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Management of acute lower limb ischemia associated with the Angio-Seal arterial puncture closing device

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Abstract

Arterial percutaneous closure devices (APCD) could lead to severe vascular complications, like acute lower limb ischemia. The aim of this study was to evaluate retrospectively our personal series of acute lower limb ischemia following the use of APCD. From January 2004 to June 2009 the Angio-Seal percutaneous closure devices was deployed in 198 patients. Eight (4%) acute lower limb ischemia required urgent surgical repair. The device was removed in all cases. A thromboembolectomy was performed in five patients (62.5%) and in three (37.5%) an endarterectomy with patch closure was carried out (two saphenous vein and one Dacron). Limb salvage rate was 87.5%. We compared Angio-Seal complications group (A) with the 190 patients in which the Angio-Seal was successfully used without complications (group B) by means of Student's *t*-test. At 36-month follow-up with color-coded duplex ultrasounds, no chronic limb ischemia or other complications requiring surgical repair occurred. Diabetes, obesity, severe femoral atherosclerotic involvement, use of sheath size >7 Fr and time-consuming procedures were significant risk factors for ischemic APCD complications. Despite vascular injuries being uncommon after APCD deployment, generally a complex surgical repair is necessary. A more careful patient selection would be advisable.

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Keywords: Angio-Seal; Percutaneous puncture; Femoral arterial repair

1. Introduction

Femoral artery access site complications following angiographic procedures range from 1% to 5% [1, 2]. Different types of arterial percutaneous closure devices (APCD) were developed in order to reduce these complications, but despite their safety, an overall complication rate of 2% has been reported [3]. The aim of our study is to present a personal series of acute lower limb ischemia following the employment of APCD and to review the literature.

2. Materials and methods

This is a retrospective study that analyzes our series of patients with acute lower limb ischemia requiring urgent surgical repair following Angio-Seal (St. Jude Medical, St. Paul, MN, USA) use from January 2004 to December 2009. During this period, we performed 723 vascular peripheral procedures. In 198 patients (27.3%), diagnostic in 60 cases and therapeutic in 138, an Angio-Seal APCD was used. The Angio-Seal deployment indications were the following: sheath size of 7 Fr, severe obesity, prolonged anticoagulation or thrombolysis. A skilled endovascular interventionist performed the procedure in all cases. We observed eight ischemic access complications that required urgent

surgical repair (4%). No chronic-like limb ischemia, bleeding, pseudoaneurysms or primary infective endarteritis were observed. Patients' medical data were collected to achieve demographic information (diabetes, obesity, chronic renal failure) and reported in Table 1.

In all complicated cases an urgent preoperative angiography was carried out showing an occlusion of the common femoral artery (CFA) in five patients (Fig. 1), severe superficial femoral artery (SFA) stenosis in two, and one popliteal occlusion. All operations were carried out under local anesthesia and the surgical repair and outcomes were reported in Table 2. In three cases of CFA occlusion and in the patient with popliteal artery occlusion a sudden acute ischemia developed and the diagnosis was immediately performed at the end of the same procedure. In the last two cases in which a CFA occlusion occurred and in two patients with severe stenosis of SFA the clinical onset appeared two to three hours later. However, a prompt diagnosis and treatment was performed in all cases.

We compared the role of the demographic data and comorbidities between these eight patients in which the Angio-Seal led to ischemic complications (group A) with the cohort of 190 patients in which the Angio-Seal was successfully used (group B) by means of Student's *t*-test to determine whether there are predictive factors of increased risk of complications. All analyses have been

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Table 1. Demographic data and co-morbidities

Mean age (years)	69 (57–84)
Male	3 (37.5%)
Time to surgery (median hours)	2 h
Median length of hospitalization	6 days
Diabetes	6/8 (75%)
Obesity	6/8 (75%)
Hypertension	7/8 (87.5%)
Ischemic heart diseases	5/8 (62.5%)
Chronic renal failure	1/8 (12.5%)
Peripheral arterial diseases	6/8 (75%)

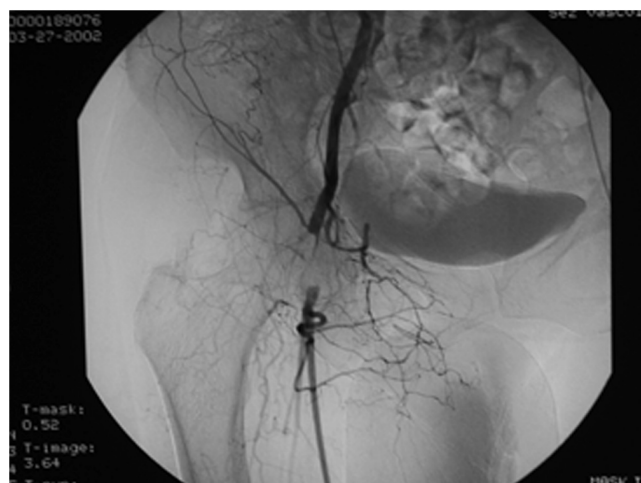


Fig. 1. Angiography shows an occlusion of the common femoral artery.

developed by software SPSS (13.0 version, SPSS Inc, Chicago, IL, USA). A $P < 0.05$ was considered significant (Table 3).

3. Results

Diabetes, obesity and severe ischemic heart disease (IHD), which are generally an expression of poly-systemic vessels involvement were found to be a statistical risk factor associated with ischemic APCD complications. Use of sheath size > 7 Fr for therapeutic and time-consuming procedures

were significant risk factors for ischemic APCD complications. No patient required a decompression fasciotomy.

A postoperative acute bleeding due to infective endarteritis occurred in a patient who received a Dacron patch angioplasty on the third postoperative day. A prompt repair using a saphenous vein patch with a sartorius muscle flap closure was performed. In one case a critical ischemia developed after thrombectomy. A thrombolysis with popliteal stenting and subintimal recanalization of the posterior tibial artery was unsuccessfully performed. A leg amputation was necessary.

No patients were lost at follow-up. One patient died after one year from a myocardial infarction. In no case did a late chronic ischemia occur at follow-up (12–36 months). The limb salvage rate was 87.5%. No late reoperations were needed.

Follow-up was carried out for a mean period of 36 months. A color-coded duplex ultrasound (US) was performed at one, three, six and 12 months and then annually and each showed a complete patency to the arterial closure device application with no hyperplastic reaction of the arterial wall.

4. Discussion

Despite recent meta-analysis failing to show the superiority of APCD over manual compression, their use in interventional and cardiology practice is now widely accepted, with an increase in related complications [4, 5] that generally require difficult and non-standardized surgical repairs [6].

In this study we reported only cases of lower limb acute ischemia following Angio-Seal closure device deployment by skilled endovascular interventionalists. Angio-Seal is actually one of the most frequently employed APCD and the device consists of three parts: a flat anchor of 2×10 mm size of polyglactic and polyglycolic acid, a collagen plug and a connection system of polyglycolic acid. The anchor is introduced into the arterial lumen through a catheter, and the collagen plug is positioned on the sub-

Table 2. Surgical data and outcomes

Age	Sex	Co-morbidities	Procedure	Sheath	Complications	Vessel	Intervention	Outcome	Follow-up (years)
74	F	DM, IHD, hypertension	Diagnostic	5 Fr	Thrombosis	PA	Thrombectomy	Limb loss	1
67	F	DM, IHD, hypertension	Therapeutic	7 Fr	Thrombosis	CFA	Thrombectomy	Good	1
82	M	DM, hypertension	Therapeutic	7 Fr	Dissection	CFA + SFA	TEA + ASV patch	Good	2
76	F	DM, IHD, hypertension	Therapeutic	8 Fr	Dissection	CFA	TEA + Dacron patch redo ASV patch + sartorius muscle flap	Good	2
74	M	CRF	Diagnostic	5 Fr	Dissection	CFA	Thrombectomy	Good	2
57	F	DM, IHD, hypertension	Therapeutic	8 Fr	Thrombosis	CFA	Thrombectomy	Good	2
84	M	DM, IHD, hypertension	Therapeutic	8 Fr	Dissection	CFA + SFA	TEA + ASV patch	Good	3
72	F	Hypertension	Diagnostic	5 Fr	Dissection	CFA	Thrombectomy	Good	3

DM, diabetes mellitus; IHD, ischemic heart disease; CRF, chronic renal failure; CFA, common femoral artery; SFA, superficial femoral artery; PA, popliteal artery; TEA, thrombo-endarterectomy; ASV, autologous saphenous vein.

Table 3. Statistical analysis

Parameter	Angio-Seal (group A) (eight patients)	Control group B (190 patients)	Total	P-value
Hypertension	7 (87.5%)	165 (86.8%)	172	0.30
Peripheral arterial diseases	6 (75%)	140 (73.6%)	146	0.30
Diabetes	6 (75%)	75 (34.9%)	81	<0.05
Obesity	6 (75%)	31 (16.3%)	37	<0.05
Therapeutic procedures > 7 Fr	5 (62.5%)	65 (36.8%)	70	<0.05
Ischemic heart disease	5 (62.5%)	72 (37.8%)	77	<0.05
Chronic renal failure	1 (12.5%)	22 (8.4%)	23	0.84
Thrombolysis	–	39 (15.7%)	39	N.S.
Time procedures > two hours	5 (62.5%)	65 (23.6%)	70	<0.05

adventitial surface. Thus, the collagen plug is pushed against the arterial wall to guarantee the hemostasis.

About the management there is no consensus regarding the better surgical approach to treat lower limb APCD-related ischemia and the management of the complications. Many authors suggest performing a systemic longitudinal arteriotomy, thrombectomy, endarterectomy with synthetic patch angioplasty or, in cases of wide intimal damage, a polytetrafluoroethylene (PTFE) graft interposition to restore femoral artery patency [7, 8]. This policy is based on the need to treat the intimal layer damage in patients with severe and diffuse calcified involvement of femoral vessels. In our opinion, and in accordance with some authors, we do not share this approach because we believe that APCD should always be considered a high-risk procedure for infection. Preferentially the use of synthetic materials should be avoided and complex reconstructions should be performed only when strictly necessary. In the experience of Geary et al. [9] and Pipkin et al. [10] several species of *Staphylococcus* were cultured from wounds or blood. Moreover, Sprouse et al. [11] reported some cases of autologous saphenous vein (ASV) patch infection treated by transobturator bypass or hip disarticulation, both procedures were carried out with high mortality rates. In one of our patients, a postoperative bleeding due to endarteritis occurred, and a saphenous patch with sartorius muscle transposition was successfully performed. The wound culture was positive for methicillin-resistant *Staphylococcus aureus* (MRSA) infection.

We believe that a longitudinal arteriotomy may not always be the better approach to arterial lesion, but should be reserved for selected cases when a diffuse atherosclerotic involvement is present or when, after transverse incision, a diffuse intimal layer injury is detected. The APCD-related thrombosis seems to be due to two mechanisms [12]. The first, which was present in five of our patients, was represented by thrombosis or distal embolization originating around the polymer bar in a stenotic length of artery without arterial wall lesion. In these cases we carried out a routine approach by means of transverse arteriotomy at the level of the Angio-Seal introduction site that led to an easy anchorage system removal and embolectomy, permitting a really safe exploration of the lateral and posterior intimal layer. In the case of the posterior intimal defect, a limited resection of the flap and Kunlin sutures were performed easily. This approach was used in order to avoid the use of a prosthetic patch for arterial reconstruction generally required after longitudinal arteriotomy. In no

cases the calcified involvement of femoral artery, which was constantly present, allow a proper exploration of the vessels without the need to convert the transverse arteriotomy in longitudinal arteriotomy.

In the second mechanism, present in three of our patients, there was a thrombosis due to anchorage of the device attachment on the lateral or posterior wall with severe intimal layer diffuse injury. In these cases we carried out a longitudinal arteriotomy only after the documentation of extensive intimal injury which was impossible to manage through the transverse arteriotomy. After endarterectomy, an ASV patch should be used to decrease the possibility of infection, as demonstrated by Gonze et al. [13].

The learning curve, the device malfunctioning or inadvertent release in the SFA were advocated to play an important role in the development of complications, although in our personal experience the interventionalists were very experienced.

Despite a prospective randomized study trial comparing different commercially-available APCDs that do not support the presence of severe calcified plaque in the femoral artery as a contraindication, we suggest caution when using these devices in cases of severe atherosclerotic involvement of femoral vessels in accordance with Michalis et al. [14]. Indeed, although our study is a case series, with possible bias due to a lack of randomization and significant differences between the two groups in terms of number of patients, diabetes, obesity and IHD, pathological conditions associated with presence of severe atherosclerotic involvement of the femoral artery and, in our experience, they seem statistically related to a significant risk of developing ischemic access site complications. Our incidence of ischemic complications of 4%, are double of those reported from large scale studies, further evidence that a severe involvement of femoral artery due to atherosclerosis may predispose patients to these complications more easily. Use of large sheath size for therapeutic interventions and time-consuming procedures are also a statistical parameter responsible for a high-risk of complications. A systematic use of pre- and postoperative color-coded duplex US of the femoral access to identify those patients at risk for ischemic complication may be mandatory. Indeed, careful clinical monitoring of the inguinal access and the viability and perfusion of the lower limb by means of clinical examination and routine duplex US after the procedure and during the postoperative period are to recommended especially for those patients in which the severe comorbidities can

lead to severe femoral artery atherosclerotic involvement and to predispose the patient to ischemic complications.

5. Conclusions

APCDs are advantageous and reliable systems but a more varied selection of patients should be advocated. The management of the complications following the use of these systems is often difficult because of the frequent presence of severe atherosclerotic lesions and the high-risk of infections. Ischemia still seems the most frequent APCD-related complication requiring complex reparative operations.

References

- [1] Wagner SC, Gonsalves CF, Eschelmann DJ, Sullivan KL, Bonn J. Complications of percutaneous suture mediated closure device versus manual compression for arteriotomy closure: a case controlled study. *J Vasc Interv Radiol* 2003;14:735–741.
- [2] Meyers SL, Feldman T, Desai TR, Leef J, Schwarz JF, McKinsey LB. Angiographic access site complications in the era of arterial closure devices. *Vasc Endovasc Surg* 2002;36:137–144.
- [3] Eidt JF, Habibipour S, Saucedo JF, McKee J, Southern F, Barone GW, Talley JD, Moursi M. Surgical complications from hemostatic puncture closure devices. *Am J Surg* 1999;178:511–516.
- [4] Koreny M, Riedmüller E, Nikfardjam M, Siostrzonek P, Mullner M. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systemic review and meta-analysis. *J Am Med Assoc* 2004;291:350–357.
- [5] Carey D, Martin LR, Moore CA, Valentine MC, Nygaard TW. Complications of femoral artery closure devices. *Catheter Cardiovasc Interv* 2002;57:297–302.
- [6] Boston US, Panneton JM, Hofer JM, Sabater EA, Caplice N, Rowland CM, Noel AA, Bower TC, Cherry KJ Jr, Gloviczki P. Infectious and ischemic complications from percutaneous closure devices used after vascular access. *Ann Vasc Surg* 2003;17:66–71.
- [7] Castelli P, Caronno R, Piffaretti G, Tozzi M, Lomazzi C. Incidence of vascular injury after use of the angioseal closure device following endovascular procedures in a single center. *World J Surg* 2006;30:280–284.
- [8] Biancari F, Ylonen K, Mosorin M, Lepojarvi M, Juvonen T. Lower limb ischemic complications after the use of arterial puncture closure devices. *Eur J Vasc Endovasc Surg* 2006;32:504–505.
- [9] Geary K, Landers JT, Fiore W, Riggs P. Management of infected femoral closure devices. *Cardiovasc Surg* 2002;10:161–163.
- [10] Pipkin W, Brophy C, Nesbit R, Mondy JS. Early experience with infectious complications of percutaneous femoral artery closure devices. *J Vasc Surg* 2000;32:205–208.
- [11] Sprouse LR, Botta DM, Hamilton IN. The management of peripheral vascular complications associated with the use of percutaneous suture mediated closure devices. *J Vasc Surg* 2001;33:688–693.
- [12] Siani A, Siani LM, Marcucci G, Mounayergi F, Baldassarre E. Regarding 'Angio-Seal arterial puncture closing device removal: some technical details'. *J Vasc Surg* 2007;46:399–400.
- [13] Gonze MD, Sternbergh WC, Salartash K, Money SR. Complications associated with percutaneous closure devices. *Am J Surg* 1999;178:209–211.
- [14] Michalis LK, Rees MR, Patsouras D, Katsouras CS, Goudevenos J, Pappas S, Sourla E, Kolettis T, Sioros L, Zotou P, Gartzou-Matsouka P, Sideris DA. A prospective randomized trial comparing the safety and efficacy of three commercially available closure devices (Angioseal, Vasoseal and Duett). *Cardiovasc Interv Radiol* 2002;25:423–429.

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