Short versus Long-Term Antibiotic Prophylaxis in Cesarean Section: A Randomized Clinical Trial

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Abstract

Objective: The objective of the present study was to compare the efficacy of intravenous (IV) 48 h course of cefuroxime/metronidazole with long-term course using 48 h cefuroxime/metronidazole plus 5 days oral regimen of cefuroxime and metronidazole for the prevention of post cesarean section wound infection. **Methods:** Two hundred and forty-eight women were randomized into two equal groups. Women in each arm of the study received IV cefuroxime 750 mg twelve hourly and IV metronidazole 400 mg eight hourly for 48 h. Those in the long-term arm received additional tablets of cefuroxime 500 mg twelve hourly and Tabs 400 mg of metronidazole eight hourly for 5 days. After the surgery, surgical site infections were evaluated. Length of hospital stay and the cost of antibiotics were also assessed. **Results:** The wound infection rate was not statistically significantly different between the 2 groups (1.3% vs. 3.3%, $P = 0.136$). The incidence of endometritis was 2.1%, with no statistically significant difference seen between the two groups (0.4% vs. 1.6%, $P = 0.213$). Escherichia coli was the most common isolate seen in 36.4% of infected wounds. The short arm group stayed for significantly shorter days in the hospital (2.9 ± 1.0 vs. 3.8 ± 1.1 days, $P < 0.001$), and the cost of antibiotics was also significantly less in the short arm group ($P < 0.001$). Organisms associated with nosocomial infections were seen only in the long arm that stayed in the hospital for longer days. **Conclusions:** Short-term prophylactic antibiotics are as effective as long-term prophylaxis and have other benefits such as shorter duration of hospital stay, reduced cost of antibiotics, and reduction of nosocomial infections.

Keywords: Antibiotics, cesarean section, postoperative, prophylaxis, wound infection

Introduction

Cesareans delivery is the most common risk factor for postpartum maternal infections, which occurs at a rate of 18%–38%.[1] Factors that have been associated with an increased risk of infection among women who have a cesarean delivery include emergency cesarean section, labor and its duration, ruptured membranes and the duration of rupture, the use of prophylactic antibiotics or not, the socioeconomic status of the woman, number of prenatal visits, vaginal examinations during labor, anemia, blood loss, obesity, diabetes, general anesthesia, the skill of the operator and the operative technique.[2]

Antibiotic prophylaxis has been documented to reduce the incidence of endometritis after cesarean delivery by as much as 66%–75%.[1] Surgical site infections are also reduced by prophylactic antibiotics.[1,3]

Although prophylactic antibiotics during cesarean section have been extensively reviewed and generally found to be effective in preventing infection, surveys suggest the inconsistent and variable application of recommendations for its use.[4] The common practice in sub-Saharan Africa is a multiple-day regimen of antibiotics for infection prevention.[2,5] This is in contrast to many high-income countries where a single prophylactic dose of antibiotics is common practice.[2]

The benefits of shorter regimens have been found to be equally effective as long-term prophylactic regimens may include convenient dosing regimens, ensuring full compliance, and

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saving man-hours dedicated to the administration of antibiotics in a human resource-challenged environment.[6]

This study has the objective of determining if there is any significant difference between the incidence of postcesarean section wound infection with the use of a 48-h prophylactic antibiotics regimen (intravenous [IV] cefuroxime and metronidazole) compared to 48 h IV antibiotics followed by a 5-day course of oral antibiotics following cesarean section in a low-resource setting.

The study hypothesized that there was no difference in the efficacy of 48-h and 7-day cefuroxime and metronidazole regimens in preventing postcesarean section infectious morbidities**.**

The outcome of this study may facilitate a change or endorse the continuation of the current practice of extended prophylactic antibiotics uses for cesarean section in Nigeria. In addition, the outcome may also form the basis for studies on shorter regimens like the use of single-dose prophylactic antibiotics as obtainable in developed countries.

Materials and Methods

This was a randomized controlled trial conducted at the Department of Obstetrics and Gynaecology of University of Abuja Teaching Hospital, Abuja between March 2016 and August 2016, in which patients were equally allocated into two groups to compare the efficacy of 48 h versus 7 days cefuroxime/metronidazole regimen in preventing post cesarean section surgical wound infection and endometritis. The department has an average of 2500 deliveries per year and cesarean section rates of 25%.

Study population

The study population comprised women with an indication for cesarean section during the study period.

Inclusion criteria

All pregnant women with an indication for cesarean section during the study period without added risks for the infection that gave informed consent were included.

Exclusion criteria

Pregnant women with a fever >38°C or maternal sepsis, cephalosporin allergy, exposure to any antibiotic agent within 1 week before delivery and women who had prolonged rupture of membranes (≥24 h) and chorio-amnionitis. Other exclusion criteria were patients with chronic diseases (diabetes mellitus, renal disease, and cardiac disease), obesity (weight ≥90 kg), anemia (packed cell volume [PCV] <30%), and human immunodeficiency virus (HIV) positive women were excluded.

Interventions

Eligible pregnant women were randomized in blocks of 5 into two groups (Group A: short-term antibiotics use, and Group B: long-term antibiotics use). Patients in Group A received IV cefuroxime 750 mg (Zinacef injection, NAFDAC registration number A4-9605. Manufacturer-Afri Generics Limited) at the induction of anesthesia, 12 h later and continued 12 hourly for 48 h as well as IV metronidazole 500 mg at the induction of anesthesia then 8 hourly for 48 h. While patients in Group B received the above medication and additionally took oral cefuroxime 500 mg twelve hourly for another 5 days and 400 mg of oral metronidazole for 5 days. Women in the short arm of the study were given white and yellow tablets of Vitamin C as placebo for 5 days after their IV medications.

Only transverse suprapubic incisions with closures of the subcutaneous layer with either polyglactin were included in the trial. Skin closure was either with synthetic multi-filamentous materials such as polyglycolic acid (Dexon; Syneture) or polyglactin 910 (Vicryl; Ethicon).

In both groups, the urethral catheter was removed after 24 h. Wound care followed a standard scheme in both groups, and the occlusive dressing applied in the theater was removed after 48 h. Each patient was examined daily, and any postoperative infectious morbidity was noted from the day of the operation up to the day of the discharge from the hospital.

Wound infection was considered as partial or total dehiscence with the presence of purulent or serous wound discharge. Wound morbidity was managed by local wound toilet with Normal saline irrigation and EUSOL. Endometritis was defined as body temperature >38.5°C with concomitant uterine tenderness or foul-smelling lochia.

Postoperative febrile morbidity was defined as an axillary temperature of 38.0°C on two occasions at least 6 h apart, excluding the first 24 h. Once febrile morbidity was identified, participants were examined to localize the potential source of infection. Wound swab and abnormal lochia collections were sent for microscopy, culture, and sensitivity. All participants who developed postoperative infections were treated based on the antibiotic sensitivity pattern. Participants found to have malaria fever were treated for malaria with a suitable Artemisinin-based combination therapy. On discharge from the hospital, they were informed to report any fever, wound dehiscence, or foul-smelling lochia immediately. All participants were seen 2 weeks after discharge and at 6 weeks post-natal visit to ensure there was no infectious morbidity. Outlined laboratory investigations were conducted based on the symptoms and examination findings.

Outcomes

The pre-specified primary outcome was post cesarean section surgical site infection, while the pre-specified secondary outcomes were endometritis and duration of hospital stay.

Sample size determination

The sample size of 248 women for both arms of the study was calculated using the formula for calculation of sample size for randomized controlled trials[7] on the following assumptions:

- The proportion of participants in the control group (long-term prophylactic antibiotics) that are

expected to exhibit the primary outcome measure of interest (wound infection). based on the report of a previous study was 16.2%[8]
- The proportion of the participants in the short-term prophylactic antibiotics group that are expected to exhibit the primary outcome measure of interest. This was put at twice that of the control group at 32.4%
- Significance level of 5% for the hypothesis test and a power of 80% (or 0.8)
- Sample size adjustment for dropout of 10%.

Randomization

The computer was used to generate the random allocation sequence. Eligible women were randomly assigned into either of the groups in permuted block sizes of 5. Allocation concealment was achieved using sequentially numbered, opaque, sealed envelopes that contained the randomization code together with protocol forms for the respective groups and were opened after surgery, as the preoperative prophylaxis was the same for both groups. The drugs were administered by the anesthetists just before surgery and subsequent administrations were done by the nurses on duty who were all sensitized about the study.

Clinical procedures

At enrolment, information on demographics was obtained and assessed: age, parity, gestational age, weight, preoperative hemoglobin, HIV status, number of vaginal examinations, duration of ruptured membranes, indication for cesarean section, repeat cesarean section, cader of surgeon, and number of inpatient postoperative days and additional need for antibiotics. Standard precautions for infection prevention were observed for all the participants before, during, and after the cesarean sections.

Specimen collection/analysis

Sterile cotton-tipped swab with transport medium (Stuart Aime's), which served as preservatives and transport systems were used for wound swab and abnormal lochia sampling. The swab tip was rotated in a 1 cm^2 area of clean granulation tissue for 5 s, using enough pressure to release tissue exudates.

Swab was inoculated aseptically on sheep blood chocolate agar, sheep blood agar, and Mac-Conkey agar. All the agars were inoculated at 37^{O}C in a moist atmosphere with 5%–10% CO_2 for 18–24 h. The characteristics of the isolate were determined, and two or three identical colonies were emulsified in sterile saline for the determination of the antibiogram pattern, which was quality, controlled using Macfalance standards and CLSI control strain. The findings were read as sensitive (S) or resistant®.

Statistical analysis

The study outcomes were assessed by per-protocol analysis. Results for continuous variables were expressed as means with standard deviation or as median with interquartile range when not normally distributed, and for categorical variables as absolute numbers with the percentage in brackets. Summary data of continuous variables were calculated using a Student's *t*-test (normal distribution) or Mann–Whitney U-test (skewed distribution), while that of categorical variables was calculated using Chi-squared test. Differences in infection rate between groups were expressed as risk differences with 95% confidence interval. Associations between duration of ruptured membranes, duration of labor and the occurrence of maternal infection were evaluated using bivariate regression analysis. Data analysis was performed using the IBM SPSS Statistics for Windows, version 20 (IBM Corp., Armonk, N.Y., USA).

Ethical approval

The ethical approval for this study was obtained from the Research Ethics Committee of the University of Abuja Teaching Hospital. Written informed consent was obtained from all participants in accordance with the Helsinki Declarations.

Results

A total of 243 participants completed the study (Short arm: 122 vs. Long arm: 121) and were therefore used in the final analysis [Figure 1].

The overall mean age of randomized women was 31.03 ± 5.7 years. There was no statistically significant difference when the mean ages in the two groups were compared (31.1 ± 5.4 vs. 30.9 ± 5.9 years, P = 0.830). Most of the cesarean sections in the two groups were repeat cesarean sections (28.8% vs. 30.9%, P = 0.464) and majority of the surgeries in the two arms were emergency cesarean deliveries (30.9% vs. 32.9%, P = 0.452) [Table 1].

Most of the women in both study arms had not ruptured their membranes before the surgery (59.0% vs. 53.7%, P = 0.405) and the average duration of those that had ruptured membranes was comparable with an average of 6.0 ± 2.6 h in the study arm versus 6.6 ± 2.6 h in the control arm, P = 0.263. The number of vaginal examinations was statistically significantly higher

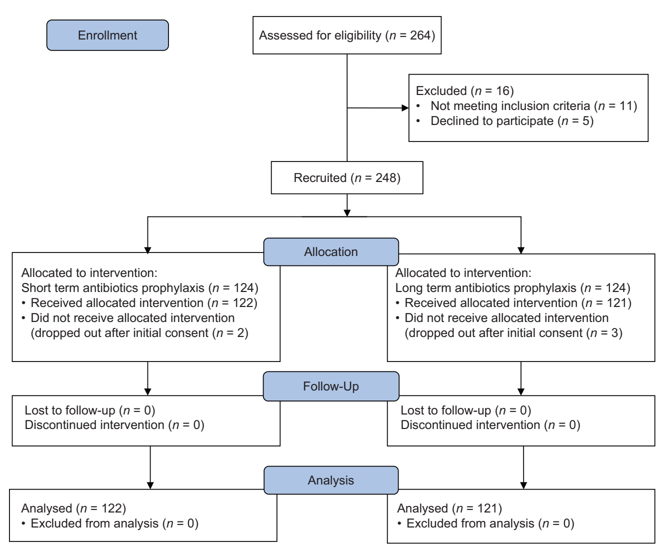

Figure 1: CONSORT flow diagram

in the long-term prophylaxis arm compared to the short-term arm (2.0 ± 1.0 vs. 2.5 ± 1.3, $P = 0.016$) [Table 2].

Overall, eleven women (4.5%) had a surgical site infection. There was no statistically significant difference in the prevalence of surgical site infection in the two groups (3 (1.3%) vs. 8 (3.3%), $P = 0.136$). Five women (2.1%) developed endometritis. The number of women that developed endometritis was also comparable in the two groups (1 (0.4%) versus 4 (1.6%), $P = 0.213$).

Bivariate regression analyses showed that the effect of dependent variables on the primary outcome (wound infection) in both groups were not statistically significant ($P = 0.533$ for nature of CS (primary or repeat), $P = 0.061$ for the type of CS (emergency or elective), $P = 0.218$ for the state of the membranes (intact or ruptured) and $P = 0.424$ for the number of vaginal examinations). Only one case of wound infection was recorded in women who had elective surgery. The other 10 cases were in women who had emergency cesarean delivery. This, however, was not statistically significant ($P = 0.061$).

Bivariate regression analyses showed that the effect of dependent variables on endometritis in both groups were not statistically significant ($P = 0.651$) for nature of CS (primary or repeat), $P = 0.656$ for type of CS (emergency or elective), $P = 0.650$ for state of the membranes (intact or ruptured) and $P = 0.424$ for number of vaginal examinations. None of the women that had multiple repeat vaginal examinations developed endometritis ($P = 0.620$).

The mean duration of days spent in the hospital was statistically significantly shorter in the short-term antibiotics' prophylaxis group (2.9 ± 1.0 vs. 3.8 ± 1.1 days, $P < 0.001$). The mean cost of antibiotics was, however, statistically significantly more in the long-term prophylaxis group (N2952.5 ± 268.2 vs. N 4063.6 ± 464.4, $P < 0.001$). Four women (1.6%) in the short-term arm required additional therapeutic antibiotics compared to 11 women (4.5%) in the control group, $P = 0.067$ [Table 3].

Escherichia coli was the most common organism cultured and was seen in 36.4% of the surgical site infections. *Staphylococcus aureus* was the second in occurrence and was seen in 27.3% of infections. *Pseudomonas aeruginosa* accounted for 18.2% of the infections, *Klebsiella pneumoniae* and Proteus vulgaris, each accounted for 9.1% of the infections. *P. aeruginosa* (18.2%), *K. pneumoniae* (9.1%), and Proteus vulgaris (9.1%) were isolated only in the long-term arm of the study. The causative organisms and antibiotics sensitivity patterns are shown in Table 3.

Discussion

This study demonstrated that there was no significant difference in the rate of postoperative wound infections between the use of 48-h cefuroxime and metronidazole regimen versus 7 days regimen on the development of surgical site infection and endometritis. Other similar randomized controlled trials have yielded similar findings.[2,4,6,9,10] This goes to buttress the

Table 1: Age and obstetric characteristics of the study participants

Characteristics	Short-termantibiotics	Long term antibiotics	OR (CI)	*P*
Age¥	31.1±5.4	30.9±5.9		0.830
Parity¥	1.9±1.4	1.9±1.4		0.746
Nature of cesarean section				
Primary	52 (21.4)	46 (18.9)		0.464
Repeat	70 (28.8)	75 (30.9)		
Type of cesarean section				
Emergency	75 (30.9)	80 (32.9)		0.452
Elective	47 (19.3)	41 (16.9)		
Intact membranes	72 (59.0)	65 (53.7)	1.2 (0.7-2.1)	0.405
Membranes ruptured	50 (41.0)	56 (46.3)	0.8 (0.5-1.4)	0.481
Membrane rupture duration (h)¥	6.0±2.6	6.6±2.6	1.1 (−0.4-1.6)	0.263
Duration of labor (h)¥	7.9±2.8	8.7±2.9	1.4 (−0.3-2.0)	0.139
Number of vaginal examinations¥	2.0±1.0	2.5±1.3	2.4 (0.1-0.9)	0.016

¥Mean±SD. SD – Standard deviation, OR – Odds ratio, CI – Confidence interval

Table 2: Outcomes of antibiotic use among the study participants

Outcomes	Short-term antibiotics	Long-term antibiotics	OR (CI)	*P*
Morbidity wound infection	3 (1.2)	8 (3.3)	0.4 (0.1-1.4)	0.136
Endometritis	1 (0.4)	4 (1.6)	0.2 (0.02-2.2)	0.213
Need for therapeutic antibiotics	4 (1.6)	11 (4.5)	0.3 (0.1-0.9)	0.067
Mean duration of hospital stay (days)	2.9±1.0	3.8±1.1	6.1 (0.06-0.1)	<0.001
Mean cost of antibiotics (naira)	2952.5±268.2	4063.6±464.4	22.9 (1015.4-1207.2)	<0.001

OR – Odds ratio, CI – Confidence interval

Table 3: Causative organisms and antibiotic sensitivity patterns

Cultured organism	*n* (%)	Short-term	Long-term	Antibiotic sensitivity
Escherichia coli	4 (36.4)	2	2	Amoxicillin/clavulanic acid, ofloxacin, levofloxacin, cefuroxime, imipenem
Staphylococcus aureus	3 (27.3)	1	2	Levofloxacin, ofloxacin cefuroxime, ceftriaxone Amoxicillin/clavulanic acid
Pseudomonas aeruginosa	2 (18.2)	0	2	Amikacin, gentamacin Imipenem, levofloxacin Amoxicillin/clavulanic acid
Klebsiella pneumoniae	1 (9.1)	0	1	Cefuroxime, azithromycin, amoxicillin, metronidazole, meropenem
Proteus vulgaris	1 (9.1)	0	1	Levofloxacin, ofloxacin meropenem, amoxicillin/clavulanic acid

recommendation by the World health organization[11] as well as other stakeholders like the Royal College of Obstetricians and Gynaecologists[12] on short-term antibiotics prophylaxis for cesarean section.

It was quite informative to note that the overall post cesarean section wound infection rate of 4.5% found in this study was lower than 16.2%,[8] 12.5%,[13] and 9%[14] reported previously by other researchers in Nigeria. The above-mentioned studies conducted in Ibadan, Nnewi, and Kano, respectively, in Nigeria, did not exclude patients with added risk factors for infections. In contrast, the rate obtained for our study was higher than the 0.10% reported by Hickson *et al*.[15] in Multicare Tacoma General Hospital in Washington DC in the United States of America. The very low rate in the latter study may be due to the use of special dressing bundle in high-risk women consisting of a film-forming skin preparation (preincision), topical skin adhesive, nanocrystalline silver anti-microbial barrier dressing, film-forming skin preparation, single-use negative pressure wound therapy system, and film-forming skin preparation (used around edges of dressing to seal). The wound infection rate was, however, similar to the 3%–4% recorded in a relatively more recent study in Ile Ife, Nigeria. [4] The reason for the comparable infection rates may be due to the inclusion of patients with similar characteristics in both studies with the exclusion of patients at risk of infection. Risk factors for surgical site infections include women with prolonged rupture of membranes (≥24 h) and chorioamnionitis, chronic diseases (diabetes mellitus, renal disease, and cardiac disease), obesity (weight ≥ 90 kg), anemia (PCV < 30%), and HIV-positive women.[16]

A higher number of women developed wound infections while on admission compared to those who had infected wounds after discharge. This was similar to findings from a trial conducted in Tanzania.[2] However, the postdischarge figure in this study was higher than the 36% postdischarge figure in the Beattie *et al*.[17] trial on risk factors for wound infection after cesarean section. This raises the question of postdischarge wound habits and the need to improve postdischarge surveillance in post-natal care.

The rate of endometritis, which was comparable in the two groups, is consistent with previous literature.[4] Endometritis is said to occur in about 1%–3% of births and is up to ten times more common after cesarean section[17,18] The low rate in this studies may be due to the difficulty in diagnosing sub-clinical endometritis and the fact that patients with increased risks like prolonged rupture of the membrane were excluded from the study.

Bivariate regression analysis showed that none of the dependent variables had an effect on wound infection rate. Importantly, the emergency cesarean section did not increase post cesarean section wound infection rate. This was similar to previous documentation in Ibadan, Nigeria.[8] Emergency procedures have traditionally been associated with a greater risk of infection than elective procedures. [19] The exclusion of emergency cases with significant added risks for infection may have been the reason for the nonsignificant difference in this study.

Similarly, bivariate regression analysis showed that none of the dependent variables had an effect on the development of endometritis even among women with multiple vaginal examinations up to three or more times. This was similar to the findings in Tanzania that compared single-dosage regimen with multiple-dosage regimen.[2] Multiple repeat vaginal examinations are conventionally associated with an increased risk of endometritis.[18,20] The difficulty in diagnosing preclinical endometritis may also be a reason for the lack of effect of multiple examinations in our study.

The most common organism isolated in this study was *E. coli* with *S. aureus* as the second most common organism. This was different from findings by other researchers[4,14,21,22] where *S. aureus* was the most common bacteriological isolate in postcesarean wound swabs. *E. coli* is a major facultative inhabitant of the large intestine.[19,23] As such, it presence in the majority of the infected wounds may have been due to improper sterilization of surgical gowns that may have been soiled earlier as the hospital was using nondisposable surgical gowns and drapes at the time the study was conducted. The introduction of disposable gowns and drapes may help in reducing the incidence of these organisms contaminating surgical sites. The postdischarge perineal habits of patients may also have played a role in the increased prevalence of *E. coli*. Good postoperative perineal hygiene has been shown to decrease the incidence of postoperative surgical site infections.[15]

P. aeruginosa, K. Pneumonia, and *Proteus Vulgaris* were isolated only in patients on long-term prophylaxis. These patients stayed for longer days in the hospital on average. In addition to *E. coli*, these organisms have been found to account for 32% of nosocomial infections.[24] As such, the shorter hospital stays for those on short-term prophylaxis may have been protective against nosocomial infections. In addition to other polymicrobial agents, chlamydia trachomatis and ureaplasma urealyticum were cultured. The women who had these probably had sexually transmitted infections even before pregnancy that predisposed them to the endometritis. The antibiotic sensitivity pattern of *E. coli* to cephalosporins and penicillins in this study has been replicated in previous studies.[4,14,21,22]

The mean duration of hospital stay was significantly shorter in the short arm group (2.9 ± 1.0 vs. 3.8 ± 1.1 days, $P < 0.001$). This was similar to the Ile-Ife study[4] and the Ayangade and Long[9] trial, where women in the short arm were admitted for a shorter number of days. The reason for this shorter stay may be that even though the oral medications were continued as placebos in the short arm group, those that have completed their antibiotic medications are more likely to be discharged since the physicians were not blinded. The added advantages of shorter hospital stay are reduced rate of nosocomial infections[4,25] and reduction of work by saving nursing time, particularly in the overcrowded hospitals in low-resource settings.[4]

The mean cost of antibiotics was statistically significantly less in the short arm group (N2952.5 ± 268.2 vs. N4063.6 ± 464.4 $P < 0.001$). This was similar to a previous report from Ife, Nigeria.[4] The reason for the higher cost in this study was the use of antibiotics for more days in the short arm group, and the rising cost of drugs as the latter trial was conducted 6 years before our study. The policy of using short course prophylactic antibiotics has been described as a significant advance in efforts to cut medical costs.[9]

The strength of this study is that unlike other studies comparing short versus long term prophylactic antibiotics,[2,4,9,10] blinding of the patients, which increases the power and credibility of studies were done in this study. Furthermore, the effects of extraneous variables like the state of the membranes and the number of vaginal examinations that might result in misleading interpretations on wound breakdown were controlled for by bivariate analysis.

The difficulty in detecting preclinical endometritis was a limitation to this study as only those who presented with symptoms were evaluated for endometritis.

The implications of these research findings for future research, therefore, would be the need for more studies with larger sample sizes comparing shorter regimens like 24 h versus longer course in poor resource settings. In addition, further research is needed on the burden of chlamydia trachomatis infection among pregnant women as a risk factor for post cesarean section wound infection.

Conclusions

This study has demonstrated that short-term antibiotic prophylaxis is as effective as long-term prophylaxis in preventing post cesarean section wound infection and endometritis in women with no added risks for infection. Short-term prophylaxis also has the added benefit of being cost-effective, shorter stay in the hospital for the patient and may, therefore, reduce nosocomial infections.

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Conflicts of interest

There are no conflicts of interest.

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