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Shunt insertion in the summer: is it safe?

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Object. The potential for increased complications related to the arrival of new residents in July each year has not previously been demonstrated in the neurosurgical literature. The authors investigated this phenomenon in children undergoing cerebrospinal fluid shunt surgery.

Methods. Data were obtained from a multicenter hydrocephalus clinical trials database and from hospital admission records in English-speaking Canada. Data pertaining to patients treated in July and August were compared with those pertaining to patients treated during the remainder of the year. The incidence of shunt failure, shunt infection, neurological deficits, wound infection, technical errors, and death were compared using a chi-square test for categorical outcomes, means for continuous outcomes, and survival analysis for time-dependent outcomes.

In the hydrocephalus clinical trials database, 138 of 737 patients were treated in July and August. The median duration of shunt lifespan (hereafter referred to as "shunt survival") was 1.7 years for patients treated during the summer months and 2.4 years for those treated throughout the rest of the year ($p = 0.10$); for shunt infection the figures were 13.8 and 8.8% ($p = 0.08$) of the total number of cases, and for wound dehiscence they were 2.9 and 0.7% ($p = 0.05$), respectively. When all shunt procedures were included, an examination of shunt survival and infection incidence rates recorded in the Canadian Hospital Discharge Database seemed to imply a significant advantage to having surgery between September and June (log-rank statistic = 7.10, $p = 0.008$).

Conclusions. The data suggest a "July effect" on some outcomes related to shunt surgery, but the effect was small. Nonetheless, the potential morbidity of shunt failure, infection, and the cost of treatment indicate that continued vigilance and appropriate supervision of new staff by attending surgeons is warranted.

Key Words • **ventriculoperitoneal shunt** • **complication** • **pediatric neurosurgery**

The annual arrival of new house staff in July brings with it concerns about quality of care and a potentially increased complication rate. This situation has been referred to as the "July effect" and has been studied in relation to several medical and surgical disciplines.[1–3,8] To date, little evidence to confirm this effect, at least in terms of measurable outcomes, has been found.

To evaluate this phenomenon in the management of hydrocephalus in children, we analyzed data from two sources: 1) our multicenter hydrocephalus clinical trials database, which includes outcomes that are common in shunt surgery and might make seasonal variations more evident, and 2) admission data from hospitals in English-speaking Canada.

Clinical Material and Methods

Hydrocephalus Clinical Trials Databases

Previously unreported data from two multicenter clinical trials related to hydrocephalus were analyzed. In the Shunt Design Trial,[7,9] 344 patients from 10 centers were randomly assigned to receive one of three valves for initial treatment of hydrocephalus. Patient data were accrued between October 1993 and October 1995. In the Endoscopic Shunt Insertion Trial,[10] we compared shunt insertion performed with and without the use of an endoscope in 393 cases from 16 centers between May 1996 and November 1999. The trials included centers from Canada, the US, and Europe, and had the same entry criteria (children younger than 18 years of age who required a shunt for treatment of hydrocephalus) and the same primary outcome (shunt failure, which was determined using clinical and imaging criteria).[6,9,10] Data in both trials were collected prospectively at each participating center, collated centrally, and subjected to a blind adjudication of eligibility and primary outcome.[11]

Data on patients who entered these studies in July and August were compared with those on patients who arrived between September and June. Outcomes common to both studies (shunt failure, shunt infection, ventricular catheter placement, the development of new neurological deficits, wound dehiscence, CSF leakage, death, and other complications) were combined. Outcomes that were unique to

Abbreviations used in this paper: CIHI = Canadian Institute for Health Information; CSF = cerebrospinal fluid; VP = ventriculoperitoneal.

each trial were analyzed separately. In the Shunt Design Trial database, we analyzed ventricle size using the occipitofrontal horn ratio,[12] surgical time, and technical errors. The latter were recorded when the blinded adjudication committee deemed that an obvious error in surgical technique had occurred, such as preperitoneal placement of the peritoneal tubing or parenchymal placement of the ventricular catheter. During this process, the committee was blinded to patient and surgeon names, center, and treatment group. Using the Endoscopic Shunt Insertion Trial database, we analyzed ventricular catheter location on the first postoperative image. Means were calculated for continuous outcomes, proportions were calculated for categorical outcomes, and survival curves were generated for time-dependent events using commercially available software (SPSS version 14.0; SPSS, Inc., Chicago, IL).

Canadian Hospital Discharge Database

A data set profiling hospital admissions for ventricular shunt insertion and revision in English-speaking Canada had been obtained for a previous study[4,5] from CIHI for the fiscal years 1989 to 2001. In the current analysis, centers were excluded if they had no neurosurgical training program. Shunt survival and the incidence of shunt infection were analyzed according to the time of year of the procedure (summer compared with the rest of the year, as previously defined).

Results

Combined Data From Both Trials

A total of 737 patients were included in the combined data set from the two shunt trials: 138 patients underwent shunt insertion during the summer (July 1–August 31 of each year of the studies) and 599 underwent shunt insertion between September 1 and June 30.

The median shunt survival time for patients treated in the summer was 1.7 years; for those treated during the rest of the year, it was 2.4 years ($p = 0.10$). One year after surgery, 55% of shunts placed during the summer were still functioning, compared with 63% of shunts inserted between September and June. The shunt survival curves for these two groups appear different, but the difference is not statistically significant (log-rank statistic = 2.71, $p = 0.10$; Fig. 1A).

Nineteen shunt infections occurred in 138 patients treated during the summer (13.8%) and 53 infections occurred in 599 patients treated during the rest of the year (8.8%; chi-square test = 3.08, $p = 0.08$). Wound dehiscence occurred in four (2.9%) of 138 patients treated in the summer and four (0.7%) of the 599 other patients (chi-square test = 7.66, $p = 0.05$). The other pooled outcomes (ventricle cannulation on the first attempt, new neurological deficit, CSF leakage, death, and other complications) occurred with similar frequencies in the two groups (Table 1).

Shunt Design Trial

Technical errors were determined by the adjudication committee in six (10%) of the 60 patients treated in the summer and in 18 (6.3%) of the 284 patients treated at other times. The mean duration of surgery was 39.4 minutes in the summer and 39.9 minutes the rest of the year.

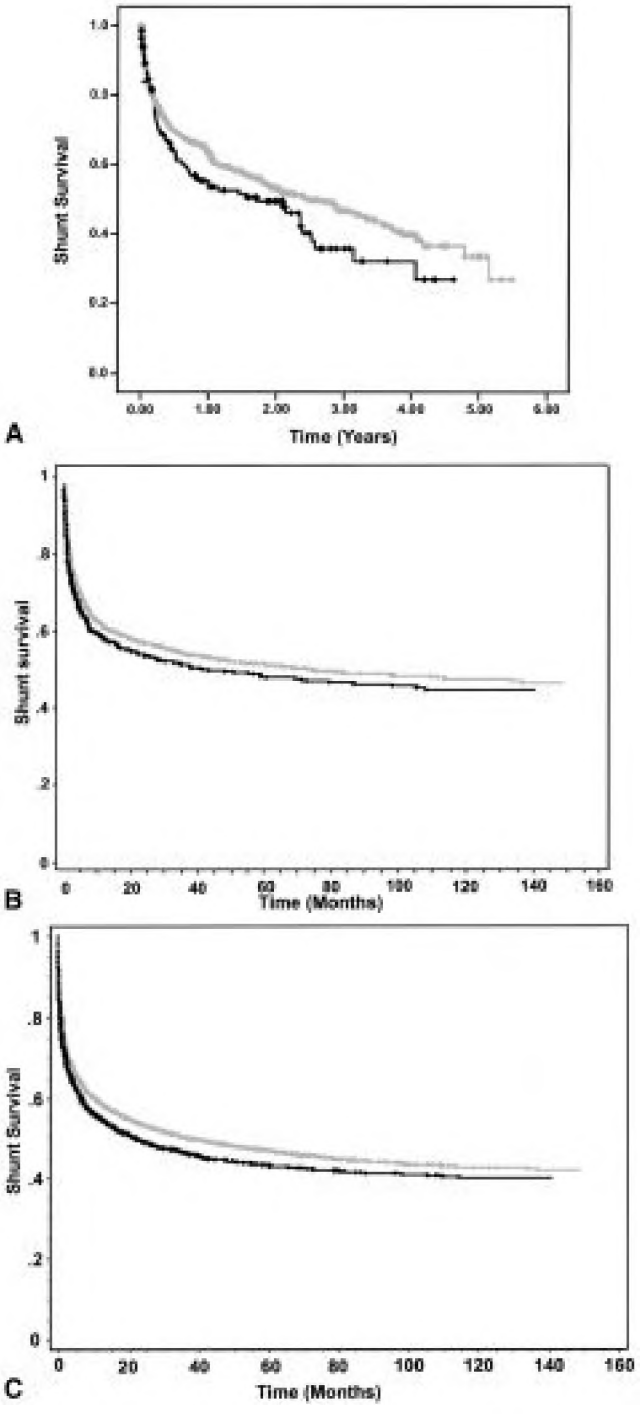

FIG. 1. A: Graph depicting VP shunt survival after first shunt insertion. Data from the Shunt Design Trial and the Endoscopic Shunt Insertion Trial were combined. For all graphs, shunts inserted in July and August are represented by the *black line*, and the *gray line* indicates shunts inserted between September 1 and June 30. B: Graph depicting shunt survival data for first VP shunt insertion from the CIHI discharge database. C: Graph depicting shunt survival for all shunt procedures (insertions and revisions) from the CIHI discharge database.

TABLE 1

*Morbidity and mortality rates associated with shunt insertions in July and August compared with September through June**

Variable	Shunts Inserted July & August	Shunts Inserted September–June	p Value
ESIT & SDT combined			
proportion of shunts w/o failure 1 yr after insertion	0.55	0.63	0.10†
infections	19/138 (14)	53/599 (9)	0.08
ventricles cannulated on 1st attempt	117/138 (85)	514/599 (86)	0.85
new neurological deficits	0	0	NA
incidence of wound dehiscence	4/138 (2.9)	4/599 (0.7)	0.05
incidence of CSF leakage	0	4/599 (0.7)	0.35
deaths	1/138 (0.7)	1/599 (0.2)	0.22
other complications	6/138 (4.3)	29/599 (4.8)	0.91
SDT			
technical errors	6/60 (10)	18/284 (6.3)	0.55
mean op time (min)	39.4	39.9	0.81
ESIT			
catheter in frontal horn on postop image	39/57 (68)	148/248 (60)	0.22

* Unless otherwise indicated, values show number (%). Abbreviations: ESIT = Endoscopic Shunt Insertion Trial; NA = not applicable; SDT = Shunt Design Trial.

† Refers to the log-rank test of survival curves shown in Fig. 1.

The degree of involvement of residents was recorded in the Shunt Design Trial; it did not appear to differ between summer and the rest of the year. The ventricular catheter was inserted by a trainee (resident or fellow) in 50% of the shunts placed during the summer and in 43% of the shunts inserted during the rest of the year. For the peritoneal catheter, a resident or fellow performed the placement in 33.3% of the cases in the summer and in 34.2% of the cases in the rest of the year.

Endoscopic Shunt Insertion Trial

In this trial of 393 patients, the goal of ventricular catheter placement was to position the tip of the catheter away from the choroid plexus (that is, in the frontal horn). Two groups of patients were used: one group received catheter placement with the aid of an endoscope, and in the other it was performed without. The postoperative images were evaluated blindly, and the catheter position was recorded. Postoperative images were available in 305 patients. Either no early postoperative image was available in the remaining 88 patients or an ultrasonography or magnetic resonance imaging study was available that did not adequately demonstrate the catheter tip position. In the group treated in the summer, the catheter was in the frontal horn on the postoperative image in 39 (68%) of 57 patients; for the patients treated in the rest of the year, it was in the frontal horn in 148 (60%) of 248 patients.

Discharge Database of CIHI

The data set from the CIHI discharge database contained records on 3068 children who underwent surgery for first shunt insertion at 11 centers between 1989 and 2001. The surgery was performed in 490 patients in July or August and in 2578 patients between September and June. Shunt infection occurred in 44 patients (9%) who had surgery in July or August and in 196 patients (7.6%) who had surgery during the other months of the year (chi-square test = 1.08, p = 0.30).

Shunt survival after initial shunt insertion (Fig. 1B) appeared to be slightly worse in the summer than during the rest of the year (log-rank statistic = 2.18, p = 0.14), but the curves were not significantly different. When all shunt procedures were included (insertions, revisions, placement of VP shunts, ventriculoatrial shunts, and shunts at other distal sites), a total of 1578 procedures were performed during the summer and 8105 procedures between September and June. In this group, the shunt survival rate was worse in the patients treated in the summer (log-rank statistic = 7.10, p = 0.008; Fig. 1C).

Discussion

Despite various attempts to identify a July effect in the medical and surgical literature, evidence for the phenomenon is sparse. Recently Smith, et al.,[13] used the National Inpatient Sample database to assess it in children who underwent brain tumor and shunt surgery at teaching hospitals in the US. They used information from the database on mortality rates, neurological complications, and discharge disposition, and were unable to detect worse results in July compared with the rest of the year, despite using a very large sample size.

As the authors acknowledge, one possible explanation for their negative result is the type of outcomes that were available in their database, particularly those related to hydrocephalus and shunt placement surgery. Death, major neurological morbidity, and prolonged hospitalization are rare in shunt surgery and may be relatively insensitive indicators of the events that occur when new house staff arrive in July.

From our data sources, we were able to analyze outcomes and complications that are common in the management of hydrocephalus. Our data suggest a July effect on some of these outcomes. The shunt survival rate appeared to be lower in patients treated in the summer in the hydrocephalus clinical trials database as well as in the CIHI data when all shunt procedures were analyzed together, although the former difference was not significant. Wound dehiscence was rare overall but was slightly more common in the summer. The incidence of shunt infection found in the CIHI database did not appear to be higher in the summer (9 compared with 7.6%), but in the hydrocephalus clinical trials database there appeared to be a difference (the infection rate in the summer was 13.8 compared with 8.8% for the rest of the year).

We chose to evaluate data on shunts inserted in July and August compared with data from the rest of the year. In North America, the summer is when many trainees change rotations and when neurosurgical fellows begin working at a new institution. These changeover schedules may differ at European centers, which contributed about a third of the patients in the Shunt Design Trial. Because our analysis included these centers, we might have underestimated a July effect.

The amount of teaching and supervision of residents during shunt surgery is a potentially significant variable in the analysis of a July effect. This factor was not measured specifically in any of our data sets. We hypothesized that significant amounts of teaching and supervision might prolong

the operation, but surgical time did not differ in the summer. The proportion of shunts inserted by residents compared with those inserted by faculty did not appear to differ in the summer compared with the rest of the year.

Conclusions

Overall, our data suggest that a July effect exists for shunt surgery, but the effect sizes appear to be small. Nonetheless, the potential morbidity caused by shunt failure and infection and the cost of treatment suggest that continued vigilance and appropriate supervision by attending surgeons is warranted.

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