# Patterns in neurosurgical adverse events: endovascular neurosurgery

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As part of a project to devise evidence-based safety interventions for specialty surgery, the authors sought to review current evidence in endovascular neurosurgery concerning the frequency of adverse events in practice, their patterns, and current methods of reducing the occurrence of these events. This review represents part of a series of papers written to consolidate information about these events and preventive measures as part of an ongoing effort to ascertain the utility of devising system-wide policies and safety tools to improve neurosurgical practice.

Based on a review of the literature, thromboembolic events appeared to be the most common adverse events in endovascular neurosurgery, with a reported incidence ranging from 2% to 61% depending on aneurysm rupture status and mode of detection of the event. Intraprocedural and periprocedural prevention and rescue regimens are advocated to minimize this risk; however, evidence on the optimal use of anticoagulant and antithrombotic agents is limited. Furthermore, it is unknown what proportion of eligible patients receive any prophylactic treatment.

Groin-site hematoma is the most common access-related complication. Data from the cardiac literature indicate an overall incidence of 9% to 32%, but data specific to neuroendovascular therapy are scant. Manual compression, compression adjuncts, and closure devices are used with varying rates of success, but no standardized protocols have been tested on a broad scale. Contrast-induced nephropathy is one of the more common causes of hospital-acquired renal insufficiency, with an incidence of 30% in high-risk patients after contrast administration. Evidence from medical fields supports the use of various preventive strategies.

Intraprocedural vessel rupture is infrequent, with the reported incidence ranging from 1% to 9%, but it is potentially devastating. Improvements in device technology combined with proper endovascular technique play an important role in reducing this risk.

Occasionally, anatomical or technical difficulties preclude treatment of the lesion of interest. Reports of such occurrences are scant, but existing series suggest an incidence of 4% to 6%. Management strategies for radiation-induced effects are also discussed. The incidence rates are unknown, but protective techniques have been demonstrated.

Many of these complications have strategies that appear effective in reducing their risk of occurrence, but development and evaluation of systematic guidelines and protocols have been widely lacking. Furthermore, there has been little monitoring of levels of adherence to potentially effective practices. Protocols and monitoring programs to support integrated implementation may be broadly effective. (http://thejns.org/doi/abs/10.3171/2012.7.FOCUS12180)

KEY WORDS • surgical safety • adverse events • perioperative care

**P**ROGRESS in the science of improving surgical safety has been notable in recent years. Methods for evaluating outcomes have been developed and deployed,<sup>10,19,20,31,48,50,81</sup> and the resulting data have been used to research patterns of errors and complications. From the findings, solutions have been designed and tested with sometimes striking improvements, whether based on simple process tools like checklists<sup>10,11,26,80</sup> or technological changes.<sup>22,55,78</sup> Neurosurgery is a high-risk surgical specialty that has begun to pursue systematic, nationwide approaches to measuring and improving outcomes. As part of a project funded by the US Agency for Healthcare Research and Quality to devise evidence-based checklists and protocols for specialty surgery, we sought to

*Abbreviations used in this paper:* AVM = arteriovenous malformation; CARAT = Cerebral Aneurysm Rerupture After Treatment; ICP = intracranial pressure.

review current evidence in neurosurgery concerning the frequency of adverse events in practice, their patterns, and the state of knowledge about how to improve them. We hypothesized that this consolidation of existing data, even if commonly known to neurosurgeons, will not only highlight the need for devising system-wide policies and safety tools to improve neurosurgical practice but also inform future efforts to develop and implement these tools and policies. We focus this review on complications common to all of endovascular neurosurgery, rather than disease or procedure-specific complications, in an effort to summarize such evidence for potential safety tools in endovascular neurosurgery as a whole.

#### **Scope of the Problem**

Since the advent of the Guglielmi detachable coil in 1991,<sup>23,24</sup> the endovascular treatment of intracranial aneurysms has increased dramatically. From 1998 to 2003, 43% of unruptured and 31% of ruptured aneurysms were treated endovascularly.<sup>7</sup> National Inpatient Survey data from 2007 demonstrate that 35,586 aneurysms were treated endovascularly in that year compared with 16,526 in 2003 (http:// hcupnet.ahrq.gov). Neuroendovascular techniques have also expanded to include cranial and spinal AVM embolization, tumor embolization, stroke thrombolysis, vaso-spasm treatment, and treatment of atherosclerotic disease, among others.<sup>56</sup>

Complications associated with neuroendovascular therapy are common and vary with the rupture status of the lesion being treated.<sup>61</sup> Overall complication rates are around 20%, with a 1-month mortality rate estimated at 1.4%.52,61 Existent data vary widely in quality, with a substantial amount being from uncontrolled series reported by neurointerventional groups. A few large randomized trials have been conducted specifically within endovascular neurosurgery, but a proportion of what is known regarding interventional angiography is from the cardiac literature. Nonetheless, the most common reported complications within endovascular neurosurgery are thromboembolic events, groin-site hematoma, contrast-induced nephropathy, intraoperative rupture, failure to treat lesion, and radiation-induced effects. Table 1 lists these complications in order of estimated incidence.

# **Thromboembolic Events**

Thromboembolic events are among the most concerning complications related to endovascular neurosurgery. The incidence is reported to range from 2% to 61%, depending on rupture status of the treatment target, mode of detection of the event, and type of procedure performed.<sup>6,25,45,52,53,58,61,62,66,70,75,79,87</sup> Carotid artery stenting tends to be associated with higher intraprocedural thromboembolic rates, with significantly higher risk in patients with symptomatic lesions. Iatrogenic dissection, catheterinduced vasospasm, and operative technique account for most of these events. Patients older than 60 years, those with cerebrovascular disease, and those with longer procedure times are also at greater risk.<sup>53</sup> Thromboembolic events resulting in persistent neurological deficit occur in 2%–5% of these patients.<sup>18,45,51,62,66</sup> Stroke rates at 30 days after stent placement in large trials remain approximately 5%.<sup>3,86</sup> Ischemic complications during AVM embolization are reported in this section for the sake of completeness, but they represent a category with different causes and management strategies that are beyond the scope of this review, which is intended as groundwork for the design and implementation of broad policies and safety tools for neurosurgery.

#### Intraprocedural Prevention Strategies

A variety of rescue therapies have recently been applied when embolism does occur. Intraprocedural administration of abciximab, a glycoprotein IIb-IIIa inhibitor, was used in small uncontrolled series with some good effect.44,58 Treatment with another glycoprotein IIb-IIIa inhibitor, tirofiban, has also been reported in uncontrolled series to be safe and effective for dissolving intraprocedural clots.<sup>4</sup> A similarly uncontrolled, but larger, series using intravenous aspirin showed similar results.<sup>57</sup> Intraprocedural administration of tissue plasminogen activator has been attempted for treatment of thromboembolic consequences, but the limited experience is not supported by any rigorous data. No large randomized studies have been performed to assess the effectiveness and hemorrhagic risk of these agents specifically for neurointerventional cases, and it may be overly difficult to do so.

Air embolism, also a feared complication, deserves mention as there are various preventive strategies that can be employed. For example, formal reconfirmation of an airless flush bag and line system at the beginning of the procedure may be a useful component of an endovascular safety pause. Widespread adherence to these techniques is suspected but has not been formally evaluated.

# Periprocedural Prevention Strategies

Current practice to prevent ischemic complications from thromboembolism may involve use of carefully titrated systemic heparin therapy with varying treatment duration before, during, and after the procedure.5,14,21,33,54,76,85 Periprocedurally, aspirin and clopidogrel are routinely used for thromboembolism prophylaxis in patients undergoing intra- and extracranial stent placement.14,16 Antiplatelet therapy is used more variably in other procedures, although there is some support in the neurointerventional literature for this approach. Yamada et al.,87 in a study of 369 consecutive aneurysm coil embolization cases, retrospectively noted that patients who had been treated preprocedurally with clopidogrel and/ or aspirin had significantly fewer thrombotic complications than those who received antiplatelet therapy only postprocedurally or those who received no antiplatelet therapy (1.9% vs 2.3%, and 16%, respectively). Any possible benefit of antiplatelet agents in patients with ruptured aneurysms, however, has to be carefully weighed against the risk of hemorrhagic complications related to other procedures, such as ventriculostomies, and the more devastating consequences of intraprocedural rupture or rerupture of the aneurysm prior to its complete repair. The majority of the data supporting combined aspirin/

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AE w/ Authors & Year	Sample Size (no. of pts)	Indication	Frequency (%)
thromboembolic events			
Soeda et al., 2003	79	unruptured aneurysm	61 (22 symptomatic)
Timaran et al., 2011	40	PTAS	50 radiographic (none symptomatic)
Qureshi et al., 2000	228	aneurysm w/ parent vessel occlusion	19 symptomatic
Qureshi et al., 2000	109	aneurysm w/ endosaccular occlusion	11 symptomatic
Weber et al., 2007	93	AVM embolization	9 symptomatic
Qureshi et al., 2000	834	PTAS	9 symptomatic
Ries et al., 2009	515	mixed aneurysm	9 radiographic
Pierot et al., 2008	739	unruptured aneurysm	7 symptomatic
Ross & Dhillon, 2005	126	mixed aneurysm	9 (6 symptomatic)
Qureshi et al., 2000	1547	mixed aneurysm	8 (5 symptomatic)
Van Rooij et al., 2007	52	AVM embolization	6 symptomatic
Coley et al., 2012	497	mixed aneurysm	5 ruptured, 6 unruptured
Qureshi et al., 2000	455	PTA	5 symptomatic
Haw et al., 2006	513	AVM embolization†	5 symptomatic
Saatci et al., 2011	350	AVM embolization†	4 permanent deficits
Yamada et al., 2007	369	unruptured aneurysm	3 symptomatic
Murayama et al., 2003	916	mixed aneurysm	2 symptomatic
access-related complication			
Foran et al., 1993	63	cardiac	32
Ernst et al., 1993	252	routine cardiac	21
Sanborn et al., 1993	455	cardiac	9
Wagenbach et al., 2010	295	mixed intracranial	1
contrast-induced nephropathy			
Morcos et al., 1999‡	NA	NA	20-30 (in high-risk pts), <5 (in low-risk pt
intraoperative rupture			
Ross & Dhillon, 2005	126	mixed aneurysm	9
Coley et al., 2012	497	mixed aneurysm	6 ruptured, 2 unruptured
Elijovich et al., 2008	299	ruptured aneurysm	5
Li et al., 2006	284	mixed aneurysm	4
Weber et al., 2007	93	AVM embolization	4
Loh & Duckwiler, 2010	117	AVM embolization	4
Haw et al., 2006	513	AVM embolization	4
Pierot et al., 2008	739	unruptured aneurysm	3
Murayama et al., 2003	916	mixed aneurysm	2
Levy et al., 2001	274	mixed aneurysm	2
Koebbe et al., 2006	1307	mixed aneurysm	1
Tummala et al., 2001	734	mixed aneurysm	1
failure to treat lesion			
Ross & Dhillon, 2005	126	mixed aneurysm	6
Murayama et al., 2003	916	mixed aneurysm	5
Pierot et al., 2008	739	unruptured aneurysm	4.3
radiation-induced effects			
Saatci et al., 2011	350	AVM embolization	6
Marti et al., 2008	1	ruptured aneurysm	case report

TABLE 1: Frequency of adverse events reported in CSF shunt surgery*
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(continued)

AE w/ Authors & Year	Sample Size (no. of pts)	Indication	Frequency (%)		
radiation-induced effects (continued)					
D'Incan et al., 2002	6	not reported	small case series		
Wen at al., 2003	1	unruptured aneurysm	case report		

 TABLE 1: Frequency of adverse events reported in CSF shunt surgery\* (continued)

\* AE = Adverse Event; NA = not applicable; PTA = percutaneous transluminal angioplasty; PTAS = percutaneous transluminal angioplasty and stenting.

† Included for completeness although these complications have different causes and management strategies.

‡ Expert consensus report.

clopidogrel therapy is derived from the cardiac literature regarding placement of stents, where large trials have demonstrated a significant impact of dual antiplatelet therapy on the periprocedural prevention of thrombotic complications.<sup>34,65</sup> Moreover, the combination of aspirin and clopidogrel versus aspirin and ticlodipine was found in a large, randomized trial to be associated with fewer complications (bleeding, neutropenia, thromobocytopenia) and lower rates of discontinuation, while maintaining similar efficacy for patients undergoing cardiac stent placement.<sup>2</sup>

Various intra- and periprocedural prevention and rescue regimens are used to minimize risk for this common but potentially catastrophic complication, but uniform guidelines do not exist. In an extensive review of the prevention and treatment of endovascular procedure-related thromboembolic complications, Qureshi et al.<sup>53</sup> make recommendations regarding preventive strategies, stratified by procedure type. However, it remains to be seen how these recommendations, if standardized, will improve practice. An additional preventive measure is further regionalization and mandates for certain levels of technical proficiency and/or volume. These issues are discussed in more detail in the summary paper of this series.<sup>84</sup>

#### **Access-Related Complications**

Groin-site hematoma is the most common puncture site-related complication. Data from the cardiac literature indicate an overall incidence of 9%–32%.<sup>14,17,64</sup> These figures agree with smaller observational series in elderly patients undergoing neurointerventional procedures.<sup>68</sup> Wagenbach et al.,<sup>77</sup> in their recent series of almost 300 patients who underwent diagnostic and therapeutic neuroendovascular procedures, report a rate of 1% even with early ambulation. When severe, groin hematomas require surgical intervention for definitive therapy,<sup>15,46</sup> and if left untreated, they may progress to retroperitoneal hematoma, which can be catastrophic. Retroperitoneal hematoma is more frequent in patients requiring aggressive anticoagulation therapy.<sup>27,67</sup>

Measures to minimize the risk of access-related complications include avoiding areas of previous surgery (such as hip replacement or hernia repair) or a lower extremity in which vascular repair has been performed (D.A. Pandey, personal communication, 2010). Classically, manual

compression is used to avoid groin-site hematoma and its related complications. Indeed, Wagenbach et al.<sup>77</sup> prospectively evaluated a protocol encouraging ambulation at 2 hours after a diagnostic or therapeutic cerebral angiogram. Patients were maintained on bed rest for 2 hours after release of manual compression, at which time the site was inspected and palpated. The site was again inspected after an uneventful first ambulation, and if no complications were noted, then the patient was dismissed from the hospital. Five percent of the patients experienced a major or minor complication prior to the 2-hour mark; only 1 patient experienced a major complication after ambulation. Care should be taken to access the femoral artery at a compressible site below the inguinal ligament.<sup>56</sup> Newer closure devices, including collagen plugs, percutaneous devices, and external compression devices, have been used to help with hemostasis.<sup>13</sup> Some of these techniques may merely decrease compression time rather than reduce incidence of groin hematomas and can cause significant complications.<sup>64</sup> Use of these preventive strategies varies among institutions. It remains to be seen whether standardization of one or a combination of these practices could improve hematoma rates.

#### **Contrast-Induced Nephropathy**

Contrast-induced nephropathy is one of the more common causes of hospital-acquired renal insufficiency, with an incidence of less than 5% in low-risk patients and 20%-30% in high-risk patients after contrast administration.<sup>42</sup> Risk factors include contrast agents with high osmolar content, ionic contrast agents, and high viscosity; contrast volume; and patient-related factors such as chronic kidney disease, diabetes mellitus, older age, and other cardiovascular risk factors. Preprocedure hydration and administration of n-acetylcysteine or bicarbonate have been proposed as nephroprotective strategies.<sup>28,37,47,49</sup> The European Society of Urogenital Radiology and the American College of Radiology have established a set of guidelines based on the existing evidence. In the presence of risk factors, alternative imaging techniques should be considered first. If the risks are thought to be outweighed by the benefits of contrast administration, then low-osmolar or iso-osmolar contrast agents are recommended at the minimum required dose. Adequate hydration and/ or additional fluid therapy are also recommended but without clear dosage regimens. Diuretic use is not rec-

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ommended. When possible, nonsteroidal antiinflammatory drugs should be withheld for at least 24 hours before and after the procedure, whereas metformin should be avoided for at least 48 hours before the procedure and until it is clear that contrast-induced nephropathy has not developed after the procedure. There is insufficient data to recommend for or against the use of n-acetylcysteine; thus its use is neither supported nor refuted in the guidelines.<sup>1,49,74</sup> No prospective, controlled data exist specifically for the neurointerventional field. It is likely that the occurrence of contrast-induced nephropathy is consistent across fields and depends on contrast- and patient-specific factors rather than the underlying indication for imaging or intervention.

# **Intraoperative Rupture**

Intraprocedural vessel rupture during neuroendovascular procedures is infrequent but potentially devastating. Reports of its incidence range from 1% to 9%.<sup>6,12,25,33,35,36</sup>, <sup>38,45,52,61,71,79</sup> Patients who experience intraprocedural rupture during endovascular therapy tend to fare worse than those who experience this complication during open surgery, since the resulting bleeding cannot be immediately decompressed, and all efforts are aimed solely at trying to repair the leakage, potentially even at the cost of vessel sacrifice. The CARAT study of 1010 ruptured intracranial aneurysms treated by coil embolization or clip ligation at 9 high-volume centers in the US found a 5% risk of intraprocedural rupture in the coil embolization group with an attendant 64% rate of death or disability, compared with a 31% rate of death or disability among patients who experienced an intraoperative rupture during open surgical clipping.12 Risk factors for intraoperative rupture during occlusion of aneurysms include small aneurysm size, recent rupture, and the presence of a daughter sac.<sup>33</sup>

Rescue therapies in the case of aneurysm rupture consist of continuing with the originally planned coil embolization process, placing coils in the subarachnoid space and retracting them toward the aneurysm dome (to seal it), leaving the microcatheter in place and deploying a second microcatheter, placement of a ventriculostomy, or even vessel sacrifice.<sup>33,35</sup> Elevated ICP is common following intraprocedural rupture; thus, many authors recommend that supplies for treatment of elevated ICP, including ventriculostomy, be available in the interventional suite in the event of intraprocedural rupture.<sup>71</sup> Recently at the Mayo clinic, a checklist was developed to help identify and guide emergent management.<sup>69</sup> Its use and real-time testing for efficacy are highly anticipated.

Vessel rupture during AVM embolization may occur when perforation of a feeding or draining vessel is caused by the microwire or microcatheter. Rescue therapy may consist of immediate injection of embolization material unless the injury is too far upstream.<sup>79</sup>

Improvements in access and embolic devices along with proper endovascular techniques in experienced hands all contribute to minimizing the risk of intraprocedural aneurysm rupture.<sup>33</sup>

# **Failure to Treat Lesion**

Occasionally, anatomical or technical difficulties preclude treatment of the targeted lesion. Reports of such occurrences are scant, but existing series suggest an incidence of 4%-6%.45,52,61 Risk factors include lack of proceduralist experience and lesion locations that are difficult to access. When an endovascular procedure has to be abandoned, alternative methods such as repeat angiography, open surgery, or radiotherapy are considered. Careful analysis of preoperative imaging, including noninvasive and invasive imaging of the access vessels and target lesion, especially with use of postprocessing of images in 3D software, may help to predict and thereby reduce the incidence of "failed" attempts or to prepare for use of assist devices. In the future, preoperative simulation of the anticipated procedure may not only prevent failed attempts, but also allow preparation for the use of the specific devices most likely to succeed in a particular anatomical setting.

# **Radiation-Induced Effects**

Exposure to ionizing radiation puts patients at risk for both acute and additive effects. The deterministic, or short-term, effects from ionizing radiation involved in continuous imaging are well documented. Skin burns may occur from exposure to radiation doses as low as 2 Gy, while hair loss may occur after 3 Gy.<sup>30</sup> Existing data for the risk of stochastic effects such as radiation-induced intracranial neoplasm are largely from children treated for tinea capitis<sup>41,59,60,63</sup> and patients treated with local and/or whole-brain radiation for neoplastic disease.72 The risk for radiation-induced neoplasm is likely dosedependent.<sup>59</sup> Not only is the patient at risk for harm due to ionizing radiation exposure during these procedures, but the treating physician is also at risk.73 Several neurointerventional groups have reported radiation doses delivered to the patient and/or treating physician in single studies or over a hospitalization,<sup>8,29,39,43,83</sup> but no prospective study has been performed to evaluate cause and effect between these exposures and long-term effects such as neoplasm. Techniques to minimize radiation to both patients and their treating physicians include lead shielding, collimation, and minimizing the exposure time and number of runs during angiography.<sup>32</sup> Adherence to these techniques is not consistently documented.

#### Conclusions

Endovascular neurosurgery is a high-risk procedural specialty. For many of the complications discussed in this paper, specific strategies have been demonstrated to be effective in reducing risk, and protocols to support integrated implementation may be broadly effective. Due to the complexity and many inherent differences in the various neurointerventional procedures, such protocols are likely to consist of a basic general set of rules applicable to most or all procedures plus subsets of rules applied to specific procedures. Increased regionalization, more stringent volume requirements, and greater standardization and more rapid assimilation of standardized devices may prove beneficial, particularly for the more technical complications of intraoperative rupture and failure to treat the lesion, but these strategies not been adequately evaluated. These ideas are discussed in more detail in the summary paper of this series.<sup>84</sup>

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