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A meta-analytic overview of thrombectomy during primary angioplasty

Giuseppe De Luca [a,*], Eliano Pio Navarese [a], Harry Suryapranata [b]

[a] Division of Cardiology, "Maggiore della Carità" Hospital, Eastern Piedmont University, Novara, Italy
[b] Division of Cardiology, De Weezenlanden Hospital, Zwolle, The Netherlands

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ABSTRACT

Introduction: Even though primary angioplasty restores TIMI 3 flow in more than 90% of STEMI patients, the results in terms of myocardial perfusion are still unsatisfactory in a relatively large proportion of patients. Great interest has been focused in the last years on distal embolization as major determinant of poor reperfusion and clinical outcome after primary angioplasty. The aim of this article is to perform an updated meta-analysis of thrombectomy devices in STEMI patients undergoing primary angioplasty.
Methods: The literature was scanned by formal searches of electronic databases (MEDLINE, Pubmed) from January 1990 to December 2010, the scientific session abstracts (from January 1990 to December 2010) and oral presentation and/or expert slide presentations (from January 2002 to December 2010) (on TCT, AHA, ESC, ACC and EuroPCR websites). No language restrictions were enforced.
Results: A total of 21 randomized trials were finally included in the meta-analysis, involving 4514 patients (2270 or 50.3% randomized to thrombectomy and 2244 or 49.7% to standard angioplasty). Overall thrombectomy did not reduce 30-day mortality, with more benefits observed only with manual thrombectomy. No difference was observed in the 30-day reinfarction rate, whereas a trend in higher risk of stroke was observed with thrombectomy ($p = 0.06$). Manual but not mechanical thrombectomy significantly improved postprocedural TIMI 3 flow, however, both devices significantly improved myocardial reperfusion as evaluated by ST-segment resolution.
By meta-regression analysis a linear relationship was observed between benefits from thrombectomy in ST-segment resolution and in the presence of thrombus at baseline angiography ($p = 0.0016$).
Conclusions: The present meta-analysis has demonstrated that, among patients with STEMI, manual thrombectomy significantly improved myocardial perfusion, with a trend in short-term mortality benefits, whereas mechanical thrombectomy, despite the benefits in myocardial perfusion, did not impact on short-term survival. However, the benefits in myocardial perfusion were significantly related to prevalence of coronary thrombus. In light of the observed higher risk of stroke, thrombectomy cannot be routinely recommended, but should be used in case of evident intracoronary thrombus. Mechanical thrombectomy devices may be considered as well to further improve reperfusion and facilitate optimal stent implantation, especially in the presence of large thrombus burden.

1. Introduction

Primary angioplasty has contributed to improved mortality in patients with ST-segment elevation myocardial infarction (STEMI) [1–3]. However, it has been shown that suboptimal myocardial reperfusion may occur in a relatively large proportion of patients undergoing primary angioplasty for STEMI despite optimal restoration of epicardial flow, resulting in unfavorable short and long-term outcome [4–6]. In recent years, mounting interest has emerged to prevent distal embolization of infarct-related thrombus [7–13]. Therefore, the aim of this article is to perform an updated meta-analysis of thrombectomy devices to prevent distal embolization in patients undergoing primary angioplasty for STEMI.

2. Methods

Results from all randomized trials on adjunctive thrombectomy devices to prevent distal embolization in primary angioplasty for STEMI were obtained. The literature was scanned by formal searches of electronic databases (MEDLINE, CENTRAL, EMBASE, and The Cochrane Central Register of Controlled Trials (http://www.mrw.interscience.wiley.com/cochrane/Cochrane_clcentral_articles_fs.html)) from January 1990 to December 2010 and the scientific session abstracts in Circulation, Journal of College of Cardiology, European Heart Journal and American Journal of Cardiology from January 1990 to December 2010. Furthermore, oral presentations and/or expert slide presentations were also included (searched on the TCT (www.tctmd.com), EuroPCR (www.europcr.com), ACC (www.acc.org), AHA (www.aha.org), and ESC (www.escardio.org) websites from January 2002 to December 2010). The reference list of relevant studies was additionally scanned.

Various combinations of the following keywords were used: randomized trial, myocardial infarction, reperfusion, primary angioplasty, rescue angioplasty, thrombectomy,

* Corresponding author. Tel.: +39 0321 3733141; fax: +39 0321 3733407.
E-mail address: giuseppe.deluca@maggioreosp.novara.it (G. De Luca).

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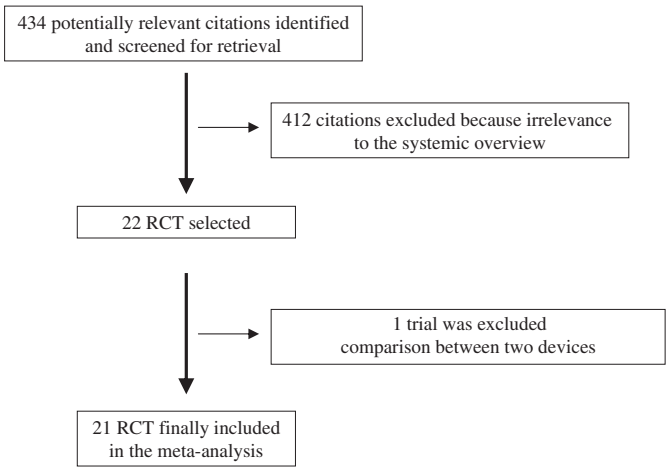

Fig. 1. Flow diagram of the systematic overview process. RCT = Randomized controlled trials.

thrombus aspiration, manual thrombectomy, mechanical thrombectomy, rheolytic thrombectomy, Diver catheter, Pronto catheter, Export catheter, Thrombus Vacuum Aspiration Catheter, Angiojet, Rescue, and X-sizer. No language restrictions were enforced.

Inclusion criteria were 1) randomized treatment allocation and 2) availability of complete clinical data, whereas exclusion criteria were 1) follow-up data in less than 90% of patients and 2) ongoing studies or irretrievable data.

2.1. Data extraction and validity assessment

Data were independently abstracted by two investigators. Agreement between investigators was evaluated by Kappa statistics. In case of disagreements, a third investigator was additionally involved to obtain a consensus. In the case of incomplete or unclear data, authors, where possible, were contacted. Data were managed according to the intention-to-treat principle.

2.2. Outcome measures

Clinical endpoints were mortality, reinfarction and stroke at 30-day follow-up. Procedural endpoints were postprocedural epicardial (as evaluated by postprocedural TIMI 3 flow) and myocardial perfusion (as evaluated by complete ST-segment resolution).

2.3. Data analysis

Statistical analysis was performed using the Review Manager 4.27 freeware package and SPSS 11.5 statistical package. Odds ratios (OR) and 95% confidence intervals (95% CI) were used as summary statistics. The pooled odds ratio was calculated by using a random effect model (The DerSimonian and Laird method). The Breslow–Day test was used to examine the statistical evidence of heterogeneity across the studies ($p<0.1$).

Potential publication bias was examined by constructing a "funnel plot", in which sample size was plotted against odds ratios (for mortality). The study was performed in compliance with the Quality of Reporting of Meta-Analyses (QUOROM) guidelines [14].

3. Results

3.1. Eligible studies

Among the 434 potentially relevant publications, a total of 22 randomized trials were initially identified (Fig. 1). One trial was excluded because of comparison between two manual thrombectomy devices [36] (Fig. 1). Therefore, a total of 21 trials were finally included [15–35], enrolling 4514 patients, with 2270 patients (50.3%) randomized to thrombectomy device and 2244 (49.7%) to conventional primary PCI. Trial characteristics are shown in Table 1.

3.2. Clinical endpoints

3.2.1. Mortality at 30 days

Data on 30-day mortality were available in 4449 patients. As shown in Fig. 2, a total of 107 patients (2.4%) died at 30-day follow-up. Overall, adjunctive thrombectomy devices did not significantly reduce 30-day mortality (2.2% vs 2.6%, OR [95% CI] = 0.88 [0.60–1.28], phet = 0.73). No potential publication bias was observed by visual analysis of the funnel plot (Fig. 3). Benefits were observed with manual devices (2.1% vs 3.3%, OR [95% CI] = 0.65 [0.39–1.09], p = 0.10, phet = 0.91) whereas higher mortality was observed with mechanical thrombectomy devices (2.3% vs 1.9%, OR [95% CI] = 1.27 [0.72–2.26], p = 41, phet = 0.46) (p interaction = 0.08), primarily due to the low mortality rate reported in the control arm of the AIMI trial (without AIMI trial: 1.8% vs 2.1%, OR [95% CI] = 0.83 [0.43–1.61], p = 0.58, phet = 0.96).

Table 1
Study characteristics.

Study	Thrombectomy	Device	Multicenter	Year enrollment	Publication status	N pts	Thrombus T (%)	Thrombus C (%)	Gp IIb–IIIa T (%)	Gp IIb–IIIa C (%)	SOB T (min)	SOB C (min)
Burzotta et al.	Manual	Diver	No	2004	Full paper	96	58	55	68	63	274	300
De Luca et al.	Manual	Diver	No	2004	Full paper	76	100	100	100	100	432	456
PIHRATE	Manual	Diver	Yes	2005–2006	Full paper	196	70	70	62	63	195	206
Noel et al.	Manual	Export	No	NR	Abstract	45	NR	NR	NR	NR	NR	NR
Sardella et al.	Manual	Export	No	2005–2006	Full paper	175	100	100	100	100	408	456
Chao et al.	Manual	Export	No	2003–2004	Full paper	74	NR	NR	19	32	361	384
Chevalier et al.	Manual	Export	Yes	2004–2005	Full paper	249	NR	NR	66	70	322	271
TAPAS	Manual	Export	No	2005–2006	Full paper	1060	49	44	93	90	190	185
Lipiecki et al.	Manual	Export	No	NR	Full paper	81	NR	NR	74	30	400	444
Liistro et al.	Manual	Export	No	2006–2008	Full paper	111	NR	NR	100	100	189	209
DEAR-MI	Manual	Pronto	No	2004–2005	Full paper	148	NR	NR	100	100	206	199
Dudek et al.	Mechanical	Rescue	No	2004	Full paper	41	100	100	0	0	258	236
Kaltoft et al.	Mechanical	Rescue	No	2004–2005	Full paper	215	69	79	96	93	242	208
VAMPIRE	Mechanical	TVAC	Yes	2004–2005	Full paper	349	NR	NR	0	0	376	426
Beran et al.	Mechanical	X-sizer	No	2000–2001	Full paper	66	100	100	73	68	291	279
Napodano et al.	Mechanical	Rescue	No	2000–2001	Full paper	92	100	100	43	41	238	204
Lefevre et al.	Mechanical	X-sizer	Yes	NR	Full paper	201	100	100	55	65	251	264
Antoniucci et al.	Mechanical	Angiojet	No	2002–2003	Full paper	100	NR	NR	98	98	234	264
AIMI	Mechanical	Angiojet	Yes	2001–2004	Full paper	480	49	44	95	94	306	300
JETSTENT	Mechanical	Angiojet	Yes	2006–2009	Full paper	501	98.6	98.6	97	98	159	166
Kuni et al.	Mechanical	Rescue	Yes	2004	Abstract	258	NR	NR	NR	NR	NR	NR

T = Thrombectomy; C = control group.