The Efficacy of Prophylactic Intravenous **Antibiotics in Elective Foot and Ankle** Surgery

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A retrospective chart review of 555 patients who received elective foot and ankle surgeries between 1995 and 2001 at 1 outpatient podiatric hospital clinic was performed to evaluate the efficacy of preoperative intravenous antibiotic use. Only those patients who were having elective foot or ankle surgery for the first time, were being followed up at the hospital's outpatient clinic, and had a nontraumatic cause for their surgery were included in this study. A wound was considered infected when purulent material from the wound sites was noted and an organism(s) was cultured. A wound complication was defined as a superficial dehiscence, edema, erythema, or stitch abscess. Three hundred six (55.1%) patients received a preoperative antibiotic and 249 (44.9%) patients did not. Of the 306 patients who received a preoperative antibiotic, 9 (1.6%) acquired a postoperative wound infection, whereas 8 (1.4%) of the 249 patients who did not receive preoperative antibiotics acquired a postoperative infection. A logistic regression model and chi square tests of association were used to determine if preoperative antibiotic use, age, gender, type of surgical procedure, operative time, tourniquet use, past medical history, and internal fixation were predictive of or associated with postoperative wound infection or complication. None of the study factors was predictive of postoperative wound infection or complication (P > .01). Preoperative antibiotic use was associated with surgical category and internal fixation use (P < .001) but not postoperative wound infection or complication (P > .01). The results suggest that prophylactic intravenous antibiotic use in routine elective foot and ankle surgery is not warranted. (The Journal of Foot & Ankle Surgery 43(2):97-103, 2004)

Key words: prophylactic antibiotics, elective foot and ankle surgery, wound infections, wound complications

T he use of preoperative antibiotics in the prevention of postoperative wound in fection is a controversial issue. To date, studies that have examined the effectiveness of preoperative antibiotics in the prevention of postoperative wound infections have had conflicting results (1–21). Some

21). The major controversy revolves around the issue of when (eg, in all surgeries or only in elective, noninfected surgeries) and how to use prophylactic antibiotic therapies. Recent studies have not shown a significant decrease in

studies indicate that preoperative antibiotics have a positive

effect on the prevention of postoperative wound infections

(1-15), whereas others do not support this conclusion (16-

infection rates when using prophylactic antibiotics in clean

general surgical cases and in clean nonimplant wounds. In

those wounds that are infected, antimicrobial resistances in

gram-positive bacteria are increasing in patients with surgi-

cal infections and remain a major concern to the attending

physician (11–15). Furthermore, the incidence of methicil-

lin-resistant staphylococci in clean surgery is also increas-

ing and can be a devastating problem when staphylococci

are the predominant pathogens seen in the wound infections

(18-21). Gram-positive cocci are the most common patho-

gens in surgical wound infections and the emergence of

multidrug resistance can create a major problem and chal-

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ics through proper patient selection should be the primary goal of physicians (18-21).

Although the incidence of postoperative wound infection is low in elective orthopaedic surgery, if an infection does occur, the final outcome can lead to a total loss of joint function, amputation, or, occasionally, death (13, 14). The incidence of infection rate in clean orthopaedic surgery is between 0.5% to 6.5% (18, 22–29). To decrease the occurrence of postoperative wound infections the use of preoperative antibiotics has been advocated by several studies (30–41). With the emergence of resistant microbial strains and superinfections, the practice of administering prophylactic antibiotics preoperatively in elective foot and ankle surgery has been questioned (42–52).

Given the lack of documentation regarding the effectiveness of preoperative antibiotics in clean foot and ankle surgery, the purpose of this study was to evaluate the efficacy of prophylactic antibiotics in the prevention of postoperative wound infections. Additionally, the other factors in the occurrence of postoperative wound infections or complications were delineated.

Materials and Methods

A retrospective chart review of 555 patients receiving elective foot and ankle surgeries between 1995 and 2001 at 1 outpatient podiatric hospital clinic was conducted by the senior author (T.Z.). All patients had a preoperative evaluation by 1 of the attending podiatric surgeons (n = 32) at the outpatient clinic of the hospital. The evaluation consisted of a history and physical examination, preoperative foot radiographs, and laboratory studies when indicated. All surgeries were performed by the same surgeon who performed the preoperative evaluation.

Only patients having elective foot or ankle surgery for the first time and were being followed up at the hospital's outpatient clinic were included in the study. Patients were excluded from the study if they had a prior history of ulcers, infection, trauma, or open fractures of the foot or ankle. All patients were followed up postoperatively at the hospital's outpatient clinic by the surgical resident and/or podiatric surgeon on duty. Postoperative care included routine physical examination, wound inspection, foot radiographs, and laboratory work-up in cases of postoperative infection and/or complications.

The 555 charts were divided into 6 surgical categories to include soft tissue, digital, lesser metatarsal, first ray, rear foot, and multiple surgeries according to the American Board of Podiatric Surgery's definition of these categories (53). Patients who had more than 1 procedure performed at the time of their surgery (eg, first metatarsal osteotomy and correction of hammertoes) were assigned to category 6 (multiple procedures).

From the patient charts, the following data were extracted: prophylactic antibiotic use, age, gender, past medical history, surgical time, tourniquet use, and use of internal/external fixation. Additionally, the incidence of postoperative wound infection or complication was noted along with the results of postoperative cultures and sensitivities, postoperative antibiotic use and dictated postoperative clinic notes. Infected cases included patients in which purulent material was noted from the wound sites and an organism(s) was cultured. Wound complication was defined as a superficial dehiscence, edema, erythema, or stitch abscess.

All patients undergoing foot and ankle surgeries were scrubbed and draped in the same manner according to the hospital's policy. Skin preparation included scrubbing twice with povidone-iodine solution (Betadine; Purdue-Frederick, Stamford, CT), washing with sterile saline, drying with a sterile towel, and painting twice with povidone-iodine solution. Although preoperative prophylactic intravenous antibiotics were ordered 30 minutes before surgery for all patients, the administration of the antibiotics ranged from 2 hours to just before surgery.

Data Analysis

The data obtained from the chart reviews of each patient were grouped according to whether or not preoperative antibiotics were administered. Descriptive statistics consisting of means and standard deviations for the quantitative data were then obtained.

Frequencies for the categorical data were calculated for each of the study groups. t tests were conducted to determine if any differences existed between the 2 study groups with respect to their mean age or operative time. Additionally, chi-square tests of association were performed to determine if preoperative antibiotic use was associated with any of the study factors (gender, internal fixation use, tourniquet use, surgical category, past medical history, postoperative infection, or postoperative wound complication). A logistic regression model was then developed to determine if any of the study factors (preoperative antibiotic use, gender, internal fixation use, tourniquet use, surgical category, past medical history, age, and surgical time) were predictive of postoperative outcome (wound complication or infection). A backwards elimination method was used to remove factors from the model. A post-hoc power analysis was conducted to ascertain the effect of the sample size on the noted statistical outcomes. For this study, the α level of significance was set at the .01 level. All statistical testing was conducted by using the Statistical Analysis System software package (SAS Institutes, Cary, NC) with the exception of the power analysis, which was conducted by

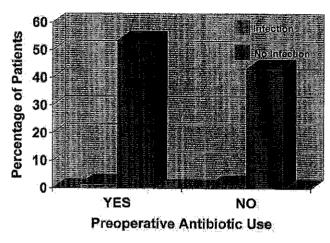


FIGURE 1 The percentage of patients acquiring a wound infection by preoperative antibiotic use. Note the percentage of patients acquiring a wound infection was similar between the preoperative (1.62%) and nonpreoperative antibiotic—use (1.44%) groups.

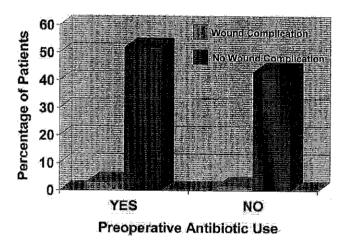


FIGURE 2 The percentage of patients acquiring a wound complication by preoperative antibiotic use. Although not significantly different, the percentage of patients acquiring a wound complication in the preoperative-use (3.24%) group was almost twice that of the nonpreoperative antibiotic-use (1.62%) group.

using the Power and Precision software package (Biostat, Teaneck, NJ).

Results

A total of 555 charts were reviewed; 306 (55.1%) patients received a preoperative antibiotic and 249 (44.9%) patients did not. Of these 555 patients, 17 (3.1%) acquired a post-operative wound infection and 27 (4.9%) acquired a post-operative wound complication (Figs 1 and 2). Preoperative antibiotic use was not associated (P > .01) with either of the postoperative outcomes (wound infection or complication). Of the 249 patients who did not receive preoperative anti-

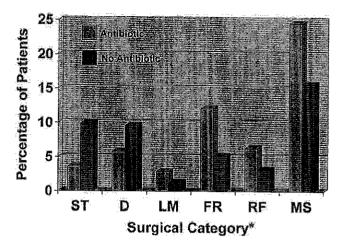


FIGURE 3 The percentage of patients (n = 555) by surgical category and preoperative antibiotic use. Patients who received an antibiotic (n = 306) had significantly (*P < .01) more complicated surgical procedures than those patients who did not receive an antibiotic (n = 249). ST, soft tissue; D, digital; LM, lesser metatarsal; FR, first ray; RF, rear foot; MS, multiple surgery.

TABLE 1 The percentage of patients with internal/external fixation (N = 555), according to preoperative antibiotic use

Internal/External Fixation ^a	Preoperative Antibiotic Use		
	Yes (%)	No (%)	
Yes	33.5	10.3	
No	21.6	34.6	

Internal/external fixation use was significantly greater (P < .001) in patients who received an antibiotic (n = 306) than in those patients who did not receive an antibiotic (n = 249). $^aP < .001$.

biotics, 8 (1.4%)—acquired a postoperative infection, whereas 9 (1.6%) of 306 patients who received a preoperative antibiotic acquired a postoperative wound infection (Fig 1).

A post-hoc power analysis was performed and noted; given the current study sample and difference in proportions between the 2 samples, only 5% of studies would be expected to yield a significant difference thus rejecting a null hypothesis of equal proportions. Furthermore, to yield a statistically significant difference with a power of 80%, given the current difference in proportions (approximately 1%) between the 2 samples, an estimated sample size of 3452 patients would have to be recruited for each group (yielding a total sample size of 6904 patients).

A statistically significant association between preoperative antibiotic use and surgical category and internal/external fixation use (P < .001) was noted (Fig 3 and Table 1). Patients receiving preoperative antibiotics had more complicated surgical procedures (first ray, rear foot, or multiple surgical categories) and more frequent use of internal/ex-

TABLE 2 The mean and SD for surgical time, according to preoperative antibiotic use

	Preoperative Antibiotic Use			
	Yes		No	
	Mean	SD	Mean	SD
Surgical Time (min) ^a	68.1	37.9	40.7	23.2

Patients who received preoperative antibiotics had significantly (P < .001) longer surgical times than those patients who did not receive preoperative antibiotics.

 $^{a}P < .001$.

ternal fixation. A statistically significant (P < .001) longer surgical time was also noted for patients receiving preoperative antibiotics (Table 2). The 2 study groups did not differ in any of the other study factors (tournique use, age, past medical history, or gender). Additionally, all patients that received preoperative antibiotic prophylaxis and developed a postoperative wound infection, had a pathogen that was resistant to penicillin and/or its derivative. Table 3 summarizes the subject demographics.

The logistic regression analysis indicated that none of the study factors were predictive of postoperative wound infection or wound complication (P > .01). A tendency for surgical category, internal fixation use, and past medical history to be predictive of postoperative wound complication was noted (P < .05). A more complicated surgical procedure and a past medical history other than diabetes tended to increase the percentage of patients acquiring a postoperative wound complication. Yet, given this tendency for these 2 factors to predict postoperative wound complication, preoperative antibiotic use was not predictive of postoperative wound complication.

Discussion

Our findings indicate that postoperative outcome (either wound infection or complication) is not affected by preoperative antibiotic use. Of the 249 patients who did not receive preoperative antibiotics, 8 (1.4%) acquired a postoperative infection, whereas 9 (1.6%) of 306 patients who received a preoperative antibiotic acquired a postoperative wound infection (Figs 1 and 2). These findings are in agreement with other studies that have documented the lack of effectiveness of prophylactic antibiotic use in clean surgery (54–57). Despite the vast literature on postoperative wound infections, the use of preoperative antibiotics in elective surgery is still a controversial issue (58–65).

The results of our power analysis confirm the findings of our study. To note a significant difference of 1% between our 2 study groups, an extremely large sample (n = 6904) would be required. Such a large sample would most likely include most of the patients receiving elective clean foot

and ankle surgeries given the low incidence of infections in this population of patients. Because of the required sample size, we believe it unlikely that the results of our study are caused by inadequate sampling.

In our study, patients receiving preoperative antibiotics had longer and more complicated surgical procedures and more frequent use of internal fixation than those patients not receiving preoperative antibiotics (Fig 3 and Tables 1 and 2). These results could partially explain the lack of an association between preoperative antibiotic use and our postsurgical outcomes. As a result of the longer surgical times and greater use of internal or external fixation, the risk for infection or wound complication might be greater in the group of patients that received preoperative antibiotics. An argument could be posed that if these patients did not receive preoperative antibiotics a greater number of patients would have developed a post operative wound infection or complication. However, among the 223 patients with multiple surgeries (those receiving and not receiving preoperative antibiotics), preoperative antibiotic use did not affect patients who did not acquire an infection. However, patients receiving a preoperative antibiotic had a greater tendency to develop an infection than patients who did not receive a preoperative antibiotic (Fig 4). Similar findings were also noted for the 243 patients receiving internal/external fixation (Fig 5). These results tend to counter the argument that preoperative antibiotic use was protective for wound infection or complication. If preoperative antibiotics were protective, then we would expect to see a greater frequency of wound infections in the group of patients with multiple surgeries and fixation who did not receive preoperative antibiotics than those patients who did receive preoperative antibiotics.

The previously mentioned findings agree with the literature and the accepted indications for administering prophylactic antibiotics in clean surgery, including the insertion of prosthetic devices or a relative prolonged surgery time (66-68). Although surgeons have a tendency to administer preoperative antibiotics in complicated and prolonged cases, the role of antimicrobial chemoprophylaxis in clean orthopaedic surgery is yet to be determined. To date, little research exists documenting the indications for prophylactic antibiotics in clean foot and ankle surgery (40, 42–44). Older patients, systemic diseases, use of internal/external fixation, and prolonged surgical time have been cited as indications for the use of prophylactic chemotherapy. But the effectiveness of prophylactic antibiotic use for the reported indications has not been supported by data obtained from well-designed research studies.

In the present study, preoperative antibiotic use, past medical history, internal fixation use, tourniquet use, age, gender, surgical time, and surgical category were not predictive of postoperative wound infection (P > .01). However, a tendency for surgical category, internal fixation, and

TABLE 3 The mean age (years) and frequency of female and male subjects eligible for participation in the study

	-	Preoperative Antibiotic Use				
	Ye	S	No			
	Females (n = 236)	Males (n = 70)	Females (n = 193)	Males (n = 55)		
Age (±1 SD)	46.2 (±16.3)	44.3 (±17.8)	42.7 (±15.7)	48.4 (±15.5)		

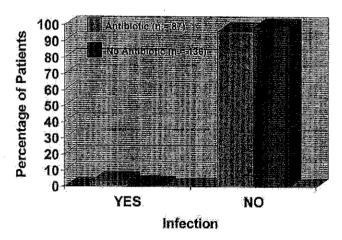


FIGURE 4 The percentage of patients having multiple surgeries, according to preoperative antibiotic use and whether or not they acquired an infection.

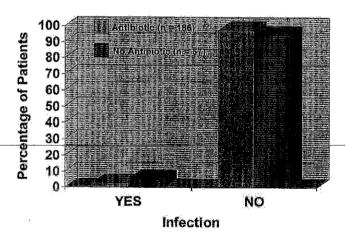


FIGURE 5 The percentage of patients having internal/external fixation, according to preoperative antibiotic use and whether or not they acquired an infection.

past medical history other than diabetes to be predictive of acquiring a wound complication was noted (P < .05). The previously mentioned findings agree with other studies that indicate that preoperative antibiotics alone will not prevent postoperative wound infections and/or complications (69–72). Hjortrup et al (69) reported that prophylactic antibiotic use in hip fracture surgery was unnecessary provided strict aseptic operating room techniques were implemented.

TABLE 4 The list of pathogens encountered in those patients who developed a postoperative wound infection

Pathogen	Frequency
Coagulase-negative Staphylococcus	
(PCNR + AMPR)	6
Coagulase-positive	_
Staphylococcus—Staphylococcus aureus	
(PCNR + AMPR)	6
Coagulase-positive	
Staphylococcus—Staphylococcus aureus	
(PCNS + AMPS)	2
Methicillin-resistant Staphylococcus aureus	1
Peptostreptococcus (PCNR)	1
Beta hemolytic Streptococus (PCNR)	1
Enterobacter cloacae (PCNR)	1
Pseudomonas auriginosa (PCNR)	1
Gram-positive cocci (PCNR)	1
Alcaligenes faecalis (PCNS)	1

Abbreviations: AMPR, ampicillin resistant; AMPS, ampicillin sensitive; PCNR, penicillin resistant; PCNS, penicillin sensitive.

Mishriki et al (70) noted that age, preoperative stay, preoperative shaving, and which surgeon performed the surgery were significantly associated with the development of a wound infection. We believe that other factor such as post-operative hematoma, tissue trauma, host resistance, nonaseptic techniques, surgical inexperience, nonsterile instruments, and a large amount of people in operating rooms (leading to increased airborne bacteria) are more important to control than the administration of preoperative antibiotics in the prevention of postoperative wound infection and its associated complications (71, 72).

The most common pathogens isolated in our study included coagulase negative and positive staphylococci (Table 4). All patients with preoperative antibiotic prophylaxis and postoperative wound infection developed a pathogen consistently resistant to penicillin and/or ampicillin. These findings agree with other studies that have noted an increase prevalence of methicillin-resistant *Staphylococcus epidermis* and vancomycin-resistant *Enterococci* in clean surgery (73–78). Mini et al (16) reported that *Staphylococcus aureus* and coagulase-negative staphylococci were responsible for 70% to 90% of wound infections in clean surgery. Several studies have also noted that the overuse of the same prophylactic antibiotic will result in a virulent pathogen that is more difficult to treat postoperatively (79–82).

Conclusion

The results of this study appear to indicate that preoperative antibiotics have no effect on the incidence of postoperative wound infections and complications. Although this retrospective study has some limitations, it is an important first step in determining the effectiveness of prophylactic antibiotic use and should help to guide future research in this area. The authors believe that a prospective study using a randomized design with a large sample size will be necessary to effectively determine what factors are associated with postoperative infection and the effectiveness of preoperative antibiotics in elective foot and ankle surgery.

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