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Clinical Article

Angio-Seal™ Evolution™ versus Manual Compression for Common Femoral Artery Puncture in Neurovascular Diagnostic Angiography : A Prospective, Non-Randomized Study

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Objective : This prospective, non-randomized study compared the safety and efficacy of the Angio-Seal™ Evolution™ to that of manual compression for common femoral artery punctures in neurovascular diagnostic angiography.
Methods : From June 2009 to September 2009, we performed 169 diagnostic trans-femoral cerebral angiographies, using either the Angio-Seal™ Evolution™ or manual compression to achieve hemostasis. We included 60 patients in this study, 30 in each group. We defined minor complications as those requiring no further treatment such as hematoma size less than 6 cm and bruise size less than 25 cm. Major complications were those requiring surgery of the femoral artery pseudoaneurysm and/or the second line increase of hospital stay even without further treatment.
Results : Mean time to hemostasis was 0.42±0.04 minutes for the angioseal and 15.83±1.63 minutes for manual compression (p<0.001). Overall complication rate did not differ between the 2 groups. After the patients were fully mobile, at 24 hours, the rate of onset of new complication differed significantly between the 2 groups (p=0.032). In the angioseal group, 5 (16.7%) of the 30 patients experienced the onset of a new complication after 24 hours, including 3 (60.0%) of the 5 who experienced major complications.
Conclusion : The Angio-Seal™ Evolution™ is effective at decreasing mean time to hemostasis, like other closing devices. However, it may not be effective at producing early ambulation and discharge, compared to manual compression, because delayed complications may occur significantly after 24 hours.

Key Words : Cerebral angiography · Angio-Seal · Mannual compression · Closure device.

INTRODUCTION

Studies have thoroughly documented that the use of closure devices in percutaneous endovascular intervention is safe and effective[4,12,14,15]. These studies have confirmed superior patient comfort, reduced time to achieve hemostasis, reduced time to ambulation, and likelihood of early discharge with such use.

Our institution has selectively used the Angio-Seal™ STS Plus (St. Jude Medical, Minnetonka, MN, USA) in neurovascular diagnostic angiography and intervention for about 2 years, finding effects similar to those of previous studies. Recently, our institution has newly introduced the Angio-Seal™ Evolution™ (St. Jude Medical, Minnetonka, MN, USA) as a substitute for Angio-Seal™ STS Plus. However, we experienced some delayed puncture-site complications, after about 24 hours, when using this newly-developed device.

A greater number of delayed complications apparently have occurred with the use of Angio-Seal™ Evolution™, even though this use has resulted in much shorter times to hemostasis as compared to manual compression. Therefore, we decided to carry out a prospective, non-randomized study comparing safety and efficacy between Angio-Seal™ Evolution™ and manual compression, for common femoral artery punctures in neurovascular diagnostic angiography.

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MATERIALS AND METHODS

We carried out this prospective, single-center, non-randomized trial from June 2009 to September 2009. Data collected for

this study were from 169 diagnostic trans-femoral cerebral angiographies (TFCAs) performed during this period. We achieved hemostasis using either the Angio-Seal™ Evolution™ or manual compression. This study included patients undergoing a diagnostic TFCA using a 6-French femoral sheath on the common femoral artery. We excluded patients who had had any multiple femoral artery punctures due to follow-up angiography or neuro-intervention, a puncture of the superficial femoral artery, a puncture adjacent to the femoral bifurcation, a preexisting groin hematoma, or a failed angioseal deployment. Angioseal deployment failure, such as difficulty in accessing the target vessel with the device or malfunction of the device due to mechanical defect, needed subsequent standard manual compression. In our institution, the angioseal was usually used for the patients who took anti-platelets or anti-coagulants or who underwent neuro-intervention. In diagnostic TFCA, manual compression was usually preferred for the patients without taking anti-platelets or anti-coagulants. In this study, we used the angioseal and manual compression alternatively for the patients who underwent diagnostic TFCA. We attempted 34 angioseals in 34 patients. (remaining patients underwent manual compression during the same period.) Of these, 4 patients (11.8%) experienced angioseal deployment failure, remaining 30 patients in the angioseal group. We included 60 of the original 169 patients (30 patients in each group) in this study. There was no complication from the common femoral artery puncture.

Two physicians (Chung J and Lee D), who had undergone appropriate training in the use of the Angio-Seal™ Evolution™ and had dealt with more than 50 cases, performed all procedures. The clinician who performed a patient's TFCA also performed the manual compression or angioseal insertion. For manual compression, patients received compression until either 10 minutes passed or hemostasis occurred, followed by 4 hours' bed rest. Then, the patients walked carefully to the restroom. Patients were fully mobile 24 hours after TFCA. All patients with successful angioseal deployment were allowed to walk carefully to the restroom after 2 hours' bed rest. These patients were also fully mobile 24 hours after TFCA. Compression bandages were not applied in any groups. In fact, the instruction from the company reported that the angioseal device was indicated for use to allow patients who had undergone diagnostic angiography to ambulate safely as soon as possible after sheath removal and device placement.

We defined complications as minor or major. Minor complications were those that required no treatment such as a hematoma of less than 6 cm, and a bruise of less than 25 cm. Major complications were those requiring surgery of the femoral artery pseudoaneurysm and/or the second line increase of hospital stay even without further treatment[7,13]. If complications occurred, the patient underwent the femoral artery CT angiography. Complications were recorded prospectively and it was done by a blinded observer (Kwon OS) to the method of hemostasis.

Statistical analysis was performed using independent t-test. We considered a p-value of less than 0.05 as statistically significant.

RESULTS

Table 1 summarized patient demographics and procedure results. There were no significant differences regarding age (p= 0.130), sex (p=1.000), hypertension (p=0.464), diabetes (p= 0.538), peripheral vascular disease (p= 0.632), or use of anti-platelets (p=0.157) and anti-coagulants (p=1.000). Mean time to hemostasis was 0.42±0.04 minutes (range, 0.2 to 0.8 minutes) using the angioseal and 15.83±1.63 minutes (range, 10 to 55 minutes) using manual compression (p<0.001).

Without considering onset time, the minor complication rates were 5 (16.7%) in the angioseal group and 8 (26.7%) in the manual compression group (p= 0.425). Major complications occurred only in the angioseal group, but there was no statistical significance (p=0.083). In addition, the overall complication rate was same, 8 (26.7%), in both groups.

Table 2, which takes onset time into account, shows a different complication distribution when compared to that shown in Table 1. Minor complications occurred less than 4 hours after the procedure in 3 (10.0%) of 30 patients in the

Table 1. Patient demographics and complication rate

	Angioseal (n=30)	Manual (n=30)	p-value
Age	53.9±2.5	48.6±2.4	0.130
Sex (female)	17 (56.7%)	17 (56.7%)	1.000
Hypertension	8 (26.7%)	11 (36.7%)	0.464
Diabetes	4 (13.3%)	5 (16.7%)	0.538
PVD	2 (6.7%)	1 (3.3%)	0.632
Anti-platelet	11 (36.7%)	6 (20%)	0.157
Anti-coagulant	0 (0%)	0 (0%)	1.000
Mean time to hemostasis (minute)	0.42±0.04	15.83±1.63	<0.001
Complication			
Minor	5 (16.7%)	8 (26.7%)	0.425
Major	3 (10.0%)	0 (0.0%)	0.083
Total	8 (26.7%)	8 (26.7%)	1.000

PVD : peripheral vascular disease

Table 2. Difference in onset time of complication between the two groups

	Angioseal (n=30)	Manual (n=30)	p-value
<4 hours	0 (0%)	3 (10.0%)	0.083
4 to 24 hours	3 (10%)	5 (16.7%)	0.623
>24 hours	5 (16.7%)	0 (0.0%)	0.032
Burst after 24 hours	5 (16.7%)	0 (0.0%)	0.032
Total	8 (26.7%)	8 (26.7%)	1.000

manual compression group, which was not significantly different from the rate of such complications in the angioseal group (p=0.083). After patients could walk carefully to restroom, from 4 to 24 hours after the procedure, 5 (16.7%) of the 30 patients in the manual compression group and 3 (10.0%) of the 30 patients in the angioseal group experienced minor complications (p=0.623). After the patients became fully mobile, at 24 hours, the onset rate of new complications differed significantly between the 2 groups (p=0.032). In the angioseal group, 5 patients (16.7%) felt a "pop" at their puncture site due to the immediate appearance of large hematoma in the inguinal area. These hematomas, caused by bleeding from the puncture site, stopped upon manual compression. Major complications occurred in 3 (60.0%) of these 5 patients. Of these, 1 experienced a pseudoaneurysm on the common femoral artery and underwent surgical primary closure, and 2 patients required 2 more days of bed rest. There were no new complications after 24 hours in the manual compression group.

DISCUSSION

Several investigators in the fields of cardiology[1,2] and neuroendovascular research[16] have recently studied the safety of manual compression and early ambulation after transfemoral catheterization. However, the procedure is still time-consuming and requires prolonged patient bed rest[12]. Thus, this procedure commonly employs closure devices these days. Such devices can contribute to patient comfort, reduce the time to achieve hemostasis, reduce the time to ambulation, and contribute to an earlier discharge[4,12,14,15]. Closure device use also can be helpful in hypertensive patients, patients taking anticoagulants, and patients who are unable to lie flat for prolonged periods of time[9].

Our institution had selectively used the Angio-Seal™ STS Plus in neurovascular diagnostic angiography or intervention for about 2 years. While using this device, we had felt it was safe and effective. Recently, our institution introduced the newly-developed Angio-Seal™ Evolution™ into use. While this new closing device was used in our institution, we experienced some delayed patient complications, at about 24 hours after employing it. Therefore, we decided to compare the safety and efficacy of the Angio-Seal™ Evolution™ to that of manual compression, for common femoral artery punctures in neurovascular diagnostic angiography.

This prospective, non-randomized study showed that the Angio-Seal™ Evolution™ led to a larger number of delayed complications, even though the overall complication rate did not differ from that of manual compression. In the manual compression group, all minor complications occurred before 24 hours, and the chance of such decreased as time passed. In the angioseal group, however, the chance of complications increased over time. Initially, the angioseal results were better than the manual compression results with regard to time to hemostasis and complication rate. However, most complications occurred after 24 hours, with a painful "pop" sound that might be the bursting of a collagen plug at the puncture site. This may suggest that, with the angioseal, early ambulation can affect collagen plug stability for up to 24 hours, which means that Angio-Seal™ Evolution™ may not be capable of reducing time to ambulation or facilitating early discharge.

The reported incidences of minor and major complications after manual compression on the femoral artery puncture site have ranged from 1.5% to 9%[10,11]. In treatments using large sheath sizes (up to 11F), multiple antiplatelet agents with heparin, or stent placement, complication rates have ranged from 5.9% to 17%[5]. Wagenbach et al.[16] suggested that early ambulation after manual compression was feasible and safe after diagnostic or therapeutic neuroendovascular procedures. Only 4.7% of their patients experienced delayed ambulation, because of bleeding from the access site. In addition, Wagenbach et al. said patients often did not require a longer bed rest period or the routine use of closure devices. Manual compression without closure devices avoids the costs and potential complications associated with the routine use of these devices. Compared to previous studies of complications, ours showed high complication rate (26.7%) after manual compression, because we counted even minimal complications, such as a small, painless bruise around the inguinal area.

Currently, there is no perfect closure device, and existing devices have significant limitations. Closure devices' considerable disadvantages include cost (about $330 at our institution) and the potential for serious complications, such as vessel dissection, occlusion, and distal embolization[6,8]. According to Eidt et al.[3], the most common device-related complication is thromboembolic occlusion of the femoral artery at the puncture site. In our cases, however, the main problem has been a delayed bursting of the collagen plug at the puncture site. Even though Angio-Seal™ Evolution™ needs very little time to produce hemostasis, our study showed that it possessed no benefit over manual compression with regard to early ambulation or early discharge.

One of the limitations of this study was that it was small series of non-randomized study. Another one was that not all patients were evaluated routinely at the puncture site by color Doppler ultrasound or the femoral CT angiography before and/or after the procedure.

CONCLUSION

Angio-Seal™ Evolution™, like other closing devices, is effective in decreasing mean time to hemostasis. However, in comparison to manual compression, it may not be effective at bringing about early ambulation or early discharge, because delayed complications may occur significantly after 24 hours. Further study with more cases will be necessary.

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