

## Original paper

# No clinical benefit from manual thrombus aspiration in patients with non-ST-elevation myocardial infarction

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## Abstract

**Introduction:** There are scarce data on the usefulness of manual thrombectomy among patients with non-ST-elevation myocardial infarction (NSTEMI). Early positive reports were not supported by the clinical outcome in the recent TATORT-NSTEMI (Thrombus Aspiration in Thrombus Containing Culprit Lesions in Non-ST-Elevation Myocardial Infarction) study.

**Aim:** To analyze the long-term outcome of NSTEMI patients treated with manual thrombectomy during percutaneous coronary intervention (PCI) in the Polish multicenter National Registry of Drug Eluting Stents (NRDES) study.

**Material and methods:** There were 13 catheterization laboratories in Poland that enrolled patients in NRDES registry in 2010–2011. Patients with a diagnosis of NSTEMI were divided into two groups: those that were treated with manual thrombectomy for their primary PCI (T) and those who were not (NT).

**Results:** There were 923 patients diagnosed with NSTEMI in NRDES. Aspiration thrombectomy was used in 71 (7.7%) patients and the remaining 852 (92.3%) NSTEMI cases were treated without thrombectomy during the index PCI. Thrombectomy was more often used in patients with TIMI less than 1, thrombus grades 4 and 5 and older male patients. Percutaneous coronary interventions complications such as distal embolization and slow flow were more often observed in the thrombectomy subgroup. Overall mortality at 1 year was 1.69% in the T and 5.92% in the NT group ( $p = 0.24$  and  $p = 0.32$  after propensity score matching adjustment with  $p = 0.11$  in the multivariate logistic regression model).

**Conclusions:** There was no mortality benefit from thrombus aspiration in NSTEMI patients at 1-year follow-up.

**Key words:** myocardial infarction, registry, thrombectomy.

## Introduction

It has been postulated that there are several strategies that can reduce damage to the heart muscle from ischemia-reperfusion injury [1]. Conflicting data on the effectiveness of manual thrombus aspiration in ST elevation myocardial infarction (STEMI) patients treated with primary percutaneous coronary intervention (PCI) have been recently published [2–5]. Updated myocardial revascularization guidelines from the European Society of Cardiology (ESC) advises the use of thrombectomy during primary PCI in STEMI only in selected patients, thus degrading its use to class IIb [6]. On the other hand, there are hardly any data on the usefulness of manual thrombectomy among patients with non-ST-elevation myocardial infarction (NSTEMI), with no clear guideline recommendations. Early positive reports have not been

supported by clinical outcome, e.g. in the recent TATORT-NSTEMI (Thrombus Aspiration in Thrombus Containing Culprit Lesions in Non-ST-Elevation Myocardial Infarction) study [7, 8].

## Aim

Our aim was to analyze the real-life registry long-term outcome of NSTEMI patients treated with manual thrombectomy during PCI in the Polish multicenter National Registry of Drug Eluting Stents (NRDES) study. The results of this all-comers registry should provide complementary and contemporary information to the already available data.

## Material and methods

The NRDES was a study based on the Polish National PCI Registry, which is a mandatory database for Polish

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catheterization laboratories since 2004 [9]. An analysis of thrombectomy value and effectiveness in STEMI patients has been previously published using the NRDES database [5, 10]. There were 13 high-volume catheterization laboratories with 24/7 PCI duty that enrolled patients in the NRDES registry in 2010–2011 (12 months of enrollment). These were the centers that agreed to fill in the extended version of the National PCI Registry called NRDES. The main aim of this analysis was to compare the outcomes of NSTEMI patients (according to the ESC definition) who were treated with manual thrombectomy (other types of thrombectomy were excluded from the analysis) for their PCI procedure (T) vs those who were not (NT). The use of thrombectomy and type of the device were left at the operators' discretion and experience in each individual case since this was a registry study with no influence on the choice of therapy. Patients who were diagnosed with NSTEMI and underwent PCI were included in the registry (there were no additional exclusion criteria). The primary end-point of this analysis was overall mortality at 12 months. Secondary clinical endpoints included: non-fatal reinfarction, definite stent thrombosis (as defined by the Academic Research Consortium – ARC) [11], urgent revascularization (PCI and/or coronary artery bypass graft (CABG)) and target vessel revascularization at 1-year follow-up. Major adverse cardiovascular events (MACE) were defined as the occurrence of death, myocardial infarction, target vessel revascularization (TVR) or urgent PCI/CABG (hierarchical). Thrombus grade category was defined according to the original paper [12]. Chronic kidney disease was defined as the presence of the disease prior to the enrollment or creatinine clearance of less than 60 ml/min/1.73 m<sup>2</sup>.

The NRDES study complied with the Declaration of Helsinki and was approved by Bioethics Committee at the Jagiellonian University in Krakow, Poland (KBET/120/B/2010 at 30<sup>th</sup> September 2010).

### Statistical analysis

Data were analyzed according to the established statistical standards. Categorical variables are expressed as percentages (frequency); continuous variables are expressed as mean ± standard deviation. Normal distribution was assessed by the Shapiro-Wilk test and equality of variances using the Levene test. Between-group differences were tested by Student's or Welch's *t*-test for normally distributed or by the Mann-Whitney *U* test for non-normally distributed continuous variables. Categorical variables were compared by Pearson's  $\chi^2$  test or Fisher's exact test for 2 × 2 tables. The risk of MACE in the 12-month follow-up was determined by univariate and multivariate logistic regression.

Due to the observational nature of the study, the statistical analysis plan included a balancing for covari-

ates step. Balancing was performed for NSTEMI subject populations with thrombectomy performed and not performed during PCI. A one-to-one matched procedure without replacement was performed. We modeled the log odds of probability of thrombectomy being performed as a function of selected confounders depending on the subpopulation. Due to the small sample size of subjects with thrombectomy performed in the NSTEMI population, nearest neighbor matching was used. This method guarantees that a match is always found for all the treated units even if the calculated propensity score values are not close. The used confounders list consisted of: access site, age, arterial hypertension, chronic kidney disease, diabetes mellitus, gender, hyperlipidemia, Killip class on admission, lower limb atherosclerosis, clopidogrel loading dose before cath lab administration, previous CABG, previous PCI, prior myocardial infarction, prior stroke, thrombus grade category, thrombolysis in myocardial infarction (TIMI) before PCI and treated vessel (Cx, Dg, IM, LAD, LMCA, Mg, RCA, SvG). Pairs obtained by propensity score matching were analyzed using paired difference tests. Continuous variables were analyzed by paired *t*-tests if the differences between pairs were normally distributed; for non-normally distributed differences the Wilcoxon signed rank test was used. Paired categorical variables were compared using the McNemar-Bowker test to assess whether differences between subjects with and without thrombectomy performed were statistically significant. Values of *p* less than 0.05 were considered statistically significant. All calculations were done with JMP, Version 9.0.0 SAS Institute Inc., Cary, NC, 1989–2007.

Power calculations were performed retrospectively. For detecting a difference in MACE rate between patients treated with manual thrombectomy and patients with no thrombectomy the sample size actually used for type I error equal to 0.05 post hoc power was 64.2%. The power would be 90% if data available for group T were twice as large assuming the same rates. It should be noted that the post-hoc power analysis has been criticized as a means of interpreting negative study results. For this reason the results of the analysis should be interpreted with caution.

### Results

There were 2686 patients enrolled in the NRDES registry, of whom 923 were diagnosed with NSTEMI (34%). Aspiration thrombectomy was used in 71 (7.7%) patients and the remaining 852 (92.3%) NSTEMI patients were treated without thrombectomy during the index PCI. The thrombectomy use ranged from 2.8% to 21% in participating centers. Patient baseline demographic, angiographic, procedural and clinical characteristics in both subgroups T or NT unadjusted and adjusted are presented in Tables I and II. Thrombectomy was more often used in patients

**Table I.** Baseline demographics and angioplasty characteristics unadjusted

| Variable                               | Level                | NT (n = 852) | T (n = 71)  | Value of p |
|--|----------------------|--------------|-------------|------------|
| Age [years]                            | –                    | 62.8 ±11.2   | 66.3 ±11.7  | 0.01*      |
| Gender                                 | Male                 | 66.2% (564)  | 80.3% (57)  | 0.02*      |
|  | Female               | 33.8% (288)  | 19.7% (14)  |            |
| Prior myocardial infarction            | Yes                  | 25.9% (221)  | 16.9% (12)  | 0.1        |
| Arterial hypertension                  | Yes                  | 82.04% (699) | 77.5% (55)  | 0.3        |
| Hyperlipidemia                         | Yes                  | 70.5% (601)  | 70.4% (50)  | 1.0000     |
| Diabetes mellitus                      | Yes                  | 23.7% (202)  | 23.9% (17)  | 1.0000     |
| Chronic kidney disease                 | Yes                  | 6.8% (58)    | 1.4% (1)    | 0.08       |
| Prior stroke                           | Yes                  | 4.8% (41)    | 7.04% (5)   | 0.4        |
| Previous PCI                           | Yes                  | 15.9% (135)  | 9.9% (7)    | 0.2        |
| Previous CABG                          | Yes                  | 4.2% (36)    | 5.6% (4)    | 0.5        |
| Killip class on admission              | I                    | 95.8% (816)  | 97.2% (69)  | 0.8        |
|  | II                   | 2.5% (21)    | 1.4% (1)    |            |
|  | III                  | 0.8% (7)     | 0.0% (0)    |            |
|  | IV                   | 0.9% (8)     | 1.4% (1)    |            |
| Arterial access site                   | Femoral              | 85.2% (726)  | 81.7% (58)  | 0.8        |
|  | Radial               | 14.4% (123)  | 18.3% (13)  |            |
|  | Brachial             | 0.2% (2)     | 0.0% (0)    |            |
|  | Other                | 0.1% (1)     | 0.0% (0)    |            |
| Number of critically stenosed arteries | 1-vessel disease     | 38.03% (324) | 47.9% (34)  | 0.3        |
|  | 2-vessel disease     | 39.0% (332)  | 39.4% (28)  |            |
|  | 3-vessel disease     | 21.5% (183)  | 12.7% (9)   |            |
|  | LMCA and RCA disease | 0.7% (6)     | 0.0% (0)    |            |
|  | LMCA disease         | 0.8% (7)     | 0.0% (0)    |            |
| LMCA                                   | Yes                  | 1.3% (11)    | 1.4% (1)    | 1.0000     |
| LAD                                    | Yes                  | 36.03% (307) | 22.5% (16)  | 0.03*      |
| Dg                                     | Yes                  | 8.2% (70)    | 8.5% (6)    | 0.8        |
| IM                                     | Yes                  | 0.7% (6)     | 1.4% (1)    | 0.4        |
| Cx                                     | Yes                  | 24.06% (205) | 36.6% (26)  | 0.02*      |
| Mg                                     | Yes                  | 14.2% (121)  | 8.5% (6)    | 0.2        |
| RCA                                    | Yes                  | 29.3% (250)  | 35.2% (25)  | 0.3        |
| SvG                                    | Yes                  | 1.2% (10)    | 4.2% (3)    | 0.07       |
| Arterial graft                         | Yes                  | 0.0% (0)     | 0.0% (0)    | –          |
| TIMI before PCI                        | 0                    | 18.3% (156)  | 73.2% (52)  | < 0.0001*  |
|  | 1                    | 15.3% (130)  | 5.6% (4)    |            |
|  | 2                    | 19.4% (165)  | 7.04% (5)   |            |
|  | 3                    | 47.07% (401) | 14.08% (10) |            |
| GP IIb/IIIa inhibitors during PCI      | Abciximab            | 2.2% (19)    | 19.7% (14)  | < 0.0001*  |
|  | Eptifibatide         | 4.6% (39)    | 15.5% (11)  |            |
|  | None                 | 93.2% (794)  | 64.8% (46)  |            |

Table I. Cont.

| Variable  | Level               | NT (n = 852) | T (n = 71)  | Value of p |
|---|---------------------|--------------|-------------|------------|
| TIMI after PCI                                      | 2 and less          | 1.8% (15)    | 2.8% (2)    | 0.4        |
|   | 3                   | 98.2% (837)  | 97.2% (69)  |            |
| Stent type  | BMS                 | 66.8% (569)  | 64.8% (46)  | 0.8        |
|   | DES                 | 33.2% (283)  | 35.2% (25)  |            |
| Thrombus grade category                             | 1                   | 79.3% (676)  | 16.9% (12)  | < 0.0001*  |
|   | 2                   | 11.9% (101)  | 21.1% (15)  |            |
|   | 3                   | 3.05% (26)   | 12.7% (9)   |            |
|   | 4                   | 2.5% (21)    | 15.5% (11)  |            |
|   | 5                   | 3.3% (28)    | 33.8% (24)  |            |
| Thrombus grade category                             | 1–3                 | 94.3% (803)  | 50.7% (36)  | < 0.0001*  |
|   | 4–5                 | 5.8% (49)    | 49.3% (35)  |            |
| PCI successful                                      | Yes                 | 98.9% (843)  | 97.2% (69)  | 0.2        |
| Lesion in bifurcation                               | Yes                 | 8.5% (72)    | 14.08% (10) | 0.1        |
| IVUS guided procedure                               | Yes                 | 0.4% (3)     | 2.8% (2)    | 0.05       |
| OCT   | Yes                 | 0.1% (1)     | 1.4% (1)    | 0.2        |
| Side branch occlusion during PCI                    | Yes                 | 0.8% (7)     | 0.0% (0)    | 1.0000     |
| Coronary artery dissection after stent implantation | Yes                 | 2.6% (22)    | 4.2% (3)    | 0.4        |
| Distal embolization during PCI                      | Yes                 | 0.1% (1)     | 2.8% (2)    | 0.03*      |
| No-reflow   | Yes                 | 0.1% (1)     | 0.0% (0)    | 1.0000     |
| Slow-flow   | Yes                 | 2.0% (17)    | 7.04% (5)   | 0.02*      |
| Artery perforation                                  | Yes                 | 0.1% (1)     | 0.0% (0)    | 1.0000     |
| Cardiac tamponade during hospitalization            | Yes                 | 0.0% (0)     | 0.0% (0)    | –          |
| Clopidogrel – loading dose before cath lab          | 300 mg              | 5.9% (50)    | 1.4% (1)    | 0.1        |
|   | 600 mg              | 57.4% (489)  | 70.4% (50)  |            |
|   | Long-term therapy   | 1.5% (13)    | 1.4% (1)    |            |
|   | Without clopidogrel | 35.2% (300)  | 26.8% (19)  |            |
| Prasugrel – loading dose before cath lab            | Long-term therapy   | 1.4% (12)    | 0% (0)      | 0.6        |
|   | Without prasugrel   | 98.6% (840)  | 100% (71)   |            |
| Clopidogrel – loading dose in cath lab              | 300 mg              | 4.7% (40)    | 2.8% (2)    | 0.6        |
|   | 600 mg              | 29.3% (250)  | 23.9% (17)  |            |
|   | Long-term therapy   | 1.8% (15)    | 1.4% (1)    |            |
|   | Without clopidogrel | 64.2% (547)  | 71.8% (51)  |            |
| Prasugrel – loading dose in cath lab                | 60 mg               | 1.2% (10)    | 0% (0)      | 0.5        |
|   | Long-term therapy   | 0.9% (8)     | 0% (0)      |            |
|   | Without prasugrel   | 97.9% (834)  | 100% (71)   |            |

CABG – Coronary artery bypass graft, Cx – circumflex artery, Dg – diagonal artery, IM – intermediate artery, IVUS – intravascular ultrasound, LAD – left anterior descending artery, LMCA – left main coronary artery, Mg – marginal artery, OCT – optical coherence tomography, PCI – percutaneous coronary interventions, RCA – right coronary artery, SvG – saphenous vein graft, TIMI – Thrombolysis in Myocardial Infarction grade. Data are presented as mean ± standard deviation or number (percentage).

**Table II.** Baseline demographics and angioplasty characteristics adjusted

| Variable                               | Level                | NT (n = 71) | T (n = 71)  | Matched pairs | Value of p |
|--|----------------------|-------------|-------------|---------------|------------|
| Age                                    | –                    | 61.9 ±11.4  | 62.8 ±11.2  | 71            | 0.6        |
| Gender                                 | Female               | 22.5% (16)  | 19.7% (14)  | 71            | 0.7        |
|  | Male                 | 77.5% (55)  | 80.3% (57)  |               |            |
| Prior myocardial infarction            | Yes                  | 18.3% (13)  | 16.9% (12)  | 71            | 0.8        |
| Arterial hypertension                  | Yes                  | 81.7% (58)  | 77.5% (55)  | 71            | 0.6        |
| Hyperlipidemia                         | Yes                  | 70.4% (50)  | 70.4% (50)  | 71            | 1.0000     |
| Diabetes mellitus                      | Yes                  | 21.3% (15)  | 23.9% (17)  | 71            | 0.7        |
| Chronic kidney disease                 | Yes                  | 0.0% (0)    | 1.4% (1)    | 71            | –          |
| Prior stroke                           | Yes                  | 4.3% (3)    | 7.04% (5)   | 71            | 0.5        |
| Previous PCI                           | Yes                  | 8.5% (6)    | 9.9% (7)    | 71            | 0.8        |
| Previous CABG                          | Yes                  | 4.2% (3)    | 5.6% (4)    | 71            | 0.7        |
| Killip class on admission              | I                    | 100.0% (71) | 97.2% (69)  | 71            | –          |
|  | II                   | 0.0% (0)    | 1.4% (1)    |               |            |
|  | III                  | 0.0% (0)    | 0.0% (0)    |               |            |
|  | IV                   | 0.0% (0)    | 1.4% (1)    |               |            |
| Access site                            | Femoral              | 81.7% (58)  | 81.7% (58)  | 71            | 1.0000     |
|  | Radial               | 18.3% (13)  | 18.3% (13)  |               |            |
| Number of critically stenosed arteries | 1-vessel disease     | 36.6% (26)  | 47.9% (34)  | 71            | 0.6        |
|  | 2-vessel disease     | 40.85% (29) | 39.44% (28) |               |            |
|  | 3-vessel disease     | 19.72% (14) | 12.68% (9)  |               |            |
|  | LMCA and RCA disease | 2.82% (2)   | 0.00% (0)   |               |            |
| LMCA                                   | Yes                  | 0.0% (0)    | 1.4% (1)    | 71            | –          |
| LAD                                    | Yes                  | 29.6% (21)  | 22.5% (16)  | 71            | 0.4        |
| Dg                                     | Yes                  | 9.9% (7)    | 8.5% (6)    | 71            | 0.8        |
| IM                                     | Yes                  | 1.4% (1)    | 1.4% (1)    | 71            | 1.0000     |
| Cx                                     | Yes                  | 29.6% (21)  | 36.6% (26)  | 71            | 0.4        |
| Mg                                     | Yes                  | 4.2% (3)    | 8.5% (6)    | 71            | 0.3        |
| RCA                                    | Yes                  | 35.2% (25)  | 35.2% (25)  | 71            | 1.0000     |
| SvG                                    | Yes                  | 2.8% (2)    | 4.2% (3)    | 71            | 0.7        |
| Arterial graft                         | Yes                  | 0.0% (0)    | 0.0% (0)    | 71            | –          |
| TIMI before PCI                        | 0                    | 64.8% (46)  | 73.2% (52)  | 71            | 0.6        |
|  | 1                    | 5.6% (4)    | 5.6% (4)    |               |            |
|  | 2                    | 9.9% (7)    | 7.04% (5)   |               |            |
|  | 3                    | 19.7% (14)  | 14.08% (10) |               |            |
| GP IIb/IIIa inhibitors during PCI      | Abciximab            | 4.2% (3)    | 19.7% (14)  | 71            | 0.03*      |
|  | Eptifibatide         | 11.3% (8)   | 15.5% (11)  |               |            |
|  | None                 | 84.5% (60)  | 64.8% (46)  |               |            |
| TIMI after PCI                         | 2 and less           | 4.2% (3)    | 2.8% (2)    | 71            | 0.7        |
|  | 3                    | 95.8% (68)  | 97.2% (69)  |               |            |

Table II. Cont.

| Variable                                   | Level               | NT (n = 71) | T (n = 71)  | Matched pairs | Value of p |
|--|---------------------|-------------|-------------|---------------|------------|
| Stent type                                 | BMS                 | 63.4% (45)  | 64.8% (46)  | 71            | 0.9        |
|  | DES                 | 36.6% (26)  | 35.2% (25)  |               |            |
| Thrombus grade category                    | 1                   | 21.1% (15)  | 16.9% (12)  | 71            | 1.0        |
|  | 2                   | 21.1% (15)  | 21.1% (15)  |               |            |
|  | 3                   | 15.5% (11)  | 12.7% (9)   |               |            |
|  | 4                   | 14.08% (10) | 15.5% (11)  |               |            |
|  | 5                   | 28.2% (20)  | 33.8% (24)  |               |            |
| Thrombus grade category                    | 1–3                 | 42.3% (30)  | 49.3% (35)  | 71            | 0.3        |
|  | 4–5                 | 57.8% (41)  | 50.7% (36)  |               |            |
| Clopidogrel – loading dose before cath lab | 300 mg              | 1.4% (1)    | 1.4% (1)    | 71            | 0.8        |
|  | 600 mg              | 67.6% (48)  | 70.4% (50)  |               |            |
|  | Long-term therapy   | 0.0% (0)    | 1.4% (1)    |               |            |
|  | Without clopidogrel | 31.0% (22)  | 26.8% (19)  |               |            |
| Prasugrel – loading dose before cath lab   | Long-term therapy   | 2.8% (2)    | 0.0% (0)    | 71            | –          |
|  | Without prasugrel   | 97.2% (69)  | 100.0% (71) |               |            |
| Clopidogrel – loading dose in cath lab     | 300 mg              | 5.6% (4)    | 2.8% (2)    | 71            | 0.9        |
|  | 600 mg              | 16.9% (12)  | 23.9% (17)  |               |            |
|  | Long-term therapy   | 1.4% (1)    | 1.4% (1)    |               |            |
|  | Without clopidogrel | 76.06% (54) | 71.8% (51)  |               |            |
| Prasugrel – loading dose in cath lab       | 60 mg               | 5.63% (4)   | 0.0% (0)    | 71            | –          |
|  | Long-term therapy   | 1.4% (1)    | 0.0% (0)    |               |            |
|  | Without prasugrel   | 93.0% (66)  | 100.0% (71) |               |            |

CABG – Coronary artery bypass graft, Cx – circumflex artery, Dg – diagonal artery, IM – intermediate artery, LAD – left anterior descending artery, LMCA – left main coronary artery, Mg – marginal artery, PCI – percutaneous coronary interventions, RCA – right coronary artery, SvG – saphenous vein graft, TIMI – Thrombolysis in Myocardial Infarction grade. Data are presented as mean ± standard deviation or number (percentage).

with TIMI less than 1, thrombus grade 4 and 5, as well as older male patients. The PCI complications such as distal embolization and slow flow were more often observed in the thrombectomy subgroup. Primary and secondary endpoints of the analysis unadjusted and with adjustment by propensity score matching are depicted in Tables III and IV. Overall mortality at 1 year was 1.7% in group T and 5.9% in group NT ( $p = 0.2$  and  $p = 0.3$  after propensity score matching adjustment). There was an overall trend of more frequent MACE occurrence in the NT group, but it was non-significant. Unadjusted Kaplan-Meier survival curves and MACE curves for both groups are shown in Figures 1 and 2. Subgroup analyses showed no significant benefit from thrombus aspiration in selected subsets of patients (thrombus grade category, age, diabetes, target artery). Results from the multivariate logistic regression model revealed that thrombectomy use during PCI for NSTEMI was not an independent predictor of MACE at 12 months – Table V.

## Discussion

Whereas there are multiple trials and registries addressing the issue of thrombectomy use in the STEMI setting [3–5, 13, 14], the NRDES study is one of only a few existing in the PubMed database that discuss the use of manual aspiration thrombectomy in the NSTEMI subgroup of patients [15]. The data are complementary to those of other trials, since they represent real-life all-comers registry data from multiple centers in Poland. Previous studies have discarded its use and have proven no benefit for surrogate endpoints such as microvascular obstruction and infarct size [8]. Moreover, even though thrombus burden is present in visual assessment in up to 70% of NSTEMI cases and the notion of mechanical removal of thrombus seems plausible, the results of a randomized trial and in a real life population of the NRDES registry have not shown its beneficial effect [7, 16]. Current ESC guidelines give no specific recommendation on the use of thrombectomy in NSTEMI and have downgraded its use in the

**Table III.** Unadjusted primary and secondary outcomes at 1 year

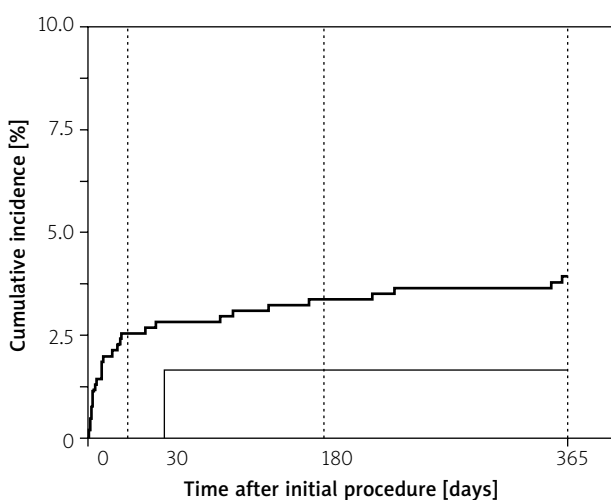
| 1-year outcome            | NT (n = 852) (%) | T (n = 71) (%) | Value of p |
|---------------------------|------------------|----------------|------------|
| Death                     | 5.9              | 1.7            | 0.2        |
| Stent thrombosis          | 0.4              | 0.0            | 1.0000     |
| TVR                       | 2.2              | 0.0            | 0.6        |
| reMI                      | 4.7              | 0.0            | 0.2        |
| Urgent PCI                | 8.2              | 3.7            | 0.4        |
| Urgent CABG               | 0.4              | 3.7            | 0.049*     |
| Urgent PCI or urgent CABG | 8.6              | 5.6            | 0.6        |
| MACE                      | 16.8             | 7.3            | 0.08       |

CABG – Coronary artery bypass graft, MACE – major adverse cardiovascular event, PCI – percutaneous coronary intervention, reMI – recurrent myocardial infarction, TVR – target vessel revascularization. Data are presented as number (percentage).

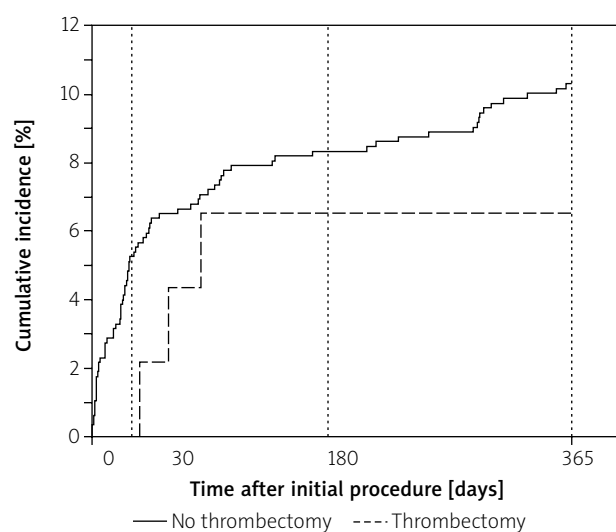
**Table IV.** Adjusted primary and secondary outcomes at 1 year

| 1-year outcome     | NT (n = 71) (%) | T (n = 71) (%) | Matched pairs | Value of p |
|--------------------|-----------------|----------------|---------------|------------|
| Death              | 5.8             | 1.9            | 52            | 0.3        |
| Stent thrombosis   | 0.0             | 0.0            | 36            | –          |
| TVR                | 5.6             | 0.0            | 36            | –          |
| reMI               | 2.8             | 0.0            | 36            | –          |
| Urgent PCI         | 11.1            | 5.6            | 36            | 0.4        |
| Urgent CABG        | 0.0             | 5.6            | 36            | –          |
| Urgent PCI or CABG | 11.1            | 8.3            | 36            | 0.7        |
| MACE               | 17.5            | 10.0           | 40            | 0.4        |

CABG – Coronary artery bypass graft, MACE – major adverse cardiovascular event, PCI – percutaneous coronary intervention, reMI – recurrent myocardial infarction, TVR – target vessel revascularization. Data are presented as number (percentage).



**Figure 1.** Kaplan-Meier survival curves for 1 year observation in T (thin line) vs. NT (thick line) groups respectively (log-rank test; adjusted results; p = 0.3)



**Figure 2.** Kaplan-Meier major adverse cardiovascular event curves for 1 year observation in T (dotted line) vs. NT (fine line) groups respectively (log-rank test; adjusted results; p = 0.2)

**Table V.** Logistic regression models for 12-month major adverse cardiovascular event occurrence

| Variable                    | OR             | Univariate     |                   | Multivariate <sup>a</sup> |                   | Multivariate <sup>b</sup> |                   |
|-----------------------------|----------------|----------------|-------------------|---------------------------|-------------------|---------------------------|-------------------|
|                             |                | OR (95% CI)    | Value of <i>p</i> | OR (95% CI)               | Value of <i>p</i> | OR (95% CI)               | Value of <i>p</i> |
| Age                         | 10 years       | 1.3 (1.07–1.6) | 0.009*            | 1.2 (1.02–1.5)            | 0.03*             | 1.3 (1.03–1.5)            | 0.02*             |
| Gender                      | Male/female    | 0.8 (0.5–1.3)  | 0.4               |                           |                   |                           |                   |
| Prior myocardial infarction | Yes/no         | 1.8 (1.08–2.8) | 0.02*             | 1.6 (1.0–2.6)             | 0.05              | 1.8 (1.1–3.02)            | 0.02*             |
| Prior stroke                | Yes/no         | 1.4 (0.5–3.3)  | 0.5               |                           |                   |                           |                   |
| Previous PCI                | Yes/no         | 1.3 (0.7–2.4)  | 0.3               |                           |                   |                           |                   |
| Previous CABG               | Yes/no         | 0.4 (0.07–1.5) | 0.2               |                           |                   | 0.3 (0.05–1.2)            | 0.09              |
| Arterial hypertension       | Yes/no         | 0.8 (0.5–1.3)  | 0.3               |                           |                   | 0.6 (0.4–1.1)             | 0.1               |
| Hyperlipidemia              | Yes/no         | 1.0 (0.6–1.6)  | 0.9               |                           |                   |                           |                   |
| Diabetes mellitus           | Yes/no         | 1.3 (0.8–2.1)  | 0.3               |                           |                   |                           |                   |
| Chronic kidney disease      | Yes/no         | 1.8 (0.8–3.8)  | 0.2               |                           |                   |                           |                   |
| TIMI 3 before PCI           | Yes/no         | 0.8 (0.5–1.3)  | 0.4               |                           |                   |                           |                   |
| TIMI 3 after PCI            | Yes/no         | 0.6 (0.2–2.6)  | 0.4               |                           |                   |                           |                   |
| LMCA                        | Yes/no         | 2.7 (0.6–10.2) | 0.2               |                           |                   |                           |                   |
| LAD                         | Yes/no         | 0.9 (0.6–1.4)  | 0.6               |                           |                   |                           |                   |
| Access site                 | Femoral/radial | 1.2 (0.7–2.2)  | 0.8               |                           |                   |                           |                   |
| Stent type                  | BMS/DES        | 1.1 (0.7–1.8)  | 0.6               |                           |                   |                           |                   |
| Thrombectomy                | Yes/no         | 0.4 (0.1–1.0)  | 0.04*             | 0.5 (0.1–1.2)             | 0.1               | 0.5 (0.1–1.2)             | 0.1               |

<sup>a</sup>Model fitted using backward stepwise regression (all listed variables initially included) with the Wald  $\chi^2$   $p < 0.05$  threshold stopping rule with the locked thrombectomy (the Wald  $\chi^2$  computed as (Estimate/Std Error)<sup>2</sup> for the hypothesis that the parameter is zero shows the prior myocardial infarction parameter to be statistically significant with  $p = 0.0499$ ; at the same time the likelihood-ratio  $\chi^2$  test calculated as twice the difference of the log-likelihoods between the full model and the model constrained by the hypothesis to be tested shows the parameter to be not statistically significant with  $p = 0.0539$ ). <sup>b</sup>Model fitted using backward stepwise regression (all listed variables initially included) with the minimum corrected Akaike information criterion stopping rule with the locked thrombectomy. CABG – Coronary artery bypass graft, CI – confidence interval, LAD – left anterior descending, LMCA – left main coronary artery, OR – odds ratio, PCI – percutaneous coronary intervention, TIMI – thrombolysis in myocardial infarction grade. Data are presented as odds ratio with 95% confidence interval and number (percentage).

STEMI population [6], largely due to the negative results of recent large trials and a meta-analysis [2–4]. Moreover, a recent survey revealed that aspiration thrombectomy is used routinely by 36% of physicians during PCI for STEMI and selectively in 60% of cases [17]. There is also reported a strong belief (89%) among interventional cardiologists that a confirmatory thrombectomy trial is needed. That is why we believe it is important to show our data as another layer of evidence in the poorly investigated issue of thrombectomy use in NSTEMI patients in contrast to the STEMI subgroup, which even in the presence of multiple data is still burdened with uncertainty as to the procedure. In the NRDES registry, the use of thrombectomy in NSTEMI patients was fairly rare (in up to 8% of patients) in comparison to STEMI [5], which suggests that it may have only been used in cases that seemed the most suitable ones for thrombus aspiration. Even though a bias to use thrombus aspiration in the case of a large thrombus burden, in older male patients and in the circumflex artery has been noted, still it was less pronounced than in the same population for the STEMI subgroup [5]. Half of the patients in our study where thrombectomy was used had a thrombus grade category 4–5, whereas in the no

thrombectomy group it was only 5.8%. This means that if thrombus was visible, aspiration was considered by the attending PCI operator. This was in fact the greatest bias that needed to be addressed by the statistical methodology to account for obvious baseline differences. The numerical difference between the thrombectomy and no thrombectomy group with regard to 1-year mortality both unadjusted and adjusted by propensity score matching is substantial but not statistically significant. Even though the T group was considered higher risk by demographics and angiography, it revealed lower mortality in long-term observation. Nevertheless, it should be noted here that the difference was not significant when either adjusted or unadjusted data were compared and may simply be a matter of chance, not reflecting a real difference. The observed mortality rates are also lower than in the previously published Polish data [18], which may reflect changing trends in treatment of acute MI in Poland over the years [19]. All the above might be the trigger to initiate a large trial focused on clinical endpoints in a selected cohort of NSTEMI patients with a visible thrombus burden. The NSTEMI patients are a heterogeneous group of patients often with a more aggravating past medical



history and outcome even in comparison to STEMI [20, 21] and certainly require scrutinized research on a specific subgroup of patients.

There was no angiographic source data verification by an independent PCI operator or corelab. No standardized procedure description was available and thrombectomy was performed according to local standards. Finally, the subgroup of NSTEMI patients with thrombectomy was too small (smaller than in e.g. the TATORT trial) to draw any definite conclusions.

## Conclusions

Use of aspiration thrombectomy in NSTEMI is rare in real life populations. There exists a selection bias for performing thrombectomy, especially in patients with a large thrombus burden. There was no mortality benefit after statistical adjustments from thrombus aspiration in NSTEMI patients at 1-year follow-up in this real-life all-comers multicenter registry. The rate of MACE was also similar.

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## Conflict of interest

The authors declare no conflict of interest.

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