Original paper/*Artykuł oryginalny*

Control of local haemostasis with the AngioSeal® vascular closure device in peripheral endovascular interventions via 6-9 F femoral artery access

Zastosowanie zapinek naczyniowych AngioSeal® w kontroli miejscowej hemostazy w przezskórnych interwencjach obwodowych z dostępu kaniulą 6–9 F przez tętnicę udową

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Abstract

Background: Complications related to the femoral access substantially contribute to peri-procedural morbidity and mortality.
Aim: To evaluate whether the use of a collagen plug as a vascular access closure device (AngioSeal®, AS) influences complications related to the femoral access and duration of hospitalization for peripheral endovascular interventions.
Material and methods: Two hundred and one consecutive patients (59.2% male, age 48-87 years) undergoing angioplasty/stenting of the internal carotid, common carotid, vertebral, subclavian, renal, iliac/femoral, innominate artery or cervical-subclavian bypass were randomized (1 : 1 ratio) prior to the intervention to standard manual compression (MC) or AS (6 F or 8 F device used for femoral access with 6-7 F or 8-9 F sheaths respectively).
Results: Manual compression was used in 110 patients and AS in 91 patients. There was no difference in the use of 8-9 F and 6-7 F sheats between the two per treatment groups (72.5% vs. 73.6% and 27.5% vs. 26.2%, respectively). Large subcutaneous haematoma, arteriovenous fistula, pseudoaneurysm or femoral artery occlusion requiring surgery occurred in 13.8% MC vs. 4.0% AS for 6-7 F sheaths (p = 0.36) and in 19.7% MC vs. 7.6% AS for 8-9 F sheaths (p = 0.035). Total access site complication rate was 18.2% for MC and 6.6% for AS (p = 0.019). Nine patients with AS (9.9%) required an additional compression dressing (≤ 12 h). Overall, AS patients were mobilized earlier (2.9 ±2.4 h vs. 14.2 ±2.8 h, p = 0.001) and discharged home earlier after the intervention (33.6 ±14.16 h vs. 68.1 ±34.08 h, p = 0.001).
Conclusions: The use of the AngioSeal® device for femoral access closure during peripheral interventions (AngioSeal® 8 F for 8-9 F sheath and AngioSeal® 6 F for 6-7 F sheath) significantly reduces the access site complication rate and allows earlier patient mobilization and discharge from hospital.

Key words: AngioSeal®, vascular closure device, vascular access complications, femoral closure device

Streszczenie

Wstęp: Miejscowe powikłania dostępu naczyniowego przez tętnicę udową po zabiegach na tętnicach obwodowych istotnie zwiększają chorobowość okołozabiegową, wydłużają czas hospitalizacji oraz mogą się przyczyniać do zwiększonej śmiertelności okołozabiegowej.
Cel: Ocena skuteczności stosowania zapinek naczyniowych AngioSeal® w redukcji liczby miejscowych powikłań dostępu naczyniowego, skracaniu czasu do uruchomienia i czasu hospitalizacji po przezskórnych interwencjach w naczyniach obwodowych.

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Materiał i metody: Do standardowej kompresji manualnej (*manual compression* – MC) *vs* zapinki AngioSeal® (AS, 6 F i 8 F odpowiednio dla dostępu kaniulą 6–7 F i 8–9 F) zrandomizowano (1 : 1) 201 chorych w wieku 48–87 lat (średnio 66,9 ±8 lat, 59,2% mężczyzn) poddawanych przezskórnej angioplastyce tętnic obwodowych (szyjnej wewnętrznej, szyjnej wspólnej, kręgowej, biodrowej lub udowej, podobojczykowej, nerkowej, pnia ramienno-głowowego, pomostu szyjno-podobojczykowego). U 7 chorych zrandomizowanych do grupy AS (7,1%) nie było warunków anatomicznych do założenia zapinki naczyniowej. Kaniule 8–9 F zastosowano w 73,6% zabiegów w grupie MC *vs* w 72,5% zabiegów w grupie AS (p = 0,986).

Wyniki: Łącznie ostre niedokrwienie kończyny, tętniak rzekomy, rozległy krwiak podskórny, przetoka tętniczo-żylna wystąpiły istotnie częściej w grupie MC niż w AS (18,2% *vs* 6,6%, p = 0,019), po kaniulacji 8–9 F (19,7% MC *vs* 7,6% AS) (p = 0,035). Po zabiegu chorzy z AS byli uruchomieni po 1–12 godzinach (średnia: 2,90 ±2,4), a MC 8,6–19,3 godziny (średnia: 14,18 ±2,28) (p < 0,001). Dziewięciu pacjentów z AS (9,9%) wymagało dodatkowo opatrunku uciskowego przez 6–12 godzin. Chorych z grupy MC wypisano ze szpitala 24–240 godzin po zabiegu (średnia: 68,1 ±34,08) *vs* AS po 24–72 godzinach (średnia: 33,6 ±14,16) (p = 0,001).

Wnioski: Zamknięcie dostępu naczyniowego zapinkami naczyniowymi AngioSeal® 6 F i 8 F po przezskórnych interwencjach na tętnicach obwodowych przez tętnicę udową po kaniulacji 6–9 F jest bezpieczne, zmniejsza ryzyko wystąpienia powikłań miejscowych oraz skraca czas unieruchomienia i hospitalizacji.

Słowa kluczowe: AngioSeal®, zapinki naczyniowe, powikłania dostępu naczyniowego, zamykanie dostępu naczyniowego przez tętnicę udową

Background

Local complications at the site of vascular access such as large subcutaneous haematoma, pseudoaneurysm, arteriovenous fistula, ischaemia of the limb or local infection complicating percutaneous cardiovascular interventions significantly increase periprocedural morbidity, prolong the hospitalization period and may affect periprocedural mortality [1].

Current coronary interventions are frequently completed with the implantation of vascular closure device instead of using conventional hemostasis (removal of the sheath after 4-6 h followed by compression dressing for 6-8 h), which allows rapid cessation of bleeding from the arterial access and earlier patient mobilization. The AngioSeal® 6 F vascular closure device is frequently used to control local haemostasis (femoral artery) after coronary interventions (6 F). However, there are no systematic analyses regarding the application of this device for peripheral interventions. Moreover it should be noted that this peripheral procedure usually requires vascular access with the use of a larger (i.e. 8-9 F) cannula.

Aim

The aim of the study was to evaluate the efficacy of the 6 F and 8 F vascular closure device AngioSeal® in the reduction of local complications related to vascular access (femoral artery) and its influence on the timing of patient mobilization and hospital discharge after percutaneous interventions on carotid and peripheral arteries (femoral access with 6-9 F cannula).

Material and methods

Two hundred and one consecutive patients between 48 and 87 years of age (59.2% male, mean 66.9 ±8 years) undergoing percutaneous interventions on carotid, vertebral or peripheral arteries (internal carotid artery (n = 140), comon carotid artery (n = 3), vertebral artery (n = 32), iliac/femoral atery-contralateral access (n = 9), subclavian artery (n = 12), renal artery (n = 2), innominate artery (n = 2) or cervical-subclavian bypass) was randomized (1 : 1 ratio). Seven of the 98 patients (7%, 48-87 years of age, mean 66.85 ±8 years) randomized prior to the procedure to the AngioSeal® device had angiographic contraindications to the use of this device (arterial puncture at the site of common iliac artery bifurcation, diffused atherosclerosis of the punctured artery, vessel diameter < 5 mm) and thus required conventional haemostasis (Figures 1-2). Therefore the MC group (manual compression-removal of the vascular sheath from the femoral artery after 4-6 h followed by compression dressing for 6-8 h) included finally 110 patients and the AS group consisted of 91 patients. There was no difference between groups in terms of sex or age (AS – 58.2% male, 66.8 ±8 years of age, MC – 60.0% male, 66.7 ±9 years of age). Patient characteristics are presented in Table 1. The 6 F closure device was used after femoral artery cannulation with 6 F (n = 24) or 7 F (n = 1) sheaths and an 8 F device was applied after cannulations with 8 F (n = 65) or 9 F (n = 1) introducers. All patients (AS and MC) were on dual antiplatelet therapy (aspirin 75 mg + + clopidogrel 75 mg) and unfractionated heparin was used during the procedure to achieve activated coagulation time (ACT) > 250 s. Oral anticoagulant therapy was stopped before the procedure in all patients on chronic treatment with acenocoumarol/warfarin (n = 2 for AS – 2.2%, n = 1 for MC – 0.9%) to obtain INR < 1.4 allowing an elective percutaneous intervention. Subcutaneous injections of low molecular weight heparin were stopped for at least 12 h prior to the procedure and after the procedure in all patients on this type of therapy (n = 4 for the AS group; n = 1 for the MC group, 0.9%). Mean INR value in the AS group before the procedure was 1.07 ±0.16 vs. and in the MC group 1.06 ±0.13 (p = 0.79). Mean platelet count (PLT) was 212.48 ±57.05 in the AS group and 218.48 ±61.193 in the MC group (p = 0.532).

Local conditions at the site of vascular access were assessed (physical examination and dopler duplex was needed) directly after the implantation of the device, 1-3 h after the procedure, and at discharge from the hospital.

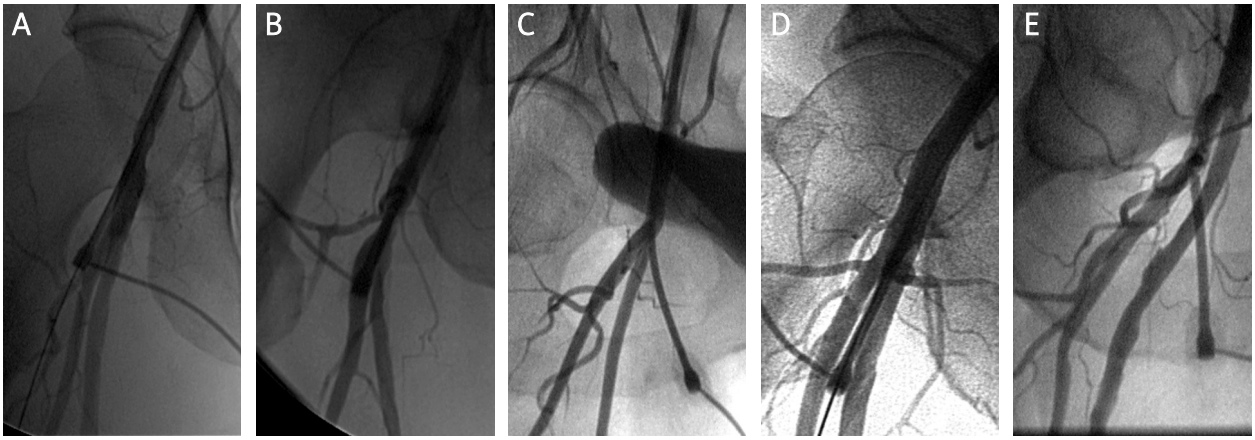

Fig. 1. Angiographic contraindications to the use of AngioSeal® (examples): **A-B** – significant atherosclerosis of a common femoral artery in the puncture site, **C-D** – puncture of a femoral artery bifurcation, **E** – puncture of a deep femoral artery

Ryc. 1. *Przykłady angiograficznych przeciwwskazań do założenia zapinki naczyniowej AngioSeal®:* ***A–B*** *– zmiany miażdżycowe w miejscu nakłucia tętnicy udowej wspólnej,* ***C–D*** *– nakłucie w bifurkacji tętnicy udowej,* ***E*** *– nakłucie tętnicy głębokiej uda*

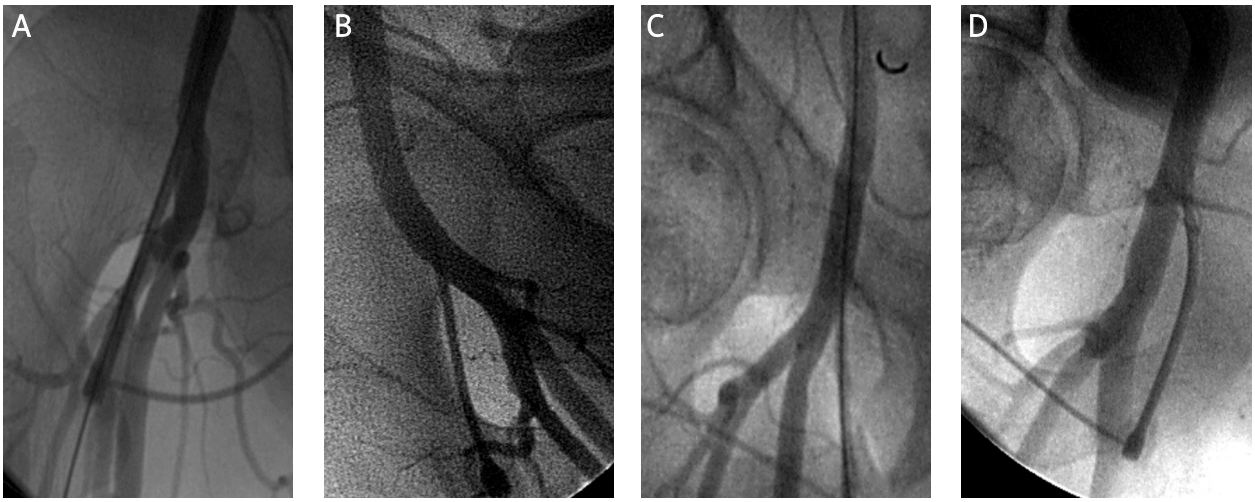

Fig. 2 A-D. Lack of angiographic contraindications to the use of AngioSeal®

Ryc. 2 A–D. *Brak angiograficznych przeciwwskazań do założenia zapinki AngioSeal®*

Statistical analysis

Qualitative variables are shown as percentages and number of cases in each group. Quantitative variables are presented as mean ± standard deviation and minimal and maximal values. Chi-square test or Fisher's exact test was used to compare qualitative variables, where appropriate. Quantitative variables were compared using Student's *t*-test or Mann-Whitney *U* test, when appropriate. Normality of distribution was assessed with the Shapiro-Wilk test, and Levene test was used to assess the equality of variances.

Analyses were performed with the R software (version 2.13.0) and with two-sided significance level of $\alpha = 0.05$.

Results

The following complications occurred in the MC ($n = 110$) vs. the AS ($n = 91$) group: acute lower limb ischaemia requiring surgical intervention – 1 (0.9%) vs. 0 (0%) ($p = 1.0$); pseudoaneurysm – 5 (4.5%) vs. 0 (0%) ($p = 0.065$); arteriovenous fistula – 1 (0.9%) vs. 0 (0%) ($p = 1.0$); large subcutaneous haematoma – 13 (11.8%) vs. 6 (6.6%) ($p = 0.235$). Complications after the use of 6 F-9 F introducers in patients from the MC and the AS group are presented in Table 2 A.

Complications including large subcutaneous haematoma (> 10 cm according to the American College of Cardiology/American Heart Association) [2], arteriovenous

Table 1. Baseline characteristics of patients
Tabela 1. *Charakterystyka pacjentów*

Parameter	AS Group (n = 91)	MC Group (n = 110)	Value of p
Age [years]	66.9 ±8	66.7 ±8	0.859
Men	58.2% (n = 53)	60.0% (n = 66)	0.800
Hypertension	94.5% (n = 86)	93.6% (n = 103)	0.795
Hyperlipidaemia	82.4% (n = 75)	87.3% (n = 96)	0.336
Diabetes	24.2% (n = 22)	24.6% (n = 27)	0.986
Previous PCI/PTA	24.2% (n = 22)	33.6% (n = 37)	0.142
BMI [kg/m^2]	27.7 ±4.5	27.0 ±4.4	0.324
Peripheral arterial disease of the lower extremities	10.9% (n = 10)	20.0% (n = 22)	0.100
Tobacco smoking	27.4% (n = 25)	30.0% (n = 33)	0.693
INR before the procedure	1.07 ±0.16	1.06 ±0.13	0.79
APTT before the procedure	31.504 ±4.5	32.71 ±5.3	0.090
PLT before the procedure	212.48 ±57.05	218.48 ±61.193	0.532
Chronic renal failure	27.4% (n = 25)	22.7% (n = 25)	0.438

PCI – percutaneous coronary intervention, PTA – percutaneous transluminal angioplasty, BMI – body mass index, INR – international normalized ratio, APTT – activated partial thromboplastin time, PLT – thrombocytes

fistula, pseudoaneurysm, and acute lower limb ischaemia occurred in 13.8% of patients after MC vs. 4.0% after AS (p = 0.36) for cannulation with 6-7 F sheaths and in 19.7% after MC vs. 7.6% after AS (p = 0.035) for cannulation with 8-9 F sheaths (Table 2 B). In total, complications including acute limb ischaemia, pseudoaneurysm, large subcutaneous haematoma, and arteriovenous fistula occurred in 20 patients after MC (18.2%) vs. 6 patients after AS (6.6%) (p = 0.019) irrespective of the sheath size (Table 2 B). Pseudoaneurysms found after MC required blood transfusion in 1 case, thrombin injection in 1 case and ultrasound-guided mechanical compression in 4 cases. There were no cases of pulmonary embolism or infection of the access site observed in any of the groups.

Mean decrease of haematocrit (HCT) values after the procedure in the AS vs. the MC group was 3.93 ±1.95% vs. 4.19 ±2.53% (p = 0.4289). Mean decrease of haemoglobin (Hgb) level in the AS vs. the MC group was 1.37 ±0.62 vs. 1.49 ±0.89 (p = 0.288).

Patients with AS were mobilized after 1-12 h (mean 2.90 ±2.4 h) vs. 8.66-19.33 h (mean 14.18 ±2.28 h) for MC (p < 0.001) (Figure 3). Nine patients with AS (9.9%) required an additional compression dressing for 6-12 h due to prolonged bleeding from the access site despite the collagen plug use. This was associated with occurrence of a large subcutaneous haematoma in 6 cases (5 for the 8 F device and 1 for the 6 F device, 4.4%). Patients who received MC

Table 2 A-B. Complications in the AngioSeal® group vs. manual compression group in relation to the arterial sheath size
Tabela 2 A–B. *Powikłania w grupie z zapinkami AngioSeal® vs z konwencjonalną hemostazą z uwzględnieniem rozmiaru kaniuli tętniczej*

A

Group	Sheath size	Large subcutaneous haematoma	Pseudoaneurysm	Arteriovenous fistula	Acute lower limb ischaemia	Total number of local complications	Number of complications in the group
MC (n = 110)	6 F Sheath (n = 29)	6.9% (n = 2)	3.44% (n = 1)	3.44% (n = 1)	0%	13.8% (n = 4)	20 (18.2%)
	7 F Sheath (n = 0)	0%	0%	0%	0%	0%	
	8 F Sheath (n = 80)	12.5% (n = 10)	5% (n = 4)	0%	1.25% (n = 1)	18.8% (n = 15)	
	9 F Sheath (n = 1)	n = 1	0%	0%	0%	n = 1	
AS (n = 91)	6 F Sheath (n = 24)	4.2% (n = 1)	0%	0%	0%	4.2% (n = 1)	6 (6.6%)
	7 F Sheath (n = 1)	0%	0%	0%	0%	0%	
	8 F Sheath (n = 65)	7.7% (n = 5)	0%	0%	0%	7.7% (n = 5)	
	9 F Sheath (n = 1)	0%	0%	0%	0%	0%	

B

Complications in the MC group for 6-7 F sheath	Complications in the AS group for 6-7 F sheath	Complications in the MC group for 6-7 F sheath	Complications in the AS group for 6-7 F sheath
13.8% (n = 4)	4.0% (n = 1)	19.7% (n = 16)	7.6% (n = 5)
p = 0.36		p = 0.035	
Total number of complications in the MC group		**Total number of complications in the AS group**	
18.2% (n = 20)		6.6% (n = 6)	
p = 0.019			

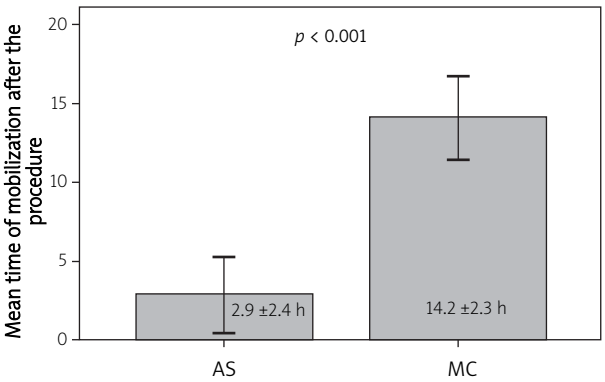

Fig. 3. Time of post-procedural mobilization of patients with AngioSeal® (AS) vs. manual compression (MC)
Ryc. 3. *Czas uruchomienia pacjentów, u których stosowano zapinkę AngioSeal® (AS) vs hemostazę konwencjonalną (MC)*

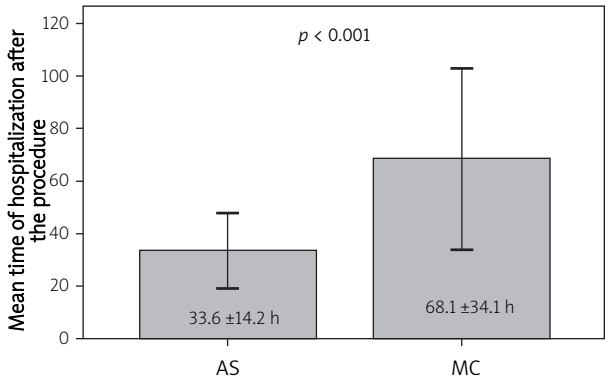

Fig. 4. Duration of post-procedural hospitalization after percutaneous intervention in patients with AngioSeal® (AS) vs. manual compression (MC)
Ryc. 4. *Czas pozabiegowej hospitalizacji pacjentów, u których stosowano zapinkę AngioSeal® (AS) vs hemostazę konwencjonalną (MC)*

were discharged from the hospital after 24-240 h (mean: 68.1 ±34.08 h) vs. 24-72 h (mean: 33.6 ±14.16 h) for AS (p = 0.001) (Figure 4).

In one case, implantation of the 8 F AngioSeal® device was complicated by distal mobilisation of the device anchor with the blood flow. There were no symptoms of limb ischaemia and the access site was controlled with standard manual compression.

Discussion

Several prior studies demonstrated the efficacy and safety of the AngioSeal® vascular closure device for coronary interventions with a 6 F vascular access. In contrast, the present study systematically assessed the use of the 6 F and 8 F AngioSeal® vascular closure device for interventions on peripheral arteries via femoral access (6 F device after 6-7 F sheats and 8 F device after 8-9 F sheats). Most of the procedures involved an internal carotid artery (n = 140, 69%) which required an 8 F and 9 F cannula to allow the use of the neuroprotective systems.

According to the AS instruction for use and pior reports we have avoided the use of the vascular closure device in the case of severly diseased arteries, especially when the vessel diameter was below 5 mm, if significant atherosclerotic lesions were localized within the distance of 5 mm from the puncture site or when they caused a 40% reduction of the vascular lumen (less advanced changes were a relative contraindication) [3]. The AngioSeal® device was also not used in the case of a femoral artery bifurcation or a superficial/deep femoral artery puncture [3]. Importantly angiography of the femoral artery was performed in each case in our study prior to the AngioSeal® use. Femoral angiogram was assessed for the presence of significant lesions of the arterial wall at the site of the puncture. In the case of contraindications to the use of the device (7/98 patients randomized to AngioSeal® – 7.0%) a classic compression dressing was applied. Longer time of hospitalization of patients after manual compression was caused not only by the longer time of immobilization, but also by more frequent and more severe complications such as pseudoaneurysms and lower limb ischaemia. On the other hand successful haemostasis was not obtained in all of the patients who received the AngioSeal® device. Nine patients in the AngioSeal® group still required the use of a classic compression dressing due to prolonged bleeding and six of them developed a large subcutaneous haematoma. In 1 case implantation of the AngioSeal® device was complicated by a rupture of a Dexon suture with intra-arterial distal dislocation of the device anchor. In this patient manual compression was performed and subsequently a full dose of low molecular weight heparin (1 mg/kg s.c. every 12 h) was administrated for 3 days to prevent lower limb ischaemia (embolisation by the polymeric fragment – 1 mm × 2 mm × 10 mm). There were no symptoms of ischaemia during the hospitalization or during ambulatory visits which followed.

One patient from the MC group cannulated with an 8 F introducer who underwent successful angioplasty of the internal carotid artery presented symptoms of acute lower limb ischaemia 6 h after the procedure caused by thrombosis of the superficial and deep femoral artery. The patient had diffused atherosclerotic lesions in femoral and iliac arteries. She required two emergency surgical interventions: the first one consisted of trombi removal followed by angioplasty with implantation of an arterial patch; the second one wich took place after reccurence of thrombosis in the index location, was a hybrid procedure consisting of angioplasty of the common iliac artery, reopening of the superficial femoral artery with stent implantation and implantation of venous femoro-femoral bypass which led to the resolution of symptoms.

Several cases of acute and chronic limb ischaemia related to the AngioSeal® device implantation have been described previously. These occurred after implantation of the device in the atherosclerotically changed vessel or in the superficial femoral artery, after dissection of the atherosclerotic plaque or after thrombosis leading to occlusion of the artery [4-9]. In some cases a collagen plug was found intra-operatively in the lumen of the superficial femoral artery [4, 10]. These patients required percutaneous [11] or surgical [4-6] interventions due to limb ischaemia. All of the procedures succesful and no symptoms of ischaemia were observed during follow-up were reported. There is also a description of a patient in whom elements of the AngioSeal® device did not undergo biodegradation and who had a critical stenosis of the vessel caused by excessive proliferation of the connective tissue at the site of the intravasculary located anchor of the device [9]. An attempted percutaneous intervention led to distal embolization and occlusion of the trifurcating popliteal artery. The patient underwent a successful surgical procedure and did not present symptoms of ischaemia during subsequent observation [10]. Less severe symptoms of ischaemia including claudication of the lower limb after the AngioSeal® device implantation were also described [6]. In this case the patient remained under ambulatory follow-up because of the lack of symptoms of severe ischaemia. The symptoms were milder and eventually resolved with the end of biodegradation of the intravascular elements of the AngioSeal® device. The patient did not require interventional treatment [6]. Most of the studies report similar to ours frequency of local complications for the AngioSeal® device such as large subcutaneous haematoma, pseudoaneurysm, arteriovenous fistula, and limb ischaemia in comparison to the use of classic compression dressing [3, 12-18]. In one of the studies there was a tendency towards higher frequency of local complications in female patients, which was probably related to the lower diameter of the femoral artery in comparison to male patients [19]. Retrospective series by Assali *et al.* [20] and Dangas *et al.* [21] suggested a higher frequency of local complications after coronary interventions in patients who received vascular closure devices (including the AngioSeal® device) in comparison to patients who had a compression dressing, but the number of patients with the AngioSeal® device was approximately 4-fold [20] or even over 13-fold [21] lower than patients with conventional haemostasis. Also, implantation of the AngioSeal® device was not routinelly preceded in by angiography of the ipsilateral femoral artery. In a large group of patients, Carey *et al.* [22] reported that the use of the AngioSeal® device increased the risk of limb ischaemia in comparison to manual compression. However, in contrast to our strategy, angiography of the femoral artery was not performed routinely before implantation of the AngioSeal® device and therefore interpretation of the results of this study should be done with caution.

Other AS complications such as pseudoaneurysms resolved spontaneously [7] after manual compression or were successfully treated with surgery in some patients.

Koreny *et al.* [23] in 2004 and Biancari *et al.* [24] in 2009 performed a meta-analysis of approximately 30 prospective, randomized studies assessing the efficacy and safety of different types of vascular closure devices (including the AngioSeal®) in comparison to conventional haemostasis for the closure of femoral access, mainly after coronary interventions, and found a tendency towards higher frequency of local complications related to the use of these vascular devices (including the AngioSeal®). Interpretation of the results of these studies is limited by high heterogeneity of the compared groups, differences in end-point definitions (regarding for example the size of a large haematoma), the use of an older generation of closure devices in some of the studies, and exclusion of patients with high risk of local complications such as obese patients. Most of the studies included patients cannulated using a 6 F introducer, while patients in our study were mainly (73%) cannulated using an 8 F or 9 F introducer. In addition it should be noted that the use of AngioSeal® (like any other interventional device) involves a learning curve, and in the present study AngioSeal® was used by operators with a major prior experience.

It should be noted that resorpti on of the AngioSeal® device elements takes around 90 days, and during that period a vascular access in the proximity of the device should be avoided (according to the manufacturer's recommendations). Some studies suggest that a 0.5-1.0 cm margin should be used [7, 25] if the index artery is used for vascular access within 90 days.

In the case of surgery, a vascular surgeon should pay special attention while operating in the proximity of the AngioSeal® device implanted into the femoral artery to avoid involuntary translocation of the device elements, which can lead to severe complications including limb ischaemia, as demonstrated in the case described by Ponton *et al*. [6]. Transradial access is currently considered as a safer approach leading to lower frequency of bleeding complications and it is used with increasing frequency for coronary interventions [26]. However, some endovascular interventions, mainly those on carotid arteries, require larger diameters of cannula to allow introduction of neuroprotective systems and therefore they currently require the femoral access.

Conclusions

We found that the 6 F and 8 F AngioSeal® device can be safely used to close the femoral access during peripheral interventions involving after cannulation with 6-7 F or 8-9 F introducers, respectively. We also showed that vascular closure device reduces the risk of peri-procedural local complications after femoral access and leads to shortening of the immobilization period and hospitalization time shortening.

Acknowledgments

The authors of the study do not have any conflict of interest (such as employment, counselling, possession of stock or honoraria) related to the producers or distributors of the AngioSeal® vascular closure device which might have caused a conflict of interest in the context of this study.

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