See the corresponding editorial in this issue, pp 109–110.

J Neurosurg Pediatrics 2:111–117, 2008

Antimicrobial suture wound closure for cerebrospinal fluid shunt surgery: a prospective, double-blinded, randomized controlled trial

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Object. Implantation of cerebrospinal fluid (CSF) shunting devices is associated with a 5–15% risk of infection as cited in contemporary pediatric neurosurgical literature. Shunt infections typically require complete removal of the device and prolonged antibiotic treatment followed by shunt replacement. Moreover, shunt infections are commonly associated with prolonged hospital stays, potential comorbidity, and the increased risk of neurological compromise due to ventriculitis or surgical complications. The authors prospectively evaluated the incidence of CSF shunt infection following shunt procedures performed using either antimicrobial suture (AMS) or conventional suture.

Methods. In a single-center, prospective, double-blinded, randomized controlled trial, the authors enrolled 61 patients, among whom 84 CSF shunt procedures were performed over 21 months. Randomization to the study (AMS) or control (placebo) group was stratified to minimize the effect of known shunt infection risk factors on the findings. Antibacterial shunt components were not used. The primary outcome measure was the incidence of shunt infection within 6 months of surgery.

Results. The shunt infection rate in the study group was 2 (4.3%) of 46 procedures and 8 (21%) of 38 procedures in the control group ($p = 0.038$). There were no statistically significant differences in shunt infection risk factors between the groups (procedure type and time, age < 6 months, weight < 4 kg, recent history of shunt infection). No suture-related adverse events were reported in either group.

Conclusions. These results support the suggestion that the use of AMS for CSF shunt surgery wound closure is safe, effective, and may be associated with a reduced risk of postoperative shunt infection. A larger randomized controlled trial is needed to confirm this association. *(DOI: 10.3171/PED/2008/2/8/111)*

Key Words • antimicrobial suture • cerebrospinal fluid shunt • randomized controlled trial • shunt infection • wound closure

Despite the advent of neuroendoscopic procedures, CSF shunt systems remain the most prevalent, effective treatment option for managing pediatric hydrocephalus. Therefore, shunt procedures and shunt-associated complications account for a large proportion of the workload in any pediatric neurosurgical service. Although shunt complications can take many forms, shunt infection remains a persistent, humbling problem in pediatric neurosurgery. The CSF shunt infection rates reported in the modern literature range widely, from < 3% to > 20%, with most series in the 5–15% range.[12,24,26,30,33,36,38,52] Shunt infections greatly increase the affected patient's risk of morbidity and death, even when recognized promptly and treated effectively.[5,8,21,30,35,40,48] Furthermore, shunt infection treatment greatly increases direct and indirect health care costs for the affected patient, family, and health care facility.[6,44]

It is widely believed that shunt infections result from intraoperative contamination of the shunt hardware or wound with microorganisms from the patient's own flora. Evidence supporting this belief includes the predominance of nonpathogenic skin flora as the cause of most shunt infections and the consistent observation that most shunt infections are diagnosed within 6 months of surgery.[9,17,18,31,39] Many techniques and several devices have been investigated and reported by numerous authors attempting to reduce shunt infection rates. Antibiotic-impregnated catheter shunt systems, in particular, appear to reduce infection risk in some, but not all, reported series.[21,25,38,45] Unfortunately, none of these studies were performed in a prospective, double-blinded, randomized controlled fashion.

Antimicrobial-coated suture has recently been shown to

Abbreviations used in this paper: AMS = antimicrobial suture; CI = confidence interval; CSF = cerebrospinal fluid; MRSA = methicillin-resistant *Staphylococcus aureus*; MSSA = methicillin-sensitive *S. aureus*; VA = ventriculoatrial; VP = ventriculoperitoneal; VPl = ventriculopleural.

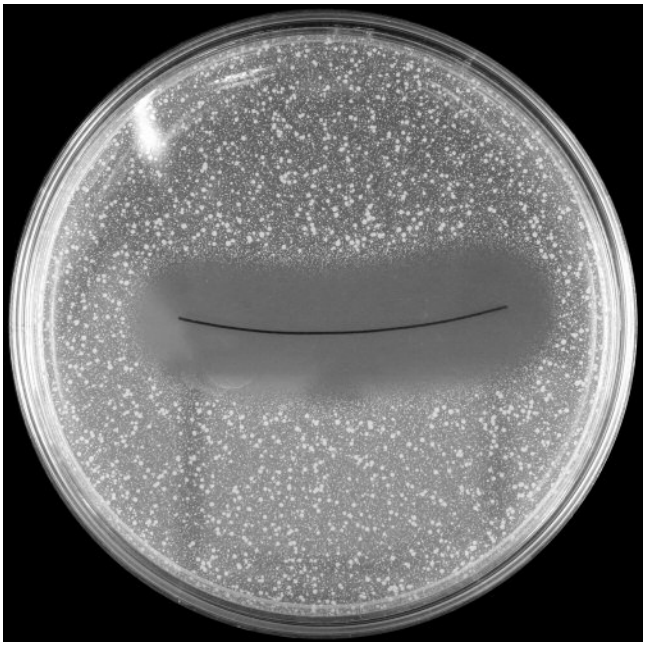

FIG. 1. Photograph of a culture dish showing that the AMS exerts a zone of inhibition to growth of *S. aureus* in vitro.

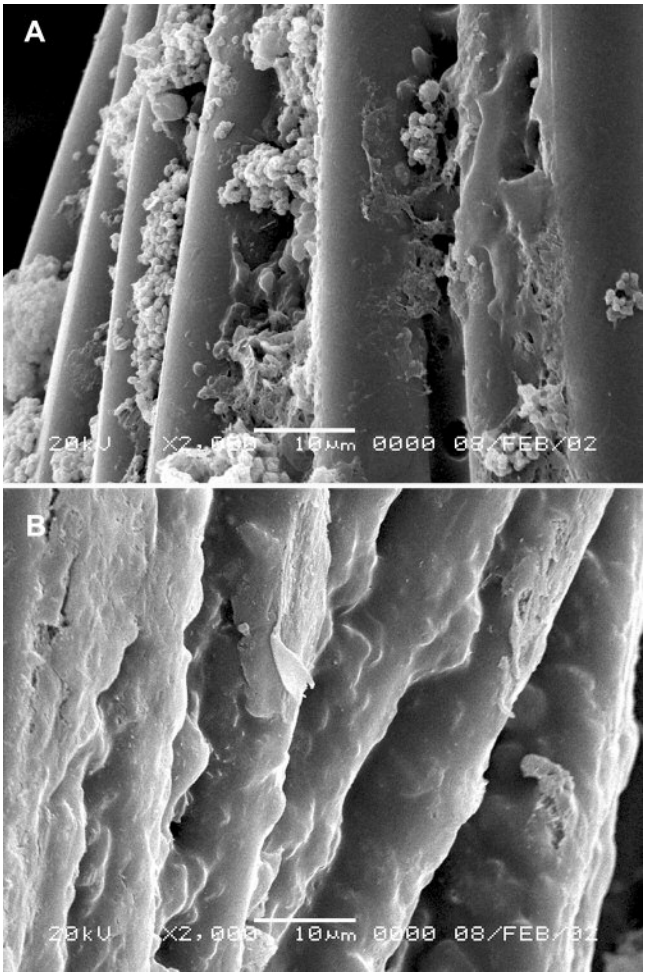

FIG. 2. Low-power scanning electron micrographs of a conventional suture (A) and an AMS (B) explanted from animal model wound closures 72 hours postprocedure. Bacterial colonization is evident on the conventional suture and absent from the AMS.

reduce bacterial adherence to suture and to decrease microbial viability in both in vitro and animal models[13,20,42] (Figs. 1 and 2). To date, only one clinical study has been published in which the efficacy of triclosan-coated AMS for prevention of surgical site infection is assessed.[15] We therefore independently designed and conducted a randomized controlled trial to determine whether wound closure with triclosan-coated absorbable sutures after CSF shunt surgery would reduce the incidence of early shunt infection (< 6 months postoperatively).

Methods

Study Design

Institutional Review Board approval was obtained for a single-center, prospective, randomized, double-blinded, and placebo-controlled study of patients undergoing CSF shunt implantation or revision surgery to determine whether AMS reduces the risk of subsequent shunt infection.

Study Population

Patients of all ages requiring CSF shunt implantation or revision surgery were recruited from the pediatric neurosurgical service at the Women and Children's Hospital of Buffalo from April 2005 through December 2006. This service, staffed by two full-time pediatric neurosurgeons, is the sole provider of neurosurgical care for the children and adult survivors of pediatric hydrocephalus in western New York. Written informed consent was obtained from the parent/legal guardian or patient, as appropriate, and assent was obtained from minors capable of understanding the study. Patients receiving ventricular access devices or ventriculosubgaleal shunts, patients with active shunt infections, and immunocompromised patients were excluded. (Ventricular access devices or ventriculosubgaleal shunts are routinely used in our service to temporize hydrocephalus in premature infants weighing < 2 kg.)

Patient Population

A total of 84 shunt procedures was performed at Women and Children's Hospital of Buffalo between April 2005 and December 2006 in 61 patients for whom proper consent had been obtained and who were enrolled in the study. These operations were performed in 48 male and 36 female patients, who ranged in age from 1 day to 48 years (median 6.3 years). Procedure types consisted of 40 implants and 44 revisions. The most common type was the VP shunt (used in 68 operations, 81%), followed by VPl shunts (9 operations, 10.7%), subdural–peritoneal shunts (6 operations, 7.1%), and VA shunts (1 operation, 1.2%).

Study Intervention

Participants were randomly assigned to receive coated polyglactin 910 sutures with triclosan (Vicryl Plus; Ethicon, Inc.) or placebo sutures (coated polyglactin 910 – Vicryl; Ethicon, Inc.) for closure of the galea and fascia. Randomization was performed by the assignment of letter codes to

study and placebo suture types. The suture type corresponding to a particular letter code was known only to operating room nurses and scrub technicians. An equal number of study and placebo letter code cards was prepared and placed individually in sealed envelopes grouped by patient characteristic categories. In this manner, randomization was stratified to minimize uneven distribution of implant versus revision procedures, patients weighing < 4 kg, patients < 6 months of age, or patients with recent (< 1 month) shunt infections. Participants and investigators were blinded to treatment assignment, because study and placebo sutures are indistinguishable after removal of the package labeling.[16,49] All shunt procedures were performed by one of two attending pediatric neurosurgeons (C.J.R. and V.L.). All participants received preoperative chlorhexidine skin cleansing, betadine skin preparation, preoperative intravenous antibiotics (cefazolin, or vancomycin if allergic to cephalosporins), iodine-impregnated adhesive drapes, and antibiotic wound irrigation prior to closure. Silicone shunt components were soaked in bacitracin solution before implantation. No antibiotic-impregnated shunt components were used in this study. Skin closures for all procedures were performed with poliglecaprone 25 sutures (Monocryl; Ethicon, Inc.).

Trial Outcomes

The primary outcome measure was the incidence of shunt infection within 6 months of CSF shunt placement surgery. Positive culture results from CSF sampled through the shunt or from explanted shunt components were considered diagnostic of shunt infection. Additional data were recorded prospectively pertaining to demographics, procedure type/time, and patient factors believed to influence infection risk. All shunt infections were treated with complete shunt removal, external ventricular drainage, and appropriate intravenous antibiotic therapy until daily CSF cultures remained negative for ≥ 5 days, followed by the placement of a new shunt. Patients requiring shunt revision (with negative shunt tap CSF cultures) within the 6-month surveillance period were reenrolled using the same suture assignment as before. Patients receiving new shunts following successful treatment of a shunt infection and patients undergoing revision > 6 months after randomization were rerandomized.

Statistical Analysis

Demographic and infection risk parameters were compared in the study and placebo groups by using chi-square tests. All continuous variable data are presented as the mean ± standard deviation or the median, and the means were compared using unpaired t-tests. The primary outcomes were compared using the Fisher exact test. All reported probability values are two sided ($p \leq 0.05$ was considered significant). All statistical analyses were performed with SPSS version 14.0 software (SPSS, Inc.).

Results

The study (46 shunt procedures) and placebo (38 shunt procedures) cohorts differed slightly with regard to sex distribution (Table 1), but no statistically significant differences were found between the groups. The mean shunt procedure time (Table 2) was slightly longer in the AMS group, but this difference was not statistically significant.

TABLE 1

*Comparison of patient and procedural factors related to CSF shunt procedures**

Variable	Placebo Group (%)	AMS Group (%)	p Value
total no. of ops	38	46	
ops in male patients	18 (47)	30 (65)	0.154
age†			
prematurity (<38 wks)	2 (5)	1 (2)	0.862
<6 mos	11 (29)	11 (24)	0.791
<12 mos	12 (32)	16 (35)	0.920
<24 mos	15 (39)	17 (37)	1.000
≥24 mos to ≤21 yrs	16 (42)	21 (46)	0.744
>21 yrs	7 (18)	8 (17)	0.862
weight <4 kg	6 (16)	7 (15)	0.823
recent CSF infection	3 (8)	6 (13)	0.689
EVD prior to shunt op	5 (13)	8 (17)	0.823
hydrocephalus origin			
congenital	14 (37)	14 (30)	0.699
posthemorrhagic	10 (26)	17 (37)	0.522
myelodysplasia	9 (24)	11 (24)	0.823
posttraumatic	3 (8)	3 (7)	0.862
other	2 (5)	1 (2)	0.862
shunt imp (vs rev)	18 (47)	22 (48)	0.862
shunt type			
VP	30 (79)	38 (83)	0.920
VPl	5 (13)	4 (9)	0.764
VA	0 (0)	1 (2)	0.920
SD–peritoneal	3 (8)	3 (7)	0.841
attending Surgeon 1 (vs Surgeon 2)	21 (55)	30 (65)	0.480

* A total of 84 shunt procedures was performed in 61 patients, and the percentages shown are based on these 84 procedures. Abbreviations: EVD = external ventricular drain; imp = implant; rev = revision; SD = subdural.

† Numbers in the first 4 age categories are inclusive (the number in the age < 24 months category includes numbers for the < 12 months, < 6 months, and prematurity variables).

Fourteen revision procedures were performed on shunts placed in the study group prior to the 6-month end point in patients in whom infection was not suspected based on their presentation and whose shunt tap CSF cultures remained negative. Two other patients were rerandomized for revisions performed > 6 months after a study procedure. Seven patients receiving new shunt implants were rerandomized after removal of an infected shunt that had been placed during the study and appropriate antibiotic therapy.

No patients were lost to follow-up during the study period. Ten shunts were removed due to infection before the 6-month surveillance period concluded. Two patients with shunt infections subsequently died within the surveillance period. Both patients were infants with severe congenital anomalies whose parents ultimately decided to withdraw care. After accounting for the 14 early revisions noted above, 60 study shunts (71.4%) remained functional and apparently infection free at the 6-month end point of the

TABLE 2

*Comparison of variables in the study population**

Variable	Placebo Group	AMS Group	p Value
age (yrs)	9.9 ± 9.8	9.7 ± 11.4	0.921
op time (mins)	68.3 ± 23.1	71.7 ± 22.9	0.495

* The values are expressed as the mean ± standard deviation.

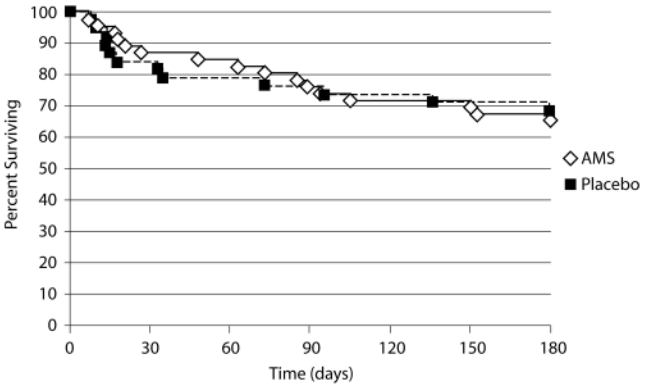

FIG. 3. Graph showing shunt survival as a function of time after shunt surgery in patients receiving wound closure with AMS and placebo suture; no statistical difference (p = 0.757) is demonstrated.

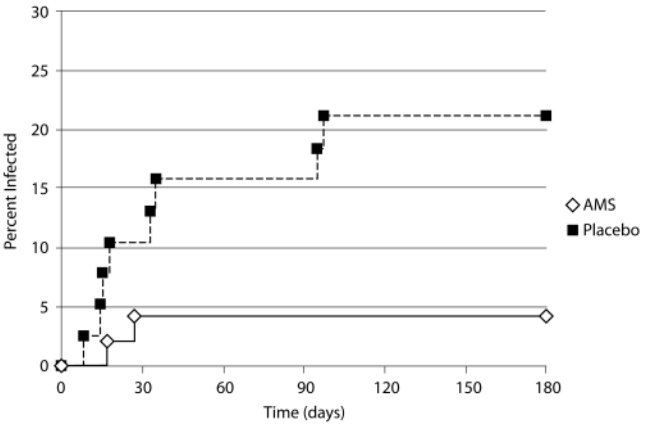

FIG. 4. Graph showing the incidence of shunt infection as a function of time after shunt surgery in patients receiving wound closure with AMS and placebo suture. By 6 months after shunt surgery, only 2 (4.3%) of the shunts with AMS wound closure were infected compared with 8 (21%) of the shunts with placebo suture wound closure. Shunt infections were 3.84 times less likely to occur in the first 6 months after shunt surgery in the AMS group (95% CI 0.257–18.78; p = 0.038).

study. Shunt survival at 6 months did not vary with suture type (Fig. 3).

Shunt Infection

The AMS group experienced significantly fewer shunt infections than the placebo group. At the first interim data analysis, 4 infections were diagnosed in the control group compared to none in the AMS group. The enrollment of new patients in the study was continued because the difference did not reach statistical significance. By the second interim analysis, 2 shunt infections (4.3%) were diagnosed in the AMS group within the 6-month surveillance period, compared with 8 (21%) in the placebo group (p = 0.038; Fig. 4). In view of the significantly higher infection rate in the control group, new patient enrollment was halted by the investigators. No additional shunt infections were diagnosed after enrollment ceased, and the study was closed with Institutional Review Board approval. Therefore, AMS suture was associated with an absolute risk reduction of 0.167 (95% CI 0.027–0.235) and a relative risk reduction of 3.84 (95% CI 0.257–18.78). These data also predict that AMS wound closure would prevent 1 shunt infection for every 6.0 procedures in which it is used (number needed to treat = 6.0; 95% CI 4.2–36.5).

All but one of the 10 infections were caused by *Staphylococcus* species (*S. aureus*, 5; coagulase-negative *Staphylococcus* species, 4); the remaining infection was due to *Pseudomonas aeruginosa* (Table 3). Eight shunt infections were diagnosed within 6 weeks of surgery, whereas 2 were detected between 12 and 14 weeks after surgery. Eight shunt infections were diagnosed based on positive CSF cultures. The VA shunt infection (Case 10) was confirmed with blood and distal catheter cultures that grew the same organism. The other CSF culture-negative infection (Case 3) presented with wound purulence over the distal tubing. Shunt infections were equally distributed (6 of 51 vs 4 of 33; p = 0.764) between the two authors who are attending pediatric neurosurgeons.

Discussion

Cerebrospinal fluid shunts represent the most widely applied neurosurgical treatment option for hydrocephalus in children. Although generally safe and effective, CSF shunts continue to carry a relatively high risk of infection compared with most other neurosurgical procedures.[17] Shunt infections unfortunately can lead to serious neurological morbidity in affected individuals.

Previous reports have identified numerous factors associated with shunt infection, including prematurity,[31] patient age,[9,31,39,41] hydrocephalus origin,[2,46] need for shunt revision,[34,46] recent shunt infection,[34,43] longer operating times,[28,30] intraoperative glove breach,[31] postoperative CSF leak,[31] and participation of surgical trainees.[11] Taken together, these risk factors support the conclusion that patient factors and surgical technique both directly influence shunt infection risk.

Patient population characteristics did not differ significantly with regard to any factors known or suspected to influence shunt infection risk. Sex distribution between the groups was unequal, with a weak statistical trend toward more males in the AMS group, but sex has never been identified as a risk factor for shunt infection. No changes in shunt surgery technique were instituted by either surgeon during the study period.

Most CSF shunt infections are believed to arise from shunt component contamination in the operating room, either by skin flora from the host[17,18] or from surgical personnel.[4,31,47] Once bacteria adhere to any shunt component, their interaction with the implant interferes with host defenses[7] and prevents intravenous antibiotics from eradicating the infection. For these reasons, shunt replacement is required for nearly all shunt infections. Prevention of shunt infection assumes paramount importance.

Meticulous surgical technique appears to reduce shunt infection risk.[11,28,30,31,45] The use of prophylactic perioperative intravenous antibiotics has been reported to reduce subsequent shunt infection risk.[22,32,40] More recently, antibiotic-impregnated catheter shunt systems have been developed to minimize bacterial colonization, theoretically reducing infection risk.[23,29] Recent reports of clinical studies evaluating these devices disagree with regard to efficacy, and use historical controls.[25,37,38,45] In the only randomized prospective

TABLE 3
*Summary of shunt infections in 10 patients**

Case No.	Age	Shunt (op type)	Suture	Hydrocephalus Origin	Presenting Symptoms/Signs	POD	Causative Organism
1	7 yrs	VPl (rev)	placebo	other (craniosynostosis)	wound purulence, tract erythema, fever	15	MRSA
2	25 yrs	VP (rev)	placebo	posthemorrhagic	headache, emesis, syncope	35	CoNS
3	11 yrs	VPl (rev)	placebo	posthemorrhagic	wound purulence, fever, emesis	14	*P. aeruginosa*
4	18 mos	VP (imp)	placebo	congenital	fever, irritability	95	MSSA
5	24 mos	VP/SD (rev)	placebo	congenital	constipation, abdominal distension, pseudocyst	97	CoNS
6	7 wks	VP (imp)	placebo	myelodysplasia	fever, irritability	33	CoNS
7	3.5 mos	VP (imp)	placebo	congenital	fever, anorexia, somnolence	8	MSSA
8	3 mos	VP (imp)	placebo	posthemorrhagic	anorexia, somnolence, abdominal distension	18	MSSA
9	24 yrs	VPl (rev)	AMS	posthemorrhagic	fever, empyema, wound purulence	17	MRSA
10	7 wks	VA (imp)	AMS	myelodysplasia	fever, positive blood culture	27	CoNS

* CoNS = coagulase-negative *Staphylococcus* species; POD = postoperative day.

trial of antibiotic-impregnated catheter shunt systems, investigators found no difference in overall shunt infection risk, but found a significant risk reduction for staphylococcal infections.[21] Antibiotic-impregnated catheter shunts in their current form (Bactiseal; Codman, Johnson & Johnson) have several inherent limitations, including incomplete shunt protection, contraindication in patients with allergy to clindamycin or rifampin, and significantly increased cost compared with that for nonimpregnated shunts.

The AMS is another recently developed technology that may be beneficial in the prevention of surgical site infections, including shunt infection. Polyglactin 910 suture coated with triclosan was approved for clinical use by the Food and Drug Administration in 2002. The antimicrobial agent, triclosan, is bacteriostatic for a wide range of microbial pathogens (including MSSA, MRSA, and *Staphylococcus epidermidis*) at concentrations found in the suture.[50] The presence of conventional suture in a surgical wound is known to lower the size of bacterial inoculi necessary to produce a wound infection[14] and to increase the overall risk of surgical site infections.[1,10,27] Triclosan-coated polyglactin 910 suture has been shown in vitro and in vivo to prevent colonization of the suture by both gram-positive and -negative bacteria.[13,20,50] Another in vitro study demonstrated a zone of staphylococcal growth inhibition surrounding the AMS.[42] Furthermore, triclosan has an extensive history of preclinical testing and clinical use demonstrating a very high safety margin, little or no risk of allergic reaction, and no evidence of microbial resistance.[3,19] In the randomized controlled trial reported here, the shunt infection rate was significantly lower in the AMS group. After all shunts reached an end point, only 2 (4.3%) of the AMS shunts were infected, compared with 8 (21%) of the placebo suture shunts. Although the placebo suture infection rate was somewhat higher than typically reported rates, it is associated with a small denominator and is not outside the range of previous reports. The shunt infection rate at our institution for the year prior to this study was 9.8% (8 of 82 procedures) (C.J. Rozzelle and V. Li, unpublished data, 2004), which is similar to the rate experienced by both study cohorts combined (10 [11.9%] of 84 procedures). There was no statistically significant difference between the historical rate and either the study or control group rates.

It is postulated that AMS wound closure might reduce the risk of surgical site infections by preventing bacterial adherence to the suture and/or by creating overlapping zones of inhibition radiating outward from each surgical knot.[13,16] Neither of these potential mechanisms seems likely to prevent bacteria from adhering to or colonizing a shunt component contaminated in the operating room. In a recent study Thompson et al.[51] concluded, "the vulnerable period for bacterial colonization of shunts may not be restricted to the operative procedure, as commonly believed, but may extend throughout the postoperative period of wound healing." The logical implication would be that bacteria from the surgical wound might colonize the shunt postoperatively, leading to shunt infection. In that case, one can easily hypothesize that AMS wound closure could protect any surgically implanted device by either of its postulated mechanisms of action. The apparent efficacy of AMS wound closure for shunt infection prevention lends further support to the conclusion drawn by Thompson et al. in this regard.

Wound closure with AMSs is conveniently applicable to a wide range of surgical procedures and may be particularly beneficial when applied to the implantation of expensive therapeutic devices (such as shunts, stimulators, and pharmaceutical delivery pumps) that typically must be explanted if infected. Its use in these settings is even more attractive given the relatively low cost of suture coated with triclosan compared to suture without it. The hospital cost difference at our institution was only $4.95 more per AMS wound closure for a routine shunt procedure. Treatment of one shunt infection can easily exceed $25,000 in direct costs (local institutional estimate) and probably incurs much greater indirect costs due to associated morbidity, lost productivity, and other factors. Considering only estimated direct costs, AMS wound closure for CSF shunt surgery would be cost-effective at a number needed to treat of < 5000 ($25,000/$5.00). On the basis of this study, the incremental cost of preventing one shunt infection is estimated to be < $181 by applying the upper limit of the 95% CI for the number needed to treat to the cost difference. To give this cost estimate some perspective, it is worth noting that the cost of a set of antibiotic-impregnated shunt catheters exceeds $181. A detailed economic analysis of the AMS and placebo cohorts from this study is currently ongoing.

This study is limited by its small sample size and relatively short duration. Had the placebo group experienced a more typical infection rate, a much larger or longer trial would have been required to show a statistically significant difference in early shunt infection risk. However, this study provides a valid basis for further investigation in a larger randomized controlled trial.

Conclusions

Wound closure with AMS was associated with a significantly lower shunt infection risk than placebo suture wound closure during the first 6 months after surgery in this prospective, double-blinded, randomized controlled trial. The apparent efficacy of this intervention lends indirect support to the hypothesis that postoperative bacterial shunt contamination represents an underrecognized cause of shunt infection. The negligible added cost of AMS maximizes its potential cost/benefit advantage for a wide variety of device implant surgical procedures. These findings warrant further investigation in a larger, longer-term, randomized, and controlled trial.

Disclaimer

This study was designed and conducted with no extramural research funding or commercial relationships. Curtis J. Rozzelle, M.D., has subsequently served on a medical advisory board for Ethicon/Johnson & Johnson. The other authors have no commercial or current research relationship with Ethicon/Johnson & Johnson.

Acknowledgments

The authors thank Diana Kachurek, P.N.P., and Sara Riemer, P.N.P., both of University at Buffalo Neurosurgery, for their invaluable assistance enrolling patients; Women and Children's Hospital of Buffalo operating room staff Helen Noblett, R.N., Rafaela Smith, R.N., and Susan Domagala, C.S.T. for their tireless efforts toward maintaining suture assignment integrity and the blinded nature of the study; and Paul H. Dressel of University at Buffalo Neurosurgery for preparation of the figures.

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Manuscript submitted December 28, 2007.
Accepted April 4, 2008.

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