Safety and Efficacy of a Potential Treatment Algorithm by Using Manual Compression Repair and Ultrasound-Guided Thrombin Injection for the Management of Iatrogenic Femoral Artery Pseudoaneurysm in a Large Patient Cohort

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Background—Because of the risk of associated complications, femoral pseudoaneurysm (PSA) formation implies further treatment. Ultrasound-guided thrombin injection (UGTI) is becoming the accepted gold standard, but manual compression (MC) represents an established treatment option including PSAs not feasible for UGTI. This study aims to assess our experience in PSA treatment using MC or UGTI according to a potential algorithm based on morphological properties in a large patient cohort.

Methods and Results—Between January 2007 and January 2011, a total of 432 PSAs were diagnosed in 29091 consecutive patients (1.49%) undergoing femoral artery catheterization. When compressible, small PSAs (<20 mm), PSAs without clearly definable neck, PSAs directly adjacent to vessels, and PSAs with concomitant arteriovenous fistula were referred to MC (n=145, 34%). All other PSAs were treated by UGTI (n=287, 66%). Follow-up duplex scans were performed within 12 to 14 hours after manual compression therapy and within 4 to 6 hours after UGTI or by the next morning and were available for 428 patients (99.1%). The overall success rate of our institutional therapeutic approach was 97.2%, which was achieved by 178 MC- and 357 UGTI-procedures, respectively. Procedural complications occurred in 5 cases (1.4%) after UGTI and in 3 cases (1.7%) after MC, respectively. The treatment algorithm was not successful in 12 patients, whereas 2 PSAs (0.5%) were successfully excluded by implantation of a covered stent-graft, and 10 patients necessitated surgical intervention (2.3%), which was associated with a high complication rate (30%).

Conclusions—The presented treatment algorithm facilitates effective and safe PSA elimination.


Key Words: algorithms ■ aneurysm, false

Postcatheterization pseudoaneurysm (PSA) is a common complication related to the arterial access site in invasive procedures. The incidence of PSA after diagnostic catheterization ranges from 0.05% to 2% and increases up to 2% to 6% in interventional procedures.1,2

Traditionally, surgical repair was the only treatment option for PSA. Although effective, surgery is associated with an increased morbidity and mortality risk of up to 7.5% all-cause mortality within 1 year.3,4 Therefore, different therapeutic strategies have been introduced during the past 2 decades including ultrasound-guided manual compression (USGC) and ultrasound-guided thrombin injection (UGTI).5,6 Although the success rates of USGC range between 71% and 99%, this technique has disadvantages, including less effectiveness in patients receiving anticoagulation, long procedure times, and patient and operator discomfort during compression.7–10 UGTI represents an elegant alternative with high success rates between 91% and 100% at low complication risk.6,11–16 For that reason, most experts recently recommend UGTI as the technique of choice for first-line management of PSAs rather than USGC or its simplified version the clinically guided manual compression repair without technical surveillance (MC).2,6,17–19 At our institution, we started to use UGTI in 2007 and developed a treatment algorithm based on morphological properties...
of the aneurysm, which defines when to apply MC or UGTI. The purpose of our study was to evaluate the safety and efficacy of this potential algorithm in a large patient cohort.

Methods

Patient Population

We retrospectively analyzed data from 29,091 consecutive patients, who had undergone diagnostic angiography, cardiac and peripheral interventions, respectively, via a femoral artery access between January 2007 and January 2011 at both sites of our institution (Klinikum Rechts der Isar & Deutsches Herzzentrum München). Angiography included examination of the heart or peripheral vessels as well as electrophysiology studies. Any procedures with an access other than via the femoral artery were excluded. The hospital records of patients were reviewed to gather the following information: age, sex, type of procedure, cardiovascular risk factors, and anticoagulation. In case of documented PSA, we analyzed the recorded ultrasound data. The morphological features of the PSA as well as the consequent treatment method, success, and complication rates were evaluated. The study was approved by our institutional review committee. Because of retrospective review of existing data, no written informed consent was obtained.

Interventional Procedures

Different investigators performed puncture of the femoral artery using sheath sizes of 5 or 6 French (F) for diagnostic and 6 or 7 F for therapeutic procedures, respectively. For cardiac and peripheral interventions, patients were pretreated with 600 mg clopidogrel or 60 mg prasugrel. For coronary interventions, a bolus of 100 international units (IU) of heparin per kilogram body weight was applied. Peripheral interventions were usually performed with a bolus injection of 5000 IU heparin. After diagnostic procedures, the arterial sheath was removed immediately. After interventions, the sheath was usually removed 2 to 4 h after the procedure when partial thromboplastin time reached <80 s. After sheath removal, manual compression of the puncture site was performed for ≥10 minutes until hemostasis was achieved. Thereafter, a compression bandage was applied, and the patients rested in bed for 6 h in case of diagnostic angiography and 12 h after intervention. Throughout the study period, no closure devices were used.

Screening for PSA

After removal of the compression bandage and before ambulation, all patients were clinically examined and evaluated for typical clinical signs of PSA. Patients with hematoma, pain, swelling, and a pulsatile mass or bruising at the puncture site were referred for color flow duplex imaging. The native vessels were identified in transverse and longitudinal axes. The identification of a PSA was confirmed by the classical triad of ultrasound findings including a hypoechoic sac in the vicinity of the parent vessel, a swirling high resistance flow on Doppler ultrasound within this mass and a to and fro type waveform in the neck or in the sac close to the neck, respectively. Once recognized as a PSA, the artery of origin was identified and recorded. Besides the PSA size, geometry, and position in relation to the artery, parameters as number of PSA chambers, length, and width of the PSA neck and compressibility as well as associated arteriovenous fistula were documented.

Treatment Algorithm of PSA

Patients with diagnosed PSA were treated at physicians’ interpretation of a special algorithm existing in our departments (Figure 1). According to this, small PSAs (diameter <20 mm), PSAs without clearly definable neck, PSAs directly adjacent to vessels, and PSAs with concomitant arteriovenous fistula were referred to MC. All other PSAs were treated by UGTL. Anticoagulation therapy was not halted.

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**Figure 1.** Flow chart of management of iatrogenic femoral artery pseudoaneurysm (PSA) according to a treatment algorithm based on morphological features of the aneurysm.
Technique of MC
MC was performed as for primary hemostasis after arterial catheterization. Pressure was mainly directed to the area of maximum pulsation and was gradually increased until the pathological pulsation of the hematoma or the femoral thrill disappeared. Pressure was maintained until the pathological pulsation of the hematoma, or the femoral bruit had permanently disappeared but not >60 minutes. After this procedure, a compression bandage was applied, and the patient rested in bed for ≥2 hours until the duplex scan. USGC instead of MC without technical surveillance was only performed in few cases as previously described.16-21

Technique of UGTI
After informed consent was obtained, we performed the 3-way stopcock technique as described by La Perna et al.6 If there were >1 PSA cavity, generally not the lobe closest to the parent artery was injected first to decrease the risk of intraarterial thromboembolism. Occasionally, further injections were required for lobes closer to the parent artery. Toward the end of the study period, we began to directly inject the lobe closest to the parent artery, especially if the other morphological properties made this lobe suitable for UGTI. After thrombus formation was visualized and success of the thrombin injection was confirmed by absence of Doppler flow, patients were placed on bed rest for ≥4 hours after the injection until the duplex scan.

Follow-Up After PSA Treatment
Follow-up duplex scans were usually performed within 12 to 14 hours after MC and within 4 to 6 hours after UGTI or by the next morning to evaluate for thrombosis or PSA recurrence. The patients rested in bed until the duplex scan. In case of failed repair of the PSA, the treatment method was again selected based on the current duplex findings.

Statistical Analysis
Categorical data were presented as percentages, and continuous variables were presented as mean±SD. Student t tests were used to compare continuous variables, whereas Fisher exact tests and χ² tests were used to compare categorical variables, as appropriate. P value of <0.05 (2-sided test) was considered to be statistically significant.

Results
Patient Characteristics
The demographic characteristics of the patients with PSA are shown in Table 1. Of the 29091 consecutive patients, who underwent angiography via the femoral artery, 432 patients with a postprocedural PSA were identified by clinical-directed ultrasound examination, resulting in an overall incidence of 1.49%. More than two thirds of PSAs arose from the common femoral artery, and nearly one third from the superficial followed by the deep femoral artery and the external iliac artery. The mean sheath size used in all patients with postprocedural PSA averaged 6.3±0.7 F.

Eighty percentage of the population underwent cardiac catheterizations with more than half of them undergoing percutaneous coronary intervention (PCI). The remaining 20% of patients underwent either peripheral interventions or electrophysiology studies.

More than half of the patients had coronary artery disease, and around one tenth had peripheral obstructive disease. Accordingly, the majority of the patients had common cardiovascular risk factors, most commonly from arterial hypertension.

Antiplatelet therapy and anticoagulation, respectively, were present in the absolute majority of patients (99.8%). ASS monotherapy was present in 9% and coumadine monotherapy in 14% of patients, respectively. Dual antiplatelet therapy was present in 53% of patients and most commonly consisted of ASS and clopidogrel (51%). A combination of anticoagulation with single antiplatelet therapy including ASS was present in 6% and including clopidogrel in 2% of patients, respectively. Finally, a combination of oral anticoagulation and dual antiplatelet therapy consisting of ASS and clopidogrel (so-called triple therapy) was found in 16%. In none of the antiplatelet/anticoagulation medication subsets, significant differences between MC and UGTI groups could be found.

The exact length of stay because of development of PSA and its associated treatment cannot be completely specified because some patients had prolonged hospitalizations attributable to other medical reasons. Keeping this bias in mind, the mean length of stay averaged 5.7±8.4 days in the MC and 5.4±5.8 days in the UGTI group.

Treatment of PSA
Of the total of 432 patients with a postprocedural PSA, 287 (66.4%) patients were initially treated by UGTI, whereas 145 patients (33.6%) were treated by MC (Figure 1). USGC instead of MC was performed in only 3 cases. Figures 2 and 3 show typical examples of duplex findings in patients treated with MC and UGTI, respectively. According to baseline characteristics, the patients in the MC group were significantly younger and had a lower body mass index. Furthermore, fewer patients were smokers and had peripheral artery disease in the MC group (Table 1).

Based on our institutional therapeutic approach, MC was undertaken in significantly smaller PSAs. Furthermore, PSAs in the MC group had a higher number of indefinable necks and a lower number of multicompartimental structures. Finally, all PSAs with concomitant arteriovenous fistula were treated with MC (Table 2).

Follow-up data were missing in 4 patients (2 in MC and 2 in UGTI group, respectively), leaving 428 patients for further evaluation (Figure 1).

Manual Compression Approach
After the first MC attempt, 111 (77.6%) PSAs were successfully closed (Figure 4). Eleven patients (7.7%) required >1 MC approach (maximal 4 attempts) to achieve complete PSA obliteration. Twelve patients whose initial UGTI therapy failed underwent MC, which was successful in 10 cases after the first attempt, whereas 2 patients underwent second MC to finally achieve complete PSA obliteration.

The overall complication rate for MC was low (Table 3). In detail, one patient developed an infection of the affected groin after compression, and another patient had a rupture of the PSA during compression. Subsequently, both patients were treated surgically. A third patient developed deep vein thrombosis of the common femoral vein after compression and received anticoagulation without further complications.

All in all, MC showed a procedural success rate of 75.3% and a procedural complication rate of 1.7%. 
UGTI Approach

After the first UGTI attempt, 212 (74.4%) PSAs were successfully occluded (Figure 4). Forty-two patients (14.7%) required >1 UGTI with a maximum of 3 applications to achieve complete PSA obliteration. Those patients with multiple thrombin injections had significantly more often multicompartimental PSAs compared with those with successful occlusion after the first attempt (P<0.001). Twenty patients whose initial MC therapy failed underwent UGTI with successful closure in 19 cases after the first and in 1 patient after the second thrombin injection. Eight patients whose initial MC therapy failed first crossed from UGTI to MC but then recrossed to UGTI with successful closure after the first attempt.

The overall complication rate for UGTI was low (Table 2).

Table 1. Demographic Characteristics of the Patients With PSA

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Total, %</th>
<th>MC Group, %</th>
<th>UGTI Group, %</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>432</td>
<td>145 (34)</td>
<td>287 (66)</td>
<td>…</td>
</tr>
<tr>
<td>Age, y</td>
<td>73±13</td>
<td>71±14</td>
<td>72±13</td>
<td>0.03</td>
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<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>234 (54)</td>
<td>77 (53)</td>
<td>157 (55)</td>
<td>0.8</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Arterial hypertension</td>
<td>351 (81)</td>
<td>112 (77)</td>
<td>239 (83)</td>
<td>0.1</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>265 (61)</td>
<td>88 (61)</td>
<td>177 (62)</td>
<td>0.8</td>
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<tr>
<td>Tobacco use</td>
<td>110 (26)</td>
<td>31 (21)</td>
<td>79 (28)</td>
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<tr>
<td>Diabetes mellitus</td>
<td>83 (19)</td>
<td>26 (18)</td>
<td>57 (20)</td>
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<tr>
<td>Body mass index, kg*(m^2)^{-1}</td>
<td>28±5</td>
<td>27±4</td>
<td>28±5</td>
<td>0.04</td>
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Comorbidities

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<tr>
<th>Condition</th>
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<th>UGTI Group, %</th>
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<tbody>
<tr>
<td>CAD</td>
<td>252 (58)</td>
<td>79 (54)</td>
<td>173 (60)</td>
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<td>Peripheral artery disease</td>
<td>48 (11)</td>
<td>8 (6)</td>
<td>40 (14)</td>
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<tr>
<td>Emergency procedure</td>
<td>26 (6)</td>
<td>9 (6)</td>
<td>17 (6)</td>
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Anticoagulation and antiplatelet therapy

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<tr>
<th>Therapy</th>
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<th>MC Group, %</th>
<th>UGTI Group, %</th>
<th>P Value</th>
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<tbody>
<tr>
<td>ASS monotherapy</td>
<td>41 (9)</td>
<td>15 (10)</td>
<td>26 (9)</td>
<td>0.5</td>
</tr>
<tr>
<td>Coumadine monotherapy</td>
<td>60 (14)</td>
<td>19 (13)</td>
<td>41 (14)</td>
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<tr>
<td>ASS+clopidogrel</td>
<td>220 (51)</td>
<td>73 (50)</td>
<td>147 (51)</td>
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<tr>
<td>ASS+prasugrel</td>
<td>8 (2)</td>
<td>1 (1)</td>
<td>7 (2)</td>
<td></td>
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<tr>
<td>ASS+coumadine</td>
<td>24 (6)</td>
<td>7 (5)</td>
<td>17 (6)</td>
<td></td>
</tr>
<tr>
<td>Clopidogrel+coumadine</td>
<td>7 (2)</td>
<td>1 (1)</td>
<td>6 (2)</td>
<td></td>
</tr>
<tr>
<td>ASS+clopidogrel+coumadine</td>
<td>71 (16)</td>
<td>28 (19)</td>
<td>43 (15)</td>
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<tr>
<td>None</td>
<td>1 (&lt;0.5)</td>
<td>1 (1)</td>
<td>0 (0)</td>
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Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
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<th>UGTI Group, %</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Diagnostic cardiac catheterization</td>
<td>326 (75)</td>
<td>104 (72)</td>
<td>222 (77)</td>
<td>0.4</td>
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<tr>
<td>Percutaneous coronary intervention</td>
<td>169 (39)</td>
<td>52 (36)</td>
<td>117 (41)</td>
<td></td>
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<tr>
<td>Peripheral angiography and intervention</td>
<td>25 (6)</td>
<td>5 (4)</td>
<td>20 (7)</td>
<td></td>
</tr>
<tr>
<td>Electrophysiology study</td>
<td>61 (14)</td>
<td>23 (16)</td>
<td>37 (13)</td>
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</table>

Sheath size

<table>
<thead>
<tr>
<th>Sheath size</th>
<th>Total, %</th>
<th>MC Group, %</th>
<th>UGTI Group, %</th>
<th>P Value</th>
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</thead>
<tbody>
<tr>
<td>5 F</td>
<td>63 (15)</td>
<td>24 (17)</td>
<td>39 (14)</td>
<td>0.6</td>
</tr>
<tr>
<td>6 F</td>
<td>168 (39)</td>
<td>59 (41)</td>
<td>109 (38)</td>
<td></td>
</tr>
<tr>
<td>7 F</td>
<td>201 (47)</td>
<td>62 (43)</td>
<td>139 (48)</td>
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</table>

Location of pseudoaneurysm

<table>
<thead>
<tr>
<th>Location of pseudoaneurysm</th>
<th>Total, %</th>
<th>MC Group, %</th>
<th>UGTI Group, %</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal external iliac artery</td>
<td>3 (1)</td>
<td>0</td>
<td>3 (1)</td>
<td>0.5</td>
</tr>
<tr>
<td>Common femoral artery</td>
<td>304 (70)</td>
<td>104 (72)</td>
<td>200 (70)</td>
<td></td>
</tr>
<tr>
<td>Superficial femoral artery</td>
<td>111 (26)</td>
<td>38 (26)</td>
<td>73 (25)</td>
<td></td>
</tr>
<tr>
<td>Deep femoral artery</td>
<td>14 (3)</td>
<td>3 (2)</td>
<td>11 (4)</td>
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</table>

ASS indicates acetyl-salicyclic-acid; CAD, coronary artery disease; MC, manual compression; PSA, pseudoaneurysm; and UGTI, ultrasound-guided thrombin injection.
and anterior tibial artery. In addition, it showed persistent flow within the PSA. This patient was referred to vascular surgery for embolectomy and operative PSA repair. Furthermore, one patient developed deep vein thrombosis of the common femoral vein, and one developed an infection of the groin, which was successfully treated by antibiotic therapy.

All in all, UGTI showed a procedural success rate of 79.0% and a procedural complication rate of 1.4%.

### Combined Treatment Algorithm

The combined therapy of PSA consisting of MC and UGTI based on our institutional treatment algorithm accounting for the morphology of the PSA was successful in 416 patients and resulted in an overall success rate of 97.2%. With the assumption that PSAs were not closed in all 4 patients lost to follow-up, treatment success reached 96.3%. The success rate in all evaluable patients was achieved by 535 noninvasive or minimal-invasive treatment attempts, resulting in a procedural success rate of 77.8%, and a procedural complication rate of 1.5%.

### Level of Adherence

The level of adherence in our overall study population was 83.2% (257/309 PSA), which comprises all PSA that could be assigned to the correct PSA treatment arm by retrospective analysis of the PSA morphology in recorded ultrasound data. There were 32 of 154 PSA of the UGTI group that would have belonged to the MC group according to our treatment algorithm (level of adherence for UGTI: 79.2%). In detail, 26 PSA did not qualify for initial UGTI because they were 2 cm, whereas 6 PSA had an indefinite neck. The nonadherence was not associated with an obvious increase in complications. In detail, there was one case of PSA infection but no thromboembolic events, and 18 PSA were closed after UGTI whereas 2 PSA were closed after crossover to MC.

In return, 20 of 155 PSA of the MC group would have belonged to the UGTI group according to our treatment algorithm (level of adherence for MC: 87.1%). In 5 cases, the patients refused UGTI and, in 10 cases, the physician preferred to perform MC on the weekend because of lack of assistance. The remaining 5 PSAs were interpreted as too small although the diameter was 2 cm. Eleven PSAs were successfully closed by MC but 6 of these 20 PSAs finally crossed over to UGTI with successful closure after the first attempt. The remaining 3 PSAs were treated alternatively, 1 by placement of a covered stent and 2 by surgery.

### Alternative Therapy

Our treatment algorithm for postprocedural PSAs was not successful in 12 of 428 patients (2.8%). In 2 patients, the PSA was successfully eliminated by the implantation of a covered stent (0.5%) without further complications. Ten of these patients (2.3%) underwent surgical repair, which was associated with a high complication rate as complications occurred in 3 of 10 cases. One patient had intensive bleeding during surgery requiring transfusion. In one case, a wound infection necessitated further wound revisions occurred, and another patient developed persistent postoperative neuralgia. All affected patients experienced a prolonged hospital stay.

### Discussion

This study reflects our experience with minimally invasive treatment methods of iatrogenic lower extremity PSAs, the manual compression therapy and ultrasound-guided thrombin injection. In consideration of published research results and recommendations to the PSA treatment, we introduced a treatment algorithm based on the morphological features of the PSA. In accordance with this algorithm, MC and UGTI were applied with a high success rate of 97.2%, in eliminating the PSA and a comparably low complication rate of 1.5%.

### Incidence of PSA

The incidence of iatrogenic PSAs in patients undergoing cardiac or peripheral endovascular procedure in our study is 1.49%. This is in line with the reported incidence after
arterial routine clinical groin examinations, which ranges from 0.05% to 2% after diagnostic catheterization and from 2% to 6% after interventional procedures. All groins were clinically examined for suitable arterial puncture site before catheterization. This is reflected in the fact that the majority of all PSAs arose from the common femoral artery, and only a small number of PSA originated from the superficial and deep femoral artery or the external iliacal artery, respectively.

Although it is not possible to draw definite conclusions because of a missing control group, the relatively high body mass, the high number of patients with dual antiplatelet therapy and combination with anticoagulation, and the high percentage of patients with 7 F sheath size confirm these parameters as risk factors for postprocedural pseudoaneurysm.

Minimal-Invasive Treatment Options for PSA
In our department, every PSA is treated immediately to avoid further complications and to shorten the duration of hospital stay. Based on the individual PSA morphology, our algorithm should support the physician in finding the best treatment option. Because of assumable disadvantages of MC compared with UGTI, including long procedure times and patient and operator discomfort during compression, UGTI was installed as the primary option. However, apart from incompressible PSAs, MC should directly be performed when morphological PSA features would predict potential risks for UGTI. Based on previous reports and own experience, we determined small diameter, an indefinable neck and direct adjacency of the PSA to vessels as relative and concomitant arteriovenous fistula as absolute contraindication for thrombin injection, the latter because of potential risk of thrombin leakage into the venous circulation.

There is a relatively high recurrence rate after PSA treatment in patients receiving anticoagulant therapy (as high as 25% to 35%). Likewise, we found significant higher INR levels in patients with repeated UGTI attempts compared with those with initial treatment success of UGTI (1.1 versus 1.3; \( P=0.001 \)). We did not find higher INR levels in patients with repeated MC attempts compared with those with initial treatment success of MC. However, this was probably because of the fact that INR levels were, in general, to some extent, higher in patients within the MC group compared with the UGTI group (1.34 versus 1.14; \( P=0.048 \)). Therefore, in regard to the treatment success, it seems reasonable to lower elevated INR levels before starting MC or UGTI, if possible. Likewise, one has to consider whether anticoagulation can be interrupted or antiplatelet therapy might be modified in patients with triple therapy.

On the contrary, these data support the notion that small PSAs can be treated with just observation, especially in patients who have no symptoms and have normal coagulation and platelet function, respectively. Likewise, Kent et al found spontaneous closure in PSA <18 mm. By doing this, the mean length of stay of actual 5.7±8.4 days in the MC group might be reduced. However, we cannot further support or disprove this thesis because observation only was not integrated in our treatment algorithm, mainly because of the expected high number of patients under antiplatelet therapy and anticoagulation. Nonetheless, we consider it as a promising alternative in patients with small PSAs who have no symptoms and have normal coagulation and platelet function, respectively.

Manual Compression Therapy
Ultrasound-guided compression has been shown to be safe and cost effective for achieving PSA closure with a success rate of 75% to 98%. At our institution, we perform direct manual compression without ultrasound control, which has been shown to be as successful and safe as USGC. Because it requires less technical equipment than USGC, MC is cost effective and can be performed on any ward and any time. Likewise, USGC instead of MC was performed in only 3 cases. Furthermore, these cases were randomly distributed.

Table 3. Periprocedural Complications

<table>
<thead>
<tr>
<th></th>
<th>Manual Compression Therapy</th>
<th>Ultrasound-Guided Thrombin Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral embolization</td>
<td>0</td>
<td>3 (0.8%)</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>1 (0.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>PSA infection</td>
<td>1 (0.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>PSA rupture</td>
<td>1 (0.6%)</td>
<td>0</td>
</tr>
<tr>
<td>Total complication rate</td>
<td>3 (1.7%)</td>
<td>5 (1.4%)</td>
</tr>
</tbody>
</table>

PSA indicates pseudoaneurysm.
over the study period and were not associated with special morphological features of the aneurysm.

However, compression therapy has considerable drawbacks. The compression time and the subsequent bed rest with compression bandage are relatively long. Coley et al found that the mean compression time was 42.6±33.9 minutes for uniloculated PSAs and 69.3±53.6 minutes for multiloculated pseudoaneurysms. In our institution, the precise compression time was not recorded, but the assumed compression time was 45 to 60 minutes. Moreover, patients were confined to bed with compression bandage for ≥12 hours, which is considerably longer than after UGTI. In addition to the long procedure, the patients usually need to be pretreated with narcotic analgesia because the procedure is associated with pain and discomfort of patients.

In the literature, the procedure carries an overall complication rate of 3.6% and risk of rupture of 1%. We assume that our low complication rate of 1.7% is because of consequent application of our treatment algorithm especially because small PSAs are relatively stable and tend to undergo spontaneous thrombosis.

Percutaneous Thrombin Injection

The success rate of thrombin injection reported in the literature has been consistently high, at an average of 97% (range, 92% to 100%), even with patients treated with therapeutic levels of anticoagulants. Most authors describe lower success rate after first thrombin application (range 69% to 92%) with increased PSA closure rate after multiple thrombin injections. Similar to previous reports, our patients with multiple thrombin injections had significantly more often multicompartimental PSAs (P < 0.001). Likewise, in multilobar PSAs, at first we did not inject the lobe closest to the parent artery. Although this technique seems to be less effective compared to injecting the lobe closest to the parent artery, we did so to decrease the risk of intraarterial thromboembolism.

However, toward the end of the study period, we began to directly inject the lobe closest to the parent artery, especially if the other morphological properties made this lobe suitable for UGTI. In our experience, this approach increased the initial success rate of UGTI without raising the complication rate.

The overall complication rate in the literature is 1.3% with an embolic rate of 0.5%. Our 1.4% overall complication rate and 0.8% rate of thromboembolic complications including the initial learning curve is low and consistent with other reported rates. There are some techniques on how to prevent a direct thrombin injection into a native vessel. The most important step is to recheck the needle placement into the center of the PSA cavity under ultrasound guidance. For this purpose, most physicians use the 3-way stopcock method with injection of saline to document that the needle tip is in the proper location.

In our study 2 of 3 cases of arterial thromboembolism developed presumably as a consequence of compression during or immediately after thrombin injection, which happened early in our experience. Therefore, we and others do not recommend any compression during or immediately after thrombin injection with incomplete occlusion of the PSA cavity.

It has been described that patients receiving thrombin are at risk for developing antifactor V antibodies, which may expose them to an immunologic cross-reaction to human factor V. At our department, human thrombin is used instead of bovine thrombin because the risk of allergy is potentially lower. With our patients, we did not observe any allergic reactions after single and particularly multiple thrombin injections.

Level of Adherence

Although all physicians in our departments were urged to apply our algorithm to PSA treatment it is obvious that this was not feasible in all cases for various reasons. Nonetheless, from our viewpoint, there was a high definite level of adherence in our overall study population (257/309 PSA: 83.2%). There are 3 main reasons for nonadherence to MC group in PSA <2 cm or indefinable necks: our growing level of experience toward the end of the study period, which gave us the accuracy to even treat smaller PSA with UGTI; the high number of patients under anticoagulation and antiplatelet therapy, which prompted us to treat the PSA; and finally the patient’s wish. Thereby the nonadherence was not associated with an obvious increase in complications. In return, the level of adherence for MC was 87.1%, and the reasons for nonadherence were mainly driven by underestimation of PSA size, patients wish and lack of assistance on the weekends.

In conclusion, the majority of nonadherence was because of noncompliance with the PSA diameter according to our treatment algorithm. Likewise, by lowering the PSA diameter assignable to UGTI to 17 mm, the level of adherence in the UGTI group rises from 79.1 to 96.1% without obvious increase in complications. On the contrary, there was a strikingly high number of alternative therapy in patients with large PSA but nonadherence to UGTI. From our viewpoint, this fact further supports our algorithm because these patients might have saved from more complicated alternative therapy including surgery if they would have been assigned correctly to UGTI.

Combined Treatment Approach

The combined therapy of PSA consisting of MC and UGTI based on our institutional treatment algorithm resulted in an overall success rate of 97.2%. Furthermore, 2 complex PSAs were successfully treated by implantation of a covered stent in crossover technique. Along with simultaneous balloon occlusion of the PSA entry site during UGTI, these endovascular crossover techniques represent promising strategies to extend minimal-invasive treatment of complex PSA. Accordingly, surgical management was only required in 2.3% of patients. Lumsden et al reported complication and mortality rates as high as 21% and 2.1%, respectively, for surgical repair in their series. In our study, surgical repair was also associated with a high complication rate of 30%.

Limitations

This was a single-center retrospective analysis that had all the known limitations of such studies. Ultrasound imaging was only performed in clinically suspected cases of PSA. Performing primary duplex scanning in all patients after catheterization, the PSA incidence might have been higher, but this approach is not feasible in such large patient population. Another limitation of the study is that the procedural techniques were operator dependent, which could potentially
confound the results, although all our specialists confirmed to have predominantly followed our treatment algorithm. Besides, procedural outcome and follow-up data were assessed only until hospital discharge.

Furthermore the trend in arterial access for PCI throughout the world is toward radial access, resulting in significantly lower vascular and bleeding complications. Accordingly, the number of arterial procedures being performed from the femoral artery access site is declining. However, even in the United States, femoral access PCI actually still accounts for >85% of PCIs. But even with rising numbers of radial access women in recently stopped SAFE-PCI study. Moreover, as PCI in which a good back-up is required, which may be more PCI because of access-site crossover, for example, in complex PCI, there will still be a relevant number of femoral access PCI because of access-site crossover, for example, in complex PCI in which a good back-up is required, which may be more achievable via the femoral access route. Likewise, crossover to femoral access occurred in >6% of radial access treated women in recently stopped SAFE-PCI study. Moreover, as in our study population, femoral access will still play a major role in peripheral interventions or electrophysiology studies. Additionally, the message in this report might be relevant to the use of percutaneous valves and closure devices as well. These procedures that are on the rise are frequently associated with femoral access complications including femoral PSAs. Likewise, we are currently testing our treatment algorithm in PSAs after transfemoral TAVI at both sites of our institution.

Finally, apart from our abovementioned reasons, our treatment algorithm is to a great extent arbitrary and other approaches might be highly effective and safe as well.

Conclusions

In summary, the presented potential algorithm, which determines the application of UGTI or MC for treatment of iatrogenic PSAs of the lower extremity based on morphological features, facilitates highly effective and safe PSA elimination. Moreover, even in case of initial treatment failure, it is worth performing further attempts according to this algorithm before escalating therapy toward surgical repair.

Disclosures

None.

References


Safety and Efficacy of a Potential Treatment Algorithm by Using Manual Compression Repair and Ultrasound-Guided Thrombin Injection for the Management of Iatrogenic Femoral Artery Pseudoaneurysm in a Large Patient Cohort

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Circ Cardiovasc Interv. 2014;7:207-215; originally published online April 1, 2014; doi: 10.1161/CIRCINTERVENTIONS.113.000836

Circulation: Cardiovascular Interventions is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2014 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7640. Online ISSN: 1941-7632

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circinterventions.ahajournals.org/content/7/2/207

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