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CLINICAL INVESTIGATION RADIATION PROTECTION

Prospective Study on Total Fluoroscopic Time in Patients Undergoing Uterine Artery Embolization: Comparing Transradial and Transfemoral Approaches

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Abstract

Purpose Comparing total fluoroscopy time (FT) to perform uterine artery embolization (UAE) with transradial approach (TRA) versus transfemoral approach (TFA). Our hypothesis was that there would be no significant procedural time penalty incurred, despite the learning curve associated with adopting a new approach.

Materials and Methods A cohort study was undertaken including 66 consecutive patients undergoing UAE with either TRA/TFA between January and September 2015. Total FT was recorded prospectively for each procedure, and data subsequently analyzed retrospectively. Each operator had at least 2 years of experience as an interventional radiologist having performed at least 200 TFA UAEs. All operators had recently incorporated TRA into their practice.

Results A total of 39 TFA and 27 TRA cases were included in the study; mean age for TFA group was 44.4 years (± 4.9) and for TRA group was 45.1 years (± 4.9) ($p = 0.59$). Mean FTs were comparable between the two groups ($p = 0.86$) despite a learning curve associated with TRA: The mean total FT with TFA was 20.36 min (± 9.48) compared to TRA 20.12 min (± 7.67).

Conclusions FTs for TRA UAE were comparable to TFA UAE, even though TRA had been recently adopted as a new approach. Despite the learning curve associated with developing a novel technique, operators should not expect the efficiency of their service to be significantly compromised. Introducing this safe and effective method of vascular access should therefore be considered.

Keywords Uterine fibroid embolization · Uterine artery embolization · Transradial · Fluoroscopic time

List of Abbreviations

DAP	Dose area product
UAE	Uterine artery embolization
TRA	Transradial approach
TFA	Transfemoral approach
FT	Fluoroscopy time
IR	Interventional radiology
UA	Uterine artery
RA	Radial artery
AV	Arteriovenous
PCI	Percutaneous coronary interventions

Introduction

The use of TRA for arterial intervention has increased significantly since its introduction in 1981. Currently, one in six interventional cardiology procedures is performed via the radial approach in the USA due to the well-established safety profile, with a significant reduction in the risk of bleeding and vascular complications as compared to TFA (1.4% TRA versus 3.7% TFA $p < 0.0001$) [1–6]. More recent studies have also demonstrated that TRA has

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at least an equivalent efficacy profile as compared with TFA when undergoing peripheral arterial intervention and has resulted in increased interest in the technique within the published literature [7–10] with established benefits relating to patient satisfaction, reduced recovery time and early ambulation with consequently shorter hospital stays [2], [3], [7], [11], [12]. Socioeconomically, TRA has also been demonstrated in large cohorts to incur significant cost savings [11–14]. Although the introduction of TRA requires a change in practice, it can significantly improve work flow without incurring the perceived penalty of slower procedural times and overall inefficiency, preventing some centers from adopting it as routine practice [15]. The purpose of this study was to compare the FT used to perform UAE using TRA versus TFA, having introduced this method of access into routine practice.

Materials and Method

Institutional review board approval was obtained for this prospective, observational study and informed consent was obtained from all patients participating in this single-arm open-label study.

All patients undergoing UAE using either TRA or TFA access between January and September 2015 were included ($n = 66$). Patients had been referred to our interventional radiology (IR) clinic via their gynecologist with symptomatic leiomyomata in the presence or absence of adenomyosis diagnosed on routine pre-procedural MRI. All patients were offered either TRA or TFA, and subsequent choice of access was selected on patient preference and was not therefore randomized. Data were recorded prospectively including age, uterine size (transverse diameter (TD), longitudinal diameter (LD), anterior–posterior diameter (APD) and volume (TD × LD × APD), time to cannulation of each uterine artery (UA), total FT and equipment used (including the use of a microcatheter, which is not routinely used in our practice). Data were analyzed retrospectively in an anonymized fashion.

Procedure

Each supervising physician performing UAE had at least 2 years of practice as an interventional radiologist (DK, JC, DL, GL, SH and LM), and all were familiar and experienced with TRA for UAE. Depending on the circumstances, the supervising physician acted as either primary operator, or secondary operator to a clinical fellow with graduated responsibility through the course of fellowship training. The decision to proceed with TRA or TFA was based on patient preference, following a detailed discussion of the risks and benefits of each approach.

Transradial Protocol

A pre-procedural radial artery (RA) assessment was performed including the Barbeau test [16] and documented in the patient chart. Following assessment, a small amount of nitroglycerin paste was placed on the intended access site and covered to assist with RA dilation. The patient was placed on the angiography table and the left arm prepped to the axilla to allow for complete RA assessment with ultrasound pre-procedure, including assessment of RA caliber and anatomical variants (aberrant or high RA origin, corkscrew artery and radial loops). The arm was placed on an arm board for support (Rad Rest, Merit Medical, South Jordan, UT) (see Figs. 1, 2).

Nine milliliters of 1% lidocaine mixed with 100 micrograms of nitroglycerine was administered to the patient in the subcutaneous tissues around the RA from approximately 2 cm proximal to the radial styloid over a distance of 4–5 cm. The artery was then accessed with a 21G or 18G needle, with a single anterior wall puncture under ultrasound guidance. Following good pulsatile blood return, a 0.018” or 0.021” inch guidewire was then inserted into the artery and a 11 cm 5Fr hydrophilic sheath (Prelude Ease, Merit Medical, South Jordan, UT) placed over the wire utilizing the Seldinger technique. A bolus of 2000 IU heparin, 200mcg nitroglycerine and 2.5 mg verapamil was then given over 20 seconds through the sheath as per

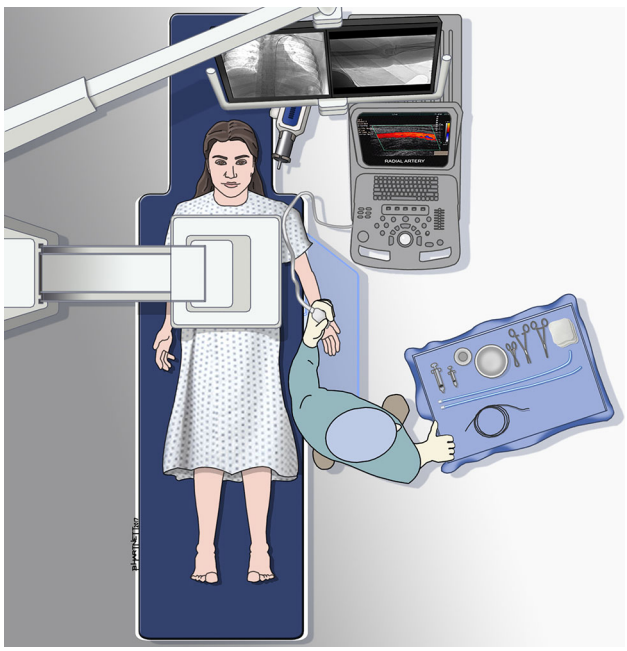

Fig. 1 Schematic diagram showing room setup with the left arm supported on a plexiglass arm board

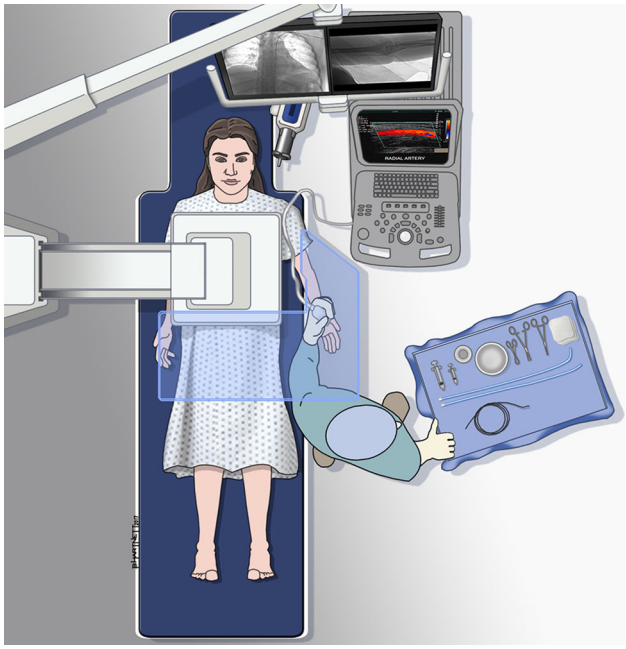

Fig. 2 Schematic diagram showing position of the plexiglass radial arm board beneath patient

institutional protocol to help prevent spasm and thrombosis. In the rare case of a radial loop, an angled 0.035" hydrophilic wire may be used to negotiate the turn, and in our limited experience, when the catheter passes through, it straightens the loop. If this is not successful, a microcatheter and angled 0.016"or 0.018" microwire are recommended. The combination is dependent on operator preference. Following safe passage of a Bentson wire into the descending aorta with a 5Fr angled catheter (Bernstein Performa catheter 125 cm, Merit Medical, South Jordan, UT), the wire was exchanged for a hydrophilic wire (Glidewire, Terumo, Somerset, NJ or, Laureate, Merit Medical, South Jordan, UT) which was then used to cannulate the UAs. Subsequent use of a microcatheter/microwire combination was at the discretion of the operator, ensuring adequate antegrade flow to avoid apparent stasis due to obstruction or spasm caused by the presence of a 5Fr catheter within the UA. Following confirmation of the catheter within the horizontal portion of the UA, digital subtraction angiography was performed to demonstrate fibroid enhancement and identify the presence of significant arteriovenous (AV) shunting. Embolization was subsequently performed using embosphere microspheres (Merit Medical, South Jordan, UT), with incremental increase in size with two vials of 500–700 μm and 700–900 μm microspheres until satisfactory stasis was achieved. In the presence of adenomyosis, providing no significant AV shunting was present, embolization was commenced with 2 vials of 100–300 μm microspheres, with incremental increase in size following a single vial until near stasis was achieved. End point of embolization was defined as slow flow over three cardiac cycles as per institutional protocol.

Following completion, the catheter was removed over a guidewire to ensure the RA was not damaged.

Hemostasis was achieved using the patent hemostasis technique with a Statseal hemostatic pad (Biolife, Sarasota, FL) and a Safeguard radial hemostasis balloon (Merit Medical, South Jordan, UT). Deflation of the balloon was performed according to institutional protocol [15], [17].

Transfemoral Protocol

Right common femoral artery access was achieved using ultrasound guidance, puncturing below the midline of the femoral head, below the inguinal ligament. After instillation of 5–10 mls 1% lidocaine into the subcutaneous tissue, a 5Fr vascular sheath was inserted.

A Bentson guidewire was inserted and a cobra shape catheter (C2 Glide catheter, Terumo, Somerset, NJ) was used to cross the aortic bifurcation. The wire was exchanged for a hydrophilic wire (Glidewire, Terumo, Somerset, NJ, or Laureate, Merit Medical, South Jordan, UT) which was then used to cannulate the contralateral UA. Subsequent use of a microcatheter/microwire combination was at the discretion of the operator, ensuring adequate antegrade flow to avoid apparent stasis due to obstruction or spasm caused by the presence of a 5Fr catheter within the UA. Embolization was performed using the same technique as described for the transradial method. Following successful contralateral embolization, a loop was formed in the aorta and the ipsilateral UA cannulated.

Following successful embolization the catheter was removed and a femoral angiogram performed to confirm vascular access site and a vascular closure device used to obtain hemostasis (Angioseal, St Jude Medical, Saint Paul, MN, Starclose SE, Abbott vascular, Santa Clara, CA).

None of the cases included in the study required ovarian artery embolization.

All procedures were performed in a dedicated angiography suite, with a flat panel detector (Siemens, Artis, Erlangen, Germany). Heterogeneity in operator imaging protocols was not recorded. Digital subtraction angiography was limited to either pre- or pre- and post-UA embolization acquisitions only. The use of fluoroscopy was minimized with pulse rate varying between 7 and 15 pulses/s depending on the operator. Maximum collimation was used at all times. In the TFA and TRA, angulated projections with hand and/or pump injection were used to optimally image the internal iliac (20–30° contralateral oblique) and UAs (approximately 30° ipsilateral oblique). If the origin of the UA was not clearly shown, further angulated projections were performed at the operators'

discretion. This not only facilitates fluoroscopic guided cannulation, but may help to reduce overall FT.

Procedural Parameters

The following procedural parameters were recorded:

1. FT to cannulation of first UA (Time 1).
2. FT to embolization of first UA with stasis as endpoint (Time 2).
3. FT to cannulation of second UA (Time 3).
4. FT to embolization of second UA with stasis as endpoint (Time 4).
5. Total FT.

Microcatheter use was recorded, as these are not routinely used as part of our departmental protocol. When the UA is sufficiently hypertrophied, embolization can be performed via the 5Fr catheter, providing its presence does not impede antegrade flow. In the event of the 5Fr catheter causing spasm or impedance of antegrade flow within the UA simulating false stasis, use of a microcatheter ensures complete embolization.

Statistical Analysis

Statistical analysis was performed by a medical statistician using STATA (StataCorp. 2015. *Stata Statistical Software: Release 14*. College Station, TX: StataCorp LP.) and included T test and Mann–Whitney U Tests. A p-value of ≤ 0.05 was regarded as statistically significant. Mean values and their standard deviations were calculated.

Results

Sixty six consecutive patients undergoing UAE for symptomatic leiomyomata with or without adenomyosis were included in the study, with a total of 39 undergoing the TFA and 27 undergoing TRA. Patient demographics and uterine volumes were comparable in each group (see Table 1). All 27 cases undergoing TRA were technically successful, with no cases requiring crossover to TFA or other intra-procedural complications. TRA patients were discharged the following day, with no access site complications. Routine follow-up to assess for radial artery patency is not routinely performed at our institution, and there were no known cases of radial artery thrombosis. For procedural parameter results, see Table 2. The mean total FT taken for the procedure was similar in both groups; the TFA mean value was 20.36 min (± 9.48) as compared with 20.12 min (± 7.67) using TRA ($p = 0.86$). Although not statistically significant, these results suggest comparable or even lower FT with TRA.

Discussion

TRA has become the preferred method of access for diagnostic and interventional cardiology procedures in many countries; however, its utilization in IR procedures is only in its evolution. Through the modification and iterative refinement of equipment, room setup and post-procedural care, the benefits to the department, operator and patient are becoming evident. TRA intervention has been demonstrated to be safer in the cardiology literature, with significantly lower access site complications [3], [18], [19]. TRA allows for immediate ambulation and greater overall patient satisfaction [3] [18], also lending a potential economic advantage due to cost savings from TRA with or without the use of closure devices [12], [14]. The apparent reluctance for this transition in IR may be explained by a perception that its introduction will incur prolonged procedural times, as a result of the learning curve that is inevitable when adopting a new technique.

In our institution, both TRA and TFA for UAE are routinely offered to patients, the former having been introduced recently (previous two years), and rapidly adopted as our default approach. Much like TFA, a learning curve and departmental wide adoption are required before the benefits and efficiencies become clear [20]. There are limited data comparing TRA and TFA as related to surrogates of radiation exposure and efficiency [21]. This manuscript demonstrates that despite the learning curve, TRA UAE does not lead to increased FT.

Table 1 Patient Demographics

	Transradial (n 27)	Transfemoral (n 39)	P-value
Mean age (years) (SD)	45.1 (4.9)	44.4 (4.9)	0.59
Uterine dimensions (cm) (SD)	LD 11.4 (4.1)	LD 10.2 (3.5)	0.23
	TD 9.6 (3.1)	TD 8.7 (1.5)	
	APD 9.0 (1.9)	APD 8.9 (2.3)	
Mean uterine volume (cm3)	1129	876	Not Calculated

SD standard deviation, *LD* longitudinal diameter, *TD* transverse diameter, *APD* anterior–posterior diameter

Table 2 Results

	Transradial (*n* 27)	Transfemoral (*n* 39)	*P*-value
Mean time 1 (min)	5.75	6.10	0.68
SD	3.07	3.62	
Mean time 2 (min)	5.06	4.20	0.26
SD	2.93	3.05	
Mean time 3 (min)	4.72	4.89	0.86
SD	3.91	4.08	
Mean time 4 (min)	4.41	4.55	0.86
SD	2.12	3.74	
Mean total FT (mins)	20.12	20.36	$p = 0.86$
SD	± 7.67	± 9.48	
Microcatheter used	12	17	$p = 0.93$

Time 1 = FT to cannulation of first uterine artery

Time 2 = FT to embolization of first uterine artery with stasis as endpoint

Time 3 = FT to cannulation of second uterine artery

Time 4 = FT to embolization of second uterine artery with stasis as endpoint

SD standard deviation, *FT* fluoroscopic time

The superior safety profile of TRA has been well described. The largest study including 2.820.874 TRA and TFA percutaneous coronary interventions (PCI) [1] demonstrated a lower bleeding risk (adjusted odds ratio, 0.51; 95% confidence interval, 0.49–0.54) and lower risk of vascular complications (adjusted odds ratio, 0.39; 95% confidence interval, 0.31–0.50) using TRA. The risk of asymptomatic stroke has been demonstrated to be low in the largest randomized control trial for coronary intervention (0.4%) (17). A recent systematic review and meta-analysis of more than 475,000 patients undergoing radial intervention for coronary procedures did not demonstrate an increased stroke risk [22]. While we consent all patients undergoing TRA for the risk of stroke, we emphasize that this risk is extremely small [10], [23]. In addition, studies have not demonstrated an increased stroke risk using either the left or right RA; in our institution, we only use the left RA, thus avoiding crossing the arch and passing only a single cerebral vessel (left vertebral). This is also the more favorable vessel for accessing the abdominal and pelvic vasculature due to the anatomy of the arch vessels and shorter distance to the target vessel compared to a right radial approach. As such, the risk of stroke, albeit minimal, should be acknowledged when considering TRA for the use of body and peripheral interventional procedures [10]. We have not encountered any symptomatic strokes following any TRA intervention at our center.

The use of TRA for body and peripheral interventions is increasing, with recent publications showing the benefit this technique brings to radiology. A study by Resnick et al. [8] reported 100% technical success in 29 UA embolizations using TRA. There were no recorded complications, and radial patency at 1 month follow-up was 100%. It has been shown to be safe and feasible in hepatic oncological procedures including chemoembolization and radioembolization [9], [11], where low complication rates were observed. RA occlusion/thrombosis occurred in 1.6% of cases [9], this rate being potentially over-reported due to many of these patients undergoing serial punctures. Vascular complication rates including thrombosis/occlusion have shown to be associated with a smaller RA diameter [24]. Initially, we used an arbitrary cutoff of 2 mm, as measured on ultrasound; however, with increased experience, we will now routinely access a RA of 1.5 mm using a 4Fr sheath and catheter. Our institutional RA occlusion rate is 0.3% [15]. TFA is preferred for more complex peripheral vascular lesions; there is a role for TRA in a range of aortoiliac and femoropopliteal interventions [10], with a study showing non-inferiority to TFA for peripheral vascular interventions [7]. The study by Roy et al. [10] not only confirmed the consistent finding that TRA reduces complications rates at the access site, but also demonstrated no difference in procedural time.

Due to inter-operator variation in fluoroscopic and DSA protocol, dose area product (DAP) was not assessed. Furthermore, patient height is not routinely measured in our institution, so body mass index was not recorded. Comparative cardiology studies evaluating DAP using TRA and TFA show variable outcomes, with several studies that have shown no increase in total FT using TRA [10], [25] [21]. There is evidence to suggest that increased operator experience reduces radiation exposure [26], [27]. The RIVAL trial [3] concluded that in higher volume centers, lowest radiation dose was irrespective of access site

approach, with differences present only in lower volume centers.

Improved cost benefits have been attributed mainly to the use of alternative hemostasis devices, with procedural savings also demonstrated despite no femoral closure device being used [12], [14].

Limitations of our study include a lack of radiation dose analysis and small sample size, with results only applicable to our single center. Patient BMI and operator radiation exposure are important indices which were not evaluated in this study.

Conclusion

Despite the learning curve and lower procedural experience associated with TRA introduction, this study has shown no fluoroscopic time penalty. TRA has a favorable efficacy, safety and economic profile, with many associated benefits for the patient. The study findings support the widespread increase in uptake of this access method across many IR procedures, and those considering adoption of TRA should be reassured that the efficiency of their practice will not be significantly compromised.

Compliance with Ethical Standards

Conflict of interest Dr. Mortensen, Dr. Ho and Dr. Legiehn declare that they have nothing to disclose. Dr. Chung reports personal fees from Merit Medical, personal fees from Boston Scientific, outside the submitted work. Dr. Liu reports other (independent director) from Merit Medical, grants from Seimens Medical, outside the submitted work. Dr. Machan reports other (medical advisory board) from Boston Scientific Corp, other (scientific advisory committee) from Cook Inc, outside the submitted work. Dr. Klass reports personal fees from Merit Medical, personal fees from Cook Medical, personal fees from Phillips Healthcare, personal fees from Liva Nova, grants from Biolife, outside the submitted work.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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