

Efficacy and safety of closing postcatheterisation pseudoaneurysms with ultrasound-guided thrombin injections using two approaches: bolus *versus* slow injection. A prospective randomised trial

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Abstract

Background: Thrombin injection is a widely accepted treatment of an iatrogenic arterial pseudoaneurysm. However, the optimal mode of injection and type of pseudoaneurysm amenable to this therapy have yet been established.

Aim: To compare efficacy and safety of two approaches to ultrasound-guided thrombin injections into a femoral artery pseudoaneurysm with or without long neck that developed as an iatrogenic complication of cardiac catheterisation.

Methods: Patients were randomised to thrombin administration in a bolus or slow injection. The length and width of aneurysm neck and blood flow velocity in the neck were measured with color Doppler ultrasonography before the closure procedure. Thrombin dose, time to thrombotic occlusion, blood oxygen saturation in a toe of the extremity with the pseudoaneurysm (a marker of silent microembolisation), and clinical signs of distal embolisation were recorded. Between 2006 and 2009, 73 consecutive patients (33 males; mean age 67.8 ± 11.9 years) with femoral pseudoaneurysms complicating cardiac catheterisation were randomised into two groups that were treated with thrombin bolus ($n = 40$) or slow injection ($n = 33$).

Results: The efficacy of aneurysm closure with either method was similarly high (100% vs 96.8%, NS, respectively) and did not depend on the length and width of the aneurysm neck. Independent risk factors for distal embolisation were: thrombin dose (OR 4.2; 95% CI 0.92–19.3), the length of aneurysm neck (OR 4.66; 95% CI 1.1–19.9), age above 80 years (OR 10.9; 95% CI 1.0–116.8), and bolus treatment (OR 7.6; 95% CI 1.3–44.9). We observed silent microembolisation phenomenon that was common (occurring in 38% of patients in the bolus group vs 33% of patients in the slow injection group) but in most cases asymptomatic.

Conclusions: Femoral pseudoaneurysm closure with a low dose of thrombin is a valid and beneficial treatment. Either method (bolus or slow injection) was similarly efficacious and safe even in the subgroup of patients with neckless aneurysms. We observed and confirmed silent microembolisation phenomenon during thrombin injections.

Key words: arterial pseudoaneurysm, thrombin injection, ultrasonographic guidance

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INTRODUCTION

Routine use of percutaneous interventional procedures in cardiology and invasive radiology is associated with an increased occurrence of iatrogenic pseudoaneurysms. The prevalence of iatrogenic pseudoaneurysms complicating artery cannulation is 1.2–7.7% [1, 2], and the rate of this diagnosis depends on the diagnostic method used. The major diagnostic tool is ultrasonography, with sensitivity of 94%, nearly seven-fold higher compared to the sensitivity of clinical evaluation, and specificity of 97% [1–14]. Factors predisposing to the occurrence of iatrogenic pseudoaneurysms include anticoagulation, antiplatelet treatment, technically inappropriate artery cannulation, simultaneous artery and vein cannulation, massive arterial calcification, dialysis therapy, obesity, hypertension, too short manual compression, technically inappropriate compression, use of large vascular sheaths (> 8 F), and female gender.

Literature data suggest that the efficacy of percutaneous pseudoaneurysm closure using thrombin injections is 93–100% and overall complication rate is 1–2% [5–14]. Most common complications include distal arterial embolisation, venous thrombosis, pulmonary embolism, injection site abscess, and allergic reactions [4].

In 2005–2006, we initiated in our department a novel approach to thrombin administration to iatrogenic pseudoaneurysms. Our experience suggested that administration of a thrombin dose in a single rapid injection (bolus) results in faster drug distribution and shortening of time necessary for thrombotic occlusion of the pseudoaneurysm, thus allowing thrombin dose reduction. We also suspected that rapid thrombin injections may be a promising method in the treatment of neckless pseudoaneurysms.

The goal of our study was to evaluate efficacy and safety of the treatment of iatrogenic pseudoaneurysm with thrombin administered in slow injection or rapid bolus in patients with the diagnosis of iatrogenic pseudoaneurysm with or without neck.

METHODS

Between January 2006 to December 2009, invasive procedures (coronary angiography, angioplasty, ablation) were performed in 7500 patients. From this population, our study included 73 consecutive patients (33 males, 40 females; mean age 67.8 ± 11.9 years) with the initial diagnosis of an iatrogenic pseudoaneurysm. The initial diagnosis was based on clinical evaluation and confirmed using colour Doppler ultrasonography with a 7–10 MHz linear array transducer and Sonos 5500 Philips and Vivid 4 GE machines. Ultrasonographic evaluation included the size and number of pseudoaneurysm sacs, width and length of the neck, and blood flow velocity within the neck. Patients were recruited for the study in two invasive cardiology units.

The inclusion criteria were as follows: 1) patients with symptomatic or asymptomatic, ultrasonographically confirmed iatrogenic pseudoaneurysms complicating femoral artery cannulation, 2) the presence of a iatrogenic pseudoaneurysm with the following characteristics: a) pseudoaneurysm diameter exceeding 1 cm; b) presence or absence of pseudoaneurysm neck; c) single or multiple pseudoaneurysm sacs, and 3) written patient consent for the participation in the study.

The exclusion criteria included the following: 1) lack of inclusion criteria, and 2) the presence of a iatrogenic pseudoaneurysm with the following characteristics: a) rapidly growing pseudoaneurysm; b) infected pseudoaneurysm.

Using simple randomisation, patients were assigned to a group treated in a standard fashion [4], i.e. slow thrombin injection into the pseudoaneurysm lumen ($n = 33$), or to a group treated in a novel fashion, i.e. with a rapid single injection (bolus) ($n = 40$).

Pseudoaneurysm closure procedure

The procedure of percutaneous closure of the pseudoaneurysm involved ultrasonographically guided administration of thrombin solution (single ampoule contained 400 IU of thrombin as dry liophilisate dissolved in 2 mL of 0.9% NaCl) into the pseudoaneurysm lumen. Prerequisites of drug administration included ultrasonographic visualisation of the needle tip inside the pseudoaneurysm lumen and visualisation of blood flow in the artery communicating with the pseudoaneurysm. The procedure was finished when 2-dimensional ultrasound showed stable thrombus filling the pseudoaneurysm lumen and no blood inflow from the artery to the pseudoaneurysm as seen in colour Doppler. Arterial blood oxygen saturation was continuously recorded before, during and after the procedure using Voyager Dolphin Medical pulse oximeter (sensitivity of SpO_2 measurement of 0.1%). The pulse oximeter was placed on the great toe of the lower extremity with the pseudoaneurysm. Reduction of arterial blood oxygen saturation below baseline values or signal disappearance were considered evidence of embolisation within microcirculation of the toe.

We recorded clinical signs of embolisation (hallux cyanosis, hallux pain, toe numbness or warmth) and signs of drug hypersensitivity (rash, urticaria), timing of thrombosis defined as the time from the onset of drug administration to cessation of blood inflow to the pseudoaneurysm, and the total drug dose. Peripheral arterial disease was diagnosed based on the medical history. Severity of atherosclerotic lesions and vessel patency were evaluated by ultrasonography. All percutaneous pseudoaneurysm closure procedures were performed by the same operator. Follow-up ultrasonography was performed at 24 hours, before hospital discharge, and at 3 months. All patients gave written informed consent for the study procedures. The study was approved by the Bioethics Committee at Medical Centre of Postgraduate Education.

Statistical methods

Study variables are presented as ranges, mean values and standard deviations, median values and quartiles, or frequency tables, as appropriate based on the variable distribution. The χ^2 test or exact Fisher test were used to compare percentages, and Student t test or non-parametric Kruskal-Wallis test were used to compare mean values. The effects of selected parameters on the embolisation rate were evaluated using multivariate logistic regression model. Stepwise elimination at the level of 0.1 for remaining in the model was used to select variables that were statistically significant at 5%. The effects of studied intervention (i.e. mode of thrombin administration) on the rate of distal embolisation were expressed as an odds ratio with 95% confidence interval, calculated using the Mantel-Haenschel method and stratified for selected variables. No variable reduction was used to account for possible unequal distribution of other parameters between the study groups and thus allowed evaluations of the effect of the mode of thrombin administration corrected for possible effects of other variables. Model fit was tested using the Hosmer-Lemeshow goodness-of-fit test.

RESULTS

Study group characteristics

At the time of percutaneous pseudoaneurysm closure procedures, patients in both groups were treated with aspirin, clopidogrel and oral anticoagulant (Table 1). Unfractionated heparin and glycoprotein IIb/IIIa receptor inhibitors were used only during invasive cardiac procedures. Atherosclerotic le-

sions were noted in lower extremity arteries but no significant stenoses were found.

Characteristics of iatrogenic pseudoaneurysms in the overall study group and in subgroups

Among the 73 patients included in the study, iatrogenic pseudoaneurysm communicated with the superficial femoral artery in 40 (54.7%) patients, the common femoral artery in 18 (24%) patients, the deep femoral artery in 9 (12.6%) patients, and in one (1.3%) patient dual communication was found with both superficial and deep femoral artery. A single pseudoaneurysm sac was found in 53 (72.6%) patients, two sacs in 16 (21.9%) patients, three sacs in 3 (4%) patients, and one patient had a complex pseudoaneurysm with 5 sacs. The pseudoaneurysm lumen was connected with the cannulated artery directly or through a neck with a length of up to 3 mm in 35 (48%) patients, and in the remaining 38 (52%) patients pseudoaneurysm neck length ranged from 3 to 30 mm (mean 7.95 ± 8.57 mm). Pseudoaneurysm neck width ranged from 1 to 5 mm (mean 3.01 ± 1.01 mm).

Subgroup characteristics

Thirty-three (45.2%) patients were randomised to the slow injection group and 40 (54.8%) patients were randomised to the bolus group. In 2 patients in the slow injection group, a iatrogenic pseudoaneurysm developed previously in the right femoral artery. Single sac pseudoaneurysms were most common in both groups (Table 2). We found no significant differences in structure and anatomy of the studied iatrogenic-

Table 1. Demographical characteristics and comparison of selected parameters between the slow injection group and the bolus group

	Overall (n = 73)	Slow injection (n = 33)	Bolus (n = 40)	P
Age [years]	67.8 \pm 11.9	65.6 (14.0%)	67.8 (12.5%)	NS
Men	33 (45%)	14 (42%)	19 (47%)	NS
Hypertension	68 (23%)	29 (88%)	39 (98%)	NS
Diabetes	28 (38%)	12 (36%)	16 (40%)	NS
Obesity	36 (49%)	18 (55%)	18 (45%)	NS
Peripheral arterial disease	15 (20%)	4 (12%)	11 (28%)	NS
History of pseudoaneurysm	2 (3%)	2 (6%)	0 (0%)	NS
Vitamin K antagonists	6 (8%)	3 (9%)	3 (7%)	NS
Aspirin	70 (96%)	30 (91%)	40 (100%)	NS
Clopidogrel	52 (71%)	23 (69%)	29 (72%)	NS
Unfractionated heparin	57 (78%)	26 (78%)	31 (77%)	NS
GP IIb/IIIa inhibitor	12 (16%)	4 (12%)	8 (20%)	NS
Coronary angiography	29 (40%)	10 (30%)	19 (47%)	NS
Angioplasty	42 (57%)	21 (63%)	21 (52%)	NS
Ablation	2 (3%)	2 (6%)	0 (0%)	NS
Urgent procedure	40 (55%)	17 (51%)	23 (57%)	NS
Elective procedure	33 (45%)	16 (49%)	17 (43%)	NS

Table 2. Comparison of iatrogenic pseudoaneurysm parameters between the slow injection group and the bolus group

	Slow injection (n = 33)	Bolus (n = 40)	P
Neck length [mm]:			NS
Min; max	0; 30	0; 22	
Mean (SD)	9.03 (9.52)	6.05 (6.88)	
Median (25%; 75%)	7 (0; 19)	4 (0; 10.5)	
Neck width [mm]:			NS
Min; max	1; 4.60	0.70; 5	
Mean (SD)	3.18 (0.77)	2.87 (1.04)	
Communication with:			NS
CFA	9 (29%)	9 (24%)	
PFA	5 (16%)	4 (11%)	
PFA+SFA	0 (0%)	1 (3%)	
SFA	17 (55%)	23 (62%)	
Blood flow velocity at the neck [m/s]:			NS
Min; max	1; 4	0; 5	
Mean (SD)	2.2 (1.0)	2.5 (1.0)	
Median (25%; 75%)	2 (1.5; 3)	3 (2; 3)	
Number of sacs:			NS ³
1	26 (79%)	27 (67%)	
2	6 (18%)	10 (25%)	
3	1 (3%)	2 (5%)	
5	0 (0%)	1 (2%)	

SFA — superficial femoral artery; PFA — profunda (deep) femoral artery; CFA — common femoral artery

Table 3. Comparison of the rates of clinically silent and evident embolisation between the slow injection group and the bolus group

	Slow injection (n = 33)	Bolus (n = 40)	P
Clinical symptoms of embolisation (a)	4 (12%)	6 (15%)	NS
Reduction in oxygen saturation (b)	10 (30%)	14 (35%)	NS
Signal disappearance (c)	6 (18%)	11 (27%)	NS
(a) or (b) or (c)	11 (33%)	15 (38%)	NS

nic pseudoaneurysms between patients in the slow injection group and the bolus group (Table 3).

Embolisation manifested clinically mainly with hallux pain subsiding within few minutes, foot numbness, or feeling of intense warmth at the area of hallux. At the same time, transient popliteal pain occurred. Such symptoms were noted in 4 patients in the slow injection group and in 6 patients in the bolus group. No signs of drug hypersensitivity were noted. No specific therapeutic intervention (administration of intravenous heparin or analgesics) was used in any patient with clinical features of embolisation. Pulsoximetry recording showed signal disappearance and arterial blood oxygen saturation of zero in 6 patients, and reduction of arterial blood oxygen saturation and signal strength below baseline values in 4 patients in the slow infusion group, and 11 and 3 patients,

respectively, in the bolus group. Overall, 10 (30%) cases of embolisation were noted in the slow infusion group compared to 14 (35%) cases in the bolus group (NS) (Table 3).

Efficacy of closure procedures, defined as lack of blood inflow to the pseudoaneurysm confirmed in the follow-up ultrasonographic evaluation before hospital discharge (efficacy to discharge) was 100% in both groups. Immediate procedural efficacy, defined as lack of blood inflow to the pseudoaneurysm in the ultrasonographic evaluation immediately after the procedure, was similar in both groups (96.8% in the slow infusion group vs 97.5% in the bolus group). In one patient in the slow infusion group, additional thrombin dose was administered due to incomplete thrombotic occlusion of the pseudoaneurysm lumen, with trace blood inflow to the pseudoaneurysm seen in colour Doppler. Similar situation was no-

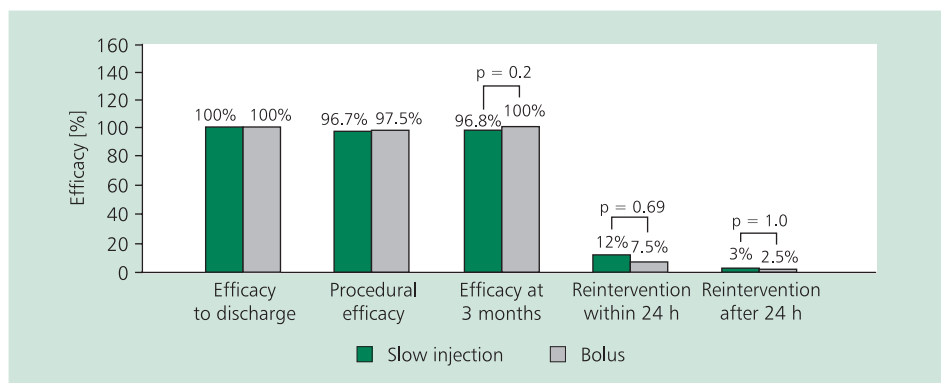


Figure 1. Comparison of the efficacy of iatrogenic pseudoaneurysm closure with ultrasound-guided thrombin administration in slow injection vs bolus

Table 4. The rate of embolisation depending on the mode of thrombin administration

	Slow injection	Bolus	P
Neck length [mm]:			
0	6/12 (50%)	8/17 (47%)	
> 0	5/21 (24%)	7/23 (30%)	
OR [95% CI]		1.14 [0.42–3.1]	NS
Neck width [mm]:			
0–3	7/20 (35%)	8/27 (30%)	
> 3	4/13 (31%)	7/13 (54%)	
OR [95% CI]		1.24 [0.47–3.23]	NS
Time to thrombotic occlusion [s]:			
0–3	0/4 (0%)	7/28 (25%)	
> 3	11/29 (38%)	8/12 (67%)	
OR [95% CI]		4.1 [1.01–16.5]	0.047
Blood flow velocity at the neck [m/s]			
< 3	8/23 (35%)	8/19 (42%)	
≥ 3	3/10 (30%)	7/21 (33%)	
OR [95% CI]		1.3 [0.48–3.47]	NS

ted in the bolus group. Incomplete obliteration of the pseudoaneurysm lumen was found in the follow-up ultrasonographic evaluation at one day after percutaneous closure procedure in 4 patients in the slow infusion group and 3 patients in the bolus group. Ultrasonography was performed due to the presence of a systolic murmur over the cannulated artery. Ultrasound-guided thrombin injections were then given in doses resulting in complete obliteration of the pseudoaneurysm lumen and no blood inflow in colour Doppler. In 2 cases, one in each group, recanalisation of the pseudoaneurysm lumen occurred after more than 24 hours but before hospital discharge. Repeated intervention was 100% effective in both cases. In one patient from the slow infusion group, late recanalisation of the pseudoaneurysm lumen was found during follow-up ultrasonographic evaluation at 3 months. Long-term efficacy in this group was 96.8% (Fig. 1).

Comparison of the embolisation rate between patients from the slow infusion group and the bolus group showed significant result for time to thrombotic occlusion (in seconds; $p = 0.047$; Table 4).

Time to thrombotic occlusion and thrombin dose differed significantly between the study groups ($p < 0.001$; Table 5). The rate of mobile thrombus formation in the pseudoaneurysm lumen during the closure procedure was significantly higher in the slow infusion group. Factors affecting the rate of embolisation are presented in Table 6.

DISCUSSION

Results of our study confirmed high efficacy of both approaches to percutaneous pseudoaneurysm closure with thrombin injection as suggested by the literature data [6, 11, 14–16]. Efficacy to discharge was 100% both in the slow infusion group

Table 5. Time to thrombotic occlusion [s], the presence of a mobile thrombus and thrombin dose [IU] in the slow injection group and the bolus group

	Slow injection (n = 33)	Bolus (n = 40)	P
Time to thrombotic occlusion [s]:			< 0.001
Min; max	2; 14	0; 8	
Mean (SD)	7.97 (3.33)	2.92 (1.49)	
Median (25%; 75%)	7 (6; 11)	3 (2; 4)	
Time to thrombotic occlusion > 3 s	29 (88%)	12 (30%)	< 0.01
Thrombin dose [IU]:			
Min; max	100; 400	50; 400	
Median (25%; 75%)	200 (200; 300)	150 (100; 200)	0.001
Mobile thrombus	6 (18%)	1 (2.5%)	0.041

Table 6. The logistic regression model to evaluate predictors of the embolisation risk

Variable	OR [95% CI]	P
Mode of administration: bolus vs slow injection	7.6 [1.3–44.9]	0.025
Dose [IU]* ≥ 200 vs < 200	4.2 [0.92–19.3]	0.06
Time to thrombotic occlusion [s]** ≥ 4 vs < 4		NS
Neck length [mm] 0 vs ≥ 1	4.66 [1.1–19.9]	0.037
Neck width [mm] > 3 vs 0–3		NS
Blood flow velocity at the neck [m/s] > 3 vs 0–3		NS
Gender: male vs female		NS
Age [years]:		
31–59 vs < 50		
60–69 vs < 50		
70–79 vs < 50		
80–86 vs < 50	10.9 [1.0–116.8]	0.049
Obesity		NS
Peripheral arterial disease		NS
Mobile thrombus		NS

*Median dose in the overall study group = 200 IU; **median time to thrombotic occlusion in the overall study group = 4 s; OR — odds ratio; CI — confidence interval

and in the bolus group. At 3-month follow-up, one patient in the slow infusion group required reintervention due to recanalisation of the pseudoaneurysm lumen. One patient did not undergo follow-up evaluation at 3 months. Late follow-up showed complete resorption of thrombi filling the pseudoaneurysm lumen. In patients with compression of arterial structures by the pseudoaneurysm, restoration of normal anatomic relations was noted. An important finding is demonstration of high efficacy of both approaches in the treatment of neckless pseudoaneurysms. We also confirmed that the absence of a pseudoaneurysm neck is a risk factor for embolisation [11, 17].

The other evaluated element of therapy was the safety of closure procedures. No major clinical events (venous thrombosis, arterial embolism, anaphylactic reaction) were noted in both groups. Clinical symptoms noted in our patients were limited to short-term foot pain or the feeling of warmth, popliteal pain, and pain located along the medial thigh surface. All these symptoms resolved spontaneously within 5 min and did not require any therapeutic intervention.

A novel aspect of our study was the use of high sensitivity pulsoximeter with continuous recording function to evaluate abnormal perfusion of the microcirculation in the treated limb. Our findings demonstrated that some patients do not show clinical symptoms of embolisation despite migration of thrombin to the arterial lumen. Our observations suggest that thrombin administration as a slow injection or bolus may result in a phenomenon which may be called silent microembolisation. Significant reduction of blood oxygen saturation below baseline or signal disappearance were usually noted shortly after thrombin administration. Complete signal disappearance indicated more massive microembolisation. Some patients showed only reduction in blood oxygen saturation and signal strength, while reduction of blood oxygen saturation and signal strength to zero could be noted in others. Blood oxygen saturation measured simultaneously in the contralateral hallux was normal and did not undergo any significant changes. These disturbances subsided spontaneously within 10 minutes.

The phenomenon of clinically silent microembolisation was first noted in studies on treatment of iatrogenic pseudoaneurysms with thrombin administration. Previous authors mostly evaluated clinical symptoms (hallux cyanosis or pain) [6, 11, 18]. In our study, we showed that the rate of microthrombus migration to the arterial bed is significantly higher than previously thought [6, 11, 16, 18]. We observed microembolisation in 33% of patients in the slow injection group and 38% of patients in the bolus group. Most importantly, however, this phenomenon had no significant clinical sequelae.

We were particularly interested in evaluating a subgroup of patients with neckless iatrogenic pseudoaneurysms. It was

suspected that the risk of embolisation during percutaneous pseudoaneurysm closure in this subgroup was higher compared to patients with a pseudoaneurysm with neck and thus it might lead to more frequent adverse events or preference of surgical interventions over percutaneous closure [11, 17]. Novel approach to thrombin administration (in a bolus) was expected to reduce the rate of distal embolisation. Our findings, however, did not confirm this hypothesis and reasons for this merit consideration. Neckless pseudoaneurysms were more common in the bolus group compared to the slow injection group (42.5% vs 36%). Our findings and observations in patients with neckless iatrogenic pseudoaneurysms show that pseudoaneurysm closure procedures using thrombin administration are effective and safe. Of note, thrombin dose should be as small as possible (in our study, mean thrombin dose was 200 IU in the slow injection group and 150 IU in the bolus group, while the maximal dose was 400 IU in both groups). In addition, clinically silent microembolisation is a possible complication.

Time to thrombotic occlusion was significantly longer in the slow injection group. This resulted in a lower rate of mobile thrombus formation in the pseudoaneurysm lumen during the closure procedure. This is probably related to inhomogeneous drug distribution in turbulently flowing blood in the pseudoaneurysm lumen. We noted 6 cases of mobile thrombus in the slow injection group compared to only one such case in the bolus group, with no effect of this difference on the rate of embolisation.

One of the most practically important pieces of information regarding efficacy and safety of both approaches is the thrombin dose. We showed that small doses were effective [19] and the increase in dose was associated with increasing risk of microembolisation.

Limitations of the study

The planned study population size was not reached. This was due to a change in arterial cannulation approach from femoral to radial route, resulting in a reduction of the rate of iatrogenic pseudoaneurysm in our centre to zero in 2009. However, femoral route is still widely used in many cath labs and electrophysiology laboratories, thus, our results are also valuable for contemporary procedures.

CONCLUSIONS

We confirmed high efficacy of thrombin administration both in slow injections and as boluses in percutaneous closure of iatrogenic pseudoaneurysms. Both approaches were highly effective in the treatment of pseudoaneurysms both with and without neck. We noted the phenomenon of microembolisation which occurred with a higher rate in the slow injection group compared to the bolus group. No significant clinical sequelae of microembolisation were noted in either group. Benefits of bolus thrombin administration in the treatment of iatrogenic pseudoaneurysms include reduction in the thrombin dose and shortened time to thrombotic occlusion of the pseudoaneurysm lumen.

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Conflict of interest: none declared

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Randomizowana ocena skuteczności i bezpieczeństwa stosowania trombiny podawanej metodą szybkiego pojedynczego wstrzyknięcia lub w dawkach dzielonych w przezskórnym leczeniu tętniaków rzekomych

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Streszczenie

Wstęp: Rutynowe stosowanie przezskórnych zabiegów interwencyjnych w kardiologii i radiologii interwencyjnej wiąże się ze wzrostem częstości występowania jatrogennych tętniaków rzekomych (JTR). W latach 2005–2006 w Klinice Kardiologii CMKP rozpoczęto stosowanie alternatywnego sposobu podawania trombiny do jamy JTR. Z doświadczenia autorów wynikało, że podanie określonej dawki trombiny w szybkim pojedynczym wstrzyknięciu (bolus) do jamy JTR powoduje szybszą dystrybucję leku, znaczące skrócenie czasu potrzebnego do wykrzepienia krwi i zmniejszenie dawki leku. Ponadto podejrzewano, że zastosowanie metody szybkiej iniekcji trombiny do światła naczynia może być obiecującą, alternatywną metodą w leczeniu JTR bez szyi.

Cel: Celem pracy było porównanie skuteczności i bezpieczeństwa dwóch sposobów przezskórnego podawania trombiny (powolny wlew v. bolus) pod kontrolą USG do jamy JTR.

Metody: Pacjenci byli losowo włączani do zabiegu przezskórnego leczenia tętniaków rzekomych w bolusie lub powolnej iniekcji. Przed podaniem trombiny do jamy JTR mierzono długość i średnicę szyi tętniaka, prędkość przepływu krwi w szyi i liczbę jam. Przed zabiegiem, w trakcie trwania i po zabiegu mierzono saturację krwi na paluchu stopy kończyny z tętniakiem rzekomym w celu wykrycia cech mikroembolizacji. Po zabiegu określano dawkę podanego leku i czas tworzenia stabilnej skrzepliny oraz rejestrowano kliniczne objawy obwodowej embolizacji. W okresie 01.2006–12.2009 z grupy 7500 chorych poddanych procedurom inwazyjnym (koronarografia, angioplastyka, ablacja) do badania włączono kolejnych 73 pacjentów (33 mężczyzn, 40 kobiet) w wieku średnio $67,8 \pm 11,9$ roku z rozpoznanym JTR. Do grupy leczonej bolusem włączono 40 osób, do grupy leczonej powolną iniekcją — 33 pacjentów.

Wyniki: Skuteczność obu metod w leczeniu tętniaków rzekomych wynosiła 100% do dnia wypisu w obu grupach i 100% v. 96.8% w obserwacji 3-miesięcznej (bolus v. wlew). Skuteczność zabiegu nie zależała od długości i średnicy szyi. Niezależnymi czynnikami embolizacji obwodowej były: dawka stosowanego leku (OR 4,2; 95% CI 0,92–19,3), długość szyi (OR 4,66; 95% CI 1,1–19,9) i wiek > 80 lat (OR 10,9; 95% CI 1,0–116,8). W grupie leczonej metodą bolusa stwierdzono istotnie częściej embolizację obwodową niż w grupie leczonej powolną iniekcją (OR 7,6; 95% CI 1,3–44,9). Zaobserwowano zjawisko niemej klinicznie mikroembolizacji, która wystąpiła w 38% przypadków w grupie, w której zastosowano bolus i 33% w grupie powolnego wlewu.

Wnioski: Zamykanie tętniaków rzekomych dwoma sposobami podania trombiny przy zastosowaniu małych dawek leku jest skutecznym sposobem leczenia. Obie metody (wlew lub bolus) są skuteczne i bezpieczne w przypadku tętniaków z szyją lub bez szyi. W badaniu zaobserwowano zjawisko niemej klinicznie mikroembolizacji,

Słowa kluczowe: tętniak rzekomy, podawanie trombiny pod kontrolą USG

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