Neurointerventional Procedural Complications in a Growing Canadian Regional Stroke Center: Single Hospital Experience Analysis in the Context of Recommended Case Volumes

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■ BACKGROUND: **Evidence continues to emerge regarding the inverse relationship between high neurointerventional case volume and complication rates, leading several medical/surgical societies to recommend minimum volumes for specific procedures. Recent data suggest few centers are meeting these requirements. We report a single center's neurointerventional complication rates with associated case volumes, along with a review of the literature.**

■ METHODS: **A retrospective cohort review of all consecutive patients undergoing diagnostic catheter cerebral angiography and/or neurointerventional procedures between January 1, 2013, and March 1, 2018, was undertaken. No diagnostic or interventional procedures were excluded. All major and minor complications were recorded.**

■ RESULTS: **A total of 1000 procedures (463 diagnostic cerebral angiograms and 537 neurointerventional procedures) were completed. Of the neurointerventional procedures, 216 (40%) were endovascular thrombectomy, 170 (32%) were aneurysmal embolization, and 48 (9%) were carotid stenting. The mean and median age was 60 years. There were 460 women and 540 men. The total number of major complications for diagnostic angiography, endovascular thrombectomy, ruptured aneurysm embolization, unruptured aneurysm embolization, and carotid artery stenting were 4 (0.9%), 4 (1.9%), 10 (11%), 4 (5.4%), and 3 (6.3%), respectively.**

■ CONCLUSIONS: **We provided a single-center experience of the relationship between neurointerventional procedural case volume and complication rates in the growth phase of our center's establishment. We demonstrated that as our center was being developed, specific procedural staffing measures allowed proficiency maintenance, acquisition of new techniques, and complication avoidance, whereas specific case volumes crossed the suggested thresholds as defined in the literature.**

INTRODUCTION

The number of yearly diagnostic catheter cerebral angiograms and neurointerventional procedures performed in the United States continues to increase. This is observed across the spectrum of diseases but mainly driven by increases in diagnostic angiograms, coiling of aneurysms, and endovascular thrombectomy (EVT).[1,2] In 2005, members of the Brain Attack

Key words
- Aneurysm
- Carotid
- Case volume
- Complications
- Neurointerventional
- Stroke

Abbreviations and Acronyms
BAC: Brain Attack Coalition
CAS: Carotid artery stenting
CREST: Carotid Revascularization Endarterectomy versus Stenting Trial
CTA: Computed tomography angiography
EVT: Endovascular thrombectomy
MCA: Middle cerebral artery
MRA: Magnetic resonance angiography
MRI: Magnetic resonance imaging
mRS: Modified Rankin Scale
SAH: Subarachnoid hemorrhage

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Coalition (BAC) developed recommendations for comprehensive stroke centers in the United States, which included minimum case volumes and complication rates for certain procedures.[3] Grigoryan et al.[4] showed that few centers in the United States met the BAC minimum volume criteria for comprehensive stroke center design, with only 7 centers in their database fulfilling all criteria.

In this study, we report the volume of our Canadian Regional Stroke Center institutional diagnostic and neurointerventional procedures and compare with the suggested case volume requirements by the BAC and other medical societies in the literature. Furthermore, we aimed to review the literature of acceptable periprocedural diagnostic and neurointerventional complication rates. The goal of this study is to provide neurointerventional stroke centers with a comprehensive and realistic guide of recommended case volumes and complication rates, while also providing our institutional experience with case volumes and associated complication rates.

METHODS

This study was done at a level 1 trauma center and regional stroke center. The stroke center is supported by 6 full-time diagnostic neuroradiologists, 3 neurosurgeons, 1 interventional neuroradiologist, and 7 stroke neurologists. Services offered include prehospital, emergency access for 24 hours 7 d/wk, and acute and secondary stroke prevention. A retrospective cohort review of all consecutive patients undergoing diagnostic catheter cerebral angiography and/or neurointerventional procedures between January 1, 2013, and March 1, 2018, was undertaken. Patients who underwent multiple diagnostic/neurointerventional procedures had each procedure included as a distinct entry for complication analysis. No diagnostic or neurointerventional procedures were excluded. Neurointerventional procedures were grouped together under the disease treated. For example, all aneurysmal embolization procedures (coiling, stent-assisted coiling, and flow

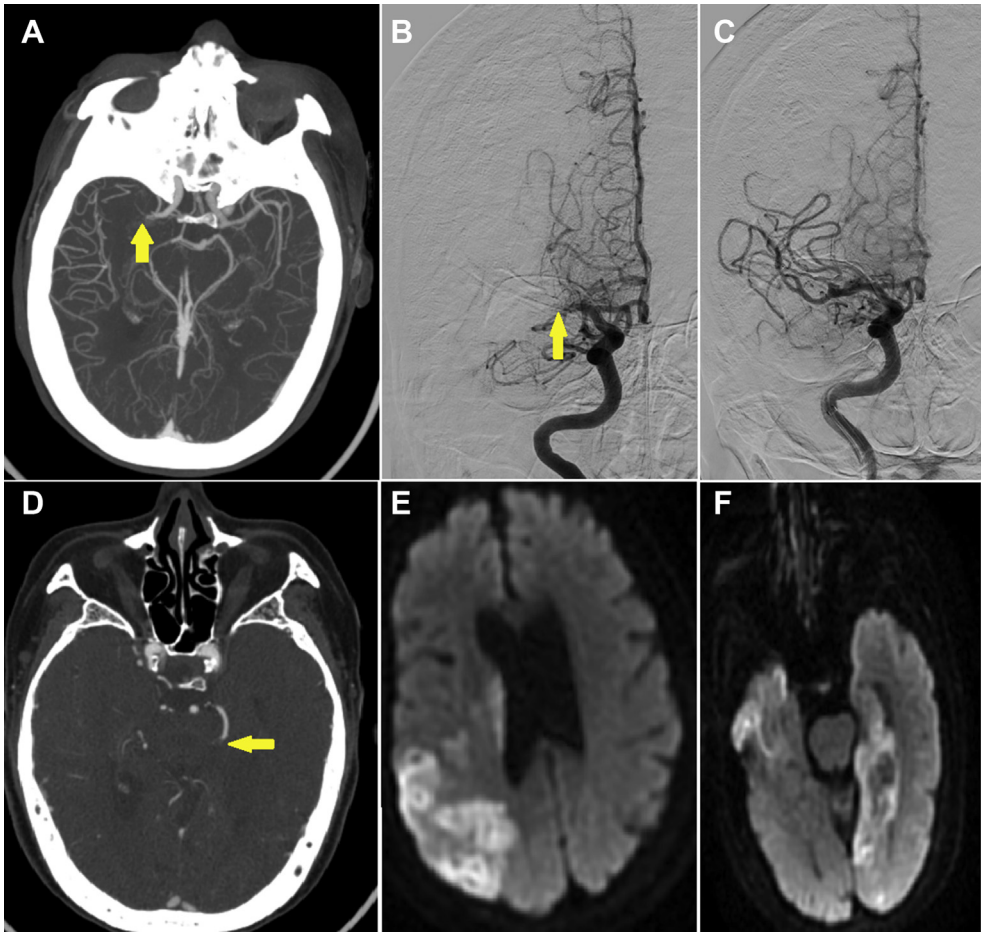

Figure 1. A 75-year-old woman presenting with acute right middle cerebral artery (MCA) stroke. (**A** and **B**) Right MCA segment 1 abrupt occlusion (*yellow arrow*) as shown on computed tomography angiography (CTA) and digital subtraction angiography. (**C**) Initial postthrombectomy angiogram showing restored MCA flow. (**D**) CTA showing new left posterior cerebral artery (PCA) P2 segment occlusion (*yellow arrow*). (**E**) Magnetic resonance imaging (MRI) diffusion weighted imaging (DWI) showing the right MCA territory infarct. (**F**) MRI DWI showing the new left PCA territory infarct.

diversion) were grouped together. Similarly, in the case of EVT, all stent retriever, aspiration, or combination techniques were grouped together.

Generally, a complication was defined as an unintended adverse or undesirable event related to the procedure. The American Society of Neuroradiology defined major complications during diagnostic angiography as stroke, death, renal failure, arterial occlusion requiring surgical thrombectomy or thrombolysis with/without permanent neurologic deficit, pseudoaneurysm, and groin hematoma requiring transfusion. We added to this list intraoperative aneurysmal rupture with/without neurologic deficit and any hardware malfunction. Minor complications included groin hematoma, vessel dissections (Figure 1) with no neurologic consequences, and coil herniation with no neurologic consequence.

Data Collection

All patient electronic records were retrospectively examined including initial consultation, procedural report, and discharge summaries. If complications were present, all relevant files (including chart entries and DICOM imaging) related to the complication and management were examined. Patient-specific characteristics included sex and age. The indications for either diagnostic catheter angiography or neurointerventional procedure were recorded. The diagnostic/interventional procedure performed, lesion anatomic location, angiographic approach, and vessel catheterized were all recorded. For all neurointerventional procedures, postprocedural imaging was reviewed according to our institutional-specific protocol for postprocedural follow-up. After carotid artery stenting (CAS), carotid Doppler ultrasound or computed tomography angiography (CTA) was performed before discharge. After unruptured aneurysmal embolization, a baseline magnetic resonance imaging (MRI)/magnetic resonance angiography (MRA) was completed before discharge. After ruptured aneurysm embolization, CTA/computed tomography perfusion was completed on postembolization day 1, followed by periodic MRI/MRA when appropriate clinically. All patients undergoing EVT undergo CTA/computed tomography perfusion on postthrombectomy day 1.

RESULTS

A total of 1000 procedures, with 463 diagnostic cerebral angiograms and 537 neurointerventional therapeutic procedures were completed between January 1, 2013, and March 1, 2018 (Table 1). The mean and median age was 60 years. There were 460 women and 540 men.

Diagnostic Cerebral Angiography

The most common indications for diagnostic angiography were arteriovenous malformation as shown on CTA or MRA (20%), cerebral aneurysm as shown on CTA (19%), CTA-negative subarachnoid hemorrhage (SAH) (15%), CTA- or MRI-/MRA-negative intracerebral hemorrhage (13%), dural arteriovenous fistula as shown on CTA/MRA (11%), and other (16%). The total number of complications was 13 (2.8%) with 4 major complications (0.9%), including 3 strokes (all modified Rankin Scale [mRS] scores ≤2 at 6 months) and 1 pseudoaneurysm managed conservatively with resolution (Table 2).

Table 1. Overview of All Diagnostic/Interventional Cases

Procedure	Number (%)
Diagnostic cerebral angiogram	463 (46)
EVT	216 (22)
Aneurysm embolization	170 (17)
CAS	48 (5)
dAVF embolization	17 (2)
AVM embolization	17 (2)
Vasospasm	18 (2)
Carotid-cavernous fistula disconnection	10 (1)
Other	30 (3)

EVT, endovascular thrombectomy; CAS, carotid artery stenting; dAVF, dural arteriovenous fistula; AVM, arteriovenous malformation.

EVT

The total number of EVT cases was 216. The yearly rate is continuing to increase at our center, with only 14 cases in 2013 and 74 cases in 2017; we are expecting >100 cases in 2018. There were a total of 10 aborted procedures because of inadequate access. In the remaining 206 procedures, modified Thrombolysis in Cerebral Infarction reperfusion grade of 3 was achieved in 96 (47%), grade 2b was achieved in 81 (39%), grade 2a was achieved in 14 (7%), grade 1 was achieved in 2 (1%), and grade 0 was achieved in 13 (6%) patients. The overall rate of modified Thrombolysis in Cerebral Infarction grade 2b/3 was 177 (86%). There were 12 cases with complications (5.6%), with 4 of them being major complications (1.9%). This includes 2 femoral artery pseudoaneurysms (1 patient required thrombin injection into the pseudoaneurysm), 1 new posterior cerebral artery territory stroke with complete hemianopia (Figure 2), and 1 stent retriever device failure during the third pass in the middle cerebral artery (MCA) with no

Table 2. Complication Profile for 463 Consecutive Diagnostic Cerebral Angiograms

Diagnostic Cerebral Angiogram Complications	Number (%)
Groin hematoma	4 (0.9)
Vessel dissection with no neurologic changes	5 (1)
Pseudoaneurysm	1 (0.2)
Stroke	3 (0.7)
Total major complications	4 (0.9)

There were no deaths and all patients suffering stokes had a modified Rankin Scale score ≤2 after 6 months. The pseudoaneurysm was managed conservatively with no consequences. Note that major complications do not include groin hematoma or vessel dissections without neurologic changes.

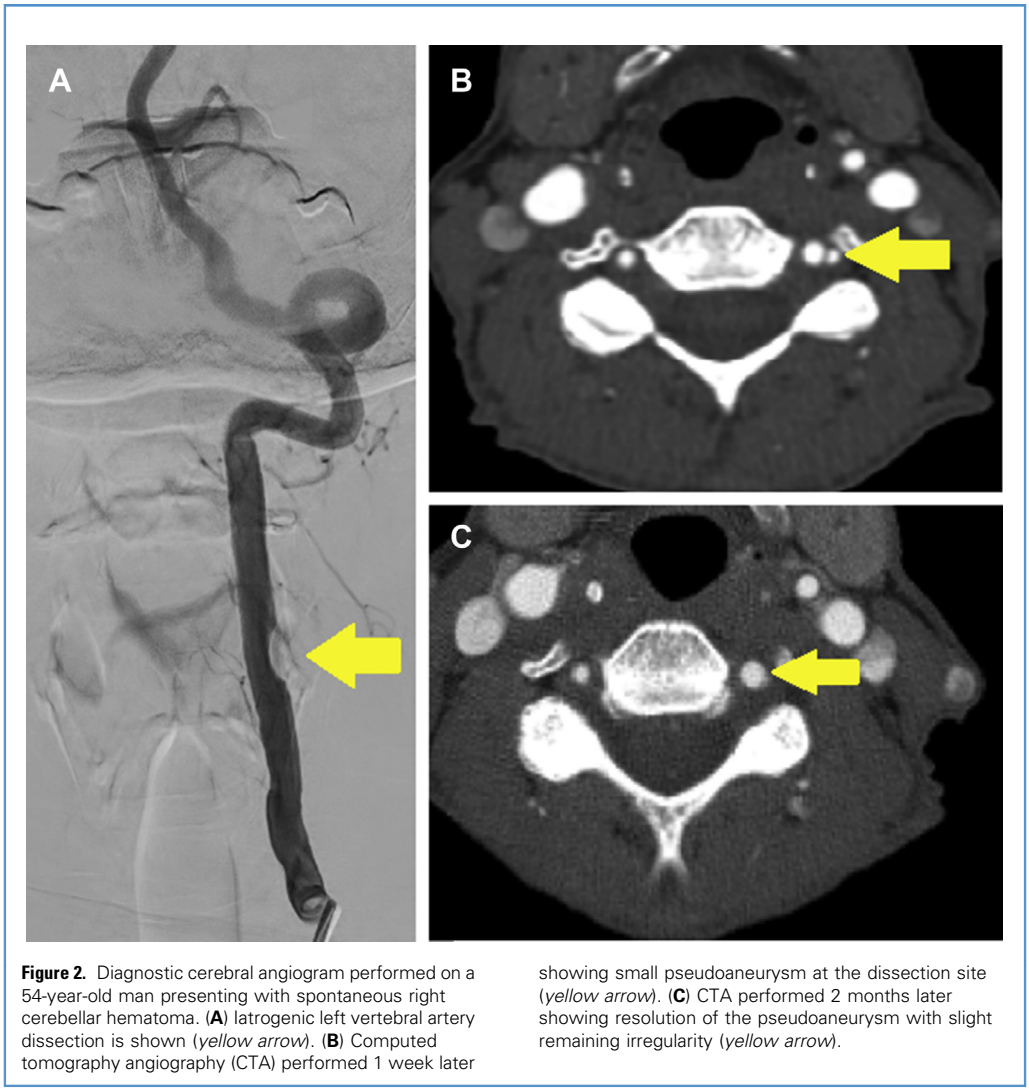

Figure 2. Diagnostic cerebral angiogram performed on a 54-year-old man presenting with spontaneous right cerebellar hematoma. (**A**) Iatrogenic left vertebral artery dissection is shown (*yellow arrow*). (**B**) Computed tomography angiography (CTA) performed 1 week later showing small pseudoaneurysm at the dissection site (*yellow arrow*). (**C**) CTA performed 2 months later showing resolution of the pseudoaneurysm with slight remaining irregularity (*yellow arrow*).

neurologic complication (Table 3). Note that we only included direct procedural-related complications here, whereas outcomes were reported separately and matched well with published randomized controlled trial results.[5]

Aneurysm Embolization: Ruptured

The total number of ruptured aneurysm embolization cases was 95. The vast majority (n = 88; 93%) underwent coiling alone. Three patients underwent stent-assisted coiling, and 4 patients had flow-diversion embolization. Balloon assistance was used in 29% of cases. For the patients that underwent coiling/stent-assisted coiling, Raymond-Roy occlusion classification grade 1 was achieved in 55 (62%), grade 2 was achieved in 30 (34%), grade 3a was achieved in 4 (5%), and grade 3b was achieved in 2 (2%) patients. The total number of complications was 14 (16%), with 10 major complications (11%). This includes 8 intraoperative ruptures (8%), 1 stroke (1%), and 1 pseudoaneurysm (1%) (Table 4). None of the patients with intraoperative rupture died. One rupture required surgical evacuation, and 1 rupture caused transient ventricular tachycardia which resolved. The remaining 6 ruptures did not cause new/worsening neurologic consequences, as determined by unchanged neurologic examination before and after the procedure. The pseudoaneurysm was treated with thrombin injection. The stroke was an MCA embolism that caused hemiparesis with an mRS score of 1 at 6 months.

Aneurysm Embolization: Unruptured

The total number of unruptured aneurysm embolization cases was 74. The number of patients undergoing coiling, stent-assisted coiling, or flow diversion was 50 (73%), 13 (19%), and 11 (16%), respectively. Balloon assistance was used in 54% of cases. For the patients that underwent coiling/stent-assisted coiling, Raymond-Roy occlusion classification grade 1 was achieved in 40 (58%), grade 2 was achieved in 18 (26%), grade 3a was achieved in 4 (6%), and grade 3b was achieved in 1 (1%) of the patients. For the 11 patients who underwent flow diversion, O'Kelly-Marotta grade of C3 was achieved in 8 (73%), A3 was achieved in 2 (18%), and B3 was achieved in 1 (9%) of the patients. The total number of

Table 3. Complication Profile for 216 Consecutive Endovascular Thrombectomy

EVT Complication	Number (%)
Groin hematoma	4 (1.9)
Vessel dissection with no neurologic deficit	3 (1.4)
Pseudoaneurysm	2 (0.9)
Stroke	1 (0.5)
Hardware malfunction	1 (0.5)
Total major complications	4 (1.9)

There were no procedural-related deaths and 1 patient suffered a new posterior cerebral artery stroke causing complete hemianopia. One pseudoaneurysm was managed with thrombin injection. A stent malfunctioned in the middle cerebral artery during clot retrieval with no neurologic complications. Note that major complications do not include groin hematoma or vessel dissections without neurologic changes.
EVT, endovascular thrombectomy.

complications was 5 (6.8%) with 4 major complications (5.4%). This includes 3 intraoperative ruptures (4.1%) and 1 pseudoaneurysm (1.3%) (Table 4). The pseudoaneurysm required surgical correction. Two intraoperative ruptures showed small postoperative SAH and 1 showed small volume intraventricular hemorrhage with no neurologic consequences.

Carotid Stenting

The total number of CAS was 48. The total number of complications was 3 (6.3%), with all being major complications. In 1 case, the embolization protection device broke off in the internal carotid and required emergent endarterectomy. The patient recovered with no neurologic deficit. One pseudoaneurysm was managed with thrombin injection. One patient suffered a left MCA stroke but returned to full power within 6 months (Table 5).

Table 4. Complication Profile for 74 Consecutive Unruptured Aneurysm Embolizations and 95 Ruptured Aneurysm Embolizations

Aneurysmal Embolization Complication	Ruptured	Unruptured
Groin hematoma	0 (0)	1 (1.3)
Pseudoaneurysm	1 (1)	1 (1.3)
Stroke	1 (1)	0 (0)
Coil herniation with no neurologic change	4 (4)	0 (0)
Intraoperative rupture	8 (8)	3 (4)
Total major complications	10 (10)	4 (5.4)

Values are number (%). In the ruptured group, 1 intraoperative rupture required surgical evacuation and 1 pseudoaneurysm required surgical repair. The patient with middle cerebral artery (MCA) stroke had left MCA stroke with a modified Rankin Scale score of 1 at 6 months. Note that major complications do not include groin hematoma or vessel dissections without neurologic changes.

Table 5. Complication Profile for 48 Consecutive Carotid Artery Stents

CAS Complication	Number (%)
Groin Hematoma	0 (0)
Vessel dissection with no neurologic change	0 (0)
Pseudoaneurysm	1 (2.1)
Stroke	1 (2.1)
Hardware malfunction	1 (2.1)
Total major complications	3 (6.3)

In the hardware malfunction case, the embolization protection device broke off in the internal carotid and required emergent endarterectomy. The patient recovered with no neurologic complications. One pseudoaneurysm was treated with thrombin. One patient suffered a left middle cerebral artery stroke but returned to full power within 6 months.
CAS, carotid artery stenting.

DISCUSSION

The goal of this study is to provide neurointerventional stroke centers with recommended case volumes, acceptable complication rates as reported in the literature, along with our institutional case volumes and associated complication rates with these volumes. We subsequently address the major procedural categories.

Diagnostic Cerebral Angiography

In 2000, the American Society of Neuroradiology released quality improvement guidelines for adult diagnostic neuroangiography.[6] Based on these guidelines, the BAC reported that diagnostic angiography procedures must demonstrate a periprocedural stroke and death rate of <1% and overall major complication rate of <2%. With respect to minimum case volumes, Dion et al.[7] showed a linear decrease in fluoroscopy time and complication rates up to a total of 100 cerebral angiograms. Connors et al.,[8] on behalf of the American Association of Neurological Surgeons/Congress of Neurological Surgeons, reported a minimum of 100 diagnostic angiograms for credentialing but did not report on subsequent yearly minimums. Although these suggestions are for total angiograms, yearly minimums are not specified. We report an average of 89 diagnostic angiograms per year and have maintained a major complication rate of 0.9%, in keeping with the complication recommendations.

EVT

In 2017, Rinaldo et al.[9] showed using regression analysis that high-volume centers, defined as having >35 EVT procedures per year, had significantly decreased mortality (9.8%) compared with medium-volume (14.9%) and low-volume (19.7%) centers. This led Fargen et al.[10] to recommend a minimum of 36 EVT procedures per year per center. In the MR CLEAN trial, participating interventionalists needed to complete at least 5 ETV procedures and have ample experience with CAS and coiling; however, this was not specifically defined.[11] The reported procedure-related complications in the intervention group included embolization into new territories outside the target

downstream territory of large vessel occlusion (8.6%), procedure-related vessel dissections (1.7%), and vessel perforations (0.9%). We report an average of 39 EVT procedures per year with a major complication rate of 1.9%. In the early phase of our center's growth, most EVT cases were performed by 2 attending staff interventionalists together when the case volume was low. As the case volume increased, this was changed to either 1 staff interventionalist with 1 fellow in training, or rarely, by a single operator.

CAS

In 2005, Rosenfield and the SCAI/SVMB/SVS Writing Committee[12] published guidelines on the technical requirements for CAS based on expert opinion. They reported a minimum of 30 diagnostic angiograms with half as primary operator and 25 CAS procedures with half as primary operator. The Carotid Revascularization Endarterectomy versus Stenting (CREST) trial had strict criteria for center/interventionalist enrollment.[13] Neurointerventionalists who did not have prior experience using the trial devices attended a didactic and hands-on training course and completed 20 lead-in cases before enrolling in the study. If the number of complications was unacceptable, further cases were required. Experienced neurointerventionalists were considered as having >30 procedures done using the trial devices. Gonzales et al.[14] in 2014 showed that there was no difference in complication rates among CREST-enrolled centers who enrolled <25, 25–51, and >51 patients. Their analysis suggested that once an interventionalist reaches a certain minimum level of expertise, the number of yearly CAS procedures does not need to be high. Interpreting these data, it seems that once an interventionalist completes >20–30 CAS procedures, the yearly rate can be <25 per center. In the CREST trial, they reported the rate of any periprocedural stroke, death, myocardial infarction, and postprocedural ipsilateral stroke as 5.2%. The BAC defined a rate of <6% perioperative (30 days) stroke or death as acceptable. We report a major complication rate of 6.3%, but that also includes pseudoaneurysm repair and hardware malfunction, which the other studies did not include.[3] Our rate of periprocedural stroke, death, myocardial infarction, and postprocedural ipsilateral stroke as defined by the BAC is 2.1%. This complication rate was achieved with an average of 9 CAS procedures per year, for neurointerventionalists who have completed >30 CAS procedures each.

Aneurysm Embolization

Based on the data from Bardach et al.[15] and Cross et al.,[16] showing that centers caring for ≥21 and ≥19 patients with SAH per year, respectively, had reduced mortality, the BAC set the recommended minimum number of ≥20 patients with SAH per year for comprehensive stroke centers.[3] The International Subarachnoid Aneurysm Trial enrolled centers treating between 60 and 200 patients with SAH per year, and participating neurointerventionalists needed to coil a minimum of 30 aneurysms before enrolling patients.[17] Given these high volumes and selected neurointerventionalists, the CLARITY study aimed to provide a complication profile for a prospective registry evaluating the use of coiling as the first-choice treatment in consecutive patients with ruptured aneurysms treated by nonselected operators.[18] They reported thromboembolic events in 13% and intraoperative rupture in 4%, with permanent morbidity of 4% and mortality of 1.5%. Other trials have reported the rate of permanent deficit and death as 4.4% and 1.9%, respectively.[3,19–21] We report treating on average 47 patients with SAH per year. Our study reports a 1% rate of thromboembolic events, no death, and higher intraoperative rupture rate of 8%. It is likely our definition of intraoperative rupture as any contrast extravasation beyond the aneurysm dome, coils beyond the dome, or definitive perioperative increase in SAH on computed tomography scan included more patients than other studies; however, the morbidity from rupture was 0.25% in keeping with the literature.

With respect to complication rates for unruptured aneurysms, the systematic review and meta-analysis by Naggara et al.[22] reported a thromboembolic complication rate of 7.6% and intraoperative rupture of 2.6%, with a total of 4.3% unfavorable outcomes for 3699 patients. Although our definition of major complications differed, we report similar numbers of a total complication rate of 5.4%, with an unfavorable outcome of 1.3%. We treated approximately 15 unruptured aneurysms per year. In the early phase of our center's growth, most aneurysm cases were performed by 2 attending staff interventionalists together when the case volume was low. As the case volume increased, this was changed to either 1 staff interventionalist with 1 fellow or resident in training or, rarely, by a single operator. This arrangement was reinforced by external proctors for flow-diverting stent treatment of aneurysms, a new capability for which our center acquired during the study period.

CONCLUSIONS

We provided a single-center experience of the relationship between neurointerventional procedural case volume and complication rates in the growth phase of our center's establishment. We demonstrated that as our center was being developed, specific procedural staffing measures allowed proficiency maintenance, acquisition of new techniques, and complication avoidance, while specific case volumes crossed the thresholds as defined in the literature. Further study is required to assess whether this single-center experience is replicable in other institutions.

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