Effect of a change in policy regarding the timing of prophylactic antibiotics on the rate of postcesarean delivery surgical-site infections

Anjali Kaimal, MD; Marya G. Zlatnik, MD, MMS; Yvonne W. Cheng, MD, MPH; Mari-Paule Thiet, MD; Elspeth Connatty, RN, RGN(UK), RM(UK); Patricia Creedy, RN; Aaron B. Caughhey, MD, PhD

OBJECTIVE: The purpose of this study was to examine the effect of a change in policy regarding the timing of antibiotic administration on the rates of postcesarean delivery surgical-site infections (SSI).

STUDY DESIGN: This was a retrospective cohort study of 1316 term, singleton cesarean deliveries at 1 institution. A policy change was instituted wherein prophylactic antibiotics were given before skin incision rather than after cord clamp. The primary outcome that was examined was SSI; secondary outcomes were the rates of endometritis and cellulitis. Multivariable regression was performed to control for potential confounders.

RESULTS: The overall rate of SSI fell from 6.4-2.5% (P = .002). When we controlled for potential confounders, there was a decline in overall SSI with an adjusted odds ratio (aOR) of 0.33 (95% CI, 0.14,0.76), a decrease in endometritis (aOR, 0.34; 95% CI, 0.13,0.92), and a trend towards a decrease in cellulitis (aOR, 0.22; 95% CI, 0.05,1.22).

CONCLUSION: At our institution, a change in policy to administer prophylactic antibiotics before skin incision led to a significant decline in postcesarean delivery SSIs.

Key words: evidence-based medicine, infection, surgical complication, systems-based practice

Cesarean delivery is 1 of the most frequently performed surgeries in the United States, accounting for 31% of births in 2006, with >1.3 million procedures performed annually. Healthcare-associated infections are 1 of the top 10 leading causes of death in the United States; 22% of hospital-acquired infections account for most complications in surgical patients. For most obstetric patients, surgical-site infections (SSIs) are not life-threatening. Nonetheless, they have significant consequences in terms of prolonged length of stay, increased healthcare costs, and socioeconomic implications for the new mother and her family. Although some surgical-site infections are unavoidable, surgical care can be improved through better adherence to evidence-based practice recommendations and more attention to systems of care.

In 1999, the Hospital Infections Program at the Centers for Disease Control and Prevention issued guidelines regarding the definition of surgical-site infections and methods to help prevent them. These guidelines included antiseptic shower or bath for the patient at least once before the procedure, appropriate skin preparation in the operating room, antisepsis for the surgical team, antimicrobial prophylaxis, and attention to surgical technique. Antibiotic prophylaxis has been shown to decrease SSIs after elective procedures. Administration of antibiotics is not intended to sterilize tissues, but as an adjunct to decrease the intraoperative contamination to a level that can be handled by the host’s defenses. These guidelines were written for surgical patients; the obstetric population poses some unique challenges to their implementation.

In contrast to the main operating room, labor and delivery is a multipurpose, family-oriented space. Personnel are frequently cross-trained as nurses and surgical technicians; cases are at best considered clean-contaminated, and procedures are often unplanned or even emergent. Perhaps as a result of these factors, cesarean surgical-site infection rates have been higher in comparison with other similar procedures. However, 1 clear, potentially modifiable difference between cesarean delivery and other procedures involves the administration of antibiotics. Although the efficacy of the administration of prophylactic antibiotics for cesarean delivery has been shown, the timing of antibiotic administration traditionally has been during the operation, after cord clamp, be-
cause of concerns of a potential effect on neonatal sepsis workup. This is in contrast to other surgical procedures for which antibiotics are administered in a timely fashion before the operation to ensure adequate tissue levels at the time of the skin incision. Given the theoretic advantages of preoperative administration of antibiotics and in the absence of clear evidence of a negative effect on the neonate, several prospective randomized controlled trials have been performed to investigate this issue.\(^5,6\) The most recent of these, by Sullivan et al.,\(^7\) showed that, in the setting of a prospective randomized trial, administration of antibiotics before incision, rather than at cord clamp, leads to a decrease in infectious morbidity without evidence of neonatal harm. A metaanalysis of the 5 most recent studies confirmed this result.\(^8\)

Our study seeks to describe the process of translating this clinical research into practice. Our objective was to examine the effect of a change in policy regarding the timing of antibiotic prophylaxis on the rates of postcesarean surgical-site infections.

**Materials and Methods**

This was a retrospective cohort study of women with term singleton pregnancies who underwent cesarean delivery. The study period began in January 2003. The data from January 2003 to March 2005 were analyzed to obtain baseline infection rates. In March 2005, systems changes regarding preparation of patients and aseptic technique were instituted. The policy change of interest, administering antibiotics before the incision, was instituted in June 2006. To isolate the effect of the change in policy regarding the timing of antibiotic administration, women who underwent cesarean delivery between June 2006 and June 2007 served as the intervention group; women who underwent cesarean delivery between March 2005 and June 2006 served as historic control subjects.\(^9\) The study received institutional review board approval from the Committee on Human Research at the University of California, San Francisco.

We estimated that, if there were 600 cesarean deliveries in each group, there would be 90% power with a 2-sided alpha of .05 to find a 50% difference in surgical-site infections with a rate of 10%, but only 63% power to find a difference with a baseline rate of 5%. Thus, we used a combined primary outcome of any surgical-site infection (including cellulitis, endomyometritis, and wound abscesses) to ensure adequate statistical power. Specific secondary outcomes that were examined were cellulitis and endomyometritis. *Endometritis* was defined as induration, erythema, and warmth at the incision site. *Wound abscess* was defined as purulent drainage in the setting of induration at the incision site.

We extracted all data from a large electronic database that contains information regarding prenatal records, labor management, and perinatal outcomes that is collected prospectively, coded, and maintained. All clinical data were recorded prospectively at the time of delivery by the managing physicians. Surgical-site infections could be diagnosed before discharge, on a return visit to triage, or on a postpartum visit with a provider. All notes that would have been generated by such visits were reviewed up to 6 weeks after delivery by trained abstractors to ensure accurate and complete information reporting.

Bivariate analysis with the chi-squared or Fisher’s exact test statistics were conducted on all categoric outcomes and to compare characteristics between the 2 groups. Multivariable logistic regression was performed to control for potential confounders that included labor, previous cesarean delivery, parity, maternal age, body mass index, diabetes mellitus, chorioamnionitis and group B streptococcus vaginal culture status.

**Results**

There were no significant demographic or obstetric differences between the intervention group and the historic control subjects (Table 1). The baseline surgical-site infection rate after cesarean delivery in our population before any intervention was 9%. Comparison of this baseline infection rate from January 2003 to March 2005 to the rate of infections from March 2005 to June 2006 showed no significant effect of our initial policy changes to improve aseptic technique \((P = .68)\).

After demonstrating that our initial policy changes had no effect, we examined the SSI rate from March 2005 to
June 2006 and compared it with the rate from June 2006 to June 2007. Our policies to improve aseptic technique were ongoing throughout both time periods; the only difference was the decision to administer antibiotics before incision, rather than at cord clamp, during the latter time period. Our results show a significant decrease in SSIs after implementation of this discrete policy change. When all cesarean deliveries are included, there is a decrease in overall SSIs from 6.4-2.5% ($P = .002$). Endometritis also decreased from 4.8-2.1% ($P = .014$). Cellulitis decreased from 1.9-0.4% ($P = .020$; Table 2).

Because the infectious risk for patients who undergo cesarean delivery in labor is different from those who undergo a planned cesarean delivery without labor, these 2 groups were examined independently. As expected, the absolute infection rate was lower in women who had planned cesarean deliveries. The cellulitis rate was reduced from 1.2% to 0, but this finding did not achieve statistical significance. When we examined patients who had cesarean deliveries in labor, a significant decrease in overall SSI was seen, with over a 50% reduction, from 10.6-4.2% ($P = .005$). This reduction primarily was due to a decrease in endometritis from 8.2-3.4% ($P = .017$).

Multivariable logistic regression was also performed to control for potential confounders. There was a decline in overall SSIs after the intervention, with an adjusted odds ratio of 0.33 (95% CI, 0.14, 0.77). There was also a decline in endometritis and a trend towards a decrease in cellulitis with adjusted odds ratios of 0.34 (95% CI, 0.13, 0.92) and 0.25 (95% CI, 0.05, 1.22), respectively.

**COMMENT**

This study shows that, at our institution, a change in policy to administer prophylactic antibiotics before skin incision led to a significant decrease in postcesarean SSIs, illustrating the integration of research findings into clinical practice. We demonstrated both an overall reduction in SSIs and in the 2 specific infections of cellulitis and endomyometritis. These differences persisted when we attempted to control for potential confounders.

Evidence-based medicine involves the integration of appropriate and timely available evidence into clinical practice. The process of translating research findings into behavioral changes is 1 of the rate-limiting steps determining the potential benefits of research. The National Institutes of Health Roadmap initiative calls for an increase in practice-based research, including guideline development and observational studies to allow for a more systematic translation of medical discoveries into clinical practice. Unfortunately, there are many examples of barriers to implementation of evidence from clinical trials. With regards to the specific issue of SSI, after the publication of a Cochrane review that included 81 studies that demonstrated a reduction in SSI with the administration of prophylactic antibiotics for cesarean delivery, studies have shown obstetricians are reluctant to adopt this as a policy. Our experience with the process and clinical outcomes of a policy change regarding timing of antibiotic prophylaxis for cesarean delivery suggests that, even in the setting of these barriers, significant improvement in patient care can be achieved through thoughtful development, implementation, and monitoring of clinical guidelines based on medical knowledge.

Systems of patient care are often complex and require multidisciplinary problem-solving for meaningful improvement; an understanding of the nature of the system and the roles of the participants within it is essential for effective, purposeful policy change. In the setting of quality assurance, SSI was identified as an area of preventable morbidity in our Obstetric Unit. A task force was
formed to define the magnitude of the problem and identify solutions. Members included physicians, nurses, administrators, and personnel from the hospital infection control service. After review of recent internal data and analysis for risk factors, an action plan was implemented. This initially consisted of a variety of interventions that included retraining nurses in aseptic technique, instituting a new surgical preparation, implementing guidelines for patient warming and oxygen administration, reducing nonessential personnel in the operating room, and improving scrub technique (Figure 2). Unfortunately, 1 year after these changes were implemented, there was no significant change in the rate of SSIs. After we examined the data regarding the timing of antibiotic administration and reviewing it with our neonatology colleagues, the decision was made to add this specific policy change to the action plan.

Based on the unique characteristics of cesarean delivery, multidisciplinary involvement from the neonatology, anesthesia, and obstetrics services was necessary to define, implement, and update the action plan. Communication and dissemination of information was crucial at every step. Implementation of the policy was carried out by nurses, physicians, and staff. Information was disseminated to all of these groups verbally and electronically; multiple messages were sent to reinforce the changes. The nurses became the primary communicators of the policy; they reported considerable reluctance to comply on the part of the physicians at times. Previous research regarding the response of doctors to changes in practice indicates that there is wide variation in the way that clinicians respond: Some clinicians may seek out research information and integrate it readily into their practice; other clinicians may rely on the judgment of respected authorities, and some clinicians rely primarily on their own training and personal clinical experience. Communicating the importance of the new policy to physicians with all of these styles was essential for success.

Although enthusiasm and attention may be high at the time that a policy is implemented, detailed adherence over time may be much more difficult to sustain. This is a major difference between the findings of a clinical trial that is performed under research conditions with the additional incentives for compliance that are inherent in that situation and the real world application of those findings. In this case, continued reinforcement of the key points of the action plan by both physicians and nurses was crucial. For example, we added the confirmation that antibiotics had been administered to the “surgical time out” before every proce-
Ongoing and iterative process of integration of clinical research into practice

**Demonstrate effect on patient care**

**Identify an area of preventable morbidity**

**Develop multidisciplinary action plan**

**Ongoing monitoring, implementation, education**

**Identify barriers to implementation**

**Incorporate research findings**

**Implement policy change**

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dure to insure that the obstetric and anesthesia teams communicated regarding this issue before the surgery began.

Finally, maintaining vigilance over time to continue tracking important outcomes is difficult. Studies have shown that simply maintaining a tracking program for SSI leads to decreased infectious morbidity. To enhance our event reporting program, starting in June 2006, we offered incentives (Starbucks cards) for informing the task force about SSIs.

Our study has limitations. It is retrospective and therefore at risk for reporting bias. It was performed at an academic center, which may limit its generalizability. There were multiple changes implemented over time to try and reduce SSIs, although the addition of the change in timing of prophylactic antibiotics was discrete. There was imperfect compliance with the action plan. But, although these aspects would make it difficult to draw a conclusion about the effect of the timing of antibiotics in the absence of other information, in the setting of a randomized controlled trial data to support this policy, these limitations could also be seen as strengthening this study’s validity as a real world demonstration of the effects of a change in policy on patient outcomes.

Our objective was to examine the effect of a change in policy regarding the timing of antibiotic prophylaxis on the rates of postscearean delivery SSIs. After the identification of an area of preventable morbidity, a multidisciplinary action plan was developed; research information was incorporated into policy; policy change was implemented; barriers to implementation were identified, and effects on patient outcome were demonstrated. Monitoring, implementation, and education continue even now (Figure 3). Our study shows that a policy change regarding the timing of antibiotics administration resulted in a decrease in SSIs in our institution. We believe that such a policy adoption should be feasible at all institutions and will lead to lower rates of postoperative infections.

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**REFERENCES**