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Intrauterine Cleaning After Delivery of Placenta during Cesarean Section: Randomized Comparative Trial

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Abstract
Background:*Post-cesarean endometritis is still regarded as serious morbidities, in spite of the strategies used to prevent these complications. To reduce the morbidity, different preventive measures have been taken including the administration of prophylactic antibiotics, use of prophylactic vaginal preparation, and the uterine cavity cleaning. The benefits of such measure remain a topic of debate.* ***Objectives:*** *To our knowledge, this is the first Egyptian trial to evaluate the value of intrauterine cleaning after placental delivery in reducing the rate of post-cesarean endometritis.* ***Subjects and Methods:*** *We conducted this RCT at the Obstetrics and Gynecology department of Ain Shams university hospitals on 400 pregnant women aged 20-35 years and would undergo cesarean section for their deliveries. These women were randomly and evenly assigned into two groups; uterine cleaning and non-cleaning.* ***Results:*** *The incidence of endometritis was higher among the cleaning group with a statistically significance difference (p = 0.02). Participants who had uterine cleaning had 2.25 increase in risk of endometritis in comparison to those who did not receive cleaning (P = 0.04). Also, women in the cleaning group complained of pelvic tenderness more frequently than those in the non-cleaning group (p = 0.008).****Conclusions:*** *Uterine cleaning was associated with a significant increased risk of endometritis; however, it didn't increase the surgical time and estimated blood loss significantly.*
Keywords: "*post-cesarean endometritis", "uterine cleaning".*

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I. Introduction

Caesarean section is one of the commonest operations performed and its incidence is increasing. The majority of these operations proceed smoothly and safely; however, caesarean section is a major, open abdominal procedure (**Dahiya, 2016**). Women undergoing caesarean sections are 5-20 times more susceptible to infection than women who had normal vaginal delivery. Infectious complications after cesarean delivery include fever, sore wounds and endometritis. These complications are major causes of maternal morbidity, and may prolong mother's hospital stay (**Mohamed et al., 2015**). The rate of post-cesarean infection varies from 7% to 20%, depending on operating time, maternal body mass index (BMI), duration of labor, number of vaginal examinations during labor, the amount of blood loss, emergency or elective caesarean delivery and surgeon's experience (**Mohamed, 2013**).

Post-cesarean wound infection and endometritis are still regarded as serious morbidities, in spite of the strategies used to prevent these complications with respect to patient complaint, patient cost, use of antibiotics and prolonged hospital stay. The most recognized risk factors for developing post-cesarean endometritis involve pathways that introduce high quantities of bacteria into the uterine cavity (**Abdallah, 2015**). To reduce morbidity, different preventive measures have been taken including the administration of prophylactic antibiotics, use of prophylactic vaginal preparation, and the uterine cavity cleaning (**Jafarzadeh et al., 2016**). The latter two measures haven't been approved by the scientific community; yet, they are discussed in some gynecologic surgery textbooks (**Haas et al., 2010**).

Despite the lack of a scientific evidence to support a policy of routine intrauterine cleaning after placental delivery at cesarean sections, the benefits of such measure remain a topic of debate. Obstetricians who don't support intrauterine cleaning argue that this procedure is not routinely performed after vaginal deliveries, and therefore, it's unnecessary to do so following cesarean sections (**Eke et al., 2016**).

Significance of the study:

To date, none of the previous studies addressing this topic, especially randomized clinical trials (RCTs), has been conducted in Egypt. Therefore, to our knowledge, this is the first Egyptian trial to evaluate the value of intrauterine cleaning after placental delivery in reducing the rate of post-cesarean endometritis.

II. Subjects And Methods

Aim of the study:
To improve the outcomes of women undergoing cesarean sections.

Study Design:
A prospective randomized comparative trial.

Research Setting:
The study was conducted in Obstetrics and Gynecology department of Ain Shams university hospitals.

Study Population:
Pregnant women undergoing cesarean section, the study participants were divided into 2 groups using simple random sampling technique.
Study group A: (Cleaning the uterine cavity): Two hundred participants had their uterine cavities cleaned.
Study group B: (Not cleaning the uterine cavity): Two hundred participants had their uterine cavities left without cleaning after complete delivery of the placenta.
Inclusion Criteria:
1. Women participants from 20 years up to 35 years old.
2. Women with singleton or multiple pregnancies.
3. Vertex or breech presentation with intact membranes presenting to our labor and delivery unit for cesarean section was evaluated for participation.

Exclusion Criteria:
1. Preterm or spontaneous premature rupture of membranes prior to cesarean section.
2. Chorioamnionitis.
3. Fetal demise.
4. Diabetes mellitus.
5. Immunosuppressive disorder and therapy.

Sampling
A convenient sampling technique was used. Sample size was calculated using an online sample size calculator "OpenEpi" using 90% confidence level, 80% power, incidence of endometritis in exposed persons 15.6%. Calculation according to these values produced a minimal sample size of 200 cases per group (total 400 cases) (**Jafarzadeh, 2016).**

Study outcomes
Primary outcome:
Our primary outcome measure was presence of endometritis after delivery. Diagnosis of endometritis according to the following criteria (**Eke et al., 2016; Andrews et al., 1995; Atkinson, Hauth and Wen, 1996)**
The presence of fever (temperature ≥ 38.0°C) postoperatively, except the first day and at least one of the following signs:

- Abnormally tender uterus on examination.
- Abnormal vaginal discharge, e.g. presence of pus.
- Abnormal smell/foul odor of discharge.

Secondary outcomes:
It included assessment of Primary post-partum hemorrhage Length of hospital stayHospital readmission ratesSurgicaltimeBlood loss

Study procedure
Preoperative assessment
All participants were subjected to:
A. Complete history taking including:
Personal history: age, race, socioeconomic status, contact information (for contacting them for following up)
Obstetric history: parity, gestational age, indication for cesarean section, membrane status at time of cesarean section, and post-operative complications.
B. Measurements and laboratory tests

Body weight was measured to estimate blood loss postoperative. Beside routine laboratory tests hematocrit value was recorded to assess initial hematocrit level.

Intraoperative interventions

The protocol for labor management was the same for both groups (for laboring patients), including continuous electronic fetal monitoring with the external Doppler device. After delivery of the placenta, Participants in group A had their uterine cavities cleaned with a dry laparotomy sponge (12*12 inch). While group B had not receive uterine cleaning.

- Administration of a prophylactic intravenous antibiotic (1-2 g cefazolin) before the start of surgery. Participants with cefazolin allergy received 900 mg clindamycin.
- A Pfannenstiel skin incision was used. The fascia was incised in the midline and the incision was extended bilaterally, and the rectus muscles were separated in the midline.
- The lower uterine segment was incised in the midline in a transverse fashion, and the hysterotomy was done.
- Inspection of the placenta after delivery to make sure it was complete and no parts were retained intrauterine.
- The hysterotomy closure was usually performed in two layers using 1vicryl suture.
- Inspection of the uterine incision, with/without closure of vesicouterine peritoneum, abdominal peritoneum, or rectus muscles (according to the attending physician's preferences).
- Standard closure of the abdominal fascia suturing with a running non-locking delayed absorbable suture.
- The subcutaneous tissue was closed if it was deep (more than 2cm in depth).
- Using non-absorbable polypropylene sutures 3/0 for skin closure in a subarticular Technique, and the incision was subsequently dressed.
- Surgical time was calculated during the whole operation.

Postoperative assessment

A. Immediately postoperative

Patients' hematocrit was measured again and blood loss was calculated.

Patients were asked to return for follow up upon their contact by the corresponding physician.

B. Follow up period

Patients were assessed twice during six weeks duration after labor at the outpatient clinic (once in the second week and again in the sixth week) for the presence of any of the following:

- Endometritis (according to the predetermined criteria)
- Postpartum hemorrhage
- Hospital readmission and its causes
- Prolonged hospital stay and its causes.

Statistical analysis

- All statistical analyses were performed using the *SPSS* statistical package for social science version 20.
- Descriptive statistics were applied in numerical form (mean, SD or percentages) to describe the quantitative variables. Diagrammatic and tabular forms were used to describe the qualitative variables.
- Associations between variables were tested for significance using Chi-square test for categorical variables and (t) test for continuous variables with normally distributed data. Non-normally distributed data were tested using Fisher's exact for categorical variables and Mann-Witney U tests for continuous variables.
- Risk estimations were expressed in the form of relative risk (RR), absolute risk increase (ARI) and number needed to harm (NNH).
- Multivariable binary logistic regression analysis was used to determine the effect of uterine cleaning, surgical time and estimated blood loss on the occurrence of endometritis.
- Two-sided p-values <0.05 were considered statistically significant.

III. Results

The study included 400 participants; their mean age was approximately 28 for both study groups. Mean gestational age was around 39 weeks in both groups. Both variables showed no statistically difference between cleaned and non-cleaned groups. Mean weight was around 82 Kilograms and despite the slight difference, yet it is statistically significant. Most of the study participants were of low parity; about one third of them were P1, followed by P2. Furthermore, less than 5% of them were P5 or more. Parity also had not statistically significant relationship with uterine cleaning **(Table 1)**.

Table (1): characteristics of patients

Variables	Intervention		P value
	Cleaning (200)	No cleaning (200)	
Age (years) (mean ± SD)	27.9 ± 4.6	27.9 ± 4.7	0.8
Weight (Kg) (mean ± SD)	80.9 ± 10.9	83.6 ± 7.6	<0.001
Gestational age (weeks) (mean ± SD)	38.8 ± 1.0	38.7 ± 1.1	0.1
Parity (N, %)			
PG	23 (11.5%)	29 (14.5%)	0.4
P1	67 (33.5%)	69 (34.5%)	
P2	58 (29%)	66 (33%)	
P3	30 (15%)	22 (11%)	
P4	12 (6%)	8 (4%)	
P5 or more	10 (5%)	6 (3%)	

The most common cause of CS among the study participants were previous CS (80% for the cleaned and 75% for the non-cleaned group) followed by Cephalopelvic disproportion (5.5% % for the cleaned and 10% for the non-cleaned group). The least common among cleaned group were: having contracted pelvis, fetal distress, placenta previa and precious baby, while least common causes among non-cleaned group were: were having twins and placenta previa. Indications of CS did not present any statistical significance between cleaned and non-cleaned **(Table 2)**.

Table (2): Indications for CS

Variables	Intervention				
	Cleaning (200)		No cleaning (200)		P value
	N	%	N	%	P value
Previous CS	160	80%	150	75%	
PE	8	4%	6	3%	0.65
CPD	11	5.5%	20	10%	
Malpresentation	6	3.%	5	2.5%	0.65
Scanty liquor	4	2.%	7	3.5%	
Twins	4	2.%	1	0.5%	
Contracted pelvis	2	1.%	3	1.5%	
Fetal distress	2	1.%	3	1.5%	

Placenta previa	1	0.5%	2	1%	
Precious baby	2	1.%	3	1.5%	

PE = preeclampsia, CPD = Cephalopelvic disproportion

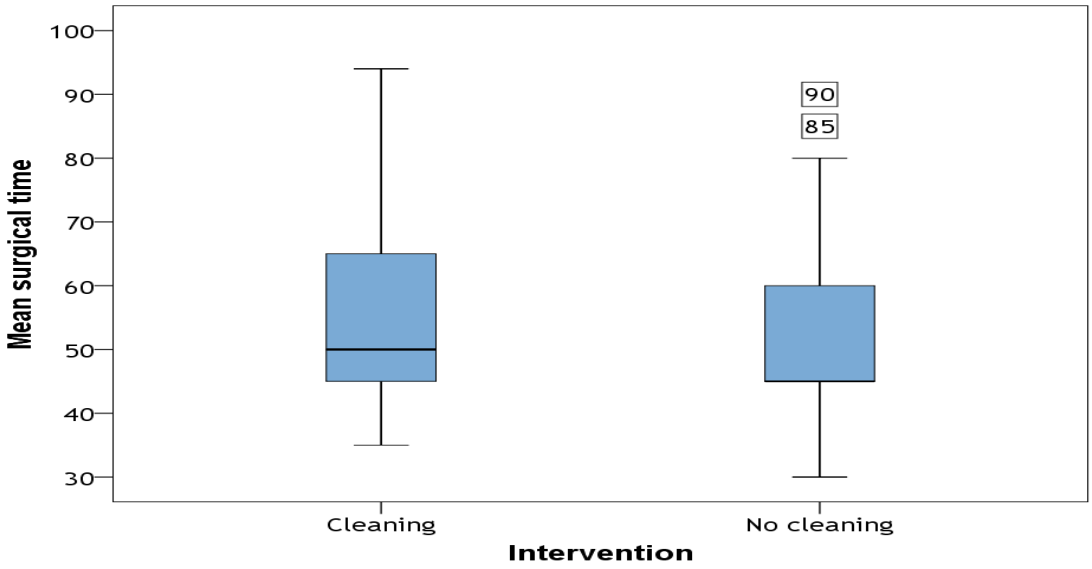
There were statistically significance differences in hematocrit level preoperatively and postoperatively between both groups. Similarly, mean estimated blood loss was higher in the cleaned group with around 37 ml statistically significant difference (P = 0.002). The mean surgical time spent on the operation was around 55 minutes in the cleaned group and about 52 minutes in the non-cleaned group, with a 3 minutes difference between both which is statistically significant as well (P = 0.01) **(Table 3, Figure 1,2).**

Table (3): Surgical details.

Variables	Intervention		P value
	Cleaning (200)	No cleaning (200)	
Preoperative Hct (g/dl) (mean ± SD)	34.6 ± 2.3	35.3 ± 1.5	**<0.001**
Postoperative Hct (g/dl) (mean ± SD)	29.7 ± 2.2	30.7 ±1.5	**0.01**
EBL (ml) (mean ± SD)	850.1 ± 191.8	812.9 ± 156.7	**0.002****
Surgical time(min.) (mean ± SD)	55.6 ± 13.7	52.3 ± 12	**0.01***

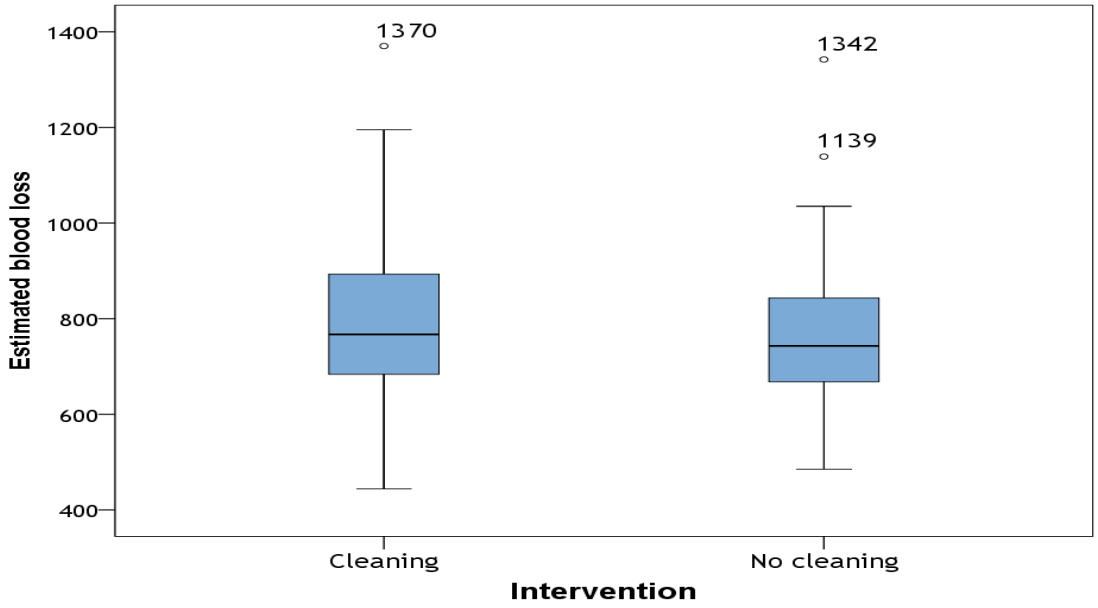
Hct = hematocrit, EBL = estimated blood loss.

Figure (1): Comparison of mean surgical time (in minutes) between study groups.



Numerical labels indicate outliers.

Figure (2): Comparison of mean estimated blood loss (in ml) between study groups.



Numerical labels indicate outliers.

Hospital length of stay was divided into three categories: 24 hours, 36 hours and 48 hours. The majority of study participants fall into the first category with no difference between both groups **(Table 4)**.

Table (4): Hospital length of stay.

Variables	Intervention				P value
	Cleaning (200)		No cleaning (200)		
	N	%	N	%	
24 h	184	92.0%	189	94.5%	
36 h	3	1.5%	0	0.0%	0.467
48 h	13	6.5%	11	5.5%	

Out of the 200 participants, 16 of the cleaned group stayed at hospital more than 24 hours, while only 11 participants of the non-cleaned group did. The major cause was postpartum hemorrhage. No statistically significant difference presented between groups **(Table 5)**.

Table (5): Causes of prolonged (>24 h) hospital stay.

Variables	Intervention				P value
	Cleaning (200)		No cleaning (200)		
	N	%	N	%	
PPH	11	22%	8	16%	0.269
PE / gestational hypertension	2	4%	3	6%	
Bladder injury	3	6%	0	0%	

PPH = postpartum hemorrhage, PE = preeclampsia.

Out of 200 participants, nine from the cleaned group were readmitted to the hospital in comparison to seven only from the non-cleaned group. Readmission happened mostly due to scar infection. No significant relationship connecting cleaning to causes of admission **(Table 6)**.

Table (6): Incidence and causes of hospital readmission

Variables	**Intervention**				**P value**
	Cleaning (200)		**No cleaning (200)**		
	N	**%**	**N**	**%**	
Readmission to hospital	9	10.5%	7	3.5%	0.4
Causes of readmission to hospital					
Scar infection	5	10%	4	8%	0.9
Breast engorgement	2	4%	2	4%	
Pyelonephritis	2	4%	1	2%	

The incidence of endometritis was higher among the cleaned group with a statistically significance difference (0.02). Of the criteria of diagnosis of endometritis, the most frequently reported symptom was abnormal vaginal discharge with foul smell **(Table 7, Figure 3,4)**.

Table (7): Incidence of endometritis

Variables	**Intervention**				**P value**
	Cleaning		**No cleaning**		
	N	**%**	**N**	**%**	
Criteria of endometritis					
Fever > 38°C	26	13%	18	9%	0.2
Pelvic tenderness	17	8.5%	5	2.5%	**0.008***
Abnormal vaginal discharge with foul smell	40	20%	28	14%	0.07
Incidence of Endometritis	19	9.5%	8	4%	**0.02***

Figure (3): Incidence of criteria of endometritis between cleaned and non-cleaned group.

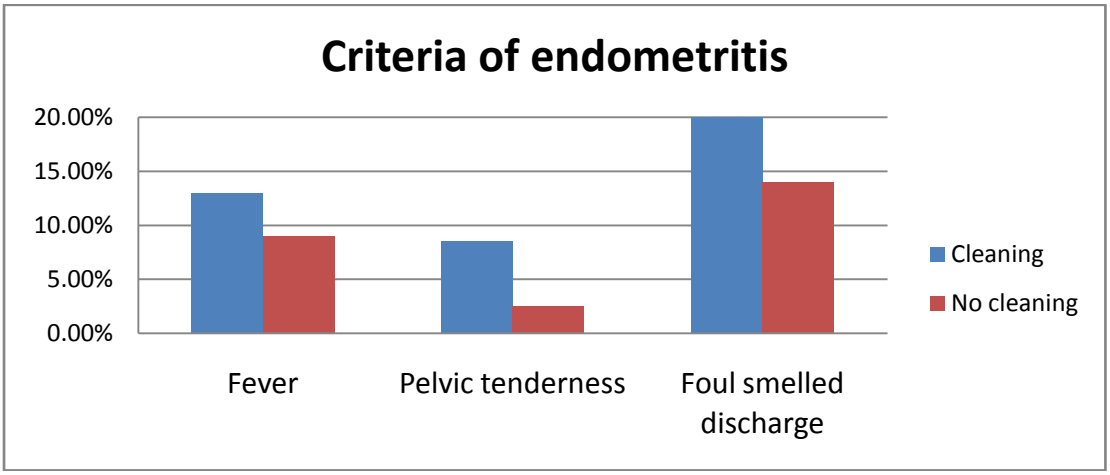
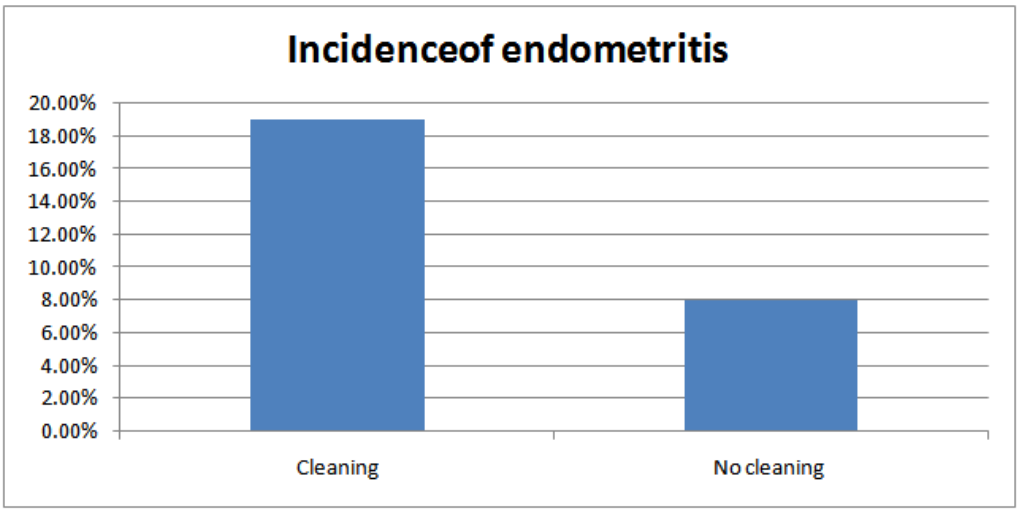


Figure (4): Incidence of endometritis between cleaned and non-cleaned group.



Participants who had uterine cleaning have 2.25 increase in risk of endomteritis in comparison to those who did not receive cleaning (P = 0.04). The difference in risk of endometritis in the cleaned group and non-cleaned groups is 0.05. Eighteen participants need to be exposed to uterine cleaning to cause harm to one participant who would not otherwise have been harmed **(Table 8)**.

Table (8): Risk analysis for the incidence of endometritis

	Risk estimates	**95% CI**		**P value**
Risk of endometritis in the Cleaning group	0.09	0.06	0.14	
Risk of endometritis in the Non-Cleaning group	0.04	0.02	0.07	**0.04***
Relative risk	2.25	1.11	1.89	
Absolute risk increase	0.05	0.10	0.005	
Number needed to harm (NNH)	20	9	191	

A logistic regression was performed to ascertain the effects of uterine cleaning, surgical time and estimated blood loss on the likelihood that participants have endometritis. Uterine cleaning was associated with an increased likelihood of endomtritis. While surgical time and estimated blood loss showed no statistically significant difference **(Table 9)**.

Table (9): Multivariable binary logistic regression analysis for the effect of uterine cleaning, surgical time and estimated blood loss on the occurrence of endometritis.

Variables	**B**	**SE**	**P-value**	**OR**	**95% CI**

Uterine cleaning	0.96	0.44	**0.02***	2.62	1.10-6.21
Surgical time (min)	0.038	0.023	0.09	1.03	0.99-1.08
Estimated blood loss (ml)	-0.002	0.002	0.18	0.99	0.99-1.00
Constant	1.99	1.11	0.07	7.38	

B = regression coefficient, SE = standard error, OR = odds ratio, 95% CI = 95% confidence interval

IV. Discussion

The rate of CS is growing, and its subsequent complications are escalating as well. Postoperative endometritis is one of the most common complications that obstetricians face every day. In this study, we investigated the role of intrauterine cleaning after placental removal during CS in reduction of the incidence of postpartum endometritis. In the following section, we are going to interpret the results, correlate these results to the literature, anticipate clinical value of these findings and identify weaknesses and strengths of the study.

Participants' characteristics (age, weight, gestational age and parity) were similar in both study groups; those who had uterine cleaning and those who had not. Noticeably, participants' age is one of the main contributing factors of endometritis; **Olsen et al., 2010** found that the younger the age the higher the incidence (OR 0.93, 95% CI 0.90-0.97). Younger women tend to be less expert and do less prenatal visits than those of older age (P = .005), thus impede early detection of risk factors of endometritis.

Past studies claim that patients' weight increase the risk of postoperative infections (**Vermillion et al., 2000**). However, we found a statistically significant difference in patients' weight between the two study groups with mean body weight is higher among those with lower risk of endometritis (the non-cleaning group). Nevertheless, it is believed that its subcutaneous thickness which increases the risk of infection not increased weight itself.

Gestational age is one of determinant factors of infection, low gestational age may be associated with low birth weight, preterm labor, and premature rupture of membranes (PROM)or other perinatal complications that increase incidence of infection (**Kawakita and Landy, 2017;Dalton and Gastillo, 2014).**

High parity is an already established maternal risk factor for surgical site infection **(Krieger, Walfisch and Sheiner, 2016).**The higher parity, the higher number of CS and its subsequent complications.

Regarding intraoperative details: both surgical time and estimated blood loss were significantly increased in the group received uterine cleaning. Uterine cleaning is supposed to be reasonably time consuming which explains prolongation of surgical time, however this difference was not marked and added only extra three minutes to the time of surgery for which risk of infection barely be attributed (55.6 minutes in cleaned versus 52.3 minutes in non-cleaned group).In addition, extra manipulation after placenta removal stimulates further blood loss which justifies the difference in blood loss between both groups. It is also important to consider which mode of placental delivery was used as manual placental removal is associated with greater blood loss beside subsequent placental retention **(Dehbashi, Honarvar and Fardi, 2004; Lasley et al., 1997).**

In **Eke et al., 2016** study these quantitative surgical details were quite comparable especially that time of surgery was also around 50 minutes in both groups, and estimated blood loss was slightly higher, however, there was no statistically significant difference between groups.

The majority of cases did CS because of previous CS (80% in cleaned versus 75% in non-cleaned group). Indication of CS did not statistically differ from one group to another. Similarly, most of previous studies reported that the main indication for CS is having a preceding one followed by fetal causes such as malpresentation. **(Eke et al., 2016; Harrigill, Miller and Haynes, 2003).** Having previous CS scar is one of the risk factors for surgical site infection, this is due to the presence of dermatological changes as loss of elasticity and change in skin configuration which lead to prolonged surgery time and as a result increase the risk of infection **(Killian et al., 2001).**

In our study hospital length of stay and causes of prolonged stay were not statistically different between study groups. The majority of patients had only 24 hours stay. We considered more than 24 hours stay at hospital is prolonged length of stay which was only 8% of intervened group and 5.5% in control group.Prolonged length of stay was mainly attributed to postpartum hemorrhage (PPH) followed by PE / gestational hypertension and bladder injury.

Surgical site infection and endometritis are two of the major causes of prolonged hospital stay as well (**Kawakita and Landy.2017)**; however, these two causes were not noticed in our study.

In our study PPH occurred in 11 patients in the cleaned group versus eight in the non-cleaned group with no statistical difference between both groups. This increased risk among the cleaned group agrees with **Eke et al., 2016** findings where PPH presented in eight participants from the cleaned group and six patients from the non-cleaned group. This increasing number is may be associated with the mode of placental delivery,

it is well established that manual delivery of the placenta was associated with higher risk of PPH **(Dehbashi, Honarvar and Fardi, 2004).Krieger, Walfisch and Sheiner, 2016** investigated the incidence of PPH among patients with wound infection versus those who without wound infection, the found that PPH is higher in the former group (0.7% versus 0.3%).

Concerning the rate and causes of readmission, there was no statistical difference between both groups despite the reasonable difference in rate; 10.5% versus 3.5% in the cleaned and non-cleaned groups respectively. Readmissions were mainly due to scar infection, breast engorgement and pyelonephritis. In previous studies, the rate of postpartum readmission was 2.16 by 2011 and was mainly due to infection (15.5%), hypertensive disorders (9.3%) and psychological disorders (7.7%) **(Clapp et al., 2016).**

Most of the studies conducted before assessed different intrauterine cleaning methods and few evaluated the dry wiping. In our study the incidence of postpartum endometritis was significantly higher, and its risk was around two and half times in the group given intrauterine cleaning (RR 2.37 % CI 1.11 – 1.89, P = 0.04).There are many risk factors of endometritis that could give rise to such high incidence such as type of cleaning material, antibiotic prophylaxis, mode of placental delivery and bacterial colonization. Data about the former three risk factors were provided in the study but no data were provided about the latter two.

In **Eke et al., 2016**study which used the same method of cleaning they found no statistically significant difference between both cleaned and non-cleaned groups with a modest decrease of incidence in the intervened group (2.0% vs. 2.9%, RR = 0.60; 95% CI 0.40-1.32). When **Jafarzadeh, 2016** attempted normal saline in uterine cleaning, results were insignificant as well between the compared groups despite the reduced incidence of endometritis in the cleaned group up to one-week post-operation. Albeit, when participants were followed up until the sixth week, incidence of endometritis was found to be significantly higher in the control group.

The role of Antibiotic prophylaxis in elective CS is debatable, some studies report reduction in the risk of endometritis and Cochrane reviews confirmed its efficacy in significant incidence reduction of surgical site infection and endometritis as well (**Smaill et al., 2014).** While others found no role for it with no marked reduction in postpartum infections **(Berghella, Baxter and Chauhan, 2005).**However, all patients were given prophylactic antibiotic which does not explain the rise in incidence of endometritis in the intervened group.

Two of the important risk factors which were not assessed in our study are presence of bacterial colonization and reporting mode of placental delivery. It was found that bacterial colonization by different organisms was associated with increased risk of endometritis (**Olsen et al., 2010; Andrews et al., 1995).** When pregnant women were screened for bacterial colonization and treated, the risk of endometritis decreased **(Locksmith, Clark and Duff, 1999)**.Mode of placental removal determines the risk of endometritis as well, as the risk is higher with manual extraction in comparison to spontaneous delivery **(Lasley et al., 1997; Anorlu, Maholwana and Hofmeyr, 2008).**

In general, higher incidence of endometritis may be attributed to many risk factors as mentioned before but unexpectedly, the incidence is much higher in the cleaned group. Patients were randomized to both arms of the study, so selection bias is not to be blamed. Nevertheless, intraoperative measures could be possible causes for this contrast: Firstly, mode of placental removal; it is already established that manual removal of placenta is associated with higher incidence of endometritis which could be the case with most of the intervened participants. Secondly, glove contamination while doing uterine cleaning may be a contributing factor**(Yancey, Clark and Duff, 1994; Dehbashi, Honarvar and Fardi, 2004).**
Haas et al., 2013 proved that incidence of endometritis is less when glove was changed during closure, lavage and antiseptic application; unfortunately, no data were collected in our study about glove changing before cleaning. Lastly, increased blood loss among the intervened group indicate the necessity for extra manipulation and retraction to control bleeding and hence extra tissue damage which rationalizes make the wound more liable to contamination and infection.

V. Conclusions

The current study concluded that uterine cleaning through wiping the uterus after placental delivery is not effective in reducing incidence of endometritis, furthermore, it can be hazardous and increase risk of infection.Of the three possible variables that could cause endometritis; uterine cleaning was associated with a significant increased risk of endometritis, while increased surgical time and estimated blood loss did not contribute to increase the risk of endomteritis.The length of hospital stay and incidence of readmission was not significantly affected by uterine cleaning.

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