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MINIREVIEWS

Risk stratification for ST segment elevation myocardial infarction in the era of primary percutaneous coronary intervention

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Abstract

Acute coronary syndromes presenting with ST elevation are usually treated with emergency reperfusion/revascularisation therapy. In contrast current evidence and national guidelines recommend risk stratification for non ST segment elevation myocardial infarction (NSTEMI) with the decision on revascularisation dependent on perceived clinical risk. Risk stratification for STEMI has no recommendation. Statistical risk scoring techniques in NSTEMI have been demonstrated to improve outcomes however their uptake has been poor perhaps due to questions over their discrimination and concern for application to individuals who may not have been adequately represented in clinical trials. STEMI is perceived to carry sufficient risk to warrant emergency coronary intervention [by primary percutaneous coronary intervention (PPCI)] even if this results in a delay to reperfusion with immediate thrombolysis. Immediate thrombolysis may be as effective in patients presenting early, or at low risk, but physicians are poor at assessing clinical and procedural risks and currently are not required to consider this. Inadequate data on risk stratification in STEMI inhibits the option of immediate fibrinolysis, which may be cost-effective. Currently the mode of reperfusion for STEMI defaults to emergency angiography and percutaneous coronary intervention ignoring alternative strategies. This review article examines the current risk scores and evidence base for risk stratification for STEMI patients. The requirements for an ideal STEMI risk score are discussed.

Key words: ST segment elevation myocardial infarction; Risk stratification; Primary percutaneous coronary intervention; Harm; Risk scores

Core tip: Risk stratification is recommended in non ST segment elevation myocardial infarction (NSTEMI) by multiple international cardiology agencies however there is no such recommendation for STEMI. The short term risk of STEMI is perceived to be high and warrant emergency percutaneous coronary intervention rather than pharmacological fibrinolysis. The risk spectrum is wide therefore consideration should be given to developing an optimal reperfusion strategy based on risk of adverse outcome and probability of reperfusion regard-

less of mode of reperfusion.

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INTRODUCTION

Acute coronary syndromes in contemporary cardiology practice

The initial management of acute coronary syndromes (ACS) depends on the presence of ST elevation on the electrocardiogram. In the United Kingdom Primary Percutaneous Coronary Intervention (PPCI) is the recommended treatment for ST segment elevation MI (STEMI). International guidelines recommend formal risk stratification using a validated risk score for all patients presenting with non ST elevation MI (NSTEMI) but not for STEMI.

In this article we review the established risk scores and their limitations. We also examine the need for a risk score for those patients presenting with STEMI.

Risk stratification and risk scores

Risk stratification is defined as "a statistical process to determine detectable characteristics associated with an increased chance of experiencing unwanted outcomes"[1]. When applied to ACS risk stratification has helped target healthcare resources and guide clinicians as to revascularisation requirement, urgency and method. Risk scores such as the Global Registry of Acute Coronary Events (GRACE) score have shown that of the spectrum of patients with ACS those who presented with STEMI had the highest short-term risk of death. This group also benefitted from rapid reperfusion therapy, an effect confirmed in the GISSI-1 and ISIS-2 trials[2,3]. Reperfusion treatment was initially limited to systemic thrombolysis (fibrinolysis). However, thrombolysis is associated with a "failure rate" of incomplete coronary reperfusion, which led to the development of mechanical reperfusion methods and the introduction of PPCI programmes[4].

Within the STEMI population, there is a spectrum of higher and lower risk patients. For example, STEMI presenting with haemodynamic instability or cardiac arrest is associated with a higher risk of mortality[5,6]. Stratification of risk in STEMI has been more difficult because PPCI has been offered and incorporated into national and international guidelines to all patients without contraindication who present with clinical and electrocardiographic criteria[7,8]. In contemporary practice it is, therefore, unlikely that a STEMI risk score would impact on decision making, since the pathway is algorithmic once a diagnosis is made. Risk scoring is therefore only used to evaluate hospital and individual operator performance. An alternative approach would be to use risk scoring in STEMI to target healthcare and refine decision-making such as by offering immediate thorombolysis to low risk patients presenting early and PPCI to other higher risk patients.

Despite progress in pre-hospital care, ambulance logistics, pharmacotherapy and PPCI techniques, STEMI continues to confer a substantial burden of morbidity and mortality and consumes significant healthcare budget. Consequently, optimal reperfusion strategy is a subject of ongoing research interest[9,10]. When compared to the NSTEMI population there has been little effort to quantify patient risk in STEMI since all randomised controlled trials studying PPCI efficacy offer PPCI as default[7,8,11].

PPCI when available or immediate fibrinolysis?

Reperfusion is most effective when delivered early. Any delay to reperfusion is associated with an increase in mortality[12-14]. In the real world patients may experience considerable delays that may negate the benefit of PPCI over immediate fibrinolysis[15,16]. The National Institute of Health and Care Excellence (NICE) has highlighted the need for further research into very early presentation of STEMI but acknowledges the current evidence in favour of PPCI[17]. The question of whether early pre-hospital thrombolysis with subsequent coronary angiography and intervention (PCI or CABG) is non-inferior to expert and timely PPCI has been evaluated recently. The Strategic Reperfusion Early after Myocardial Infarction (STREAM) study investigated early fibrinolysis *vs* PPCI. For those with early fibrinolysis with Tenecteplase (TNK) there was a suggestion of outcome equivalence albeit with an increase in intracranial bleeding[18].

PPCI RISK MODELS FOR DEATH AND BLEEDING IN CONTEMPORARY PRACTICE

The Myocardial Ischaemia National Audit Project (MINAP) is a United Kingdom national registry database of all acute coronary syndromes. The MINAP database was established in 1999 to examine the quality of management of acute myocardial infarction (AMI) in England and Wales and to meet the audit requirements of the national service framework for coronary heart disease[19,20]. Risk scores have been constructed based on trial data and statistical modelling using databases such as MINAP as bench markers for validity. The other major risk scores are summarised in the table below (Table 1).

The risk scores outlined have demonstrated some ability to predict survival. However, whilst their use has been recommended by international guidelines, their uptake by the clinical community has been poor. There are several reasons for this: The GRACE score is the most widely used but lacks point of care convenience whilst the TIMI score has this functionality but is less discrimi-

Table 1 Summary of major risk scores utilised in percutaneous coronary intervention

Risk score	Type	Population	No of patients	Outcomes	No of variables	Validation	c- statistic	Ref.
GRACE	Clinical	NSTEMI, STEMI	85771	In hospital and 6 mo mortality (8.6% and 12.9%)	7	FAST-AMI	0.8 and 0.8	[21]
GRACE – 2	Clinical	NSTEMI, STEMI	32037	1 and 3 yr mortality	8	FAST AMI	0.82 and 0.82	[22]
GUSTO -1	Clinical	STEMI	41021	30 d to 1 yr mortality (2.9%)	7	MINAP	0.8 at 30 d 0.75 at 1 yr	[21,23]
SRI	Clinical	STEMI	100686	30 d mortality	3	In time II/MINAP	0.79	[21,24]
TIMI	Clinical	STEMI	14114	30 d mortality	10	External with TIMI-9 trial	0.746	[25]
CADILLAC	Clinical	STEMI	2082	1 yr mortality	7	Stent– PAMI (900 patients, internal)	0.78	[26]
APEX - AMI	Clinical	STEMI	5745	90 d mortality	7	Internal (no external)	0.81	[27]
EMMACE	Clinical	All MI	100686	30 d mortality	3	Internal	0.78	[28]
SYNTAX	Angiographic	NSTEMI CSA		5 yr mortality	n/a	LEADERS trial	0.62	[29-33]
Clinical SYNTAX	Clinical and angiographic	NSTEMI CSA	512	5 yr mortality	Syntax score and modified ACEF score	LEADERS trial	0.69	[29]
EURO Heart	Clinical and angiographic	ACS and STEMI	23032	In-hospital mortality	16	Internal	0.89	[34]
MINAP (reference)				30 d to 1 yr mortality (5.0%)				

GRACE: Global registry of acute coronary events; FAST-AMI: French registry of Acute ST-elevation and non-ST elevation MI; GUSTO: Global utilisation of streptokinase and tissue plasminogen activator (TPA) for Occluded coronary arteries; SRI: Simple risk index; TIMI: Thrombolysis in acute myocardial Infarction; CADILLAC: Controlled abciximab and device investigation to lower late angioplasty complications trial; APEX: Ami assessment of pexelizumab in acute myocardial infarction trial; EMMACE: Evaluation of methods and management of acute coronary events; SYNTAX: Synergy between pci with taxus and cardiac surgery trial; CSA: Chronic stable angina; ACEF: Age, creatinine, ejection fraction score; LEADERS: Limus eluted from a durable versus erodable stent coating trial.

natory. The SRI, GUSTO and CADILLAC scores are seldom used in clinical practice and external validation is limited. Perhaps the major limitation of all these scores is that myocardial infarction is not always sub-divided into NSTEMI or STEMI. Finally some of the scores (including the TIMI risk score) are based on data derived from a pre-PPCI era or are based on angiographic findings that can not be known at the time of patient presentation.

However, the single dominant reason risk scores are rarely used for STEMI patients is the assumption that all patients presenting with STEMI are at high risk. Furthermore current evidence and international guidelines encourage the rapid diagnosis and treatment with no requirement for risk stratification. The fallibility of risk scores for STEMI is compounded by the issue of timing of data availability for data for a risk score calculation the emergency management of STEMI should not be delayed for the purpose of completing a range of risk parameters which may not be immediately available. For example some scores use parameters such as blood pressure measured on admission and troponin (GRACE) whilst others do not specify.

There are several other risk models which have been developed with varying degrees of validation across a variety of patient cohorts, *e.g.*, All ACS or all PCI. Others have been developed in an era which do not reflect contemporary practice, *e.g.*, The Primary Angioplasty in Myocardial Infarction score (PAMI)[35]. These will not be reviewed in detail in this manuscript as they are of limited clinical applicability, and have often excluded the highest risk patients such as the National Cardiovascular Data Registry (NCDR) PCI risk score[36].

BLEEDING RISK SCORES

Bleeding is an important outcome of ACS. The majority of patients with ACS will receive anti-coagulants and dual anti-platelet therapy and some patients will receive fibrinolysis or PCI that increase bleeding risk. There are limited data on bleeding risk scores in the setting of PPCI. The CRUSADE bleeding risk score (CBRS, Can Rapid risk stratification of Unstable angina patients Suppress ADverse outcomes with Early implementation of the ACC/AHA Guidelines) has been utilised and validated in a NSTEMI population but not in the STEMI cohort[37]. A prospective study from Spain has suggested that the bleeding risk in patients with PPCI in their cohort was less than that of the NSTEMI group. The lower rate of bleeding observed in this group may be due to the cohort having a lower baseline risk (younger, predominantly male) there was also a lower incidence of cardiovascular disease. A radial approach for PCI was associated with a decreased risk of major bleeding although the exact cause for this is unclear. This study lacked data on contemporary practice as patients on newer antiplatelet agents such

as Ticagrelor were excluded[38].

PPCI outcome-survival

In contemporary practice, survival rates following PPCI are high and approach 95% to 97% at 3 years[13,19,40]. However, within this group there is a wide range of individuals with varying levels of underlying risk. The elderly have worse absolute outcomes compared to their younger counterparts. In the APEX-AMI study the 90-d mortality was 13.1% in the elderly (> 75 years) and 2.3% in the < 65 years cohort. In this study age was the strongest predictor of mortality (hazard ratio 2.07 per 10 year increase (95%CI: 1.84-2.33)[41,42].

Mitigating against this absolute higher mortality is the fact that the elderly have a higher baseline risk and their relative risk is reduced by PPCI more effectively than by fibrinolysis. In the elderly STEMI population this has been demonstrated in the TACTICS-TIMI 18 trial in which there was a greater absolute risk benefit in favour of revascularisation[43]. Registry data support this finding, in the Australian ACACIA registry decreased referral rate and rate of revascularisation was noted in the elderly population. The exact reason for this is not clear; however it may be due to a perceived increase in risk by referring physicians or judgements based on frailty. In the same registry there was increased absolute benefit to early revascularisation in the elderly compared to the young following adjustment for baseline risk[44].

A final limitation of studies that report all-cause mortality is a failure to consider that longer-term survival may be affected by non-cardiac pathology. These factors may influence outcome beyond the index STEMI event. The elderly population are exposed to increased mortality attributable to non-cardiovascular factors than compared with their younger counterparts whether they have recovered from STEMI or not[45].

PPCI outcome-absolute risk reduction

The impact of any treatment is dependent on the baseline risk. The relative risk reduction of treatment in a low risk group is small and the number needed to treat (NNT) is high, this was illustrated in the In the PCAT-2 collaboration (Primary Coronary Angioplasty Trialist versus Thrombolysis) where the NNT with PPCI for a lowest quartile was 516 compared with 17 in the highest risk quartile. A patient with a risk score of 5 would decrease their absolute risk by 10% whereas the patient with a risk score of 1 would decrease their absolute risk by less than 1%[46]. Yet the potential benefit of PPCI must also be considered in context of the risk of harm. In a young age group the risk of bleeding from fibrinolysis is low whereas the elderly have a higher incidence of intracranial bleeding[47].

The challenge of optimally treating high-risk patients is exacerbated by the increased prevalence of an atypical presentation. A failure or delay to make a diagnosis prevents risk evaluation and reduces the benefit of treatment, up to 90% of patients under the age of 65 present with chest pain *vs* 57% over 85 years[40]. Elderly patients are more likely to present with atypical features such as left bundle branch block (34%), acute heart failure without significant chest pain (45%) all of which may delay diagnosis. In the real world delays in diagnosis and access to treatment are common and contribute to harm. Some authors advocate tailoring trials and treatment specifically to include the elderly high risk cases[45,47,48].

PPCI-important secondary outcomes

Post infarct complications other than mortality are important factors in determining overall efficacy. Gharacholou *et al*[27] showed that compared to their younger counterparts the elderly have a higher baseline risk and a higher rate of post infarct/PPCI complications, in particular stroke (1.5% *vs* 0.4%), CCF (11.5% *vs* 2.7%) and shock (6.9% *vs* 2.1%). After correction for baseline characteristics age was a predictor of death (HR = 2.07; 95%CI: 1.84-2.33, $P < 0.001$)[41]. For high risk elderly patients there are no randomised trials to guide optimal management. Inferences about management have been drawn from analysis of sub-groups from PPCI trials[51].

Hospital length of stay is less following PPCI than with fibrinolysis (3 d *vs* 5 d)[50]. But there is relatively little data on quality of life in STEMI patients beyond 1 year and no data on the relative quality of life between high risk patients (often the elderly) and lower risk patients. Recent data from the GRACE registry suggests favourable 5 year survival but there are no long term data for quality of life following PPCI in either the younger or elderly group[49].

Recently the United Kingdom National Health Servicehas begun to focus attention on this by introducing measures of patient report experiences and outcomes. There is some evidence (outwith PPCI) that while it may provide more information it does not necessarily alter clinicians management strategies[52]. Data from the FREEDOM study (Future Revascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multivessel Disease) has suggested quality of life benefits for PCI at 2 years however these were in chronic stable angina patients[53].

THE IDEAL PPCI RISK SCORE

A discriminatory risk score is required when the effectiveness of treatment depends on baseline risk. An optimal risk score for PPCI would predict which patient would benefit maximally from an intervention and predict who would come to harm and what weighting should be ascribed to that. The risk of death and morbidity in the context of an anterior STEMI is high and reperfusion treatment with thrombolysis or PPCI outweighs the risk of bleeding in most patients. Conversely the risk of harm in a late presenting or limited inferior STEMI may outweigh the perceived benefits of reperfusion treatment and conservative treatment could be advocated.

Currently there is no risk scoring system within the context of STEMI and physicians are encouraged to rapidly activate a treatment pathway with little or no as-

sessment of perceived risks and benefits. The reasons for this practice have been discussed and are summarised by a lack of guideline recommendation, impractical or non-discriminatory scoring systems and a perception that all STEMI patients are high risk. A further limitation is that the clinical trials on which evidence is based are highly selective samples. Typically these trials recruit less than 10% of patients screened and often the very highest risk patients are excluded. This has the effect of excluding 'real world' patients from evaluation of interventions. Any scoring system derived from a clinical trial by default is not applicable to a real world population. A lack of applicability of trial data to the real world is often cited as a reason to not offer therapies. Trials performed in highly selected patients that show efficacy of treatment may drive the widespread delivery of this treatment to an "all-comers" population. This may be effective but may not be cost effective. The same treatment (PPCI) may be offered for example, to a 40-year-old male presenting within 60 min of onset of STEMI. Currently PPCI would be offered, with an number needed to treat of > 500 to save one life. Thrombolysis delivered immediately may be as effective with little chance of harm. Conversely a late presenting elderly female who has a much higher risk of death, lower likelihood of reperfusion with fibrinolysis, higher rate of significant bleeding and therefore is much more likely to benefit from mechanical reperfusion, number needed to treat = 17[46].

Opportunities and missed opportunities of care

Is the current philosophy of STEMI treatment correct? PPCI has been calculated to cost the NHS in England £5176 per patient during office hours versus fibrinolysis at £3509[54,55]. This represents a significant burden of healthcare resource devoted to a treatment that in some patients is probably life saving in many others not. There is little licence or encouragement for physicians to discriminate between these very different patient groups and the mandate is to treat rapidly. However, there is no doubt that this approach has been effective and real world survival following STEMI treated by PPCI is remarkably high.

Can refinement with risk adjustment improve the pathways further? Clearly the determination of absolute risk and absolute benefit in high-risk populations is difficult, as is proving that the elderly benefit in the long term from intervention and aggressive secondary prevention. One of the challenges confronting front line clinicians is lack of clear prognostic data that takes into account the patient as a whole and not simply their acute STEMI presentation. The idea of assessing potential harm as well as possible/likely benefit has recently been given increased attention.

In the United States the wide disparity of care has in recent years been highlighted. There is considerable variation in practice both in geographical terms and in differing financial arrangements. Since the introduction of The Affordable Care Act (ACA, Obamacare) a substantial amount (United States $1.1 billion) of the United States health budget has been appropriated to funding towards Comparative Effectiveness Research. The intention being to improve quality, streamline care and demonstrate not only medical efficacy but medical effectiveness. This alteration in the funding landscape has profound implications for physician choice and may influence clinical decision making. Some authors have suggested that it may lead to creeping government control of medical practice by influencing reimbursement[56]. This is analogous to the system in the United Kingdom where NICE delivers guidelines based both on treatment efficacy and overall clinical effectiveness. While this system has its merits in trying to alleviate some of the problems associated with the so called "postcode lottery" NICE is not empowered to make funding allocations although patients have a right to NHS approved treatments NICE recognises that further research is recommended into optimal reperfusion strategies for those presenting early.

In contrast to the front loading of healthcare provision at the time of presentation with STEMI there remains a significant failure in prescribing simple evidence based treatments following the initial treatment. Provision of secondary prevention pharmacotherapy has been described using a missed opportunities for care model. A study using a large United Kingdom national database (MINAP) which demonstrated that outcome (death) was related to not prescribing clinically indicated and evidence based treatments, *e.g.*, statins[57]. In another study of elderly patients the authors found that following PCI healthcare inequalities expressed as missed opportunities for care in the short term (30 d) correlated with mortality[58].

Efficacy of treatment

The MINAP based study result above illustrates the importance of proof of benefit and not simply reduction of risk[57,58]. The efficacy of secondary preventative medication in a population has been established. What is less clear is the prognostic benefit in high risk individuals. We have already seen above that missed opportunities equate to outcome.

As pressure on healthcare budgets have come under increased scrutiny, research methodology, *e.g.*, high cost of Randomised Control Trials (RCTs) have come under review. This has reinvigorated interest in research methods that provide prognostic information. Comparative effectiveness research has been suggested as a possible route towards improving outcomes and reducing costs whilst providing policy makers and clinicians with clinically useful and evidence based tools to achieve optimal care. An example of this would be the use of electronic medical records to generate evidence from different areas and compare outcomes based on geographical locations[59]. Altesrnatively a design similar to the recent STREAM study when ethical approval was granted for a centre to conduct a trial of early fibrinolysis *vs* PPCI for early presenters[18].

CONCLUSION

Clinicians are generally poor at judging risk and predicting the absolute benefit and harm of their interventions.

The evidence in NSTEMI care has clearly shown the importance of calculating these metrics. This has led to a plethora of risk scores and recommendation to use these in international guidelines.

Provision of STEMI care in the United Kingdom is currently algorithmic and not risk adjusted yet we have seen that the same treatment pathway (PPCI) may deliver treatment that is very beneficial in some but not in others. One reason to risk stratify is to target healthcare resource; many patients should continue to be treated by emergency PCI, others may be treated with immediate fibrinolysis and others without reperfusion treatment at all.

The STREAM and GRACIA-2 data have suggested that some patients can be treated as effectively and certainly more cost effectively with rapid thrombolysis avoiding emergency angiography[14,17]. These data come from trials and consequently have all the limitations of selection and applicability but have generated an important hypothesis. If discriminatory STEMI risk scores were available, applicable to real world patients and widely used could the current algorithm of emergency angiography be adapted to include fibrinolysis? If this change were incorporated would the outcomes be non-inferior or the cost benefit calculation superior. There are huge challenges to proving this hypothesis. Some clinicians will feel that such a change is retrograde step and there is a risk of generating a complicated pathway that may harm the very patients it is intending to improve outcomes for. The trials involved to mark such a paradigm shift in the current guidelines may be costly, difficult to recruit to and may not provide a definitive answer. Thus the question "Would this change be non-inferior to PPCI overall and would it be cost beneficial" may be difficult to answer. The first step is to generate a practical discriminatory risk score that is based on real world data in a STEMI population. Ideally the score should account for potential harm associated with PCI or thrombolysis, should generate baseline risk and calculate treatment effects. Such a risk score does not yet exist although registry data are available on which these could be derived. A validated score has ability to predict the impact of healthcare on treatment and evaluate cost-benefit.

If substantial health care resource is being driven towards treatments that are only minimally effective in some patients then refinement of the STEMI pathway by risk adjustment should be formally evaluated. There are merits to keeping treatment pathways simple and providing algorithmic care if this is globally effective. However stratifying patients by risk and calculating treatment effects with thrombolysis or PCI may be as effective. Such a pathway could be delivered with reduced overall cost and no less efficacy[60].

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