Study title: Incisional vacuum-assisted closure therapy after posterior spinal fusion for pediatric neuromuscular scoliosis

NCT Number: NCT03000010

Version Date: **3**.23.20

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BACKGROUND/SIGNIFICANCE:

The purpose of this study is to evaluate the effectiveness of incisional vacuum-assisted closure (VAC) therapy in the prevention of wound dehiscence and infection after posterior spinal fusion for pediatric neuromuscular scoliosis. The incidence of surgical site infection (SSI) after pediatric spinal deformity surgery varies depending on patient diagnosis. Reported rates of infection after surgery for adolescent idiopathic scoliosis range from 0.5 to 6.7%. The incidence of infection following surgery for neuromuscular scoliosis is greater, with an overall rate of 4.3 to 14.3%. Among the neuromuscular population, rates of infection after spinal deformity surgery vary from 6.1 to 15.2% for cerebral palsy, to 8 to 41.7% for myelodysplasia.

Multiple patient- and surgery-related risk factors have been proposed for the increased incidence of infection after posterior spinal fusion in neuromuscular patients. Poor preoperative nutrition may lead to poor or delayed wound healing, which can increase the risk of wound contamination and subsequent infection. Bowel and bladder incontinence may increase the risk of wound contamination as well. SSIs after neuromuscular scoliosis have been found to be more commonly caused by gram-negative organisms, many of which are present in the gastrointestinal tract.

VAC therapy has revolutionized the management of complex wounds and wound infections. This has been widely published, mostly in the adult plastic surgery and orthopaedic surgery literature. The VAC is a type of negative pressure wound therapy. Several basic science studies have demonstrated that negative pressure therapy increases tissue perfusion and oxygenation, decreases swelling of the soft tissues, and stimulates cell growth and expansion. The VAC is also applied with a tight seal and can prevent postoperative wound contamination.

More recently, the VAC has been used as a postoperative dressing over primarily closed surgical wounds in adult patients who are at high risk of postoperative wound complications and infection (eg. diabetes, obesity), and high-risk wounds (eg. pelvic fractures, periarticular fractures). The prophylactic use of the incisional VAC has been shown to decrease the incidence of wound dehiscence and infection after high-risk fractures in adults compared to standard postoperative dressings. Pediatric neuromuscular patients are at high risk of wound complications and infection after spinal deformity surgery. No studies have investigated the use of the incisional VAC after posterior spinal fusion in pediatric neuromuscular patients.

Objectives (If not stated previously):
The goal of our study is to evaluate the effectiveness of incisional VAC therapy in the prevention of wound dehiscence and infection after posterior spinal fusion for pediatric neuromuscular scoliosis.

METHODS:

Inclusion Criteria: any patient 17 years and younger with neuromuscular scoliosis undergoing posterior spinal fusion

Exclusion Criteria: idiopathic and congenital scoliosis, any type of spine surgery other than posterior spinal fusion (eg. vertical expandable prosthetic titanium rib placement, growing rod placement, anterior spinal fusion), intraoperative dural tear, documented allergy to adhesive dressings

How many subjects are you seeking to enroll? 50 patients

Summary of human subject involvement:
This will be a prospective randomized controlled study. Informed consent will be obtained from the patient's parents or legal guardians preoperatively. Pediatric neuromuscular patients undergoing posterior spinal fusion will be randomized to a standard postoperative dressing versus an incisional VAC dressing. Both groups will have hematocrit, total lymphocyte count, and albumin checked preoperatively to assess nutritional status. This will allow us to later determine whether any differences in preoperative nutritional status existed between the two groups, which would potentially affect the rates of wound dehiscence and infection. These labs will be drawn at the same time as the standard preoperative labs during the history and physical visit so that patients will not undergo additional needle sticks. Both groups will undergo standard wound closure and dressing application before breaking the sterile field. The incisional VAC group will undergo placement of an Adaptic dressing over the incision. A standard VAC sponge is cut into long strips of approximately one inch in width. The sponge strips are placed over the Adaptic and are secured with an adhesive dressing. Part of the adhesive dressing over the sponge is cut away and the suction tubing is placed on top of the exposed sponge. The suction tube is connected to the VAC machine. The VAC machine is set to 75 mm Hg of continuous suction. Any leaks in the system are sealed off with additional adhesive dressing. The incisional VAC will be left in place for 72 hours postoperatively. The remainder of the postoperative care will follow our standard posterior spinal fusion protocol and will be identical in both groups. Patients will be followed for a minimum of 2 years postoperatively. Our primary outcomes will be wound dehiscence or infection requiring unplanned dressing changes, antibiotics, or surgery.

If patients have not follow-up at Michigan Medicine 2-year post-surgery, a study team member will follow-up via phone call to the patient and/ or parent/ guardian. This follow-up phone call will confirm if the patient did sustain an infection at the site of their posterior spinal fusion, as it may have been treated at an outside hospital.

Would these procedures occur if the subject were not enrolled as a research subject?

Most neuromuscular patients undergoing posterior spinal fusion currently have labs drawn preoperatively to assess nutritional status. However, this is not consistently performed in all patients and the time at which these labs are drawn varies widely. In this study, these labs will be drawn at the same time as the standard preoperative labs during the history and physical visit so that patients will not undergo additional needle sticks. Application of a standard postoperative dressing instead of an incisional VAC would occur if patients were not enrolled in this study. Application of the incisional VAC is noninvasive and has a minimal risk of complications.

BENEFITS & RISKS:

Describe the potential benefits of this research to society:

Wound-related complications and SSI after pediatric spinal deformity surgery can have a substantial medical, social, and financial impact on patients. Prevention of SSI after spinal fusion is currently a major area of interest as new regulations may lead to altered reimbursements to hospitals for surgical complications. The incidence of infection following surgery for neuromuscular scoliosis is high, with an overall rate of 4.3 to 14.3%. Among the neuromuscular population, rates of infection after spinal deformity surgery vary from 6.1 to 15.2% for cerebral palsy, to 8 to 41.7% for myelodysplasia. Numerous authors have reported potential risk factors for SSI after pediatric spinal deformity surgery. Certain patient-related risk factors, such as underlying medical condition and previous surgery, are not modifiable. Recent literature has focused on identifying modifiable risk factors and prevention strategies that may decrease the rates of SSI after spinal fusion. The incisional VAC has been shown to decrease the incidence of wound dehiscence and infection after high-risk fractures in adults compared to standard postoperative dressings. The results of this study may reduce the rate of wound dehiscence and infection after posterior spinal fusion in pediatric neuromuscular patients.

Provide a description of the foreseeable risks to the subjects:

Patients may develop skin maceration if the technique for incisional VAC application is not followed.

We would like to provide a $10 VISA gift card to all of the subjects who choose to participate as our way of thanking them for their time.

DATA COLLECTION:

The data collected will be patient age, gender, past medical history (including degree of cognitive impairment, seizure disorder, ambulatory status, neurogenic bladder requiring catheterization, and bowel and bladder incontinence), past surgical history (including presence of tracheotomy and feeding tubes), preoperative nutrition labs (hematocrit, total lymphocyte count, and hematocrit), American Society of Anesthesiologists score, preoperative antibiotic prophylaxis, addition of gentamicin to bone graft, intraoperative blood loss, transfusion requirement and volume of blood products transfused, pre- and postoperative Cobb angles, number of levels fused, presence of wound dehiscence and/or evidence of superficial or deep incisional SSI according to the Centers for Disease Control definitions (see below) during the inpatient hospitalization and at follow-up visits, and any unplanned dressing changes, antibiotics, or surgery for treatment of wound dehiscence or infection.

Centers for Disease Control definitions for SSIs:

- Superficial incisional SSI:
    - Involves only the skin or subcutaneous tissues
    - Occurs within 30 days after the procedure
    - Additional criteria: purulent drainage, positive cultures from fluid or tissue obtained sterilely from the superficial incision, pain or tenderness, localized swelling, erythema, and warmth
    - A stitch abscess is not considered a superficial SSI
- Deep incisional SSI:
    - Involves the fascia and muscle layers
    - Occurs within 1 year if an implant is placed and the infection appears to be related to the procedure

- Additional criteria: purulent drainage, deep wound dehiscence, fever, pain or tenderness, presence of an abscess or other evidence of infection diagnosed by direct examination, radiographs, or cultures

Deep SSIs after spinal deformity surgery can be further classified into acute and delayed infection. The definition of a delayed infection is controversial and has been described as greater than 1 month, 2 months, 3 months, 6 months, and 1 year after the initial procedure.

SURVEY ASESSMENTS:

None