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Decreasing of Post-Cesarean Section Surgical Site Infection: Role of Early Dressing Removal - A Prospective Randomized Study

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Abstract

Background: We aim to compare the surgical site infection rate according to the postoperative dressing duration after an elective term cesarean section: 2nd postoperative day removal versus change every two days beyond 48 h.

Materials and Methods: A prospective randomized study of 400 patients who underwent an elective term caesarean section (200 in each group): Group A (dressing removed 2nd day postoperatively) *vs.* group C (dressing kept and replaced beyond 48 h postoperatively). Rate of SSI and the rate of patient's satisfaction were analyzed using SPSS 18.0 software.

Results: There was no difference between the two groups regarding the demographic, obstetrical and operative characteristics. The postoperative SSI rate was significantly reduced when wound dressing was removed the 2nd day postoperatively (3.5% (A) *vs.* 10% (C) respectively, p=0.01). The average cost of the management of postoperative SSI was also reduced ($p<10^{-3}$) and the patient's satisfaction rate was significantly higher (94.5% (A) *vs.* 70% (C) respectively, $p<10^{-3}$). In multivariate analysis, wound dressing kept and replaced beyond 48 h was an independent risk factor of postoperative surgical site infection.

Conclusion: Our results suggest that maintaining and changing wound dressing beyond 48 h postoperatively is an independent risk factor for surgical site infections.

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Introduction

Obstetric infections account for more than 12% of maternal deaths. They were mostly nosocomial and were manifested as postoperative infections in 25% of cases. The rate of surgical site infections, in particular post cesarean section, ranged from 3% to 15%. Before those researches, this rate was 8.2% in our institutions of the surgical site. This infectious morbidity is responsible for longer hospital stayed and increased health care expenses.

Advances in surgery had led to an important reduction in the rate of surgical site infections through a better understanding of infectious diseases, improvement in prevention and surgical techniques, and control of new classes of antibiotics.

The prevention of surgical site infections depended on several factors involved at the different steps of the Caesarean section:

1. At the preoperative stage, especially the preoperative shower of the parturient.

2. At the per-operative stage in which the prevention concerned not only the medical team that was the surgeon (washing and surgical dressing), and the anesthesiologist who was responsible for maintaining the patient's homeostasis (vascular filling, temperature, blood glucose), but also the parturient (preparation of the skin with an antiseptic solution, antibiotic prophylaxis), the type of intervention as well as the type of the skin closure and the surgical environment that must meet operating room standards.

3. At the postoperative stage, in particular the operative wound dressing, in the literature, the dressing was curiously forgotten or evoked succinctly or evasively. There had been few studies about it that preceded the one we deal with it, most of them devoted to new, often expensive, commercial products. Practices varied from school to school. Some teams were unanimous on the removal of

the dressing on the dressing on the second postoperative day. Indeed, in the Meta analysis of Toon et al. [1]. Which retained 4 prospectives randomized studies including a total of 317 patients, the authors opted for that attitude. This was also adopted by the World Health Organization (WHO) in its 2016 guidelines [2]. In contrast., most teams had not adopted that attitude at that time and kept maintaining the wound dressing until the sutures are removed, especially as the National Institute for Health and Care Excellence (NICE) did not address this issue in its "evidence update" of 2013 [3-5].

In our institution we have maintained post-caesarean dressing beyond 48 h and its final ablation was only performed after the last wound control from 10 to 12 days after surgery. Our main concern was the postoperative risk of infection. It was within this framework that our study, whose main objective was to investigate this risk, compares the removal of the dressing after two days to its conversation beyond the 48 h and its definite ablation at the last wound control [6].

Materials and Methods

This is a one-year prospective, randomized, mono-centric study conducted at the Department of Obstetrics and Gynecology at Farhat Hached University Hospital of Sousse, Tunisia (between June 2017 and May 2018).

We included 500 low-risk parturients who met the following inclusion criteria: Term ≥ 28 weeks of gestation, elective caesarean section, out-of-work, intact amniotic sac and informed consent.

The exclusion criteria were as follows: parturient in labor, Premature Rupture of Membranes (PRM), chorioamnionitis, documented infection in progress or within 15 days prior to caesarean section, infection with Human Immunodeficiency Virus (HIV), long-term corticotherapy, antibiotherapy in progress or in the previous 15 days of caesarean section and chronic diabetes. Parturients who had withdrawn their consent were excluded, as well as those who had not complied with the protocol, or who required post-operative antibiotherapy because of concomitant infection (independent of the surgical site).

Randomization was done before starting work by a third person who drew lots from a closed enclosure containing two balls which represent two groups:

1. Group A (study): Whose dressing was removed on the 2nd postoperative day (before discharge from hospital).

2. Group C (control): Whose dressing was kept and changed every two days until removal of the stitches.

The patients who were operated on even days were those belonging to the first group. Patients belonging to the second group were those operated on odd days.

To detect 6% difference in post surgical infection rate (from 9.3% to 3%), which is considered clinically significant with a power of 80% and α 0.05, a sample size of 392 patients was necessary. Given the risk of dropout or excluded patients, a total of 500 parturients were included (250 in each group).

Upon admission, all the parturients were examined. The examination was noted on a pre-established and pre-tested individual survey card containing several sections: Identification of parturients, summary of the course of pregnancy, clinical examination on the day of the caesarean section, caesarean section, (Potential incidents), data on immediate and late postpartum maternal observation, maternal discharge data from the hospital, and postoperative control examination data.

All caesarean sections were performed according to the Pfannenstiel technique. Anesthesia was loco regional (perimedullary anesthesia). General anesthesia was only available in cases of contra indication or failure. Antibiotic prophylaxis consisted in administering 2 g of CEFAZOLINE (Keflin®) in a single dose 30 min before the cutaneous incision. The surgeon was specialized in obstetrics and gynecology and was supervised by a senior surgeon who was in charge of the operating room on the day of the caesarean section (a total of five surgeons consisting of a homogeneous group participated in the caesarean section). Closure of the subcutaneous tissue was done by simple separate dots using a braided resorbable thread (Vicryl 00, CR 26 mm, Ethicon) when its depth was estimated to be more than 2 cm. The skin was closed in all cases by an intra-dermal suture with a resorbable thread (Vicryl 000 with rapid resorption, 26 mm triangular needle, Ethicon). All the parturients had their operative wounds covered by a compressive dressing at the end of surgery, without any application of local antiseptic and were hospitalized for at least two days [7].

Forty eight hours after surgery: In group A, the dressing was removed and no dressing was applied until the last check. A shower with an antiseptic solution (betadine scrub®) was recommended as soon as the parturient went back home. In group C, the dressing was kept and changed every two days until the 10th postoperative day. Wound control was performed for all parturients on the 2nd, 4th, 10th and, if necessary, 30th postoperative days. The main endpoint was the occurrence or not of a Surgical Site Infection (SSI). Other endpoints were: Overall maternal infection rate; duration of hospitalization; direct cost of the dressing and degree of satisfaction. The Surgical Site Infection was defined according to the standard definition of CDC (Centers for Disease Control and Prevention) and National Healthcare Safety Network (NHSN) [8].

This encompassed any infection occurring within 30 days of surgery.

It is called superficial when it concerns only the skin and the under skin. The presence of at least one of these signs is necessary: Purulent secretions, isolation of a germ of the wound, and at least one of these signs: Pain or tenderness, localized edema, erythema or local heat, and disunity of the edges of the wound. Scar infection diagnosis was made by a surgeon or attending physician.

The infection is called deep when it reaches the aponeurosis and meets at least one of these criteria: Deep purulent secretions, dehiscence of the deep planes of the wound with isolation of a germ, or presence of at least one of these signs: Fever >38° or localized sensitivity, presence of an abscess and diagnosis made by a surgeon or attending physician.

Data entry and statistical calculations were performed by SPSS software version 20.0 (IBM® Statistical Package for Social Science (SPSS), version 20.0, New York, USA). The statistical analysis was carried out for the categorical variables by the chi^2 test or the Fisher test for numbers below 5. For the continuous variables, the analysis was carried out by the Student test. A multivariate analysis was performed by binary logistic regression to search for independent risk factors and to eliminate confounding factors. The inclusion of independent variables in the regression models was performed when their degree of significance was less than 0.1 in the univariate analysis.

The accepted statistical significance level (p) was set at 5%. The results were expressed as means ± SD (Standard Deviation) and relative risk with a 95% confidence interval.

Results

Among the 500 included parturients, 100 were excluded as they did no respect the protocol and only 400 were retained (200 in each group) according to the following flow chart.

As summarized in Table 1, both groups had comparable demographic characteristics, as well as age (P=0.917), socio-economic status (p=0.44), educational attainment (p=0.812), smoking history (p=0.159), body mass index (p=0.087) and pathological history (p=0.076).

The parturients' obstetric characteristics were similar. There was no difference in gestational age at the time of the Caesarean section (P=0.372), history of uterine scar (p=0.447), history of surgical wound infection in previous pregnancies (p=0.159), existence of an inter-current pathology (P=0.243), systolic blood pressure (p=0.76) or diastolic blood pressure before caesarean section (p=0.863) (Table 1).

As mentioned in Table 2, the operating characteristics were also comparable. Mainly as 98% of group A and 97% of group C did not present any intra-operative complications. Five patients in each group had complications: Intra-operative hemorrhage (4 cases in each group), bladder wound in one patient from group C and a digestive wound in a patient from group A. The difference was not significant (p=0.57). The visceral complications were managed surgically in both groups. However, the treatment of hemorrhagic complications was only medical in group A and medico-surgical in group C. There were no significant differences (p=0.264) (Table 2).

The duration of postoperative hospitalization was 50.1 (± 8.28) hours (h) *vs.* 52.58 h (± 24.34), p=0.173. The surgical wound infection rate was 3.5% (7 cases) (A) *vs.* 10% (20 cases) (C), p=0.01. The mean time for the onset of the postoperative infection was similar between the two groups (7.56 ± 3.4 days (4 to 13 days, p=0.369). The treatment of the infection was medical in 71.4% of cases in group A against 65% of cases in group C. A surgical resumption was necessary in both groups (28.6% of cases in group A *vs.* 35% in group C, p=0.756). More than 94% of Group A patients expressed satisfaction with only 70% (140 cases) in Group C with a very significant difference ($p=10^{-3}$). The direct cost of the dressing per patient (in group C) was on average 21.42 USD ± 19.1 (3.22 to 193.5 USD). Finally, the mean direct cost of infection treatment per patient was 4.3 USD ± 4.92 (3.22 to 193.5 USD) in group A, compared to 24.9 USD ± 25.2 (3.22 to 258 USD) in group C with a very significant difference ($P<10^{-3}$) (Table 3).

The factors involved in the postoperative infection were variable

Table 1: Demographic and obstetrical characteristics of the study population (n=400).

		Group A N=200	Group C N=200	P
Demographic characteristics				
Age		32.45 (± 5.18)	32.32 (± 5.21)	0.81
Socioeconomic level	low	24%	19%	0.44
	Medium	56%	57.50%	
	High	20.50%	23.50%	
Instruction level	illiterate	7%	7%	0.812
	Primary	35.50%	32.50%	
	Secondary	31.50%	36%	
	university	26%	24.50%	
smoking		4.50%	2%	0.159
BMI	≤ 25	6%	10%	0.257
	[25–29]	29%	31%	
	≥ 30	65%	59%	
Pathological history		8%	13.50%	0.076
Obstetrical characteristics				
MGA (days)		273.12 (± 9.64)	272.13 (± 12.36)	0.372
History of caesarean section	Without antecedent	32%	34.50%	0.447
	Single uterine scar	30.50%	34%	
	Multiscarred uterus	37.50%	31.50%	
History infection of the wall		4.50%	2%	0.159
Unwinding pregnancy	GD	11%	15%	0.243
	Urinary tract infection	3%	5%	
	TPD	5%	3%	
	Others	8%	11%	
SBP before caesarean section		115.88 (± 13.17)	116.42 (± 13.27)	0.682
DBP before caesarean section		69.84 (± 9.98)	71 (± 10.60)	0.261

MGA: Mean Gestational Age; GD: Gestational Diabetes; TPD: Threat Premature Delivery; SBP: Systolic Blood Pressure; DBP: Diastolic Blood Pressure

Table 2: Surgical characteristics of the study population (n=400).

Characteristics		Group A	Group C	P
	Cicatricial uterus	76%	73%	0.17
	Feto-pelvic disproportion	31%	30%	
	Seat presentation	14%	16%	
	Others	11%	16%	
Operating time	Average	45.69 (± 12.58)	46.78 (± 12.91)	0.393
	≤ 45 mn	57.50%	55%	0.614
	>45 mn	42.50%	45%	
Mode of delivery	Directed	57%	61.50%	0.36
	Artificial	43%	38.50%	
Place of hysterography	Intra-abdominal	51%	42.50%	0.088
	Extra-abdominal	49%	57.50%	
Per-operative complications	No	98%	97%	0.57
	Yes	2%	3%	
Treatment of hemorrhage	Medical	100%	50%	0.264
	Surgical	0%	50%	
Surgical drain	No	99.50%	89.50%	0.315
	Yes	0.50%	1.50%	

Table 3: Characteristics of postoperative follow-up (n=400).

Characteristics		Group A N=200	Group C N=200	P
Duration of hospitalization (in h)		50.1 (± 8.28)	52.58 (± 24.34)	0.173
Infection	No	96.50%	90%	**0.01**
	Yes	3.50%	10%	
Delay of infection (in d)		8.57 (± 2.99)	7.2 (± 3.53)	0.369
Treatment of infection	Medical	71.40%	65%	**0.756**
	Medical + Surgical	28.60%	35%	
Satisfaction	No	5.50%	30%	**<0.001**
	Yes	94.50%	70%	
Cost of dressing (in USD)		-	21.42 ± 19.1 (3.22 to 193.5)	-
Cost of infection treatment (in USD)		4.3 ± 4.92 (3.22 to 193.5)	24.9 ± 25.2 (3.22 to 258)	**<0.001**

h: hour; d: day; USD: United States Dollar

depending on the time of dressing removal. Indeed, in a univariate analysis, the infection risk was more marked in group A in women over 40 years old (p=0.05). This risk was more significant in group C, in case of smoking, gestational diabetes, and history of defects and artificial delivery (p=0.001) (Table 4). In a multivariate analysis, two independent factors influenced the risk of postoperative infection: the continuance of the dressing beyond 48 h (p=0.003) and gestational diabetes (p=0.011) (Table 5).

Discussion

The risk of post-surgical infections represents a major issue in all types of surgery. The contamination risk of surgical wounds during the cutaneous incision by endogenous pathogen bacteria from the abdominal wall is estimated to be 80% [9,10]. In fact, the endogen skin flora represents the major source of contamination and post-surgical skin infections [9], especially for surgeries considered "clean" and non-contaminating [11,12].

The infection is generally multi-microbial and the most incriminated germs are coagulase-negative *Staphylococcus* and *Staphylococcus aureus* from the endogenous skin flora. Other germs, from the genital tract found in case of endometritis, may be involved [13]. They are represented by GNB such as *E. coli* or Proteus, and Anaerobics such as *Enterococcus* and *Corynebacter* [10,13,14].

The Post-surgical infections rate is even higher in case of caesarean section compared to other types of interventions [15]. In our study, the global rate of operative site infections was 6.75% compared to 8.1% in 2014. In most cases they were superficial in-situ infections [16].

Throughout the literature, the operative site infections rate in the obstetrical field varies from 2.8% to 26.6%, described with significant heterogeneity depending on the specialty and the mode of observation [17,18]. The disparity between these rates would be related to the potential existence of risk factors. In fact, the CDC and the NNIS have provided an international index to assess the risk of post-surgical infections including 3 settings:

- The ASA score representing the basic health status of each patient prior to surgery.

Table 4: Risk factors for post-operative infection in a univariate analysis.

	Group A		Group C	
	% Infection	**P**	**% Infection**	**P**
Age >40 years	11.5	0.05	16.7	0.32
Low socio-economic level	4.2	0.77	7.9	0.63
Higher educational level	2.8	0.82	23.4	0.34
History of infection	11.1	0.2	25	0.32
Tare antecedent	0	-	22.2	**0.02**
Smoking	11.1	0.2	50	**0.01**
Obesity	3.7	0.49	10	1
Gestational Diabetes	9.2	0.11	23.3	**0.01**
Operating time >30 mn	3.5	0.98	10.5	0.46
Artificial delivery	2.3	0.43	18.2	**0.001**
Extra-abdominal hysterorrhaphy	5.1	0.22	8.7	0.47

Table 5: Risk factors for post-operative infection in a multivariate analysis.

Variable		Infection (%)	P Univariate	OR [95% CI]	P Multivariate
Dressing	No	3.5	0.01	4.44 [1.64 – 12.02]	0.003
	Yes	10			
Age	≤ 40 years	6	0.063	1.80 [0.55 – 5.98]	0.332
	> 40 years	14.3			
Smoking	No	6.2	0.017	3.01 [0.65 – 14.12]	0.16
	Yes	23.1			
Gestational Diabetes	No	5.20%	0.001	3.31 [1.31 – 8.35]	0.011
	Yes	17.6%			

- The extent of the wound contamination, considering that the programmed C-sections are class II surgeries according to the Altemeier Classification.
- The technical aspect during the intervention.
- These three settings combined allow us to define the NNIS index which is useful to predict the SSI for patients at similar risk levels [19].

The correlation between NNIS index and the post C-section infection is yet to be proven. Still, specific factors remain related to the C-section. We can divide them into 2 groups:

1. Intrinsic factors related to the patient such as maternal age [20,21], social and economic levels [21], parity [22,23], tobacco consumption [24], obesity [21-30], number of prior C-sections [22-24,31-34] and Gestational Diabetes [21-24,35,36].

2. Extrinsic factors related to the medical support throughout and after the surgery, such as the duration of the operation [16,21,22,30], whether the delivery was directed or artificial [37,38], whether the uterus was stitched within or outside the abdominal cavity [39], possible post-partum hemorrhage [21,24], whether a sub-cutaneous drainage was performed or not [4,25,41,42], and finally the type and duration of the post-surgical dressing.

Taking into account these different factors, the NNIS reports an infection rate of 3.35% in the absence of any risk factors as compared to 8.1% in the presence of one of these risk factors.

In our study, there were two independent factors found to increase the risk of SSI, namely Gestational Diabetes where the infection rate was 17.6% as compared to non-diabetic patients who had a risk of 5.2%; and the act of maintaining and changing the wound dressing for more than 48 h after surgery.

There are different ways to prevent this infection risk which have to be undertaken at different moments of the surgery and even after. In the medical practice, it is common after surgery to stitch the skin and then cover the wound with a conventional dressing or a commercial gel. It is thought that the dressing acts as a physical barrier protecting the skin until the restoration of its continuity which usually takes place within 48 h. Therefore, it allows the absorption of skin exudates, keeping the wound dry and clean and preventing its contamination with any external bacteria.

Nevertheless, the usefulness of keeping a surgical wound under dressing for more than 48 h is still controversial. In fact, there is no solid proof that the dressing really prevents skin infection, reduces post-surgical pain or even improves the patient's well-being [43]. On the other hand, within less than 48 h, skin healing is good enough to stop germs from penetrating through the scar from the outside. Therefore, natural re-colonization or scar manipulation should not influence its contamination. Moreover, a certain number of studies have shown that the moist environment created by some dressings slows down the wound healing [1,44,45].

In 2005, Frank R. Witter et al. [46] applied a preventive strategy for post caesarean infections in which the early removal of the dressing within the second day after surgery has proven to reduce the risk of SSI from 7.7% to 3.24%. A meta-analysis gathering randomized clinical trials which compared different types of dressings did not prove any significant differences in terms of infection, pain, quality of the section scar, or the patient's level of well-being [47,48]. Dosseh Ekoué et al. [49] did not prove any additional infectious risk related to the early removal of the wound dressing on the second day after surgery. These results were shared by Toon et al. [10], who provided evidence that the early removal of the dressing within two days of the act allows shortening the hospital stay and reducing the costs without further increasing the risk of post-surgical complications.

In our study, early removal of the dressing did not raise the risk of infections. It also significantly reduced SSI: 3.5% (A) *vs.* 10% (C) with a significant difference (p=0.01). In this multivariate analysis, maintaining the dressing for more than 48 h was found to be an independent risk of SSI (RR=4.44; p=0.003; 95% IC [1.64-12.02]).

The average delay for the occurrence of post-surgical infections was that of 7.59 ± 3.4 (4 to 13 days). It was comparable between the two groups: 8.57 ± 2.99 (A) *vs.* 7.2 ± 3.53 (C), p=0.369.

A complete healing was more frequently observed in group A: 96.5% (193) *vs.* 90% (180) for group C with a significant difference (p=0.01). Those results were also correlated with those provided by Dosseh Ekoué et al. [49].

On the other hand, repetitive changes of the dressing are painful moments for the patient, not to mention the high rate of skin reactions. It is also easier for nurses to monitor an uncovered wound.

The dressing removal within the first 48 h after the C-section is adopted by the WHO as one of the recommendations for good practice when it comes to preventing SSI.

The average cost of dressings per patient (in group C) was estimated to be 21.42 USD ± 19.1 with extremes going from 3.22 to 193.5 USD.

The total expenses of treating the infections for our patients were lower for patients belonging to group A with an average of 4.3 USD ± 4.92 (3.22 to 193.5 USD) per patient compared to 24.9 USD ± 25.2 (3.22 to 258 USD) in group C with a significant difference (p<0.001).

This has allowed us to confirm that the absence of dressing on surgical wounds does have any economic benefit. These findings were correlated with other authors who found a gain in terms of hospital stay duration, stitches removal delay and direct costs. In fact, they demonstrated a saving of 1.7 times in the minimum inter professional wage growth when the surgical dressing was not changed [1,49].

When asking our patients about their satisfaction levels regarding the medical care: 94% from group A provided a positive feedback compared to only 70% from group C who were equally satisfied with a significant difference (p=0.001).

The feeling of satisfaction was motivated by different factors; in particular, the scar healing, the low rate of infections, the low cost, the women feeling cleaner with the possibility of an early shower and the absence of the distressing moments related to the multiple changing of the dressing.

Conclusion

Changing the wound dressing for more than 48 h after surgery seems to be an independent risk factor of OSI. Its removal on day 2 after surgery allows not only the reduction of infectious risk but also the care cost. It also increases patient's satisfactory levels and well-being.

For these reasons, we believe that dressing removal on day 2 after surgery should be recommended for a better post-caesarean section care.

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