

Cerebrospinal fluid shunt infection: a prospective study of risk factors

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Object. Hydrocephalus is a common condition of childhood that usually requires insertion of a cerebrospinal fluid (CSF) shunt. Infection is one of the most devastating complications that may arise from the presence of CSF shunts. In this study, the authors prospectively analyzed perioperative risk factors for CSF shunt infection in a cohort of children.

Methods. Between 1996 and 1999, 299 eligible patients underwent CSF shunt operations (insertions and revisions) that were observed by a research nurse at a tertiary care pediatric hospital. Several perioperative variables were recorded. All cases were followed postoperatively for 6 months to note any development of CSF shunt infection. A Cox proportional hazards model was used to analyze the relationship between the variables and the development of shunt infection.

Thirty-one patients (10.4%) experienced shunt infection. Three perioperative variables were significantly associated with an increased risk of shunt infection: 1) the presence of a postoperative CSF leak (hazard ratio [HR] 19.16, 95% confidence interval [CI] 6.96–52.91); 2) patient prematurity (< 40 weeks' gestation at the time of shunt surgery: HR 4.72, 95% CI 1.71–13.06); and 3) the number of times the shunt system was inadvertently exposed to breached surgical gloves (HR 1.07, 95% CI 1.02–1.12).

Conclusions. Three variables associated with an increased incidence of shunt infection have been identified. Changes in clinical practice should address these variables, as follows. 1) Great care should be taken intraoperatively to avoid a postoperative CSF leak. 2) Alternatives to placement of a CSF shunt in premature infants should be studied. 3) Surgeons should minimize manual contact with the shunt system and consider the use of double gloves.

KEY WORDS • hydrocephalus • infection • cerebrospinal fluid shunt • neurosurgery • children

HYDROCEPHALUS, a common condition of childhood, is associated with numerous other diseases, including spina bifida and other congenital anomalies, brain tumors, head injury, brain hemorrhage, and meningitis. The majority of children with hydrocephalus are treated with CSF shunt insertion. In the United States, there are nearly 70,000 yearly hospital admissions for hydrocephalus, with CSF shunt placement procedures costing \$100 million annually.⁶ However, CSF shunts are associated with several complications, including a 2-year failure rate of greater than 40% and—of greater concern—an infection rate of 3 to 15%.^{15,17,19,31,35,39,43}

Shunt infection usually occurs within a few months of shunt surgery and is associated with substantial risks of morbidity, including increased risk of seizure disorder and decreased intellectual performance.^{8,16,25,28,34,35} The treatment of shunt infection requires removal of the shunt system, placement of a temporary external CSF drain, a course of appropriate antibiotic therapy, and eventual insertion of a new shunt system. This involves a minimum

of two separate operations and a hospital stay lasting as long as 2 to 3 weeks.^{22,34} In addition, shunt infection is associated with a long-term risk of mortality greater than 30%, which is nearly double that observed in children without infection.⁴⁰

Various risk factors for CSF shunt infection have been indicated in the literature, including the cause of the hydrocephalus,^{1,36} the young age of the patient,^{10,26,31–33,37} the duration of the shunt operation,^{24,25} the presence of a previous shunt system,³³ and the presence of a postoperative CSF leak.⁴² However, given the fact that most current data come from retrospective series and that there appears to be no clear agreement among these data, the risk factors for CSF shunt infection are still not well known. We conducted a prospective, observational study of preoperative, intraoperative, and early postoperative risk factors for CSF shunt infection in children with the goal of identifying potentially modifiable perioperative practices.

Clinical Material and Methods

Patient Population

From April 1996 to February 1999, a prospective,

Abbreviations used in this paper: CI = confidence interval; CSF = cerebrospinal fluid; HR = hazard ratio.

TABLE 1
Perioperative variables recorded in study

| | |
|--|--|
| <i>preop variables</i> | |
| patient | |
| age postconception (<40 wks' gestation; 40 wks' gestation–1 yr; >1 yr) | |
| sex (M/F) | |
| weight (kg) | |
| cause of hydrocephalus (9 categories: intraventricular hemorrhage, myelomeningocele, tumor, aqueductal stenosis, meningitis, trauma, other, unknown) | |
| length of in-hospital stay preop (days) | |
| presence of previous shunt system (yes/no) | |
| priority level of operation (range, 1 [highest priority, emergency case]–4 [lowest priority, elective case]) | |
| <i>intraop variables</i> | |
| operation occurring during regular operating room hrs of 0800–1700 (yes/no) | |
| use of prophylactic antibiotic agents w/in 30 mins of 1st incision (yes/no) | |
| duration of operation from 1st incision until final wound closure (mins) | |
| total no. of persons present in operating room at any time during operation, excluding surgical team | |
| presence of hole(s) in surgical gloves, checked by filling all gloves w/ water postop (yes if ≥ 1 hole present; if double gloves were used, yes only if ≥ 1 hole in both layers of gloves) | |
| no. of times shunt system was inadvertently exposed to breached surgical gloves (0 = no holes found in any surgical gloves) | |
| no. of times shunt system was manipulated by a surgical instrument | |
| lowest recorded intraop core body temperature ($^{\circ}\text{C}$) | |
| use of surgical ultrasound or endoscope during operation (yes/no) | |
| operating room score calculated as sum of following: | |
| no. of holes present in sterile drapes | |
| no. of persons wearing stained operating scrub suits or stained shoes | |
| no. of persons wearing reused operating head covers | |
| no. of persons wearing operating mask w/ nose left uncovered | |
| no. of persons incorrectly gowned | |
| no. of persons w/ cuff of gown exposed over gloves | |
| no. of times sterile drapes were applied incorrectly or moved | |
| no. of times a person not appropriately scrubbed & gowned leaned over operative field or was w/in 1 ft of operative field | |
| no. of times light handles were contaminated | |
| <i>postop variable</i> | |
| presence of CSF leak from operative wound (yes/no) | |

observational cohort study of all CSF shunt operations (shunt insertions and shunt revisions) was conducted at the Hospital for Sick Children, a tertiary care, university-affiliated pediatric institution with four full-time pediatric neurosurgeons. Patients were considered eligible for this study if they were undergoing either insertion or revision of a CSF shunt (a ventriculoperitoneal, ventriculopleural, ventriculoatrial, subdural–peritoneal, cystoperitoneal, or cystopleural shunt) and a CSF specimen obtained during the operation proved to be sterile after aerobic and anaerobic cultures had been grown. Patients were excluded if they had been enrolled in the study at an earlier time, had a history of shunt infection, or displayed evidence of one or more of the following conditions: active concurrent infection in any body system (for example, urine or blood), wound breakdown around the shunt preoperatively, or immunodeficiency. Patients were also excluded if no CSF obtained during the shunt operation had been sent to the laboratory for culture.

Observation of Perioperative Risk Factors

A full-time, dedicated research nurse examined the op-

erative list daily to identify pending shunt operations. In addition, each surgeon contacted the research nurse before any shunt surgery, including emergency cases in which operations were performed outside of regular hours. The research nurse observed the entire shunt operation from the moment the child entered the operating room until the final wound was closed.

Several pre- and intraoperative variables (Table 1) were recorded by the research nurse by using standardized data collection forms. After wound closure, the nurse examined all surgical gloves for holes by filling them with water and observing whether there were any leaks.^{4,13,18} If any member of the surgical team wore two pairs of gloves, holes in both pairs signified perforated gloves.

Operating room records were examined weekly to check whether any CSF shunt cases had been missed and had not been observed. Baseline and follow-up data were recorded in these patients as well.

The only postoperative variable recorded was the presence or absence of a CSF leak from the operative site. This required the presence of a flow of clear fluid from the operative site for at least several hours and was determined after adjudication by two independent physicians. In cases of disagreement, consensus was reached following discussion.

Follow Up and Outcome Measurement

All patients underwent follow-up clinic visits at 6 weeks, 3 months, and 6 months postoperatively. Between 86% and 100% of CSF shunt infections are known to be diagnosed within this time period.^{25,37,41} Circumstances regarding readmission of any patient in this study during this 6-month period were recorded prospectively. Our institution has a large, exclusive catchment area, and thus children requiring reoperation return to our hospital. The number of patients seeking follow-up care elsewhere was negligible. This was verified with each patient's family at the regular follow-up visits.

The primary outcome measure used in our analysis was the time (in days) to verified shunt infection. This was defined as the time from initial surgery to reoperation (removal of the shunt system with or without placement of an external CSF drain) for verified shunt infection. The diagnosis of a verified shunt infection required at least one of the following criteria: surgical wound infection or wound breakdown; positive CSF culture from shunt aspirate obtained using sterile procedures; bacteremia in patients with ventriculoatrial shunts; and peritoneal infection in patients with ventriculoperitoneal shunts. All other reoperations and deaths within 6 months after the observed shunt surgery that were not related to shunt infection were censored.

Statistical Analysis

Survival curves were calculated using the Kaplan–Meier method. Survival analysis covering the time to shunt infection was performed using a Cox proportional hazards model. The proportional hazards assumption was checked for each variable by plotting partial residuals against time. Initially, a univariate analysis was performed on all variables, and those with a probability value of 0.1 or less (determined using the likelihood ratio test) were

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entered into a multivariable Cox proportional hazards model. Variables that had been eliminated after the univariate analysis were reentered individually into the multivariable model and were retained if the likelihood ratio test was significant at the 0.05 level. Interaction among the variables in the multivariable model was tested using the likelihood ratio test at a significance level of 0.05. The final multivariable model was used to provide an adjusted estimate and the 95% CI of the HR for the variables. The Wald test was used for significance testing of HRs in the multivariable model. To account for the possibility of multiple testing, we chose a significance level of 0.01. The single postoperative variable (presence of a postoperative CSF leak) was treated as a time-dependent covariate; it became viable when the CSF leak was first noted and remained so thereafter in the analysis. All statistical analyses were performed with the aid of a statistical computer software package (SPSS Advanced Statistics, version 8.0; SPSS, Inc., Chicago, IL).

Results

There were a total of 536 shunt operations, of which 341 met the eligibility criteria (Fig. 1). Of the eligible cases, 42 (12.3%) were not observed because either the surgeon neglected to notify the research nurse or, in cases of extreme emergency, the research nurse had insufficient time to get to the operating room before surgery commenced. Seven (16.7%) of these 42 patients went on to experience a verified shunt infection. Table 2 contains baseline data in 299 patients who were observed and the 42 patients who were not observed.

The 299 patients who underwent observed shunt operations formed the basis of our analysis. We obtained complete follow-up data on all of these patients. The Kaplan-Meier survival curve for this sample is shown in Fig. 2 upper left. Thirty-one (10.4%) of these patients later experienced verified shunt infection. Baseline data for the infected and noninfected groups are listed in Table 2. The mean time to reoperation in patients with infections was 36 days (range 4–177 days). The most common infecting organisms were *Staphylococcus aureus* (15 cases [48.4%]) and coagulase-negative staphylococcus (12 cases [38.7%]). Because they were among the 268 patients in whom infection did not develop, 14 patients (4.7%) were censored for reoperation and four (1.3%) because they died. The remaining 250 patients were free of infection at the end of their 6-month follow-up period.

In seven patients (2.3%) a CSF leak developed at a mean of 4.9 postoperative days (range 1–13 days). In six of these patients (85.7%) a verified shunt infection developed at a mean of 16.3 days (range 7–26 days).

Survival Analysis

No variable appeared to violate the proportional hazards assumption. The values for these variables are listed in Tables 2 and 3. Univariate analysis, which was performed using a Cox proportional hazards model, revealed three variables that met the criteria for entry into the multivariable model ($p < 0.1$, likelihood ratio test): the presence of a postoperative CSF leak ($p < 0.0001$), the number of times the shunt system was inadvertently exposed

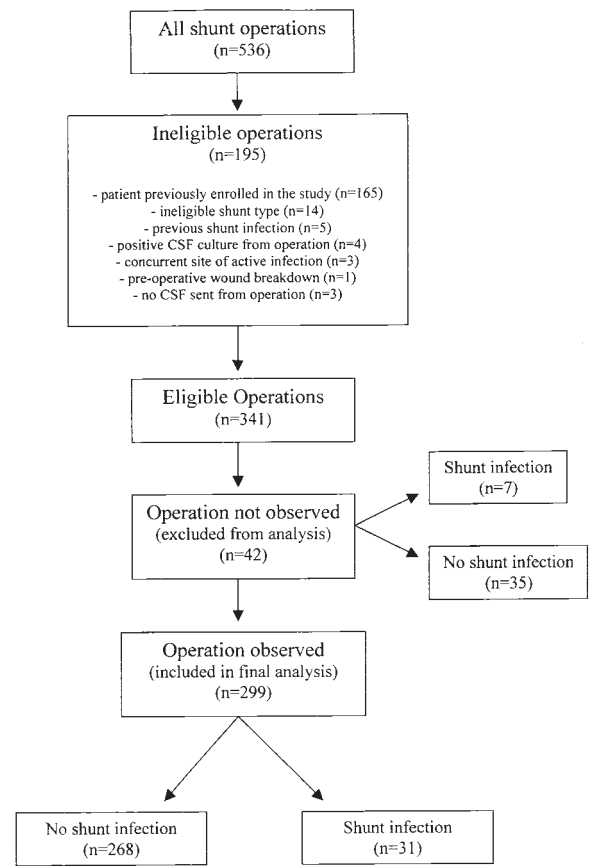


FIG. 1. Patient flowchart summarizing ineligible and eligible shunt operations during the period of study. n = number of patients.

to breached surgical gloves ($p = 0.01$), and patient age ($p = 0.02$). After these variables were entered into a multivariable model, all were found to have HRs significantly different from one (Table 4). Survival curves for these three variables are shown separately in Fig. 2. Addition of other pre- and intraoperative variables did not add significantly to the model. Interaction terms for the three variables were tested and none was significant.

Discussion

In this study we attempted to identify perioperative risk factors for CSF shunt infection by using careful prospective observation of shunt operations in children. Our results indicate that three perioperative variables appear to be associated with a significantly higher risk of infection: postoperative CSF leak, patient's prematurity at the time of shunt surgery, and increased touching of the shunt while exposed to breached surgical gloves.

Risk Factors

Postoperative CSF Leak. The presence of a postoperative CSF leak was the strongest risk factor for shunt infection (HR 19.16, 95% CI 6.96–52.91). Previous descriptions of this in the literature are limited. Welch⁴² reported CSF leak as the causative factor in 15% of shunt infec-

TABLE 2
Baseline data for eligible patients*

| Factor | Observed Cases | | | Not Observed† |
|---------------------------------|----------------|----------------|----------------|-----------------|
| | Not Infected | Infected | Total | |
| no. of patients | 268 | 31 | 299 | 42 |
| age (yrs) | | | | |
| mean | 6.6 ± 5.9 | 4.9 ± 5.9 | 6.5 ± 5.9 | 6.6 ± 5.5 |
| range | 1 day–20.3 yrs | 1 day–17.2 yrs | 1 day–20.3 yrs | 3 days–16.6 yrs |
| age (%) | | | | |
| <40 wks' gestation | 2.6 | 16.1 | 4.0 | 2.4 |
| 40 wks' gestation–1 yr | 26.1 | 29.0 | 26.4 | 23.8 |
| >1 yr | 71.3 | 54.8 | 69.6 | 73.8 |
| weight (kg) | | | | |
| mean | 25.9 ± 22.4 | 22.0 ± 28.9 | 25.5 ± 23.1 | 24.3 ± 18.4 |
| range | 1.7–110 | 1.2–131 | 1.2–131 | 2.6–65 |
| sex (% male) | 53.4 | 54.8 | 53.5 | 54.8 |
| preop in-hospital stay (days) | | | | |
| mean | 3.6 ± 9.0 | 5.1 ± 7.4 | 3.7 ± 8.9 | 2.9 ± 5.3 |
| range | 0–81 | 0–32 | 0–81 | 0–30 |
| previous shunt system (% yes) | 70.5 | 64.5 | 69.9 | 54.8 |
| priority level of operation (%) | | | | |
| 1 (highest priority) | 2.7 | 0 | 2.4 | 14.6 |
| 2 | 7.2 | 6.5 | 7.1 | 24.4 |
| 3 | 53.2 | 61.3 | 53.9 | 39.0 |
| 4 (lowest priority) | 36.9 | 32.3 | 36.3 | 22.0 |
| cause (%) | | | | |
| IVH | 17.5 | 32.3 | 19.1 | 14.3 |
| MMC | 23.1 | 9.7 | 21.7 | 16.7 |
| tumor | 14.2 | 12.9 | 14.0 | 28.6 |
| AS | 7.8 | 9.7 | 8.0 | 4.8 |
| meningitis | 3.7 | 6.5 | 4.0 | 4.8 |
| trauma | 2.2 | 3.2 | 2.3 | 0 |
| hemorrhage | 1.1 | 3.2 | 1.3 | 2.4 |
| other | 17.9 | 12.9 | 17.4 | 9.5 |
| unknown | 12.3 | 9.7 | 12.0 | 19.0 |

* Mean values reported with ± standard deviation. Abbreviations: AS = aqueductal stenosis; IVH = intraventricular hemorrhage; MMC = myelomeningocele.

† Not included in final analysis.

tions and Davis, et al.,¹² described accumulation of CSF at the operative site as a potential risk factor. Although in some cases a CSF leak may actually indicate an underlying shunt infection, it may also act as a conduit for contamination of the underlying shunt system by external skin organisms, or it may act as a marker for poor wound healing—reflecting an increased risk for infection. Given the extremely high risk associated with a CSF leak, every attempt should be made intraoperatively to prevent this complication. Postoperatively, careful attention should also be paid to the detection of CSF leakage. If a leak does occur, additional symptoms suggestive of shunt infection should be treated with the highest degree of suspicion.

Age of the Patient. Authors of some previous studies have implicated young patient age as a possible risk factor for shunt infection,^{10,21,29,31–33,37} whereas others have reported no such association with age.^{7,12} In our study we found a significant association, with the greatest risk limited to premature infants in whom the gestational age was younger than 40 weeks at the time of shunt surgery (HR 4.72, 95% CI 1.71–13.06). Children older than this did not appear to be at significantly increased risk for infection. Factors such as a poorly developed immune system, generally poorer skin condition, and high skin bacterial density

may be attributable factors for this increased risk.^{21,32} Because of the substantially higher infection risk, alternatives to shunt insertion should be seriously studied for this age group.²⁰

Glove Holes and Shunt Handling. The overall incidence of at least one hole in a surgical glove used by a member of the operating team was 33.4%. This is similar to results of other studies of orthopedic, gynecological, and general surgeries, in which holes have been observed in 12 to 20% of individual gloves and in 31 to 39% of operations.^{9,13,14,27,30} Furthermore, our results indicate that increased touching of the CSF shunt system while exposed to breached surgical gloves carries a higher risk of infection (HR 1.07, 95% CI 1.02–1.12). Although the estimate of the HR appears relatively small, if the variable is converted to units of five touches of the shunt system, the HR estimate increases to 1.39 (95% CI 1.11–1.74).

This finding brings into question the role of surgical personnel as sources of contamination and infection of some shunt systems. Authors of other studies have suggested that the patient's own bacterial flora do not account for all sources of contamination in many cases of shunt infection. In a prospective study of 100 CSF shunt operations, Bayston and Lari³ found that 58% of surgical

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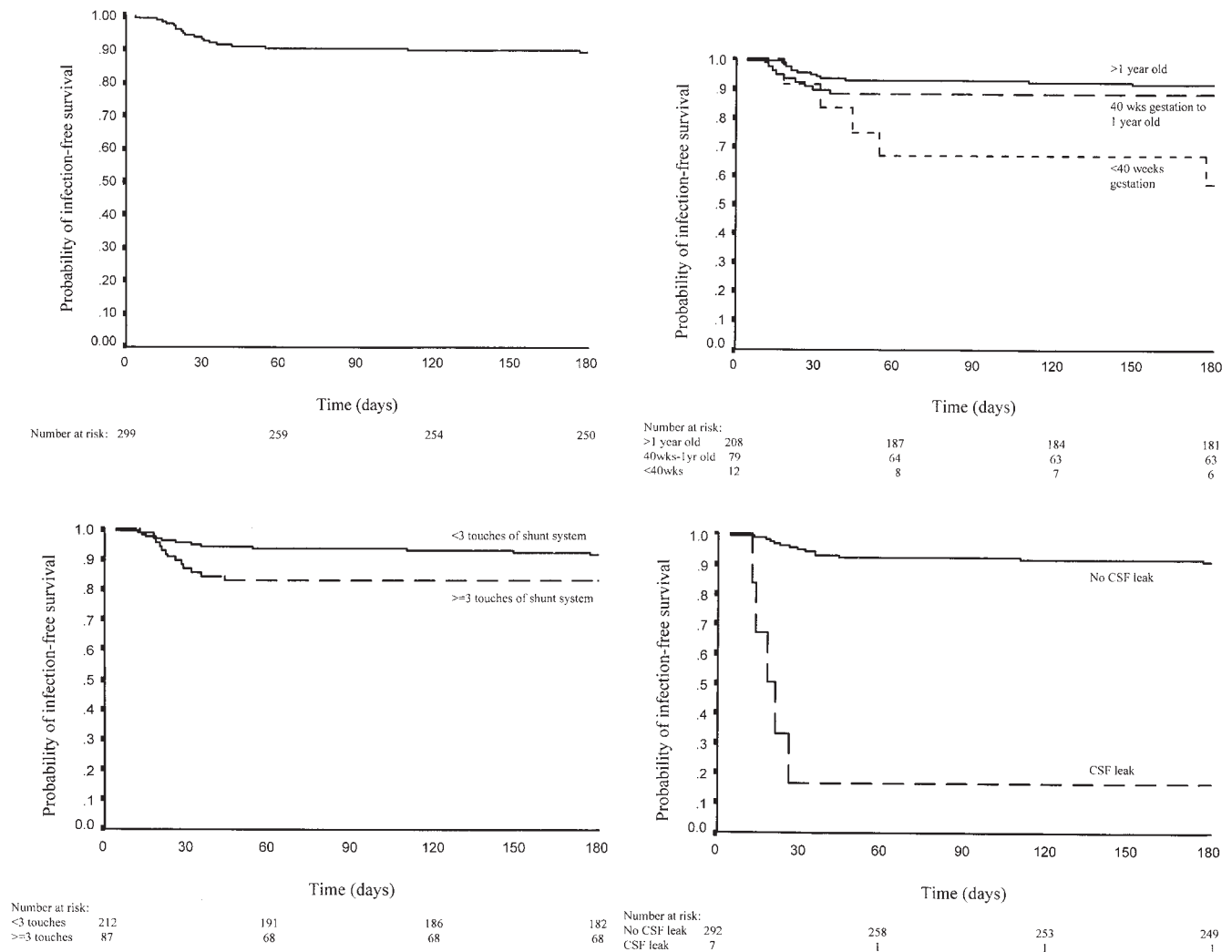


FIG. 2. Graphs displaying Kaplan–Meier survival curves. *Upper Left:* Infection-free survival curve for all 299 eligible, observed cases. *Upper Right:* Infection-free survival curves categorized by age group. In premature infants of less than 40 weeks' gestation at the time of shunt surgery (*lowest curve*), there was a significantly higher risk of shunt infection. *Lower Left:* Infection-free survival curves of cases in which the shunt system was inadvertently touched three or more times (*lower curve*) or less than three times (*upper curve*) by someone wearing breached surgical gloves. This grouping was chosen for graphic purposes to illustrate survival curves for groups above and below the mean value of 2.7 touches. Increased touching of the shunt system in the presence of breached surgical gloves was related to a significantly higher risk of infection. *Lower Right:* Infection-free survival curves in relation to postoperative CSF leak. The presence of a postoperative CSF leak (*lower curve*) was related to a significantly higher risk of shunt infection.

wounds were contaminated at the end of the procedure, but 42% of the contaminating species could not be isolated from the patient's flora. Shapiro, et al.,³⁷ compared bacterial strains infecting CSF shunts with the patient's preoperative skin flora and found that they were identical in only 22% of cases. Therefore, other sources of contamination are likely, and it is possible that surgical personnel, perhaps via breached surgical gloves, might provide at least one viable additional source. Breached gloves were implicated as the route of contamination for at least one epidemic of prosthetic valve endocarditis.³⁸

This is a particularly important variable because it is potentially avoidable on two fronts: the avoidance of glove holes and the minimization of manual shunt handling. Double gloving, as a method of avoiding glove holes, ap-

pears to reduce the incidence of a breached protective layer (holes in both the inner and outer layers of gloves) substantially compared with single gloving.^{9,11,13,18,23} However, because the majority of glove holes are not recognized by surgeons during the procedure,^{4,5,9,18,30} it might be considered prudent to minimize manual handling of the shunt whenever possible. Using historical controls, Faillace¹⁷ reported a reduced incidence of shunt infection while using a no-touch operative protocol that involved doubling the number of gloves worn and minimizing manual contact with the shunt. However, this has not been replicated in a prospective randomized fashion.

Other Factors. Authors of earlier studies have suggested that other variables may be associated with a higher incidence of shunt infection, including the causes of

TABLE 3

*Intra- and postoperative data for eligible, observed patients**

| Factor | Observed Cases | | |
|---|----------------|-------------|-------------|
| | Not Infected | Infected | Total |
| no. of patients | 268 | 31 | 299 |
| operation occurring during regular hrs (% yes) | 94.0 | 96.7 | 94.3 |
| antibiotics given w/in 30 mins (% yes) | 87.3 | 87.1 | 87.3 |
| length of operation (mins) | | | |
| mean | 47.3 ± 20.2 | 53.0 ± 35.8 | 47.9 ± 22.3 |
| range | 11–133 | 15–167 | 11–167 |
| no. of persons present in the operating room | | | |
| mean | 8.9 ± 1.9 | 8.9 ± 2.2 | 8.9 ± 2.0 |
| range | 0–16 | 7–18 | 0–18 |
| cases w/ at least 1 breached glove (%) | 32.1 | 45.2 | 33.4 |
| no. of times shunt was exposed to breached gloves | | | |
| mean | 2.4 ± 4.4 | 5.3 ± 8.4 | 2.7 ± 5.1 |
| range | 0–24 | 0–39 | 0–39 |
| no. of times shunt was manipulated w/ surgical instrument | | | |
| mean | 7.9 ± 4.2 | 9.0 ± 7.4 | 8.0 ± 4.6 |
| range | 0–28 | 2–38 | 0–38 |
| lowest core temperature (°C) | | | |
| mean | 35.5 ± 2.4 | 35.3 ± 0.6 | 35.4 ± 2.3 |
| range | 32.7–38.2 | 33.8–36.2 | 32.7–38.2 |
| use of ultrasound or endoscope (% yes) | 19.0 | 22.6 | 19.4 |
| operating room score† | | | |
| mean | 33.7 ± 17.0 | 33.6 ± 15.0 | 33.7 ± 16.7 |
| range | 0–124 | 6–69 | 0–124 |
| postop CSF leak (% yes) | 0.7 | 16.1 | 2.3 |

* Mean values reported with ± standard deviation.

† See Table 1 for explanation.

hydrocephalus,^{1,36} duration of the shunt operation,^{24,25} and presence of a previous shunt system.³³ In our study, no other variable demonstrated significance. It is possible, however, that, given 31 events, our study lacked sufficient power to detect all significant variables.

Limitations of the Study

We were unable to observe 42 eligible operations (12.3%). A relatively larger percentage of these operations had a higher priority level and infection developed in 16.7% of these patients. Because we do not have observational data for these patients, we cannot comment on the cause of this possibly higher infection rate.

The surgeons and other operating room personnel were aware of the study and its purpose and knew that their operative procedure was being observed. This knowledge may have elicited a reaction, thereby altering their standard operating room procedures. This could theoretically limit the degree to which our findings are generalizable to real-world shunt surgery as it is usually practiced.

Conclusions

We have identified three risk factors for the develop-

TABLE 4

*Hazard ratios from multivariable Cox proportional hazards model**

| Variable | HR | 95% CI | p Value† |
|---|-------|------------|----------|
| presence of postop CSF leak | 19.16 | 6.96–52.91 | <0.0001 |
| patient age | | | |
| <40 wks' gestation | 4.72 | 1.71–13.06 | 0.003 |
| 40 wks' gestation–1 yr | 1.40 | 0.61–3.22 | 0.43 |
| >1 yr | 1.00 | — | — |
| no. of times shunt system was exposed to breached surgical gloves | 1.07 | 1.02–1.12 | 0.009 |

* — = not applicable.

† According to the Wald test.

ment of CSF shunt infection, and changes in clinical practice should address them as follows. 1) Great care should be taken intraoperatively to avoid a postoperative CSF leak. 2) Alternatives to CSF shunt placement in premature infants should be studied and such patients should be considered high risk. 3) Surgeons should minimize manual contact with the shunt system and consider the use of double gloves. These findings may have implications for other clean surgeries involving implantation of prosthetic devices and biomaterials.

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