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Original

Predictors of rescue percutaneous coronary intervention after pharmacoinvasive strategy in women

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ABSTRACT

Background: Pharmacoinvasive therapy (PIT) is feasible in patients with acute myocardial infarction with ST-segment elevation (STEMI) when timely primary percutaneous coronary intervention (PCI) is unavailable. In this study, we compared women who underwent successful reperfusion PIT with those who required rescue PCI, to identify potential predictors of thrombolytic failure.
Methods: From January 2010 to November 2014, 327 consecutive women with STEMI were referred to a tertiary hospital, 206 after successful thrombolysis (63%) and 121 who required rescue PCI. The groups were compared regarding demographic, clinical and angiographic outcomes, and clinical (TIMI, GRACE, and ZWOLLE CADILLAC) and bleeding (CRUSADE) risk scores. A multivariate logistic regression model was used to identify predictors of thrombolytic failure.
Results: There was no significant difference between the demographic characteristics or the medical history of the groups. Rescue PCI group had significantly higher values of the evaluated scores. Clinical hospital complications and mortality (2.5% vs. 22.0%; $p < 0.0001$) were more frequent in rescue PCI group. The independent variables associated with rescue PCI were pain-to-needle time > 3h (OR: 3.07, 95%CI: 1.64 to 5.75; $p < 0.0001$), ZWOLLE score (OR: 1.25; 95%CI: 1.14 to 1.37; $p = 0.0001$) and creatinine clearance (OR: 1.009, 95%CI: 1.0 to 1.02; $p = 0.04$).
Conclusions: Women with STEMI who underwent PIT and who required rescue PCI had significantly higher mortality compared to those who achieved initial success of PIT with elective PCI. Pain-to-needle time > 3h, ZWOLLE score and creatinine clearance were independent predictors of the need for rescue PCI.

Fatores preditivos de intervenção coronária percutânea de resgate após estratégia fármaco-invasiva em mulheres

Palavras-chave:
Infarto do miocárdio
Terapia trombolítica
Angioplastia

RESUMO

Introdução: A estratégia fármaco-invasiva (EFI) é viável em pacientes com infarto agudo do miocárdio com supradesnivelamento do segmento ST (IAMCST), quando a intervenção coronária percutânea (ICP) primária em tempo hábil não é possível. Neste estudo, comparamos mulheres submetidas à EFI com sucesso para reperfusão àquelas que necessitaram de ICP de resgate, para identificar possíveis preditores de insucesso do trombolítico.
Métodos: De janeiro de 2010 a novembro de 2014, 327 mulheres com IAMCST e EFI foram encaminhadas ao hospital terciário, sendo 206 após trombólise com sucesso (63%) e 121 que necessitaram de ICP de resgate. Os grupos foram comparados quanto a variáveis demográficas, desfechos clínicos e angiográficos, e escores de risco clínico (TIMI, GRACE, ZWOLLE e CADILLAC) e de sangramento (CRUSADE). Um modelo de regressão logística multivariada foi utilizado para identificar preditores de insucesso do trombolítico.

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Resultados: Não houve diferença significativa entre as características demográficas ou os antecedentes clínicos dos grupos. O grupo ICP de resgate apresentou valores significantemente maiores dos escores avaliados. Complicações clínicas hospitalares e mortalidade (2,5% vs. 22,0%; $p < 0,0001$) foram mais frequentes no grupo ICP de resgate. As variáveis independentes associadas à ICP de resgate foram tempo dor-agulha > 3 horas (OR 3,07; IC95% 1,64-5,75; $p < 0,0001$), escore ZWOLLE (OR 1,25; IC95% 1,14-1,37; $p = 0,0001$) e *clearance* de creatinina (OR 1,009; IC95% 1,0-1,02; $p = 0,04$).
Conclusões: Mulheres com IAMCST submetidas à EFI e que necessitaram de ICP de resgate tiveram mortalidade significativamente maior quando comparadas àquelas que obtiveram sucesso inicial da EFI com ICP eletiva. Tempo dor-agulha > 3 horas, escore de ZWOLLE e *clearance* de creatinina foram preditores independentes da necessidade de ICP de resgate.

Introduction

Although primary percutaneous coronary intervention (PCI) is the gold standard for patients with ST-segment elevation acute myocardial infarction (STEMI), low availability still prevents its broad use, as recommended by the most contemporary guidelines.[1,2] Therefore, pharmacoinvasive therapy (PIT) has shown to be a feasible and valuable option in terms of public health, with efficacy results similar to those of primary PCI in several studies, and in national and international registries.[3-5] In brief, PIT is the rapid application of a fibrin-specific thrombolytic therapy in primary care, followed by transfer to cardiac catheterization in 3-24 h and performance of PCI in the culprit artery, if applicable. However, its weak point is thrombolytic therapy failure in one-third of cases. In the STREAM randomized trial,[4] which compared PIT with primary PCI in almost 1,900 patients, rescue PCI occurred in 36% of cases.

STEMI is the leading cause of death among Western women and is already a leading cause of death among women in Brazil.[6,7] The authors recently analyzed mortality data and major cardiac events in women with STEMI submitted to PIT and observed mortality rates twice as high as those observed in men.[8] However, in the multivariate analysis, gender was not a risk factor in itself, but rather the fact that women presented more risk factors.

The present analysis compared women with STEMI submitted to PIT who achieved successful lytic reperfusion with women who required rescue PCI, identifying possible predictors of thrombolytic therapy failure.

Methods

From January 2010 to November 2014, 1,261 patients were prospectively included in the Sao Paulo ST-Segment Elevation Myocardial Infarction (STEMI) Registry, as specified in a previously published protocol[3] and also in clinicaltrials.org NCT 02090712. In this registry, patients with STEMI were treated with up to 12 h of evolution using preferably primary PCI, but performing PIT if PCI was not available. Of these, 327 women (26% of the cohort) were treated with PIT and early elective catheterization (PIT, n = 206) or rescue PCI after failed thrombolysis (rescue PCI, n = 121). PIT success was defined as systematic cardiac catheterization and elective PCI, if necessary, performed 3 to 24 hours after thrombolytic use. The criteria to define reperfusion failure were persistent chest pain in prethrombolysis levels, and persistent ST-segment elevation > 50% of the original elevation or early relapse or symptom worsening, with or without hemodynamic instability. These two groups were compared for demographic variables, clinical outcomes (mortality at catheterization and in-hospital mortality), pain-to-needle and door-to-needle time, risk scores (TIMI, GRACE, ZWOLLE, CADILLAC),[9,10] risk of bleeding (CRUSADE),[11] and complications such as congestive heart failure (CHF), cardiogenic shock, total atrioventricular block (TAVB), major and minor bleeding, and stroke. Left ventricular ejection fraction was obtained in the echocardiographic assessment performed within the first 48 hours.

Definitions

Thrombolysis in Myocardial Infarction (TIMI) flow and myocardial blush were assessed as previously reported[12,13] Creatinine clearance was estimated according to the Cockcroft-Gault formula.[14] Renal failure was defined as the presence of creatinine clearance estimated at < 60 mL/min. Bleeding severity was established according to the Bleeding Academic Research Consortium (BARC) criteria.[15] Patients considered as having major bleeding were those with BARC ≥ 3; minor bleeding, those with BARC < 3. Death during catheterization was defined as death that occurred in the hemodynamics laboratory, during the index procedure.

Statistical analysis

Data were prospectively stored in an Excel™ spreadsheet (Microsoft Corporation, Redmond, USA) and submitted to statistical analysis using Statistical Package for Social Science (SPSS), version 22.0. Continuous variables were expressed as means and standard deviations, and categorical variables as absolute numbers and percentages. Categorical variables were compared using Pearson's chi-squared test, while numerical variables with normal distribution were compared using Student's *t*-test or the Mann-Whitney test, when applicable. Moreover, stepwise logistic regression was performed to evaluate independent predictors of rescue PCI. Statistically significant variables in the univariate analysis were included in the regression, in addition to those considered important as rescue PCI predictors, such as pain-to-needle and door-to-needle time. Interactions between the several risk scores, age, and renal failure were corrected. *P*-values < 0.05 were considered as statistically significant.

Results

The rate of need for rescue PCI in this analysis was 37.0%. Age in the overall group ranged from 24 to 86 years, with a mean of 59.9 ± 11.9 years. There were no significant differences in any demographic variable or clinical history between the two groups (Table 1).

On admission, mean blood pressure and heart rate (76.5 ± 15 bpm vs. 78 ± 21 bpm; $p = 0.36$) were similar; however, patients from the rescue PCI group showed lower systolic blood pressure (132.8 ± 24.6 mmHg vs. 126 ± 31 mmHg, $p = 0.03$). Mean door-to-needle time (1.9 ± 2.0 hours vs. 2.0 ± 3.0 hours; $p = 0.82$) and pain-to-needle time (8.3 ± 13.6 hours vs. 7.9 ± 16.7 hours, $p = 0.85$) were also the same in both groups. Mean time between the onset of thrombolysis and coronary