Ventriculoperitoneal Shunt 30-Day Failure Rate: A Retrospective International Cohort Study

BACKGROUND: With the need for transparency of surgical results, 30-day outcome measures have become increasingly important. Ventriculoperitoneal (VP) shunt failure is a substantial burden to patients and health care systems.

OBJECTIVE: This study introduces the 30-day VP shunt failure rate as a possible barometer of surgical outcome and demonstrates its use in a national (United Kingdom [UK]) study and makes comparison with 2 published randomized, controlled trials (RCT).

METHODS: A cohort study of all (except 1) pediatric neurosurgical centers in the UK and Ireland. All new and revision VP shunt operations were recorded for 2008 and 2009. Both newly placed and revised VP shunts were subject to Kaplan-Meier analysis, and 30-day failure rate was obtained. Data from 2 RCTs investigating new VP shunt technology were analyzed, and the 30-day failure rate was extracted for comparative purposes.

RESULTS: The overall 30-day and 1-year failure rates for new shunts were 12.9% and 28.8%, respectively. The 30-day failure rate from 2 RCTs was comparable (14% and 16%, respectively). The failure rate of the subsequent revision of those new shunts was 20.7% at 30 days and 40.4% at 1 year. According to these data, shunt survival appears to be better if performed by a consultant pediatric neurosurgeon for revision surgery only.

CONCLUSION: VP shunt survival in the UK is comparable to the published multicenter data investigating shunt survival. The 30-day failure rate may represent a better barometer of surgical outcome and should be used as a separate outcome measure in the design of future trials.

KEY WORDS: Hydrocephalus, Pediatric, Ventriculoperitoneal shunt

The treatment of hydrocephalus was revolutionized in the 1950s by the advent of ventriculostidal shunting through a one-way valve. Since then, surgeons and manufacturers have striven to improve the length of time these devices survive, but to date, no valve design has been shown to be superior in a randomized trial. Ventriculoperitoneal (VP) shunting remains the most common procedure undertaken by pediatric neurosurgeons, and in the United States, there are approximately 36,000 shunt-related procedures each year at an estimated cost of US$100 million and 400,000 hospital days. Revision procedures constitute a significant proportion of this. Review of the literature gives an estimate of the 1-year failure rate for new VP shunts of approximately 25% to 35%, although multicenter data suggest this figure to be as high as 40% to 60%. Much of the data available are based on single-institution experiences and trials investigating new shunt technology. The survival of shunts at the time of revision or the effects of one failure on subsequent failures are often not included. Factors associated with shunt failure can be broadly divided into those relating to the patient, the mechanical design of the shunt, and the surgeon/perioperative events. Patient factors include the age at the time of shunt placement and the etiology and type of hydrocephalus. Perioperative factors that have been implicated include the number of manual contacts between the surgeon and the shunt prosthesis, duration of the surgical exposure, intraoperative breach of gloves, and accuracy of intracranial catheter location. Other surgical factors include postoperative cerebrospinal fluid leak and the case...
load of the operating surgeon/institution. Reasons for shunt failure include obstruction, mechanical disconnection, infection, and overdrainage.\textsuperscript{16}

There are increasing requirements by regulators and patients/parents for transparency of surgical results.\textsuperscript{17} To date, there are no comparative national data investigating VP shunt survival. Although historically, shunt survival is assessed at 1-year, the 30-day marker is a time scale often used to judge the outcome of inpatient care but has not been applied to VP shunt survival.\textsuperscript{17}

This could provide further insight into surgical causes of VP shunt failure and help to evaluate the individual causes of failure better, as well as potentially being used as a barometer of individual surgeon and institution standards of care.

The aims of this study were to report VP shunt survival over a 2-year period on a national scale in an unselected population (United Kingdom [UK]); introduce the 30-day failure rate for VP shunt survival analysis; and compare the 30-day failure rate from the national UK data with that from two international randomized, controlled trials (RCTs).

**PATIENTS AND METHODS**

The study period was from January 1, 2008, to December 31, 2009. All pediatric neurosurgical units in the UK and Ireland were given the ability to prospectively upload data on all neurosurgical operations performed in each individual unit to a central database managed by the British Pediatric Neurosurgery Group through the Royal College of Surgeons of Edinburgh portal. Some units would do this monthly and others only at the end of each year before the annual audit held by the British Pediatric Neurosurgery Group.

Anonymous records for all VP shunt operations (insertion of new shunt and revision of preexisting shunt) were extracted from this database. The data from each unit were combined and analyzed. The data collected included the age of the patient, date of an operation, type of operation and subspecialty (pediatric neurosurgeon or not), and grade of the operating surgeon. As the analysis used anonymous data, no specific research ethics or information governance approval was required.

The analysis took 2 forms. The first analysis (new shunt analysis) was for those with newly diagnosed hydrocephalus requiring a new VP shunt during the study period. If no subsequent episodes of shunt failure were recorded during the remaining study period, this shunt would have been recorded as a survived shunt with a survival period to the end of the known follow-up period (December 31, 2009). If the shunt had subsequently failed, this would have been recorded as a failure event. The second analysis (all revisions) included all revision procedures, revision of those new shunts described earlier and those revision procedures on preexisting shunts placed before the study period. Any interim procedures performed between failure of the shunt and placement of another shunt (eg, insertion of an external ventricular drain to treat infection) were excluded. For the purpose of analyzing revision procedures (and in particular, repeated revision procedures on the same patients), all revision procedures were combined in this analysis. For the 30-day failure rate analysis, there is a separate group of revision procedures (labeled first-time revision) that describes the first-time revision of new shunts that were placed during the study period.

Data from two previously published RCTs was reanalyzed to calculate 30-day failure rates.\textsuperscript{1,18} These data were analyzed for comparative purposes with the current dataset. For the purpose of comparing individual units with the overall cohort, a funnel plot has been constructed for illustrative purposes. Because of the small number of patients available for this analysis when new and revision shunts are considered separately, all procedures were combined for this analysis. For the analysis of type/grade of operating surgeon, trainee neurosurgeons and consultant “adult” neurosurgeons were grouped together and compared with consultant pediatric neurosurgeons. Nine patients had received bilateral VP shunts. Because interpretation of subsequent survival was made difficult by a lack of reference to laterality, these patients were excluded from the new shunt analysis.

**Statistics**

The survival analysis was performed using Kaplan-Meier graphs, and the log-rank test was used to test the difference in survival between different types of operating surgeons ($P < .05$ was considered significant). Survival tables were used to obtain 30-day and 1-year survival and comparisons between pediatric and nonpediatric neurosurgical operations tested for significance with Wilcoxon Gehan statistic ($P < .05$ considered significant). All patients had 30-day follow-up, whereas patients operated on in 2009 did not have 1-year follow-up because the study ended on December 31, 2009.

**RESULTS**

Of the 20 pediatric neurosurgical units throughout the UK and Ireland, all (except Belfast) contributed to this study. Table 1 shows the cohorts involved in both analyses.

Figure 1 compares the survival of new VP shunts with those preexisting shunts requiring revision. Mean (95% confidence interval [CI]) survival was 17.4 months (95% CI: 16.8-18.0 months) and 14.3 months (95% CI: 13.7-14.9 months) for new shunts and all revisions, respectively. There was a significantly higher survival rate of new shunts compared with revised shunts ($P < .0001$). Of the number of revision operations per patient, the mode was 1 operation with a mean of 1.6 operations per patient. There were 124 patients (13.5%) undergoing 3 or more revision operations.

Figure 2 compares the cumulative survival of procedures performed by pediatric neurosurgeons with nonpediatric neurosurgeons for new shunts and all revisions. Significant differences in survival are noted for all revisions only ($P = .01$).

Table 2 demonstrates 30-day and 1-year failure rates for all data and those comparing pediatric and nonpediatric neurosurgeons separated into the previously described categories of new shunts and all revisions. There is a third analysis (labeled first-time revision) that specifically looks at the first-time failure of new shunts that were placed as part of the new shunt analysis. Figure 3 demonstrates a funnel plot of 30-day failure rate for all procedures. This demonstrates that all units (except 1) were not considered as outliers to the complete cohort.

Table 3 demonstrates the 30-day failure rates from 2 RCTs.\textsuperscript{1,18}

**DISCUSSION**

This study has demonstrated that the overall 30-day and 1-year failure rates for new shunts placed in the UK and Ireland during...
2008 and 2009 are 12.9% and 28.8%, respectively. The same data for the subsequent revision of those new shunts are 20.7% and 40.4%, respectively. Shunt survival is better if performed by a consultant pediatric neurosurgeon for revision surgery only. The 30-day failure rates are comparable (albeit slightly lower) than the data extracted from two RCTs.

Outcome after shunt surgery has historically been measured by the number of shunt revisions per patient. What has had some impact on the design of trials investigating shunt technology is the introduction of Kaplan-Meier survival analysis to this type of data. Thirty-day mortality and readmission rates are being extensively used by policymakers and health care providers as a measure of outcome after hospital treatment and a potentially modifiable endpoint. Although reliance on such measures does have its problems, the 30-day endpoint as a barometer of surgical outcome has not previously been investigated in VP shunt analyses and may well be more representative of surgical technique. Nonsurgical factors likely to affect the 30-day shunt revision rate might include the indication for and timing of shunt insertion (eg, the continued presence of ventricular blood) or mechanical factors (eg, valve susceptibility to blockage by debris). The fact that 13% of new shunts and one fifth of revised shunts require further surgery within 30 days of insertion is worrying and warrants detailed analysis as to the cause. The fact that almost half of new shunt failures in the first year occur in this 30-day period also raises questions about the design of trials to assess new valve technology. The 30-day failure rate should be incorporated into the design of future trials investigating both shunt technology and outcome after shunt surgery as a barometer of outcome related to surgery and surgical decision making. One-year failure rate and overall survival analyses may be more relevant for investigating failure due to technical or mechanical failure of shunts (eg, disconnection).

Data from the ESIT (Endoscopic Shunt Insertion Trial) showed that the 1-year failure rate of newly inserted shunts was 34% and 42% in the nonendoscopic and endoscopic groups, respectively. This is higher than the 1-year failure rate in the current study. The same is true of the extracted 30-day failure rate (16%). The shunt design trial had demonstrated for newly placed shunts an overall 1-year failure rate of 39% with an approximate cumulative survival of 0.55 (range, 0.4-0.6 depending on valve type) at 2-years with approximately 51% of all children experiencing a shunt malfunction. The extracted 30-day failure rates are comparable to those of the current study, particularly for the nonstandard shunt valves (11% and 14%, respectively). Both of these international randomized studies had strict entry criteria, and the mean age at the time of new shunt insertion was lower than in the current study, which may explain the slightly higher 30-day and 1-year failure rates in these studies compared with this study. In addition, both of these trials were conducted approximately 15 years before the current study, and so the difference in failure rate may be a result of change in practice over this time. In support of this, the 1-year failure rate of 29.1% in the current study is comparable to that of a more recent large retrospective study (7399 patients) investigating VP shunt survival in a regional pediatric network in the United States (27%). Comparable findings were also reported in a comprehensive review of the literature published in 2008, incorporating

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<th>TABLE 1. Cohort and Operative Demographicsa</th>
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<tr>
<td>Full Cohort</td>
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<td>No. of patients</td>
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<td>No. of operations performed by consultant pediatric neurosurgeon (% of total operations)/missing data (%)</td>
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aN/A, not applicable. The new VP shunt cohort was younger than those undergoing revision procedures. A larger proportion of new VP shunt procedures were performed by a pediatric neurosurgeon.
pooled data from more than 33,000 cases, reporting a 31.3% (95% CI: 25.7-36.8) pediatric shunt failure rate for the first year and 4.5% per year thereafter.19 This meta-analysis looked to determine whether failure rates of shunts had decreased over the years as a result of experience or technical improvements. There were no significant changes in either rate over time, and the authors concluded that progress in preventing shunt failures had not been made over the past several decades (1960-2000).

There is evidence that mortality rates are lower when complex medical or surgical procedures are performed at high-volume centers.12 The same is true for VP shunts.12,13 However, because VP shunt procedures are not, in the large part, considered complex and have a low mortality rate, shunt survival rather than mortality has been used as a barometer of overall outcome.1,20 Supporting this is the observation that mortality is higher after a new shunt rather than revision procedures and so mortality is likely to be influenced by the underlying systemic or neurological disease rather than the hydrocephalus and shunt procedure per se.21 Reoperation is the most important determinant in establishing the true financial and clinical cost of a VP shunt. Although exact caseloads have not been determined in the current study, it would be reasonable to assume that pediatric neurosurgeons do have a larger caseload of pediatric VP shunts than other neurosurgeons (trainees and “adult” neurosurgeons). This is evidenced by the fact that half of the procedures in the current study were performed by pediatric neurosurgeons, despite their representing a minority of the total number of consultant and trainee neurosurgeons that may perform shunt procedures. Contrary to previous reports, the results of the current study suggest that shunt survival is not different for new shunts when pediatric and nonpediatric neurosurgeons are compared.13 Previous studies have given conflicting reports as to whether high annual turnover influences new shunt survival.8,13 In this study, benefits conferred by pediatric neurosurgeons are seen in the
revised shunts, particularly those requiring repeated revision. This difference does not appear to narrow on the survival analysis at 2 years, but it is difficult to determine whether this is a true narrowing of the difference or a result of the limited dataset at 2 years in the current study. Given that revision surgery constitutes a larger proportion of all shunt surgery (~1:1.5), the true economic and clinical burden of shunt surgery lies here. This has bearing on the design of future trials that have traditionally focused on the survival of newly placed shunts rather than the effect of a particular shunt type on revision surgery.

A study in the United States demonstrated regional variation in shunt survival even after correction for social and demographic factors. Reasons for this are thought to be differences in clinical decision making and possibly access to health care. The results of the current study suggest that this variation does not exist in the UK, with most units lying within 2 SDs of the whole cohort (Figure 3). The single unit that was found to have failure rates lower than this limit did have an older cohort of pediatric patients (median age of all patients, 43.5 months vs 32.1 months for the whole cohort), which may account for the lower failure rate in this unit. With biological data, it is common practice to exclude data beyond 3 SDs of the mean as an outlier. For the purpose of this study relying solely on nonbiological self-reported data, this outlier was not excluded for the analysis.

Limitations

There are limitations to the current study. Each individual unit supplied operative data, and so prospective collection of the data was not independently verified. An assumption has been made that on any individual patient, a second VP shunt operation after an original record of a newly inserted or revised VP shunt is due to failure of this shunt unless there is a specific reference to suggest otherwise. As is clear from the literature, the definition of shunt failure is not completely straightforward and for the purpose of this study was defined as requirement for further exploration/replacement. These are self-reported data from each individual unit, and in approximately half the cases, it was recorded that the surgery was not performed by a pediatric neurosurgeon. However, it is not possible to completely exclude the involvement of a pediatric neurosurgeon in these cases from this dataset. The difficulties in analyzing shunt survival data have already been clearly noted. There is evidence to suggest that new shunts behave differently with subsequent revisions, and each subsequent revision within certain timeframes is likely to exhibit different survival characteristics. This makes interpretation and analysis of such data more difficult. As a result of this, the current analysis separated new and revised procedures, and only the 30-day failure rate was used to analyze first-time revisions of newly placed shunts. Another difficulty is the interpretation of interim procedures such as external ventricular drainage that may have a bearing on subsequent failure rates. They have been excluded for the purpose of this study.

| TABLE 3. Comparison of 30-Day Failure Rates From 2 Randomized, Controlled Trials* |
|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| **No. of patients**             | 344                             | 393                             |
| **Trial subgroups**             | 1. Delta                        | 1. Endoscopy-assisted shunt insertion |
|                                 | 2. Standard                     | 2. Nonendoscopy-assisted shunt insertion |
|                                 | 3. Orbis-Sigma valve            |                                 |
| **Median age, mo**              | 1. 1.4                          | 1. 1.28                        |
|                                 | 2. 1.7                          | 2. 2.7                         |
|                                 | 3. 2.3                          |                                 |
| **30-d failure rate, % (95% confidence interval)** | 1. 14 (8-20)                   | 16 (12-20)                      |
|                                 | 2. 18 (11-25)                   |                                 |
|                                 | 3. 11 (7-15)                    |                                 |

*The shunt design trial compared 3 types of valves, and the ESIT compared shunt procedures using endoscopic placement with those without endoscopic assistance.
CONCLUSION

VP shunt survival in the UK is comparable to the published multicenter data investigating shunt survival. The 30-day failure rate may represent a better barometer of surgical outcome and should be used as a separate outcome measure in the design of future trials. A surprisingly high percentage of shunt failures occurs within this 30-day period and represents a significant proportion of the burden of VP shunt surgery.

Disclosure

The authors have no personal financial or institutional interest in any of the drugs, materials, or devices described in this article.

REFERENCES


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COMMENT

This is an excellent report on pooled data from a large group of specialty centers in Britain and Ireland. The authors report on 30-day and 1-year shunt failure rates for new VP shunt placement and shunt revision operations. The shunt survival rates at 1 year are similar to those of previously published studies, but this article does serve to validate these previous reports. The finding that pediatric neurosurgeons have a lower shunt failure rate after revision surgery is interesting and is reminiscent of similar findings for specialty surgeons performing pediatric brain tumor resections.1

Cormac O. Maher
Ann Arbor, Michigan