ORIGINAL ARTICLE

FLUOROSCOPY TIME DURING CARDIAC CATHETERIZATION PROCEDURES USING THE RADIAL AND FEMORAL ROUTES

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Background: Use of trans-radial route for cardiac catheterization is on the rise but is associated with increased radiation exposure to the operator. Our aim was to compare the radiation exposure, by taking fluoroscopy time (FT) as a surrogate of radiation exposure, to the operator with femoral and radial routes. **Methods**: This prospective observational study was carried out at Army Cardiac Center Lahore from 1st Jan to 1st June 2013. Mean fluoroscopy times via trans-radia (TR) and trans-femoral (TF) routes were compared. Procedure time was considered as time from sheath insertion to the finish of the diagnostic and interventional procedure. Descriptive statistics were used to explain the data. Chi square test was applied to compare qualitative variables between them. **Results:** A total of 1,110 diagnostic & PCI cases were performed out of which there were 850 diagnostic CA and 260 PCI cases. The mean procedure time & mean fluoroscopy time for TF-CA was 15.5±5.5 minutes and 4.3±3.2 minutes respectively in the current study while for TR-CA was 6.6±4.1. For TF-PCI, mean procedure time was 42.3±16.7 minutes, mean fluoroscopy time was 11.6±7.7 minutes & for TR-PCI it was 55.3±19.2 and 15.4±12.1. **Conclusion:** Radial route for cardiac catheterization procedures is associated with longer fluoroscopy time leading to increased radiation exposure to the operator along with an increased use of contrast.

Keywords: Fluoroscopy time, radiation exposure, radial route, coronary angiography
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INTRODUCTION

The femoral artery has traditionally been the favored access site for coronary interventions mainly due to its large diameter but has bleeding as the most feared complication. In 1989 Campeau et al described the trans-radial (TR) route for the first time[1] and since then it is being increasingly used to perform coronary angiograms (CA) and percutaneous coronary interventions (PCI) due to fewer access site complications, a lowering in major bleeding events and shorter hospital duration[2–5]. However, radial access is associated with increased radiation exposure to the operator due to longer fluoroscopy times and closer positioning of the operator to the X-ray source.[6–10] Although, it has been underestimated by interventional cardiologists, increased radiation exposure of operators and patients during CAs and PCIs is currently a major concern, mainly due to the risk of cancer induction. Cumulative, low-dose radiation exposure is associated with various deleterious effects on skin and even a small increased risk of certain types of cancer.[11,12] This has raised concerns among interventional cardiologists and limited the widespread adoption of this approach for diagnostic and interventional cardiac catheterization procedures, in spite of the advantages radial access offers to the patient. In some of the recent studies it has been reported that less than 2% of percutaneous coronary interventions were performed by a trans-radial (TR) approach in the United States between 2004 and 2007.[13]

Our aim was to study and compare the radiation exposure, by taking fluoroscopy time (FT) as a surrogate of radiation exposure, to the operator both with femoral and radial routes.

MATERIAL AND METHODS

We prospectively evaluated patients who underwent coronary angiography with or without percutaneous coronary intervention (PCI) by experienced operators at a tertiary center. Experienced operators were defined as those that perform >75 PCIs/year with >95% of cases performed using the TR or TF approach for ≥5 years. The outcomes of interest were fluoroscopy time (FT). The study was carried out at Army Cardiac Center Lahore, which is a tertiary care center, during the time period of 1st Jan to 1st June 2013. Patient characteristics, procedural and clinical variables, as well as the clinical outcomes of TR approaches were compared with TF approaches. Patients with ST-elevation myocardial infarction (STEMI), chronic total occlusion (CTOs), and previous coronary artery bypass grafting (CABG), or procedures involving right heart catheterization were excluded. This was done in order to have homogeneous data set and also to reduce bias in the study.

The choice of access sites was left on the discretion of the consultant. A modified Allen test was done in all patients before TR access.[14] The major techniques utilized for radial access were either a modified Seldinger technique using a 21-gauge micro-puncture needle or a through-and-through Seldinger technique was performed using a 20-gauge angio-catheter. A 5F or 6F sheath (Terumo Medical Corp, Somerset, NJ) was normally used for diagnostic TR-CA whereas a 6F sheath was used for TR-PCI. For TF-CA and TF-PCI a 5F or 6F sheath and 6For 7F sheaths were used respectively. The fluoroscopy time, procedural duration and contrast use included both diagnostic and intervention times when performing PCI.

Baseline patient characteristics and procedural data were collected regarding procedure time, fluoroscopy time as well as use of contrast for diagnostic CA and PCI using TR and TF access routes. Procedure time was considered as the time from sheath insertion to the finish of the diagnostic and interventional procedure. Success of the procedure was for CA or PCI was defined as the successful completion of the procedure without having to switch from radial to femoral approach or from femoral to radial and again were left to the discretion of the consultant. The characteristics of the procedure and lesion were also recorded in PCI.

Various procedural complications were also noted including major bleeding, aneurysm formation, dissections, perforations, AV fistulas, contrast-induced nephropathy (CIN), stroke and peri-procedural myocardial infarction (>3× the upper limits of normal for CK-MB and/or positive Trop-T as well as the other signs and symptoms of MI).

Statistical analysis was performed using the SPSS-13.0. Descriptive statistics were used to describe this information and data. Chi square test was applied to compare qualitative variables between the groups. Independent samples' *t*-test was used to compare age between the groups. Continuous and categorical variables are reported as mean±SD and percentages, respectively. A *p*-value <0.05 was considered as significant.

RESULTS

During a 6-month period (Jan 1–Jun 30, 2013), a total of 1,110 diagnostic and PCI cases where performed at the Army Cardiac Center, Lahore out of which 850 diagnostic CA and 260 PCI cases making a total of 1,110 met our inclusion criteria and were analyzed. From this initial data set, 385 (35%) and 725 (65%) cases were performed via the TF and TR route, respectively. A TR approach was used in 657 (77%) of the diagnostic CA cases and in 68 (26%) of the PCI procedures. The right radial artery was utilized in 98% of the diagnostic CA cases and 100% of the PCI cases. A 5F or 6F sheath (61% and 39%, respectively) was used for the diagnostic coronary angiograms via the TR approach, whereas the 6F sheath was predominantly used for TR-PCIs (97%). In TF-CAs, a 6F sheath was usually used (91%) whereas 7F was also used for some cases of TF-PCIs (22%).

The baseline characteristics of the patients and indications for diagnostic CA are summarized in table-1.

A total of 850 diagnostic angiograms were performed out of which 193 (23%) were TF-CA and 657 (77%) were TR-CA. For patients undergoing diagnostic CA, the baseline characteristics were quite similar for the TR group as compared with the TF group, except that the TR group had a higher BMI and had central obesity and also had a higher proportion of patients with diabetes mellitus. As far as the indications for carrying out the angiogram were concerned, there wasn't any statistically significant difference between the TR and the TF groups. Significant difference in use of fluoroscopy time was observed in patients who underwent TR-CA as compared to the TF-CA group (p<0.001). Similarly increased volume of contrast was used in TR-CA (p=0.001).

Table-1: Baseline and procedural characteristics of patients undergoing Coronary Angiography

Variables	Femoral Approach N=193 (23%)	Radial Approach N=657 (77%)	p
Demographics			
Age, Years	63.2±12.1	64.9±11.6	0.22
Male Sex, n (%)	122 (63)	368 (56)	0.24
BMI, Kg/m2	22±3.4	24±3.1	<0.001
Past History			
Hypertension, n (%)	151 (78)	493 (75)	0.45
Diabetes Mellitus, N (%)	58 (30)	269 (41)	0.03
Active Smoker, n (%)	39 (20)	37 (19)	0.81
Procedural Variable			
Fluoroscopy Time, Min.	4.3±3.2	6.6±4.1	< 0.001
Contrast Volume Used, ml	90±45	115±55	<0.001
Procedure Time, Min.	15.5±5.5	19.1±6.6	0.021
Switch Over, n (%)	3 (1.55)	25 (3.81)	<0.001

Data are expressed as mean±SD. *BMI,* Body Mass Index

Table-2: Baseline and procedural characteristics of patients undergoing PCI

Variables	Femoral Approach N=192 (74%)	Radial Approach N=68 (26%)	p
Demographics			
Age, Years	67.1±13.6	63.1±10.3	0.06
Male Sex, N (%)	132 (69)	44 (65)	0.58
BMI, Kg/m2	23.3±2.5	24.4±3.1	0.011
Past History			
Hypertension, N (%)	154 (80)	55 (81)	0.76
Diabetes Mellitus, N (%)	75 (39)	27 (40)	0.99
Active Smoker, N (%)	23 (12)	31 (46)	0.12
Procedural Variable			
Fluoroscopy Time, Min.	11.6±7.7	15.4±12.1	0.013
Contrast Volume Used, ml	155.3±73.2	181.4±63.8	0.022
Procedure Time, Min.	42.3±16.7	55.3±19.2	<0.001

Data are expressed as mean±SD. *BMI,* Body Mass Index

The baseline characteristics of the patients and indications for PCI are summarized in table-2. A total of 260 PCI were done out of which 192 (74%) were TF-CA and 68 (26%) were TR-CA. For patients undergoing PCI, the baseline characteristics of the TR and TF groups were similar, except for the fact that the mean age was lower in the TR group. Similar to the diagnostic group, no statistically significant difference was seen in regards to the indication for TR-PCI and TF-PCI. In this also the fluoroscopy time of the TR-PCI vs. TF-PCI was significantly increased. Similarly the contrast volume was also enhanced.

Overall crossover rates were very low. For diagnostic CA, 25 of the TR-CA cases required crossover to TF-CA, and 3 of the TF-CA cases required crossover to TR-CA. For PCI, 3 of the TR-PCI cases required crossover to TF-PCI, and none of the TF-PCI cases required crossover to TR-PCI.

DISCUSSION

Exposure to radiation during cardiac catheterization procedures is a major concern for both the patient undergoing the procedure and the laboratory staff performing the procedure, and to minimize this it is recommended for the health care staff to their ensure minimal possible exposure during the procedure. It is therefore advocated that an extensive use of special devices for radiation protection be used. However, it is has been reported that many cardiologists believed that as the expertise in radial procedures increases the radiation becomes less dues to decreased procedure time and so special radiation precautions are considered by them to be superfluous as fluoroscopy times and radiation exposures trended to same levels when compared with the femoral access route. The conclusions of our present study invalidate these assumptions as all of the operators were high volume experienced radialists.

This study demonstrates that the use of radial access during cardiac catheterization is associated with an increase in radiation exposure to the patient as well as the operator when compared with the use of femoral access. Fluoroscopy time has been used as a surrogate of the radiation exposure in this study. Increased radiation exposure during the radial route is related to increased fluoroscopy time, which shows technical difficulties and the slightly closer standing position of the operator to the X-ray source and as well as the patient during the radial procedure when compared with the femoral route.

The increased fluoroscopy times in TR-CA may be from a variety of reasons, but are usually due to navigating radial artery anatomic variations, tortuosity of the right subclavian artery, and difficult positioning of the catheter requiring change to another catheter. In case of the femoral approach, the catheter engagement was seen to be much easier, although we do not have quantitative data to support this fact.

Previous studies reported TR to TF switch rates of 1–7%[15–18], whereas we had a rate of 3.81%. There was no routine follow up of patients for radial artery patency after TR access and therefore cannot comment on radial artery occlusion rates but we did not have any patient who developed complications due to radial artery occlusion.

The baseline demographic features were almost same in both groups except that patients in radial group seemed to be heavier than the patients in femoral group. This may be due to selection bias of femoral operators who would rather choose radial access to perform coronary angiography on obese patients. For the femoral route the choice of catheters was invariably Judkin's left (JL 3.5–4), Judkin's right (JR 3.5–4) and pigtail catheters whereas TIGER (TERUMO Corporation, Tokyo, Japan) 5F catheter was also employed in the radial group.

Trans-radial procedures tend to be technically more challenging and time- consuming especially during early learning curve.[11] The mean procedure time and mean fluoroscopy time for TF-CA was 15.5±5.5 minutes and 4.3±3.2 minutes respectively in the current study while for TR-CA was 6.6±4.1. For TF-PCI, mean procedure time was 42.3±16.7 minutes and mean fluoroscopy time was 11.6±7.7 minutes while for TR-PCI it was 55.3±19.2 and 15.4±12.1. Significantly high fluoroscopy time of TR-CA and TR-PCI groups is consistent with previous studies. In the CARAFE study[19], the procedural duration from the radial approach was 12.4±5.8 min and fluoroscopy time was 3.8±2.2 min for coronary angiography. In another study, Brueck *et al*[20] also showed that the procedure time in the TR group (40.2 min) was longer than the TF group (37.0 min). The volume of contrast in TF-CA was 90±45 ml and in TR-CA it was 115±55ml. For TF-PCI the volume of contrast was 155.3±73.2 ml and for TR-PCI it was 181.4±63.8 ml. This shows a significantly increased volume of contrast in the radial group as compared to femoral group. This is understandable if we consider the complexity of radial artery anatomy and technical difficulties that a radial operator has to face while performing the trans-radial procedure. This new finding in our study shows that concerns about trans-radial procedure are not only limited to prolonged procedure time and high radiation exposure but volume of contrast is another issue that can make the procedure more complicated and should be especially done with care in patients deranged renal function or depressed LV systolic function. This study should be interpreted in the context of its design. Due to the fact that the study was nonrandomized, there might be a potential selection bias in choosing patients for TR approach, which may somewhat limit the validity of comparative data analysis done between the groups. We therefore recommend that operators should ensure that best practices regarding the implementation of safety equipment and adequate radiation protection devices and protocols are employed[21,22] and operators are encouraged to be meticulous in the use of shielding and coning, and to ensure the patient's arm is extended so that the operator may stand at a maximal distance from the X-ray tube during such procedures.

CONCLUSIONS

Transradial is a feasible, effective and safe route for both coronary angiography and PCI and can be applied in the majority of cases. But despite the fact that it lowers the vascular complication rate along with other adverse effects, increased exposures to radiation of both the operator and patient through the radial route is an underestimated problem especially in the face of evidence that it is responsible for causing skin diseases as well as cancer. There are various protection devices available to reduce radiation exposure but they still have to gain widespread acceptance in the Cath labs. The radial route indications should be reconsidered in the light of the present findings and strict use of radiation protection methods be employed, especially when a long procedural fluoroscopy time is expected. Finally, it should be mandatory to have dosimeters on all staff of the Cath Lab to accurately measure the radiation exposure.

AUTHOR'S CONTRIBUTIONS

AU: literature search, write-up of manuscript and helped in data collection, FH, TI: data collection and data analysis FT: helped in proof reading, bibliography and data analysis

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