Dialkylcarbamoyl chloride-impregnated dressing for the prevention of surgical site infection in women undergoing cesarean section: a pilot study

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Introduction:

Incisional surgical site infections (SSIs) occur in approximately 1.8–9.2% of patients subject to a cesarean section and contribute to prolonged hospitalization time and increased treatment costs.

Objective:

The objective of this study was to compare the new DACC dressing with a standard surgical dressing in the prevention of SSI in women undergoing cesarean section.

Material and methods:

This was a single-blinded randomized, controlled pilot study that evaluated the presence of superficial and deep SSIs during the first 14 days after a cesarean section. Enrolled patients were randomly allocated to receive treatment with either a DACC impregnated dressing (Sorbact® Surgical Dressing) or a standard surgical dressing. The primary study outcome was development of superficial or deep SSI within the first 14 days after a cesarean section. The surgical team was blinded to the dressing type until the time of skin closure.

Main activities/study assessments

At 48 h	Wound evaluation 1	• Dressings removed and a first clinical wound evaluation performed (according to CDC criteria) • The presence of surgical wound dehiscence (separation of the skin, subcutaneous tissue and/or fascia resulting from an incisional SSI) evaluated • For patients with signs of wound infection the following was noted: the time the first symptom occurred, need for systemic antibiotic treatment and need for a surgical intervention • From patients with clinical symptoms of SSI, wound swabs for culture were collected
Day 3	Patient discharged	• Patient informed about the need to report at hospital in case of symptoms suggesting a possible infection (fever, pus from the surgical site, redness, edema, warmth, pain or tenderness of the surgical site area)
Day 7	Revisit to hospital Wound evaluation 2	• Skin sutures were removed • A second clinical wound evaluation (according to CDC criteria) • The presence of surgical wound dehiscence evaluated (see details in wound evaluation 1) • For patients with signs of wound infection (see details in wound evaluation 1) • From patients with clinical symptoms of SSI, wound swabs for culture were collected
Day 14	Revisit to hospital Wound evaluation 3	• A third clinical wound evaluation (according to CDC criteria) • The presence of surgical wound dehiscence evaluation (see details in wound evaluation 1) • For patients with signs of wound infection (see details in wound evaluation 1) • From patients with clinical symptoms of SSI, wound swabs for culture were collected

Results:

- 162 women undergoing elective or emergency CS were enrolled in the study and randomly allocated to receive treatment; 81 patients per group.
- No significant differences between the two study groups regarding basic demographic characteristics.
- 20 patients did not report for the scheduled follow-up visits after 7 and 14 days and were excluded from the analysis, leaving a total of 142 patients with follow-up data; 71 patients per group.
- The rate of surgical site infections was 2.8% in the Sorbact® group and 9.8% in the control group ($p = 0.08$).
- The rate of wound infection requiring systemic antibiotic treatment was 7.0% in the control group whereas systemic antibiotic treatment was not necessary in the study group ($p = 0.03$).
- The pre-pregnancy body mass index (BMI) was found to be a significant predictor for SSI after cesarean section.

Conclusion:

This is the first published study of Sorbact® in wound infection prophylaxis after cesarean section and the results indicate a decreasing tendency (NS/0.08) of the SSI rate after use of Sorbact® dressings.

Patients with SSIs who received a standard surgical dressing required systemic antibiotic therapy significantly more frequently ($p = 0.03$).

Summary:

The study did not show a statistical significant difference related to its primary objective.

A clear trend ($p = 0.08$) for a decreasing SSI tendency was however observed. This observation was supported by a significantly less need for systemic antibiotics in the Sorbact® group.