

Original Article

SAVEME (Myocardial Salvage After Rescue Angioplasty: Evaluation by Magnetic Resonance) Study: Rationale and Study Design

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ABSTRACT

Introduction: Atherosclerotic disease accounts for one-third of deaths annually, as it often leads to complications such as ST-elevation myocardial infarction (STEMI). Rescue percutaneous coronary intervention (PCI) is indicated in case of thrombolytic therapy failure administered in this scenario. However, the benefits regarding mortality rate reduction and the amount of myocardium that is actually salvaged are not well established. The development of new tools, including cardiac magnetic resonance imaging, to identify the myocardium at risk and the infarcted area has increased diagnostic accuracy. Differently from the context of primary PCI, little is known about the association between epicardial and microvascular coronary flow following rescue PCI and the salvaged myocardial area. The aim of this study is to evaluate whether there is an association between coronary flow and the salvaged myocardial area identified by magnetic resonance imaging.

Methods: This will be a prospective, open, single-center, intervention study. A total of 72 patients with STEMI who underwent rescue PCI after documented failure of the fibrinolytic therapy, and were transferred to our institution, will be selected, observing a pharmacoinvasive strategy.

Conclusions: At the end of this study, the authors expect to contribute to the knowledge about coronary flow and its association with the amount of salvaged cardiac muscle after rescue PCI. This type of information that can help to understand which cases can benefit the most from rescue PCI.

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Estudo SAVEME (Salvamento Miocárdico Após Angioplastia de Resgate: Avaliação por Ressonância Magnética). Racional e desenho do estudo

RESUMO

Introdução: A doença aterosclerótica é responsável por um terço dos óbitos ocorridos anualmente, pois frequentemente leva a complicações como infarto do miocárdio com supradesnívelamento do segmento ST (IMCST). A intervenção coronária percutânea (ICP) de resgate é indicada caso ocorra falha da terapia trombolítica administrada neste cenário. No entanto, os benefícios, em termos de redução da taxa de mortalidade e da quantidade de miocárdio efetivamente salvo, não são bem estabelecidos. O desenvolvimento de novas ferramentas, entre elas a ressonância magnética cardíaca, para identificar a área miocárdica em risco e infartada, elevou a acurácia diagnóstica. Diferentemente do contexto da ICP primária, pouco se sabe sobre a relação entre o fluxo coronário epicárdico e microvascular após a ICP de resgate e a área de miocárdio salva. O objetivo deste estudo é avaliar se existe relação entre tais fluxos e a área de miocárdio salva identificada pela ressonância magnética.

Palavras-chave:

Infarto do miocárdio

Terapia fibrinolítica

Imagem por ressonância magnética

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Métodos: Estudo prospectivo, aberto, unicêntrico, de intervenção. Serão selecionados 72 pacientes com IMCST que tiverem realizado ICP de resgate após falha documentada da terapia fibrinolítica transferidos para este serviço, obedecendo uma estratégia fármaco-invasiva.

Conclusões: Ao término desta pesquisa, esperamos contribuir para o conhecimento sobre o fluxo coronariano e sua relação com a quantidade de músculo cardíaco salvo após a ICP de resgate. Esta é uma informação que pode ajudar a entender quais casos mais se beneficiam da ICP de resgate.

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Introduction

Although primary percutaneous coronary intervention (PCI) was shown to be superior to fibrinolysis, the latter is still the most commonly used therapeutic strategy, mainly due to logistic difficulties in transferring patients to carry out primary PCI in a timely fashion.¹⁻³ In 30 to 50% of cases, thrombolysis cannot restore adequate flow to the culprit artery (Thrombolysis in Myocardial Infarction – TIMI < 3).⁴ These patients have higher early and late mortality when compared with those who achieve TIMI flow 3.⁵ Additionally, a change in myocardial perfusion assessed by TIMI Myocardial Perfusion Grade (TMPG) may persist, despite normal epicardial flow. This change is associated with greater thrombotic load, larger infarct size, and worse and slower resolution of ST-elevation, as well as worse survival in the short and long terms.⁶⁻¹³

Rescue PCI is indicated in cases of fibrinolytic failure; it also aims to treat the culprit lesion, reestablishing normal epicardial flow and myocardial perfusion. However, the level of recommendation class IIa for this procedure in the guidelines reflects the fact that the benefits are not well established in terms of mortality rate reduction and the amount of myocardium that is actually salvaged.¹⁴⁻¹⁹ Thus, a number of studies have tried to evaluate this treatment, assessing predictors of mortality, vascular complication rates, and differences in mortality reduction between developed and emerging countries.²⁰⁻²²

Cardiac magnetic resonance (CMR) is an imaging modality that may provide additional insight into the underlying pathophysiology of myocardial perfusion failure observed by TMPG. It allows assessing not only myocardial function, but also the extent of the myocardial infarction, estimating the size of the possible area at risk, myocardial viability, and the degree of persistent microvascular obstruction after reperfusion therapy.²³⁻²⁷

Appelbaum et al. evaluated the association between TMPG and the persistent microvascular obstruction measure assessed by CMR performed at 1 week and after 3 months in 21 patients with ST-elevation myocardial infarction (STEMI) treated with primary PCI. After the procedure, TIMI 3 flow was observed in 90% of patients, altered TMPG (0/1 or 2) in 48%, and evidence of persistent microvascular obstruction at the CMR in 52%. An association was observed between altered TMPG and persistent microvascular obstruction at the CMR (90% persistent microvascular obstruction in patients with TMPG 0/1 or 2 vs. 18% persistent microvascular obstruction in those with TMPG 3; $p < 0.01$) and with a larger infarct size (17.3 vs. 5.2%; $p < 0.01$, respectively).²⁸

Another study, which assessed 50 patients with failed thrombolytic therapy who underwent rescue PCI and follow-up with CMR (performed within 6 days), showed a small amount of salvaged myocardium (3 ± 4%) and no difference between patients with TIMI flow ≤ 2 or 3 (3.3 ± 3.6% in those with TIMI 0-2 vs. 3.0 ± 3.7% in those with TIMI 3; $p = 0.80$) or among those who underwent early vs. late rescue PCI. Also, no associations were observed between ST resolution or presence of TIMI 3 flow after the rescue PCI and the amount of salvaged myocardium. These associations were not listed as pre-specified outcomes for analysis and cannot be considered conclusive.²⁹

Bodí et al.³⁰ compared the outcomes related to left ventricular alterations in the pharmacoinvasive strategy (151 patients) and primary PCI (93 patients). The CMR performed after 1 week showed a similar extent of the area at risk in both groups (29 ± 15% vs. 29 ± 17%; $p = 0.9$). Non-significant differences in infarct size, salvaged myocardial area, persistent microvascular obstruction, ejection fraction, and end-diastolic and end-systolic volumes were detected at the CMR performed at 1 week and after 6 months ($p > 0.2$ in all cases). Patients treated with rescue PCI ($n = 35$) were evaluated separately and compared with patients in the successful thrombolysis and primary PCI groups. The rescue PCI group had worse ejection fraction, left ventricular mass, myocardial area at risk, and infarct size ($p \leq 0.05$ in all cases), as well as a trend towards greater microvascular obstruction ($p = 0.06$) in the initial CMR than the other groups. At the CMR performed after 6 months, no significant differences were observed in the parameters evaluated between the three groups.³⁰

The few studies in the literature shown here used diverse analysis criteria post-acute myocardial infarction, and it is not clear which is the best period for CMR outcomes to be analyzed.

Our hypothesis is that there is an association between the alteration in TMPG and in the TIMI flow at the end of rescue PCI and the size of myocardial infarction and microvascular obstruction observed at the post-PCI CMR.

The main objective of this study is to evaluate TMPG and TIMI flow after rescue PCI and to establish an association with the CMR findings related to infarct size and post-PCI microvascular obstruction.

Methods

Study design and patient selection

This will be a prospective, open, interventional, single-center study carried out at Hospital São Paulo of Escola Paulista de Medicina, Universidade Federal de São Paulo, in São Paulo (SP). Seventy-two patients with STEMI submitted to rescue PCI after documented fibrinolytic therapy failure, transferred to this service, will be selected.

Patients older than 18 years, with STEMI, who underwent thrombolysis within 12 hours of symptom onset will be included.

Thrombolytic therapy failure will be defined by an electrocardiogram performed 60 minutes after the thrombolytic agent administration, showing a resolution of the ST-segment < 50% when compared to the initial electrocardiogram, associated or not with persistent chest pain or hemodynamic instability. Once the thrombolytic treatment failure is identified, the Interventional Cardiology team must be urgently called in to perform the rescue PCI.

Patients with a new or presumed new left bundle branch block will be excluded from the study. Other exclusion criteria reflect the known contraindications to CMR or the use of adjuvant medications to percutaneous treatment; impossibility to perform pre-procedure CMR (e.g., pre-existing pacemaker and hemodynamic instability among others) or impossibility to perform post-procedure CMR (severe heart failure, low output, and need for pacemaker due to high-

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