Patterns in neurosurgical adverse events: cerebrospinal fluid shunt surgery

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Object. As part of a project to devise evidence-based safety interventions for specialty surgery, the authors sought to review current evidence in CSF shunt surgery concerning the frequency of adverse events in practice, their patterns, and the state of knowledge regarding methods for their reduction. This review may also inform future and ongoing efforts for the advancement of neurosurgical quality.

Methods. The authors performed a PubMed search using search terms "cerebral shunt," "cerebrospinal fluid shunt," "CSF shunt," "ventriculoperitoneal shunt," "cerebral shunt AND complications," "cerebrospinal fluid shunt AND complications," "CSF shunt AND complications," and "ventriculoperitoneal shunt AND complications." Only papers that specifically discussed the relevant complication rates were included. Papers were chosen to be included to maximize the range of rates of occurrence for the adverse events reported.

Results. In this review of the neurosurgery literature, the reported rate of mechanical malfunction ranged from 8% to 64%. The use of programmable valves has increased but remains of unproven benefit even in randomized trials. Infection was the second most common complication, with the rate ranging from 3% to 12% of shunt operations. A meta-analysis that included 17 randomized controlled trials of perioperative antibiotic prophylaxis demonstrated a decrease in shunt infection by half (OR 0.51, 95% CI 0.36–0.73). Similarly, use of detailed protocols including perioperative antibiotics, skin preparation, and limitation of OR personnel and operative time, among other steps, were shown in uncontrolled studies to decrease shunt infection by more than half.

Other adverse events included intraabdominal complications, with a reported incidence of 1% to 24%, intracerebral hemorrhage, reported to occur in 4% of cases, and perioperative epilepsy, with a reported association with shunt procedures ranging from 20% to 32%. Potential management strategies are reported but are largely without formal evaluation.

Conclusions. Surgery for CSF shunt placement or revision is associated with a high complication risk due primarily to mechanical issues and infection. Concerted efforts aimed at large-scale monitoring of neurosurgical complications and consistent quality improvement within these highlighted realms may significantly improve patient outcomes.
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KEY WORDS   •   surgical safety   •   adverse events   •   perioperative care

PROGRESS in the science of improving surgical safety has been notable in recent years. Methods for evaluating outcomes have been developed and deployed.[17,28,29,47,56,61,95] The resulting data have been used to investigate patterns of errors and complications. From these findings, solutions have been designed and tested, sometimes with striking improvements, whether using simple process tools like checklists[17,18,38,94] or technological and conceptual changes.[31,69,91] Neurosurgery is a high-risk surgical specialty and is beginning to pursue systematic, nationwide approaches to measuring and improving outcomes and to developing evidence-based guidelines for a variety of neurosurgical disorders. 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 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. This review

Abbreviation used in this paper: AIC = antibiotic-impregnated catheter.

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. This paper reviews the patterns of neurosurgical adverse events in CSF shunt surgery in both adult and pediatric populations. Although pediatric and adult hydrocephalus represent distinct entities with wide disparities in etiology that influence treatment outcome, in this paper CSF shunt surgery is considered more generally, in order to identify universal areas of potential improvement.

Methods

We performed a PubMed search for studies published in or translated into English, using the search terms "cerebral shunt," "cerebrospinal fluid shunt," "CSF shunt," "ventriculoperitoneal shunt," "cerebral shunt AND complications," "cerebrospinal fluid shunt AND complications," "CSF shunt AND complications," and "ventriculoperitoneal shunt AND complications." Only papers that specifically discussed the relevant complication rates were included. Papers were chosen for inclusion in order to maximize the range of rates of occurrence for the adverse events reported rather than to include all possible studies. The majority of the studies discussed in this review pertain to ventriculoperitoneal shunts; however, studies were not excluded if their sample contained patients who received pleural or atrial shunts.

Scope of the Problem

Cerebrospinal fluid shunts are the mainstay of therapy for hydrocephalus of various causes[43] and are among the most common procedures in pediatric neurosurgery.[62] According to the Healthcare Cost and Utilization Project, 14,683 new ventricular shunts were placed in 2008 (http://hcupnet.ahrq.gov). Shunt failure is, and historically has been, a very serious problem. Reported failure rates are as high as 70% in the 1st year after surgery and approximately 5% annually thereafter; indeed, the shunt failure rate has not changed significantly since 1960.[66,82] CSF shunt-related hospital admissions are costly, accounting for $1.4–2.0 billion in hospital charges yearly.[60,81]

The vast majority of shunt-related complications consist of failure from valvular or mechanical dysfunction and/or infection. Shunt infection is a feared entity, and patients who develop infection have approximately twice the risk of death and undergo approximately 3 times the number of shunt-related procedures as those who do not develop infection.[76] Other adverse events include intraabdominal complications, intracerebral hemorrhage, and perioperative epilepsy (Table 1). Many of these events are interrelated.

Valvular/Mechanical Malfunction

The rate of mechanical shunt malfunction is very high, ranging from 8% to 64%.[20,23,36,37,42,53,57] It can occur in various locations along the shunt, including the proximal catheter, valve, or distal catheter, and occurs for various reasons, including obstruction, disconnection

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

AE w/ Authors & Year	No. of Cases	Pt Age	AE Freq (%)
valvular/mechanical dysfunction			
Notarianni et al., 2009	253	ped	64
Hardie et al., 1986	129	mixed	47
Kestle et al., 2000	344	ped	42
McGirt et al., 2007	279	ped	40
Drake et al., 1998	344	ped	35
Hanlo et al., 2003	557	mixed	15
Farahmand et al., 2009	450	adult	8
infection			
Casey et al., 1997	155	ped	12
Govender et al., 2003	110	mixed	12
Kulkarni et al., 2001	299	ped	10
Hardie et al., 1986	129	mixed	9
Drake et al., 1998	344	ped	8
Hanlo et al., 2003	557	mixed	8
Kestle et al., 2000	344	ped	8
Kestle et al., 2011	1571	ped	6
Farahmand et al., 2009	450	adult	6
Ritz et al., 2007	258	mixed	6
Steinbok et al., 2010	433	mixed	3
intraabdominal complications†			
Grosfeld et al., 1974	185	ped	24
Hanlo et al., 2003	557	mixed	0.9
Gutierrez & Raimondi, 1976	1585	mixed	0.7
intracerebral hemorrhage			
Savitz & Bobroff, 1999	125	adult	4
perioperative epilepsy			
Bourgeois et al., 1999	802	ped	32
Klepper et al., 1998	283	ped	20

* AE = Adverse Event; Freq = Frequency; ped = pediatric; Pt = Patient.
† The frequency reported by Grosfeld et al. represents all intraabdominal complications, including hernia and pseudocyst formation. The frequencies reported by Hanlo et al. and Gutierrez and Raimondi are for pseudocyst only.

of tubing and/or a valve, valve malfunction/occlusion, or overdrainage.[51,79] The rates reported here include all etiologies, but we discuss obstruction in detail as it is the most common and therefore the most logical target for safety interventions. To prevent complications associated with proximal blockage, placement of the catheter in a location away from the choroid plexus is advised. Indeed, shunts placed in frontal or occipital locations had lower failure rates than those placed elsewhere in a multicenter post hoc analysis.[85] However, accurate placement is often difficult given that most ventricular catheters are passed into the ventricular system using anatomical landmarks only.[79] In uncontrolled series, stereotactic guidance has been found beneficial, particularly with slit-ventricle conditions.[10,70,98] Intraoperative ultrasonography has also been used with

good effect;[96] larger controlled trials are now underway. Shunts frequently disconnect at stress points where plastic or metal connectors rub against the tubing. Disconnections at these points may be prevented by securing the connection with 2-0 nonabsorbable suture, avoidance of kinking of the shunt components against the bur hole, and allowing for some slack in the tubing.[79] Coordination of these techniques within the operating room requires good communication among surgical teams.

The use of adjustable shunt valves has increased as a means for providing better regulation of CSF flow. Despite their theoretical advantages, the relationship between these valves and complications is not clear. The only randomized trial of a programmable versus conventional valve system did not show any difference between rates of valve or shunt obstruction, though it was only powered as a safety and efficacy study.[65] Similarly, other series do not convincingly support the use of programmable over conventional valves, though one study did find the programmable feature useful in the management of postoperative subdural fluid collection.[8,57] However, there are a small number of uncontrolled series suggesting that the use of programmable valves decreases overall revision rates and the incidence of proximal catheter obstruction.[4,23,53,99] It is similarly unclear whether the use of an antisiphon device improves shunt survival. A multicenter randomized trial compared 2 valves with antisiphon devices against a standard differential pressure valve in the management of pediatric hydrocephalus. This trial showed no significant difference in shunt survival among any of the 3 valves in either short- (1 year)[20] or long-term (median 3 years)[42] follow-up. A small but randomized study also failed to show any statistically significant difference in shunt failure within 6 months but likely was not powered to do so.[46]

Other less common approaches have been employed with varying success. Use of distal slit valves was associated with increased risk of blockage in a single-institution observational study.[15] Others have postulated that catheter length may have an effect, but use of extended-length catheters was not associated with increased blockage in a single-institution observational study.[14] CSF protein levels have not been associated with shunt blockage in observational studies,[27,67] though for many indications such as posthemorrhage or malignancy, many surgeons delay shunt placement until protein levels drop below a certain threshold when possible.

In select patients, endoscopic third ventriculostomy with or without choroid plexus electrocoagulation is a viable option that may circumvent dependence on shunt hardware.[92,93] This technique, however, requires specialized equipment as well as surgical experience.

Infection

Infection is the second most common complication of CSF shunt procedures and is estimated to occur in 3% to 12% of shunt operations.[9,20,23,30,36,37,42,44,50,71,83] A 2009 study of infection rates following initial CSF shunt placement procedures across pediatric hospitals in the US, including 7071 pediatric patients, demonstrated that the rate of shunt infection depended in part on surgeon and hospital volume.[80] The mortality rate associated with shunt infection is reported to be 10.1%, and shunt infection is associated with worse Glasgow Outcome Scale scores and worse school performance in the long term.[90]

Risk factors include young age, female sex, African-American race, public insurance, etiology of hydrocephalus from intraventricular hemorrhage, complex chronic respiratory conditions, subsequent revision procedures, hospital volume, and surgeon case volume.[25] There are also a number of procedural factors that may reduce the rate of CSF shunt infections. As with other surgical procedures, antibiotic prophylaxis appears to reduce shunt infections. A 2008 meta-analysis that included 17 randomized controlled trials of perioperative antibiotic prophylaxis demonstrated a significant decrease in the rate of shunt infection (OR 0.51, 95% CI 0.36–0.73). These results remained consistent across all ages, shunt types, and pre- and postoperative durations of antibiotic use.[68]

Recently introduced antibiotic-impregnated catheters (AICs) have been shown to decrease shunt colonization by *Staphylococcus* species,[3,30,35] though controversy remains whether their use should be standardized. Several nonrandomized studies showed a reduction in early shunt infection and hospital costs with their use.[2,41,77,78] A retrospective before-and-after study suggested benefit in the adult population as well.[24] The only prospective, randomized study on the subject was performed at a single institution and involved 110 patients (age range 1 month to 72 years. This study showed a significant reduction in shunt infection within 2 months with AIC use, but although the trend remained, this difference was not statistically borne out at longer-term follow-up. Additionally, it remains unclear whether randomization resulted in 2 groups that were demographically balanced and whether the results of the study are truly generalizable.[30] Two recent meta-analyses suggest that AICs may be of benefit, reducing shunt infection rates as well as hospital costs.[49,84] Another review suggests the same, for both pediatric and adult populations.[59] All these pooled data need to be interpreted in the context of the lack of prospective controlled studies. The existing studies are characterized by heterogeneity in the examined patient populations and definition of shunt infection, as well as lack of control of other confounders affecting shunt infection rates. There is also concern for publication bias, in that positive studies are more likely to be published.[45] On the other hand, a number of other uncontrolled studies do not show benefit to AICs.[40,71,83] There is also some concern that use of AICs may select for resistant, harder-to-treat organisms.[19]

Other mechanisms aimed at preventing shunt infections have been employed as well, to some effect. One study noted that a risk factor for shunt infection appeared to be an unrecognized defect in gloves worn by the surgical team.[50] Double gloving has since been shown to reduce this complication by more than 50% in one retrospective, before-and-after study.[86] This technique also appears to decrease infection rates when combined with others in the protocols outlined below.

Perioperative shunt protocols integrating these and other strategies have demonstrated beneficial effect. In the most recent of these reports, Kestle et al.[44] describe the results of a prospective, nonrandomized study of 1571

pediatric procedures performed after implementation of the Hydrocephalus Clinical Research Network (HCRN) protocol. Their findings suggested a reduction in the shunt infection rate from 9% to 6% after implementation of the protocol, which included a sign on the OR door to limit traffic, positioning the patient's head away from the door, perioperative administration of antibiotics, appropriate use of ChloraPrep, traditional hand scrub, double gloves, use of Ioban drape, and intrathecal antibiotic administration. Another observational study implemented a strict infection-control protocol including limitation of OR personnel and traffic, limitation of implant and skin edge manipulation, scheduling shunt surgery as first case of the day, avoidance of postoperative CSF leakage, double gloving, limitation of operative time to less than 30 minutes, and antibiotic prophylaxis; during the 4- to 70-month follow-up period the authors found no shunt infections among the 100 pediatric patients included in the study.[64] Other older studies found similar results with the use of similar infection-control protocols, with the only additional steps of changing gloves prior to handling shunt hardware, and opening the sterile hardware packaging at the last minute.[11,72] Another uncontrolled, before-and-after study found a significant decrease in infections with a "no-touch" policy wherein the shunt hardware was handled only with instruments and shunt tubing was kept on a separate table from instruments used for skin incision.[22] Full adherence to such protocols requires good communication within the surgical team. The importance of communication and effective team dynamics are discussed in the summary paper of this series.[97]

Intraabdominal Complications

The majority of CSF shunts placed in the modern era are ventriculoperitoneal shunts, and placement of the distal catheter into the peritoneal cavity can be difficult in the setting of multiple shunt revisions, prior abdominal surgery, prior abdominal infection, or obesity. These difficulties may result in placement of the distal catheter into the preperitoneal fat instead of the peritoneal space, or worse, may result in bowel or visceral injury.[55,79]

Laparoscopic placement of the distal catheter is becoming more common and has potential advantages. These include direct visualization of the catheter in the intraperitoneal space, avoidance of an abdominal incision overlying shunt tubing, potentially shorter operative times and postoperative stays, and reduced bowel or catheter complications. One prospective, uncontrolled study demonstrated an infection rate of 0.9%, a mean operative time of 49 minutes (during the final 4 months of the study), and a 1-year shunt survival rate of 91%.[87]

Delayed bowel injury may also occur with erosion of a hollow viscus by the shunt catheter, sometimes extruding through the anus.[89] In fact, the distal catheter may penetrate or migrate into multiple locations including the oral cavity, bladder, colon, umbilicus, gall bladder, and scrotum.[5,21,52,54,58] Methods of preventing such injury are debated but may include limiting distal catheter length and minimizing the angle at which the distal catheter is cut prior to insertion, though these techniques remain unproven in a systematic way.

Abdominal pseudocysts represent an additional abdominal complication with an estimated rate between 0.7% and 10%.[7,13,32,33] They are most common in the setting of infection,[1,12,13,34,73] and are also likely to occur in the setting of prior abdominal operations and adhesions.[1] Strategies to reduce pseudocyst formation are limited but may include consideration of other drainage sites in patients who have had prior abdominal surgery.

In the setting of challenging cases such as multiple reoperations, consulting a general surgeon for assistance may be helpful or even necessary.[79]

Intracerebral Hemorrhage

Intracerebral hemorrhage from shunt placement is a rare but potentially catastrophic complication.[39] No study has carefully documented its frequency, though one retrospective study showed a 4% rate of radiographically confirmed hemorrhage following routine shunt placement. None of the hemorrhages was symptomatic.[75] Efforts aimed at minimizing risk of intracranial hemorrhage include meticulous attention to the bur-hole site and dural penetration, careful avoidance of choroid plexus during placement, perhaps using real-time image guidance,[10,70,98] perioperative screening protocols and medical optimization,[26] and use of high-dose anticoagulant therapy only when the benefits outweigh the hemorrhage risk.

Perioperative Epilepsy

Because of the association between hydrocephalus and seizures or epilepsy, seizure rates following shunt placement remain high. The risk of seizure as a result of shunt placement itself, however, is controversial.[6,48,74] Some work has suggested that frontal rather than parietal bur-hole placement was associated with increased incidence of seizure,[16] though these data have not been corroborated by other studies.[63,79,88] Thus perioperative seizures related to shunt placement are not an independent complication of surgery but warrant discussion given that they are common and can be problematic. Minimizing seizure risk parallels treating the root cause of the epilepsy, and perioperative antiseizure medication is usually given only when part of the patient's routine regimen.

Conclusions

Surgery for CSF shunt placement is associated with a high risk of complications due primarily to mechanical problems and infection. The wide ranges of adverse event rates reported here reflect the need for risk stratification and highlight the need for national data, discussed in further detail in the summary paper of this series.[97] A significant proportion of complications are likely avoidable using standardized protocols, improved teamwork and communication, and potentially increased use of beneficial technologies such as intraoperative image guidance. Although the use of these strategies is increasing, it is far from universal. Concerted efforts aimed at large-scale monitoring of neurosurgical complications and consistent quality improvement within these highlighted realms may significantly improve patient outcomes.

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