

# Percutaneous treatment of femoral pseudoaneurysms: comparison of fibrin sealant against thrombin

## *Tratamento percutâneo do pseudoaneurisma femoral: comparação entre selante de fibrina e trombina*

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### Abstract

**Introduction:** Femoral pseudoaneurysms are a complication that occurs in connection with up to 8% of percutaneous procedures. Of the available treatments, ultrasound guided thrombin injection has a high success rate and is well-tolerated by patients. The combination of thrombin and fibrinogen known as fibrin sealant forms a stable clot and can be used to treat pseudoaneurysms, particularly those with complex anatomy and larger size. **Objective:** To compare the results of treating femoral pseudoaneurysm in two ways: Group T was treated with thrombin alone and Group T+F was treated with fibrin sealant (thrombin+fibrinogen). **Methods:** A retrospective analysis was conducted of femoral pseudoaneurysm cases treated between January 2005 and December 2012. **Results:** Twenty-eight patients were treated, 21 with thrombin alone and seven with fibrin sealant. All patients in group T were treated successfully, but only four patients in group T+F were treated successfully (57.1% success rate in Group T+F,  $p<0.01$ ). The three cases of failure in group T+F needed surgery and in one of these cases the complication was embolization to the femoral bifurcation. The pseudoaneurysms that were treated with fibrin sealant were larger (25 cm<sup>3</sup> in Group T and 57.7 cm<sup>3</sup> in Group T+F,  $p=0.02$ ) and required larger volumes of thrombin (0.5 mL in Group T and 1.0 mL in Group T+F,  $p<0.01$ ). There was one complication in Group T and two complications in Group T+F ( $p<0.01$ ). **Conclusions:** Irrespective of the small number of cases reviewed, treatment with thrombin alone was superior to treating with fibrin sealant, since it caused few complications and was more effective at correcting pseudoaneurysms.

**Keywords:** thrombin; fibrin; factor XIII; pseudoaneurysm; false aneurysm; fibrinogen.

### Resumo

**Introdução:** O pseudoaneurisma femoral é complicação descrita em até 8% dos procedimentos percutâneos. Dentre os tratamentos, a injeção de trombina guiada por ultrassom tem alta taxa de sucesso e boa tolerância pelos pacientes. O uso da trombina associada ao fibrinogênio, chamado selante de fibrina, forma um coágulo estável que pode ser usado para o tratamento do pseudoaneurisma, principalmente aqueles de anatomia complexa e maiores. **Objetivo:** Comparar os resultados do tratamento do pseudoaneurisma femoral em dois grupos: Grupo T, tratado com trombina isoladamente, e Grupo T+F, tratado com selante de fibrina (trombina+fibrinogênio). **Método:** Análise retrospectiva dos casos de pseudoaneurisma femoral tratados entre janeiro/2005 e dezembro/2012. **Resultados:** Foram tratados 28 pacientes, 21 com trombina isolada e sete com selante de fibrina. Houve sucesso no tratamento de todos os pacientes do grupo T e somente em quatro casos do grupo T+F (57,1% no Grupo T+F,  $p<0,01$ ). Os três casos de insucesso no grupo T+F necessitaram cirurgia, sendo que, em um deles, a causa foi embolização para a bifurcação femoral. Os pseudoaneurismas tratados com selante de fibrina apresentaram maior tamanho (25 cm<sup>3</sup> no Grupo T e 57,7 cm<sup>3</sup> no Grupo T+F,  $p=0,02$ ) e houve necessidade de maior volume de trombina (0,5 mL no Grupo T e 1,0 mL no Grupo T+F,  $p<0,01$ ). Houve uma complicação no Grupo T e duas no Grupo T+F ( $p<0,01$ ). **Conclusão:** Apesar do número reduzido de casos, o tratamento com trombina isolada foi superior ao selante de fibrina, levando a poucas complicações e à maior eficácia para resolução do pseudoaneurisma.

**Palavras-chave:** trombina; fibrina; fator XIII; falso aneurisma; fibrinogênio.

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## ■ INTRODUCTION

Femoral pseudoaneurysms are a possible complication of percutaneous vascular procedures. They have an incidence of 0.05% to 2% in diagnostic procedures and 8% in therapeutic procedures<sup>1-3</sup>. The incidence of this complication is increasing because endovascular procedures are becoming more common<sup>4</sup>. A femoral pseudoaneurysm is a serious complication of puncture because it can lead to bleeding into deep tissues that is hard to control. Furthermore, arterial thrombosis has also been reported in connection with femoral pseudoaneurysms, leading to acute ischemia of the affected limb and infection of soft tissues, compromising the femoral vessels<sup>5</sup>.

Several different studies have reported successful percutaneous treatment of pseudoaneurysms using puncture guided by ultrasound and thrombin injection<sup>5-8</sup>. The first choice treatment for pseudoaneurysms is now percutaneous thrombin injection and surgery is reserved for cases in which this fails or for more complicated pseudoaneurysms<sup>9-11</sup>.

Fibrin sealant is formed by combining fibrinogen and factor XIII with thrombin by simultaneous injection. Combining these two components triggers formation of a stable fibrin clot, polymerized by the factor XIII. This material is used in surgery on several different organs<sup>12</sup>. In vascular surgery, it is used as a hemostatic sealant to facilitate arterial anastomosis.

Our institution began providing percutaneous treatment of femoral pseudoaneurysms in May of 2005. Initially, percutaneous injections of fibrin sealant were used, working from the authors' experience using the substance in open vascular surgery<sup>3</sup>. In December of 2006 we began to conduct these treatments with thrombin alone.

The objective of this retrospective analysis is to compare these two groups of femoral pseudoaneurysm cases: the first treated using fibrin sealant and the second using thrombin alone. The objective of the analysis is to compare the results of these treatments and their complications.

## ■ METHODS

A retrospective analysis was conducted of data on patients treated for femoral pseudoaneurysms between January 2005 and December 2012. Epidemiological data and variables related to clinical status and the percutaneous treatment were collected.

Data were split into two groups: data from patients treated with thrombin alone in one group (Group T) and data from patients treated with fibrin sealant, which is basically thrombin and fibrinogen, in the other (Group T+F). Retrospective analysis showed that the decision on whether to treat pseudoaneurysms using thrombin or fibrin sealant was empirical, in that it was not based on a protocol or on rigid criteria for choice. Large or multilobed pseudoaneurysms were preferably treated with fibrin sealant. From January 2007 onwards, all pseudoaneurysms were treated with thrombin alone. This change in conduct was made in response to observation of complications in cases treated with fibrin sealant.

Pseudoaneurysms were diagnosed and had their diameters measured using vascular ultrasound. Volume was calculated as length  $\times$  width  $\times$  height  $\times$  0.523 (correction factor). The correction factor of 0.523 is used to calculate the volume of an elongated ellipse. The formula to estimate volume calculated as length  $\times$  width  $\times$  height  $\times$  0.523 is used for organs such as the thyroid and prostate and for collections with an irregular elliptical shape. We chose this formula on the basis that other authors have used it previously to estimate the volume of femoral pseudoaneurysms<sup>9,10</sup>.

The commercial preparations employed were Beriplast® (Aventis Behring, Marburg, Germany) and Tissucol® (Baxter AG, Vienna, Austria). They are similar and in both cases the components come in separate presentations. There is one vial containing frozen dried coagulation proteins, primarily fibrinogen and factor XIII, and a second containing approximately 500 UI of human lyophilized thrombin. The contents of the fibrinogen and factor XIII vial are reconstituted using aprotinin, which is a solution of bovine origin that prevents natural fibrinolysis. The thrombin is reconstituted in a solution of calcium chloride. Fibrin sealant is formed when the contents of the vial containing fibrinogen+factor XIII and the contents of the thrombin vial are injected simultaneously using a Y-shaped connector that comes with the kit. The fibrin sealant injection, given to patients in the T+F group, leads to formation of a thrombus that is highly echogenic on ultrasound.

The thrombin only injection, used with patients in the T group, is given using a diluted solution. The commercially available thrombin preparation contains approximately 500 UI/mL. A 1 mL volume of this solution was diluted with 10 mL of saline at 0.9%. After puncture of the pseudoaneurysm, the diluted thrombin is injected slowly and color mode

vascular ultrasound is used to observe interruption of the blood flow. A slightly echogenic thrombus is formed.

The majority of patients were treated in the hospital's ultrasound department. Ultrasound guided puncture is performed under local anesthetic, without anesthetic sedation. The pseudoaneurysm neck is not compressed while the thrombin or fibrin sealant is injected. After injection the patient is prescribed a compressive dressing over the groin and 24 hours' rest. If a second ultrasound scan on the following day shows that the aneurysm has remained closed, the patient is discharged. If not, another attempt is made to close it via percutaneous access.

Two patients were treated in the operating theatre via ultrasound guided percutaneous access. Initial success was defined as immediate closure of the pseudoaneurysm. Late success was defined as closure by the time the second ultrasound scan was performed on the following day.

The technique employed, potential complications and treatment options were all explained to the patients, all of whom signed informed consent forms and authorized the procedures. Both the treatment with thrombin and the treatment with fibrin sealant were approved by the hospital's nosocomial infection control service. The study was approved by the Research Ethics Committee and registered against ethics assessment submission certificate number 06925012.6.0000.5128.

Quantitative variables for groups T and T+F were compared using the Mann-Whitney test. Fischer's exact test was used for qualitative variables. Analysis of quantitative variables was based on medians and quartiles because data were nonparametric. The significance level adopted was 5%, meaning that *p* values below 0.05 were considered statistically significant.

## RESULTS

Twenty-eight patients were diagnosed with femoral pseudoaneurysms, 21 of whom were treated with thrombin injection alone (group T) and seven of whom were treated with thrombin+ fibrinogen injection (group T+F). There were 25 men and three women in the sample.

Table 1 lists data for qualitative variables relating to these groups. There was no difference in terms of therapeutic anticoagulation and all patients were on antiplatelet drugs. There was also no difference in relation to the types of procedure that led to pseudoaneurysms, although cardiac interventions predominated, primarily for treatment purposes.

Initial success was achieved in 20 patients (95.2%) in group T (Table 2). The control scan on the following day showed that the only pseudoaneurysm that had not been closed immediately had closed the next day, so late success in this group was 100%. In the T+F group, initial success was achieved in four out of seven cases (57.1%). All three unsuccessful cases required surgery: two because of non-closure of the pseudoaneurysm and one case due to embolization to the femoral bifurcation.

There was one complication in group T and there were two complications in group T+F. This difference was not statistically significant (Table 2). The outcome of all 21 cases treated with thrombin alone was closure of the pseudoaneurysm. In the T+F group, surgery was required in three cases ( $p=0.01$ ), which is a very significant association, as shown by the elevated odds ratio.

The group treated with fibrin sealant (T+F) had larger pseudoaneurysms, both in volume and in terms of largest diameter (Table 3). This meant that a greater volume of thrombin was required. Since the fibrin sealant is created by combining thrombin with the fibrinogen and factor XIII mixture, the volume

**Table 1.** Qualitative variables for patients treated with thrombin only (Group T) and fibrin sealant (Group T+F).

	Group T (n=21)	Group T+F (n=7)	<i>p</i>
Sex			0.55
Male	18 (85.7%)	7 (100%)	
Female	3 (14.3%)	0	
Anticoagulation	16 (76.2%)	7 (100%)	0.29
Antiplatelet treatment	21 (100%)	7 (100%)	1.00
Type of procedure that led to pseudoaneurysm			0.36
Coronary angioplasty	13 (61.9%)	3 (42.9%)	
Peripheral angioplasty	3 (14.3%)	0	
Diagnostic coronary catheterization	4 (19%)	3 (42.9%)	
Closure of ductus arteriosus	1 (4.8%)	0	
Puncture for double-lumen catheter	0	1 (14.3%)	

**Table 2.** Results of percutaneous treatment.

	Group T (n=21)	Group T+F (n=7)	p	O.R.
Initial success	20 (95.2%)	4 (57.1%)	0.03	0.06 (0.01-0.82)
Late success	21 (100%)	4 (57.1%)	0.01	0.03 (0.01-0.76)
Complications	1 (4.8%)	2 (28.6%)	0.14	3.33 (0.66-57.90)
Needed surgery	0	3 (42.9%)	0.01	31.5 (1.31-756.79)

**Table 3.** Quantitative variables for patients treated with thrombin only (Group T) and fibrin sealant (Group T+F)<sup>a</sup>.

	Group T (n=21)	Group T+F (n=7)	p
Age	66 (58; 73)	65 (62.5; 72.5)	0.87
Characteristics of pseudoaneurysms			
Volume of pseudoaneurysm (cm <sup>3</sup> )	25 (21; 23)	57.7 (30.3; 75.6)	0.02
Largest diameter (cm)	3.6 (3.2; 4.0)	4.8 (4.0; 5.7)	0.007
Lobes	1 (1; 1)	2 (1; 3)	0.07
Volume of thrombin injected (mL)	0.5 (0.4; 0.6)	1.0 (1.0; 1.5)	< 0.01
Total volume injected (mL)	0.5 (0.4; 0.6)	2.0 (2.0; 2.5)	< 0.01
Units of thrombin (UI) <sup>b</sup>	250 (200; 300)	500 (500; 750)	< 0.01

<sup>a</sup>Figures are medians (1<sup>st</sup> quartile; 3<sup>rd</sup> quartile); <sup>b</sup>Approximate number of units of thrombin (1 mL of reconstituted thrombin contains approximately 500 UI).

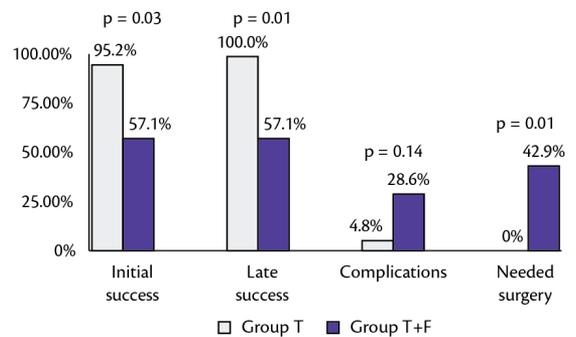
**Table 4.** Complications of percutaneous treatment in 28 cases of femoral pseudoaneurysm.

Group T (n=21)	
Subcutaneous infection	1
Group T+F (n=7)	
Subcutaneous infection	1
Embolization to femoral bifurcation needing surgery	1

of these components injected is greater than when thrombin alone is used.

Complications were more frequent in the T+F group (Table 4). Just one of the 21 patients treated with thrombin alone suffered a complication, which was subcutaneous infection. In contrast, two of the seven patients treated with fibrin sealant suffered complications: one subcutaneous infection and one embolization to the superficial femoral artery requiring emergency embolectomy. Coincidentally, the patient was being treated in the operating theatre, which facilitated a rapid surgical intervention involving dissection of the femoral vessels and embolectomy.

Figure 1 illustrates the statistically significant difference between the outcomes of the two treatments. Rates of initial and late success were both higher in the T group. There were more complications in the T+F group, but the difference was not statistically significant. Surgery was required more often in the T+F group.

**Figure 1.** Results of treatment of dos pseudoaneurysms with thrombin (Group T) and fibrin sealant (Group T+F).

## DISCUSSION

Femoral pseudoaneurysms (PA) have a reported incidence of up to 8% and are most commonly related to therapeutic cardiac procedures<sup>4,8</sup>. In peripheral vascular interventions diagnostic arteriography is linked with an incidence of 0.1% to 0.2% and therapeutic procedures are linked with an incidence of 0.8% to 2.2%<sup>4,6</sup>.

Since it was described by Kang et al.<sup>13</sup>, countless subsequent publications have shown that treatment with thrombin is effective, rapid and comfortable for the patient and has an efficacy rate of 96% to 100%<sup>14,15</sup>. Small pseudoaneurysms, especially those with diameters smaller than 2.0 cm, can be treated conservatively and spontaneous thrombosis can be expected<sup>16,17</sup>. Compression guided by ultrasound is a treatment that has variable results and success rates of 50 to 95% and also causes patients discomfort<sup>18</sup>.

Endovascular treatments for PA have been described: placement of covered stents, obliteration of the lumen of the femoral artery with a balloon and percutaneous thrombin injection, and embolization of the pseudoaneurysm with coils or liquid agents. When the several treatment options described in the literature are considered, percutaneous injection of thrombin offers several advantages: high success rates, simple technique, short duration of procedure, no radiation use, patient comfort and low complication rates<sup>8,14</sup>.

Lönn et al. published the only prospective randomized study that has compared percutaneous thrombin injection against compression guided by ultrasound, with just 15 patients in each group, observing a 100% success rate with percutaneous techniques and 40% with compression alone<sup>19</sup>. Other prospective studies have reported satisfactory results. The largest published case series included 274 patients, with 97% success after thrombin injection<sup>20</sup>.

The use of plasma proteins as a tissue adhesive had already been described in the last century, employed for surgical hemostasis<sup>21,22</sup>. The primary coagulation agent is fibrinogen. The fibrinogen is transformed into stable fibrin under the action of thrombin and factor XIII. The stable fibrin clot works as a guide for the hemostatic process, attracting fibroblasts and stimulating the formation of an extracellular matrix, basically composed of collagen<sup>12</sup>.

There is little data in the literature on the results of using fibrin sealant. Matson et al.<sup>16</sup>, treated pseudoaneurysms with fibrin sealant and achieved initial success in 16 out of 19 patients (20% failure rate). They used an endoluminal balloon to protect the femoral artery and injected the fibrinogen substrate first, followed by the thrombin immediately afterwards. Loose and Haslam<sup>23</sup> observed thrombosis in all 13 cases treated this way.

We used the 'Y' connector with our fibrin sealant patients, making it possible to inject both the fibrinogen+factor XIII and the thrombin components simultaneously. Our results with simultaneous injection were poor, since the pseudoaneurysm was only thrombosed in four out of seven cases. One possible explanation is the fact that when they are injected together, the thrombin is consumed by the fibrinogen. They form a stable clot, but the thrombin does not propagate within the pseudoaneurysm to the same extent. The clot that is formed by the bonding of thrombin and fibrinogen would therefore have a reduced capacity to trigger thrombosis in the remainder of the pseudoaneurysm. In contrast, the slower thrombin injection is diffused throughout the

pseudoaneurysm cavity by the turbulent flow, leading to thrombosis of the entire cavity. This may explain the fact that results were better when treatment was with thrombin alone.

Where pseudoaneurysms were of larger size or had more complex anatomy, preference was given to the fibrin sealant treatment, although the hospital had no specific protocol for selecting which treatment should be used. Both volume and largest diameter of the PAs were greater in the T+F group and the difference was statistically significant. The PAs in the T+F group also had more complex anatomy, with a greater number of lobes, although this difference was not significant. The larger size of the T+F group's PAs meant that larger volumes were injected and, in particular, that a greater quantity of thrombin was used.

Multilobulated pseudoaneurysms are more difficult to treat. Treatment success rates are lower with multilobulated PAs and there it is necessary to puncture the PA repeatedly<sup>9</sup>. The anatomical complexity and size of the PAs in the T+F group may have contributed to the poor results. Additionally, injecting larger volumes of thrombin leads to increased complications, such as leakage into the systemic circulation and distal embolization<sup>9,15</sup>.

Embolization after percutaneous treatment is a serious complication and was observed in one of the patients in group T+F. It is rare that embolectomy becomes necessary, but there are descriptions of subclinical embolization with percutaneous thrombin<sup>14</sup>. Distal embolization requiring surgery is described in around 2% of femoral pseudoaneurysm treatments<sup>24</sup>. Lewandowski et al. found signs of distal embolization diagnosed clinically and on the basis of abnormal pulse oximetry in 30 to 38% of a sample<sup>7</sup>. We did not observe this phenomenon in our patients. We did not monitor patients' feet with pulse oximeters, but none of the other 27 cases exhibited any clinical signs of embolization (pain, paresthesia or cyanosis of toes).

One complication that was observed in our case series was subcutaneous infection, which occurred in one patient from each group. This is a complication that is associated with invasive techniques and it has been described in several case series, but does not occur in association with ultrasound guided compression<sup>20</sup>. It is more common in connection with conventional surgery and studies report surgical site infection rates of up to 19%<sup>25</sup>.

The major limitation of our study was the lack of a protocol for choosing the treatment method. Where PAs were large and lobulated, the idea of using

fibrin sealant was based on the authors' previous experience using the preparation in conventional vascular surgery. However, when fibrin sealant treatments were observed to be prone to failure and complications, we switched to treatment with thrombin. Additionally, the small sample size of the T+F group limits the utility for reliable decision making, although statistical analysis of the nonparametric data was possible.

## ■ CONCLUSIONS

The results of this study confirm that satisfactory results can be obtained by treating femoral pseudoaneurysms with percutaneous thrombin injections. The slower injection rate of dilute thrombin allows it to diffuse throughout the pseudoaneurysm interior provoking thrombosis and allowing for treatment with smaller volumes and few complications. The results of treatment with fibrin sealant were unsatisfactory, irrespective of the small number of cases. Fibrin sealant is no longer a treatment option for this condition at our hospital. Femoral pseudoaneurysms can be safely and effectively treated by injection of thrombin alone.

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Conception and design: DMP, PB  
Analysis and interpretation: DMP, PB  
Data collection: DMP, PB  
Writing the article: DMP, PB  
Critical revision of the article: DMP, PB  
Final approval of the article\*: DMP, PB  
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