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Radial *vs* femoral approach with StarClose clip placement for primary percutaneous coronary intervention in patients with ST-elevation myocardial infarction. RADIAMI II: a prospective, randomised, single centre trial

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Abstract

Background: Compared to the transfemoral approach (TFA), the transradial approach (TRA) for primary percutaneous coronary intervention (PCI) is associated with less risk of access site complications, greater patient comfort and faster mobilisation. Using vascular closure devices during TFA can offer similar advantages.

Aim: To compare the results of TRA and TFA using a StarClose device for primary PCI in patients with ST-elevation myocardial infarction (STEMI).

Methods: Patients were randomised to PCI using TRA (n = 49) or PCI using TFA and StarClose (n = 59).

Results: Door-to-balloon inflation time was 67.4 ± 17.1 *vs* 57.5 ± 17.5 min (p = 0.009) in the TRA and TFA groups respectively. Procedural success rate was 100% and 98.3%, respectively (NS). There were no significant differences in the incidence of major adverse cardiac events (MACE) or bleeding complications between the groups: 2.1% and 8.2% in the TRA group *vs* 1.7% and 10.2% in the TFA group (NS). Time to resume an upright position and time to full mobility was comparable in both groups.

Conclusions: The TRA for PCI in patients with STEMI is related to a significantly longer door to balloon time compared to the TFA. This had no influence on the incidence of MACE. The duration and efficacy of PCI were comparable in both groups. Using StarClose after PCI performed via the TFA resulted in an incidence of access site and bleeding complications comparable to that found when using TRA.

Key words: percutaneous coronary intervention, vascular closure device, STEMI, radial approach, femoral approach

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INTRODUCTION

Percutaneous coronary interventions (PCI) performed via the radial artery (RA) are associated with a lower risk of access site (AS) complications, a greater degree of patient comfort and earlier mobilisation after the procedure, without affecting its efficacy [1–3]. Moreover, a transradial approach (TRA) is related to a reduced incidence of bleeding complications, which may also be related to lower

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mortality [4, 5]. However, performing procedures via the RA is technically more difficult, requires longer training and is more time-consuming, which may be of significance in the case of myocardial infarction (MI), leading to a longer time to reperfusion.

Introducing vascular closure devices (VCD) to close the arterial access site after haemodynamic interventions was designed to reach the same goals as the introduction of TRA into clinical practice: early mobilisation of the patient, decreased incidence of AS and bleeding complications, and enhanced patient and staff comfort [6, 7]. Using VCD to close the puncture site after interventions performed via the traditional femoral artery (FA) approach may offer the same advantages as the TRA, while achieving a shorter time to reperfusion in patients with ST-elevation MI (STEMI). Very few studies have compared PCI procedures performed via the RA to those performed via the FA using a VCD in patients with STEMI [8].

The aim of this study was to compare the results of primary PCI (pPCI) in patients with STEMI performed using a TRA (TRA group) with the results obtained using a transfemoral approach and a StarClose device (TFA-VCD group).

METHODS

Study inclusion criteria were: (1) age 18–75 years, (2) MI defined as retrosternal pain lasting between 20 min and 12 h and not relieved by nitroglycerine, accompanied by ECG changes in the form of ST-elevation of at least 0.01 mV in two adjacent leads or new left bundle branch block (qualifying ECG obtained in admission room, in the referring hospital or emergency service), and (3) patient's consent to participate in the trial.

Exclusion criteria were: (1) Killip class III or IV, (2) necessity to use an intra-aortic counterpulsation balloon or temporary right ventricular pacing, with the decision made before coronary arteriography (CA), (3) patient's height < 150 cm, and (4) history of coronary artery bypass grafting (CABG). The study protocol was approved by the local Bioethics Committee. Patients aged over 75 years were excluded from the study due to the expected technical difficulties in performing CA via TRA in this patient group.

Patient selection

The study population included patients who fulfilled inclusion criteria and did not meet exclusion criteria, consecutively admitted to our department in the presence of physicians who perform procedures using TRA and who are trained in placing VCD. After admission to the hospital, the patient's consent was obtained and the patients undergoing CA and pPCI were randomly assigned to a TRA or a TFA-VCD approach. Randomisation was based on year of birth (even number — TRA; odd number — TFA-VCD).

Coronary catheterisation

Three physicians with 17–20 years of experience in performing PCI via TFA and several years experience in performing PCI via TRA, took part in the study. In the TRA group, CA was performed via the right RA. Coronary catheterisation via the TRA was preceded by performing a modified Allen's test using a pulse oximeter on the right upper limb. If the test demonstrated a lack of efficient collateral circulation through the ulnar artery on RA compression, a similar test was performed on the left upper limb. If the circulation in the left upper limb also proved to be insufficient, the procedure was performed via TFA. The RA puncture was performed using 21 G needles, 0.021' guidewires and 6 F sheaths (Cordis, USA). A dose of 5 mg of verapamil was administered into the vascular sheath. In cases of arterial spasm, the dose was repeated up to a maximum of 15 mg. During the procedure, 4–8 mg of morphine was administered, with additional 2 mg doses given until the elimination/reduction of pain. The FA puncture was performed using 18 G needles, 0.035' guidewires and 6 F vascular sheaths (Cordis, USA). After placing the sheath, activated clotting time (ACT) was determined and heparin was administered in doses that permitted the obtaining of ACT of 350–450 s during procedures performed without the use of abciximab, and 250–350 s when abciximab was used. Whether to use abciximab was a decision left to the operator. Standard Judkins and Amplatz type 6 F catheters (Asahi Intecc, Japan) were used for CA.

Percutaneous coronary interventions

The PCI was performed using 6 F Judkins guiding catheters, Launcher (Medtronic, USA), angioplasty guidewires: Piolot 50, 150, Whisper, BMW (Guidant, USA), Zinger-Light (Medtronic, USA), angioplasty balloons: Voyager (Abbott, USA), Crossale (Cordis, USA), stents: Driver and Micro-Driver (Medtronic, USA), Chopin (Balton, Poland), Multi-link Zeta, Multilink Vision (Abbott, USA), Skylor (Invatec, Italy). After completion of the procedure, vascular sheaths were removed and in the case of TRA, Terumo bands (Terumo, Japan) were applied and usually removed after 4 h. In the case of a TFA, a VCD (StarClose, Abbott, USA) was placed.

Rehabilitation was started 12 h after hospital arrival. On the fifth day, patients underwent the FA and RA ultrasonography and photographic documentation was obtained. Complete blood count was performed on admission, 24–48 h after the procedure, and again at discharge.

Definitions

The following definitions were adopted for the purpose of this study. Successful pPCI: a procedure that resulted in obtaining TIMI 3 flow and residual stenosis of < 20%. Major adverse cardiac events: death from any cause, repeated MI, need for CABG and need for repeated PCI of the infarct-

Table 1. Clinical characteristics of patients

	Study population (n = 108)	TRA group (n = 49)	TFA-VCD group (n = 59)	P
Mean age [years]	59.6 ± 10.0	62.1 ± 9.3	57.6 ± 10.3	0.02
Height [cm]	168.0 ± 7.8	168.5 ± 7.7	167.5 ± 8.0	NS
Body mass [kg]	79.1 ± 13.0	81.0 ± 14.4	77.5 ± 11.6	NS
Male	69 (64%)	32 (65%)	37 (63%)	NS
Diabetes	20 (19%)	10 (21%)	10 (17%)	NS
Tobacco use	72 (67%)	29 (60%)	43 (73%)	NS
Arterial hypertension	42 (39%)	22 (46%)	20 (34%)	NS
Hyperlipidaemia	22 (21%)	12 (25%)	10 (17%)	NS
History of MI	12 (11%)	4 (8%)	8 (14%)	NS
Family history of early CVD	44 (41%)	22 (46%)	22 (37%)	NS
Circulatory status on admission:				
Killip class 1	90 (83%)	40 (82%)	50 (85%)	NS
Killip class 2	18 (17%)	9 (18%)	9 (15%)	NS
Mean duration of symptoms [min]	271.8 ± 168.5	252.2 ± 181.3	288.2 ± 156.6	NS
Heart rate [bpm]	81.4 ± 18.4	80.3 ± 19.5	82.3 ± 17.5	NS
Systolic blood pressure [mm Hg]	141.5 ± 22.9	139.9± 21.6	142.9 ± 24.1	NS
Diastolic blood pressure [mm Hg]	90.7± 14.6	90.8 ± 14.4	90.7± 14.9	NS
MI location:				
Anterior	40 (37%)	21 (43%)	19 (32%)	NS
Inferior	61 (56%)	24 (49%)	37 (63%)	NS
Other	7 (13%)	4 (8%)	3 (5%)	NS

TRA — transradial; TFA — transfemoral; VCD — vascular closure device; MI — myocardial infarction; CVD — cardiovascular disease

-related artery (IRA). Major bleeding complications (BC): BC that resulted in death or a need for blood transfusion or surgical intervention, caused haemoglobin level decrease by > 3 g/dL, and central nervous system bleedings. Other bleedings were qualified as minor BC. Total procedural time: time from arrival at the CathLab to time of vascular sheath removal and placement of Terumo band dressing (in the TRA group) or vascular sheath removal and VCD implantation (in the TFA-VCD group).

Statistical analysis

Numerical data are expressed as mean ± SD when normally distributed. In the case of distributions different from normal, median value and interquartile range were additionally given. The significance of differences between the groups was assessed using Student's two-sided *t*-test for independent variables, after a previous verification of distribution normality with the use of Shapiro-Wilk W test. When *t*-test could not be used (unequal variances, distribution different from normal), the groups were compared using Mann-Whitney U test. Differences in proportions were assessed based on the proportion test. A p value < 0.05 was considered significant.

RESULTS

Our study population included 108 patients with the symptoms of STEMI admitted to our department between November 2006 and March 2008. Forty eight (30.7%) patients were not included in the study due to exclusion criteria, as follows: Killip class III or IV — 12 (25%) patients; age > 75 years — 11 (22.9%) patients; lack of consent, mostly concerning patients after circulatory arrest — eight (16.7%) patients; time from onset of symptoms > 12 h — seven (14.5%) patients; combination of two exclusion criteria, e.g. Killip class III or IV, history of CABG, third-degree atrioventricular block — five (16.7%) patients, third-degree atrioventricular block — three (6.25%) patients, history of CABG — two (4.1%) patients. Forty nine (45.4%) patients were assigned to the TRA group and 59 (55.6%) patients were assigned to the TFA-VCD group. In two (4.08%) patients assigned to the TRA group, PCI was performed via TFA and in one (1.69%) patient from the TFA-VCD group, PCI was performed via TRA.

Table 1 presents the characteristics of the patients. Mean patient age was significantly higher in the TRA group compared to the TFA-VCD group. There were no other significant differences between the groups.

Table 2. Angiographic and procedural data

	Study population (n = 108)	TRA group (n = 49)	TFA-VCD group (n = 59)	P
1-vessel disease	50 (47%)	21 (44%)	29 (49%)	NS
2-vessel disease	43 (40%)	21 (44%)	22 (37%)	NS
3-vessel disease	14 (13%)	6 (12%)	8 (14%)	NS
Infarct-related artery:				
Left main stem	0 (0%)	0 (0%)	0 (0%)	NS
Left anterior descending artery	38 (35%)	21 (43%)	17 (29%)	NS
Circumflex artery	14 (13%)	4 (8%)	10 (17%)	NS
Right coronary artery	55 (51%)	24 (49%)	31 (53%)	NS
Initial TIMI flow:				
0	57 (53%)	22 (45%)	35 (59%)	NS
1	8 (7%)	4 (8%)	4 (7%)	NS
2	18 (17%)	13 (27%)	5 (8%)	0.012
3	25 (23%)	10 (20%)	15 (25%)	NS
Percutaneous coronary intervention				
Final TIMI flow:				
0	0 (0%)	0 (0%)	0 (0%)	NS
1	0 (0%)	0 (0%)	0 (0%)	NS
2	1 (1%)	0 (0%)	1 (2%)	NS
3	107 (99%)	49 (100%)	58 (98%)	NS
RS post-procedure < 20%	108 (100%)	49 (100%)	59 (100%)	NS
Maximum ACT [s]	322.8 ± 68	304.8 ± 64.8	336 ± 68	0.025
Abciximab administration	57 (53%)	25 (51%)	32 (54%)	NS
Fluoroscopy time [min]	7.0 ± 3.0	7.5 ± 3.0	6.9 ± 3.0	NS
Contrast material [mL]	163.4 ± 43.7	165.0 ± 41.4	162.0 ± 46.0	NS
Number of stents implanted:	1.36 ± 0.60	1.35 ± 0.56	1.37 ± 0.64	NS
1 stent	70 (65%)	34 (69%)	36 (61%)	NS
2 stents	31 (29%)	13 (27%)	18 (31%)	NS
3 stents	5 (5%)	2 (4%)	3 (5%)	NS
Stenting ratio	98.2%	100%	94.9%	NS
Successful placement of StarClose clip [%] or Terumo band [%]		48 (98.0%)	55 (93.2%)	

RS — residual stenosis; ACT — activated clotting time; rest of abbreviations as in Table 1

In Table 2, angiographic and procedural data are presented. The distribution of initial and final TIMI flows did not differ significantly between the groups, with the exception of initial TIMI 2 flow, which occurred significantly more often in the TRA group. Procedural success rate was 100% in the TRA group and 98% in the TFA-VCD group (only in one patient final flow in the IRA was TIMI 2). In one patient from the TFA-VCD group, PCI was not performed due to lack of significant stenosis, and another patient in the same group underwent balloon angioplasty only because the infarction was caused by reocclusion at the site of a previously implanted stent. The ACT was significantly longer in the TFA-VCD group compared to the TRA group. The VCD placement was effective in 55 (93.2%) patients, partially effective with intensive but non-arterial bleeding in two (3.4%) patients, and ineffective with arterial bleeding requiring prolonged manual compression and the use of a compression dressing during several hours in two (3.4%) patients. In one patient from the TFA group, the application of the Terumo band was unsuccessful due to excessively high upper limb circumference at the distal part of the forearm. This resulted in an extensive hematoma of the forearm which led to prolonged hospitalisation.

Time intervals

Time from hospital arrival to CathLab arrival, and time to the beginning of the procedure, tended to be longer in the TRA

Table 3. Time intervals during coronary angiography and PCI

Time from hospital arrival to:	Study population (n = 108)	TRA group (n = 49)	TFA-VCD group (n = 59)	P
CathLab arrival [min]	31.9 ± 18.8 (25.0; 20.0–40.0)	35.5 ± 22.1 (25.0; 25.0–45.0)	28.9 ± 15.06 (25.0; 25.0–33.0)	NS
Beginning of procedure (local anaesthesia)	42.3 ± 19.6 (35.0; 30.0–54.0)	46.7 ± 22.6 (40.0; 30.0–58.0)	38.6 ± 15.9 (35.0; 30.0–45.0)	NS
Vascular sheath introduction [min]	45.5 ± 19.7 (40.0; 33.0–55.0)	51.3 ± 22.1 (45.0; 35.0–62.0)	40.6 ± 16.1 (38.0; 30.0–48.0)	0.009728
Contrast agent injection [min]	50.0 ± 21.0 (44.0; 39.0–61.0)	54.7 ± 24.8 (49.0; 40.0–67.0)	45.7 ± 15.9 (41.5; 37.0–55.0)	0.024126
Balloon inflation [min]	61.7 ± 17.9 (59.0; 50.0–73.0)	67.4 ± 17.1 (62.5; 55.0–82.0)	57.5 ± 17.5 (54.5; 45.0–68.5)	0.00884
Stent implantation [min]*	69.6 ± 21.6 (65.0; 56.0–80.5)	75.1 ± 23.6 (67.0; 59.0–88.0)	64.7 ± 18.6 (60.0; 54.0–77.0)	0.019229
End of procedure [min]	82.5 ± 28.6 (76.0; 65.0–98.0)	89.6 ± 31.0 (80.0; 71.0–100.0)	76.8 ± 25.3 (74.0; 60.0–90.0)	0.049038
Interval from CathLab arrival to beginning of the procedure [min]	10.3 ± 5.6 (10.0; 5.0–13.0)	11.2 ± 6.5 (10.0; 5.0–15.0)	9.6 ± 4.7 (10.0; 6.0–10.0)	NS
Interval from beginning of procedure to vascular sheath introduction [min]	4.7 ± 5.16 (3.0; 2.0–5.0)	5.8 ± 6.8 (4.0; 2.0–5.0)	3.8 ± 3.0 (3.0; 2.0–5.0)	NS
Interval from vascular sheath introduction to first contrast injection [min]	5.4 ± 5.5 (4.5; 3.0–5.0)	5.4 ± 3.9 (5.0; 3.5–6.0)	5.4 ± 6.6 (4.0; 3.0–5.0)	NS
Interval from contrast injection to balloon inflation [min]	12.6 ± 6.3 (11.0; 10.0–14.0)	11.9 ± 4.9 (11.0; 10.0–13.0)	13.3 ± 7.1 (11.5; 10.0–14.0)	NS
Interval from balloon inflation to stent implantation [min]	7.3 ± 5.7 (9.0; 6.0–9.0)	7.3 ± 7.2 (5.5; 4.0–8.0)	7.3 ± 4.2 (6.5; 5.0–10.0)	NS
Interval from stent implantation to end of procedure [min]*	11.0 ± 7.2 (10.0; 6.0–15.0)	9.4 ± 6.8 (7.0; 5.0–13.00	12.6 ± 7.3 (10.0; 8.0–16.0)	0.005
Total procedural time (from CathLab arrival to end of procedure) [min]	50.2 ± 20.2 (48.0; 40.0–58.0)	53.7 ± 20.6 (50.0; 41.5–60.0)	47.3 ± 19.6 (45.0; 40.0–56.0)	NS

Results are presented as mean ± SD, median and interquartile range; *in cases of implantation of more than one stent, this is the interval from final stent implantation to the end of the procedure; PCI — percutaneous coronary intervention; rest of abbreviations as in Table 1

group, but the difference was not significant. Time periods from hospital arrival to successive stages of the procedure, such as vascular sheath introduction, contrast agent administration, balloon inflation, stent implantation and termination of the procedure, were significantly longer in the TRA group (Table 3). The analysis of individual time intervals revealed that all the intervals after arrival at the CathLab, apart from the last one, were comparable in both groups, thus giving no advantage to either of the two catheterisation methods employed. It was also shown that there was no significant difference in the total procedural time between the groups. The last interval from stent implantation to the termination of the procedure, i.e. to Terumo band placement in the TRA group and to VCD placement in the TFA-VCD group, was significantly longer in the latter group.

Complications during the in-hospital period are presented in Table 4. Two patients from the TRA group underwent a repeated CA due to a recurrence of symptoms and ischaemic changes in ECG. One of these patients also developed clinical and ECG signs of reocclusion and pulmonary oedema on the ninth day after the procedure. In the first patient, no significant changes were found during CA, whereas in the latter subject reocclusion of the vessel was found and the patient underwent a repeated successful PCI. Pulmonary oedema occurred post-procedure in one patient from each group. Dressler's syndrome also occurred in one patient in each group. In one patient from the TRA group, echocardiography revealed a floating thrombus in the left ventricular apex. In two patients, a FA pseudoaneurysm was found on ultrasonography. In one of these patients, treatment

Table 4. In-hospital complications

	Study population (n = 108)	TRA group (n = 49)	TFA-VCD group (n = 59)	P
Mortality	0 (%)	0 (%)	0 (%)	NS
Myocardial infarction	0 (%)	0 (%)	0 (%)	NS
Stroke	1 (0.9%)	0 (0%)	1 (1.7%)	NS
Repeated revascularisation of the IRA	1 (0.9%)	1 (2.0%)	0 (0%)	NS
Coronary artery bypass grafting	0 (0%)	0 (0%)	0 (0%)	NS
Serious clinical events (MACE)	2 (0%)	1 (2.1%)	1 (1.7%)	NS
PCI of a vessel other than the IRA	2 (1.9%)	0 (0%)	2 (3.4%)	NS
Serious bleeding	10 (9.3%)	4 (8.2%)	6 (10.2%)	NS
Serious bleeding resulting in death	0 (0%)	0 (0%)	0 (0%)	NS
Serious bleeding requiring blood transfusion	1 (0%)	1 (0%)	0 (0%)	NS
Serious bleeding requiring surgery	0 (0%)	0 (0%)	0 (0%)	NS
Serious bleeding resulting in haemoglobin level decrease of > 3 g/dL	9 (8.3%)	3 (6.1%)	6 (10.2%)	NS
Intracranial bleeding	0 (0%)	0 (0%)	0 (0%)	NS
Hematoma > 5 cm	20 (18.5%)	8 (16.3%)	12 (20.3%)	NS

IRA — infarct-related artery; MACE — major adverse cardiac events; PCI — percutaneous coronary intervention

was conservative (a compression dressing) and in the other patient the pseudoaneurysm was treated with a thrombin injection. Rehabilitation was started 12 h after admission. Time from hospital arrival to the start of rehabilitation after the intervention was 16.8 ± 8.7 h in the TRA group and 14.8 ± 6.9 h in the TFA-VCD group (NS), time to upright position was 26.8 ± 17.6 h *vs* 25.0 ± 11.4 h (NS) and time to full mobility (walking the stairs) was 4.2 ± 1.3 days *vs* 4.4 ± 1.3 days (NS), respectively.

DISCUSSION

Many studies have been published comparing TFA and TRA for PCI procedures in patients with MI [8–11]. However, only one study presented a comparison of TRA *vs* TFA with the use of VCD [8]. These studies have most often been conducted in small groups of patients. A meta-analysis has recently been published which included randomised studies comparing diagnostic and PCI procedures in patients with and without MI performed via FA against procedures performed via TRA. This meta-analysis assessed the effects of vascular access site on the incidence of BC and ischaemic episodes [12]. Similar to the studies mentioned above, in our trial the efficacy of PCI procedures performed via TRA and TFA was comparably high.

In patients with MI, duration of ischaemia is of great importance. The longer the time to successful reperfusion, the worse the prognosis [13, 14]. We observed a longer total time from hospital arrival to balloon inflation in the group of patients who underwent the procedure via RA. The initial time intervals, from hospital arrival to CathLab admission and to the start of the procedure, which were unrelated to the type of procedure being performed already, tended to be longer in the TRA group (NS). Successive time intervals from hospital admission to the individual stages of the PCI, starting from sheath introduction, through balloon inflation and stent implantation, to the end of the procedure, were significantly longer in the TRA group. However, the analysis of the individual stages of the procedure showed that there were no significant differences between the groups regarding individual procedure stages that are important for MI. Neither was there any significant difference between the groups regarding total procedural time. Only the final stage of the procedure, from last stent implantation to the end of the procedure, was significantly longer in the group in which VCD was used. Such time relations indicate that the procedure performed using TRA is not in itself significantly longer than the procedure performed via TFA. The differences in time intervals from the hospital arrival to various stages of the procedure in both groups are caused by the summing up of differences occurring during the first phases of management. Two initial time intervals were longer in the TRA group (NS), and significant differences only occurred starting from the third interval, i.e. from hospital arrival to vascular sheath introduction, and they persisted until the end of the procedure.

Analysis of this data revealed that the prolongation of the time from hospital admission to balloon inflation occurred for the most part during the initial preparations for the procedure at the admission room and the preparation of the patient in the CathLab, as well as during artery puncture and vascular sheath introduction. The only interval that was significantly longer in the TFA group in our analysis was the time from stent

implantation to the VCD placement. While sheath withdrawal and the Terumo band dressing placement are quick to perform, clip placement requires longer time due to the necessity of changing the sheath, widening the puncture site with a scalpel and implanting the clip (usually about 1 min).

The prolongation of the time from hospital arrival to balloon inflation in the TRA group had no impact on mortality. No patient died in our study population. This can be related to the low initial risk level in our patients (all patients were Killip class I or II) but also to the low incidence of BC in both groups. Many studies have demonstrated that an increased incidence of BC is related to higher mortality [15–17]. One of the advantages of TRA for heart catheterisation is a lower incidence of AS and BC [12]. The use of VSD is also potentially related to a lower incidence of such complications. However, lower incidence of BC and vascular complications with the use of VCD as compared with manual compression of FA has not as yet been demonstrated [18]. The only advantages that have been demonstrated are faster haemostasis, earlier mobilisation and greater patient comfort. In the recently published ACUITY trial, the authors managed to show a lower incidence of BC in patients who underwent interventional procedures for acute coronary syndromes with the use of VCD compared to manual compression of FA [19]. In our study population, we observed only one BC that required blood transfusion (in the TRA group) and a total of nine cases of decreased haemoglobin level. Thus both methods are associated with a comparable risk of BC. This low incidence of BC was observed in spite of a rather long ACT during catheterisation (significantly longer in the TFA-VCD group) and the use of IIb/IIIa receptor inhibitors in over half of all cases.

The use of VCD in patients with MI has not as yet been assessed in a randomised trial. Studies describing the use of VCD have reported a clip implantation success rate of 86.8––96% [7]. Despite a short training period (before the trial, every investigator performed three implantations required by the manufacturer) we attained a high percentage of successful clip placement, which attests to the ease of implantation of the clip. Every new VCD can possibly be related to some problems. In our study, implantation was ineffective in only four cases. In one case, this was caused by a too small skin incision, which did not allow the applier to pass under the skin and consequently the clip was placed within subcutaneous tissue — the patient required manual compression and the use of a dressing. In the other three cases, intense bleeding occurred that also required manual compression (abundant, probably arterial bleeding). Published papers mention frequent, non-arterial tissue bleeding (27–38%) resulting from a wide and deep skin incision and the possible use of aggressive anticoagulation and antiplatelet therapy as being the major inconvenience of this method [6, 7]. In our study, we limited the incidence of this complication by the preventive application of a light compression dressing composed of a few gauze pads and kept in place for a short time (usually 2–4 h).

The main advantages of TRA for coronary interventions are very low incidence of bleeding and AS complications, high patient comfort and early mobilisation, while maintaining comparable efficacy. Both methods provide the possibility of performing the second procedure in the same place: TRA after the wound has healed, TFA after a few hours, only if VCD has been successfully deployed.

Our study demonstrated that performing PCI in patients with MI using TFA and VCD implantation is an attractive alternative to TRA. Performing PCI procedures using this strategy is easy for most operators, effective, minimises BC to the level of TRA, and allows an equally early rehabilitation of the patient. The additional cost of the device is a disadvantage of the method. In view of our results, it seems worth considering a return to the technically easy heart catheterisation via TFA completed by VCD placement in patients with MI and other acute coronary syndromes.

Limitations of the study

The results of a single centre study cannot be generalised, as they depends on the experience of interventional cardiologists. Our trial included a small study population.

CONCLUSIONS

1. Performing PCI in patients with MI via radial artery is related to significantly longer times from hospital admission to artery puncture and to balloon inflation compared to transfemoral approach. This had not impact on the incidence of major cardiac events.
2. The duration and efficacy of PCI were comparable in both groups.
3. The use of vascular closure devices after PCI in the transfemoral group resulted in a similar incidence of access site and bleeding complicatopns rates as in the transradial group.
4. The use of vascular closure devices allows early mobilisation of the patients after the procedure which is comparable to the time of mobilisation after the procedures performed using transfemoral approach.

Conflict of interest: *none declared*

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Porównanie przezskórnych interwencji wieńcowych (PCI) u chorych z zawałem serca z uniesieniem odcinka ST wykonanych przez tętnicę promieniową z PCI wykonanymi przez tętnicę udową z użyciem klipsa StarClose: RADIAMI II — prospektywne, randomizowane, jednoośrodkowe badanie kliniczne

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Streszczenie

Wstęp: Wykonywanie przezskórnej interwencji wieńcowej (PCI) przez tętnicę promieniową (TP) w porównaniu z przeprowadzaniem PCI przez tętnicę udową (TU) wiąże się z mniejszym ryzykiem powikłań miejscowych, większym komfortem pacjentów, szybszym uruchomieniem chorych po zabiegu. Zastosowanie urządzeń do zamykania tętnic po zabiegach wykonywanych przez TU może przynieść podobne korzyści.

Cel: Celem badania było porównanie wyników leczenia pierwotną PCI chorych z zawałem serca z uniesieniem odcinka ST (STEMI) przy użyciu dostępu przez TP oraz przez TU z użyciem StarClose.

Metody: Pacjentów kwalifikowano losowo do wykonania PCI z dostępu przez TP (n = 49) lub przez TU z użyciem StarClose (n = 59).

Wyniki: Czas od przyjęcia do inflacji balonu wyniósł 67,4 ± 17,1 *v.* 57,5 ± 17,5 min (p = 0,009) odpowiednio w grupie TP i TU. Skuteczność zabiegu wynosiła 100% w grupie TP i 98,3% w grupie TU (NS). Nie zaobserwowano istotnych różnic pod względem częstości występowania poważnych zdarzeń sercowych i powikłań krwotocznych między badanymi grupami: 2,1% i 8,2% w grupie TP *v.* 1,7% i 10,2% w grupie TU (NS). Czas do uzyskania pionizacji i pełnego uruchomienia był porównywalny w obu grupach.

Wnioski: Wykonywanie PCI u chorych ze STEMI z dostępu przez TP wiąże się z istotnym wydłużeniem czasu od przyjęcia do inflacji balonu w porównaniu z dostępem przez TU. Nie miało to wpływu na częstość występowania poważnych zdarzeń sercowych. Czas trwania i skuteczność zabiegu PCI były w obu grupach porównywalne. Zastosowanie klipsa StarClose po zabiegu PCI spowodowało, że częstość występowania powikłań miejscowych i krwotocznych w tej grupie była porównywalna z występującymi przy wykonywaniu PCI z dostępu przez TP. Zastosowanie klipsa StarClose umożliwia szybkie uruchomienie chorych po zabiegu porównywalne z szybkością uruchomienia po zabiegach wykonanych z dostępu przez TP.

Słowa kluczowe: przezskórne interwencje wieńcowe, urządzenia do zamykania tętnic, zawał serca z uniesieniem odcinka ST, dostęp przez tętnicę promieniową oraz udową

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