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Groin complications in endovascular mechanical thrombectomy for acute ischemic stroke: a 10-year single center experience

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ABSTRACT

Background The increasing utilization of balloon guide catheters (BGCs) in thrombectomy therapy for ischemic stroke has led to concerns about large-bore sheaths causing vascular groin complications.

Objective To retrospectively assess the impact of large large-bore sheaths and vascular closure devices on groin complication rates at a comprehensive stroke center over a 10-year period.

Methods Radiological and clinical records of patients with acute ischemic stroke who underwent mechanical endovascular therapy with an 8Fr or larger sheaths were reviewed. A groin complication was defined as the formation of a groin hematoma, retroperitoneal hematoma, femoral artery pseudoaneurysm, or the need for surgical repair. Information collected included size of sheath, type of hemostatic device, and anticoagulation status of the patient. Blood bank records were also analyzed to identify patients who may have had an undocumented blood transfusion for a groin hematoma.

Results A total of 472 patients with acute ischemic stroke who underwent mechanical thrombectomy with a sheath and BGC sized 8Fr or larger were identified. 260 patients (55.1%) had tissue Plasminogen Activator (tPA) administered as part of stroke treatment. Vascular closure devices were used in 97.9% of cases (n=462). Two patients were identified who had definite groin complications and a further two were included as having possible complications. There was a very low rate of clinically significant groin complications (0.4–0.8%) associated with the use of large-bore sheaths.

Conclusions These findings suggest that concerns for groin complications should not preclude the use of BGCs and large-bore sheaths in mechanical thrombectomy for acute ischemic stroke.

removal of the thrombus. Because BGCs are relatively large (7Fr–9Fr), some neurointerventionalists have been reluctant to use them because of concerns relating to groin complications in a population of patients who are frequently anticoagulated or who have received tissue Plasminogen Activator (tPA).

To circumvent these concerns, many neurointerventionalists instead rely on thrombectomy devices through standard guide catheters, distal access catheters and via 6Fr long sheaths. However, Nguyen and colleagues³ reported inferior recanalization rates and poorer clinical outcomes without the use of a BGC as the delivery platform for stent retriever devices. As such, use of a BGC and the requisite larger sheath appears to be of benefit provided groin complications do not negate good clinical outcomes.

Femoral artery complications have been described by several authors in the setting of acute stroke⁴ and other interventions,^{5, 6} however, few have correlated the size of the sheath and type of vascular closure device used with the incidence of such complications. We aimed to retrospectively evaluate the impact of large sheath sizes and vascular closure devices on groin complications, in a high-volume neurointerventional center.

METHODS

The study institution is a Comprehensive Stroke Center certified by The Joint Commission, averaging 682 annual ischemic stroke admissions over a period spanning 2005–2014. Neurointervention rates over this period have ranged between 8.3% and 21% of patients presenting with acute stroke. All aspects of the thrombectomy procedure (including groin puncture and vascular closure device deployment, if used) were performed by fellowship trained neurointerventional specialists. Our neurointerventional patient database was reviewed for all patients who underwent endovascular mechanical thrombectomy for acute ischemic stroke between 1 January 2005 and 31 December 2014. Inclusion criteria included all patients who had a sheath and BGC sized 8Fr or 9Fr used during their procedure. Only 8Fr and 9Fr sheath sizes were used for BGCs at our study institution. Any patients who had a smaller sized sheath used were excluded. Arteriotomy access in all cases was performed without ultrasound guidance. Procedure reports were used to obtain information on: (1) the use of a micro-puncture kit for femoral artery

INTRODUCTION

Cerebral arterial thrombectomy for the treatment of acute ischemic stroke has been available in the USA outside clinical trials for the past decade. There has been considerable evolution in thrombus retrieval technology resulting in rates of good recanalization climbing from 48% (TIMI grade 2 or 3) in the MERCI trial in 2004,¹ to greater than 86% (modified TICI grade 2b or 3) reported in the EXTEND-IA trial in 2015.² One component that has evolved only modestly over this period is the reliance upon the balloon guide catheter (BGC), available since 2001. This type of catheter allows temporary proximal arterial occlusion during



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access, (2) the size of the sheath, (3) the type of vascular closure device used (if any), (4) whether the patient received pre-procedure intravenous (IV) tPA and/or intra-procedural intra-arterial (IA) tPA, and (5) whether a pelvic angiogram was performed prior to hemostasis. Electronic Medical Records (EMR) were reviewed for each patient to determine pre-procedure anticoagulant use and demographic information including age and gender. Patients on antiplatelet agents were not considered to be anticoagulated. Patients were kept on bed-rest for a minimum of 6 h post-procedure.

Patient radiological reports were reviewed for evidence of ultrasound imaging of the groin or CT of the abdomen and/or pelvis, up to 30 days post-procedure. EMR were also examined for descriptions of complications at the groin site. Groin complications were sub-classified into ‘definite’ or ‘possible’. A definite groin complication was defined as groin hematoma, retroperitoneal hematoma or femoral artery pseudoaneurysm meeting any of the following criteria: (a) requiring surgical or radiological intervention to treat, (b) requiring at least 1 unit of blood transfusion, (c) causing >3 g drop in hemoglobin, (d) causing a 10% drop in hematocrit, (e) requiring surgical intervention to correct vessel injury due to vascular closure device deployment, or (f) contributing to or resulting in the death of the patient. A possible groin complication was defined as blood transfusion within 72 h of the thrombectomy procedure without a clear documented explanation as to the reason for the transfusion. Other hematomas not meeting the above criteria were not included in the analysis.

Finally, patients in our neurointerventional database were cross-checked with the hospital blood-bank records for a specified time period (2005–2014) to identify any patient who may have had a blood transfusion during their admission for stroke treatment. This was carried out to minimize the possibility of the EMR failing to document a significant groin hematoma. This study was approved by the local institutional review board.

RESULTS

A total of 472 patients with acute ischemic stroke who underwent mechanical thrombectomy with a 8Fr or larger sheath and BGC were identified. The mean age±SD was 70±16 years, and

50% were female. Full demographic information is noted in table 1.

Two hundred and sixty patients (55.1%) had tPA administered as part of stroke treatment. Out of these, 103 patients (21.8%) had intra-arterial tPA administered while 123 patients (26.1%) had intravenous tPA administered. 34 patients (7.2%) had both intra-arterial and intravenous tPA, while 212 patients (44.9%) had no tPA given. 59 patients (12.5%) were noted to be on warfarin, with a mean INR of 1.6 (range 0.9–2.9). Only 28 patients (5.9%) had an INR>1.7. A single patient was taking an oral Xa-inhibitor and no patients were taking a direct thrombin inhibitor during the time of review.

Four hundred and forty-eight patients (95%) were treated using an 8Fr sheath and BGC and 24 patients (5%) had a 9Fr sheath and BGC used. The use of a micro-puncture kit for arterial access was documented in 185 cases (39.2%). Vascular closure devices were used in 97.9% of cases (n=462). The 8Fr Angioseal VIP (St. Jude Medical, St Paul, Minnesota, USA) was the most common vascular closure device, used in 443 patients (93.9%) (table 2). A variety of other devices, which are labeled for use in 6Fr sheaths, were also used in a small minority of cases. A pelvic angiogram was documented in 199 cases (42.2%).

Only two patients were identified whom had definite groin complications that met the criteria listed above. The first patient, who was on Warfarin and admitted with an INR of 1.5, had a groin hematoma and pseudoaneurysm post-procedure that was treated by the interventional radiology service with thrombin injection. Although there was a drop in hemoglobin from 13 g to 10.7 g, the patient did not undergo blood transfusion and the hematoma was otherwise allowed to resolve without intervention.

The second patient, who was also on Warfarin and admitted with an INR of 1.2, had a groin hematoma post procedure. She was also noted to have a decrease in hemoglobin from 12.6 g to 6.5 g attributed to the hematoma and was transfused 2 units of blood. For both patients an 8Fr sheath and BGC were used, with the Angioseal as the closure device. Both patients had a pelvic angiogram performed post-procedure that was normal.

A search of blood bank records revealed two additional stroke patients who had blood transfusions within 48 h of groin puncture. One patient had a history of thalassemia minor and iron deficiency anemia. He demonstrated a drop from his baseline hemoglobin of 11.0–8.6 g post-procedure. Five passes were made with the retrieval device and the estimated blood loss was 250 mL. The other patient had no listed confounding hematologic diagnoses and demonstrated a hemoglobin drop from 10.3

Table 1 Demographic and pre-procedural information

Characteristic	N	Percent
Total cases	472	
Gender		
Male	236	50
Female	236	50
Age		
Mean±SD	70±16	
Anticoagulation status		
Warfarin	59	12.5
Mean INR±SD (n=55)	1.6±0.5	
Rivaroxaban	1	0.2
No prior anticoagulation	412	87.3
Patients with INR>1.7	28	5.9
Dual Antiplatelet therapy	10	2.1
Thrombolytic therapy		
IA tPA	103	21.8
IV tPA	123	26.1
IV and IA tPA	34	7.2
No tPA	212	44.9

IA, intra-arterial; tPA, tissue Plasminogen Activator.

Table 2 Sheath size and method of hemostasis

Characteristic	N	Percent
Size of sheath		
8 Fr sheath and guide catheter	448	94.9
9 Fr sheath and guide catheter	24	5.1
Method of hemostasis		
Angioseal VIP (St. Jude Medical, St Paul, Minnesota, USA)	443	93.9
Mynx (AccessClosure, Mountain View, California, USA)	1	0.2
Vasoseal (Datascope, Montvale, New Jersey, USA)	3	0.6
Starclose (Abbott Vascular, Abbott Park, Illinois, USA)	1	0.2
Perclose (Abbott Vascular, Abbott Park, Illinois, USA)	14	3.0
Manual compression	10	2.1

to 7.0 g. Two passes were made with the retrieval device with an estimated blood loss of 100 mL. In neither patient's clinical notes was a groin hematoma nor bleeding described. Neither patient had groin ultrasound imaging nor CT of the abdomen or pelvis to lend support to a groin complication as the source of the anemia. As such, both of these patients have been classified as possible groin complications.

There were no retroperitoneal hematomas requiring transfusion nor intervention. There were no deaths attributed to groin complications. The overall definite groin complication rate was therefore 0.4% (n=2), with a definite and possible groin complication rate of 0.8% (n=4).

DISCUSSION

The main finding in this study was the low rate of groin complication associated with large bore sheaths in thrombectomy therapy. This reflects favorably on one aspect of using BGC during the thrombectomy procedure. BGCs have been associated with superior outcomes for patients receiving thrombectomy therapy. An analysis from the North American Solitaire Stent-Retriever Acute Stroke registry showed that the use of a BGC (versus no BGC) was associated with a shorter procedure time (120 vs 161 min; $p=0.02$), a higher rate of TICI 3 recanalization (53.0% vs 32.5%; $p<0.001$), and a higher rate of good clinical outcome (51.6% vs 35.8%; $p=0.02$).³ Recent randomized clinical trials using stent retriever technology have shown efficacy for the use of endovascular intervention in stroke treatment.^{2 7 8} It appears likely that these studies will result in an increase in procedure rates for acute ischemic stroke. This points to the importance of continued study of procedure complication rates including complications of arterial access.

Arterial puncture site complications during endovascular procedures infrequently cause significant morbidity to the patient, ranging from retroperitoneal hemorrhage and pseudoaneurysm formation to overt arterial bleeding. This in turn can lead to increased hospital time and a need for transfusion or intervention. In addition, achieving hemostasis can be a challenge in patients on anticoagulation, uncooperative patients and those with morbid obesity.

In our study, almost all patients (97.9%) had a vascular closure device used. Larger systematic reviews and meta-analyses reviewing groin complications, usually in the setting of comparing various vascular closure devices and manual compression, have tended to underrepresent sheath sizes greater than 7Fr. The ISAR-CLOSURE study was a randomized clinical trial that showed non-inferiority of vascular closure devices to manual compression in terms of vascular access-site complications and reduced time to hemostasis, in patients undergoing transfemoral coronary angiography.⁹ However, only 6-Fr sized sheaths were used. A meta-analysis by Das and colleagues comparing vascular closure devices and manual compression in interventional radiologic procedures showed no statistically significant difference between the two, although marginally fewer femoral complications with closure devices were noted. Sheaths >8Fr were excluded.⁶

It has been suggested that increasing sheath size leads to a sheath-artery size mismatch and a larger entry site in the artery, requiring longer periods of manual pressure and possibly longer period of bed rest after sheath removal.¹⁰ Most studies evaluating groin complications do so in the context of femoral arterial catheterization during percutaneous coronary interventions (PCIs). The use of arterial sheaths with diameter >6Fr have been identified as an independent predictor of vascular complications and major femoral artery bleeding, with incidences ranging from 1% to 9%.¹¹⁻¹⁵ Use of arterial sheaths >8 Fr has

also been reported to be an independent predictor of retroperitoneal hematoma after PCI.^{10 16}

Other authors have evaluated groin complications in patients who underwent peripheral vascular interventions (PVI). In a retrospective study of the Vascular Study Group of New England (VSGNE) database, Kalish *et al*¹⁷ noted an overall post-procedural groin hematoma rate after PVI of 4.5% and a rate of combined moderate and major hematoma of 0.8%. A sheath size >6Fr was found to be a risk factor of groin hematoma. In addition, interventional procedures usually require some type of antithrombotic medication, and intra-procedural (antiplatelet or anticoagulant) or post-procedural medications (intravenous heparin) have been shown to increase the risks for groin hematoma in some studies¹⁸ but not in others.¹⁷

Our cohort of patients is similar to those described in other international stroke trials, with 12.7% on anticoagulation on admission and 5.9% of total patients having an INR>1.7.¹⁹ Our puncture site complication rate was slightly less than that reported by Applegate and colleagues²⁰ who summarized complications of Angioseal deployment in 3898 patients. This retrospective study demonstrated a minor complication (hematoma, arteriovenous fistula, or pseudo-aneurysm) rate of 0.8% and major complication (vascular death, vascular repair, vessel occlusion, or bleeding with >3 g hemoglobin drop) rate in 0.6% of patients.

In our study, the number of groin complications was too low to meaningfully infer possible relationships between groin complications and anticoagulation, thrombolysis, antiplatelet therapy and type of closure device use. Being that all groin punctures and closure device deployments were performed by neurointerventional attending physicians, it is conceivable that practitioner experience may have played a role. Weaknesses of the study include a single-center retrospective design and its reliance on accurate medical record keeping and coding that could have resulted in a reduced retrospective detection rate. This was in part mitigated this by carefully reviewing all clinical, radiological and blood bank records associated with the patients' admission for stroke treatment. Lastly, this analysis excluded non-clinically significant hematomas and does not represent the rate of minor groin hematoma complications.

CONCLUSION

In our series, there is a very low rate (0.4–0.8%) of clinically significant groin complications associated with the use of 8Fr and 9Fr sheaths. Concerns for vascular groin complications should not preclude the use of large-bore sheaths and BGCs in the endovascular treatment of stroke.

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