Giving Birth to a New Approach: A Retrospective Comparison of Radiation Safety Parameters between Transradial and Transfemoral Approaches for Uterine Fibroid Embolization at Groote Schuur Hospital, South Africa

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DECLARATION

I, Jateel Kassim, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgments indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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1. List of Abbreviations

ALARA	As low as reasonably achievable
CI	Confidence interval
GSH	Groote Schuur Hospital
HREC	Human Research Ethics Committee
IQR	Interquartile range
mGy	Milligrays
min	Minutes
PACS	Picture archiving and communications system
SD	Standard deviation
TAH	Total abdominal hysterectomy
TFA	Transfemoral access
TRA	Transradial access
UAE	Uterine artery embolisation

2. Abstract

2.1 Background

Uterine artery embolisation (UAE) is a recognised minimally invasive, effective and fertility-preserving treatment option for patients with symptomatic uterine leiomyomas. The conventional transfemoral access (TFA) in UAEs remains the method of choice for the majority of South African interventional radiologists. Transradial access (TRA) has grown as a viable alternate vascular access. The advantages of TRA over TFA have been well documented, however a lack of safety parameter comparison in procedures performed via TRA versus TFA remains.

2.2 Objectives

To compare the mean radiation dose and accumulative fluoroscopy time measured in between TRA and TFA UAEs performed for the treatment of uterine leiomyomas.

2.3 Method

A single-institution retrospective study was conducted on all female patients having undergone UAE for symptomatic uterine leiomyomas at GSH between 1 January 2018 and 31 March 2020. Safety parameters between TFA and TRA UAEs were compared.

2.4 Results

Of the 61 patients having undergone UAEs, 29 were TFA and 32 TRA UAEs. No statistical difference was observed between the procedural and screening times, however there was a statistically significant difference for mean radiation dose: TFA recorded a mean radiation

dose of 1 158 (95% CI 721- 1596), TRA had a mean of 639 (95% CI 36-1243 units) higher than TFA (p-value = 0.038).

2.5 Conclusion

The comparison of the majority of the safety parameters between TRA and TFA UAEs in our study demonstrated no statistical significance. The increase in radiation dose in the TRA vs TFA group is comparable to other studies and although statistically significant, is small. Therefore, TRA still forms a safe viable alternate form of access for UAEs.

3. Chapter 1: Literature Review

3.1 Rationale

Uterine artery embolisation (UAE) is a recognised minimally invasive effective treatment option for patients with symptomatic uterine leiomyomas. Within the ever-changing and advancing field of interventional radiology, interventionists are striving for new techniques to improve the overall outcome and success rate of endovascular treatment options.

Before the implementation of a new radiological modality or therapy (or approach specifically in this case), its safety profile should be paramount and the very first aspect of consideration, aligning with the Hippocratic oath and one of the key pillars of medical ethics of first do no harm. In radiology, we are governed by the ALARA (as low as reasonably achievable) principle in the context of ionising radiation exposure, which is fundamental to the principles of radiation protection. In any interventional radiology procedure, radiation exposure and procedure duration (and therefore fluoroscopy time) are intimately linked and directly proportional (1). It is therefore the basis of this study, which is the first of its kind in a South African government/public health institution.

A recent comparative study from China completed in 2023 comparing various outcomes and safety parameters of a TRA-UAE vs a TFA for the treatment of haemorrhagic diseases in obstetrics and gynaecology demonstrated a significantly lower radiation exposure dose in the TRA group compared to the TFA group (2). The study also concurrently demonstrated significantly reduced fluoroscopy time in the TRA group versus that of the TFA cohort taken to achieve uterine artery access as well as embolization completion – the two most critical

and time-consuming periods in the UAE procedure (2). This is most likely related to the time-consuming technical and anatomical aspect of the procedure where a TFA sometimes requires refashioning of the catheter to form a loop to access the contralateral common iliac artery and subsequent contralateral uterine artery, as opposed to a more direct course of access of either uterine artery via a TRA (2), in addition to the need for multiple varying catheters.

There remains a lack of available data comparing patient radiation exposure, and thus safety, in procedures performed via TRA versus TFA (2–4).

3.2 Background

Uterine leiomyomas (also known as uterine fibroids) are the most common benign tumour in premenopausal women (5–9). Within the South African context, we are particularly seeing a significant prevalence of uterine leiomyomas in our African ethnic subset, which represents the majority of the South African population. In fact, in the USA, African ethnicity is a reported risk factor for uterine leiomyomas (10). This ethnic risk factor is also evident globally – a Cochrane Review looking at interventions to reduce haemorrhage in fibroids stated that not only are uterine leiomyomas three times more prevalent in the African ethnic population, but this specific race group is also more likely to have larger and more numerous fibroids (11). Uterine leiomyomas have known significant morbidity with extensive debilitating symptomatology of menometrorrhagia, dysmenorrhoea, urinary symptoms, dyspareunia, pelvic and back pain, anaemia, infertility and recurrent pregnancy loss (5–10,12).

Traditionally, and even currently in South Africa, the management of symptomatic uterine leiomyomas involves surgical myomectomy in an attempt at uterine-preserving treatment (6,9,11,13). However, in some cases, traditional management may be as extreme as total abdominal hysterectomy (TAH), which remains the only available definitive treatment (5–9,11). With growing interest and demand in fertility medicine especially, uterine preservation therapy is an important goal of surgical outcomes. UAE is now a recognised level 1 alternative to myomectomy (and superior to TAH) as fertility-preserving therapy for symptomatic uterine leiomyomas (14).

UAE is an internationally recognised safe, effective, minimally invasive, and uterine-preserving treatment option for symptomatic uterine leiomyomas (1,5,9,15–19). The procedure involves tumour devascularisation through embolization of its arterial supply to promote ischaemic infarction and subsequent tumour regression, with an end goal of symptomatic relief (7,9,16,17).

In our institution, the procedure is usually performed under procedural sedation and local anaesthetic at the puncture site, thereby negating the need for general anaesthetic (and all its encompassed risks) required in traditional surgical therapies. In addition, UAE is superiorly advantageous to surgical management in reducing the rate of surgical complications and degree of post-procedural pain, minimising patient recovery time and thereby the length of hospital admission which has significant advantages in terms of financial and budgetary considerations (5,7,8,10,13,17,18).

UAE was first introduced in 1974, with transfemoral access (TFA) traditionally used as the conventional approach (5,15) for the majority of its existence and it remains the method of choice for the majority of South African interventional radiologists (13). This is mainly due to the familiarity, experience and confidence South African interventionalists have in TFA.

Transradial access (TRA) has grown in popularity through its exposure as a current mainstay in cardiac interventions (3,15,20). It has now been adopted as a viable alternate vascular access by many interventional radiologists in other body endovascular work (3,6). However, since its documented inception in 1989 (15,21) and the first case series 25 years ago, TRA use by interventional radiologists has fallen significantly short of our cardiology counterparts (2,3,20). Despite this, virtually all of the reviewed relevant literature supports the fact that TRA is advantageous over TFA due to several reasons including increased patient comfort, decreased access-related and vascular complications, improved outcomes, lower morbidity and mortality rates, earlier patient mobilisation, shorter duration of hospitalisation and need for nursing care, and economic favourability (2–6,12,13,15,20,21). TRA is also advantageous in morbid obesity, a reported relative contraindication to TFA in cardiac interventions, with technically less complicated arterial access in this subset patient population (12,21).

The only significant limiting technical factor for TRA as opposed to TFA is patient height, due to the catheter length restriction required to adequately access the uterine arteries (21), which is limited to a maximum patient height of 178 cm (12). A rare potential procedural complication of TRA is cerebral emboli (3,15,20). Due to dual arterial supply to the hand, inadvertent radial artery injury such as thrombosis or dissection is rarely detrimental (3,15,21). More concerning is the fact that there has been a wide misconception that TRA

incurs longer procedural times (3) (and hence fluoroscopy time) as well as increased patient radiation exposure (13) in comparison to TFA.

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5. Chapter 2: Full Text Journal Article for Submission

Radiation Safety Comparison: Transradial vs Transfemoral Access in Uterine Fibroid Embolisation.

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6. Abstract

6.1 Background

Uterine artery embolisation (UAE) is a recognised minimally invasive, effective and fertility-preserving treatment option for patients with symptomatic uterine leiomyomas. The conventional transfemoral access (TFA) in UAEs remains the method of choice for the majority of South African interventional radiologists. Transradial access (TRA) has grown as a viable alternate vascular access. The advantages of TRA over TFA have been well documented, however a lack of safety parameter comparison in procedures performed via TRA versus TFA remains.

6.2 Objectives

To compare the mean radiation dose and accumulative fluoroscopy time measured in between TRA and TFA UAEs performed for the treatment of uterine leiomyomas.

6.3 Method

A single-institution retrospective study was conducted on all female patients having undergone UAE for symptomatic uterine leiomyomas at GSH between 1 January 2018 and 31 March 2020. Safety parameters between TFA and TRA UAEs were compared.

6.4 Results

Of the 61 patients having undergone UAEs, 29 were TFA and 32 TRA UAEs. No statistical difference was observed between the procedural and screening times, however there was a statistically significant difference for mean radiation dose: TFA recorded a mean radiation

dose of 1 158 (95% CI 721- 1596), TRA had a mean of 639 (95% CI 36-1243 units) higher than TFA (p-value = 0.038).

6.5 Conclusion

The comparison of the majority of the safety parameters between TRA and TFA UAEs in our study demonstrated no statistical significance. The increase in radiation dose in the TRA vs TFA group is comparable to other studies and although statistically significant, is small. Therefore, TRA still forms a safe viable alternate form of access for UAEs.

6.6 Keywords

Radiation dose, fluoroscopy screening time, transradial access, transfemoral access, uterine artery embolisation, uterine fibroid embolisation.

7. Introduction

Uterine artery embolisation (UAE) is a recognised minimally invasive, effective and uterine-preserving treatment option for patients with symptomatic uterine leiomyomas (1–8). The procedure involves tumour devascularisation through embolization of its arterial supply to promote ischaemic infarction and subsequent tumour regression, with an end goal of symptomatic relief (3,5,6,9).

UAE is superiorly advantageous to surgical management in reducing the rate of surgical complications and length of hospital admission, which has significant advantages in terms of financial and budgetary considerations (2,6,7,9–12). Importantly, UAE is now a recognised level 1 alternative to myomectomy (and superior to TAH) as fertility-preserving therapy for symptomatic uterine leiomyomas (13).

Transfemoral access (TFA) has been traditionally used as the conventional approach (2,4) in UAEs and it remains the method of choice for the majority of South African interventional radiologists (12).

Within the advancing field of interventional radiology, interventionists are striving for new techniques to improve the overall outcome and success rate of endovascular treatment options.

Transradial access (TRA) has grown in popularity through its exposure as a current mainstay in cardiac interventions (4,14,15). It has now been adopted as a viable alternate vascular access by many interventional radiologists in other endovascular body interventions (14,16). However, TRA use by interventional radiologists has fallen significantly short of our cardiology counterparts (14,15,17). Despite this, virtually all of the reviewed relevant literature supports the fact that TRA is advantageous over TFA due to several reasons including increased patient comfort, decreased access-related and vascular complications,

improved outcomes, lower morbidity and mortality rates, earlier patient mobilisation, shorter duration of hospitalisation and need for nursing care, and economic favourability (2,4,12,14–20).

There however remains a lack of available data comparing patient radiation exposure, and thus safety, in procedures performed via TRA versus TFA (14,17,20).

Before the implementation of a new radiological modality or therapy (or approach specifically in this case), its safety profile should be paramount and the very first aspect of consideration, aligning with the Hippocratic oath and one of the key pillars of medical ethics of first do no harm. In radiology, we are governed by the ALARA (as low as reasonably achievable) principle in the context of ionising radiation exposure, which is fundamental to the principles of radiation protection. In any interventional radiology procedure, radiation exposure and procedure duration (and therefore fluoroscopy time) are intimately linked and directly proportional (1). It is therefore the basis of this study, which is the first of its kind in a South African government/public health institution.

8. Objectives

The primary objectives of this study were to compare the mean radiation dose, measured in milligrays (mGy), and the mean accumulative fluoroscopy time measured in minutes (min), between transradial and transfemoral access UAEs performed for the treatment of uterine leiomyomas at GSH.

9. Research Methods and Design

A single-institution retrospective study was conducted at Groote Schuur Hospital (GSH), an academic tertiary-level hospital in Cape Town, Western Cape, South Africa. All female

patients having undergone UAE for symptomatic uterine leiomyomas at GSH between 1 January 2018 and 31 March 2020 were included. Aborted procedures due to failed access or any other reason, and patients with incomplete or inadequate data were excluded.

9.1 Data collection

Data was collected from study participant electronic database records as defined by the study population and inclusion/exclusion criteria. A total of 61 patients had undergone UAEs for symptomatic uterine leiomyomas during the specified time period and were included in the study population, with no exclusions.

The GSH radiology department Philips picture archiving and communications system (PACS) was accessed to gain the relevant data required, specifically the procedural time, fluoroscopy time and radiation dose of each procedure, which were anonymised on a Microsoft Excel spreadsheet. The biostatistician was provided with the anonymised data for statistical analysis.

10. Statistical Analysis

Demographic characteristics and variables of interest were described using median interquartile range (IQR) for continuous variables and frequency and proportion for categorical variables. The outcome of interest (radiation dose) was assessed for normality. Difference in the mean radiation dose, accounting for other potential confounding, was assessed via a multivariate linear regression model with the explanatory variables being the type of procedure and demographic variables. Inclusion of variables in the model was informed by the Bayesian information criterion. The outcome was the mean radiation dose.

Secondary objectives were assessed with similar methods with the outcome variable being mean accumulative fluoroscopy time.

11. Ethical Considerations

Ethical approval was obtained from the Faculty of Health Sciences Human Research Ethics Committee of the University of Cape Town (HREC reference number 865/2024). Institutional approval was also granted by Groote Schuur Hospital.

Informed consent was not applicable due to the retrospective design of this study.

12. Results

61 patients were included in the study, of which 29 had undergone UAE with TFA and 32 TRA. In 1 patient access was converted to femoral due to failed radial artery cannulation. 1 case was rescheduled due to high blood pressures once adequately optimised. In total, successful embolisation as defined by adequate cessation of blood flow in both uterine arteries was achieved in 53 patients. Semi-successful embolisation as a result of failed cannulation of one of the uterine arteries and technical successful embolisation in the contralateral uterine artery was achieved in the remainder of the 8 patients.

The mean radiation dose of all TFA UAEs was 1.158mGy, and 1798mGy in the TRA cases (p-value of 0.087), with a mean radiation dose per minute (mGy/min) of 67 and 91, respectively (p-value 0.12). The mean procedural time was 102min in the TFA cases, and 120 in the TRA UAEs (p-value 0.13), with a mean accumulative fluoroscopy time of 18min and 21min, respectively (p-value 0.27). (Table 1).

Table 1: Patient demographics and procedural characteristics of the study population

	Femoral N = 29	Radial N = 32	p-value [1]
Age (years), Mean (SD)	38 (7)	41 (7)	0.087
Total Radiation Dose (mGy), Mean (SD)	1,158 (915)	1,798 (1,370)	0.035
Procedural Time (min), Mean (SD)	102 (48)	120 (46)	0.13
Radiation Dose per Minute (mGy/min), Mean (SD)	67 (43)	91 (70)	0.12
Accumulative Fluoroscopy Screening Time (min), Mean (SD)	18 (11)	21 (10)	0.27

1. [1]Welch Two Sample t-test

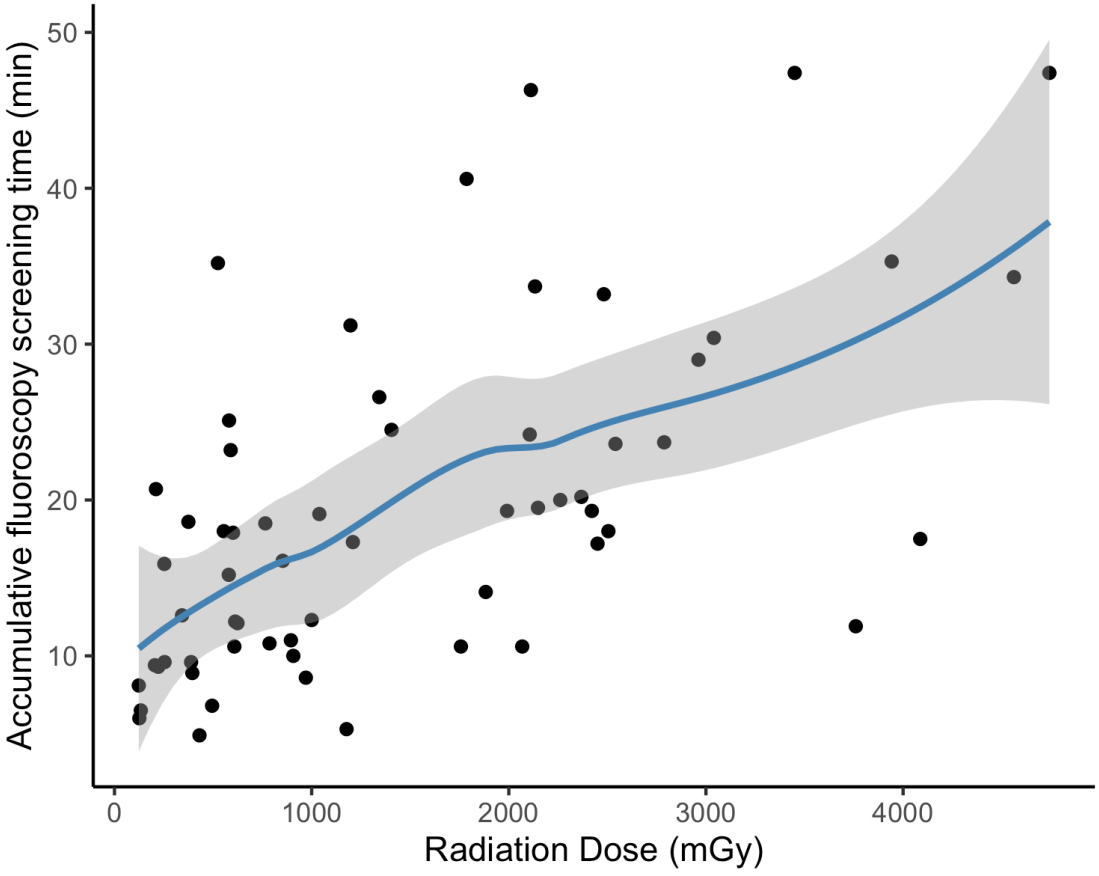

Figure 1: Radiation and surgical minutes

The graph in figure 1 illustrates plotted values comparing radiation dose to the accumulative screening time (mGy/min) of each case, demonstrating the expected increasing radiation dose with increased duration of accumulative screening time.

Figure 2 illustrates the comparison of accumulative screening time between the 2 approaches, demonstrating increased accumulative screening time in the TRA cases compared to that of the TFA cases.

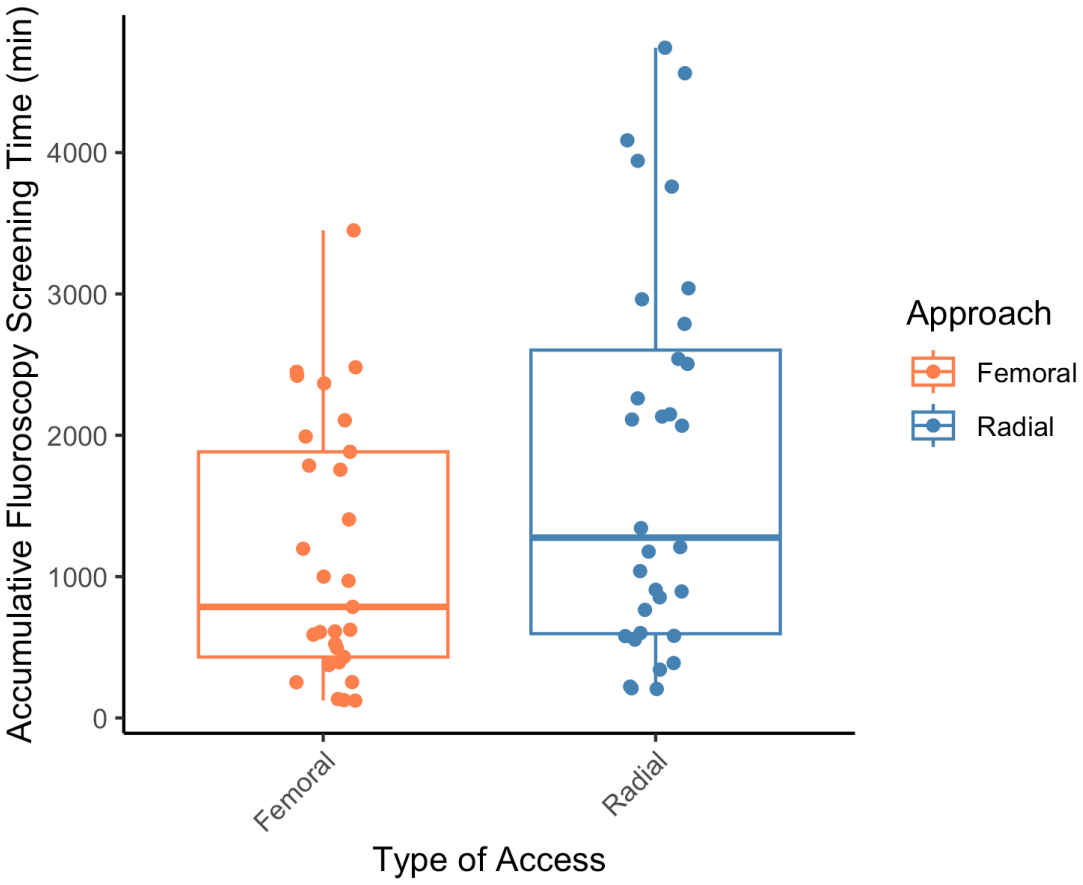

Figure 2: Radiation dose by approach

Table 2: Regression analysis of radiation dose and surgical time

Group		Beta (95% CI)[1]	p-value
Procedural Time (min)	**(Intercept)**	102 (84 to 119)	<0.001
	Type of Access		
	Femoral	—	
	Radial	19 (-5.5 to 43)	0.13
Radiation Dose (mGy)	**(Intercept)**	1,158 (721 to 1,596)	<0.001
	Type of Access		
	Femoral	—	
	Radial	639 (36 to 1,243)	0.038
Accumualtive Fluoroscopy Screening Time (min)	**(Intercept)**	18 (14 to 22)	<0.001
	Type of Access		
	Femoral	—	
	Radial	3.1 (-2.4 to 8.5)	0.27

[1]CI = Confidence Interval

Table 2 shows the resultant linear models of the relationship between access type and procedural minutes, radiation dose, and fluoroscopy. There was insufficient evidence to reject the null hypothesis of no difference between procedural minutes and fluoroscopy screening time between radial and femoral access, however there was a statistically significant difference for mean radiation dose: femoral access recorded a mean radiation dose of 1 158 (95% CI 721- 1596), radial access had a mean of 639 (95% CI 36-1243 units) higher than the femoral access (p-value = 0.038).

This study demonstrated a higher mean radiation dose among patients undergoing radial access compared to femoral access. No difference was observed between the procedural time and screening time.

The analysis did not control for confounders such as patient age, height, weight, nor severity of condition. In addition, the procedures were performed by different interventional radiologists and trainees.

13. Discussion

On review of the current literature, the paucity of research comparing the safety parameters between TRA and TFA is evident (14,15,17,20). This gap highlights and strengthens the importance of our study where the primary focus was on safety parameters of both approaches in the same interventional procedure.

The results of this study demonstrating a statistically significant higher mean radiation dose in TRA UAEs as compared to that with TFA conflicts with some of the current published literature which show no statistically significant difference in this safety parameter between the two approaches (12,14,16–19). There are however a few studies which do demonstrate

small but still statistically significant increase in radiation exposure in TRA vs TFA, as is the case in this study (2). Our study did however demonstrate no statistically significant difference in procedural time, accumulative screening time or radiation dose per minute between the two approaches. This is in contrast to some of the reviewed literature which mention studies in which the fluoroscopy time were significantly higher in TRAs vs TFAs (2). In addition, our mean accumulative fluoroscopic screening times were favourably comparable to those documented in other studies – 18-21min vs 18.9min in Pron et al (8). Therefore, TRA still forms a safe viable alternate form of access for UAEs.

Given the teaching environment in an academic institution such as GSH, procedures were performed by different interventional radiology consultants teaching different trainees of differing skill level and experience, irrespective of the type of access. This represents a confounder and significant limitation of this study.

TRA was first utilised for UAEs in our institution in 2018, which represents the start point of our collected data set for this study. TRA was therefore at the time a novel and unfamiliar type of access in comparison to the conventional TFA, which in turn carries a steeper learning curve. This inevitably incurs lengthier procedural and fluoroscopic screening times, and hence higher total radiation doses (8) – radiation exposure and procedure duration (and therefore fluoroscopy time) are intimately linked and directly proportional (1).

However, as with most interventional procedures, efficiency improves with time and growing familiarity of the newer technique. Therefore, a recommendation for a future study comparing the change in safety parameters over time and with more gained experience would be fitting.

UAE as a treatment option for symptomatic uterine leiomyomas is superiorly advantageous to surgical management in reducing the rate of surgical complications and degree of post-procedural pain, minimising patient recovery time and thereby the length of hospital admission which has significant advantages in terms of financial and budgetary considerations (2,6,7,9–12). Similarly, it is well documented in the literature that TRA UAEs have better outcomes in terms of patient comfort, vascular complications, mobility and therefore length of hospital stay than those of TFA UAEs (2,4,12,14–20).

Therefore, in addition to comparing the safety parameters between the two approaches at a future date, a more comprehensive study incorporating the above measurable outcomes would be a fairer more robust comparison of the two approaches.

Further limitations of the study include the retrospective study design and small cohort of patients at a single centre.

14. Conclusion

There are limited studies in the literature which comprehensively compare the safety parameters between TRA vs TFA, specifically in UAEs. The comparison of the majority of the safety parameters between TRA and TFA UAEs in our study demonstrate no statistical significance, which is in contrast to some of the reviewed literature. Despite the demonstrable statistically significant increase in radiation dose in the TRA group vs TFA, this is comparable to some studies in the reviewed literature and although statistically significant, is small.

Therefore, TRA still forms a safe viable alternate form of access for UAEs.

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16. Competing Interests

The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in the writing of this article.

17. Authors Contribution

Dr J Kassim was the principal investigator and prepared the manuscript. Dr D K Creamer supervised the thesis, made conceptual contributions, edited and approved the final manuscript for submission.

18. Funding

No external funding was received for conducting of this research.

19. Data Availability

Data is available from the authors upon reasonable request.

20. Disclaimer

The views and opinions expressed in this article are those of the authors and do not necessarily reflect official policy or that of our institution.

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22. Appendix

22.1 Appendix A: Human Research Ethics Committee Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45, E-52 Old Main Building
Groote Schuur Hospital
Observatory 7925
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

29 October 2024

HREC REF NO: 865/2024

Dr Dale Creamer
Department of Diagnostic Radiology/ Radiation Medicine
Interventional Radiology
Email: dale.creamer@uct.ac.za
Student: Jateel.Kassim@gmail.com

Dear Dr Creamer

PROJECT TITLE: GIVING BIRTH TO A NEW APPROACH: A RETROSPECTIVE COMPARISON OF RADIATION SAFETY PARAMETERS BETWEEN TRANSRADIAL AND TRANSFEMORAL APPROACHES FOR UTERINE FIBROID EMBOLIZATION AT GROOTE SCHUUR HOSPITAL, SOUTH AFRICA. (MMED DEGREE - DR JATEEL KASSIM)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review and approval.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 October 2025.

Please submit a progress report, using the standardised Annual Progress Report Forms (FHS016) **or** (FHS 017) if the study continues beyond the approval period. Please submit a Standard Closure form (FHS 010) when the study has been completed, this includes after publication or thesis submission and final completion.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledges that the following MMED Degree student will be involved in the study: Dr Jateel Kassim.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC reference number 865/2024 in all your correspondence.

Yours sincerely

Signed by candidate

PROFESSOR MARC BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

HREC REF: 865/2024

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC REF: 865/2024

22.2 Appendix B: GSH Research Permission

Western Cape Government

GROOTE SCHUUR HOSPITAL
Enquiries: Mr Lionel Naidoo
e-mail: GSHResearch.Request@westerncape.gov.za

Dr Dale Creamer
Department of Diagnostic Radiology / Radiation Medicine

E-mail: dale.creamer@uct.ac.za

Dear Dr Creamer

RESEARCH PROJECT: Giving Birth to a New Approach: A Retrospective Comparison of Radiation Safety Parameters Between Transradial and Transfemoral Approaches for Uterine Fibroid Embolization at Groote Schuur Hospital, South Africa

Your recent letter to the hospital refers.

You are granted permission to proceed with your research, which is valid until **30 October 2025**

Please note the following:

a) Your research may not interfere with normal patient care.
b) Hospital staff may not be asked to assist with the research.
c) **Confidentiality must always be maintained.**
d) No additional costs to the hospital should be incurred as indicated in your Annexure 2 i.e. Lab, consumables or stationery. **If access to TRACK Care/NHLS is required, kindly attach our letter of approval to the application form and approach Information Management to assist with data.**
e) **No patient folders may be removed from the premises or be inaccessible.**
f) Please provide the research assistant/field worker with a copy of this letter as verification of approval.
g) **Should you at any time require photographs of your subjects, please obtain the necessary indemnity forms from our Public Relations Office (E45 OMB or ext. 2187/2188).**
h) Should you require additional research time beyond the stipulated expiry date, please apply for an extension.
i) Please discuss the study with the HOD before commencing.
j) Please introduce yourself to the person in charge of an area before commencing.
k) On completion of your research, please forward any recommendations/findings that can be beneficial to use to take further action that may inform redevelopment of future policy / review guidelines.
l) If the researcher is not GSH staff member, a supernumerary contract is required before commencement of the research.
m) Please contact Michelle Riley (Patient Fees) at ext. 2276 to ascertain if there will be charges for conducting the Research and to obtain a quote or to discuss charges
n) **Kindly submit a copy of the publication or report to this office on completion of the research.**
o) **At no time should any posters encouraging patients to partake in research, be displayed within a clinical area.**
p) **All Clinical Trials to be registered on Clinicom with Michelle Riley. michelle.riley@westerncape.gov.za**
q) **All clinical personnel viewing/using patient folders for research purposes, must be carried out according to the following:**
Patient folders must be researched in the Medical Records Department (Medical Research Suite, A14, New Main Building).
No research patient folders may be removed from the Medical Records Department.
Patient folders required for research purposes may not be requested via clerical staff and the Clinicom system.
Non-compliant researchers could have their GSH institutional research approval revoked.

I would like to wish you every success with the project.

Yours sincerely

Signed by candidate

LIONEL NAIDOO
HEAD: ALLIED HEALTH
Date: 11 December 2024
C.C. Mr. L. Naidoo, Mr. A. Mohamed, Dr T. Numanoglu, Professor S. Moosa

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Observatory 7925
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22.3 Appendix C: South African Journal of Radiology Instructions to Authors

Original Research Article full structure

Original Research Article full structure

Title: The article's full title should contain a maximum of 95 characters (including spaces).

Abstract: The abstract, written in English, should be no longer than 250 words and must be written in the past tense. The abstract should give a succinct account of the objectives, methods, results and significance of the matter. The structured abstract for an Original Research article should consist of six paragraphs labelled Background, Objectives, Method, Results, Conclusion and Contribution.

- Background: *Why do we care about the problem?* State the context and purpose of the study. (What practical, scientific or theoretical gap is your research filling?)
- Objectives: *What problem are you trying to solve*? What is the scope of your work (e.g. is it a generalised approach or for a specific situation)? Be careful not to use too much jargon.
- Method: *How did you go about solving or making progress on the problem*? State how the study was performed and which statistical tests were used. (What did you actually do to get the results?) Clearly express the basic design of the study; name or briefly describe the basic methodology used without going into excessive detail. Be sure to indicate the key techniques used.
- Results: *What is the answer*? Present the main findings (that is, as a result of completing the procedure or study, state what you have learnt, invented or created). Identify trends, relative changes or differences in answers to questions.
- Conclusion: *What are the implications of your answer*? Briefly summarise any potential implications. (What are the larger implications of your findings, especially for the problem or gap identified in your motivation?)
- Contribution: What key insights into the research results and its future function are revealed? How do these insights link to the focus and scope of the journal? It should be a concise statement of the primary contribution of the manuscript; and how it fits within the scope of the journal.

Do not cite references and do not use abbreviations excessively in the abstract.

Introduction: The introduction must contain your argument for the social and scientific value of the study, as well as the aim and objectives:

- Social value: The first part of the introduction should make a clear and logical argument for the importance or relevance of the study. Your argument should be supported by the use of evidence from the literature.
- Scientific value: The second part of the introduction should make a clear and logical argument for the originality of the study. This should include a summary of what is already known about the research question or specific topic and should clarify the knowledge gap that this study will address. Your argument should be supported by the use of evidence from the literature.
- Conceptual framework: In some research articles it will also be important to describe the underlying theoretical basis for the research and how these theories are linked together in a conceptual framework. The theoretical evidence used to construct the conceptual framework should be referenced from the literature.
- Aim and objectives: The introduction should conclude with a clear summary of the aim and objectives of this study.

Research methods and design: This must address the following:

- Study design: An outline of the type of study design.
- Setting: A description of the setting for the study; for example, the type of community from which the participants came or the nature of the health system and services in which the study is conducted.
- Study population and sampling strategy: Describe the study population and any inclusion or exclusion criteria. Describe the intended sample size and your sample size calculation or justification. Describe the sampling strategy used. Describe in practical terms how this was implemented.
- Intervention (if appropriate): If there were intervention and comparison groups, describe the intervention in detail and what happened to the comparison groups.
- Data collection: Define the data collection tools that were used and their validity. Describe in practical terms how data were collected and any key issues involved, e.g. language barriers.
- Data analysis: Describe how data were captured, checked and cleaned. Describe the analysis process, for example, the statistical tests used or steps followed in qualitative data analysis.
- Ethical considerations: Approval must have been obtained for all studies from the author's institution or other relevant ethics committee and the institution's name and permit numbers should be stated here.

Results: Present the results of your study in a logical sequence that addresses the aim and objectives of your study. Use tables and figures as required to present your findings. Use quotations as required to establish your interpretation of qualitative data. All units should conform to the **SI convention** and be abbreviated accordingly. Metric units and their international symbols are used throughout, as is the decimal point (not the decimal comma).

Discussion: The discussion section should address the following four elements:

- Key findings: Summarise the key findings without reiterating details of the results.
- Discussion of key findings: Explain how the key findings relate to previous research or to existing knowledge, practice or policy.
- Strengths and limitations: Describe the strengths and limitations of your methods and what the reader should take into account when interpreting your results.
- Implications or recommendations: State the implications of your study or recommendations for future research (questions that remain unanswered), policy or practice. Make sure that the recommendations flow directly from your findings.

Conclusion: Provide a brief conclusion that summarises the results and their meaning or significance in relation to each objective of the study.

Acknowledgements: Those who contributed to the work but do not meet our authorship criteria should be listed in the Acknowledgments with a description of the contribution. Authors are responsible for ensuring that anyone named in the Acknowledgments agrees to be named. Refer to the acknowledgement structure guide on our *Formatting Requirements* page.

Also provide the following, each under their own heading:

- Competing interests: This section should list specific competing interests associated with any of the authors. If authors declare that no competing interests exist, the article will include a statement to this effect: *The authors declare that they have no financial or personal relationship(s) that may have inappropriately influenced them in writing this article.* Read our **policy on competing interests**.
- Author contributions: All authors must meet the criteria for authorship as outlined in the **authorship** policy and **author contribution** statement policies.
- Funding: Provide information on funding if relevant
- Data availability: All research articles are encouraged to have a data availability statement.
- Disclaimer: A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder.

References: Authors should provide direct references to original research sources whenever possible. References should not be used by authors, editors, or peer reviewers to promote self-interests. Refer to the journal referencing style downloadable on our *Formatting Requirements* page.