Original Article

Visual Outcome Following Posterior Capsule Rupture during Manual Small Incision Cataract Surgery

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ABSTRACT

Background: The quality of cataract surgery can be measured by visual outcome, which is sometimes limited by intraoperative complications, most commonly posterior capsular rupture. **Aims:** The aim of the study was to assess visual outcome at the last visit (≥8 weeks) following posterior capsule rupture (PCR) in patients who had manual small incision cataract surgery (MSICS) managed without access to an automated vitrector. **Methods:** A review of medical records of all manual small incision cataract surgeries performed between January 2013 and December 2016 at the National Eye Centre, Kaduna, Nigeria was conducted. Descriptive statistics and logistic regression analysis were performed using STATA 14.0 to examine risk factors for the development of a *poor* visual outcome and to assess the impact of PCR on development of *poor* visual outcome. **Results:** In total, 405 patients were operated on with MSICS (50.6% males). Mean age was 62.4 (SD 12.6) years. PCR was the most common complication (n = 19 (4.7%)). The proportion of *good* outcomes (≥6/18) rose from 12.4% non-PCR and 0.0% for those with PCR at day 1 postoperative review, to 71.5 and 26.3%, respectively, by final follow up (P = 0.001). Patients with PCR were 7.0 (P = 0.0001) times more likely to have *borderline/poor* visual outcome (<6/18) compared to those without PCR. Age >60 years increased the odds of *borderline/poor* by 1.4 times (P = 0.002). **Conclusion:** PCR significantly affects the visual outcome of cataract patients in settings with no facilities for automated vitrectomy. Minimizing complications will improve visual outcome of cataract patients and increase uptake of cataract surgical services.

KEYWORDS: *Manual small incision cataract surgery, posterior capsule rupture, visual outcome*

INTRODUCTION

Despite the efforts and notable successes of the Vision 2020: *The right to sight* campaign, cataract remains the leading cause of blindness on earth contributing over one-third of the global total of 36 million blind.[1] In Nigeria, this proportion is higher, with an estimated 43% of all blindness being due to cataract and an estimated national cataract surgical rate (CSR) of only 300 cataract operations per million population per year.[2]

While the response to this situation would intuitively be to focus on increasing the quantity of cataract surgery being delivered, attention must equally be paid to the quality of surgery on offer. The drive to promote accessibility of cataract surgical services in India has seen the CSR rise to over 10,000 operations per million population per year.[3] However, early in this drive to increase CSR, there were often reports of substantial problems with quality of surgery being delivered. A 2003 survey from Andhra Pradesh found that 40% of cataract operations had failed to deliver a presenting

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visual acuity of 6/60 postoperatively, with over three quarters of those poor outcomes due to complications of surgery.[4]

The drive to increase the quantity of cataract surgery on offer must be matched by attention to the quality of that cataract surgery. The WHO set aspirational benchmarks for the outcome of cataract surgery of 80% to achieve "*good*" outcomes (6/18 or better presenting visual acuity (PVA)) (or 90% best corrected visual acuity (BCVA)) and fewer than 5% of patients having "*poor*" outcome of <6/60 PVA and <5% posterior capsular rupture (PCR) rate.[5]

PCR is the most common intraoperative complication of cataract surgery, but in series or trials of manual small incision cataract surgery (MSICS) (which is the most frequently employed surgical technique in the study centre), the incidence varies widely, being reported from 0 events (0/124) to 10% (10/100), including a report from Nigeria of 4.2% (3/71) (Mpyet *et al*.).[6-8] This variation suggests that reduction in PCR might be a potential target for improving the quality of surgery being performed. It is not clear how much long-term visual impairment is attributable to PCR and therefore how much benefit is potentially available by working to reduce the PCR rate or promote better management of the complication when it arises. Utilization of an automated vitrector was ranked 12th out of 17 factors in a Delphi exercise to identify potential targets for improving outcomes of cataract surgery in sub-Saharan Africa,[9] but there is no data to inform the extent to which an automated vitrector provides any benefit for long-term visual outcomes in dealing with PCR, and "sponge and scissors" vitrectomy are still widely utilized.

The aim of this study was to assess the extent to which PCR during MSICS, managed without access to an automated vitrector, affects the odds of a patient getting a *good* visual outcome (≥6/18 PVA) compared to those who undergo uncomplicated surgery and to determine the factors associated with PCR in MSICS. Findings from this study will inform the discussion around the importance of PCR as a target for cataract quality improvement initiatives.

Materials and Methods

Ethical approval for this hospital-based study was obtained from the Ethical and Research committee of the London School of Hygiene and Tropical Medicine, UK, and the Ethical committee of the National Eye Centre, Kaduna, Nigeria in June 2017. Data collection took place from June 12 to July 28, 2017 at the study centre. The study was carried out in accordance with the Declaration of Helsinki.

Included in the study were adults (aged 18 years or older) who underwent routine MSICS without preoperative expectation of complication or *poor* prognosis for age-related cataract at the National Eye Centre, Kaduna, Nigeria between January 2013 and December 2016 for whom ≥8 weeks postoperative records were available. Patients were excluded who were recorded as having ocular copathologies that would limit visual outcomes such as corneal opacities. Also, those with diabetes mellitus and hypertension (systolic >200 mmHg) were excluded.

In estimating the sample size, the following assumptions were made: 1. 10% of MSICS without PCR will not attain good vision 2. From previous studies,[10] the odds of developing poor vision in MSICS with PCR is 3.7 times the odds of developing poor vision in MSICS without PCR.

To increase the power of the study, a ratio 1:2 for cases and control was used. Using the following formula in STATA: *Power two proportions prop1 prop2, power (0.8) alpha (0.05)*, where prop1 = 10% = 0.10, prop2 = 3.7 × prop1 = 0.37, power = 80% = 0.8, and alpha = 5% = 0.05. Estimated sample size was 38, adding 10% attrition (≈4) = 42 cases, Control = 2 × N cases = 2 × 42 = 84. Total = 42 + 84 = 126.

Due to the small number of patients who met the inclusion criteria, all those with PCR (n = 19) and without PCR (n = 386) were recruited as cases and controls, respectively, for the study.

Data collection and analysis

The operating theatre register was used to identify all MSICS performed during the study period. Eligible patients who met the inclusion criteria had their medical records retrieved, and data were double entered into a Microsoft Access database (Microsoft Corporation, Redmond, USA).

The variables collected were age, gender, preoperative BCVA (Snellen), intraocular pressure, presence of biometry data, intraoperative complications, type of intraocular lens used, postoperative complications, postoperative pin-hole VA at day 1, week 1, and ≥8 weeks, postoperative refractive error, and grade of surgeon.

The data was analyzed using STATA 14.0 (Statacorp, College Station, Texas, USA). Descriptive statistics were done for socio-demographics; categorical variables described as number and percentage; and continuous variables described as mean and standard deviation (SD) provided that the data were approximately normally distributed (assessed by inspection of a histogram). To

investigate the primary outcome of the study, univariate logistic regression was used to determine the odds of failing to achieve a *good* visual outcome (≥6/18 BCVA) in PCR cases.

Results

Socio-demographics

A total of 405 patients (205/405 (50.6%) males) who had MSICS within the review period (January 1, 2013 to December 31, 2016) met the inclusion criteria. The mean age was 62.4 (12.6) years [Table 1]. Nineteen (4.7%) were recorded as having had PCR.

Preoperative assessment

The preoperative BCVA was counting fingers (CF) or worse in 88.4% (358/405) of eyes; all 19 of the PCR cases had CF or worse BCVA preoperatively. Biometry data were recorded in the notes of 399/405 (98.5%) patients. Mean preoperative IOP was 15 mmHg.

Intraoperative complications

Intraoperative complication was recorded in 22/405 (5.4%) patients; PCR was the most common intraoperative complication ($n = 19$) with a nonsignificant majority (13/19) of males ($P = 0.11$, 95% CI: 0.15–1.21).

Table 1: Age and sex distribution of participants

	Participants		Total
	PCR	No PCR	
Gender ***n*** (%)			
Male	13 (68)	192 (49.7)	205 (50.6)
Female	6 (32)	194 (50.3)	200 (49.4)
Overall	19 (100)	386 (100)	405 (100)
Mean Age Years (SD)			
Male	63.3 (12.8)	63.1 (12.7)	63.2 (12.8)
Female	62.1 (12.5)	61.0 (12.3)	61.6 (12.4)
Overall	62.7 (12.7)	62.1 (12.5)	62.4 (12.6)
Mean weeks to final follow-up (SD)	12.2 (3.5)	12.6 (3.6)	12.5 (3.5)

Other intraoperative complications recorded were iridodialysis (1), Descemet's membrane stripping (1), and zonule dialysis with no vitreous loss (1).

A variety of grade of surgeons operated with 276/393 (70.2%) being consultant ophthalmologists, leaving 117/393 (29.8%) residents (12 missing data). There was no significant difference between consultants and trainees for PCR (10/18 PCR were with consultant surgeons, 8/18 trainees (1 missing datum)).

Postoperative complications

At first day postoperative review, there were 283/405 (69.9%) postoperative complications recorded, most commonly striate keratopathy ($n = 225$). This reduced to 21/405 (5.2%) at final review (≥8 weeks). The mean time to final follow-up was 12.2 (SD3.5) weeks for patients with PCR, and 12.6 (SD3.6) weeks for non-PCR. Breakdown of all complications is presented in [Table 2].

Visual outcomes

The proportion of *good* outcomes (≥6/18 BCVA) rose from 12.4% non-PCR and 0.0% for those with PCR at day 1 postoperative review, to 71.5 and 26.3%, respectively, by final follow-up ($P < 0.05$) [Table 3].

Univariate logistic regression analysis was undertaken to evaluate risk factors for failure to achieve a *good* outcome. Patients with PCR were 7.0 times (95% CI: 2.47–19.97) more likely to have a *borderline/poor* (<6/18 BCVA) outcome compared to those without PCR ($P = 0.0001$). Those >60 years of age were 1.4 times (95% CI: 1.15–1.83) more likely to have <6/18 vision compared to those younger ($P = 0.002$; Table 4).

As the WHO benchmark also suggests not more than 5% of patients should end up with a *poor* outcome (BCVA <6/60), additional analysis was undertaken, which showed that the odds of a *poor* outcome were increased 19.3 times (95% CI: 5.99–62.39, $P = 0.0001$) by PCR occurring.

Table 2: Postoperative complications

Postoperative complications (*N*=405)	Day 1		Week 1		Week≥8	
	N	%	*N*	%	*N*	%
SK/Cornea oedema Non-PCR PCR	238 16	61.7 84.2	52 10	13.5 52.6	1 3	0.3 15.8
Cortical remnant Non-PCR PCR	14 2	3.6 10.5	5 2	1.3 10.5	- -	- -
Hyphema Non-PCR PCR	6 2	1.6 10.5	- 2	- 10.5	- 1	- 5.3
Iris prolapse Non-PCR PCR	2 -	0.5 -	5 2	1.3 10.5	- -	- -
Displaced IOL Non-PCR PCR	1 -	0.3 -	1 -	0.3 -	1 -	0.3 -
PCO Non-PCR PCR	1 -	0.3 -	11 -	2.9 -	14 1	3.6 5.3
Macular oedema Non-PCR PCR	- -	- -	- 1	- 5.3	- 1	- 5.3
Vitreous prolapse Non-PCR PCR	- 1	- 0.3	- -	- -	- -	- -
Retinal detachment Non-PCR PCR	- -	- -	- -	- -	- 1	- 5.3

Table 3: Postoperative visual acuity (pinhole) of participants

Postoperative Visual Acuity (pinhole)		
Postoperative Period	**Good ≥6/18 (%)**	**Borderline/ Poor <6/18 (%)**
Day 1 Non-PCR	47 (12.4)	332 (87.6)
Day 1 PCR	0.0 (0.0)	19 (100)
Week 1 Non-PCR	149 (39.0)	233 (61.0)
Week 1 PCR	2 (10.5)	17 (89.5)
Week≥8 Non-PCR	276 (71.5)	110 (28.5)
Week≥8 PCR	5 (26.3)	14 (73.7)

Table 4: Univariate logistic regression analysis for potential predictors of borderline/poor visual outcome

Variable	Unadjusted Odds ratio (OR)	95% Confidence interval (CI)	*p* value
Posterior capsular rupture	7.0 (<6/18)	2.47–19.97	0.0001
Age>60 years	1.4	1.15–1.83	0.002
Male gender	1.4	0.95–2.25	0.08

Of those without PCR, 47/386 (22.2%) had preop BCVA better than CF (no patient with PCR had BCVA of better than CF preoperatively); however, even exclusion of those with preop VA better than CF from the non-PCR group in order to provide a better comparison group (leaving 339 patients with preop VA of CF or worse who did not experience PCR) did not materially alter the results, with 247/339 (72.9%) achieving a *good* outcome compared to 276/386 (71.5%) when the entire non-PCR group is considered.

Postoperative refraction

Of those with PCR, 3 had PC-IOL, 2 were aphakic, and 14 had anterior chamber IOL (AC-IOL); all non-PCR patients received PC-IOL.

For patients without PCR, 276/386 (71.5%) had a *good* visual outcome; for those with PCR, the proportion was 5/19 (26.3%). Formal postoperative refraction permitted a further 49 patients in the non-PCR group to achieve ≥6/18 raising the proportion to 325/386 (84.2%), still short of the WHO benchmark of 90% ≥6/18 postoperative BCVA.

Refraction did not move any patient with PCR into the ≥6/18 *good* outcome category; the causes of *borderline*/*poor* outcomes among the 14 PCR cases being attributed to retinal detachment (1), chronic macular oedema (1), corneal oedema (3), persistent hyphaema (1), PCO (1), and seven PCR patients, where a combination of factors (refractive, corneal, retinal) resulted in vision that could not be corrected up to 6/18.

Of the 110 *borderline*/*poor* visual outcomes with pinhole at final follow-up in the non-PCR group, 49 achieved *good* outcome with formal refraction, and data were identified to explain a further 16 (one displaced IOL, one corneal oedema, and 14 cases of PCO). The remaining 11.7% (45/386) non-PCR patients with *borderline*/*poor* outcomes did not have data to inform the cause of this, but previously published cataract case series from the same setting describe copathologies (primarily glaucoma and ARMD (9.1% and 2.5%)[11,12] limiting best corrected visual outcome in a similar percentage.

Discussion

With the annual total of cataract operations being performed worldwide estimated at well over 10 million,[13] and a PCR rate reported at 1–2% even in well-resourced health economies[14] and nearer 5% in less resource intense settings,[6] outcomes of this complication are a matter of substantial importance.

Much evidence exists to support the claim that, while PCR is associated with worse visual outcomes than uncomplicated surgery, good outcomes of cataract extraction by phacoemulsification can be achieved despite PCR.[15,16] Far less data exist to describe expected outcomes where phacoemulsification is not used, or from settings where automated vitrectomy is unavailable to manage PCR, as was our situation during the study period.

This paucity of data impedes the process of informed consent and postoperative counselling regarding prognosis for patients who have experienced this complication. One Indian study compared the visual outcomes following PCR during phacoemulsification and MSICS finding that they were able to achieve similarly *good* outcomes regardless of the technique employed; however, this was with the use of automated vitrector. A Kenyan study from 1999 reported a 7.2% PCR rate in a series of 461 extra-capsular cataract extractions with IOL, but from the whole series, only six operations (1.3%) resulted in a *poor* (<6/60) visual outcome at long term follow-up;[17] this again was from a situation where automated vitrectomy was available.

With an odds ratio for failing to achieve a *good* outcome when PCR is experienced of 7.0 (95% CI: 2.47 to 19.97) and the odds of a *poor* postoperative BCVA (<6/60) being increased 19.3 times (95% CI: 5.99 to 62.39), the results of our study are not encouraging for patients who experience PCR during MSICS in this setting.

A study of final visual outcomes following complicated cataract surgery would of necessity have to exclude those patients who were lost to follow-up. Although

some complications such as retinal detachment or IOL dislocation may not manifest for many months, we took a pragmatic cut-off of a minimum of 8 weeks, coinciding with the WHO benchmark for final visual assessment. If a longer follow-up had been possible, it is conceivable that later complications might have further worsened the outcomes for those with PCR in this study; however, it is also possible that some residual corneal or macular edema limiting vision might settle to create an improved BCVA among the PCR cases.

Follow-up rates in developing countries after postoperative discharge can be as low as 20–30%[5] potentially explained by *poor* transportation infrastructure, costs to patients, and failure to communicate the benefits of returning.[18] This introduces the potential for bias in many studies as those who are lost to follow up are likely to differ from those that present for review, but it is not possible to say in this specific setting whether those for whom long-term data was available had worse or better visual outcomes than the overall cohort of those operated during the study period. The Prospective Review of Early Cataract Outcomes and Grading study offers some hope that this bias is limited; early (≤72 h) vision assessment for all patients and follow-up assessment (≥40 days) only for patients who return to the clinic without prompting were shown to be valid measures of operative quality in settings, where follow-up is *poor*.[19]

If the results of this study were generalized to Nigeria as a whole, taking an estimated CSR of 300/million population/year at an estimated population of 183 million,[2] and a 4.7% PCR rate,[6] this would result in 2,580 PCR events, each with an increased odds of poor vision being seven times that in those without PCR. At a CSR of 2000, which has previously been proposed as the target activity level, this would increase to 17,200 PCR events annually, and many individuals each year failing to get a *good* outcome who might otherwise have done so.

Conclusion

This study demonstrates the detrimental effect of PCR during MSICS managed without automated vitrectomy on visual outcome compared to those whose surgery was not complicated by PCR. Research in other settings suggests that PCR rates can be reduced, perhaps most invitingly by increasing the number of operations individual surgeons perform each year.[20] The first step towards reducing the PCR rate is for each surgeon and institution to monitor their cataract surgery complication rates and visual outcomes, which is not currently systematized, and to reflect on the outcomes in a continuous cycle of quality improvement.[21]

Despite every effort to reduce the incidence of PCR, it will inevitably be experienced, and attention needs also to be paid to the management of this complication. Given the lack of availability of automated vitrectomy equipment in much of sub-Saharan Africa, research is needed on the impact of this equipment to manage PCR on complication rates and visual outcomes, and analysis conducted of the cost-effectiveness of such equipment.

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Conflicts of interest

There are no conflicts of interest.

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