

Percutaneous coil embolization of postcatheterization arterial femoral pseudoaneurysms

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Study design: This study was a prospective monocentric study to assess the safety and effectiveness of percutaneous embolization with coils of postcatheterization femoral pseudoaneurysm (PCFP).

Patients and methods: Seventeen PCFPs of 32-mm mean diameter in 16 patients were embolized while anticoagulant or antiplatelet therapy was maintained. Ultrasound scan-guided compression repair failed at least one time in 13 cases and was contraindicated in the four remaining cases. With ultrasound-Doppler scan guidance, the PCFPs were percutaneously punctured with a 16-gauge intravenous catheter. An angiogram was performed through the catheter to ensure its location within the sac. Stainless steel spring coils with synthetic fibers were introduced within the PCFP with fluoroscopic control. Successful thrombosis was checked with ultrasound-Doppler scan and was repeated at days 1, 30, and 180 when possible.

Results: All PCFPs of 32-mm mean diameter were successfully treated with two to nine coils. After embolization, gentle additional compression was necessary for complete occlusion, with a mean duration of 6.3 minutes (range, 0 to 15 minutes), except in one case with treatment with abciximab in which it was 45 minutes. All procedures were uneventful and painless. The mean follow-up period was 9.5 months (range, 1 to 21 months). Two recurrences (11.7%) were observed, and one was successfully treated with a second embolization.

Conclusion: Percutaneous embolization with coils appears to be a safe and effective method for treatment of PCFP. It may be performed in patients undergoing anticoagulant or antiplatelet therapy and must be attempted when ultrasound scan-guided compression repair has failed or is contraindicated. (*J Vasc Surg* 2002;36:127-31.)

Femoral artery pseudoaneurysms are common complications after diagnostic (0.2% to 0.5%)¹ or therapeutic (up to 9%) catheterization.^{2,3} Postcatheterization femoral pseudoaneurysms (PCFPs) are most commonly associated with the use of larger catheter size, continued anticoagulation therapy or administration of antiplatelet therapy, and catheterization of diseased arteries, particularly in an elderly population.^{2,4,5} During the past two decades, surgical treatment has been the recommended approach for prevention of the risk of rupture, compression neuropathy, limb ischemia, distal embolization, and skin necrosis. This procedure is fast and can be performed with local anesthesia. However, the incidence rate of postoperative complications can be estimated as high as 20%, with a 2% to 3% mortality rate.¹⁻⁶ Because of wound complications, the hospital stay is prolonged (average, >3 days),¹ increasing the cost significantly. Furthermore, anticoagulation or antiplatelet therapies have to be stopped to avoid postoperative local hemorrhage compromising a proper wound healing.

Since its introduction in 1991, ultrasound scan-guided compression repair (UGCR) has become the first line treat-

ment for PCFP.⁷ Although success rates can reach 90%, the significant disadvantages of UGCR include patient discomfort, long procedure duration, and lower immediate-term and long-term success rates in patients undergoing anticoagulation therapy.⁸ As an alternative, treatment of PCFP with direct bovine thrombin injection with sonographic guidance has been proposed. This procedure lacks the discomfort of UGCR and, despite the small number of reported cases, appears to have a success rate greater than 93%.⁹⁻¹⁴ The Food and Drug Administration has recently discouraged the use of bovine thrombin, except for topical use, after receiving four reports of improper administration (three fatal and one serious but nonfatal) through MEDWATCH.¹⁵ Although none of these cases concerned treatment of PCFP, we believe sufficient concern mandates the investigation of an alternative approach for PCFP treatment.

Recently, isolated cases of PCFP have been treated successfully with direct percutaneous coil embolization.¹⁶⁻¹⁸ We therefore conducted a prospective study to evaluate the treatment of PCFP with percutaneous puncture and coil embolization in selected patients undergoing continuous anticoagulant or antiplatelet therapy in whom UGCR was either contraindicated or failed.

PATIENTS AND METHODS

This prospective study was conducted between November 1997 and November 1999. During that period, 16 patients (six women and 10 men; mean age, 68 years; range, 37 to 79 years) underwent treatment for 17 PCFPs in our institution. Patient characteristics are detailed in the Table (online only). This was a successive series of patients.

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Competition of interest: nil.

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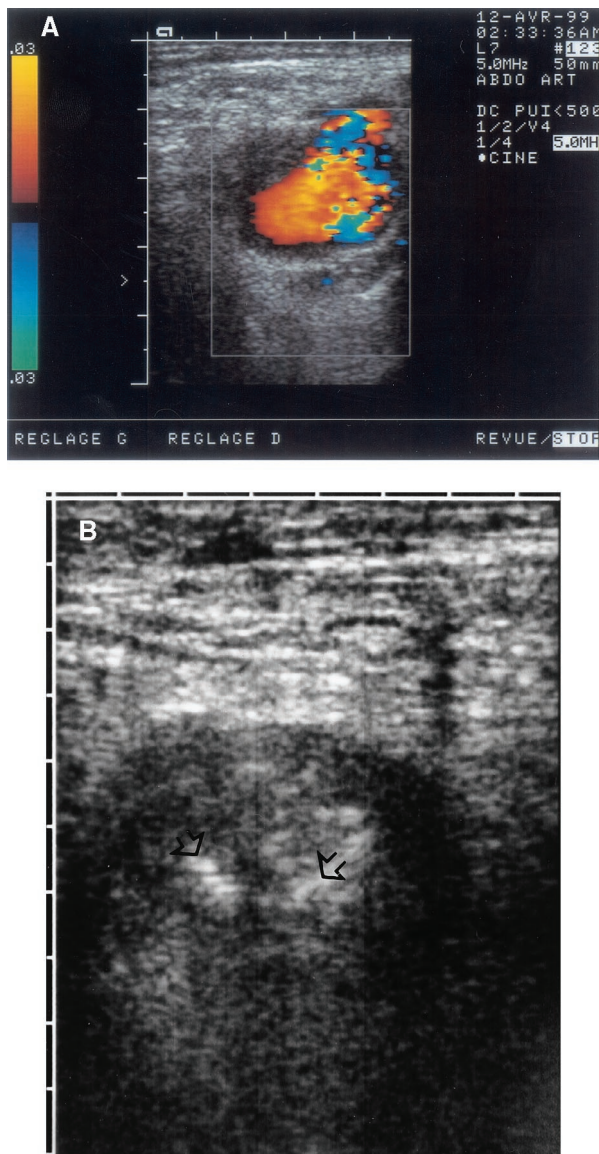


Fig 1. Duplex ultrasound scan of pseudoaneurysm located at femoral bifurcation before (A) and after (B) coil embolization. Coils appear as hyperechoic images within lumen of PCFP (arrows).

During the period of the study, four patients were excluded and needed prompt surgery: two patients because of ruptured PCFP, one patient because of an infected PCFP, and the last patient because of a severe allergy to contrast media. The applicability of the embolization treatment during the period of the study was then 17/21 (81%). According to the American Society of Anesthesiology physical status classification, all patients had at least classification 3. According to the American College of Cardiology, 12 patients were at major risk of increased perioperative cardiovascular risk, three were at intermediary risk, and one was at minor risk.¹⁹ All patients were at least undergoing

antiplatelet or anticoagulant therapy (Table, online only). One patient was undergoing treatment with abciximab (Reopro), an inhibitor of the platelet glycoprotein IIb/IIIa receptor, and aspirin. Patients had 17 PCFPs occurring after diagnostic coronary angiography in nine cases, after coronary angioplasty in six cases, with coronary stenting in five cases, after renal angioplasty in one case, and after retrieval procedure with a snare in one case. One patient had two PCFPs on both femoral arteries after two coronary angiographies performed at a 6-week interval. The catheter sheath size range was 6F (n = 11), 8F (n = 5), and 10F (n = 1).

After informed consent was obtained, all patients underwent exploration with duplex ultrasound scan and color flow imaging (Fig 1, A). The PCFP maximal diameter size ranged from 1.7 to 5.0 cm, with a mean diameter of 3.2 cm. UGCR failed one time in seven cases and two times in three cases, with compression times ranging between 25 and 45 minutes. In three cases, UGCR in combination with Femostop (3 hours, 12 hours, and 12 hours) failed. In four cases, UGCR was contraindicated because the patients had discomfort and pain.

The procedures were performed with local anesthesia (10 mL of Xylocaine 1% [Astra Zeneca, France]). With ultrasound-Doppler scan guidance, a 16-gauge intravenous catheter was percutaneously positioned within the PCFP. An angiogram was performed through the catheter to ensure its location and to detect associated arteriovenous fistula (AVF). With fluoroscopic guidance, stainless steel spring coils with synthetic fibers (IMWCE-35, Cook, Bjæverskov, Denmark) of 4 to 15 cm in length and 10 mm in diameter once deployed were delivered through the catheter within the PCFP. No migration within the native artery was observed while the coils were delivered. The catheter was withdrawn in case of contrast media stagnation within the pseudoaneurysm sac and the absence of visualization of femoral arterial tree after repeated control angiogram (Fig 2). If necessary, manual compression was performed after coil embolization until the final control with ultrasound-Doppler scan confirmed the total thrombosis of the PCFP. Distal pulses were checked, and patients were kept on bed rest for 24 hours. Patients underwent clinical review, and an ultrasound-Doppler scan was performed at day 1 and at 1, 3, 6, and 12 months.

RESULTS

Immediate results (Table I, online only). The puncture of the PCFP was successful in all of the cases. The angiograms confirmed the precise location of the intravenous catheter within the sac of the pseudoaneurysm. PCFPs were located on the superficial femoral artery (n = 8), on the common femoral artery (n = 6), and on the femoral bifurcation (n = 3). Three additional AVFs were observed. All procedures were uneventful. An average of 3.8 coils (two to nine) was delivered without pain or other difficulty. No rupture of the PCFP or migration of coils was observed. After coil embolization, no compression was necessary in three cases. For the patient undergoing treat-

ment with abciximab and aspirin, the time of compression necessary for complete occlusion was 45 minutes. In the 16 remaining cases, the mean duration of a gentle compression necessary for complete occlusion was $6.3 \pm$ minutes (range, 0 to 15 minutes). Ultrasound-Doppler scan confirmed the thrombosis of all PCFPs immediately and after 24 hours (Fig 1, B). No local or general complications were observed. All patients were discharged from our care at 24 hours.

Late results (Table I, online only). Two recurrences were observed during the follow-up period. In a first patient, hospitalized in another center, a new ultrasound-Doppler scan showed a partial recanalization of the PCFP 1 week after successful embolization. The patient underwent successful operation without any new attempt of coil embolization. (The ultrasound-Doppler scan report shows a possible residual flow in the neck, but we nevertheless consider this was a recurrence because an additional treatment was performed). The second patient was seen 1 month after the first embolization with a new 15-mm diameter PCFP located next to the first treated PCFP, which remained occluded. The new PCFP was successfully embolized with two coils of 4-mm diameter and 3-cm length. This patient died of terminal cardiac insufficiency 11 months later while waiting for heart transplantation without recurrence. All the 15 remaining patients (including the patient with recurrence treated with new efficient embolization) were available for clinical follow-up (mean period, 9.5 months; range, 1 to 21 months) and sonographic follow-up (mean period, 5 months; range, 1 day to 17.5 months).

In the remaining 16 PCFPs, clinical follow-up was satisfactory without recurrence. Ultrasound-Doppler scan confirmed the thrombosis in at least 13 PCFPs at 1 month. In two patients, only clinical follow-up was available and confirmed thrombosis at 16 and 18 months. Seven patients were available for follow-up after 6 months with ultrasound-Doppler scan showing no recurrence. Twelve patients were available for clinical follow-up after 6 months. Three patients have had another ipsilateral femoral catheterism without difficulty.

DISCUSSION

Simple observation is not recommended in patients with PCFPs larger than 2 cm in diameter.²⁰ Consequently, surgical treatment has been advocated as the reference treatment. Although the surgical repair is definitive, the incidence rate of complications is increased and scar formation may make future groin access difficult.¹ Moreover, it prolongs the hospital stay and increases the cost significantly. In the same way, patients with PCFPs needing continued anticoagulation and antiplatelet therapy are currently not considered good candidates for UGCR.⁸ This method consists of the compression of the neck of the pseudoaneurysm with the ultrasound scan transducer to interrupt aneurysmal flow inducing the thrombosis of the PCFP. UGCR can be performed safely and is inexpensive, yet it can be time consuming. The mean duration of compression necessary for successful thrombosis is commonly

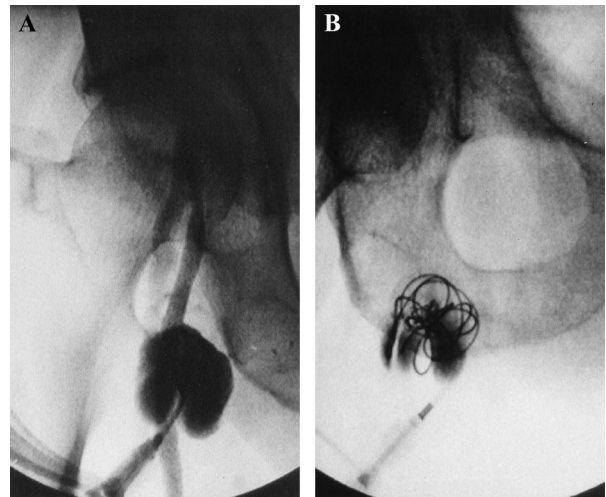


Fig 2. Angiogram performed through 16-gauge catheter shows large, bilobed PCFP located at superficial femoral artery (A). After embolization with coils, absence of visualization of arterial tree and stagnation of iodine contrast within lumen of PCFP indicates complete thrombosis (B).

high (28 to 104 minutes),^{8,21-24} and multiple attempts are sometimes necessary. In addition, the patients may have pain, discomfort, and bradycardia. The failure rates of UGCR range from 7% to 70%, especially when patients are undergoing anticoagulation or antiplatelet therapy.^{8,25-27}

In this report, we present a less invasive alternative for operative treatment of PCFP without modification of anticoagulant or antiplatelet regimens. In our series, apparition of PCFP seems to be related to the size (superior than 6F) of the sheath. In addition, the location of the initial puncture, too low in the superficial femoral artery or at the bifurcation, far from the femoral head may favor the emergence of PCFP because of inefficient compression maneuver.

The direct puncture of PCFP is a 100% efficient method compared with the contralateral approach proposed by some authors, which is more complex and presents risks of development of contralateral PCFP or any other local complication.^{17,28} Moreover, catheterization of the neck is time-consuming and sometimes unsuccessful, making those techniques anecdotal. We choose to control our procedure with ultrasound-Doppler scan and fluoroscopy to avoid downstream migration of coil and to confirm thrombosis of PCFP.

The success rate of coil embolization of 88.3% is correct but not the greatest for a problem like PCFP. However, one case of recurrence occurred in bilobed pseudoaneurysm, which is more prone to recurrence and frequently necessitates a second treatment.¹⁴ Concerning the other patient who underwent reoperation in another center, the so-called recurrence was in fact a persistent flow in the neck that should not have necessitated reintervention. However, to be totally honest, it was difficult to withdraw the patient from the study.



Fig 3. Angiogram performed for abdominal aortic aneurysm evaluation in patient with PCFP treated with coil embolization 1 year previously. Note that coils are well in place, and note absence of recurrence of PCFP. Common femoral artery is suitable for new puncture.

Recently some publications reported highly successful treatment of PCFP with direct injection of thrombin with ultrasound-Doppler scan guidance.⁹⁻¹³ Thrombin injection is a quick method, uses less expensive resources, and avoids a foreign body. This technique is better than UGCR and seems to have now a wide acceptance within the vascular community. However, we think that thrombin injection is not 100% safe because thrombotic complications have been reported at least in five cases resulting from leakage of thrombin into systemic circulation.^{10,29-32} In addition, one fatal pulmonary embolism occurred in a case in which an AVF was associated to the pseudoaneurysm.³³ In fact, association of AVF and PCFP is relatively common, and in our series of 17 PCAPs, AVF was present three times. According to its promoters, one could avoid that complication by injecting slowly a lower volume, adapted to aneurysm size, of highly concentrated thrombin without filling the neck. Kang et al¹⁰ emitted special limits concerning thrombin injection in PCFP with short and wide neck. In our reported method, morphology of the neck is not a

limit because of the possibility of use of a coil larger than the neck.

Probably because of its mammalian origin, bovine thrombin is associated with risk of anaphylactic reaction. Moreover, bovine thrombin induced antibodies directed against bovine thrombin and other coagulation factors.³⁴ A prolonged generalized urticarial reaction has been described after percutaneous thrombin injection for treatment of PCFP.³⁵ Similarly, a patient with a PCFP and a history of exposure to bovine thrombin had a severe anaphylactic reaction after thrombin treatment.³⁶ Consequently, injection in patients with previous exposure to thrombin should be avoided.³⁵ Furthermore, bovine thrombin is not allowed for use in France and in other European countries exposed to bovine spongiform encephalopathy, in addition to the Food and Drug Administration recommendations.

In our series, all patients were undergoing anticoagulation or antiplatelet therapy. These treatment could not have been removed because of coronary risk. It seems intuitive that conservation of these treatments decreases cardiac mortality or morbidity in those cases of patients at high risk, particularly for PCFP occurring in early follow-up of coronary angioplasty or stenting (six cases in our series) or when cardiac arrhythmia is associated (three cases). No local bleeding complications were observed.

Theoretic complications of coil embolization include local infection as the result of hematoma, implantation of synthetic material, and percutaneous access. Infection of embolization material had been described³⁷ but remains rare and was not observed in our series. However, we think that coil embolization is contraindicated in infected groin.

In this preliminary study, we can conclude that percutaneous coil embolization is a safe, quick, and well-tolerated treatment of PCFP and authorizes preprocedure and postprocedure conservation of anticoagulant or antiplatelet therapy. Unlike bovine thrombin, coil embolization avoids adverse events as immune or anaphylactic response and is authorized in all countries. Our study suggests that in case of PCFP, percutaneous coil embolization should be attempted when ultrasound scan-guided compression has failed or is contraindicated.

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Appendix, online only. Calculating process in mathematical model

At the end of the first tiptoe cycle, the pressure P_1 can be expressed as follows:

$$P_1 = P_0 - x P_0 + I,$$

where P_0 is the resting pressure, x is the pressure reduction fraction per each step, and I is the constant pressure increase per step. Similarly, at the end of n th tiptoe cycle, the following equation can be derived:

$P_n = P_{n-1} - x P_{n-1} + I$, which can be transformed to:

$$P_n = (1 - x) P_{n-1} + I.$$

When a is substituted for $(1 - x)$, the previous equation becomes:

$$P_n = a P_{n-1} + I \quad (1)$$

With equation 1, the pressure at each tiptoe cycle can be expressed as follows:

$$P_1 = a P_0 + I$$

$$P_2 = a P_1 + I = a^2 P_0 + a I + I$$

$$P_3 = a P_2 + I = a^3 P_0 + a^2 I + a I + I$$

$$\begin{aligned} P_n &= a^n P_0 + a^{n-1} I + a^{n-2} I + \dots + I \\ &= a^n P_0 + (a^{n-1} + a^{n-2} + \dots + 1) I \quad (2) \end{aligned}$$

$$P_n = a^n P_0 + (1 - a^n) I / (1 - a)$$

At the asymptotic behavior when the pressure reduction per step is equal to I , n becomes infinite and a^n is approximated to zero because $a < 1$. Therefore, equation 2 can become:

$$P_\infty = I / (1 - a) \quad (3)$$

Then, substituting $I / (1 - a)$ in equation 2 with P_∞ from equation 3,

$$P_n = a^n P_0 + (1 - a^n) P_\infty \quad (4)$$

$$P_n - P_\infty = a^n (P_0 - P_\infty)$$

Taking logarithms of equation 4, the following equation can be obtained:

$$\log_{10} (P_n - P_\infty) = n \log_{10} a + \log_{10} (P_0 - P_\infty) \quad (5)$$