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Evaluation of the Use of Ultrasound Guided Compression versus Ultrasound Guided Thrombin Injection for Post-Catheterization Femoral Pseudoaneurysms

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ABSTRACT

Background: After femoral artery catheterization, pseudoaneurysms are linked with considerable morbidity. Recently, percutaneous ultrasound-guided thrombin injection has become a possible first-line therapy.

Objectives: This study aimed to compare the efficacy and safety of ultrasound-guided compression repair vs ultrasound-guided thrombin injection in treating post-catheterization femoral artery pseudoaneurysms were compared.

Methods: One hundred patients with femoral pseudoaneurysms were randomised to receive either an ultrasound-guided compression or ultrasound-guided thrombin injection in this interventional study.

Results: Success rates for ultrasound-guided thrombin injection were one hundred percent, whereas those for ultrasound-guided compression repair were only eighty percent, perhaps because of anticoagulant medication, hypertension, and aneurysms greater than six centimeters in size. Nevertheless, neither of these elements had an impact on how well thrombin injections worked.

Conclusion: The success rate of ultrasound-guided thrombin administration is quite high and is simple procedure that were accepted and tolerated well by the patients.

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

INTRODUCTION

False aneurysms, or pseudoaneurysms, are areas of constrained pulsatile blood flow that have tissues around them and all three vessel layer disruptions (intima, media, and adventitia) [(1)].

The main entry point in the vast majority of therapeutic and diagnostic endovascular procedures is the femoral artery (cardiac, aortic, and peripheral). In the literature, the incidence of femoral artery fake aneurysms ranges considerably from 0.05% to 8.0% [(2)]. Iatrogenic femoral artery pseudoaneurysms (FAP) can arise if the arteriotomy is not sealed properly following endovascular procedures or if the clot obstructing the arteriotomy gets moved during the time after the procedure. The lumen of the artery at the base of the neck is being communicated with, and blood is leaking out into the surrounding tissue. The only parts of the pseudoaneurysm's wall are the squeezed thrombus and the soft tissue around it [(3)].

FAP may result in skin necrosis, infection, critical limb ischemia, compressive neuropathy, venous thrombosis, or even rupture [(4)]. If a follow-up duplex scan is performed after two months, small pseudoaneurysms that are asymptomatic can be treated without surgery if they aren't visible. Large (> 2 cm), symptomatic, or difficult FAPs, on the other hand, need to be treated [(5)].

The most often utilised procedures are thrombin injection, surgical repair, and ultrasound-guided compression (UGC) [(6)]. In 1991, it was written that femoral artery pseudoaneurysms could be fixed with ultrasound-guided compression repair (UGCR) [(7)]. In many cases, doctors have found that this method can achieve the same results as surgery without causing as much damage. Compression should be avoided in cases of skin ischemia, infection, pressure sensations on the neighbouring neurovascular systems, and intense pain. The literature documented success rates for UGCR ranging from 54% to 100%, and it is unclear what factors contribute to UGCR success [(8)].

In order to treat iatrogenic pseudoaneurysms, in 1997, **Liau and his colleagues** [(9)] came up with ultrasound-guided percutaneous thrombin injection (UGTI). The UGTI had success rates between 91% and 100%, with a complication rate of only 1.3% and an embolic event rate of only 0.5% [(10)]. High success rates, rapidity of surgery, good patient tolerance, and independence of operation success from anticoagulation are only some of the benefits of UGTI despite the hazards involved [(11)].

The goal of this study was to compare how well ultrasound-guided compression repair and ultrasound-guided thrombin injection work to treat femoral artery pseudoaneurysms after catheterization.

MATERIAL AND METHODS

At the brand-new Damietta Hospital, this retrospective clinical research was carried out. There were 100 patients in our research population. They were identified as post-catheterization femoral pseudoaneurysms by Doppler ultrasonography and treated by compression or thrombin injection during the same scanning session. They were above the age of 18. Patients who required surgical repair or who had a history of thrombin hypersensitivity were not included in the research. Patients were randomly assigned to either a UGTI group or a UGCR group.

The following data about each patient were collected: Personal history, pain characters, murmur, or edema, as well as the results of a physical examination were clinical indications of post-catheterization femoral pseudoaneurysms.

All patients' ultrasound pictures, exact locations, aneurysmal diameters, and peripheral pulse status were

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documented before and after the procedure, at 24 hours, on Days 7 and 30 following the procedure, as well as immediately after the therapy.

INTERVENTIONS

UGCR:

Methodology created by **Fellmeth *et al.*** [7]. After administering 1% lidocaine solution as a local anaesthetic, using the ultrasound transducer, a downward force was applied by hand while being guided by ultrasound all the time. By applying compression to the aneurysmal neck for 10–15 minutes, blood flow was stopped in the pseudoaneurysm sac while remaining unaffected in the femoral artery. If blood was still flowing through the pseudoaneurysm after 15 minutes, during the next five to ten minutes, the pressure was slowly lowered. This process was done at least three times during each therapy session. Exactly the same steps were taken the next day if the compression therapy was just not working, up to a maximum of three times. If medical intervention did not improve the patient's condition, or if UGCR was deemed not an option, surgery was suggested. To maximise the benefits of compression therapy, the bandage should be worn continuously for at least 12 hours.

UGTI: The procedure was carried out utilising **Kang *et al.*** [12] approach. In a nutshell, real-time ultrasound guidance was used to introduce a 20-gauge needle into the pseudoaneurysm's lumen while maintaining sterility. Quick blood aspiration and reinjection produced the recognisable colour Doppler pictures, which proved that the needle tip was in the right place. The needle's point was pointed away from the pseudoaneurysm's neck. To achieve a concentration of 1,000 units per milliliter, bovine thrombin solution (King Pharmaceuticals, Thrombin-JMI®, Inc., and Bristol, TN, USA) was diluted in 0.9% sterile saline. The pseudoaneurysm's blood flow was then halted by gradually administering diluted thrombin. If the treatment didn't work, surgery could be done up to three more times. To find out if the treatment worked, the ultrasound was done again to check if the femoral vessels were open. Before and after thrombin injection, we also checked the peripheral pulses on the same side. In both cases, the adjacent arteries and veins were scanned following the surgery to confirm their patency and to compare the results to the pre-procedure baseline. The patient was maintained supine with bed rest for 30 minutes following successful thrombosis. After a week, a follow-up ultrasound was performed to check for recurrence.

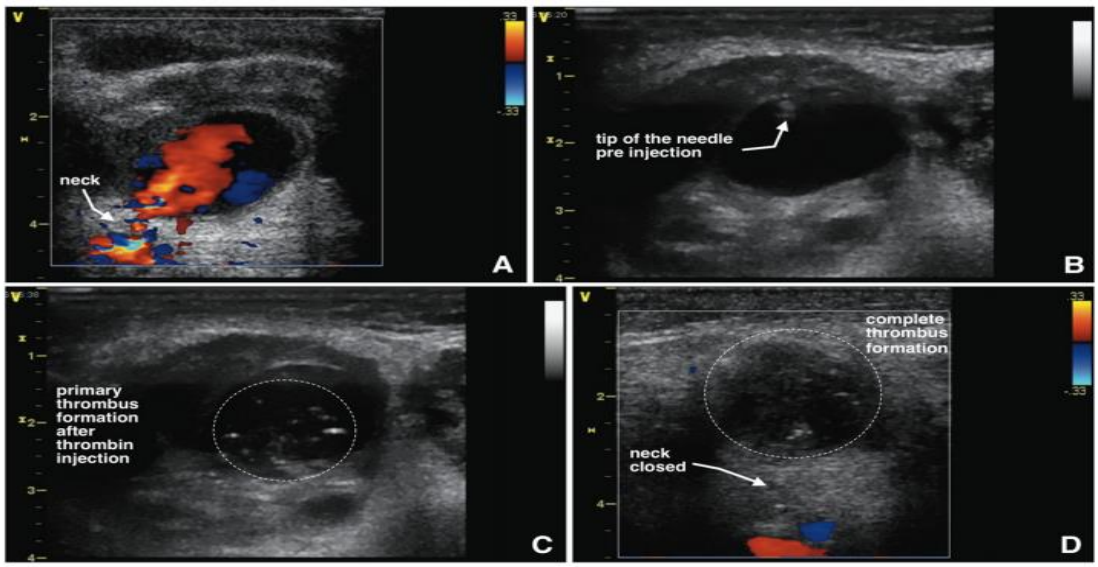

Figure (1): 69-year-old man underwent percutaneous transluminal coronary angioplasty and stent placement and developed a straightforward pseudoaneurysm. A, A colour flow ultrasonography shows a typical back-and-forth blood flow pattern. B: A greyscale ultrasonography of the pseudoaneurysm lumen with the 0.90 x 40 mm needle tip at its centre. C, A sonogram in grayscale showing the establishment of a main thrombus five seconds after thrombin injection. D, A colour flow ultrasonography taken 12 hours after an ultrasound-guided thrombin injection showed full thrombus development and a closed neck.

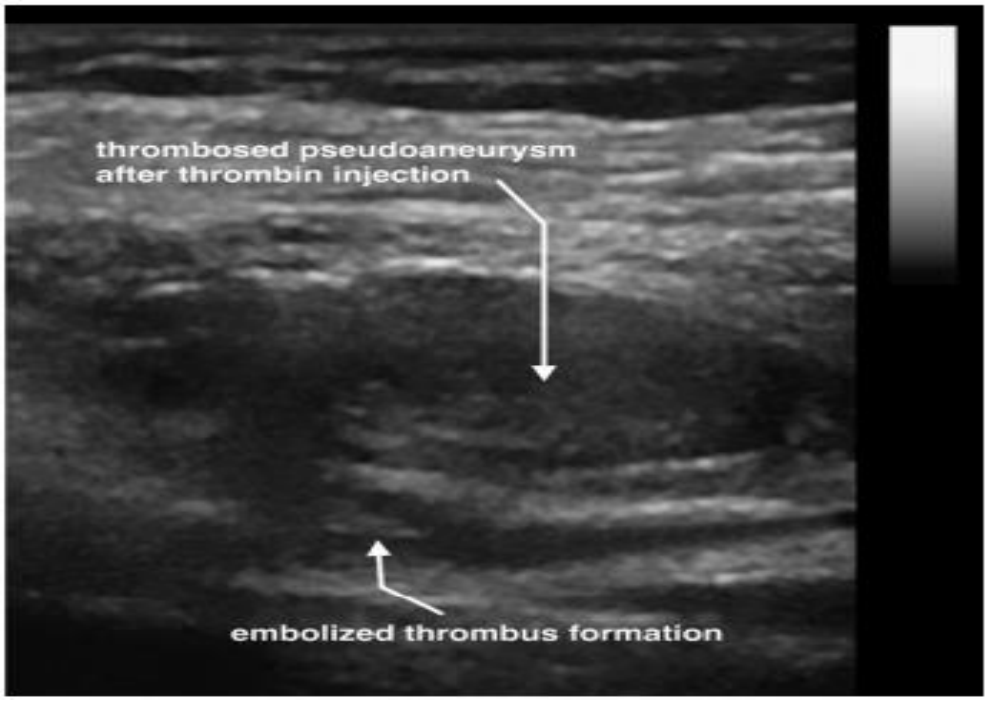

Figure (2): Following thrombin injection, a longitudinal grey-scale ultrasonography can be seen indicating the successfully thrombosed lobe of the pseudoaneurysm and an unintentional thrombus development (11 × 5 mm) in the common femoral artery (white arrow). In the 24-hour follow-up after therapy with intravenous heparin for 24 hours and an activated thromboplastin time of 70–80 s, thrombus development was not seen.

Ethical Approval:

The study was approved by Al-Azhar University Ethics Board. All participants supplied written informed consent.

This study was done in compliance with the Declaration of Helsinki, which is the ethical guidelines for medical research involving people from the World Medical Association.

Statistical analysis

Data were entered onto a computer and analysed using IBM's SPSS program version 20.0. (IBM Armonk, New York). Qualitative data were expressed in terms of numbers and percentages. The Kolmogorov-Smirnov test was used to check for distributional normality. Quantitative data were described by its range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR). Significant findings were judged at the 5% level.

The used tests were: Chi-square test to compare between different groups for categorical variables. Student t-test was used for quantitative variables that are normally spread, to compare between two studied groups.

This table showed that there was statistically insignificant difference between the studied groups according to demographic and clinical data (Table 1).

Table (1): Comparison between the studied groups as regard demographic and clinical data

	UGTI (n=50)		**UGCR (n=50)**		**p-value**
Age (years)	51.0 ± 10.96		48.98 ± 9.05		0.317
Gender	No.	%	No.	%	
Female	21	42.0	20	40.0	0.839
Male	29	58.0	30	60.0	
Hypertensive	11	22.0	12	24.0	0.812
Anticoagulant treatment	4	8.0	9	18.0	0.137
Femoral catheterization procedure					
Cardiac catheterization	36	72.0	37	74.0	0.386
Peripheral angiography	11	22.0	7	14.0	
Peripheral angiography	3	6.0	6	12.0	
Aneurysm size (cm)	4.3 ± 1.73		4.15 ± 1.61		0.659
Femoral catheterization procedure					
Common femoral artery	28	56.0	27	54.0	0.800
Superficial femoral artery	18	36.0	17	34.0	
Superficial femoral artery	4	8.0	6	12.0	

t: Student t-test **χ^2: Chi-square test** p: p the value of a comparison between several categories *: Statistically significant at p less than or equal to 0.05

Table (2) and figure (3) showed that there was statistically significant difference between the studied groups as regards outcome.

Table (2): Comparison between the studied groups as regard outcome

	UGTI (n=50)		UGCR (n=50)		p-value
	No.	%	No.	%	
Failure	0	0.0	10	20.0	0.001*
Success	50	100.0	40	80.0	

χ^2: Chi-square test p: p the value of a comparison between several categories *: Statistically significant at p less than or equal to 0.05

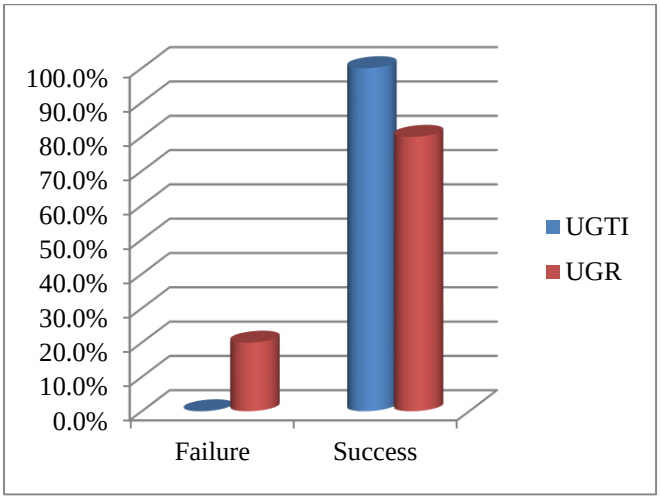

Fig (3): Comparison between the studied groups as regard outcome

Table (3) and figure (4) showed that there was statistically significant relation between the failure and hypertension, anticoagulant treatment and aneurysm size > 6.

Table (3): Factors that affect the results of compression therapy in the UGC group (n=50)

	Total number	UGC		p-value
		Success	Failure	
Hypertensive	12	6	6	0.003*
Anticoagulant treatment	9	0	9	<0.001*
Aneurysm size >6	7	0	7	<0.001*

χ^2: Chi-square test p: p the value of a comparison between several categories *: Statistically significant at p less than or equal to 0.05

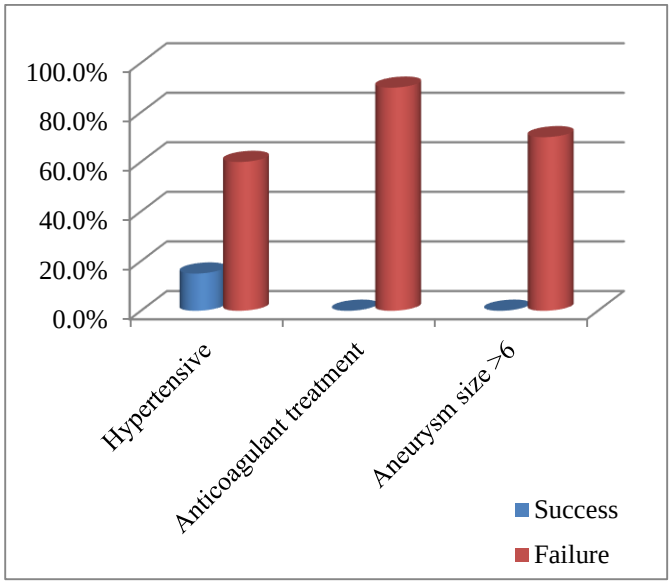

Fig (4): Compression treatment results in the ungrafted collagen (UGC) group: influencing factors

DISCUSSION

The most often performed technique for percutaneous arterial access has by far been common femoral artery catheterization. It frequently serves as a tool for therapeutic and diagnostic procedures [(13)]. Iatrogenic femoral artery pseudoaneurysms can occur if the arteriotomy is just not properly sealed after endovascular procedures or the clot that is blocking the arteriotomy is broken up while it is healing. The lumen of the artery at the base of the neck is being communicated with, and blood is leaking out into the surrounding tissue. In a pseudoaneurysm, just the surrounding soft tissue and compressed thrombus make up the wall. Femoral pseudoaneurysms are a complication that can arise in.5% to 1% of diagnostic procedures and 3.2% to 7.7% of therapeutic procedures [(14)].

At first, patients preferred ultrasound-guided compression repair (UGCR), but in the end, surgery was the best way to treat them. Compression can be effective for pseudoaneurysms, with success rates between 27 and 100%. However, it has a number of downsides, such as local pain and discomfort, the need for sedation and painkillers, and a high recurrence rate, especially in people who are taking antiplatelet anticoagulant, or both medications. Compression therapy also needs an extra day in the hospital [(6)].

Percutaneous thrombin injection with feeder vessel blockage is an alternative to surgery and UGCR for the treatment of femoral pseudoaneurysms. UGTI has no restrictions on compression repair and is secure and efficient. This study was swiftly followed by several publications with identical content. There is a relatively low complication rate associated with this procedure, and its success rate ranges from 69 percent to 100 percent [(15)].

The goal of this study was to compare how well ultrasound-guided compression repair works compared

to ultrasound-guided thrombin injection for treating femoral artery pseudoaneurysms after catheterization.

Regarding demographic and clinical data, we discovered no statistically significant difference between the analysed groups in the current study (Age and gender). **Kurzawski *et al.*** [16] discovered that of the 65 patients in their study, 29 had UGTI and 36 had UGCR. This is the same as what we found. There were no big differences between the groups in terms of age, gender, number of femoral catheterizations, size of aneurysms, or the artery from which the aneurysm started. Even though three UGTI patients and four UGCR patients were taking anticoagulant drugs, nothing was changed about their treatment plans. There were 19 people with high blood pressure in the UGTI group and 8 people with high blood pressure in the UGCR group. Similar numbers of femoral catheterizations, cardiac catheterizations, peripheral angiograms, and femoral pseudoaneurysms caused by iatrogenic injury during dialysis catheter placement that were done in both groups (UGTI and UGCR) (3 vs. 4). The average size of an aneurysm in people with UGTI was 4.3 cm, while an aneurysm in people with UGCR was 4 cm. The common femoral artery is where most of these fake aneurysms started.

According to **Sachs *et al.*** [17], 992 patients were exposed to UGC and/or UGTI. There were 206 subjects submitted to UGTI and 786 underwent UGC. Additionally, 112 participants from the earlier group moved to UGTI following failing UCG, making the final number of subjects underwent UGTI to become 318. According to **Hegab *et al.*** [18] bovine thrombin injections were effective in 66 out of the 70 patients (94%). In the majority of patients, the pseudoaneurysms thrombosed immediately. But 26 individuals (or 37% of the patients) needed 1 injections to completely obliterate the pseudoaneurysm cavity. On the initial injection, the pseudoaneurysm cavity was eliminated in three individuals. Nevertheless, the pseudoaneurysm was once again evident on an ultrasound the next day.

In the current investigation, we discovered that there was a statistically significant difference in the results between the analysed groups (Failure and success). According to **Bellmunt *et al.*** [19] thrombin was statistically significant with a P value of 0.014, and successfully injections (n=29, 100%) in all of the patients from the first time they came in. This is what we found based on what we discovered (10-40 s). Normal injections of thrombin were given in doses of 1,000 U. (range between 500 to 1,500 U). No one required medical intervention like surgery or anesthetics/painkillers. In contrast, the UGCR was successful in 80.6% of cases (n=29), with 58.6% of those cases requiring more than one session (n=17). Also, UGCR needed more time (between thirty and sixty minutes) to get rid of the pseudoaneurysms. Because the UGCR didn't work for some people (n=7, 19.4%), they had to have surgery on top of it. Results from a study by **Kamierski *et al.*** [20] showed that Ultrasound guided thrombin injection was effective in the majority of patients (94%), including 139 (95.9%) with single-chamber and 36 (87.8%) with complex pseudoaneurysms ($p = 0.07$). However, 11 patients (6 with simple and 5 with complex pseudoaneurysms) required repeat injections. The success percentage for simple pseudoaneurysms after a second try was 98.6% (143 patients), while the success rate for complex pseudoaneurysms was 97.6% (40 patients).

In the present investigation, we discovered a statistically significant relationship between failure, hypertension, anticoagulant therapy, and aneurysms larger than 6 mm (hypertensive, anticoagulant therapy, aneurysm larger than 6). **Jiang *et al.*** [21] also reported similar findings, stating that no patients having UGCR experienced any problems or recurrences. All four patients on anticoagulant medication failed compression therapy (n=4, p=0.001), and aneurysms bigger than 6 cm also contributed to this failure. (n=3, $p < 0.005$). Five of the eight hypertensive patients in the UGCR group did not respond to therapy ($p < 0.003$). The effectiveness of thrombin injections was unaffected by these variables. A study by **Heis *et al.*** [22] looked at data from 505 patients who had UGC and 292 patients who had UGTI. The rates of complications were 0.79 percent (4/505) and 0.68% (2/292), respectively. The patients in the UGC group had two cases of DVT and two cases of skin necrosis. In the UGTI group, one person had a peripheral embolism and another person had skin necrosis. The complication rate did not differ across groups in a statistically meaningful way (OR 1.77, 95% CI 0.40e7.88, I2 ¼ 0%). According to **Yang *et al.*** [23] a considerable (3.6%) complication rate associated with compression cannot be disregarded. During compression, it is possible to have unfavourable responses such as the new beginning of atrial fibrillation, angina, and vasovagal reactions in addition to local consequences such pseudoaneurysm enlargement or rupture, DVT, etc.

CONCLUSION

The success rate of ultrasound-guided thrombin injection was very high, and it is a simple procedure that patients accept and do well with. In individuals with hypertension, big aneurysms, and those taking anticoagulants, it is more successful than compression treatment. When treating simple femoral pseudoaneurysms, ultrasound-guided thrombin injection should be the primary option since it has greater thrombosis and recurrence-free rates than ultrasound-guided compression therapy.

DECLARATIONS

Consent for Publication: I confirm that all authors have agreed to submit the manuscript.

Availability of data and material: Available

Competing interests: None

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Conflicts of Interest: The authors stated that they had no conflicts of interest.

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