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Comparison of Radial and Femoral Percutaneous Coronary Intervention

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ABSTRACT

Background: The use of radial access for percutaneous coronary intervention is increasing in Nepal. However, there is limited study on the comparison of radial and femoral access in Nepal. This is the study comparing net adverse clinical events of radial with femoral access for intervention.

Methods: This prospective study was conducted at Shahid Gangalal National Heart Center from January 2014 to June 2015 among 849 participations who underwent percutaneous coronary interventions, and 418 radial interventions were compared with 418 femoral interventions. A comparison was done in terms of 30- day rate of net adverse clinical events defined as the composite of death, myocardial infarction, stroke, target lesion revascularization and major bleeding.

Results: Incidence of net adverse clinical events was significantly lower in radial compared to femoral approach 18(4.30%) vs. 51 (12.2%), p= <0.001). Mortality observed in the radial approach was significantly lower (p=<0.001) compared to femoral. Procedure success was not significantly different p=0.629. The trans-radial approach had significantly higher crossover rate (p=0.001). Observed vascular access site complications (p=0.026) and hospital stay (p=<0.0001) were lower in the radial group. Radiation exposure measured by fluoroscopy exposure time was not significantly different between the two groups (p=0.290).

Conclusions: Radial access is associated with a lower rate of net adverse clinical events at 30 days compared to femoral access. Radial access is safer and equally effective compared to femoral access in the context of Nepal.

Keywords: Femoral; percutaneous coronary intervention; radial

INTRODUCTION

Percutaneous coronary intervention (PCI) is an integral part of treatment for ischemic heart disease.[1] The first radial PCI was reported in 1993.[2] In Nepal, trans-radial PCI was introduced in 2007[3], which was five years after the start of the transfemoral approach. The proportion of radial procedures has continued to rise worldwide. There are considerable variations across countries.[4] In Nepal, 43.5 % PCI was performed by radial access in 2012.[3]

The focus on procedure-related non-ischemic complications, particularly bleeding and vascular complications, has increased over time.[4] Bleeding is associated with adverse outcomes.[5] Vascular complications are associated with patient discomfort, increased length of stay, and cost.[4] Asians have smaller radial artery size than Europeans.[6] Data on safety and efficacy for PCI is limited in Nepal. Therefore, this study is designed to compare safety and efficacy, procedural success, vascular and access site complications of radial in comparison to femoral PCI in the context of Nepal.

METHODS

This observational study was conducted at Shahid Gangalal National Heart Centre, Nepal from January 2014 to June 2015. The sample size was calculated as 418 in each group, considering the power of study as 80% and occurrence of NACE(net adverse clinical event) in radial 13.6% and femoral PCI 21% in the previous study.[7]

Selection and description of participants: Patients undergoing elective or primary PCI were included after informed consent, whereas patients less than 18

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years, requiring intra-aortic balloon counter-pulsation, prior bypass graft surgery were excluded. The patient underwent radial or femoral access for PCI on operator's discretions. Study subjects were divided into radial and femoral groups using a non-randomized purposive sampling method.

This study aimed to compare the primary outcome of the 30-day rate of NACE [defined as a composite of death, myocardial infarction, stroke, target lesion revascularization and major bleeding academic research consortium (BARC) 3 or 5] and procedural success between radial versus femoral access for PCI. Bleeding was assessed according to BARC which includes type 0:no bleeding,1:bleeding not actionable, 2:overt actionable hemorrhage 3:Overt bleeding plus hemoglobin drop of ≥3 g/dL, requiring transfusion or intracranial hemorrhage, Type 4:Coronary Artery Bypass Graft-related bleeding and Type 5: fatal bleeding.[5] Morphology of lesion classified as type I and II being patent, and Type III and IV occluded. Furthermore, type II and IV are diffuse (>2 cm length) or excessively tortuous or extremely angulated (>90˚).[8] Secondary outcomes were individual components of NACE, stent-thrombosis, access site crossover, procedure time, contrast volume used, fluoroscopy exposure time, hospital stay.

Demographic characteristics, angiographic findings, access and procedure outcomes were collected using structured Performa. Patients were monitored for in-hospital outcomes and followed at 30 days. Data were entered in Epi Data 3.1 version and analyzed in SPSS (Statistical package for social sciences) version 20. proportion, mean, standard deviation and median were calculated for descriptive analysis. For analytical analysis, the chi-square test was used for qualitative data, and independent t-test for quantitative data in a 95% confidence interval and p-value less than 0.05 was taken as significant. Bivariate analysis was used to identify factors associated with NACE. Factors with significant (p-value <0.05) association were analyzed in multivariate logistic regression analysis to identify independent predictors of NACE. Ethical approval was taken from the Institutional Review Board of National Academy of Medical Sciences and written informed consent was taken from patients.

RESULTS

Total of 849 PCI was evaluated. Eleven patients were excluded, where six patients had a history of CABG; five patients required intraarterial balloon pulsation during the procedure. Patients were followed up until 30 days. One patient in each group lost to follow up. Final analysis was done among 418 trans-radial and 418 transfemoral PCI. The demographics and baseline characteristics of the two groups were similar except for cardiogenic shock, which was higher in the femoral group, as shown in table1. The comparison of the various lesion and procedural characteristics are presented in Table 2, were all are similar except PCI to RCA, arterial sheath size. The higher number of seven French sheaths was used in femoral access as compared to radial access, and type II or III or IV lesion were more in femoral compared to the radial group.

Table 1.Demographic and baseline characteristics.

Characteristics		Radial group (n=418) (%)	Femoral group (n=418) (%)	P value
Age (mean± SD) years		58.11±12.14	58.93±11.69	0.317
Sex	Male	317(75.84%)	323(77.27%)	0.624
	Female	101(24.16%)	95(22.73%)	
Family history of CAD		13(3.1%)	20(4.7%)	0.214
Smoking		320(76.55%	328(78.46%)	0.508
Hypertension		248(59.33%)	255(61.004%)	0.621
Diabetes mellitus		98(23.44%)	88(21.05%)	0.406
Dyslipidemia		70(16.74%)	77(18.42%)	0.525

CAD - Coronary artery disease

Table 2. Lesion and procedure characteristics.

Variables	Radial (n=418)	Femoral (n=418)	P value
Severity of CAD			
SVD	268(64.1)	282(67.5)	0.307
Multivessel disease	150(35.9)	136(32.5)	
Target vessel:			
PCI to one vessel	382(91.4)	387(92.6)	0.531
PCI to>one vessel	36(8.6)	31(7.4)	
Single vessel PCI:			
LM	210(50.2%)	190(45.6%)	0.102
LCX	62(14.8%)	45(10.8%)	0.065
RCA	108(25.8%)	146(34.9%)	0.005
LAD	2(0.5%)	6(1.4%)	0.287
Arterial sheath size			
6F	409(97.8)	380(90.9)	<0.0001
7F	9(2.15)	37(8.85)	
Lesion type I	173(41.4)	138(33.1)	0.012
Lesion type II or III or IV	245(58.6)	280(66.9)	

SVD - Single vessel disease, LM - Left main artery, LCX - Left circumflex artery, RCA - Right coronary artery, LAD - Left anterior descending artery, 6F - 6 French, 7F - 7 French

In this study, Incidence of NACE was significantly lower in the trans-radial approach in comparison to the transfemoral approach [18 (4.3%) Vs. 51(12.2%), OR 0.32, CI (0.18 to 0.56), p= <0.001] as presented in Table 3. PCI success was not significantly different between two routes of interventions 406(97.13%) in radial Vs. 402 (96.2%) in femoral, (p=0.629). The composite of death, myocardial infarction or stroke was 18 (4.30%) radial Vs. 49 (11.7%) femoral (p=<0.001) The mortality observed in radial 15 (3.58%) was significantly lower than that of femoral 45 (10.7%) (OR: 0.309, CI: 0.169 to 0.563, p=<0.001). Periprocedural myocardial infarction was similar. Moreover, stroke was higher in femoral group [0 vs. 5 (1.19%) (p=0.031)]. Target lesion revascularization and stent thrombosis were similar. Radial intervention had lower bleeding, minor bleeding 32(7.6%) vs. 52 (12.4%) and major bleeding 1(0.23%) vs. 3(0.71%) p=0.041, difference was significant. Table 4 demonstrates the association of multiple variables with NACE by multivariable logistic regression analysis. Multivariate analysis confirmed radial approach as an independent predictor of 30 days NACE together with age more than 60 years, primary PCI, Cardiogenic shock and systolic dysfunction with LVEF < 40%.

Table 3. NACE and other outcomes.

Outcome variables	Radial (n=418) (%)	Femoral (n=418) (%)	P value	OR (95% CI)
NACE	18 (4.30)	51 (12.2)	<0.0001	0.32(0.18 to0.56)
Procedural success	406 (97.1)	402 (96.2)	0.629	0.80(0.34 to 1.92
Composite of death, MI, stroke or BARC bleeding 3or 5	18 (4.3)	51 (12.2)	<0.0001	0.32(0.18 to0.56)
Composite of death, MI or stroke	18 (4.3)	49 (11.7)	<0.0001	0.33(0.19to 0.59)
Death	15 (3.5)	45 (10.7)	<0.0001	0.30(0.16 to 0.56)
Myocardial infarction	8 (1.9)	6 (1.43)	0.591	1.34(0.461 to 3.89)
Vascular complications	35 (8.3)	55 (13.1)	0.026	0.60(0.38 to0.94)
Access site switchover	24 (5.7)	6 (1.4)	0.001	4.18 (1.69 to 10.34)
Bleeding BARC 1or2	32 (7.6)	52 (12.4)	0.041	
BARC 3or 5	1 (0.2)	3 (0.7)		
Fluoroscopy exposure time	11.1±7.3	11.7±7.5	0.290	
Hospital stay	3.10±2.1	4.56± 2.4	<0.0001	

Table 4. Relationship of variables to 30- day NACE in Multivariate analysis.

Variables	Unadjusted OR	Sig.	Adjusted OR (95.0% C.I)
Age > 60 years ≤ 60 years	1.869	0.004	2.469(1.335 to 4.566)
Primary PCI Elective PCI	7.357	0.008	2.862(1.323 to 6.191)
Cardiogenic shock	28.258	<0.0001	10.448(4.598 to 23.742)
LVEF < 40 ≥40	6.011	0.004	2.546(1.347 to 4.812)
Radial access Femoral access	0.324	0.008	0.417(0.218 to 0.797)
PCI to LCX	0.269	0.492	0.645(0.185 to2.253)
PCI to LM	6.516	0.709	1.493(.182 to12.235)
Lesion complex morphology	4.330	0.336	1.565(0.628 to3.899)

DISCUSSION

This study compared the thirty-day rate of NACE (defined as a composite of death, myocardial infarction, stroke, target lesion revascularization and major bleeding) and procedure success of radial access with that of femoral access for PCI among Nepalese patient. The primary and secondary outcomes were analyzed in elective and primary percutaneous coronary interventions. PCI success was not significantly different between two groups 406 (97.13%) radial vs. 402(96.2) femoral p=0.629. A similar finding was observed in the RIVAL study with PCI success in 95.4% Vs. 95.2% in radial Vs. femoral group, the difference being statistically not significant.[9]

Incidence rate of NACE was significantly lower in trans-radial approach [18 (4.30%) radial vs. 51(12.2%) femoral OR 0.324 C I 0.186 to 0.564, p= <0.0001]. The mortality observed in radial access was significantly lower than that of femoral access [15 (3.5%) vs. 45 (10.7%), p=<0.001]. Similar to our findings, prospective observational study from United Kingdom among 571 patients in radial and 480 in femoral reported significantly lower major adverse cardiac event 15(2.6%) radial vs. 25(5.2%) in femoral.[10] However, another observational study from Greece, reported no difference in death, myocardial infarction or stent thrombosis.[11]

In our study, the occurrence of periprocedural myocardial infarction was similar. However, stroke was significantly higher in femoral access. Furthermore, Radial intervention tended to have lower bleeding, minor BARC bleeding 32 (7.6%) vs. 52 (12.4%) and major BARC bleeding 1(0.23%) vs. 3(0.71%) p=0.041. The present study demonstrates that trans-radial intervention is associated with a lower incidence rate of NACE, which is mainly driven by a lower rate of mortality, reduced rate of stroke and a lower tendency for vascular bleeding. Similarly, in STEMI-RADIAL study, NACE was 4.6% vs.11.0% (p = 0.0028). However, mortality in radial and femoral groups were 2.3% vs. 3.1% (p = 0.64) at 30 days.[12] In contrary, TEMPURA study reported similar major adverse cardiac events among two groups.[13] A RIVAL study demonstrated the primary outcome of death, MI, stroke, or major bleeding 128 (3.7%) vs. 139 (4.0%).[9]

One study from china demonstrated similar major adverse cardiac events with a higher vascular complication in the femoral intervention.[14] However, in our study, among 311 patients undergoing primary PCI, the incidence rate of NACE was significantly lower in trans-radial approach. The mortality observed in radial was significantly lower. The RIFLE-STEACS demonstrated 30-day rate of NACE 68 (13.6%) in radial Vs 105 (21.0%) in femoral group (p 0.003).[7] These findings are similar to observations in our study. Furthermore, radial access was associated with lower mortality (5.2% vs. 9.2%, p 0.020), Another study from UK radial access was associated with lower mortality.[15]

Our study identified radial approach as an independent predictor of 30 days NACE (OR: 0.418; CI: 0.219 to 0.799; p .008), together with age more than 60 years, primary PCI, cardiogenic shock and LV systolic dysfunction with LVEF < 40%. A similar trend was demonstrated in RIFLESTEACS study, which illustrated radial approach as a predictor of 30-day NACE, together with female gender chronic kidney disease, impaired left ventricular ejection fraction.[7]. However, in SAFARI-STEMI study, there were no significant differences in 30-day mortality 17(1.5%) in radial Vs. 15 (1.3%) in femoral access (*P*=.69) and bleeding (1.4% vs 2.0%; *P*=.28).[16] In MATRIX study, bleeding was higher in femoral (1.6% vs. 2.3%, p=0.013.).[17] In our study, two patients in femoral and none in radial had major bleeding. Study from Poland reported major bleeding among 5.8% radial vs. 3.9% femoral, p = 0.509).[18] Utilization of different classification may have resulted in different findings. In our study, BARC bleeding classification was used.

Crossover rate was higher in radial 24(5.7%) compared to femoral route 6(1.43), (p=0.001). The various reasons leading to crossover were spasm of the radial artery, arterial tortuosity, failure to engage coronary artery, failure to puncture. One patient in femoral route crossover to radial due to hematoma during puncture. Vascular access site complication observed was high in femoral access 55 (13.15%) vs. (35(8.37%) in the radial (p 0.025). Vascular access site complications in the present study were mainly driven by hematoma in femoral access. One patient had large thigh hematoma requiring blood transfusion. One patient developed pseudoaneurysm of the femoral artery, which was managed by doppler guided compression. One patient in the radial access-group developed arteriovenous fistula, which was managed by doppler guided compression. Two patients developed evulsion of radial artery, which was managed by surgical exposure and ligation of the radial artery. One patient had radial artery perforation, which was managed conservatively by compression. One patient in the femoral intervention had ischemia of right lower limb leading to gangrene. Unfortunately, that patient developed mortality. Similar to our findings, a study from UK had higher crossover rate in radial group (7.7% vs. 0.6%, p<0.001) and major vascular complications were more frequent femoral access (0% radial versus 1.9% femoral, p = 0.001).[10] The RIVAL study showed higher access site crossover 7.6% in radial vs. 2.0% in femoral. Major vascular complications, 49(1.4%) vs. 131(3.7%) was significant. Large hematoma 42 (1.2%) in radial vs. 106(3%), (p<0.0001), Pseudoaneurysm requiring closure 7 (0.2%) Vs. 23(0.6%), p=0.006. Ischemic limb needing surgery one in radial and none in femoral. Five arteriovenous fistulas were observed in the femoral group.[9] A study from India had minor and major procedure-related complications lower in the trans-radial group. Two patients in the femoral group developed limb ischemia. One patient had a retroperitoneal hematoma.[19] In one meta-analysis, incidence rates of vascular complications and major bleeding events were reduced in radial approach.[20] One patient in our study in the radial group had coronary perforation, which managed by prolonged balloon inflation. Two patients in the radial group had coronary artery dissection requiring CABG. One patient in the femoral group had abrupt vascular closure following stent deployment. Similarly, in RIVAL study coronary complications were dissection with reduced flow 30 (1.3%) in radial vs. 25(1.1%) in femoral p=0.46, coronary perforation 5 (0.2%) radial Vs. 4 (0.2%)in femoral p=0.72 and abrupt closure 12(0.5%) radial vs. 11(0.5%)femoral. [9] In the present study, radiation exposure measured by fluoroscopy exposure time was similar between radial and femoral groups 11.1±7.3 min vs. 11.7±7.5 min, p 0.290. Procedure time to complete intervention was lower in radial route 36.9±16.8 min vs. 40.3±18.9 min, p=0.007. Although in primary PCI, procedure time was similar 34.9±13.5 min vs. 38.06±16.9 min, p=0.076, the elective femoral intervention had longer procedure time37.8±18.1 min in radial vs41.8±20.09 min in femoral, p=0.018. More complex lesion type II, III and IV were present in the femoral group. This may explain the prolonged procedure time observed in the femoral group. In a study from India, mean fluoroscopy time was13.53 ± 2.53 min for radial and 12.61 ± 9.524 min for femoral PCI ($p < 0.001$).[19] A study from China reported similar procedural time and fluoroscopy time in the radial and femoral approach. The procedural time was 37.2 ± 7.1 min, and fluoroscopy time was 11.8 ± 2.0 min.[14] The contrast required for the procedure was similar161.9±46.3 ml vs163.5±51.3 ml, p 0.631. The contrast in primary PCI was also not significant. 161.58±37.9 ml Vs. 159.74±.9 ml, p=0.725. A similar tendency was observed in elective procedures also,162.06±49.8ml vs. 166.3±51.4ml, p=0.343. In the RIVAL study, PCI procedural time 35 (22-50) min vs. 34 (22-50) and contrast volume 181 (140-240) ml vs. 180 (145-240) with no significant difference, fluoroscopy time was more in radial group 9.3 (5.8-15.0) vs. 8.0 (4.5-13.0) min which was statistically significant.[9] STEMI-RADIAL use of contrast (170 +/- 71 ml vs. 182 +/- 60 ml, p = 0.01) was significantly reduced in the radial group.[12] However, Asian countries have a smaller radial artery size than Europeans.[6] One meta-analysis has shown increased radiation exposure with radial interventions.[21] One study reported, Radial patients experienced fewer vascular access site complication (1.44% vs. 4.19%; OR: 0.33, CI: 0.23 to 0.48; p 0.001).[22] In present study, mean hospital stay was lesser in radial 3.10±2.1 vs. 4.56± 2.4, p=<0.0001. A similar trend was observed with a shorter stay in the radial(2.87±2.04 days vs. 3.3±3.12,p=0.023) in other studies.[23]

We did not use the randomization process to allocate study participants into the radial and femoral group. Allocation was based on operator discretion with diverse experience. We did follow up at one month, so long-term outcome could not be determined. However, this study compared the outcome of radial to femoral approach at one month meticulusly.

CONCLUSIONS

Trans-radial access is associated with a lower rate of net adverse clinical events at 30 days as compared with femoral access. Procedural success is similar in both accesses. Radiation exposure and volume of contrast used are similar, and radial access has shorter hospital stay. Radial access is safer and equally effective as compared to femoral access in the context of Nepal.

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