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Clinical Originals

Impact of thrombus aspiration on angiographic and clinical outcomes in patients with ST-elevation myocardial infarction

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Abstract Background: Primary percutaneous coronary intervention (PCI) in ST-elevation myocardial infarction (STEMI) may be limited by thrombus embolization. Export aspiration catheter (EAC) is a thrombectomy device which may enhance angiographic results, but its impact on clinical outcomes is unclear. This trial objective was to assess the impact of EAC on angiographic and clinical outcomes in patients with STEMI.

Methods: All STEMI patients undergoing primary or rescue PCI in a tertiary care center were included. Patients were divided in two groups according to the use of the EAC. Patients were followed up prospectively for death, reinfarction, revascularization, or stroke. Thrombolysis In Myocardial Infarction (TIMI) flow in the culprit vessel was assessed before and after PCI.

Results: Included in the analysis were 535 patients. EAC was used in 165 patients before angioplasty (Group 1) and 370 patients underwent PCI without thrombus aspiration (Group 2). More patients in Group 1 had initial TIMI flow 0–1 compared to Group 2 (88% vs. 62%, P<.001). Proportion of patients with a final TIMI flow 3 was the same in both groups (89.1% vs. 87.6% for Groups 1 and 2, respectively; P=.67). An analysis restricted to patients with initial TIMI flow 0–1 yielded similar results. No difference in clinical outcomes was observed between the two groups (P=.70).

Conclusions: Selective use of the EAC based on the judgment of operators results in excellent angiographic and clinical results. Further clinical investigation is needed to definitely answer whether thromboaspiration needs to be performed in all STEMI patients undergoing primary PCI. Crown Copyright © 2010 Published by Elsevier Inc. All rights reserved.

Keywords: Acute myocardial infarction; Primary percutaneous coronary intervention; Thrombectomy; Angioplasty

1. Introduction

When readily available, primary percutaneous coronary intervention (PCI) with angioplasty and stenting of the

 * Corresponding author. Hôpital Laval, 2725 chemin Ste-Foy, Quebec City (Quebec), Canada, G1V 4G5. Tel.: +1 418 656 4564; fax: +1 418 656 4703. *E-mail address:* jean-pierre.dery@med.ulaval.ca (J.-P. Dery). culprit lesion is the preferred approach for acute STelevation myocardial infarction (STEMI) [1]. Despite its efficacy in achieving epicardial reperfusion, primary PCI is often limited by debris and thrombi embolization, which leads to impaired microvascular perfusion. Because noreflow has been associated with poorer prognosis [2–5], several strategies, including the use of thrombectomy devices, have been developed to limit this phenomenon. The export aspiration catheter (EAC) is a component of the GuardWire Plus system (PercuSurge) and is often used to reduce thrombus burden at the time of PCI [6,7]. Previous

Abbreviations: STEMI, ST-elevation myocardial infarction; EAC, Export Aspiration Catheter; TIMI, Thrombolysis in Myocardial Infarction; PCI, percutaneous coronary intervention.

studies suggest that thrombectomy before angioplasty can improve angiographic result and limit infarct size [8,9]. However there are conflicting data concerning the efficacy of EAC [10]. Recently, two randomized trials showed improvement in flow and clinical outcomes at 1 year [11,12]. Whether EAC should be used in all patients undergoing primary PCI or be restricted to specific subgroups needs to be determined.

We report the results of a retrospective analysis investigating the use of the Export Aspiration Catheter in patients undergoing primary or rescue PCI for STEMI in a high-volume tertiary care center.

2. Patients and methods

This is a retrospective study including all patients undergoing primary or rescue PCI for STEMI at Quebec Heart and Lung Institute between May 2006 and August 2007. Acute STEMI was defined as chest pain or equivalent symptoms at rest >30 min, with either STsegment elevation in ≥ 2 contiguous leads (≥ 2 mm in precordial leads, ≥ 1 mm in limb leads). ST-segment depression ≥ 1 mm in the precordial leads suggesting posterior myocardial infarction and new or presumed new left bundle-branch block were also included when coronary occlusion was confirmed by coronary angiogram. Patients with presentation >12 h after the onset of symptoms were included only if persistent chest pain was present at the time of initial evaluation. Patients underwent radial or femoral coronary angiography. All patients received aspirin, clopidogrel (300-600 mg) and either heparin or enoxaparin prior to procedure. The use of glycoprotein IIb/IIIa (GP IIb/IIIa) antagonists was at the discretion of the operator.

Patients were divided in two groups according to the use of EAC. Patients in the first group had thrombus aspiration in the culprit vessel with EAC before angioplasty. Patients were included in the second group when PCI was performed without prior thrombectomy. The decision to use EAC before angioplasty was left at the discretion of the attending physician.

Each angiogram was reviewed offline by two trained investigators. Thrombolysis in Myocardial Infarction (TIMI) flow grade in the culprit vessel before and after angioplasty was assessed. Procedural success was defined as final TIMI 3 flow in the culprit vessel. Total procedural and fluoroscopy time was recorded. The use of intracoronary vasodilators such as adenosine or sodium nitroprussiate during the procedure was also reviewed.

Patients were followed up by phone contact at 30 days and at 1 year. When an event was suspected based on the questionnaire, the complete medical file of the medical center taking care of the patient was reviewed. The patient's primary care physician and cardiologist were consulted if any further information was needed.

The angiographic primary end point was the percentage of patients with TIMI flow 3 in the culprit artery at the end of the procedure. The clinical end points consisted of death, revascularization, reinfarction, stroke and the same clinical composite at end of follow-up. Reinfarction was adjudicated when ST elevation ≥ 0.1 mV reoccurred in a patient having a lesser degree of ST elevation or new pathognomonic Q waves, in at least two contiguous leads, and/or either creatine kinase-MB or troponins re-elevation $\geq 20\%$ above the previous nadir value, particularly when associated with ischemic symptoms for 20 min or longer [13]. Revascularization was defined as any unplanned PCI performed for recurrent symptoms. Stroke was defined as a neurologic deficit lasting more than 24 h confirmed by a brain imaging study and/or a clinical diagnosis made by a neurologist or an internist.

The data are presented as mean±standard deviation or as percentage for continuous or categorical variables respectively. Differences in proportions were tested with the χ^2 test, and continuous variables were compared with the Student's t test. The univariate normality assumptions were verified with the Shapiro-Wilk test, and the Brown and Forsythe's variation of Levene's test statistics were used to verify the homogeneity of variances. Procedural success and clinical outcomes of patients in EAC group were compared to those of patients in non-EAC group. A secondary analysis was done on patients with baseline TIMI flow 0 or 1 on their diagnostic angiogram. A logistic regression analysis was performed to identify variables independently associated with EAC use. Variables with a probability value <0.20 were candidate for the multivariate regression model building. The variables used to build the statistical model were age, gender, door-to-balloon time, clopidogrel loading dose (600 vs. 300 mg), GP IIb/IIIa inhibitors use, rescue vs. primary intervention, and initial TIMI flow grade (0-1 vs. 2-3). First, the stepwise and backward variable selections were used in the logistic regression model. Both approaches gave similar results. An alternative procedure to select variables was to use the best subset selection containing one to seven variables. The same approach was used for stepwise selection of interactions with main effects forced into the initial model. Using the 20% level of significance, no interaction effect was added to the model. Continuous variables were checked for the assumption of linearity in the logit, and the graphical representations suggested linear relationships. Survival free of event was estimated using Kaplan-Meier method. Difference in survival between groups was compared using the log-rank test. Cox proportional hazards model was used to adjust for differences in baseline characteristics. Variables included in the model were those of the Zwolle risk score (Killip class, final TIMI flow, age ≥ 60 years, presence of three-vessel disease, anterior infarction and ischemia time >4 h) [14]. Two-tailed values of P<.05 were considered significant. All statistical analyses were performed utilizing SAS statistical software version 9.1.3 (SAS Institute, Cary, NC, USA).

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