



Ultrasound-guided thrombin injection versus ultrasound-guided compression repair in the treatment of post-catheterization femoral artery pseudoaneurysm: King Saud University Medical Center Experience

Kateterizasyon sonrası femoral arter psödoanevrizmasının tedavisinde ultrason eşliğinde kompresyon onarımına kıyasla ultrason eşliğinde trombin enjeksiyonu: Kral Saud Üniversitesi Tıp Merkezi Deneyimi

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ABSTRACT

Background: This study aims to evaluate the effectiveness of ultrasound-guided thrombin injection versus ultrasound-guided compression repair in the management of iatrogenic femoral artery pseudoaneurysms.

Methods: Between June 2006 and December 2015, a total of 29 consecutive patients (15 males, 14 females; mean age 54 years; range 26 to 81 years) with a femoral pseudoaneurysm treated by ultrasound-guided thrombin injection were retrospectively analyzed. These patients were compared with a historical group of 36 patients (21 males, 15 females; mean age 44 years; range 32 to 65 years) who underwent ultrasound-guided compression repair between February 1999 and May 2006. Medical records and vascular laboratory findings of all patients were reviewed. Successful treatment was defined as complete cessation of flow into the false lumen with preservation of flow in the femoral artery.

Results: The ultrasound-guided thrombin injection showed a success rate of 100%, whereas ultrasound-guided compression repair had a success rate of 80.5%, which was possibly affected by anticoagulant therapy, hypertension, and an aneurysm size of >6 cm. However, none of these factors did not affect the success of thrombin injections.

Conclusion: Ultrasound-guided thrombin injection is a highly successful, easy to perform, accepted, and well-tolerated method by patients. It is more effective compared to compression therapy in patients with hypertension, large aneurysms, and who are on anticoagulant therapy.

Keywords: Femoral pseudoaneurysm, ultrasound-guided compression, ultrasound-guided thrombin injection.

ÖZ

Amaç: Bu çalışmada iatrojenik femoral arter psödoanevrizmalarının tedavisinde ultrason eşliğinde kompresyon onarımına kıyasla ultrason eşliğinde trombin enjeksiyonunun etkinliği değerlendirildi.

Çalışma planı: Haziran 2006-Aralık 2015 tarihleri arasında ultrason eşliğinde trombin enjeksiyonu ile tedavi edilen femoral psödoanevrizmalı toplam 29 ardışık hasta (15 erkek, 14 kadın; ort. yaş 54 yıl; dağılım, 26-81 yıl) retrospektif olarak incelendi. Bu hastalar Şubat 1999 - Mayıs 2006 tarihleri arasında ultrason eşliğinde kompresyon onarımı yapılan 36 hastadan oluşan (21 erkek, 15 kadın; ort. yaş 44 yıl; dağılım, 32-65 yıl) bir kronolojik grup ile karşılaştırıldı. Tüm hastaların tıbbi kayıtları ve damar laboratuvar bulguları incelendi. Tedavi başarısı, femoral arterdeki akımın korunarak, akımın yanlış lümene hareketinin tamamen sona ermesi olarak tanımlandı.

Bulgular: Ultrason eşliğinde trombin enjeksiyonunun başarı oranı %100 olup, ultrason eşliğinde kompresyon onarımının başarı oranı muhtemelen antikoagülan tedavi, hipertansiyon ve >6 cm'lik anevrizma çapından etkilendiğinden %80.5 idi. Ancak, bu faktörlerin hiçbiri trombin enjeksiyonlarının başarısını etkilemedi.

Sonuç: Ultrason eşliğinde trombin enjeksiyonu son derece başarılı, uygulaması kolay, kabul edilebilir ve hastalar tarafından iyi tolere edilen bir yöntemdir. Hipertansiyonu olan, anevrizması büyük olan ve antikoagülan tedavisi alan hastalarda, kompresyon tedavisinden daha etkilidir.

Anahtar sözcükler: Femoral psödoanevrizma, ultrason eşliğinde kompresyon, ultrason eşliğinde trombin enjeksiyonu.

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Historically, the common femoral artery catheterization has been, by far, the most widely used procedure for percutaneous arterial access. It is commonly used for diagnostic investigations and therapeutic interventions.^[1,2] Iatrogenic femoral artery pseudoaneurysms develop following endovascular procedures, if the arteriotomy is not adequately sealed or if the occluding clot in the arteriotomy is dislodged in the post-procedural period. There is a communication with the arterial lumen (neck) and blood extravasating into the surrounding soft tissue. The wall of the pseudoaneurysm consists solely of compressed thrombus and surrounding soft tissue.

Femoral pseudoaneurysms may be a complication in 0.5 to 1% of diagnostic procedures and in 3.2 to 7.7% of therapeutic procedures.^[3] Multiple factors can increase the incidence, such as poor selection of puncture site and technique, therapeutic interventional procedures, use of large-bore needle and sheaths, use of anticoagulant and multiple antithrombotic drugs, poor control of puncture site bleeding after the procedure, and diseased calcified vessels.^[4] To avoid rupture risk, the traditional management of iatrogenic femoral pseudoaneurysms consisted of surgical repair. However, surgery was invasive and increased the hospital stay and cost.^[5-7] In 1991, Fellmeth *et al.*^[8] introduced ultrasound-guided compression repair (UGCR) which rapidly replaced by surgery as the first-choice treatment modality in most patients. Although the success rate varied between 27 and 100% and the compression time for pseudoaneurysms ranged from 30 to 120 min,^[4,9,10] it has multiple drawbacks including local discomfort and pain and requires sedation and analgesia with a high rate of recurrence, particularly in patients on anticoagulant, antiplatelet medications, or both.^[11] Also, compression therapy requires at least one additional day in the hospital.

As an alternative to surgery and UGCR, in 1986, Cope and Zeit^[12] reported percutaneous thrombin injection with occlusion of the feeding vessels for the treatment of femoral pseudoaneurysms. In 1997, Liao *et al.*^[13] published a series of five patients treated by ultrasound-guided thrombin injection (UGTI). In 1998, Kang *et al.*^[14] reported that UGTI was safe, effective, and free of compression repair limitations. This report was rapidly followed by similar several publications.^[15-19] The success rate of this technique has been shown to range between 69 and 100% with a very low complication rate.^[13,20]

In the light of literature data, we aimed to evaluate the effectiveness of UGTI versus UGCR in the treatment of post-catheterization femoral pseudoaneurysms.

PATIENTS AND METHODS

This single-center, retrospective, non-randomized clinical study of prospectively maintained data was conducted at King Saud University Medical Center between June 2006 and December 2015. A total of 29 consecutive patients (15 males, 14 females; mean age 54 years; range 26 to 81 years) with a femoral pseudoaneurysm treated by UGTI were retrospectively analyzed. These patients were compared with a historical group of 36 patients (21 males, 15 females; mean age 44 years; range 32 to 65 years) who underwent UGCR between February 1999 and May 2006. Medical records and vascular laboratory findings of all patients were reviewed. A written informed consent was obtained from each patient. The study protocol was approved by the King Saud University Institutional Review Board. The study was conducted in accordance with the principles of the Declaration of Helsinki.

In our institution's vascular laboratory, a protocol for femoral pseudoaneurysm is followed for all patients with clinical signs of post-catheterization femoral pseudoaneurysms such as pain, murmur, or swelling. All patients are evaluated by an experienced technician using a color Doppler scanner (Philips-ATL HDI-5000, Bothell, USA) utilizing a linear 4-7 MHz probe. The ankle-brachial indices (ABIs) are measured bilaterally. Ultrasound images, precise location, aneurysmal sizes, and status of the peripheral pulses for all patients before and during the procedure are recorded immediately after the treatment and at 24 h and on Days 7 and 30 after the post treatment. Conservative follow-up by ultrasonography is performed in all patients, until spontaneous resolution was achieved in patients with an aneurysm size of <1.5 cm. Patients with larger aneurysms are considered eligible for non-invasive management.

In our institution, until 1998, all femoral pseudoaneurysms were treated surgically. From 1999 until 2006, they were treated by UGCR. As of 2006, UGTI has been increasingly adopted, as this was the period when the bovine thrombin was available in our country, and UGTI showed promising results. Exclusion criteria for thrombin injection include all indications for surgical repair or known hypersensitivity to thrombin.

Surgical technique

In the UGCR group, the operation was performed in accordance with the Fellmeth *et al.*'s technique.^[8] In brief, after local anesthesia by 1% lidocaine solution, a manual straight downward force was applied with the ultrasound transducer under continuous ultrasound guidance. Compression was applied for 10 to 15 min

on the aneurysmal neck and increased, until the flow within the pseudoaneurysm sac was stopped; however, the flow in the femoral artery was still maintained. After 10 to 15 min, the pressure was released gradually and repeated after 5 to 10 min, if there was still flow in the pseudoaneurysm, up to three times per treatment session. If compression therapy was not effective, the same procedure was repeated the following day, up to a maximum of three sessions. If the treatment still failed or the patient was unsuitable for UGCR, the patient was indicated for surgery. If compression therapy was successful, compression bandage was applied for a minimum of 12 h.

The UGTI was performed according to Kang et al.'s^[14] technique. In brief, under sterile conditions, a 20-gauge needle was inserted into the lumen of the pseudoaneurysm using real-time ultrasound guidance. Quick aspiration and reinjection of blood led to characteristic color Doppler images, confirming the correct position of the needle tip. The needle tip was directed away from the neck of the pseudoaneurysm. Bovine thrombin solution (Thrombin-JMI®, King Pharmaceuticals, Inc., Bristol, TN, USA) was diluted to a concentration of 1,000 µ/mL in 0.9% sterile saline. The diluted thrombin was, then, slowly injected until the flow within the pseudoaneurysm ceased. If the treatment failed, the procedure was repeated up to a maximum of three sessions. If the treatment was successful, we repeated the ultrasound examination for nearby femoral vessels to ensure patency. In addition,

we evaluated the ipsilateral peripheral pulses before and immediately after thrombin injection. All patients were kept in bed for four h following the procedure and were reevaluated before discharge based on clinical signs, ultrasonography, and ABI values to confirm complete resolution.

Successful treatment was defined as complete cessation of flow into the false lumen with preservation of flow in the femoral artery.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (min-max), or number and frequency. The Student's t-test was used to compare categorical variables between the UGCR and UGTI groups, while the Fisher's exact test was used to compare continuous variables. A *p* value of <0.05 was considered statistically significant.

RESULTS

Of a total of 65 patients included in the study, 29 underwent UGTI and 36 underwent UGCR. There was no significant difference in the age, gender, femoral catheterization procedures, aneurysm size, and artery of origin between the two groups. Anticoagulant medications were not modified in any groups: three patients in the UGTI group and four patients in the UGCR group were on anticoagulant treatment. There

Table 1. Demographic and clinical characteristics of patients (n=65)

Variable	UGTI (n=29)			UGCR (n=36)		
	n	Mean	Range	n	Mean	Range
Age (year)		54	26-81		44	32-65
Gender						
Male	15			21		
Female	14			15		
Anticoagulant treatment	3			4		
Hypertensive patients	19			8		
Femoral catheterization procedure						
Cardiac catheterization	20			22		
Peripheral angiography	6			10		
Renal dialysis catheterization	3			4		
Aneurysm size (cm)		4.3	2.5-8.4		4	2-10
Artery of origin						
Common femoral artery	16			19		
Superficial femoral artery	10			13		
Deep femoral artery	3			4		

UGTI: Ultrasound-guided thrombin injection; UGCR: Ultrasound-guided compression repair.

Table 2. Procedural outcomes of UGTI and UGCR (n=65)

Variable	UGTI (n=29)	UGC (n=36)	<i>p</i>
	n	n	
Success	29	29	
Failure	0	7	0.014

UGTI: Ultrasound-guided thrombin injection; UGCR: Ultrasound-guided compression repair.

were 19 and eight hypertensive patients in the UGTI group and UGCR group, respectively. The femoral catheterization procedures did not significantly differ between the groups (UGTI vs. UGCR), cardiac catheterization (n=20 vs. 22), peripheral angiography (n=6 vs. 10), and femoral pseudoaneurysms resulting from iatrogenic injury during dialysis catheter insertion (n=3 vs. 4). The mean aneurysm sizes for UGTI and UGCR groups were 4.3 and 4 cm, respectively. Most of the pseudoaneurysms arose from the common femoral artery (Table 1).

As shown in Table 2, thrombin injections were successful (n=29, 100%) in all designated patients from the initial session (10-40 s). The mean dose of thrombin injections was 1,000 U (range, 500 to 1,500 U). None of them needed surgery, developed complications, or required analgesia or sedation. On the contrary, the success rate with the UGCR was 80.6% (n=29), and 58.6% (n=17) of them required more than one session. In addition, UGCR required more time (30 to 60 min) to completely obliterate the pseudoaneurysms. Some patients (n=7, 19.4%) also required surgery due to the UGCR failure.

No complications or recurrence were observed in any patients receiving UGCR. Further, compression therapy failed in all patients on anticoagulant therapy (n=4, p=0.001), and aneurysm size >6 cm also resulted in failure of the compression therapy (n=3, p<0.005). Of eight hypertensive patients in the UGCR group, treatment failed in five of them (p<0.003). These factors did not affect the success of thrombin injections (Table 3).

DISCUSSION

In the present study, we examined the effectiveness of UGTI versus UGCR in the treatment of post-catheterization femoral pseudoaneurysms. The results of the study indicated that UGTI was more effective compared to UGCR for the treatment of iatrogenic femoral pseudoaneurysms. We achieved successful results in all patients who received thrombin injections, regardless of anticoagulant treatment used, hypertension status, and aneurysm size. Furthermore, our high success rate can be attributed to a meticulous selection of the patients and careful monitoring of multiple factors during and after the procedure.

Iatrogenic femoral pseudoaneurysms occur twice as frequently after therapeutic interventions as it does after diagnostic interventions.^[6] Although spontaneous resolution of the femoral pseudoaneurysms has been reported in the literature,^[21] a spontaneous rupture rate of 24% within 72 h has been reported, as well.^[22] Unfortunately, it is difficult to predict which aneurysm should be observed or which required an intervention.^[23]

Thrombin is a major clotting factor that catalyzes the conversion of fibrinogen to fibrin and activates procoagulant factors 5, 8, 11, and 13. However, thrombin may result in thromboembolic complications.^[24] Allergic reactions are other concerns of UGTI, and can be seen only with bovine thrombin.^[25] In our study, we examined any history of allergy to thrombin prior to the procedure, and we were prepared to take actions, if any event took place. In addition, we were accurately able to visualize the tip of the needle during the insertion inside the cavity of the pseudoaneurysm. Also, injections were done very slowly at a rate of 0.1 to 0.3 mL/s to avoid downstream embolization.

Ultrasound-guided compression repair is still considered a successful treatment modality. However, patients who failed the compression therapy still need a surgical intervention. Compression distorts the anatomy of the pseudoaneurysm, preventing the adequate placement of the thrombin needle, which

Table 3. Factors affecting compression therapy outcomes in the UGCR group (n=36)

Variable	No.	Success	Failure	<i>p</i>
	n	n	n	
Anticoagulant treatment	4	0	4	0.001
Hypertension	8	3	5	0.003
Aneurysm size >6 cm	3	0	3	0.005

UGCR: Ultrasound-guided compression repair.

can put the patient at risk of thrombin escaping into the lumen of the femoral artery and occluding a healthy vessel, resulting in an ischemic limb.^[26] There are a few reports on the occlusion of a healthy artery after UGTI and were successfully treated by thrombolysis, thrombectomy, or bypass without enduring damage.^[14,24,27]

Pain is one of the major disadvantages of UGCR and, despite adequate analgesia, pain may persist. Langella et al.^[11] reported that they abandoned UGCR procedure in three patients due to pain. On the contrary, thrombin injections were painless except for a slight discomfort due to skin puncture. In the light of this fact, no analgesia was required. The mean compression time in our study was 45 min, which is relatively short than earlier publications.^[10] Time efficiency is a very significant advantage of thrombin injections. Compression therapy failed in all patients on anticoagulant treatment, consistent with previous publications.^[10,28-30]

The size of ≥ 6 cm of femoral pseudoaneurysm was found to be a factor determining the success of UGCR in our study. This finding is consistent with that of Dean et al.^[31] However, this is an area of controversy, since some authors have advocated that the pseudoaneurysm volume does not affect the compression outcome. However, most of the pseudoaneurysms in previous studies were < 4 cm in size, which may have affected their conclusions.^[10,32] In our study, we observed no complication or recurrence after both treatments. Conceivably, time efficiency, technical ease, patient comfort, and excellent results of thrombin injections considerably made it superior to compression therapy.

Nonetheless, this study has some limitations. First limitation is our small sample size. Another limitation is the retrospective study design. However, our results are consistent with earlier studies.^[13,20] Of note, this was a single-center experience and, thus, uniformity in the technique and staff was a strong point of our study.

In conclusion, this study shows the superiority of UGTI over UGCR in the treatment of iatrogenic femoral pseudoaneurysms. As thrombin injection treatment is simple, safe, convenient for the patient, and applicable in most cases, it has a high rate of success. Furthermore, UGTI is more effective than UGCR in patients on anticoagulant treatment, hypertensive patients, or those with large aneurysms (> 6 cm). Ultrasound-guided thrombin injection has become the procedure of choice in our practice with a word of caution. However, as the number of published cases treated by UGTI has been on the rise, larger-

scale sample, prospective, randomized, or design with reproduction of published studies are warranted to better evaluate the effectiveness and risk of thrombin injections.

Declaration of conflicting interests

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