawal	40%	40%	40%	25%
Lifetime post-surgical relapse rate	15%	15%	15%	15%
Predicted prevalence				
50-54	.004	.002	.005	.002
55-59	.038	.036	.043	.034
60-64	.099	.112	.102	.110
65-69	.038	.137	.137	.135
70-74	.147	.140	.144	.140
75-79	.138	.131	.133	.131
80-84	.120	.114	.113	.113
85-89	.106	.107	.097	.102
Estimated incidence/10,000 men aged 55-89	141	131	137	119
Estimated incidence in a typical population of 250,000	492	460	478	416
Root mean square of model fit (cases)				
age 55-79	71.5	34.6	64.6	32.8
age 80+	61.2	68.6	69.9	71.0

Appendix A9 - Consensus panel ratings

A - Chronic retention - median (range)

Irritative symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-2)	5 (2-9)	8 (7-9)
Mild	2 (1-2)	7 (4-9)	9 (7-9)
Moderate	5 (3-6)	8 (7-9)	9 (8-9)
Severe	6 (5-7)	9 (8-9)	9 (9-9)

Obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-1)	6 (2-9)	8 (5-9)
Mild	2 (2-2)	7 (4-9)	8 (8-9)
Moderate	5 (4-6)	7 (7-9)	9 (8-9)
Severe	7 (6-8)	8 (8-9)	9 (9-9)

Combination of irritative & obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-2)	6 (2-9)	8 (6-9)
Mild	2 (2-3)	7 (3-9)	9 (8-9)
Moderate	5 (3-6)	8 (7-9)	9 (8-9)
Severe	7 (6-8)	9 (8-9)	9 (9-9)

1 = Never indicated
9 = Always indicated

B - Acute retention - median (range)

Irritative symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-2)	3 (2-4)	5 (2-6)
Mild	2 (2-3)	4 (3-6)	6 (3-7)
Moderate	4 (4-5)	8 (5-8)	8 (6-9)
Severe	8 (5-8)	8 (6-9)	9 (8-9)

Obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-2)	4 (2-6)	6 (2-8)
Mild	2 (1-4)	4 (3-7)	8 (4-9)
Moderate	5 (4-7)	8 (6-9)	8 (7-9)
Severe	8 (7-9)	8 (8-9)	9 (9-9)

Combination of irritative & obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-2)	5 (2-6)	6 (2-9)
Mild	2 (1-3)	6 (4-8)	7 (4-9)
Moderate	5 (4-7)	8 (7-9)	8 (8-9)
Severe	8 (7-9)	8 (8-9)	9 (8-9)

1 = Never indicated
9 = Always indicated

C - Acute on chronic retention - median (range)

Irritative symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	2 (1-3)	7 (5-9)	8 (7-9)
Mild	2 (1-5)	8 (6-9)	8 (8-9)
Moderate	5 (3-8)	9 (8-9)	9 (9-9)
Severe	7 (5-9)	9 (9-9)	9 (9-9)

Obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	2 (1-5)	7 (6-9)	9 (7-9)
Mild	4 (2-6)	8 (7-9)	9 (8-9)
Moderate	6 (5-9)	8 (8-9)	9 (9-9)
Severe	8 (6-9)	9 (9-9)	9 (9-9)

Combination of irritative & obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	3 (1-8)	7 (5-9)	9 (8-9)
Mild	4 (1-8)	8 (7-9)	8.5(8-9)
Moderate	6 (5-8)	8 (8-9)	9 (9-9)
Severe	8 (7-8)	9 (9-9)	9 (9-9)

1 = Never indicated
9 = Always indicated

D - No symptoms - median (range)

Irritative symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-1)	1 (1-1)	1 (1-1)
Mild	1 (1-2)	1 (1-2)	1 (1-2)
Moderate	2 (1-2)	4 (1-4)	5 (3-5)
Severe	4 (1-4)	5 (1-6)	5 (4-6)

Obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-1)	1 (1-1)	1 (1-1)
Mild	1 (1-2)	1 (1-2)	2 (1-3)
Moderate	3 (2-4)	5 (5-7)	7 (6-8)
Severe	5 (3-7)	8 (7-8)	8 (7-9)

Combination of irritative & obstructive symptoms

	Comorbidity		
	High	**Medium**	**Low**
None	1 (1-1)	1 (1-2)	1 (1-1)
Mild	1 (1-2)	1 (1-3)	2 (1-3)
Moderate	4 (3-4)	6 (5-7)	7 (6-8)
Severe	7 (6-7)	8 (7-9)	8 (7-9)

1 = Never indicated
9 = Always indicated

Appendix A10 - Published papers related to thesis

1. Hunter DJW, McKee CM, Sanderson CFB, Black NA. Appropriate indications for prostatectomy in the U.K. - results of a consensus panel. J Epidemiol Comm Health 1994; **48**:58-64.

2. Hunter DJW, McKee CM, Black NA, Sanderson CFB. Urinary symptoms: prevalence and severity in British men aged 55 and over. J Epidemiol Comm Health 1994; **48**:569-575.

3. Hunter DJW, McKee CM, Black NA, Sanderson CFB. Health care sought and received by men with urinary symptoms, and their views on prostatectomy. Brit J Gen Pract 1995; **45**:27-30.

Appropriate indications for prostatectomy in the UK – results of a consensus panel

D J W Hunter, C M McKee, C F B Sanderson, N A Black

Abstract

Study objective **– The use of formal consensus development to determine appropriate indications for prostatectomy and to identify factors underlying clinical decisions about appropriateness is described.**

Design **– A nominal group technique was used.**

Settings **– The study took place in an academic research institution.**

Participants **– The panel consisted of six urologists and three general practitioners.**

Measurements and main results **– The panel identified agreed indications for prostatectomy, expressed in terms of different combinations of type of retention, type and severity of symptoms, and level of comorbidity. Agreement was reached for 67% of the indications considered. For acute on chronic retention, surgery is indicated, regardless of symptom severity, if life expectancy is greater than one year. For acute *or* chronic retention, surgery is generally indicated if symptoms are severe, or if symptoms are moderate and life expectancy is greater than five years. For patients with neither acute nor chronic retention, surgery is indicated if symptoms are severe, or if these are moderate and life expectancy is greater than five years. For chronic or acute retention surgery is inappropriate if symptoms are mild and life expectancy is less than one year, or if there is no retention and only mild symptoms. An "appropriateness score" was developed. This confirmed that in general the ratings were internally consistent, that the panel attached little weight to mild symptoms, that a combination of irritative and obstructive symptoms was no more indicative of surgery than obstructive symptoms alone, and that the type of symptom was less important than the other factors considered.**

Conclusions **– The results provide a basis for population based surveys of the need for prostatectomy.**

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In the reformed National Health Service, health authorities are required to assess the needs of their populations and to purchase appropriate care. There is emerging agreement about the means to be used in assessing need or the requirement for specific health care interventions.[1-2] The first step is to reach consensus, based on the best available evidence, about the appropriate indications for the intervention. The second step is to ascertain the population prevalence of individuals with appropriate indications. The final step is to determine which individuals with clinically appropriate indications actually want the intervention in question. Despite the importance of this type of research, relatively little has been undertaken.

Prostatectomy to remove obstruction of the urethra arising from benign prostatic hyperplasia (BPH) is one of the commonest elective surgical procedures. Patients commonly present with acute retention, chronic retention, or with a complex of obstructive and irritative symptoms such as hesitancy, poor flow, terminal dribbling, frequency, feeling of fullness, dysuria, and nocturia.[3] Reported prostatectomy rates in western countries vary considerably, from 60 to 368 per 100 000.[4-8] In general, the rates in North America are more than twice as high as in Europe. Even within the United Kingdom there is wide variation. The standardised prostatectomy ratio adjusted for age and private sector contribution varies in English regions from 77 to 144 (England = 100).[9] There is little evidence that this is the result of differences in the prevalence of BPH, and much of the variation seems to result from the supply of surgical services, including the availability of surgeons and their judgement of the clinical appropriateness of surgery.[8,10,11]

A review of published reports suggests only limited agreement about the appropriate indications for prostatectomy. For example, while some authors state that acute retention in the absence of detrusor failure or neuropathic obstruction is an absolute indication,[12] others argue in favour of conservative treatment for those who can void successfully after a period of catheter drainage.[13,14] A recent study of the practice behaviour of urologists concluded that consensus about appropriate practice has yet to be achieved.[15] A further controversy centres on whether it is better to perform surgery early, in order to avoid the greater risk when the patient grows older, or to limit surgery to those patients with symptoms that significantly affect their quality of life.[16] These arguments have assumed greater importance after the publication of reports casting doubt on previous beliefs about the level of risk associated with transurethral resection of the prostate (TURP)[17] and claims that up to 75% of TURPs performed in the United States may be inappropriate.[18]

Formal consensus development is a method of providing, on the best available evidence, an

Table 1 Example of weights for dimensions of indications for surgery

Retention			
None: 0	Acute: 1	Chronic: 2	Acute on chronic: 3
Symptom severity			
None: 0	Mild: 1	Moderate: 2	Severe: 3
Symptom type			
Irritative: 0	Obstructive: 1	Irritative & obstructive: 2	
Comorbidity			
High: 0	Medium: 1	Low: 2	

Table 2 True and false positive and negative scores at lower and upper thresholds

	Appropriateness score			
Panel judgement	*Below lower threshold*	*On above lower threshold*	*Below upper threshold*	*On above upper threshold*
Surgery inappropriate	True −ve type 1	False +ve type 1	True −ve type 2	False +ve type 2
Unclear	False −ve type 1	True +ve type 1	True −ve type 2	False +ve type 2
Surgery indicated	False −ve type 1	True +ve type 1	False −ve type 2	True +ve type 2

1–3 and appropriate if the median rating fell between 7–9. A rating of 4–6 was judged to be equivocal. The rationale for the use of this scoring system has been described elsewhere.[23] Data were analysed using programs written in the statistical program SAS.[24]

The practical value of listing the appropriateness of each of 118 patient categories is limited and an attempt was made to summarise the results by devising a scoring system that could be used to estimate the appropriateness of surgery for any given patient category. With type of retention, symptom severity, symptom type, and comorbidity as the four factors that determine appropriateness, this involved assigning different weights to each "point" on four corresponding "dimensions". An example of one such set of weights is shown in table 1. With this particular set, patients in acute retention with mild obstructive symptoms and low comorbidity would score $1+1+1+2=5$.

The conclusions of the panel were divided into three groups: "appropriate", "inappropriate", and "unclear" where the panel either disagreed, agreed only partially, or were equivocal. The question was whether these conclusions were consistent with an underlying set of judgements about the relative importance in determining appropriateness of the four different "dimensions" and the various "scale points" in each dimension. If so, it would be possible to devise a scoring system that could predict the panel's ratings reasonably well. Patient categories with scores below a certain threshold would tend to have been rated by the panel as inappropriate for prostatectomy. Categories with scores above a second and higher threshold would tend to have been rated as appropriate. And categories with scores within a middle band between these two thresholds would tend to be those about which the panel results were unclear.

To examine this question the following procedure was used: (1) a set of weights was chosen; (2) a score was calculated for each category of patient; (3) a lower threshold value was chosen and rates of "type 1" true and false positives and negatives calculated, using the definitions shown in table 2; (4) an upper threshold value was chosen and rates of "type 2" true and false positives and negatives were calculated (table 2). A set of weights together with a lower and an upper threshold value thus constitute a scoring scheme.

This procedure was repeated for a variety of scoring schemes. In the main analysis only whole numbers were considered for the weights and threshold values. An intuitive set of weights was chosen as a starting point. First, a variety of ways of aggregating the weights in each dimension to form scores, including the sum, the product, and combinations (for example, symptom type × symptom severity + retention + comorbidity) was tried. Then a systematic procedure was followed to test the effect of giving more or less weight to each dimension and to selected scale points. Once a satisfactory weighting scheme had been found, the effect of various departures from it was examined. Over 40 schemes were tried in all. To assist in interpreting the results, an upper limit on the proportion of categories that could be correctly assigned by any scheme using the panel data (including one with non-integer weights and thresholds) was derived using conventional discriminant analysis. This produced two functions that divided the patient categories into inappropriate, unclear, and appropriate. Also it was necessary to take account of the fact that some categories will be correctly assigned by chance even if a scoring scheme has no real predictive value.

Figure 1 represents an "ideal" result with no false positives or false negatives at either threshold. In this hypothetical example, only the categories that the panel considered inappropriate scored less than 4, only the categories that they considered appropriate scored 6 or more, and only those about which the panel were unclear scored 4 or 5. This is only ideal given the observed distribution of panel ratings. Of course a result in which there were fewer categories for which the panel results were "unclear" would be better. Also it should be emphasised here that the figures given for the percentage agreement and disagreement, and for the percentage of false positive and false negatives, would only match those found in a survey of clinical practice if each category of patient were equally prevalent.

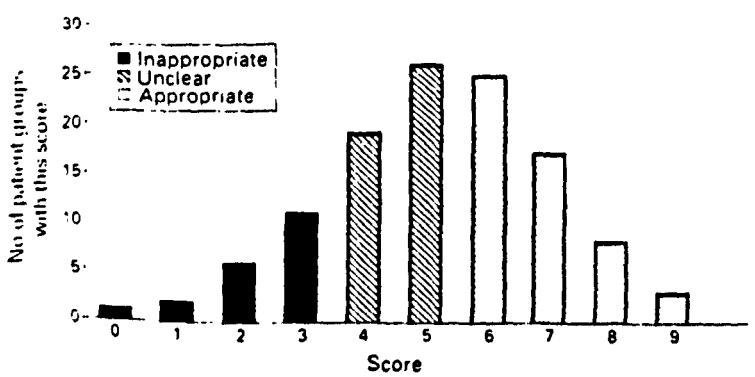

Figure 1 Prostatectomy indication score. Hypothetical ideal scheme

Table 4 Proportions of correct assignments to inappropriate, unclear, and appropriate using different sets of weights for type of retention, severity and type of symptoms, and degree of comorbidity

Scheme	Retention	Symptom severity	Symptom type	Comorbidity	T1	T2	Match using 3 groups: inappropriate v unclear v appropriate (%)	Match using 2 groups: inappropriate v unclear + appropriate (%)	Match using 2 groups: inappropriate + unclear v appropriate (%)
1	0123	0123	012	012	3	6	76·3	89·0	87·3
2	0122	0123	012	012	3	6	75·4	88·1	87·3
3	0123	0023	012	012	3	6	79·7	92·4	88·1
4	0123	0023	011	012	3	5	82·2	94·1	88·1
5	0223	0023	011	023	4	6	83·9	94·9	89·0
6	0224	0024	011	024	4	7	85·6	96·6	89·0
7	0224	0024	000	024	4	6	78·0	96·6	81·4
8	0222	0024	011	024	4	7	80·5	93·2	87·3
9	0222	0023	011	023	4	6	83·1	94·9	88·1
10	0000	0024	011	024	2	4	73·7	89·8	83·9

T1 = lower threshold, between inappropriate and unclear; T2 = upper threshold, between unclear and appropriate.
Match = % of assignments that match the conclusions of the panel about whether appropriate, unclear or inappropriate.

In scheme 6, the weights given to retention, symptom severity, and comorbidity are all increased relative to symptom type. This is the best overall scheme using integer weights. Scheme 7 explores the extent to which the appropriateness of surgery can be determined without information about the type of symptoms. Plainly this is much worse than other schemes at identifying appropriate cases, but is as good as any at identifying inappropriate ones, and is still better overall than schemes 1 and 2. Scheme 8 explores the question of how far the appropriateness of surgery can be predicted with no information about type of retention – whether it is acute, chronic, or acute on chronic. Scheme 9 is a slightly better variant of this in which less weight is given to severe symptoms and low comorbidity.

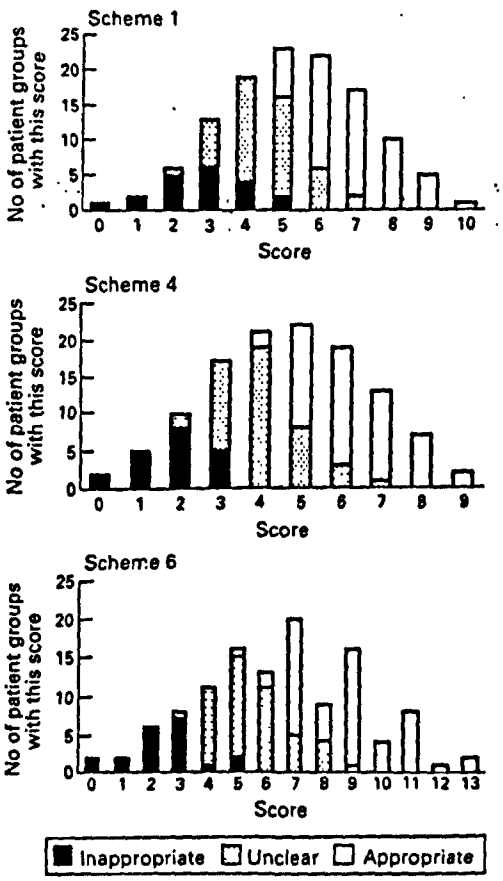

Figure 3. Prostatectomy appropriateness score.

Scheme 10 confirms that information about whether the patient is in retention or not is, as one might expect, an important factor in determining the appropriateness of surgery.

The analysis in table 4 makes no distinction between false positives and false negatives. This matter is addressed in table 5. If the scores were to be used as part of a screening procedure in primary care, it would be important to avoid false negatives. If the risks of surgery were generally substantial compared with the benefits, it would be important to avoid false positives.

One further consideration is that scheme 4 is one that avoids the situation in which patient categories which have been rated by the panel as appropriate have the same score as categories that have been rated as inappropriate. One can thus say with scheme 4 that groups scoring 3 or less include all those judged by the panel as inappropriate for prostatectomy, and that groups with scores of 4 or more include all those for which prostatectomy was judged appropriate.

Tables 4 and 5 suggest a number of points. Firstly, retention, symptom severity, and the degree of comorbidity were given roughly equal weight by the panel when rating patient categories, whereas the type of symptoms was much less important. Secondly, the presence of retention is important. The difference between acute and chronic retention is less so, and acute on chronic retention is a stronger indication than either acute or chronic retention alone. Thirdly, in effect the panel did not distinguish between patients with mild symptoms and patients with no symptoms at all. Fourthly, the panel considered obstructive symptoms to be more important in indicating surgery than irritative symptoms. And fifthly, the type of symptom was not important in determining the groups for which prostatectomy was *inappropriate*.

Discussion

Consensus development has been advocated as a means of making explicit the basis for clinical decisions. Although the nominal group technique of consensus development is well established, the development of a model to explain the ratings given by a panel is new. We believe that this approach has clarified much of the thinking behind the normally implicit decision

Table 5 Rates of false positives and false negatives for different threshold values discriminating between inappropriate, unclear and appropriate, and different sets of weights for type of retention, severity and type of symptoms, and degree of comorbidity

Scheme		Type 1 (threshold for "unclear")						Type 2 (threshold for "appropriate")					
		1	2	3	4	5	6	3	4	5	6	7	8
1	% false +ve			60	30	10	0			37	12	3	
	% false −ve			1	8	23	45			0	13	43	
2	% false +ve			60	30	10	0		63	32	8	0	
	% false −ve			2	10	28	51		0	2	19	53	
3	% false +ve			35	10	0				26	8	3	
	% false −ve			2	12	30				2	19	49	
4	% false +ve			25	0				48	18	6	2	
	% false −ve			2	14*				0	4	30	60	
5	% false +ve			50	10	0			66	48	17†	6	
	% false −ve			0	4	15			0	2	4	32	
6	% false +ve			50	15	10	0			55	32	15	8
	% false −ve			0	1	11	26			0	2	6	34
7	% false +ve		80	15	15	0			72	32	32	8	8
	% false −ve		0	1	1	26			0	2	2	34	34
8	% false +ve		80	50	15	10	0		66	48	25	11	5
	% false −ve		6	8	11	22	39		11	11	17	26	60
9	% false +ve		50	10	0				63	43	12	5	0
	% false −ve		2	6	18				0	2	11	40	60
10	% false +ve	70	40	30	15	10	0	58	37	22	8	2	
	% false −ve	2	4	13	27	41	63	0	4	13	42	49	

False −ves %: type 1: *denominator:* number of patient groups judged by panel -> appropriate or unclear
numerator: subset of denominator indicated by score -> inappropriate
type 2: *denominator:* number of patient groups judged by panel -> appropriate
numerator: subset of denominator indicated by score -> unclear or inappropriate

False +ves %: type 1: *denominator:* number of patient groups judged by panel -> inappropriate
numerator: subset of denominator indicated by score -> unclear or appropriate
type 2: *denominator:* number of patient groups judged by panel -> inappropriate or unclear
numerator: subset of denominator indicated by score -> appropriate

* Indicates a false negative rate of 14% for a type 1 threshold of 4. This implies that if a score of less than 4 is taken to mean that prostatectomy is inappropriate, then 14% of all indications judged by the panel as appropriate or unclear were indicated as inappropriate by the score.
† Indicates a false positive rate of 17% for a type 2 threshold of 6. This implies that if a score of 6 or more is taken to mean that prostatectomy is appropriate, then 17% of all indications judged by the panel to be inappropriate or unclear were indicated as appropriate by the score.
The results for thresholds at the upper and lower ends of the scale do not appear in the table because there are either no false positives or no false negatives.

to recommend prostatectomy, and we suggest that it could be usefully employed with the results of similar panels that have considered other procedures. The panel discussion was lively, with all members participating, and very little clear disagreement. In addition, as can be seen from fig 2, the ratings were generally internally consistent. This internal consistency may have been helped by the layout of the forms which the participants were asked to complete.

The panel did not consider that surgery was necessarily appropriate in patients with a history of acute retention, although there is a large group of these patients in whom surgery will sometimes be appropriate. There is also support for the approach described as "watchful waiting".

This study has highlighted a question that has received little attention in the published reports: do irritative symptoms have a different prognostic implication than obstructive symptoms? Some panellists felt that the exercise had involved an artificial distinction between obstructive and irritative symptoms which was seldom made in practice, whereas others expressed the view that prostatectomy should be performed for obstructive but not for irritative symptoms, because irritative symptoms were caused by detrusor instability rather than an enlarged prostate. The weighting analysis showed that the latter view was the more consistent with the panel's final judgements. Attaching equal weight to obstructive and to combined obstructive plus irritative symptoms but less weight to irritative symptoms alone gave the best "fit", but the type of symptom was the least important of the four "dimensions" considered by the panel. It also confirmed, despite the view of some that comorbidity is unimportant because of the ability to perform prostatectomy under spinal anaesthesia, that comorbidity does play a part in determining appropriateness.

The weighting analysis also indicated that if the objective is simply to eliminate patients who are inappropriate for TURP, then although the *presence* of retention is important, the *type* of retention is less so. This suggests that it may be possible to devise useful guidelines for general practitioners about what kinds of patients to refer.

In considering these results, the limitations of consensus development techniques need to be remembered. Firstly, there is a potential bias in the selection of the panellists. We cannot be sure of the extent to which our panel reflected the views of other urologists and general practitioners. Although it has been shown that those doctors who are willing to participate in expert panels are representative of their colleagues,[25] the exact composition of a panel can effect the results obtained.[26] In this study, all the panel members came from one health region, in which the prostatectomy rate was 23% lower than the national average in 1985.[7] It may well be that a panel consisting of consultants from other regions would have given different results. Secondly, as well as any selection bias, the results will also be affected by any "random" variation in panel behaviour. Ideally the whole process should be replicated using different panels.

Thirdly, the ratings of a panel are dependent on the definitions used. As in many areas of clinical work, terms in everyday use are used differently by different clinicians. Although there was some uncertainty among a few of the panellists at first, agreed definitions were developed and used as a basis for the second round, in some cases leading to modification of earlier scores. We do not know to what extent

panellists made use of the review of published reports that had been provided, although most stated that they had found it helpful.

Fourthly, we do not know how far stated opinions correspond to actual clinical practice, though this will be examined and reported in another paper.

Fifthly, the importance that should be attached to the figures given for the percentage agreement and disagreement, and to the percentage of false positive and false negatives, remains uncertain. As was pointed out earlier, they would only match those found in a survey of clinical practice if each category of patient was equally prevalent. In practice, some of the combinations of signs, symptoms, and comorbidity that the panel was asked to consider may be very rare. A proper interpretation of the importance of the extent of agreement over ratings would need to take the prevalence of each patient category into account, and the necessary data are not yet available. This is the subject of current research.

Finally, the existence of a consensus does not in itself mean the consensus view is correct and there is a danger that the nominal group process will arrive at collective ignorance rather than wisdom. As such it is not a replacement for either rigorous scientific reviews of published reports or for research, but rather a means of identifying current medical opinion and areas of disagreement. Ideally, indications for surgery should be based on studies of the relationship between patient characteristics and clinical outcome. To be reliable these need to be based on large numbers of patients and such data are beginning to become available.

How will the results of the study be used? In the immediate future, it will be used to assess the prevalence of individuals with appropriate indications for surgery among the population. The appropriateness score could be used to develop guidelines for general practitioners about the kind of patients to refer. Further work will examine its ability to predict outcome and the extent to which surgeons follow these policies in practice.

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Health care sought and received by men with urinary symptoms, and their views on prostatectomy

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SUMMARY

Background. *Urinary symptoms are common among middle aged and elderly men.*

Aim. *A study was undertaken to describe the health care sought by men aged 55 years and over with urinary symptoms, the action taken by general practitioners and urologists, and the men's views on prostatectomy.*

Method. *A postal questionnaire was sent to 516 men aged 55 years and over in the North West Thames Regional Health Authority, with previously identified mild, moderate or severe urinary symptoms.*

Results. *The response rate among eligible subjects was 83%. Of 420 respondents 45% had seen their general practitioner for their symptoms. General practitioners had referred 62% of these men to a urologist, reassured 21% and prescribed medication to 17%. The probability of a man seeking medical advice increased with increasing symptom severity. In contrast, the decision to refer was independent of symptom severity. Of the men referred to a urologist, the majority (71%) were offered and accepted surgery. The remainder were reassured (17%), or received a prescription (4%). Eight per cent were offered surgery but declined. When presented with details and information on the risks and benefits of prostatectomy, 22% of men with symptoms would probably or definitely refuse treatment, while a further 47% of men were unsure.*

Conclusion. *There are many men who do not seek treatment for urinary symptoms and, of those who do, subsequent referral is not associated with symptom severity. There is scope for improving the referral process through the shared development of guidelines between general practitioners, hospitals and commissioning agencies.*

Keywords: urination disorders; prostate diseases; men's health; patient self referral.

Introduction

MODERATE or severe urinary symptoms affect up to 25% of middle aged and elderly men.[1-3] These are commonly due to benign prostatic hyperplasia, a condition for which an effective intervention exists.[4,5] However, many men with symptoms do not receive treatment.[3] The relationship between the need for and use of health care involves a chain of events in which intervention rates are influenced by: whether individuals seek medical advice; whether clinicians judge the intervention to be appropriate; and if, when presented with information about the intervention and its risks and benefits, individuals choose to receive it. Planning and purchasing of health care require an understanding of this process.

Little information on these three steps is available. First, as regards whether or not individuals seek medical advice, a Danish study found that a third of healthy men with urinary frequency, post-micturition dribbling, and a weak urinary stream believed that these symptoms did not justify seeking treatment.[6] Secondly, variation in clinical judgement about the appropriateness of surgery is believed to account for much of the variation in prostatectomy rates within countries although this view is based largely on studies of men undergoing prostatectomy, with no information about those who have symptoms but do not undergo surgery.[7] Thirdly, even after being offered treatment, men may not wish to accept it. In a British study, 30% of 107 men with minimal symptoms who were on a waiting list for prostatectomy declined surgery after being reassured about the natural history of prostatic obstruction.[8] An American study to validate a quality of life questionnaire among men awaiting prostatectomy had to exclude 37 men (55%) who elected not to have surgery.[9] Preliminary results from studies in the United Kingdom and the United States of America of symptomatic men considering prostatectomy found that many declined surgery after viewing an interactive video disc that provided information on the risks and benefits of treatment.[10,11]

While these studies give some indication of the importance of these factors in different countries, there is little information about their overall effect on the relationship between need and use in a defined population. This study sought to: determine the advice-seeking behaviour of men with mild, moderate or severe urinary symptoms; describe their subsequent management by general practitioners and urologists; and determine whether these men would choose surgery when provided with information about the outcomes of prostatectomy. This paper describes the results of a two-stage survey, the first stage of which is being reported elsewhere.[3]

Method

A two-page questionnaire was sent to 2000 men over the age of 55 years selected from eight randomly chosen general practices in North West Thames Regional Health Authority in 1992. With the exception of the smallest practice, where the entire list was used, 265 men were randomly sampled from the whole of each practice's list to create a database of 2000 names and addresses. The purpose of the survey was to measure the prevalence and severity of urinary symptoms. The survey achieved a response rate of 77.7% (1480) among eligible respondents. Questions on urinary symptoms were taken from the American Urological Association symptom index, with some minor modifications to the wording of some questions to make them more appropriate for a British population.[12]

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A symptom index, ranging from 0 to 30, was calculated by adding together the scores of six urinary symptoms (fullness, frequency, intermittency, urgency, poor flow and hesitancy) where each symptom was assigned one of the following values: 0 = never, 1 = hardly ever, 2 = less than half the time, 3 = about half the time, 4 = more than half the time and 5 = almost always. The symptom index was categorized into five levels of severity: none (0), very mild (1–6), mild (7–9), moderate (10–18) and severe (19–30). These cut-off points were derived from information gained from the results of a consensus panel that considered the appropriateness of indications for treatment.[13] Further details of the method are described elsewhere.[3]

The follow-up survey involved 516 men (34.9%) in the initial survey who reported a symptom index score of seven or more, that is mild, moderate or severe symptoms. They were sent a second questionnaire six weeks after the initial survey that sought information about their health behaviour and views on prostatectomy. The seven page questionnaire was sent together with a personal covering letter from the man's general practitioner and a stamped, addressed envelope for reply. All non-respondents were sent a reminder letter and a second questionnaire one month later. Participants were asked whether they had sought advice for their urinary symptoms and from whom, whether they had visited their general practitioner or urologist, and what had been the results of these consultations.

To investigate the possible effects of response bias, the non-respondents were compared with the respondents in terms of age, severity of symptoms, previous surgery and previous episodes of acute urinary retention, using data from the initial survey.

In order to discover whether men would accept treatment or not, participants were presented with currently available evidence about the outcome of treatment and a simple description of the procedure. The information was worded as follows: 'The most common treatment for urinary problems caused by enlargement of the prostate gland is surgery. This involves passing an instrument like a small telescope up the penis to clear the blockage. It usually involves a hospital stay of about eight days. About 80% of men experience an improvement in their symptoms following surgery, about 15% are unchanged and 5% worse off. Some men will also have difficulty getting an erection after surgery. In addition, about 10% have complications, such as bleeding, infections and leakage of urine, which normally clear up within a few weeks. If your urinary symptoms were found to be due to an enlarged prostate and you were offered surgery for it, feeling the way you do now, would you choose to have it?'

Respondents were asked to score their preference on a scale of zero to five (0 = definitely want, 1 = probably want, 2 = not sure but inclined to yes, 3 = not sure but inclined to no, 4 = probably do not want, 5 = definitely do not want).

Data analysis consisted of frequency distributions. Confidence intervals for proportions were calculated at the 95% level using the method of Fleiss.[14] The significance of observed differences was tested using chi square statistics calculated using procedures written in *SAS*. Wilcoxon matched-pairs signed-ranks were calculated to test for a change in bothersomeness and urinary frequency between the initial and follow-up surveys using procedures written in *SPSS*.

Results

Characteristics of the sample

Of the 516 men with mild, moderate or severe symptoms who were sent a questionnaire, eight had died and three had moved, so that the final study population was 505. Seventy two questionnaires were not returned and a further 13 were returned without response, so that the response rate was 83.2%. A comparison of non-respondents and respondents showed little difference in mean age (69.5 years versus 67.1 years, respectively). Respondents were significantly more likely than non-respondents to have moderate or severe symptoms (239/420 respondents versus 7/85 non-respondents, Mantel Haenszel $\chi^2 = 70.2$, 2 degrees of freedom, $P<0.01$). Respondents were also more likely than non-respondents to have had previous prostate surgery, and to have experienced an episode of acute urinary retention, although these differences were not significant. In total, 420 men with mild, moderate or severe symptoms were included in the analyses.

To test the extent to which men's urinary problems may have changed between the initial survey (from which their symptom index scores were derived) and the follow-up survey (from which patient preference was determined), questions on bothersomeness and urinary frequency were included in both. The results of a Wilcoxon matched-pairs signed-ranks test suggested that while there was no significant change in the measures of bothersomeness, urinary frequency decreased between the two surveys ($Z = -3.02$, $P<0.05$).

Advice-seeking behaviour

The pattern of the advice-seeking behaviour by men with urinary symptoms is shown in Table 1. About half the men had not sought any advice for their symptoms; this was more common among those with mild or moderate symptoms than among those with severe symptoms. Of those seeking advice, the principal source was their general practitioner (88.8% of those with moderate symptoms, 97.2% of those with severe symptoms). The percentage of men who sought advice from their general practitioner about their symptoms increased from 40.3% of those with mild symptoms to 64.8% with severe symptoms.

Action by general practitioners and urologists

Of the 175 men who had consulted their general practitioner and for whom data were available, 21.1% were reassured, 16.6% were prescribed medication, and 62.3% were referred to a surgeon or urologist (Table 2). The percentage referred to a urologist or surgeon did not vary with symptom severity. Of the 109 men who were referred, nine were still waiting to see their sur-

Table 1. Source of advice used by men with urinary symptoms, by symptom severity.

	% of men with symptoms				
	Mild (n = 181)	Moderate (n = 185)	Severe (n = 54)	Total (n = 420)	95% CI
Sought no advice	*56.9*	*51.9*	*33.3*	*51.7*	*46.8* to *56.3*
Consulted GP	*40.3*	*42.7*	*64.8*	*44.5*	*39.7* to *49.2*
Other[a]	*2.8*	*5.4*	*1.9*	*3.8*	*2.3* to *6.0*

n = number of men in group. CI = confidence interval. [a]Other = friends, relatives, practice nurse.

geon. The majority (71.4%) had been offered and accepted surgery (Table 2). Of the remainder, 15 had been reassured, four had been prescribed medication and seven had been offered and declined surgery. There was no significant difference between symptom severity and action by the urologist, but the numbers were small.

Men's views on prostatectomy

The distribution of men's views on prostatectomy, by symptom severity is also shown on Table 2. At their current level of symptoms, 30.6% of men would definitely or probably choose to have a prostatectomy, while 22.1% would probably or definitely not want treatment. Nearly half of men (47.3%) were unsure what they would choose, although more men were inclined to have the operation than not (32.0% versus 15.3%). Overall, men were more likely to choose surgery (62.6% versus 37.4%). The proportion of men choosing surgery was not significantly related to symptom severity, a history of previous prostate surgery or of an episode of acute urinary retention (Table 3).

Using data from all 420 respondents, a separate analysis was undertaken of only those men who expressed a firm view about surgery (that is, that they definitely or probably would or would not choose it). In this group, men who had consulted their general practitioner were more likely to have indicated that they definitely or probably would choose surgery (63, 71.6%) than those who had not consulted their general practitioner (64, 57.1%). Although this difference was small, it was statistically significant ($\chi^2 = 4.4$, 1 df, $P<0.05$).

Table 3. Choice of whether or not to have a prostatectomy, by symptom severity, previous prostate surgery and a previous episode of acute urinary retention.

	% of men choosing prostatectomy	95% CI
Symptom severity[a]		
Mild ($n = 122$)	*60.7*	*51.4 to 68.5*
Moderate ($n = 128$)	*64.1*	*55.1 to 71.5*
Severe ($n = 31$)	*64.5*	*45.4 to 77.6*
Previous prostate surgery[b]		
Yes ($n = 14$)	*71.4*	*42.0 to 86.0*
No ($n = 266$)	*62.4*	*56.3 to 67.8*
Acute urinary retention[c]		
Yes ($n = 22$)	*68.2*	*45.1 to 82.0*
No ($n = 253$)	*61.3*	*54.9 to 66.9*

n = number of men in group. CI = confidence interval. [a]Data missing for 34 men. [b]Data missing for 35 men. [c]Data missing for 40 men.

Discussion

This study has described the pattern of advice-related behaviour of middle-aged and elderly men who experience mild, moderate or severe urinary symptoms, and the response made by clinicians. Slightly fewer than half of men with symptoms (45%) reported that they had consulted their general practitioner, of whom the majority (62%) were referred to a surgeon, and of these the majority (71%) reported that they were offered and accepted surgery. However, a substantial proportion (22%) of men said that in theory they would choose to accept their symptoms and forego surgery, and a further 47% were unsure whether or not to go for surgery.

Before any conclusions may be drawn, two aspects of the method need to be considered: the response rate and the validity and reliability of the questions about symptoms and preferences. The response rate in the initial survey had been 78% and in this survey was 83%. Although the response rate was high, it is of concern that respondents to this survey were more likely than non-respondents to have moderate or severe urinary problems. This means that the proportions of the population seeking and receiving treatment may have been slightly overestimated.

The way in which the questions were phrased could bias the results. The symptom index used has been extensively tested and shown to be internally consistent and have good test–retest reliability, as judged by the Pearson correlation coefficient.[12] The question about men's views on prostatectomy was developed specifically for this study and has not been tested for its reliability and validity, in particular, its power to predict the decision that a man will take in practice. Eleven per cent of respondents

Table 2. Action taken by general practitioners and by urologist or surgeon, and patient choice for surgery.

	% of men with symptoms				
	Mild	Moderate	Severe	Total	95% CI
Action taken by GP[a]	*(n = 69)*	*(n = 71)*	*(n = 35)*	*(n = 175)*	
Reassured patient	*17.4*	*25.4*	*20.0*	*21.1*	*15.5 to 27.5*
Prescribed a drug	*20.3*	*11.3*	*20.0*	*16.6*	*11.6 to 22.5*
Referred patient	*62.3*	*63.4*	*60.0*	*62.3*	*54.6 to 68.9*
Action taken by urologist/surgeon[b]	*(n = 39)*	*(n = 35)*	*(n = 17)*	*(n = 91)*	
Reassured patient	*10.3*	*20.0*	*23.5*	*16.5*	*9.8 to 24.8*
Prescribed a drug	*0*	*11.4*	*0*	*4.4*	*1.4 to 10.0*
Offered surgery:					
Patient declined	*10.3*	*5.7*	*5.9*	*7.7*	*3.4 to 14.3*
Patient accepted	*79.5*	*62.9*	*70.6*	*71.4*	*60.9 to 79.2*
Men's views on prostatectomy[c]	*(n = 122)*	*(n = 128)*	*(n = 31)*	*(n = 281)*	
Definitely want	*13.9*	*17.2*	*25.8*	*16.7*	*12.7 to 21.3*
Probably want	*14.8*	*14.1*	*9.7*	*13.9*	*10.2 to 18.2*
Not sure, inclined to yes	*32.0*	*32.8*	*29.0*	*32.0*	*26.7 to 37.5*
Not sure, inclined to no	*13.9*	*16.4*	*16.1*	*15.3*	*11.4 to 19.8*
Probably do not want	*8.2*	*6.3*	*12.9*	*7.8*	*5.1 to 11.4*
Definitely do not want	*17.2*	*13.3*	*6.5*	*14.2*	*10.5 to 18.6*

n = number of men in group. CI = confidence interval. [a]Data missing for 12 men. [b]Data missing for nine men; another nine men still waiting to see urologist. [c]Data missing for 34 men; excludes those seen by a urologist.

Urinary symptoms: prevalence and severity in British men aged 55 and over

D J W Hunter, C M McKee, N A Black, C F B Sanderson

Abstract

Objective **– To measure the prevalence and severity of urinary symptoms among men aged 55 and over in the British population.**

Design **– Cross sectional population survey using a postal questionnaire.**

Setting **– North West Thames health region.**

Subjects **– 1480 men aged 55 years and over randomly selected from 8 general practices.**

Main outcome measures **– Self reported frequency and severity of urinary symptoms, their bothersomeness and previous prostate surgery.**

Results **– The response rate among eligible subjects was 78%. The prevalence of moderate and severe symptoms was 204 per 1000, rising from 160 per 1000 in the 55–59 age group to 259 per 1000 in the 70–74 age group and declining after the age of 80 to 119 per thousand in the 85+ age group. Twelve per cent of men reported previous prostate surgery, and the probability of having had surgery increases steadily with age. About a third of those undergoing surgery have recurrence or persistence of symptoms after surgery. Of men with moderate and severe symptoms, 27·9% reported that their symptoms were a medium or big problem, 36·9% reported that their symptoms interfered with their daily activities at least some of the time, and 43·1% were unhappy or 'felt terrible' about the prospect of a future with their current symptoms.**

Conclusion **– The prevalence of urinary symptoms in men is lower than previously reported, although there is a substantial number of men who are bothered by, or who find their lives adversely effected by them.**

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Benign prostatic hyperplasia is the commonest cause of urinary symptoms affecting middle aged and elderly men. It is becoming an increasing challenge to the health service because of an aging population and the introduction of new forms of treatment. Knowledge of the prevalence of urinary symptoms and their impact on men form the basis of the three measures required by those involved in the planning and provision of services for benign prostatic hyperplasia: the number of men in the population experiencing urinary symptoms that bother them (felt need); the number of men with symptoms who seek treatment (demand); and the number of men considered by surgeons to be in need of treatment, based on both men's urinary symptoms and on clinical findings (normative need).

Estimates of the prevalence of urinary symptoms among men vary widely. In general health surveys of men over the age of 65, between 16 and 40% report having either urinary symptoms or a previous prostatectomy, or both (Spain 16%; USA 25%; Israel 40%).[1-3] A household survey undertaken in Michigan in 1983–84 found that 35% of men over the age of 60 had one or more symptoms of prostatism.[4] A review of general practice case notes in the UK suggested that 6% of men over the age of 60 had undisclosed 'marked prostatism', based on the presence of four urinary symptoms, and a further 14% had 'mild prostatism', with three symptoms.[5] In a questionnaire administered to men over the age of 60 who attended a health screening clinic in the UK, 18% reported five or more urinary symptoms.[6] A recent study, defining benign prostatic hyperplasia using a combination of urinary symptoms, flow rates, and prostatic size, reported a prevalence among Scottish men aged 40 to 79 of 253 per 1000.[7] A virtually identical study in the USA found that prostatism rose from 26% in the 40–49 age group to 46% in 70+ age group, higher than the prevalence found in the Scottish study.[8]

These studies are not sufficient to assess the 'felt need'. They provide little information on the severity of symptoms and do not measure the extent to which men are bothered by their symptoms. The latter point is important as it has been suggested that a third of men with mild symptoms may not want treatment.[9] This paper describes a survey of felt need for treatment of benign prostatic hyperplasia in the UK that addresses these issues. A subsequent paper will report on the relationship between the prevalence of urinary symptoms and demand for treatment.

Methods

A cross sectional population survey of the prevalence of urinary symptoms in men aged 55 years and over was carried out in North West Thames health region. This age group was selected on the basis of the results of a study in the Oxford and North West Thames regions in which more than 99% of men undergoing prostatectomy were aged 55 or more.[10] Initially 30 general practices were selected randomly from all practices in North West Thames region and invited to participate. The 15 practices that expressed an interest in the study were sent further information and a background literature

did not answer this question and, of those who did answer, 47% were unsure whether they would choose surgery. It is unclear whether this uncertainty arises from the wording of the question, insufficient information being provided, or from the difficulties in deciding about treatment. Studies of patient preference are susceptible to variations in the amount of data presented and the way that questions are framed (that is, whether the question refers to the probability of a good or adverse effect).[15] Most of the published work about patient preferences has been applied to cancer patients where trade-offs between quality of life and life expectancy are made using methods taken from econometrics. Other studies have found low levels of test–retest reliability.[16] Among the substantial proportion of men who were unsure if they would choose to have surgery it is likely that some have what has been termed an 'external locus of control'[17] and would transfer the decision to treat to the surgeon.

Few men in the present survey reported seeking advice from relatives, friends or the practice nurse for their symptoms. This may be because they believed that lay carers and nurses have little to offer for urinary problems or it may reflect under-reporting — having received advice from family or friends to see their general practitioner, they only reported that they saw a general practitioner. It is also possible that there was some reporting bias because they viewed these sources of advice in a less formal way. It has been estimated that 25% to 75% of symptoms are dealt with by patients themselves or friends and family[18,19] and that the decision to consult a general practitioner is dependent on the influence of advisers, the effectiveness of self-care and the need for information.[20] Many men may consider their urinary symptoms as part of the normal ageing process and thus do not consider their condition worthy of consulting their general practitioner. A study in Denmark found that men aged 70 years and over with voiding difficulties did not consult a doctor for their urinary symptoms.[21]

Although men were more likely to visit their general practitioner if their symptoms were more severe, the decision of the general practitioners to refer appeared to be independent of symptom severity. This study confirms the important gatekeeper function of general practitioners: 38% of the men who went to see their general practitioner were not referred on to a surgeon. This is consistent with the considerable volume of work done on the referral decision that shows that a wide variety of factors, and not just the patient's condition are important.[22] Semi-structured interviews with family physicians in Canada found that of non-medical factors in the decision to refer, patients' wishes were the most important.[23] Difficulties with travel, access to a consultant, and family wishes also influenced the decision.[23]

Some men were prescribed medication for their urinary symptoms, either by their general practitioner (17%) or their urologist (4%) despite a lack of any definitive evidence of the efficacy of such treatments and the recommendation that prostatectomy is still the treatment of choice for benign prostatic hyperplasia.[24-27] During the period of the study, finasteride (Proscar®, MSD), was being marketed and some men may have been prescribed it as participants in studies to evaluate the drug.

How will the results of the study be used? When combined with information on clinicians' views of appropriateness of prostatectomy[13] and population estimates of the prevalence of urinary symptoms from the initial survey,[3] these data will provide evidence of the level of provision of treatment a population requires and thus inform planning and commissioning of urological services. The findings are being applied to the purchasing process. This involves collaboration between general practitioners, urologists and the commissioning agency to set agreed activity levels and develop referral guidelines. The results of this process will be reported in a separate paper.

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Table 1 Demographic characteristics of responders, urinary symptom prevalence survey, North West Thames health region, 1992

	Sample (%)	Population (%)
Age group (y):		
55–59	275 (19)	89 073 (24)
60–64	322 (22)	80 261 (22)
65–69	298 (21)	68 962 (19)
70–74	236 (16)	51 837 (14)
75–79	157 (11)	41 059 (11)
80–84	104 (7)	23 932 (6)
85+	51 (4)	13 437 (4)
Total	1443 (100)	368 561 (100)
Ethnicity (>55 y)		
White	1389 (97)	345 756 (92)
Non-white	40 (3)	30 829 (8)
Total	1429 (100)	376 585 (100)

Notes on table: (1) Missing data are not included in column totals. (2) Population estimates for North West Regional Health Authority are taken from the OPCS 1991 Census, *County Monitors*.

review. Seven practices withdraw at this stage. The remaining eight practices were distributed throughout the region and included inner city, suburban, and rural practices. These practices were asked to provide a list of all men aged 55 years and over. In total, 3716 men were identified, with the number in each practice ranging from 143 to 1180. With the exception of the smallest practice, where the entire list was used, 265 men were randomly sampled from the whole of each practice's list to create a database of 2000 names and addresses. This number was chosen to yield 95% confidence intervals of ±1·5% if the true prevalence of moderate or severe symptoms was around 25%.

A two page questionnaire, together with a personally addressed covering letter from the individual's general practitioner and a stamped, addressed envelope for reply, were sent to each man. Non-responders were sent a reminder letter and a second questionnaire one month later. The questionnaire sought information about the men's sociodemographic characteristics (age and ethnicity) and any urinary symptoms they had experienced over the preceding month. Questions on urinary symptoms were taken from the recently published American Urological Association (AUA) symptom index,[11] with some minor modifications to the wording of the questions to make them more appropriate to a British population. For example, the AUA question on fullness 'Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?' was changed to 'In the past month, how often did you feel that your bladder did not empty fully after urinating?'. A pilot version of the questionnaire, sent to 30 men selected from a general practice in the North East Thames region, achieved a response rate of 80% and led to minor modifications in the layout of the questions. For comparison, population estimates and demographic information for residents of North West Thames region were obtained from the 1991 census.[12] Ethical approval was sought and obtained from the relevant district ethics committees.

To investigate the possible effects of response bias, general practice case notes from 100 randomly selected non-responders were compared with the case notes of 100 randomly selected responders. Information taken from these case notes included age, history of urinary symptoms, previous prostate surgery, and medical history. Reasons for the unavailability of any case notes, such as the patient having died or moved away, were recorded.

A symptom index, ranging from 0 to 30, was calculated by summing the scores of six urinary symptoms (fullness, frequency, intermittency, urgency, poor flow, and hesitancy) where each symptom was assigned one of the following values: never = 0, hardly ever = 1, less than half the time = 2, about half the time = 3, more than half the time = 4, and almost always = 5. Unlike the AUA-7 symptom index, nocturia was not included in our symptom index for three reasons: (a) it has many causes other than urinary tract disorders, such as cardiovascular disease and the person's fluid intake before going to bed, and is the symptom that responds least well to prostatectomy;[13] (b) in a validation study of the AUA index, the highest intersymptom correlation was between nocturia and frequency, and frequency was already included in the index; and (c) the categories of nocturia severity we obtained were too crude to use. The symptom index was categorised into four levels of severity; none (0), very mild (1), mild (2–9), moderate (10–18), and severe (19–30). These cut off points were consistent with those used in a cohort study of men undergoing prostatectomy in Oxford and North West Thames region.[13]

Data analysis consisted of frequency distributions. Confidence intervals for proportions were calculated at the 95% level using the method of Fleiss.[14] Patterns of symptoms and surgical status based on age by individual years were smoothed using five point moving averages.

Table 2 Characteristics of responders and non-responders, urinary symptom prevalence survey, North West Thames health region, 1992

	Responders	Non-responders	Standard error of the difference
Mean age (y):	70	71	
Status (no (%)):			
On GP list	98 (98)	81 (81)	4·17**
Deceased/moved/ghost	0 (0)	8 (8)	2·71**
Notes not found	2 (2)	11 (11)	3·43**
Total	100 (100)	100 (100)	
Urinary symptoms (no (%)):			
No urinary symptoms	79 (81)	72 (89)	5·33
Previous prostate surgery	7 (7)	1 (1)	2·80*
Urinary symptoms	5 (5)	4 (5)	3·92
Urinary symptom, referral	4 (4)	2 (2)	2·50
Other urology	3 (3)	2 (2)	2·31
Total	98 (100)	81 (100)	

* $p<0.05$, ** $p<0.01$.

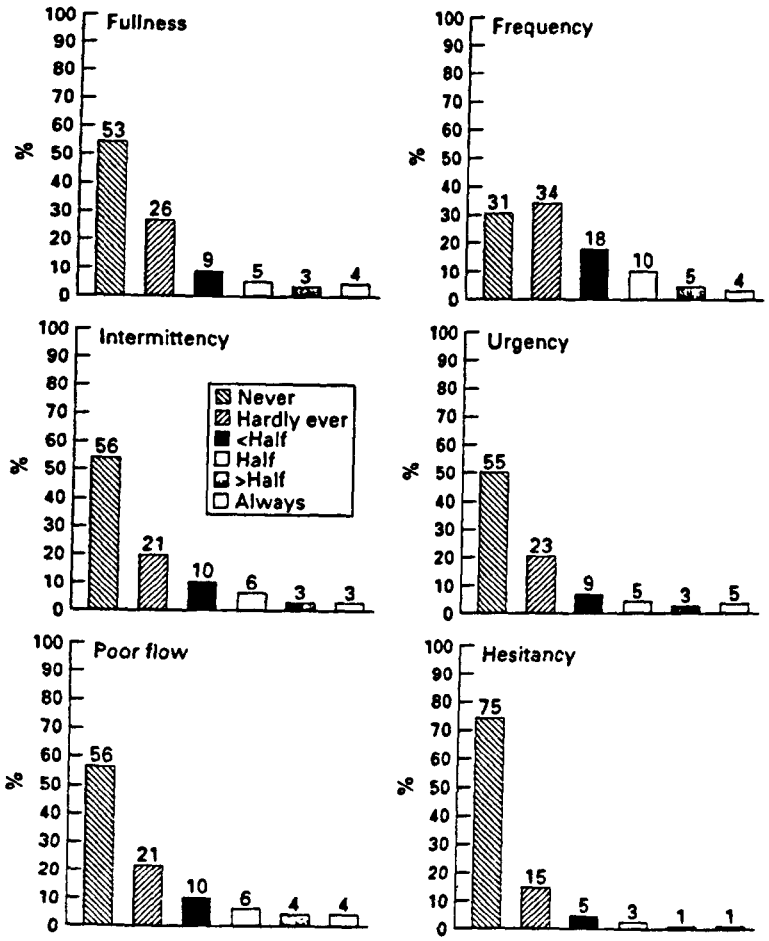

Figure 1 Distribution of urinary symptoms, men aged 55 years and over in North Thames health region.

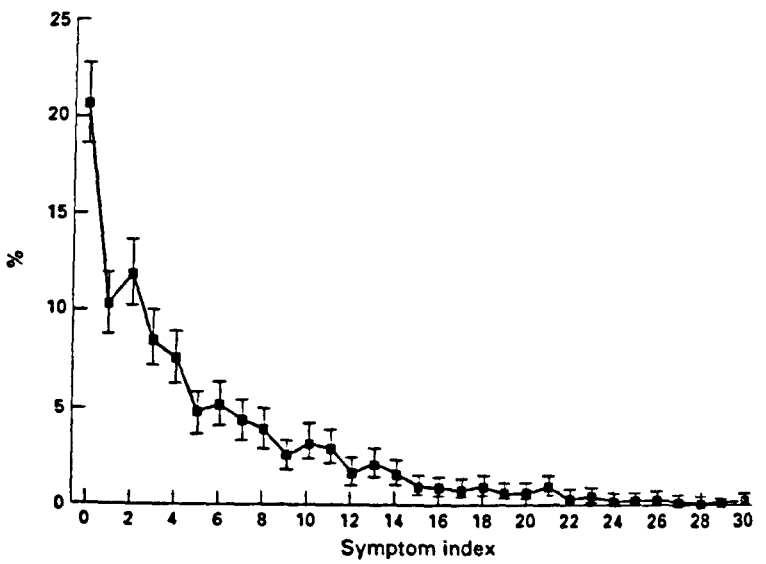

Figure 2 Distribution of symptom index (95% CI) in men aged 55 years and over in North Thames health region, 1992.

Results

CHARACTERISTICS OF THE SAMPLE

Of the 2000 men who were sent a questionnaire, 21 had died and 74 were unknown at the address in the general practice records, so that the final study population was 1905. The response rate after the first mailing was 64%, rising to 78% (1480 returned questionnaires) after a postal reminder. The age structure of those responding was similar to that of all men living in North West Thames region, except for those in the 55 to 59 age group, who seemed to be under-represented in our sample (table 1). Responders were more likely to be white than would be expected from the male population in this age group.

The comparison of subsamples of responders and non-responders (table 2) found no difference in mean age. Apparent non-responders included 8% who had either died or moved or for whom the general practitioner had no evidence of a medical record. In addition, for 2% of responders and 11% of non-responders, although there was evidence that a record existed, these records could not be located. Comparison of the medical records available showed that responders were more likely to have undergone previous prostate surgery (7% *v* 1%; $p<0.05$), but there was no significant difference in their medical histories of urinary symptoms.

PREVALENCE AND SEVERITY OF SYMPTOMS

The distribution of each urinary symptom in relation to the level of severity is shown in figure 1. Most men report that they never, or hardly ever, experience these symptoms. The distribution of the symptom index is also strongly skewed to the left (fig 2); few men experience high composite symptom scores. On categorising the data, 20·8% report no symptoms, 10·4% very mild symptoms, and 48·5% mild symptoms (table 3). The overall proportion of men with moderate/severe symptoms was 20·4%. This increased from 16·2% in those aged 50 to 59 years to a plateau of between 20 and 25% in the age group between 65 and 79. It then fell to 11·9% in the over 85s.

IMPACT OF SYMPTOMS

The extent to which men were bothered by their symptoms increased significantly with increasing symptom severity (table 4). Of those with very mild and mild symptoms, only 0·5% felt they were a medium or big problem; this increased to 15·9% of those with moderate symptoms and 66·2% of those with severe symptoms. Of those with moderate symptoms, 2·8% reported interference in their daily activities most or all of the time (table 5). This increased to 17·9% for those with severe symptoms. When asked about spending the rest of their life with their current symptoms, 11% of men reported they would feel unhappy or terrible (table 6). This proportion varied in relation to symptom severity from 3·5% of those with very mild and mild symptoms to 76·4% with severe symptoms.

PREVIOUS PROSTATE SURGERY AND OTHER UROLOGICAL SYMPTOMS

The prevalence of urinary symptoms will partly depend on prostatectomy rates in the past and the effectiveness of this surgery. Altogether 164 (12%) men reported having undergone previous prostate surgery (table 7). To allow for

Table 3 Frequency distribution of symptom severity in relation to age group in men aged 55 and over, North West Thames health region, 1992

Age group (years)	Symptom severity: None No (%)	Very mild No (%)	Mild No (%)	Moderate No (%)	Severe No (%)	Total No (%)	Moderate & severe combined No (%)	(95% CI of % moderate & severe)
55–59	57 (21·0)	32 (11·8)	139 (51·1)	35 (12·8)	9 (3·3)	272 (100)	44 (16 2)	(12·1, 20·8)
60–64	72 (23·2)	34 (11·0)	144 (46 6)	49 (15·8)	11 (3 6)	310 (100)	60 (19·4)	(15·2, 23·9)
65–69	63 (22·0)	30 (10·5)	134 (46·7)	49 (17·1)	11 (3 8)	287 (100)	60 (20·9)	(16·4, 25·8)
70–74	43 (18·9)	22 (9·7)	104 (45 8)	38 (16·7)	21 (9·2)	228 (100)	59 (25·9)	(20·4, 31·7)
75–79	30 (20·3)	11 (7·4)	77 (52·0)	22 (14·9)	8 (5·4)	148 (100)	30 (20·3)	(14·3, 27·1)
80–84	12 (12·8)	10 (10·6)	48 (51·1)	18 (19·2)	6 (6·4)	94 (100)	24 (25·5)	(17·3, 34 6)
85+	10 (23·8)	4 (9·5)	23 (54·7)	5 (11·9)	0 (0)	42 (100)	5 (11·9)	(4·5, 23·5)
Total	287 (20 8)	143 (10·4)	669 (48·5)	216 (15·6)	66 (4·8)	1381 (100)	281 (20·4)	(18·3, 22·5)

N = 1480, 99 missing; percentages have been rounded.

Table 4 Frequency distribution of bothersomeness in relation to symptom severity in men aged 55 and over, North West Thames health region, 1992

Bothersomeness	Symptom severity: None No (%)	Very mild No (%)	Mild No (%)	Moderate No (%)	Severe No (%)	Total No (%)	Moderate & severe combined No (%)	(95% CI of % moderate & severe)
No problem	290 (99·0)	142 (97·3)	509 (73·7)	44 (20·5)	4 (5·9)	989 (70·0)	48 (17·0)	(12·9, 21·6)
Very small problem	3 (1·0)	4 (2·7)	143 (20·8)	75 (34 9)	3 (4·4)	228 (16·2)	78 (27·6)	(22·5, 32·9)
Small problem	0 (0)	0 (0)	34 (4 9)	62 (28·8)	16 (23·5)	112 (7·9)	78 (27·6)	(22·5, 32 9)
Medium problem	0 (0)	0 (0)	4 (0·6)	30 (14·0)	30 (44·1)	64 (4·5)	60 (21·2)	(16·7; 26·1)
Big problem	0 (0)	0 (0)	0 (0)	4 (1·9)	15 (22·1)	19 (1·4)	19 (6·7)	(4·2, 10·0)
Total	293 (100)	146 (100)	690 (100)	215 (100)	68 (100)	1412 (100)	283 (100)	

N = 1480, 68 missing; percentages have been rounded.

Table 5 Frequency distribution of interference in daily activities in relation to symptom severity in men over the age of 55, North West Thames health region, 1992

Interference in daily activities	Symptom severity: None No (%)	Very mild No (%)	Mild No (%)	Moderate No (%)	Severe No (%)	Total No (%)	Moderate & severe combined No (%)	(95% CI of % moderate & severe)
Never	284 (99·0)	145 (100)	625 (92·8)	154 (71·6)	24 (35·8)	1232 (88·1)	178 (63·1)	(57·2, 68 4)
Some of the time	3 (1 1)	0 (0)	57 (6·9)	55 (25·6)	31 (46·3)	146 (10·4)	86 (30 5)	(25·2, 35·9)
Most of the time	0 (0)	0 (0)	3 (0·4)	6 (2·8)	9 (13·4)	18 (1·3)	15 (5·3)	(3·1, 8 4)
All of the time	0 (0)	0 (0)	0 (0)	0 (0)	3 (4·5)	3 (0·2)	3 (1·1)	(0·3, 2·8)
Total	287 (100)	145 (100)	685 (100)	215 (100)	67 (100)	1399 (100)	282 (100)	

N = 1480, 81 missing; percentages have been rounded.

Table 6 Frequency distribution of perception of future in relation to symptom severity in men over the age of 55, North West Thames health region, 1992

Perception of future	Symptom severity: None No (%)	Very mild No (%)	Mild No (%)	Moderate No (%)	Severe No (%)	Total No (%)	Moderate & severe combined No (%)	(95% CI of % moderate & severe)
Delighted	213 (75 3)	85 (59·9)	183 (27 1)	3 (1·4)	0 (0)	484 (35·0)	3 (1·1)	(0·3, 2·8)
Pleased	59 (20·9)	47 (33·1)	310 (45·9)	49 (22 8)	3 (4 4)	468 (33·8)	52 (18·4)	(14·1, 23·1)
Not bothered	11 (3·9)	10 (7·0)	155 (22·9)	93 (43·3)	13 (19·1)	282 (20·4)	106 (37·5)	(31·9, 43·0)
Unhappy	0 (0)	0 (0)	29 (4·1)	65 (30 2)	43 (63·2)	137 (9·9)	108 (38·2)	(32·5, 43 8)
Terrible	0 (0)	0 (0)	0 (0)	5 (2 3)	9 (13·2)	14 (1·0)	14 (4·9)	(2·8, 7·9)
Total	283 (100)	142 (100)	677 (100)	215 (100)	68 (100)	1385 (100)	283 (100)	

N = 1480, 95 missing; percentages have been rounded.

the different numbers of men at risk of having surgery, the probability of having surgery when in each age group was calculated by dividing the number of men who had surgery when in each age group by the number of men that had reached that age group (table 7). The probability of having surgery when under 50 years of age was only 0·1% and increased to 8% in the age group 75 to 79 years. This is equivalent to a doubling in the probability of having surgery every five years. Because there are fewer men in older age groups, this gives a different picture to that seen in urological practice. Almost half (45·7%) the men who had undergone surgery were aged between 60 and 69.

Of the 156 (6%) men who reported a previous episode of acute retention, only 38·5% had undergone surgery (table 8). Altogether 8% of men reported a previous urinary tract infection. When asked about urinary incontinence, 7·5% leaked enough urine to be embarrassed, and 0·8% needed to wear pads.

SUMMARY

The current pattern of urinary symptoms in men aged 55 and over and the urological response to them is best illustrated by combining the data on the prevalence of men with a history of prostate surgery (table 7) and the prevalence of urinary symptoms (table 3). Figure 3 shows the proportions of men in each age group in each of the following states: (a) no, very mild, or mild symptoms and no previous surgery; (b) moderate/severe symptoms but no previous surgery; (c) previous surgery with no current moderate/severe symptoms; and (d) previous surgery and current symptoms. The percentage of men with either moderate or severe symptoms or a history of previous prostate surgery, or both, increased from 17% at age 57 years

Table 7 Experience of prostate surgery in men over the age of 55, North West Thames health region, 1992

Age group (y)	*No of sample reached or exceeded age group*	*No (%) having surgery within age category*	*% probability of having surgery when in age group*	*No (%) with previous surgery in current age group*	*Current % probability of having had previous surgery by age*
<50	1443	2 (1·3)	0·1		
50–54	1443	8 (5·2)	0·6		
55–59	1443	17 (11·1)	1·2	7 (4·3)	0·5
60–64	1168	34 (22·2)	2·9	17 (10·4)	1·5
65–69	846	36 (23·5)	4·3	31 (18·9)	3·7
70–74	548	21 (13·7)	3·8	32 (19·5)	5·8
75–79	312	25 (16·3)	8·0	34 (20·7)	10·9
80–84	155	8 (5·2)	5·2	26 (15·9)	16·8
85+	51	2 (1·3)	3·9	17 (10·4)	33·3
Total		153 (100)		164 (100)	

N = 169 (with previous surgery), missing age at previous surgery = 16, missing current age = 5.

to 38% at age 81. The percentage of men with moderate/severe symptoms who have not had prostate surgery increases until the age of 73 and then seems to decrease. Of men who have had prostatectomy, the percentage with recurrence or persistence of moderate or severe symptoms seems to remain relatively constant across the age range, at about 30%.

Discussion

This study has described the prevalence and severity of urinary symptoms in British men aged 55 and over. Although most men report no urinary symptoms, 20% reported moderate or severe symptoms. Of these, only 28% found their symptoms a medium or big problem. Thirty seven per cent experienced interference with their daily activities at least some of the time, and 43% would be unhappy at the prospect of a future with their symptoms continuing at their current level.

Before any conclusions may be drawn, the limitations of this survey should be considered. Men in the 55 to 59 year age group were under-represented compared with the general population, although comparison of the mean age of responders and non-responders suggests that this may have been due to characteristics of the practices studied rather than a difference in response rate.

Secondly, those who do not respond to surveys may differ in some way from those who do. From the examination of case notes we found that 8% of men who did not respond had died, moved, or had no general practice medical records. This suggests that our true response rate may have been as high as 80%. Non-responders did not differ from responders in terms of their history of urinary symptoms as recorded in the general practice records but they were less likely to have had previous prostate surgery.

Thirdly, the way the questions were phrased could bias the results. The AUA symptom index for the symptoms of benign prostate hyperplasia has been extensively tested and has been shown to be internally consistent and have good test-retest reliability, as judged by Pearson correlation coefficients.[11] Symptom severity categories were derived from cut off points used in a previous study. The use of different cut offs would have important implications for the numbers of individuals in each category. For example, we defined moderate or severe symptoms as a symptom index of greater than 9, giving a prevalence in the male population aged 55 and over of 204 per 1000. Reduction of the threshold to 8 would result in a prevalence of 227 per 1000; a threshold of 11 would result in a prevalence of 170 per 1000.

Our survey measured the felt need for treatment rather than the normative need. The clinical decision to offer treatment is based on a combination of urinary symptoms and the results of urological investigation. Assessment of normative need is complicated by the absence of an accepted definition of benign prostate hyperplasia. Currently, there is a debate in the urological literature about the importance of each. Several studies have shown a poor correlation between symptoms and objective urological measures such as flow rates and residual volume.[15–18] Given that most surgery

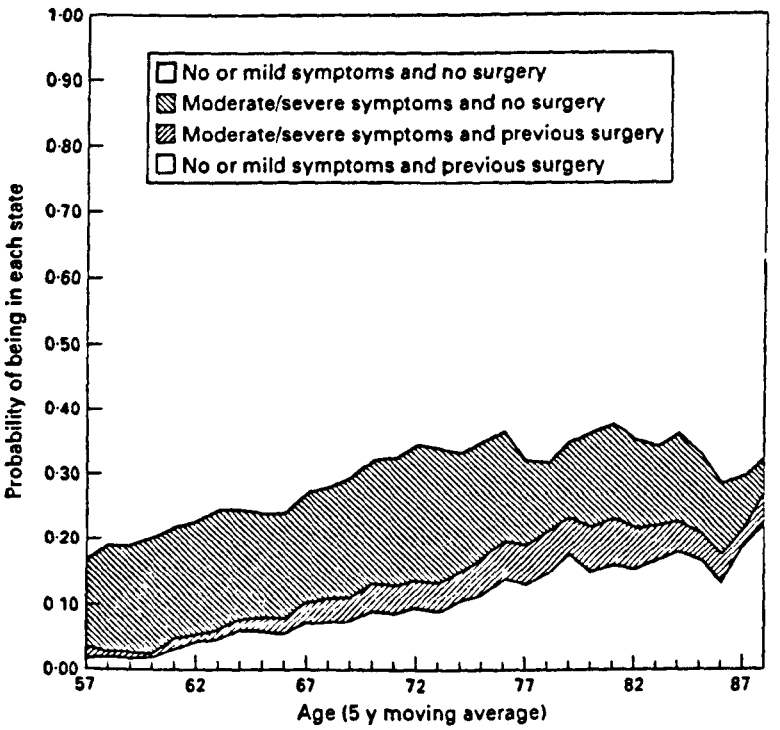

Figure 3 Age specific probabilities of moderate/severe symptoms and previous prostate surgery in men aged 55 years and over, North West Thames health region, 1992.

Table 8 Distribution of previous surgery in relation to acute urinary retention in men aged 55 and over, North West Thames region, 1992

Retention	*Previous surgery*		
	Yes No (%)	*No No (%)*	*Total No (%)*
Yes	60 (38·5)	96 (61·5)	156 (100)
No	24 (1·9)	1239 (98·1)	1263 (100)
Total	84 (5·9)	1335 (94·1)	1419 (100)

is carried out to improve a man's quality of life, we therefore believe that the presence of urinary symptoms is an essential, though not the only, factor that should be measured when assigning the need for surgery in the population.

It has been suggested that there is a large proportion of men in the British population with undiagnosed but symptomatic prostatism.[7] Our study supports this view. The only other study on the prevalence of urinary symptoms in men in the UK has been reported by Garraway *et al*. They reported a prevalence in men aged 40–79 years of 104 per 1000.[19] These figures refer to men with a symptom score of at least 11 out of a possible 48 points (eight symptoms each with a maximum score of six). If we were to use an equivalent cut-off point with our data, 7 out of 30, we would produce a prevalence of 292 per 1000. However, some important methodological differences between the two studies remain. In the study by Garraway *et al*, the men were younger (over 50% were under 55 years), 9% of men in the study population were excluded, and the response rate was lower (only 64%[19] compared with 78%). All of these might explain why they obtained a lower estimate of prevalence than we did. These factors could therefore reconcile our results with theirs.

The finding that 61·5% of men with a history of acute retention had not undergone surgery indicates that the view that this is an almost absolute indication for surgery[20] is no longer held. This finding is consistent with the views of a consensus panel on the appropriate indications for prostatectomy that was held recently.[21]

These results and evidence from other studies suggest that prostatism begins to develop in some men under the age of 50. Although we based our sample on evidence that prostatectomy was almost never performed on men under the age of 55, the relatively high prevalence of moderate or severe symptoms among men in the 55 to 59 age group indicates that future studies should include younger men. This is consistent with the population based survey by Garraway *et al* that described the onset of urinary symptoms among men in their 40s[7] and a review of necropsy data by Berry *et al* suggesting that the first changes in prostatic weight appear in men as young as under 30.[22] From the age of 55 until the early 70s, the percentage of men with moderate or severe symptoms who have not had surgery increases slowly from 15% to 20%, decreasing thereafter. A few individuals have surgery under 50, but the probability of surgery only exceeds 1% in the 55 to 59 age group. Thereafter it increases steadily. This leads to a progressive increase in the number of men who have had surgery by the age of 85. Of those who have had surgery, the proportion who have residual or recurring symptoms is roughly constant. The figure of about a third in this study is higher than that found in two cohort studies of men undergoing surgery[13,23] but both followed up patients for only one year. Some of the men in our survey had surgery up to 10 years previously.

These results suggest that prostatism, shown by the prevalence of either urinary symptoms or a past history of prostatic surgery, increases steadily throughout middle and old age, with the first signs appearing under the age of 55 and with almost 40% of men having been affected by the age of 80. After 80, the prevalence of prostatism does not increase further, and may actually decrease. These findings may occur by chance because there were only 29 men over the age of 80 in our sample with moderate or severe symptoms, but if the suggested decrease is true, there are three possible explanations. The first is that some cases of benign prostate hyperplasia resolve spontaneously. This has been suggested by other authors, although there is no strong empirical supporting evidence.[24] Secondly, most of those men who are going to suffer from benign prostate hyperplasia begin to do so by the time they reach 80, and the population contains subgroups with varying susceptibilities to the disease. Some support for this hypothesis comes from a review of series of necropsy data that suggested that at least 10% of men have no histological evidence of benign prostate hyperplasia by the time they reach the ninth decade.[22] The third possibility is that men with benign prostate hyperplasia have a reduced life expectancy, leading to selection out of the population in this age group. If the last of these is true, it could be due to either the effects of the disease or the complications of treatment. This explanation is consistent with the results of the study by Wennberg *et al* that suggested that transurethal prostatectomy was associated with an increase in mortality compared with men not undergoing surgery.[25] If any of these suggestions, or a combination thereof, are true there are important implications for urology research and practice, especially as new treatments designed to prevent the development of benign prostatic hypertrophy becomes available. For example, it would be useful to compare the characteristics, such as differences in androgen responsiveness, of those men who will and will not suffer from benign prostate hyperplasia.

Although 20·4% of men have moderate or severe symptoms, this does not reflect the degree of concern that they express. Only 5·9% of men report that their symptoms are a medium or big problem and 1·5% report that they interfere with their daily activities all or most of the time. In contrast, 10·9% feel unhappy or terrible about the prospect of a future with their current level of symptoms, indicating a difference between the extent to which men are affected at present and how they would like to be in the future. A possible explanation for this is that men are able to cope with their existing level of symptoms but feel that they will be unable to do so in the future as they become older and more infirm. This is supported by evidence from a study of women suffering from urinary incontinence.[26]

How will the results of this study be used? A second survey of those men who reported moderate or severe symptoms has been undertaken. This will report on the ways that their symptoms affect their health status and

whether or not they would choose to have surgery. When combined with information on clinicians' views of appropriateness and patient preference for treatment, these data will provide estimates both of the normative need for treatment and demand in the population and inform planning of the provision of urological services.

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