

A randomized comparison of transradial and transfemoral access in uterine artery embolization

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PURPOSE

We aimed to compare duration of uterine artery embolization, radiation exposure, safety and quality of life associated with the procedure in patients undergoing uterine artery embolization using transradial and transfemoral access.

METHODS

This randomized controlled trial was conducted from February 2013 to March 2017 in three hospitals. Transradial access was used in 78 patients and transfemoral access in 75 patients. Clinical characteristics of the patients were comparable between the two groups. Patients were evaluated for the success and duration of the procedure, radiation exposure, major and minor complications. Quality of life associated with the procedure was assessed among patients with uterine fibroids.

RESULTS

Embolization procedures were successfully performed in all patients in both groups. The duration of uterine artery embolization (32.27 ± 7.99 vs. 39.24 ± 9.72 minutes, $p < 0.001$), uterine artery catheterization time (12.36 ± 5.73 vs. 19.08 ± 6.06 minutes, $p < 0.001$) and radiation exposure (0.28 ± 0.14 vs. 0.5 ± 0.21 mZv, $p < 0.001$) were significantly lower in the transradial access group. The rate of major (0% vs. 2.7%, $p = 0.37$) and minor (11.53% vs. 17.3%, $p = 0.42$) complications was comparable between the two groups. Transradial access was associated with a statistically significant improvement in the quality of life associated with the procedure among patients with uterine fibroids.

CONCLUSION

Transradial access in uterine artery embolization has the same efficacy and safety compared to transfemoral access. This access reduces radiation exposure and duration of the procedure.

Uterine fibroids are the most common neoplasm in women, with a negative impact on women's health and reproductive function. According to statistics, the incidence of uterine fibroids is more than 70% by the onset of menopause (1). Most often it occurs in women aged 30 to 50 years, including patients who plan to retain reproductive function (2).

One of the contemporary methods of treatment for uterine fibroids is uterine artery embolization (UAE), which was first performed by Oliver et al. (3) in 1979 in a patient with postpartum hemorrhage. Ravina (4) started to use this technique in patients with uterine leiomyoma in 1991. Since then, uterine fibroid embolization (UFE) has received wide interest and acceptance.

Most UAE are currently performed using a transfemoral approach (TFA). In case of failure, transbrachial or transaxillar vascular access can be used, but these techniques have more access-related complications.

Transradial approach (TRA) can significantly reduce the incidence of access-related complications, which was confirmed in numerous interventional cardiology studies (e.g., RIFLE-STEACS, RIVAL, MATRIX) (5–7). Moreover, this vascular access allows early mobilization of the patient, increases quality of life associated with the procedure, reduces cost and duration of hospitalization (8, 9). TRA was first described by Campeau (10) in 1989 in a series of patients who underwent coronary angiography. Since then this vascular access got a wide-

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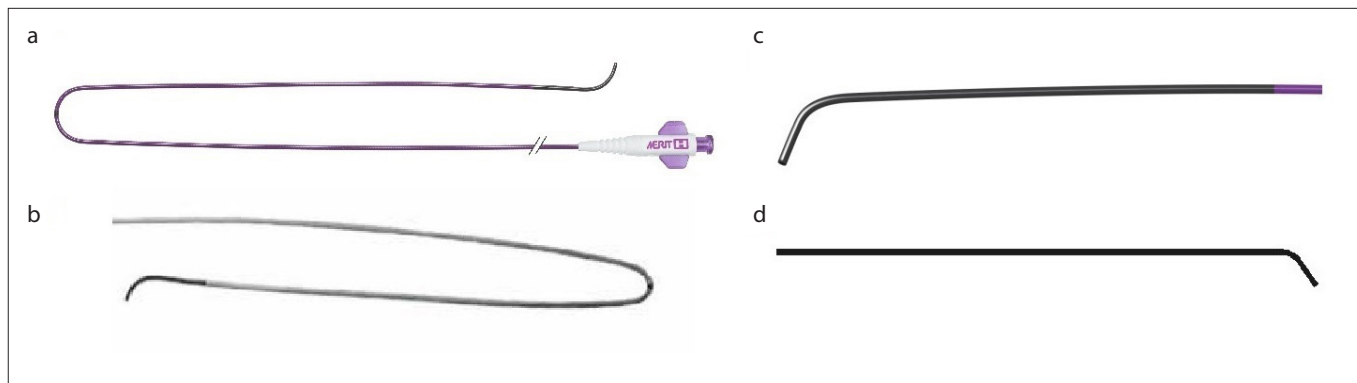


Figure 1. a–d. Types of catheters used in the study: (a), uterine artery catheter; (b), Roberts uterine curve catheter; (c), Bern catheter; (d), non-tapered angled catheter.

spread use in interventional cardiology. According to statistics, in 2012 more than 65% of percutaneous coronary interventions in the UK were done using TRA, and in some hospitals in Europe, Canada and Asia, more than 95% of all coronary interventions are performed through this vascular access (11, 12). Moreover, TRA is used for brachiocephalic, renal, visceral, iliac and femoral artery interventions (13, 14).

Until recently, the use of TRA in interventional radiology has been limited. The first study involving TRA in liver chemoembolization was published by Shiozawa et al. (15) in 2003 and showed significant reduction in the incidence of access-related complications compared to TFA. The retrospective analysis of TRA in 29 UFE patients was published in 2014. The technical success of the procedure was 100%, showing no major or minor complications (16). Moreover, recent reports have shown the benefits of TRA in prostatic artery em-

bolization, embolization of epistaxis and hemoptysis (17–19).

The aim of our study was to perform a comparative prospective randomized study of TRA and TFA efficacy and safety in patients undergoing UAE.

Methods

Study design

This was a prospective, randomized, controlled clinical trial, which was approved by our hospital review board (protocol number of ethics committee approval – №47, from 11.12.2012). The study was conducted from February 2013 to March 2017. Indications for UAE included uterine fibroids, accompanied by clinical symptoms (bleeding, pain, feeling of heaviness, dyspareunia, urinary frequency) and postpartum hemorrhage. Before randomization of patients, collateral perfusion to the hand was evaluated through Barbeau test. A pulse oximetry was placed on the patient's thumb. The radial artery was compressed for 2 minutes and the waveform changes were recorded through the pulse oximetry. Depending on the type of waveform, responses were categorized as: A – no damping of the pulse tracing immediately after compression; B – damping of pulse tracing, but the waveform always present; C – loss of pulse tracing followed by recovery within 2 minutes; and D – loss of pulse tracing without recovery within 2 minutes. Contraindications for participation in the trial were: bilateral iliofemoral bypass grafts and bilateral iliofemoral or aortoiliac occlusive disease, absence of left radial artery pulse, arteriovenous shunt for renal dialysis, Raynaud's phenomenon, presence of significant stenosis or occlusion proximal to the radial artery puncture site and Barbeau type D response. Simple

randomization was performed just before the procedure using an electronic random number generator.

Endovascular technique

Benefits and risks of the procedure were discussed with all patients before obtaining informed consent. All procedures were performed by one of two experienced interventional radiologists (more than 50 UAE through TRA and TFA performed). A fixed pain management protocol (combination of nonsteroidal anti-inflammatory drugs, paracetamol and fentanyl, when necessary) was used in all patients. Premedication was done with fentanyl and midazolam in all cases.

In the TFA group femoral artery puncture was performed by the Seldinger technique. A 5 F artery sheath (Prelude, Merit Medical) was utilized in all cases. During the operation 5000 IU of unfractionated heparin was administered intravenously to all patients. Uterine artery catheterization was done using a uterine artery catheter (diameter 5 F, length 90 cm, Merit Medical; Fig. 1a) or Roberts uterine curve catheter (diameter 5 F, length 90 cm, Cook Medical; Fig. 1b). Coronary guidewires (HT Whisper LS, Abbott Vascular) or microcatheters (Maestro, Merit Medical) were additionally employed in case of difficult anatomic features. Arterial embolization was performed by Embosphere particles 500–700 μm or 700–900 μm (Merit Medical) in all cases. Diagnostic catheter and artery sheath were immediately removed after the procedure. Hemostasis was obtained by manual compression with compressive bandage for 8 hours or vascular closure device (Perclose Proglide, Abbott Vascular) with compressive bandage for 4 hours.

In the TRA group all procedures were done through the left radial artery. In order

Main points

- Transradial access is a relatively new approach in interventional radiology.
- This is the first randomized study where effectiveness and safety of the transradial and transfemoral approaches were compared in patients undergoing uterine artery embolization.
- Transradial access in uterine artery embolization has the same effectiveness and safety compared with transfemoral access.
- Transradial access reduces radiation exposure and procedure time compared with transfemoral access.
- Patients with uterine fibroids have increased comfort after uterine artery embolization using the transradial access compared with transfemoral access.



Figure 2. a, b. Right (a) and left (b) uterine artery angiography via left radial artery access.

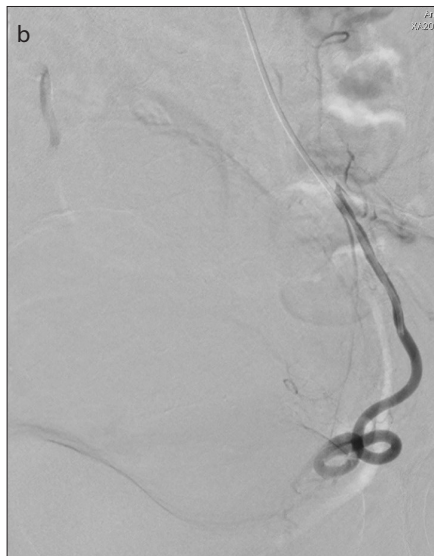
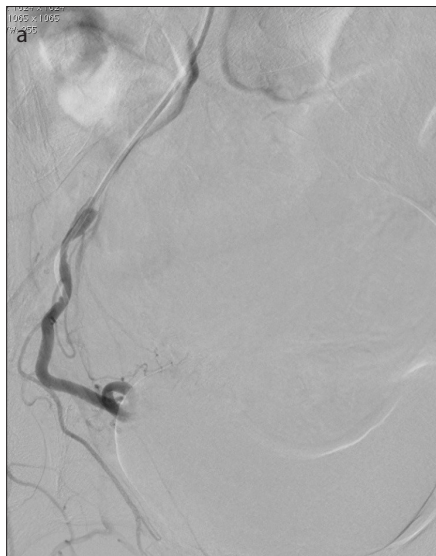


Figure 3. a, b. Right (a) and left (b) uterine artery angiography after embolization via left radial artery access.

to facilitate the work of the operator the following patient position was used: patient legs positioned at the head end of the angiography table, left arm abducted approximately 60–90 degrees and wrist hyperextended on a rolled sterile towel. Puncture of the left radial artery was performed by the Seldinger technique without ultrasound guidance. A 5 F hydrophilic artery (mini access) sheath (Prelude, Merit Medical) was utilized in all cases. To prevent thrombosis and spasm of the radial artery 2.5 mg verapamil and 5000 IU of unfractionated heparin were administered intraarterially. Bern catheter (diameter 5 F, length 125 cm, Merit Medical; Fig. 1c) or non-tapered angled catheter (diameter 4 F, length 150 cm, Ter-

umo; Fig. 1d) were used for uterine artery catheterization (Fig. 2). In case of difficult anatomy, coronary guidewires (HT Whisper LS, Abbott Vascular) or microcatheters (Maestro, Merit Medical) were additionally employed. Arterial embolization was performed by Embosphere particles 500–700 or 700–900 μm (Merit Medical) in all cases (Fig. 3). Diagnostic catheter and artery sheath were immediately removed after the procedure. Finale (Merit Medical) or TR Band (Terumo) was placed on the left wrist over the arteriotomy site. To reduce the risk of radial artery occlusion after the procedure, nonocclusive patent hemostasis was used for 2 hours. The duration of bed rest after the intervention was 1 hour.

Assessment criteria and follow-up

Technical success of the procedure was defined as successful bilateral uterine artery embolization, made through originally selected artery access. The inability to cannulate the access artery or catheterize the uterine artery was assessed as a technical failure.

During the procedure the following parameters were evaluated: duration of the procedure, uterine artery catheterization time (time from begin of access artery puncture to catheterization of the first uterine artery and time from end of the first UAE to catheterization of the contralateral uterine artery), radiation exposure, consumption of diagnostic catheters used during the procedure, inability to cannulate uterine artery with the first choice catheter and the amount of additional angiography instruments.

To assess the rate of complications quality improvement guidelines published by the Society of Interventional Radiology were used. All complications were divided in three groups: access site, systemic, and catheter-induced. Access site complications were also divided into major (major hematoma, pseudoaneurysm, limb ischemia, arteriovenous fistula, any access site complication requiring open surgical intervention) and minor (minor hematoma, radial artery occlusion without evidence of distal ischemia). Access site complications were evaluated clinically and with duplex ultrasound after the procedure, after the band removal, and 30 days after the procedure.

Quality of life was assessed in patients with uterine fibroids the day after the procedure using a series of procedure-specific questions. The following parameters were evaluated: the pain of compression, difficulty eating, discomfort at bed rest, difficulty urinating and general discomfort associated with the procedure. Each parameter was assessed using a 0 to 10 scale (0, no discomfort or pain; 10, maximum discomfort or pain). Each parameter was evaluated on its presence and severity. We did not assess the quality of life among the patients with postpartum hemorrhage, because of overlap with postpartum difficulties and discomfort.

Statistical analysis

Categorical variables were presented as percentages and compared using the chi-square and Fisher's exact tests. Continuous

	TRA group (n=78)	TFA group (n=75)	<i>p</i>
Age (years)	40.42±5.32	39.08±5.88	0.14 ^a
Weight (kg)	67.15±5.73	68.21±5.89	0.25 ^a
Height (cm)	169.16±9.23	167.21±8.72	0.21 ^a
Body mass index (kg/m ²)	26.15±3.57	25.83±3.89	0.32 ^a
Diabetes mellitus	6 (7.69%)	5 (6.66%)	0.12 ^b
Uterine fibroid	74 (94.9%)	72 (96%)	0.23 ^b
Postpartum hemorrhage	4 (5.1%)	3 (4%)	0.16 ^b

Data are presented as mean ± standard deviation.
 TRA, transradial access; TFA, transfemoral access.
^a*p* value was based on Fisher's exact test.
^b*p* value was based on t-test.

	TRA group	TFA group	<i>p</i> [*]
Duration of the procedure (min)	32.27±7.99	39.24±9.72	<0.001
Uterine artery catheterization time (min)	12.36±5.73	19.08±6.06	<0.001
Radiation exposure (mZv)	0.28±0.14	0.5±0.21	<0.001

Data are presented as mean±standard deviation.
 TRA, transradial access; TFA, transfemoral access.
^{*}*p* value was based on Wilcoxon Rank-Sum test.

	TRA group	TFA group	<i>p</i> [*]
Pain of compression (%)	7.89	32.16	<0.001
Difficulty eating (%)	4.35	13.31	<0.001
Discomfort during bed rest (%)	3.15	43.23	<0.001
Difficulty urinating (%)	3.31	12.23	<0.001
General discomfort associated with the procedure (%)	11.09	51.12	<0.001

^{*}*p* value was based on chi-square test.

variables were presented as mean ± SD and compared using a t-test or Wilcoxon Rank-Sum test. Statistical analysis was performed using Statistica 7.1 program. A *p* value of <0.05 was considered statistically significant.

Results

During the study period, 157 patients were screened for participation in the study. Four patients were excluded: one patient with no radial artery pulse and three patients with Barbeau type D response. In total, 153 patients were included in the study (146 had uterine fibroid and 7 postpartum hemorrhage) and randomized in 2 groups: 78 patients were included in the TRA group, and 75 patients were included in the TFA group. Age of the patients ranged from 26 to 48 years. Basic clinical character-

istics were comparable between the two groups (Table 1).

Bilateral UAE via selected artery access was successfully performed in 100% of patients in both groups.

In the TRA group the following catheters were used for uterine artery catheterization: Non-tapered angled catheter in 50 patients (64.1%) and Bern catheter in 28 patients (35.9%). In the TFA group the following catheters were used for uterine artery catheterization: Roberts uterine curve catheter in 44 patients (58.7%) and uterine artery catheter in 31 patients (41.3%). The mean number of diagnostic catheters used per procedure was significantly lower in the TRA group (1.11±0.13 vs. 2.1±0.21, *p* < 0.001). Inability to cannulate uterine artery with the first choice catheter and requirement for additional instruments was comparable

between the study groups: TRA, n=9, 11.5% vs. TFA, n=12, 16%, *p* = 0.48). The frequency of the catheterization problems depending on the type of the angiography catheter in the TRA group (non-tapered angled catheter, n=5, 55.5% vs. Bern catheter, n=4, 44.5%; *p* = 0.68) and in the TFA group (Roberts uterine curve catheter, n=7, 58.3% vs. uterine artery catheter n=5, 41.7%; *p* = 0.39) was not significantly different. Coronary guidewires were used during UAE as additional angiography instruments in 9 cases (11.5%) in the TRA group and 12 cases (16%) in the TFA group (*p* = 0.48). Microcatheters were used during UAE as additional angiography instruments in 4 cases (5.1%) in the TRA group and 4 cases (5.3%) in the TFA group, *p* = 0.63. Vascular closure devices (Perclose Proglide, Abbott Vascular) were used in 25 patients (33.3%) in the TFA group.

The duration of the procedure, uterine artery catheterization time and radiation exposure were significantly lower in the TRA group (Table 2).

The frequency of complications was comparable between the study groups. Systemic and catheter-induced complications were not seen in either group. Major access site complications did not occur in the TRA group. In the TFA group, pseudoaneurysm of the common femoral artery was detected in 2 cases (2.7%) and successfully treated by long-term compression. The frequency of minor access site complications was comparable between the study groups (11.5% in the TRA group vs. 17.3% in the TFA group, *p* = 0.42). Asymptomatic radial artery occlusion was registered in 3 cases (3.8%) in the TRA group. At the follow-up examination 30 days after the procedure, spontaneous recanalization of this artery was seen. Minor hematoma (less than 5 cm in diameter) was found in 6 cases (7.7%) in the TRA group and 13 cases (17.3%) in the TFA group, *p* = 0.088.

Among patients with uterine fibroids, TRA was associated with a statistically significant improvement in the quality of life associated with the procedure, compared to TFA (Table 3). In the TRA group, 43.2% of patients had no signs of discomfort associated with the procedure compared to 0% of the patients in the TFA group (*p* < 0.001).

Discussion

The present study is the first prospective, randomized study evaluating efficacy and safety of TRA and TFA in patients undergoing UAE.

Currently, UAE is most commonly performed using TFA. Usually, this vascular access allows selective catheterization of both uterine arteries. Nevertheless, in 1.5% of cases it is impossible to perform selective catheterization of one of the uterine arteries, and in this case, it is necessary to perform the contralateral femoral artery puncture (20). The frequency of access site complications for TFA varies from 2% to 15% (8, 10). According to several studies, vascular closure devices reduce the incidence of complications by 42% but increase the cost of the procedure (21). Another disadvantage of TFA is prolonged bed rest after the procedure, which does not allow early mobilization.

Alternative vascular access for UAE is transbrachial or transaxillary access. This vascular access is technically easier for uterine artery catheterization, but is also accompanied with a higher rate of access-related complications. Nowadays, this vascular access is not commonly used anymore and is usually preferred in cases of significant atherosclerotic lesions or tortuosity of the iliac arteries (22). The most dangerous complication of transbrachial access is the brachial artery thrombosis, which may result in acute ischemia of the hand. The incidence of hematoma that requires a surgical treatment is low, approximately 0.28% of the cases. The most dangerous complications of transaxillary access are hematoma that constrict the brachial nerve (2.8%–8%) and axillary artery thrombosis (1.2%).

A significant reduction of access site complications associated with TRA has been previously demonstrated. Several randomized trials showed that TRA reduces the incidence of bleeding by 75% and the rate of access-related complications by 63% (23). The advantages of the TRA are preserved when the vascular closure devices are used. The incidence of hematomas after radial artery puncture is 1%–3%. Compartment syndrome is observed in <0.01% of the cases. Other complications are pseudoaneurysm formation (<0.1%), arteriovenous fistula (<0.1%) and the access-site infections (<0.1%) (24). The most common complication of TRA is radial artery thrombosis, with an incidence of 0.8%–10%. In most cases the radial artery thrombosis is asymptomatic. Surgical treatment of TRA complications is necessary in <0.1% of cases (25).

Several studies have shown the application of TRA in peripheral interventions. The largest retrospective study included 936

patients (1512 noncoronary interventions). The frequency of complications in this study was 2.51%. Two (0.13%) of them met the criteria for major complications. The most frequent minor complications ($n=36$) were hematomas (0.86%) and radial artery thrombosis (0.73%) (26). In a retrospective study by Resnick et al. (16) including 29 patients, the UFE was performed using TRA and no access-related complications were reported. Our study shows a low incidence of complications in UAE procedures performed through TRA. All complications were evaluated as minor access site complications and did not require any additional treatment. In 3 cases (3.85%), asymptomatic thrombosis of the radial artery was registered, which resolved spontaneously within 30 days after the procedure. The rate of major vascular complications was comparable between TRA and TFA groups, most likely due to small sample size of the study.

The left radial artery is preferred for UAE via TRA. The distance from this artery to the uterine arteries is 5–10 cm shorter compared to the right radial artery. The catheterization of the descending thoracic aorta is easier when the left TRA is used, because it does not involve aortic arch manipulation. Furthermore, it is difficult in some cases to introduce guidewire through the aortic arch into the descending thoracic aorta due to the shape of the diagnostic catheters used for UAE via TRA. Left radial artery access reduces the risk of cerebral embolization, because there is no need to introduce catheter across the origin of the carotid arteries. Hamon et al. (27) showed that the rate of acute cerebral embolism during the coronary artery catheterization through the right radial artery was 4.9%; however, all of these cases were asymptomatic. Comparative analysis showed reduction of the cerebral embolism risk in coronary artery catheterization using left radial artery access (28). However, it is important to note that these studies have been performed on patients with atherosclerotic lesions of the arteries and it is difficult to extrapolate this data to the population of patients undergoing UAE.

The patient position that we used for UAE via TRA (patient legs positioned at the head end of the angiography table, left arm abducted approximately 60–90 degrees and wrist hyperextended on a rolled sterile towel) is optimal, because there is no need to move the control panel of the angiography table and it is more comfortable for the

operating physician. The length of the diagnostic catheters should be 125 cm (Bern, Merit Medical) or 150 cm (Non-tapered angled, Terumo), because of the greater distance from the artery sheath to the uterine arteries when TRA is used. We prefer 125 cm long catheters, because they allow using 150 cm long microcatheters, when it is necessary. The results of our study demonstrate that different shapes of diagnostic catheters for UAE using TRA have the same efficacy for uterine artery catheterization.

In the study by Resnick et al. (16), all UFE were performed via left TRA and were successful in 100% of the cases. The authors have also analyzed mean procedure duration (55 minutes), mean fluoroscopy time (18.9 minutes) and mean radiation dose (499 Gy·cm²) (16). All procedures in both groups were successfully performed in our study. Duration of the procedure and radiation exposure were significantly lower in the TRA group. We have also analyzed uterine artery catheterization time, which was significantly lower in the TRA group. This parameter indicates more reasonably the advantages and disadvantages of the selected arterial access.

Some studies have reported a significant decrease in procedural discomfort when TRA was used. This benefit is preserved even when vascular closure devices are used (9). Our study demonstrated that TRA allows not only earlier ambulation of the patients, but also significantly reduces discomfort associated with the procedure.

The present study has some limitations. First, sample size of the study was relatively small. Second, we did not measure the radiation exposure of the operator. Third, we used 5000 IU of unfractionated heparin during procedures in both groups. Using a weight-adapted regimen with 60 IU of unfractionated heparin/kg, the frequency of access-related bleeding complications, especially in the transfemoral group, could have been reduced.

In conclusion, our study demonstrates that TRA and TFA have similar safety and effectiveness in UAE. TRA facilitates catheterization of the uterine arteries resulting in reduced procedure time and radiation exposure. UAE via TRA has low complication rate, which is presented mostly by minor access site complications that do not require any additional treatment. TRA is associated with better quality of life and provides early ambulation. This vascular access offers a feasible alternative to TFA in patients undergoing UAE.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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