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Major article

## Implementation of an antibiotic prophylaxis protocol in an intensive care unit

Silvana Maria de Almeida PharmD<sup>a,\*</sup>, Alexandre R. Marra MD<sup>a</sup>, Sergio B. Wey MD<sup>b</sup>, Elivane da Silva Victor PhD<sup>c</sup>, Oscar Fernando Pavão dos Santos MD<sup>d</sup>, Michael B. Edmond MD, MPH, MPA<sup>e</sup>

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Background: When properly employed, the prophylactic use of antimicrobials is associated with a reduction in surgical site infections (SSIs). We found that the appropriate use of antimicrobial prophylaxis was only 50.5% (53/105) among patients undergoing surgery in the adult intensive care unit of our hospital. In 2001, a protocol was designed to improve compliance with recommended practice. Methods: We used a prospective interventional study and a case control study carried out between 2001 and 2007, including follow-up and daily intervention to improve compliance with antimicrobial prophylaxis guidelines and to monitor antimicrobial consumption and SSI rates. Cases of noncompliance to the prophylaxis protocol (group I) were matched to controls (group II) with appropriate prophylaxis and compared with regards to type of surgery, operative duration, intraoperative antimicrobial use, type of antimicrobial used, length of hospital stay, severity of illness, comorbidities, invasive devices, possible adverse reactions, and death.

Results: Compliance with antimicrobial prophylaxis metrics reached 85%; however, we were unable to detect a change in SSI rate or consumption and cost of antimicrobials. Inappropriate use was not associated with higher likelihood of death. There were no other significant differences between the 2 groups. Conclusion: Our intervention increased compliance with appropriate antimicrobial surgical prophylaxis with no negative impact on patient safety.

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It is estimated that, globally, 234 million surgical procedures are performed every year. Even though these procedures improve the health of many people, they are also associated with risks and complications, and, in many cases, the complications are avoidable.<sup>2</sup>

It is known that approximately 500,000 surgical site infections (SSIs) occur every year in the United States; and, among patients who develop these infections, 60% will remain longer in the intensive care unit (ICU), are 5 times more likely to be readmitted to the hospital, and are twice as likely to die as patients who had not developed infections. Moreover, the costs of these infections are high, and they are associated with other adverse events.<sup>3-5</sup>

Prophylactic use of antimicrobials, started up to 1 hour before the beginning of clean contaminated or contaminated surgical

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procedures, reduces the intraoperative microbial contamination burden and is directly associated with reduction in the risk for SSI, in addition to reducing costs, preventing adverse events, and avoiding exposing the microbial flora of the infected patient to other patients in the hospital.<sup>4,5</sup>

To reach these objectives, the antimicrobial should be active against the pathogens that are likely to contaminate the surgical wound and administered in a dose that can ensure appropriate concentration in the surgical incision site during the potential contamination period and over the least possible time to minimize adverse events and the development of resistance and costs.<sup>4,5</sup>

Emergence and rapid dissemination of multidrug-resistant bacteria is a reality at hospitals, especially in ICUs. Therefore, antimicrobial prophylaxis programs to avoid incorrect use of surgical antibiotic prophylaxis are needed to improve therapeutic practice and are important to ensure the continued efficacy of available antimicrobials.6-8

The present study was designed to evaluate the compliance with and the maintenance of an antimicrobial surgical prophylaxis

<sup>&</sup>lt;sup>a</sup> Intensive Care Unit, Hospital Israelita Albert Einstein, São Paulo, Brazil

<sup>&</sup>lt;sup>b</sup> Department of Infectious Diseases, Universidade Federal de São Paulo (UNIFESP), São Paulo, Brazil

<sup>&</sup>lt;sup>c</sup> Statistics Department, Instituto Israelita de Ensino e Pesquisa (IIEP), São Paulo, Brazil

<sup>&</sup>lt;sup>d</sup> Division of Medical Practice, Hospital Israelita Albert Einstein, São Paulo, Brazil

<sup>&</sup>lt;sup>e</sup> Department of Internal Medicine, Virginia Commonwealth University School of Medicine, Richmond, VA

<sup>\*</sup> Address correspondence to Silvana Maria de Almeida, PharmD, Avenue Albert Einstein 627, Bl. E. SISM, Morumbi, São Paulo-CEP 05651-901, São Paulo, Brazil, E-mail address: silvanama@einstein.br (S. Maria de Almeida).

program to discontinue antibiotics within 48 hours after surgery in ICU patients.

#### **MATERIALS AND METHODS**

Study

We performed a quasiexperimental study on the discontinuation of prophylactic antimicrobial therapy. Based on this study, we also carried out a case-control study to investigate the main reasons for not appropriately discontinuing prophylaxis and a cohort study to analyze the risk factors for death related to not discontinuing prophylactic antibiotics. This study was carried out in an open staffing model, 38-bed, medical-surgical ICU of a private hospital between October 2001 and December 2007 in Sao Paulo, Brazil. The unit has a management team formed by intensivists and medical residents. We excluded patients who had been treated with antibiotics for infections at the time of elective surgery and those who stayed less than 48 hours in the ICU after surgery. The project was approved by the institutional Research Ethics Committee as well as the Pharmacy and Therapeutics Committee.

During the preintervention stage (January to May 2001), a survey of all antimicrobial prescriptions in the ICU showed that only 50.5% (53/105) of the surgical patients with antimicrobial prophylaxis in the ICU actually had discontinuation of prophylaxis within 48 hours after surgery. The consensus for time of discontinuation of antimicrobial prophylaxis is a maximum of 24 hours, and, in cases of thoracic or cardiac surgery, the administration duration may last up to 48 hours postoperatively.<sup>3</sup>

In 2001, a project was designed to improve compliance with discontinuation of antimicrobial agents within 48 hours after surgery in ICU patients. The protocol was presented to surgical teams using a newsletter, and a letter was sent to the top 10 surgical teams in terms of volume from different specialties, explaining the problem of noncompliance with appropriate antibiotic prophylaxis duration and requesting commitment to compliance to the protocol by formal signature of the letter. A manual on surgical antibiotic prophylaxis was designed by the Hospital Infection Control Committee, and there were adhesive messages placed on the patients' charts regarding the correct use of prophylactic antibiotic therapy.

In the second stage of the project (intervention stage, October 2001 through December 2007), an ICU pharmacist and an infectious diseases physician, supported by the intensivists, identified the surgical patients daily and followed up on the duration of antimicrobial prophylaxis. All surgical patients were followed, but the patients included in the study were those with length of stay over 48 hours in the ICU; patients transferred from the ICU before 48 hours postoperatively were excluded from follow-up.

The standard for surgical prophylaxis was based on the Centers for Disease Control and Prevention recommendations,<sup>5</sup> described in the protocols of the institution for elective surgery cases. An infectious diseases physician and pharmacist discussed each case with the intensivist and discontinued the surgical prophylaxis before 48 hours had elapsed. The attending physician was informed that, if he wanted to maintain the prophylaxis, the antibiotic could be prescribed again.

Monthly and annual reports on compliance were prepared. Compliance data were shared with the ICU medical team every 3 months using newsletters, clinical meetings, and talks given to resident physicians. Compiled data were analyzed monthly using a compliance rate calculation (number of patients with compliant prophylaxis/total number of surgical patients followed up  $\times$  100), with compliance defined as discontinuation of prophylactic antimicrobials within 48 hours.

Surveillance for SSI was conducted by the hospital infection control team using Centers for Disease Control and Prevention definitions.<sup>5</sup> SSI were defined as superficial (involving the skin and subcutaneous tissue), deep, or organ space (when involving deep organs or cavities approached during the operation) and could occur up to 30 days, unless there was an implant in which case surveillance was continued for 1 year.<sup>5</sup> However, case ascertainment was limited to the duration of the patient's hospital stay.

The use of antimicrobial agents was followed up based on the defined daily dose and compared against reference data from the National Nosocomial Infectious Surveillance System. The consumption of antimicrobial agents was assessed through the calculation of the defined daily dose per 1,000 patient-days.

The APACHE II score was used to assess the severity of illness of the ICU patients. <sup>10</sup> For patients who died, the ICD-10<sup>11</sup> was used to identify cause of death.

Among the followed up patients, those classified as having noncompliant surgical prophylaxis were matched to those patients whose prophylaxis was discontinued within 48 hours. Matching was based on the following criteria: gender, age within 20 years, and surgery date (within 4 months). If there was more than 1 match available, the patient closest in age and the closest date of surgery were used.

We abstracted the following data elements for each patient: type of surgery, duration of surgical procedure, time of intraoperative antimicrobial administration (according to the literature, the appropriate time is up to 1 hour before the surgical incision), redosing of the antimicrobial during the procedure (if the surgery lasts more than the half life of the antimicrobial, it should be repeated during the procedure to ensure plasma concentration at the target tissues), number of days of prophylactic antimicrobial use, comorbidities, infection sites, presence of invasive devices, length of stay in the ICU, severity of illness, death, and adverse reactions

The goal for compliance adopted in October 2001 for the institution overall was 70%. As of the beginning of 2002, the compliance goal was re-set to 80% and, in 2005, to 85%.

Statistical analysis

Data were analyzed in absolute frequency and percentage, in the case of qualitative variables. Quantitative variables were analyzed as means and standard deviations if normally distributed or as medians and interquartile intervals. The assessment of distribution of quantitative variables was made using the analysis of boxplot charts, asymmetry coefficients, kurtosis, and the Shapiro-Wilk normality tests. Groups were compared using the Student t test or Mann-Whitney test for quantitative variables and  $\chi^2$  or Fisher exact test for qualitative variables. To investigate factors associated with death, we constructed a logistic regression model, including variables that had P < .10 in the univariate analysis. All analyses were performed using statistical software (version 17; SPSS Inc, Chicago, IL), and a P value < .05 was considered statistically significant.

#### RESULTS

Overall results

Before the intervention, there was 50.5% (53/105) compliance with appropriate antimicrobial prophylaxis duration. After the intervention, in the first quarter, there was 89.5% (77/86) compliance, exceeding the 70% defined goal for the period (Fig 1). In 2002, the target was raised to 80% compliance, and, in 2005, it was changed to 85% compliance.

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