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A comparison of the efficacy of single-dose cefazolin versus single-dose cefazolin plus 7-day mupirocin ointment wound application in preventing surgical site infection among patients undergoing major obstetric and gynecologic procedures at a tertiary university hospital: A single-blinded, randomized controlled trial

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Abstract:

BACKGROUND: Surgical site infection (SSI) is a common complication among all surgical cases. It is the most common nosocomial infection identified in the developing world with pooled incidence of 11.8 per 100 surgical procedures. In our institution, the SSI rate in major obstetric and gynecologic cases in years 2000–2013 is 12.68%.

OBJECTIVE: To compare the efficacy of a single-dose cefazolin versus a single dose cefazolin plus 7-day mupirocin ointment wound application in preventing SSI among women undergoing major obstetric and gynecologic abdominal surgical procedures.

MATERIALS AND METHODS: The study included are 164 female participants, aged 18–65 years old who underwent major obstetric and gynecologic surgical procedures. Participants were randomly assigned to Groups A and B, wherein all participants were given single dose of 2 g cefazolin, intravenous, 30 min before skin incision. For the participants in Group B, an additional 7-day application of mupirocin ointment on incisional wound during the postoperative period was given. Assessment for occurrence of SSI and healing time using a standardized collection tool and Southampton wound scoring system, respectively, was done on the 8th, 15th, and 30th postoperative days.

RESULTS: The incidence of SSI is 2.45% (4 out of 164 participants). It was slightly higher in the Cefazolin only arm having three cases, while only one case in the Cefazolin plus mupirocin group. However, the difference of SSI occurrence between the two groups is not statistically significant. Wound healing time was also evaluated which was comparable between treatment groups.

CONCLUSION: Single dose Cefazolin plus 7-day once daily Mupirocin ointment application is

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comparable to single dose of cefazolin in preventing SSI in patients undergoing major low-risk obstetric and gynecologic surgeries. Therefore, the addition of mupirocin in uncomplicated major obstetric and gynecologic surgical cases is not cost-beneficial.

Keywords:

Cefazolin, gynecologic surgery, mupirocin, obstetric surgery, surgical site infection

Introduction

Surgical site infection (SSI) is defined as an infection occurring within 30 days after procedure.^[1] It is the most common nosocomial infection identified in the developing world with pooled incidence of 11.8 per 100 surgical procedures and remains the second most common in high-income countries such as America and Europe.^[2]

SSI is preventable, yet it remains to be one of the most common and costly cause of health care-associated infection leading to substantial morbidity and mortality.

In general, there is a perception that presence of SSI reflects poor quality of care. For these reason, various infection control protocols were developed and are being constantly updated to lower its incidence. Most institutions comply to the advancements in operating room practices yet, SSI remains to be the most common nosocomial infection in surgical obstetric patients.^[3-5]

One of the major variables in the prevention of SSI is the administration of surgical antibiotic prophylaxis. The antibiotic recommended to prevent SSIs is a single-dose first-generation cephalosporin.^[6]

Additional treatment modality on top of the standard surgical practice may be of benefit in further reduction of SSI. One which showed potential is the use of Mupirocin as an adjunct to the basic surgical recommendations.^[7] Topical mupirocin possess properties that is most ideal for it has excellent coverage on major skin pathogens, it increases patients compliance and has a safe profile.^[8] In this regard, aside from a single dose of antibiotic, about 10% of obstetrician and gynecologist prescribe the application of mupirocin during each dressing.^[9,10] Hence, this study would like to address this query: Is the combination of single dose cefazolin with mupirocin be better than single dose Cefazolin alone in reducing the incidence of SSI among women undergoing obstetric and gynecologic procedures?

Objectives

General objective

To compare the efficacy of a single dose cefazolin versus a single dose cefazolin plus 7-day Mupirocin ointment wound application in preventing SSI among women undergoing major obstetric and gynecologic abdominal surgical procedures.

Specific objectives

Compare the following:

Primary outcome

A. Incidence of SSI.

Secondary outcome

- B. Occurrence of adverse effects
- C. Healing time of wound.

Materials and Methods

Study design

This is a single-blinded, randomized controlled trial.

Setting and population

This study was conducted among private and service patients of a tertiary hospital.

Inclusion criteria

This study included women with the following:

1. Ages between 18 and 65 years old
2. Uncomplicated cesarean section for term pregnancy
3. Cesarean section with internal examination of ≤ 6 cm, intact bag of waters, and Exploratory laparotomy: Salpingectomy, salpingostomy, oophorectomy, salpingoophorectomy and myomectomy, and total abdominal hysterectomy with bilateral salpingoophorectomy, as well as hysterectomy.

Exclusion criteria

Those participants with following profile were excluded.

1. Antibiotic use in the past 2 weeks
2. Known medical comorbidities such as obesity, malignancy, diabetes mellitus, and hypertension. Connective tissues and immunosuppressive disease
3. For pregnant women, ruptured bag of waters for more than or equal to 6 h, thickly meconium stained amniotic fluid and multifetal pregnancy
4. History of substance abuse with tobacco, alcohol, or illicit drug use
5. Has known allergy to any the study drug.

Withdrawal criteria

Those participants who after recruitment developed the following were withdrawn.

1. Procedure duration extended to more than 3 h
2. Intraoperative blood loss reached more than 1.5 L for hysterectomy and >1 L for cesarean section
3. Intraoperative bowel perforation

4. Allergic reaction to any of the study drug
5. Expressed desire to and or voluntarily withdraws at any time during the study.

Methodology proper

Patients who underwent major Obstetrical and Gynecologic procedure and eligible to participate were recruited for the study. Recruitment for this study began on October 2019 and ended on July 2020. Prior to inclusion, the purpose and procedure of the study were discussed with the participant who was later asked to sign an informed consent. The participants were then randomized to their respective treatment group using the computer-generated random numbers. Those who were assigned to Group A was given single dose intravenous Cefazolin. For those in Group B aside from Cefazolin, Mupirocin ointment was generously applied on their incision wound postoperation. All the participants were given single dose of 2 g cefazolin administered intravenously 30 min before surgery.

Aside from private patients, those who were admitted at the service ward were included. For the participants admitted in the service ward, the primary surgeon of the operation for major gynecologic procedures was a 4th year resident. For obstetric procedures, the primary surgeon was a 3rd year or 2nd year resident. Closing of the subcutaneous tissue up to the skin was done by a 2nd year resident for both gynecologic and obstetric procedures. The repair was done in a standardized fashion. The peritoneum was closed using Chromic 2-0 sutures with the simple continuous suturing technique. The fascia was closed using Vicryl 0 suture with simple interlocking suturing technique. The subcutaneous layer was closed using Vicryl 2-0 suture using simple continuous suturing technique, and the skin was closed using Vicryl 4-0 suture with subcuticular suturing technique.

All the participants were instructed on proper wound care. The wound was cleaned and dressed once a day by the application of povidone iodine using cotton balls in one swipe repeated three times and was dressed. Wound cleaning was started on the 3rd day postoperation, and every day until, the wound has healed. To assess for wound healing, the Southampton wound scoring system was used. The end point for wound healing was achieved once a score of 1 was obtained. The wound healing was recorded on the postoperative day follow-up with which a score of 1 was obtained. For all participants, sterile gauze was applied after wound cleaning.

The wound of all participants was inspected and evaluated for the signs of infection from the 3rd day postoperation,

and on the 8th, 15th, and 30th postoperative days. The evaluation included inspection for occurrence of SSI and healing. Inquiry regarding adverse effects of mupirocin was made on the 3rd and 8th postoperation days. Those admitted in the charity ward were instructed to follow-up at the outpatient department and private patients had their follow-up with their attending physician's clinic. The residents who evaluated the wound on the follow-up days were from the 2nd year level. Thus ensured that the resident who assessed the wound was blinded to treatment received by the participants.

The primary endpoint of this study is gross disruption or purulent discharge at site of incision. Once diagnosed with SSI, specimen from the wound discharge was sent for gram stain and culture and sensitivity and was managed with the administration of the appropriate antibiotic.

A standardized data collection tool was used to gather the data which included the participants' age, body mass index, type of surgical procedure, designation of the surgeon, duration of the surgery, estimated blood loss, adverse effects, and time of healing.

Sample size calculation

The basis for the sample size computation is the formula on proportion comparing independent samples. Computation was based on the proportion 1 (P1) which is 63%, the incidence of SSI among patients given single dose Cefazolin alone as reported from the study of Reyes.^[10] While proportion 2 (P2) is based on the possible absolute reduction in SSI incidence of 20%. With an alpha error 5%, power of 80%, and a one-tailed alternative hypothesis, the sample size required for this study is 76 per group or a total of 152 for the two groups. However, to account for possible 20% dropout during the study, the sample size was increased to 92 per group or a total of 184 for the two groups.

Data analysis

The results were entered and encoded using Microsoft. Data analysis was done using Strata 9.0.

Univariate analysis such as mean and range was used to describe age, duration of the surgery, blood loss, and time of healing.

Frequency distribution was used to describe the proportion of participants having the type of procedure, subjects with and without SSI and proportion of subjects with adverse effects.

For the comparison of the proportion of participants with SSI and occurrence of adverse effects between the two treatment arms, Chi-square or Fischer exact test were used. For the comparison of the mean healing

time between the two treatment arms, *t*-test was used. The analysis was separately conducted for obstetric and gynecologic procedures.

Results

In this study, a total 164 participants were recruited. There were 82 participants who were randomized to Cefazolin with Mupirocin group and 82 participants were assigned to the Cefazolin treatment arm. The overall age range of the participants is 19–68 years old, with mean age of 31.53 years. The gravidity of the participants ranged from 0 to 6 with a mean of 1.90, while parity ranged from 0 to 6 and a mean of 1.71. The age of gestation has a mean of 27.81 weeks, which ranged from 0 to 41 weeks. The mean length of surgery time is 117.05 min, ranging from 45 to 210 min. The mean estimated blood loss is 501.22 ml which ranged from 200 to 1500 ml. Healing time of abdominal incision site ranged from 8 to 30 days, with a mean of 13.59 days. With regards to the type of surgery there were 119 (72.56%) participants who underwent obstetric surgery while 45 (27.44%) had gynecologic surgery [Table 1].

Stratified sampling was done wherein the stratification variable is the type of surgery which are obstetric and gynecologic. Among the obstetric cases, there were 69 (57.98%) who underwent primary Cesarean Section, about 44 (36.97%) underwent repeat CS and 6 (5.04%) had CS with bilateral tubal ligation. There was no significant difference in terms of the type of obstetrical procedures that the participants had between the two treatment arms [Table 2].

The participants' who underwent obstetrical surgical procedures were aged 19–40 years old, with mean age of 29 years. Their gravidity ranged from 1 to 5, with mean of 1.8. While the parity ranged from 1 to 4, with mean of 1.7. The age of gestation ranged from 34 to 41 weeks with the mean of 38.32 weeks. The mean length of surgery time is 119 min with range of 45–175 min. For the estimated blood loss, it ranged from 300 to 900 ml with a mean of 473.53 ml. There was no significant difference in the baseline characteristics of the participants who underwent obstetrical cases between the two arms [Table 3].

Healing time of abdominal incision site ranged from 8 to 30 days with a mean of 12.87 days. Out of all obstetrics cases, only two developed SSI. While none had side effects. With regard to the comparison of outcome between the two treatment arms among patients who underwent cesarean section, there was no statistically significant difference in the mean healing time and proportion of the SSI [Table 4]. There was no adverse effect noted among all obstetric participants.

For the gynecologic cases, there were 16 (35.56%) who underwent hysterectomy and 29 (64.44%) underwent adnexal surgery [Table 5].

The age of the participants who underwent gynecologic surgery ranged from 19 to 68 years old, with a mean age of 37 years. The gravidity ranged from 0 to 6, with a mean of 2.13. The parity ranged from 0 to 6 with mean 1.75. The mean length of surgery time is 139.11 min with range of

Table 1: Comparison of the means of the baseline characteristics between Cefazolin with Mupirocin and Cefazolin among obstetric and gynecologic cases

Baseline characteristics	Mean (±SD)		P
	Cefazolin with Mupirocin	Cefazolin	
Age (years)	32.46 (±9.68)	30.60 (±8.17)	0.18
Gravidity	2.01 (±1.33)	1.79 (±1.09)	0.25
Parity	1.82 (±1.24)	1.61 (±1.03)	0.25
Age of gestation (weeks)	28.89 (±16.53)	26.73 (±17.18)	0.42
Surgery time (min)	118.99 (±36.20)	115.12 (±31.98)	0.47
EBL (ml)	496.95 (±210.28)	505.49 (±266.09)	0.82

Statistical test done: *t*-test statistically significant *P*<0.0. SD: Standard deviation, EBL: Estimated blood loss

Table 2: Comparison of the proportion of participants according to type of cesarean section between Cefazolin with Mupirocin and Cefazolin among obstetric cases

Type of CS	Cefazolin with Mupirocin, n (%)	Cefazolin, n (%)	P
Primary CS	35 (56.45)	34 (59.65)	0.29
Repeat CS	22 (35.48)	22 (38.60)	
CS with BTL	5 (8.06)	1 (1.75)	

Statistical test done: *t*-test statistically significant *P*<0.05. CS: Cesarean section, BTL: Bilateral tubal ligation

Table 3: Comparison of the means of the baseline characteristics between Cefazolin with Mupirocin and Cefazolin among obstetric cases

Baseline characteristics	Mean (±SD)		P
	Cefazolin with Mupirocin	Cefazolin	
Age (years)	29.89 (±4.96)	28.54 (±3.70)	0.10
Gravidity	1.97 (±1.12)	1.65 (±0.80)	0.08
Parity	1.79 (±0.96)	1.61 (±0.77)	0.28
Age of gestation (weeks)	38.2 (±1.04)	38.4 (±1.18)	0.23
Surgery time (min)	110.65 (±35.05)	106.61 (±29.12)	0.50
EBL (ml)	478.23 (±175.70)	468.42 (±185.08)	0.77

Statistical test done: *t*-test statistically significant *P*<0.05. SD: Standard deviation, EBL: Estimated blood loss

Table 4: Comparison of outcomes between Cefazolin with Mupirocin and Cefazolin among obstetric cases

Outcome	Cefazolin with Mupirocin (n=62)	Cefazolin (n=57)	P
SSI, n (%)	0	2 (3.51)	0.14
Healing time, \bar{x} in days (±SD)	13.03 (±5.6)	12.70 (±4.8)	0.36

SSI: Surgical site infection, SD: Standard deviation

60–210 min. For the estimated blood loss, it ranged from 200 to 1,500 ml with a mean of 574.44 ml. There was no significant difference between the baseline characteristics of the participants in the two treatment arms [Table 6].

The healing time of the abdominal incision site for those who had gynecologic surgery ranged from 8 to 30 days with a mean of 15.48 days. Two developed SSI. There was no significant difference in the mean healing time and proportion of SSI between the two treatment groups [Table 7]. Among all the gynecologic cases, there were also no side effects noted to occur in both treatment arms.

The overall rate of SSI in this study is 2.45%. The SSI rate was noted to be eight times higher in gynecologic procedures with 2 (4.44%) cases compared to obstetrical procedures having only 2 (1.7%). There were 3 out of 82 (3.66%) cases in the cefazolin only group as compared to only 1 out of 82 (1.22%) in the cefazolin plus mupirocin

arm. However, the difference in SSI rate between the two arms is not statistically significant. The difference in healing time between the two treatment groups was also found to be not statistically significant [Table 8].

The original sample size of 76 per arm was achieved in this study since we had 82 participants per treatment group. The computed 92 participants per treatment arm were made to adjust for possible dropouts. Since we do not have dropouts, the 82 participants included per treatment group sufficed.

Discussion

SSI in cesarean section procedures, the incidence of SSI is 11.7% in low- to middle-income countries while a much lower rate was observed in Europe at 2.9%.^[1] With regard to the incidence of SSI in the United States, it was reported to occur in 1.70% of hysterectomy surgeries.^[11]

In this study, the SSI rate for cefazolin only group is 3.66% and 1.22% in the cefazolin plus mupirocin group. As per procedure, the SSI rate for obstetric group is 1.7%, whereas rate in gynecologic surgeries is significantly higher at 4.44%. Further analysis on the SSI occurrence in this study showed: (1) 3.5% (2/57) obstetric case in cefazolin only group developed SSI (2), about 4.2% (1/25) gynecologic cases in cefazolin only group had SSI occurrence, and (3) 5.0% (1/20) gynecologic case in cefazolin plus mupirocin group had SSI. These 4 cases had similar profile in terms of surgical time ranging 110–180 min and estimated blood loss ranging from 500 to 1000 ml. Adequate preparation of the procedure is also taken into consideration in the development of SSI as 2 of the cases above were emergency procedures.

Higher incidence of SSI in emergency cases was noted in a study by Pabitha Devi and Saravanakumar, with the possible explanation why the risk of developing SSI is higher among surgery cases wherein the overall SSI rate in elective clean and clean-contaminated cases was 4.34%, whereas emergency cases had 12.41%. Furthermore, the most common isolated microorganism from elective surgeries was *Escherichia coli*, and *Proteus mirabilis* was the common isolate for those who underwent emergency cases. Therefore, first- or second-generation cephalosporins as surgical antimicrobial prophylaxis may not be the optimal choice of drug in emergency cases.^[12]

In the study of Promentilla *et al.*, the prevalence of SSI was two times higher in the emergency surgeries as compared to the elective. The reason for this is because the standard preoperative preparation normally done within the facility is inadequately met. Preoperative preparations such as timed antibiotic prophylaxis,

Table 5: Comparison of the proportion of participants according to type of gynecologic procedure between Cefazolin with Mupirocin and Cefazolin

Type of gynecologic surgery	Cefazolin with Mupirocin, n (%)	Cefazolin, n (%)	P
TAHBSO	9 (47.37)	10 (52.63)	0.74
Adnexal surgery	11 (42.31)	15 (57.69)	

Statistical test done: t-test statistically significant $P < 0.05$. TAHBSO: Total Abdominal Hysterectomy Bilateral Salpingo-oophorectomy

Table 6: Comparison of the means of the baseline characteristics between Cefazolin with Mupirocin and Cefazolin among gynecologic cases

Baseline characteristics	Mean (\pm SD)		P
	Cefazolin with Mupirocin	Cefazolin	
Age (years)	40.45 (\pm 15.21)	35.28 (\pm 12.66)	0.22
Gravidity	2.15 (\pm 1.87)	2.12 (\pm 1.53)	0.95
Parity	1.95 (\pm 1.90)	1.6 (\pm 1.47)	0.49
Surgery time (min)	144.85 (\pm 26.84)	134.52 (\pm 30.15)	0.24
EBL (ml)	555 (\pm 291.05)	590 (\pm 385.14)	0.74

Statistical test done: t-test statistically significant $P < 0.05$. EBL: Estimated blood loss, SD: Standard deviation

Table 7: Comparison of outcomes between cefazolin with mupirocin and cefazolin among gynecologic cases

Outcome	Cefazolin with Mupirocin (n=20)	Cefazolin (n=25)	P
SSI, n (%)	1 (5)	1 (4)	0.87
Healing time, \bar{x} in days (\pm SD)	16.25 (\pm 7.66)	14.88 (\pm 7.47)	0.27

SSI: Surgical site infection, SD: Standard deviation

Table 8: Comparison of outcomes between cefazolin with mupirocin and cefazolin among overall obstetric and gynecologic surgical cases

Outcome	Cefazolin with Mupirocin (n=82)	Cefazolin (n=82)	P
SSI, n (%)	1 (1.21)	3 (3.66)	0.32
Healing time, \bar{x} in days (\pm SD)	13.45 (\pm 5.74)	13.80 (\pm 6.33)	0.64

SSI: Surgical site infection, SD: Standard deviation

adequate antiseptic skin preparation, bowel preparation, correction of anemia, or other medical problem are among the recommended practices that are usually not met in an emergency case. Hence, predisposition for SSI development is expected.^[9]

In our study, the incidence of SSI is 2.45% which is lower than the pooled global rate. Likewise, it is lower compared to the prevalence of SSI in our institution from 2009 to 2013 which was 12.68%.^[9] The possible reason why the SSI rate in this study is lower is that we only included uncomplicated and low-risk cases with surgical time of <3 h and estimated blood loss of <1000 ml for obstetric and 1500 ml for gynecologic surgical cases.

In terms of SSI occurrence, there is a tendency to have lesser SSI when mupirocin was added, although the difference is not statistically significant. This means that adding mupirocin in the wound care of the participants did not produce significant benefit in reducing SSI rate in low-risk cases. Similar observation was noted in a study which evaluated the effect of the application of ointment including mupirocin to clean surgical wounds.^[7]

The tendency to lower SSI rate with the addition of mupirocin could be due to the occlusive nature of the ointment that drives the active ingredient into the skin rapidly and it's the bactericidal properties. It has high level of activity against Gram-positive cocci which are the most common pathogens isolated in SSI.^[8,13] However in the study of Heal *et al.*, they concluded that use of a topical antibiotic such as mupirocin decreased the rate of SSI.^[14]

Mupirocin used in our study is formulated as 2% mupirocin ointment in a polyethylene glycol vehicle. These components contribute to the occlusive nature of mupirocin. Occlusive dressing increases reepithelization by 30%–50% and increase in collagen synthesis by 20%–60%. Occlusive dressings increase wound healing through promotion of epithelial cell migration. Presence of a moist wound environment prevents air exposure that causes tissue desiccation leading to enhanced wound healing.^[15] A Cochrane systematic review concluded that the use of antibiotic ointment such as mupirocin may have a role in accelerating wound healing.^[8,14]

In our study, wound healing is a little faster in the cefazolin only arm compared with the cefazolin plus mupirocin group. Although the difference is not statistically significant, this was similar to the study conducted by Dixon *et al.* wherein the addition of mupirocin ointment has no beneficial effect in terms of wound healing as they noted higher occurrence of scar formation. This was attributed to the increased risk of skin necrosis, which is hypothesized to impede skin

perfusion.^[7] With decreased blood flow to area of the wound, healing is not expected to hasten. Although based on available literatures, there are still limited studies regarding the occurrence or nonoccurrence of tissue necrosis with mupirocin use.

Documented adverse effects include allergic contact dermatitis, pruritus, burning pain, dry skin, and adverse scar outcomes.^[7] These were not observed in our study. Another factor that raises concern are the reports of increasing incidence of mupirocin resistant *Staphylococcus aureus* isolates.^[16,17] In our study, wound culture was not done.

The cost of 2 g cefazolin ranges from PHP 904 to 1262.00. While a 15 g tube of mupirocin costs PHP 198–840. Based on our participants' usage, a 15 g tube is enough to be generously applied on the incision site once a day for 7 days with an incision length of 10 cm or lesser, while additional tube was added to those having an incision of 11 cm to 18 cm. The difference in price range of the products depended on the brand used. Therefore, adding mupirocin to patients with 10 cm or lesser skin incision will have to shoulder an additional PHP 840.00. While for those with skin incision of 11–18 cm, an additional expense of PHP 1,680.00 may be incurred. Hence, for low-risk obstetric and gynecologic surgical cases, the addition of mupirocin is not cost beneficial.

Conclusion

Single-dose cefazolin plus application of mupirocin ointment is comparable to single dose of cefazolin in preventing SSI in patients undergoing major low-risk obstetric and gynecologic surgeries. The addition of mupirocin does not significantly lower the incidence of SSI nor improve wound healing. Hence, mupirocin as an adjunct to the Cefazolin may not be beneficial as it contributes to additional cost and increases risk of antibiotic resistance. Therefore, addition of mupirocin in clean, uncomplicated major obstetric, and gynecologic cases is not recommended.

Limitation

Our study included uncomplicated cases only. Thereby, the results of this study can only take into account the effect of Mupirocin as an additional modality on the incidence of SSI for low-risk cases only.

Recommendation

Mupirocin is not necessary part of post-operative wound care among low risk surgical cases. Hence, we would like to recommend that single dose of Cefazolin with

Mupirocin be investigated among patients undergoing major obstetric and gynecologic procedures at high risk for infection. To further investigate on the effects of mupirocin, we suggest inclusion of the following parameters: (1) pain on the incision site, (2) wound scar appearance, (3) ease of use, and (4) overall patient satisfaction.

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Conflicts of interest

There are no conflicts of interest.

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