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COmparison between COronary THrombus aspiration with Angiojet® or Export® catheter in patients with ST-elevation myocardial infarction submitted to primary angioplasty: The COCOTH Study

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ABSTRACT

Aims: To compare the effects of two thrombus aspiration devices, the manual catheter Export® and the more complex and expensive mechanical Angiojet®, on several indices of reperfusion in acute ST-elevation myocardial infarction (STEMI).
Methods and results: Clinical, hemodynamic and procedural characteristics of 185 STEMI patients, randomized to treatment with Export (n = 95) or Angiojet (n = 90) during primary percutaneous coronary intervention (PPCI) were analyzed. The primary endpoint was ST-segment elevation reduction 90 min after culprit vessel re-opening. Secondary endpoints included variations in some angiographic parameters (TIMI Flow, TIMI Frame Count and Myocardial Blush Grade) and Infarct Size and Severity at myocardial scintigraphy. A significant reduction in ST-elevation was observed in both groups after PPCI without significant differences between the two groups. No significant difference between Angiojet vs. Export was observed in ST-segment resolution >50% and ≥70%, in TIMI Flow, TIMI Frame Count and Myocardial Blush Grade before vs. after PPCI and in Infarct Size and Severity.
Conclusions: PPCI with thrombus aspiration was effective in both groups of patients, without differences in myocardial reperfusion and necrosis indices. These results could support the routine use of manual devices during PPCI, reserving the more expensive Angiojet in case of manual device failure and persistent or massive intracoronary thrombosis, with favorable implications in terms of cost containment.

1. Introduction

Primary percutaneous coronary intervention (PPCI) is considered the "gold standard treatment" for patients with ST-elevation myocardial infarction (STEMI) [1]. The most frequent pathologic substrate of STEMI is an occlusive thrombus complicating a ruptured or eroded atherosclerotic plaque [2], and the aim of PPCI is to mechanically restore a valid flow in the infarct related artery as a persistent reduced flow is associated with heart failure and death [3,4]. However, the passage of the PCI-devices across the thrombotic lesion during the procedure may be complicated by athero-thrombotic embolization in the distal portion of the coronary tree with resulting microvessel occlusion and failed myocardial reperfusion.

Compared to the classical occlusion of an epicardial segment, distal embolization produces patchy microinfarcts in the area at risk, with different degrees of myocardial damage [5,6].

This mechanism, in addition to vasoconstriction and reperfusion injury following flow restoration, could account for the mismatch between the achievement of a normal flow in the affected epicardial vessel in more than 90% of patients submitted to PPCI and myocardial reperfusion not being fully restored in up to 40% [7].

In the past few years, in addition to anti-platelet drug administration, PPCI procedures have been further enhanced by the use of thrombus aspiration devices finalized to optimize stent implantation and improve myocardial reperfusion. Thrombus aspiration devices can be classified as "manual" or "mechanical" depending on the presence or absence of a motorized system [8]. Several studies have been conducted on the efficacy of manual thrombus aspiration systems compared with standard PCI [9–16], and a lower number of studies and also some meta-analyses have examined the effects of mechanical devices versus standard PCI [17–20] or manual devices [21,22]. Angiojet is usually considered as more expensive and complex but it is also more powerful in

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thrombus removal as compared with manual systems [21]. Although the clinical benefits of thrombus aspiration during PPCI for STEMI patients are still a matter of debate, and the recent publication of the TASTE trial [23] doubted their ability in reducing 30-day all-cause mortality, thrombus aspiration systems are still widely used in PPCI all over the world, owing to the rationality of their use and relative simplicity. Therefore, we believe that it would be useful to understand which kind of thrombus aspiration device (manual or mechanical) is more cost-effective in improving myocardial reperfusion.

In order to clarify this, in a randomized, prospective single-center study, we compared the effects of two different thrombus aspiration devices, the manual Export and the mechanical Angiojet, on ST-resolution and other indices of acute myocardial reperfusion in 185 STEMI patients submitted to PPCI, assuming that Export would be not inferior to Angiojet. We also compared the effects of the two different devices on Infarct Size as evaluated, in the acute phase, by means of Single Photon Emission Computed Tomography (SPECT).

2. Methods

The COCOTH study (COmparison between COronary THrombus aspiration with Angiojet® or Export® catheter in patients with ST-elevation myocardial infarction submitted to primary angioplasty) is a no-profit, single center, randomized, 2 arms prospective study (Fig. 1).

2.1. Patients

All patients with STEMI were considered eligible for the study without restrictions based on age or clinical status on presentation. The diagnosis of STEMI consisted of: 1) chest pain persisting >30 min <12 h; and 2) ST-segment elevation >1 mm in at least 2 contiguous leads. Clinical exclusion criteria were: 1) thrombolysis for current acute myocardial infarction; 2) major surgery <4 weeks; 3) stroke <30 days or any history of hemorrhagic stroke; 4) comorbidities with expected survival <1 year; and 5) participation in another study. The local Ethics Committee

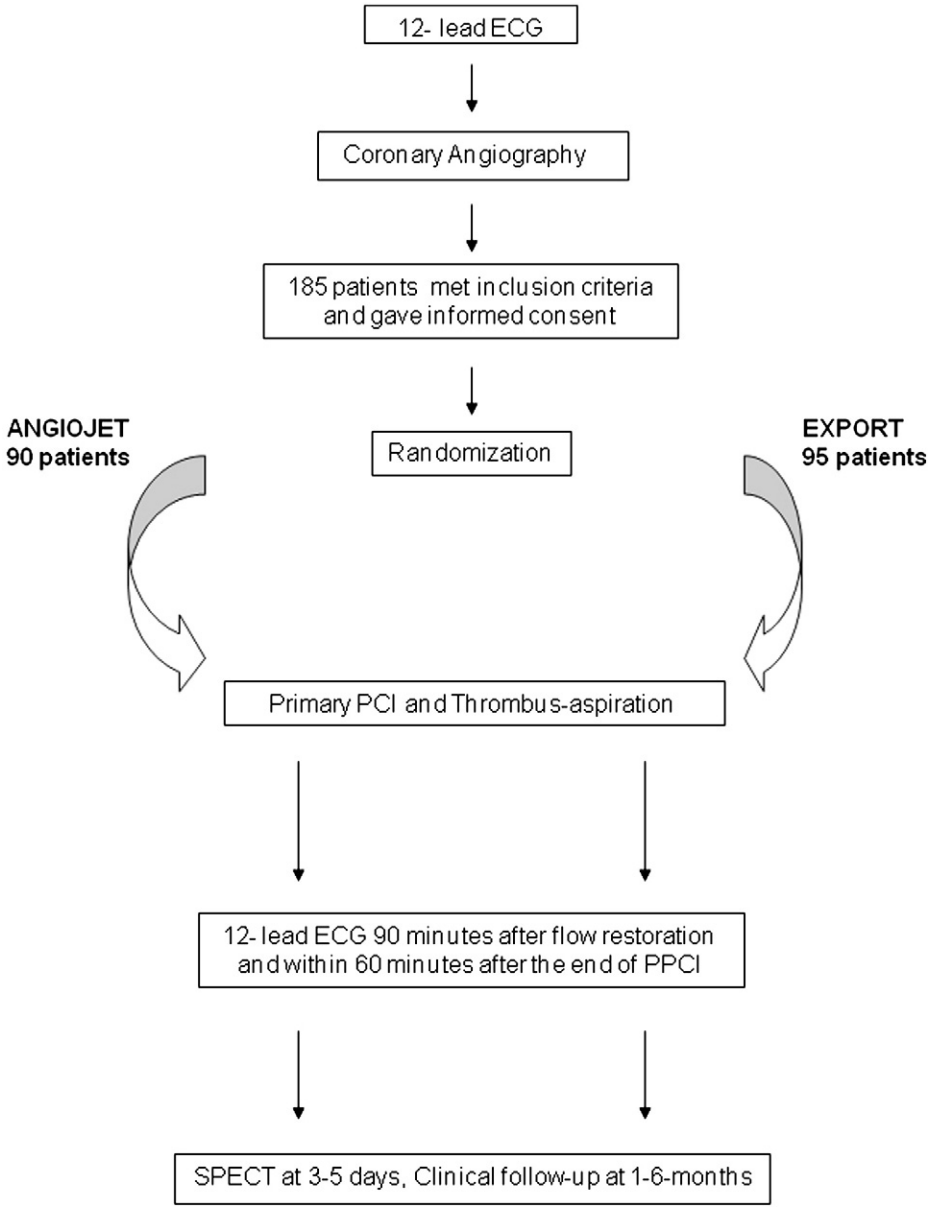

Fig. 1. Flow chart of COCOTH study.