Effect of introducer length on the rate of radial artery occlusion after endovascular coronary procedures: a pilot randomised clinical trial

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Aim

To examine the effect of the introducer length during transradial therapeutic and diagnostic endovascular interventions on incidence of radial artery occlusion (RAO).

Methods

Patients (n = 100) who had coronary angiography (CA) and/or percutaneous coronary intervention (PCI) in treatment plans were enrolled in the study. Patients were randomized into two groups. The first group comprised 50 patients who underwent transradial CA and/or PCI using long introducer (6Fr, 25 cm; Radifocus Introducer II, Terumo, Japan). However, one patient was excluded from the analysis due to an emergency transfer to another hospital and was not considered in the comparison of outcomes (n = 49). A comparison group consisted of patients who underwent transradial endovascular procedures using a short introducer (6Fr, 10 cm; Radifocus Introducer II, Terumo, Japan) (n = 50). The primary endpoint of the study was RAO rate according to the Doppler ultrasound (DU) results. The secondary endpoints were hematomas, radial artery perforation/dissection, neuritis of the median nerve, puncture site bleeding, incidence of needle-type conversion during the puncture time, puncture time, procedure time from the introducer placement to its extraction, duration of fluoroscopy and total absorbed air kerma dose rate. A comparative analysis of the patency of the radial artery during the hospital stay was performed according to the DU results.

Results

Average age of patients was 60.7 ± 10.6 years. Primary endpoint study analysis showed no statistically significant differences in RAO incidence in both observation groups (8.2% vs 4.0%; p = 0.436). Secondary endpoints analysis showed no difference in post-puncture hematomas incidence (16.3% vs 16.0%; p = 0.965) or local bleeding (2.0% vs 0.0%; p = 0.310). In addition, no complications such as perforation/dissection of the radial artery or neuritis of median nerve were detected. However, it was noted, needle-type conversion rate increased in patient group, where long introducer was used (10.2% vs 0.0%; p = 0.027). An increase of puncture time was demonstrated (94.0 [67.5; 162.5] vs 42.5 [33.0; 65.3] s, p < 0.001) and total duration of procedure using a long introducer (448.0 [337.5; 633.0] s, vs 350.5 [307.0; 506.8] s; p = 0.04). At the same time, the duration of fluoroscopy (82.0 [48.5; 133.0] s, vs 69.5 [48.0; 118.3] s; p = 0.672) and total absorbed air kerma dose rate did not statistically differ (140.8 ± 97.7 mGy vs 128.2 ± 71.3 mGy; p = 0.721).

Conclusion

Use of 25 cm length introducers did not demonstrate decrease in incidence of RAO development compared with the use of 10 cm introducers. However, use of long introducers is characterized by increase in puncture time and total duration of endovascular coronary procedures. Furthermore, the time of fluoroscopy and total air kerma rate did not statistically differ.

Keywords: access site complications; radial artery occlusion; percutaneous coronary intervention; transradial access

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Introduction

The annual number of endovascular diagnostic and therapeutic procedures, such as coronary angiography (CAG) and percutaneous coronary intervention (PCI), has been increasing in the Russian Federation. In conjunction, the use of radial artery access (RAA) to perform these procedures in our country has increased as well; in 2016, >75% of CAG and >74% of PCI were performed using RAA [1]. RAA was first used for endovascular intervention in 1989 [2]. The method has become widespread in clinical practise owing to its several advantages. Compared with the femoral artery route, RAA has significantly fewer puncture site complications [3]. In addition, effective haemostasis can be achieved because of the superficial location of the radial artery, even in patients receiving anticoagulants and inhibitors of platelet glycoprotein IIb/IIIa receptors [4–7]. Furthermore, the haemorrhagic complication rate after RAA is very low (<0.1/1000) [2]. Consequently, in accordance with European Guidelines on myocardial revascularisation, the use of RAA is recommended in all of CAG and PCI cases (recommendation, class I; level of evidence, A) [8].

Despite these advantages, radial artery occlusion (RAO) occurs in 1%–10% of cases after transradial puncture. RAO often has an asymptomatic clinical course [9]; however, its presence precludes the further use of RAA for subsequent interventions. Endothelial damage and reduced or completely blocked blood flow secondary to introducer placement during RAA may lead to thrombosis, which is a predisposing factor for RAO development [10–12]. Considering this, the use of a longer introducer may reduce the possibility of radial artery endothelial damage during endovascular and catheter replacement procedures, thereby reducing the incidence of RAO. Therefore, the aim of the study was to investigate the effect of introducer length during transradial therapeutic and diagnostic endovascular interventions on the rate of RAO.

Methods

We conducted a pilot single-blind prospective randomised study (Fig. 1) of 107 consecutive adult patients aged ≥18 years who underwent CAG or PCI using RAA at the Tyumen Cardiology Research Center in 2019. Seven patients were excluded due to technical

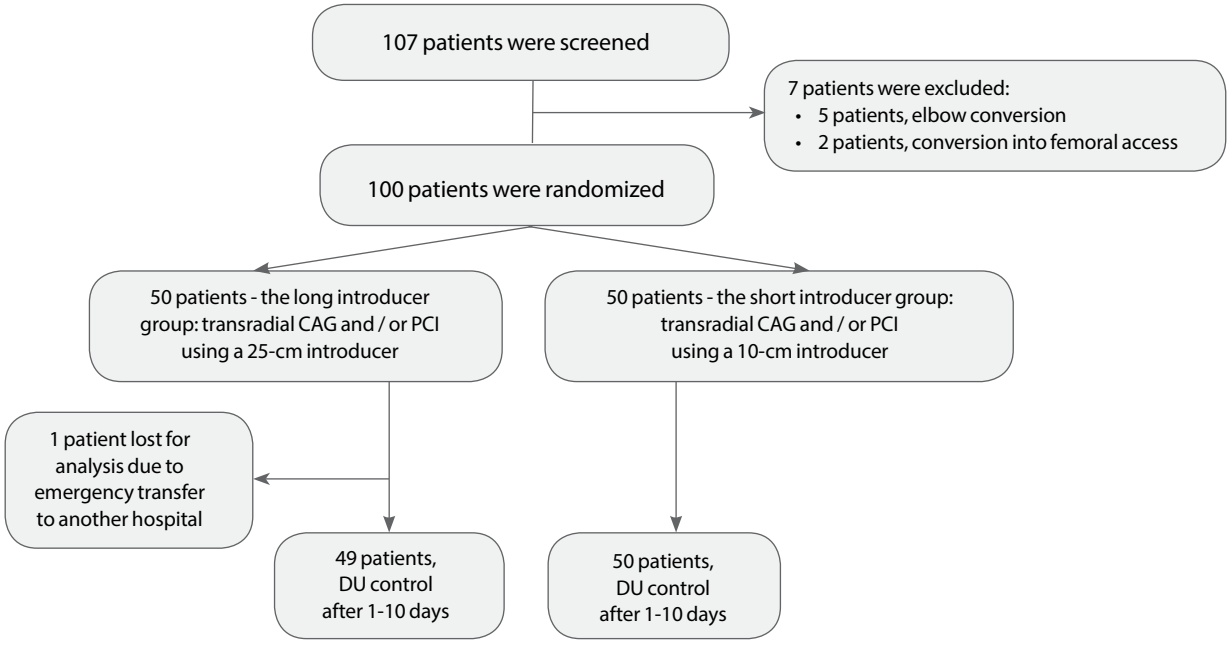

Fig. 1. Study design. *CAG, coronary angiography; PCI, percutaneous coronary intervention; DU, Doppler ultrasound*

inability to obtain RAA. Institutional ethics committee approval was obtained (protocol no. 146, meeting date 11/02/2019). All study participants provided written informed consent.

Patients were randomised into two groups according to introducer length (long or short) by generating random numbers at a remote site just prior to the procedure. The long introducer group comprised 50 patients who underwent transradial CAG and/or PCI using a 25-cm introducer. The short introducer group comprised 50 patients who underwent transradial procedures using a 10-cm introducer. Figure 2 shows the Radifocus Introducer II (Terumo, Tokyo, Japan) kits used in the short (A) and long (B) introducer groups and the accompanying inner metal needles and plastic cannulae (C and D).

The primary endpoint of the study was RAO as established by Doppler ultrasound (DU) performed within the first 10 days after the procedure. Secondary endpoints were post-puncture haematoma, radial artery perforation/dissection, neuritis of the median nerve, puncture site bleeding, rate of needle type conversion, puncture time, procedure time from the introduction of the introducer to its extraction, time of fluoroscopy and total air kerma rate (mGy). Local haematomas were classified as follows: stage I, diameter ≤5 cm; stage II, diameter ≤10 cm; stage III, diameter ≤10 cm, but no extension above the elbow; stage IV, extension above the elbow and stage V, threatened hand ischaemia [13].

All endovascular interventions were performed by five experienced endovascular surgeons using an AlluraClarity Interventional X-Ray system (Phillips, Amsterdam, the Netherlands). After introducer placement, 10 mcg nitroglycerine solution and heparin (5000 units after CAG, 7500 units after PCI) were injected. Subsequently, catheterisation and CAG or PCI were performed with 6 Fr diagnostic catheters. Once the procedure was completed, the introducer was removed and a standard pressure bandage was applied for 6 h. The control DU was then performed >24 hours after the procedure using an iE 33 Ultrasound System (Phillips, Amsterdam, the Netherlands). Finally, the primary and secondary endpoints in both groups were analysed and compared. All patients in the short introducer group were included in the analysis; one patient in the long introducer group was lost to follow-up due to emergency transfer to another hospital.

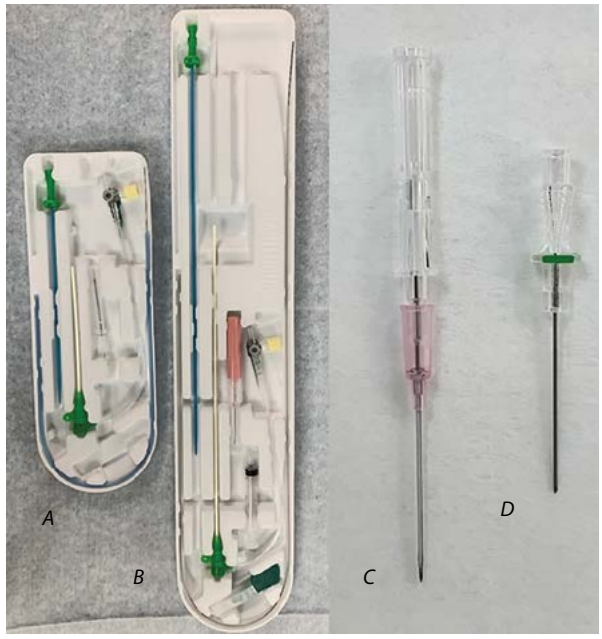

Fig. 2. Radifocus Introducer II (Terumo), 6 Fr diameter and 10 cm length, equipped with a 21 G needle and steel conductor (*A*); Radifocus Introducer II, 6 Fr diameter, 25 cm length, equipped with inner metal needle along with a 20 G plastic cannula and a hydrophilic conductor (*B*); inner metal needle and 20 G plastic cannula (*C*) and 21 G metal needle (*D*)

Statistical analysis

SPSS software version 21.0 was used for data analysis (SPSS Inc., Chicago, IL, USA). Results with a normal distribution are presented as means ± standard deviation; asymmetrically distributed results are presented as medians with interquartile range. The distribution of quantitative variables was evaluated using the Kolmogorov–Smirnov test. The nonparametric Mann–Whitney U test was used to compare quantitative variables. The Fisher's exact test was used to compare qualitative variables. $P < 0.05$ was considered statistically significant.

Table 1 Clinical and procedural characteristics of the examined patients

Treatment outcome		All patients, n = 99	The long introducer group, n = 49	The short introducer group, n = 50	p
Age, years		60.7 ± 10.6	58.0 ± 11.2	63.5 ± 9.3	0.025
Male, gender		63.0 (63.6)	35.0 (71.4)	28.0 (56.0)	0.144
Body mass index		31.6 ± 5.8	31.5 ± 5.5	31.8 ± 6.2	0.682
History of diabetes mellitus		21.0 (21.2)	11.0 (22.4)	10.0 (20.0)	0.810
RAA history		33.0 (33.3)	14.0 (28.5)	19.0 (38.0)	0.395
Taking anticoagulants		29.0 (29.3)	10.0 (20.4)	19.0 (38.0)	0.077
CAG		82.0 (82.8)	43.0 (87.7)	39.0 (78.0)	0.287
PCI		9.0 (9.1)	4.0 (8.1)	5.0 (10.0)	1.000
CAG + simultaneous PCI		8.0 (8.1)	2.0 (4.0)	6.0 (12.0)	0.269
Surgeons	1	32.0 (32.3)	17.0 (34.7)	15.0 (30.0)	0.671
	2	20.0 (20.2)	9.0 (18.3)	11.0 (22.0)	0.803
	3	21.0 (21.2)	10.0 (20.4)	11.0 (22.0)	1.000
	4	24.0 (24.2)	12.0 (24.5)	12.0 (24.0)	1.000
	5	1.0 (2.0)	1.0 (2.0)	1.0 (2.0)	1.000

Results

The baseline clinical and demographic characteristics of patients in both groups were comparable; however, the mean age in the long introducer group was lower. Additionally, the number of patients with repeated RAA, as well as endovascular surgeons performing interventions, were distributed in both groups without statistical differences (Table 1).

There was no significant difference in the median time from endovascular procedure to DU between the long and short introducer groups. RAO incidence did not significantly differ between the groups (Table 2).

Table 2 RAO incidence in the first 10 days after endovascular procedure

Indicator		The long introducer group, n = 49	The short introducer group, n = 50	p
RAO		4.0 (8.2)	2.0 (4.0)	0.436
DU control, days		1.6 ± 1.7	1.3 ± 0.9	0.330
Hematoma, stage	I	8.0 (16.3)	8.0 (16.0)	0.965
	II	–	–	
	III	–	–	
	IV	–	–	
	V	–	–	
Perforation / Dissection		–	–	
Median Nerve Neuritis		–	–	
Needle conversion		5.0 (10.2)	0 (0)	0.027
Bleeding of the puncture site		1.0 (2)	0 (0)	0.310
Puncture time, s		94.0 [67.5; 162.5]	42.5 [33.0; 65.3]	<0.001
Procedure time, s		448.0 [337.5; 633.0]	350.5 [307.0; 506.8]	0.040
The time of fluoroscopy, s		82.0 [48.5; 133.0]	69.5 [48.0; 118.3]	0.672
Total air kerma, mGy		140.8 ± 97.7	128.2 ± 71.3	0.721

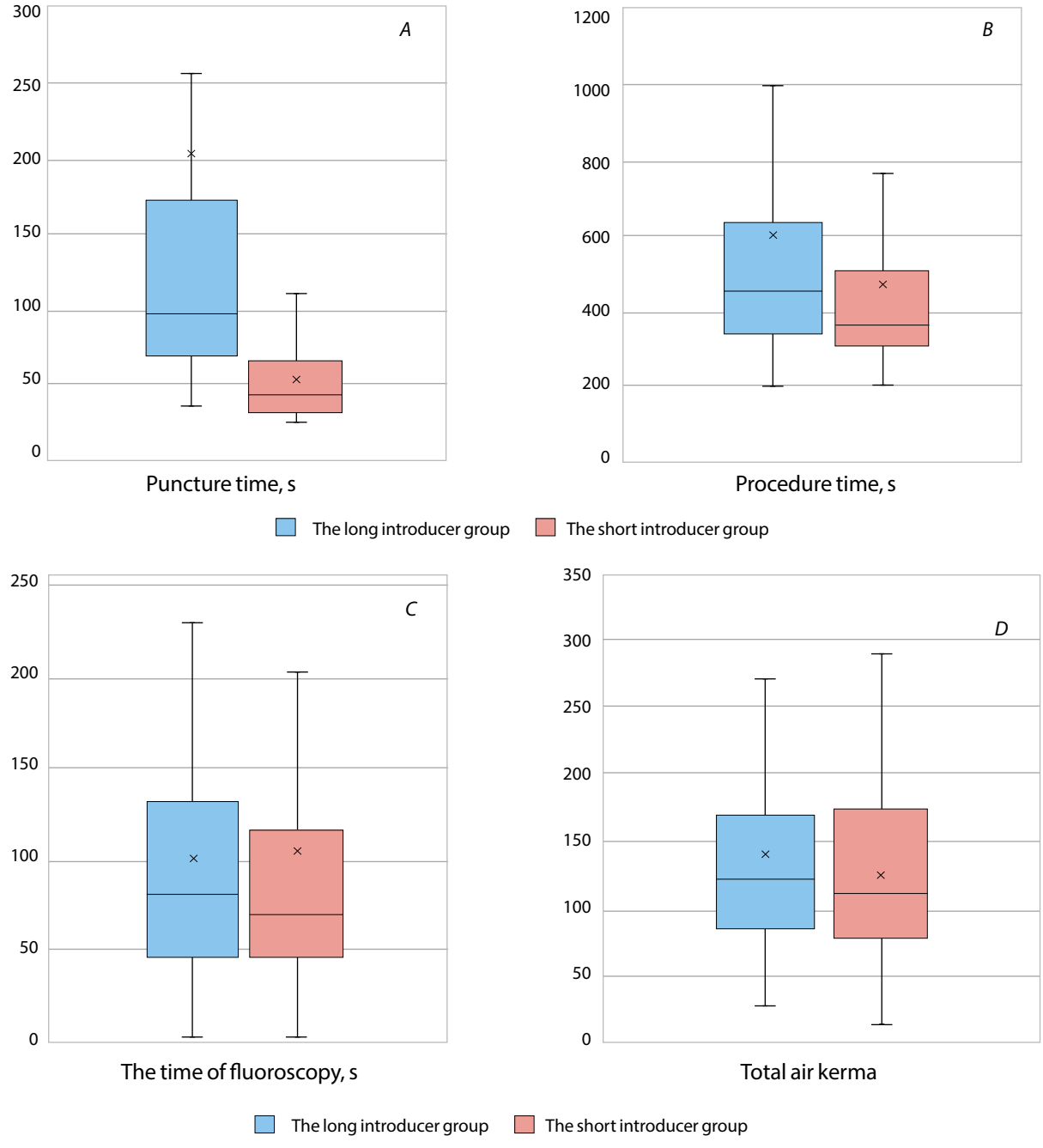

Fig. 3. Puncture time (*A*); Procedure time (*B*); Fluoroscopy time (*C*); Total air kerma (*D*)

With respect to the secondary endpoints, there were no differences between the long and short introducer groups in the incidence rates of local post-puncture haematoma or puncture site bleeding. No stage II, III, IV, or V haematomas were observed in either group. Similarly, neither perforation/dissection of the radial artery nor neuritis of the median nerve occurred. However, the long introducer group had an increased incidence of needle-type conversion (10.2%). In addition, the short introducer group had a significantly

lower median puncture time and an accordingly significantly shorter total procedure time. (Fig. 3). Despite this, the time of fluoroscopy did not statistically differ between the groups, and the total air kerma rates were comparable.

Discussion

Age, female gender, body mass index and diabetes mellitus have been previously identified as predictors of RAO development after RAA [14, 15]. The diameter of the introducer and pharmacological agents such as anticoagulants and vasodilators can also potentially affect RAO development [16]. Spaulding et al. found that RAO occurred in 71% of patients not receiving heparin, 24% of patients receiving 2000–3000 units of heparin and 4.3% of patients receiving 5000 units of heparin ($p < 0.05$) [17]. A recent meta-analysis that included three randomised and eight non-randomised studies compared the rate of RAO between procedures using 5 Fr and 6 Fr diameter introducers and found no significant difference (odds ratio, 0.88; 95% confidence interval, 0.50–1.56), $p = 0.67$). However, the meta-regression analysis showed that the use of the 5 Fr introducer was advantageous ($p = 0.02$) [18].

To our knowledge, this is the first study to examine the effect of introducer length on RAO development after transradial interventions. We found that the use of longer 25-cm introducers in diagnostic and therapeutic endovascular interventions was not associated with a decrease in the incidence of post-procedure RAO compared with 10-cm introducers. However, their use was associated with an increase in radial artery puncture time and prolonged total procedure duration. In our opinion, much of this was due to the use of a puncture needle cannula, which accompanies the 25-cm introducer in the kit. The use of this needle cannula can present certain difficulties in a patient with reduced pulsation or small radial artery diameter, as evidenced by the fact that it was frequently converted to a standard puncture needle (20 G with a metal conductor). Nevertheless, in previous studies, the type of puncture needle was not considered as a factor associated with RAO development [14, 15].

The primary reason for RAO development is endothelial damage during the intervention [10], which has been partially confirmed in studies investigating an introducer-free technique using the specialised SheathLess Eaucath™ (Asahi, Tokyo, Japan) guiding catheter, which is passed directly through the radial artery puncture site to the coronary artery ostium. This technique eliminates damage to the radial artery and significantly reduces the rate of RAO compared with standard RAA techniques that use an introducer [19]. However, the introducer-free technique cannot always be applied to therapeutic and diagnostic endovascular procedures. Theoretically, a -5 cm introducer should protect the radial artery from endothelial damage, similar to the SheathLess Eaucath™. However, our results do not support this. Therefore, there are likely additional mechanisms involved in RAO development in addition to endothelial damage that require further study.

Despite the advantages of RAA, complications occur in approximately 5% of patients [13], as confirmed by this study. In addition to RAO, puncture site bleeding, localised or extensive haematomas and false aneurysms of the radial artery may also develop [20]. However, RAA remains favourable to femoral artery access, which may be complicated by bleeding, haematomas, false aneurysms, arteriovenous fistulas and retroperitoneal haematomas in 4%–9% of patients. Many of these require additional intervention, which leads to prolonged hospitalisation and an increase in cost of treatment [3, 21, 22].

Limitations

Some limitations of this study should be noted. Despite randomisation, the patients in the long introducer group were younger. This was primarily because of the inclusion of the youngest patient (age, 18 years) in the long introducer group and the oldest patient (age, 87 years) in the short introducer group. In addition, a higher proportion of patients in the short introducer group were receiving anticoagulants. Finally, one patient in the long introducer group was lost to follow-up due to transfer to another hospital because of an acute cerebrovascular accident.

Conclusion

The use of 25-cm introducers in endovascular procedures performed by RAA is not associated with a decrease in the incidence of RAO development compared with 10-cm length introducers. However, their use is associated with an increase in puncture time and total procedure duration.

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