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A New Hemostasis Tool after Percutaneous Angioplasty: The Hemcontm Pad Hemostasis Device

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Abstract

Objective: This prospective, randomized study compared the efficacy of the HemConTM pad to that of manual compression for peripheral artery puncture in peripheral artery disease.

Methods: This study was a prospective single center, investigation in 50 consecutive patients undergoing interventional procedures for peripheral artery disease. After completion of catheter procedure a 1:1 randomization to HemConTM pad versus conventional manually pressure (control) was performed. Before the removal of the artery sheath (4 to 6Fr), a blood examination was taken for activated clotting time (ACT). The femoral sheath was removed at the patient's bed immediately after the procedure. Slightly blood was allowed to exit from the access site and pressure with HemConTM pad or directory was then applied manually for 2×ACT seconds. After the time the operator released the compression. If the bleeding continued, additional compression was continued until complete hemostasis. Before and after hemostasis blood pressure and the total time to hemostasis were recorded. We checked puncture site and performed ultra sound detecting abnormality before discharge.

Results: We have successful hemostasis in 48 of 50 patients (96% success); two patients had been converted into over size sheath (10Fr) during catheter procedure. The average time to successful hemostasis following sheath removal was significant shorter with the HemConTM pad by 53% compared to the conventional manual compression (681 ± 243 vs. 362 ± 82 seconds, $p<0.001$). In duplex ultrasound examination, there were no thromboses in access site artery.

Conclusion: The HemConTM pad is effective at decreasing average time to hemostasis. This device may save the time for physician and the cost for hospital. Furthermore, this device can contribute to patient comfort, reduce the time to compression, and promise to a planned discharge.

Introduction

Recently, many peripheral artery diseases are performed via peripheral artery. After procedure, hemostasis of artery is performed by applying local pressure either manually for femoral artery or by mechanical devices for brachial artery. However, vascular complications requiring surgical repairing may be seen in 1 to 5% of patients undergoing interventional procedures [1,2]. The HemConTM pad (HemConTM Medical Technologies, Inc., Portland, OR, USA) is used armies to control traumatic bleeding in many countries. It consists of carbohydrate called chitosan produced by deacetylation of chitin, which is extracted from crustaceans. The positive charged chitosan attract the negative charged blood cells and platelets, therefore promoting hemostasis [3]. We describe here our experiences to evaluate the performance of HemConTM pad device for hemostasis after percutaneous transluminal angioplasty for peripheral artery disease.

Material and Methods

From June 2011 to May 2012, we performed 50 diagnostic and interventional catheterizations for peripheral artery using either the HemConTM pad or manual compressions to complete hemostasis. This study was a prospective single center investigation in 50 consecutive patients undergoing catheter procedures for peripheral artery disease. The authors declare no conflict of interest associated with this manuscript.

Hemostasis procedure

After completion of catheter procedure a 1:1, open label randomization to HemConTM pad versus conventional manually pressure (control) was performed. Therefore we were simply divided into control group and HemCon group in order consecutive patients of these patients. Exclusion criteria were sheath size ≧ 7Fr, hematoma requiring surgical repair, severe atherosclerosis. Before the removal of the artery sheath, a blood examination was taken for activated clotting time (ACT). The femoral sheath was removed at the patient's bed immediately after the procedure. Slightly blood was allowed to exit from the access site and pressure with HemConTM pad or directory was then applied manually for 2×ACT seconds. After the time the operator released the compression. If there was oozing or bleeding puncture site, we performed additional compression for 1 minute and after that we were evaluated again until haemastosis could be confirmed. Before and after hemostasis blood pressure and the total time to hemostasis were recorded. After achieving hemostasis a pressure bandage was applied 4 hours at the access site as routinely in our hospital. Tomorrow morning, we checked puncture site and performed ultra sound detecting abnormality. After achieving all studies passed, patients were

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routinely discharged. After two weeks later, we checked all patients at our clinic.

Statistics analysis

All data are expressed as mean ± SD. Patients' data was stored on an Excel database. Independent sample two tailed Student's t-test for continuous variables. Comparisons between discrete variables were based on chi-square analysis. A P value of <0.05 was considered statistically significant.

Results

We have successful hemostasis in 48 of 50 patients (96% success); two patients had been converted into over size sheath (10Fr) during catheter procedure. There were no significant differences in patient's characteristics (Table 1). 29 cases were sealed in the femoral artery, and 19 cases were in the brachial artery. There were no major bleeding and hematoma to require surgical repair. In procedural data, this study showed no difference between the two groups in procedure time, pre blood pressure and ACT just before sheath removal (Table 2). Although post blood pressure were showed tendency to higher than before compression with HemConTM pad, the average time to successful hemostasis following sheath removal was significant shorter with the HemConTM pad by 53% compared to the conventional manual compression (681 ± 243 vs. 362 ± 82 seconds, p<0.001) (Table 2). Sheath size in the 4-6 Fr range used in this study did not influence compression time. The use of any antiplatelets did not also influence outcome. In duplex ultrasound examination, there were no thromboses in access site artery (Figure 1). Although HemConTM pad group have tended to using smaller sheath, sheath size did not influence patients' outcome in this study.

Discussion

Many peripheral artery patients around the world undergo peripheral angiography and angioplasty procedure performed via peripheral artery. In order to improve in the devices for catheter procedure, the number of vascular complication has occurred. Vascular complications requiring surgery may be occurred in 1 to 5% of patients undergoing catheter procedure [1-4]. Many alternative procedures exist for hemostasis following a percutaneous procedure. The most common technique is manual pressure applied to the puncture site. Furthermore, a pressure bandage is applied once hemostasis has been achieved. In the last decade, Angio-SealTM hemostatic puncture closure device is intended for use in sealing the defect in the puncture site wall produced by percutaneous access [5]. The use of this closure device significantly improves patients' and physicians' comfort, however, this device also have been reported to increase thrombosis complications [6]. Recently, chitosan -a polymer of poly-d-glucosamine and poly-n-acetyl-d-glucosamine found in the crustaceans have been shown

	Control	HemCom
Numbers	24	24
Male/females	14/10	12/12
Age	74.8 ± 10	73.3 ± 9.8
Comobid risk factor		
Hypertention	8	7
Hyperlipidemia	4	5
Diabetes	8	5
Collagen Disease	6	6
Renal failer	0	1
Medication		
Aspirin + Clopidogrel	5	3
Aspirin + Warfarin	4	3
Aspirin + Sarpogrelate	3	1
Cilostazol + Clopidogrel	2	1
Cilostazol	5	9
Sarpogrelate	2	3
Clopidogrel	1	1
Beraprost	1	0
Warfarin	0	1
No medication	1	2

*Data are mean ± SD unless otherwise defined

Table 1: Baseline Characteristics in the 48 patients.

	Control	HemCon	ρ Value
Access artery (cases)			
Femoral artery	12	17	
Brachial artery	12	7	
Sheath size (cases)			
4Fr	6	10	
5Fr	6	8	
6Fr	12		
Procedure time (min)	110 ± 29	92 ± 53	0.15
Hemostatsis			
Pre systoric BP (mmHG)	137 ± 13	141 ± 14	0.32
Pre diastoric BP (mmHG)	74 ± 11	73 ± 10	0.59
Post systoric BP (mmHG)	137 ± 13	142 ± 11	0.06
Post diastoric BP (mmHG)	73 ± 10	73 ± 11	0.96
ACT (sec.)	181 ± 31	175 ± 32	0.63
Compression time (sec.)			
All patients	681 ± 243	362 ± 82	<0.001
Femoral artery	780 ± 178	375 ± 83	<0.001
Brachial artery	598 ± 218	359 ± 69	<0.05
4Fr	770 ± 44	364 ± 98	<0.01
5Fr	540 ± 245	365 ± 75	<0.05
6Fr	631 ± 285	354 ± 79	<0.001

*All data are expressed as Mean ± SD
ACT: Activated Coagulation Time

Table 2: Procedure Information and outcomes.

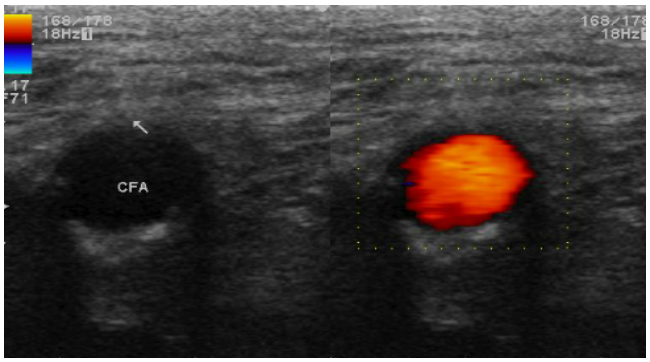

Figure 1: Post procedure echo. There is no thrombosis, hematoma, or another trouble inside artery and puncture site (↑).

effective in promoting hemostasis [7]. The chitosan positive charged molecules attract the negatively charged blood cells and platelets thus promoting clotting. The HemComTM pad is composed of chitosan. In battle-field, military personnel have used this pad to successfully stop arterial hemorrhage [8].

The present study describes our experience with the early safety and efficacy of HemConTM pad for immediate hemostasis in patients undergoing diagnostic or interventional procedure using 4 to 6 Fr catheter introducer via peripheral artery. We found that the HemConTM pad significantly decrease time to hemostasis by 53% from 681 ± 243 to 362 ± 82 seconds for arterial puncture. Although the absolute decrease in time is only about 5 minutes, it is very important for the patients to shorten the pressure time. It is also significant for a busy physician who performed over 5 procedures a day. This is meaning that we can save 25 minutes every day, about 2 hours every week, and about 100 hours every year. Furthermore, this device can contribute to patient comfort, reduce the time to compression, and promise to a planned discharge.

Normally, interventional procedure time is different between diagnostic angiography and treatment angioplasty. Therefore, there are difference heparin dose, ACT, and duration for manual compression. Recently, there are some reports for HemComTM pad for hemostasis after cathetel [9,10], however there are no precious guideline for compression time for using HemComTM pad. In our study, blood pressure and sheath sizes had not affected hemostasis duration. However, HemConTM pad group completed hemostasis less than ACT×2 duration. It is very important that ACT×2 minutes is one of the safety compression time with HemConTM pad after sheath removal.

As mentioned above, Angio-SealTM is one of the major devices for puncture closure. Because this device remains anchor inside the puncture site, there are some fatal complications such as embolization or intra-arterial migration of collagen, which may require surgical repair [11-13]. In our study with HemConTM pad, there were no major complication by embolization and thrombosis. Furthermore we detected no significal deterioration in the puncture site under duplex ultrasound examination. From the cost-conscious, HemConTM pad is a one-tenth cost for Angio-SealTM. We have to spend short compression time; however, this device may reduce the total cost including complication, and save our time.

Limitations

The open label design could bias the results because the operators were aware of the pad used for haemostasis. Double blinded study would be very difficult to produce a placebo pad, because there were no similar devices in our hospital. We performed only 4 to 6Fr devices in this study. If the procedure needs to use over 8Fr sheath, we perform open repair for access artery. Furthermore, the intensity of compression was not controlled. In this study, we hypothesized that ACT×2 minutes is the compression time with HemConTM pad after sheath removal. However, there are no evidences to be clearly defined hemostasis duration. HemCon Pad decreased only time of compression after catheterization but not affect for the time to discharge. The similarity between groups regarding time to discharge is a reflection of our hospital to observe patients until the day after catheterization. Further studies with larger size sheath and several hemostasis durations are needed to investigate the clinical outcomes of HemConTM pad.

Conclusion

In summary, the HemConTM pad may shortens the time to hemostasis compared to conventional manual compression in patients undergoing puncture for peripheral artery. We suggest that the compression time with 4 to 6Fr sheath and HemConTM pad is ACT×2 seconds after sheath removal. The use of the new hemostasis pad improves patients' comfort and physicians' stress.

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