Comparison Between Ultrasound-Guided Compression and Para-Aneurysmal Saline Injection in the Treatment of Postcatheterization Femoral Artery Pseudoaneurysms

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Management of postcatheterization femoral artery pseudoaneurysm (FAP) is problematic. Ultrasound-guided compression (UGC) is painful and cumbersome. Thrombin injection is costly and may cause thromboembolism. Ultrasound-guided para-aneurysmal saline injection (PASI) has been described but was never compared against other treatment methods of FAP. We aimed at comparing the success rate and complications of PASI versus UGC. We randomly assigned 80 patients with postcatheterization FAPs to either UGC (40 patients) or PASI (40 patients). We compared the 2 procedures regarding successful obliteration of the FAP, incidence of vasovagal attacks, procedure time, discontinuation of antiplatelet and/or anticoagulants, and the Doppler waveform in the ipsilateral pedal arteries at the end of the procedure. There was no significant difference between patients in both groups regarding clinical and vascular duplex data. The mean durations of UGC and PASI procedures were 58.14 ± 28.45 and 30.33 ± 8.56 minutes, respectively ($p = 0.045$). Vasovagal attacks were reported in 10 (25%) and 2 patients (5%) treated with UGC and PASI, respectively ($p = 0.05$). All patients in both groups had triphasic Doppler waveform in the infrapopliteal arteries before and after the procedure. The primary and final success rates were 75%, 92.5%, 87.5%, and 95% for UGC and PASI, respectively ($p = 0.43$). In successfully treated patients, there was no reperfusion of the FAP in the follow-up studies (days 1 and 7) in both groups. In conclusion, ultrasound-guided PASI is an effective method for the treatment of FAP. Compared with UGC, PASI is faster, less likely to cause vasovagal reactions, and can be more convenient to patients and physicians. **(Am J Cardiol 2014;113:871−876)**

Femoral artery pseudoaneurysm (FAP) is a troublesome groin complication related to the femoral arterial access. The incidence of FAP may reach up to 6%[1] and is more likely with complex structural, coronary, or peripheral interventions, using large-sized introducer sheath and potent antithrombotic therapy.[2] FAP may cause compression neuropathy, venous thrombosis, critical limb ischemia, skin necrosis, infection, or may even rupture.[3] Small asymptomatic pseudoaneurysms can be managed conservatively unless they are still present on a follow-up duplex scan 2 months later. In contrast, large (>2 cm), symptomatic, or complicated FAPs should be treated.[4] The most commonly used techniques are ultrasound-guided compression (UGC), surgical repair, and thrombin injection. UGC is safe and effective but entails a lengthy procedure, patient discomfort, and a high failure rate in patients receiving dual antiplatelet and/or anticoagulant therapy. With surgical repair, the incidence of wound-healing disorders and permanent neuralgias is 32% and lymphatic leakage is 40%.[5,6] Ultrasound-guided percutaneous thrombin injection is a costly procedure, and serious complications including thromboembolism and allergic reaction secondary to thrombin injection have been described.[7−9] Another, minimally invasive, technique has been described by Gehling et al[10] and uses ultrasound-guided para-aneurysmal saline injection (PASI) for treating FAPs. This technique has not been compared systemically with UGC or thrombin injection. We aimed at comparing the success rate and complications of PASI versus UGC.

Methods

From December 2009 till December 2012, we recruited 80 patients with post−cardiac catheterization FAPs. Patients were clinically examined, and the diagnosis of FAP was established after detailed duplex examination, using Advanced Technology Laboratories HDI 5,000, Siemens Elegra (Siemens Medical Solutions USA, Inc., Mountain View, California), and HP Sonos 2,000 systems (Philips Koninklijke, Eindhoven). All had high-resolution broadband width linear array transducers L5-7/10 MHz (Figures 1 and 2). All included patients had either large pseudoaneurysms >2 cm and/or symptoms related to the pseudoaneurysm. Exclusion criteria were patient refusal to grant consent or to be randomized, presence of synthetic arterial graft, rapidly expanding pseudoaneurysm, skin ischemia or compromised soft tissue viability, infection at the anticipated site of

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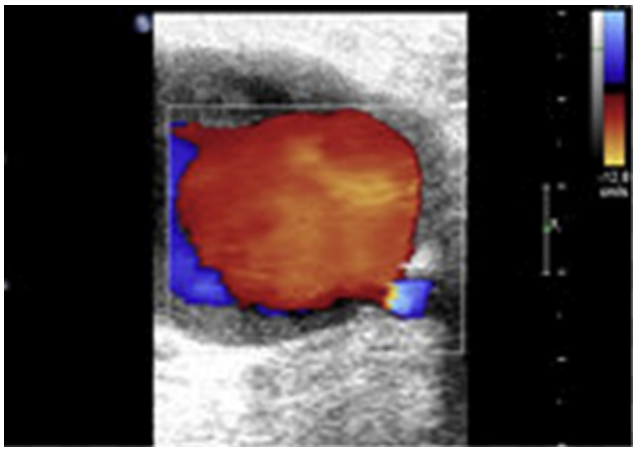

Figure 1. Color Doppler image showing swirling flow in the pseudoaneurysm cavity.

compression or infected pseudoaneurysm, presence of uncontrollable hemorrhage, and limb-threatening ischemia resulting from a pseudoaneurysm. The study was approved by our local ethical committee. Informed consent was obtained from all patients after being instructed about the nature and risks of the study and both procedures.

The following data were reported for all included patients: age, gender, presence of diabetes mellitus, hypertension, obesity defined as body mass index $\geq$30 kg/m^2, onset of presentation after catheterization: within 3 days, 3 to 7 days, or >7 days, type of the catheterization done, gauge of introducer sheath, and the use of single (aspirin or clopidogrel) or dual antiplatelet (aspirin plus clopidogrel) and/or anticoagulant therapy, with measurement of the international normalized ratio value for patients receiving warfarin. Discontinuation of antiplatelet and/or anticoagulation was either left to the discretion of the referring physician or performed after failed attempt of either UGC or PASI.

The following parameters were reported during duplex scanning:

1. The Doppler waveform in the ipsilateral infrapopliteal arteries (triphasic, monophasic damped, or absent).
2. The presence or absence of spontaneous thrombosis within the FAP cavity or lining its wall.
3. Number of lobes of FAP, either single lobe (unilocular) or multilocular.
4. Feeding artery: common femoral, superficial femoral, or profunda femoral artery.
5. Number of necks communicating the feeding artery with the FAP (single or multiple).
6. Width and length of the neck, if there were multiple necks, only the measurements of the largest one was reported.
7. FAP length, width, height, and volume. The volume was calculated by the following formula:

$$(\text{Length} \times \text{width} \times \text{height} \times 0.5).$$[11,12]

In cases with multiloculated FAP, the volume of the proximal lobe only was calculated.

The 80 patients who had definitive diagnosis of FAP were randomly assigned to treatment by either UGC or PASI. UGC was performed after the feeding artery and the neck of the aneurysm were properly identified by ultrasound. Compression was then done with the linear array ultrasound transducer aiming to obliterate the flow within the neck and FAP completely. Pressure was applied in cycles of 10-minutes compression alternating with 1 to 2 minutes without compression to re-evaluate perfusion of the FAP, start of thrombosis, reposition the probe at the proper site and give some relief for the patient.[8]

PASI was done by the following technique: after the patient's skin at the groin was prepared with povidone iodine, sterile drapes were placed around the inguinal area. The ultrasound transducer was covered with a sterile laminated bag, and sterile gel was applied to the patient's skin to prevent infection. All patients had a peripheral intravenous line for atropine injection if necessary. After administration of subcutaneous anesthesia with 10 ml of 2% lidocaine, an 18-gauge needle mounted on a plastic syringe filled with 0.9% saline solution (drawn from a 500-ml saline bag) was advanced and positioned within 2 to 5 mm from the neck communicating the femoral artery and the FAP. After confirmation of extravascular and extra-aneurysmal needle position, saline solution was slowly injected until the resultant tissue swelling completely obliterated the FAP neck (Figure 3). Puncture of the femoral artery and/or the FAP was avoided in all patients. Repositioning of the needle and reinjection on the opposite side of the neck was performed if ultrasound monitoring indicated insufficient compression of the pseudoaneurysm neck. After saline injection, manual compression was applied for a 5-minute period.[13]

The following data were reported for every treated patient with either technique (UGC or PASI): discontinuation of antiplatelet and/or anticoagulant therapy before the procedure, incidence of vasovagal attacks, total time of the procedure, successful obliteration of the FAP and its neck, failure of the attempt and the need for another attempt or other modality of management, and the Doppler waveform in the ipsilateral pedal arteries at the end of the procedure. Success was considered if both of the following conditions were justified: (1) complete thrombosis of the pseudoaneurysm cavity with no residual blood flow, using the highest possible color gain and lowest possible pulse repetition frequency to detect any minimal residual flow and (2) obliteration of the neck, with loss of the characteristic to-and-fro Doppler waveform at the previous site of the neck. If by the end of the attempt, either of the previous conditions was not observed, another attempt (for PASI) or 2 attempts (for UGC only) were planned within 24 hours. In cases with successful thrombosis of FAP, a dressing was wrapped around the thigh, and the patient was instructed to maintain bed rest after the procedure until the first follow-up examination. Primary success was considered if the aneurysm was obliterated completely from the first attempt. Final success reflects the number of cases that were successfully treated with UGC or PASI, fulfilling the criteria describing success and regardless the number of attempts needed.

Follow-up was done after 24 hours (follow-up 1) and 7 days (follow-up 2), and the following points were reported: (1) any symptoms reported by the patients, including signs of inflammation, new occurrence or exacerbation of

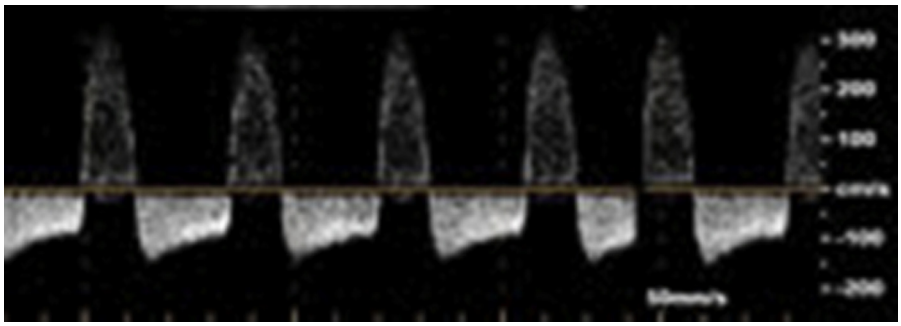

Figure 2. Characteristic to-and-fro Doppler waveform at the neck of the pseudoaneurysm.

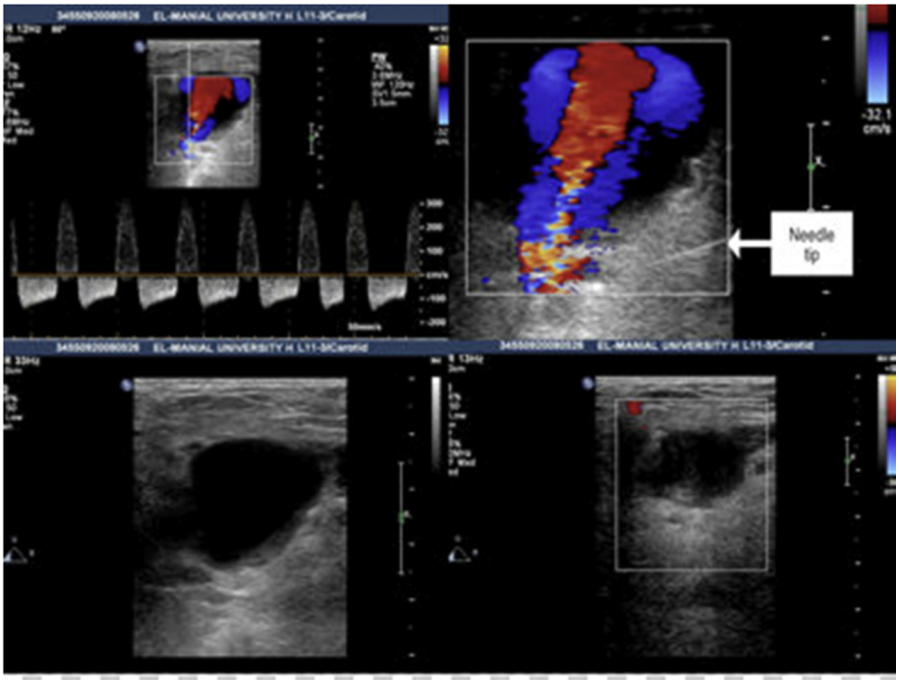

Figure 3. Para-aneurysmal saline injection. *(A)* the classic to-and-fro Doppler waveform in the neck of the aneurysm; *(B)* the shadow of the needle close to the neck of the aneurysm; *(C)* gray-scale ultrasound showing the aneurysm cavity after saline injection; *(D)* absent color flow in the cavity after successful obliteration of the neck.

claudication symptoms, and groin pain, (2) reperfusion of the FAP detected by duplex scanning, (3) evidence of compromised soft-tissue viability or infection at the site of arterial puncture, (4) thromboembolic complication: defined as direct visualization of a thrombus at any segment of the arterial tree, absent blood flow, damped monophasic Doppler waveform, reduced peak blood flow in the anterior or posterior tibial artery, or exacerbation of arterial occlusive disease, and (5) Doppler waveform in the ipsilateral pedal arteries.

A descriptive statistical study was done of each variable by obtaining the distribution of absolute and relative frequencies. The mean and SD were calculated for quantitative variables. Comparison of groups was done using the Student *t* test for numerical variables and the Mann-Whitney nonparametric test for categorical variables. Reference to statistical significance was made by presenting a p value $<5\%$; thus, any measurement with a value of $p < 0.05$ was considered statistically significant.

Results

In this study, 80 patients with post−cardiac catheterization FAPs were prospectively recruited over 3 years. All of them had undergone coronary angiography and/or percutaneous coronary intervention by way of femoral access. Demographic data, incidence of hypertension, diabetes, obesity, and the type of catheterization were not significantly different between the UGC and PASI groups (Table 1). Also, no significant differences between the 2 groups were detected regarding the use of antiplatelet (single or dual) and anticoagulant therapies (Table 2). The mean value of international normalized ratio for patients on oral anticoagulant therapy was 1.9 and 1.8 for patients in the UGC and PASI groups, respectively. Spontaneous thrombosis in the FAP cavity was equally detected among the patients in the 2 groups. FAPs were connected to the common femoral artery in 75% (30 of 40) and 80% (32 of 40) of patients in the UGC and PASI groups, respectively, whereas the rest of FAPs were connected to the superficil

Table 1
Clinical characteristics of patients in the 2 groups

Variable	UGC, n = 40 (%)	PASI, n = 40 (%)
Age (mean ± SD)	52.23 ± 9.86	54.8 ± 10.9
Men	18 (45)	16 (40)
Hypertension*	25 (62.5)	23 (57.5)
Diabetes mellitus	19 (47.5)	20 (50)
Obesity (body mass index ≥30 kg/m^2)	33 (82.5)	37 (92.5)
Interventional catheterization	13 (32.5)	12 (30)
Diagnostic catheterization	27 (67.5)	28 (70)
7Fr femoral sheath	2 (5)	2 (5)
6Fr femoral sheath	38 (95)	38 (95)
Onset within 3 days after catheterization	19 (47.5)	20 (50)
Onset within 3−7 days after catheterization	15 (37.5)	15 (37.5)
Onset 7 days after catheterization	6 (15)	5 (12.5)

* Systolic blood pressure ≥140 mm Hg, diastolic blood pressure ≥90 mm Hg, or on treatment for hypertension.

Table 2
Anticoagulation in the 2 groups

Variable	UGC, n = 40 (%)	PASI, n = 40 (%)
Aspirin only	7 (17.5)	8 (20)
Aspirin and clopidogrel	13 (32.5)	12 (30)
Aspirin, clopidogrel, and LMWH	5 (12.5)	5 (12.5)
Warfarin	11 (27.5)	11 (27.5)
Warfarin and aspirin	3 (7.5)	4 (10)

LMWH = Low-molecular weight heparin.

femoral artery. Other FAP-related features obtained by duplex scanning in the 2 groups are illustrated in Table 3. Antithrombotic therapy was discontinued in 5 patients (12.5%) in the UGC group and in 3 patients (7.5%) treated with PASI (p = NS). The mean procedure duration was significantly longer with UGC compared with PASI. There was a trend toward fewer self-limited vasovagal attacks with PASI compared with UGC (Table 4).

PASI was done by single injection in 30 patients (75%), whereas double injections were needed in 10 patients (25%). The mean amount of injected saline solution was 50 ± 33 ml. All patients in the 2 groups had well-felt pedal pulsations with triphasic Doppler waveform in the infrapopliteal arteries before the procedure, and none of them showed altered waveform after treatment. The primary success rate was 75% (30 of 40) and 87.5% (35 of 40) for UGC and PASI, respectively (p = 0.43; Figure 4). In the UGC group, 10 patients needed a second attempt and 3 of the 10 needed a third attempt. In the latter 3 patients, we failed to obliterate the FAP. Two of the failed cases were treated successfully by PASI, and 1 case had surgical repair. In the PASI group, 5 patients needed a second attempt. In 3 of them, the FAP was obliterated successfully, and in 2 of them, PASI failed to obliterate the FAP and the patients were repaired surgically. The final success rate was 92.5% (37 of 40) and 95% (38 of 40) for UGC and PASI, respectively (p = 0.75). In successfully treated patients, there was no reperfusion of the FAP in the follow-up studies 1 and 2 in both groups; also, there were no new symptoms, thromboembolic complication, infection at the site of arterial puncture, and the Doppler

Table 3
Anatomic features of the pseudoaneurysm in the 2 groups

Variable	UGC, n = 40 (%)	PASI, n = 40 (%)
Uniloculated FAPs	32 (80)	33 (82.5)
Multiloculated FAPs	8 (20)	7 (17.5)
Single neck	35 (87.5)	36 (90)
Multiple necks	5 (12.5)	4 (10)
Mean FAP volume, cm^3	44.09 ± 14.73	46.20 ± 15.73
Mean width of the neck, cm	1.85 ± 0.38	1.86 ± 0.32
Mean length of the neck, cm	4.55 ± 0.92	4.32 ± 0.63

Table 4
Procedure details in both groups

Variable	UGC (n = 40)	PASI (n = 40)	p Value
Procedure duration (minutes)	58.14 ± 28.45	30.33 ± 8.56	0.045
Self-limited vasovagal reaction (%)	10 (25)	2 (5)	0.05
Reperfusion in follow-up studies	0	0	NS
Discontinuation of antithrombotic therapy (%)	5 (12.5)	3 (7.5)	NS
Infection or thromboembolism	0	0	NS

waveform in the pedal arteries was triphasic during the follow-up studies (1 and 2) in both groups.

Discussion

Despite the widespread shift toward radial access for coronary interventions, femoral access is still indispensable for a variety of procedures including transcatheter aortic valve implantation, thoracic aortic stenting, and carotid and renal interventions. These procedures usually require large introducers with an increased risk of local groin complications, including femoral pseudoaneurysms. In addition to prolonged hospitalization, risk of peripheral ischemia and the need to stop antiplatelet therapy with pseudoaneurysms and major groin vascular complications have been identified as predictors of mortality.[14]

The current treatment options of FAPs have significant limitations. Open surgery is associated with considerable risk and may end in bypass rather than repair. Thrombin injection is currently widely used as the best option for patients who failed the conservative approach or manual compression. However, the cost of thrombin preparation is high (around €300) and has a short expiry date. Bovine thrombin can cause prolonged urticarial reactions[15] and life-threatening anaphylaxis,[16] which has been lowered by the use of recombinant human thrombin.[17] The procedure also requires direct intraluminal injection of a thrombogenic material, which entails the risk of arterial thrombosis and distal embolization. The risk may be greater in multilocular aneurysms. Some investigators recommend filling the cavity of the aneurysm with physiological saline solution to improve the safety of the procedure and to confirm the presence of the needle inside the aneurysm.[18] In complex pseudoaneurysm treatment, it is may be necessary to inject thrombin first into the lobe that is not directly joined to the femoral artery followed by the treatment of other lobes if still patent after 24 hours.[19] Compression of the femoral

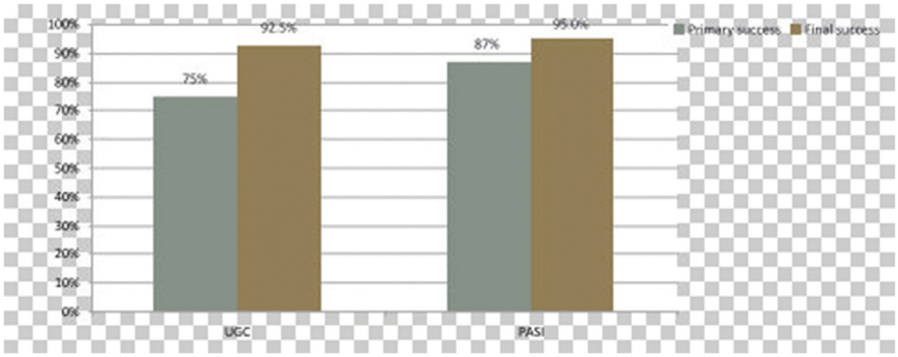

Figure 4. The primary and final success rates of UGC versus PASI.

vein by the FAP cavity can be a contraindication to thrombin injection.[20]

The technique of UGC has been used successfully in our center since 1997. It was the only noninvasive technique available in our center as thrombin is not commercially available in Egypt. However, UGC requires lengthy compression(s), which is cumbersome for both the patients and physicians. It is difficult to maintain pressure in the correct position for prolonged periods of time. The mechanism by which UGC leads to FAP closure is the compression of the FAP channel and consecutive thrombosis of the whole cavity. However, the pressure exerted transcutaneously is diffuse, indirect, and often painful. This might be the reason for a reported failure rate of up to 1/3 in all procedures.[21]

The technique of PASI around the neck of the FAP has been described in 2003 in 6 patients with small FAPs. That study proved the concept that minimal invasive application of a fluid depot at the FAP channel would be able to compress it.[10] In our study, we aimed at comparing UGC with PASI. To our knowledge, this is the first prospective randomized study to compare UGC with PASI. The previous reports on PASI recruited very small numbers of patients, selected only the small FAPs, or did not compare the technique against UGC or thrombin injection.[10,13,17]

We found that UGC and PASI have similar primary and final success rates. Both PASI and UGC were safe in terms of the absence of embolization and ischemic complications. However, we found that PASI can be accomplished in a significantly shorter time, almost half the time required for successful UGC. There was also a strong trend toward fewer self-limited vasovagal attacks with PASI. These differences should result in greater convenience for the operator and the patient. We found the technique of PASI to be easy and required short period of training. The duration of the procedure decreased as we proceeded in the study till it became $<$20 minutes in the last cases. The procedure time in our study (30.33 $\pm$ 8.56 minutes) is close to that reported by Gehling et al (29 $\pm$ 20 minutes). The final success rate of PASI in our study (95%) is comparable with that reported by Finkelstein et al[13] (92%). We were unable to specify factors associated with failure of PASI because of the small number of failures. Also, we observed that patients with multilocular FAPs, who represent a problem during thrombin injection, could be successfully treated by PASI. The technique of PASI also fits well the laboratories with limited financial resources in the developing world as it does not require any sophisticated equipment or expensive drugs. We conclude that ultrasound-guided PASI is an effective method for treatment of femoral pseudoaneurysms. Compared with UGC, it is faster, less likely to cause vasovagal reactions, and can be more convenient to patients and physicians. We recommend future studies to compare para-aneurysmal saline injection with percutaneous thrombin injection.

Disclosures

The authors have no conflicts of interest to disclose.

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