GAVIN PUBLISHERS

Journal of Orthopedic Research and Therapy

Robinson D. J OrthopTher. J132.
DOI: 10.29011/JORT-132.000032

Research Article

The Efficacy of Prophylactic Single Dose Intravenous Antibiotics Vs. Multi Dose Intravenous/Oral Antibiotics in Elective Foot and Ankle Surgery

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Citation: Robinson D, Yassin M, Garti A, Heller E(2017) The Efficacy of Prophylactic Single Dose Intravenous Antibiotics Vs. Multi Dose Intravenous/Oral Antibiotics in Elective Foot and Ankle Surgery. J OrthopTher. J132. DOI: 10.29011/JORT-132.000032

Received Date: 11April, 2017; **Accepted Date:** 05 June, 2017; **Published Date:** 12 June, 2017

Abstract

A prospective evaluation of wound healing of 675 patients who received elective foot and ankle surgeries between 2011 and 2015 at 1 hospital clinic was performed to evaluate the effect of two prophylactic antibiotic regimens. Only those patients who were having elective foot or ankle surgery and were being followed up at the hospital's outpatient clinic, patients had a traumatic or non-traumatic cause for their surgery. The ASEPSIS classification system was used to define wound healing with a grade of more than 20 considered effective. Two hundred and twenty patients (32.6%) patients received a single dose pre-operative antibiotic and 455 (67.4%) patients received a prolonged prophylactic treatment. Of the 455 patients who received a prolonged antibiotic treatment, 444 had unimpaired healing (97.8%), 3 had impaired healing and the rest (8 patients, 1.5%) had postoperative infections.Among the single dose antibiotic group, 181 (82.7%) had normal healing, 24 (10.9%) had impaired healing and 15 (6.8%) had an infection. The intergroup difference was significant (ANOVA, $p<0.001$). The results suggest that prophylactic intravenous antibiotic use combined with post-operative treatment in routine elective foot and ankle surgery might be expected to reduce the complication rates and impaired wound healing.

Keywords: Prophylactic Antibiotics; Foot and Ankle Surgery; Wound Infections; Impaired Wound Healing

Introduction

There is a controversy regarding the appropriateness of single dose pre-operative antibiotics in foot and ankle surgery though it is well documented that skin preparation does not eliminate surgical site bacteria in most elective foot operations [1]. Some studies indicate that preoperative antibiotics have a positive effect on the prevention of postoperative wound infections in certain foot procedures [2], while other studies failed to indicate an advantage for antibiotic prophylaxis [3].A recent task force of the American College of Foot and Ankle Surgeons stopped short of clear cut recommendations regarding antibiotic prophylaxis in elective foot surgery [4], though suggesting that antibiotic prophylaxis routine prophylaxis will likely be continued at most institutions, because few complications have been reported with the practice.

Although the incidence of postoperative wound infection is low in elective orthopaedic surgery, if an infection does occur, the final outcome can lead to to unfortunate consequences. The incidence of infection rate in clean orthopaedic surgery is between 0.5% to 9.2% [5,6] depending on the author and procedure.Apparently the higher range of infection rates occur in foot surgery possibly due to operative site contamination that appears to be very common in foot surgery1. A drawback of antibiotic prophylaxis might be the generation of highly antibiotic resistant bacteria and thus routine antibiotic surgery in low infection risk patients has been questioned [7,8]. However, most foot surgeries are not low-risk as a large proportion of patients are diabetic, elderly or with some degree of circulatory deficiency. In addition, there is a sig-

nificant risk of contamination by multi-drug-resistant bacteria of surgical scrubs [7] that might indicate a risk of contamination by the medical team rather than bactermia that appears to be rare in foot surgery [9].

Materials and Methods

A prospective wound evaluation of 675 patients receiving elective foot and ankle surgeries 2011 and 2015 at a single hospital clinic was performed to evaluate the effect of two prophylactic antibiotic regimens.by one of the authors (D.R.). All patients had a preoperative evaluation by one of the foot and ankle surgeons (n = 2) 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 both surgeons who performed the preoperative evaluation.

Group Designation

The series represents a sequential series of patients operated by both surgeons and followed up in the hospital outpatient clinic. Up to May 2013 patients were treated by a single dose preoperative antibiotics.From May 2013 onward, due to a change in departmental policy, a multi-dose treatment regimen was used.Patients were excluded from the series if they had a prior history of open wounds, infection, or open fractures of the foot or ankle. All patients were followed up postoperatively at the hospital's outpatient clinic by one of the authors. Postoperative care included physical examination, wound inspection, foot radiographs on a routine basis with laboratory work-up reserved for cases of postoperative infection and/or complications.

Classification of Operative Procedure

It was assumed that closed and endoscopic surgery might be associated with less infection risk, and that longer hindfoot procedures might carry a higher risk of infection than forefoot surgeries. Thus, the 675 charts were divided into several surgical categories to include forefoot surgery with implants and without implants as well as percutaneous forefoot surgery.Mid foot surgery either open or closed and hindfoot surgery again divided between closed percutaneous approaches and open surgeries.A last category was endocopic surgery at all foot regions.Patients who had more than 1 procedure performed at the time of their surgery (eg, first metatarsal osteotomy and correction of hammertoes) were assigned according to the procedure that was of the presumed higher risk category.

Data Extraction

From the patient charts, the following data were extracted: prophylactic antibiotic use, age, gender, presence of diabetes (defined as either fasting blood glucose higher than 125 mg/dl or an A1C level of 6.5 percent or higher), and use of implants. Additionally, the ASEPSIS wound healing score [10] was available for analysis.

Surgical Technique and Follow-up Procedure

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 chlorhexidine gluconate (Septal Scrub, Teva Medical Ltd, Israel), drying with a sterile towel, and painting twice with Chlordhexidine Alcohol solution (Chlorhexidine gluconate 0.5%W/, Isopropanolol 70% V/V, Teva Medical Ltd, Israel). Preoperative prophylactic intravenous antibiotics were administered 30-60 minutes before skin-cut for all patients.

Cefazolin sodium 1 gram (Cefamezin 1 gram, Teva Medical Ltd. Israel) was administered for all patients without a known allergy to penicillin.In 67 patients with previous history of penicillin allergy, clindamicin300 mg IV (Dalacin-C, Teva Medical Ltd., Israel) was administered.Post-operative treatment depended on time of discharge and known penicillin allergies.Routine postoperative treatment included intravenous cefazolin sodium 1 gram (Cefamezin 1 gram, Teva Medical Ltd. Israel), every eight hours for 24 hours for patients hospitalized overnight (128 patients) followed by amoxicillin trihydrate 875 mg / potasium clavulanic acid 125 mg (Smithkline Beecham Plc, UK) twice a day for one week. Patients who were same-day discharged were treated by oral augmentin alone. Penicillin-allergic patients were treated by oral clindamycin 600 mg twice a day for one week.

Postoperative follow-up was performed at the outpatient clinic at one week post-operative, two weeks post-operative and six weeks postoperative. The ASEPSIS score was graded at every visit and the worse score recorded was used in the current analysis (Figure 1).

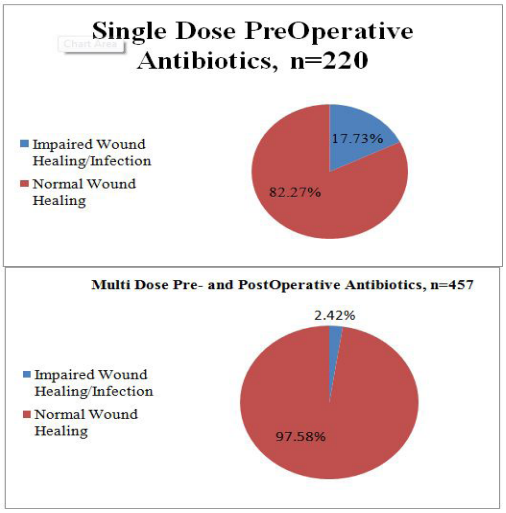

Figure 1: The percentage of patients acquiring a wound infection by type of antibiotic regimen used.Note the percentage of patients having impairedwound healing or having an infection was significantly higher in the single dose preoperative antibiotic group than in the prolonged multidose antibiotic treatment group.

Data Analysis

The data obtained from the clinical follow-up and chart reviews of each patient were grouped according to whether or notsingle dose preoperative antibiotics were administered or a combination of preoperative antibiotics and postoperative treatment. 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, genderor the presence of diabetes. Additionally, chi-square tests of association were performed to determine if the antibiotic regimen used was associated with any of the study factors (gender, metal fixation use, surgical category, presence of diabetes).All statistical testing was conducted by using the Analyze-it software package (version 2.30, Excel 12+).

Results

A total of 675 charts were reviewed; Two hundred and twenty patients (32.6%) patients received a single dose preoperative antibiotic until a change in departmental policy took place.Since then 455 (67.4%) patients received a prolonged multidoseprophylactic treatment (Table 1).

Parameter	Single Pre-Operative Dose	Multiple Post-Operative Treatment
Number of Subjects	220	455
Females	131 (39.6%)	275 (60.4%)
Males	89 (40.4%)	180 (59.5%)
Age Average ±SD (Range)	41±19 (18-92)	44±22 (18-89)
Diabetes	65 (29.5%)	141 (31%)
Procedure Classification		
Forefoot Percutaneous	20 (9%)	67 (15%)
Forefoot with Implants	66 (30%)	107 (24%)
Forefoot Open No Implants	46 (21%)	46 (10%)
Mid Foot Open	11 (5%)	24 (5%)
Mid Foot Closed	0	12 (3%)
Hindfoot Open	24 (11%)	95 (21%)
Hindfoot Closed	7 (3%)	21 (5%)
Arthroscopic	46 (21%)	83 (18%)

Table 1: Patient Demographics

The distribution of the type of the procedures was not similar in both groups (Kruskal-Wallis test, chi-square 5.68, p<0.02) with more open forefoot procedures without implants in the single antibiotic group and more open hindfoot procedures in the multiple antibiotic group (Table 1). Administration of single dose antibiotic was associated with higher impaired healing rates in patients with implants as well as in patients without implants as compared to multiple dose antibiotic treatement (Kruskal-Wallis' statistic 108.8, p<0.001).ASEPSIS score was significantly higher in the single dose preoperative antibiotics group (5.4±9.2) versus the multiple dose antibiotic treatment group (0.83±3.7). Of the 455 patients who received a prolonged antibiotic treatment, 444 had unimpaired healing (97.8%), 3 had impaired healing and the rest (8 patients, 1.5%) had postoperative infections.Among the single dose antibiotic group, 181 (82.7%) had normal healing, 24 (10.9%) had impaired healing and 15 (6.8%) had an infection (Table 2) (Figure 2).

Healing Grading	ASEPSIS Score	Antibiotic treatment	No Antibiotic Treatment
satisfactory healing	0-10	444	181
impaired healing	11-20	3	24
mild wound infection	21-30	8	6
moderate wound infection	31-40	0	6
severe wound infection	>40	0	3
Total		**455**	**220**

Table 2: Healing of Surgical Incisions by Type of Antibiotic Treatment

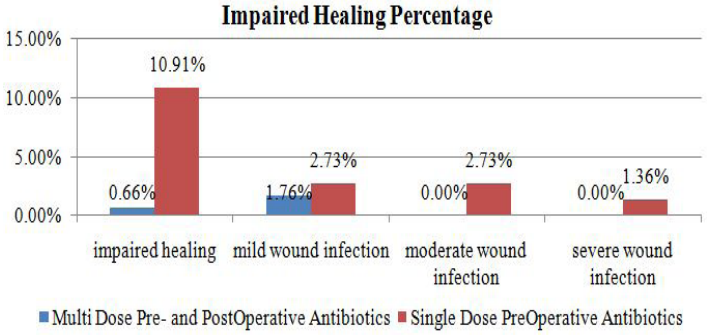

Figure 2: Distribution of ASEPSIS wound score by type of antibiotic regimen used.It appears that the major groups that are improved by the prolonged antibiotic treatment regimen are the impaired wound healing group as well as the moderate to severe infection groups

The overall intergroup difference was significant (ANOVA, p<0.001).Most intergroup difference was in the impaired healing group.

Preoperative single dose antibiotic use was associated (P <0.01) with postoperative impaired wound healing and infection in a post-hoc analysis of the entire cohort.Diabetic patients in the single antibiotic dose group had a significantly worse ASEPSIS score (8.4±12.6) than non-diabetic patients (4.2±6.9, ANOVA, F-Statistic 37.7, p<0.001), but ASEPSIS scores were similar in the multiple antibiotic dose group (Table 3).

ASEPSIS SCORE by diabetes and antibiotics	n	Mean	SE	Pooled SE	SD
single & no diabetes	155	4.2	0.56	0.48	6.9
single & diabetes	65	8.4	1.59	0.74	12.8
multiple & no diabetes	314	0.5	0.15	0.34	2.7
multiple & diabetes	141	1.6	0.45	0.50	5.3
Source of variation	Sum squares	DF	Mean square	F statistic	p
diabetes and antibiotics	4041.2	3	1347.1	37.68	<0.0001
Residual	23987.5	671	35.7		
Total	28028.6	674			
Tukey					
Contrast	Difference	95% CI			
single & no diabetes v single & diabetes	-4.2	-6.5	to -1.9	(significant)	
single & no diabetes v multiple & no diabetes	3.7	2.2	to 5.2	(significant)	
single & no diabetes v multiple & diabetes	2.6	0.8	to 4.4	(significant)	
single & diabetes v multiple & no diabetes	7.9	5.8	to 10.0	(significant)	
Single&diabetes v multiple &diabetes	6.8	4.5	to 9.1	(significant)	
multiple & no diabetes v multiple & diabetes	-1.1	-2.7	to 0.5		

Table 3: The effect on antibiotic regimen on the ASEPSIS score by presence of diabetes.

Use of implants was not associated with increased rates of impaired wound healing (2.0±6.1) as compared to operations without implants use (2.3±6.7, ANOVA F-statistic 1.82, p>0.17).

Discussion

This study results seem to indicate that the type of antibiotic prophylaxis affects the frequency of impaired wound healing and infection in clean foot and ankle surgery.This study is unique in the approach of treating the supposedly clean surgical patient as potentially infected and treating the patient pre-incision and for a week after operation.The concept is due to the relatively high frequency of infection and impaired wound healing in clean foot surgery [6]. Traditionally, studies investigating antibiotic prophylaxis in foot and ankle surgery compared frequency of infection between groups with and without antibiotic prophylaxis [11] and failed to show a clear-cut advantage. Other studies have not shown an advantage of one antibiotic over the other [12]. However, these studies have not used the ASEPSIS score [10] as an endpoint. The advantage of this score is that it is sensitive enough to define a group with impaired wound healing and allows diagnosis of three times as many clinically infected wounds as evaluations based on the presence of pus alone [13]. In additions, the ASEPSIS score appears to correlate quite well with the definitions of the Center for Disease Control [14]. A few studies have looked at multidose versus single dose treatment especially in trauma settings and seem to indicate that a single dose is equivalent to multidose therapy in open tibial fractures [15]. The population treated in the current study is very different than the one treated by the open tibial fracture study. The definition of infection in the Patzakis study was presence of fever, erythema, wound discharge and positive wound culture [16]. This definition would exclude many cases of impaired wound healing as defined by the ASEPSIS criteria and tend to underestimate the frequency of impaired wound healing.On the one hand the risk of infection is apparently higher as that was a group of open tibia fractures, but on the other hand the patients were younger (average age 33 years in the cephalosporin group). Another major difference in the treated population of the current study is the high prevalence of diabetes, while the Patzakis study does not mention the frequency of diabetes in their population, the prevalence in the current study population is very high and the advantage of the multidose therapy appears to be in reducing the rate of impaired wound healing subjects with ASEPSIS scores of 10 to 20 and reducing the excess risk of infection in diabetic patients.Thus, it is possible that the results in open tibial fractures do not reflect the optimal treatment regimen in elective foot and ankle surgery.

Conclusion

It appears reasonable to conclude that due to the high risk of skin contamination in foot and ankle surgery even after surgical skin preparation reported to vary between 79 and 38% depending on exact protocol, the surgery should be considered clean-contaminated and wound healing and infection rates can be reduced by prophylactic administration of a one week long multidose antibiotic treatment. The study reported above represents a sequential series of patients operated by the same surgical team and using the same protocol.A weakness of the study is the lack of randomiza-

tion of the study cohorts, making it impossible to rule out changes over time in surgical techniques or patient propensity for impaired wound healing.

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