## Stability through time of a Statistical Model for indicators of Posterior Capsule Rupture in Cataract Surgery

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**Stability through time of the risk model for Posterior Capsule Rupture (PCR) during cataract surgery.**

**Background**

Posterior capsular rupture (PCR) is defined for the purposes of the National Audit as “posterior capsule rupture with or without vitreous prolapse or zonule rupture with vitreous prolapse” and abbreviated simply as PCR. It should be noted that the definition excludes zonule dehiscence where no vitreous prolapse has occurred. PCR is the most frequent intraoperative complication and when it occurs as defined above there is an approximately 6-fold increased risk of vision loss, an approximately 40-fold increased risk of post cataract retinal detachment and an approximately 8-fold increased risk of endophthalmitis (serious postoperative infection in the eye).

A statistical risk model is used to adjust surgeon and centre results for case complexity in the National Cataract Audit in order to ensure that surgeons who take on difficult operations in patients who are likely to benefit from surgery, are not penalised for doing so. A clear understanding of the stability through time of the risk adjustment model is thus important to give confidence to surgeons that the model in use is relevant and applicable to current surgical practice.

**Data**

Data were obtained from the National Ophthalmology Database (NOD) through a data sharing agreement with the data controller, the Health Quality Improvement Partnership (HQIP). Data were cleaned prior to transfer with data available for analysis on 602,459 operations on 404,857 patients from 2000 to 2014. PCR data was available for all operations and was recorded as having occurred in 10,960 (1.82%) operations.

**Analysis**

Three approaches to candidate risk predictor selection for model building were used:

a) A clinically sound list of predictors; b) Chi-square p-value p<0.10 for predictors to exclude at the outset those unlikely to be statistically important; c) Univariate regression effect size satisfying 0.9>OR>1.20 to exclude small and therefore clinically unimportant effects. Table 1 provides a bivariate analysis of the data with regard to candidate risk indicators for PCR.

Table 1. Bivariate analysis of candidate risk indicators for PCR

|  |  |  |  |
| --- | --- | --- | --- |
| Characteristic (%;n [in the whole sample of eyes]) | Eyes with PCR: %;n [in given subgroup] | Chi-square;df;p | Odds-ratio\*;p |
| ***PATIENT***  |  |  |  |
| **Gender** |  |  |  |
| Female (59.35%;357,555) | 1.75%;6,241 | 26.781;1;<0.001 | 1.106;<0.001 |
| Male (40.65%;244,904) | 1.93%;4,719 |
| **Age** |  |  |  |
| <70yo (25.11%;151,294) | 1.59%;2,407 | 227.278;5;<0.001 | Ref. category |
| 70–74 years (15.72%;94,699) | 1.73%;1,641 | 1.091;0.007 |
| 75–79 years (21.28%;128,188) | 1.66%;2,133 | 1.047;0.128 |
| 80–84 years (20.94%;126,129) | 1.93%;2,439 | 1.220;<0.001 |
| 85–89 years (12.66%;76,293) | 2.17%;1,654 | 1.371;<0.001 |
|  ≥90 years (4.29%;25,856) | 2.65%;686 | 1.686;<0.001 |
| **Eye** |  |  |  |
| Right Eye (50.82%;306,144) | 1.81%;5,545 | 0.222;1;0.638 | 1.009;0.638 |
| Left Eye (49.18%;296,315) | 1.83%;5,415 |
| **First-second eye** |  |  |  |
| First eye operated (57.40%;345,837) | 1.88%;6,517 | 19.325;1;<0.001 | 0.917;<0.001 |
| Second eye operated (42.60%;256,622) | 1.73%;4,443 |
| **Socio-economic class (IMD)** |  |  |  |
| 1st quintile (20.00%;120,519) | 1.65%;1,990 | 165.771;4;<0.001 | Ref. category |
| 2nd quintile (20.00%;120, 492) | 1.70%;2,045 | 1.028;0.379 |
| 3rd quintile (20.00%;120,481) | 1.64%;1,972 | 0.991;0.781 |
| 4th quintile (20.00%;120,491) | 1.89%;2,272 | 1.145;<0.001 |
| 5th quintile (20.00%;120,476) | 2.23%;2,681 | 1.356;<0.001 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Socio-economic class (IMD)- shortened** |  |  |  |
| 1-3 quintile (60.00%;361,492) | 1.66%;6,007 | 125.501;1;<0.001 | 1.242;<0.001 |
| 4-5 quintile (40.00%;240,967) | 2.06%;4,953 |
| **Patient is diabetic** |  |  |  |
| No (82.15%;494,921)  | 1.78%;8,807 | 24.510;1;<0.001 | 1.128;<0.001 |
| Yes (17.85%;107,538) | 2.00%;2,153 |
| **Alpha-blockers** |  |  |  |
| No alpha-blockers (94.16%;567,294) | 1.82%;10,328 | 0.101;1;<0.751 | 0.987;<0.751 |
| Alpha-blockers (5.84%;35,165) | 1.80%;632 |
| ***EYE/OCULAR CO-MORBIDITIES*** |  |  |  |
| **Patient has age-related macular degeneration**  |  |  |
| No (90.08%;542,721)  | 1.82%;9,861 | 0.156;1;0.693 | 1.013;0.693 |
| Yes (9.92%;59,738) | 1.84%;1,099 |
| **Patient has amblyopia** |  |  |  |
| No (98.46%;593,175) | 1.81%;10,712 | 38.327;1;<0.001 | 1.492;<0.001 |
| Yes (1.54%;9,284) | 2.67%;248 |
| **Patient has corneal pathology** |  |  |  |
| No (97.38%;586,681) | 1.81%;10,647 | 2.457;1;0.117 | 1.095;0.117 |
| Yes (2.62%;15,778) | 1.98%;313 |
| **Patient has diabetic retinopathy** |  |  |  |
| No (94.60%;569,914) | 1.80%;10.272 | 16.738;1;<0.001 | 1.177;<0.001 |
| Yes (5.40%;32,545) | 2.11%;688 |
| **Patient has glaucoma** |  |  |  |
| No (91.45%;550,921) | 1.80%;9,902 | 17.225;1;<0.001 | 1.145;<0.001 |
| Yes (8.55%;51,538) | 2.05%;1,058 |
| **Patient has high myopia** |  |  |  |
| No (96.16%;579,343) | 1.81%;10,508 | 2.495;1;0.114 | 1.080;0.114 |
| Yes (3.84%;23,116) | 1.96%;452 |
| **Patient has an inherited eye disease** |  |  |  |
| No (99.85%;601,543)  | 1.82%;10,948 | 1.332;1;0.249 | 0.716;0.251 |
| Yes (0.15%;916) | 1.31%;12 |
| **Patient has optic nerve or central nervous system disease** |  |  |
| No (99.60%;600,062) | 1.82%;10,927 | 2.638;1;0.104 | 0.753;0.105 |
| Yes (0.40%;2,397) | 1.38%;33 |
| **Eye has uveitis / synechiae at the time of surgery** |  |  |
| No (99.04%;596,669) | 1.81%;10,820 | 11.734;1;0.001 | 1.342;0.001 |
| Yes (0.96%;5,790) | 2.42%;140 |
| **Eye has psuedoexfoliation / phacodonesis at the time of surgery** |  |  |
| No (98.89%;595,749) | 1.78%;10,577 | 574,971;1;<0.001 | 3.349;>0.001 |
| Yes (1.11%;6,710) | 5.71%;383 |
| **Eye has a brunescent / white mature cataract** |  |  |
| No (96.71%;582,631) | 1.69%;9,842 | 1,674;1;<0.001 | 3.478;>0.001 |
| Yes (3.29%;19,828) | 5.64%;1,118 |
| **Eye has no fundal view / vitreous opacities at the time of surgery** |  |  |
| No (99.09%;596,977) | 1.78%;10,647 | 468,796;1;0.001 | 3.335;>0.001 |
| Yes (0.91%;5,482) | 5.71%;313 |
| **Eye has other macular pathology at the time of surgery** |  |  |
| No (98.65%;594,298) | 1.82%;10,836 | 4.163;1;0.041 | 0.831;0.042 |
| Yes (1.35%;8,161) | 1.52%;124 |
| **Eye has other retinal pathology at the time of surgery** |  |  |
| No (99.03%;596,592) | 1.82%;10,839 | 1.961;1;0.161 | 1.138;0.162 |
| Yes (0.97%;5,867) | 2.06%;121 |
| **Eye has undergone vitrectomy surgery (Retinal detachment’)** |  |  |
| No (98.24%;591,880) | 1.82%;10,747 | 2.274;1;0.132 | 1.111;0.132 |
| Yes (1.76%;10,579) | 2.01%;213 |
| **Eye has previously undergone trabeculectomy surgery** |  |  |
| No (99.49%;599,391) | 1.81%;10,874 | 16.714;1;<0.001 | 1.561;<0.001 |
| Yes (0.51%;3,068) | 2.80%;86 |
| **Eye has any other ocular co-pathology** |  |  |  |
| No (96.29%;580,137) | 1.77%;10,264 | 218.926;1;<0.001 | 1.787;<0.001 |
| Yes (3.71%;22,322) | 3.12%;696 |
| ***Axial length measurement*** |  |  |  |
| <21mm (0.17%;1,012) | 3.06%;31 | 11.552;2;0.003 | 1.710;0.003 |
| 21-28mm (98.62%;594,123) | 1.81%;10,777 | Ref. category |
| >28mm (1.22%;7,324) | 2.08%;152  | 1.147;0.096 |
| **Pre-op Visual Acuity** |  |  |  |
| <0.00 LogMAR (0.58%;2,924) | 1.06%;31 | 1,182.480;5;<0.001 | Ref. category |
| 0.00–0.30 LogMAR (34.21%;171,910) | 1.43%;2,463 | 1.356;0.093 |
| 0.31–0.60 LogMAR (35.32%;177,514) | 1.61%;2,855 | 1.525;0.020 |
| 0.61–0.90 LogMAR (13.03%;65,494) | 1.90%;1,246 | 1.810;0.001 |
| 0.91–1.20 LogMAR (7.04%;35,356) | 2.08%;735 | 1.981;<0.001 |
| >1.20 LogMAR (9.82%;49,361) | 3.69%;1,823 | 3.579;<0.001 |
| **Pre-op Visual Acuity- shortened** |  |  |  |
| <=0.60 LogMAR (70.11%;352,348) | 1.52%;5,349 | 605.978;1;<0.001 | 1.686;<0.001 |
| >0.60 LogMAR (29.89%;150,211) | 2.53%;3,804 |
| ***OPERATIVE ISSUES*** |  |  |  |
| **Bilateral operation** |  |  |  |
| Not bilateral operation (99.70%;600,545) | 1.82%;10,926 | 0.020;1;0.888 | 0.976;0.888 |
| Bilateral operation (0.30%;1,914) | 1.78%;34 |
| **Patient able to lie flat**  |  |  |  |
| patient was able to lie flat (99.24%;597,887) | 1.82%;10,855 | 5.787;1;0.015 | 1.271;0.016 |
| patient was not able to lie flat (0.76%;4,572) | 2.30%;105 |
| **Patient was able to cooperate** |  |  |  |
| patient cooperated (99.35%;598,550) | 1.82%;10,899 | 1.474;1;0.225 | 0.855;0.225 |
| patient did not cooperate (0.65%;3,909) | 1.56%;61 |
| **Pupil size** |  |  |  |
| Large (81.18%;21,727) | 1.72%;8,435 | 299.931;2;<0.001 | Ref. Category  |
| Medium (15.22%;91,668) | 1.98%;1,815 | 1.152;<0.001 |
| Small (3.61%;489,064) | 3.29%;714 | 1.937;<0.001 |
| ***SURGEON CHARACTERISTICS*** |  |  |
| ***Surgeon grade*** |  |  |  |
| Consultant (58.00%;349,421) | 1.47%;5,144 | 1,122.430;3;<0.001 | Ref. Category |
| Independent non-consultant (13.13%;79,127) | 1.58%;1,250 | 1.074;0.024 |
| Experienced trainee (24.84%;149,644) | 2.43%;3,637 | 1.667;<0.001 |
| Inexperienced trainee (4.03%;24,267) | 3.83%;929 | 2.664;<0.001 |

In order to account for the structure of the data, four statistical approaches were initially used:

1. A naïve approach in which nesting of eyes within patients was ignored; 2. Robust standard errors; 3. Generalized estimating equations; and 4. Multilevel modelling. *Each of these resulted in the same set of candidate predictors so in order to simplify the analysis for the focus on stability through time, only the naïve approach (ignoring the data structure) was taken forward to the next stage*.

To ensure that sufficient data was present for each year to be included in the annual comparisons through time the number of operations and presence of the candidate predictors in each year was checked. It was found that the early years did not contain sufficient numbers for credible analysis and the most recent decade only, from 2005 to 2014 was therefore accepted for further analysis.

Model stability was assessed by several methods

* The consistency of inclusion of candidate predictors when offered to models for each year individually
	+ assesses as the number of times individual candidate predictors showed up across all the years
* Comparison of performance measures across the years
	+ Calibration:
		- linear intercept and slope of regressions of predicted probabilities vs. observed for each of the years
		- separate graphs for years depicted PCR rates per decile of estimated probability (horizontal axis) against both the average predicted PCR probability for the decile and the observed PCR rate for the decile (vertical axis)
	+ Discrimination: c-statistics for individual years
* Assessment of stability of model parameters across years
	+ explored by inclusion of year as a factor in the model
	+ exploration of groupings of years to clarify regions of stability and instability across the decade

These methods were applied in turn to the three approaches to risk predictor selection: a) A clinically sound predictors; b) Chi-square p-value p<0.10; c) Univariate regression effect size satisfying 0.9>OR>1.20.

**Results**

The stability through time findings from the three approaches (a,b,c) were similar. In order to avoid repetition of similar results, and in the interests of keeping this document a manageable size, only approach ‘b’ will be included in detail in this report.

**Model based on the list of factors with univariate Chi-square p-value p<0.10**

For years 2005-2014 this model took the form presented in Table 2. The model is relatively parsimonious with 14 predictors with moderate fit, C-stat=0.62.

Table 2. Significant predictors at the P<0.05 level in the multivariable model.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PCR | Odds Ratio | Std. Err. | z | P>z | 95% CI |
|  C-stat=0.62 |   |   |   |   |   |   |
| amblyopia | 1.24 | 0.085 | 3.1 | 0.002 | 1.08 | 1.41 |
| glaucoma | 1.08 | 0.037 | 2.2 | 0.027 | 1.01 | 1.15 |
| psuedophaco | 2.32 | 0.134 | 14.6 | 0.000 | 2.08 | 2.60 |
| brunescent | 2.17 | 0.083 | 20.2 | 0.000 | 2.01 | 2.34 |
| Nofund | 1.29 | 0.087 | 3.8 | 0.000 | 1.13 | 1.48 |
| Othmac | 0.82 | 0.075 | -2.2 | 0.027 | 0.68 | 0.98 |
| othercopath | 1.61 | 0.067 | 11.6 | 0.000 | 1.49 | 1.75 |
| preVACAT\_d1 | 1.10 | 0.029 | 3.6 | 0.000 | 1.04 | 1.16 |
| preVACAT\_d2 | 1.32 | 0.044 | 8.2 | 0.000 | 1.23 | 1.41 |
| preVACAT\_d3 | 1.43 | 0.058 | 8.8 | 0.000 | 1.32 | 1.55 |
| preVACAT\_d4 | 1.99 | 0.067 | 20.5 | 0.000 | 1.87 | 2.13 |
| Gender | 1.10 | 0.023 | 4.4 | 0.000 | 1.05 | 1.14 |
| age\_d1 | 1.18 | 0.040 | 4.9 | 0.000 | 1.10 | 1.26 |
| age\_d2 | 1.15 | 0.036 | 4.3 | 0.000 | 1.08 | 1.22 |
| age\_d3 | 1.34 | 0.041 | 9.4 | 0.000 | 1.26 | 1.42 |
| age\_d4 | 1.43 | 0.049 | 10.3 | 0.000 | 1.33 | 1.53 |
| age\_d5 | 1.66 | 0.077 | 10.9 | 0.000 | 1.52 | 1.82 |
| 1st or 2nd eye | 0.95 | 0.020 | -2.5 | 0.012 | 0.91 | 0.99 |
| imd\_d1 | 0.99 | 0.033 | -0.3 | 0.804 | 0.93 | 1.06 |
| imd\_d2 | 0.96 | 0.032 | -1.2 | 0.229 | 0.90 | 1.03 |
| imd\_d3 | 1.08 | 0.035 | 2.5 | 0.012 | 1.02 | 1.16 |
| imd\_d4 | 1.21 | 0.038 | 5.9 | 0.000 | 1.13 | 1.28 |
| isdiabetic | 1.12 | 0.028 | 4.4 | 0.000 | 1.06 | 1.18 |
| pupil\_d1 | 1.09 | 0.030 | 3.3 | 0.001 | 1.04 | 1.15 |
| pupil\_d2 | 1.45 | 0.062 | 8.6 | 0.000 | 1.33 | 1.58 |
| cons | 0.01 | 0.000 | -121.5 | 0.000 | 0.01 | 0.01 |

*Consistency of predictors across years*

Indicators highlighted in red were not present reliably in all 10 years when these were separately modelled. Frequencies were, glaucoma 4/10, other macular degeneration 6/10, and 1st or 2nd eye operated 7/10. All the other predictors were consistently present in each year separately, 10/10.

*Consistency of performance measures across the years*

As seen in Table 3, a change in intercept arose in 2012, accentuated in 2013 and 2014 indicating a shift in calibration in later years. Slopes and C-statistics were consistent throughout.

Table 3. Calibration and Discrimination: Linear intercept, slope and C-statistics for individual years

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Year** | **Intercept (calibration)** | **Slope (calibration)** |  | **C-stat (discrimination)** |
| 2005 | 0.23 | 0.93 |  | 0.61 |
| 2006 | 0.12 | 0.98 |  | 0.62 |
| 2007 | 0.13 | 1.10 |  | 0.63 |
| 2008 | 0.04 | 1.05 |  | 0.63 |
| 2009 | 0.11 | 1.15 |  | 0.63 |
| 2010 | 0.12 | 0.92 |  | 0.61 |
| 2011 | 0.07 | 0.94 |  | 0.61 |
| 2012 | -0.03 | 0.99 |  | 0.61 |
| 2013 | -0.26 | 1.00 |  | 0.62 |
| 2014 | -0.26 | 0.92 |  | 0.61 |
| Mean | **0.03** | **1.00** |  | **0.62** |
| SD | **0.16** | **0.08** |  | **0.01** |

Calibration plots are presented in Figure 1 showing the graphs for individual years of proportions of PCR vs. deciles of the estimated probabilities of PCR. Graphs show both predicted values and observed values. The proximity of the blue (estimated) and the red (observed) dots in each estimated probability of PCR indicates reasonably close agreement between model estimation and observed probabilities across the deciles of the estimated probabilities of PCR.

Figure 1. Calibration plots for each year showing proportions of PCR vs. deciles for both predicted values and observed values.

|  |  |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

Table 4. Significance of including year as a predictor in the model. Both global tests (LR & Wald) are highly significant indicating variation between years with individual year indices confirming that the discrepancy arises from the year 2012 onwards.

|  |  |  |
| --- | --- | --- |
| **Year of Surgery** | **OR** | **P** |
| 2005 | Reference category |
| 2006 | 0.90 | 0.079 |
| 2007 | 0.90 | 0.070 |
| 2008 | 0.84 | 0.001 |
| 2009 | 0.89 | 0.030 |
| 2010 | 0.90 | 0.038 |
| 2011 | 0.85 | 0.002 |
| 2012 | 0.78 | 0.000 |
| 2013 | 0.64 | 0.000 |
| 2014 | 0.64 | 0.000 |
|  |  |  |
| **LR chi2** | **195.03** |   |
| **p** | **<0.001** |   |
| **Wald chi2** | **188.73** |   |
| **P** | **<0.001** |   |

Table 5. Assessment of temporal stability through time by likelihood ratio tests for groupings of years. These tests illustrate a change in stability with 2012 manifesting as a ‘rogue year’, followed by establishment of a new (different) model stability of the final two years in 2013 and 2014.



The other two approaches to selection of candidate predictors revealed broadly similar patterns of stability and instability through time with the pivot year at 2012.

**Conclusions**

These analyses have revealed that stability of the risk model for PCR existed from 2005-2011 with a ‘rogue year’ at 2012 followed by two stable years, 2013 and 2014. It will be interesting to undertake similar analyses on more recent data to assess stability forward of 2014. The importance of these analyses is that these insights provide guidance as to the frequency with which models for risk adjustment of surgeons’ outcomes should be refreshed.

Analyses: Mariusz Grzeda

Written: John Sparrow