Tissue Adhesive Compared With Sterile Strips After Cesarean Delivery: A Randomized Controlled Trial

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Project Abstract

The goal of this project is to identify a strategy to reduce wound complications in women who undergo cesarean delivery by Pfannenstiel skin incision. Currently, many Pfannenstiel skin incisions are closed by subcuticular sutures followed by either placement of Steri-Strips or a tissue adhesive. Either Steri-Strips or tissue adhesive can be placed over the wound as a covering but it is unclear which may reduce wound complication rates. The hypothesis of this study is that a tissue adhesive will result in a reduction in wound complication rates when compared to Steri-Strips. Previously published studies in non-obstetric populations have identified the use of a tissue adhesive as a potential intervention to reduce wound complications[1]. The eligible population for this study will include women at University of Chicago Hospital and NorthShore University HealthSystem and who will undergo primary or repeat cesarean delivery via Pfannenstiel skin incision. Women in the study will be randomized to receive either Steri-Strips or tissue adhesives as a wound covering. The primary outcome to be evaluated will be wound complication which will include wound infection (cellulitis or subcutaneous infection), wound separation (partial or complete), wound seroma/hematoma. Secondary endpoints to be investigated include cosmetic outcome, patient satisfaction, cost comparison, and difference in total time for application.

Background

A surgical wound complication occurs in approximately 6.5-18.8%[2,4] of patients undergoing cesarean delivery with a Pfannenstiel skin incision. Prior efforts to reduce the rate of complication have included routine use of preoperative antibiotics and chlorhexidine scrub for abdominal preparation[2,3]. Both of these interventions are utilized at the University of Chicago Hospital and NorthShore University HealthSystem. Application of tissue adhesive is a relatively inexpensive method that has shown good results in reducing infections in other wound types[1], however no randomized controlled trial exists to show its impact on cesarean wound outcomes.

Eligibility

All women undergoing cesarean deliveries via Pfannenstiel skin incision at University of Chicago Hospital and NorthShore University HealthSystems.

Inclusion Criteria

- Women must receive routine antibiotic prophylaxis prior to incision per institutional protocol.
- Abdomen must be prepared with chlorhexidine per institutional protocol

Vulnerable Populations

Only pregnant women will be included in this study as only they can undergo cesarean deliveries. The intervention will occur after delivery of the infant and both the control (sterile strips) and intervention (tissue adhesive) are currently in use at both study sites.

Subject Enrollment

- Subjects undergoing cesarean deliveries will be enrolled through the labor and delivery units, antepartum floor and outpatient clinics at University of Chicago and NorthShore University HealthSystem.

- All efforts will be made to approach participants with planned cesarean delivery prior to the date of their delivery. Where possible, consent will be obtained prior to consent for cesarean delivery.
- For patients who undergo an unplanned or emergent cesarean delivery, efforts will be made to discuss the study prior to the decision for cesarean delivery.
- However, some women will arrive to labor and delivery with the intention of achieving a vaginal delivery. These women may not be receptive to discussing the possibility of a cesarean delivery. For these women, enrollment in the study will be deferred until the decision is made to proceed with a cesarean delivery.

Study Design and Procedures

- The study is an un-blinded randomized controlled trial.
- Once a subject consents to participate in the trial she will be enrolled in the trial. Randomization will occur at the time of the cesarean delivery. Each participant will be randomized to receive either Tissue adhesive or Steri-Strips over a subcutaneous suture closure.
- Randomization will be stratified by repeat cesarean delivery versus primary cesarean delivery.
- Each participant will receive a study ID upon randomization.
- The study ID will be linked to a corresponding sealed envelope that contains the subject's assigned wound closure method.
- The wound closure method will be assigned to the subject numbers by a random number generator.

Intervention

- All patients will receive pre-operative antibiotics per institutional protocol
- All patients will have abdomen prepared with chlorhexidine per institutional protocol
- If subcutaneous fat is >2 cm thick it will be closed with sutures
- Inside of the randomization envelope will be a worksheet with detailed wound closure instructions and a space to fill out intervention application time.
- Intervention: placing tissue adhesive over subcuticular wound closure
- Control: placing Steri-Strips over subcuticular wound closure

Endpoints

- Primary: Wound complication rates at 6 weeks postpartum
- Complication is defined as any of the following:
    - purulent drainage
    - cellulitis
    - abscess
    - wound requiring drainage (partial or complete wound separation)
    - spontaneous wound separation
    - seroma
    - hematoma

- Secondary complications defined as:
    - Readmission rates
    - Satisfaction with scar
    - Cost analysis
    - Time of intervention
    - Treatment of wound complication (antibiotics, packing, wound vacuum, debridement, primary closure)

Assessment

- Maternal demographic, obstetric and medical characteristics will be collected for each subject.
- For subjects who follow-up with a provider in the NorthShore or University of Chicago health system chart review will be used to assess for readmission.
- All subjects will be called 6-8 weeks after delivery to assess scar satisfaction using the patient and observer scar assessment scale and inquire about any wound complications. For those patients who request an electronic survey or cannot be reached by telephone, a protected link with the survey questions will also be sent to a patient -specified email address at 6-8 weeks after delivery. All subjects who complete the survey will receive a $5 gift card, which will be sent via email. For those subjects who do not have an email address, we may also mail the gift card to their preferred address if the patient requests this method.
- The phone script is attached in the appendix. These same survey questions will be used for the electronically administered survey.

Baseline Characteristic

- Age: At time of procedure in years
- BMI: At time of admission in kg/m^2
- Smoking: Within last 3 months as yes or no
- Diabetes: recorded as GDMA1, GDMA2, Type I or Type II
- HTN: recorded as Chronic or gestational
- Race: Recorded as Black, White, Hispanic, Asian, Other
- HIV: Viral Load >400, Viral Load <400, Negative
- Immunocompromised: yes or no
- Hospital Course
- Labor or induction or no labor
- Use of internal monitors in labor: yes or no
- Chorioamnionitis: yes or no
- Length of rupture of membranes: in minutes
- Repeat or primary cesarean delivery
- Operative Time (incision to closure): in minutes
- Specific antibiotic used for surgical prophylaxis
- Antibiotics other than those for surgical prophylaxis

Expected Risks/Benefits

- There are minimal risks to the subjects. Both forms of wound closure are in use at University of Chicago Hospital and NorthShore University HealthSystem and are currently selected for patients based on provider preference.
- There is the possibility of benefit to some subjects if one intervention proves more beneficial than the other.
- Tissue adhesive can be "sticky" and can stick to bandages or clothing. Tissue adhesive will be allowed to dry fully (for at least 5 minutes and until it does not feel "tacky") before any contact is made with bandages or clothing.

Quality Control and Quality Assurance

- An initial educational session for residents will be held to describe the purpose of the study and their role in the consent and data collection process.
- A session for nurses will be held to describe their roll in data collection.
- Short review education sessions will be held at beginning of L&D rotations.
- Completed worksheets will be evaluated in an ongoing fashion for completeness and errors.

Statistical Considerations

- Fisher's exact test or Chi Squared will be used to determine if Tissue adhesive lowers the risk of wound complications when compared to steri-strips.
- Baseline characteristics of cases and controls will be evaluated using Student's t test and chi squared where appropriate.
- To estimate our sample size we calculated that 10% of women undergoing caesarean delivery with Pfannenstiel incision experience some type of wound complication. This was based on data showing that 18.8% of extremely obese women, 9.6% of obese women and 7.5% of non-obese women have wound complications[4]. Given the CDC data on obesity and extreme obesity[5] and our population's slightly higher than average rates of obesity we estimated that 45% of our patients are not obese, 40% are obese, and 15% are extremely obese. Using the complication rates above stratified by BMI status and our estimates of the population under study's obesity rates we performed the following calculation to estimate our 10% infection rate. Additional studies have also supported a 10% complication rate[2,6].
- %non-obese(non-obese infection rate)+%obese(obese infection rate)+%extremely obese(extremely obese infection rate)
- 0.45(0.075)+0.4(0.096)+0.15(.188)=0.034+0.038+0.028=10%
- Based on prior research, we hope to see a 50% reduction in complications. In order to achieve a power of 80% with a 95% confidence interval we estimate needing to randomize 864 subjects. We anticipate that 10% will be lost to follow-up and aim to enroll 950 subjects (600 at NorthShore University HealthSystem, 350 at University of Chicago).
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INFORMED CONSENT

- All subjects will be consented to participate in the study either at a clinic appointment or during a hospital admission (antepartum or on labor and delivery). University of Chicago residents and fellows will be responsible for obtaining consent. Consent form is attached in appendix.

SUBJECT CONFIDENTIALITY

- Data will be kept in RedCap, which is secure and password protected.
- Only the PI and co-investigators will know the password and have access to the files.

UNANTICIPATED PROBLEMS

- Both the intervention and control are currently in regular use for wound closure. No serious adverse outcomes have been linked to either method of wound covering. Tissue adhesive may occasionally cause skin irritation, which will be included on our consent form

References

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