Original Research Article

Percutaneous vascular closure device of the femoral access site after coronary interventions for acute coronary syndrome -immediate and short term follow-up

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ABSTRACT

Background: Around 7 million patients undergo percutaneous interventional vascular procedures worldwide annually and this number is expected to escalate further in coming years. The aim of this study was to analyse immediate and short term follow up of patients with acute coronary syndrome (ACS) who had undergone percutaneous coronary intervention (PCI) through femoral route and closure with vascular closure device.
Methods: This was non randomised, single centre study and was conducted in a tertiary care institution between January 2013 to June 2014 with 62 ACS patients undergoing femoral access invasive cardiac interventional procedure. Perclose A-T system was used in all patients as closure device. Patients were followed up to 15 days of clinical evaluation.
Results: Of 62 ACS patients, 40 (64.5%) were with non-ST elevation myocardial infarction and 22 (35.5%) patients had history of unstable angina. The perclose device achieved closure within 5 to 10 minutes and all patients were kept in hospital stay for 2 to 3 days. There was one major complication of continuous bleeding, one incidence of small pseudo aneurysm, and two incidences of small hematomas with need of blood transfusion.
Conclusions: This study demonstrates the ability of arterial closure device to safely and effectively achieve arterial closure in patients undergoing percutaneous intervention for ACS.

Keywords: Acute coronary syndrome, Hemostasis, Percutaneous coronary intervention, Vascular closure devices

INTRODUCTION

Around 7 million patients undergo percutaneous interventional vascular procedures worldwide annually and this number is expected to escalate further in coming years.[1] Majority of the procedures are performed via common or superficial femoral artery with an increasing number of procedures being performed via transradial approach. Interventional procedures may necessitate the use of larger sheaths than diagnostic procedures. In addition, the use of heparin and glycoprotein IIb/IIIa inhibitors during percutaneous coronary intervention (PCI) especially in acute coronary syndrome (ACS) makes achieving immediate hemostasis more challenging. Moreover, vascular complications account to be about 6% in some series, which remains the prominent cause of morbidity following cardiac interventional procedures.[2]

Manual compression had been considered the traditional and gold standard approach for closure of arteriotomy site.[3] But with larger sheath sizes, the immobilisation time is prolonged and complication tendency are slightly more with manual compression. Since introduction of vascular closure devices (VCD) in the mid-1990s there was rapid progress in its use.[4,5] Vascular closure devices

have improved patient comfort, and shortened the time needed for hemostasis, ambulation and thereby discharge.[6] Several VCDs are available with different mode and method of closure (intravascular or extravascular), time of hemostasis, time of ambulation and type of healing (primary or secondary).[7] But there was paucity of data to support use of arterial closure devices in patients with ACS. Therefore, we analysed immediate and short term follow up of patients with ACS who had undergone PCI through femoral route and closure with vascular closure device.

METHODS

This was non randomised, single centre study and was conducted in a tertiary care institution between January 2013 to June 2014 with 62 ACS patients undergoing femoral access invasive cardiac interventional procedure. Patients were selected between the ages of 18 and 75 years who were scheduled emergency coronary interventional procedures. The target vessel lumen diameter was at least 6 mm and 7 Fr arterial sheaths were utilised.

Patients were excluded if they had a body mass index (BMI) of <20 or >40, previous femoral arterial access within 3 months, any bleeding diathesis or anaemia. ST elevation myocardial infarction (STEMI), Cardiogenic shock, hemodynamic unstable patients were excluded. All patients underwent iliac and femoral angiogram prior to closure. Outcomes evaluated include time to hemostasis, time to ambulation, rates of vascular complications. Vascular complications that were evaluated include major complications including vascular injury requiring surgical repair, need for blood transfusion, groin site hematoma, femoral artery thrombus, deep vein thrombosis and pseudo aneurysm. Patients were followed up to 15 days of clinical evaluation.

Device characteristics

We used closure device, Perclose (Abbott Vascular, Redwood city, CA, USA) in all cases, which is suture based device. The Perclose A-T system (auto tie) is newly designed to deliver polyester suture to close femoral artery puncture sites following diagnostic or interventional procedures. The 6 Fr Perclose A-T has one suture and two needles, and is designed for use in 5 Fr to 8 Fr access sites.

Definition and endpoints

Hemostasis was defined as no subcutaneous oozing without hematoma. Manual compression was given for two to three minutes soon after device sheath removal. The time to hemostasis was measured as time between removal of arterial device and completion of manual compression. Patients were allowed to sit only after 2 to 4 hours of bed rest. Bleeding was defined as hematocrit

drop ≥ 10 g/ dL; and or haemoglobin drop of ≥ 3 g/dL; transfusion of whole blood or packed red blood cells; surgical intervention to reverse bleeding. Independent predictors of complications were evaluated including anticoagulant strategy, age, gender, body mass index (BMI), hypertension, and diabetes.

RESULTS

Baseline characteristics are presented in Table 1. A total of 62 acute coronary syndrome (ACS) patients were enrolled in the study. Mean age of population being studied was 63.2±10.4 years. Forty patients (64.5%) were with non-ST elevation myocardial infarction (NSTEMI) and 22 (35.5%) patients had history of unstable angina (UA) and both groups were taken for early percutaneous coronary intervention (PCI) within 24 - 72 hours. Out of total 62 patients, 70.9% were male sex, 67.7% were hypertensives and 57.4% were diabetic. 28 patients (45.1%) were slightly obese with BMI >30 Kg/m^2.

Table 1: Baseline and procedural characteristics.

Characteristics	N = 62 patients
Age (mean ± SD, years)	63.2±10.4
Male, n (%)	44 (70.9%)
Hypertension, n (%)	42 (67.7%)
Diabetes, n (%)	36 (57.4%)
BMI >30Kg/m^2, n (%)	28 (45.1%)
NSTEMI, n (%)	40 (64.5%)
Unstable angina, n (%)	22 (35.5%)
Heparin, n (%)	55 (88.7%)
Gp IIb/IIIa inhibitor, n (%)	14 (22.5%)
Bivalirudin, n (%)	7 (11.2%)

BMI = Body mass index; NSTEMI = Non-ST elevation myocardial infarction.

Unfractionated heparin was used in all patients as bolus 5000 units followed by maintenance dose with ACT 250 -270 except in 7 patients (11.2%) where bivalirudin was used as anticoagulant. Glycoprotein IIb/IIIa inhibitor (Tirofiban) was used as per bodyweight for 14 patients (22.5%) and showed no additional risk of bleeding. Using Perclose device, hemostasis was accomplished within 5 to 10 minutes with activated clotting time (ACT) between 170 to 250. The hemostasis in both groups (NSTEMI and UA) also didn't demonstrate any dependence on type of anti-platelets and anticoagulants. The Perclose device achieved closure within 5 to 10 minutes and all patients were kept in hospital stay for 2 to 3 days.

Complications

In 62 cases performed, 1 major vascular complication was occurred as continuous bleeding at the puncture site which was treated with femoral surgical arterial repair. The bleeding probably related to incomplete closure due to device procedure failure. 1 patient had small pseudo aneurysm with size 1.5 x 1.2 mm on duplex

ultrasonography which was treated conservatively. 2 patients had minor hematoma which did not require blood transfusion. At 15 days, short term follow up, 8 patients missed follow up at hospital but there were no local complications upon telephonic follow up. 1 patient had local infection which was treated with 5 days' antibiotics and healed after that. All the minor and major complication subsets were having body mass index (BMI) of more than 30 Kg/m².

DISCUSSION

Femoral complications following vascular access are inevitable and proportion of non-coronary vascular complications ranges from 2-6% following PCI.[1] With an intention to reduce the incidence of these complications, VCDs have been introduced as adjuncts or alternative to manual compression for achieving rapid hemostasis.[8] VCDs can be classified as either active closure devices, which include devices that close the arteriotomy site via either suture devices, clips or collagen plug devices, or passive closure devices, which include devices that help with compression such as clamps, enhanced coagulation and sealants.[6] There is no data to suggest clearly an increased risk of vascular complications with VCD use. Some studies suggest that VCDs decrease complications compared with manual compression, some studies suggest a potentially increased risk with VCDs, and some suggest complications rates are similar.[9-11]

The ACUITY trial showed a reduction in major bleeding complications in patients with acute coronary syndromes managed invasively when the transradial approach was used and this has been consolidated by many meta-analyses.[12,13] This is most likely due to the relative ease of compression of the radial artery. In present study, the access for PCI was femoral, which is more prone to complications than the transradial route. The VCD used was Perclose A-T system. Perclose is the original suture-mediated, intravascular closure device available in multiple configurations allowing closure of artery punctures up to 10 Fr. It is approved for both diagnostic and interventional procedures. A previous study had utilized Perclose for arteriotomy closure after percutaneous abdominal aorta endograft stenting reported promising results and success rate of 85%.[14] Various other studies have demonstrated device success of the Perclose devices as 91–94%.[15-17] While traditionally considered difficult to handle and utilize, the latest versions of Perclose, like Perclose A-T system have improved ease of use. In this study, use of Perclose A-T system was associated with one major complication of continuous bleeding, one incidence of small pseudo aneurysm, and two incidences of small hematomas with need of blood transfusion.

Applegate et al. had conducted a prospective study in 4525 patients with an aim to compare manual compression vs. Angio-Seal vs. Perclose in patients treated with anticoagulation and GP IIb/IIIa inhibitors during PCI, reported that vascular complication rates with VCDs were similar to or lower than with manual compression.[15] Another study investigated whether VCDs reduce the risk of vascular complications in selected patient populations. They observed that the use of closure devices was associated with a lower vascular complication rate (p<0.002) and a shorter length of hospital stay (p<0.001).[18] However, every advantage has a disadvantage, so is with VCDs. These are also allied with some of the risks like increased the risk of groin infection and leg ischemia and some complications requiring surgical repair.[19,20] But, these can be avoided with some measures. For controlling infection during cardiac catheterization, it is recommending to use aseptic technique, including a cap, mask, sterile gown, sterile gloves, and a large sterile sheet.[21] Moreover, apt measures should be taken while placement of VCD and the risk of vascular complications can be avoided by taking into consideration, the multiple factors (both patient related and device related) applicable during the procedure.

Study limitations

This is a single centre study and there was no direct comparison with manual compression or other vascular closure devices.

CONCLUSION

The Perclose is novel vascular closure device that can be used in percutaneous coronary intervention in ACS with good hemostasis in femoral artery puncture site. The material used is biologically inert with good short term follow up. It prevents major peripheral complication in high risk subset like ACS. This study demonstrates the ability of arterial closure device to safely and effectively achieve arterial closure in patients undergoing percutaneous intervention for ACS. The Perclose device achieved closure within 5 to 10 minutes. Early hemostasis has significant role in decreasing in-hospital stay and avoids prolonged bed rest.

REFERENCES

1. Patel MR, Jneid H, Derdeyn CP, Klein LW, Levine GN, Lookstein RA, et al. Arteriotomy Closure Devices for Cardiovascular Procedures A Scientific Statement From the American Heart Association. Circulation. 2010;122(18):1882-93.
2. Meyerson SL, Feldman T, Desai TR, Leef J, Schwartz LB, Mckinsey JF. Anglographic Access Site Complications in the Era of Arterial Closure Devices. Vascular and endovascular surgery. 2002;36(2):137-44.

3. Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: the second decade. J Amer Colle Cardio. 2007;50(17):1617-26.
4. Behan M, Large J, Patel N, Lloyd G, Sulke A. A randomised controlled trial comparing the routine use of an Angio-Seal STS device strategy with conventional femoral haemostasis methods in a district general hospital. Inter J clin pract. 2007;61(3):367-72.
5. Alshehri AM, Elsharawy M. Comparison of Angioseal and Manual Compression in Patients Undergoing Transfemoral Coronary and Peripheral Vascular Interventional Procedures. Inter J Ang. 2015;24(02):133-6.
6. Schwartz BG, Burstein S, Economides C, Kloner RA, Shavelle DM, Mayeda GS. Review of vascular closure devices. J Inv Cardio. 2010;22(12):599-607.
7. Rashid MN, Bailey SR. Percutaneous femoral access and vascular closure devices. Science Innovation Synergy Yearbook 2007. 2008.
8. Tordini A, Polkampally PR, Jovin IS. Vascular closure devices in percutaneous coronary and peripheral interventions: rationale and results. Interv Cardio. 2012;4(5):569-76.
9. Vaitkus PT. A meta-analysis of percutaneous vascular closure devices after diagnostic catheterization and percutaneous coronary intervention. Journal Inv Cardio. 2004;16(5):243-6.
10. Dangas G, Mehran R, Kokolis S, Feldman D, Satler LF, Pichard AD, et al. Vascular complications after percutaneous coronary interventions following hemostasis with manual compression versus arteriotomy closure devices. J Amer Colle Cardio. 2001;38(3):638-41.
11. Applegate RJ, Sacrinty MT, Kutcher MA, Baki TT, Gandhi SK, Santos RM, et al. Propensity score analysis of vascular complications after diagnostic cardiac catheterization and percutaneous coronary intervention using thrombin hemostatic patch-facilitated manual compression. J Inv Cardio. 2007;19(4):164-70.
12. Hamon M, Rasmussen LH, Manoukian SV, Cequier A, Lincoff MA, Rupprecht H-J, et al. Choice of arterial access site and outcomes in patients with acute coronary syndromes managed with an early invasive strategy: the ACUITY trial. EuroIntervention. 2009;5(1):115-20.
13. Vorobcsuk A, Kónyi A, Aradi D, Horváth IG, Ungi I, Louvard Y, et al. Transradial versus transfemoral percutaneous coronary intervention in acute myocardial infarction: systematic overview and meta-analysis. Amer heart J. 2009;158(5):814-21.
14. Torsello G, Tessarek J, Kasprzak B, Klenk E. Treatment of aortic aneurysm with a complete percutaneous technique. Deutsche medizinische Wochenschrift. 2002;127(27):1453-7.
15. Applegate RJ, Grabarczyk MA, Little WC, Craven T, Walkup M, Kahl FR, et al. Vascular closure devices in patients treated with anticoagulation and IIb/IIIa receptor inhibitors during percutaneous revascularization. J Amer Colle Cardio. 2002;40(1):78-83.
16. Gerckens U, Cattelaens N, Lampe E-G, Grube E. Management of arterial puncture site after catheterization procedures: evaluating a suture-mediated closure device. Amer J Cardio. 1999;83(12):1658-63.
17. Baim DS, Knopf WD, Hinohara T, Schwarten DE, Schatz RA, Pinkerton CA, et al. Suture-mediated closure of the femoral access site after cardiac catheterization: results of the suture to ambulate and discharge (STAND I and STAND II) trials. Amer J Cardio. 2000;85(7):864-9.
18. Resnic FS, Blake GJ, Ohno-Machado L, Selwyn AP, Popma JJ, Rogers C. Vascular closure devices and the risk of vascular complications after percutaneous coronary intervention in patients receiving glycoprotein IIb-IIIa inhibitors. Amer J Cardio. 2001;88(5):493-6.
19. Koreny M, Riedmüller E, Nikfardjam M, Siostrzonek P, Müllner M. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. Jama. 2004;291(3):350-7.
20. Biancari F, D'Andrea V, Di Marco C, Savino G, Tiozzo V, Catania A. Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty. Amer J Cardio. 2010;159(4):518-31.
21. Chambers CE, Eisenhauer MD, McNicol LB, Block PC, Phillips WJ, Dehmer GJ, et al. Infection control guidelines for the cardiac catheterization laboratory: society guidelines revisited. Catheterization and Cardiovascular Interventions. 2006;67(1):78-86.