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Research Brief

Comparison of radial versus femoral access using hemostatic devices following percutaneous coronary intervention

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ABSTRACT

Arterial access site complications are the important predictor of successful percutaneous coronary interventions (PCI). We prospectively studied 722 consecutive PCI patients for access site complications. A total of 303 trans-femoral access (TFA) patients who had suture based vascular closure devices (VCD) were compared with 419 transradial access (TRA) patients. Incidence of hematoma was more in TFA (2.3% vs 0.23%, p 0.01). Median ambulation time (4 h vs 1 h, $p < 0.01$) was significantly higher in TFA. In conclusion, TRA had fewer access site complications like haematoma, compared to TFA with VCD. TRA also resulted in earlier ambulation and discharge, compared to TFA with VCD.
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1. Introduction

Vascular access site management plays an important role in the outcomes of percutaneous coronaryintervention (PCI). The access site bleeding can lead to increased morbidity, mortality, costs and length of hospital stay.[1–3] Trans-femoral vascular closure device (VCD) have shown safety and efficacy in achieving rapid hemostasis and early ambulation, compared to manual compression.[4,5] Similarly, transradial access (TRA)has also shown a reduced access site bleeding and vascular complications.[6,7] We hereby present a prospective study of consecutive PCI patients who had either TRA or trans-femoral access (TFA) with VCD. The access site complications and clinical outcomes were compared between the two groups.

2. Methods

It was a prospective, un-blinded, single-centre observational study. The study protocol was approved by the institute ethics committee. Out of the total 771 consecutive PCI during the study period, 722 patients were enrolled in the study. Forty patients of TFA without the use of VSD because of unsuitable anatomy (n = 7), needs for post-procedure arterial monitoring or non-affordability, were excluded from the study. Nine patients who had in-hospital death due to cardiogenic shock and/ventricular arrhythmias were also excluded. Either TFA or TRA was considered for all the PCI patients. The preference of TFA over the TRA was considered for those requiring 7F sheath, inability to selectively cannulate the coronary artery with TRA, complex and chronic total occlusion lesions, and absent radial due to prior catheterization. The unfractionated heparin (70 IU/kg) was given during the standard PCI procedure. An additional heparin dosage was given during prolonged interventions to maintain an activated clotting time of >250 s. The local hemostasis was achieved by using a vascular compression device (*TR Band, Terumo Corporation, Japan*) and a PercloseProGlide suture based closure device (*Abbott Vascular Devices, CA, US*) for all the TRA and TFA, respectively. Patients were ambulated after 1 h and 4 h of TRA and TFA, respectively. The primary outcome was the discharge time following PCI. The secondary outcomes were any local access site bleeding or vascular complications. All the patients were discharged on the next calendar day or thereafter. Brisk bleeding was defined when less than 1-min time was taken to soak a 4 x 4-inch gauge with blood. Any bleeding of less than the above-defined brisk bleeding was considered as oozing.[8] Any significant blood loss was defined when a fall in hemoglobin was ≥3 gm/dl form the baseline or there was a need for blood transfusion.[8] The hematoma was defined as a blood-filled swelling of ≥ 4 cm in dimension,[8] which was confirmed by ultrasound. All patients had an out-patient department follow-up at 6 weeks.

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2.1. Statistics

Normal distribution was tested using the Shapiro–Wilk test for continuous variables. The mean (±1 standard deviation) or median (interquartile range) were calculated for continuous variables in normal and skewed distribution, respectively. Percentages were calculated for discrete variables. Statistical difference between the continuous variables was analysed using the Mann–Whitney U test. Categorical data were presented as frequencies and percentage and were compared by chi-square or Fisher's exact tests. All statistical analysis was done using SPSS version-26.

3. Results

Out of a total of722 enrolled patients, 419 had TRA and 303 had TFA. The median age was higher (59 vs 58 years, p 0.02) and females were more common (20.1vs 14.1%, p 0.03) in the trans-femoral group (Table 1). The conventional CAD risk factors were comparable in both the groups except smoking which was more in TRA ($p < 0.01$). The majority of the patients with ST-elevation myocardial infarction had TRA and those with chronic stable angina had TFA (p 0.001). All transradial patients had a 6F sheath. Out of 303 trans-femoral patients, 28 (9.3%) had 7F sheath, while resthad 6F sheath. A total of 49 (6.7%) patients had local site complications. Incidence of access site oozing was similar between the two groups, while local hematoma was significantly more in TFA (2.3% vs 0.23%, p 0.01). None of the patients had any major bleeding requiring blood transfusion, or vascular complications such as arterio-venous fistula, pseudoaneurysm and local site infection. None of the patients had any device failure or death. The median ambulation time (4 vs. 1 h, $p < 0.01$) and duration of hospital stay (1.94 ± 1.1 vs. 1.78 ± 1.08 days, p 0.04) were significantly higher in TFA (Table 1).

4. Discussion

Access site bleeding complications is an independent predictor of adverse clinical outcomes following PCI.[1,2] Its incidence varies from 1.1% to 2.9%,[2] while overall bleeding and vascular complications range from 5% to 15%.[8,9] The use of VCD helps in rapid haemostasis and early ambulationin post PCI patients.[8,10] The registry data had shown decreased access site complications with the use of VCD.[11,12] A recent meta-analysis showed that VCDs reduces the time to hemostasis & ambulation, and prevent the formation of large hematoma >5 cm, with a similar incidence of major bleeding and other vascular complications, in comparison to manual compression.[10] The American Heart Association (AHA) also recommends that VCDs can be used to achieve rapid hemostasis and early ambulation (Class IIa) but not to reduce vascular complications (Class III).[13]

We mainly had minor access site complications such as oozing. The incidence of hematoma was higher with TFA compared to TRA (p 0.01), and the results were comparable with published studies.[4,9,14] The incidence of major vascular complications in the present study (2.3 vs. 0.23% in TFA and TRA, respectively) was lower compared to other studies.[4,15] The mean ambulation time was 5.5 h in a randomized trial of Perclose VCD by Martin et al,[15] A recent meta-analysis had also suggested that TRA is superior in the prevention of access site bleedings and vascular complications, irrespective of usage of manual compression or VCD for TFA.[4] Our study results are consistent with the published data, indicating TRA is a better strategy in achieving rapid hemostasis, early ambulation and reduction of access site complications, although VCDs are better in achieving rapid hemostasis and early ambulation with TFA.

There are certain limitations in the present study. It was a single centre, non-randomized observational study with small sample size. We did not compare the two groups with the patients of manual or mechanical compression. We did not consider radial artery occlusion as a complication of TRA and did not assess its patency at 6 weeks of follow-up. In conclusion, TRA had fewer assess site complications like haematoma, compared to TFA with VCD. TRA also resulted in earlier ambulation and discharge, compared to TFA with VCD.

Table 1
Clinical characteristic and outcomes of the study population.

Access site	Radial (N = 419)	Femoral (N = 303)	P-value
Age (years)[a]	58 (50–65)	59 (52–67)	**0.02**
Male (n %)	360 (85.9%)	242 (79.9%)	**0.03**
BMI (Kg/m^2)[a]	25 (24–27)	25 (23–27)	0.15
Risk factors			
Diabetes (n %)	131 (31.2%)	103 (33.9%)	0.46
Hypertension (n %)	172 (41.0%)	145 (47.8%)	0.08
Smoker (n %)	114 (27.2%)	55 (18.1%)	< **0.01**
Family history of CAD (n %)	7 (1.6%)	4 (1.3%)	0.76
Clinical presentation			
STEMI (n %)	190 (45.3%)	94 (31.0%)	< **0.01**
NSTEMI/USA (n %)	137 (32.6%)	100 (33.0%)	0.93
CSA (n %)	93 (22.2%)	109 (35.9%)	< **0.01**
Vascular access site complication			
Oozing	22 (5.3%)	19 (6.3%)	0.62
Hematoma	1 (0.23%)	7 (2.3%)	**0.01**
Ambulation time in hours[a]	1 (1–1)	4 (4–4)	< **0.01**
Discharge in days[b]	1.78 ± 1.08	1.94 ± 1.1	**0.04**

P-value in the bold letter is significant.
Abbreviations:- BMI-body mass index, CSA-chronic stable angina, NSTEMI- non-ST-elevation myocardial infarction, STEMI -ST-elevation myocardial infarction, USA-unstable angina.
[a] Value in median (interquartile range).
[b] Value in mean ± 1 standard deviation.

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Author's contribution

All the authors were involved in [1] substantial contributions to research design, acquisition, analysis, or interpretation of data; [2] drafting the paper or revising it critically; [3] approval of the submitted and final versions.

Declaration of competing interest

There is no conflict of interest of any of the authors about the present study.

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