Comparison of Angioseal and Manual Compression in Patients Undergoing Transfemoral Coronary and Peripheral Vascular Interventional Procedures

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Abstract

Vascular closure devices (VCDs) were introduced in the early 1990s with the goal of limiting the time, labor, bed rest, and patient discomfort associated with manual compression (MC) for hemostasis after cardiovascular interventions. However, its advantage over MC has not been extensively studied after interventional procedures. The aim of this study was to do prospective, randomized study comparing the safety and efficacy of the Angio-Seal (AS) to that of MC in patients undergoing transfemoral coronary and peripheral vascular interventional procedure.

A prospective, randomized trial was undertaken on consecutive series of patients admitted to King Fahd Hospital of the University for transfemoral coronary and peripheral vascular interventional procedures over 1 year. The study was designed to compare the hemostasis time in minutes and the incidence of vascular complications in patients receiving AS with those undergoing MC. All patients were on antiplatelets and received heparin during the procedure.

During the study period, 160 patients were included, 80 in each group. There was a significant difference in mean time to hemostasis in minutes (15.83 ± 1.63 minutes for MC and 0.42 ± 0.04 minutes for the AS; $p < 0.001$), time to ambulation in minutes (280 ± 15 for MC and 120 for AS; $p = 0.04$) and in minor complications (33.8% in MC vs. AS 5%; $p < 0.001$). However, the major complication rate did not significantly differ between the two groups (0% in AS vs. 2.5% in MC; $p = 0.15$).

AS was found to achieve rapid closure of the femoral access site safely in patients undergoing coronary and peripheral vascular interventional procedures under antiplatelets and systemic heparinization.

Keywords

- ▶ coronary artery disease
- ▶ peripheral artery disease
- ▶ vascular closure devices

Manual compression (MC) has been the gold standard for hemostasis after femoral catheterization.¹ Vascular closure devices (VCDs) were introduced in the early 1990s with the goal of limiting the time, labor, bed rest, and patient discomfort associated with MC for hemostasis after cardiovascular interventions.² However, its advantage over MC has not been extensively studied after interventional procedures. The aim of this study was to do prospective, randomized study comparing the

safety and efficacy of the Angio-Seal (AS) to that of MC in patients undergoing transfemoral coronary and peripheral vascular interventional procedure.

Patients and Methods

A prospective, randomized trial was undertaken on consecutive series of patients admitted to King Fahd Hospital of the

Table 1 Baseline patient characteristics

Characteristic	No.
Age, y; mean $\pm$ SD	52 $\pm$ 11.62
Sex, male/female	105/55
Smoking, n (%)	92 (57%)
Diabetes, n (%)	120(75%)
Hypertension, n (%)	73(47%)
Renal failure, n (%)	8(5%)
Dyslipidemia, n (%)	122(76%)
BMI, mean $\pm$ SD	29.5 $\pm$ 2.6
CAD/PAD	98/62

Abbreviations: BMI, body mass index; CAD, coronary artery disease; PAD, peripheral arterial disease; SD, standard deviation.

University for transfemoral coronary and peripheral vascular interventional procedures over 1 year. The study was designed to compare the hemostasis time in minutes and the incidence of vascular complications in patients receiving Angio-Seal VIP (AS, St. Jude Medical, Inc., MN) with those undergoing MC for hemostasis after the intervention. The study was approved by local ethical committee. All procedures were performed using a 6-French femoral sheath on the common femoral artery. All the patients were on antiplatelets and received heparin during the procedure. We excluded patients who had any previous femoral artery punctures within 1 week or previous vascular intervention, a puncture of the superficial femoral artery, a preexisting groin hematoma, also patients who had just diagnostic coronary or peripheral angiography or unsuccessful deployment. For MC, patients received compression until either 10 minutes passed or hemostasis occurred, followed by 4 hours' bed rest. Then, the patients were allowed to walk carefully to the restroom. All the patients with AS deployment were permitted to walk carefully to the restroom after 2 hours' bed rest. Compression bandages were applied in any groups if hemostasis was delayed more than 30 minutes. Time from removal of the

sheath to full mobilization was recorded. All patients were expected to be fully mobile 24 hours after AS or MC. All patients had color duplex 24 hours after the procedure. Only acute procedure-related complications were recorded. We defined minor complications as those requiring no further treatment and major complications were those requiring surgery or blood transfusions.

Statistical Analysis

Comparison between prevalence of risk factors in both AS and MC was done. Data of the two groups were summarized either as the mean $\pm$ standard deviation (SD) or as percentage of the risk factors. Differences between the groups were tested for statistical significance using *t*-test, chi-square test or Fisher exact test as appropriate. Significance was set at $p < 0.05$ and 0.05–0.1 was considered as statistical trend for all comparisons. Statistical analyses were performed using SPSS 15 software (Chicago, CA).

Results

During the study period, 160 patients were included, 80 patients in each group. Mean age was 52 $\pm$ 11.62 years (**Table 1**). A total of 118 patients were performed with retrograde arterial access and the rest with antegrade access. In the AS group, 53 patients were CAD and the rest were PAD. There was no significant difference between MC and AS groups as regard to risk factors (**Table 2**).

There was a significant difference in mean time to hemostasis in minutes (15.83 $\pm$ 1.63 minutes for MC and 0.42 $\pm$ 0.04 minutes for the AS; $p < 0.001$), time to ambulation in minutes (280 $\pm$ 15 for MC and 120 for AS; $p = 0.04$), and in minor complications (33.8% in MC vs. AS 5%; $p < 0.001$). Color duplex was done in all cases 24 hours after the procedure and did not show major complications in AS group and big hematoma which required blood transfusion in two patients in MC groups. However, this difference in major complication rate did not reach statistical significant difference (0% in AS vs. 2.5% in MC; $p = 0.15$) (**Table 3**). In the AS group, there was no significant difference of the minor

Table 2 Risk factors for complications in the study groups

	MC	Angioseal	<i>p</i> Value
Age, y; mean $\pm$ SD	59 $\pm$ 9.3	49 $\pm$ 7.8	0.13
Sex, male/female	55/25	50/30	0.23
Smoking	52	42	0.57
Diabetes	62	58	0.59
Hypertension	37	36	0.21
Renal failure	5	3	0.45
Dyslipidemia	64	58	0.38
BMI, mean $\pm$ SD	28.6 $\pm$ 4.2	29.7 $\pm$ 3.5	0.29
CAD/PAD	45/32	53/30	0.27

Abbreviations: BMI, body mass index; CAD, coronary artery disease; PAD, peripheral arterial disease; SD, standard deviation.

Table 3 Primary end points

	MC	Angioseal	p Value
Time to hemostasis (mean $\pm$ SD)	15.83 $\pm$ 1.63	0.42 $\pm$ 0.04	< 0.001
Time to ambulation (mean $\pm$ SD)	280 $\pm$ 15	120	0.04
Major complications, n (%)	2 (2.5%)	0	0.15
Minor complications, n (%)	27 (33.8%)	4 (5%)	< 0.001

Abbreviations: MC, manual compression; SD, standard deviation.

complication rate between the CAD cases and PAD cases (2, 3.7% vs 2, 6.6%; $p = 0.61$).

Discussion

The incidence of vascular access site–related complications is recorded up to 9% after percutaneous coronary interventions.³ Few studies have been published recently, evaluated the safety of the MC, and early ambulation after transfemoral catheterization.^{4,5} Those studies indicated that such procedure is time-consuming and requires prolonged patient bed rest. VCDs have all been used with a hope to minimize these complications. Such devices can contribute to patient's comfort, reduce the time to achieve hemostasis, reduce the time to ambulation, and contribute to an earlier discharge.^{6–9} Hypertensive patients, patients taking anticoagulants, and patients who are unable to lie flat for prolonged periods of time can benefit from the use of these devices posttransfemoral catheterization.¹⁰

Our study evaluated the use of Angio-Seal VIP, a collagen plug–based femoral closure device in patients who underwent coronary or peripheral interventional procedures. Previous studies did not show advantage of other types, for example, Starclose SE (Abbott Vascular Devices, Redwood City, CA)¹¹ over Angio-Seal (AS). AS was found to be not associated with increased bleeding risk compared with standard care with bed rest.¹²

We used AS in both significant coronary and peripheral vascular diseases. Presence of significant PAD was suggested to be associated with an increased risk of complications.¹ VCDs affect the inner arterial lumen, which may represent an extra source of complications in patients with PAD of the lower limbs.¹³ Therefore, patients with significant PAD are considered to be high-risk patients for the use of VCDs.^{1,14,15} Also, the suppliers of VCDs are caution against the use of VCDs in patients with PAD.¹³ In our prospective study, we report comparable complication rates using collagen-based VCDs in patients with PAD when compared to VCDs in patients with coronary artery disease. In another series, major and minor complication rates were 1.7 and 6.7%, respectively, after the utilization of a collagen-based VCDs in patients with PAD¹⁶ compared with 0 and 6.6% in our series. These results are comparable to those with CAD.¹⁷

There was concern about the use of VCDs because of few reported serious complications.^{18–21} However, if complications were looked in big series VCDs were found to be safe. Major complications were reported from 0% in this study and

others¹² – 1.5%.^{11,22} In comparative studies with MC, VCD was found to have similar (present, others²³) or lesser major complications rates^{24,25} than MC. The minor complication rate of AS was 5% in this study as compared with 6.7% in others¹⁷ and was significantly lower than MC. However, other studies did not show significant difference.²⁶

In summary, this prospective study revealed that Angio-Seal achieved rapid closure of the femoral access site safely in patients undergoing coronary and peripheral vascular interventional procedures under antiplatelets and systemic heparinization

Note

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Conflict of Interest

The authors declare that they have no conflict of interest.

References

- 1 Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: the second decade. *J Am Coll Cardiol* 2007;50(17):1617–1626
- 2 Behan MW, Large JK, Patel NR, Lloyd GW, Sulke AN. 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. *Int J Clin Pract* 2007; 61(3):367–372
- 3 Kolluri R, Fowler B, Nandish S. Vascular access complications: diagnosis and management. *Curr Treat Options Cardiovasc Med* 2013;15(2):173–187
- 4 Boztosun B, Günes Y, Yildiz A, et al. Early ambulation after diagnostic heart catheterization. *Angiology* 2007;58(6):743–746
- 5 Doyle BJ, Konz BA, Lennon RJ, Bresnahan JF, Rihal CS, Ting HH. Ambulation 1 hour after diagnostic cardiac catheterization: a prospective study of 1009 procedures. *Mayo Clin Proc* 2006; 81(12):1537–1540
- 6 Hermiller J, Simonton C, Hinohara T, et al. Clinical experience with a circumferential clip-based vascular closure device in diagnostic catheterization. *J Invasive Cardiol* 2005;17(10):504–510
- 7 Ratnam LA, Raja J, Munneke GJ, Morgan RA, Belli AM. Prospective nonrandomized trial of manual compression and Angio-Seal and Starclose arterial closure devices in common femoral punctures. *Cardiovasc Intervent Radiol* 2007;30(2):182–188
- 8 Upponi SS, Ganeshan AG, Warakaulle DR, Phillips-Hughes J, Boardman P, Uberoi R. Angioseal versus manual compression for haemostasis following peripheral vascular diagnostic and interventional procedures—a randomized controlled trial. *Eur J Radiol* 2007;61(2):332–334

- 9 Veasey RA, Large JK, Silberbauer J, et al. A randomised controlled trial comparing StarClose and AngioSeal vascular closure devices in a district general hospital—the SCOAST study. *Int J Clin Pract* 2008;62(6):912–918
- 10 Macdonald S, Thomas SM, Cleveland TJ, Gaines PA. Outpatient vascular intervention: a two-year experience. *Cardiovasc Interv Radiol* 2002;25(5):403–412
- 11 Lucatelli P, Fanelli F, Cannavale A, et al. Angioseal VIP® vs. Starclose SE® closure devices: a comparative analysis in non-cardiological procedures. *J Cardiovasc Surg (Torino)* 2013 (e-pub ahead of print)
- 12 Larsen EN, Hansen CB, Thayssen P, Jensen LO. Immediate mobilization after coronary angiography or percutaneous coronary intervention following hemostasis with the AngioSeal vascular closure device (the MOBS study). *Eur J Cardiovasc Nurs* 2013; 13(5):466–472
- 13 Angio-Seal Vascular Closure Device. Instructions for use. 2010. Available at: www.sjmphprofessional.com
- 14 Piper WD, Malenka DJ, Ryan TJ Jr, et al; Northern New England Cardiovascular Disease Study Group. Predicting vascular complications in percutaneous coronary interventions. *Am Heart J* 2003; 145(6):1022–1029
- 15 Applegate RJ, Sacrinty M, Kutcher MA, et al. Vascular complications with newer generations of angioseal vascular closure devices. *J Interv Cardiol* 2006;19(1):67–74
- 16 Kara K, Mahabadi AA, Berg MH, et al. Utilization of collagen-based vascular closure devices in patients with severe peripheral artery disease. *J Invasive Cardiol* 2013;25(1):19–22
- 17 Silber S. Hemostasis success rates and local complications with collagen after femoral access for cardiac catheterization: analysis of 6007 published patients. *Am Heart J* 1998;135(1):152–156
- 18 Gupta A, Sadiq I, Borer S. Distal embolization from Mynx device. *Conn Med* 2012;76(9):545–548
- 19 Khaldi A, Waldau B, Skowlund C, Velat GJ, Mocco J, Hoh BL. Delayed complication from a percutaneous vascular closure device following a neuro-interventional procedure. *Interv Neuroradiol* 2011; 17(4):495–500
- 20 Durack JC, Thor Johnson D, Fidelman N, Kerlan RK, LaBerge JM. Entrapment of the StarClose Vascular Closure System after attempted common femoral artery deployment. *Cardiovasc Interv Radiol* 2012;35(4):942–944
- 21 Cianci C, Kowal RC, Feghali G, Hohmann S, Stoler RC, Choi JW. Critical lower limb ischemia from an embolized Angio-Seal closure device. *Proc (Bayl Univ Med Cent)* 2013;26(4):398–400
- 22 Kara K, Kahlert P, Mahabadi AA, et al. Comparison of collagen-based vascular closure devices in patients with vs. without severe peripheral artery disease. *J Endovasc Ther* 2014;21(1): 79–84
- 23 McDonald JS, Kallmes DF, Lanzino G, Cloft HJ. Percutaneous closure devices do not reduce the risk of major access site complications in patients undergoing elective carotid stent placement. *J Vasc Interv Radiol* 2013;24(7):1057–1062
- 24 Gurm HS, Hosman C, Share D, Moscucci M, Hansen BB; Blue Cross Blue Shield of Michigan Cardiovascular Consortium. Comparative safety of vascular closure devices and manual closure among patients having percutaneous coronary intervention. *Ann Intern Med* 2013;159(10):660–666
- 25 Gregory D, Midodzi W, Pearce N. Complications with Angio-Seal™ vascular closure devices compared with manual compression after diagnostic cardiac catheterization and percutaneous coronary intervention. *J Interv Cardiol* 2013;26(6):630–638
- 26 Das R, Ahmed K, Athanasiou T, Morgan RA, Belli AM. Arterial closure devices versus manual compression for femoral haemostasis in interventional radiological procedures: a systematic review and meta-analysis. *Cardiovasc Interv Radiol* 2011;34(4):723–738