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CLINICAL STUDY

The Cataract National Dataset electronic multicentre audit of 55 567 operations: risk stratification for posterior capsule rupture and vitreous loss

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Abstract

Aims **To identify and quantify risk factors for posterior capsule rupture or vitreous loss or both (PCR or VL or both) during cataract surgery and provide a method of composite risk assessment for individual operations.**
Methods **The Cataract National Dataset was extracted on 55 567 operations from 12 National Health Service (NHS) Trusts using an electronic patient record (EPR) system between November 2001 and July 2006. Risk indicators for variations in the rate of 'PCR or VL or both' were identified by univariate and multivariate analyses. Adjusted odds ratios (ORs) were used to formulate a composite 'bespoke' risk for individual cases.**
Results **Overall 'PCR or VL or both' rate was 1.92% (95% CI = 1.81–2.04%). Risk indicators for this complication were increasing age, male gender, presence of glaucoma, diabetic retinopathy, brunescent/white cataract, no fundal view/vitreous opacities, pseudoexfoliation/phacodonesis, reducing pupil size, axial length $\geqslant$26.0 mm, the use of the α-blocker doxazosin, inability to lie flat and trainee surgeons performing operations. Adjusted ORs for these variables are used to estimate overall composite risk across multiple risk indicators in the form of a predicted probability of PCR or VL or both. Predicted probability for this complication ranged from less than 0.75% to more than 75%, depending on risk profile of individual operations.**
Conclusions **Higher-risk cases can be predicted, thus better informing the consent process and allowing surgeons to take appropriate precautions. Case-mix is a major determinant of the probability of an intraoperative complication. A simple composite risk estimation system has been developed.**
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Keywords: cataract surgery; cataract national data set; complications risk; posterior capsule rupture; vitreous loss

Introduction

Posterior capsular rupture (PCR) with or without vitreous loss is the most common intraoperative complication during cataract surgery.[1,2] It is important as it is associated with the need for additional surgical procedures, a greater number of follow-up visits and increased frequency of postoperative complications, which may adversely affect the final visual outcome.[3] It is widely regarded as the benchmark complication to judge the quality of cataract surgery. As the overall rate of PCR is low, prospective identification of preoperative risk factors for PCR is difficult but, if achieved, has the potential to improve informed consent for patients and for surgeons to modify their surgical strategies.

The Royal College of Ophthalmologists has promoted the development of a minimum Cataract National Dataset (CND)[4] over the past

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several years. More recently, the CND has been further refined by the Cataract Do Once and Share (DOAS)[5] programme, which is a clinical engagement arm of Connecting for Health (CfH). Sponsored by the Royal College of Ophthalmologists, a multicentre data extraction of electronic cataract surgery records has been undertaken as part of ophthalmic dataset development work. The purpose of this extraction has been several-fold, including a demonstration to the NHS Information Standards Board that the CND is 'fit for purpose'. The electronic patient records (EPR) data analysed in the present study have been collected as part of routine clinical care, either preoperatively or at the time of surgery.[6] These data were derived from a single EPR system (Medisoft UK) implemented across multiple NHS sites. As a result of EPR software design, which includes forced data collection for key items, the completeness of these records is detailed and unusually high.

The primary aim of this paper was to identify and quantify preoperative risk factors for PCR or vitreous loss (VL) or both. The secondary aim was to illustrate the use of these values to calculate a bespoke risk score for PCR or VL or both based on individual patient's preoperative characteristics, to inform the consent process and to alert surgeons to the need to take appropriate operative precautions where risks are elevated.

Materials and methods

The methods used in this large prospective cross-sectional survey have been described in detail in the first paper of the series.[6] This study analysed all systemic, ocular, and surgeon variables within the CND considered by the authors to be candidate variables, which may contribute to an increased risk of PCR or VL or both. Where VL did occur, this was most often associated with PCR, but VL in association with zonule rupture was also included. Ocular comorbidities were only noted, if they were deemed by the surgical team to be sufficiently severe to indicate a postoperative 'guarded visual prognosis'.

Statistical methods

The univariate association with factors with a possible risk of PCR was initially examined using χ^2-test (or Fisher's exact test as appropriate). Those factors that were statistically significant at a univariate level were then entered into a logistic regression model. Any factors found to be nonsignificant in the multivariate model were excluded from the final model. Variables that were not significant in the univariate analysis were then checked in the logistic regression model. The logistic regression modelling was repeated using a backwards, stepwise logistic regression to ensure that the same model was obtained. Due to the large number of possible interactions, a main effects-only model was considered. $P<0.05$ was used to assess statistical significance. The fit of the final logistic model was examined using the Hosmer–Lemeshow goodness of fit test. Adjusted odds ratios (ORs) were used to estimate a risk score for combinations of risk factors. Because the data were anonymised, we did not have access to information about which patients contributed one eye or both eyes to the data set. For this reason, we advise caution in interpreting significance levels $0.05<P<0.01$. A number of sites did not collect preoperative medications data consistently, and there was uncertainty regarding the completeness of these data for approximately 10% of records. As a precaution, the multivariate regression model was, therefore, repeated with medications data for these uncertain records identified as a separate category. The model thus obtained was virtually identical, with only minimal differences being observed in adjusted ORs. The model was, therefore, accepted as valid. Using the predicted probability of the 'reference category' (all risks at baseline) in the logistic regression model, we have calculated predicted probabilities across a range of 'composite ORs', which reflect the presence of any combination of risk features for a given individual patient. The method for calculating the relevant predicted probability was based on the relationship: $OR=(P2/(1-P2))/(P1/(1-P1))$, where P1 is the predicted probability for the reference category (all risks at baseline) and OR is the composite OR encapsulating the 'risk profile' for a given patient. P2, the predicted probability for that patient, is calculated from the formula. These data are presented in a user-friendly graphical form as a convenient way to 'look up' the relevant predicted probability of PCR or VL or both based on the composite OR' for a given patient's individual risk profile. Statistical analysis was performed in Microsoft Excel and Stata.

Results

A total of 55 567 operations were available for analysis between November 2001 and July 2006. The mean age of the patients undergoing surgery was 75.4 years and 62% were female. Data collection was at or near 100% complete for all variables in these analyses, with no model variable having $<99.6\%$ completeness.

Factors statistically significant at the univariate level ($P<0.05$) were age, gender, glaucoma, diabetic retinopathy, brunescent white cataract, no fundal view/vitreous opacities, pseudo-exfoliation (PXF)/phacodonesis, pupil size, doxazosin, able to lie flat,

surgeon grade, and uveitis/synechiae. Factors which were not statistically significant at the univariate level ($P>0.05$) were corneal pathology, amblyopia, AMD, previous retinal detachment surgery, previous vitrectomy, previous retinal detachment surgery or previous vitrectomy (combined), high myopia, axial length coded as <26.0 mm and $\geqslant 26.0$ mm, unable to cooperate, and use of α-blockers tamsulosin, alfuzosin, indoramin, prazosin, and terazosin.

The ORs from the univariate analysis and logistic regression analyses are presented in Table 1. In terms of significant variables at $P<0.05$, the analyses were in broad agreement apart from axial length, which was nonsignificant in the univariate analysis but significant in the multivariate model and uveitis/synechiae, which was significant in the univariate analysis but not in the logistic regression model; this latter item is, therefore, being excluded from the final model. Both multivariate methods arrived at the same final model.

For patient-related factors, the risk of PCR or VL or both was higher with increasing age, male gender, presence of glaucoma, diabetic retinopathy, brunescent/white cataract, no fundal view/vitreous opacities, PXF/phacodonesis, reducing pupil size, axial length $\geqslant 26.0$ mm, the use of the α-blocker doxazosin, and inability to lie flat. In terms of surgeon grade, the risk of PCR or VL or both was higher for trainee surgeons than career grades with staff grades showing the lowest risk. The Hosmer–Lemeshow goodness of fit test indicated that the logistic regression model was a good fit for the data ($\chi^2=11.2$, d.f $=8$, $P=0.19$).

The overall rate of PCR or VL or both for all operations was 1.92%. Within this overall rate, however, there were important gradients between subgroups. Table 1 provides the unadjusted and adjusted ORs for statistically significant risk indicators, thus, for example, a person with a brunescent/white cataract would have an approximately threefold increased risk of a complication compared with someone who did not have such a cataract, and similarly, a person taking the α-blocker doxazosin would have a 50% increased risk of a complication.

A patient whose risk profile was in the reference group for all risk indicators (ie adjusted OR $=1.00$ for all in Table 1) may be regarded as having a 'baseline risk profile', and the logistic regression model indicates a 'baseline predicted probability' for PCR or VL or both $=0.736\%$. From Table 1, we see that such a person will be aged <60, female, have no ocular copathology, a large pupil, not on doxazosin, able to lie flat, and being operated on by a consultant. For a patient with a different risk profile, we are able to derive the relevant predicted probability of a complication from the ORs. This can be done by multiplying together all the 'non-baseline' ORs for that person's profile, to arrive at a composite OR, and then using the graph in Figure 1 to look up the relevant predicted probability. For example, a female patient aged $90+$ years with no other risk indicators, who is being operated on by a consultant, has an adjusted OR of 2.37 compared with 'baseline'. In this example, the only 'non-baseline' OR is for age $90+$. From Figure 1, it can be seen that the predicted probability of PCR or VL or both for such a person would not be particularly high, approximately 1.7%. Where the risk profile of a patient is more complex, the adjusted OR for each contributing risk must be multiplied, thus for a male patient aged 80–89 with a white cataract, no fundal view, and a small pupil being operated on by a specialist registrar, the composite OR from Table 1 would be $1.28\times 1.58\times 2.99\times 2.46\times 1.45\times 1.60=34.5$, and from the graph in Figure 1, we see that this OR corresponds with a predicted probability of PCR or VL or both of around 20%. The worst-case scenario would in theory be a patient with all risks at maximum, which in reality would be very unlikely to arise. From Table 1, such a 'theoretical' person being operated on by a consultant, would according to the model, have an OR of over 564 and a predicted probability of PCR or VL or both of around 80%. Since this is very unlikely to arise in practice, the maximum OR in Figure 1 has been restricted to OR $=150$, which facilitates the reading of values lower down on the curve, which would be encountered more frequently in clinical practice.

Discussion

This study examines a large and detailed multicentre cataract surgery data set with high levels of completeness for the variables of interest. The 55 567 records are derived from 12 different NHS trusts with 406 surgeons of all levels of experience contributing information. Although the contributing trusts are at the forefront of cataract EPR use, it is likely that our data are representative of cataract surgery as practiced in the English NHS.[6] Variables examined in this analysis were complete or very near complete due to EPR design, which forced standardised data collection for key items of data. This sample size has adequate statistical power to investigate the number of variables we have included in our analyses. Due to anonymisation of the data (required for reasons of data protection), the authors do not have access to information regarding which operations were performed on two eyes of individual patients. Approximately 40% of surgery was on second eyes, and for a proportion of these second eyes data from the first eye operation would be included in the data set. Where this has occurred, it has not been possible to account for the within person correlation. For this reason,

Table 1 Unadjusted and adjusted odds ratios (OR) for 'PCR or VL or both' obtained from the logistic regression model ($n = 55\,358$)

	Unadjusted OR (95% CI)	χ^2, P-*value*	*Adjusted OR (95% CI)*	χ^2, P-*value*
Age				
<60	1.00	29.8,	1.00	34.8,
60–69	1.08 (0.80–1.46)	$P<0.0001$	1.14 (0.84–1.54)	$P<0.0001$
70–79	1.30 (1.00–1.70)		1.42 (1.08–1.86)	
80–89	1.42 (1.09–1.86)		1.58 (1.20–2.08)	
90+	2.18 (1.56–3.04)		2.37 (1.69–3.34)	
Gender				
Female	1.00	12.1,	1.00	15.1,
Male	1.25 (1.10–1.41)	$P=0.0005$	1.28 (1.13–1.45)	$P=0.0001$
Glaucoma				
No	1.00	9.7,	1.00	4.6,
Yes	1.47 (1.17–1.84)	$P=0.0018$	1.30 (1.03–1.64)	$P=0.0325$
Diabetic retinopathy				
No	1.00	14.5,	1.00	10.9,
Yes	1.74 (1.34–2.27)	$P=0.0001$	1.63 (1.24–2.14)	$P=0.0010$
Brunescent/white cataract				
No	1.00	107.8,	1.00	57.6,
Yes	4.19 (3.34–5.27)	$P<0.0001$	2.99 (2.32–3.85)	$P<0.0001$
No fundal view/vitreous opacities				
No	1.00	57.4,	1.00	19.5,
Yes	4.67 (3.36–6.49)	$P<0.0001$	2.46 (1.70–3.55)	$P<0.0001$
PXF/phacodonesis				
No	1.00	39.1,	1.00	25.5,
Yes	3.74 (2.64–5.30)	$P<0.0001$	2.92 (2.02–4.22)	$P<0.0001$
Pupil Size				
Large	1.00	24.6,	1.00	7.5,
Medium	1.28 (1.06–1.54)	$P<0.0001$	1.14 (0.95–1.38)	$P=0.0231$
Small	1.93 (1.48–2.52)		1.45 (1.10–1.91	
Axial Length (mm)				
<26.0	1.00	2.0,	1.00	6.8,
⩾26.0	1.22 (0.93–1.60)	$P=0.1537$	1.47 (1.12–1.94)	$P=0.0090$
Doxazosin				
No	1.00	6.2,	1.00	5.7,
Yes	1.52 (1.11–2.08)	$P=0.0130$	1.51 (1.09–2.07)	$P=0.0173$
Able to lie flat				
Yes	1.00	25.4,	1.00	11.7,
No	1.40 (1.23–1.60)	$P<0.0001$	1.27 (1.11–1.45)	$P=0.0006$
Surgeon Grade				
Consultant	1.00	211.4,	1.00	198.5,
Associate Specialist	0.78 (0.61–1.01)	$P<0.0001$	0.87 (0.67–1.12)	$P<0.0001$
Staff grade	0.30 (0.14–0.64)		0.36 (0.17–0.76)	
Fellow	1.72 (1.35–2.19)		1.65 (1.29–2.11)	
Specialist Registrar	1.65 (1.42–1.91)		1.60 (1.38–1.85)	
Senior house officer	3.53 (2.93–4.26)		3.73 (3.09–4.51)	

Pxf = pseudo-exfoliation.

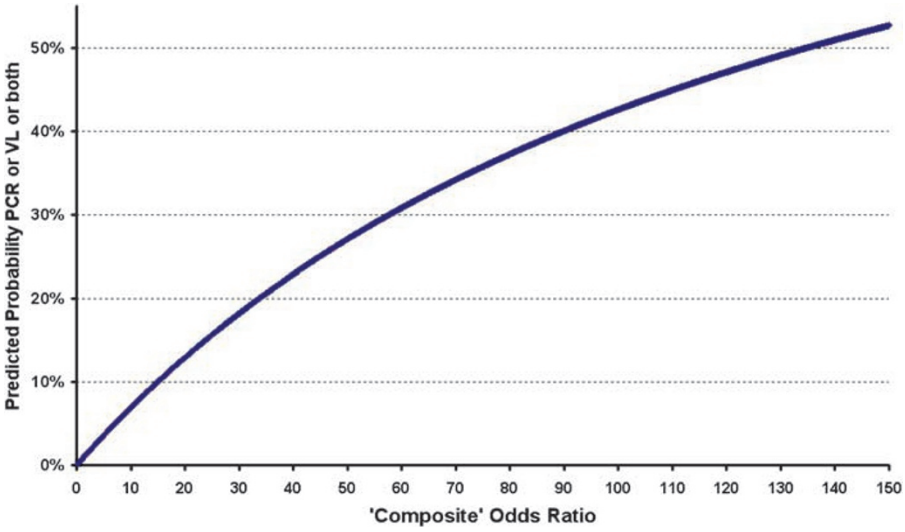

Figure 1 Predicted probability of posterior capsule rupture or vitreous loss or both based upon composite odds ratio for a patient with a given preoperative risk profile. The graph is used to 'look up' the predicted probability from the calculated composite ORs (see text).

statistical significance should be interpreted with caution where $0.05 < P < 0.01$.

The analyses have confirmed about which preoperative features are associated with the cataract surgery 'index complication' PCR and/or VL, which is widely accepted as an indicator of quality of surgery.[1,2,7] From the ORs (Table 1), we have illustrated a method for estimating a composite risk for any combination of risk indicators. Our data show that the accumulated risk of PCR or VL or both for individual patients with multiple risk indicators stack up such that the predicted probabilities for 'high-risk cases' are substantial. The importance of being able to quantify the cumulative risk for a given risk profile is twofold. Firstly, patients can be given bespoke information regarding the risk of this complication arising during their cataract operation, so that the consent process is properly informed and patients may make better judgements on the 'risk to benefit' ratio for themselves, and secondly, surgical teams can adopt strategies to reduce the risk for high-risk individuals by ensuring, for example, that an experienced senior surgeon performs the operations for high-risk cases. This can be illustrated by the following scenarios: a 65-year-old female patient with an otherwise 'baseline risk' profile will have a predicted probability of an intraoperative complication of 0.84%, if operated on by a consultant. The same patient, if operated on by the most junior trainee (SHO), would have a predicted probability of 3.05%, an increase of just over 2 percentage points. Similarly, a higher risk male patient of 85 years with PXF, a small pupil, a brunescent cataract, and axial length $\geqslant$26.0 mm will have a predicted probability of an intraoperative complication of 21.8%, if operated on by a consultant, but 51.0% if operated on by SHO, a huge increase of almost 30 percentage points. This large difference in predicted probability of a complication in the two case scenarios arises because of the multiplicative nature of the ORs for each individual risk feature and underlines the need to ensure that trainee surgeons avoid high-risk cases. Although it is straightforward to estimate the risk profile for a given patient from the ORs in Table 1 and the 'look-up graph', it is unlikely that many surgeons will wish to do this for every case. Minor modification of a cataract EPR system, which already captures these data, would allow this information to be presented in the preoperative record following standard data collection. Surgical teams could thus be routinely alerted to higher-risk situations, which would allow appropriate risk reduction strategies to be deployed for individual patients.

Risk avoidance by trainees would be advisable and should be encouraged. The authors are aware, however, that a tool for preoperative identification of high-risk surgical cases could result in an inappropriate risk-aversive behaviour by trained surgeons wishing to minimise their complication rates. Such behaviour may be counter to the best interests of individual patients, who may as a result be denied access to necessary surgery. Furthermore, in the current NHS climate of plurality of providers, where cherry picking of straightforward cases by certain providers has raised concern, these data do have the potential to be misused. On the other hand, surgeons whose surgical case-mix contains an excess of higher-risk operations will be in a

position to use these data to demonstrate their levels of skill by risk stratification of a complex case-mix.

It is of interest that the surgeons with the lowest complication rates were nonconsultant career grades. Staff grade surgeons in particular had low rates of complications reflecting high levels of experience of routine surgery. From the ORs, we identified higher-risk cases as those who were aged 90+ or had brunescent/white cataract or had PXF/phacodonesis. Examination of the case-mix across different grades of surgeons revealed statistically significant differences in the proportion of higher-risk cases performed by different surgeon grades ($\chi^2 = 116$, d.f. $= 5$, $P < 0.001$), such that consultants were most likely to perform higher-risk cases (8.1%), and staff grades were least likely to operate on such cases (3.0%). Associate specialists also performed fewer higher-risk cases (5.0%) with training grades performing surgery on intermediate proportions of higher-risk cases (SHO = 6.8%, SpR = 7.5%, and Fellow, 7.4%). This examination of case-mix illustrates the importance of knowledge of such details when considering surgical outcomes for individuals or groups of surgeons. In addition, this analysis indicates that the case-mix of trainees could be better selected to avoid higher-risk cases where possible. More experienced trainees should be exposed to more challenging cases as they approach completion of surgical training, but the most junior trainees should not be permitted to attempt such surgery.

The overall PCR or VL or both rate of 1.92%, in this study, is lower than some early studies. The first National Cataract Surgery Survey (1993) reported rates of PCR without VL of 4% and PCR with VL 1%,[7] and the second National Cataract Surgery Survey 1997–1998 (1999) had an overall PCR with or without VL of 4.4%.[1] However, the proportion of phacoemulsification procedures performed in these studies was lower than the current figure of 99.9%, and since then, also there have been some advances in technology and technique, improving the quality of surgery. The First Pilot National Electronic Cataract Surgery Survey (2005) found an overall posterior capsular/zonular rupture rate of 2.7% (published only in Royal College Cataract Guidelines[8]) and two more recent studies in 2006 reported a rate of 1.7% for PCR with or without VL[9] and 1.1% for PCR with VL and 0.4% for PCR alone,[2] similar figures to those described in this paper. Misra *et al*[10] reported an overall PCR rate of 15 in 2000 or 0.75% in a single-surgeon consecutive case series and did not find a statistically significantly increased incidence of this complication in 117 (1.7%) eyes that had previously undergone a vitrectomy.

A previous study found a variation in complication rate with age (PCR, VL, and retained nuclear fragment increase over the age of 88 years).[11] The present analysis confirms a steady rise in complication rate with increasing patient age. The complication rate was significantly higher in eyes with PXF, a finding that has previously been documented in the literature. Drolsum *et al*[12] found a 2.6-fold increase in capsule or zonule tear or vitreous loss in eyes with PXF undergoing cataract surgery compared to eyes without the disease. Our finding of higher PCR or VL or both rates in brunescent/white cataracts is also consistent with previous data. Brazitikos *et al*.[13] found a PCR with or without VL rate of 10% in 100 eyes with white cataract which they had preoperatively assessed using ultrasound.[13] In addition to these previously identified risks, our analyses have uncovered further preoperative risk indicators as detailed in Table 1. We were, however, unable to comment on other clinical circumstances where these were not included in the standard dataset; for example, the literature describes higher PCR rates in eyes with posterior polar cataracts.[14,15]

Two studies have published scoring systems to help stratify preoperative risk factors for cataract surgery.[16,17] Both, however, were derived from information in previous literature comparing potential risk features with perioperative complications. One study, in addition, took into account consultant surgeons' subjective opinions about factors that were associated with increased complications.[17] The two systems, however, were derived from arbitrarily defined scores depending on perceived degree of risk, and although these were validated on reasonable samples, the number of patients were relatively small ($n = 1441$ and $n = 533$) in comparison with the sample size of the present study. Our work has the advantage of being empiric and based on standard data collected on a large number of operations performed by many surgeons across multiple centres.

Conclusion

The use of an EPR has enabled us to extract and analyse data on a large number of surgical procedures from several units and identify preoperative risks for PCR or VL or both. Enforced data collection by an EPR has ensured almost 100% completeness of relevant data which were collected prospectively, either before or at the time of surgery. These findings underline the importance of case-mix in determining the risk of this index operative complication. A simple method for calculating a bespoke risk, tailored to an individual operation, has been developed based on readily available preoperative data. All levels of risk can be identified preoperatively to ensure that patients are correctly counselled at the time of taking consent, and that appropriate precautions are in

place to minimise the likelihood of an operative complication arising during surgery.

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