Local ultrasound-guided thrombin injection for treatment of post-catheterization femoral artery pseudoaneurysm — a short term follow-up

Zamykanie jatrogennych tętniaków rzekomych tętnicy udowej metodą przezskórnego podania trombiny pod kontrolą ultrasonograficzną – wyniki obserwacji krótkoterminowych

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Abstract

Background: Femoral artery false aneurysms are a relatively common complication after cardiac catheterization. The majority of small pseudoaneurysms undergo spontaneous occlusion but larger ones usually require treatment.

Aim: To prospectively evaluate the efficacy and safety of percutaneous ultrasound – guided thrombin injection (UGTI) in the management of femoral artery pseudoaneurysms.

Methods: One hundred and eighty six consecutive patients (95 female, age 64.8 \pm 11.3 years) with postcatheterization femoral artery pseudoaneurysm were treated with ultrasound-guided local thrombin injection. At the time of diagnosis 39 (21%) patients were receiving anticoagulation therapy, 103 (55.4%) antiplatelet therapy only, and 44 (23.6%) both types of therapy.

Results: A single-chamber pseudoaneurysm was diagnosed in 145 (78%) patients and complex pseudoaneurysm in 41 (22%). A total number of 198 thrombin injection was performed: 1.04 injection per patient with single-chamber pseudoaneurysm and 1.12 injections per patient with complex pseudoaneurym. The mean dose of injected bovine thrombin was 620 IU. UGTI was primarily successful in 175 of 186 patients (94%): in 139 (95.9%) patients with single-chamber and in 36 (87.8%) patients with complex pseudoaneurysms (p = 0.07). Including a second attempt the success rate was 143 (98.6%) patients for single-chamber and 40 (97.6%) patients for complex pseudoaneurysm (p = 0.52). In addition, one single-chamber pseudoaneurysm was obliterated after a third injection. Overall, the treated pseudoaneurysms were completely occluded in 184 (98.9%) patients. Final success rate did not differ between patients with single-chamber and complex pseudoaneurysms (99.3 vs. 97.6%, p = 0.39, respectively). Two major complications occurred: a symptomatic peripheral thrombosis and an episode of loss of consciousness.

Conclusions: Ultrasound guided occlusion of iatrogenic femoral artery pseudoaneurysms using thrombin injection is an efficacious and safe procedure.

Key words: iatrogenic femoral pseudoaneurysm, thrombin, false aneurysm, vascular access complications

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Streszczenie

Wstęp: Tętniaki rzekome tętnicy udowej są jednym z najczęstszych powikłań po zabiegach przezskórnych. Większość małych tętniaków rzekomych ulega samoistnemu wykrzepieniu, ale duże tętniaki wymagają leczenia.

Cel: Prospektywna ocena skuteczności i bezpieczeństwa zamykania tętniaków rzekomych tętnicy udowej poprzez podanie do ich światła trombiny pod kontrolą ultrasonograficzną.

Metody: Stu osiemdziesięciu sześciu kolejnych pacjentów (95 kobiet, średni wiek 64,8 ± 11,3 roku) z jatrogennymi tętniakami rzekomymi tętnicy udowej poddano zabiegowi obliteracji tętniaka poprzez podanie do jego jamy trombiny po kontrolą ultrasonograficzną. W chwili diagnozy tętniaka 39 (21%) pacjentów otrzymywało leczenie przeciwkrzepliwe, 103 (55,4%) przeciwpłytkowe, a 44 (23,6%) oba rodzaje leków.

Wyniki: Tętniaki rzekome jednojamowe wystąpiły u 145 (78%) chorych, a tętniaki wielojamowe u 41 (22%). Wykonano 198 iniekcji trombiny: średnio 1,04 iniekcji u jednego pacjenta z tętniakiem rzekomym jednojamowym i 1,12 iniekcji u pacjenta z tętniakiem wielojamowym. Średnia jednorazowa dawka podanej trombiny wyniosła 620 jednostek. Jednorazowe podanie trombiny było skuteczne u 175 spośród 186 pacjentów (94%): u 139 (95,9%) osób z tętniakiem jednojamowym i 36 (87,8%) osób z tętniakiem wielojamowym (p = 0,07). Po drugiej próbie uzyskano zamknięcie tętniaka u 143 (98,6%) pacjentów z tętniakiem jednojamowym i 40 (97,6%) pacjentów z tętniakiem wielojamowym (p = 0,52). Po trzecim podaniu trombiny uzyskano wykrzepienie kolejnego tętniaka jednojamowego. W sumie całkowite wykrzepienie tętniaka uzyskano u 184 (98,9%) pacjentów. Nie obserwowano różnic w ostatecznej skuteczności zabiegu między pacjentami z tętniakami jedno- i wielojamowymi (odpowiednio 99,3 vs 97,6%, p = 0,39). W całej grupie wstąpiły dwa poważne powikłania: objawowa zakrzepica tętnicy obwodowej oraz krótkotrwały incydent utraty przytomności. W obu przypadkach objawy ustąpiły całkowicie samoistnie.

Wnioski: Leczenie jatrogennych tętniaków rzekomych poprzez podawanie do ich jamy pod kontrolą ultrasonograficzną trombiny jest procedurą skuteczną i bezpieczną.

Słowa kluczowe: jatrogenny tętniak rzekomy, trombina, powikłania dostępu naczyniowego

Introduction

The number of cardiac catheterization procedures has been increasing continuously over the past decade [1]. Vascular access complications may be a major cause of morbidity and longer hospital stay in patients undergoing arterial puncture [2]. The most common of these are false aneurysms [3]. They may occur at any site used for arterial access, but usually are associated with femoral artery, most frequently used for arterial catheterization. Until recently, the treatment of this iatrogenic complication has been conservative, surgical or with prolonged compression using ultrasound transducer [2]. Surgical repair is effective, but often problematic in patients requiring ongoing anticoagulation or intensive antiplatelet therapy. Ultrasound-guided compression is painful for the patient, uncomfortable for the person performing the procedure and time consuming. The efficacy is also worse than that of surgery [4, 5]. Over the last several years, duplex--ultrasound topical thrombin injection (UGTI) into the femoral artery pseudoaneurysm (FAP) cavity has become increasingly popular and accepted [6]. Most centers using this technique routinely report excellent success and low complication rates [6-9]. However, there is some controversy with respect to patients having large, multichamber (complex) FAP, where optimal closure technique is still a matter of discussion. There is also little data on long-term efficacy of the procedure.

The aim of the study was to assess prospectively the feasibility, safety and efficacy of treating FAP with local UGTI in patients receiving antiplatelet or anticoagulation therapy and to compare the success rate of the procedure in patients with single-chamber (simple) and complex femoral pseudoaneurysms.

Patients and methods

From February 2003 to November 2007, 186 consecutive patients (95 women, 91 men, age 64.8 \pm 11.3) treated with local ultrasound-guided thrombin injection were enrolled into the study and followed prospectively. Clinical and demographic characteristics of the studied patients are presented in table 1. During this time period a total of ca. 30 000 diagnostic angiographies, percutaneous coronary interventions and non-coronary interventions requiring arterial vascular access were performed at our center. Patients who underwent radiofrequency catheter ablations were not included in this analysis. Thus the incidence of pseudoaneurysm formation treated with UGTI was around 0.6%. The puncture of femoral artery was performed using 5 to 6 F sheath size for diagnostic and 6 to 8 F for interventional procedures.

Our routine post-procedure heamostasis protocol is manual compression for at least 10 min after vascular sheath removal and compression dressing for further 4 to 12 h.

Next day all patients were examined by the physician for clinical signs of the presence of pseudoaneurysm. In cases of pseudoaneurysm suspicion (pain, large hematoma, pulsatile mass, bruit in the groin) ultrasound Doppler examination (6.0 MHz transducer Vivid I, GE or 5-12 MHz transducer HDI 5000, ATL/Philips) was performed to establish the diagnosis. The size and number of pseudoaneurysm chambers were noted. Patients with small (< 2 cm), single-chamber pseudoaneurysms not receiving chronic anticoagulation were not routinely referred for thrombin injection and were not analyzed.

Bovine thrombin (400 IU, Biomed, Poland) was reconstituted in 2-4 ml of normal saline and injected slowly into the pseudoaneurym chamber under continuous ultrasound guidance (fig. 1-3). Under most circumstances, a 4 cm, 21-gauge (0.8 mm) needle was used for thrombin injection. In selected patients (e.g. obesity) with FAP that were deep a spinal needle was used. Tip of the needle had to be well visualized and positioned inside the cavity, away from the FAP neck (fig. 4). In case of complex false aneurysms, an attempt was made to induce thrombosis in the chamber most proximal to the neck (fig. 5). Injections were continued over 2 to 5 s until pseudoaneurysm cavity thrombosed completely. In selected cases thrombin was injected directly into the pseudoaneurysm neck by an experienced operator trained previously in ultrasound guided procedures (K.K.) After the procedure patients were placed on bed rest 6-12 h. Ultrasound follow-up was performed one day later. If necessary, a second attempt was repeated according to the same protocol, usually on the next day after the first procedure, but no later than 7 days following the first injection.

The protocol was approved by Local Ethics Committee. Written informed consent was obtained from all patients.

Statistical analysis

Values are given as mean \pm standard deviations or percentages. Fisher exact test was used to compare the differences in procedural success rate between patient with simple and complex pseudoaneurysms. Statistical significance was considered at a p value of < 0.05. SAS Version 9 was used for all analyses.

Results

Among 186 analyzed patients 95 (51.1 %) underwent diagnostic angiography and 91 (48.9%) interventional procedures: 48 (25.8%) elective angioplasty, 36 (19.3%) angioplasty in the setting of acute coronary syndrome, and 7 (3.8%) percutaneous mitral commissurotomy. In 155 (83.4%) of all patients the sheath size was 6 F, in 22 (11.8%) 7 F, in 8 (4.3%) 8 F and in only one (0.5%) 5 F. A single-chamber pseudoaneurysm was diagnosed in

145 (78%) patients and complex pseudoaneurysm in 41 (22%). The average number of chambers was 1.54 (range, 1-4), the average length and width of the pseudoaneurysm neck was 16 mm and 1.5 mm respectively, and the average distance from the skin to the pseudoaneurysm neck was 40.2 mm. The mean maximal dimension of the pseudoaneurysm chamber was 37 mm (range 17-100 mm). At diagnosis 39 (21%) patients were receiving anticoagulation therapy, 103 (55.4%) antiplatelet

Table 1. Demographic and clinical characteristics
Tabela 1. Kliniczna i demograficzna charakterystyka pacjent

Age [years], mean ± SD	64.8 ± 11.3
Gender, n (%) female male	n = 186 (100) 95 (51) 91 (49)
Comorbidity, n (%) arterial hypertension diabetes mellitus coronary artery disease atrial fibrillation NYHA class ≥ III	174 (93.5) 39 (21) 138 (74.2) 70 (37.6) 46 (24.7)
BMI [kg/m ²], mean \pm SD	27.3 ± 5.6
Procedures, n (%) diagnostic angiography elective angioplasty angioplasty during acute coronary syndrome percuatneous mitral commissurotomy	n = 186 (100) 91 (48.9) 48 (25.8) 36 (19.3) 7 (3.8)
Sheath size, n (%) 5 F 6 F 7 F 8 F	n = 186 (100) 1 (0.5) 155 (83.4) 22 (11.8) 8 (4.3)
Treatment, n (%) anticoagulation only anticoagulation and aspirin anticoagulation and aspirin and clopidogrel aspirin aspirin and clopidogrel or ticlopidine aspirin and clopidogrel and Ilb/Illa inhibitor	$ n = 186 (100) \\ 39 (21) \\ 36 (19.4) \\ 8 (4.3) \\ 22 (11.8) \\ 67 (36) \\ 14 (7.5) $

therapy only, and 44 (23.6%) both types of therapy. Among patients on antiplatelet therapy (but without anticoagulation) 22 (11.8%) were treated with aspirin only and 81 (43.5%) with aspirin and clopidogrel or ticlopidine. In addition, all interventional procedures were performed under anticoagulation with weight adjusted intravenous heparin and 14 patients who undervent primary angioplasty received a Ilb/Illa glycoprotein inhibitor.

A total number of 198 thrombin injections was performed: 1.04 injection per patient with single-chamber pseudoaneurysm and 1.12 injections per patient with multi-chamber pseudoaneurysm.

The mean dose of injected thrombin was 620 IU (median 400 IU, range 200-1600 IU).

Ultrasound guided thrombin injection was primarily successful in 175 of all 186 patients (94%), in 139 (95.9%) patients with single-chamber and in 36 (87.8%) patients with complex pseudoaneurysms (p = 0.07) (tab. 2). Eleven patients (6 with simple and 5 with complex pseudoaneurysms) required repeated injection. After second attempt the success rate was 98.6% (143 patients) for single-chamber and 97.6% (40 patients) for complex pseudoaneurysms (p = 0.52) (tab. 2). One



Fig. 1. An example of closure of a single-chamber pseudoaneurysm – color flow reveals typical blood flow pattern in pseudoaneurysm chamber Ryc. 1. Przykład zamknięnia jednojamowego tętniaka rzekomego – w badaniu kolorowym doplerem widoczny napływ krwi do jamy tętniaka



Fig. 2. An example of closure of a single-chamber pseudoaneurysm – grey-scale view. Arrow shows the tip of the needle in center of pseudoanuerysm chamber Ryc. 2. Przykład zamknięnia jednojamowego tętniaka rzekomego – obrazowanie w skali szarości. Strzałką zanaczono widoczny koniec igły w jamie tętniaka rzekomego



Fig. 3. An example of closure of a single-chamber pseudoaneurysm – color flow reveals completely thrombosed pseudoaneurysm Ryc. 3. Przykład zamknięnia jednojamowego tętniaka rzekomego – w badaniu kolorowym doplerem widoczny brak napływu krwi do jamy tętniaka

patient with single-chamber pseudoaneurysm required a third injection to achieve treatment success. Third injection was not performed in any patients with complex pseudoaneurysms.

Overall complete procedural success was achieved in 184 (98.9%) patients. The final success rate did not differ between patients with simple and complex pseudoaneurysms (99.3 vs. 97.6%, p = 0.39, respectively) (tab. 2).

Two patients (one with single-chamber and one with complex pseudoaneurysm) were treated by surgical repair one day after first thrombin injection because of rapidly expanding pseudoaneurysms and hemodynamic instability. Both patients received anticoagulation and antiplatelet medications at the time of the procedure.

A symptomatic peripheral thrombosis occurred in one obese patient, during a second attempt. However, she required neither surgical nor thrombolytic treatment and symptoms resolved spontaneously. There were no anaphylactic reactions noted, but one woman suffered transient loss of consciousness with marked bradycardia lasting less than a minute. Overall the rate of severe complications was 1%. In addition, 17 patients experienced transient paresthesiae or a mild burning sensation lasting up to 30 s after injection, of no clinical relevance. There were no other complications noted.

Discussion

In the current study, we showed that ultrasound-guided bovine thrombin injection is a practical and safe method for treatment of postcatheterization simple and complex femoral pseudoanuerysms.

Femoral artery pseudoaneurysm is one of the most frequent complications of using femoral artery for vascular access. It forms when an arterial puncture site does not seal properly, allowing extravasation of arterial blood into the surrounding tissues [2]. The growing use of vascular procedures means that pseudoaneurysms remain a common problem in clinical practice [2]. In addition, greater number of procedures requiring larger vascular sheaths and increased proportion of patients treated with anticoagulants increase the risk of complications related

to arterial access. Reported incidence of femoral pseudoaneurysms varies from 0.3-7.7% depending on the screening method, either clinical assessment or systematic ultrasound examination [3, 10, 11]. Since the introduction of ultrasound, most sonographic studies have found a higher incidence of pseudoaneurysms compared



Fig. 4. The strategy of simple pseudoaneurysm closure *Ryc. 4.* Strategia zamykania tętniaków jednojamowych





Table 2. Results of ultrasound-guided thrombin injection

Tabela 2. Wyniki leczenia za pomocą podania trombiny pod kontrolą ultrasonograficzną

	All femoral pseudoaneurysms n = 186	Simple pseudoaneurysm n = 145	Complex pseudoaneurysms n = 41	р
Complete thrombosis after first injection, n (%)	175 (94)	139 (95.9)	36 (87.8)	0.07
Complete thrombosis after second injection, n (%)	183 (98.4)	143 (98.6)	40 (97.6)	0.52
Complete thrombosis after third injection, n (%)	184 (98.9)	144 (99.3)	NA	
Final success rate, n (%)	184 (98.9)	144 (99.3)	40 (97.6)	0.39

to clinical evaluation alone [3, 12]. Several patient- and procedure-related factors associated with the risk of pseudoaneurysm were described [2, 11, 13-15]. The most important of these were summarized in table 3.

Many small pseudoaneurysms (diameter < 1.5-2 cm) in patients who are not on chronic anticoagulation usually undergo spontaneous occlusion and may be treated conservatively [10]. On the other hand, this strategy sometimes requires prolonged hospitalization and repeated ultrasound examinations to determine pseudoaneurysm thrombosis. This approach may be expensive and many small FAP (especially in patients receiving anticoagulation) are treated even though they may undergo spontaneous closure with time [16]. In contrast, pseudoaneurysms larger than 1.8 cm usually do not thrombose without intervention [17].

An established nonoperative method for treating iatrogenic femoral pseudoaneurysms is prolonged compression with ultrasound probe [2]. The reported efficacy of this procedure is over 90% in patients who are not on anticoagulation therapy at the time of compression, but the success rate decreases to around 70% if anticoagulation therapy has been initiated or if largediameter sheaths have been used [18, 19]. Although the technique is safe and easy to learn, it has considerable limitations. The compression may be very painful, it may lead to vasovagal reactions and is often very time--consuming. [19]. In addition, the procedure requires operator's ability to maintain adequate pressure [12].

Until recently open surgical repair was the standard of care for femoral pseudoaneurysms [2]. Although it may be performed under local anesthesia with light intravenous sedation the complication rates still reach 20% and include wound infection, bleeding, lymphocele, perioperative myocardial infarction and even death [20]. However, rapidly expanding or infected pseudoaneurysms, distal or skin ischemia caused by local pressure and mass effect, neuropathy and failure of other treatment methods are still indications for surgical repair [2].

Percutaneous ultrasound-guided thrombin injection into the lumen of the pseudoaneurysm was first introduced in 1986 by Cope and Zeit [21]. Since then, it has became an alternative option and replaced surgery in many centers [14]. Thrombin (factor IIa) is a potent enzyme that converts

 Table 3. Risk factors for femoral pseudoaneurysm formation

 Tabela 3. Czynniki ryzyka powstania tętniaka rzekomego tętnicy udowej

Patient-related factors	Procedure-related factors
Arterial hypertension Anticoagulation Obesity Calcified arteries Hemodialysis Female gender Age of patient	Left groin puncture Large sheath size (≥ 6 F) Brief and improper manual compression Interventional procedure Simultaneous catheterization of vein and artery Puncture of the superior or deep femoral artery

fibrinogen to active fibrin. Fibrin contributes directly to thrombus formation. Bovine and human preparations are available. The bovine form is a foreign substance and its injection may induce allergic reactions, especially in patients with a history of previous exposure. In addition, there are some concerns about the transmission of bovine spongiform encephalopathy [2, 14]. Furthermore, patients who require more than one thrombin injection, are premedicated with intravenous steroids and antihistaminic drugs. Potentially, the use of human thrombin may help avoid the risk of allergic reactions but this preparation is much more expensive. On the other hand, Vazquez and colleagues did not find significant differences in efficiency and safety between patients treated with bovine or human thrombin [22].

Our results are in line with previous data that confirm the advantage of UGTI over prolonged compression [7, 8, 22, 23]. The overall success rate for the use of bovine thrombin was 98.9% (184/186). The final success rate did not differ between patients with single-chamber and complex pseudoaneurysms (99.3 vs. 97.6%, p = 0.39). However, at first attempt complete occlusion of pseudoaneurysm cavity occurred in 95.9% (139/145) of patients with simple and 87.8% (36/41) patients with multi-chamber pseudoaneurysms. Surgical repair was required in two patients treated with vitamin K antagonist and aspirin because of expanding pseudoaneurysms with significant blood loss.

In Krueger's series of 240 consecutive patients a single thrombin injection was sufficient to induce complete occlusion of 95.6% of the simple and 89% of the complex pseudoaneurysms. After repeated procedure the overall success rate was 99.6% [8]. In a recent study of 274 patients on antiplatelet or anticoagulation therapy, UGTI was primarily successful in 247 cases (97%) but simple and complex pseudoaneurysms were not analyzed separately [23].

Some controversies remain regarding the amount of thrombin necessary to achieve pseudoaneurysm thrombosis [13]. According to Krueger et al. an injection of 100 IU only may be sufficient to permanent obliterate pseudoaneurysm with the exception of complex pseudoaneurysms [13]. In our current practice we use the larger doses of thrombin i.e. at least a bolus containing 400 IU, as suggested in the literature previously [24].

In addition, there is no consensus on the management of complex pseudoaneurysms, more demanding technically. In the study of La Perna et al. the most superficial cavity was injected first [7]. In contrast, we agree with the experience of German groups, where the aim was to induce thrombosis in the chamber closest to the artery [8, 23].

In selected cases, when residual blood flow persisted, we injected thrombin very cautiously into the pseudoaneurysm neck. Although Hughes et al. proposed such strategy as a standard therapy, in our opinion direct injection into pseudoaneurysm neck may be very risky and should be avoided. It may be performed only by experienced physicians when the tip of the needle is well visualized.

In the present study we observed a relatively high proportion of patients after diagnostic procedures. It may be explained by a substantial number of patients with valvular heart disease, who underwent diagnostic angiography at our institution. These patients often have severe comorbidities, calcified arteries and require chronic anticoagulation.

Larger sheath size (≥ 6 F) increases the risk of femoral pseudoaneurysm formation [11]. It has been demonstrated that the incidence of FAP dropped with the use of 5 F catheters [26]. Indeed, since the 5 F sheath size has been routinely used for diagnostic angiography at our center the occurrence of femoral pseudoaneurysm is rare. However, patients who underwent catheterization after we switched to routine use of 5 F sheaths are not included into the present study and the exact incidence of pseudoaneurysm formation in this group has not been analyzed.

In the current study the complication rate after thrombin injection was low. However, we observed one symptomatic peripheral embolization and one severe case of bradycardia and loss of consciousness. Both events promptly resolved spontaneously. Distal embolization is the most feared complication and may occur in as many as 2% of all patients treated with UGTI [2, 27, 28]. In most cases symptoms improve spontaneously without surgical intervention, but sometimes endovascular or pharmacological treatment with heparin and/or tissue plasminogen activator are necessary [28]. Moreover, the escape of thrombin into the feeding artery from FAP may occur frequently but is usually clinically insignificant [2]. Very small thrombi resulting from this are probably resolved spontaneously by physiological blood fibrinolitic system.

Hypotension and bradycardia are documented potential reactions to exposure to bovine thrombin [7, 29]. In addition, anaphylaxis and generalized urticaria were reported in previous studies, but no allergic reactions occurred after thrombin injection in our group [30, 31].

Conclusions

Ultrasound guided thrombin obliteration of postcatheterization femoral artery pseudoaneurysms is an efficacious, well-tolerated and safe treatment method for this complication. It should be generally accepted and considered a first-line therapy, if the patient is not actively bleeding. Success appears to be relatively independent of anticoagulation status, pseudoaneurysm structure and size or operator experience. However, it must be noted, that there is a certain learning curve and especially the treatment of complex pseudoaneurysms should only be attempted after acquiring sufficient experience.

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