A prospective randomized study for evaluation of wound retractors in the prevention of incision site infections after cesarean section

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Summary

Surgical site infections (SSIs) after cesarean section appear to be more common than generally believed. We prospectively evaluated 231 consecutive pregnant women who underwent elective or emergency cesarean section, and were assigned to have either the Alexis wound retractor (study group) or a conventional Doyen retractor (control group) during the operation. There was no evidence of SSI, defined as wound dehiscence, pain or tenderness in the lower abdomen, localized swelling, redness, heat or purulent discharge from the wound in any woman in the study group. Moreover, no endometritis occurred in this patient collective. There were three SSI in the control group, but no endometritis. Our preliminary data show excellent protection of wound infections with an additive protective effect to that given by antibiotic cover. After a short learning curve, the handling of the Alexis device became easier and the median insertion time was 18 sec.

Key words: Cesarean section; Surgical site infection.

Introduction

Surgical site infections (SSIs) after cesarean section appear to be more common than generally believed. Moir-Bussy et al estimated that at least 6% of women who had cesarean section developed wound infection. They found that the wound infection rate varied between 0-20.5% among different hospitals in England and Wales [1]. More recently, in a prospective population-based cohort study, it was reported that the total rate of SSI was 8.9% when the observation period was extended for 30 days post-operatively according to the definition of the US Centers for Disease Control and Prevention (CDC), compared to only 1.8% registered at regular hospital discharge. The authors stress the underestimation of the rate of SSIs when the observation time is limited only to the hospital stay [2].

We evaluated the use of the Alexis wound retractor in the prevention of incision site infections after cesarean section as well as the overall convenience during the procedure.

Material and Methods

Two hundred and thirty-one consecutive pregnant women who underwent cesarean section (CS), elective or emergency, from January 2008 to July 2008 were randomly prospectively assigned either to have the Alexis wound retractor (study group) or a conventional Doyen retractor (control group) during the operation. The purpose of this study was the evaluation of the new wound retractor by means of a) feasibility of use, and b) protection of wound infection, defined as wound dehiscence, pain or tenderness at the lower abdomen, localized swelling, redness, and heat or purulent discharge from the wound. The indications for cesarean section for both groups are listed in Table 1.

It should be taken into account that previous cesarean section as well as breech presentation is considered routine in Greece as an indication for cesarean section [3]. The median age of the women was 31 years (range 15-44 years) in the study group and 32 years in the control group (range 16-43 years). The median BMI was 32 in both groups (range 26-43 in the study group and 27-44 in the control group) (Table 2), while most women at the time of operation were in the 38th gestational week (range 27-42 weeks).Women with suspected chorioamnionitis were excluded from the study. Gestational diabetes was not an exclusion criterion and complicated the pregnancy of three women in the study group (two who underwent CS due to fetal distress and one due to previous CS) and of two women in the control group (one who underwent CS due to fetal distress and one due to breech presentation). Two women in the study group and one in the control group were on insulin therapy during pregnancy.

Cesarean section was performed routinely in all cases via the Pfannenstiel incision; after skin preparation with povidone iodine, in the same theatre allocated in the labor ward and used solely for CSs. After inspection of the lower abdomen for the presence of adhesions, the Alexis wound retractor was placed, with one retraction ring (green in color) being inserted into the peritoneal cavity. The retractor is a single-use device that consists of a flexible polymer sheath formed into the shape of a cylinder. Attached to each end of the cylinder are two semirigid polymer (pellethane) rings. The external (white in color) ring is placed in traction and the sheath between both rings is folded over itself until it contacts the skin.

When in place, the Alexis wound retractor keeps the incision open. In this manner no further retraction with metal side wall retractors was needed. The uterovesical peritoneum was incised and transversely opened; the attached bladder was pushed inferiorly with a swab. No gauze was placed intraabdominally. A

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Table 1. — *Indications for cesarean section in 231 consecutive pregnant women*.

Indication (main)	Alexis retractor Patients	Conventional retractor Patients
Previous CS	45 (39.13%)	44 (37.93%)
Breech presentation	18 (15.65%)	16 (13.79%)
Abruptio placentae	6 (5.21%)	8 (6.89%)
Placenta praevia	6 (5.21%)	9 (7.75%)
Twin gestation	6 (5.21%)	5 (4.31%)
Preeclampsia	6 (5.21%)	7 (6.03%)
Fetal distress	15 (13.04%)	17 (14.65%)
Fetal abnormalities	3 (2.61%)	3 (2.58%)
Other	10 (8.7%)	7 (6.03%)
Total	115 (100%)	116 (100%)

Table 2. — *Characteristics of mothers and neonates*

Mother's median age (yrs)	31 (15-44)	32 (16-43)
Mother's median BMI	32 (26-43)	32 (27-44)
Median birth weight (g)	3,010 (890-4,335)	3,030 (915-4,280)

Table 3. — *Surgical site infections in the control group*.

	Gestational week	Co-morbidity	BMI	Neonate	Kind of SSI	Post-operative day
Patient 1	37	No	36	male/3,200 g	wound redness	4th
Patient 2	39	Gestational diabetes	38	male/3,980 g	wound redness with pus excretion	6th
Patient 3	38	No	43	female/3,160 g	wound dehiscence	18th

low transverse incision was performed and the infant was delivered through the retractor.

After delivery of the placenta the incision was routinely closed in two layers with size 0 vicryl running absorbable sutures. The uterovesical peritoneum and the parietal peritoneum were not closed. The rectus sheath was closed with a running size 1 vicryl absorbable suture. The fat layer was closed with 3-5 interrupted size 2/0 vicryl absorbable sutures and the skin was closed intracutaneously with a running 3/0 monofilament absorbable suture. No drains were placed and the Folley catheter was removed in all cases 12-16 hours after CS. All women received prophylactically low-dose heparin for seven days post partum, and all received cefuroxime sodium as standard prophylactic antibiotic therapy (1500 mg after the clamping of the umbilical cord with a repeated dose 12 hours later). No allergic reaction due to the antibiotic cefuroxime was noted.

Results

The Alexis wound retractor was used in 115 women (study group) while the conventional Doyen method was used in 116 women (control group). The median time for the placement of Alexis wound retractor was 18 sec (range 11- 137 sec). A learning curve was necessary at the beginning due to the novel apparatus. Longer insertion time was noted in the first applications or in the presence of adhesions, mainly due to previous CSs.

The vast majority of CSs were performed under neuraxial anesthesia (combined spinal-epidural or epidural). Only one woman in the study group received general anesthesia versus five women in the control group.

The median weight of the neonates was 3,010 g in the study group (range 890-4335 g) and in the control group 3,030 g (range 915-4280g).

During postoperative hospitalization there was no evidence of SSIs, in any woman in the study group. Moreover, no endometritis occurred in this patient collective. There were three SSIs in the control group (Table 3), but no endometritis. The wound culture swab results isolated *Staphylococcus aureus* in two women and *E. coli* in one woman. There were two women in the study group who developed an acute urinary tract infection and three in the control group, which required a course of antibiotics (based on the results of the antibiogram). There was no case with deep venous thromboembolism or chest infection in any of the operated women.

Discussion

Incisional SSIs are divided into those involving skin and subcutaneous tissue (superficial incisional SSI) and those involving deeper soft tissues of the incision (deep incisional SSI), according to the Guidelines for Prevention of Surgical Site Infection of the CDC [4].

There are medical risk factors known to be associated with poor wound healing, as diabetes mellitus and malnutrition, as well as surgical risk factors as the duration of surgery, the placement of gauze packs intraabdominally, the use of drains, suture material, and even the closure technique employed. There are also some other risk factors as ascites and anemia and – especially for obstetrical procedures – even the duration of labor or the higher initial recovery-room temperatures – indicative of the presence of subclinical infection at the time of cesarean section [5, 6]. Several authors also found an association between history of previous cesarean sections and wound infection. The possible explanation in those circumstances might be deficient vascularization of the connective scar tissue, creating favorable conditions for infection due to impaired healing quality [7]. The relation to indications for cesarean section (i.e., elective vs emergency) does not seem to be clarified. Whereas some authors find no difference between the two indications and the rate of SSIs [8], the results of others indicate that there might be a difference. In the paper of Chaim *et al*., Apgar scores at 1 min < 3 and at 5 min < 7 were observed in 9.1% and 6.6% in the group of patients who developed wound infection vs 5.3% and 3.9% in the non-infection group, respectively ($p = 0.003$ for the 1 min Apgar and $p = 0.017$ for the 5 min Apgar, OR = 1.8756). However the authors do not discuss emergency cesarean as a plausible explanation for the lower Apgar scores (a stressed – for several reasons – embryo usually gives an indication for proceeding to cesarean section), but try to explain the lower Apgar score by deficient tissue oxygenation which could lead to anerobic-like conditions that enhance microbial invasion or implicate impaired neonatal wellbeing most probably related to a subclinical or clinical infectious state. In the particular study, no data about emergency or elective procedures are given [7].

Especially for cesarean sections, the most common source of pathogens is endogenous flora on the patient's skin, and quantitative tissue culture has shown that if more than 10^5 microorganisms per gram of tissue are present, the risk of SSI is markedly increased [9, 10].

Our preliminary data show an excellent protection against wound infection with an additive protective effect to that given by intraoperative antibiotic. After a short learning curve, the handling of the device became easier and the median insertion time was 18 sec. Although not measured in any way during this study, the wound exposure was very satisfactory as reported by all physicians who were involved in the cesarean sections. More studies are necessary to support the effectiveness of the Alexis retractor use in cesarean section.

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