Reducing the risks of proximal and distal shunt failure in adult hydrocephalus: a shunt outcomes quality improvement study

Albert M. Isaacs, MD, PhD, Chad G. Ball, MD, FRCSC, Nicholas Sader, MD, Sandeep Muram, MD, David Ben-Israel, MD, MA, Geberth Urbaneja, MD, Jarred Dronyk, BA, Richard Holubkov, PhD, and Mark G. Hamilton, MD, CM, FRCSC

OBJECTIVE Patient outcomes of ventriculoperitoneal (VP) shunt surgery, the mainstay treatment for hydrocephalus in adults, are poor because of high shunt failure rates. The use of neuronavigation or laparoscopy can reduce the risks of proximal or distal shunt catheter failure, respectively, but has less independent effect on overall shunt failures. No adult studies to date have combined both approaches in the setting of a shunt infection prevention protocol to reduce shunt failure. The goal of this study was to determine whether combining neuronavigation and laparoscopy with a shunt infection prevention strategy would reduce the incidence of shunt failures in adult hydrocephalic patients.

METHODS Adult patients (age ≥ 18 years) undergoing VP shunt surgery at a tertiary care institution prior to (pre–ShOut Outcomes [ShOut]) and after (post-ShOut) the start of a prospective continuous quality improvement (QI) study were compared. Pre-ShOut patients had their proximal and distal catheters placed under conventional freehand approaches. Post-ShOut patients had their shunts inserted with neuronavigational and laparoscopy assistance in placing the distal catheter in the perihepatic space (falciform technique). A shunt infection reduction protocol had been instituted 1.5 years prior to the start of the QI initiative. The primary outcome of interest was the incidence of shunt failure (including infection) confirmed by standardized criteria indicating shunt revision surgery.

RESULTS There were 244 (115 pre-ShOut and 129 post-ShOut) patients observed over 7 years. With a background of shunt infection prophylaxis, combined neuronavigation and laparoscopy was associated with a reduction in overall shunt failure rates from 37% to 14%, 45% to 22%, and 51% to 29% at 1, 2, and 3 years, respectively (HR 0.44, p < 0.001). Shunt infection rates decreased from 8% in the pre-ShOut group to 0% in the post-ShOut group. There were no proximal catheter failures in the post-ShOut group. The 2-year rates of distal catheter failure were 42% versus 20% in the pre- and post-ShOut groups, respectively (p < 0.001).

CONCLUSIONS Introducing a shunt infection prevention protocol, placing the proximal catheter under neuronavigation, and placing the peritoneal catheter in the perihepatic space by using the falciform technique led to decreased rates of infection, distal shunt failure, and overall shunt failure.

KEYWORDS hydrocephalus; neuronavigation; laparoscopy; quality improvement

Hydrocephalus affects approximately 175 per 100,000 adults worldwide. Ventriculoperitoneal (VP) shunt insertion remains the mainstay treatment for hydrocephalus. In adults, however, 15%–23% of new VP shunts fail, typically within the first 6 months, and upwards of 50% fail in high-risk populations. Each shunt failure requires repeat surgery that is associated with a cumulative risk of perioperative complications, as well as stress for patients and their families and increased healthcare infrastructure costs. The “traditional” VP shunt insertion technique, which involves freehand insertion of the proximal catheter and placement of the distal

ABBREVIATIONS INPH = idiopathic normal pressure hydrocephalus; QI = quality improvement; ShOut-QI = Shunt Outcomes Quality Improvement; VP = ventriculoperitoneal.


INCLUDE WHEN CITING Published online August 27, 2021; DOI: 10.3171/2021.2.JNS202970.

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J Neurosurg Volume 136 • March 2022
catheter via mini-laparotomy or trocar conduit,\(^9\)\(^{-11}\) does not allow real-time tracking or direct visualization of the final location during or after catheter insertion. Failure to achieve an ideal position for these catheters contributes to shunt failure, which is the most frequent long-term complication associated with VP shunt treatment of hydrocephalus.\(^12\)\(^{-13}\)

There is evidence that shunt failure can be reduced with modifications to the surgical technique in three important ways: the use of neuronavigation (stereotactic navigation) to aid in the insertion of the ventricular catheter,\(^14\) the use of laparoscopy to place the peritoneal shunt catheter,\(^10\)\(^,\)\(^15\) and the institution of shunt infection control protocols.\(^16\)\(^,\)\(^17\)

Assessed independently, neuronavigation and laparoscopy can reduce the risk of failure at the proximal\(^14\) and distal\(^10\)\(^,\)\(^15\) sites, respectively, but usually have less effect on overall shunt failure rates. Studies showing a significant reduction in the rates of shunt surgery–related infections have primarily been performed in the pediatric population.\(^16\)\(^,\)\(^17\)

To our knowledge, there has been no study in adults that primarily been performed in the pediatric population.\(^16\)\(^,\)\(^17\)

The general aspects associated with the surgical approach for VP shunt insertion have been described elsewhere.\(^25\) With regard to this study, there were three intervention changes: 1) a shunt infection–prevention strategy was implemented, and 2) frameless navigation was accomplished using AxiEM (Medtronic International), which was typically performed with preoperative MRI or CT prior to surgery. The entry site for insertion of the ventricular catheter was typically the posterior right side. All entry locations were selected based on image-guided preoperative planning, and passage of the ventricular catheter was undertaken with real-time use of the image guidance.\(^24\)

Programable shunt valves were consistently used.\(^24\)\(^\)\(^,\)\(^25\) 3) The peritoneal catheter was inserted through a small right para-xiphoid incision using an 11-Fr peel-away sheath and was positioned in the peritoneal cavity with laparoscopic assistance undertaken by a general surgeon. In addition, a modification of the distal catheter insertion technique described by Svoboda et al.\(^20\) was used. The catheter was anchored behind the right lobe of the liver through a small hole created in a rostral, posterior location of the falciform ligament with the catheter tip positioned superior to the right lateral paracolic gutter. There was no preset length for the peritoneal catheter within the abdomen. Rather, the catheter was positioned and then trimmed to end just above the lowest right edge of the liver. The residual free catheter was removed from the peritoneal cavity. The goal was to have the shunt peritoneal catheter tip positioned free from omentum, adhesions, or bowel, which have the potential to cause obstruction of CSF flow.\(^25\)

### Study Timeline

A prospective database documenting all shunt insertions performed by the senior author (M.G.H.) was established in January 2012. Commencement of the laparoscopy-guided peritoneal catheter insertion marked the official start date of the ShOut-QI study on April 1, 2015. Frameless neuronavigation-guided ventricular catheter insertion was introduced 4 months prior to the official study start date. The proximal and distal interventions were staggered to facilitate integration into the institution’s operating room logistical framework. The shunt infection prevention bundle was implemented on July 1, 2013, and ran contemporaneously with the ShOut-QI study.\(^24\)\(^,\)\(^26\)

A continuous QI approach\(^15\)\(^,\)\(^27\)\(^,\)\(^28\) was used. Study enrollment ended December 31, 2018. Small incremental improvements in the surgical technique were made as a result of quarterly reviews, and there were minor changes to shunt hardware during the 7-year study time frame. All patients were treated with programmable valves because of the potential benefit for mitigating symptomatic subdural effusions noninvasively.\(^29\) All peritoneal catheters were of the open tip variation. No antibiotic-impregnated catheters were used. Patient follow-up was closed for the purposes of the study on December 31, 2019.

### Definition of Measures

Shunt failure was defined as the requirement for additional shunt surgery (revision) for any part of the shunt system because of either shunt malfunction or shunt infection. Clinical criteria for shunt malfunction required a history compatible with neurological deterioration confirmed by cranial neuroimaging (CT or MRI) changes and/or an abnormal nuclear medicine shunt flow study.\(^30\)
Shunt malfunction was classified as proximal or distal catheter obstruction, which was verified by intraoperative confirmation of catheter malposition, dislodgment from the ventricle or peritoneal cavity, breakage, or blockage by intraventricular or intrabdominal particulate matter, debris, omentum, or adhesions. Shunt infection was defined according to the Canadian Nosocomial Infection Surveillance Program (CNISP) definition as a positive CSF culture or leukocytosis from a shunt tap or culture of removed shunt hardware or as evidence of a surgical wound dehiscence occurring within the 1st postoperative year. A complication was defined as any VP shunt insertion–related adverse event not described as an outcome measure of this study and occurring within 30 days of surgery.

Clinical Measures

The types of hydrocephalus diagnoses prompting initial shunt insertion were classified according to the Adult Hydrocephalus Clinical Research Network (AHCERN) criteria as 1) acquired, 2) unrecognized congenital, or 3) idiopathic normal pressure hydrocephalus (iNPH). Hospital charts, imaging reports, operative records, and follow-up notes for patients who met inclusion criteria were used to prospectively complete the Calgary Adult Hydrocephalus Clinic registry. Patient demographics included sex and age at the time of initial VP shunt insertion. Preoperative CT or MRI confirmed ventriculomegaly with an Evans index ≥ 0.3. The operative technique used during VP shunt insertion was documented to identify compliance regarding the use of a shunt infection bundle, whether neuronavigation was used for the ventricular catheter, and whether laparoscopy or standard approaches for distal peritoneal catheter placement were used. The position of the tip of the ventricular catheter was graded with an early (day 1–2) postoperative 3-point CT grading system initially proposed by Hayhurst et al.: grade 1, optimal position free-floating in CSF; grade 2, touching choroid or ventricular wall; or grade 3, intraparenchymal (Fig. 1). The position of the distal catheter within the peritoneal cavity was dichotomized into those anchored within the perihepatic space or those free-floating in the abdomen, as evidenced by an early (day 1–2) postoperative abdominal radiograph.

Outcome Measures

The primary outcome measure was shunt failure. Secondary measures included time to additional shunt revi-
sions and complications. VP shunt insertion outcomes were compared between patients treated before (pre-ShOut group) and those treated after (post-ShOut group) the ShOut-QI start date (April 1, 2015). For those who presented with shunt failure, the etiology of failure (mechanical obstruction, catheter fracture, catheter migration, infection, CSF overdrainage) and site of failure (proximal or distal catheter, valve) were assessed. Perioperative and delayed complications were assessed as well.

Statistical Analysis

Statistical Analysis System (SAS version 9.4, SAS Institute Inc.) was used for all data analyses. Independent-samples t-tests were used to compare groups with respect to age at initial shunt insertion. The chi-square and Fisher’s exact tests were used to compare categorical data. For comparing the duration of follow-up, the Mann-Whitney U-test was used. Differences in shunt failure outcome were compared to determine associations between independent variables and the primary outcome. Associations of all covariates with the primary outcome and operative technique were examined. Kaplan-Meier survival analysis was used to assess shunt failure–free survival between the groups with significance determined using the log-rank test. A Cox proportional hazards model quantified the intervention-based reduction in shunt failures over time. The validity of the proportional hazards assumption was assessed using a Kolmogorov-type Supremum test based on 1000 resampled martingale residual patterns. All tests were two-tailed, and p values < 0.05 were considered statistically significant.

Ethical Considerations

The study was assessed by the University of Calgary Conjoint Health Research Ethics Board and was considered exempt from review in accordance with the QI methodology that was planned. At the completion of the QI study, ethics approval was obtained to undertake detailed analysis with a waiver of consent. There were no investigator or patient conflicts of interest.

Results

Timeline of Interventions

This study includes a total of 244 consecutive patients undergoing a new VP shunt insertion surgery. Before QI implementation, 115 patients underwent VP shunt placement, 18 of whom had proximal catheters placed with neuronavigation and 1 of whom had a proximal catheter placed with basic laparoscopy. After QI implementation, 129 patients underwent VP shunt insertion with combined neuronavigation and laparoscopy (Table 1). The study timeline and modifications of the operative technique are presented in Fig. 2.

Patient Characteristics

The mean age at initial shunt surgery did not differ between groups (p = 0.813). While there were more males than females in both groups, there were no differences in the sex distribution between groups (p = 0.138). The etiol-
ogy of hydrocephalus for the majority (75%) of patients was iNPH with no difference between groups regarding the distribution of hydrocephalus etiology (p = 0.117). There was higher accuracy of proximal catheter placement (CT grade 1) in the post-ShOut group than in the pre-ShOut group (91% vs 72%, p < 0.001). On postoperative abdominal radiographs, 9% of distal catheters intraoperatively placed in the perihepatic space were free-floating in the peritoneal cavity. The pre- and post-ShOut groups had median follow-up durations of 5 and 2 years, respectively, after the first shunt surgery. Given these between-group differences in follow-up times, all shunt failure rates are reported as Kaplan-Meier estimates at 2 years unless otherwise specified (Table 1).

### Patient Outcomes

#### Overall Shunt Failure

Among all patients, 38% of implanted shunts failed during follow-up, including 54% in the pre-ShOut group and 24% in the post-ShOut group (Table 1). Failure rates over time were significantly lower in the post-ShOut group than in the pre-ShOut group (p < 0.001; Fig. 3). Estimated

<table>
<thead>
<tr>
<th>Shunt Failure (continued)</th>
<th>Pre-ShOut Group</th>
<th>Post-ShOut Group</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative shunt failures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>33 (53.2)</td>
<td>27 (87.1)</td>
<td>60 (64.5)</td>
</tr>
<tr>
<td>2</td>
<td>16 (25.8)</td>
<td>3 (9.7)</td>
<td>19 (20.4)</td>
</tr>
<tr>
<td>3</td>
<td>8 (12.9)</td>
<td>1 (3.2)</td>
<td>9 (9.7)</td>
</tr>
<tr>
<td>&gt;3</td>
<td>5 (8.1)</td>
<td>0 (0.0)</td>
<td>5 (5.4)</td>
</tr>
</tbody>
</table>

FU = follow-up.
Values are expressed as the mean ± standard deviation or number (%), unless indicated otherwise. Percentages of baseline characteristics are based on the total number of patients in the respective columns. Percentages of shunt failures are based on the overall number of shunts in the respective columns.

![Study timeline of the ShOut-QI study. A prospective database documenting VP shunt insertions was established in January 2012. A shunt infection prevention bundle was implemented in July 2013. Frameless neuronavigation-guided ventricular catheter insertion was introduced in January 2015 and was piloted for 4 months until the first laparoscopy-guided peritoneal catheter insertion was performed on April 1, 2015, marking the official start of the ShOut-QI study. The trend line (blue) within the specified upper confidence limit (UCL) and lower confidence limit (LCL) demonstrates the steady decline in the percent of shunt failure rates (dots) at biannual analyses following initiation of the QI initiative. Study enrollment was completed on December 31, 2018. All patients were followed up for a minimum of 1 year post–shunt surgery.](image-url)
failure rates in the post-ShOut group after the 1st, 2nd, and 3rd years of implantation were 14%, 22%, and 29%, respectively, versus corresponding rates of 37%, 45%, and 51% in the pre-ShOut group. The combined use of neuronavigation and laparoscopy reduced the relative risk of shunt failure over time by an estimated 44% (95% CI for hazard ratio 0.28%–0.68%, p < 0.001) per Cox regression. There was no difference between groups with respect to isolated valve failures over time.

Proximal Failures
There were 4 (2%) patients with proximal failures, all occurring in the pre-ShOut group and within the first 100 days of surgery. Those patients had no further proximal failure when their failed shunts were revised with the aid of neuronavigation. Subgroup analysis of the 18 patients whose distal catheter had been placed with the freehand approach revealed that proximal catheter placement with neuronavigation was associated with a lower incidence of overall shunt failure than the freehand approach (2-year rates of 33% vs 47%); however, the difference was not statistically significant (p = 0.1; Table 1 and Figs. 4 and 5).

Distal Failures
The distal catheter was the most common site of shunt failure, accounting for more than 90% of the failures in each group. There was a higher rate of distal shunt failure among the pre-ShOut (42%) than the post-ShOut (20%) group (p < 0.001), reflecting the reduced failure rates observed with the use of laparoscopy with the falciform technique to place the distal catheter (p < 0.001). In addition, distal catheters within the perihepatic space had a lower rate of overall failure (2-year failure rate of 16%) than those placed free-floating in the peritoneal cavity (42%; p < 0.001). Subgroup analysis of the post-ShOut group demonstrated that patients whose peritoneal catheter did not stay in the perihepatic space (free-floating in the abdomen) had a higher rate of shunt failure (50% at 2 years vs 19%); however, the difference was not statistically significant (p = 0.1; Table 1 and Figs. 4 and 5).

Etiology of Failure
The most common etiology of failure was mechanical obstruction, which occurred in 77% of all shunt failure cases, accounting for 39% and 21% of all pre-ShOut and post-ShOut cases, respectively. Shunt infection decreased from 8% in the pre-ShOut group to 0% in the post-ShOut group. There were no shunt failures due to catheter migration in the post-ShOut group, and the rate of overdrainage-related failures was 2% in each group (Table 1).

Over the course of the study, 51 (21%) patients died, all from causes unrelated to hydrocephalus treatment, and the higher number of deaths in the pre-ShOut group was attributed to a significantly longer duration of follow-up compared to that for the post-ShOut group (Table 1). There were no reportable major early (30-day) postoperative complications other than those associated with the study outcomes.

Discussion
Summary of Findings
This prospective QI study evaluating 224 consecutive patients established that with a background of shunt infec-
tion prophylaxis, adult hydrocephalus patients treated with combined neuronavigation and laparoscopy had a risk of shunt failure over time reduced by 44%, with a 21%–23% absolute reduction in failures rates within the first 3 years of VP shunt surgery. There were no proximal catheter failures in the post-ShOut group. With neuronavigation, the rate of ventricular catheters properly situated in the ventricle (i.e., grade 1 or 2) improved from 89% to 100%. Most shunt failures (90%) were attributable to distal catheter issues, with a 42% versus 20% distal catheter failure rate within 2 years of implantation in the pre- and post-ShOut groups, respectively.

Interpretation of Findings

VP shunt failure in adults can occur at the site of the proximal catheter, the valve, or the distal catheter or can be related to surgery-associated infection. Most of the literature, which constitutes retrospective studies, reports VP shunt failure occurring in 15%–23% of new VP shunts typically within the first 6 months and 50% at 1 year. Startlingly, LeHanka and Piatt recently reported, based on VP shunt insertion data obtained from the 2015 US Nationwide Readmissions Database, 30-day reoperation rates of 47.4% for adults (i.e., 19–55 years of age) and 32.4% for elders (i.e., older than 55 years of age). Some of the causes of ventricular catheter failure include malposition or occlusion by choroid plexus or inflammatory debris. Shunt valve failure is uncommon. Distal peritoneal catheter failure, which is a common cause of VP shunt failure in adults, usually occurs because of occlusion by omentum, bowel, debris, or intraabdominal fibrous adhesions. Shunt-related infection, which is reported to occur in approximately 6%–10% of shunt-associated surgeries in adults, is an additional significant cause of shunt failure. Shunt infection typically requires, in addition to prolonged intravenous antibiotic treatment, a series of surgeries involving shunt removal, temporary control of high intracranial pressure and the hydrocephalus with an external ventricular drain, and eventually replacement of the shunt system.

Previous studies have supported the concept that neuronavigation is associated with a reduction in proximal catheter failures. Hayhurst and colleagues’ randomized
A study of neuronavigation during VP shunt insertion demonstrated a significant reduction in proximal catheter and early (30-day) shunt failure from 22% (n = 41) to 6% (n = 34) in the neuronavigation group but not a significant difference in overall shunt failure.14 In our study, there were no proximal ventricular catheter failures in 129 individuals when neuronavigation was used.

The laparoscopic technique of creating a hole within the falciform ligament of the liver and placing the catheter within the right paracolic gutter has been described by Svoboda et al. in 58 patients undergoing VP shunt insertion or revision.20 Our results underscore the benefit of placing the catheter in the perihepatic space (superior paracolic gutter) away from the omentum, making it less susceptible to obstruction.

Implementation of the ShOut-QI initiative was associated with a 21%–23% absolute reduction in overall shunt failure rates during the first 3 years, with an additional steady decline over the course of the study and only a 2% failure rate in the last 6 months of the study (Fig. 2). This may represent the effects of the reduced rate of early shunt malfunction, the incremental effect of minor modifications to the surgical technique, and potentially a learning curve effect. In addition, there were no failures due to shunt infections in the post-ShOut group, which corresponds with the use of a standardized infection prevention protocol.16,17

**Study Limitations**

This study has a single-center and single-surgeon non-randomized study design. However, its prospective methodology and large consecutive patient numbers may mitigate some of the potential design limitations. While minor changes were made in shunt hardware over the course of the study, there is currently no evidence to indicate outcome differences among similar valve types. Finally, this study does not address the costs, direct or indirect, associated with the addition of neuronavigation and laparoscopy. A cost analysis study is underway.

**Conclusions**

This study provides compelling evidence on how to improve adult hydrocephalus VP shunt insertion outcomes by using the combination of a shunt infection prevention protocol, placement of the proximal catheter under neuronavigation, and laparoscopic placement of the peritoneal catheter in the perihepatic space via the falciform technique.
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**Disclosures**
Dr. Hamilton has received honoraria from Integra Canada.

**Author Contributions**
Conception and design: Hamilton, Isaacs, Ball, Holubkov. Acquisition of data: Hamilton, Ball, Sader, Muram, Ben-Israel, Urbaneja, Dronyk. Analysis and interpretation of data: Hamilton, Isaacs, Sader, Muram, Ben-Israel, Holubkov. Drafting the article: Isaacs. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Hamilton. Statistical analysis: Isaacs, Holubkov. Administrative/technical/material support: Hamilton, Isaacs, Sader, Urbaneja, Dronyk. Study supervision: Hamilton, Isaacs, Ball.

**Supplemental Information**

**Previous Presentations**
Portions of this work have been presented as oral abstract presentations at the Ninth Annual Meeting of the International Society for Hydrocephalus and Cerebrospinal Fluid Disorders held on September 23–25, 2017, in Kobe, Japan; the 51st Annual Congress of the Canadian Neurological Sciences Federation held on June 21–24, 2016, in Quebec City, QC, Canada; and the 2019 Western Neurosurgical Society Meeting held on November 8–11, 2019, in Scottsdale, Arizona.

**Correspondence**
Mark G. Hamilton: Foothills Medical Centre, Calgary, AB, Canada. mghamilton.hydro@gmail.com.