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Original Article

Evaluation of the Method of Hemostasis after Femoral Arterial Puncture

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Abstract. [Purpose] This study assessed the advantages and shortcomings of methods for hemostasis in patients who had received angiography after femoral arterial puncture using manual, compression device, or a combination of manual compression and a compression device. In addition, the success rates, complications, etc, were analyzed. [Subjects and Methods] One hundred and eighty patients who had undergone angiography after femoral arterial puncture were divided into three groups according to the method of hemostasis. For group A, immediately after angiography, an Angio-Seal device was placed in the puncture area and compressed using a compression device. For group B, after angiography, the puncture area was compressed with the hands directly. For group C, the puncture area was compressed using a compression device for approximately 10 min, and the puncture area was then compressed with the hands. In each group, the following correlations were analyzed: the time to hemostasis after angiography and gender, the time to hemostasis of each generation and the hemoglobin value, and platelet value and the time to hemostasis. [Results] The results showed a similar time to hemostasis regardless of gender or generation. The correlation between the hemoglobin value, platelet value, and the time to hemostasis were not significant. Group A showed the shortest mean time to hemostasis of the three groups (20.37 ± 8.23 min). No complications caused by the hemostasis method were detected in group B. Group A showed the highest incidence of complications caused by hemostasis. [Conclusion] Overall, hemostasis performed mutually is safe and effective for patients according to their condition.

Key words: Femoral arterial puncture, Hemostasis, Compression device

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INTRODUCTION

Arterial puncture occurs at the start of angiography and interventional radiology, and is a very important factor determining the success or failure of successive procedures. Recently, this procedure has been performed by a range of approaches depending on the type of surgery, e.g, through the radial artery. Until now, the procedure through the femoral artery has been used most widely as the most basic puncture area for angiography. On the other hand, hemostasis and the pertinent complications are problems in the femoral artery, in which the pressure is high after the procedure and the size of the blood vessels is relatively high.

Therefore, hemostasis in the puncture area for angiography or interventional radiation is a very important last step of the procedure. The methods of hemostasis for the femoral artery include manual compression, which is the removal of the sheath and compression with the hands, and methods that apply compression devices[1)]. Of these, manual compression requires absolute bed rest for a few hours. On the other hand, the level of patient discomfort is increased due to lengthy bed rest and the restriction of walking. Moreover, hematoma in the punctured area of blood vessels, formation of a pseudoaneurysm, and vascular occlusions develop in approximately 1–5% cases[2, 3)]. A variety of hemostasis devices have been developed to treat these complications that allow for rapid recovery of patients from bed rest. These include Angio-seal device (collagen sponge and copolymer anchor) and percutaneous placement of a device (Prostar) that utilizes two nonabsorbable sutures (Perclose, Redwood City, CA, USA). The Angio-seal device uses a method of adsorption with a collagen sponge placed within the blood vessels. The Prostar device uses a method in which the blood vessels are sutured[4, 5)]. These hemostasis devices can reduce the discomfort and the time to hemostasis (clotting time) in the puncture area when used in patients, who cannot lie down in bed for a long time or in patients with low platelet values who have received anti-coagulation treatments. Therefore, they allow rapid walking, which shortens the hospitalization period of the patient. At the time of hemostasis, however, hematoma or complications of peripheral blood vessels can occur, and several problems, such as a long time to hemostasis, can develop in patients who have

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Table 1. The distribution of age and gender of the patients (n = 180)

	Gender		Total (%)
	Male	Female	
30's	17	7	24 (12.2)
40's	21	13	34 (17.7)
50's	31	12	43 (23.3)
60's	37	10	47 (25.5)
70's	26	6	32 (17.7)
Total (%)	132 (73.3)	48 (26.4)	180 (100.0)

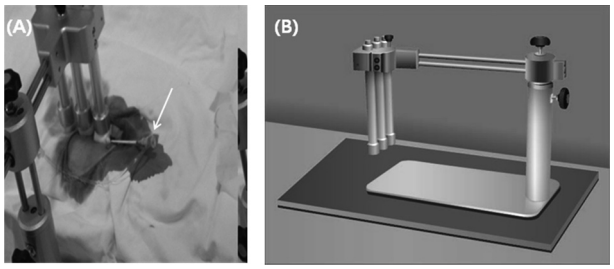

Fig. 1. An Angio-Seal device (A) was placed in the puncture site of the blood vessels, and the site was compressed using a compression device (B).

received urokinase and in obese patients.

Therefore, this study examined the change in complications or success rate of hemostasis according to the hemostasis method. Patients, who had received angiography after femoral arterial puncture and hands, or a combination of manual compression and, were enrolled in this study. The advantages and shortcomings of the hemostasis method were examined. The success rate, complications, etc., were compared.

SUBJECTS AND METHODS

The subjects were 180 patients who underwent angiography after femoral arterial puncture from November 2010 to August 2011. Their ages ranged from 10 years to 60 years. The highest proportion of patients were between 50 and 60 years of age (48%, 44 cases). The mean age of the patients was 54.3 ± 10.32 years. The male to female ratio was 2.8:1 (Table 1). In 60 of the patients (group A: 52.2 ± 9.83 years, 41 males, 19 females), femoral arterial hemostasis had been performed after angiography using an Angio-Seal device (St. Jude Medical Europe, Belgium), and compression was performed with a compression device. For another 60 patients (group B: 50.7 ± 11.23 years, 47 males, 13 females), after angiography, hemostasis was performed by compressing the puncture area with the hands. For the remaining 60 patients (group C: 54.27 ± 12.21 years, 44 males, 16 males), after angiography, femoral arterial hemostasis was performed using an Angio-Seal device and a compression device, and the puncture area was then compressed again with the hands. Among the patients who had undergone angiography, those who did not receive a blood test, those who presented with pain during hemostasis, those whose conditions were unstable, and those whose times to hemostasis were not accurate were excluded. All participants signed a written informed consent form approved by the Institutional Review Board at the University of Soonchunhyang.

For group A, femoral arterial angiography was without abnormal findings immediately after angiography, such as stenosis of blood vessels and, arterial detachment, an Angio-Seal device was placed in the puncture area of the blood vessel, and a compression device (Easy-stop, Tae woong, Seoul, Republic of Korea) was used (for compression, refer to Fig. 1). For group B, after angiography, the sheath inserted into the femoral artery was removed, and the puncture area was compressed with the hands. For group C, immediately after angiography, an Angio-Seal device was placed in the puncture area of the blood vessel, and the puncture area was compressed for approximately 10 min using a compression device and then compressed with the hands.

In each group, after performing angiography, the effect of gender, the time to hemostasis of each generation, the results of blood correlation between hemoglobin value, platelet value, and the time to hemostasis were examined. In addition, the frequency of complications according to the hemostasis methods of each group and incidence were compared. Complications were defined as the development of a hematoma > 5 cm, and a decrease in the hemoglobin level to < 3 g/dl. A questionnaire was used to assess the presence or absence of pain after hemostasis.

The time to hemostasis after angiography of each group was compared by ANOVA. For comprehensive analysis, post hoc analysis was performed using a Scheffe's test. Through this, the gender of each group and the time to hemostasis of each generation were compared and analyzed. The pearson correlation coefficient was applied to determine the correlation between the hemoglobin value, platelet value, and time to hemostasis. Frequency analysis and ANOVA were applied to examine the development frequency of complications according to the hemostasis method of each group and the incidence and frequency. The SPSS statistical software (SPSS, 17.0, Chicago, IL, USA) was applied for statistical analysis. P values < 0.05 at the 95% confidence level were considered significant. In addition, cases with a Pearson correlation coefficient > 0.5 were considered to be correlated.

RESULTS

The mean ages of groups A, B, and C were 52.2 ± 9.83, 50.7 ± 11.23, and 54.27 ± 12.21 years, respectively; there was no significant difference between the three groups. The male to female ratios in groups A, B, and C were 68.33%:31.66%, 78.33%:21.66%, and 73.33%: 26.66%, respectively. The gender ratio was similar in the three groups. The type of tests, hemoglobin, and platelet values were also similar in the three groups (Table 2).

Groups A, B and C showed a mean times to hemostasis of 20.37 ± 8.23, 29.30 ± 6.87, and 28.9 ± 7.25 min, respectively. In other words, the time to hemostasis of the com-

Table 2. Baseline clinical characteristics (n = 180)

	Group A (n=60)	Group B (n=60)	Group C (n=60)
Age (mean ± SD[e])	52.2 ± 9.83	50.7 ± 11.23	54.27 ± 12.21
Male (%)	68.33	78.33	73.33
Female (%)	31.66	21.66	26.66
Type of examination			
Hepatic angiography (%)	8 (13.33%)	5 (8.33%)	9 (10.5%)
TFCA[a] (%)	25 (41.66%)	22 (36.66%)	27 (45%)
TACE[b] (%)	17 (28.33%)	16 (26.66%)	17 (28.33%)
Femoral angiography (%)	10 (16.66%)	4 (6.66%)	3 (5%)
Coronary angiography (%)	10 (16.66%)	13 (21.66%)	14 (23.33%)
Blood level (g/dL)			
Hb[c]	13.32 ± 3.27	14.27 ± 4.98	14.25 ± 4.77
Plt[d]	183.28 ± 23.75	176.78 ± 31.25	191 ± 24.65

TFCA[a], tramsfemoral cerebral angiography; TACE[b], transcatheter arterial chemoembolization; Hb[c], hemoglobin; Plt[d], platelet; SD[e], standard deviation

Table 3. Hemostasis time according to gender and generation (Unit: min)

Gender	Mean ± SD[a]		
	Group A (n=60)	Group B (n=60)	Group C (n=60)
Male	29.83 ± 5.17	18.67 ± 2.81	28.19 ± 2.23
Female	28.67 ± 2.38	21.12 ± 1.89	31.89 ± 4.87
Generation	Mean ± SD		
30's	26.35 ± 3.25	16.50 ± 9.19	30.67 ± 9.40
40's	32.43 ± 16.57	19.25 ± 9.78	30.23 ± 8.94
50's	22.29 ± 5.82	18.14 ± 5.98	25.43 ± 10.94
60's	28.00 ± 9.42	20.43 ± 9.81	35.83 ± 18.28
70's	32.80 ± 13.10	21.83 ± 7.41	24.40 ± 6.27

SD[a], standard deviation

pression device (group A) was the shortest ($p < 0.05$). The correlation coefficient between the time to hemostasis and hemostasis method was 0.58, indicating a correlation.

When the patients were classified according to gender, the time to hemostasis of males was shorter than that of females. In group A, the times to hemostasis of males and females were 29.83 ± 5.17 and 28.67 ± 2.38 min, respectively. In group B, the times to hemostasis of males and females were 18.67 ± 2.81 and 21.12 ± 1.89 min, respectively. In group C, the times to hemostasis of males and females were 28.19 ± 2.23 and 31.89 ± 4.87 min, respectively. There were no statistically significant differences according to gender ($p > 0.05$). In regard to the hemostasis method according to age, the shortest times in group A, B, and C was respectively, 22.29 ± 5.82 min in those in their 50s, 16.50 ± 9.19 min in those in their 30s, and 24.40 ± 6.27 min in those in their 70s, respectively. No statistically significant differences were observed between the three groups ($p > 0.05$). The correlation coefficients between gender, generation, and hemostasis time were 0.232 and 0.125, indicating no correlation (Table 3).

In each hemostasis method, the correlation between the hemoglobin value, platelet value, and the time to hemostasis was examined. The correlation coefficients for the association between the time to hemostasis and the hemoglobin and platelet values in group A were −0.249 and −0.085, respectively. In group B, the correlation coefficients for the association between the time to hemostasis and the hemoglobin and platelet values were −0.012 and −0.207, respectively. In group C, the correlation coefficient for the association between the time to hemostasis and the hemoglobin and platelet values were 0.200 and −0.206, respectively. In each hemostasis method, although the hemoglobin or platelet values showed slight individual differences, the overall value was significantly different (Table 4).

Table 4. Correlation between hemoglobin, platelet value, and the time to hemostasis

		Hb[a]	Plt[b]
Group A	Pearson correlation coefficient	−0.249	−0.085
Group B	Pearson correlation coefficient	−0.012	−0.207
Group C	Pearson correlation coefficient	0.200	−0.206

Hb[a], Hemoglobin; Plt[b], Platelet

Fifteen patients (25.0%) in group A had complications; 5 (8.33%) showed a hematoma size > 5 cm, and 10 (16.66%) presented with pain. No complications developed in group B. In group C, 9 patients (15.0%) had complications; 2 (3.33%) showed a hematoma size > 5 cm, and 7 (11.66%) presented with pain. Therefore, complications developed at the highest rate when hemostasis was carried out using a compression device only ($p < 0.05$).

DISCUSSION

With the development of interventional radiology, arterial puncture has played an important role in the initiation of surgery. Although a range of approach routes can be applied according to the type of surgery, it is generally performed via the femoral artery approach, and the common femoral artery has been shown to be the ideal puncture site. The risk of intra-abdominal or retroperitoneal bleeding is high if the proximal area of the inguinal ligament, i.e., the external iliac artery, is punctured, which might injure the inguinal canal and intra-abdominal structures. Laceration of blood vessels, pseudoaneurysm, arteriovenous fistula, thrombosis, and excess bleeding can develop if the distal area of the common femoral artery, i.e., the deep femoral artery of the superficial femoral artery, is punctured[6, 7].

Previously, at the time of hemostasis after surgery, manual compression that using the hands as well as hemostasis using compression devices have been performed. Recently, patients have been able to walk within 1–2 h, and the discomfort of patients caused by lengthy bed rest and a lengthy hospitalization period has been reduced using the arterial closure device, Angio-Seal arterial closure device[4, 5]. On the other hand, when compression devices are used, infections in the inguinal area, acute arterial occlusion, and other large and small complications have been reported[8]. Nicolas reported that in the group that used a hemostasis device, a pseudoaneurysm developed in 1 case (0.60%)[9]. In addition, among 156 cases, allergic reactions or inguinal hematoma developed in 18 cases (11.5%). The present study examined the side effects of the use of compression devices.

In addition, the pain of patients was examined by a questionnaire survey. The results showed that side effects occurred 15 patients (25.0%) using compression devices; 5 patients (8.33%) had a hematoma > 5 cm, and 10 patients (16.66%) presented with pain. No complications developed when manual hemostasis was performed. When hemostasis was performed with a compression device and the hands together, 9 patients (15.0%) had complications, 2 patients (3.33%) had a hematoma > 5 cm, and 7 patients (11.66%) presented with pain. In other words, the highest rate of complications developed when hemostasis was performed only with compression devices.

In addition to side effects, the following correlations were compared: between the time to hemostasis after angiography and gender; the time to hemostasis of each generation and hemoglobin value; and platelet value and the time to hemostasis. In manual hemostasis, the mean time to hemostasis was 20 min, which was the shortest. On the other hand, the mean time was 28 min when a compression device was used. When compressed with a compression device and subsequently with the hands, the mean time was 29 min. Other studies measured the period from hemostasis to walking, not the time to hemostasis. Jeong et al. reported that walking was possible 7.2 ± 2.7 h after hemostasis with a compression device, and 17.3 ± 4.3 h after manual hemostasis[10]. Seok et al. showed that the period to the initiation of walking was 7.9 h when hemostasis was carried out using compression devices[11]. Kim et al. reported 6.8 h[12]. The results of the present study were different from the above results, and this was attributed to the difference in research methods. In the present study, the interval from angiography to hemostasis was measured instead of the time to walking, which can explain the different results. In addition, there was no difference in the time to hemostasis according to gender or generation, and the correlations of the hemoglobin value, platelet value, and the time to homeostasis were not significant. Therefore, gender, age, hemoglobin value, and platelet value have no significant involvement in hemostasis.

Manual hemostasis can stop bleeding most accurately within a short time with a low incidence of complications. On the other hand, in hemostasis using a compression device, it is difficult to assess the level of pressure that compresses the blood vessels. When a fixation device is inserted, the compression bar is slanted if the bottom surface is not hard. Consequently, it cannot compress the point for hemostasis properly. In addition, if patients are unconscious or unstable, the hemostasis points may move due to movement of the patient, resulting in bleeding[13]. On the other hand, as in our hospital, if the number of personnel in the angiography room is small (1 radiologist, 2 nurses, 1 specialist clinician), unnecessary use of professional personnel can be prevented by the application of a compression device. In addition, the discomfort of the person who performs hemostasis by manual compression when bleeding lasts for a long time due to the use of anticoagulants can be resolved, and low-cost equipment can perform the task of one person. Therefore, it is anticipated that the turnover of patients can be increased. The incidence of complications and the time to hemostasis are increased when hemostasis is carried out using a compression device. On the other hand, the incidence of side effects and the time to hemostasis are reduced when hemostasis is carried out using the hands. Nevertheless, when compression devices are used, unnecessary use of professional personnel can be prevented. In addition, in hemostasis for a long time, the discomfort of the person for whom hemostasis by manual compression is performed can be resolved. Overall, hemostasis performed mutually is safe and effective for patients according to their condition.

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