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Ayman Mohamed Abd-El Aziz

*Obstetrics and Gynecology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt,*  
Memotnt6@gmail.com

Ehab Hasanin Mohamad Hasanin

*Obstetrics and Gynecology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt*

Mostafa Rabia El-Sharkawy

*Obstetrics and Gynecology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt*

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# Subcutaneous Fusidic Acid Instillation for Prophylaxis against Surgical Site Infection in Cesarean Section

Ayman M. Abd-El Aziz \*, Ehab H. M. Hasanin, Mostafa R. El-Sharkawy

Department of Obstetrics and Gynecology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

## Abstract

**Background:** Cesarean section (CS) delivery is the most significant risk factor for postpartum maternal infection, with thirty percent incidence rates of surgical site infection (SSI) reported after CS. Wound healing failure caused by SSI results in increased treatment costs, prolonged hospital stays, and higher postoperative mortality rates.

**Aim and Objectives:** To investigate the role of subcutaneous Fusidic acid instillation for prophylaxis against SSI in cesarean section.

**Subjects and Methods:** This prospective randomized controlled clinical research was performed on 150 Pregnant women of reproductive age between 18–40 years with term pregnancy and normal weight for CS in Al-Azhar University Maternity Hospital from the period between 1st January 2022 to June 2022.

**Results:** There was a statistically significant difference in lower rate of infection, endometritis, and fever in a patient who received fusidic acid than those who did not receive fusidic acid.

**Conclusion:** Subcutaneous fusidic acid was applied prior to skin closure utilizing absorbable stitches, and the infection rate was nearly six times lower than in the control group. Subcutaneous instillation of fusidic acid is safe and effective in preventing SSI and can be suggested for use in the prevention of wound infections.

**Keywords:** Cesarean Section (CS), Surgical Site Infection (SSI), Subcutaneous fusidic Acid

## 1. Introduction

Cesarean section (CS) birth is the most significant risk factor for postpartum maternal infection, as well as rates of SSI following CS have been reported to approach 30%.<sup>1</sup> Because of the huge increase in the number of cesarean sections performed around the world, there are now worries that the surgery may be overused or applied for causes that are not suitable. There is a concerning high prevalence of CS in Egypt, which accounts for over fifty-two percent of all births.<sup>2</sup> With increasing demand for CS, SSI presents a potentially significant burden on the health care system.<sup>3</sup>

Wound healing failure due to SSI is associated with increased treatment expenses, an extended hospital stay, and increased postoperative mortality. Studies have shown that individuals with SSI require an additional seven to ten days of hospitalization. As a result, surgeons and numerous other healthcare professionals are concerned with SSI and its prevention due to the increased cases of

morbidity and the financial burden that accompanies it.<sup>4</sup>

In surgical practice, local or topical antimicrobial agents are frequently administered to the site of surgery in an effort to reduce postoperative surgical infections, particularly SSI. An examination by Lipsky and Hoey reveals that topical or local delivery of an antibiotic has several potential drawbacks in comparison to systemic antibiotic therapy.<sup>5</sup>

High and sustained concentrations at the site of infection, where local physiological changes may reduce the efficiency of systemic antibiotics, are two advantages of local administration.<sup>6</sup>

Additional advantages encompass the restricted likelihood of systemic absorption and toxicity, decreased antibiotic usage volumes, and potentially reduced potential for antibiotic resistance development (due to the diminished impact on the intestinal flora, for instance).<sup>7</sup>

Fusidic acid was isolated from a strain of *Fusidium coccineum*. It is a steroid-like antibiotic belonging to the class of fusions, chemically related to cephalosporin P and to phenolic acid.<sup>8</sup>

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\* Corresponding author at: Obstetrics and Gynecology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt.  
E-mail address: [Memotnt6@gmail.com](mailto:Memotnt6@gmail.com) (A. M. Abd-El Aziz).

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Fusidic acid binds to EF-G after translocation and GTP (guanosine-5'-triphosphate) hydrolysis. This interaction prevents the necessary conformational changes for EF-G release from the ribosome, effectively blocking the protein synthesis process. Fusidic acid can only bind to EF-G in the ribosome after GTP hydrolysis.<sup>9</sup>

The objective of this research was to assess the effectiveness of subcutaneous fusidic acid instillation for prophylaxis against SSI in CS.

## 2. Patients and methods

This prospective randomized controlled clinical research was carried out on 150 Pregnant women of reproductive age between 18-40 years with term pregnancy and normal weight for CS in Al-Azhar University Maternity Hospital from the period between 1st January 2022 to June 2022. The participants were separated into two groups. Group no 1: (study group) 75 women who received postoperative installed fusidic acid subcutaneously, then skin closure by subcuticular sutures followed by dressing. Group no 2: (control group) 75 women who did not receive postoperative installed fusidic acid subcutaneously. Just skin closure by subcuticular sutures followed by dressing.

2.1.Inclusion criteria: Women referred for cesarean section with a BMI that varied from 18.5 to 29.9 kg/m<sup>2</sup> and term pregnancies (early term: 37 weeks, 0 days to 38 weeks, six days) were consisted of. Among 39 weeks and 0 days as well as 40 weeks and six days is full gestation. The late-term refers to the period between 41 weeks and six days, excluding conditions such as diabetes mellitus, Cushing disease, thyroid disorders, as well as abdominal cancer.

2.2.Exclusion criteria: Abnormal placental invasion and placenta Previa, prolonged rupture of membranes for a duration exceeding twenty-four hours, a medical history of radiation therapy for cancer, a history of gynecological infections (PID), abdominal infections (e.g., peritonitis, wound infection, burst abdomen), evidence of substantial bleeding during a previous cesarean section, an allergy to fusidic acid, and pregnant women with severe anemia (defined as Hb <10 g/dl) are all contraindications.

2.3.Study procedures: Verbal and written consent was obtained before the history was taken. All women were subjected to history taking (personal, present, obstetric, menstrual, past, and family history).

2.4.Examinations: Full clinical examination included (temperature, pulse, and blood pressure); the general examination included (blood pressure, body temperature, bilateral lower limb examination, heart rate, head and neck examination, body mass index, chest, and heart),

local clinical examination: Obstetric abdomen examination for assessment of maternal health, fundal level, fetal presentation, estimation of fetal weight, scars from prior operations, uterine contractions, and auscultation of fetal heart rate (FHR), preoperative investigations: (Rh, Hb, HTC, CBC, fasting and postprandial, blood sugar Coagulation profile & complete urine analysis) and ultrasonography examination.

### 2.5.Intervention:

Operative technique: General, spinal, or epidural anesthesia was performed by the anesthesiologist according to his preference, and preoperative prophylactic antibiotics were given to the patients on induction of anesthesia. The American College of Obstetricians and Gynecologists (ACOG) recommends infusion of intravenous (1 g) cefazolin within 30-60 min before skin incision, insertion of urinary catheter under complete aseptic condition through peri urethral sterilization with 10% povidone-iodine, abdominal scrub with 10% povidone-iodine was done, skin incision by Pfannenstiel incision was done, opening of anterior abdominal wall in layers was done, c-shape Incision of the uterus was done, followed by delivery of the fetus and complete placenta, closure of the uterus in 2 layers with good homeostasis was done, closure of the anterior abdominal wall in layers with good homeostasis was done, topical fusidic acid installed subcutaneously before subcuticular suture then closure of the skin followed by dressing.

2.6.Postoperative follow-up: Patients received their postoperative antibiotics every 12 hours; patients were followed up during the first 24 hours postoperative for the presence of the triad of endometritis (fever 38°C and greater uterine tenderness and foul-smelling lochia); the wound was assessed, re-dressing was done and then discharged from the hospital, patients were followed up after one week to reassess the wound status. Also, cases that developed a fever over this week were recruited; patients who had fever had a full history of talking and physical examination to exclude other causes of fever; physical examination included vital signs and examination of the respiratory system (by auscultation by stethoscope), breast (to exclude breast engorgement), surgical site (to exclude SSI), perineum and lower limbs (to exclude deep venous thrombosis) to exclude other causes of fever, every the individual's dressing will be examined for signs of infection during the subsequent weeks following the operation, on the third and fifth post-operative days. In our investigation, we consist of any SSI that occurs within the five days after the procedure.

2.7.The study outcomes: Primary outcome: The efficacy of Subcutaneous fusidic acid installation for prophylaxis against SSI in cesarean section

(which is defined as erythema, tenderness, purulent drainage from the incision site, with or without fever, required antibiotic therapy) and secondary outcome: Post cesarean endometritis, post-cesarean fever, a side effect of the drug as allergy and irritation.

**2.8. Statistical Analysis:** The Pearson correlation coefficient, the chi-square test, and the Fischer exact test will be utilized for comparing variances among groups, and numerical and percentage statistics will be used to represent categorical data. The chi-squared test for pattern comparison will be applied to the ordinal data. To check if data are regularly distributed, a Kolmogorov-Smirnov test will be performed. The unpaired t-test will be utilized to contrast the means of the two groups, whereas continuous numerical variables will be provided as means and standard deviations. If the data are parametrically normally distributed, they will be displayed as mean and standard deviation; otherwise, they will be presented as median and range, and the Mann-Whitney U test will be utilized to contrast the two groups. If the P value is below 0.05, then the result is significant.

**3. Results**

*Table 1. Comparison of age and BMI of the examined population*

	FUSIDIC ACID		NO FUSIDIC ACID		TEST OF SIG.	
	N=75		N=75		t	P-value
	Mean	SD	Mean	SD		
AGE (YEARS)	26.53	4.02	26.80	4.06	-0.404	0.686
BMI	24.93	2.32	24.89	2.26	0.107	0.915

This table illustrated that there was no significant disparity among both groups concerning age & BMI.

*Table 2. Comparison of obstetric data of the examined population*

	FUSIDIC ACID		NO FUSIDIC ACID		TEST OF SIG.	
	N=75		N=75		X2	P-value
	N	%	N	%		
ABORTIO N	No	73 97.30%	67 89.30%	3.8	0.050	
	Yes	2 2.70%	8 10.70%	57		
PARITY	PG	7 9.30%	6 8.00%	0.7	0.862	
	P1	19 25.30%	23 30.70%	48		
	P2	32 42.70%	32 42.70%			
	P3	17 22.70%	14 18.70%			

This table revealed that there was no

*Table 6. Comparison of infection rate of the studied population*

	FUSIDIC ACID		NO FUSIDIC ACID		TEST OF SIG.	
	N=75		N=75		X2	P-value
	N	%	N	%		
INFECTION (PURULENT, ABSCESS) ENDOMETRITIS	No	70 93.30%	55 73.30%	10.800	0.001	
	Yes	5 6.70%	20 26.70%			
FEVER	No	73 97.30%	63 84.00%	7.878	0.005	
	Yes	2 2.70%	12 16.00%			
	No	72 96.00%	60 80.00%	9.091	0.003	
	Yes	3 4.00%	15 20.00%			

significant variation among both groups regarding abortion & parity

*Table 3. Comparison of vital data of the studied population*

	FUSIDIC ACID		NO FUSIDIC ACID		TEST OF SIG.	
	N=75		N=75		t	P-value
	Mean	SD	Mean	SD		
HR	78.08	5.64	78.92	5.75	-0.903	0.368
RR	17.44	0.96	17.27	0.78	1.214	0.227
TEMP	37.03	0.23	36.99	0.17	0.998	0.32
SBP	109.33	7.09	109.07	7.61	0.222	0.825
DBP	70.47	4.12	71.00	4.35	-0.771	0.442

This table demonstrated that there was no significant variation among both groups according to vital data.

*Table 4. Comparison of hematological data of the examined population*

	FUSIDIC ACID		NO FUSIDIC ACID		TEST OF SIG.	
	N=75		N=75		t	P-value
	Mean	SD	Mean	SD		
HB	10.31	0.93	10.15	1.14	0.939	0.349
HCT	33.60	3.41	32.90	2.77	1.381	0.169
WBCS	8.12	0.49	8.08	0.47	0.494	0.622
PLAT	296.32	32.23	294.53	28.88	0.358	0.721

This table showed that there was no significant variance among both groups concerning hematological data.

*Table 5. Comparison of biochemical data of the studied population*

	FUSIDIC ACID		NO FUSIDIC ACID		TEST OF SIG.	
	N=75		N=75		t	P-value
	Mean	SD	Mean	SD		
ALT	20.35	4.62	18.23	4.79	2.759	0.007
AST	27.16	4.85	25.71	5.55	1.707	0.09
UREA	25.24	3.12	24.79	3.23	0.878	0.381
CREAT	0.71	0.11	0.71	0.12	-0.354	0.724
F.RBG	96.33	17.20	95.49	16.65	0.304	0.762
P.RBG	141.47	14.59	142.56	13.07	-0.483	0.629

This table indicated that there was no significant variation among both groups concerning biochemical data.

This table demonstrated that there was significant variation lower rate of infection, endometritis and fever in cases who received fucidinic acid than those who did not receive fucidinic acid.

Table 7. Side effects of fucidinic acid instillation.

		N=75	
		N	%
SE (SKIN IRRITATION)	No	71	94.70%
	Yes	4	5.30%

This table showed that out of 75 patients who received postoperative installed fusidic acid 71 (94.70%) showed no side effects while 4(5.30%) showed side effects.

#### 4. Discussion

Contagion and delivery pose a risk of infection for pregnant women. As 38% of hospital-acquired infections, SSI is the most prevalent nosocomial infection among obstetrics surgical patients. Despite the sterilized environment in which C-sections are conducted, there is always the possibility of SSI. It has been demonstrated that prophylactic antibiotic use significantly reduces infectious morbidity following cesarean section. The most recent committee opinion from the ACOG suggests that antibiotics should be administered within sixty minutes of cesarean section or immediately if this is not feasible.<sup>10</sup>

Our results were supported by the study of Pradhan and Agrawal, who reported that The research aimed to compare the efficacy of topical fusidic acid with and without regard to the rate of wound infection subsequent to emergency cesarean section. The research was conducted between April 2006 and January 2008 at Himal Hospital. The study sample consisted of 70 pregnant women who required emergency cesarean sections. Subcuticular absorbable sutures were administered to every single patient. Thirty-five individuals out of seventy were administered topical fusidic acid immediately following subcuticular sutures, followed by a dry dressing. The remaining 35 patients were dressed with povidone-iodine dressings. A wound infection at the surgical site was observed in six individuals (17.1%) who received dressings containing povidone-iodine. In contrast, only one patient (2.8%) among the 35 patients who received fusidic acid developed a wound infection. Six times as many infections were prevented through the use of fusidic acid. Statistically speaking, fusidic acid had a significant correlation with wound infections ( $p = 0.0460$ ).<sup>11</sup>

In the study of Gupta et al., A 7.9 percent incidence of infection was observed following sterile abdominal procedures. The group treated with Savlon and spirit exhibited the highest infection rate (14.28%), whereas the group

exposed to fusidic acid spray had the lowest infection rate (5.68%). The incidence of sepsis in clean, contaminated abdominal wounds was 16.52 percent overall. The concentration was greatest in the Savlon & spirit group (23.07%), lowest in the P-I & metronidazole group (13.04%), and fusidic acid spray group (16.28%). Local reactions such as irritation, sneezing, and coughing were observed in 3.33% of the cases in this study when fusidic acid spray was applied. However, one patient in the group treated with PI and metronidazole developed moderate erythema. Every individual did not experience any systemic adverse effects.<sup>12</sup>

The risk of infection is eight times higher following a C-section contrasted with a natural birth. Recent studies put the SSI rate at around 5%, whereas previous ones put it as high as 25%. Different reporting methods, postnatal follow-up times, and diagnostic criteria could account for this discrepancy. Approximately 5% of hospitalized patients have an HCAI, with SSIs accounting for 1 in 7 of these infections, as well as nearly five percent of those who had undergone a surgical procedure were found to have developed an SSI in a recent survey of HCAs in four countries, including the Republic of Ireland carried out in 2006.<sup>13</sup>

Post-CS SSI has been linked to a variety of causes. Age and body mass index (BMI) are examples of host-related or intrinsic characteristics. Limited antenatal visits, smoking during pregnancy, type 1 and type 2 diabetes mellitus, hypertensive problems, and numerous pregnancies are all associated with the antenatal period. Emergency CS, protracted labor, longer time between membrane rupture and surgery, number of vaginal examinations, duration of operation, chorioamnionitis, and operation by teaching service or non-consultant hospital doctor in training are all identified risk factors for complications during labor and delivery. Subcutaneous drainage, anemia, and postoperative hematoma have all been cited as surgical risk factors for SSI.<sup>14</sup>

Staphylococcus aureus, beta-hemolytic streptococci, the majority of coagulase-positive staphylococci, Corynebacterium species, and the majority of clostridium species are all susceptible to fusidic acid's in vitro activity. Enterococci and the majority of Gram-negative bacteria are not eradicated by sulfuric acid, with the exception of Neisseria, Moraxella, Legionella pneumophila, and Bacteroides fragilis. Mycobacterium leprae is killed in vitro and clinically by fusidic acid, but its effect on M. tuberculosis. Fusidic acid is one of the most effective antibiotics against staphylococcus aureus, one of the most frequent skin pathogens. Fusidic acid treats mild to moderate skin and soft tissue infections.<sup>15</sup>



Fusidic acid is effective against methicillin-resistant *Staphylococcus aureus* (MRSA), making it a potentially useful clinical tool. Because the genetic barrier to drug resistance is so low (a single point mutation is all that is required), fusidic acid should not be utilized alone to treat serious MRSA infections. Instead, it should be combined with another antimicrobial, such as rifampicin, in accordance with the oral or topical dosing regimens approved in Europe, Canada, and elsewhere. Fusidic acid is still effective against many strains of MRSA. On the other hand, when organisms are tested with substantial drug exposure, resistance selection could be more effective. In the United States, researchers are working on a high-loading dose monotherapy that may be taken orally.<sup>16</sup>

#### 4. Conclusion

In contrast to the condition in which no fusidic acid was applied before skin closure utilizing absorbable sutures, the application of subcutaneous fusidic acid prior to skin closure reduced the infection rate by nearly six times, in accordance with our research. As a result, subcutaneous fusidic acid instillation may be recommended without risk for the prevention of surgical site infection (wound infection).

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The authors have no financial interest to declare in relation to the content of this article.

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All authors have a substantial contribution to the article

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