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Ultrasound Guided Thrombin Injection is a Safe and Effective Treatment for Femoral Artery Pseudoaneurysm in the Morbidly Obese

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Abstract

Introduction—Ultrasound guided thrombin injection (UGTI) is a well-established practice for treatment of femoral artery pseudoaneurysm. This procedure is highly successful but dependent on appropriate pseudoaneurysm anatomy and adequate ultrasound visualization. Morbid obesity can present a significant technical challenge due to increased groin adiposity, resulting in poor visualization of critical structures needed to safely perform the procedure. We aim to evaluate the safety and efficacy of UGTI to treat femoral artery pseudoaneurysm in the morbidly obese.

Methods—This is a retrospective cohort study in which all patients who underwent UGTI at The Ohio State University Ross Heart Hospital from 2009 to 2014 were analyzed for patient characteristics and stratified by body mass index (BMI). Patients with BMI ≥ 35 were considered morbidly obese and were compared to patients with a BMI < 35. Outcome was failed treatment resulting in residual pseudoaneurysm.

Results—Our cohort consisted of 54 patients who underwent thrombin injection. There were 41 non-morbidly obese, and 13 morbidly obese patients. Mean age was 64.5 years. The cohort was 44.4% male. There were 6 failures of which 1 underwent successful repeat injection, and 5 underwent open surgical repair. There was no statistically significant difference in failure between non-morbidly obese, and morbidly obese patients (9.8% vs. 15.4%, p=0.45). There were no embolic/thrombotic complications.

Conclusion—UGTI is a safe and effective therapy in the morbidly obese for the treatment of femoral artery pseudoaneurysm. In the hands of experienced sonographers and surgeons with adequate visualization of the pseudoaneurysm sac, ultrasound guided thrombin injection should remain standard therapy in the morbidly obese.

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Keywords

Femoral artery pseudoaneurysm; morbid obesity; ultrasound guided thrombin injection

1.1 Introduction

Femoral artery pseudoaneurysm (FAP) after endovascular intervention is a common complication with an incidence as high as 2.9%.¹ The current standard of treatment for FAP is ultrasound guided thrombin injection (UGTI), in which an ultrasound probe is used to locate and guide a needle into the sac where thrombin is injected, promoting thrombosis and sealing the luminal defect.² Though this procedure spares the patient from the morbidity of an open surgical repair, UGTI is not without risk.^{3,4,5} Complications of UGTI can include distal embolization resulting in acute limb ischemia.⁵ In addition, UGTI is not always initially successful, requiring repeat injection or surgical repair.^{5,6}

In the United States obesity is epidemic, making up approximately 30% of the adult population and is a significant risk factor for FAP.⁷ Concurrently, improving technology and drive for less invasive procedures has notably increased the number of endovascular procedures performed, increasing the incidence of FAP.^{8,9} When FAP occurs in the morbidly obese (MO), greater tissue adiposity makes UGTI more technically difficult due to the reduction in ultrasound imaging quality necessary for safe and effective treatment.^{5,10} Thus, the present study was undertaken to evaluate whether MO is associated with increased failure or complications after UGTI.

1.2 Materials and Methods

1.2.1 Study Design

This is a single institution retrospective cohort study. In order to find patients treated with FAP, treated with UGTI, billing records for CPT code 36002 identifying patients who underwent thrombin injection, as well as lower extremity duplex were queried from June 2009 – June 2014 at the Ross Heart Hospital at The Ohio State University Wexner Medical Center. Patient chart review was performed and patient characteristics were recorded. UGTI is reserved at our institution for femoral pseudoaneurysms 1.5 – 6.5 cm in maximal diameter with a neck width < 1.0 cm, in patients without hemodynamic instability, infected pseudoaneurysm, expanding pulsatile mass, distal limb ischemia/neurologic deficit, or overlying skin necrosis/cellulitis. No patients had arteriovenous fistula or concurrent deep venous thrombosis.

The primary endpoint recorded was persistent pseudoaneurysm after UGTI, as defined by continued flow into the femoral pseudoaneurysm resulting in need for surgical repair or re-injection. Secondary endpoints include thrombotic/embolic complications from UGTI, and persistent pseudoaneurysm after UGTI that resolved on follow up imaging.

1.2.2 Femoral Artery Pseudoaneurysm Imaging and Analysis

All pseudoaneurysm imaging was conducted with color Doppler ultrasound imaging via a sector 7–10 MHz or 2.5–3.5 MHz transducer. The vascular ultrasound machines used by our institution for FAP diagnosis and UGTI treatment include the Philips iU22, General Electric Logiq E, and Zonare Z. Using VascuPro™ imaging software (Consensus Medical Systems Inc., Richmond, BC), pseudoaneurysm neck length, width, and overall size, depth of the common femoral artery, and depth to the pseudoaneurysm sac were measured by vascular surgeons.

1.2.3 Ultrasound Guided Thrombin Injection

Patients were treated with thrombin injection per surgeon preference using concentrations of either 100 IU/mL or 1000 IU/mL (Pfizer Inc., New York). The thrombin was injected under ultrasound guidance with color flow. Saline injection was initially performed to confirm needle entry in the FAP followed by thrombin. The volume of thrombin injected was determined by cessation of color flow. All injections were performed by trained vascular surgeons at a single institution. Follow up duplex imaging was performed within 24–48 hours to assess resolution or recurrence as per our institution's standard of care.

1.2.4 Statistical Analysis

Student's t test was used for normally distributed data. Univariate comparisons between groups were made using χ^2 and Fischer's Exact test as appropriate. Calculations were performed using commercially available STATA software (v 8.0, College Station, TX). This study was approved by the Ohio State University Institutional Review Board.

1.3 Results

1.3.1 Patient Demographics

573 patients who underwent femoral artery duplex studies were identified by CPT code and 121 were diagnosed with FAP. 67 cases were deemed clinically insignificant and resolved spontaneously on follow up imaging without further intervention. The remaining 54 patients were classified into two separate groups based on BMI: morbidly obese (MO, BMI ≥ 35 , $n = 13$) or non-morbidly obese (non-MO, BMI < 35 , $n = 41$) (Table 1). There were no statistically significant differences in patient sex or anticoagulation, or anti-platelet therapy between groups.

1.3.2 Ultrasound Characteristics of Morbidly Obese and Non-Morbidly Obese Patients

The ultrasound measured distance from the probe to the common femoral artery was used as our measure of thigh adiposity. There was a nearly significant increase in the mean depth to the common femoral artery in MO patients. (Table 2, 4.3 cm vs 3.7 cm, $p=0.05$).

There was no significant difference in mean depth to the pseudoaneurysm sac (Table 2, 1.6 cm vs. 1.5 cm, $p=0.50$). Interestingly, further analysis of other FAP characteristics indicate significant increase in mean neck length in MO patients (1.1 cm vs 0.7 cm, $p<0.02$), however, overall dimensions including neck width and maximal diameter were otherwise similar (Table 2). All FAPs were able to be completely visualized by ultrasound imaging.

1.3.3 Morbid Obesity is Not Associated with UGTI Treatment Failure or Complication

There was no significant difference in failure requiring re-intervention between MO and non- MO patients (Table 3, 9.8 % vs. 15.4%, $p=0.58$). When we included patients with residual FAP, which was defined as persistent flow on follow up ultrasound that did not require reinjection into our UGTI failure analysis, there was no significant difference in failure (Table 3, 15.4% vs. 19.5%, $p=0.52$). There was also no increased risk of receiving open surgical repair (Table 3, 17% vs. 15.4%, $p=0.35$) and there were no thrombotic or embolic complications in our cohort (Table 3).

1.3.4 Clinical and Ultrasound Characteristics of Patients with UGTI Treatment Failure

Five patients had a large residual FAP > 2.5 cm and underwent open surgical repair (Table 4, patients 1–5). One patient with a 1.6 cm residual FAP underwent successful repeat UGTI (Table 4, patient 6). In order to determine if there were any significant patient or ultrasound characteristics associated with treatment failure, clinical and pseudoaneurysm factors were compared between patients with primary UGTI failure and those who had successful treatment (Table 5). There were no significant covariates associated with UGTI failure in our cohort. There was a trend of increased pseudoaneurysm depth in the treatment failure group (Table 5, 1.5 cm vs. 1.9 cm, $p=0.16$). Therefore, we further subdivided patients based on depth to pseudoaneurysm, and found that those as deep as 2 cm or more had trended towards an increased risk of failed UGTI needing operative intervention (Table 6, Range 0.5 cm – 2.75 cm, RR 6.8, CI 0.8–57, $p=0.06$). Pseudoaneurysm depth ≥ 2 cm was not significantly associated with primary UGTI failure, or residual FAP.

1.4 Discussion

There has been an increase in the treatment of vascular diseases utilizing femoral percutaneous access, with progressively larger sized sheaths that independently increase the risk of FAP.^{8,9} Concurrently, obese patients in previous studies have been shown to have a higher incidence of FAP and increased risk of complications.^{5,9,11} In a large cohort evaluating 630 FAPs in a single institution, BMI ≥ 28 was independently associated with an increased risk of FAP (OR 2.21, $p<0.01$) as was sheath size $\geq 6F$ (OR 5.13, $p<0.001$).⁹ Thus, the number of post-catheterization FAPs will continue to increase, especially among the obese.

Adequate ultrasound imaging to evaluate FAP is essential to safe and reliable treatment. However, increased adiposity from larger body habitus detrimentally affects ultrasound more than any other imaging modality.^{10,12} Fat tissue greatly attenuates ultrasound energy as a function of tissue thickness, resulting in decreased beam intensity, poorer image quality, and decreased assessment of vascular structures.^{10,12} Thus, our study addresses an important issue of whether significant obesity interferes with the safety and efficacy of UGTI.

Using the depth to the common femoral artery as a measure of tissue adiposity, we found that MO patients had a significant additional 0.6 cm of increased thigh adiposity compared to non-MO patients. However, there was no significant difference in UGTI treatment failure in MO vs. non-MO patients. We found that MO did not have an increased ultrasound-

measured depth to the pseudoaneurysm sac as soft tissue compression during UGTI and the significantly increased 0.4 cm pseudoaneurysm neck length in MO patients, placed the pseudoaneurysm sac at a similar depth to non-MO patients. We believe this may explain why there is no increased risk of UGTI failure when stratifying by MO; characteristics of the FAP and compression during UGTI placed the pseudoaneurysm sac at a similar depth, regardless of MO. Patients with a depth to pseudoaneurysm of 2 cm or more, trended towards an increased risk of failed UGTI needing open operative repair, indicating that perhaps, the absolute depth to the pseudoaneurysm, rather than the presence of MO may be a risk factor for UGTI failure. The only other paper that addresses BMI as a risk factor UGTI failure was in a cohort of 140 patients undergoing UGTI, which found that BMI > 30 slightly increased the risk of failure (OR 1.39, $p < 0.05$).¹³ We believe that our differing results may be due to difference in patient population and advances in technology. Their cohort was older than our own (76 vs. 64 years), did not utilize arterial closure devices after catheterization, and used older ultrasound technology where adequate FAP visualization may have been limited.¹³ At any rate, repeat UGTI successfully treated most recurrences regardless of BMI in their cohort, sparing patients the historically significant morbidity and mortality of open surgical repair.^{4,13}

An alternative therapy to FAP is ultrasound-guided compression. This approach has been shown to be effective with low complication rate.^{3,14} However, compression is time and labor intensive for the ultrasonographer, can cause significant pain with compression that often need further analgesics and sedation, and has recurrence rates as high as 30%.^{6,14} Compression therapy alone is also more likely to fail in patients taking anti-coagulation, often necessitating reversal before treatment.^{15,16,17,18} In contrast, several studies report that UGTI outcomes are unaffected by anti-coagulation use, abrogating the need for reversal.^{15,16,17,18} Thus, at our institution, for FAP over between 1 and 6.5 cm in size in the stable patient, UGTI is used as first-line therapy. Furthermore, our study reiterates the safety of UGTI, as we had no post-procedural thrombotic or embolic complications. Indeed, complications directly attributed to UGTI in the literature are uncommon, with a reported embolic rate of 0.8%, venous thrombosis risk of 0.2%, exceedingly rare anaphylactic response to bovine thrombin, and no directly attributed mortality.^{16,19}

There are several limitations in our study. Our data represents a retrospective review at a single institution. Given that diagnostic and therapeutic utility of ultrasound imaging is user-dependent, these results may not be generalizable. However, our FAP characteristics and overall UGTI success, recurrence, and surgical conversions rates were similar to other institutions, suggesting that our results have broader applicability.^{5,6,13,14,15,16} Our study has a relatively small cohort of patients representing our 5-year experience that may be underpowered to detect significant differences. Lastly, the largest patient in our study had a BMI of 44. Our results may not be generalizable to patients with greater degrees of obesity.

1.5 Conclusion

Ultrasound guided thrombin injection appears to be a safe and effective treatment for femoral pseudoaneurysm in the morbidly obese. At experienced centers, ultrasound guided

thrombin injection should remain first-line therapy in hemodynamically stable patients, irrespective of body mass index.

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Abbreviations

UGTI	Ultrasound guided thrombin injection
FAP	Femoral artery pseudoaneurysm
MO	Morbid obesity
BMI	Body mass index

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Table 1

Summary Characteristics of Femoral Artery Pseudoaneurysm Cohort by Morbid Obesity

Characteristic	Total (n=54)	non-MO (n=41)	MO (n=13)	<i>p-value</i>
Age (Years)	64.5 (13.0)	64.4 (12.9)	64.7 (13.6)	0.94
Sex (Male)	44.4%	46.1%	43.9%	0.89
BMI	29.9 (6.3)	27.1 (4.1)	38.7 (3.3)	< 0.001 *
Anti-platelet Use	43 (79.6%)	32 (78.0%)	9 (69.2%)	0.43
Anti-coagulation Use	17 (31.5%)	13 (31.7%)	4 (30.7%)	0.99
Multiple anti-thrombotic Use	23 (42.6%)	19 (48.7%)	4 (30.7%)	0.36
Successful UGTI	49 (91%)	36 (92.3%)	13 (86.6%)	0.61

Values are means or number, parentheses are standard deviation or percentages. MO, Morbid Obesity; BMI, Body Mass Index; UGTI, Ultrasound Guided Thrombin Injection,

* indicates statistically significant value

Table 2

Femoral Artery Pseudoaneurysm Characteristics

Characteristic	Total (n=54)	non-MO (n=41)	MO (n=13)	<i>p-value</i>
Depth to Pseudoaneurysm	1.5 (1.2)	1.5 (0.6)	1.6 (0.9)	0.50
Depth to Common Femoral Artery	3.8 (1.0)	3.7 (1.0)	4.3 (1.0)	0.05 *
Maximal Diameter	3.1 (1.4)	3.0 (1.3)	3.4 (1.6)	0.30
Neck Length	0.8 (0.5)	0.7 (0.3)	1.1 (0.2)	0.02 *
Neck Width	0.4 (0.2)	0.4 (0.2)	0.4 (0.2)	0.52

All measurements in cm. Parentheses are standard deviation. MO, Morbid Obesity,

* indicates statistically significant value

Table 3**Outcome After UGTI by Morbid Obesity**

Outcome	Total (n=54)	non-MO (n=41)	MO (n=13)	<i>p-value</i>
UGTI Failure Requiring OR	5 (9.3%)	3 (7%)	2 (15.4%)	0.35
UGTI Failure Requiring OR/Reinjection	6 (11.1%)	4 (9.8%)	2 (15.4%)	0.45
Persistent FAP after UGTI	10 (18.5%)	8 (19.5%)	2 (15.4%)	0.52
Limb Ischemia/Thromboembolism	0 (0%)	0 (0%)	0 (0%)	--

Values are number, parentheses are percentages. MO, Morbid Obesity; UGTI, Ultrasound Guided Thrombin Injection, OR, Operating Room

Table 4

Characteristics of Patients Needing Re-intervention After UGTI

Patient	Age (Years)	Sex	BMI	Initial Diameter (cm)	Residual Diameter (cm)	Intervention
1	52	M	25	2.6	2.6	OR
2	74	M	21	2.8	2.8	OR
3	53	F	22	3.6	3.6	OR
4	60	M	42	3.6	3.6	OR
5	62	M	38	2.9	2.9	OR
6	76	F	24	1.7	1.6	Repeat UGTI

UGTI, Ultrasound Guided Thrombin Injection; BMI, Body Mass Index; OR, Operating Room.

Table 5

Covariate Analysis of Patient and Pseudoaneurysm Characteristics by UGTI Failure Requiring Re-intervention

Characteristic	Success (n=48)	Failure (n=6)	<i>p-value</i>
Patient Factors			
Age (Years)	64.2 (10.5)	62.9 (10.1)	0.76
Sex (Male)	40.9%	66.7%	0.39
Anti-platelet Use	34	5	0.99
Anti-coagulation Use	14	3	0.37
Multiple anti-thrombotic Use	19	3	0.68
Pseudoaneurysm Factors (cm)			
Depth to Pseudoaneurysm	1.5 (0.7)	1.9 (0.7)	0.16
Depth to Common Femoral Artery	3.9 (1.0)	4.0 (1.4)	0.71
Maximal Diameter	3.2 (1.5)	2.9 (0.7)	0.61
Neck Length	0.8 (0.5)	0.9 (0.9)	0.54
Neck Width	0.4 (0.2)	0.4 (0.2)	0.97

Values are means or number, parentheses are standard deviation. UGTI, Ultrasound Guided Thrombin Injection.

Table 6**Outcome After UGTI by Pseudoaneurysm Depth**

Outcome	Total (n=54)	FAP Depth < 2 cm (n=34)	FAP Depth ≥ 2 cm (n=20)	<i>p-value</i>
UGTI Failure Requiring OR	5 (9.3%)	1 (2.9%)	4 (20%)	0.06
UGTI Failure Requiring OR/Reinjection	6 (11.1%)	2 (5.9%)	4 (20%)	0.13
Persistent FAP after UGTI	10 (18.5%)	5 (14.7%)	5 (25%)	0.25

Values are number, parentheses are percentages. UGTI, Ultrasound Guided Thrombin Injection, FAP, Femoral Artery Pseudoaneurysm, OR; Operating Room.