

Initial Experience in Establishing an Academic Neuroendovascular Service: Program Building, Procedural Types, and Outcomes

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ABSTRACT

OBJECTIVE

To report our initial experience in setting up a neuroendovascular service in a university-based comprehensive stroke center.

METHODS

We determined the rates of referral path, procedural type, and independently adjudicated 1-month outcomes (actual rates) in first 150 procedures (120 patients) and subsequently compared with rates derived from pertinent clinical trials after adjustment for procedural type (predicted rates).

RESULTS

The patients were referred from the emergency department ($n = 44$), transferred from another hospital ($n = 13$), or admitted for elective procedures from the clinic ($n = 63$). The procedures included treatment of acute ischemic stroke ($n = 12$); extracranial carotid stent placement ($n = 33$); extracranial vertebral artery stent placement ($n = 13$); intracranial angioplasty and/or stent placement ($n = 12$); embolization for intracranial aneurysms ($n = 35$), arteriovenous malformations ($n = 5$), and tumors ($n = 10$); cerebral vasospasm treatment ($n = 26$); and others ($n = 4$). The technical success rate was 100% for intracranial aneurysm obliteration and extracranial carotid artery stent placement, and 95% for those undergoing intracranial or vertebral artery stent placements; and partial or complete recanalization was achieved in 72% of patients undergoing intra-arterial thrombolysis. After adjusting for procedural type, the actual adverse event rate of 3% compared favorably with the predicted rate of 7% based on the results of clinical trials.

CONCLUSIONS

We provide estimates of procedure volumes and outcomes observed in the initial phase of setting up a neuroendovascular service with an active training program.

Keywords: Cerebrovascular diseases, endovascular procedures, stent, angioplasty, embolization.

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Endovascular treatment is emerging and expanding as a minimally invasive approach to treat a variety of cerebrovascular diseases and possibly intracranial neoplasms.^{1,2} In 2005, a consensus statement from the Brain Attack Coalition³ identified surgical and endovascular techniques for treatment of intracranial aneurysms, carotid artery stenosis, and ischemic stroke as key expertise areas. The statement further asserted that much of what distinguishes a comprehensive stroke center from other facilities is expertise and infrastructure in three key areas—diagnostic radiology, endovascular therapy, and surgery—because these areas were considered vital in the management of patients with complex ischemic and hemorrhagic strokes. A neuroendovascular specialist was recommended as a necessary component of a comprehensive stroke center. Based on the emerging needs and certification requirements, several centers around the world are contemplating to either initiate or

further develop neuroendovascular services. In the planning for such a service there is need for data specific to the initial period in regards to endovascular volume and procedural type. We report our initial experience in setting up a neuroendovascular service at a university-based comprehensive stroke center.

Materials and Methods

The Minnesota Stroke Initiative was established in mid-2006 with the intention of providing clinical services at two hospitals, the University of Minnesota Medical Center, Fairview (UMMC) and Hennepin County Medical Center (HCMC), both located in metropolitan Minneapolis, Minnesota. HCMC is a Level-1 Trauma Center and UMMC is a division of Fairview Health Services, a statewide network of hospitals and medical facilities. Both are the core teaching hospitals of the University

of Minnesota Medical School. Prior to the Minnesota Stroke Initiative, both hospitals had a stroke response system and had developed systems to track quality indicators required for certification by the Joint Commission for Accreditation of Hospital Organizations (JCAHO) as primary stroke centers.⁴ As part of the comprehensive stroke center initiative, a neuroendovascular service was initiated on September 1, 2006.

Over a period of 2 months after its initiation, two fellowship-trained interventional neurologists and two interventional neurology fellows were recruited. The service was initially started at UMMC and in December 1, 2006 officially extended to HCMC. Another interventional neurology fellow and faculty were recruited in February and April 2007, respectively. Endovascular coverage was provided on a 24-hour basis. A central call number was established at each of the hospitals to facilitate referral of patients from outside facilities. The emergency departments at each hospital sought consultation with the brain attack team, neurology team, or neurosurgery team as deemed appropriate. In-patients from either the neurology or neurosurgery service were referred to the endovascular service if cerebrovascular diseases amenable to treatment were identified during the hospital stay. The endovascular service conducted weekly clinics at UMMC and bimonthly at HCMC (since February 2007).

As part of the initiative, a prospective database was created to record any procedure performed by the neuroendovascular team. The details of the procedure were recorded. A monthly morbidity and mortality conference was conducted in association with the department of neurosurgery to identify any complications related to the procedures and to institute or modify protocols. After the first 150 endovascular procedures were completed, a detailed review of the in-hospital records and follow-up visits was conducted. The review protocol was approved by the local Institutional Review Boards at both hospitals. The charts were reviewed by a research associate (MZM) and patients were contacted (if no follow-up visits were performed) by a nurse clinician (AEP) to ensure complete ascertainment of endpoints for a 30-day postprocedure period for the treated patients. Information regarding demographics and preexisting cardiovascular risk factors was recorded for each patient. The indications for the procedure, procedure type, and devices used, and type of anesthesia used were also recorded. The occurrence of a recurrent or new stroke, intracranial hemorrhage, major percutaneous arterial access site complication, renal failure within 1 week of the procedure, and any death was recorded along with the time interval between the initial procedure and new event. Details were acquired regarding any recurrent stroke and cause of mortality (if indicated). Percutaneous arterial access complications such as groin hematoma, or retroperitoneal hematoma, were operationally defined as major if blood transfusion or surgical intervention was required. Functional status defined by modified Rankin scale (mRS)⁵ at 1 month was also estimated based on clinic visit or telephone interview.

We wanted to determine how our rate of procedure-related adverse events compared with predicted or permissible rates. We developed a model for calculating the expected procedure-related adverse rate associated with the types of procedures

performed by our service. The model was developed on two principles: (1) identification of procedure-related adverse events that could be ascertained reliably and reported consistently in previous clinical trials; and (2) determination of the selected procedure-related adverse event rates in previous practice-defining clinical studies. Practice-defining clinical studies were considered to be randomized trials that demonstrated benefit of an endovascular procedure or prospective registries that resulted in approval of an endovascular device by the Food and Drug Administration.

The biggest challenge was to select the reference trials for carotid artery stent placement with distal protection. A total of 29 multicenter prospective studies were reviewed (<http://content.onlinejacc.org/cgi/content/full/49/1/126/TBL10>). Six studies that were overseen by Food and Drug administration with an independent Data and Safety Monitoring Board were selected: Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE),⁶ Boston Scientific EPI: A Carotid Stenting Trial for High-risk Surgical Patients (BEACH),⁷ Carotid Artery Revascularization Using the Boston Scientific EPI FilterWire EXTm and the EndoTex TM Nexstent (CABERNET),⁸ Acculink for Revascularization of Carotids in High-Risk Surgical Patients (ARCHER),⁹ Medtronic AVE Self-expanding Carotid Stent System with Distal Protection in the Treatment of Carotid Stenosis (MAVERIC),¹⁰ A Registry Study to Evaluate the NeuroShield Bare Wire Cerebral Protection System and X.act Stent in Patients at High Risk for Carotid Endarterectomy (SECURITY)¹¹ were considered. Data for symptomatic and asymptomatic treated patients was available for SAPPHIRE, ARCHER, and BEACH, and therefore the procedure-related adverse event rates were based on these studies. In case of embolization for ruptured intracranial aneurysms, no trials overseen by Food and Drug administration or National Institutes of Health were available. Therefore, we calculated the rates based on the two randomized trials conducted in Europe.^{12,13} For other procedures, we calculated the rate as the adverse event rate expected with cerebral angiography based on the two trials which determined the rates associated with angiography independent of interventional procedures.^{14,15}

A multilevel independent adjudication system was set in place to ensure identification of all events and their relationship to the procedure. Patients with new neurological deficits or death were identified by a research associate. Subsequently, a stroke and neurocritical care specialist (M.A.E) not involved in the care of any of the patients reviewed clinical summaries and neuroimaging studies. A summary of all events and adjudications is reported below.

Results

A total of 210 procedures were performed, of which 150 were neuroendovascular procedures involving 120 patients. The other sixty procedures were diagnostic angiograms. The mean age (\pm standard deviation) of the patients was 58 ± 18 years; 64 were men. Two patients were under 18 years of age. The presenting diagnoses were subarachnoid hemorrhage ($n = 22$), ischemic stroke ($n = 33$), transient ischemic attack ($n = 28$), intracerebral hemorrhage ($n = 1$), asymptomatic

cerebrovascular disease ($n = 15$), traumatic vascular injury ($n = 5$), tumors ($n = 10$), and others ($n = 6$). The patients were referred from the emergency department ($n = 44$), transferred from another hospital ($n = 13$), or admitted from the clinic for elective procedures ($n = 63$).

Table 1 demonstrates the distribution of neuroendovascular procedures. A total of 35 embolization procedures were performed in 33 patients with intracranial aneurysms (20 ruptured and 15 unruptured). Balloon assistance was used in 5 of the embolizations and stent assistance in 7. Carotid stent procedures were performed in 33 patients. A total of 12 intracranial and 13 extracranial vertebral artery angioplasty and/or stent placement were performed. Ten tumor embolizations were performed, for meningioma ($n = 3$), C3 cervical body ($n = 1$), hemangioma ($n = 1$), angiofibroma ($n = 2$), carotid body tumor ($n = 1$), jugular foramen tumor ($n = 1$), and metastatic spinal cord tumor ($n = 1$). Technical success rates among patients undergoing intracranial aneurysm embolization (near complete or complete obliteration) was 100%, those undergoing cervical carotid artery stent placement ($< 30\%$ residual stenosis) was 100%, those undergoing intracranial or vertebral artery stent placement ($< 50\%$ residual stenosis) was 95%, and those who underwent intra-arterial thrombolysis (partial or complete recanalization) was 72%.

At 1 month, there were a total of five deaths and two new strokes were observed. A 1-month mRS of 0-2 was observed in 104 (72%) of 145 surviving patients. One death was adjudicated by an independent physician to be related to the procedure. That patient had coronary artery disease and severe aortic valvular disease and developed several posterior circulation transient ischemic attacks refractory to medical therapy. The patient was diagnosed with severe basilar artery stenosis and underwent primary angioplasty. During the procedure, the patient developed wire perforation and subarachnoid hemorrhage. Due to severe mass effect and brain stem deficits, and preexisting comorbidities, the care was withdrawn by the family.

There were four deaths adjudicated as not related to the procedure. Two of those patients were admitted with basilar occlusion and died due to severe brain stem deficits despite intra-arterial thrombolysis. The third patient had a history of congestive heart failure and was admitted with acute ischemic stroke following coronary angioplasty for acute myocardial infarction. The patient underwent intra-arterial thrombolysis but suffered another cardiac event during hospitalization with new left bundle branch block, hypotension, and subsequent cardiac arrest. The fourth patient had stage IV nonsmall cell lung carcinoma and was admitted with respiratory failure. The patient developed an acute ischemic stroke during hospitalization treated with intra-arterial thrombolysis. The patient had minimal interval improvement following thrombolysis. He subsequently died of worsening respiratory failure and multiorgan failure.

Two patients suffered ischemic strokes related to the procedure. One patient developed an infarct during embolization of a broad neck ruptured intracranial aneurysm at the junction of A3 segment of anterior cerebral artery and pericallosal artery. There was an arteriovenous malformation distal to the aneurysm precluding surgical approach. The patient underwent

an attempted embolization which was aborted due to prolapse of coils despite balloon assistance. After a detailed discussion with the neurosurgery team and the family, it was decided that the neurosurgical clipping would be very high risk and to proceed with a second endovascular procedure with the understanding that the parent vessel will probably be sacrificed as part of coiling the wide-necked ruptured aneurysm. The coils were placed in the aneurysm but resulted in thrombosis of parent vessel resulting in a distal anterior cerebral artery ischemic stroke. The second patient underwent carotid angioplasty and stent placement for symptomatic severe right extracranial carotid stenosis. The patient was neurologically intact after the procedure and was discharged in good health. The patient developed left upper extremity focal seizures with imaging findings consistent with hyperperfusion syndrome at day 10 following the procedure. Patient was readmitted for aggressive blood pressure control. On the third day of readmission, patient developed posterior circulation ischemic stroke related to a preexisting high grade vertebral artery origin stenosis.

There were two major femoral access complications. One patient had thrombocytopenia prior to the procedure (platelet count of 55,000 per mm^3) and was receiving high dose heparin for pulmonary embolism. Immediately postprocedure there was active bleeding at the insertion site necessitating platelet and red blood cell transfusions and fresh frozen plasma infusions to achieve hemostasis. Another patient received intra-arterial thrombolysis for ischemic stroke followed by anticoagulation for atrial fibrillation 3 days later. Seven days after the procedure, the patient developed a femoral hematoma due to a pseudoaneurysm in the femoral artery. The pseudoaneurysm was conservatively managed and the patient was treated with antibiotics for cellulitis associated with the hematoma.

Two patients had worsening of renal function within 7 days following the procedure with spontaneous resolution. One patient had preexisting popliteal and superficial femoral artery thrombosis, complicated by rhabdomyolysis and renal insufficiency, and was being treated with continuous infusion of low dose thrombolytics and serial angiography. The patient developed a new ischemic stroke and underwent intra-arterial thrombolysis. Serum creatinine worsened with normalization in 2 days. The second patient had fluid overload following a carotid stent placement requiring pharmacological diuresis with subsequent prerenal failure 2 days after the procedure.

Discussion

We report our initial experience with procedure demand and procedure related outcomes in the initial phase of starting a neuroendovascular service with associated fellowship training. We think that this information will be valuable for hospital systems planning to develop new neuroendovascular services. Data regarding the rate of growth and procedural type is essential for any planning to ensure adequate numbers of interventional personnel are enlisted to meet the number and complexity of procedures. In addition, growth of a new venture has direct implications for nurses and technologists that provide care in the interventional suite, neurosurgical, and neurocritical care

Table 1. Rates of One-month Adverse Events in Clinical Trials, and Expected and Actual Rates Based on Procedural Type

Type of procedure	Adverse event outcome measure	Data from published studies				Data from the current report		
		Trials used	Number of patients	Number of events	Rate per patient	Procedures performed	Events predicted	Events observed
Intra-arterial thrombolysis	Symptomatic intracranial hemorrhage at 24-36 hours	PROACT I, ¹⁴ PROACT II, ³ IND 9180 ¹	166	15	.090	6	.54	0
Mechanical thrombectomy	Symptomatic intracranial hemorrhage at 24-36 hours	MERCI, ³⁷ Multi-MERCI ³⁸	222	19	.085	6	.51	0
Bridging approach (IV rt-PA received)	Symptomatic intracranial hemorrhage at 24-36 hours	EMS, ³⁹ IMS, ⁴⁰ Multi-MERCI ³⁸	145	13	.089	6	.534	0
Intracranial stent placement	Any stroke or death	Wingspan, ⁴¹ SSYLVIA ⁴²	87	6	.068	12	.816	1
Carotid stent placement-asymptomatic patients	Any stroke or death	SAPPHIRE, ⁶ ArCHER, ⁹ BEACH ⁷	1,105	67	.060	3	.18	0
Carotid stent placement-symptomatic patients	Any stroke or death	SAPPHIRE, ⁶ ArCHER, ⁹ BEACH ⁷	375	31	.083	30	2.49	1
Extracranial vertebral artery stent	Any stroke or death	SSYLVIA ⁴²	18	0	.00	13	0	0
Embolization of intracranial aneurysms-ruptured	Rebleeding, second treatment, vascular occlusion requiring intra-arterial treatment	ISAT, ¹² Vanninen et al. ¹³	1,125	106	.094	20	1.88	1
Embolization of intracranial aneurysms-unruptured	Any rebleeding, stroke, or death	ISUIA ⁴³	451	41	.09	15	1.35	0
Arteriovenous malformation	Intracranial hemorrhage, new ischemic stroke, catheter glued or fracture	nBCA-Trial ²⁰	106	20	.188	5	.94	0
Cerebral vasospasm	Vessel rupture, dissection, or aneurysmal rupture	BPAV ¹⁵	106	6	.056	26	1.456	0
Others (estimated as risk associated with cerebral angiography)	Any stroke, death	BPAV, ¹⁵ PROACT-I ¹⁴	400	7	.018	14	.252	0

continued

Table 1. (continued)

Type of procedure	Adverse event outcome measure	Data from published studies				Data from the current report		
		Trials used	Number of patients	Number of events	Rate per patient	Procedures performed	Events predicted	Events observed
Overall rates of specific adverse events					7			3
Any interventional procedure	Access complications requiring transfusion or surgery	EMS, ³⁹ IMS, ⁴⁰ MERCI, ³⁷ Multi-MERCI, ³⁸ IND 9180, ¹ Wingspan, ⁴¹ SAP-PHIRE, ⁶ ArCHER ⁹	1,377	29	.021	150	3.15	2
Overall rates of specific adverse events including arterial access complications					9			5

PROACT = prolyse in acute cerebral thromboembolism; EMS = emergency management of stroke; IMS = interventional management of stroke; IND = investigational new drug application; MERCI = mechanical embolus removal in cerebral ischemia; SSYLVIA = stenting of symptomatic atherosclerotic lesions in the vertebral or intracranial arteries; SAPPHIRE = stenting and angioplasty with protection in patients at high risk for endarterectomy, ArCHER = acculink for revascularization of carotids in high-risk surgical patients; BEACH = Boston Scientific EPI: A Carotid Stenting Trial for High-risk Surgical Patients; ISAT = International Subarachnoid Aneurysm Trial; ISUIA = International Study of Unruptured Intracranial Aneurysms; nBCA = N-butyl-2-cyanoacrylate; and BPAV = balloon prophylaxis of aneurysmal vasospasm.

services, and anesthesia services. Another issue of considerable importance is the equipment procurement with an emphasis on endovascular devices such as a multitude of stents, coils, microcatheters, liquid, and solid embolization agents, catheters, microwires, and guidewires.

Quality Assurance Program

We present here a model that can be used to assess the expected rates of procedure related adverse events that we think maybe helpful to hospital quality assurance programs. The model should be used with the understanding that the estimates are based on patients treated in clinical trials. It has been previously observed that patients recruited in clinical trials have more favorable characteristics than those treated in clinical practice (cherry-picking phenomenon).¹ Therefore, the estimates should be interpreted with this understanding and with appropriate adjustment for clinical severity if required. We chose to calculate the adverse event rate per procedure instead of per patient to be consistent with event rates reported in clinical trials. The predominant source of multiple procedures was treatment of cerebral vasospasm in our report; the event rate was reported per procedure in the Balloon Prophylaxis of Aneurysmal Vasospasm trial.¹⁵ We also acknowledge

that independent ascertainment of endpoints (without knowledge of procedure) was not performed in our study. This may have lowered the ascertainment rate for minor events compared with clinical trials that employed this methodology. A review of the literature revealed that only UK Neurointerventional Group (UKNG)¹⁶ has developed a unified database for purposes of recording, analysis, and clinical audit of neuroangiography and neurointerventional procedures. The database had information about 350 aneurysm embolizations and compared clinical outcome scores to clinical standards set by ISAT. The reporting database allowed “real-time” audit and analysis of one’s clinical practice. For interventional cardiology procedures, several models are available, which incorporate existing knowledge regarding event rates into the estimation of risks.¹⁷ The most commonly reported types of predictive models were developed using logistic regression and Bayesian techniques, followed by neural networks, rule-based artificial intelligence, simultaneous equation system, and multiple linear regression. A review found 71 articles published in English from 1980 to 1999.¹⁷ More recent articles have described new approaches for risk adjusted auditing of procedural outcomes.¹⁸⁻²⁰ There is a clear discrepancy in efforts towards development, validation, and application of such models between interventional cardiology and interventional neurology practices

highlighting the need for further efforts in the field of interventional neurology. Application of these models to an individual patient can spur quality improvement efforts that can lead to system-wide improvements in outcomes.

Financial Considerations

The financial considerations of establishing a new neuroendovascular program are important. The main financial input into the practice consists of academic base salaries consistent with academic rank from the medical school, compensation from hospitals for administrative (directorship) responsibilities, salary support from research grants, and professional fees from procedures and professional encounters. However, further financial support is necessary from partnering institutions to support fellows, nurses and nurse practitioners, and office staffs' salaries. Fellowships accredited by the Accreditation Council for Graduate Medical Education (ACGME) are eligible for financial support from Medicare depending upon the allocated number of funded slots in the respective institution.²¹ It should be noted that reimbursement from any endovascular procedure consists of professional and facility components.²² The facility component is incorporated into the total hospitalization charges for in-patient admission based on Diagnosis-Related Group (DRG) adjusted for severity. Since the facilities component is the predominant proportion of financial reimbursement, financial support from recipients of the facilities components (hospitals) for the global infrastructure is important for financial viability of the service. In our system, to support a multidisciplinary interest from the Departments of Neurology, Neurosurgery, and Radiology, a unique financial model was conceptualized and continues to be refined. The model allows pooling of revenue generated from professional fees under selected Current Procedural Terminology (CPT) codes into a common account. The common account receives revenue from any endovascular or surgical procedure performed for cerebrovascular diseases and allows distribution of revenues between departments. This system creates a joint financial account between departments reducing the competitive incentive and promotes patient oriented care.

Academic Considerations

Another observation is that that rapid practice growth can have unique challenges for academic development of faculty. In the present competitive environment for federal and local funding, dedicated time for research is mandatory for faculty to develop a strong research background. Lack of protected research time has been identified as the most important reason for inability to achieve academic success.²³⁻²⁸ Availability of protected research time has been correlated to higher academic productivity^{29,30} and earlier promotion to higher academic ranks.³¹ The minimum amount of time considered to be adequate as protected research time is estimated as 33% of total time in some studies.^{32,33} Since the completion of the first 200 cases, we have recruited an endovascular neurosurgeon to relieve the demands of the growing endovascular practice while supporting the academic interests of faculty. The fellowship program has also been expanded to include four interventional fellows

(two in the first year and two in the second). This increase allows our initiative to provide protected time for research to faculty. However, the implications are reduced clinical revenue per faculty and increased support requirement from the medical school. The incentive for the medical school for providing additional support is the possibility of receiving federal grants and associated facilities and administrative cost.³⁴ Our model has resulted in acquisition of three grants from the National Institutes of Health and one grant from American Heart Association. A total of 37 scientific publications have been authored by faculty since joining the initiative validating the academic value of this approach.

Fellowship Program

Endovascular practice has now evolved into a multidisciplinary field, and a considerable effort has been placed on standardizing training and qualification requirements.³⁵ The ACGME in June 2000, officially approved the Guidelines for Training in Endovascular Surgical Neuroradiology. Endovascular surgical neuroradiology was defined as a subspecialty that uses catheter technology, radiologic imaging, and clinical expertise to diagnose and treat diseases of the central nervous system. Since May 2003, the program has been made available to candidates from Neurology, Neurological Surgery, and Radiology. The rate of procedure related adverse events in our study suggests that a fellowship training program does not adversely affect patient care and may actually contribute to favorable results in endovascular practice. This observation is consistent with another study that demonstrated better outcomes in teaching hospitals for all stroke admission in United States.¹ This maybe attributable to higher number of endovascular procedures performed and experienced gained in teaching hospitals. A survey of 57 academic practices and 70 surveys nonacademic practices³⁶ suggested that 84% of all endovascular procedures were performed at academic centers (90% of aneurysm embolization, 71% of thrombolysis, and 82% of stent placement procedures).³⁶ Since the initiation of program, our group has performed a total of 490 procedures providing an average experience of 150 endovascular procedures and 120 diagnostic cerebral angiograms to each of the senior fellows (18 of 24 months of training completed). This experience is consistent with the existing recommendations of ACGME, Neurovascular coalition,³ and joint statement from the Society of Vascular and Interventional Neurology and American Society of Neuroimaging.¹

Conclusions

The data provided in the present report may not be accurately reflective for other systems, depending upon the patient population treated and the available triage and referral patterns. However, the local variations are expected to be relatively minor and should be of value to other hospital systems developing similar services, especially those with university affiliations in large metropolitan areas.

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