Original Research

Minimizing Femoral Access Complications in Patients Undergoing Percutaneous Coronary Interventions: A Proposed Strategy of Bony Landmark Guided Femoral Access, Routine Access Site Angiography and Appropriate Use of Closure Devices

Ioannis N. Tzinieris, Georgios I. Papaioannou, Spyridon I. Dragomanovits, Efthymios N. Deliargyris

Interventional Cardiology Department, Athens Medical Center, Athens, Greece

Introduction: In this study we report local complication rates in patients undergoing percutaneous coronary intervention (PCI) utilizing a strategy of fluoroscopically guided puncture and preferential use of a closure device based on access site angiography.

Methods: We included 201 consecutive PCIs where the initial puncture was fluoroscopically guided using the inferior border of the femoral head as the guiding bony landmark. At the end of each PCI, access site angiography determined whether the deployment of a closure device, specifically the Angioseal™ device, was anatomically feasible. The access site was evaluated 3 and 24 hours post PCI. All patients were contacted by phone 30 days following the index procedure and questioned about any further incidents following hospital discharge.

Results: Deployment of the Angioseal™ device was feasible in 76% (153/201) of cases with a success rate over 99% (152/153). In the remaining 48 patients the access site was managed with manual compression, elastic bandage placement and prolonged bed rest. Patients who received the Angioseal™ device could be mobilized after 6 hours, while the group that was managed with manual compression required overnight bed rest. Local complication rates where very low for the study group as a whole (1.5%) without significant differences associated with the use of the Angioseal™ device. We did not observe any significant influence of the established risk factors for local complications, such as age, female sex, sheath size, elevated systolic blood pressure or use of glycoprotein IIb/IIIa platelet inhibitors, within our study population.

Conclusion: The appropriate use of the Angioseal™ is feasible in three quarters of patients undergoing PCI and allows for more rapid mobilization while ensuring very low local complication rates.

The number of percutaneous coronary interventions (PCI) performed worldwide has been growing rapidly due to important technological advances, improved long term clinical outcomes, and also the lower morbidity associated with PCI when compared with the surgical treatment of coronary artery disease.[1] At the end of each PCI the operators need to manage the site of arterial access, which for the majority of cases is through the femoral route. This part of the procedure remains an important step, since over the years it represents the most common source of PCI-associated complications. Specifically, for cases performed via

the femoral route, potential complications include the formation of a hematoma, frank hemorrhage, retroperitoneal bleeding, pseudoaneurysm or arteriovenous fistula formation, or even the loss of peripheral pulses with associated leg ischemia.[2] The most common underlying cause for local complications remains the anatomically incorrect arteriotomy site (too high above the inguinal ligament, or too low in one of the femoral artery branches) but there are also other patient-related risk factors, such as female sex, advanced age, a high systolic blood pressure, and even the inappropriate use of closure devices.

In addition, the introduction of more potent antiplatelet and anticoagulant regimens (low molecular weight heparins, glycoprotein [GP] IIb/IIIa inhibitors, high doses of clopidogrel, direct thrombin inhibitors, etc.) has contributed to significant reductions in the ischemic complications of PCI, at the expense, however, of persistently high local complication rates (with the exception of the recently introduced direct thrombin inhibitors, specifically bivalirudin).[3-6] Specifically, while a recent meta-analysis demonstrated a 90% reduction in emergency coronary artery bypass operations in patients undergoing PCI over a ten-year period,[7] in another recent meta-analysis including almost 13,898 PCIs the rates of local complications, even in contemporary practice, still remain high with an overall incidence of 3.4%.[8]

In recent years, a number of closure device systems have been introduced with the purpose of reducing immobilization times post PCI and the hope of reducing the frequency of local complications. Large clinical trials have indeed demonstrated the patients' preference for the use of these closure devices compared to the long bed rest associated with the more traditional manual compression. However, in these studies reductions in local complications associated with the use of these devices were not demonstrated.[9-12]

There are various mechanisms by which these closure devices can achieve hemostasis, including the placement of bio-absorbable collagen plugs, the percutaneous placement of absorbable sutures on the femoral artery wall, local injections of thrombin, and finally the placement of superficial pads that promote ionic attraction of red cells and platelets to the arteriotomy site.[13] The selection of a specific closure device system relies primarily on the operator's preference, but also on some of the technical characteristics of the device and specific anatomical features of each patient.

The Angioseal™ closure device, which was used exclusively in our study population, is based on the placement of a bioabsorbable anchor inside the arterial lumen, which is then retracted via a string against the intimal surface of the femoral artery. The arteriotomy is subsequently sealed by the advancement of a collagen plug over the string, which tamponades the exterior wall of the femoral artery. The whole system is absorbable within 3-4 weeks following placement. However, as a study by Applegate et al has demonstrated, restick on the same side is feasible as early as necessary (even the same day) as long as it is 1 cm above or below the previous stick.[14]

Multiple published reports have demonstrated a quick operator learning curve, excellent device performance, significant reductions in patient immobilization times and acceptable rates of local complications.[15-17] Importantly, in a prospective study by Michalis et al that included 146 patients who underwent PCI, the Angioseal™ device achieved earlier ambulation compared with two other closure device systems.[18] In this study we evaluated whether a strategy aimed at achieving high rates of anatomically correct puncture sites in conjunction with the angiographically guided appropriate use of the Angioseal™ could result in improved rates of local complications in an unselected, consecutive sample of 201 PCI procedures.

Methods

We included 201 consecutive PCIs performed at Athens Medical Center between January 2004 and June 2006. The indications for PCI included silent ischemia, stable angina, and acute coronary syndromes, including primary PCI for ST-elevation myocardial infarction (STEMI). All patients were on aspirin prior to PCI and a large percentage of patients were also on clopidogrel treatment. For those patients not already on clopidogrel, a loading dose of 300 mg was given at the time of the PCI. The first 195 PCIs were performed with unfractionated heparin (70 units/kg without GP IIb/IIIa inhibitors or 50 units/kg with GP IIb/IIIa inhibitors), while the last 6 cases were performed with the weight base protocol of bivalirudin (Angiox™). In the cases where the operators deemed the use of GP IIb/IIIa inhibitors necessary the double-bolus eptifibatide regimen was used (Integrilin™).

At the start of each case the site of the arterial stick was guided by fluoroscopy using the inferior border of the femoral head as a landmark (Figure 1).[19-20] Accordingly, the skin was nicked at the level of the inferior border of the femoral head, and the Seldinger needle advanced at a 45° angle, aiming for the entry point

Figure 1. Fluoroscopic guidance of the femoral stick. The tip of the needle holder corresponds to the inferior border of the femoral head and represents the level for the skin nick. Subsequently, the Seldinger needle is advanced at a 45˚ angle, so that entry into the femoral artery is at the level of the middle of the femoral head.
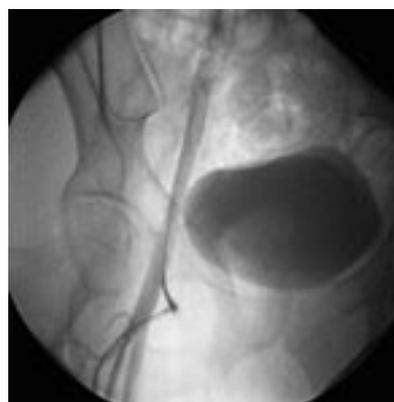
Figure 2. Example of suitable anatomy for the placement of the Angioseal™ device. Arterial entry is in the common femoral artery and there is no local atherosclerosis.

Figure 3. Example of local atherosclerosis. In this case there was significant atherosclerosis present at the entry site (arrow), precluding the use of a closure device. The site was managed with external manual compression.
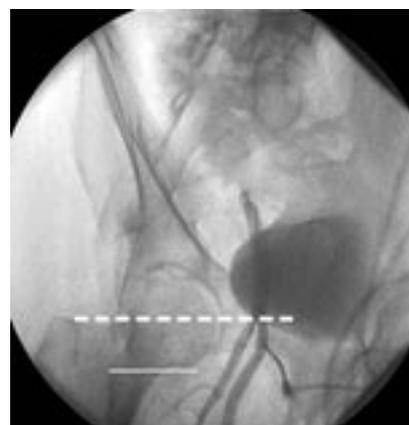
Figure 4. Example of a high bifurcation of the common femoral artery (dashed line). Despite arterial entry at the correct level (thin, solid line) the sheath was placed in a branch of the common femoral artery. In this case the use of a closure device was not deemed appropriate and the access site was managed with external manual compression.

inside the common femoral artery to be at the level of the middle of the femoral head. At the completion of each PCI an angiogram was performed via the femoral sheath to demonstrate the exact location of sheath entry and to evaluate the presence of atherosclerotic disease (Figures 2-4).

Our strategy aimed at placement of the Angioseal™ device in all patients. The Angioseal™ device was not used when the sheath entry point was at the bifurcation of the common femoral artery, or in one of the branches, or when significant atherosclerosis was present. A 6 F Angioseal™ device was used for cases completed using 6 F angioplasty systems while an 8 F

Angioseal™ device was used in the cases completed with 7 F systems.

In the cases where the use of the Angioseal™ was deemed inappropriate, access site hemostasis was achieved with manual compression until the activated coagulation time dropped below 150 s, followed by elastic pressure bandage placement and bed rest for 12-24 hours. The arteriotomy site and the peripheral pulses were clinically evaluated 3 hours after the end of the PCI and also on the morning of discharge. The clinical status of all patients was evaluated through a phone interview at 30 days following the PCI.

Statistical analysis

All statistical analyses were performed with the SPSS 11.01 software (SPSS, Inc., Chicago, IL, USA). Continuous variables are expressed as mean ± SD. For comparisons between continuous variables we used the t-test or Mann-Whitney test and for comparisons of dichotomous variables the χ^2 or Fisher's exact tests were used. A p-value <0.05 was deemed statistically significant.

Results

Baseline characteristics for the 201 patients included in the study are outlined in Table 1. The age was 61.6 ± 12 years and 85% of the study patients were male. The majority of PCIs were performed using 6 F systems (86%), while GP IIb/IIIa inhibitors were used in 37% of cases. Based on the sheath angiogram performed at the end of each PCI, deployment of the Angioseal™ device was deemed appropriate in 153/201 patients (76.1%). Table 2 also lists the characteristics for the 2

groups of patients according to the use or not of the closure device. As stated earlier, we considered 2 exclusion criteria for the use of the Angioseal™ device: namely a high bifurcation of the common femoral artery (sheath entry at the bifurcation or in one of the branches-profunda or superficial femoral artery), which was present in 31 patients (15.4%), or significant local atherosclerosis, which was evident in 17 patients (8.4%). The mean systolic arterial pressure for the group as a whole at the time of PCI was 130.3 mmHg.

The overall incidence of local complications for the 201 patients was low at 1.5% (3/201) and compared very favorably with international benchmarks (3-4%). One of the three complications may be considered major, as it involved the acute occlusion of the common femoral artery with absence of peripheral pulses in a patient with chronic atrial fibrillation who had discontinued his anticoagulation therapy for 3 days prior to the index PCI. Following the diagnosis during the routine clinical check 24 hours post-PCI, the patient underwent vascular surgery, where intraoperatively an occlusion of the common femoral artery central to

Table 1. Baseline characteristics of the study group as a whole and of the two groups according to the use or not of the Angioseal™ device. There was no significant difference between the groups in any of the parameters listed.

	Total cases (n=201)	Angioseal™ (n=153)	Manual compression (n=48)
Age (yrs.)	61.6 ± 11.6	60.3 ± 11.5	65.2 ± 11.2
Male (%)	140 (84.8%)	106 (84.8%)	34 (85%)
Sheath size 6F	142 (86%)	110 (88%)	32 (80%)
Sheath size 7F	23 (14%)	15 (12%)	8 (20%)
SBP (mmHg)	130 ± 21	130 ± 19	131 ± 25
GP IIb/IIIa	61 (37%)	48 (38.4%)	13 (32.5%)

GP IIb/IIIa – glycoprotein IIb/IIIa inhibitors; SBP – systolic blood pressure.

Table 2. Rates of local complications. There was no significant difference between the Angioseal™ and manual compression groups.

	Total cases (n=201)	Angioseal™ (n=153)	Manual compression (n=48)
Hematoma	0	0	0
Hemorrhage	0	0	0
Retroperitoneal bleeding	0	0	0
Psedoaneurysm	0	0	0
Arteriovenous fistula	2	1	1
Loss of peripheral pulses	1	1	0
Transfusion	0	0	0
Total	3 (1.49%)	2 (1.3%)	1 (2.1%)

the closure device was noted. It is conceivable that the closure device may have not been involved in the acute occlusion of the common femoral artery and the culprit may have been a left atrial embolus due to the atrial fibrillation. The patient ended up prolonging his hospital stay by one day and was discharged the following day with restored peripheral pulses.

During the clinical check 24 hours post-PCI we identified 2 cases of new femoral bruits. Ultrasound examination confirmed the presence of small arteriovenous fistulas in both cases, which were successfully managed using ultrasound-guided external compression for 30 minutes. Both patients were discharged the same day and had a follow-up ultrasound a week later, confirming the sealing of the arteriovenous fistula. It is interesting to note that in both cases the patients received GP IIb/IIIa inhibitors during PCI. In addition, there was one incidence of device malfunction (lack of a collagen plug in the system), which was not associated with any clinical sequelae since hemostasis was achieved with prolonged manual compression.

Overall, we did not observe any significant hematomas (greater than 10 cm), pseudoaneurysms, retroperitoneal bleeds, bleeding incidences (minor or major), and there were no blood transfusions among the 201 cases. The procedural outcomes were satisfactory for the group as a whole and are outlined in Table 3. Finally, there were no further clinical events related to the arteriotomy site reported by any of the patients in the 30-day telephone interview.

Discussion

Our data suggest that the appropriate use of the Angioseal™ closure device is feasible in about three quarters of an unselected PCI population and can improve patient comfort by reducing immobilization times while securing very favorable local complication rates. Length of hospital stay was not different according to use of the Angioseal™ device, since it is our policy to keep all patients undergoing an angioplasty procedure for an overnight stay. We believe that the determining factor for the satisfactory results presented here was the careful and conservative selection of the cases that could receive the device according to the post-procedural access site angiogram.

The strategy we followed included the routine fluoroscopic guidance of each arterial puncture based on bony landmarks, as well as a routine access site angiogram at the end of the procedure. Our goal was to achieve sheath entry at the level of the middle of the femoral head. The anatomic advantages of this location are that in the majority of patients the sheath enters the common femoral artery instead of side branches; the entry site is below the inguinal ligament, thereby eliminating the risk of a retroperitoneal hematoma;[21] and the presence of bony structures under the arteriotomy site allows much more effective external manual compression. Previous anatomical studies have demonstrated the common femoral artery bifurcation to be below the inferior border of the femoral head in approximate 76-80% of patients, between the inferior border and the middle of the femoral head in about 12-15%, while only in less than 5% of the patients was the common femoral bifurcation above the femoral head.[22-24] In accordance with that data, in our 201 cases sheath entry was achieved in the common femoral artery in 84% (170/201) of cases, while the puncture was at or below the bifurcation in 16% (31/201) of cases. In addition, in 8% (17/201) of cases we noted significant local atherosclerosis. Overall, in 24% (48/201) of cases the use of the Angioseal™ closure device was not deemed safe and the access site was handled by manual compression and prolonged bed rest. It is important to note that the ma-

Table 3. In-lab outcomes. There was no significant difference between the Angioseal™ and manual compression groups.

	Total cases (n=201)	Angioseal™ (n=153)	Manual compression (n=48)
Success rate	197/201 (98%)	150/153 (98%)	47/48 (98%)
Death	0	0	0
Myocardial infarction	0	1	0
Stroke	0	0	0
Emergency CABG	0	0	0
Emergency reperfusion	0	0	0

CABG – coronary artery bypass grafting.

jority of cases (86%) were performed with 6 F angioplasty systems and the rate of GP IIb/IIIa inhibitor use was 37%, which is consistent with European standards. It is estimated that the use of the Angioseal™ device increased the total cost of the angioplasty procedure by approximately 3%.

The percentage of local complications observed in our study group (3/201, 1.5%) of unselected PCI cases (including primary PCI for STEMI) compares favorably with the rates published in the international literature (3-4%).[8] Overall, only one patient (1/201, 0.5%) experienced prolongation of hospital stay by one day, due to vascular surgery repair, and not a single patient required a blood transfusion. We did not observe any infections of the arteriotomy site, a potentially catastrophic but extremely rare complication. We believe our strategy of fluoroscopic guidance and routine postprocedure access site angiography protected us from the most common risk factor for local complications, namely the anatomically incorrect position of sheath entry.[25] The rest of the risk factors that have been associated with local complications, such us the intensity of antithrombotic or antiplatelet therapy, sheath size, systolic arterial pressure, advanced age and female sex, did not appear to influence our very low percentage of local complications. We believe that the fact that none of these risk factors was associated with increased complications underscores the value of an anatomically correct arteriotomy site.

Our study is limited by the fact that it was not randomized regarding the use of the Angioseal™ device versus the classic manual compression; it also involved a relatively small number of cases. However, an important advantage of the study is that it included consecutive cases with a variety of clinical indications (stable angina, acute coronary syndrome and primary PCI for STEMI), thus allowing for extrapolation of the results to a very broad population of patients undergoing PCI. Finally, we have to emphasize the fact that our findings can only be applied to the use of the specific closure device (Angioseal™) and may not necessarily be applicable to other devices whose mechanism of action and indications or contraindications for use may be different.

References

1. American Heart Association: Heart disease and stroke statistics (2006 Update).
2. Samal AK, White CJ: Percutaneous management of access site complications. Catheter Cardiovasc Interv 2002; 57: 12-23.
3. Exaire JE, Tcheng JE, Kereiakes DJ, et al: Closure devices and vascular complications among percutaneous coronary intervention patients receiving enoxaparin, glycoprotein IIb/IIIa inhibitors, and clopidogrel. Catheter Cardiovasc Interv 2005; 64: 373-374.
4. Applegate RJ, Grabarczyk MA, Little WC, et al: Vascular closure devices in patients treated with anticoagulation and IIb/IIIa receptor inhibitors during percutaneous revascularization. J Am Cardiol 2002; 40: 78-83.
5. El-Jack SS, Ruygrok PN, Webster MW, et al: Effectiveness of manual pressure hemostasis following transfemoral coronary angiography in patients on therapeutic warfarin anticoagulation. Am J Cardiol 2006; 97: 485-489.
6. Nikolsky E, Mehran R, Halkin A, et al: Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures. J Am Cardiol 2004; 44: 1200-1209.
7. Yang EH, Gumina RJ, Lennon RJ, et al: Emergency coronary artery bypass surgery for percutaneous coronary interventions: changes in the incidence, clinical characteristics, and indications from 1979 to 2003. J Am Cardiol 2005; 46: 2004-2009.
8. Tavris DR, Dey S, Albrecht B, et al: Risk of local adverse events following cardiac catheterization by hemostasis device use - Phase II. J Invasive Cardiol 2005; 17: 644-650.
9. Koreny M, Riedmuller E, Nikfardjam M, et al: Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. JAMA 2004; 291: 350-357.
10. Simon A, Bumgarner B, Clark K, et al: Manual versus mechanical compression for femoral artery hemostasis after cardiac catheterization. Am J Crit Care 1998; 7: 308-313.
11. Lehmann KG, Heath-Lange SJ, Ferris ST: Randomized comparison of hemostasis techniques after invasive cardiovascular procedures. Am Heart J 1999; 138: 1118-1125.
12. Schickel SI, Adkisson P, Miracle V, et al: Achieving femoral artery hemostasis after cardiac catheterization: a comparison of methods. Am J Crit Care 1999; 8: 406-409.
13. Munoz OC, Jimenez J: Vascular Closure Devices. Interventional Cardiology Secrets. Hanley and Belfus 2003: pp 143-146.
14. Applegate RJ, Rankin KM, Little WC, et al: Restick following initial Angioseal use. Catheter Cardiovasc Interv 2003; 58: 181-184.
15. Eggebrecht H, Haude M, Woertgen U, et al: Systematic use of a collagen-based vascular closure device immediately after cardiac catheterization procedures in 1,317 consecutive patients. Catheter Cardiovasc Interv 2002; 57: 496.
16. Vaitkus PT: A meta-analysis of percutaneous vascular closure devices after diagnostic catheterization and percutaneous coronary intervention. J Invasive Cardiol 2004; 16: 243-246.
17. Lasic Z, Mehran R, Dangas G, et al: Comparison of safety and efficacy between first and second generation of angio-seal closure devices in interventional patients. J Invasive Cardiol 2004; 16: 356-358.
18. Michalis LK, Rees MR, Patsouras D, et al: A prospective randomized trial comparing the safety and efficacy of three commercially available closure decices (Angioseal, Vasoseal and Duett). Cardiovasc Intervent Radiol 2002; 25: 423-429.
19. Baim DS: Percutaneous approach, including transseptal and apical puncture, in Baim DS, Grossman W (ed): Cardiac Catheterization, Angiography, and Intervention, 5th Edition. Williams and Wilkins, Maryland, 1996: pp 57-81.
20. Patel MR, Holmes DR Jr: Access site for cardiac catheterization. Am Heart J 2004; 147: 1-2.

21. Omar Farouque HM, Tremmel JA, Shabari FR, et al: Risk factors for the development of retroperitoneal hematoma after percutaneous coronary intervention in the era of glycoprotein IIb/IIIa inhibitors and vascular closure devices. J Am Cardiol 2005; 45: 363-368.

22. Garrett PD, Eckart RE, Bauch TD, et al: Fluoroscopic localization of the femoral head as a landmark for common femoral artery cannulation. Catheter Cardiovasc Interv 2005; 65: 205-207.

23. Schnyder G, Sawhney N, Whisenant B, et al: Common femoral artery anatomy is influenced by demographics and comorbidity: implications for cardiac and peripheral invasive studies. Catheter Cardiovasc Interv 2001; 53: 289-295.

24. Spector KS, Lawson WE: Optimizing safe femoral access during cardiac catheterization. Catheter Cardiovasc Interv 2001; 53: 209-212.

25. Sherev DA, Shaw RE, Brent BN: Angiographic predictors of femoral access site complications: implication for planned percutaneous coronary intervention. Catheter Cardiovasc Interv 2005; 65: 196-202.