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The Impact of Low Dose versus High Dose Antibiotic Prophylaxis Regimens on Surgical Site Infection Rates after Cesarean Delivery: Randomized Controlled Trial

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Abstract

Background: Cesarean section (CS) is one of the most common operations done in the obstetric ward, and its usage is rapidly rising. Surgical site infections (SSI) are a common consequence following a CS, and they are primarily responsible for increased maternal mortality and morbidity, as well as patient dissatisfaction, longer hospital stays, and greater treatment expenses.

Aim of Study: The current study aimed to evaluate the impact of low-dose versus high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery.

Patients and Methods: This randomized controlled trial was conducted at Matarya Teaching Hospital between December 2021 and December 2022 A total of 380 pregnant women who attended for elective CS were enrolled and randomly assigned to two groups; group 1 "control group" received a low-dose regimen (1g) of cefazolin sodium and group 2 "study group" received a high-dose regimen (2g) 30 minutes before skin incision.

Results: In the current study, there were no significant differences between both groups as regards age, parity, and BMI. However, we demonstrated that higher parity, older age, and obesity were significantly associated with a high rate of wound infection. In our study, the median duration of CS was 60 minutes and the minimum is 25 minutes and the maximum is 90 minutes in both groups. We found that longer surgical duration is associated with a high rate of wound infection. In the present study, there were no significant differences between groups as regards previous medical history, including bronchial asthma, chronic hypertension, gestational hypertension, and hypothyroidism. Also, no significant relation was noted between the patient's medical diseases and wound infection. Concerning Southampton follow-up scoring system grades in the present study (wound healing, bruising, erythema, hematoma formation, and inflammation); there were no significant differences between both groups as regard 24 hours, one week, and 30 days after surgery, p=0.968, 0.343 and 0.438 respectively. Also, there were no significant differences between both groups as regard wound infection 24 hours, 1 week, and 30 days after surgery, p=0.707, 0.093, and 0.492 respectively.

Conclusion: We concluded that low-dose antibiotic is as efficacious as high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery. Current ACOG guidelines should be followed until further level I clinical trial evidence is available.

Key Words: *Low dose – High dose antibiotic prophylaxis regimens – Surgical site infection rates – Cesarean delivery.*

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Introduction

CESAREAN section (CS) is one of the most common operations done in the obstetric ward, and its usage is rapidly rising. The rate of 52 percent that was recorded in Egypt Demographic and Health Survey (EDHS) 2014 is almost double that reported at the time of the 2008 EDHS (28 percent) and 2.5 times the level observed at the time of the 2005 EDHS (19.9 percent) **[1]**.

Women undergoing cesarean section have a five to 20-fold greater risk for infection and infectious morbidity compared with a vaginal birth. In Western countries the percentage of live births by cesarean section is around 27% (range 14.7% to 49%); in developing countries the overall rate is around 12% but varies widely by region (0.40% to 40%) **[2]**.

Infectious complications that occur after cesarean births are an important and substantial cause of maternal morbidity and are associated with a significant increase in hospital stay. Infections can affect the pelvic organs, the surgical wound, and the urinary tract. Infectious complications following cesarean birth include fever (febrile morbidity), wound infection, endometritis (inflammation of

the lining of the uterus), and urinary tract infection. Surgical site infection (SSI) being one of them. The rate of SSI ranges from 3% to 15% worldwide [3].

The surgical site infection (SSI) is defined by the Centers for Disease Control and Prevention (CDC) criteria as an infection which occurs within 30days after a surgical procedure and is further divided into superficial incisional primary and secondary SSIs, deep incisional primary and secondary SSIs and organ/space SSIs if involving structures deeper than muscle and fascia space [4].

According to superficial incisional SSI, infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following: purulent drainage, with or without laboratory confirmation, from the superficial incision, organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision, at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative, diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do not report the following conditions as SSI: Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration), infection of an episiotomy or newborn circumcision site, infected burn wound, incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

According to deep incisional SSI, infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following: Purulent drainage from the deep incision but not from the organ/space component of the surgical site, a deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38ºC), localized pain, or tenderness, unless site is culture-negative, an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination, diagnosis of a deep incisional SSI by a surgeon or attending physician.

According to organ/space SSI, Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following: Purulent drainage from a drain that is placed through a stab wound into the organ/space, organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space, an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination, diagnosis of an organ/space SSI by a surgeon or attending physician [5].

Many different risk factors for SSIs following CS have been reported include subcutaneous hematoma, chorioamnionitis, maternal comorbidities, tobacco use in pregnancy, incision length >1 6.6cm, body mass index >30 or 35kg/m^2, corticosteroid use, no antibiotic prophylaxis, pregestational diabetes, hypertensive disease/preeclampsia, nulliparity, twin gestations, premature rupture of membranes, gestational diabetes, blood loss (increased for every increase in blood loss of 100mL), previous cesarean delivery and emergency delivery [6].

The risk for developing SSI has significantly decreased in the last three decades, mainly owing to improvements in hygiene conditions, antibiotic prophylaxis, sterile procedures, and other practices. Despite this decrease, the occurrence of SSI is expected to increase given the continuous rise in the incidence of cesarean deliveries [7].

A significant component that affects the rate of SSI is the use of antibiotic prophylaxis in cesarean section. When comparing antibiotic prophylaxis to no prophylaxis or placebo for preventing infection following cesarean section, the use of prophylactic antibiotics significantly reduced the incidence of wound infection, endometritis, and maternal serious infectious complications [8].

In terms of timing of prophylactic antibiotic administration, women who received antibiotics preoperatively had a lower composite infectious morbidity compared to women who received antibiotics after cord clamping [9].

The American College of Obstetricians and Gynecologists, in its committee opinion, recommends antimicrobial prophylaxis for all cesarean deliveries unless the patient is already receiving an antibiotic regimen with appropriate coverage.

The antibiotics should be administered within 60 minutes before the procedure. A single dose of a targeted antibiotic, such as a first-generation cephalosporin, is the first-line antibiotic of choice **[10]**. Recently, a higher dose of cefazolin has been suggested, with the hypothesis that higher levels above the minimal inhibitory concentration (MIC) lead to lower postoperative maternal infection complications in the obstetrical population **[11]**.

Aim of the work:

To evaluate the impact of low-dose versus high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery.

Patients and Methods

This study was a randomized controlled trial conducted on a total of 380 pregnant women who attended for elective C-sections at Matarya Teaching Hospital between December 2021 and December 2022 to evaluate the impact of low-dose versus high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery.

Inclusion criteria:

1- Any pregnant woman candidate for elective lower segment Cesarean section.
2- Full-term pregnancy (more than 37 weeks of gestation).
3- Singleton pregnancy.
4- Pfannenstiel incision.
5- Primi and repeated Cesarean sections.
6- BMI (Body mass index) <30.

Exclusion criteria:

1- Declined informed consent.
2- Women received antibiotics preoperatively.
3- Women with premature rupture of membranes.
4- Nonviable fetus.
5- Multiple pregnancy.
6- Patients on immunosuppressive therapy or corticosteroids.
7- Severely anemic patients. (Hb <7g/dl).
8- Diabetic patients.
9- Patients with hypersensitivity to the antibiotic in our study
10- Intraoperative complications (hematoma, bladder or intestinal injury) or blood transfusion.
11 - Intraperitoneal drains.
12- Procedure duration exceeds 2 hours (Skin to Skin).
13- History of renal and hepatic impairment.
14- History of surgical site infection in previous surgeries.

Study procedure:

All included females were subjected to: Detailed history, examination, investigations were done to select eligible patients for the study.

Safety measures: Before the administration of cefazolin was instituted, careful inquiry was made to determine whether the patient has had previous hypersensitivity reactions to Cefazolin, Cephalosporins, Penicillins, or other drugs as if Cefazolin was given to penicillin-sensitive patients, caution was exercised because cross-hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction to cefazolin occurred, we discontinued treatment with the drug. Serious acute hypersensitivity reactions were treated with epinephrine and other emergency measures, including oxygen, iv fluids, iv antihistamines, corticosteroids, pressor amines, and airway management. As well as all patients with renal and hepatic impairment were excluded for fear of cefazolin adverse reactions and its impacts on the kidney and liver. All eligible women were then randomly assigned to two groups as follows: Group 1: Women who received a low-dose regimen of cefazolin sodium and dose was as follows (1 gm) 30 minutes before skin incision. (Control group), Group 2: Women who received a high-dose regimen of cefazolin sodium and dose was as follows (2gm) 30 minutes before skin incision. (Study group).

Throughout both the high-dose and low-dose periods, the procedures were consistent; all cases had hair clipped at incision before surgery initiation by 24 hours, a foley's catheter was inserted under complete aseptic technique before skin preparation using povidone-iodine 10%. All Cesarean sections were done by a senior resident. All patients had Pfannenstiel skin incision, low transverse hysterotomy, spontaneous placenta extraction, two-layers hysterotomy, and rectus sheath closure using vicryl 1/0 (polyglactin 910), subcutaneous layer, and subcuticular skin suturing using vicryl 2/0 (polyglactin 910).

All patients received postoperative antibiotic as follow: 1gm cefazoline sodium within 24 hours postoperatively. After surgery, data documenting pre and postoperative antibiotic prophylaxis, duration of the surgery, type of surgery, type of anesthesia, were prospectively extracted from the medical charts, anesthesia list, patients' medication, and

from the discharge list, discharge was placed after 24 hours postoperatively, all subjects participating in the study were followed until 30 days after the operative procedure. Follow-up was held as follows: After 24 hours to check for surgical site complications, after 1 week at the outpatient clinic to check for SSI (seroma, pus, or any discharge, re-open of the wound), after 30 days follow-up was done by phone call.

Primary outcome:

The primary outcome was the incidence of SSI occurring within one-week post-surgery.

Secondary outcome:

Incidence of SSI occurring within 30 days post-surgery, correlation between high-dose antibiotic and puerperal sepsis.

Ethical considerations:

The study was approved by the Ethical Committee of the Department of Obstetrics and Gynecology, Matarya Teaching Hospital.

Statistical analysis:

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level.

Results

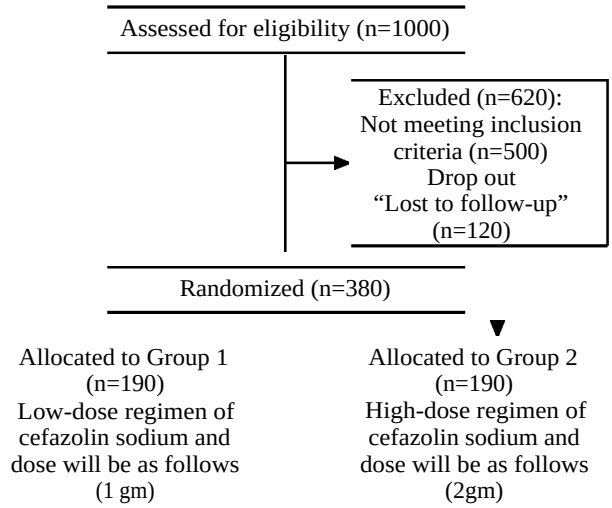

Fig. (1): CONSORT Flow Diagram of the progress through the phases of a parallel randomized trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis).

Table (1): Southampton scoring system.

Wound	Grade	Grade	Appearance
Normal wound healing	Grade 0	Grade 0	Normal healing
	Grade 1: Normal wound healing with mild bruising or erythema	Grade I-A	Some bruising
		Grade I-B	Considerable bruising
		Grade I-C	Mild erythema
Minor wound complication	Grade II: Erythema plus other signs of inflammation	Grade II-A	At one point
		Grade II-B	Around sutures
		Grade II-C	Along wound
		Grade II-D	Around wound
	Grade III: Clear or haemoserous discharge	Grade III-A	At one point only (<2cm)
		Grade III-B	Along wound (>2cm)
		Grade III-C	Large volume
		Grade III-D	Prolonged (>3 days)
Wound infection	Grade IV: Pus	Grade IV-A	At one point only (<2cm)
		Grade IV-B	Along wound (>2cm)
Major wound complication	Grade V: Deep/severe wound infection	Grade V	Wound infection with or without tissue breakdown, haematoma, requiring aspiration

Table (2): Comparison between the two studied groups according to demographic data.

	Group 1 (n=190)	Group 2 (n=190)	Test of Sig.	*p*
Age (years):				
Min. - Max.	18.0-41.0	15.0-44.0	*t*=1.418	0.157
Mean ± SD.	30.36±6.07	31.25±6.15		
Median (IQR)	30.0 (26.0-35.0)	32.0 (26.0-37.0)		
Parity:				
Nulli Parous	43 (22.6%)	28 (14.7%)	χ^2=5.129	0.077
Primi Parous	57 (30.0%)	53 (27.9%)		
Multi Parous	90 (47.4%)	109 (57.4%)		
Min. - Max.	0.0-5.0	0.0-4.0	U=16191.0	0.070
Mean ± SD.	1.43±1.07	1.59±0.94		
Median (IQR)	1.0 (1.0-2.0)	2.0 (1.0-2.0)		
BMI (kg/m ^{2}):				
Min. - Max.	22.0-30.0	20.0-30.0	*t*=1.597	0.111
Mean ± SD.	28.08±1.88	28.38±1.85		
Median (IQR)	28.0 (27.0-30.0)	29.0 (27.0-30.0)		

IQR : Inter quartile range.
SD : Standard deviation.
t : Student *t*-test.
U : Mann Whitney test.
$\chi 2$: Chi square test.
p: *p*-value for comparing between the studied groups.
Group 1: Low-dose regimen of cefazolin sodium and dose was (1gm).
Group 2: High-dose regimen of cefazolin sodium and dose was (2gm).

Regarding demographic data; there were no significant differences between both groups regarding age (years), parity and BMI (kg/m^2); mean ± SD 30.36±6.07 vs. 31.25±6.15, 1.43±1.07 vs. 1.59±0.94 and 28.08±1.88 vs. 28.38±1.85, *p*=0.157, 0.077, 0.070 and 0.111 respectively.

Table (3): Comparison between the two studied groups according to medical diseases.

	Group 1 (n=190)		Group 2 (n=190)		χ^2	*p*
	No.	%	No.	%		
Medical diseases:						
Free	123	64.7	120	63.2	0.103	0.749
Present	67	35.3	70	36.8		
Bronchial asthma	12	6.3	15	7.9	0.359	0.549
CHTN	9	4.7	14	7.4	1.157	0.282
GHTN	36	18.9	25	13.2	2.363	0.124
Hypothyroidism	4	2.1	11	5.8	3.401	0.065

χ^2 : Chi square test.
p : *p*-value for comparing between the studied groups.

Regarding medical diseases; there were no significant differences between groups, free 123 vs. 120, bronchial asthma 12 vs. 15, chronic hypertension (CHTN) 9 vs. 14, gestational hypertension (GHTN) 36 vs. 25 and hypothyroidism 4 vs. 11, *p*=0.749, 0.549, 0.282, 0.124 and 0.065 respectively.

Table (4): Comparison between the two studied groups according to type of anesthesia.

	Group 1 (n=190)		Group 2 (n=190)		χ^2	*p*
	No.	%	No.	%		
Type of anesthesia:						
Spinal	189	99.5	177	93.2	10.679*	0.001*
General	1	0.5	13	6.8		

χ^2 : Chi square test.
p : *p*-value for comparing between the studied groups.
* : Statistically significant at *p*≤0.05.

Regarding type of anesthesia; spinal anesthesia was significantly more frequent and general anesthesia was less frequent in group 1, 189 vs. 177 and 1 vs. 13, *p*=0.001.

Regarding relation between 24 hours follow-up score with different parameters, higher parity, older age, obesity and longer duration of surgery were significantly associated with wound infection. On the other hand, no significant relation was noted between patient's medical diseases as bronchial asthma, CHTN, GHTN and hypothyroidism and wound infection.

Regarding relation between follow-up score after 1 week with different parameters, higher parity, older age, obesity and longer duration of surgery were significantly associated with wound infection. On the other hand, no significant relation

was noted between patient's medical diseases as bronchial asthma, CHTN, GHTN and hypothyroidism and wound infection.

Regarding relation between follow-up score after 30 days with different parameters, higher parity, older age, obesity and longer duration of surgery were significantly associated with wound infection. On the other hand, no significant relation was noted between patient's medical diseases as bronchial asthma, CHTN, GHTN and hypothyroidism and wound infection.

Table (5): Relation between 24 hours follow-up score with different parameters in total sample (n=380).

	24 hours follow-up score				Test of Sig.	*p*
	No infection (n=299)		Infection (n=81)			
	No.	%	No.	%		
Parity:						
Nulli Parous	64	21.4	7	8.6	χ^2=11.371*	0.003*
Primi Parous	91	30.4	19	23.5		
Multi Parous	144	48.2	55	67.9		
Min. - Max.	0.0-5.0		0.0-4.0		U=8846.0*	<0.001*
Mean ± SD.	1.41±1.0		1.89±0.95			
Median	1.0		2.0			
Age (years):						
Min. - Max.	15.0-41.0		21.0-44.0		*t*=3.607*	<0.001*
Mean ± SD.	30.23±6.09		32.95±5.81			
Median	30.0		34.0			
BMI (kg/m ^{2}):						
Min. - Max.	20.0-30.0		26.0-30.0		*t*=4.413*	<0.001*
Mean ± SD.	28.02±1.92		29.02±1.40			
Median	28.0		30.0			
Duration of surgery:						
Min. - Max.	25.0-85.0		40.0-90.0		*t*=3.720*	<0.001*
Mean ± SD.	59.58±14.20		66.17±13.93			
Median	60.0		65.0			
Medical diseases:						
Free	197	65.9	46	56.8	χ^2=2.287	0.130
Present	102	34.1	35	43.2		
Bronchial asthma:						
Free	277	92.6	76	93.8	χ^2=0.136	0.713
Present	22	7.4	5	6.2		
CHTN:						
Free	284	95.0	73	90.1	χ^2=2.647	FE*p*=0.116
Present	15	5.0	8	9.9		
GHTN:						
Free	253	84.6	66	81.5	χ^2=0.465	0.496
Present	46	15.4	15	18.5		
Hypothyroidism:						
Free	288	96.3	77	95.1	χ^2=0.267	FE*p*=0.535
Present	11	3.7	4	4.9		

SD : Standard deviation.
t : Student *t*-test.
U : Mann Whitney test.
χ^2 : Chi square test.
FE : Fisher Exact.

p: *p*-value for comparing between No infection and Infection.
*: Statistically significant at $p \leq 0.05$.

Table (6): Relation between After 1 week follow-up score with different parameters in total sample (n=380).

	After 1 week follow-up score				Test of Sig.	*p*
	No infection (n=230)		Infection (n=150)			
	No.	%	No.	%		
Parity:						
Nulli Parous	55	23.9	16	10.7	χ^2=35.807*	<0.001 *
Primi Parous	83	36.1	27	18.0		
Multi Parous	92	40.0	107	17.3		
Min. - Max.	0.0-3.0		0.0-5.0		U=10415.5*	<0.001 *
Mean ± SD.	1.23±0.89		1.95±1.03			
Median	1.0		2.0			
Age (years):						
Min. - Max.	18.0-41.0		15.0-44.0		*t*=5.226*	<0.001 *
Mean ± SD.	29.53±5.84		32.77±6.04			
Median	29.0		34.0			
BMI (kg/m ^{2}):						
Min. - Max.	20.0-30.0		23.0-30.0		*t*=4.474*	<0.001 *
Mean ± SD.	27.91±2.02		28.72±1.49			
Median	28.0		29.0			
Duration of surgery:						
Min. - Max.	25.0-85.0		30.0-90.0		*t*=2.141*	0.033 *
Mean ± SD.	59.72±13.68		62.93±15.24			
Median	60.0		65.0			
Medical diseases:						
Free	158	68.7	85	56.7	χ^2=5.698*	0.141
Present	72	31.3	65	43.3		
Bronchial asthma:						
Free	214	93.0	139	92.7	χ^2=0.020	0.889
Present	16	7.0	11	7.3		
CHTN:						
Free	221	96.1	136	90.7	χ^2=4.691*	0.23
Present	9	3.9	14	9.3		
GHTN:						
Free	194	84.3	125	83.3	χ^2=0.069	0.792
Present	36	15.7	25	16.7		
Hypothyroidism:						
Free	222	96.5	143	95.3	χ^2=0.338	0.561
Present	8	3.5	7	4.7		

SD : Standard deviation.
t : Student *t*-test.
U : Mann Whitney test.
χ^2 : Chi square test.
p : *p*-value for comparing between No infection and Infection.
* : Statistically significant at $p \leq 0.05$.

Table (7): Relation between After 30 days follow up score with different parameters in total sample (n=378).

	After 30 days follow-up score				Test of Sig.	*p*
	No infection (n=294)		Infection (n=84)			
	No.	%	No.	%		
Parity:						
Nulli Parous	69	23.5	2	2.4	χ^2=33.723 *	<0.001 *
Primi Parous	94	32.0	16	19.0		
Multi Parous	131	44.6	66	78.6		
Min. - Max.	0.0-3.0		0.0-5.0		U=6640.0*	<0.001 *
Mean ± SD.	1.31±0.94		2.19±0.92			
Median	1.0		2.0			
Age (years):						
Min. - Max.	15.0-44.0		21.0-41.0		*t*=4.961*	<0.001 *
Mean ± SD.	29.98±6.05		33.63±5.54			
Median	30.0		34.0			
BMI (kg/m^2):						
Min. - Max.	22.0-30.0		20.0-30.0		*t*=2.880*	0.004*
Mean ± SD.	28.08±1.88		28.74±1.76			
Median	28.0		29.0			
Duration of surgery:						
Min. - Max.	25.0-90.0		30.0-90.0		*t*=2.541*	0.011 *
Mean ± SD.	59.97±13.95		64.46±15.50			
Median	60.0		65.0			
Medical diseases:						
Free	197	67.0	44	52.4	χ^2=6.048 *	0.186
Present	97	33.0	40	47.6		
Bronchial asthma:						
Free	273	92.9	78	92.9	χ^2=0.0	1.000
Present	21	7.1	6	7.1		
CHTN:						
Free	282	95.9	73	86.9	χ^2=9.289	0.93
Present	12	4.1	11	13.1		
GHTN:						
Free	246	83.7	71	84.5	χ^2=0.035	0.852
Present	48	16.3	13	15.5		
Hypothyroidism:						
Free	283	96.3	80	95.2	χ^2=0.179	FE*p*=0.751
Present	11	3.7	4	4.8		

SD : Standard deviation.
t : Student *t*-test.
U : Mann Whitney test.
χ^2 : Chi square test.
FE : Fisher Exact.
p : *p*-value for comparing between No infection and Infection.
*: Statistically significant at $p \leq 0.05$.

Discussion

Surgical site infections (SSI) are a common consequence following a cesarean section (C-section), and they are primarily responsible for increased maternal mortality and morbidity, as well as patient dissatisfaction, longer hospital stays, and greater treatment expenses **[12]**.

In a committee opinion, the American College of Obstetricians and Gynaecologists advises antimicrobial prophylaxis for all cesarean births unless the patient is currently on an antibiotic regimen that provides enough coverage **[3]**.

There is strong evidence of the protective role of antibiotic prophylaxis to reduce the SSI rate with a remarkably low SSI incidence rate among the patients with antibiotic administration prior to surgery. The main source of error in the clinical setting is the choice of the antibiotics related to procedure as well as dosing of the antimicrobials **[13]**.

The first-line antibiotic of choice is a single dosage of a targeted antibiotic, such as a first-generation cephalosporin. A larger dosage has recently been proposed, with the premise that doses above the minimum inhibitory concentration (MIC) result in fewer postoperative maternal infection problems in the obstetrical population **[14]**.

This randomized controlled trial was conducted at Matarya Teaching Hospital between December 2021 and December 2022 to evaluate the impact of low-dose versus high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery. A total of 380 pregnant women who attended for elective C-sections were enrolled and randomly assigned to two groups; group 1 "control group" received a low-dose regimen (1g) of cefazolin sodium and group 2 "study group" received a high-dose regimen (2g) 30 minutes before skin incision.

Although several studies assessed the effect of cefazolin lowering the risk of SSI after surgical operations including a CS **[15,16]**. Overall the SSI rate in our current study was noticeably high (within 30 days; ranged from 20%-43.7%). There is a wide range globally of reported SSI after C-sections varying from SSI rate of 2.7% in a retrospective study conducted in Nova Scotia **[17]** to 5.5% in the USA **[18]** followed by high incidence rate of SSI up to 48% in low-resource settings in a Tanzanian tertiary Hospital **[19]** 23.5% in Brazil **[20]** 18.8% in Malaysia **[21]** and 14.4% in Jordan **[22]**. These studies demonstrate that the overall SSI rate differs widely, based on the study sample, preexisting diseases, use of antibiotics as well as reliable methods for SSI documentation and reporting.

Regarding demographic data; statistical analysis of current results showed that there were no significant differences between both groups regarding age (years), parity and BMI (kg/m^2); mean ± SD 30.36±6.07 vs. 31.25±6.15, 1.43±1.07 vs. 1.59±0.94 and 28.08±2.04 vs. 28.38±2.02, p=0.157, 0.077, 0.070 and 0.143 respectively. Regarding relation between 24 hours, 1 week and 30 days Southampton follow-up scoring system with different parameters, higher parity, older age and obesity were significantly associated with wound infection.

Regarding duration of surgery (mins); there was no significant difference between both groups; mean ± SD 60.68±14.49 vs. 61.29±14.31, p=0.682. Regarding relation between 24 hours Southampton follow-up scoring system with different parameters. longer duration of surgery was significantly associated with wound infection.

Regarding medical diseases; there were no significant differences between groups, free 123 vs. 120, bronchial asthma 12 vs. 15, chronic hypertension (CHTN) 9 vs. 14, gestational hypertension (GHTN) 36 vs. 25 and hypothyroidism 4 vs. 11, p=0.749, 0.549, 0.282, 0.124 and 0.065 respectively. Also, no significant relation was noted between patient's medical diseases as bronchial asthma, CHTN, GHTN and hypothyroidism and wound infection.

Regarding type of anesthesia; spinal anesthesia was significantly more frequent and general anesthesia was less frequent in group 1, 189 vs. 177 and 1 vs. 13, p=0.001.

Regarding Southampton follow up scoring system (wound healing, bruising, erythema, hematoma formation and inflammation); there were no significant differences between both groups as regard 24 hours, 1 week and 30 days after surgery, p=0.968, 0.343 and 0.438 respectively. Also, there were no significant differences between both groups as regard wound infection 24 hours, 1 week and 30 days after surgery, p=0.707, 0.093 and 0.492 respectively.

La Rosa and his colleagues **[11]** performed a retrospective cohort study of 343 women who underwent a CS. Two preoperative antibiotic regimens were compared: Low dose versus high dose. There were no differences between study groups regarding age and gravidity which was similar to our findings. Current study agreed with La Rosa and his colleagues **[11]** who stated that higher doses of antibiotic prophylaxis did not decrease the rates of SSI after cesarean delivery. The rate of SSI did not differ between the low-dose and high-dose groups [14/367 (4%) vs. 19/365 (5%), p=0.38]. However, in contrast to our results, La Rosa et al. **[11]** found a significant difference between both groups as regards BMI and they reported that women who had the high-dose regimen had a lower BMI (35.6±0.40 vs. 33.1±0.42; p<0.0001).

Hussain et al. **[23]** stated a strong relationship between obesity and post-cesarean wound infection. They reported that there were approximately two-fold increases in SSI prevalence in obese compared to non-obese patients and in those who weighed, ≥120kg compared to those who weighed <120 kg. Similarly, we found that patients with higher BMI are liable to SSI than patients with lower BMI.

However, our results do not support previous studies among obese women undergoing cesarean delivery. Stitely et al. **[24]** randomized women with

BMIs higher than 35 to 2g or 4g cefazolin before cesarean delivery and found comparable adequate tissue concentrations in both groups and comparable SSI rates. Similarly, Maggio et al. [25] randomized women with BMIs higher than 30 to 2g or 3g cefazolin before cesarean delivery, and they did not find a difference in tissue concentrations.

There are conflicting results regarding the relationship between age and increased risk for SSI [12]. In a study conducted by Kaye et al. [26], age was identified as a strong predictor for SSI. A significant correlation was reported between the increased age and increased risk for SSI. In the current study, younger patients (median 30 years) had a reduced chance for SSI development compared to older patients (median 34 years) (p <0.001 *).

Regarding the duration of CS, it was found that in one of previous studies majority of women their operation was ended within (31-60) minutes [27]. Another study showed that the majority of women (62%) had their operation finished in a timeless than 90 minutes [28]. In our study, the median duration of CS was 60 minutes and the minimum is 25 minutes and the maximum is 90 minutes in both groups which are near to the previous studies.

Also, we found longer duration of surgery was significantly associated with wound infection and surgery of less than 1h had a protective effect for SSI prevention. In accordance with our findings, previous studies demonstrated that the risk of postoperative wound infection was considerably reduced when the operation time was short. In the course of prolonged operation, there was significant tissue destruction resulting from tissue handling and reduced tissue perfusion [29,30].

Data from the present study were in accord with a study conducted by Killian et al. [31] in which duration of operation >1h posed increased the risk for SSI development after C-Section and that prolonged surgery time is an independent risk factor for the development of SSI. Other studies reported similar results revealing a significant correlation between the duration of the surgical procedure and wound infection [12]. Furthermore, prolonged surgery, lasting more than 3h, was associated with a 4 fold increased risk for SSI occurrence [32].

In the present study, there were no significant differences between groups as regards previous medical history, including bronchial asthma, chronic hypertension, gestational hypertension, and hypothyroidism. Also, no significant relation was noted between the patient's medical diseases and wound infection.

This was in agreement with La Rosa and his colleagues [11] who stated that there were no differences between study groups regarding preexisting diabetes, chronic HTN, and preeclampsia.

In contrast, a number of studies previously reported that there is an increased risk for SSI in the presence of other comorbidities [33] explicitly: Anemias, obesity [34] hypertension, diabetes mellitus as well as other associated morbidities in the patient [35].

In the current study, the use of spinal anesthesia was significantly more frequent than general anesthesia in both groups (p=0.001) reflecting the high safety of spinal anesthesia that was stated in recent years. In the same line, in a prospective observational cohort study conducted by Zejnullahu et al. [12] to evaluate SSI after CS, 305 out of 325 patients (93.8%) underwent spinal anesthesia. Also, Mitwaly [30] reported that all cases in his study who were delivered by CS were done under spinal anesthesia.

Concerning Southampton follow-up scoring system grades in the present study (wound healing, bruising, erythema, hematoma formation, and inflammation); there were no significant differences between both groups as regard 24 hours, one week, and 30 days after surgery, p=0.968, 0.343 and 0.438 respectively. Also, there were no significant differences between both groups as regard wound infection 24 hours, 1 week, and 30 days after surgery, p=0.707, 0.093, and 0.492 respectively. These findings indicated that low-dose antibiotic is as efficacious as high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery.

The finding observed in this study mirror those of previous studies that have examined the impact of different antibiotic prophylaxis doses on surgical site infection rates. La Rosa and his colleagues [11] stated that higher doses of antibiotic prophylaxis did not decrease the rates of SSI after cesarean delivery. The rate of SSI did not differ between the low-dose and high-dose groups [14/367 (4%) vs. 19/365 (5%), p=0.38].

Also, our findings support the conclusion from a prior study by Ahmadzia et al. [36] on morbidly obese pregnant women undergoing cesarean delivery. They reported that a higher dose of cefazolin for preoperative surgical prophylaxis does not improve SSI rates despite its low cost and safety profile.

Mitwaly **[30]** in his study was inconsistent with our results. He concluded that the use of preoperative broad-spectrum antibiotics compared to a single dose of 2 grams of ceftriaxone is more effective in decreasing soft tissue infections in post elective Cesarean section.

Conclusion:

We concluded that low-dose antibiotic is as efficacious as high-dose antibiotic prophylaxis regimens on surgical site infection rates after cesarean delivery. Current ACOG guidelines should be followed until further level of clinical trial evidence is available.

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تأثير المضادات الحيوية منخفضة الجرعة مقابل جرعة عالية من المضادات الحيوية على معدلات الإصابة فى الموقع الجراحى بعد الولادة القيصرية

المقدمة : تعتبر العملية القيصرية من أكثر العمليات التى يتم إجراؤها فى قسم التوليد، ويتزايد استخدامها بسرعة. معدل ٥٢ فى المائة الذى تم تسجيله فى المسح الديموغرافى والصحى لمصر لعام ٢٠١٤ هو تقريباً ضعف ما تم الإبلاغ عنه فى وقت المسح الديموغرافى والصحى لمصر لعام ٢٠٠٨ (٢٨ فى المائة) و ٢.٥ ضعف المستوى الذى لوحظ فى وقت ٢٠٠٥ الديموغرافى والصحى لمصر. المسح الصحى (١٩.٩٪).

الهدف من الدراسة : هدفت الدراسة الحالية إلى تقييم تأثير الجرعات المنخفضة مقابل الجرعات العالية من العلاج الوقائى بالمضادات الحيوية على معدلات الإصابة بالموقع الجراحى بعد الولادة القيصرية.

المقدمة وطرق البحث : أجريت هذه التجربة العشوائية فى مستشفى المطرية التعليمى بين ديسمبر ٢٠٢١ وديسمبر ٢٠٢٢. تلقت المجموعة الأولى (مجموعة المراقبة) نظام جرعة منخفضة (١جم) من صوديوم سيفازولين وتلقت المجموعة ٢ (مجموعة الدراسة) نظام جرعة عالية (٢جم) قبل ٣٠ دقيقة من شق الجلد.

النتائج : كان معدل التهابات الموقع الجراحى فى دراستنا الحالية مرتفعاً بشكل ملحوظ (فى غضون ٣٠ يوماً، تراوحت بين ٢٠٪-٤٣.٧٪). فى الدراسة الحالية، لم تكن هناك فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بالعمر، والتكافؤ، ومؤشر كتلة الجسم. ومع ذلك، فقد أظهرنا أن ارتفاع التكافؤ، وكبر السن، والسمنة ارتبطت بشكل كبير بارتفاع معدل إصابة الجروح. فى دراستنا، كان متوسط مدة العملية القيصرية ٦٠ دقيقة والحد الأدنى ٢٥ دقيقة والحد الأقصى ٩٠ دقيقة فى كلا المجموعتين. وجدنا أن مدة الجراحة الأطول ترتبط بمعدل مرتفع من عدوى الجروح. فى هذه الدراسة، لم تكون هناك فروق ذات دلالة إحصائية بين المجموعات فيما يتعلق بالتاريخ الطبى السابق، بما فى ذلك الربو القصبى، وارتفاع ضغط الدم المزمن، وارتفاع ضغط الدم المصاحب للحمل، وقصور الغدة الدرقية. كما أنه لم يلاحظ وجود علاقة ذات دلالة إحصائية بين أمراض المريض الطبية و عدوى الجرح.

الاستنتاج : فيما يتعلق بدرجات نظام متابعة ساوثهامبتون فى الدراسة الحالية (التئام الجروح والكدمات والحمامى وتشكيل الورم الدموى والالتهاب)، لم تكن هناك فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بـ ٢٤ ساعة وأسبوع واحد و ٣٠ يوماً بعد الجراحة، p=0.968 و0.343 و 0.438 على التوالى. كما لا توجد فروق ذات دلالة إحصائية بين المجموعتين فيما يتعلق بعدوى الجرح ٢٤ ساعة، ١ أسبوع، و ٣٠ يوم بعد الجراحة، p=0.707 و0.093 و 0.492 على التوالى.