Antibiotic Prophylaxis in Orthopedic Surgeries: The Results of an Implemented Protocol

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Though the basic principles of antibiotic prophylaxis have been well established, there is still considerable incorrect usage, including how much is prescribed and especially in the duration of treatment, which is generally superior to what is indicated. The adequate use of these drugs contributes towards decreasing the time of internment of the patient, prevents surgical site infection (SSI), decreasing the development of resistant microorganisms, and towards reduced costs for the hospital pharmacy. A protocol for the use of antibiotic prophylaxis in the Orthopedics and Traumatology Service of the Hospital do Servidor Público Estadual de São Paulo was developed. The objectives of the study were to promote rational antibiotic surgical prophylaxis, through the implantation of a protocol for the use of these drugs in a surgical unit, with the direct contribution of a druggist in collaboration with the Infection Control Committee, to evaluate the adhesion of the health team to the protocol during three distinct periods (daily pre-protocol, early post-protocol and late post-protocol) and to define the consumption of antimicrobials used, measured as daily defined dose.

Key Words: Antibiotic prophylaxis, protocol, surgical site infection, pharmacy.

The prophylactic use of antibiotics is but one of many measures to reduce the risk of surgical site infection (SSI), the most common nosocomial infections among surgical patients [1]. Though a lowered incidence of SSI with the use of prophylactic antibiotics is well documented, the inappropriateness of antibiotic prophylaxis has also been extensively demonstrated in many situations. Antibiotics are often used in wrong doses, for too long, and with too broad a spectrum of antimicrobial activity [2-5]. Antimicrobial resistance, superinfection and unnecessary costs are common consequences of inappropriate surgical antibiotic prophylaxis [3,6]. Many multidisciplinary educational and managerial interventions have been implemented in attempts to modify this scenario [7-9].

The use of antibiotics as prophylaxis for SSI in orthopedic surgeries is indicated when prostheses are implanted, or when any sort of osteosynthetic materials, such as nails, wires, plates, and screws, are used. In these cases cefazolin, a first generation cephalosporin, is the antibiotic of choice [1,10-13].

We describe a multidisciplinary experience in implanting a protocol for prophylactic antibiotic prescription in the orthopedic department of a general hospital.

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Material and Methods

Hospital

The study was conducted in a 711-bed general public hospital. The orthopedic ward had 37 beds and performed an average of 87 surgeries per month

during 1999. There were no formal guidelines for surgical antibiotic prophylaxis in the orthopedic surgeries.

Protocol

The protocol for surgical antibiotic prophylaxis was prepared at the request of the head of the orthopedic department; it was the consensus result of a multidisciplinary discussion group involving the medical staff, members of the Infection Control Committee (ICC) and the pharmacist. This protocol complied with internationally-accepted guidelines [14-16]. To promote compliance with the protocol, the multidisciplinary team offered lectures on the subject to the residents, and discussed the rationale of perioperative antibiotic prophylaxis during the daily ward visits of the medical staff.

The role of the hospital pharmacy

The hospital pharmacy developed a form for dispensing prophylactic antibiotics based on the protocol. The surgeon signed the antibiotic order form the day before surgery for elective surgeries, and the pharmacist assured that the patients received the correct intra - and postoperative doses of the indicated antibiotic in the operating room. The pharmacist also provided emergency antibiotic kits whenever needed. Each time a prophylactic antibiotic prescription that was not in accordance with the protocol reached the pharmacy, the pharmacist asked the prescriber the reason for the prescription. If the prescriber insisted on the prescription, a physician from the ICC was called in to discuss the issue until a consensus decision was reached. This decision involved either the withdrawal of the antibiotic or modification of the antibiotic schedule.

Data collection

The data were collected by the pharmacist from the medical records, from the daily prescription sheets, and during the daily medical ward visits. Prescriptions that diverged from the protocol were considered "errors". Six aspects concerning antibiotic prophylaxis were evaluated; they included the indication of antibiotic prophylaxis, the choice of the antibiotic, the timing of the first prophylactic dose, the prescribed dose, the need for extra intraoperative doses when indicated, and the number of postoperative doses. The SSI rates during the three study periods (see below) were recorded.

The amount of prophylactic antibiotics prescribed during the study periods was expressed in daily defined doses (DDD)/100 bed-days [17,18].

Study design

All surgical orthopedic patients not on antibiotic treatment were included in the study. Three study periods were designed. The first, from July to September 1998, described the pre-protocol pattern of prophylactic antibiotic prescriptions. During this three-month period, the multidisciplinary team established close contact with the staff of the orthopedic department. The prophylaxis protocol started on September 1998, and a three-month period was allowed to consolidate the new praxis. An early post-protocol survey was conducted from December 1998 to February 1999. From then on, the multidisciplinary team only went to the orthopedic ward when requested, on average once a week. A third late post-protocol survey was carried out five months later, from July to September 1999, in order to evaluate the compliance with the established protocol after a period without the daily presence of the pharmacist and the ICC representatives.

Exclusion criteria

Surgical orthopedic patients were excluded from the study if: 1) they had been on therapeutic antibiotics before the surgery, 2) the postoperative follow up was missed, for example, by discharge within 24 h of surgery, 3) the patient needed a further surgery within 72 hours, or 4) information about the intraoperative use of antibiotics was lacking.

Cost evaluation

The cost of the prophylactic antibiotics was expressed as cost/surgery and as the cost of the DDD of prophylactic antibiotics in each study period. The values were expressed in US$.

Statistical analysis

The chi-square test and Fisher's exact test were used as appropriate. Statistical significance was considered when $p \leq 0.05$. The statistical analysis was done using the software EpiInfo, version 6.1 (CDC, Atlanta, GA).

Results

Patients and surgeries

Of the 299 surgeries evaluated, 74 were in the pre-protocol period, 113 were in the early post-protocol period and 112 were in the late post-protocol period. Nine patients met the exclusion criteria. Forty percent of the patients were male, and the mean age of all the patients was 52.5 ± 25.7 years. There were no significant differences in the age or gender composition of the patients in the three study periods.

Sixty-eight percent of the surgeries were for osteosyntheses and total hip arthroplasties. More than 95% of the surgeries were elective and clean. There was no significant difference in the rate of incidence of SSI in the three study periods (4.0% in the pre-protocol, 3.6% in the early post-protocol, and 2.8% in the late post protocol periods). The number of "errors" in the three study periods and the respective incidence of SSI were not significantly related ($\chi^2 = 2.52$, $p = 0.28$).

Surgical antibiotic prophylaxis

Prophylactic antibiotics were prescribed in 237 surgeries (81.7%). The DDD/100 bed-days for the prophylactic antibiotic in the pre-protocol period (cefalotin) was 8.53, and in early post-protocol and in late post-protocol periods (cefazolin) it was 9.42 and 7.90, respectively.

The frequency of the appropriateness of the antibiotic prophylaxis according to the established protocol during the three study periods was determined (Table 1). The number of "errors" was analyzed by recording the number of times there were prescriptions that disagreed with the established protocol for each patient. In the pre-protocol period, only 3.3% of the surgeries with antibiotic prophylaxis had no "errors", but this value reached 50% in the late post-protocol period ($p < .0001$) (Figure 1).

Cost of the antibiotic prophylaxis

Cost per surgery. For the 61 surgeries in the pre-protocol period, the expenditure for antibiotics was US$16.62/surgery. For 176 surgeries with antibiotic prophylaxis in the two post-protocol periods, the expenditure fell to US$6.61/surgery.

Cost of the DDD. In the pre-protocol period, 8.53 DDD/100 beds/day of cefalotin cost US$36.49. In the early post-protocol period, 9.42 DDD/100 beds/day of cefazolin cost US$29.13, and in the late post-protocol period, 7.90 DDD/100 beds/day of cefazolin cost US$24.43.

Discussion

The improvement in the pattern of surgical antibiotic prophylaxis resulted from the joint efforts of a multidisciplinary team, which provided educational intervention, and the hospital pharmacy, which made managerial adjustments to dispense prophylactic antibiotics according to the protocol and to check compliance with the established protocol. Educational plus restrictive interventions gave the best results for rational antibiotic prophylaxis [19].

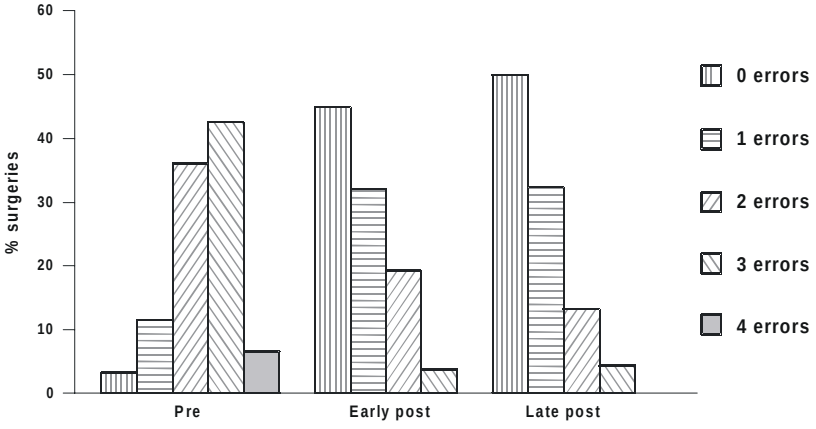
The frequency of the proper indication of prophylactic antibiotics in orthopedic surgeries was not affected by the protocol, probably because most of the surgeries performed in this orthopedic department

Table 1. Frequency (%) of the appropriateness of antibiotic prophylaxis in orthopedic surgeries during three study periods

Items	Study period			P
	Pre-protocol	Early post-protocol	Late post-protocol	
Indication of antibiotic prophylaxis	84.8	94.5	91.6	NS
Choice of antibiotic	98.3	100.0	100.0	NS
Timing of the first prophylactic dose	80.0	94.9	95.6	< .05
Prescribed dose	38.3	74.4	80.9	< .05
Extra intraoperative doses	10.2	69.2	80.9	< .05
Number of postoperative doses	33.3	83.3	83.8	< .05

NS = not significant.

Figure 1. Distribution of the number of "errors" relative to the established antibiotic prophylaxis protocol during the three study periods.



used osteosynthetic materials or implant prostheses, and in both situations antibiotic prophylaxis is indicated. The same observation applies to the choice of antibiotic. For orthopedic surgeries, first generation cefalosporins are recommended, and before the protocol the prescribed antibiotic was cefalotin. Despite the well-known pharmacokinetic advantages of cefazolin [1,10,20], which was recommended in the established protocol, the use of cefalotin in the pre-protocol period cannot be considered incorrect.

There were significant differences in the prophylactic antibiotic prescriptions after the implantation of the protocol, particularly in the dosages, the intraoperative repetition of the antibiotic, and the number of postoperative doses. Excessive duration of antibiotic prophylaxis is one of the most common errors in surgical antibiotic prophylaxis [3]. It is noteworthy that compliance with the protocol remained high months after the enforcing multidisciplinary team stopped its daily visits to the orthopedic ward. Apart from the

probable clinical benefits for the patients, there was marked reduction in the cost of the antibiotic prophylaxis, thus strengthening the need for enforcing the proper use of antibiotics in the prophylaxis of SSI. Since the costs of the two antibiotics for the hospital were almost the same, the reduction in costs resulted mainly from the proper number of post-operative doses.

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