Comparison of fluoroscopy time during coronary angiography and interventions by radial and femoral routes- can we decrease the fluoroscopy time with increased experience? An observational study

Radiyal ve femoral yollardan gerçekleştirilen koroner anjiyografi ve girişimler sırasında geçen sürenin kıyaslanması - Deneyimin artması ile floroskopi süresini kısaltabilir miyiz ? Gözlemsel bir çalışma

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ABSTRACT

Objective: Radial route of access is increasingly being used for coronary angiograms and intervention. However, radiation exposure of operators was not known in our set up with either transfemoral or transradial procedures. The objective of the study was to compare related peripheral arterial route radiation exposure of operators by assessing fluoroscopy time. The secondary objective was to determine the relationship of operator experience with fluoroscopy time.

Methods: This observational study was conducted in a tertiary care center - Cardiovascular Institute of Karachi (Pakistan) during the period of July 1st 2009 to September 30th 2009. We studied 1016 consecutive adult patients referred for coronary angiography (CA) or percutaneous coronary intervention (PCI). Patients who underwent right heart catheterization or for valvuloplasty were excluded from the study. Out of these 1016 patients, 928 were diagnostic CAs (734 via femoral route [f-CA] and 194 via radial route [r-CA]) and 88 were PCI (64 via femoral route [f-PCI] and 24 via radial route [r-PCI]). Fluoroscopy time was recorded as a surrogate of radiation exposure. Statistical analysis was performed using unpaired t, Mann-Whitney U, Chi-square and ANOVA tests.

Results: Mean fluoroscopy time was found to be significantly higher in patients who underwent r-CA (6.3±3.8 vs 4.0±2.9 min; p<0.001) and r-PCI (15.1±11.8 vs 10.3±7.4 min; p=0.02) as compared with those underwent f-CA and f-PCI. Mean fluoroscopy time of well experienced operators was also high in r-CAs (5.4±2.9 vs 4.2±3.5 min; p=0.004).

Conclusion: Radial procedures are associated with longer fluoroscopy time that may result in high radiation exposure to radial operators. Even well experienced radial operators cannot minimize their fluoroscopy time to the level of well experienced femoral operators.

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Key words: Coronary angiography, transradial approach, fluoroscopy time

ÖZET

Amaç: Radiyal yol erişimi koroner anjiyografiler ve girişimler için giderek daha fazla kullanılmaktadır. Bununla beraber, girişimcilerin, transfemoral ya da transradiyal işlemler sırasında maruz kaldıkları radyasyon bilinmemektedir. Çalışmanın amacı, floroskopi zamanını değerlendirerek işlemi yapanların periferik arter yolu ile ilgili maruz kaldıkları radyasyonu karşılaştırmaktı. İkinci amaç, foloroskopi süresi ile operatör deneyimi arasındaki ilişkiyi belirlemekti.

Yöntemler: Bu gözlemsel çalışma 1 Temmuz 2009 ile 30 Eylül 2009 periyodu arasında, Karaçi (Pakistan)'de bir üçüncü basamak tedavi Kardiyovasküler Enstitüsünde yapıldı. Koroner anjiyografi (KA) veya perkütan koroner müdahale (PKM) için gelen 1016 ardışık hastada çalışma yaptık. Sağ kalp kateterizasyonu veya valvüloplasti hastaları çalışma dışı bırakıldı. Bu 1016 hastanın 928'i tanısal KA'lar (734 femoral yolla [f-KA] ve 194 radiyal yolla[r-KA]) ve 88 hasta PKM (64 femoral yolla[f-PKM] ve 24 radiyal yolla [r-PKM]) idi. Floroskopi zamanı radyasyona maruz kalma yerine kayıtlara geçti. İstatistiksel analiz eşleştirilmemiş t, Mann-Whitney U, Ki-kare ve ANOVA tesleri ile yapıldı.

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Bulgular: Ortalama floroskopi zamanı femoral yolla KA ve PKM uygulanan hastalara göre radiyal yolla KA (6.3±3.8'e karşı 4.0±2.9 dak; p= <0.001) ve PKM (15.1±11.8'e karşı 10.3±7.4 dak; p=0.02) uygulanan hastalarda anlamlı olarak yüksek bulundu. Oldukça deneyimli operatörlerin ortalama floroskopi zamanı da r-KAs'da (5.4±2.9'a karşı 4.2±3.5 dak; p=0.004) yüksekti.
Sonuç: Radiyal işlemler, radiyal operatörlerin yüksek radyasyona maruz kalmaları ile sonuçlanabilen, daha uzun floroskopi zamanı ile ilişkilidir. Oldukça deneyimli radiyal operatörler bile floroskopi sürelerini, iyi deneyimli femoral operatörlerin floroskopi süre düzeyine indiremediler. *(Anadolu Kardiyol Derg 2011; 11: 607-12)*
Anahtar kelimeler: Koroner anjiyografi, transradiyal yaklaşım, floroskopi zamanı

Introduction

Radial route of access is increasingly being used for coronary angiography (CA) and percutaneous coronary intervention (PCI) mainly due to decreased access site bleeding complications, increased patient comfort and early mobilization (1-3). However, concerns have been raised about prolonged procedure time and increased radiation exposure to the operators by using radial route of access (4-6). Although, some studies have shown that with increasing operator experience radiation exposure can be minimized with transradial approach (TRA) and hence majority of radial operators assume that special radiation exposure precautions are unnecessary (7, 8). On the contrary, few other studies demonstrated increased fluoroscopy time and radiation exposure with radial access and advocated special radiation protection methods to reduce operator radiation exposure (9, 10). While this controversy continues, very few studies have compared the operator radiation exposure with radial versus femoral approach particularly in our part of the world.

The purpose of this study was to evaluate the difference in operator radiation exposure by using fluoroscopy time with both TRA and transfemoral approach (TFA) at a high volume tertiary care centre in Pakistan. Our second objective was to determine the relationship of operator experience with radiation exposure to answer the question that whether we can minimize fluoroscopy time with increased operator experience.

Methods

Study design

This prospective observational study was conducted at Catheterization Laboratory of National Institute of Cardiovascular Diseases (NICVD) a tertiary care center of Karachi (Pakistan) during the period of July 1st 2009 to September 30, 2009.

Patients and data collection

A total of 1016 consecutive patients were enrolled. Patients referred for right heart catheterization and valvuloplasty were excluded. Written informed consent was taken before the procedure and a questionnaire was filled about the demographic and clinical features. Route of access, switch over to other access site, number of catheters used, volume of contrast consumed, anatomical variations (radial or subclavian loop, accessory brachial artery, subclavian or iliac artery occlusion, dilated ascending aorta, etc) and left main coronary artery (LMCA) involvement were also noted. In case of PCI anatomical details (type of lesion, ostial or chronic total occlusion involvement etc) and type of procedure (emergency or elective) were noted. After the procedure fluoroscopy time was recorded as a surrogate of radiation exposure.

Effort to reduce the bias

The special feature of this study was that majority of operators (17 out of 20) were blinded to the collection of data and its purpose. This was done to minimize the operator bias. All the operators were free to select the patient either for TRA or TFA. Among 20 operators there were 13 consultants, 3 interventional fellows and 4 post graduate trainees. 3 operators were pure radialists and remaining were femoral operators. Some femoral operators used TRA in selected patients.

Definitions

Fluoroscopy time of femoral coronary angiography (f-CA) was separately analyzed in consultants (well-experienced femoral operators, in general), fellows (less experienced), and post graduate fellows (trainees). Fluoroscopy time of radial coronary angiography (r-CA) was analyzed separately in well experienced radial operators (defined as the person who has performed >500 radial procedures including >200 procedures in a recent year), less experienced (the person who has done 200-500 radial procedures in a recent year), and trainee (the person who has done <200 radial procedures) (11).

The study project was assessed and approved by the Ethics committee of the institution whose members were not part of the study group.

Statistical analysis

All the data were entered and analyzed through SPSS software, Windows version 15 (Chicago IL, USA). Categorical variables like gender, hypertension, diabetes mellitus, smoking status, family history, type of contrast, LMCA, atypical anatomy and level of experience were presented in frequencies and percentages whereas continuous variables like age, height, weight, fluoroscopy time and contrast volume were presented as mean±SD. Chi-square test was used for comparison of categorical variables. Comparison of continuous variables was done using: unpaired t-test for normally distributed data, Mann-Whitney U test for not normally distributed data and ANOVA was used to compare mean fluoroscopy time between level of experience subgroups for femoral and radial routes. For post-hoc, Tukey's HSD test was used to observe differences between a pair of means. A p value <0.05 was considered as statistically significant.

Results

Clinical and procedural characteristics of patients undergoing CA

A total of 1016 patients were included in this study out of which 928 were diagnostic coronary angiograms and 88 were PCI. The duration of study was 3 months. Among coronary angiograms 734 (79%) were f-CA and 194 (21%) were r-CA. Table 1 shows demographic and procedural characteristics of patients undergoing CA via femoral versus radial route. The mean age was under 53 years in both groups. Approximately two-third were hypertensive and nearly 25% were diabetic in both groups. Significant difference was observed in mean weight of r-CA group. These patients were much heavier as compared to patients underwent CA via femoral route. However, no significant difference was observed in mean height.

Non-ionic contrast was used more frequently in r-CA group (p<0.001). Similarly, increased volume of contrast was used in r-CA (p=0.001). Atypical anatomy was found in 21.1% patients in r-CA group while it was 11% in f-CA group (p<0.001). Switchover to other access site was significantly more frequent in r-CA group (p<0.001). Significant difference in use of fluoroscopy time was observed in patients who underwent r-CA as compared to the f-CA group (p<0.001). However, significantly less number of catheters was used in r-CA group.

Table 1. Baseline demographic and procedural characteristics of patient undergoing angiography

Variables	Femoral approach (n=734)	Radial approach (n=194)	p*
Age, years	52.6±10.1	52.2±10.2	0.533
Height, cm	162.2±10.1	163±13.2	0.149
Weight, kg	70.1±12.9	74.5±16	0.001
Male sex, n (%)	525 (72)	147 (75.8)	0.232
Hypertension, n (%)	477 (65)	131 (67.5)	0.511
Diabetes mellitus, n (%)	183 (24.9)	44 (22.7)	0.524
Current smoker, n (%)	195 (26.6)	58 (29.9)	0.355
Use of non-ionic contrast, n (%)	319 (43.5)	147 (75.8)	<0.001
Use of contrast volume, ml	75.6±27.2 70 (20-270)	82.9±28.7 80 (30-200)	<0.001
Fluoroscopy time, min	4.0±2.9 3.2 (0.4-33.2)	6.3±3.8 5.5 (1.1-33.5)	<0.001
Significant LMCA disease, n (%)	63 (8.6)	14 (7.2)	0.552
Switch over, n (%)	16 (2.1)	07 (3.6)	<0.001
Number of catheters used, n	2.3±0.5	1.8±0.5	<0.001
Procedures performed by, n (%)			
Consultant	221 (30.1)	81 (41.8)	<0.001
Interventional fellow (in training)	427 (58.2)	111 (57.2)	0.893
Postgraduate trainee	86 (11.7)	02 (1.0)	<0.001
Graft studies, n (%)	15 (2.0)	01 (0.5)	0.152
Atypical anatomy, n (%)	81 (11)	41 (21.1)	<0.001

Data are presented as mean+SD, median (min-max) values and number (percentage)
*unpaired t-test, Mann-Whitney U test and Chi-square test
LMCA - left main coronary artery

Clinical and procedural characteristics of patients undergoing PCI

Table 2 shows clinical and procedural characteristics of patients undergoing percutaneous coronary intervention via femoral versus radial route. Out of 88 PCI, 64 were f-PCI and 24 were r-PCI. Baseline features were same in both groups. No significant difference was observed in anatomical considerations. However, significant difference was observed in duration of fluoroscopy time (p=0.013).

Effects of operator experience on fluoroscopy time

Table 3 shows difference of fluoroscopy time in various groups with respect to their experience. Significant difference was observed among well experienced, less experienced and trainees groups as far as use of fluoroscopy time are concerned. Difference was more significant in r-CA group (p<0.001) as compared to f-CA group (p=0.042). Mean fluoroscopy time of well-experienced radial operators was also significantly high as compared to well-experienced femoral operators (p=0.004).

Discussion

Over 60 years back radial arterial access was described, but it was not favored due to equipment and technical limitations (12). Then 20 years back, it received new interest after the work of Campeau (13). After that, Kiemeneij introduced successful interventional procedures through radial route (14). Since then, transradial catheterization has gained widespread adoption in many parts of the world (15). Although transradial catheterization is being used more commonly due to increased convenience for the patient but its acceptance among interventional cardiologists is somewhat slow. As many of them argue that due to prolonged procedure time and increased radiation exposure, radial route is not a viable choice for busy catheterization labs. On the other hand, it has been demonstrated that differences between the femoral and radial approach can be diminished with increased operator experience (7, 16).

This is the first study in Pakistan that not only reported the difference of radiation exposure between the femoral and radial route of access but also showed the effect of operator's experience on this difference.

The baseline demographic features were almost same in both groups except that patients in radial group were significantly heavier than the patients in femoral group. This may be due to selection bias of femoral operators who would choose radial access to perform coronary angiography on their heavier patients. Non-ionic contrast was used more commonly in radial group as compared to femoral group. This was again due to selection bias of operators because most of our radial operators

Table 2. Baseline clinical and procedural characteristics of patients undergoing percutaneous coronary intervention

Variables	Femoral approach (n=64)	Radial approach (n=24)	p*
Age, years	50.5±10.8	54.2±8.8	0.139
Height, cm	165±10.5	165.7±9.8	0.778
Weight, kg	73.6±12.4	75±11.9	0.627
Male sex, n (%)	49 (76.6)	21 (87.5)	0.257
Hypertension, n (%)	39 (60.9)	19 (79.2)	0.108
Diabetes mellitus, n (%)	18 (28.1)	05 (20.8)	0.488
Current smoker, n (%)	19 (29.6)	07 (29.2)	0.923
Use of contrast volume, ml	145.3±69.0 128 (60-430)	171.6±58.8 170 (70-300)	0.036
Fluoroscopy time, min,	10.3±7.4 7.5 (3.3-38.4)	15.1±11.8 11.4 (4.5-50.6)	0.013
Mode of procedure, n (%)			
Elective	55 (85.9)	23 (95.8)	0.193
Emergency	09 (14.1)	01 (4.2)	
Number of vessels intervened, n (%)			
SVD	52 (81.3)	19 (79.2)	0.826
2VD	12 (18.8)	05 (20.8)	
CTO, n (%)	03 (4.7)	02 (8.3)	0.124
Ostial lesion, n (%)	07 (10.9)	02 (8.3)	0.372
Lesion risk, n (%)			
Type A	09 (14.1)	06 (25.0)	0.225
Type B	30 (46.9)	08 (33.3)	0.248
Type C	25 (39.1)	10 (41.7)	0.803
Bifurcation	06 (19.4)	03 (12.5)	0.345

Data are presented as mean±SD, median (min-max) values and number (percentage)
*unpaired t-test, Mann-Whitney U test and Chi-square test
CTO - chronic total occlusion, SVD - single vessel-disease, 2VD - 2-vessel disease

Table 3. Difference of fluoroscopy time (minutes) in various experience level subgroups of radial versus femoral approach CA

Operator experience level	Femoral-CA	Radial-CA	p*
Well-experienced operator	4.1±3.7 (3.5-4.7)	5.5±3.1 (4.8-6.2)	0.004
Less-experienced operator	3.6±2.7 (3.2-3.9)	5.7±3.1 (4.8-6.6)	<0.001
Trainee	4.3±2.7 (4.0-4.6)	7.8±4.6 (6.7-8.9)	<0.001
F†	3.2	8.4	
p†	0.042	<0.001	
Tukey's HSD	0.032**	0.007**	
		0.001***	

Data are presented as mean+SD (95%CI) values
*unpaired t-test
†One-way ANOVA
Tukey's HSD posthoc test: ** - significant difference between less-experienced operator and trainee
*** - significant difference between well-experienced operator and trainee
CA - coronary angiography

preferably used non ionic contrast. Interestingly, more contrast was consumed in radial group (mean volume~83 ml) as compared to femoral group (mean volume~76 ml), p value=0.001. This is understandable if we keep considering the complexity of radial anatomy and technical difficulties that a radial operator has to face while performing the transradial procedure. This new finding in our study shows that concerns about transradial procedure are not limited to prolonged procedure time and high radiation but volume of contrast is another issue that can make the procedure more complicated.

Transradial procedure has been proved to be cost effective in terms of use of limited number of catheters (2, 17). Transradial diagnostic coronary angiography can be done with one multipurpose catheter. In contrast, transfemoral coronary angiogram needs at least two and usually three catheters. In our institution transradial coronary angiogram is usually done with multipurpose (MPA 5 Cordis, Johnson & Johnson Co, Miami Lakes, Florida, USA) or TIGER (TERUMO Corporation, Tokyo, Japan) 5F catheters. While f-CA is usually done with Judkin's left (JL 4), Judkin's right (JR 4) and pigtail catheters. Therefore, in our study significantly less number of catheters was used in r-CA group and that reasonably reduced the cost of the procedure. This economical factor is more important in our setup where most of the expense (if not all) of the procedure has to be borne by the patient.

Anatomical variations (atypical anatomy) are commonly encountered during TRA for diagnostic and interventional procedures and may cause access failure (18). Lo et al. (19) recently studied 1,540 consecutive radial procedures and found radial artery anomaly in 13.8% patients while Valsecchi et al. (20) has reported quite a high incidence as 22.8% in his study of 2, 211 cases. In our study, atypical anatomy was found 21.1% in r-CA group while it was 11% in f-CA group (p<0.001). Keeping this fact in mind it was not surprising if we found significantly high switchover rate (3.6% vs 2.1%; <0.001) and fluoroscopy use (p<0.001) in r-CA group.

In our study, significantly high fluoroscopy time of r-CA and r-PCI groups is consistent with previous studies (9, 21, 22). It may be argued that mean fluoroscopy time of f-CA as well as r-CA is relatively high. As we mentioned above there were about 20 operators including trainees, fellows and consultants who had a marked variation in their experience, skills and training. This was the reason of difference of their fluoroscopy use. Moreover, most of them were blinded to the collection of data and therefore they were not conscious about the use of fluoroscopy. This was an obligation due to our study design, as we wanted to know the difference of fluoroscopy use in various groups. If they were not blinded then there would have been more selection bias towards the suitable case for either route by more experienced operators. It has been revealed in our study that fluoroscopy time can be minimized with increased experience particularly in r-CA where a significantly high difference in fluoroscopy use was noted among experienced and inexperienced groups. On the contrary, if we compare the fluoroscopy time of a well experienced femoral operator with a well experienced radial operator then it appears that well experienced radial operator

cannot minimize his fluoroscopy time to as low as well experienced femoral operator. Thus, it can be suggested that radial operator may be more exposed to radiation despite his greater experience. This was validated by the findings of Fernandez et al. (23) who studied 526 radial procedures and compared them with 1697 femoral procedures. He found significant difference in fluoroscopy use among less experienced and well- experienced groups (6.4 vs 5.0 min; p<0.001). He concluded that although a significant decrease was observed in the length of time needed for fluoroscopy among less experienced and well-experienced radial operators but it continued to be greater than that seen in the transfemoral group. This was also observed in other randomly assigned studies (1, 24).

Recently, Weaver et al. (25) compared the TRA versus TFA in patients presenting with STEMI and reported significantly less fluoroscopy use in TRA (12.5±7.9 versus 15.2±10.1 minutes; p=0.02). Similarly, Rathore et al. (26) reported no significant difference in the length of fluoroscopy time when comparing TRA with TFA in patients who underwent PCI for chronic total occlusions. However, these studies were not designed to specifically evaluate the difference of radiation exposure with either route of access. Secondly, in that study radial operators were highly experienced and were free to select the route of access (25). Therefore, selection bias for patients more favorable for either radial or femoral artery access cannot be excluded. In contrary, we found a significantly higher fluoroscopy use when comparing r-PCI with f-PCI in our study (p=0.013). Although there was a clear disparity among r-PCI and f-PCI groups despite of that high number of complex interventions like multivessel, chronic total occlusion and type C lesions were treated via radial route. This could be the explanation of higher fluoroscopy time in our study. Secondly, radialists who did most of interventions were blinded with the purpose of study and therefore they did all types of interventions via radial route as they normally do. This ruled out the selection bias unlike Weaver's study (25) and resulting in higher fluoroscopy time. But, Rao et al. (27) (from the National Cardiovascular Data Registry) also reported higher fluoroscopy time in r-PCI group as compared to f-PCI group (13.5 vs 11.3 min; p<0.01). Moreover, Lange et al. (9) demonstrated 50 % increase in radiation exposure with radial approach despite the non-significant difference in fluoroscopy time among r-PCI and f-PCI groups. This shows the diversity in available data and demands further randomized, blinded studies in larger cohorts.

Study limitations

As mentioned above that the study was not randomized and therefore not free from selection bias. However, sub group analysis of fluoroscopy time as per experience has decreased the effect of bias on the results. Secondly, dose area product was not measured as we could not check electronic dosimeters. Although fluoroscopy time does not accurately reflect radiation exposure, it was an obligation due to our study design for if we checked the dosimeters the study would not be blinded and we would have to inform the operator about the study purpose. Thirdly, we performed most of our radial procedures either with multipurpose or with TIGER catheters. We do not know whether these results would be same if we used Judkins left and right catheters that have been using in radial procedures in various centers.

Conclusion

Although fluoroscopy time can be minimized with increased experience, however, even well-experienced radial operators cannot minimize their fluoroscopy time to the level of well-experienced femoral operators. This may lead to increased radiation exposure to radial operators that could be a serious health problem for interventional cardiologists. Therefore, extensive use of specific protection devices should still be employed by pure radialists and use of radial route for every patient should be reconsidered.

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