Cardiovascular Revascularization Medicine 17 (2016) 5–9

Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

Clinical

Temporal changes in the current practice of primary angioplasty: a real life experience of a single high-volume center☆,☆☆

Francesco Tomassini [a], Lorena Charrier [b], Ferdinando Varbella [a], Enrico Cerrato [a,*,1], Andrea Gagnor [a], Cristina Rolfo [a], Mauro Echavarria-Pinto [b], Sara Palacio Restrepo [a], Rosa Nevola [a], Denise Baricocchi [a], Javier Escaned [c,d], Davide Minniti [c,d], Maria Rosa Conte [e,f], Paola Berchialla [g], Maria Michela Gianino [g]

[a] Department of Cardiology, Infermi Hospital, Rivoli, Italy
[b] Hospital General ISSSTE, Querétaro, Facultad de Medicina, Universidad Autónoma de Querétaro, México
[c] Cardiovascular Institute, Hospital Clínico San Carlos, Madrid 28040, Spain
[d] Health Directorate, Infermi Hospital, Rivoli, Italy
[e] Department of Public Health and Pediatrics, University of Turin, Turin, Italy
[f] Department of Cardiology, Mauriziano Hospital, Turin, Italy
[g] Department of Clinical and Biological Sciences, University of Turin, Turin, Italy

ARTICLE INFO

Article history:
Received 5 August 2015
Received in revised form 18 October 2015
Accepted 20 October 2015

Keywords:
Acute myocardial infarction
Primary angioplasty
Temporal changes of primary angioplasty

ABSTRACT

Background: In the last years, new techniques, drugs and devices have been introduced in the current practice of primary angioplasty (PPCI) and validated by pivotal studies The objective of our study was to evaluate if these studies have led to significant changes on the current practice of primary PCI in our center.
Methods: From March 2003 to December 2013 1980 patients with ST-segment elevation myocardial infarction underwent PPCI within 12-hours of onset of symptoms. We considered 2 periods of our activity: from 2003 to 2009 (P1) with 1078 patients and from 2010 to 2013 (P2) with 902 patients, and compared them in terms of pharmacological and arterial access strategies and of devices utilization.
Results: In P2 there was a significant increase of radial access (34.1% vs. 1.5, $p < 0.001$), as well as of the use of bivalirudin (22.7% vs. 0.5%, $p < 0.001$) and of new antiplatelet drugs (prasugrel or ticagrelor) (18.3% vs. 0%, $p < 0.001$) whereas the use of GP IIb–IIIa and of intraaortic balloon pump significantly decreased (from 82.3% to 52%, $p < 0.001$ and from 17% to 7.5%, $p < 0.001$ respectively). In the P2 there was a significant increase of the procedural efficacy (97.2% vs. 95.1%, $p = 0.01$) that persisted after the logistic regression adjustment (OR 2.09, CI 95%, 1.04–4.21).
Conclusions: Our study shows that in the last years, in a high-PCI center, after the publication of pivotal randomized trial and nationwide registries, there were significant changes in the PPCI current practice that could have had an impact on procedural efficacy.

1. Purpose

Primary angioplasty (PPCI) has been demonstrated to be superior to fibrinolytic therapy in the management of patients with ST-segment elevation myocardial infarction (STEMI) [1–3] becoming the leading treatment in this setting [4]. In the last years, new drugs and devices have been introduced in the practice of PPCI which have been validated by pivotal studies. In particular, the radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL) and the Radial Versus Femoral Randomized Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE-STEACS) randomized trials [5,6], have demonstrated that the transradial artery access (TRA) can reduce bleeding complications and even the 30-days mortality, compared to transfemoral artery access (TFA) in patients with STEMI. The same result was achieved by a direct thrombin inhibitor, bivalirudin, in the Harmonizing Outcomes with Revascularization and Stents in Acute Myocardial Infarction (HORIZONS-AMI) trial [7,8], compared to unfractioned heparin (UFH) plus Glicoproteins (GP) IIb–IIIa inhibitors, and these advantages were extended at 12 months. Finally, the Plateler Inhibition and Patient Outcomes (PLATO) and the Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel–Thrombolysis in Myocardial Infarction 38 (TRITON-TIMI 38) [9,10] showed that new antiplatelet drugs, ticagrelor and prasugrel respectively, reduced the cardiovascular and the total mortality compared to

☆ Funding: none
☆☆ Conflict of Interest: none
* Corresponding author at: Ospedale degli Infermi, strada Rivalta 29, 10098, Rivoli, Italy. Tel.: +39 011/9551421; fax: +39 011/9551422.
E-mail address: enrico.cerrato@gmail.com (E. Cerrato).
[1] http://www.cardiogroup.org.

http://dx.doi.org/10.1016/j.carrev.2015.10.004
1553-8389/

clopidogrel, even if they increased the bleeding complications at least in more frail patients. Furthermore, the Bavarian Reperfusion Alternatives Evaluation-3 (BRAVE-3) randomized trial [11] did not show any superiority of GP IIb–IIIa over UFH in terms of reduction of infarct size. As a result, the 2010 European Guidelines on revascularization put the bivalirudin use, as well as that of new antiplatelet drugs in class I, whereas they downgraded the upstream use of GP IIb–IIIa inhibitors in class III [12]. Yet, the net benefit effect demonstrated in randomized clinical trials (RCT) might not be the same as that observed in different clinical settings, because most RCT focus on the assessment of a single maneuver, and the investigated population might not be representative of the real-world practice [13]. Therefore, large observational registries are needed in order to assessing treatment effectiveness in patients encountered in day-to-day clinical practice, undergoing everyday therapy. Aim of this large observational registry is to assess the impact of these recent pivotal studies in terms of changing the current practice of PPCI in a high volume hospital.

2. Methods

The Infermi Hospital in Rivoli, Italy, is a community hospital without cardiac surgery backup with a high volume catheterization laboratory (>900 PCI and >200 PPCI per year), which provides a 24-hour PCI service and is only 14 Km far from the nearest hospital with cardiac surgery backup. In 2008, the catchment area increased up to 583,000 inhabitants, including another hospital with intensive cardiac care unit, but without PCI facility.

2.1. Study population

The data of all consecutive patients with STEMI admitted to the Infermi Hospital between March 2003 and December 2013 and treated by primary PCI within 12 hours of symptom onset were reviewed. Demographic, clinical and procedural data were prospectively collected in a dedicated database (Cardioplanet V.3.0.8, Ebit Aet S.p.A., Genoa, Italy).

The study protocol was approved by the ethics committee of our institution (ASL 103, Piemonte Region, Italy) and informed consent was obtained in all patients.

2.2. Study definitions, procedures and medications

STEMI was defined as typical chest pain lasting more than 30 minutes associated with ≥0.1 mV ST-segment elevation in ≥2 contiguous electrocardiogram (ECG) leads or with new left bundle branch block. Door-to-balloon (D2B) time was defined as the time interval from arrival to the hospital (the initial referral hospital for transferred patients) to the first balloon inflation during PPCI. Total ischemic time was defined as the time interval from symptom onset to first balloon inflation during PPCI. Lesion characteristics were evaluated according to the ACC/AHA classification [14].

All STEMI patients who complained symptoms for ≤12 hours were immediately transferred to the catheterization laboratory for urgent coronary angiography.

The indications to manual thrombus aspiration (TA) were driven by few parameters evaluated after diagnostic angiography as already reported [15]: a) visual estimation of infarct related artery (IRA) diameter ≥3 mm; b) the absence of severe proximal tortuosity and/or calcifications; c) complete vessel occlusion with distal convex contrast stain and the presence of visual thrombus in case of a patent IRA. However, the final decision to its use of TA as well as of intra-aortic balloon pump (IABP) support was left to the discretion of the operator.

A successful procedure was defined as a residual stenosis of treated vessels <30% associated with a thrombolysis in myocardial infarction (TIMI) 3 grade flow [16].

All patients were routinely given aspirin (325 mg upon arrival, and then 100 mg daily) and an intravenous bolus of UFH (5000 U) in ambulance or in emergency room. The use of either bivalirudin (bolus of 0.75 mg/kg and 1.75 mg/kg/h thereafter), or UFH (100 U/kg or 60 U/kg if abciximab was used) or abciximab (bolus of 0.25 mg/kg and 0.125 mcg/kg/min for 12 hours) was left to the discretion of the operator. UFH therapy was stopped after the procedure, but, in case of IABP use, it was continued until its removal. When used, abciximab infusion was continued for 12 hours after the procedure. At the beginning of this use, we used to stop bivalirudin at the end of the procedure, but, since the publication of the European Ambulance Acute Coronary Syndrome Angiography (EUROMAX) randomized trial [17], it has been continued for 4 hours thereafter.

Until 2010, clopidogrel (loading dose 300 or 600 mg and 75 mg daily thereafter) was given as second antiplatelet drug but, afterwards, prasugrel (60 mg loading dose and 10 mg daily thereafter) and ticagrelor (180 mg loading dose and 90 mg bid thereafter) were used as well. Beta-adrenergic blockers, ACE inhibitors and statins were used as in-hospital standard therapy, if not contraindicated.

2.3. Study objectives

Two time-frames of activity were considered: from 2003 up to the end of 2009 (P1) and from 2010 up to the end of 2013 (P2). We chose this cut-off since our current practice did not have significant modifications up to the end of 2009 [18], whereas at the beginning of 2010, bivalirudin and the new antiplatelet drugs became available in our center. Furthermore, in the same year, a TRA intervention program in the urgency setting has been set up. We also took into account the differences in using TA, drug-eluting stents (DES) as well as of IABP support.

The aim of the study was to evaluate the changes in procedural characteristics in terms of vascular access, pharmacological treatment and device utilization. Thus we investigated the impact of these changes on procedural efficacy rate (defined as TIMI III grade flow and residual stenosis <30%) and in terms of in-hospital outcomes, defined as major cardiovascular cardiac events (MACE), i.e. death, recurrent myocardial infarction, stroke and target vessel revascularization. The rate of definite and probable stent thrombosis (ST) defined according to the Academic Research Consortium [19] and of bleeding complications according to Bleeding Academic Research Consortium (BARC) classification [20] were also taken into account.

2.3.1. Statistical analysis

Descriptive data are shown as absolute and relative frequencies of the different modalities for categorical data; as median and interquartile range (IQR) for continuous variables. Chi-square test for categorical variables and Wilcoxon test for independent data for continuous variables were carried out to assess whether significant differences could be demonstrated between time periods (before and after 2010).

Due to the observed differences in patients' characteristics between time periods, a propensity score analysis was carried out using a logistic regression model with time period as outcome. In the propensity score model, patient's characteristics which resulted associated with the time period (obesity, hypercholesterolemia, anterior location and transfer from other hospitals) were entered in the model.

Validation of the model was done through graphical examination of the residual diagnostics. Discrimination Index D (the higher the better) and the Somer's concordance index Dxy (the closer to 1 the better) were also computed. In the absence of an external data source for model validation, to account for the degree of optimism in model accuracy induced by the use of the same data for training and testing purposes, goodness of fit indexes were computed using bootstrap (20 runs). Checking of the balance after the matching was performed using chi-square and t test. Using individual propensity score, 876 patients in time period 2010–2013 were matched to 876 patients in time period 2003–2009; a caliper size equal to one-fifth of the standard