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Effectiveness of a Pneumatic Compression Device and Coagulation-Fibrinolytic Factors on Hemostasis of the Femoral Artery after Cardiac Catheterization

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ABSTRACT

The effectiveness of a pneumatic femoral artery compression device, FemoStop, was evaluated in 102 patients with ischemic heart disease, 50 of whom underwent diagnostic coronary angiography (CAG) with a 6-French catheter, and 52 of whom underwent perctaneous transluminal coronary angioplasty (PTCA) with an 8-French catheter. A secondary objective was to clarify the relationship between hemostasis time and coagulation-fibrinolytic factors. The time required to achieve hemostasis with this device was 24.1±10 (mean±SD) minutes in patients undergoing CAG and 56.5±23.3 minutes in patients undergoing PTCA. In patients undergoing CAG neither activated clotting time (ACT) nor coagulation factors differed significantly between those in whom hemostasis was achieved within the protocol time (20 minutes) and those in whom it was not. However, in patients undergoing PTCA ACT was longer and levels of coagulation factors were lower in those in whom hemostasis was achieved within the protocol time (40 minutes) than in those in whom it was not. These results suggest that hemostasis time is affected by the positioning and the pressure in the bubble of the pneumatic compression device as well as by hematological factors, such as coagulability and ACT. (Jikeikai Med J 2003 ; 50 : 51-7)

Key words : hemostasis, pneumatic compression device, coagulation factors, coagulability, catheterization

INTRODUCTION

Recent advances in coronary angioplasty have increased the use of large guide catheters. In addition, anticoagulation and antiplatelet medicines, including intravenous heparin, are routinely administered to patients who undergo coronary angioplasty. With the use of large catheters and antithrombotic treatment, achieve hemostasis can take considerable time. However, most cardiologists do not have a lot of time to spend to achieve hemostasis with manual compression after cardiac catheterization.

Several types of compression device for the femoral artery have been introduced, determining which is best can be difficult. Therefore, we examined the benefits of a pneumatic compression device (FemoStop, Radi Medical Systems AB, Uppsala, Sweden) in a clinical setting. We also examined the relation between the time required to achieve hemostasis and coagulation-fibrinolytic factors.

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MATERIAL AND METHODS

1. *Subject*

The subjects were 102 consecutive patients with ischemic heart disease who underwent cardiac catheterization. The pneumatic compression device was used in 50 patients after diagnostic coronary angiography (CAG) with a 6-French (Fr) Judkins catheter (6-Fr group) and in 52 patients after elective percutaneous transluminal coronary angioplasty (PTCA) with an 8-Fr guiding catheter (8-Fr group). The procedures were performed with Judkins's method through a sheath in the femoral artery.

2. *Pretreatment*

At the start of catheterization, intravenous heparin was administered as a bolus injection of 3,000 units for the 6-Fr group and at a dose of 120 units/kg body weight for the 8-Fr group. Each patient in the 6-Fr group received an intravenous injection of 3 mL protamine at the end of CAG, after which the sheath was immediately removed. In the 8-Fr group, the sheath was removed without the use of protamine 3 hours after PTCA. In both groups, patients with blood pressure over 150 mmHg received 10 mg nifedipine sublingually before hemostasis.

3. *Protocol*

FemoStop was used as a pneumatic compression device (Fig. 1). The bubble was inflated with the pump until it reached suprasystolic pressure (130% systolic pressure), then the sheath was removed.

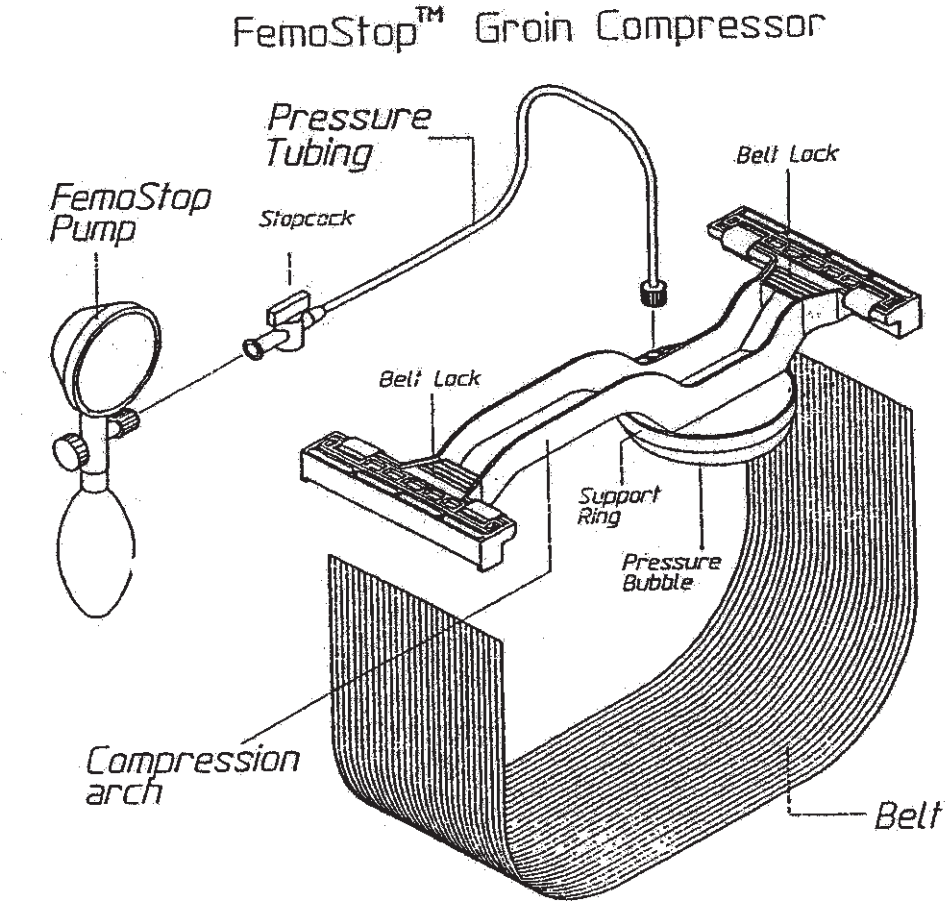

Fig. 1. The compression device consisted of three parts: a pneumatic, inflatable transparent bubble connected to a 12 cm-wide hard plastic arch; a compressor with a manometer; and a 120cm-long polyester belt. The bubble and the arch were sterilized and disposable. The center of the bubble is placed on the puncture site and the belt is fastened, with the sheath remaining on the femoral artery.

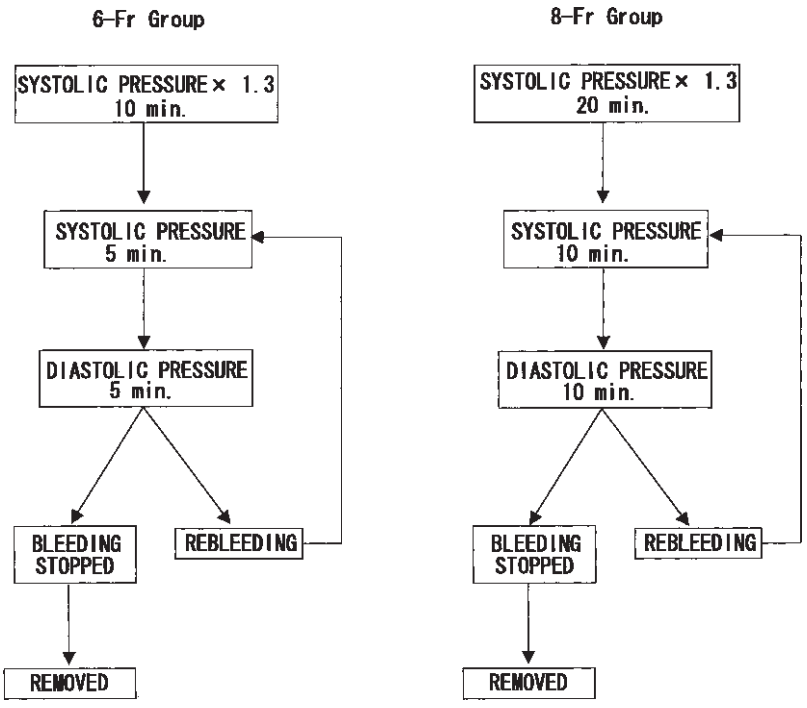

Fig. 2. The protocol of hemostasis was shown. When the hemostasis could be recognized, the device was removed. After then a compressed dressing with rolled hard guaze was put on the puncture site and affixed with an elastic bandage for 8 hours in the 6-Fr Group and 16 hours in the 8-Fr Group.

Compression time for the 6-Fr group totaled 20 minutes: 10 minutes at suprasystolic pressure, 5 minutes at systolic pressure, and 5 minutes at diastolic pressure. The pressure was then reduced slowly until it reached zero, and the device was removed (Fig. 2, left). Compression time for the 8-Fr group was a total of 40 minutes, with the above steps increased to 20, 10 and 10 minutes, respectively. The device was then removed after the pressure had been reduced to zero (Fig. 2, right).

If rebleeding occurred, the compression device was used for an additional 10 minutes in the 6-Fr group (5 minutes at systolic pressure and 5 minutes at diastolic pressure) and an additional 20 minutes in the 8-Fr group (10 minutes at systolic pressure and 10 minutes at diastolic pressure). These steps were repeated until bleeding stopped. However, if the patient complained of leg pain or hematoma developed the compression device was immediately removed and manual compression was done. After hemostasis had been achieved and sustained for some time, the device was removed. After removal, a compression dressing with a firm, rolled gauze was placed on the puncture site and fixed with an elastic bandage for 8 hours in the 6-Fr group and 16 hours in the 8-Fr group.

Both the 6-Fr and 8-Fr groups were further divided into two groups: patients in whom hemostasis was achieved within the protocol time (Subgroup A) and patients in whom hemostasis was not achieved within the protocol time (Subgroup B).

4. *Analysis*

The following patient characteristics and hematologic variables were evaluated in each group and subgroup: gender, age, height, body weight, blood pressure before and after catheterization, activated clotting time (ACT), fibrinogen concentration, prothrombin time (PT), thrombin time (TT), hepaplastin time (HT), and activated partial thrombin time (aPTT). We calculated the data using the t-test and χ^2 test. Differences were considered significant when the p value was less than 5%.

RESULTS

The 6-Fr group and the 8-Fr group did not differ significantly in terms of gender ratio, age, height, weight, or obesity rate (greater than 20% above ideal weight) (Table 1). The compression time was significantly longer in the 8-Fr group (56.5±23.3 minutes, $p<0.001$) than in the 6-Fr group (24.1±10 minutes). All coagulation factors, except HT, decreased significantly, and ACT was longer in the 8-Fr group (126±21.7 seconds) than in the 6-Fr group (189±36 seconds, $p<0.001$, Table 2). In both the 6-Fr and 8-Fr groups, systolic blood pressure was significantly lower at the end of compression (146.4±10.6 mmHg) than at the start of compression (112.5±15.3 mmHg, $p<0.05$).

Hemostasis was achieved within the protocol time (20 minutes) in 28 patients (average, 18.2±2.4 minutes) and outside the protocol time in 22 patients (31.5±11 minutes) of the 6-Fr group (Table 3). Neither clinical characteristics (Table 3) nor hemotologic variables (Table 5) differed between the two subgroups of patients. Hemostasis was achieved within the protocol time (40 minutes) in 23 patients (average, 38.4±5 minutes) and outside the protocol time in 29 patients (average, 70.9±22 minutes) of the 8-Fr group (Table 4). Clinical characteristics did not differ significantly between the two subgroups of the 8-Fr group; however, patients in whom hemostasis was achieved within the protocol time had longer ACT and aPTT and lower TT (Table 6). Small hemotomas

Table 1. Characteristics of 6-Fr Group and 8-Fr Group

	6-Fr Group $n=50$	8-Fr Group $n=52$	p value
sex male	$n=36$	$n=41$	NS
female	$n=14$	$n=11$	NS
age (years)	59.0±7.9	61.6±10.0	NS
weight (kg)	59.5±9.4	61.9±9.4	NS
height (cm)	161.7±6.9	161.8±7.4	NS
numbers of obesity ratio greater than 20% above ideal weight	$n=5$	$n=12$	NS
hemostasis time (min)	24.1±10.0	56.5±23.3	<0.01

Table 2. ACT and coagulation-fibrinolytic factors in 6-Fr Group and 8-Fr Group

	6-Fr Group $n=50$	8-Fr Group $n=52$	p value
ACT (sec)	126±21.7	189±36	<0.01
fibrinogen (mg/dL)	264±74.5	305±79.3	<0.01
PT (sec)	13.8±1.7	13.1±1.2	<0.05
TT (%)	71±29	46±30	<0.01
HT (sec)	94±30	84±25	NS
aPTT (sec)	48.8±12.1	84.6±33.2	<0.01

Table 3. Characteristics of subgroup A (compression time within 20 minutes) and subgroup B (compression time over 20 minutes) in 6-Fr group

	Subgroup A $n=28$	Subgroup B $n=22$	p value
age (years)	59.5±7.8	58.4±8.3	NS
numbers of obesity ratio greater than 20% above ideal weight	$n=3$ (10.7%)	$n=3$ (13.6%)	NS
B.P at start (mmHg)	125±19	125±18	NS
B.P at end (mmHg)	119±16	119±14	NS
height (cm)	163.8±5.5	159.1±7.6	NS
weight (kg)	59.6±8.6	59.3±10.5	NS

Table 4. Characteristics of subgroup A (compression time within 40 minutes) and subgroup B (compression time over 40 minutes) in 8-Fr group

	Subgroup A $n=23$	Subgroup B $n=29$	p value
age (years)	62.2±7.9	61.2±11.5	NS
numbers of obesity ratio greater than 20% above ideal weight	$n=5$ (21.7%)	$n=6$ (20.7%)	NS
B.P at start (mmHg)	136±16	131±15	NS
B.P at end (mmHg)	127±12	124±14	NS
height (cm)	161.4±7.9	162.2±7.9	NS
weight (kg)	61.9±9.5	61.8±9.5	NS

Table 5. ACT and coagulation-fibrinolytic factors of Subgroup A (compression time within 20 minutes) and Subgroup B (compression time over 20 minutes) in 6-Fr group

	Subgroup A $n=28$	Subgroup B $n=22$	p value
ACT (seconds)	125±25.6	127±15.7	NS
fibrinogen (mg/dL)	250±54.2	282±92.5	NS
PT (seconds)	13±1.4	14±2.0	NS
TT (%)	72±30	69±29	NS
HT (seconds)	93±27	96±34	NS
aPTT (seconds)	47±11	51±13	NS

Table 6. ACT and coagulation-fibrinolytic factors of Subgroup A (compression time within 40 minutes) and Subgroup B (compression time over 40 minutes) in 8-Fr group

	Subgroup A $n=23$	Subgroup B $n=29$	p value
ACT (seconds)	205±24	177±40	<0.01
fibrinogen (mg/dL)	321±85.5	285±77.1	NS
PT (seconds)	13.1±1.1	13±1.3	NS
TT (%)	32±13	54±35	<0.01
HT (seconds)	80±21	87±27	NS
aPTT (seconds)	96±32	75±30	<0.05

Table 7. Distribution of complications

	6-Fr Group $n=50$	8-Fr Group $n=52$
small hematoma	2 (4%)	5 (9.6%)
hypotension	1 (2%)	1 (1.9%)
leg pain	0 (0%)	3 (5.8%)
total	3 (6%)	9 (15.4%)

developed in 2 patients (4%) and blood pressure and heart rate decreased in 1 patient (2%) of the 6-Fr group (Table 7). These complications improved with intravenous administration of atropine, and compression with FemoStop was continued. In the 8-Fr group, small hematomas developed in 5 patients (9.6%) and blood pressure decreased in 1 patient (2%). When blood pressure decreased, compression with FemoStop was continued after intravenous administration of catecholamines and atropine. Compression was changed from pneumatic to manual because of complaints of leg pain or numbness in 3 patients (6%) and because of a small hematoma in 1 patient.

Discussion

To our knowledge, this is the first report to evaluate the relations between coagulation-fibrinolytic factors and hemostasis time with a pneumatic compression device. Our hemostasis time with a 6-Fr catheter of 24.1±10 minutes was similar to results from Yabe, et al[1], who reported a compression time with a 6-Fr sheath introducer of 20.5±6.5 minutes. Their protocol reduced pressure by 10 mmHg at 2-minute intervals after compression for a few minutes at 10 mmHg higher than systolic pressure. When pressure reached 30 mmHg, the FemoStop was left in place for 10 hours, then removed. Nordrehaug, et al[2] found that after CAG manual compression produced hemostasis in 12±4 minutes and caused hematoma in 11% of patients, whereas FemoStop produced hemostasis in 60 minutes and caused hematoma in 7% of patients.

According to Adams, et al[3], the compression time from catheter extraction until complete hemostasis depends on: 1) the size of catheter used, 2) the depth of the femoral artery, 3) the detention time of the catheter in the femoral artery, and 4) the type of anticoagulation treatment.

The hemostasis time was significantly longer in the 8-Fr group (56.5±23.3 minutes) than in the 6-Fr group (24.1±10 minutes). We found that the difference does not depend only on the size of the catheter used. The coagulation factors, such as TT, PT, aPTT, and fibrinogen, were significantly lower in the 8-Fr group than in the 6-Fr group. In addition, ACT was significantly longer in the 8-Fr group, probably because intravenous protamine was not administered to neutralize heparin after PTCA. At our institution, sheath introducers are removed immediately after CAG but are usually removed several hours after PTCA. The sheath was left in the femoral artery much longer after PTCA in the 8-Fr group than after CAG in the 6-Fr group. For this reason and because the coagulation factors became inactive, a longer time was naturally needed for hemostasis in the 8-Fr group. Accordingly, our protocol time for compression after PTCA was 40 minutes, within which bleeding was still sometimes difficult to stop.

Stables, et al[4] have established a new poststent protocol using FemoStop and self-injected low molecular weight heparin in 92 patients. Vascular or bleeding complications occurred in 6% of patients but two-thirds resolved without transfusion or other intervention.

There were no significant differences in ACT, coagulation factors, patient weight, and obesity rate between subgroups of patients in the 6-Fr group in whom hemostasis was or was not achieved within the protocol time. In the 8-Fr group patients' weights

and obesity rates did not differ significantly between the subgroups ; however, ACT was longer and coagulation factors were lower in patients in whom hemostasis was achieved within the protocol time. Accordingly, hemostasis time is apparently affected by the positioning of the FemoStop and the pressure of the bubble as well as by hematologic factors and patient stature.

Small hematomas developed in 2 patients in the 6-Fr group and 5 patients in the 8-Fr group but did necessitate blood transfusion and did not cause gait disturbance. Values of most coagulation factors in patients of the 8-Fr group with hematomas did not differ significantly from those in other patients. However, TT ranged from 13% to 23% in four patients with small hematomas and was 43% in a fifth patient, who moved considerably to urinate during compression. The numbers of platelets were within the normal range in all five patients. All patients received antiplatelet treatment with aspirin and dipyridamole. The number of past catheterizations in the 5 patients with small hematoma was 2 in 1 patient, 4 in 3 patients, and 6 in 1 patient. Therefore, complications are more frequent in patients who have undergone catheterization more often in the past. Clark, et al[5] have reported that FemoStop is easy to handle but does not reduce reducing vascular complications significantly compared with manual compression.

The ACT was longer than 190 seconds in 3 of 5 patients in the 8-Fr group with small hematomas when the sheath was extracted after PTCA. In addition to the antiplatelet treatment, factors that increase the likelihood of hematoma include many previous catheterizations, decreased TT due to anticoagulation agents, and prolonged ACT due to heparin. In the 8-Fr group, FemoStop compression had to be stopped because of pain and numbness in the leg in three patients and because of decreased blood pressure, presumably due to the vasovagal reflex, in 1 patient. Our protocol, which specifies compression at 1.3 times systolic pressure for the first 20 minutes, might cause pain and numbness in the leg. To prevent leg pain and the vasovagal reflex, local anesthesia was given at the puncture site when the sheath was extracted.

Dangas, et al[6] found that prolonged femoral compression with FemoStop is a simple and effective method for treating femoral artery pseudoaneurysm after interventional cardiac procedures.

Nilsson, et al[7] chose to continue FemoStop compression for 2 to 4 hours when ACT became lower than 200 seconds after heparin had been infused for PTCA. No severe hematoma or complications of the peripheral vessel developed. However, in 8 patients (3.8%) who continued to receive heparin, even during compression, rebleeding occurred within 24 hours. An important point to remember is that if the sheath is extracted several hours after the procedure and the FemoStop is removed quickly (e.g., after 40 minutes), initial compression pressures must be high. This requirement is based on the fact that ACT does not recover completely and, therefore, leg pain and vasovagal reflex are more likely to occur. Furthermore, hematoma may develop more easily if the compression device is removed after only a short time. Accordingly, we conclude that to efficiently prevent hematoma and other complications, the extraction time of the sheath should be delayed and low-pressure compression with FemoStop should be prolonged. Postcompression decreases in blood pressure were observed in both the 6-Fr and 8-Fr groups but were thought to be due to nifedipine.

CONCLUSION

We evaluated the effectiveness of a pneumatic compression device for achieving hemostasis in 102 patients with ischemic heart disease. The compression time of 24.1 ± 10 minutes was thought to be adequate for patients undergoing CAG with 6-Fr catheter. However, given the lower coagulability due to infusion of heparin, prolonged ACT, and long catheter retention, this length of compression time was not suitable for patients undergoing PTCA with a 8-Fr catheter ; further examination is required to determine a protocol for clinical use. This study confirmed that, in addition to patient physical and hematological factors, such as coagulability and ACT, the positioning of FemoStop and the air pressure in the bubble is likely to be important factors influencing

hemostasis time.

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