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Comparison of radiation exposure and clinical outcomes between transradial and transfemoral diagnostic cerebral approaches: a retrospective study

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ABSTRACT

Objective To identify and compare patient and procedural variables that are associated with a high radiation dose exposure and worse clinical outcomes between transradial arterial (TRA) and transfemoral arterial (TFA) approaches.

Design This was a retrospective analysis.

Setting A community hospital during the initial phase of adopting a TRA-first approach.

Participants A resultant 215 subjects who only underwent diagnostic cerebral angiograms (DCA) after excluding all therapeutic procedures and patients under 18 years.

Interventions Only DCA from 1 May 2018 to 31 January 2021.

Main outcome measures We compared radiation exposure parameters (total fluoroscopy time (FT), total radiation dose (TD) and dose area product (DAP), number of vessels injected and Patient-Reported Global Health Physical and Mental Outcome Scores (PROGHS) at 30 days postprocedure between groups.

Results FT was significantly greater in TRA compared with TFA (p<0.001). In addition, TRA had a significantly higher TD (p=0.002) and DAP (p=0.005) when compared with TFA. Analysis of only 6-vessel DCAs also showed that TRA had a significantly higher FT, DAP and TD in comparison to TFA. Despite observing a longer FT in TRA, results showed fewer vessels injected and a notably lower success rate in acquiring a 6-vessel DCA using the TRA. Further analysis of the effect of vessel number on FT using general linear models showed that with every increase of one vessel, the FT increases by 2.2 min for TRA (p<0.001; 95% CI 1.03 to 3.36) and by 1.3 min for TFA (p<0.001; 95% CI 0.72 to 1.83). There was no significant difference between groups in PROGHS mental and physical t-scores at 30 days postprocedure, even though our cohort showed a significantly greater percentage of TRA procedures done in the outpatient setting.

Conclusions Adopting a TRA first approach for DCAs may be initially associated with a higher radiation dose for the patient. Better strategies and devices are needed to mitigate this effect.

Key messages

What is already known about this subject?

- The transradial approach (TRA) for catheterisation in neuroendovascular procedures is more effective and safer with fewer complications than the transfemoral approach.
- The TRA is associated with better patient satisfaction and decreased length of stay when compared with the transfemoral approach.

What are the new findings?

- Higher radiation exposure with the TRA during the initial adoption period.
- Difficulty in achieving a complete 6-vessel diagnostic cerebral angiogram in TRA because of the anatomy of arteries from radial to subclavian region or pathological arteries especially in the elderly with cardiovascular comorbidities. This difficulty leads to prolonged time and more patient radiation exposure.
- We reported no difference in immediate 30-day patient-reported quality of life (QOL) outcomes between the transradial arterial (TRA) and transfemoral arterial in the initial adoption phase. For the first time, we compared not delayed but immediate 30-day QOL outcomes using the Patient-Reported Outcomes measurement Information System Global Health Scale to assess patients' physical and mental status after surgery.

How might these results affect future research or surgical practice?

- The results of this study will be valuable to the neuroInterventional community because there is a growing trend to perform TRA diagnostic cerebral angiograms (DCAs). Our findings will provide additional insights into the use of TRA in DCA for early adopters especially in older patients with cardiovascular disease comorbidities. This will call for better strategies, techniques and the development of more radial-specific devices to minimise radiation exposure to prevent long-term biological effects.

INTRODUCTION

Cerebral angiography remains the gold standard fluoroscopic imaging procedure for diagnosing cerebrovascular diseases, and the transfemoral arterial access (TFA) has been the conventional approach. There is a growing trend to perform Diagnostic

Cerebral angiogram (DCA) using the transradial arterial access (TRA) due to recent data demonstrating improved outcomes with decreased complications,[1–5 6 7 8] hence a safer and more feasible alternate technique.

Despite these advantages, TRA has also been shown to be associated with longer procedural and fluoroscopy times (FTs), with increased exposure to radiation in both cerebral[3 4 9] and coronary[10 11] angiography studies. Efforts to minimise radiation exposure are of paramount importance because of the potential for biological effects, including skin injuries and radiation-induced cancers.[12] The parameters affecting the patient radiation dose exposure and the clinical consequences are the duration of the procedure, operator experience, catheters and devices used, independent patient and vascular characteristics (lesions or anatomic variants) as well as the type of vascular approach (TRA and TFA).[13] However, the studies comparing TRA versus TFA approaches have not been comprehensive and have mostly only evaluated the absorbed radiation dose as a secondary outcome variable. Also, data on quality of life (QOL)/patient satisfaction in previous studies[2 5 14] has been limited to postprocedure complication rate and recovery time. In our study, we chose a globally accepted patient reported QOL outcomes scale and to our knowledge, no prior study has also analysed and compared patient-reported QOL outcomes between these two approaches at 30 days postprocedure.

This study will also seek to identify patient and procedural variables that are associated with a high radiation dose exposure and worse clinical outcomes, which will be valuable to neurointerventionalists when transitioning from TFA to a TRA.

METHODS

Study design and patient selection

The study was conducted retrospectively at a community hospital from 1 May 2018 to 31 Januar 2021. All data were collected from the patients' electronic medical records. DCAs were performed by three neurointerventional surgeons during the initial phase of adopting a TRA-first approach. To be included in the study sample, patients had to be eighteen years of age or older, have 30 days clinical follow-up information available, and be performed on the Siemens Artis Q biplane fluoroscopy machine. We excluded all therapeutic interventions (n=263), and from the remaining DCA-only cohort, we also excluded cases that were lost to follow-up (n=76) and cross-over cases (n=3). The final analytical sample consisted of 215 patients accounting for these inclusion and exclusion criteria. Of the 215 patients, there were 66 patients (30.7 %) who underwent TRA DCA and 149 patients (69.3%) who underwent transfemoral DCA.

Variables of interest and statistical analysis

Baseline sociodemographic factors analysed are listed in table 1. The primary variables compared included Real-Time Radiation exposure parameters which were as follows: FT in minutes, dose area product (DAP) in microGym2 and total radiation dose in mGy as recorded by Siemens Artis Q. The number of vessels successfully accessed and injected, and 3-dimensional rotational angiography cases were also surveyed. A second radiation exposure comparative analysis was performed among patients who received a complete 6-vessel DCA. Patient-Reported Global Health Physical and Mental Outcome Scores (PROGHS) at 30 days postprocedure were also compared between approaches. Lastly, a general linear modelling was performed to analyse the effect of access route (TRA vs TFA) on radiation exposure and patient-reported outcomes. Each model was also adjusted for cardiovascular disease status (CVD-hypertension, congestive heart failure, atrial fibrillation, coronary artery disease) (present vs absent), 3D status, patient care type (outpatient vs inpatient), patient age at time of procedure and number of vessels.

We used median, IORs and percentages when appropriate for the outcomes variables and patient's characteristic description. Group differences were compared using the Pearson χ^2 or Fisher's exact test for categorical variables, or the Student's t-test or the Mann-Whitney U test for continuous variables. Data that were not normally distributed were analysed using non-parametric tests. General linear models were used to analyse the effects of variables on primary outcomes. P values of 0.05 or less were considered statistically significant. Statistical Package performed statistical analysis for the Social Sciences (SPSS V.20.0, from SPSS.

The data supporting the conclusions of this manuscript will be made available by the authors, without undue reservation to any qualified researcher.

Procedural protocol

TRA and TTFA for DCA

For TRA and TFA a 5 F sheath and diagnostic catheter was used (Terumo Glidecath used for TRA). Access was obtained either manually or via ultrasound guidance. A 6-vessel DCA procedure was performed in cases (n=111), which included intracranial imaging and catheterisation of right and left vertebral artery, right and left internal carotid artery, right and left external carotid artery. Three-dimensional arteriography cases (n=118) were separated from the native fluoroscopy. Amount of magnified views was at the discretion of the physician and for this purpose was not counted separately.

Radiation dose exposure measurements

All procedures in this study were performed using the Biplane Siemens Artis Q catheterisation laboratory (Siemens Healthcare, Germany) only to eliminate the effect of influencing factors like system characteristics. A standard fluoroscopy and acquisition protocol was typically used for procedures and every effort was routinely made to reduce radiation exposure.

The following real time radiation dose exposure parameters were measured; DAP, which reflects both the dose of

Table 1 Baseline sociodemographic information

		TRA (n=66)	TFA (n=149)	P value
Gender	Male	(29) 43.9%	(63) 42.3%	0.88
	Female	(37) 56.1%	(86) 57.7%	
Median age		62 (44–70)	58 (49.5–68)	0.92
	≥65	(25) 7.9%	(49) 32.9%	0.53
	<65	(41) 62.1%	(100) 67.1%	
Ethnicity	Hispanic and African	(11) 16.7%	(24) 16.1%	0.99
	White	(55) 83.3%	(125) 83.9%	
Smoking	Current	(9) 13.6%	(16) 10.7%	0.78
	Former	(26) 39.4%	(57) 38.3%	
	Never	(31) 47.0%	(76) 51.0%	
Alcohol Hx	Casual	(15) 22.7%	(26) 17.4%	0.13
	Never/rare	(42) 63.6%	(113) 75.8%	
	Abuse/freq	(9) 13.6%	(10) 6.7%	
CVD	Present	(38) 57.6%	(90) 60.4%	0.76
	None	(28) 42.4%	(59) 39.6%	
Diabetes	Present	(8) 12.1%	(16) 10.7%	0.82
	None	(58) 87.9%	(133) 89.3%	
PT Care type	In PT	(12) 18.2%	(63) 42.9%	0.001
	Out PT	(54) 81.8%	(84) 57.1%	

CVD, cardiovascular diseases; DM, diabetes mellitus; Freq, frequently; Hx, history; N, number; PT, patient; TFA, transfemoral arterial; TRA, transradial arterial.

radiation administered from planes and the area on the patient it is administered to (ie, DAP=dose× area and is independent of distance to the source, total DAP=DAP obtained in plane A+DAP obtained in plane B). DAP is a continuous variable measured in microgray metre squared (μGym^2). Other radiation dose parameters were FT measured in minutes, which reflects the length of time the patient and operator are exposed to radiation; and total radiation dose (TD) administered from the angiography system measured in milligray (mGy). In calculation of measured DAP, FT and TD, the Artis Q angiography system uses several factors such as X-ray parameters (collimation size, focus-to-skin distance, catheter table position and angle view of image intensifier), patient size (height and weight) and position (defined by the location of the tabletop).

After procedure, the exam protocol including patient demographics, procedure details, generated images and parameters of radiation exposure (automated measurements obtained from built-in software in the Siemens cardiac angiography system) were uploaded into our Electronic Medical Records system (Meditech). An imaging technology specialist calibrates the device quarterly and checks for accuracy to ensure reliability as part of annual compliance tests.

Clinical outcome variables acquisition

As part of standard clinical protocol, patients completed the Global Health Scale (GHS) assessments by hand or interview at 30 days (target 28–45 days). Patient responses to each of the ten GHS items were scored on a scale from 1 to 5 (1=poor, 2=fair, 3=good, 4=very good, 5=excellent).

These raw scores converted to a Global Mental Health (GMH) score and a Global Physical Health (GPH) score, each using four GHS items that pertained to mental or physical health. The t-scores ranged from 21.2 to 67.7 for GMH scores and 16.2–67.7 for GPH scores. A higher t-score indicated a better outcome. The average t-score for the general population of the United States is 50. Respondents who fall within one SD of the mean will score a GMH t-score in the range of 41.1–59 or a GPH t-score within the range of 42.3–57.7. The questionnaires

Table 2 Radiation exposure and clinical outcome variables comparison in TRA versus TFA

	TRA (n=66)	TFA (n=149)	P value
FT	17.2 (11.8–22.1)	10.5 (8.7–14.4)	<0.001
DAP	3323.6 (2291.5–4658.8)	2442 (1702.4–3558.1)	0.005
TD	298.5 (208.3–413.0)	220.3 (149.7–306.7)	0.002
Median # Vessels	5 (4–6)	6 (4–6)	0.12
1–5	(38) 57.6%	(66) 44.3%	0.08
6	(28) 42.4%	(83) 55.7%	
TS P	50.8 (42.3–57.7)	50.8 (44.9–57.7)	0.71
TS M	53.3 (45.8–56)	50.8 (45.8–59)	0.75
3D	(39) 59.1%	(79) 53%	0.46
No 3D	(27) 40.9%	(70) 47%	

#, number; 3D, three dimensions; DAP, dose area product; FT, fluoroscopy time; M, mental; P, physical; TD, total dose; TFA, transfemoral access; TRA, transradial access; TS, T Score.

provided to the subjects were in English and we excluded anyone who did not complete a 30-day questionnaire.

RESULTS

The patients' sociodemographic information along with their clinical status and patient care type are shown in table 1. There were no significant differences between TRA and TFA groups in gender distribution, smoking and alcohol consumption, comorbid conditions and ethnicity ($p > 0.05$).

FT was significantly greater in TRA compared with TFA (17.2 min vs 10.5 min; p<0.001). In addition, TRA had a significantly higher total dose (298.5 mGy vs 220.3 mGy; p=0.002) and DAP (3323.6 µGym^2 vs 2442 µGym^2; p=0.005) when compared with TFA (table 2, figure 1). Analysis of only 6-vessel DCAs also showed that TRA had a significantly higher FT, DAP and TD in comparison to TFA (table 3). Despite observing a longer FT in TRA, results showed lesser median number of vessels injected in TRA technique (TRA vs TFA; 5 vs 6, p=0.12), and a notably lower success rate in acquiring a 6-vessel DCA (TRA vs TFA; 42.4% vs 55.7%, p=0.08) using the TRA technique (table 2).

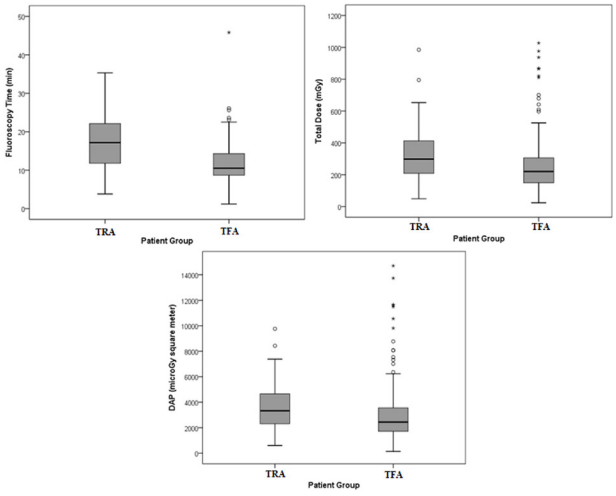

Figure 1 Comparison of radiation exposure (FT, DAP and TD) in TRA versus TFA. DAP, dose area product; FT, fluoroscopy time; TD, total dose, TFA, transfemoral access; TRA, transradial arterial access.

We performed a general linear model (figure 2) to understand better the relationship between FT and other measured variables such as vessel number and age (figure 2). With every increase of 1 vessel, the FT increased by 2.2 min for TRA (p<0.001; 95% CI 1.03 to 3.36) and by 1.3 min for TFA (p<0.001; 95% CI 0.72 to 1.83). In TRA patients, there was no statistically significant relation between FT and Age, but in TFA patients every 1-year increase in age increased mean FT by 0.17 min (p<0.001; 95% CI: 0.11 to 0.24) as seen in figure 2. The adjusted model (for CVD status, 3D status, inpatient vs outpatient care, patient age, and number of vessels) also showed that on average, FT is 6.01 min longer for the TRA patients (95% CI 4.31 to 7.71 min), and total dose is 59.1 mGy higher for the TRA patients (95% CI 6.89 to 111.31 mGy).

Our comparative analysis also showed that younger patients (<65 years) regardless of approach had more complete 6-vessel DCAs comparing to older patients (p<0.05, figure 3). Our final comparative analysis between 6 vessel DCA and <6 vessel DCA showed more comorbid CVDs in <6 v DCAs (figure 3, CVDs in 6 vessel DCA vs <6 vessel DCA; 53% vs 69%, p<0.05). The percentages of patients who received 3D were not significantly different between TRA and TFA groups, as seen in table 2. Overall, the highest radiation exposure was recorded in older patients who underwent 3D TRA angiogram, and lowest seen in younger patients who underwent TFA without 3D.

There was no significant difference between groups in PROGHS mental and physical t-scores at 30 days postprocedure, even though our cohort showed a significantly greater percentage of TRA procedure done in the outpatient setting. (Outpatient care, TRA vs TFA; 81.8% vs 57.1%, p=0.001) (table 1).

Table 3 TRA versus TFA in 6-vessel DCA (radiation exposure and age comparison)

	TRA	TFA	P value
FT	19.1 (15.28–23.2)	11 (9.3–14.4)	<0.001
DAP	3978.5 (3123.03–4713.75)	2604 (1938.5–3603.8)	0.001
TD	317.65 (251.5–455.6)	224.5 (168.5–302)	0.001
Age	47 (38.8–59.5)	53 (46–64)	0.056

DAP, dose area product; DCA, diagnostic cerebral angiogram; FT, Fluoroscopy time; TD, total dose; TFA, transfemoral access; TRA, transradial access.

DISCUSSION

The TRA approach for neuroendovascular procedures has continued to gain traction over the past several years. Recent neurointerventional and cardiointerventional studies[15 16] have reported higher patient and operator preference for TRA over TFA because of a wide array of benefits, including reductions in access site-related morbidity, length of stay, major bleeding and shorter time to ambulation.[1–5 10 11] However, a drawback finding in our study about patient radiation dose exposure during the initial TRA-adoption phase offers an additional perspective to TRA and TFA comparative studies.

In our first comparative analysis, TRA was found to be associated with a significantly higher radiation exposure than in TFA. In our study, we only analysed diagnostic angiograms and excluded therapeutic interventions to eliminate the complexity of treatment procedures which prolonged procedure and FT. This study was also performed during our institution's transition to a 'radial

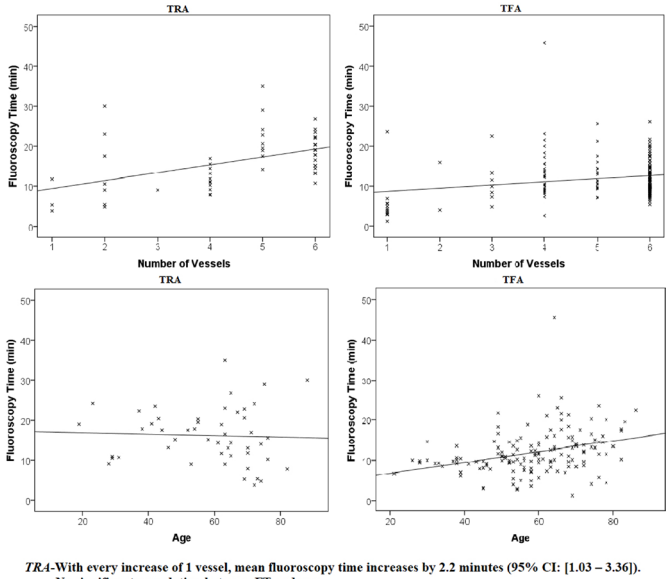

Figure 2 General linear modelling comparing effects of age and vessel number on FT in TRA and TFA.TRA—with every increase of 1 vessel, mean fluoroscopy time increases by 2.2 min (95% CI 1.03 to 3.36). No significant correlation between fluoroscopy time and age. TFA—with every increase of 1 vessel, mean fluoroscopy time increases by 1.3 min (95% CI 0.72 to 1.83). with every 1-year increase in age, mean fluoroscopy time increases by 0.17 min (95% CI 0.11 to 0.24). FT, fluoroscopy time; TFA, transfemoral arterial access; TRA, transradial arterial access.

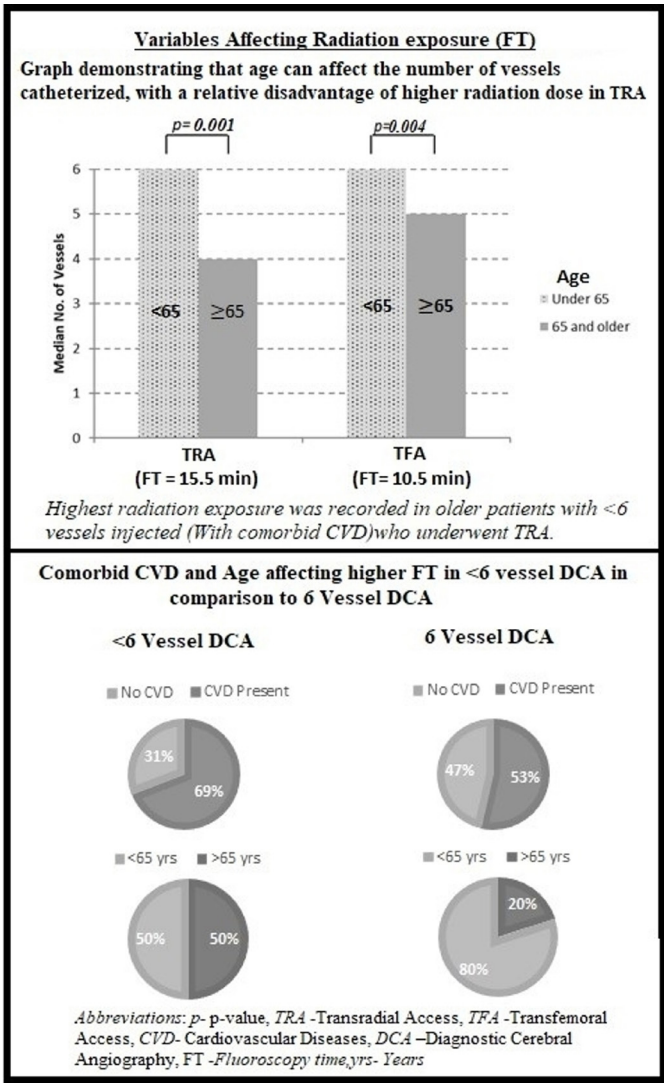

Figure 3 Variables affecting radiation Exposure. Graph demonstrating that age can affect the number of vessels catheterised, with a relative disadvantage of higher radiation dose in TRA. Highest radiation exposure was recorded in older patients with<6 vessels injected (with comorbid CVD) who underwent TRA. Comorbid CVD and Age affecting higher FT in <6 vessel DCA in comparison to 6-vessel DCA.

first' practice. Similar higher FT in TRA have been reported in comparative studies that analysed FT as a secondary variable,[3 9] and others that analysed both diagnostic and therapeutic procedures together.[4 9] A possible explanation for this finding is the steep learning curve which remains a significant challenge for experienced Neurointerventionalists trained initially with TFA.[2 17–19 20] We did not study if there is a learning curve but it is presumed from these reports that after performing 30–50 cases it can be overcome with a significant decrease in FT and improved injection success rate.

Another contributing factor was the catheters used by the initial adopters in our study which were not specifically designed for the TRA. A recent national survey[2] reported that neurointerventionalists would prefer modified and improved tools designed specifically for TRA, mostly because of the technical and intraoperative challenges resulting from aforementioned comorbidities, and anatomical variants associated with the transradial route[13] ultimately leading to increased vascular access time.

We explored other (confounding) variables that affected FT. Considering age as one of the factors described in previous studies,[3 4 13 21] we performed an additional comparative analysis in the TRA group between the elderly (>65) and younger (<65) patients. We discovered that it may be more challenging in attaining a predefined complete 6-vessel DCA in the elderly compared with their younger counterparts with a significant increase in radiation exposure as well. Our analysis also pointed to higher cardiovascular comorbidities in the elderly as another contributing factor. Other studies[3 13 21] have also demonstrated age as a predictor of failed TRA because of associated sicknesses and higher incidences of pathologic/tortuous vessel morphology in the elderly (>65 years). However, it remains unclear from our study whether better techniques and tools could have led to a complete 6-vessel DCA regardless of atherosclerosis or other pathological factors.

With the number of vessels being a confounder in the elderly population affecting FT, we performed several analyses to establish this relationship. We first compared the 6-vessel DCA cohort to a less tha 6-vessel DCA which showed a greater percentage of patients in the less than 6-vessel cohort being older (>65 years) with comorbid CVD and a corresponding higher FT. Furthermore, linear modelling (figure 2) showed that with every increase of 1 vessel the FT was a minute greater in TRA comparing to TFA. To our knowledge, no prior study has examined the relationship between these confounders affecting radiation exposure.

We reported that the type of vascular approach (TRA and TFA) did not affect the 30 days post-operative PROGHS QOL outcomes even though the majority of TRA approaches were performed in the outpatient setting (table 1). We chose to use the 10-item Patient-Reported Outcomes measurement Information System GHS because it is a well-known valid and reliable scale used in assessing and tracking the impact of healthcare interventions in health and functional disability over time. This novel finding from our 30-day postprocedural PRO adds to previous literature[1–5] that only reported immediate QOL outcome with the TRA approach during the postoperative phase. These studies demonstrated a higher satisfaction rate with the radial approach mainly because of a shorter recovery time likely related to postprocedural comfort and reduced hospital stay. In our study, we did not report complication rates and cross-over cases (n=3) because first, they were too few, and second, they were not our main variables of interest in this study. Numerous previous studies have compared complications rates favouring the TRA approach.[1–5 10 11]

Our study has some limitations. First, our study has the inherent limitations of a retrospective study. Second, we did not include therapeutic procedures in this study. Third, we were unable to assess the learning curve because our analysis was performed during the initial TRA-adoption period. Fourth, our sample size was relatively low due to the following reasons. Patients who were lost to follow-up at 30 days were not included and that may have created a type of selection bias. Another limitation was that we excluded and did not analyse crossover cases from TRA to TFA which were only a few cases. Despite the low sample size, our results were still significant, and this speaks to the major difference in radiation dose exposure between TRA and TFA.

Our study had multiple unique strengths. First, we were able to use detailed sociodemographic and hospital data including many possible confounding variables (number of vessels successfully catheterised and 3D rotational angiograms) to complete a multivariate analysis in our study. Second, we focused on only diagnostic cerebrovascular procedures, which to our knowledge has not been reported in the literature to date for in-depth comparative radiation exposure parameters analysis. Third, all DCAs were performed with only the Biplane-Siemens Artis Q catheterisation lab. Fourth, we used widely accepted scales for functionality and overall global health in clinical outcomes analysis. Fifth, our broader inclusion criteria including age, comorbid conditions and preoperative diagnosis allowed for a more representative and generalisable sample in the setting of cerebrovascular diseases to limit selection bias.

The neurointerventionalist community largely agrees that TRA improves patient comfort, and overall there is no concern about TRA's safety for diagnostic or therapeutic interventions. However, the increased radiation dose exposure reported in our study is a substantial drawback. With the growing trend to perform TRA DCAs, future research should address better radiation dose reduction technical skills and strategies, and the development of more TRA-specific devices.

CONCLUSION

Adopting a TRA for DCAs may be initially associated with longer procedure times and higher radiation dose

for the patient. Better strategies and tools are needed to mitigate this effect. We hope that the results of this study will provide insights into the use of TRA for DCA for early adopters especially in older patients with CVD comorbidities. Comparative radiation exposure analysis between these two approaches with newer TRA-specific devices following the 'initial TRA-adoption' phase should be a focus of future inquiry.

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Contributors Conception or design of the work: CA and DA. Data acquisition and analysis: CA, LL, JR and DA. Interpretation of data: CA and DA. Drafting the work: CA and DA. Revising the work for valuable intellectual content: CA, LL, JR, AS, BC and DA. Approval of the final version: DA. Guarantor: DA.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study was approved by the Western Institutional Review Board, which determined that this research met the requirements for a waiver of consent under 45 CFR 46.116(d). The Western Institutional Review Board also gave authorisation for the use and disclosure of protected health information for this research.

Provenance and peer review Not commissioned; externally peer reviewed.

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