Femoral access management: comparison between two different vascular closure devices after percutaneous coronary intervention

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Objectives — Several devices have been proposed as an alternative to manual compression (MC) for femoral access management (FAME) following catheterization. Although these devices allow earlier ambulation, they have not always been shown to reduce vascular complications. As a consequence, their cost efficacy is not obvious.

Methods — During MC a special catheter deployed temporarily within the artery to achieve haemostasis (Bio-DISC™) (BD) was compared with an anchor-collagen based system Angio-Seal™ (AS) among 463 consecutive patients undergoing PCI. We examined vascular or systemic complications, nursing time spent to puncture site management and patient's satisfaction.

Results — Relative contra-indications to the use of vascular closure devices were encountered in 158 patients. There were no significant differences in baseline characteristics between the patients assigned to each of the 3 treatment groups. The deployment success rate was 98% for AS and 90% for BD ($p = 0.037$). Vascular complications occurred in 10.8%, 4.0% and 5.8% (p: NS) of MC, AS and BD patients, respectively. The longer sheath dwell time contributed to most of the complications in MC and BD. Nursing time spent for access management was 48.9 min in MC; 28.1 min in BD and 9.9 min in AS ($p < 0.0001$). Satisfaction score above 70 was noted in 46%, 86% and 92% of patients managed by MC, BD and AS, respectively.

Conclusion — AS use is associated with fewer complications, improved patient well being and saves 39 minutes of nursing time. The additional cost of AS is justified when used in selected patients undergoing PCI. *(Acta Cardiol 2005; 60(5): 482-488)*

Keywords: *coronary angioplasty – closure device – femoral access – cost-effectiveness.*

Femoral access management (FAME) is an important aspect of invasive cardiac procedures involving arterial punctures, particularly those requiring intense anticoagulation such as percutaneous coronary interventions (PCI). In recent years, mechanical clamps (Compressar™, FemoStop™)[1-3], suture-mediated closure systems (Perclose™, The Closer™)[4-6], vascular sealing devices utilizing anchor-collagen (Angio-Seal™)[7-9], or thrombin-collagen Duett™[10-12] based products and a haemostatic intraluminal disc deployment device (BioDISC™)[13] have been proposed as alternatives to manual compression for haemostasis.

Time to haemostasis has been shown to be dramatically reduced using haemostatic puncture closure devices allowing earlier ambulation and improved patient comfort [7,12,14-16]. Unfortunately, these devices carry a similar risk of vascular or haemorrhagic complications to manual compression[8,17-19] and sometimes result in groin infections[20-22], which limit their widespread use, although several reports have shown that this relative efficacy is largely explained by learning curve and/or failure of adequate deployment[17-19,23].

As a consequence, the cost efficacy of these devices is not immediately obvious, and manual compression remains the traditional method of haemostasis when early mobility is not a prerequisite, such as after PCI, or in a European context of budgetary restrictions.

The present study investigated the safety and efficacy of the BioDISC™ system compared to the 6F anchor-collagen based closure device Angio-Seal™ and

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to manual compression following PCI. We also addressed the questions of cost efficacy and patient comfort in subjects undergoing coronary interventions through the femoral approach.

Methods

Protocol

This randomized trial was conducted by five investigators.They received the minimum level of instruction in the use of the closure devices. All consecutive patients who had a coronary intervention performed before noon by one of the qualified cardiologists (VL, CM, OG, MB) through a femoral 6F access sheath were considered for the study.

Exclusion criteria included uncontrolled hypertension (above 200 mm Hg), platelet count below 75,000, septicaemia, acute myocardial infarction, cardiogenic shock, severe acute non-cardiac systemic disease or terminal illness, sheath in place for more than 24 hours, multiple femoral punctures, significant femoral disease and/or vascular tortuosity in the region of puncture, vessel diameter below 5 mm, arterial puncture performed in the profunda femoris or close to the bifurcation, access through a femoral prosthesis, access sheath in the femoral vein and presence of a palpable haematoma at the end of the procedure.

Before PCI, all patients gave written informed consent in accordance with the policies of the institutional research review board. At the end of the interventional procedure, angiography of the femoral artery was performed and the eligible patients were randomized to one of the treatment arms: manual compression (group A), Angio-Seal™ (group B) and BioDISC™ (group C).

The computer-assisted randomization procedure ensured that approximately 100 patients would be included in each group.

Puncture site management

Group A (manual compression) serves as the control condition. Patients in group A had their sheath removed in accordance with the standards applied in the unit at a time determined by the investigator, 3 to 4 hours after PCI. Hand compression and bed rest followed sheath removal. The duration of hand pressure application to achieve haemostasis was recorded, as well as the activated pro-thrombin time (aPTT value) at sheath removal.

Group B (Angio-Seal™) represents the population treated with a reference device for arterial closure. The Angio-Seal™ vascular closure device produces direct haemostasis by anchoring a collagen plug to the anterior vascular wall through a sheath delivery system[8]. Group B patients had the device deployed by the investigator at the end of PCI. Arterial haemostasis was checked at intervals of 30 minutes. Patients were ambulated 4 hours later.

Group C (BioDISC™) evaluates the femoral artery haemostasis achieved by a miniature disc that is placed temporarily inside the arterial lumen. This system allows the natural clotting process to occur within the puncture tract and obviates the need for a long manual compression. A trained nurse was allowed to place the device when the aPTT was below 90 seconds. We assessed aPTT values at 3 hours post PCI, then every hour, if necessary. The BioDISC™ catheter was inserted into the artery through the 6F introducer sheath. After insertion, the distal tip of the catheter was deployed to form a disc that was applied against the inner surface of the arterial puncture following pull back of the 6F introducer sheath[14]. After 15 minutes, the microdisc was removed and this procedure was followed by mild hand compression for 3 minutes to ensure complete haemostasis.

Data collection

Demographic data gathered included medical history and cardiovascular risk factors. For patients excluded from the study, the reasons were recorded. Procedural data included the type of procedure being performed, anti-coagulant and anti-platelet therapies given before, during and after PCI. aPTT was measured before sheath removal, at the end of PCI in group B and 3 or more hours later in groups A and C. Platelet count and haemoglobin were obtained the following day before discharge and compared with the values measured at baseline before PCI. The time of sheath removal, any device deployment failure, and the duration and type of compression (light digital or firm) were all recorded. For group A, haemostasis time was measured from the end of the PCI until haemostasis was finally observed after partially releasing firm manual compression every 2 minutes beginning 15 minutes after sheath removal. For group B, haemostasis time consisted of the time elapsed from device deployment to absence of bleeding. For group C, haemostasis time was measured from the end of the PCI until haemostasis was achieved after the BioDISC™ catheter removal. Ambulation time was recorded as the time interval between the end of the PCI and the moment when bed rest ceased.

Complications

The primary end point was freedom of puncture site-related complication after randomization. Any of the following complications were recorded: vasovagal response requiring atropine and fluid administration, large haematoma defined as any palpable mass >5 cm

of diameter, pseudoaneurysm detected by Doppler ultrasound, and significant bleeding occurring after an initial period of haemostasis. Loss of pulse, vessel occlusion, deep venous thrombosis, retroperitoneal haemorrhage, infection, a-v fistula, and crural nerve compression were also considered as complications.

Nursing care

Recording of vital signs and inspection of the groin puncture site were performed at 15 minutes, then hourly for 4 hours, then every 6 hours for 24 hours. The following additional nursing care parameters related to patient management were recorded: puncture site dressing, need for manual compression after an initial period of haemostasis, bed pan, bladder catheterization, and unscheduled nursing visits or patient's toilet. The nursing time spent to perform these additional acts related to puncture site management or complications, was recorded for each patient and used to assess the need for nursing management for each of the treatment strategies.

Patient satisfaction

The analysis of patient satisfaction was achieved by means of the Euro Qol questionnaire in which patients grade their general health status. The questionnaire comprises five items: ambulation, self-care, usual activity, pain or discomfort and anxiety or depression. Each item may be rated as «no problem», «moderate problem» or «severe problem». The questionnaire also includes a visual analogue scale for patients to use in rating their femoral puncture management from 0 (worst imaginable care) to 10 (best imaginable care). This rating was used to assess the patient's perception of femoral access management for each of the treatment strategies.

Statistical analysis

Continuous variables were estimated as mean ± SD and compared with use of the Student's unpaired t-test. Discrete variables were reported as counts and percentages and assessed by the chi-squared test or Fischer's exact test. A p value < 0.05 was considered statistically significant.

Results

Patient characteristics

A total of 463 patients were screened for randomization. 158 patients (34%) were excluded - the reasons are listed in table 1. Of the remaining 305 patients, 102 were randomized to group A (manual compression), 100 to group B (Angio-Seal™) and 103 to group C (BioDISC™). All three groups had no significant differences with regard to baseline demographic or procedural characteristics (tables 2 and 3).

Primary efficacy

In group A, sheaths were removed 3.5 ± 1.1 hours after PCI. Haematoma around the puncture site developed in eighteen patients before sheath removal (< 5 cm in 15 pts and > 5 cm in 3 pts). Two patients required earlier sheath removal at 30 and 60 minutes after PCI because of persistent bleeding, but did not experience further complications.

In group B, two patients experienced deployment failure. Manual haemostasis was successfully employed, but one of the patients developed a severe vasovagal reaction during the firm manual compression. Persistent bleeding was observed in five patients after device deployment, requiring firm manual compression for 10 minutes to achieve complete haemostasis. Another patient had a vagal reaction following device manipulation. The device success rate was 93%.

In group C, three patients had early active bleeding and progressive haematoma at the puncture site requiring premature sheath removal and firm manual compression without use of the BioDISC™ device. One of these patients developed an uncomplicated > 5 cm haematoma. In the remaining 100 patients, sheaths were removed and the BioDISC™ catheter inserted 3.3 ± 0.5 hours after PCI. Deployment failure was experienced in ten patients, all of whom were successfully treated by manual compression. In addition, two patients had residual arterial bleeding after

Table 1. – *Exclusion criteria in non-randomized patients (n = 158).*

Uncontrolled hypertension	0	Multiple femoral punctures	40
Platelet count < 75,000/µl	5	Iliofemoral disease	8
Cardiogenic shock	9	Distal femoral puncture	16
Acute myocardial infarction	13	Haematoma post PCI	5
Severe non-cardiac disease	11	Venous sheath	9
Sheath in place for > 24 hours	11	Aortofemoral prosthesis	31
Septicaemia	0	Vessel < 5 cm	0

Table 2. – *Baseline characteristics of the patients.*

	Manual N = 102	Angio-Seal™ N = 100	BioDISC™ N = 103
Age (years)	62.1 ± 13.0	62.6 ± 10.3	61.7 ± 11.1
Male/female (%)	75/25	79/21	80/23
Diabetes (%)	19	16	14
Hypertension (%)	45	54	43
Body mass index (kg/m^2)	26.9 ± 4.7	27.3 ± 3.7	26.8 ± 3.3
Prior PCI (%)	18	22	24
Medication before PCI :			
heparin or LMWH (%)	19	16	19
aspirin (%)	92	82	87
Haematology values before PCI :			
haemoglobin (gm/dl)	14.4 ± 1.7	14.4 ± 2.1	14.2 ± 1.5
platelet count (10^3 /µl)	257 ± 69	261 ± 70	265 ± 77
aPTT (sec)	36.4 ± 20.5	35.7 ± 20.0	33.7 ± 10.0

Table 3. – *Procedural characteristics.*

Manual N = 102	Angio-Seal™ N = 100	BioDISC™ N = 103
Coronary intervention :		
procedural success (%)	99	100	100
stent placement (%)	77	74	79
Concomitant therapy:		
heparin (IU)	7317 ± 2044	7435 ± 2125	7245 ± 1744
abciximab use (%)	12	8	13

Table 4. – *Monitoring and haematology values after sheath removal.*

	Manual N = 102	Angio-Seal™ N = 100	BioDISC™ N = 103
Time to haemostasis (hours)	3.5 ± 1.1	— *	3.3 ± 0.5
aPTT at sheath removal (sec)	75.4 ± 49.3 **	>150	58.1 ± 23.6
Tensioner time (min)	—	21.1 ± 3.8	16.6 ± 6.4
Firm manual compression (min)	19.2 ± 8.8	(10.7 ± 3.5)*	(5.5 ± 4.0) ***
Ambulation time (hours)§	12.2 ± 1.5	4.5 ± 2.0	5.1 ± 2.9
aPTT at ambulation (sec)	30.3 ± 4.8	47.2 ± 34.0	31.7 ± 7.37
Haemoglobin at day 1 (gm/dl)	13.6 ± 1.8	13.8 ± 1.7	13.8 ± 2.1
Platelet count at day 1 (10^3/µl)	244 ± 70	241 ± 71	252 ± 71

*Manual compression after device deployment in 7/100 patients (device failure in 2 and residual bleeding in 5). **aPTT above 90 sec in 25/102 patients. ***Firm manual compression after device deployment in 12/100 patients (device failure in 10 and residual bleeding in 2). Light compression (6.7 ± 5.5 min) in 4 patients for residual cutaneous bleeding.
§ p group C vs. group B: NS, p group C or group B vs. group A: < 0.0001.

BioDISC™ catheter removal requiring firm compression for 10 minutes to achieve complete haemostasis. Four other patients had minor residual bleeding controlled by 5 minutes of light compression. One patient developed a vagal reaction following catheter removal. The device success rate was 88%.

The relevant clinical and biological results noted at and after arterial sheath removal are depicted in tables 4 and 5.

Late complications (noted at day one)

Four group A patients had recurrent arterial bleeding 1 to 6 hours after initial successful haemostasis. They were treated by manual compression. One of them developed a large haematoma. Large haematomas (> 5 cm) were noted in five patients. Pseudoaneurysms were confirmed using Doppler ultrasound in two patients, and successfully treated by external compression. Minor haematomas (< 5 cm) were noted in nineteen patients. One patient experienced a vagal reaction. Overall, the proportion of patients experiencing one or more puncture site-related major complications was 10.8 % in the manual compression group.

Large haematomas (> 5 cm) were noted in two group B patients. No patients experienced a recurrent haemorrhage. Two patients experienced a vagal reaction. Seven patients complained of groin pain. Minor

Table 5. – *Incidence of device failure and complications.*

	Manual N = 102	Angio-Seal™ N = 100	BioDISC™ N = 103
Device failures:			
failure to deploy	—	2	10
incomplete haemostasis	—	5	2
Vascular complications:			
major bleeding pre-sheath removal	2	0	3
major bleeding post-sheath removal	4	0	1
haematoma >5 cm	5	2	2
pseudoaneurysm	2	0	1
vagal reaction	1	2	1
any of the above†	11 (10.8%)	4 (4.0%)*	6 (5.8%)**

†some patients experienced more than one complication.
* p = 0.12 **p = 0.30.

Table 6. – *Nursing time (minutes) related to puncture site management.*

	Manual N = 102	Angio-Seal™ N = 100	BioDISC™ N = 103	p values
Before sheath removal	15.7 ± 4.1	—	13.7 ± 4.6	0.001
After sheath removal	33.2 ± 7.7	9.9 ± 3.9	14.4 ± 10.3	0.0001*

* for all comparisons.

cutaneous bleeding persisted in sixteen patients for 3 to 4 hours after arterial sealing. Overall, the proportion of patients experiencing one or more puncture site-related major complications was 4 % in the Angio-Seal™ group.

One group C patient experienced a recurrent late bleeding controlled by prolonged firm manual compression. The patient subsequently developed a large haematoma and a pseudoaneurysm that was treated by external compression. Two other patients had large haematomas (> 5 cm) at follow-up and minor haematomas developed in six patients. Overall, the proportion of patients experiencing one or more puncture-site related major complications was 6.8 % in the BioDISC™ group.

On discharge, a similar drop in haemoglobin and platelet count was noted for each group.

Nursing care

Table 6 shows that patients receiving a closure device needed less care. Overall, use of the Angio-Seal™ device saved 39 minutes nursing time per patient, and use of the BioDISC™ saved 20.8 minutes nursing time per patient when compared to manual compression ($p < 0.0001$ for all comparisons). Absence of need for nursing supervision before sheath removal and minimal groin management after deployment in the Angio-Seal™ group were primarily responsible for the reduction in nursing time. Reduction in groin management contributed to the savings in nursing time in the BioDISC™ group.

Patient satisfaction

Patients who received an Angio-Seal™ device recorded the greatest level of satisfaction with the groin management process (figure 1). Only 46% of patients treated by manual compression reported a score above 7 compared to 86.4% and 92% of the patients treated by BioDISC™ and Angio-Seal™ ($p < 0.0001$), respectively. The data from the self-rated Euro Qol questionnaire indicated that the difference was attributable to higher ratings for ambulation and lack of pain or discomfort.

Discussion

This randomized study compared two different closure devices and is the first to assess their clinical and economic advantages over the traditional method of manual compression. The use of these devices, notably the anchor-collagen system Angio-Seal™, enables earlier ambulation, with less nursing care and improved patient comfort.

Our results confirm that vascular closure devices are not harmful and can be a valuable alternative to manual compression to manage arterial puncture sites after PCI as reported previously[5,12]. Several reports have shown similar complication rates to manual compres-

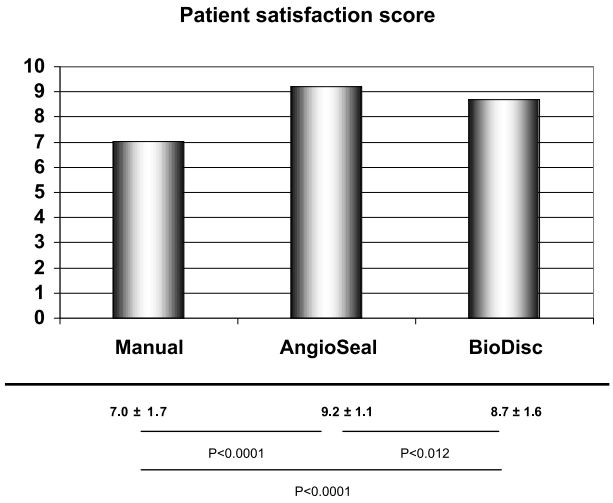

Fig. 1. – Visual analogue scale rating of the patient's perception of femoral access management for each of the treatment strategies (0 represent the worst imaginable care and 10 the best imaginable care).

sion[8,18-20]. In some reports, these complications were found to be related to operator inexperience, postprocedure heparin[16], low or high body mass index[6,18,20], female gender and diabetes[6,18,19]. Our evaluation is not sufficiently powered to determine the superiority of either device over manual compression to reduce access site complications. Nevertheless, the anchor-collagen device Angio-Seal™ was associated with a 63% reduction in vascular related events ($p = 0.12$) in our population. This result is partly explained by patient selection. Table 1 lists the frequency of application of exclusion criteria. Multiple access punctures and aortofemoral prostheses were the most common grounds for exclusion. Excluded patients represented one third of the patients undergoing PCI. Given these limitations imposed for this evaluation, we consider that haemostatic devices, notably the anchor-collagen-based system, appear to offer a clinical advantage over manual compression to manage femoral access site after PCI. Some may argue that manual compression after early sheat removal or the use of smaller catheters (4-5F) could further reduce complications rates in the "no device" arm. This hypothesis is speculative and needs to be assessed, however.

Various devices have been developed for the closure of femoral puncture site. These devices either suture the puncture site[4-6], deploy sealing material[7-9] or allow the temporary placement of a microdisc against the vessel wall[14]. The two latter approaches have been evaluated in this trial. We have demonstrated the benefit of the sealing material over the micro disc device. First, the success rate of device deployment was greater with the anchor-collagen system (98% versus 90%, $p = 0.037$). Secondly, the anchor-collagen system allowed earlier time to haemostasis that translated to fewer vascular complications, less nursing care and improved patient comfort. In our trial, post-procedural haemorrhage at the puncture site occurred in 5/205 patients before sheath removal, notably among patients randomized to Bio-DISC™. These haemorrhages were complicated by the development of a pseudoaneurysm in 2 patients. Closure devices that allow immediate sheath removal such as Angio-Seal™ avoid these potentially serious complications. Furthermore, immediate sheath removal helps to reduce the nursing management, and improves patient satisfaction by allowing earlier ambulation and independence. The Bio-DISC™ catheter also had some advantages. A trained nurse can easily place it, with minimal manipulations of vascular structures. It utilizes the natural clotting and closure mechanisms of the body rather than leave any foreign material behind, like the Angio-Seal™ device, which leaves bioabsorbable material that may act as a focus for infection[20], may result in an allergic reaction or lead to a thrombus[22]. None of these drawbacks were encountered in this study. Moreover, the residual bioabsorbable material may preclude repeat puncture or surgery of the same artery without special precautions for at least 2 months.

The major goals of this study were to assess the economic impact and the patients' acceptance of vascular sealing devices. Our results clearly demonstrate a marked reduction in nursing time. Immediate haemostasis with the Angio-Seal™ device was associated with less supervision of puncture site, no preparation for sheath removal and no need for dressing, no help for hygienic necessities and fewer vascular complications. All together, this saved 39 minutes of personnel time. In comparison, use of the Bio-DISC™ catheter saved 20.8 minutes. This study suggests that in selected cases as defined by our inclusion criteria, there would be no puncture-related vascular risk in allowing a patient to return home a few hours after PCI when haemostasis is completed by one of the sealing devices used in this study. Although it has been standard practice to keep patients hospitalized overnight following PCI, we could consider ambulatory PCI in some cases, which would lead to a further reduction in hospital costs. The potential contribution to patient comfort by use of closure devices is also demonstrated in this study. Significant differences were found in patients' ratings; those managed with the anchor-collagen plug being happier than those in whom haemostasis was controlled by microdisc ($p < 0.012$) or by manual compression ($p < 0.0001$). As expected, patient satisfaction was related to greater independence and a decrease in time to ambulation. Whether salvage of twenty minutes of nursing care, earlier ambulation and more patient comfort offset the incremental costs of closure devices and costs associated with device-related complications is debatable, however. Specifically, cost-effectiveness calculation is highly dependent upon the price of the closure device, on the one hand, and the cost of each specific health care system, on the other hand.

Conclusion

After PCI, the use of femoral closure devices in selected patients resulted in the need of fewer personnel and improved patient comfort. The anchor-collagen device, which allows immediate sheath removal, avoided complications that occurred during the dwell time of the sheath and thereby further reduced the nursing management and improved the patient comfort compared to the endovascular micro disc-based system. The additional value of Angio-Seal™ following PCI translated to a high patient satisfaction score and 39 minutes personnel time saved, whereas the use of Bio-DISC™ generated less patient comfort and only saved 20.8 minutes of nursing time. In addition, ambulatory PCI could be allowed in selected patients, thus further improving the cost savings associated with the use of these devices.

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