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Development and validation of a novel risk score for primary percutaneous coronary intervention for ST elevation myocardial infarction

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ABSTRACT

Background: Primary percutaneous coronary intervention (PPCI) is the default treatment for patients with ST elevation myocardial infarction (STEMI) and carries a higher risk of adverse outcomes when compared with elective and urgent PCI. Conventional PCI risk scores tend to be complex and may underestimate the risk associated with PPCI due to under-representation of patients with STEMI in their datasets. This study aimed to develop a simple, practical and contemporary risk model to provide risk stratification in PPCI.

Methods: Demographic, clinical and outcome data were collected for all patients who underwent PPCI between January 2009 and October 2013 at the Northern General Hospital, Sheffield. Multiple regression analysis was used to identify independent predictors of mortality and to construct a risk model. This model was then separately validated on an internal and external dataset.

Results: The derivation cohort included 2,870 patients with a 30-day mortality of 5.1% (145 patients). Only four variables were required to predict 30-day mortality: age [OR:1.047, 95% CI:1.031-1.063], call-to-balloon (CTB) time [OR:1.829, 95% CI:1.198-2.791], cardiogenic shock [OR:13.886, 95% CI:8.284-23.275] and congestive heart failure [OR:3.169, 95% CI:1.420-7.072]. Internal validation was performed in 693 patients and external validation in 660 patients undergoing PPCI. Our model showed excellent discrimination on ROC-curve analysis (C-Stat = 0.87 internal and 0.86, external), and excellent calibration on Hosmer-Lemeshow testing (p=0.37 internal, 0.55 external).

Conclusions: We have developed a bedside risk model which can predict 30-day mortality after PPCI using only four variables: age, CTB time, congestive heart failure and shock.

Background

Primary percutaneous coronary intervention (PPCI) is the preferred revascularisation treatment for ST-elevation myocardial infarction (STEMI)[1, 2]. Compared with PCI for elective and urgent PCI, PPCI carries a higher risk of adverse outcomes [3]. Early identification of these risks and their likely effect on patient outcomes enables care to be tailored to the individual. Under-use of risk scores is common due to their complexity, and inclusion of variables that are not readily available at the bedside in an emergency situation. Conventional PCI risk scores may underestimate the risk associated with PPCI due to under-representation of patients with STEMI in their datasets [3-9]. Currently there are very few dedicated PPCI risk scores and many are based on outdated data [10-12]. A recent model aimed at PPCI, excluded many high-risk but low-incidence variables such as shock, limiting its ability to identify the highest risk patients [13]. Other studies have included many variables, but few are immediately available when a patient presents with STEMI [14, 15], limiting their use in the acute setting. This study therefore aimed to develop a simple and practical risk model from contemporary data to provide risk stratification in the emergency room or ambulance before PPCI is undertaken.

METHODS

We constructed a PPCI risk score by examining the procedural and clinical database of the Northern General Hospital Sheffield, a tertiary interventional Cardiology centre providing PPCI services for a population of 1.8 million people in the north of England. This centre performs approximately 700 PPCI per annum. We examined the records of all patients who underwent PPCI between January 2009 and October 2013. In Sheffield risk data is currently

gathered via the New York Risk Score, we tested the calibration and discrimination of this model on our data using Hosmer-Lemeshow testing and ROC-curve analysis respectively.

In order to create our risk model only variables that are readily available at the bedside pre-PCI were included in the analysis. For each patient we gathered information on age, sex, 'call-to-balloon' (CTB) time, haemodynamic state (cardiogenic shock), previous MI, diabetes, smoking status, a prior cerebrovascular event, significant valvular heart disease, hypercholesterolemia, hypertension, peripheral vascular disease, congestive cardiac failure and renal failure (see appendix for definitions). Age was analysed as both continuous and binary with different thresholds for binary split analysed. The primary outcome was 30-day mortality. Univariate logistic regression was used to assess the effect of each variable upon 30-day mortality. A threshold of $p<0.05$ was used for entry into multivariate analysis. Significant univariate predictors of 30-day mortality were then entered into a backward stepwise logistic regression with $p\leq0.01$ as the threshold for entry into the final model. To avoid 'complete case' bias, we used *multiple imputation*, in which missing data are replaced with substituted values, whilst accounting for uncertainty by creating multiple plausible estimates [16, 17]. Internal validation was performed on patients undergoing PPCI in Sheffield between November 2013 and October 2014. External validation was performed on a cohort of PPCI patients from Manchester Royal Infirmary who had been treated between 2012 and 2014. Discrimination of the model was determined with ROC-curve analysis [18]. Calibration of the model was measured by the Hosmer-Lemeshow test. A P-value of <0.05 indicated statistical significance.

RESULTS

2564 patients had sufficient data to calculate a risk probability using the New York risk model. 132 (5.14%) of these patients were dead at 30-days. The New York risk score produced a C-statistic of 0.847 under ROC-curve analysis indicating excellent discrimination. The ROC-curve can be seen in Figure 1a. However Hosmer-Lemeshow testing indicated that there was a significant difference between the predicted and observed values (p=0.003).

The derivation cohort included 2,870 patients who underwent PPCI at Sheffield. Of these, 145 (5.1%) patients had died by 30 days. The average age of the patients that died was 69 years vs 61 for the survivors. Age was split into ≤70 vs >70 years with mortality rates of 3.6% vs 9.2% respectively. Variables with a significant univariate relationship with 30-day mortality included age, CTB time, shock, congestive heart failure, peripheral arterial disease, renal failure, prior cerebrovascular accident, and sex **(Table 1)**. Following multivariate logistic regression analysis, four variables were found to be significant; age (P<0.001, OR: 1.047, CI: 1.031-1.063), CTB time (P=0.005, OR: 1.829, CI: 1.198-2.791), shock (P<0.001, OR: 13.886, CI: 8.284-23.275) and congestive heart failure (P=0.006, OR: 3.169, CI: 1.420-7.072) **(Table 2)**. The results of this analysis were used to create the following equation for the probability (p) of a patient dying.

$$p = \frac{e^{(0.046\boldsymbol{A}+0.604\boldsymbol{B}+2.631\boldsymbol{C}+1.153\boldsymbol{D}-6.582)}}{(1+e^{(0.046\boldsymbol{A}+0.604\boldsymbol{B}+2.631\boldsymbol{C}+1.153\boldsymbol{D}-6.582)})}$$

Where **A** = age, **B** = CTB time, **C** = shock, and **D** = congestive heart failure.

When applying this equation to the original dataset, 2491 patients had sufficient data to calculate a probability. 2328 (93%) patients had predicted risks of between 0 and 10% and 36 (1.4%) had a predicted risk above 50%. Hosmer-Lemeshow test indicated that there was no significant difference between the observed and predicted number of deaths (p=0.66). ROC-

curve analysis produced a C-statistic of 0.839 indicating excellent discrimination **(Figure 1b)**. A user friendly version app has been created to facilitate the use of this risk score.[19]

Internal Validation

The model was internally validated on patients who underwent PPCI in Sheffield between November 2013 and October 2014. In total 693 patients underwent PPCI during this period and of these 44 (6.3%) died. The mean age of these patients was 62 years, and the mean age of survivors vs those who died was 61 vs 72 years. Twenty five patients had cardiogenic shock, and of these 12 (48%) died; 10 had congestive heart failure and of these 4 (40%) died; and 165 had a CTB time ≥3h, and of these 15 (9.1%) died. 614 patients had sufficient data to calculate a risk probability, and of these 569 (93%) patients had a predicted risk 0-10% and 4 (0.8%) had a predicted risk >50%. ROC-Curve analysis yielded a C-statistic of 0.87 indicating excellent discrimination **(Figure 1c)**, and Hosmer-Lemeshow testing was insignificant (P=0.37) indicating no significant difference between the number of predicted and observed deaths.

External Validation

Data were collected from 1474 patients who underwent PPCI between January 2012 and December 2014 at Manchester Royal Infirmary. In total 100 patients died by 30 days (6.7%). Their average age was 61, and the mean age of survivors vs those who died was 60 vs 70 years. 74 patients had cardiogenic shock, and of these 32 (43.2%) died; 274 patients had CTB time ≥3h, and of these 28 (10.2%); and 101 patients had congestive heart failure, of which 27 (26.7%) died. 660 patients had data sufficient to calculate a risk probability, and of these 591 (90%) had a predicted risk 0-10%, and 21 (3.1%) a predicted risk >50%. The model was

shown to have excellent discrimination (C-statistic = 0.86) on ROC-curve analysis **(Figure 1d)**, and excellent calibration on Hosmer-Lemeshow test (p=0.55) indicating no significant difference between predicted and observed values.

DISCUSSION

We have developed and validated a simple, practical, dedicated risk score for patients undergoing PPCI for STEMI. This score included four variables; age, CTB time, cardiogenic shock and congestive heart failure; these being clinical variables commonly available in the acute setting without the need to wait for the results of laboratory tests or the coronary angiogram.

Our study used a similar sample size (2870) to previous studies (1791 to 3252), has a similar mean patient age (62 years vs 59-61 in the CADILLAC, RISK PPCI, ZWOLLE and PAMI risk scores) [10-13] and a similar proportion of females (27% vs 27% in the CADILLAC, RISK PPCI, and PAMI risk studies). The Sheffield 30-day mortality rate was considerably higher than that of the older PPCI risk scores (5.1% vs 2.1% and 3.6% in the Cadillac, and Zwolle studies, respectively). It had a similar mortality rate to the RISK-PCI (2013) score (4.9%) and a lower mortality than the more contemporary validation sets (6.3% and 6.7% for the Sheffield, 2013-14, and Manchester, 2012-14, datasets respectively). This may be due to operators offering treatment to a wider range of patients, a lower threshold for PPCI in recent times, or a difference in demographics. The UK PCI mortality has steadily risen over the last decade, from 0.92% in 2007 to 1.9% in 2015 [20], a trend largely explained by the rapid expansion of PPCI in the UK in that era.

Age is an important predictor of mortality in many interventions, and particularly coronary interventions [21]. In our study the average age of those who died was 69 vs 61 for those who survived. Elderly patients represent a high risk group for adverse events in peri-procedural phase [22]. These patients can potentially be frail and have more comorbidities, which can lead to poor outcomes [23]. Indeed, in our cohort, patients over the age of 70 were more likely to have peripheral arterial disease (5.8% vs 18.3%), cerebrovascular event (1.7% vs 4.5%) and renal disease (0.6% vs 2.4%) than those under the age of 70 years.

Delays to treatment are of importance in STEMI [22, 23]. Although not known precisely at the time of presentation, we therefore also studied call-to-balloon (CTB) time, and divided them into CTB<3h vs ≥3h. There was no significant difference in age (62 vs 63 years), but a significantly higher rate of cardiogenic shock (4.4% vs 8.3%, P=<0.001), peripheral arterial disease (8.3% vs 11.3%, P=0.040) and congestive heart failure (1.6% vs 3.7%, P=0.003). .

Cardiogenic shock was the strongest predictor of 30-day mortality, albeit with a large confidence interval (9.1 – 24.1), probably because only 138 (4.8%) patients out of 2869 had this condition. Patients with shock were four years older than those without (66 vs 62 years) and were more likely to suffer from congestive heart failure (23.7 vs 1.0%, P=<0.001) and peripheral arterial disease (16.7% vs 8.6%, P=0.002). Shock is a major risk factor in PCI [24] and has been included in many of the major risk scores [3, 6, 9, 11, 12]. Congestive heart failure conferred a 3-fold higher risk of 30-day mortality than for patients without this condition. Patients with congestive heart failure were 7 years older than those without (69 vs 62 years) and more likely to suffer from peripheral arterial disease (23.6% vs 8,6%, P=<0.001). Congestive heart failure features in many risk scores [4, 5, 10-12], but there is

marked variation in how it is stratified. Many risk scores use either Killip or NYHA class to stratify heart failure [3, 6, 10-12]. In order to maximise sensitivity and simplify the process, we decided to include CHF as categorical variable (present or absent).

A simple and accurate bedside risk score for STEMI would be useful for early risk stratification. It would inform the judgment of a PCI operator, enabling them to more adequately prepare for a complex or hazardous procedure and contribute to the awareness of the risks by emergency department staff and cardiac catheterization laboratory staff. Early risk stratification also provides the patient and family with a fair indication of what might occur. In the most high risk cases, a judgment has to be made as to whether to undertake a procedure at all, and a numerical risk score can help contribute to that difficult decision. In addition, the score could, more accurately than currently available scores, allow for risk adjustment to published individual operator outcomes and help avoid risk adverse behaviour.

Limitations

The main limitation of the study is the relatively modest sample size derived from a single PPCI centre. This may have the consequence that infrequent but important conditions such as cancer may be under-represented. The advantage of a single centre approach is that the data are consistent. Another weakness of this analysis is inter-observer variability, such as precisely defining cardiogenic shock. In addition, some important variables were deliberately excluded, because of their not being immediately available, such as creatinine level or left ventricular ejection fraction. Also, CTB time is not strictly speaking a pre-procedural variable,

but it can be estimated with fair precision at the time of arrival of the patient (at least an estimate of > or <3h, as studied here.)

Conclusion

We have successfully created a bedside risk model which can predict 30-day mortality after primary PCI which has performed favourably at both internal and external validation. The model contains only four variables; age, CTB time, congestive heart failure and shock, all of which are available prior to PCI. This model can be used in a clinical setting. The model will need to be recalibrated from time to time, and in a larger cohort.

Conflicts of interest

All authors report no conflicts of interest relevant to this paper.

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Appendix
1 – Definitions

1.1 - Call to balloon time

This is the length of time elapsed between the patient calling for professional help and PCI.

1.2 - Shock

This was defined as blood pressure <90mmHg (or maintained by balloon pump/inotropes) with signs of hypoperfusion, e.g. impaired consciousness, oliguria, peripheral cyanosis and cold skin.

1.3 - History of renal disease

This was defined as a serum creatinine >200µmol/l, or dialysis dependence, or the presence of a functioning transplanted kidney.

1.4 – Diabetes

This refers to both Type 1 and Type 2 diabetes regardless of treatment regime.

1.5 – Previous MI

This is defined as any myocardial infarction which has occurred prior to the current period of care.

1.6 - New York Risk Score Definitions

All of the following definitions are quoted from the appendix of the paper for the New York risk score. [4]

1.6.1 – Haemodynamic state

Unstable patients were defined as those requiring mechanical or pharmacological support to maintain blood pressure or cardiac output. Patients in cardiogenic shock were defined as suffering from acute hypotension (systolic BP <80mmHg) or low cardiac index (<2.0 L/min^2) despite pharmacological or mechanical support.

1.6.2 – LV ejection fraction

This was the value of ejection fraction (as a percentage) taken closest to PCI. Missing values were combined with the ≥30% group and were treated as the reference group in this study. thrombus in the stented segment of the artery or adjacent area following a previous PCI.

1.6.3 – Peripheral arterial disease

This was defined as angiographic evidence of ≥50% stenosis in a major aortoiliac or femoral/popliteal vessel, previous surgery for this disease, absent femoral or pedal pulses or the inability to insert a catheter/intra-aortic balloon due to an iliac aneurysm or obstruction of the aortoiliac or femoral arteries.

1.6.4 – Congestive heart failure

CHF was diagnosed by the presence of one of the following: paroxysmal nocturnal dyspnoea, dyspnoea on exertion due to heart failure, or crackles or rales on the lungs.

1.6.5 – Left main stem disease

The patient has angiographic evidence of ≥50% stenosis in the left main coronary artery.

Table 1 – Summary Statistics and univariate analysis results

Continuous Variables		Overall (±SD)	Alive @ 30 days (±SD)	Dead @30 days (±SD)	P-Value	Odds ratio	Confidence interval	
							Lower	Upper
Average Age		62 (±12)	61 (±12)	69 (±12)	<0.001	1.053	1.038	1.068

Discrete Variables		Non-imputed		Pooled Imputer data					
		Count	Mortality %	Count	Mortality %	P-Value	Odds Ratio	Confidence Interval	
								Lower	Upper
Congestive Heart Failure	No	2546	4.2	16580	4.3	<0.001	15.917	9.012	28.113
	Yes	55	41.8	371	41				
Call to Balloon Time	<3hrs	2221	3.8	13795	4.0	<0.001	2.36	1.622	3.435
	≥3hrs	530	8.5	3306	9.1				
Shock	No	2731	3.1	16058	3.1	<0.001	20.611	13.687	31.039
	Yes	138	39.9	902	39.4				
Peripheral Arterial Disease	tab	2360	4.4	15379	4.3	<0.001	3.207	2.084	4.935
	Yes	235	12.8	1566	12.5				
Hx of Renal Disease	No	2837	4.9	17036	4.9	0.001	4.853	1.952	12.064
	Yes	30	20	181	19.9				
Cerebrovascular Accident	No	2800	4.9	16800	4.9	0.004	2.89	1.406	5.942
	Yes	70	12.9	420	12.9				
Gender	Male	2103	4.5	12618	4.5	0.031	1.474	1.036	2.098
	Female	767	6.5	4602	6.5				
Previous MI	No	2308	4.8	14322	5.0	0.89	0.938	0.576	1.528
	Yes	446	4.5	2782	4.9				
Diabetes	No	2434	4.5	15058	4.8	0.106	1.548	0.972	2.463
	Yes	337	6.8	2063	6.9				
Hypercholesterolaemia	Non Known	1839	5.5	11034	5.5	0.152	0.767	0.534	1.102
	Yes	1031	4.3	6186	4.3				
Hypertension	Non Known	1965	5.3	11790	5.3	0.387	0.849	0.586	1.230
	Yes	905	4.5	5430	4.5				
Smoking Status	Non Smoker	605	4.5	4979	5.9	--	--	--	--
	Previous	535	4.5	4271	5.9	0.967	1.005	0.573	1.765
	Current	981	2.8	7221	3.6	0.051	0.606	0.352	1.043

Table 2 - Results of backward stepwise logistic regression on imputed data

Variable	Odds Ratio	95% Confidence interval		P-value
		Lower	Upper	
AGE (<70, ≥70)	1.047	1.031	1.063	<0.001
CTB Time	1.829	1.198	2.791	0.005
Shock	13.886	8.284	23.275	<0.001
CHF	3.169	1.42	7.072	0.006

Highlights

- Current PCI risk models are complex and there is a lack of contemporary risk models specifically for STEMI patients undergoing Primary PCI.
- We have created a simple and effective risk model to predict 30-day mortality following a STEMI. We use only 4 readily available bedside variables; Age, Call to Balloon time, Congestive heart failure and Shock.
- Our model has performed favourably in both internal and external validation

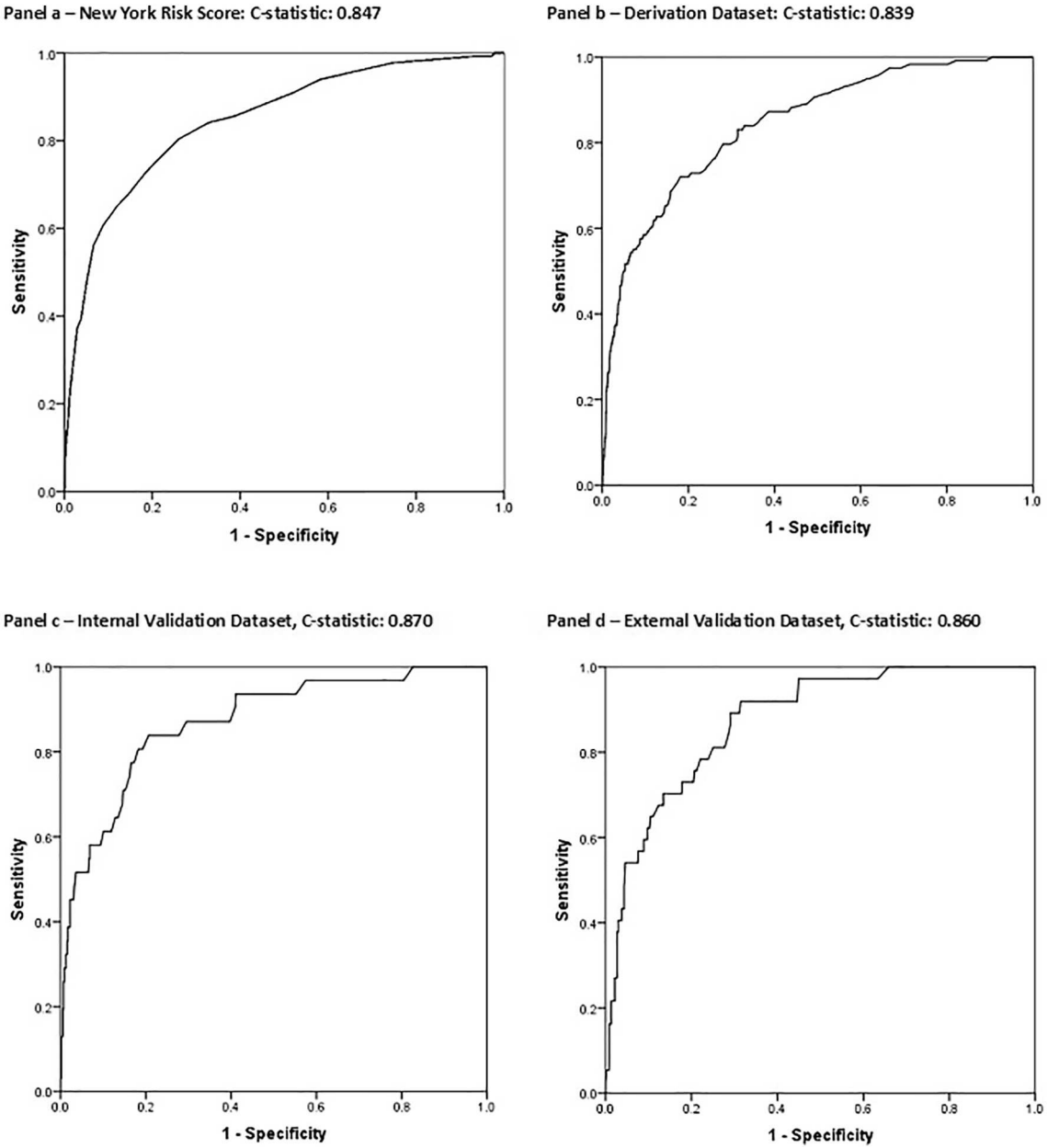
Panel a – New York Risk Score: C-statistic: 0.847
Sensitivity
1 - Specificity
Panel b – Derivation Dataset: C-statistic: 0.839
Sensitivity
1 - Specificity
Panel c – Internal Validation Dataset, C-statistic: 0.870
Sensitivity
1 - Specificity
Panel d – External Validation Dataset, C-statistic: 0.860
Sensitivity
1 - Specificity

Figure 1