



Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc



Original article

Manual thrombus aspiration during primary percutaneous coronary intervention: Impact of total ischemic time

Doo Sun Sim (MD, PhD)^a, Myung Ho Jeong (MD, PhD, FACC, FAHA, FESC, FSCAI, FAPSC)^{a,*},
Youngkeun Ahn (MD, PhD, FACC)^a, Young Jo Kim (MD, PhD)^b,
Shung Chull Chae (MD, PhD)^c, Taek Jong Hong (MD, PhD)^d, In Whan Seong (MD, PhD)^e,
Jei Keon Chae (MD, PhD)^f, Chong Jin Kim (MD, PhD)^g, Myeong Chan Cho (MD, PhD)^h,
Seung-Woon Rha (MD, PhD, FACC)ⁱ, Jang Ho Bae (MD, PhD, FACC)^j,
Ki Bae Seung (MD, PhD, FACC)^k, Seung Jung Park (MD, PhD, FACC)^l other
Korea Acute Myocardial Infarction Registry (KAMIR) Investigators

^a Chonnam National University Hospital, Gwangju, Republic of Korea

^b Yeungnam University Hospital, Daegu, Republic of Korea

^c Kyungpuk National University Hospital, Daegu, Republic of Korea

^d Busan National University Hospital, Busan, Republic of Korea

^e Chungnam National University Hospital, Daejeon, Republic of Korea

^f Chonbuk National University Hospital, Jeonju, Republic of Korea

^g Kyung Hee University Hospital at Gangdong, Seoul, Republic of Korea

^h Chungbuk National University Hospital, Cheongju, Republic of Korea

ⁱ Korea University Guro Hospital, Seoul, Republic of Korea

^j Konyang University Hospital, Daejeon, Republic of Korea

^k Catholic University Seoul St. Mary's Hospital, Seoul, Republic of Korea

^l Asan Medical Center, Seoul, Republic of Korea

ARTICLE INFO

Article history:

Received 12 September 2015

Received in revised form 28 December 2015

Accepted 4 January 2016

Available online xxx

Keywords:

Myocardial infarction

Percutaneous coronary intervention

Thrombectomy

ABSTRACT

Background: The benefit of manual thrombus aspiration (TA) during primary percutaneous coronary intervention (PCI) remains uncertain, and the effect of TA in relation to total ischemic time has not been evaluated.

Methods: We analyzed 5641 patients with ST-elevation myocardial infarction (STEMI) (<12 h) from the Korea Acute Myocardial Infarction Registry undergoing primary PCI. Patients were divided into 2 groups: TA ($n = 1245$) and PCI only ($n = 4396$). Propensity-matched 12-month clinical outcome was compared between the groups according to different total ischemic times (≤ 2 h, 2–4 h, 4–6 h, >6 h).

Results: Twelve-month rates of death and major adverse cardiac events (MACE: composite of death, recurrent myocardial infarction, target-vessel revascularization, and coronary artery bypass grafting) were not different between TA and PCI only. After propensity matching ($n = 1162$ for each group), there were no differences in the 12-month outcome between TA and PCI only, which was consistent across subgroups. In the propensity-matched cohort, the effect of TA on 12-month outcome showed a U-shaped relationship with longer total ischemic time: TA in patients with total ischemic time between 4 and 6 h was associated with lower rates of death [hazard ratio (HR): 0.53, 95% confidence interval (CI): 0.24–1.19, p for interaction = 0.01] and MACE (HR: 0.28, 95% CI: 0.12–0.66, p for interaction = 0.01).

Conclusions: Manual TA during primary PCI was not associated with improved clinical outcome at 12 months. The impact of TA may become clinically relevant with longer total ischemic time, forming a U-shaped relationship.

© 2016 Japanese College of Cardiology. Published by Elsevier Ltd. All rights reserved.

* Corresponding author at: Principal investigator of the Korea Acute Myocardial Infarction Registry, Director of The Heart Research Center of Chonnam National University Hospital Designated by Korea Ministry of Health, Welfare and Family Affairs, 671 Jaebong-ro, Dong-gu, Gwangju 501-757, Republic of Korea. Tel.: +82 62 220 6243; fax: +82 62 228 7174.

E-mail address: myungho@chollian.net (M.H. Jeong).

<http://dx.doi.org/10.1016/j.jjcc.2016.01.003>

0914-5087/© 2016 Japanese College of Cardiology. Published by Elsevier Ltd. All rights reserved.

Introduction

Manual thrombus aspiration (TA) during primary percutaneous coronary intervention (PCI) reduces thrombus burden and improves markers of myocardial reperfusion in patients with acute ST-elevation myocardial infarction (STEMI) [1,2]. However, its clinical benefit has been a contentious point of debate. The Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS) trial [3] and other several studies [4–6] showed a mortality reduction with TA. In contrast, 2 recent multi-center randomized trials, the Trial of Routine Aspiration Thrombectomy with PCI versus PCI Alone in Patients with STEMI (TOTAL) [7] and the Thrombus Aspiration in ST-Elevation myocardial infarction in Scandinavia (TASTE) [8,9] failed to show a significant reduction in clinical events including mortality.

There remain unanswered questions on the efficacy of TA including whether TA truly is of clinical benefit and which subgroups may or may not benefit from the procedure. In the present study, we sought to evaluate clinical impact of TA during primary PCI in relation to total ischemic time.

Methods

Study population and data collection

The study population was derived from the Korea Acute Myocardial Infarction Registry (KAMIR) between December 2007 and December 2012. The KAMIR is the first nationwide, population-based, multi-center data collection registry in Korea, designed to capture outcomes of patients with acute myocardial infarction (MI) [10,11]. We analyzed a total of 5641 patients (≥ 18 years) with acute STEMI (< 12 h) undergoing primary PCI. Patients receiving fibrinolysis and coronary bypass graft surgery (CABG) were excluded. Patients were divided into 2 groups according to use of TA during PCI: TA group ($n = 1245$) and PCI only group ($n = 4396$). The study flow diagram is shown in Fig. 1.

Primary PCI was performed according to the standard guidelines [12,13]. All patients received loading doses of aspirin (300 mg) and clopidogrel (300–600 mg) before PCI. The use of glycoprotein IIb/IIIa receptor blocker or intravascular ultrasound, type of stent, and duration of dual anti-platelet therapy were all left at the discretion of the physician. All TA were performed manually using 6 or 7 French aspiration catheters: Thrombuster II (Kaneka Corporation, Osaka, Japan, 50%), Export (Medtronic,

Minneapolis, MN, USA, 30.8%), Eliminate (Terumo Medical Supply, Tokyo, Japan, 11.5%), and others including Rebirth Pro (Goodman Corporation, Nagoya, Japan) in 7.7%.

The present study was conducted according to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee. The institutional review board of all participating centers approved the study protocol. The approval number was 05-49 of Chonnam National University Hospital. Written informed consent was obtained from all participating patients.

Clinical endpoints and definitions

STEMI was defined as chest pain suggestive of myocardial ischemia for at least 30 min, ST-segment elevation > 0.1 mV in ≥ 2 contiguous leads, or new or presumably new left bundle-branch block on the 12-lead electrocardiogram and elevated cardiac markers (creatinine kinase-MB or troponin I/T). Primary PCI was defined as PCI within 12 h of symptom onset in a patient not receiving fibrinolysis [14,15]. Total ischemic time was defined as the time from onset of symptoms to the time of the first intracoronary reperfusion instrument, such as a TA catheter, a balloon, or a stent [16,17].

The primary endpoint of the study was the occurrence of major adverse cardiac events (MACE: composite of death from any cause, recurrent MI, target-vessel revascularization, and CABG) at 12 months. The secondary endpoint of the study included death from any cause, recurrent MI, target lesion revascularization, target vessel revascularization, CABG, and stent thrombosis. Recurrent MI was defined as the recurrence of symptoms or the presence of electrocardiographic changes in association with a rise in cardiac biomarker levels above the upper limit of normal. Target-lesion revascularization was defined as a repeat PCI in the same coronary segment as the index procedure. Target-vessel revascularization was defined as a repeat PCI of any segment within the entire major coronary vessel proximal and distal to a target lesion, including the target lesion itself. Stent thrombosis was classified as definite, probable, or possible according to the Academic Research Consortium definitions [18].

Statistical analysis

Baseline differences between the 2 groups were compared using the Mann–Whitney U test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables. Unadjusted hazard ratios (HR) and their 95% confidence intervals (CI) were calculated for outcome variables using Cox regression analysis.

To adjust for the bias inherent to the decision of choosing TA or PCI only, propensity scores were used [19,20]. The propensity scores were estimated for the likelihood of receiving TA using a multiple logistic regression model that contained all of the 43 covariates shown in Tables 1 and 2. Model discrimination was measured by the c -statistic and calibration was assessed by the Hosmer–Lemeshow goodness-of-fit test (c -statistic: 0.73, Hosmer–Lemeshow: $p = 0.64$). Matching was performed using a greedy matching protocol (1:1 matching without replacement) with a caliper width of 0.6 of the standard deviation [21]. We were able to match 1162 patients receiving TA to 1162 patients receiving PCI only. We estimated standardized differences for all covariates before and after matching to assess the balance of the covariates between the matched TA and PCI only groups. After matching, none of the covariates showed a standardized difference exceeding 10%, suggesting that all of the measured covariates were well balanced between the matched groups (Fig. 2) [22,23]. Differences between the matched pairs were evaluated using the paired t

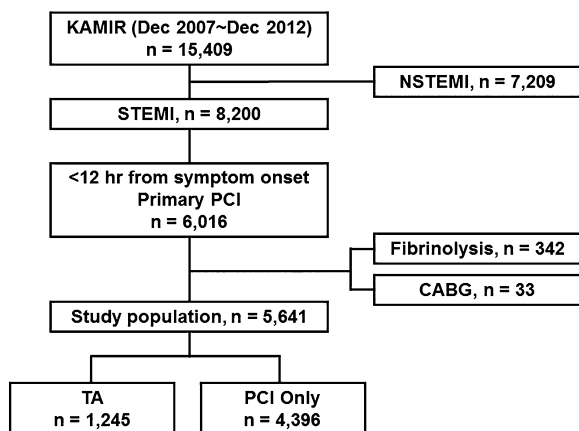


Fig. 1. The study flow diagram of the patients. CABG, coronary artery bypass graft surgery; KAMIR, Korea Acute Myocardial Infarction Registry; NSTEMI, non-ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; TA, thrombus aspiration.

Download English Version:

<https://daneshyari.com/en/article/5614776>

Download Persian Version:

<https://daneshyari.com/article/5614776>

[Daneshyari.com](https://daneshyari.com)