Title Page

Quantifying severe urinary complications after radical prostatectomy: the development and validation of a surgical performance indicator using hospital administrative data

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ABSTRACT

Objectives

To develop and validate a surgical performance indicator based on severe urinary complications that require an intervention within two years after radical prostatectomy (RP) identified in hospital administrative data.

Patients and Methods

Men who underwent RP between 2008 and 2012 in England were identified using hospital administrative data. A transparent coding-framework based on procedure codes was developed to identify severe urinary complications which were grouped into “stricture”, “incontinence” and “other”. Their validity as a performance indicator was assessed by evaluating the consistency with diagnosis codes and association with patient and surgical characteristics. Kaplan-Meier methods were used to assess time to first occurrence and multivariable logistic regression to estimate adjusted odds ratios (OR) for patient and surgical characteristics.

Results

17,299 men were included, 2,695 (15.6%) experienced at least one severe urinary complication within two years. High proportions of men with a complication had relevant diagnosis codes: 86% for strictures and 93% for incontinence. Urinary complications were more common in men from poorer socio-economic backgrounds(OR comparing lowest with highest quintile: 1.45; 95%CI, 1.26-1.67) and those with prolonged length of hospital stay (OR 1.54, 95% CI, 1.40-1.69) and were less common in men who had robotic surgery (OR 0.65, 95% CI, 0.58-0.74).

Conclusion

These results demonstrate severe urinary complications identified in administrative data provide a medium-term performance indicator after RP. They can be used for research assessing outcomes of treatment modalities and for service evaluation comparing performance of prostate cancer surgery providers.

INTRODUCTION

Men undergoing radical prostatectomy (RP) for prostate cancer (PCa) may experience treatment-related urinary complications. Their occurrence may reflect the quality of surgical care(1) but it is essential to demonstrate that they provide a valid outcome measure before they are used as an indicator of surgical performance.

Studies using administrative datasets have reported the incidence of complications after PCa treatment in the United States, England and Canada (2-6). However, none define a coding system to identify these complications explicitly or assess their validity as a performance indicator.

In this study, a transparent coding-framework is proposed based on procedure codes to identify complications severe enough to require a hospital readmission for a surgical procedure. Comparisons with relevant diagnosis codes were performed to demonstrate coding consistency. Further validation assessed the timing of these procedures and association with patient characteristics, including age, comorbidity, socioeconomic deprivation, and surgical characteristics, including length of hospital stay post-RP and surgical approach used.

PATIENTS& METHODS

Patient population

The Hospital Episode Statistics (HES) database, an administrative database of all admissions to hospitals of the National Health Service in England was used to identify patients who underwent RP between 1 January 2008 and 31 December 2012. HES records contain a unique patient identifier that allows for longitudinal follow-up(7). Diagnoses are coded using the International classification of Diseases, 10th revision (ICD-10)(8) and procedures are coded using the UK Office for Population Census and Surveys classification, 4th revision (OPCS-4)(9).Inpatient HES records were linked to the English National Cancer Data Repository (NCDR) to verify the diagnosis of PCa (10).

Data items in HES records were used to determine age, Charlson comorbidity score (11), socioeconomic deprivation status (12),length of hospital stay post-RP and the surgical approach used (Appendix, Table 1 for detailed description of coding-framework).

Inclusion and exclusion criteria

The records of 18,761 men with a procedure code for RP (OPCS-4 “M61”) were studied. Patients were excluded if they did not have a matching NCDR record (n=22), if they could not be linked to one of the 48 regional hubs providing RP (n=345) or if we could not determine their socioeconomic deprivation status according to the national ranking from the Index of Multiple Deprivation (n=41) (12) (Figure 1).

Men with an associated diagnosis of bladder cancer (n=229, ICD-10 “C61”) were excluded as their surveillance often requires interval cystoscopies which could be incorrectly captured as a treatment of a complication of RP. Men who received adjuvant or salvage radiotherapy (n=825) were excluded because it is not possible to distinguish between complications that occurred as a consequence of RP or radiotherapy (OPCS-4 codes defined in Appendix, Table 1). As a result, we included 17,299 men for whom we had complete data and at least two years of follow-up (Figure 1).

Technical coding

All HES records of readmissions two years after RP were examined to identify medium-term urinary complications(2).This 2-year follow-up period was chosen as a preliminary time-to-event analysis demonstrated that 80% of men who experienced a severe urinary complication within 5 years following RP had experienced the complication within the first 2 years. Therefore, to standardise our outcome measure we report urinary complications within 2 years of RP.

Based on earlier studies, a comprehensive index list of OPCS-4 procedure codes related to urinary complications after RP was pre-specified (“forward-coding”) (2-4, 6). We also examined the most frequently occurring procedure codes in records of readmissions and added these to the pre-specified list if they were not already included but likely to be related to urinary complications (“backward-coding”). These specified procedure codes were further stratified into those related to the treatment of a “stricture” or “urinary incontinence”. Procedure codes not clearly related to either complication were labelled as

"other". Importantly, HES records never included both stricture and incontinence procedures in the same readmission.

If more than one relevant procedure code related to a specific urinary complication was present in a readmission record, the first procedure code in the record was used. Based on the above coding rules, the frequency of readmissions was separated according to type of urinary complication and by specific OPCS-4 procedures codes (Table 2).

Patients were considered as not having experienced a severe urinary complication if there were no hospital readmissions in the first two years after RP or if there were no relevant procedure codes in the first seven procedural fields of a readmission.

Coding consistency

We assessed whether consistent diagnostic codes were present in the first seven diagnosis fields in records of episodes that contained procedure codes for treatment of a stricture or urinary incontinence. An index list of diagnosis codes for stricture or urinary incontinence was generated according to the ICD-10 classification using the forward-coding approach (Appendix, Table 2).

Statistical analysis

Kaplan-Meier curves were used to assess the time to the first occurrence of a stricture, incontinence or "other" severe urinary complication or to the first occurrence of any of these complications.

Multivariable logistic regression modelling was used to assess the impact of patient (age, comorbidity, socioeconomic deprivation status) and surgical characteristics (length of stay and surgical approach) on the occurrence of a urinary complication in the first two years after RP as defined above. Results are reported as odds ratios and a p-value smaller than 0.05 was considered statistically significant. P-values were based on the Wald test or the likelihood ratio test as appropriate.

A funnel plot for any medium-term severe urinary complication was generated to assess whether the study outcome measure could be used as a performance indicator comparing the proportion of patients with one or more complication across 48 specialist hubs that provide RP in England (13). Risk adjustment was performed to account for possible differences in case-mix using indirect standardisation whereby a standardised event ratio was obtained for each provider by dividing the observed by the expected number of complications(14). The adjusted rate for a provider was generated by multiplying this standardised event ratio by the national average complication rate. The expected number of complications was estimated with the multivariable logistic regression model adjusting for covariates as described earlier. The funnel plot was generated using two-sided control limits defining differences corresponding to two standard deviations (inner limits) and three standard deviations (outer limits) from the national average complication rate. If a provider's "true" complication rate is the same as the national rate, the probability that the adjusted complication rate for this provider will fall outside the funnel is 5% for the inner control limits and 0.2% for the outer control limits. Stata® version 14 (StataCorp, College Station, Texas, USA) was used for all statistical calculations.

RESULTS

Patient population

Approximately 60% of the 17,299 men included were between 60 and 69 years old, one in seven had at least one recorded comorbidity, and one in three stayed in hospital for longer than three days post-RP(Table 1).During the study period, open-RP was the most commonly used (39.7%) and robotic the least commonly used surgical approach (28.6%).

Frequency of severe urinary complications

2,695 men (15.6%) experienced at least one severe urinary complication within two years of RP. These men required 3,609 readmissions for complication-related procedures (1.3 readmissions/man) (Table 2). The most frequent complication-related procedure (1,436 of 3,609 complications, 39.8%) was an “unspecified endoscopic examination of the bladder”. The most frequent procedure for strictures (408 of 1567 complications, 26.0%) was “endoscopic incision of outlet of male bladder” and for incontinence (143 of 149 complications, 96.0%) was “implantation of an artificial urinary sphincter”.

Type and timing of urinary complications

Within two years of RP, 6.5% of men had experienced at least one recorded readmission with a treatment code related to a stricture, 0.8% related to incontinence and 11.5% of men related to “other” complications (Figure 2). The treatment codes related to these “other” complications could be grouped into cystoscopy (1,159 out of 1860 readmissions [62.3%]) and procedures addressing catheter problems (701 out of 1860 readmissions [37.7%]),

based on first occurring complication (Appendix, Figure 1). Approximately two thirds of men experienced a severe urinary complication within the first six months after RP (1,712 out of 2,695 [63.5%]) (Figure 3).

Coding consistency

There was high degree of consistency between the OPCS-4 codes used to capture procedures related to urinary complications and ICD-10 diagnosis codes for strictures and urinary incontinence in the records of readmission episodes. A consistent diagnosis code was observed for 1,350 out of 1,567 (86%) of records that contained a procedure code related to a stricture and for 138 out of 149 (93%) of records that related to incontinence.

Association with patient and surgical characteristics

Multivariable analysis demonstrated that the occurrence of at least one complication in the first two years after RP was significantly lower in those from more affluent socioeconomic backgrounds, in those who stayed three days or less in hospital following RP, and in those who had a robotic approach (Table 3). The univariable analysis also demonstrated significant associations between the year in which RP was carried out, the patient's age, comorbidity status and the occurrence of urinary complications but these associations were no longer observed in the multivariable analysis, adjusting for other patient characteristics and treatment factors.

A risk-adjusted funnel plot was generated for two-year rates of any severe urinary complication in each of the 48 regional PCa surgery providers (Figure 4). Ten of the

48providers were located outside the outer limits of the funnel (five above the upper and five below the lower outer limit).

DISCUSSION

A transparent coding-framework was developed to identify severe urinary complications after RP within English hospital administrative data. Because the coding-framework is solely based on procedure codes it includes complications severe enough to require a readmission to hospital. We demonstrated that the rate of complications identified in this way appears to be a valid indicator of surgical performance of RP providers given the consistency with relevant diagnosis codes, the anticipated pattern of the timing of these complications, and the association with treatment factors which have been reported to be linked to surgical complications. When this two-year complication rate was used as an indicator of the performance of PCa surgery providers we found a pattern often reported for other established surgical indicators (15).

Methodological considerations

We developed a comprehensive coding list that reflects current coding practice by using both a forward and a backward-coding approach. Using this methodology we were able to demonstrate that 86% of stricture-related complications and 93% of incontinence-related procedures had appropriate diagnosis codes. This high level of compatibility in operative and diagnostic coding validates our approach and is comparable to that reported in other published studies using administrative data (16).

Procedure codes were used in preference to diagnosis codes for two reasons. First, there is evidence that the accuracy of procedural coding is greater than diagnostic coding within administrative data (17). Second, the use of procedure codes ensured only complications

severe enough to require hospital-based treatments were captured. In this way, we avoided "overestimation" of the complication rate, a recognised problem when diagnosis codes are used for this purpose(18).

Multivariable modelling corroborated the associations between patient/surgical characteristics and urinary complications previously reported in the literature. Men who stayed in hospital three days or less after surgery and those who underwent a robotic-RP were found to be significantly less likely to experience a severe urinary complication, as reported in other studies(19-21). We also found that the complication rate was affected by the patient's socioeconomic background which corresponds with earlier observations in men who underwent RP in the English National Health Service (NHS) between 1997 and 2004(5).

The observed timing of the different types of complications reflects what can be expected based on pathophysiological considerations. For example, most severe urinary complications that occurred within the first month after surgery were recognised as "other" complications (i.e. those that were not grouped into stricture or incontinence) and they consisted of unplanned cystoscopies and procedures related to catheter problems. We found that stricture-related treatments occurred after the immediate post-operative period and increased steadily thereafter in keeping with the physiological process of stricture formation. Interventions for incontinence were rare in the first two years after RP with less than 1% requiring a procedure, consistent with earlier observations (22).

We used a classification system for procedures (OPCS-4) that is only currently used for hospital administrative data in the UK. This implies that the proposed indicator can only be applied in other health systems after the coding-framework presented in the current study

has been “translated” for other procedure coding classification systems. We however expect that this will have minimal effect on the validity of the surgical performance indicator presented in the current study. A number of different procedural classification systems are employed to code for procedures within datasets of a number of different countries. For example, in the US the Healthcare Common Procedure Coding System (HCPS) is used to code for operative procedures whereas in Canada, the Canadian classification of Diagnostic, Therapeutic, and Surgical procedures is employed. By using the backward coding approach presented in the current study, local coding practice within these different procedure coding systems can be determined and as such a similar surgical performance indicator to that presented in the current study can be developed.

A limitation of using procedure codes as a surrogate for urinary complications is that patients who were symptomatic but did not undergo an intervention for their symptoms are not captured and so absent from our analysis. We were not able to identify this cohort of patients and as such the overall burden of urinary complications is likely to be an underestimate, particularly for urinary incontinence. A further limitation is that we were not able to externally validate our study indicator using clinical records. Nonetheless we feel that the transparent coding framework and step-wise internal validation used to develop the study indicator, a process which is lacking in other studies using administrative database, justifies its validity as a surgical performance indicator.

<u>Comparison with other studies</u>

Two recent studies used physician billing codes to determine a list of "urologic minimally invasive procedures" which acted as a surrogate for urinary complications (2, 6). These studies focussed on differences in outcome between men undergoing RP versus radiotherapy. In contrast to the present study, these studies did not provide a transparent coding-framework nor did they assess the validity of this outcome as a performance indicator. Earlier studies carried out in the US (3), Canada (4) and England (5)(6) used diagnosis codes solely or in combination with procedure codes which may lead, as indicated above, to overestimation of the complication rates(18).

Applicability of study performance indicator

Using a funnel plot, we found that the proportion of patients who experienced a severe urinary complication according to our performance indicator was distributed among the 48 regional providers of RP in England as could be expected based on results of comparisons of other outcomes of urological cancer treatment across secondary care providers (15). This provides further support that severe urinary complications identified in administrative data can be used to assess variation in surgical performance. This is of particular relevance in the UK NHS where initiatives such as the National Prostate Cancer Audit (NPCA)(23) exist to evaluate variation in the quality of prostate cancer surgery. The surgical performance indicator presented in the current study will be used alongside other outcome metrics including Patient Reported Outcome Measures (PROMs) to provide an overall assessment of the quality of prostate cancer surgical care in England. While we were not able to reliably

identify the operating surgeon using our existing database; it is envisaged that further data-linkage within the NPCA will allow surgeon-level reporting in the future. Moreover, given the rapid diffusion of robotic RP, this outcome measure has the potential to be used to compare the medium-term outcomes of different approaches to RP.

Conclusions

The current study provides a transparent coding-framework to capture severe urinary complications in the first two years after radical prostatectomy in hospital administrative data. These complications can be used as a performance indicator for service evaluation and research.

Conflicts of Interest

No competing interests were declared.

Table 1: Patient and surgical characteristics of men undergoing radical prostatectomy (RP) (2008 – 2012)

No. of men receiving RP		17,299
Year of RP (%)		
	2008	2,004 (11.6)
	2009	3,501 (20.2)
	2010	3,694 (21.4)
	2011	4,002 (23.1)
	2012	4,098 (23.7)
Age (%)		
	<60	5,391 (31.2)
	60-69	10,117 (58.5)
	>70	1,791 (10.4)
Charlson comorbidity score (%)		
	0	14,382(83.1)
	≥1	2,917 (16.9)
Socioeconomic deprivation (%)		
	1(least)	4,432 (25.6)
	2	4,239 (24.5)
	3	3,590 (20.8)
	4	2,888 (16.7)
	5 (most)	2,150 (12.4)
Length of stay post RP (days) (%)		
	≤3	11,597 (67.0)
	>3	5,702 (33.0)
RP surgical approach (%)		
	Open	6,873 (39.7)
	Laparoscopic	5,479 (31.7)
	Robotic	4,949 (28.6)

Table 2: Frequency of readmissions for treatment-related complications within two years of radical prostatectomy

OPCS-4 code	Description	Total readmissions	
M44.8/9	Other endoscopic operations on bladder	27	**"Other" urinary complication**
M45.5	Examination of bladder using rigid cystoscope	79	
M45.8	Other specified endoscopic examination of bladder	30	
M45.9	Unspecified endoscopic examination of bladder	1,436	
M47.1	Urethral irrigation of bladder	150	
M47.8/9	Other specified urethral catheterisation of bladder	171	
M48.1	Suprapubic aspiration of bladder	3	**Stricture-related complication**
M64.8	Other specified open operations on outlet of male bladder	28	
M65.1-5	Endoscopic resection of prostate	13	
M65.8/9 M66.9	Other specified endoscopic resection of outlet of male bladder	13	
M66.2	Endoscopic incision of outlet of male bladder	408	
M66.8	Other specified therapeutic endoscopic operations on outlet of male bladder	115	
M76.3	Optical urethrotomy	388	
M76.4	Endoscopic dilation of urethra	368	
M76.8/9	Other therapeutic endoscopic operations on urethra	5	
M79.2	Dilation of urethra	202	
M79.4	Internal urethrotomy	24	
M64.2	Implantation of artificial urinary sphincter into outlet of male bladder	143	**Incontinence-related complication**
M64.3	Insertion of prosthetic collar around outlet of male bladder	4	
M64.6	Reconstruction of neck of male bladder	2	
	Total	**3,609**	

Table 3: Relationship between patient and surgical characteristics and occurrence of at least one urinary complication following radical prostatectomy (RP)

Patient Characteristics	No. of men with a Urinary complication (%)	Unadjusted OR (95% CI)	*p*	Adjusted OR* (95% CI)	*p*
Year of RP					
2008	349 (17.4)	1.0	<0.01	1.0	0.08
2009	633 (18.1)	1.05 (0.91-1.21)		1.12 (0.97-1.29)	
2010	581 (15.7)	0.89 (0.77-1.02)		1.00 (0.87-1.17)	
2011	578 (14.4)	0.81 (0.69-0.93)		0.98 (0.84-1.13)	
2012	554 (13.5)	0.74 (0.64-0.86)		0.94 (0.81-1.09)	
Age					
<60	823 (15.3)	1.0	0.04	1.0	0.11
60-69	1555 (15.4)	1.01 (0.92-1.10)		0.99 (0.90-1.09)	
≥70	317 (17.7)	1.19 (1.04-1.38)		1.14 (0.99-1.32)	
Charlson comorbidity score					
0	2196 (15.3)	1.0	0.01	1.0	0.18
≥1	499 (17.1)	1.15 (1.03-1.27)		1.08 (0.97-1.20)	
Socioeconomic deprivation					
1(least)	580 (13.1)	1.0	<0.01	1.0	<0.01
2	661 (15.6)	1.23 (1.09-1.38)		1.18 (1.04-1.33)	
3	528 (14.7)	1.15 (1.01-1.30)		1.07 (0.94-1.22)	
4	506 (17.5)	1.41 (1.24-1.60)		1.32 (1.15-1.50)	
5(most)	420 (19.5)	1.61 (1.40-1.85)		1.45 (1.26-1.67)	
Length of stay					
≤3	1497 (12.9)	1.0	<0.01	1.0	<0.01
>3	1198 (21.0)	1.79 (1.65-1.95)		1.54 (1.40-1.70)	
RP surgical approach					
Open	1309 (19.1)	1.0	<0.01	1.0	<0.01
Laparoscopic	866 (15.8)	0.79 (0.73-0.88)		0.98 (0.88-1.08)	
Robotic-assisted	520 (10.5)	0.50 (0.45-0.56)		0.65 (0.58-0.74)	

CI= confidence interval
*Odds Ratio derived using multivariable logistic regression

Figure 1: Flow chart of men included in study

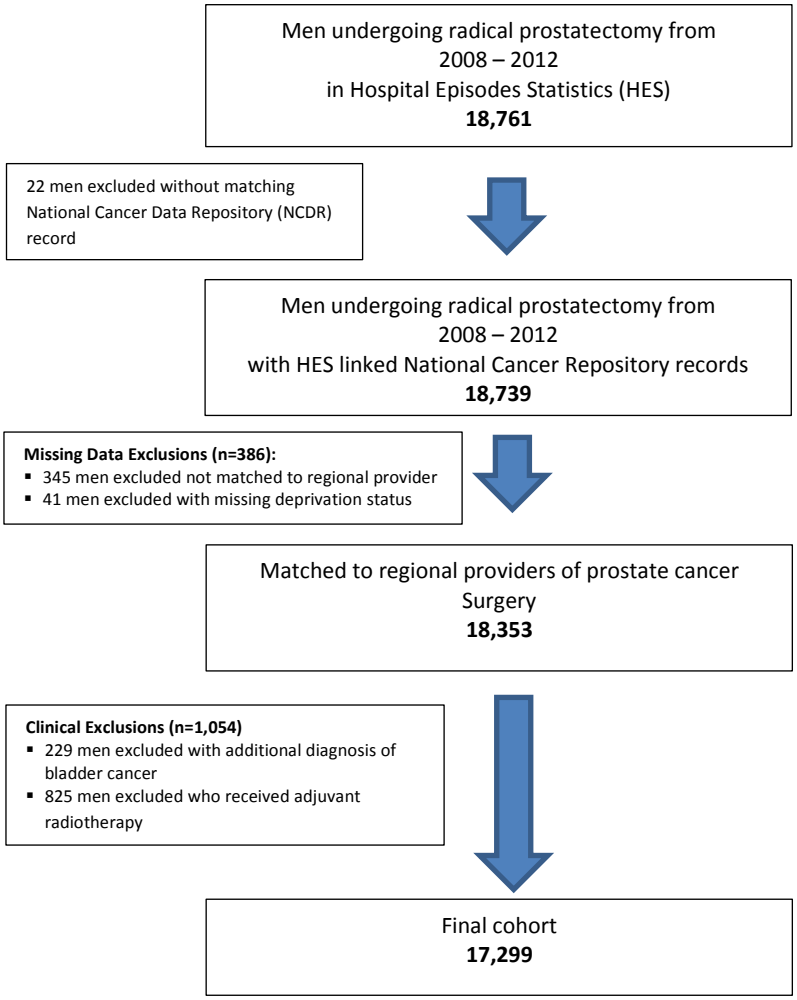


Figure 2: Kaplan-Meier curves for urinary complications according to type of complication

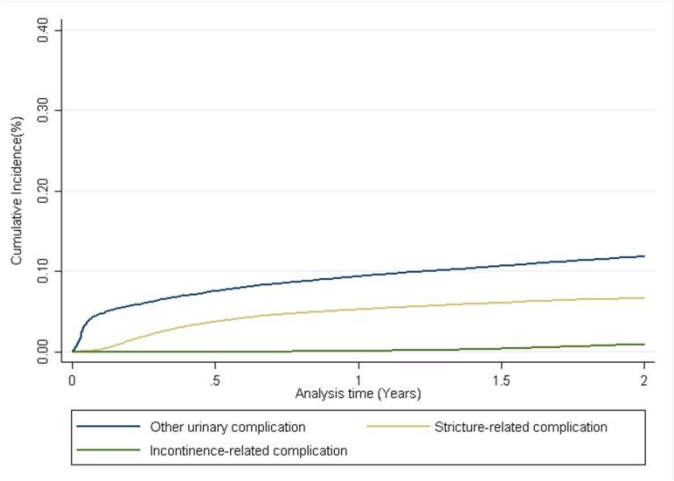


Figure 3: Kaplan-Meier curve for any urinary complication following radical prostatectomy

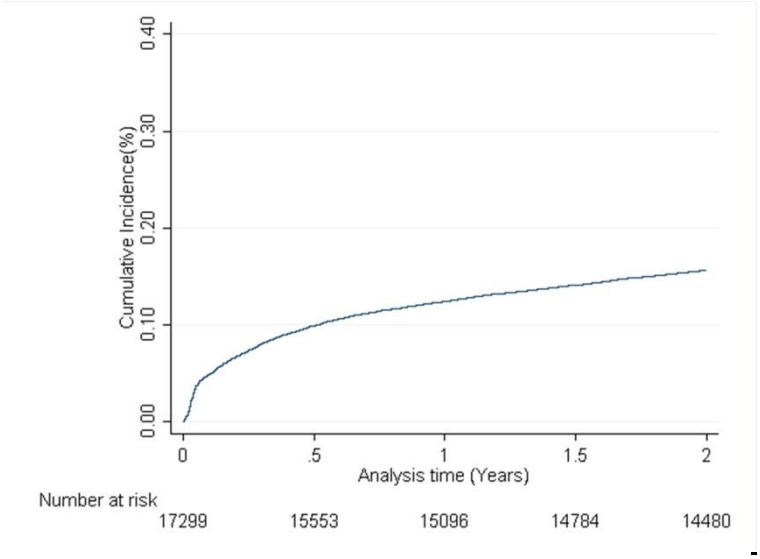
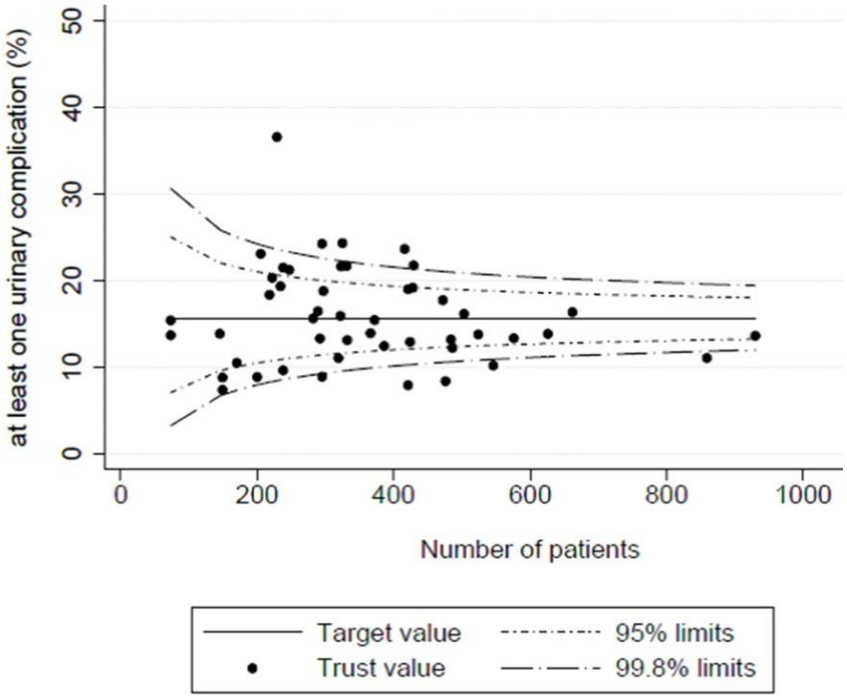


Figure 4: Risk-adjusted funnel plot of any urinary complication in 48 regional providers of prostate cancer surgery in England



Supplementary Files & Data

Appendix

Table 1: OPCS-4 and ICD-10 codes used to identify men receiving adjuvant radiotherapy and type of radical prostatectomy approach.

Procedure Description	OPCS-4 codes	ICD-10 codes
Adjuvant Radiotherapy	X65, X67, Y91, Y92	Y842, Z0081, Z091, Z510, Z58, Z923
Robotic-assisted Prostatectomy	Y753, Y765	-
Laparoscopic Prostatectomy	Y752, Y768, Y763, Y751, Y508	-

Figure 1: Treatment codes associated with first occurring urinary complication according to type of urinary complication.

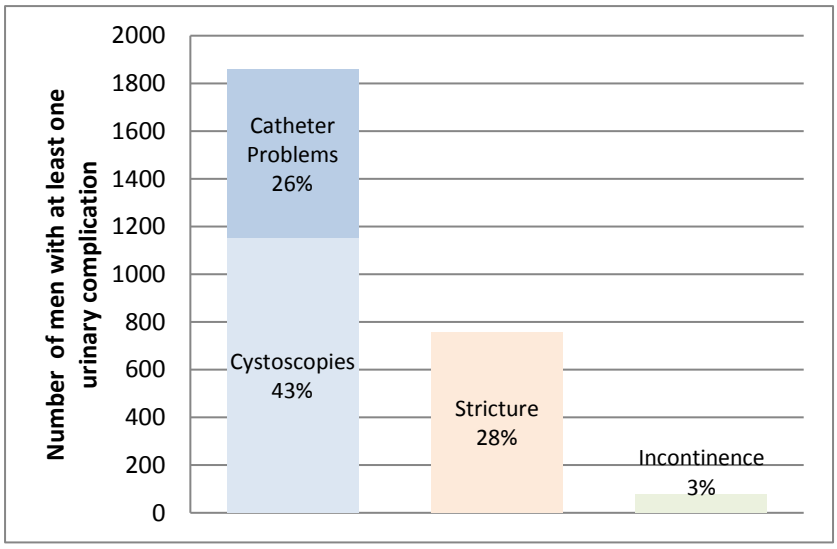


Table 2: ICD-10 codes used to identify diagnoses of a stricture and incontinence

ICD-10 Diagnosis Codes	Description of diagnosis
N320 N35, N991, R33	Stricture-related
N393, N394, N398, R32	Incontinence-related

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