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Postinterventional percutaneous closure of femoral artery access sites using the Clo-Sur PAD device: initial findings

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Abstract The purpose of this study was to evaluate a percutaneous hemostatic device in patients to achieve immediate hemostasis at the vascular access site as well as early ambulation after vascular interventional procedures. In a randomized trial, a hemostatic device (Clo-Sur PAD, Medtronic AVE, Inc., Santa Rosa, CA, USA; *n*=60) was compared with manual compression (*n*=60) in patients after endoluminal intervention through an inguinal access (sheath sizes: 5–7 French). Device safety was evaluated by assessing complications within 24 h and 14 days. System efficacy was measured by the percentage of achieved immediate hemostasis and early ambulation. Device application was possible in 57 cases (95.0%), with 93.3% (56/60) of the patients rising 2 h after application. Hemostasis time was 10.15±1.96 min (control group: 16.20± 1.79 min), with a pressure bandage time of 3.47± 5.53 h (control group: 13.8±4.32 h). Ambulation was possible after 2.13± 0.50 h (control group: 8.57± 3.47 h). Complications encountered were access-site bleeding with hematoma (device: *n*=3; control: *n*=9). All complications were managed conventionally without blood transfusion or surgical intervention. The system is an easy to use device permitting early ambulation without additional pressure bandaging in the majority of patients. Preliminary data show that hemostasis does not depend on the level of anticoagulation.

Keywords Percutaneous closure · Vascular intervention · Arterial occlusive disease · Chemoembolization · Access-site complication

Introduction

Percutaneous interventional arterial procedures have undergone a constant increase in the last 15 years. Vascular access is usually obtained via the common femoral artery employing introducer sheaths of different sizes, thus enabling placement of different types of catheters in the vascular region of interest (ROI). Therapeutic interventional procedures usually require employment of larger sheaths in combination with intravenous anticoagulation so that achieving immediate hemostasis at the arterial puncture site is challenging. With large sheaths, both manual compression time and immobilization are generally proportional to the size of the introducer sheath and the level of anticoagulation and are also the major source for a high complication incidence (approximately 11%) [1, 2]. With the advent of percutaneous closure devices, improvement not only in the safety of arterial access-site closure but also an improved quality of care after the procedures can be achieved. Several systems, widely ranged in price, are available. All require training prior to application [3–5].

Recently, a novel arterial hemostatic device (Clo-Sur PAD; Medtronic AVE Inc., Santa Rosa, CA, USA) consisting of hydrophilic biopolymer polyprolate acetate

was introduced. The system can be used as a sealing device following percutaneous procedures with sheath sizes from 4–7 French (F). This system uses a simple approach and is designed to rapidly seal the femoral artery puncture site, thus reducing time until hemostasis and ambulation. The Clo-Sur PAD works through electrical interference between erythrocytes and therefore does not depend on anticoagulation level or platelet function [6, 7].

The purpose of this study was to prospectively evaluate the Clo-Sur PAD with regard to immediate hemostasis at the vascular access site and early ambulation of fully anticoagulated patients after interventional procedures.

Subjects and methods

The investigation was designed as a prospective, randomized, single-center feasibility study in consecutive patients undergoing diagnostic or interventional angiography. The device studied has already been approved for clinical use, and the study was approved by the institutional review board. All patients gave written informed consent to the use of the device and were made aware of potential associated risks in accordance with the Declaration of Helsinki. Specific risks the participants were advised of included insufficient closure of the arterial puncture, immediate or delayed bleeding, formation of a hematoma or pseudoaneurysm that could necessitate surgery, peripheral nerve injury, occlusion of the femoral artery or distal embolization with acute limb ischemia, allergic reaction to the pad, and puncture tract infection or abscess formation. Patients were not aware to which arm of the study they were enrolled. Randomization was performed by envelop drawing.

The hemostatic device and technique of percutaneous closure

The device is approved in Europe for the closure of arterial access sites and was used in this study according to the approved application. The device is delivered as a sterile pad in the approximate size of a 2×2 in. (5×5 cm) gauze. Cost per device in Germany is 55 euros. The linear biopolymer of the Clo-Sur PAD is positively charged in its dry state. The chain of positive charges along with the polymeric structure and molecular weight endow polyprolate with its blood coagulating properties [6, 7]. The positively charged polyprolate forms a coagulum with heparinized blood, defibrinated blood, and washed red blood cells. No clot formation has been described with serum albumin, serum globulin, or white blood cells, which indicates that polyprolate reacts with the cellular elements of blood outside of the normal clotting cascade. The hemostatic property or coagulum formation of positively charged polyprolate in blood is believed to involve polyprolate-mediated agglutination of negatively charged red blood cells. Neuraminic acid residues on the red blood cell membrane surface react with the positively charged polyprolate. Polyprolate, even at very low concentrations, causes agglutination in red blood cells. This property led to polyprolate's consideration as a hemostatic agent [6, 7]. After intervention, the arterial access site is prepared by cleaning blood contamination and verifying that the arterial puncture site is dry. Blood is then aspirated through the side port of the introducer sheath, keeping blood in the sheath (Fig. 1).

The Clo-Sur PAD is placed to two thirds over the insertion site and sheath (Fig. 2). The device is covered with clean, sterile 2×2-in. (5×5 cm) gauze (folded 4×4-in. (10×10 cm) gauze). With one hand, two fingers are placed proximal and one finger distal to the sheath. Occlusive pressure proximal to the puncture site is applied. The introducer sheath is removed, allowing a small amount of blood to reach the skin surface. The puncture site is then covered with the Clo-Sur PAD The pad is held firmly with moderate pressure over the access site. Proximal occlusive pressure is maintained (Figs. 3, 4). After approximately 3 min of holding, the pressure is gradually eased over the next 7 min to complete an up to 10-min hold. Bleeding is checked every minute after the 3-mi hold. The Clo-Sur PAD is left in place (Fig. 5), and clean 2×2-in. (5×5 cm) gauze applied over the device. A plaster is then placed over the site.

Diverging from the instructions of the manufacturer, a pressure bandage was then applied for 2 h. Bed rest was maintained for 2 h after successful device application. After that, the patient was allowed to rise. The device was removed 24 h after application. In cases with rebleeding during the observation period, prolonged application of pressure bandage was necessary, and these patients were not allowed to rise until 4 h after the intervention.

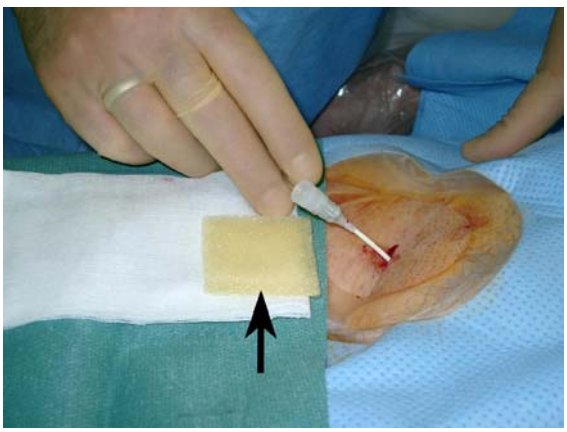

Fig. 1 Hemostatic device (*arrow*) and sterile gauze prepared for device delivery. The 5 French introducer sheath is slightly withdrawn. Blood has already been aspirated via the side port, and the puncture site has been cleaned of cutaneous blood contamination

Enrolment

In December 2004 and January 2005, 120 consecutive patients were included in the study. Mean patient age was 66.6±10.8 years. Patients were randomized to receive either the hemostatic device (n=60) or manual compression (n=60). Exclusion criteria were age younger than 18 years, pregnancy, ipsilateral prior femoral access within 30 days, history of prior femoral closure with another device, significant anemia (hematocrit<30%), or preexisting hematoma. Results of the device group were compared to those of the control group.

Intervention and indication

The hemostatic device was applied in 60 patients after interventional procedure, with retrograde arterial access via the right (n=47) or left (n=13) common femoral artery. In 30 patients, transarterial chemoembolization (TACE) was performed. A 5 F introducer sheath was employed in all cases. In another 30 patients with peripheral arterial occlusive disease (PAOD), a peripheral intervention (PTA) was performed via a 6 F (n=23) or 7 F (n=7) introducer sheath. All interventions were performed by two experienced radiologists (AT, TJV) with more than 10 years' experience in the field. All PAOD patients received 5,000–10,000 IU of heparin intraarterially during intervention based on body weight and time of intervention. All PAOD patients received 100 mg acetylsalicylate (ASA) daily on a lifetime basis and received 300 mg clopidogrel prior to intervention. The Clo-Sur PAD device was applied by one radiologist, who did not perform the intervention (JOB), with 8 years' experience in the field and 6 years' with closure device application.

All control patients also received either chemoembolization of liver lesions (n=31, sheath size 5 F) or balloon angioplasty for PAOD (n=29, sheath size 6 F) after retrograde puncture of the common femoral artery. All patients in the PAOD control group received 5,000–10,000 IU of heparin intraarterially during the intervention. Pre- and postinterventional measurements for platelets,

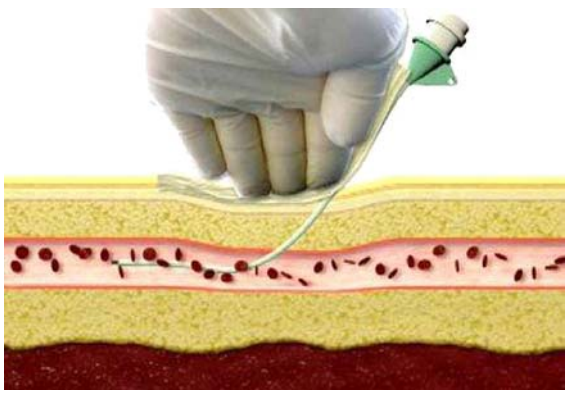

Fig. 2 Application of the device at the arterial access site with the introducer sheath still in place

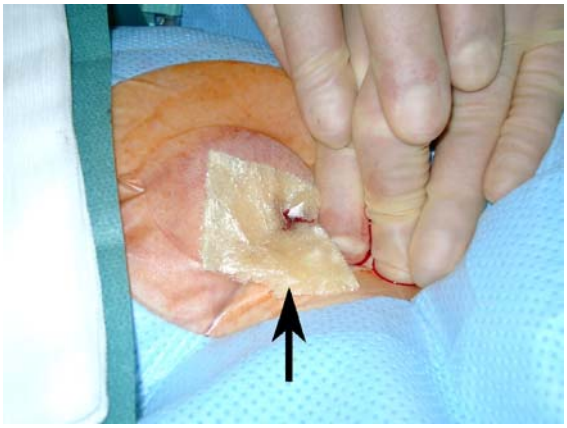

Fig. 3 Application of occlusive pressure proximal to the puncture site, with the hemostatic device (*arrow*) covering the access site in order to allow clot formation

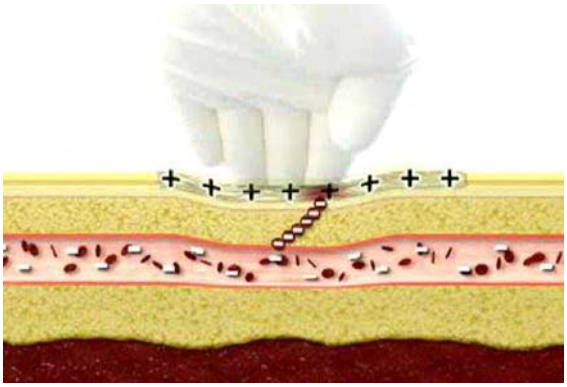

Fig. 4 Formation of a clot after sheath removal through interaction of the positive pad charge and the negative red blood cell charge

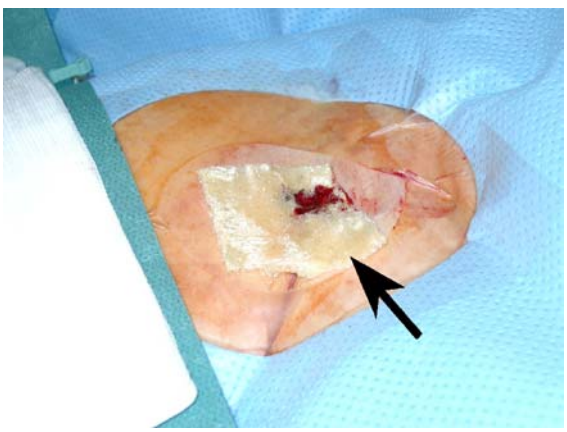

Fig. 5 Access site after successful device application and achievement of hemostasis. The device (*arrow*) is left on the puncture site and is covered with sterile gauze and a plaster

partial thromboplastin time (PTT), and Quick values were determined.

For each patient, the time from sheath removal to hemostasis was recorded. Additionally, all control patients received a pressure bandage for 12 h and maintained bed rest for 4 h (sheath size 5 F) or 6 h (sheath size 6 F). Time to hemostasis was checked after a 3-min hold every minute thereafter until hemostasis was achieved.

Efficacy measurements and follow-up

For every patient in this analysis, platelet count, PTT, and Quick values were performed within 48 h prior to the intervention and immediately before sheath removal after the intervention. Activated coagulation time could not be performed. For each patient, the time from sheath removal to achievement of hemostasis and then to mobilization was recorded, as well as the amount of time for pressure bandage application. Results were compared with the control group. All patients (device and control) were examined 24 h and 14 days after intervention. Follow-up consisted of clinical examination [pulse status at the lower extremities, inspection of puncture site, measurement of ankle-brachial-index (ABI)], and color-coded Doppler ultrasound (CCDUS) examination. Criteria checked with CCDUS were: local hematoma, false aneurysm, vessel wall integrity, vessel lumen at the access site, and surrounding soft tissue situation in the area of the puncture site. Additionally, in all PAOD patients, complete examination of the pelvic and peripheral vasculature was performed, as these patients had received percutaneous recanalization. The examination was carried out by two experienced staff radiologists (WS, AT) with 5 and 8 years' experience, respectively, in particular, with ultrasound examinations. The 14-day follow-up was chosen since all PAOD patients are routinely scheduled for follow-up at 14 days post-intervention. To avoid inconsistency in follow-up, all patients were seen 14 days after intervention.

Statistical analysis

Continuous variables are presented as mean±SD values, if appropriate. The Wilcoxon-Mann-Whitney test was used to analyze continuous data from unpaired samples and calculate the *P* values to evaluate statistical significance of hemostasis time, time to mobilization, PTT values, gender, and age distribution between study and control groups. Additionally, statistical significance between PTA and TACE groups (study vs control) for the above-mentioned parameters was analyzed. For all statistical analysis, SPSS for Windows 12.0 (SPSS Inc. Chicago, IL, USA) was used.

Results

Patient population

The device population consisted of 60 patients (TACE subgroup: n=30; PTA subgroup: n=30), with a male to female ratio of 35:25 in the device population, 16:14 in the TACE subgroup, and 19:11 in the PTA subgroup. Mean age of the patients in the device group was 65.82±10.40 (TACE: 65.82±10.40; PTA: 65.82±10.40). A 5-F sheath was used in 30 (TACE subgroup) of the 60 device cases, in 23 cases a 6-F sheath was employed, and in 7 cases a 7-F sheath was used(PTA subgroup). The control population also consisted of 60 patients (TACE subgroup: n=31; PTA subgroup: n=29), with a male to female ratio of 37:23 in the control population, 20:11 in the TACE subgroup, and 17:12 in the PTA subgroup. Mean age of the patients in the control population was 65.60±9.80 (TACE: 63.77±9.29; PTA: 67.47±10.16). A 5-F sheath was used in 31 (TACE subgroup) of the 60 control cases, and in 29 cases (PTA subgroup) a 6-F sheath was employed. There was uneven distribution of sheath sizes employed in the PTA subgroups (device population vs control population).

Efficacy results: hemostasis and ambulation

Of the 60 patients included in the device population, successful device application was possible in 57 (95.0%). In the remaining three (5.0%) patients, immediate hemostasis could not be achieved. These cases required a conversion to conventional manual compression technique. Overall, 56 (93.3%) patients were able to rise 2 h after successful device application without any pressure bandage. In the device group, mean time to reach hemostasis was 10.15±1.96 min after sheath removal (TACE subgroup: 9.53±1.04 min; PTA subgroup: 10.77±2.45 min). Mean time for pressure bandage was 3.47±5.53 h (TACE subgroup: 2 h, PTA subgroup: 4.93±7.61 h). Mean time until ambulation (after hemostasis) was 2.13±0.50 h (TACE subgroup: 2 h; PTA subgroup: 2.27±0.69 h). In the control population, the mean time to reach hemostasis was 16.20±1.79 min (TACE subgroup: 16.50±2.10 min; PTA subgroup: 15.90± 1.40 min). Mean time for pressure bandage was 13.8± 4.32 h (TACE subgroup: 5.13±0.35 h, PTA subgroup: 12.00 h). Mean time until ambulation (after hemostasis) was 8.57±3.47 h (TACE subgroup: 5.13±0.35 h; PTA subgroup: 12 h).

Blood samples

Mean PTT and Quick and platelet values are shown in Table 1. There was no statistically significant difference between device and control groups in the pre- and postprocedural platelet count (P=0.028; TACE: P=0.074;

PTA: P=0.126) or for Quick values (P=0.033; TACE: P=0.251; PTA: P=0.916). There was no statistically significant difference in the PTT values immediately after intervention between device and control groups overall (P=0.290) and the TACE device subgroup versus TACE control subgroup (P=0.679). The difference in PTT values in the PTA group (device vs control: P=0.003) was statistically significant.

Safety results: complications

The three patients with insufficient hemostasis suffered from minor complications, with development of a minor hematoma at the arterial access site. These patients received a PTA of the peripheral artery employing a 7-F sheath and revealed PTT values after the intervention of 88–96 s. Additionally, two of the three patients received clopidogrel before the intervention and ASA on a life-time basis. All three patients were obese. In an additional patient (1.7%), rebleeding occurred 1 h after appropriate device delivery and hemostasis. Additional manual compression and application of a pressure bandage was required in this case to achieve hemostasis at the arterial puncture site. This patient received a PTA of the peripheral arteries employing a 6-F sheath and revealed a PTT value of 96 s after intervention. The patient also received clopidogrel and ASA prior to the PTA. All four patients with insufficient hemostasis had a prolonged period of bed rest for a total of 4 h and delayed ambulation. Additionally, these patients received a pressure bandage for 24 h. At the 24-h follow-up, all four had developed a large hematoma at the access site (>5 cm) but did not require any additional measures (e.g., blood transfusion, surgical revision, etc.).

No surgical repair, infection, pseudoaneurysm, or groin-related transfusion was noted in the entire study population.

In the control group, nine complications were encountered, eight were in the PTA subgroup. All rebled after successful pressure bandage application, resulting in a large hematoma of >5 cm in six cases and >10 cm in three cases. All complications were managed conventionally without blood transfusion or surgical intervention. There was no case of false aneurysm. The analysis of complications between device and control groups revealed no statistical significance (overall: P=0.144; TACE: P=0.040; PTA: P=0.720).

Ultrasound and follow-up results

All patients underwent peripheral CCDUS examination 24 h and 14 days after intervention. There was no evidence of device-induced arterial lumen reduction, local thrombosis, or distal embolization. No delayed bleeding or large hematoma was observed. In the four patients with insufficient hemostasis after device application, US and CCDUS examination revealed a hematoma at the access site without any sign of pseudoaneurysm development or local infection. At the 14 day follow-up, all patients revealed inconspicuous access sites, as evaluated by clinical and CCDUS examination.

Comparison with the control group

The comparison of time until achievement of hemostasis, time until mobilization, and the time period of application of a pressure bandage are listed in Table 2. Statistical analysis revealed a statistically significant difference between the control group using the manual compression technique and the device group with employment of the hemostatic device concerning time for achievement of hemostasis (P<0.0001), time for the pressure bandage (P<0.0001), and time until ambulation (P<0.0001). This could also be found for the subgroups (device TACE vs control TACE and device PTA vs control PTA). There was no statistically significant difference between device and control groups regarding age (P=0.809; TACE: P=0.636; PTA: P=0.836), gender (P=0.711; TACE: P=0.296; PTA: P=0.601), and PTT values before the intervention (P=0.803; TACE: P=0.784; PTA: P=0.568). There was also no statistically significant difference concerning preinterventional values of platelets (overall: P=0.028; TACE: P=0.074; PTA: P=0.126) and Quick value (overall:

Table 1 Platelet count, partial thromboplastin time (PTT) value pre- and postintervention, and Quick value (mean±SD) connected with Clo-Sur PAD use (device) and manual compression (control)

	Platelets (n * 10^3)	Quick value (%)	PTT pre (s)	PTT post (s)	P value PTT post
TACE device	200.00±105.14	83.27±16.39	34.83±14.25	42.3±21.83	0.770
TACE control	250.87±109.19	79.33±16.04	31.70±7.25	39.10±20.73	
PTA device	279.57±63.64	98.83±7.29	31.17±5.25	82.20±13.52	0.054
PTA control	313.17±79.27	99.10±7.84	32.93±8.37	93.13±13.36	
Overall device	239.78±95.05	91.05±14.82	33.00±10.80	66.25±27.00	0.205
Overall control	282.02±99.67	89.22±16.00	32.32±7.79	66.12±32.27	

TACE transarterial chemoembolization, *PTA* peripheral intervention
Statistical significance was calculated using the Wilcoxon-Mann-Whitney- test

P=0.326; TACE: *P*=0.251; PTA: *P*=0.916) between the different groups.

Discussion

Both collagen-based and suture-based closure systems have been evaluated in studies with large patient populations [5, 8]. While some studies report a decreased time to ambulation [4, 8, 9], others [10] could not show the superiority of closure compared with manual compression. Some investigators found a higher complication rate than with manual compression [11], especially with collagen-based closure devices. Recent publications dealing with suture-based closure devices also report a greater incidence of local infection, which has been linked to the introduction of a foreign body [12–14]. In addition, with collagen-based devices, repeated access at the same site is impaired until complete resorption of the intravascular anchor of the collagen plug has been achieved. So far, none of these devices is a completely satisfactory solution to maximizing patient safety and comfort or to shortening hospital stay [5].

The efficacy and safety of various closure devices have been evaluated in patients undergoing coronary intervention [5, 9] and in patients with PAOD, with efficacy ranging from approximately 80–96% [8, 15, 16]. In our device population, immediate hemostasis could be achieved in 95% of cases, which is similar to reported findings with other closure devices [5, 12, 16]. Compared with the standard manual compression technique applied in our control population, the period of bed rest (6–20 h) could be significantly reduced to 2 h in 93% of cases. Additionally, these patients could be dismissed without a pressure bandage. Both mobilization time and pressure bandage application time were significantly less for the device group in comparison with the control group. Mechanical or manual compression techniques are not only a source of patient discomfort but represent a potential risk of puncture-site-related complications, such as bleeding, development of large hematoma, and pseudoaneurysms. This is of particular concern after employment of large sheaths and/or aggressive anticoagulation therapy [1, 2, 5, 17–19]. Furthermore, it has been proposed that applying mechanical or manual compression in patients with severe peripheral arterial occlusive disease may be critical due to considerably reduced blood flow during compression. This could provoke acute reocclusion of a successfully treated vessel, particularly after recanalization of long and complex pelvic or femoral artery occlusions [8]. The Clo-Sur PAD allowed immediate sheath removal independent of platelet function or anticoagulation with ASA or clopidogrel. Collagen-based closure devices, on the other hand, have shown successful application to be difficult, with insufficient platelet function or reduced platelet count [5, 9].

Limitation (5% in the device population) in the use of this device lies mainly in obese patients. However, for the risk-to-benefit ratio, it should be taken into account that these potentially difficult cases for cutaneous closure are very often also the source of serious complications for other closure devices or conventional compression methods [5, 8, 12].

With regard to the safety of the system, the results presented in this study clearly indicate lower complication rates than those reported in previous studies using conventional compression or collagen-based sealing devices [5, 9, 10, 17]. Another advantage to this hemostatic system is that it is possible to switch to conventional compression techniques at any time during the application process to avoid major bleeding complications in case of incomplete hemostasis.

No unanticipated side effects or adverse reactions due to the Clo-Sur PAD were noted in this study. The observed complications were due to insufficient hemostasis at the arterial puncture site. However, there were no major complications requiring vascular surgery, blood transfusion, or surgical revision due to infection among our population. The absence of delayed complications during clinical and CCDUS examination at the 14-day follow-up after device application validated the effectiveness of this technique. The hemostatic device may be particularly advantageous in institutions with a large patient population and high patient turnover, necessitating early and safe

Table 2 Time to achieve hemostasis, pressure bandage application time, and time until mobilization (mean±SD) with Clo-Sur PAD use (device) and manual compression (control)

	Hemostasis (min)	Pressure bandage (h)	Mobilization (h)	*P* value
TACE device	9.53±1.04	2.00±0	2.00±0.00	<0.0001
TACE control	16.50±2.10	13.60±4.15	5.13±0.35	
PTA device	10.77±2.45	4.93±7.61	2.27±0.69	<0.0001
PTA control	15.90±1.40	14.00±4.55	12.00±0	
Overall device	10.15±1.96	3.47±5.53	2.13±0.50	<0.0001
Overall control	16.20±1.79	13.80±4.32	8.57±3.47	

TACE transarterial chemoembolization, *PTA* peripheral intervention
Statistical significance was calculated using the Wilcoxon-Mann-Whitney test

ambulation. Comparison of the device group to the manual compression group revealed a markedly reduced time for achievement of hemostasis and earlier mobilization than in the control group. Both differences were highly statistically significant. Additionally, a potential advantage of the Clo-Sur PAD technique is the possibility of immediate repuncture at the same site and the lack of excessive scar formation, thus facilitating possible eventual subsequent surgery and reducing the risk of puncture-site infection.

The limitation of this study was that the measurement of time until hemostasis is not clear cut. Hemostasis is a dynamic process and depends on the skill and experience of the person performing manual compression. To rule out any bias, all device applications were carried out by one interventionalist who did not perform the procedure. Furthermore, the distribution of sheath sizes in the PTA subgroups differed between the device and control group. The overall population of this initial study was small compared with other closure devices studies, but it does allow statistical analysis. Further studies with larger patient populations are required to more accurately determine possible complications with this device.

Conclusion

The closure of an arterial access site using a strictly cutaneous device was associated with improved patient comfort after peripheral intervention, without an increase in complications. As demonstrated by CCDUS examination, the device achieved immediate hemostasis and permitted early ambulation in the majority of patients and was not associated with damage to the arterial wall. The device is a viable alternative to manual compression and solves the constant and recurring problem of improving the quality of patient care without increasing treatment cost.

In conclusion, the Clo-Sur PAD device provides a feasible, effective, and safe means of hemostasis after arterial interventional procedures. The low cost per system, coupled with the possibility of avoiding pressure bandage, makes this system attractive for routine use. Large, prospective, multicenter trials, however, are necessary to definitively demonstrate safety and cost effectiveness of this novel hemostatic device.

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