OBSTETRICS

A barrier retractor to reduce surgical site infections and wound disruptions in obese patients undergoing cesarean delivery: a randomized controlled trial

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BACKGROUND: Surgical site infections (SSIs) are an important cause of morbidity following cesarean delivery, particularly in obese patients. Methods to reduce SSIs after cesarean delivery would have an important impact in obese obstetric patients.

OBJECTIVE: The purpose of this study was to determine whether the Alexis O cesarean delivery retractor, a barrier self-retaining retractor, reduces SSIs and wound disruptions in obese patients undergoing cesarean delivery.

STUDY DESIGN: This was a randomized controlled trial of obese women (body mass index $\geq$ 30 kg/m^2) undergoing nonemergent cesarean delivery. Patients were randomized to the treatment group (using the Alexis O cesarean delivery retractor) or to the control group (using conventional handheld retractors). The primary outcome was SSI or wound disruption during the 30 day postoperative period. Secondary outcomes included operative time, estimated blood loss, change in hemoglobin, antiemetic use, length of postoperative hospital stay, hospital readmission, and other postoperative complications.

RESULTS: A total of 301 patients were enrolled in the study. One hundred forty-four patients were randomized to the treatment group and 157 to the control group. Baseline characteristics and indications for cesarean delivery were similar between the 2 groups. Median body mass index was 40.1 kg/m^2. There were no significant differences between the treatment and the control group in the primary outcome of SSI or wound disruption rates at the 30 day assessment (20.6% vs 17.6%, $P = .62$), during the postoperative inpatient hospitalization or at the 1−2 week postoperative visit. There were also no differences in the primary outcome when adjusting for obesity class or thickness of the subcuticular layer. Patients in the treatment group had lower rates of uterine exteriorization (54.3% vs 87.3%, $P < .001$), but there were no differences in all other outcomes.

CONCLUSION: Use of the Alexis retractor in cesarean delivery deliveries did not decrease SSI or wound disruption rates in an obese population. Its use as a retractor should be left to the discretion of the surgeon and clinical circumstances.

Key words: Alexis retractor, barrier retractor, cesarean delivery, obesity, surgical site infections

Surgical site infections (SSIs) and wound disruptions are important causes of postoperative morbidity following cesarean delivery, estimated to occur between 3% and 30%, depending on the population studied, definition used, and length of time patients are followed up.[1-4] Morbidities include increased hospital stay and readmissions, health care costs, emotional stress, and decreased productivity.

Obesity is one of the most important risk factors associated with the development of wound complications.[2,3,5-7] Importantly, the risk increases with advancing body mass index (BMI) to an incidence as high as 30% in the massively obese patient (BMI $\geq$ 50 kg/m^2).[1] Strategies to prevent wound complications after cesarean delivery, particularly in populations at high risk, would have important health care implications and should be a goal of obstetric care.

Wound protectors are designed to act as a form of barrier protection, while also retracting wound edges, during surgical procedures. The Alexis wound retractor (Applied Medical, Rancho Santa Margarita, CA) consists of 2 plastic rings joined by an impervious plastic sheath, providing circumferential retraction and wound protection to the abdominal wall edges during surgery. Previous studies have shown decreased rates of SSIs associated with the use of the Alexis wound retractor during colorectal and other gastrointestinal and biliary surgeries,[8-11] possibly through a mechanism of decreasing bacterial colonization of the abdominal wall edges.[12,13]

The Alexis O cesarean delivery retractor is designed specifically for use during cesarean delivery to allow the passage of the neonate while still providing retraction and wound protective properties. The objective of this study was to evaluate whether the Alexis O cesarean delivery retractor reduces the rate of SSI and postoperative wound disruptions following nonemergent cesarean deliveries in an obese population. We hypothesized that the retractor would decrease the incidence of SSI and wound disruptions in this population.

Materials and Methods

This study was a prospective, randomized controlled trial at a single-center perinatal care institution, conducted from March 2013 to September 2014. The study was approved by the Saint Louis University Institutional Review Board.

Pregnant women with a predelivery BMI $\geq$ 30 kg/m^2 undergoing nonemergent cesarean delivery between the

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FIGURE 1
Criteria for SSI

Superficial incisional SSI
Infection occurs within 30 days after the operation *and* infection involves only skin or subcutaneous tissue of the incision *and* at least *one* of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat *and* superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional surgical site infection by surgeon or attending physician.

Deep incisional SSI
Infection occurs within 30 days after the operation and infection involves deep soft tissue (e.g. fascial and muscle layers) of the incision *and* at least *one* of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38° C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Organ/space SSI
Infection occurs within 30 days after the operation and infection involves any part of the anatomy (e.g. organs or spaces), other than the incision, which was opened or manipulated during an operation *and* at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

Criteria for defining SSI from the US Centers for Disease Control and Prevention[14]

SSI, surgical site infection.

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FIGURE 2
Postoperative telephone questionnaire

1. Did you experience any problems with your C-section incision healing?
2. Did you see a doctor or go to an emergency room for fevers or problems with your C-section incision?
3. Did you have any abnormal yellow or green discharge coming from your wound while it was healing?
4. Were you prescribed antibiotics for any problems with your wound healing?
5. Did a doctor tell you that you had an infection of your C-section incision?

Thirty questions asked during the 30 day postoperative telephone interview include the following:

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ages of 14 and 50 years with either singleton or twin gestations and who were capable of consent were eligible for the study. Nonemergent cesarean delivery was defined by our institution's cesarean delivery acuity scale and included those in which there was no immediate threat to the life of the patient or fetus. Although not all cesarean deliveries in the study were elective, patients were included only if there was typical time for routine cesarean delivery preparation, the use of chlorhexidene gluconate scrub, and preoperative antibiotics.

Exclusion criteria were BMI < 30 kg/m^2, non-English speaking, immunosuppression (eg, human immunodeficiency virus, chronic steroid use > 2 days), current concomitant infection other than chorioamnionitis (eg, pneumonia, urinary tract infection), or emergency cesarean delivery. Women were randomized to either the treatment group or to the control group in a 1:1 ratio by a computer-generated random numbers sequence.

Patients were approached for study enrollment by members of the research team during their hospital admission after the decision was made to proceed with cesarean delivery. Randomization was concealed by sequentially numbered opaque envelopes until surgery. The patient was blinded to the treatment group.

For patients assigned to the Alexis group, the retractor was placed onto the instrument table prior to patient arrival in the operating room and was not mentioned during the surgery so that the patient was blinded to her treatment group. Because of the nature of the intervention, it was not possible to blind the surgeon.

Women in the treatment group had the Alexis O cesarean delivery retractor placed after entry and extension of the peritoneal incision and clearance of adhesions. The internal ring of the retractor was placed inside the peritoneum, and the outer ring was rolled until the plastic barrier between the rings became taut. The retractor was checked to ensure that there was no inadvertent trapping of intrabdominal contents.