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PRACA ORYGINALNA
ORIGINAL PAPER

In vivo comparison of small- and large-bore aspiration catheters in patients with ST elevation myocardial infarction

Porównanie *in vivo* cewników aspiracyjnych o różnej średnicy u pacjentów z zawałem mięśnia sercowego z uniesieniem odcinka ST

Katarzyna Pigoń, Maciej Pękała, Natalia Tomecka, Edyta Radzik, Ewa Nowalany-Kozielska, Andrzej Tomasik

II Katedra i Oddział Kliniczny Kardiologii, Wydział Nauk Medycznych w Zabrzu, Śląski Uniwersytet Medyczny w Katowicach, Polska / 2nd Department of Cardiology, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Katowice, Poland

ABSTRACT

INTRODUCTION: Aspiration thrombectomy is recommended only in selected patients with ST elevation myocardial infarction (STEMI). Optical coherence tomography analysis revealed limitations of some aspiration catheters in thrombus removal. Additionally, *in vitro* tests show significant differences in their effectiveness depending on the design of the distal tip and their internal diameter. The aim of this study is to compare the results of percutaneous coronary intervention (PCI) alone and adjunctive aspiration thrombectomy using catheters with small and large cross-sectional areas, compare the effectiveness of coronary angioplasty with and without aspiration thrombectomy, as well as check the effectiveness of different catheters depending on their internal diameter.

MATERIAL AND METHODS: 773 patients with STEMI were enrolled in the study: 586 patients with PCI alone (Ctrl group), and 187 patients with PCI and aspiration thrombectomy. All the aspiration catheters were categorized as large--bore – 146 patients (LB group) and small-bore – 41 patients (SB group). Myocardial perfusion, left ventricular ejection fraction (LVEF) and the long-term all-cause mortality were compared. Statistical analysis was based on non--parametrical, ANOVA and Kaplan-Meier survival analysis.

RESULTS: The groups were significantly biased with respect to demographics and the angiographic presentation of myocardial infarction. In comparison with the Ctrl group the LB and SB groups were younger and presented worse epicardial flow and thrombus burden according to the Thrombolysis in Myocardial Infarction (TIMI) classification. There is an insignificant trend towards inferior myocardial perfusion in the SB group in comparison with the Ctrl group. The LB group had a lower pre-discharge LVEF in comparison to the Ctrl group. The long-term all-cause mortality was comparable across the groups.

CONCLUSIONS: There is not enough evidence to prove that SB catheters are less effective. A positive observation is the fact that the long-term all-cause mortality in the group of patients with adjunctive aspiration thrombectomy is comparable to the control group. However, this observation requires confirmation in future studies.

KEY WORDS

acute myocardial infarction, aspiration thrombectomy, percutaneous coronary intervention, STEMI, thrombectomy catheters, thrombus

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Address for correspondence: lek. Katarzyna Pigoń, II Katedra i Oddział Kliniczny Kardiologii, Wydział Nauk Medycznych w Zabrzu, Śląski Uniwersytet Medyczny w Katowicach, ul. M. Skłodowskiej-Curie 10, 41-800 Zabrze, tel. +48 32 373 23 72, e-mail: katarzynapigon@gmail.com

Publisher: Medical University of Silesia, Katowice, Poland

STRESZCZENIE

WSTĘP: Trombektomia aspiracyjna jest zalecana jedynie u wybranych pacjentów z zawałem mięśnia sercowego z uniesieniem odcinka ST (*ST elevation myocardial infarction* – STEMI). Analiza z wykorzystaniem optycznej tomografii koherencyjnej wykazała ograniczenia niektórych cewników aspiracyjnych w usuwaniu skrzepliny. Ponadto testy *in vitro* wskazują na istotne różnice w ich skuteczności zależnie od konstrukcji końcówki dystalnej oraz wewnętrznej średnicy. Celem pracy jest porównanie skuteczności przezskórnej interwencji wieńcowej (*percutaneous coronary intervention* – PCI) z zastosowaniem trombektomii aspiracyjnej oraz bez jej użycia, a także sprawdzenie skuteczności różnych cewników w zależności od ich wewnętrznej średnicy.

MATERIAŁ I METODY: Badaniem objęto 773 chorych ze STEMI: 586 chorych tylko po PCI (grupa Ctrl) oraz 187 chorych po PCI i trombektomii. Cewniki podzielono na te o dużym otworze (*large-bore* – LB), zastosowane u 146 pacjentów (grupa LB), oraz te o wąskim otworze (*small-bore* – SB) – u 41 pacjentów (grupa SB). Porównano perfuzję mięśnia sercowego, frakcję wyrzutową lewej komory (*left ventricular ejection fraction* – LVEF) i długoterminową śmiertelność z jakiejkolwiek przyczyny. Analizę statystyczną oparto na nieparametrycznej analizie przeżycia ANOVA oraz Kaplana i Meiera.

WYNIKI: Grupy charakteryzowała stronniczość wyboru w odniesieniu do danych demograficznych oraz prezentacji angiograficznej zawału mięśnia sercowego. W porównaniu z grupą Ctrl grupy LB i SB były młodsze, prezentowały wolniejszy przepływ nasierdziowy i większy materiał zakrzepowy w klasyfikacji TIMI (Thrombolysis in Myocardial Infarction). W grupie SB, w porównaniu z grupą Ctrl, obserwowano nieistotny trend w kierunku gorszej perfuzji mięśnia sercowego. Grupa LB miała niższą LVEF przed wypisem w porównaniu z grupą Ctrl. Długoterminowa umieralność z przyczyn ogólnych była porównywalna we wszystkich grupach.

WNIOSKI: Nie mamy wystarczających dowodów na to, że cewniki SB są mniej skuteczne. Pozytywną obserwacją jest fakt, że długoterminowa śmiertelność z jakiejkolwiek przyczyny w grupie pacjentów po trombektomii aspiracyjnej jest porównywalna z tą w grupie kontrolnej, wymaga ona jednak potwierdzenia w przyszłych badaniach.

SŁOWA KLUCZOWE

ostry zespół wieńcowy, trombektomia aspiracyjna, przezskórna angioplastyka wieńcowa, STEMI, cewniki aspiracyjne, skrzeplina

INTRODUCTION

Primary percutaneous coronary intervention (PCI) is the gold standard for the treatment of acute myocardial infarction [1,2]. Despite the continuous progress in interventional tools and techniques, the immediate results of primary coronary angioplasty remain far from optimal. Up to 40% of patients with restored normal epicardial blood flow TIMI III (Thrombolysis in Myocardial Infarction) have impaired myocardial perfusion [3] and microvascular obstruction arises as a major obstacle in complete heart muscle recovery [4]. In striving for procedural optimization, we have recently witnessed the introduction of appealing thrombus aspiration as an adjunct to primary PCI and an equally quick end to the hope. Due to the publication of results of the TOTAL and TASTE trials [5,6], which have questioned the effectiveness and safety of thrombus aspiration in an ST elevation myocardial infarction (STEMI) patients, its routine use was downgraded to the class III indication [1]. Currently, aspiration thrombectomy, as well as the use of stent retrievers, is mostly used in the management of cerebrovascular accidents. Though less popular in cardiology, aspiration thrombectomy may result in the improvement of coronary flow [7]. Numerous models of aspiration catheters can be found on the market, but the research for comparing the efficacy of their usage and long-term effects is very scarce. The aim of this study was to conduct an *in vivo* comparison of the angiographic effectiveness and long-term outcomes of primary PCI performed with adjunctive large-bore and small-bore aspiration catheters.

MATERIAL AND METHODS

There were 773 patients with STEMI enrolled in the study, who were admitted between 2004 and 2014 to 2nd Department of Cardiology, Faculty of Medical Sciences in Zabrze, Medical University of Silesia, Katowice, Poland. STEMI was diagnosed based on the patients' symptoms, electrocardiography (ECG) findings, creatine kinase–myocardial band (CK-MB) and cardiac troponin tests on presentation. If the time from the onset of chest pain was less than 12 hours, the participants were deemed eligible for primary PCI. Before PCI intervention, the patients were given 300 mg of acetylsalicylic acid and 600 mg of clopidogrel. The patients were divided into two groups: a control (Ctrl) group of 586 patients who underwent PCI alone, while the second group was comprised of 187 patients who received adjunct manual thrombus aspiration. Coronary angiography was performed via femoral or radial artery access. The decision to perform aspiration was based solely on intraoperative findings. All the aspiration catheters were 6 French ones, compatible with 146 patients in the large-bore (LB) group (Export – 0.87 mm^2, Hunter – 0.95 mm^2) and 41 patients in the small-bore (SB) group (Pollux –

0.78 mm^2, Quickcat – 0.86 mm^2, Diver – 0.64 mm^2). The distinction into aspiration catheter lumen reflected the results of *in vitro* tests performed by Rioufol et al. [8]. Myocardial perfusion was visually compared with the myocardial blush grade (MBG), and quantitatively with the on-line software Quantitative myocardial Blush Evaluator (QuBE). The left ventricle ejection fraction (LVEF) at hospital discharge, and long-term all-cause mortality was collected according to data provided by the Silesian Division of the National Health Fund.

All the patients were scored for sex, age, hypertension, diabetes, hyperlipidemia, smoking, family history, creatinine level, Killip class, infarct location, symptom duration, infarct related artery (IRA), initial TIMI flow, TIMI thrombus grade, administration of glycoprotein IIb/IIIa (GP IIb/IIIa) inhibitor, intra-aortic balloon pump, temporary pacing, stent and type of stent implantation, final TIMI flow and corrected TIMI frame count (cTFC). A detailed description of the materials and methods was published previously by Tomasik et al. [9]. Statistical analysis was based on non-parametrical, ANOVA and Kaplan-Meier survival analysis.

RESULTS

Demographic, angiographic, and procedural data are presented in Table I.

Table I. Demographic, angiographic, and procedural data
Tabela I. Dane demograficzne, angiograficzne i proceduralne

Data	Ctrl group n = 586	LB group n = 146	SB group n = 41	P
1	2	3	4	5
Men n (%)	410 (70.0)	103 (70.5)	22 (53.7)	0.045
Age yrs (X ± SD)	62.5 ± 11.0	59.2 ± 11.7	62.0 ± 12.6	0.01 (ANOVA)
Hypertension n (%)	368 (62.8)	83 (56.8)	30 (73.2)	NS
Diabetes n (%)	137 (23.4)	33 (26.4)	13 (31.7)	NS
Hyperlipidemia n (%)	298 (50.9)	84 (57.5)	23 (56.1)	NS
Smoking n (%)	280 (47.8)	72 (49.3)	20 (48.8)	NS
Family history n (%)	163 (27.8)	40 (27.4)	13 (31.7)	NS
Creatinine µmol/L (X ± SD)	82.2 ± 45.0	78.1 ± 23.5	77.8 ± 26.7	NS
Killip class n (%)				NS
I	565 (96.4)	140 (95.9)	39 (95.1)	
II–IV	21 (3.6)	6 (4.1)	2 (4.9)	
Infarct location n (%)				NS
anterior	251 (42.8)	59 (40.4)	15 (36.6)	
inferior	335 (57.2)	87 (59.6)	26 (63.4)	
Symptom duration min (X ± SD)	329 ± 427	344 ± 301	368 ± 282	NS
IRA n (%)				NS
LAD	251 (42.8)	59 (40.4)	15 (36.6)	
Cx	99 (16.9)	10 (6.9)	2 (4.9)	
RCA	236 (40.3)	77 (52.7)	24 (58.5)	
Initial TIMI flow n (%)				
0	218 (37.2)	115 (78.7)	30 (73.1)	0.0000
I	38 (6.5)	8 (5.5)	7 (17.1)	
II	72 (12.3)	3 (2.1)	2 (4.9)	
III	258 (44.0)	20 (13.7)	2 (4.9)	0.0000
TIMI thrombus grade n (%)				
0	92 (15.7)	3 (2.1)	0 (0.0)	
I	128 (21.8)	3 (2.1)	0 (0.0)	
II	79 (13.6)	10 (6.8)	4 (9.8)	
III	46 (7.8)	3 (2.1)	1 (2.4)	
IV	13 (2.2)	12 (8.2)	2 (4.9)	
V	228 (38.9)	115 (78.7)	34 (82.9)	0.0000

cd. tab. I

1	2	3	4	5
GP IIb/IIIa inh n (%)				
none	402 (68.6)	22 (15.1)	7 (17.1)	0.0000
abciximab	115 (19.6)	87 (59.6)	19 (46.3)	0.0000
integrilin	69 (11.8)	37 (25.3)	15 (36.6)	0.0000
IABP n (%)	14 (2.4)	4 (2.7)	1 (2.4)	NS
Temporary pacing n (%)	13 (2.2)	8 (5.5)	2 (4.9)	NS
Stent implantation n (%)				
BMS	433 (73.9)	99 (67.8)	26 (63.4)	
DES	99 (16.9)	15 (10.3)	10 (24.4)	0.037
Final TIMI flow n (%)				NS
0	13 (2.2)	1 (0.7)	0 (0.0)	
I	8 (1.4)	13 (8.8)	2 (4.9)	
II	53 (9.0)	23 (15.8)	3 (7.3)	
III	512 (87.4)	109 (74.7)	36 (87.8)	
cTFC n (X ± SD)	30.4 ± 19.5	33.9 ± 23.5	33.4 ± 25.6	NS

Ctrl – control; LB – large-bore; SB – small-bore; P – test probability; X – variable; SD – standard deviation; IRA – infarct related artery; LAD – left anterior descending artery; Cx – circumflex artery; RCA – right coronary artery; TIMI – Thrombolysis in Myocardial Infarction; GP – glycoprotein; IABP – intra-aortic balloon pump; BMS – bare metal stent; DES – drug-eluting stent; cTFC – corrected TIMI frame count; NS – not significant.

The groups were significantly biased with respect to the demographics and angiographic presentation of myocardial infarction. Thrombectomy was performed in younger patients mostly. The mean age was 59.2 ± 11.7 for LB and 62.0 ± 12.6 for SB compared to 62.5 ± 11.0 for the Ctrl group. The patients selected for thrombectomy had significantly worse epicardial flow graded in the TIMI classification. 78.7% patients of the LB group and 73.1% of the SB patients were classified as TIMI 0. In contrast, the Ctrl group only had 37.2% of patients that scored as 0 in the TIMI classification. A significantly higher thrombus burden as determined by the TIMI thrombus classification was also observed for the thrombectomy group – 78.7% of the patients from the LB group and 82.9% from the SB group scored class V, while the Ctrl group only scored 38.9%. In our study, no statistically significant differences for long-term TIMI flow among the three groups were found. As shown in Table II, there is an insignificant trend towards inferior myocardial perfusion (lower percentage of MBG III and lower QuBE score) in the SB group in comparison with the Ctrl. The LB group had a significantly lower pre-discharge LVEF (42.4 ± 11.0%) compared to the Ctrl (45.2 ± 10.5%).

Table II. Myocardial perfusion and QuBE assessment
Tabela II. Perfuzja mięśnia sercowego z oceną QuBE

Data	Ctrl group n = 586	LB group n = 146	SB group n = 41	P
MBG n (%)				NS
0	31 (5.3)	6 (4.1)	2 (4.9)	
I	46 (7.8)	28 (19.2)	7 (17.1)	
II	181 (30.9)	43 (29.4)	16 (39.0)	
III	328 (56.0)	69 (47.3)	16 (39.0)	
QuBE score arb. u. (X ± SD)	9.4 ± 4.3	9.4 ± 4.8	8.7 ± 3.0	NS
LVEF % (X ± SD)	45.2 ± 10.5	42.4 ± 11.0	44.5 ± 10.1	0.02

Ctrl – control; LB – large-bore; SB – small-bore; P – test probability; MBG – myocardial blush grade; QuBE – Quantitative myocardial Blush Evaluator; arb. u. – arbitrary unit; X – variable; SD – standard deviation; LVEF – left ventricular ejection fraction; NS – not significant.

There was no increase in the stroke rates during the peri-interventional period. The follow-up time was up to 1590 days. According to the Kaplan-Meier curves shown in Figure 1, the long-term all-cause mortality was comparable across the studied groups.

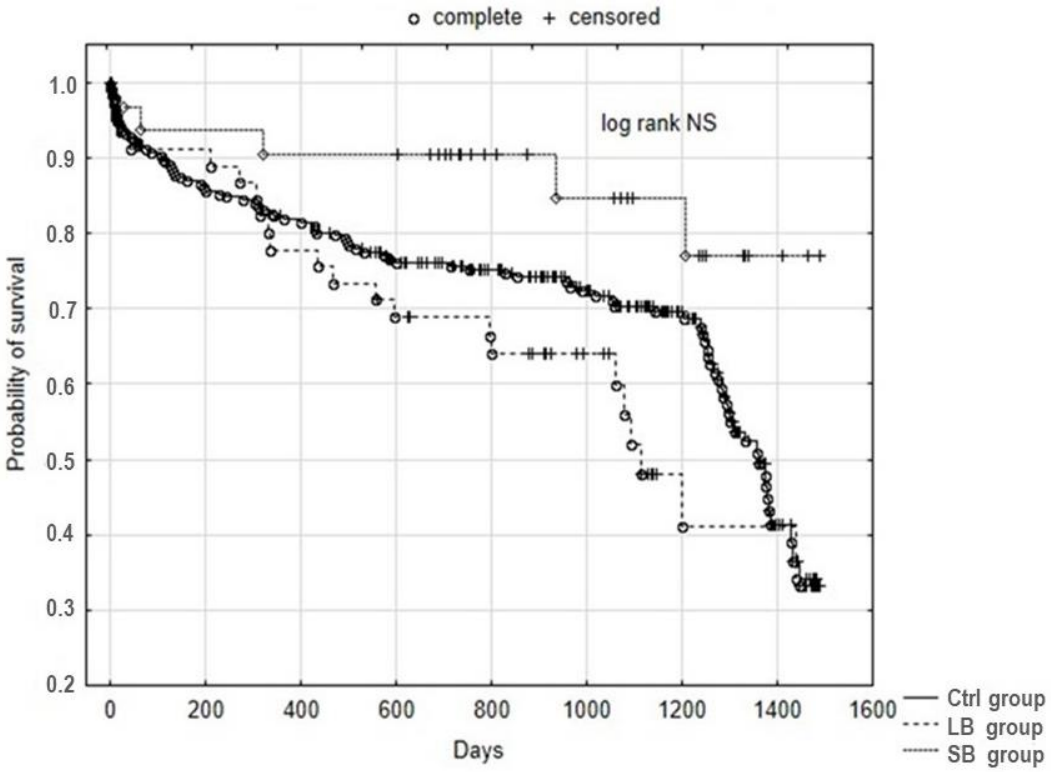

Fig. 1. Kaplan-Meier survival analysis in groups.
Ryc. 1. Krzywe przeżycia Kaplana i Meiera.

DISCUSSION

The data collected in this study found was that there is no significant difference between the long-term effects of using large- or small-bore catheters compared to primary PCI. The primary PCI has some limitations. One of them is the fact that insufficient myocardial reperfusion is observed in almost one fourth of the patients who had primary PCI performed [10]. This is the main reason why researchers are looking for alternatives. De Luca et al. [11] proved that the administration of abciximab following primary PCI can reduce the 30-day reinfarction rate and long-term mortality. In the TAPAS study, the authors noted that thrombectomy before stenting the occluded artery improved the 1-year clinical outcome compared to conventional PCI [12]. Bhindi et al. [13] in a substudy of the TOTAL trial proved with use of optical coherence tomography that aspiration thrombectomy does not reduce the thrombus burden before stenting compared to PCI-alone. Fröbert et al. [5] in the TASTE study found that manual thrombectomy does not increase the 30-day mortality as compared to the PCI--alone group. In this study, there was no difference for the stroke rates between the studied groups. In the TROFI study, no significant difference between primary PCI and the combination of primary PCI and aspiration thrombectomy was found [14]. As shown with optical coherence tomography, a similar flow area was noted in both groups.

Aspiration thrombectomy has limitations as well. In comparison to the TASTE trial, the TOTAL clinical trial found that thrombectomy use was associated with an increased risk of stroke within 30 days [6]. Selection of the most effective aspiration catheter would be the ideal solution. In this study, we searched for a difference between thrombectomies using large- and small-bore catheters. There are studies comparing aspiration thrombectomy with primary PCI, but not many exist evaluating the differences between various types of these devices. To date, only one study – by Vlaar et al. [15] – compared the immediate results of primary PCI with two different aspiration catheters. The authors found no differences either in the myocardial perfusion indices or in the electrocardiographic ST segment elevation resolution. Our study provides some more data on comparable outcomes in long-term follow-up between large- and small-bore aspiration catheters.

Our study has some limitations. It is a retrospective observational study in which we could not have access to all the variables. It was not randomized either, and the number of patients was relatively small. Another limitation is that it was a single center study, indicating a less variable population. There is still a need for more

research relevant to the usage of aspiration thrombectomy catheters in percutaneous coronary interventions.

CONCLUSIONS

The thrombectomy procedure performed in our study population is safe and the long-term prognosis in these patients is similar to the prognosis observed in patients who do not have thrombectomy performed. Thus, the study indicates that the individual decision of an interventional cardiologist to perform aspiration thrombectomy in STEMI may be acceptable.

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Author's contribution

Study design – K. Pigoń, A. Tomasik, E. Nowalany-Kozielska
Data collection – K. Pigoń, A. Tomasik, M. Pękała, N. Tomecka, E. Radzik, E. Nowalany-Kozielska
Data interpretation – K. Pigoń, A. Tomasik
Statistical analysis – A. Tomasik
Manuscript preparation – K. Pigoń, A. Tomasik, M. Pękała, N. Tomecka, E. Radzik, E. Nowalany-Kozielska
Literature research – K. Pigoń, A. Tomasik, M. Pękała, N. Tomecka, E. Radzik

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