Cardiovasc Intervent Radiol (2007) 30:1139–1143
DOI 10.1007/s00270-007-9136-0

CLINICAL INVESTIGATION

Prospective Study of Elective Bilateral Versus Unilateral Femoral Arterial Puncture for Uterine Artery Embolization

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Received: 18 April 2007 / Accepted: 23 June 2007 / Published online: 14 September 2007

Abstract The purpose of this study was to assess the effect of elective bilateral femoral arterial punctures for uterine artery embolization (UAE) of symptomatic fibroids on fluoroscopy and procedural time, patient dose, and ease of procedure. We conducted a prospective study of UAE with either the intention to catheterize both uterine arteries using a single femoral puncture ($n = 12$) or elective bilateral arterial punctures from the outset ($n = 12$). The same two operators undertook each case. Main outcome measures were total procedure time, fluoroscopy time, dose-area product (DAP), and total skin dose. A simulation was then performed on an anthropomorphic phantom using the mean in vivo fluoroscopy parameters to estimate the ovarian dose. Bilateral UAE was achieved in all patients. None of the patients with initial unilateral arterial puncture required further contralateral arterial puncture. The mean fluoroscopy time in the group with elective bilateral punctures was 12.8 min, compared with a mean of 16.6 min in patients with unilateral puncture ($p = 0.046$). There was no significant difference in overall procedure time ($p = 0.68$). No puncture-site complications were found. Additional catheters were required only following unilateral puncture. The simulated dose was 25% higher with unilateral puncture. Although there was no significant difference in measured in vivo patient dose between the two groups (DAP, $p = 0.32$), this is likely to reflect the wide variation in other patient characteristics. Allowing for the small study size, our results show that the use of elective bilateral arterial punctures reduces fluoroscopy time, requires less catheter manipulation, and, according to the simulation model, has the potential to reduce patient dose. The overall procedure time, however, is not significantly reduced.

Keywords Uterine artery · Fibroid · Embolization · Radiation dose

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Introduction

Uterine artery embolization (UAE) is an accepted treatment option for symptomatic uterine fibroids [1–5]. The majority of interventional radiologists currently adopt a technique involving unilateral arterial puncture, usually the right femoral artery, with subsequent catheterization of both uterine arteries [6, 7]. Catheterization of the ipsilateral uterine artery can be technically challenging because of the steep angulation involved. This may lead to prolonged screening and manipulation, with several catheter changes or the use of microcatheters. The bilateral femoral puncture technique has been described [8, 9], but it still tends to be reserved for technical failures.

We performed a prospective, comparative study to evaluate the two techniques after noting prolonged screening times and high radiation doses in cases where ipsilateral catheterization had proved difficult.

We assessed the effect of using elective bilateral femoral artery punctures, catheterization of both uterine arteries, and simultaneous bilateral embolization, compared with unilateral femoral puncture and sequential embolization on procedural time, patient dose parameters, and overall ease of procedure.

Materials and Methods

A prospective study was undertaken between July 2006 and December 2006. Patient selection was on a consecutive basis of women referred for UAE. Informed consent was obtained and all patients consented to the use of data collection from UAE for audit purposes as required by the National Institute for Health and Clinical Excellence (NICE). All procedures were undertaken by the same experienced interventional radiologist (A.M.B.) and interventional fellow (M.B.) using an Axiom Artis x-ray C-arm unit (Siemens, Munich, Germany). Initial catheter manipulation was performed by M.B., with A.M.B. intervening if there was significant difficulty in progression of the procedure. M.B. had performed approximately 15 UAE procedures prior to this study, although having experience with >300 other interventional vascular procedures. The range of expertise reflected by this study should allow these results to be applicable to a wide spectrum of radiologists undertaking UAE.

The first 12 patients underwent UAE with bilateral arterial puncture and placement of 6-Fr vascular sheaths (Cordis, Miami, FL) in both common femoral arteries. A flush aortogram was not routinely performed. Both uterine arteries were catheterized sequentially with our preferred method of a 4-Fr RIM catheter (Cordis) for contralateral catheterization or, if this failed, ipsilateral catheterization. Roadmaps were used to guide catheterization, but acquisition of angiographic runs was not performed in any cases. AP and oblique projections were used as appropriate, and collimation maximized as much as possible by the operator. Filtration was 2.5 mm Al and 0.3 mm Cu, with automatic control.

With a catheter positioned in each uterine artery, simultaneous embolization was performed by two operators using nonspherical polyvinyl particles of 355–500 μm (Contour; Boston Scientific-Target Therapeutics, Fremont, CA). Our end point for embolization using nonspherical PVA is stasis of flow. We routinely used an arterial closure device, either StarClose (Abbott Vascular, Berkshire, UK) or AngioSeal (St Jude Medical Ltd., Stratford-upon-Avon, UK), at the end of the procedure.

The next 12 patients underwent UAE, with placement of a 6-Fr vascular sheath in the right common femoral artery. We aimed to complete the procedure with sequential catheterization and embolization of the uterine arteries using a 4-Fr RIM catheter for contralateral and then for ipsilateral catheterization. If this proved difficult, the operator selected other suitable 4- or 5-Fr catheters. If catheterization of either uterine artery was not successful within 30 min of trying, our protocol was to proceed to a contralateral puncture. Again, an arterial closure device was routinely used.

All patients underwent transabdominal ultrasound prior to the procedure, and uterine volume was recorded. Patient weight, procedural time, and fluoroscopy time were also recorded. Procedure time was taken from the start of the arterial puncture to hemostasis at the puncture site. Note was made of the catheter types used, including the need to use a microcatheter. All patients were reviewed at 24 h to assess puncture-site complications.

Mean fluoroscopy times were calculated for the two techniques. Task-based analyses (Table 1) were performed in order to break each technique down into a set of subtasks, with their own corresponding fluoroscopy times. Simulations of both techniques were then performed on an ART-200 anthropomorphic phantom (PI Medical Diagnostic Equipment, Tynje, The Netherlands). A conventional radiograph was taken of the phantom in order to locate the positions of the ovaries into which the thermoluminescent dosemeters were inserted to measure ovarian dose. The simulations were carried out using the same fluoroscopic unit, pulse rate (7.5 per second), kilovolts, and focus-to-film distance used during each UAE patient procedure. These values were kept constant for the unilateral and bilateral simulations.

Summary descriptive statistics were used for demographic parameters and uterine/fibroid volume prior to embolization. Parametric analysis (unpaired *t*-test or Mann-Witney *U* test) was used to compare means, and statistical significance was defined as $p < 0.05$, two-sided level. Analysis was performed using Prism software (GraphPad Software, Inc.).

Results

The first 12 patients (Group 1) were treated with elective bilateral femoral arterial punctures. All patients were catheterized from the contralateral approach via a 4-Fr RIM catheter, except for one case where it was difficult to negotiate the aortic bifurcation but both uterine arteries were easily catheterized via an ipsilateral approach. Elective bilateral sheaths allowed rapid switch to this strategy. The mean age of the patients was 42.0 years (95% CI, 39.3–44.8 years); uterine volume, 963 ml (95% CI, 342–1584 ml); and weight, 72.8 kg (95% CI, 58.9–86.7 kg). Patients required a median of 3.0 vials of PVA. Mean fluoroscopy time was 12.8 min (95% CI, 10.4–15.2 min), with a mean procedural time of 38.4 min (95% CI, 34.4–

Table 1 Summary of task-based analyses for simulator phantom based on mean screening time and approximate times for each component part of the procedure

Unilateral technique	Bilateral technique
No screening for puncture	No screening for punctures
Left uterine artery catheterization including average of 2 roadmap sequences (4 min 30 s)	Left uterine artery catheterization including average of 2 roadmap sequences (4 min 30 s)
Left uterine artery embolization (3 min 20 s)	Right uterine artery catheterization including average of 2 roadmap sequences (4 min 30 s)
Right uterine artery catheterization including average of 2 roadmap sequences (5 min 30 s)	Simultaneous embolization of both uterine arteries (4 min 12 s)
Right uterine artery embolization (3 min 20 s)	

42.5 min). The mean dose-area product (DAP) was 3248 cGy/cm^2 (95% CI, 1325–5172 cGy/cm^2). The mean total skin dose, calculated from the DAP and displayed on the unit, was 195.3 mGy (95% CI, 98–292 mGy). Closure was with bilateral AngioSeal in 10 patients, bilateral StarClose in one, and StarClose and contralateral AngioSeal in another. No puncture-site complications were evident on clinical examination the following day.

The second group of 12 patients (Group 2) was treated with unilateral femoral arterial puncture. Bilateral UAE was performed in all patients, with contralateral arterial puncture not required in any patient. Mean patient age was 43.5 years (95% CI, 40.2–46.8 years), uterine volume was 867 ml (95% CI, 270–1465 ml), and weight was 77.0 kg (95% CI, 64.4–89.5 kg). Patients required a median of 3 vials of PVA, although there were two outliers requiring 18 and 20 vials, respectively. Mean fluoroscopy time was 16.6 min (95% CI, 13.5–19.8 min), with a mean procedural time of 40.0 min (95% CI, 32.6–47.4min). The mean DAP was 4577 cGy/cm^2 (95% CI, 2342–6813 cGy/cm^2). The mean total skin dose was 316.5 mGy (95% CI, 190.4–442.6 mGy). StarClose was used in nine patients, AngioSeal in two patients, and no closure device in one patient. No puncture-site hematomas were seen in any of the patients on the following day.

In seven patients (Group 2) the whole procedure was completed with the single RIM catheter. In four patients an SOS-Omni (AngioDynamics, New York) reverse-curve catheter was required for catheterization of the ipsilateral internal iliac artery. In one of these patients a Glide-Cobra (Terumo, Surrey, UK) was also required to obtain catheterization of the uterine artery. In one further patient a Tracker 325 (Meditech; Boston Scientific, St Albans, Hertfordshire, UK) microcatheter was required. In Group 1 the procedure was performed in all cases with 4-Fr RIM catheters.

Main outcome measures and calculated *p*-values are listed in Table 2. In the simulated bilateral puncture model the measured DAP was 1378 cGy/cm^2 and the total skin dose 85 mGy. The ovarian dose was recorded as 7 mGy for both the left and the right ovaries. The simulated unilateral arterial puncture model recorded a DAP of 1808 cGy/cm^2 and a total skin dose of 109 mGy. The ovarian dose was 9.2 mGy for the left and 9.5 mGy for the right ovary.

Table 2 Summary of mean outcome measures for bilateral versus unilateral femoral arterial puncture for UAE (in vivo and simulator results)

Parameter	Bilateral access	Unilateral access	*p*-value
Fluoroscopy time (min)	12.8	16.6	**0.046**
Patient weight (kg)	72.8	77.0	0.62
Uterine volume (ml)	963	867	0.80
Procedure time (min)	38.4	40.0	0.68
DAP (cGy/cm^2)	3248	4577	0.33
Total skin dose (mGy)	225	316	0.11
Simulator dose DAP (cGy/cm^2)	1378	1808	
Simulator total skin dose (mGy)	85	109	
Simulated ovarian dose (mGy) Left ovary	7	9.2	
Right ovary	7	9.5	

Discussion

UAE is established as a safe and effective treatment option for symptomatic fibroids [1–5]. Although UAE is not recommended for treatment of infertility and associated uterine fibroids [10], nearly all patients are of a child-bearing age. There are increasing reports of completed pregnancies following UAE [11]. Women may choose UAE who wish to retain the potential for future fertility despite the fact that planned pregnancy is a contraindication. Thus considerations of radiation dose are paramount.

Elective bilateral arterial punctures are reported in the literature [8, 9] with the aim of reducing patient irradiation by using pulsed fluoroscopy, avoidance of aortography, and simultaneous bilateral embolization. Increased operator experience has shown a decrease in mean screening time from 21.9 to 10.9 min between the two series by the same authors [8, 9]. However a direct comparison was not made with single femoral puncture techniques, and therefore it is difficult to ascertain the benefit of elective bilateral femoral puncture.

Ho and Cowan [12] reported the use of the RIM catheter for UAE in 75 patients, with success in all patients from an ipsilateral approach and with a mean fluoroscopy time of 13.6 ± 5.3 min. Kroencke et al. [13] also recently reported successful catheterization of both internal iliac arteries from a unilateral approach using the RIM catheter in 322 of 364 cases. We have adopted the use of the RIM catheter for ipsilateral and contralateral internal iliac catheterization with considerable success.

Our results demonstrate a small but statistically significant reduction in fluoroscopy time following bilateral elective femoral artery puncture ($p = 0.046$). It must be noted that two cases in Group 2 required large volumes of embolic agent, which is a potential bias in this study, but the fluoroscopy times in these cases were 17.5 and 23.3 min, respectively, and were not the longest in this group.

We found that elective bilateral puncture gives a number of distinct advantages in terms of ease of procedure. This technique allows for accurate identification of the aortic and iliac bifurcation position on the second catheterization due to the position of the first catheter. In one case the aortic bifurcation was steep and difficult to cross, and the presence of bilateral punctures allowed rapid progression to ipsilateral catheterization with the RIM catheter, when this was found to be easier. Screening time is further reduced due to synchronous embolization, and this becomes more significant the larger the volume of embolic material required. The fact that both catheters are in situ potentially reduces the procedure time and over- and underembolization, as catheters can be left in place while waiting for the embolic agent to achieve its effect. Additional catheters were only required following ipsilateral access, reflecting increased manipulation to catheterize the ipsilateral uterine artery.

Despite a significant difference in screening times, no significant differences were seen in overall procedural time or, more notably, measured patient dose. Patient dose is, however, dependent on multiple factors including patient weight, collimation, magnification, and use of digitally subtracted acquisitions. We believe that the wide variance in patient mass had a great influence on patient dose. Although there was no significant difference in patient characteristics in terms of weight and uterine volume in this small study, a larger study may have sufficient power to prove this assertion.

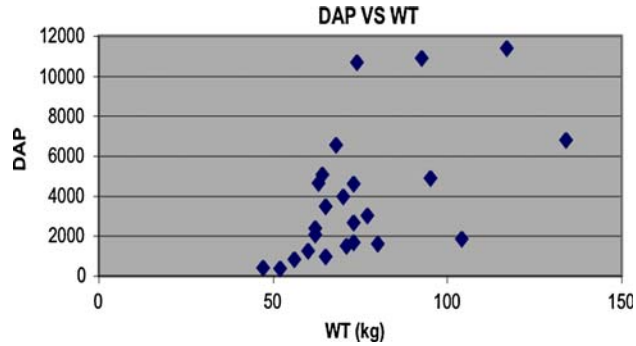

Fig. 1 Scatter-plot of dose-area product (cGy/cm^2) versus patient weight (kg) for all patients ($n = 24$)

There was a 30% increase in dose on the simulated phantom with unilateral puncture, which is roughly proportional to the difference in simulated fluoroscopy time. The simulation does, however, take account of other differences between the two techniques (mainly collimation between sequential and simultaneous embolization). The phantom is modeled on a patient of average weight and build, and the difference in dose between the two techniques is likely to increase with increase in patient weight (Fig. 1). The measured DAP for the same fluoroscopy time in our study was considerably higher (almost double) than the simulated dose, a reflection of the limitations of a phantom model. As the phantom model represents a 70-kg hermaphrodite subject, it can never fully translate to female patients of varying weights, shapes, and sizes.

The procedures were performed by an interventional radiology trainee as the principal operator (<15 UAEs prior to the study). It is well recognized that increasing experience of the operator leads to reduced fluoroscopy and procedural times [5]. Bilateral femoral punctures were performed sequentially for the first 12 patients in this study, and as such there is potential bias against demonstrating a reduction in fluoroscopy time due to this method.

The overall fluoroscopy time and patient dose (Table 3) compares favorably to previously published results [8, 9, 12, 14–16]. This technique could be performed by a single operator, with the bilateral simultaneous embolization performed with the aid of an assistant. This is particularly relevant because the results of our study point to a direct relationship among fluoroscopy time, DAP, total skin dose, and ovarian dose.

We did not encounter any puncture site-related complications, although there is a potential increased risk of puncture-site complications with bilateral femoral access, including hematoma, arterial dissection, thrombosis, and infection [17, 18]. Since this study, and in light of the lack of need for catheter changes from a contralateral approach, we now electively place bilateral 4-Fr catheters into the femoral arteries and compress the puncture site manually.

Table 3 Comparison of catheter choice, femoral access strategy, mean fluoroscopic time, and dose among previously published studies

Reference	Primary catheter	Groin puncture method	Mean fluoroscopic time (min)	Mean dose-area product (cGy/cm^2)	Mean effective dose (mSV)	Estimated absorbed ovarian dose (mGy)
Nikolic et al. [8]	5-Fr Glidecath	Bilateral	21.9			223
Nikolic etal. [9]	5-Fr Glidecath	Bilateral	10.9			95
Kroncke et al. [16]		Unilateral	11.8 (median)	8547	31.5	
Vetter et al. [14]	4-Fr Simmons 2 catheter	Unilateral	22.5	5990		52
Vetter et al. [15][a]	4-Fr Simmons 2 catheter	Unilateral	18.4	1300	10.6	7.8
Ho & Cowan [12]	4-Fr RIM	Unilateral	13.6			
Present data[a]	4-Fr RIM	Bilateral	12.8	3248		7 (simulator)

[a] No digital subtraction angiography acquisitions

Conclusion

Bilateral elective femoral arterial puncture achieves a reduction in mean fluoroscopy time. We feel that this technique offers overall increased ease of procedure and less catheter manipulation. We were not able to show a significant difference in measured procedural dose. There is, however, a marked reduction in simulated dose for the bilateral compared to the unilateral femoral access technique using a standard phantom, and this effect is likely to increase with increased patient body mass.

Unilateral access was successful in all our cases and is a valid technique. However, when difficulty is encountered catheterizing either uterine artery, early recourse to a second femoral access site may facilitate overall decreased fluoroscopy times. All operators should be aware of radiation dose and methods to reduce this. This is important, as the majority of women undergoing UAE are of potential childbearing age.

Acknowledgment We would like to thank Mr. I. Manyonda, Consultant Gynaecologist at St. George's Hospital, without whom this study would not have been possible.

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