

# Manual thromboaspiration during primary percutaneous intervention in the Brazilian practice

Trombectomia aspirativa manual durante intervenção coronária percutânea primária na prática brasileira

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**ABSTRACT – Background:** Manual thromboaspiration during primary percutaneous coronary intervention was very often used in the end of the last decade; however, there was a drop in its recommendation class due to results of recent publications. The objective of this work was to evaluate the use of this technique in Brazil. **Methods:** Based on data from the *Central Nacional de Intervenções Cardiovasculares* (CENIC) in the period 2008 to 2016, we assessed patients submitted to primary percutaneous coronary intervention and manual thromboaspiration. The analysis was divided into three periods: 2008 to 2012 (P1), 2013 to 2014 (P2), and 2015 to 2016 (P3), according to the year of publication of the main studies on this subject. **Results:** In this period, a total of 14,003 primary percutaneous coronary interventions were performed, and manual thromboaspiration was employed in 5.7% (P1), 6.1% (P2) and 5.6% (P3) of procedures. P3 had the lower proportion of hypertensive patients (44.2%, 41.3% and 27.7%; p=0.036) and smokers (64.1%, 69.4% and 50.8%; p=0.03), with higher prevalence of occluded arteries and lesions with visible thrombus on angiography. There was an increased use of thromboaspiration in the first period, with a peak of 8%, in 2012; whereas in 2016, it was only employed in 2% of cases (p<0.05). **Conclusions:** The use of manual thromboaspiration during primary percutaneous coronary intervention was low in all periods analyzed, with a significant drop in 2016.

**Keywords:** Thrombectomy/methods; Percutaneous coronary intervention; Brazil

**RESUMO – Introdução:** A aspiração manual de trombos durante a intervenção coronária percutânea primária foi muito utilizada no fim da década passada, mas, a partir de resultados de publicações recentes, houve queda em seu grau de recomendação. O objetivo deste trabalho foi avaliar o uso desta técnica no Brasil. **Métodos:** Utilizando dados da Central Nacional de Intervenções Cardiovasculares (CENIC) do período de 2008 a 2016, avaliamos pacientes submetidos à intervenção coronária percutânea primária que realizaram tromboaspiração manual. Dividimos a análise em três períodos: 2008 a 2012 (P1), 2013 a 2014 (P2) e 2015 a 2016 (P3), de acordo com o ano de publicação dos principais estudos relacionados ao tópico. **Resultados:** Foram realizadas, no período, 14.003 intervenções coronárias percutâneas primárias, sendo a trombectomia aspirativa manual empregada em 5,7% (P1), 6,1% (P2) e 5,6% (P3) dos procedimentos. O P3 exibiu menor proporção de pacientes hipertensos (44,2%, 41,3% e 27,7%; p=0,036) e de tabagistas (64,1%, 69,4% e 50,8%; p=0,03), com maior prevalência de artérias ocluídas e lesões com trombo visível à angiografia. Observou-se maior utilização de tromboaspiração no primeiro período, com auge de 8% em 2012, sendo que, em 2016, o uso foi de apenas 2% (p<0,05). **Conclusões:** Foi baixo o uso de trombectomia aspirativa manual durante a intervenção coronária percutânea primária em todos os períodos analisados, com queda expressiva em 2016.

**Descriptores:** Trombectomy/métodos; Intervenção coronária percutânea; Brasil

## INTRODUCTION

Acute myocardial infarction (MI) is the leading cause of mortality in Brazil and worldwide.<sup>1</sup> In the majority of cases, acute MI occurs due to atherosclerotic plaque

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rupture associated to overlying thrombosis.<sup>2</sup> In 75 to 90% of ST-segment elevation MI patients, the thrombus is visible on the coronary angiogram, and this finding is associated with greater occurrence of no-reflow phenomenon, defined as absence of coronary flow after reopening the occluded vessel. One of the causes of no-reflow is distal embolization during primary percutaneous coronary intervention (PCI).<sup>3</sup> This is associated with an increase in mortality and reinfarction rates.<sup>4</sup>

Hence, there is pathophysiological support for preventing distal embolization - one of the causes of no-reflow - with the use of thrombus aspiration devices. In the TAPAS study (Thrombus Aspiration during Primary Percutaneous Coronary Intervention), routine use of a manual thrombus aspiration catheter (MTA) resulted in improved myocardial blush grade and ST-segment elevation resolution in the electrocardiogram.<sup>5</sup> In the 2011 American College of Cardiology/American Heart Association (ACC/AHA) guidelines, the use of this device obtained a class IIa recommendation.<sup>6</sup> However, despite the initial enthusiasm, results from later studies, such as TASTE (Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction),<sup>7</sup> and TOTAL (Randomized Trial of Primary PCI with or without Routine Manual Thrombectomy),<sup>8</sup> failed to demonstrate clinical benefits with routine MTA use, and the recommendation was revised to class III in the updated 2015 ACC/AHA guidelines.<sup>6</sup>

The objective of this study was to characterize the use of MTA in the Brazilian interventional practice, evaluating its temporal trends of use, according to the results of published clinical studies and the most impactful guidelines.

## METHODS

This was a cross-sectional study using the database of the *Central Nacional de Intervenções Cardiovasculares* (CENIC; <http://www.corehemo.net/>), involving ST-segment elevation MI patients who underwent primary PCI.

CENIC was established by the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI) in 1991, and is maintained and managed by it. The members contribute spontaneously, and are required to include clinical, angiographic, procedure-related data and information about in-hospital outcomes. The methodology and definitions were previously published.<sup>9</sup> Patients were treated at the discretion of the attending physician, in order to reflect current medical practice. The study was carried out after the approval of the Research Ethics Committee of the Hospital Leforte (CAAE 90669418.7.0000.5485).

For the purpose of this study, we selected ST-segment elevation MI patients, who underwent primary PCI from January 2008 to May 2016. We defined the following pe-

riods for comparison: 2008 to 2012 (P1); 2013 to 2014 (P2); and 2015 to 2016 (P3). The periods were defined based on the publication of the most important studies evaluating the use of MTA. The first period comprises the year in which the TAPAS study<sup>5</sup> was published; the second period begins with the publication of TASTE;<sup>7</sup> and the last period is marked by the publication of TOTAL.<sup>8</sup> Finally, we selected only patients who underwent MTA.

## Statistical analysis

Categorical data were compared using the Chi-square test or Fisher's exact test. Whenever necessary, the likelihood ratio test was used. Analysis of variance (ANOVA) was used for continuous data, and the Bonferroni correction for multiple comparisons. In all analyses, the significance level was set at 5% (p-value <0.05).

## RESULTS

A total of 14,003 primary PCI were recorded in the CENIC registry, from 2008 to 2016; in that, 10,238 were in P1, 2,608 in P2, and 1,157 in P3. MTA was used in 588 (5.7%), 160 (6.1%), and 65 (5.6%) procedures in the three respective periods ( $p=0.72$ ). Regarding clinical data, age, male ratio and risk factors, such as dyslipidemia and diabetes mellitus, did not differ among groups (Table 1), except for a lower prevalence of smoking and high blood pressure in P3. In the first period, the patients' condition was more severe, considering the higher percentage of patients in Killip class  $\geq 2$  ( $p=0.037$ ).

The angiographic extent of coronary artery disease, measured by the number of vessels affected, was similar among periods (Table 2). The right coronary artery and the left anterior descending artery were the vessels in which thrombus aspiration was most frequently performed. Compared with previous periods, P3 presented a higher prevalence of visible thrombus on angiography (76.6% vs. 88.8% vs. 92.3%;  $p<0.001$ ); with decreased use of adjunct glycoprotein IIb/IIIa inhibitors (45.1% vs. 30.2% vs. 29.2%;  $p<0.001$ ) (Table 3).

Over the periods, the MTA was used in vessels that were initially occluded (84.7% vs. 91.1% vs. 93.8%,  $p<0.001$ ). The pre-intervention coronary blood flow was similar among groups. The number of vessels treated and stent implantation and the diameter and mean length of stents were similar in all three periods. The drug-eluting stent use rate was low in all periods analyzed, ranging from 3.5 to 7.4%, with no difference in the success rate of the procedure.

Analyzing the temporal trends of MTA use, there was an initial increase of its use in 2008 (3%), reaching its peak in 2012 (8%). In 2016, there was a significant decline in its use (2%) (Figure 1). Analyzing the demographic regions, the South and Southeast used the device more often in all periods of the study (Figure 2).

**Table 1.** Clinical characteristics

Variables	2008-2012 (n=588)	2013-2014 (n=160)	2015-2016 (n=65)	p-value
Age, years	58.7±12.5	60.2±11.3	57.8±12.2	0.298
Male	428 (72.8)	118 (73.8)	44 (67.7)	0.637
Smoking	260 (44.2)	66 (41.3)	18 (27.7)	0.036
HTN	377 (64.1)	111 (69.4)	33 (50.8)	0.031
Dyslipidemia	261 (44.4)	71 (44.4)	29 (44.6)	0.999
Diabetes mellitus	126 (21.4)	40 (25.0)	15 (23.1)	0.621
Previous MI	37 (6.3)	10 (6.3)	6 (9.2)	0.653
Previous PCI	34 (5.8)	9 (5.7)	5 (7.7)	0.822
Previous CABG	10 (1.7)	2 (1.3)	0 (0.0)	0.335
Killip classification				0.037
1	447 (76.0)	131 (81.9)	58 (89.2)	
2	92 (15.6)	16 (10.0)	6 (9.2)	
3	15 (2.6)	4 (2.5)	1 (1.5)	
4	34 (5.8)	9 (5.6)	0 (0.0)	

Results expressed as mean±standard deviation and n (%). HTN: systemic arterial hypertension; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft.

**Table 2.** Angiographic characteristics

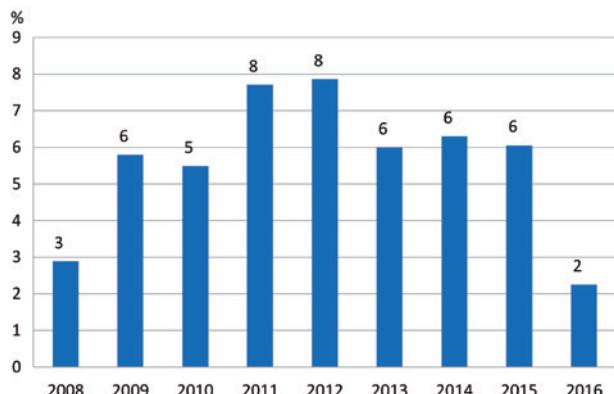
Characteristic	2008-2012 (n=592 procedures/ n=628 vessels)	2013-2014 (n=162 procedures/ n=169 vessels)	2015-2016 (n=65 procedures/n=65 vessels)	p-value
Extent of coronary artery disease				0.212
Single vessel	333 (57.1)	103 (64.0)	45 (70.3)	
Two-vessel	157 (26.9)	37 (23.0)	12 (18.8)	
Three-vessel	93 (16.0)	21 (13.0)	7 (10.9)	
Treated vessels				0.912
RCA	280 (44.6)	79 (46.7)	31 (47.7)	
LCx	49 (7.8)	16 (9.5)	5 (7.7)	
LAD	290 (46.2)	71 (42.0)	29 (44.6)	
Graft	7 (1.1)	2 (1.2)	0 (0.0)	
LMCA	2 (0.3)	1 (0.6)	0 (0.0)	
Type B <sub>2</sub> /C lesions	65 (98.5)	3 (100.0)	65 (100.0)	>0.999
Calcified lesions	90 (14.3)	16 (9.5)	6 (9.2)	0.160
Thrombotic lesions	481 (76.6)	150 (88.8)	60 (92.3)	<0.001
Lesions >20 mm	262 (41.7)	62 (36.7)	27 (41.5)	0.492
Bifurcations	135 (21.5)	28 (16.6)	8 (12.3)	0.103
TIMI flow pre				0.426
0/1	548 (87.3)	143 (84.6)	59 (90.8)	
2/3	80 (12.7)	26 (15.4)	6 (9.2)	
Left ventricular dysfunction	106 (67.9)	34 (59.6)	20 (74.1)	0.360
Collateral circulation	118 (23.9)	48 (35.6)	16 (24.6)	0.023

Results expressed as n (%). RCA: right coronary artery; LCx: left circumflex artery; LAD: left anterior descending artery; LMCA: left main coronary artery TIMI: Thrombolysis in Myocardial Infarction.

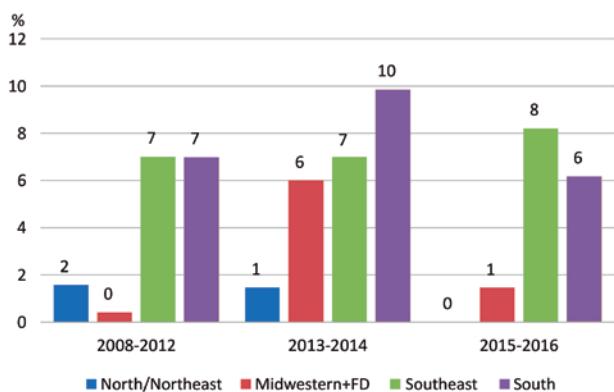
**Table 3.** Procedure characteristics

	2008-2012 (n=588 patients/n=592 procedures/n=658 stents)	2013-2014 (n=160 patients/n=162 procedures/n=176 stents)	2015-2016 (n=65 patients/n=65 procedures/n=68 stents)	p-value
Treated vessels/patient	1.1±0.3	1.0±0.2	1.0±0.0	0.101
Use of stent	588 (100.0)	160 (100.0)	65 (100.0)	NA
Stent/patient ratio	1.1±0.3	1.1±0.3	1.0±0.2	0.203
Drug-eluting stents	23 (3.5)	8 (4.5)	5 (7.4)	0.277
Stent diameter, mm	3.3±0.5	3.3±0.5	3.4±0.6	0.043
Stent length, mm	21.6±6.2	21.7±6.7	22.5±7.2	0.575
Glycoprotein IIb/IIIa inhibitors	267 (45.1)	49 (30.2)	19 (29.2)	<0.001
TIMI flow post				0.280
0/1	28 (4.3)	4 (2.3)	1 (1.5)	
2/3	630 (95.7)	172 (97.7)	67 (98.5)	
Stenosis grade				
Pre	98.5 (8.2)	99.3 (3.1)	99.8 (0.9)	0.163
Post	4.3 (1.4)	5.1 (1.4)	5.1 (0.9)	0.563
Success of procedure	575 (97.1)	157 (96.9)	65 (100.0)	0.373

Results expressed as mean±standard deviation and n (%). NA: not applicable; TIMI: Thrombolysis in Myocardial Infarction.



**Figure 1.** Proportion of patients submitted to manual thromboaspiration, per year.



**Figure 2.** Proportion of use of manual thromboaspiration, per region of the country.

## DISCUSSION

The main findings of this study were: low use of MTA in all periods, with a significant decrease in 2016; in the period between 2015 and 2016, patients who underwent MTA had higher percentage of lesions with a visible thrombus on angiography; the South and Southeast were the regions that more frequently used MTA in all periods.

Several percutaneous treatment strategies were developed to prevent the no-reflow phenomenon, but there was no consistency among the results.<sup>10-12</sup> Only in 2008, with the publication of TAPAS, the benefits of the routine use of MTA during primary PCI in the acute MI patients were demonstrated.<sup>5</sup> However, the primary outcome was a surrogate event, the myocardial blush, and the clinical trial had no statistical power to assess severe clinical outcomes. Nevertheless, aspiration thrombectomy received a class IIa recommendation in the 2011 ACC/AHA guidelines, possibly due to the “oculothrombotic reflex” and the risk of occurrence of no-reflow.<sup>6,13</sup>

In our registry, despite this recommendation class, low use of the device was observed in the first period, with a slight increase and a peak of only 8%, between 2011 and

2012. This contrasts to other series, such as the Swiss registry, in which the MTA was used in approximately 88% of cases from 2009 to 2012.<sup>14</sup> In the German ALKK (*Arbeitsgemeinschaft Leitende Kardiologische Krankenhausa*) PCI-registry, the use of the device was 20.2%,<sup>15</sup> whereas in the Euro Heart Survey PCI Registry, comprising data collected from 33 European Union countries, the use of the MTA occurred in 12.6% of primary PCIs — a rate closer to that of our registry.<sup>16</sup>

CENIC was not designed specifically for the analysis of MTA use, and data related to the circumstances of its use were not collected. Therefore, the following has been speculated as possible reasons for its low utilization: physician-related, such as diffusion of the new technology, and internalization and implementation of its use; or system-related, such as reimbursement and limitation of resources in the Brazilian health system.<sup>17,18</sup>

The second period analyzed begins in the year of publication of the TASTE study, whose objective was to assess whether the routine use of MTA in primary PCI reduced the mortality outcome when compared to the standard procedure. In an interim analysis, a low mortality rate was observed, rendering it necessary to increase the sample, with a final number of 7,244 patients included. The study was negative for reducing mortality. Despite this, there was no change in the recommendation class of the device, which can be attributed to limitations of the research, such as the lack of blinding, the system used for recruitment of centers, and the lack of adjudication of events.<sup>19</sup> In addition, a subsequent meta-analysis including TASTE results still demonstrated benefits from routine use of MTA.<sup>20</sup>

Only with the publication of the TOTAL study, in 2015, which marks the beginning of the third period analyzed in our research, the MTA has fallen into disuse. This randomized, controlled, event-adjudicated clinical study, with a sample size large enough to assess clinical outcomes (10,732 patients), demonstrated no clinical benefits from routine use of MTA in primary PCI.<sup>8</sup> In this study, the use of MTA was allowed in the control group in situations such as Thrombolysis in Myocardial Infarction (TIMI) grade flow 0 or 1, after pre-dilatation of the lesion with a balloon catheter, or persistence of a large thrombus load after stent implantation. MTA was used in approximately 8.5% of procedures. Using 2016 as a comparison, the use of MTA in CENIC was even lower than that observed in the TOTAL study control group.

As with any observational study, it has limitations. Since it is a voluntary contribution registry, the population profile may differ from the Brazilian reality. Although the CENIC registry contains more than 50% of primary PCI performed in the country, the mortality rate was almost half of that observed in the Brazilian Health System.<sup>21</sup> One possible reason for this is the lack of a systematic inclusion of patients who had events, and also the non-representativeness of all of the actively participating centers in the country.

## CONCLUSIONS

The use of a manual thrombus aspirator as an adjunct tool to primary percutaneous coronary intervention was low. The decrease in its utilization was immediate after the medical literature confirmed that its routine use does not reduce clinical events.

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