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A contemporary risk model for predicting 30-day mortality following percutaneous coronary intervention in England and Wales

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ABSTRACT

Background: The current risk model for percutaneous coronary intervention (PCI) in the UK is based on outcomes of patients treated in a different era of interventional cardiology. This study aimed to create a new model, based on a contemporary cohort of PCI treated patients, which would: predict 30 day mortality; provide good discrimination; and be well calibrated across a broad risk-spectrum.
Methods and results: The model was derived from a training dataset of 336,433 PCI cases carried out between 2007 and 2011 in England and Wales, with 30 day mortality provided by record linkage. Candidate variables were selected on the basis of clinical consensus and data quality. Procedures in 2012 were used to perform temporal validation of the model. The strongest predictors of 30-day mortality were: cardiogenic shock; dialysis; and the indication for PCI and the degree of urgency with which it was performed. The model had an area under the receiver operator characteristic curve of 0.85 on the training data and 0.86 on validation. Calibration plots indicated a good model fit on development which was maintained on validation.
Conclusion: We have created a contemporary model for PCI that encompasses a range of clinical risk, from stable elective PCI to emergency primary PCI and cardiogenic shock. The model is easy to apply and based on data reported in national registries. It has a high degree of discrimination and is well calibrated across the risk spectrum. The examination of key outcomes in PCI audit can be improved with this risk-adjusted model.

1. Introduction

In the UK National Health Service (NHS), efforts to improve the outcomes of coronary revascularisation have received coordinated attention since March 2000 [1]. More recently, the outcomes for units, and now clinicians, have been published —starting with ten surgical domains as part of the "candour" agenda of opening up NHS performance data to public scrutiny [2].

The British Cardiovascular Intervention Society (BCIS, www.bcis.org.uk) is the professional body representing all those involved in the field of interventional cardiology. Since 2005, BCIS has incorporated patient-level data in its long running annual audit of all percutaneous coronary intervention (PCI) procedures performed in the UK. This audit is used for benchmarking performance to help improve services and underpin clinical governance [3]. Due to wide variations in case mix between both operators and PCI centres, crude mortality metrics cannot be used to compare clinical and procedural outcomes. Using index cases to compare outcomes for patients with more homogenous clinical features has several limitations. The preferred approach is to use risk-adjustment techniques that take into account the variability of expected outcomes for patients who present with different combinations of risk factors [4].

Abbreviations: AUC, area under the receiver operating characteristic curve; BCIS, British Cardiovascular Intervention Society; LVEF, left ventricular ejection fraction; NHS, (UK) National Health Service; MI, myocardial infarction; NICOR, National Institute for Cardiovascular Outcomes Research; NWQIP, North West Quality Improvement Programme; PCI, percutaneous coronary intervention.

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The North West Quality Improvement Programme (NWQIP) model has been used for risk-adjusted outcome surveillance since 2006 [5]. This model was developed from data on patients treated in North West of England between 2001 and 2003. Since then there have been major changes in PCI techniques, adjunctive therapies, and in clinical indications for PCI. In 2003 the mainstay of treatment for patients with ST elevation myocardial infarction (MI) was thrombolysis, but by 2012, over 93% of patients were treated with primary PCI [6]. The NWQIP model has been used over this time to adjust for case-mix when auditing the outcomes of PCI. Since the NWQIP model was developed, more than a decade ago, there have been changes in case-mix and clinical practise, most significantly the systematic uptake of primary PCI. Evaluation in a contemporary cohort from the BCIS dataset suggests that while the model retains reasonable overall discrimination for major adverse cerebrovascular or cardiovascular events (MACCEs) it has been subject to significant calibration drift with consistent over-prediction of risk (see Supplementary materials). This inaccuracy demands a new model based on contemporary data. For UK national audit purposes both the data and models need quality assurance. The quality of current adverse event reporting depends on local practises at PCI centres. In this regard, in spite of a series of internal validation checks on data consistency, there are substantial variations in the quality of the audit data returned by different centres [7].

The aim of this study was to produce an updated robust risk adjustment model with good discrimination and correct calibration for contemporary PCI practise in the UK. A similar updating exercise has recently been undertaken in the National Cardiovascular Data Registry in the US [8]. We chose to assess 30 day mortality rather than in-hospital major adverse cerebrovascular or cardiovascular event because the former can be derived from linkage with the Office for National Statistics records (a consistent end point that is not influenced by local variation in data completeness). We excluded patients suffering a cardiac arrest and being treated outside of hospital prior to PCI because this group contains a heterogeneous combination of patients with different risk profiles, and also because of concerns that including such patients might lead to inappropriately risk-averse clinical behaviour [9].

2. Material and methods

2.1. Definition of dataset and pre-processing

The BCIS database comprises 113 variables describing baseline demographics, clinical presentation, procedural details and outcomes to hospital discharge. Data for all procedures performed in the UK are collected at each PCI centre, encrypted and then uploaded to servers now hosted by the National Institute for Clinical Outcomes Research (NICOR) based at University College London [3]. The Office for National Statistics provides reliable independent tracking of mortality (for patients living in England and Wales only), using linkage by each patient's unique identifier. Cases in Scotland and Northern Ireland were therefore excluded from the model development. Linkage was carried out by the Medical Research Information Service on behalf of NICOR. Analysis was conducted at the University of Manchester with Local Research Ethics Committee approval (reference no.11/NW/0694). The data were cleaned and analysed using Stata® MP v11.2 (StataCorp LP).

Although there is no independent validation of data entry, a number of range checks and assessments of internal validity are applied as data are uploaded to NICOR. We performed a sequence of further procedures to clean the dataset. A number of exclusion criteria were applied (Fig. 1). We limited our analysis to patients aged over 18 and under 100 at the time of procedure. Patients outside of these age limits are small in number, but could contribute disproportionately to outcomes. Patients without tracked mortality data were also excluded (this excluded group incorporating all patients from Scotland and Northern Ireland). Patients who were ventilated before PCI were also excluded, this field being used as a proxy indicator for out of hospital cardiac arrest.

A total of 1112 procedures were identified as likely duplicate entries and were also excluded. These were identified by comparing records across age, gender, pseudonymised hospital identifier, pseudonymised patient identifier, pseudonymised date of operation, month of operation, time of operation, urgency, clinical indication for procedure and status at discharge. Data used for the final model are available from the authors where the requester has sought permission from NICOR.

2.2. Variable selection and definition

Of the available fields in the BCIS dataset, a shortlist of 10 candidate risk factors was identified by the authors on the basis of clinical consensus and data quality. As the model was intended to be used to predict outcome before the start of a procedure, variables relating to decisions or events occurring during or after the procedure were excluded.

Age at procedure was given in years and months. For modelling, age was mean-centred within the development cohort (mean = 64.8 years); a quadratic age term was also explored. Diabetes was defined as present whether patients were diet controlled, or treated with medication including insulin. Serum creatinine levels were only recently added to the dataset and were therefore missing in earlier years of the development cohort. However, a binary variable indicating whether creatinine measures were greater than 200 μmol/l was available throughout the time period, so this was used as the measure of renal function. Use of dialysis for acute or chronic renal failure was also recorded, and if both this and a creatinine measure of >200 μmol/l were present, the patient was assigned to the 'dialysis' group. Patients with functioning transplants were grouped with those who had no renal impairment, unless on dialysis or with a creatinine >200 μmol/l.

Definitions of the fields are available online (www.ucl.ac.uk/nicor/audits/adultpercutaneous/datasets). Clinical indication for PCI procedure is recorded as one of 12 possible options in the database. For the purposes of this model we derived a simpler five-group classification to combine the clinical indication and the urgency of the procedure, to avoid the problem of collinearity between these two variables. These groups are described in Table 1.

There were insufficient data available on ethnicity of patients to consider this as a variable in the model. We did not include a measure of left ventricular ejection fraction as data on this characteristic were missing in 50.7% of all patients, and in 67.4% of emergency or salvage patients. Furthermore, not only is LV function rarely known at the time of emergency PCI for STEMI, but also can be labile following intervention. Sensitivity analysis was conducted to evaluate alternative modelling strategies which would enable the inclusion of this risk factor; firstly in a model trained only on cases where data on this risk factor were available, and secondly on a fully multiply-imputed training dataset.

2.3. Missing data handling

The percentage of data missing in the shortlisted variables is shown in Table 2. Before excluding patients aged over 100, in cases where age at procedure was recorded as greater than 120 years this was assumed to be erroneous and re-coded as missing. Missing age values in the development cohort were replaced with the median by gender within that cohort (males 63.6 years, females, 69.6 years). The same values were used to replace missing age values in the training cohort, as it was assumed that during model use the median population ages might not be available. For categorical variables, missing values were assigned to the baseline category i.e. it was assumed that if a risk factor was not recorded then it was absent. This represents a plausible missing not at random mechanism that is likely to operate in this case (multiple imputation assumes that data are missing at random), and incentivises