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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

A prospective randomised comparison of minor bleedings in transradial vs. transfemoral access percutaneous coronary interventions for STEMI: a new FEMORAL bleeding classification

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Abstract

Background: Local bleedings related to vascular access site in percutaneous procedures are relatively common complications. However, no uniform definitions exist to classify them.

Aim: To compare minor bleedings related to transradial (TR) and transfemoral (TF) percutaneous coronary intervention (PCI) approaches in ST elevation myocardial infarction (STEMI). In addition, a new classification of TF access-related bleeding — the FEMORAL scale — was proposed.

Methods: OCEAN RACE is a prospective, randomised, open-label, clinical trial performed in STEMI patients treated with primary PCI. Patients were randomly assigned to the TR or TF arm. Bleedings related to the TR approach were assessed by the EASY scale, whereas bleedings related to the TF approach were classified according to the new FEMORAL scale. A combined analysis of all bleedings was performed using the TIMI scale.

Results: There were 103 patients analysed, including 52 in the TR arm and 51 in the TF arm. Analysis of demographic and clinical baseline characteristics revealed no significant differences between the two study groups. In-hospital bleedings related to the access site were observed in 29.8% of patients. In the TR group, a trend towards lower risk of local bleedings was observed compared to the TF group (TR: 22.4% vs. TF: 37.7%, $p = 0.081$). Analysis of each class of access site bleeding according to EASY/FEMORAL scales showed that patients in the TR group had a significantly lower risk of class III local haematoma compared to the TF group (TR: 0% vs. TF: 9.8%, $p = 0.027$). The risk of bleeding in other classes was comparable in both groups. A trend towards less frequent minimal bleedings according to the TIMI scale was observed in the TR group (HR: 0.41, 95% CI: 0.152–1.112, $p = 0.059$).

Conclusions: TF patients had a higher risk of access-related bleedings than TR patients. The FEMORAL scale was effective in the classification of TF access-related bleedings. Although the popularity of TF access in PCI decreases, this approach is increasingly used in transcatheter aortic valve implantation, renal denervation and closure of paravalvular leaks. Therefore a scale accessing local bleeding in the TF approach may be useful.

Key words: access site bleedings, percutaneous coronary interventions, bleeding grading scales, STEMI

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INTRODUCTION

Minor bleedings are relatively frequent in primary percutaneous coronary interventions (PCI) in patients with ST-segment elevation myocardial infarction (STEMI). The choice of vascular access in PCI is regarded as one of the modifiable elements that affect the efficacy, safety and cost effectiveness of the treatment. Due to the increasing role played by transradial (TR) access in PCI procedures, numerous studies have been

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performed comparing the TR and transfemoral (TF) access strategies and related complications [1–5]. Most of them, however, have focused mainly on major bleeding complications.

Appropriate bleeding classification is crucial for the management of acute cardiac syndrome patients with access-related bleeding complications. In the Early Discharge after Transradial Stenting of Coronary Arteries (EASY) trial, bleedings related to TR access have been classified according to the EASY grading scale [6]. Although the TF approach has a well-established role in PCI procedures, no uniform definitions exist to classify TF-related minor bleedings.

The aim of this study was to compare minor bleedings related to the TR and TF PCI approaches in STEMI. As a result, a new classification of TF access-related bleeding — the FEMORAL scale — was proposed.

METHODS

Study design

OCEAN RACE was a prospective, randomised controlled trial comparing the TR to the TF approach in STEMI patients treated with PCI. Patients who underwent primary PCI at the 1st Department of Cardiology, Medical University of Warsaw between September 2012 and October 2013 were enrolled. Due to methodological reasons and the procedure based nature of the study, blinding was not possible. The ethics committee of the Medical University of Warsaw approved the study and all patients provided written informed consent.

In this subanalysis, radial artery with femoral artery access site bleedings were compared with the use of the EASY trial haematoma grading scale (Table 1) and the FEMORAL grading scale respectively. The FEMORAL grading scale is a new scheme for the assessment of femoral artery access site bleeding developed by the OCEAN RACE authors on the basis of the EASY scale [6]. Taking into account the size of the haematoma, muscular infiltration and ischaemic threat due to compartment syndrome, it classifies the bleeding into five grades (Table 2). Figure 1 displays the FEMORAL grading system with the corresponding treatment strategies' suggestions. Additionally, in order to perform a combined analysis of all bleedings, the Thrombolysis in Myocardial Infarction (TIMI) classification was used [7].

Participants

The eligibility criteria consisted of acute coronary syndrome with STEMI lasting less than 24-h, age more than 18 years, and normal Allen's test [8]. Exclusion criteria included the international normalised ratio of > 1.4, platelet count below 100,000, history of coronary artery bypass grafting, reported previous difficulty in receiving an intra-arterial access, active bleeding, history of stomach or duodenal ulcers, present or planned dialysis, end-stage liver failure (MELD score > 10 points), uncontrolled hypertension (> 160/100 mm Hg), cardiogenic shock or lack of follow-up after hospitalisation.

Table 1. The EASY scale: classification of transradial access-related bleedings in percutaneous coronary interventions

Class	Description
I	Local superficial haematoma of diameter below 5 cm
II	Haematoma with moderate muscular infiltration of 5–10 cm
III	Forearm haematoma with muscular infiltration larger than 10 cm below the elbow
IV	Forearm haematoma with muscular infiltration larger than 10 cm extending above the elbow
V	Haematoma with ischaemic threat (compartment syndrome)

The EASY Scale — Early Discharge After Transradial Stenting of Coronary Arteries trial [6]

Table 2. The FEMORAL scale: classification of transfemoral access-related bleedings in percutaneous coronary interventions

Class	Description
I	Local superficial haematoma of diameter below 5 cm
II	Haematoma infiltrating muscle tissue with diameter 5–10 cm
III	Haematoma infiltrating muscle tissue with diameter > 10 cm but not extending below the knee or above the hip, false aneurysm, retroperitoneal space haematoma
IV	Haematoma infiltrating muscle tissue with diameter > 10 cm, haematoma extending below the knee or above the hip, false aneurysm, retroperitoneal space haematoma
V	Ischaemia threatening haematoma, hypovolemic shock, persistent false aneurysm, retroperitoneal space haematoma

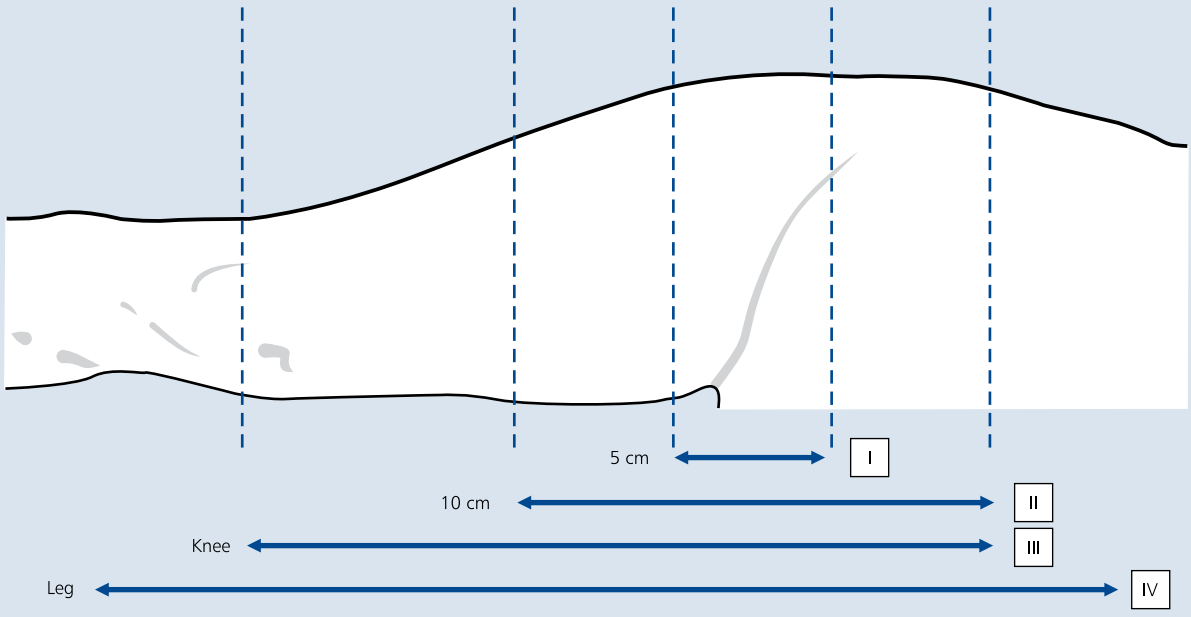
Modified on the basis of the EASY scale [6]

Randomisation

A total of 103 STEMI patients were randomly assigned to TR or TF access in a 1:1 ratio. Six (5.8%) patients were crossed over between the study arms at the discretion of the operator (three in the TR group and three in the TF group). Eventually, 52 patients had a TR PCI and 51 patients had a TF PCI procedure.

Procedures

Patients were treated according to the current guidelines of the European Society of Cardiology [9]. All operators had the experience of performing more than 90% of procedures from the TR approach. Patients included in the study did not participate in other studies. All patients received dual



Class	I	II	III	IV	V
Definition	Local haematoma < 5 cm	Haematoma infiltrating muscle tissue with diameter 5–10 cm	Haematoma infiltrating muscle tissue with diameter > 10 cm but not extending below the knee or above the hip, false aneurysm, retroperitoneal space haematoma	Haematoma infiltrating muscle tissue with diameter > 10 cm but not extending below the knee or above the hip, false aneurysm, retroperitoneal space haematoma	Ischaemia threatening haematoma, hypovolemic shock, persistent false aneurysm, retroperitoneal space haematoma
Treatment	Painkillers Prolonged comparison Ice packs	Painkillers Prolonged comparison Ice packs Diagnostic ultrasound/Doppler Full blood count	Painkillers Prolonged comparison Ice packs Palpitation/osculation Diagnostic ultrasound/Doppler Full blood count	Painkillers Prolonged comparison Ice packs Diagnostic ultrasound/Doppler	Surgical/endovascular treatment Full blood count
Action points		Inform the treating physician and write in the medical notes	Inform the treating physician and write in the medical notes	Inform the treating physician and write in the medical notes	Urgently inform the treating physician and write in the medical notes

Figure 1. The FEMORAL grading scale: classification of transfemoral access-related bleedings in percutaneous coronary interventions. The FEMORAL grading scale was developed on the basis of the EASY scale describing transradial access-related bleeding [6]

antiplatelet therapy and a bolus of unfractionated heparin (UFH 70–100 IU/kg). Administration of glycoprotein (GP) receptor IIb/IIIa antagonists (eptifibatide or abciximab) was left to the operator's decision. If administered, a dose of UFH was limited to 50–60 IU/kg.

During the procedure, either a bare metal stent or a drug eluting stent was implanted. The interventions were restricted only to the culprit lesion. Six-French vascular sheaths were used in all patients. No intra-aortic balloon pump was used in the cohort. According to our centre's protocol, an arterial femoral sheath was not removed for 6 to 8 h after the procedure. Thereafter, haemostasis was achieved by manual compression for 7 min. Vascular closure devices were not applied in the TF access group. Subsequently, a compression

Table 3. Baseline characteristics of the analysed population

	Radial access	Femoral access	P
Age [years]	61 (49.7–72.2)	62.8 (50.2–75.4)	0.436
Height [cm]	170.4 (163.2–177.7)	169.2 (159.9–178.5)	0.475
Weight [kg]	76 (60.5–91.5)	77.8 (62.9–92.7)	0.567
Body mass index [kg/m^2]	26 (21.7–30.2)	27 (22.7–31.3)	0.212
Body surface area [m^2]	1.89 (1.659–2.116)	1.89 (1.674–2.104)	0.948
Pulse [bpm]	82 (60.8–103.0)	78 (58.5–97.1)	0.295
Systolic BP [mm Hg]	140.5 (110.2–170.8)	132.2 (107.1–157.3)	0.136
Diastolic BP [mm Hg]	77.5 (59.1–95.9)	70.8 (55.8–85.9)	0.051
Hypertension	69.8%	68.2%	1.00
Diabetes type 2	18.2%	27.7%	0.33
Previous MI	7.7%	8.3%	1.00
Hyperlipidaemia	69.2%	75.0%	0.66
Chronic kidney disease	12.0%	18.4%	0.41
Peripheral artery disease	13.2%	15.4%	1.00
Smoking	65.3%	66.7%	1.00
Oral anticoagulation	2.6%	0.0%	0.49
Hypo-/hyperthyroidism	10.0%	12.5%	1.00
Carotid artery stenosis	7.9%	5.1%	0.66
Haemoglobin [g/dL]	13.7 (12.2–15.2)	13.9 (12.5–15.3)	0.446
Platelets [10^3/μL]	235.1 (169.2–301.0)	226.5 (157.3–295.7)	0.524
Troponin [ng/mL]	6.5 (0.00–18.17)	20.4 (0.00–77.28)	0.089
Creatinine [mg/dL]	1.0 (0.6–1.4)	1.0 (0.6–1.4)	0.457
eGFR [mL/min/1.72 m^2]	86.5 (62.4–110.6)	87.9 (59.7–116.2)	0.794
Total cholesterol [mg/dL]	201 (153.3–248.7)	197.6 (155.7–239.4)	0.71
LDL-C [mg/dL]	128.4 (89.4–167.4)	121.9 (82.1–161.7)	0.434
HDL-C [mg/dL]	42.6 (26.7–58.5)	44.4 (30.5–58.3)	0.561
Triglycerides [mg/dL]	169.3 (31.8–306.8)	144.7 (70.1–219.3)	0.28
Procedure time [min]	42.55 (24.35–60.77)	39.65 (18.66–60.64)	0.45

Values presented as average (95% confidence interval) if not indicated otherwise; BP — blood pressure; MI — myocardial infarction; eGFR — estimated glomerular filtration rate; LDL-C — low density lipoprotein cholesterol; HDL-C — high density lipoprotein cholesterol

bandage was used for the following 8 h. Patients were evaluated for access-related minor bleedings according to the EASY, FEMORAL and TIMI scales.

Statistical analysis

IBM SPSS Statistics (version 21) was used for all analyses. Continuous variables were described as mean ± standard deviation with categorical variables described as number (%). To analyse the differences between the groups, nonparametric χ^2 test was used for variables with normal distribution. Continuous data was compared by *t* test with assumption of equal variances. Meta-analysis was performed per the recommendations of the Cochrane Collaboration and the MOOSE statement [10]. I2 statistic was calculated to estimate heterogeneity among studies. Since significant heterogeneity was present, random-effects models were used to compute odd ratios (OR) with 95% confidence interval (CI). Statistical significance was defined as a p value < 0.05. Analyses were done according to the intention-to-treat principle.

RESULTS

A group of 103 patients was analysed, including 52 patients in the TR arm and 51 patients in the TF arm. Analysis of baseline characteristics revealed no significant differences between these groups; baseline variables are presented in Table 3.

In-hospital bleedings related to the access site were observed in 29.8% of patients. A trend of lower risk of access

Table 4. Access site-related bleedings: the EASY/FEMORAL grading scales

Class	Summary	Transradial access	Transfemoral acces	P
I	14.9% (n = 14)	9.6% (n = 5)	17.6% (n = 9)	0.184
II	5.3% (n = 5)	5.8% (n = 3)	3.9% (n = 2)	0.509
III	5.3% (n = 5)	0% (n = 0)	9.8% (n = 5)	0.027
IV	4.3% (n = 4)	5.8% (n = 3)	2.0% (n = 1)	0.316
V	0% (n = 0)	0% (n = 0)	0% (n = 0)	–
Summary	29.8% (n = 28)	22.4% (n = 11)	37.7% (n = 17)	0.081

FEMORAL scale — transfemoral access-related bleeding classification; EASY scale — transradial access-related bleeding classification

Table 5. Bleedings according to the Thrombolysis in Myocardial Infarction classification [7]

Bleeding	Transradial access	Transfemoral access	P
Major	3.8% (n = 2)	2.0% (n = 1)	0.507
Minor	13.5% (n = 7)	15.7% (n = 8)	0.484
Minimal	9.6% (n = 5)	17.6% (n = 9)	0.184

site bleedings was observed in the TR group compared to the TF group (TR: 22.4% vs. TF: 37.7%, p = 0.081). Analysis of each class scale showed that patients treated with TR PCI had significantly lower risk of class III haematomas according to EASY/FEMORAL scales compared to the TF group (TR: 0% vs. TF: 9.8%, p = 0.027). The risk of bleeding in other classes was comparable in both groups (Table 4). The risk of site bleeding was associated with the efficacy of gaining arterial access. Minor bleedings were observed more often when the primary attempt was ineffective and the operator had to change the target vessel (TR: 22.2% vs. TF: 3.2%, p = 0.059). A trend towards less frequent minimal bleedings according to the TIMI scale was observed in the TR group (HR: 0.55, 95% CI: 0.196–1.515, p = 0.184). The risks of major, minor and minimal bleeding according to the TIMI classification in TR and TF groups are presented in Table 5.

Bleedings leading to haemoglobin drop were rare (TR: 5.8% vs. TF: 3.9%, p = 0.509). Average haemoglobin decrease was moderate; in the TR group 0.99 ± 1.37 g/dL and in the TF group 1.12 ± 1.38 g/dL (p = 0.64). There were no dissections or retroperitoneal bleedings in the analysed groups.

Additionally, we performed a simplified meta-analysis of the randomised clinical trials evaluating minor bleedings connected with TR and TF access (Fig. 2). We collected data from 11 studies including the OCEAN RACE trial involving a total of 2,800 patients. Only studies presenting the incidence of minor bleedings according to the TIMI and EASY classification or the size of haematoma were included. This meta-analysis confirmed the superiority of the TR over the TF access in terms of minor bleeding risk in PCI, and the OCEAN RACE study was consistent with this finding.

DISCUSSION

The results of this study revealed that TR access was associated with a lower risk of class III haematoma according to the EASY/FEMORAL scales compared to TF access.

These findings are consistent with those of such large clinical trials as the Radial Versus Femoral Randomised Investigation in ST-Elevation Acute Coronary Syndrome (RIFLE-STEACS) study, the ST Elevation Myocardial Infarction Treated by RADIAL or Femoral Approach in a Multicentre Randomised Clinical Trial (STEMI-RADIAL), and the Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL) trial [2, 3, 11].

However, some recent literature has discussed the reliability of the above studies [12]. The arguments are raised that these trials employed suboptimal antithrombotic practices, the dose of heparin and percent of patients on GP IIb/IIIa inhibitors were unnecessarily high, few patients received bivalirudin, which decreases bleeding risk. Additionally the larger gauge catheters used in TF access patients could predispose to bleeding. In the OCEAN RACE, patients did not receive bivalirudin. Therefore it remains uncertain whether a comparably significant difference in minor bleeding risk between TR and TF access would be observed in patients on bivalirudin and without adjunctive GP IIb/IIIa inhibitors.

The reported incidence of access-related haematomas larger than 5 cm is estimated as 2.2–4.4% [13, 14]. However, their clinical significance and impact on prognosis are ambiguous. Besides, there are no uniform classifications of this type of complication. According to some grading scales used in clinical trials related to acute cardiac syndrome, such

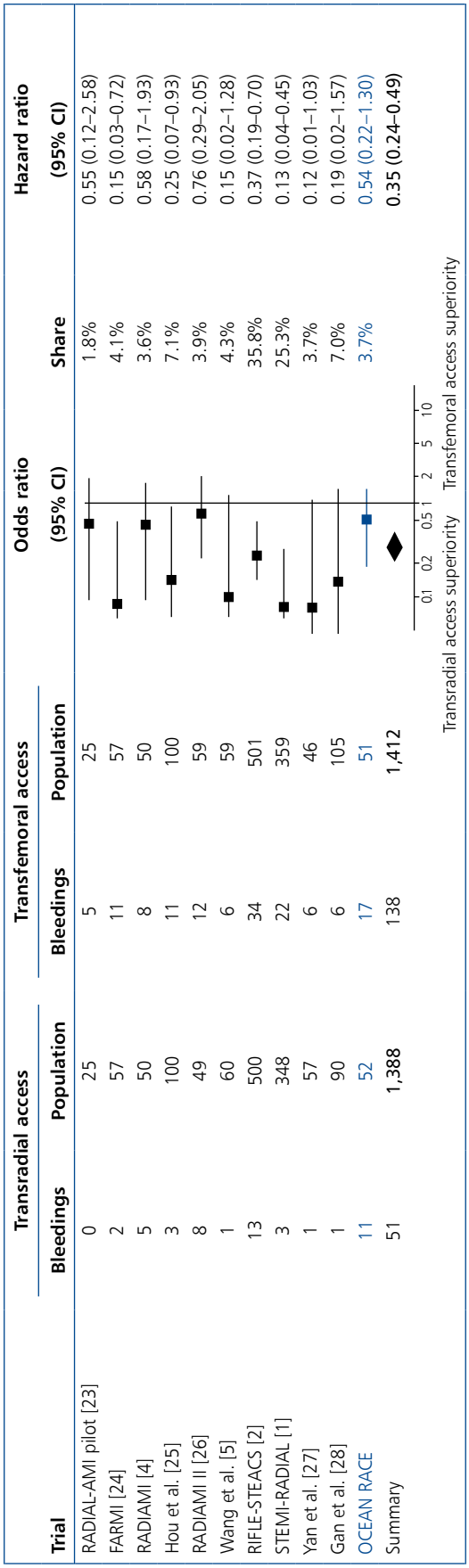


Figure 2. A simplified meta-analysis of randomised trials comparing minor bleedings related to transradial and transfemoral access; CI — confidence interval

as TIMI or STEEPLE [15, 16], haematomas of this size are classified as minor bleedings. In contrast, other studies have assessed haematomas of above 5 cm as major bleedings that could possibly increase the risk of death, rehospitalisation and cardiovascular complications [15, 17].

The FEMORAL scale was effective in the assessment and discrimination of TF access-related bleedings. Quick recognition and implementation of appropriate procedures are crucial in the bleeding treatment; therefore clear definition of femoral haematoma may facilitate early management of such complications and improve outcomes.

The bleedings evaluated in this study were not classified according to the Bleeding Academic Research Consortium (BARC) developed to standardise the method of reporting of bleeding complications in clinical trials in cardiovascular disease due to the fact that the study had started before the BARC criteria were published in 2011 and a reliable data supplement for patients already enrolled was not possible [18]. The new BARC classification, however, does not differentiate the access site bleeding in terms of haematoma size, muscular infiltration or ischaemic threat risk and, as a consequence, the proposed FEMORAL scale may constitute a good supplement for this initiative.

Although the popularity of TF access in PCI decreases, this approach is increasingly used in transcatheter aortic valve implantation, percutaneous interventions with MitraClip device implantation, and atrial septal defects or ventricular septal defects occlusion procedures [19–22]. Therefore the problem of minor bleedings related to TF access will remain in daily clinical practice, and a grading system of haematomas connected with this approach may be useful.

Limitations of the study

The main limitation of our study was the low number of enrolled patients. Calculated p values oscillated around 0.05, which is the threshold for statistical significance. A term of 'statistical trend' was implemented to describe the differences that were not statistically significant. However, it is very likely that a larger cohort of the study population would improve the statistical power. Due to the low number of patients, we did not confirm a higher rate of TIMI minor bleeding, although there was a numerical difference. Another limitation is the single-centre character of the trial. The 1st Department of Cardiology of Warsaw Medical University is a tertiary referral centre where patients with multiple comorbidities and, as a consequence, with higher bleeding risk at baseline, are hospitalised. This must be taken into consideration when the OCEAN RACE results are compared to other studies.

CONCLUSIONS

The risk of minor bleeding may be related to the vascular access type and is likely to be higher in patients undergoing PCI from a TF approach. The FEMORAL scale is a new tool

that supports comprehensive classification of TF-related local bleedings. There is a need for continuous assessment of bleeding risk in patients undergoing percutaneous procedures from a TF approach.

Conflict of interest: *none declared*

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Skala FEMORAL: nowa klasyfikacja krwawień miejscowych wśród pacjentów z STEMI leczonych przezskórną interwencją wieńcową. Subanaliza randomizowanego, kontrolowanego badania OCEAN RACE

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Streszczenie

Wstęp: Krwawienia miejscowe związane z dostępem naczyniowym w przezskórnych interwencjach wieńcowych (PCI) są stosunkowo częstym powikłaniem, nadal jednak brakuje jednolitych definicji dotyczących ich klasyfikacji.

Cel: Celem badania było porównanie miejscowych krwawień związanych z dostępem promieniowym (TR) oraz dostępem udowym (TF) w PCI u pacjentów z zawałem serca z uniesieniem odcinka ST (STEMI). Ponadto zaproponowano nową klasyfikację krwawień związanych z dostępem udowym — skalę FEMORAL.

Metody: OCEAN RACE to prospektywne, kontrolowane, randomizowane badanie kliniczne, które przeprowadzono w grupie osób z STEMI leczonych pierwotną PCI. Pacjentów losowo przydzielano do grup TR i TF. Krwawienia miejscowe związane z TR klasyfikowano na podstawie skali EASY, natomiast krwawienia związane z TF wg nowej skali FEMORAL. W celu wykonania złożonej analizy wszystkich krwawień oceniono je wg skali TIMI.

Wyniki: Przenalizowano dane 103 pacjentów, wśród nich 52 z grupy TR oraz 51 z grupy TF. Ocena wyjściowej charakterystyki badanej populacji nie wykazała istotnych statystycznie różnic między porównywanymi grupami. Wewnątrzszpitalne krwawienia związane z miejscem dostępu zaobserwowano u 29,8% osób. Zanotowano trend w kierunku niższego ryzyka krwawień miejscowych w grupie TR w porównaniu z grupą TF (TR: 22,4% *vs*. TF: 37,7%; p = 0,081). Analiza poszczególnych klas wykazała istotnie częstsze występowanie krwiaków podskórnych w klasie III wg EASY/FEMORAL u chorych leczonych z dostępu udowego (TR: 0% *vs*. TF: 9,8%, p = 0,027). Ryzyko krwawienia w pozostałych klasach było podobne w obu grupach. Ponadto zaobserwowano trend w kierunku mniejszej częstości krwawień minimalnych wg skali TIMI w grupie TR (HR: 0,41; 95% CI: 0,152–1,112; p = 0,059).

Wnioski: Pacjenci leczeni z dostępu TF charakteryzowali się wyższym ryzykiem krwawień związanych z dostępem naczyniowym niż chorzy leczeni z dostępu TR. Skala FEMORAL była skuteczna w ocenie krwawień miejscowych związanych z TF. Chociaż częstość stosowania TF zmniejsza się, dostęp ten jest coraz częściej wykorzystywany w takich procedurach, jak przezcewnikowa implantacja zastawki aortalnej, implantacja MitraClip czy zamykanie ubytków przegrody międzyprzedsionkowej i międzykomorowej, dlatego skala służąca do oceny krwawień związanych z TF może być przydatna w praktyce klinicznej.

Słowa kluczowe: krwawienia z związane z miejscem dostępu naczyniowego, przezskórne interwencje wieńcowe, klasyfikacje krwawień, STEMI

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