Randomized Controlled Trial Evaluating Dialkylcarbamoyl Chloride Impregnated Dressings for the Prevention of Surgical Site Infections in Adult Women Undergoing Cesarean Section

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Introduction:

Surgical site infections (SSI) occur in 1.8%–9.2% of women undergoing cesarean section (CS) and lead to greater morbidity rates and increased treatment costs.

Objective:

The aim of the study was to evaluate the efficacy and cost-effectiveness of dialkylcarbamoyl chloride (DACC) impregnated dressings to prevent SSI in women subject to CS.

Material and methods:

This was a single-blinded randomized, controlled study conducted at one hospital site that evaluated the presence of superficial or deep SSIs during the first 14 days after an emergency or elective CS. Enrolled patients were randomly allocated to receive either DACC impregnated dressings (Sorbact® Surgical Dressing) or standard surgical dressings.

The cost-effectiveness of the selected dressings in the group of patients who developed SSI was analyzed. This assessment included costs for systemic antibiotic therapy, ambulatory visits, additional hospitalization and additional nursing care.

Independent risk factors for SSI were determined by multivariable logistic regression.

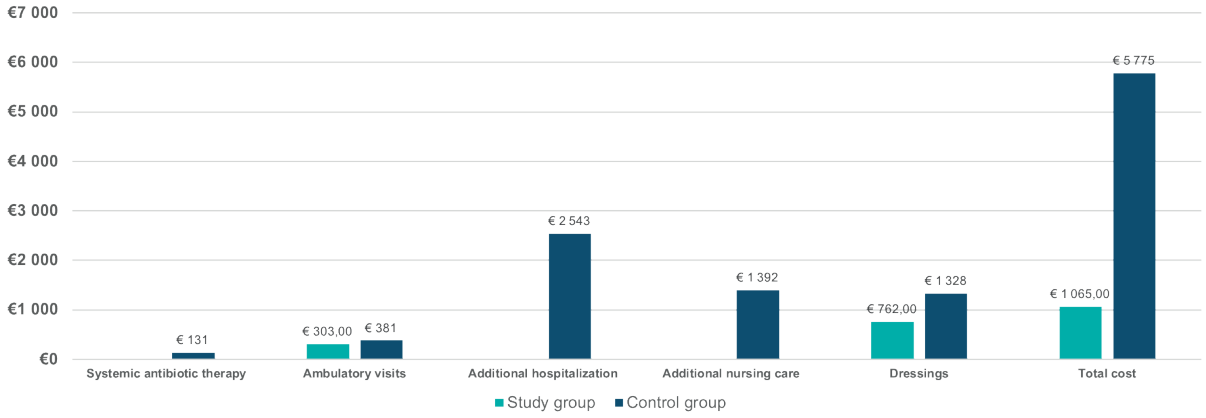
Antibiotic prophylaxis was administered before the surgery and wound irrigation was performed before subcutaneous tissue closure. The surgical team was blinded to the type of dressing before skin closure. The wound assessments were performed by one physician blinded to the dressing type used.

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 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 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 collected

Results:

- 543 women undergoing elective or emergency CS were enrolled and evaluated after 7 or 14 days in the study; 272 in the Sorbact® group and 271 in the standard surgical dressing group.
- There were no substantial differences between the study groups with regard to patient demographics and perioperative course.
- A significantly lower rate (p = 0.04) of surgical site infections was observed in the Sorbact® group compared to standard surgical dressing group; 1.8% vs 5.2%.
- No statistically significant differences were found related to presence of post-operative wound dehiscence, receipt of systemic antibiotic therapy or re-admission rates.
- Despite the fact that women in the Sorbact® group did not require systemic antibiotic therapy and additional hospitalization, the number of ambulatory visits was substantially higher in the study group as compared with the control group, 4.6 vs. 2.9 (p = 0.02).
- Predictors found to increase the risk for SSI after cesarean section were obesity, hypertension, smoking and use of standard surgical dressings.
- Use of the Sorbact® dressings demonstrated cost savings versus standard surgical dressings
- (1065 EUR vs 5775 EUR respectively). The costs included in calculations were those related to ambulatory visits, additional hospitalization, nursing care and systemic antibiotic therapy.



Conclusion:

A significantly lower rate (p = 0.04) of surgical site infections was observed in the Sorbact® group compared to the standard surgical dressing group; 1.8% vs 5.2%.

Use of Sorbact® dressings demonstrated pronounced cost savings versus use of standard surgical dressings.

Summary:

The study on more than 500 women showed a statistical significant reduced rate of CS related surgical site infections after use of Sorbact® dressings compared to standard surgical dressings.

Additionally use of the Sorbact® dressings was associated with pronounced total cost savings versus standard surgical dressings.