	Efficacy and Safety of the Transracial Approach (TRA) Versus
	Transfemoral Approach (TFA) in Uterine Artery Embolization
	(UAE) for the Management of Uterine Fibroids; A Systematic
Original Article	Review and Meta-Analysis
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ABSTRACT

Objectives : To compare efficacy and safety of the Transradial approach (TRA) with that of the transfemoral approach (TFA) in uterine artery embolization (UAE) for the management of uterine fibroids.

Methods: We searched PubMed, SCOPUS, and Web of Science for relevant clinical trials and observational studies. Quality appraisal was evaluated according to GRADE and we assessed the risk of bias of the trials using Cochrane's risk of bias tool. Observational studies were evaluated according to the National Heart, Lung, and Blood Institute (NHLB).

Results: We included a total of four studies one of them is a RCT and the others are obsrvitional studies. The pooled analysis showed that TRA was associated with a significant reduction of the procedure time (MD= -7.13 [-9.92, -4.35], (P = 0.001). There is no significant difference between both groups regarding the fluoroscopy time (MD= -1.07 [-3.92, 1.78], (P = 0.46), radiation exposure (MD= -0.14 [-0.35, 0.08]), (P = 0.21), major access site complications (OR= 0.66 [0.24, 1.85], (P = 0.43), and minor access site complications (OR= 0.69 [0.33, 1.43]), (P = 0.32).

Conclusion: Transradial and transfermoral approaches have the same safety and efficacy but the transradial was associated with a short duration of the procedure.

Key Words: Transfemoral, transradial, uterine artery embolization, uterine fibroids.

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INTRODUCTION

One of the most common tumors in women is uterine fibroid which badly affects the women's condition. Uterine fibroids may affect the reproductive function of women. By the onset of menopause, more than seventy percent of women suffer from uterine fibroids^[1]. Uterine fibroids commonly affect middle-aged women which are seeking reproduction^[2]. Many symptoms such as menstrual bleeding, bowel obstruction, pelvic pain, abdominal pain, and urinary tract affection may occur because of uterine fibroids^[3]. There are many options for the management of uterine fibroids like myomectomy, hysterectomy, and uterine artery embolization (UAE)^[4]. We perform UAE using a local anesthetic agent that's why UAE is considered as a minimally invasive technique. The purpose of the UAE for the management of uterine fibroids is to produce ischemic necrosis of the fibroids by inducing nonpermanent blockage of uterine blood supply^[5,6].

The transfermoral approach (TFA) was the standard access for many operations in interventional radiology

(IR) like UAE which is demonstrated by several studies^[7]. The transradial approach (TRA) is new access in IR compared with TFA that has been used for the last decades in interventional cardiology^[8]. Resnick *et al* proved that we can use TRA as a safe replacement for TFA in UAE. But in this study, they did not compare the two approaches^[9]. TRA provides a comfortable posture after the operation as patients do not have to stay in bed and could walk or bend their legs or sit^[10]. Many recent studies prove that TRA has more efficacy than TFA as it provides satisfaction to the patients, short time of recovery, and short duration of hospital stay^[9,11–13]. Large cohorts demonstrated that TRA provides minor access sites and lower costs than TFA^[14–16].

We conducted this study to compare TRA and TFA regarding the efficacy and safety for patients indicated to have UAE.

METHODS

Our study was performed according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)^[17].

Search strategy

We searched the different electronic databases using the following strategy: (transfemoral) AND (transradial) and ((UAE) OR (uterine artery embolization) OR (uterine artery) OR (embolization)).

Study Selection

We did the screening in the subsequent steps: Firstly, we imported the data from research databases to a Microsoft Excel^[18] sheet by EndNote Software^[19]. Then we performed titles and abstract screening of the articles presented in our Excel sheet. Finally, we performed a full-text screening of the included studies from the second step.

Eligibility Criteria

The inclusion criteria for study selection were:

- Study design: We included observational studies and randomized clinical trials (RCTs) and we excluded the other study designs, conference abstracts, meta-analyses, all animal studies, and reviews.
- **Participants:** women suffering from uterine fibroids and indicated to have UAE.
- Intervention: transradial access in UAE.
- Comparator: transfemoral access in UAE..
- **Outcomes:** mean procedural time(min), mean fluoroscopy time (min), radiation exposure (mZv), major access site complications, and minor access site complications.

Data Collection

We searched Scopus, PubMed, and Web of Science databases till March 2022 for articles that matched our inclusion criteria. We collected three categories of data from included studies: the first category is the baseline and demographic characteristics of the included participants, such as the author, year, weight, age, height, BMI, gender, uterine fibroid;n(%), and diabetes mellitus;n(%). The second category included the main outcomes for analysis such as mean procedural time(min), mean fluoroscopy time (min), radiation exposure (mZv), major access site complications, and minor access site complications. The third category was data of quality assessment. The process of data collection was done using Microsoft Excel^[18].

Risk of bias Assessment

We used the quality assessment tools from the National Heart, Lung, and Blood Institute (NHLB) to assess the risk of bias in observational studies^[20]. We followed The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Guidelines for assessing the quality of this study. We assessed the risk of bias in our included trials using Cochrane's risk of bias tool^[19]. The tool assesses adequate randomization of patients, allocation concealment, and adequate blinding through seven domains. Each domain is put to either "low", "unclear", or "high" risk of bias.

Statistical Analysis

We used Review Manager for the analysis of our outcomes. Our study included continuous and dichotomous outcomes. We analyzed continuous data using mean difference (MD) and 95% confidence interval (CI) by Review Manager software, while dichotomous data were analyzed using risk ratio (RR) and 95% confidence interval (CI). The homogeneous data were analyzed using a fixed-effects model, while heterogeneous data were analyzed under a random-effects model. To measure heterogeneity among the studies, we used the I2 and the *p-value* of the Chi-square tests^[21]. Values of P < 0.1 or I2 > 50% were significant indicators of the presence of heterogeneity.

RESULT

Summary of Included Studies

The PRISMA flow demonstrates the results of our search in different databases as shown in (Figure 1). We included four studies that have our inclusion criteria^[22–25]. 425 women suffering from uterine fibroids and indicated to have UAE were analyzed in our study. A total of 207 women underwent TRA and 218 underwent TFA. In TRA group the averge age was 42.5 \pm 5.3 years, while that of the TFA group was 42 \pm 5 years. A summary of included studies, year, author, the demographic data of the women are demonstrated in (Table 1,2).

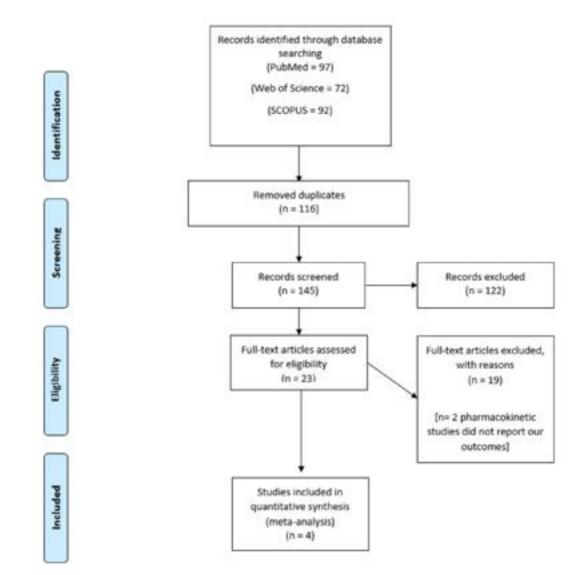


Fig. 1: PRISMA flow chart

Table 1: Shows a summary of the included studies and the demographic data of patients

STUDY ID	year -	Sampl	le Size	Age;yrs i	mean(Sd)	Weight,kg mean(sd)		
		TRA	TFA	TRA	TFA	TRA	TFA	
Gjoreski et al	2019	11	13	38.5(5.6)	38.5(4.1)	NR	NR	
Khayrutdinov et al	2021	78	75	40.42±5.3	39.08 ± 5.8	67.15±5.7	68.21±5.8	
Mortensen et al	2019	27	39	45.1 (4.9)	44.4 (4.9)	NR	NR	
Nakhaei et al	2019	91	91	46.2±4.9	45.4±5.4	84.9±28.6	80.9±21.7	

N= number, SD= standard deviation, and NR= not reported

Table 2: Shows a summary of the included studies and the demographic data of patients

STUDY ID	Height:cn	n mean(sd)	BMI,m	nean(sd)	Uterine fit	proid;n(%)	Diabetes mellitus;n(%)	
	TRA	TFA	TRA	TFA	TRA	TFA	TRA	TFA
Gjoreski <i>et al</i>	NR	NR	NR	NR	NR	NR	NR	NR
Khayrutdinov et al	169.16±9.2	167.21±8.7	26.15±3.5	25.83±3.8	74 (94.9)	72 (96)	6 (7.69)	5 (6.66)
Mortensen <i>et al</i>	NR	NR	NR	NR	NR	NR	NR	NR
Nakhaei et al	164±6.8	165.0±6.9	31.5±9.8	29.7±7.6	NR	NR	NR	NR

N= number, SD= standard deviation, and NR= not reported

Results of Risk of Bias Assessment

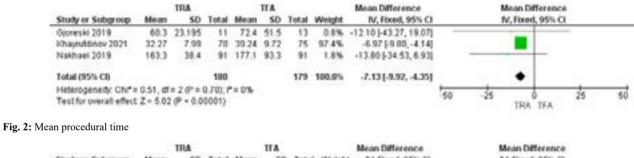
Our quality assessment yielded an overall score of 10.7 out of 14 according to NHLB tool of quality assessment. The quality assessment of the observational studies^[22,24,25] was demonstrated in supplementary (Table 1). We used the Cochrane's tool of risk of bias to assess the quality of the only included clinical trial. This trial 23 has low risk of randomization, high risk of blinding of participans and personnel, and inadequate data of allocation concealment and blinding of outcome assessment. The other domains were at low risk.

Analysis of Outcomes

- 1. Mean procedural time (min): A total of 359 patients were analyzed from three studies^[22–24] that reported this outcome. We found that there was a reduction in the duration of the procedure in the TRA group (MD= -7.13 [-9.92, -4.35], (P = 0.001). Pooled data were homogeneous (P = 0.78); I² = 0% (Figure 2).
- 2. Mean fluoroscopy time (min): Three studies^[22,24,25] reported the mean fluoroscopy time. The overall mean difference shows a similarity between both approaches in the fluoroscopy time

(MD= -1.07 [-3.92, 1.78], (P = 0.46). Pooled data were homogeneous (P = 0.74); I² = 0% (Figure 3).

- 3. Radiation exposure: Radiation exposure was reported by two studies^[22,23]. We found that there was no significant difference between both groups (MD= -0.14 [-0.35, 0.08]), (P = 0.21). Pooled data were heterogeneous (P = 0.08); I² = 68% which could not be solved by the leave-one-out method or subgroup analysis (Figure 4).
- 4. Major access site complications: A total of 335 women were analyzed from two studies^[22,23]that reported major access site complications. We found that both approaches cause the same rate of major access site complications (OR= 0.66 [0.24, 1.85], (P = 0.43). Pooled data were homogeneous (P = 0.36); I² = 0% (Figure 5).
- 5. Minor access site complications: A total of 335 women were analyzed from two studies^[22,23] that reported minor access site complications. We found that both approaches cause the same rate of minor access site complications (OR= 0.69 [0.33, 1.43]), (P = 0.32). Pooled data were homogeneous (P = 0.72); I² = 0% (Figure 6).



		1 HOA			11.4			Mean Unterence		Mean Date	ence	
Study or Subgroup	Mean	50	Total	Mean	50	Total	Weight	IV, Fixed, 95% CI		IV, Fixed, 95	5% CI	
Gjorecki 2019	21.1	10.635	11		12.74	13	9.3%	-4.20[-13.66, 6.15]	-			
Mortensen 2019	20.12	7.67	27	20.36	9,48	39	47.1%	-0.24 [-4.39, 3.91]				
Nakhael 2019	39.8	13.6	91	41.1	16	91	43.6%	-1.30[-5.61, 3.01]			-	
Total (95% CI)			129			143	100.0%	-1.07 [-3.92, 1.78]		-		
Heterogeneity: Chills				= 0%					-10	3 0	5	10
Test for overall effect	2=0.74	6.000	97							TRA TR	A	

Fig. 3: Mean fluoroscopy time

		TRA			TFA			Mean Difference	Mean Difference		
Study or Subgroup	Mean	50	Total	Mean	50	Total	Weight	IV, Random, 95% CI	IV, Randon	n, 95% CI	
Khayrutdinov 2021	0.28	0.14	78	0.5	0.21	75	64.6%	-0.22[-0.28, -0.16]		the second second	
Nakhaei 2019	0.67	0.99	91	0.66	0.71	91	35.4%	0.01 [-0.24, 0.26]			
Total (95% CI)			169			166	100.0%	0.14 [0.35, 0.08]			
Heterogeneity: Tau*	0.02; 0	hP+3	00, df	1 (P =	0.09);	1*= 68	6		1. 1.	1. 1.	
Test for overall effect									+0.2 +0.1 0 TRA	0.1 0.2 TEA	

Fig. 4: Radiation exposure

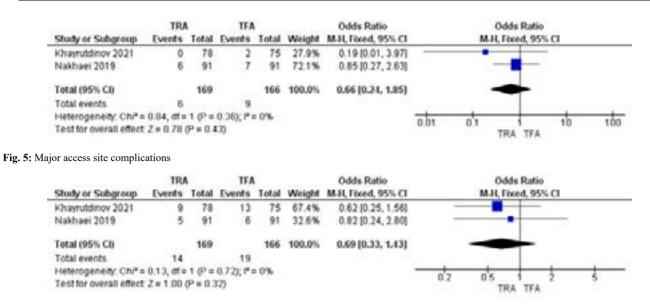


Fig. 6: Minor access site complications

DISCUSSION

UAE is usually done using TFA as it provides selective catheterization of the two uterine arteries. However, it is impossible in some cases to do selective catheterization of any of them and we should try the other femoral artery to do the catheterization^[26]. TFA is associated with a high frequency of approach site complications, long duration of bed rest, and late mobilization^[27-29]. The transaxillary approach and transbrachial approach are alternative approaches for UAE. These approaches are easier than TFA but associated with a higher rate of complications. That's why these approaches are not used unless the patient suffering from significant atherosclerosis or tortuous iliac arteries^[30]. Thrombosis of the brachial artery, which may cause hand ischemia, is the most serious complication of the transbrachial approach. The transaxillary approach may cause thrombosis of the axillary artery and hematoma which may compress the brachial nerve^[23]. In the last decades, TRA has been used for UAE^[8]. There is a significant reduction in the incidence of hemorrhage by 75% and site complications by 63% with TRA^[31]. Using devices of vascular closure helps to achieve maximum benefits from TRA in UAE. Hematoma may occur in 1%-3% of the patients after UAE by TRA. Compartmental syndrome, pseudoaneurysm, arteriovenous fistula, or surgical site infection may occur in <0.1% of the patients after UAE by TRA^[32].

In our systematic review and meta-analysis, we perform a comparison between TRA and TFA in UAE regarding safety and efficacy. We found that TRA was associated with a shorter time of procedure than TFA. On the other hand, there was no significant difference between both approaches regarding fluoroscopy time (min), radiation exposure (mZv), major access site complications, and minor access site complications. Khayrutdinov *et al*^[23] is a randomized controlled trial that compares TRA and TFA in UAE. This trial showed that the efficacy and safety of both approaches are similar but there was a reduction in the radiation exposure and procedure time. TRA was associated with a lower complication rate and good quality of life. There are some limitations of this trial such as the small sample size and the unmeasured radiation exposure during the operation.

In 2019 Nakhaei *et al*^[22] reported that TRA and TFA have the same clinical and technical outcomes but TRA is associated with low site complications. Increased catheter length is considered a limitation in this study.

In Canada Mortensen *et al*^[25] conducted a prospective study comparing TRA and TFA in UAE. They found that TRA was more efficient, safer, and lower cost than TFA. Small sample size, reduced radiation dose, unmeasured BMI, and unmeasured radiation exposure during the procedure should be considered as a limitation of this study.

Gjoreski *et al*^[24] performed a retrospective analysis for two groups to compare TRA and TFA in UAE. Gjoreski *et al* reported that TRA was associated with lower fluoroscopy time and procedural time than TFA. There was a significant similarity between both approaches regarding overall adverse events. However, there were potential limitations like unavailability of materials (microcatheters and catheters), small sample size, and restriction to a single center.

This study has some strength points as it is the first systematic review and meta-analysis that directly compares the efficacy and safety of TRA with that of TRF in the UAE. Besides, we adhered to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines and the Cochrane handbook of systematic review and meta-analysis of interventions^[33,34].

Limitations

The interpretation of our results is limited by the small sample size of patients and the small number of studies that compare both approaches. Also, there was a lack of evidence on different important outcomes that may affect the choice of the assessment tool. Also, the heterogeneity in some outcomes is another limitation and we included only one clinical trial, which weaken the certainty of evidence according to GRADE^[35].

CONCLUSION

Transradial and transfemoral approaches have a significant similarity in safety and efficacy but the transradial was associated with a shorter time of procedure than the transfemoral approach.

Conflict of interests

There are no conflicts of interest.

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