CHAPTER **19**

# PROPHYLACTIC ANTIBIOTICS IN CLEAN FOREFOOT SURGERY: Are They Necessary?

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## INTRODUCTION

Prophylaxis in surgery is defined as use of anti-microbial agents prior to surgery in the hopes of preventing infectious complications. These may include wound infection, peritonitis, broncho-pulmonary infection, meningitis, etc.[1-46] Chodak et al define prophylaxis as preventive use of antibiotics where contamination might occur but is not yet present.[12] The use of antibiotics on a prophylactic basis has been a topic of controversy for many years. Central to the controversy on this subject is a disagreement on the indications for antibiotic use. This article will look at the use of prophylactic antibiotics for elective clean forefoot surgery.

It is estimated that 30 to 50% of all antibiotics administered in the United States are intended to prevent rather than treat an established infection.[8,13,15] The so called "clean surgeries" account for approximately 70% of all surgical cases and carry an associated infection rate of less than 5%. In many hospitals, implementation of modern operating room techniques have lowered this figure to below 2%.[13] A prevalence study of antibiotic administration at Duke University Medical Center revealed that 45% of surgical patients received antibiotics during their hospital stay. Of the antimicrobials administered to these patients, 64% were judged either not indicated or inappropriate. Another report had revealed that up to one third of all hospitalized patients on antimicrobial therapy received them without adequate indications or without documentations of bacteriologic appropriateness.[7] Are we overusing prophylactic antibiotics?

Burke was the first to demonstrate the importance of prophylactic antibiosis in 1961 by inoculating skin and experimental incision lesions with Staphylococcus aureus. He found that the best suppression of infection occurred when the antibiotic was administered before bacteria gained entrance into the tissue.[2] Since Burke's article in 1961 many review article have appeared in the literature expounding the virtues of prophylactic antibiosis. Pavel et al in 1974 performed a study of 1,591 clean orthopedic procedures where they study prophylaxis of clean orthopedic procedures. The group of patients that received antibiotics had an infection rate of 2.8% compared with a 5% infection rate in the group that did not. They strongly advocate prophylactic antibiotics.[1] Haye and Rimold stated that the greatest advance in surgical technique in the last twenty years was the development of infection protection. During this time, the most significant improvement in combating infection has been the development of new antibiotics in the perioperative period.[10] However, more recent literature questions the use of prophylactic antibiotics.[3,5,7,24-25]

When selecting an antibiotic for surgical prophylaxis, the type of surgery, current hospital sensitivity-resistant patterns, and the risk of adverse reaction should be considered. The antibiotic chosen should be on the basis of efficacy against the most likely organism to be encountered. In most orthopedic cases the most likely organism encountered are skin flora organisms, Staphylococcus epidermis and Staphylococcus aureus.[18] Therefore, the most commonly used antibiotic in orthopedic cases is cefazolin (Ancef), and other first generation cephalosporins. These are effective against Staphylococcus species, relatively non-toxic, and inexpensive.[3,4,8-16]

There are many reasons one would want to give antibiotics perioperatively. Preventing an infection is the ultimate goal. With infection comes delay in recovery time, increase suffering, increase cost for patient and hospital, and increasing use of the resources at the hospital. Postsurgical infections

are the second most common nosocomial infection. Infection can lead to amputation, loss of function of that limb, and even death. These are all good reasons to give antibiotics peri-operatively if doing so is effective. A great deal of literature suggests that patients that are immunocompromised, have mitral valve prolapse, are elderly, or have multiple medical problems that make them a greater risk for developing infections should be given prophylactic antibiotics. Prolonged surgery time, use of significant implants or hardware, significant trauma, and patients with dirty or contaminated wounds are also indications for prophylaxis.[1-46]

Many surgeons believe that these antibiotics are benign drugs and may get into the routine of giving antibiotics to all of their patients. Others feel that the routine use of prophylaxis will protect them from lawsuits in case a subsequent infection develops. With wholesale use of these antibiotics there is an increase risk of an anaphylaxic attack or other side effects. Gastrointestinal complications are a concern with C. difficle, diarrhea, nausea, and vomiting.[3-46] One of the greatest concerns is the continuing emergence of resistant organisms and the possibility of superinfections with. wholesale use of prophylactic antibiotics. Recent studies show that patients are becoming infected with more resistant bacteria. With this increase in resistance comes increase need for more toxic antibiotic agents.[14] This concern is voiced frequently and data suggests that prolonged perioperative prophylaxis can alter the anti-microbial susceptibilities of infecting pathogens.

Infection rates may be so low in clean surgeries that the use if prophylaxis may be more risky than not using it. For instance if there is a suspicion of a postoperative infection, when no prophylaxis was given, cephalexin or cefazolin can be given. But if these antibiotics were given prophylactically, a more toxic less benign antibiotic will be required. In some settings the risk of infection is already so low that the cost of prophylaxis may be far more than the cost of treating an occasional infection. Thus, if there is no statistical difference in the infection rates in elective clean forefoot surgery in healthy patients with and without prophylaxis, there would be strong evidence to avoid the use of prophylaxis in these patients.

## MATERIAL AND METHODS

A retrospective and prospective review of 256 patients undergoing elective clean forefoot surgery between August 2002 to December 2003 was conducted. Five of the podiatric attending physicians at Scripps Mercy Hospital participated in the study. The surgeries were performed at Scipps Mercy Hospital and at San Diego Outpatient Surgical Center.

Clean forefoot surgery included surgeries distal to Choparts joint in this study such as various bunionectomies, hallux limitus sugeries, first metatarsal cuneiform fusion, lesser metatarsal tarsal fusions, hammer toe arthroplasties and arthrodeses, metatarsal lengthenings and osteotomies, metatarsophalangeal joint repair, neuroma surgery, hallux interphalangeal fusion, and soft tissue mass removal. Patients were evaluated for the incidence of post-operative infection following these types of procedures for a period of three months. Patients were divided into two categories those who received prophylactic antibiotics (group A) and those who did not receive any prophylactic antibiosis (group N). The decision to administer antibiotics preoperatively and choice of antibiotics was solely the responsibility of the attending physician. All patients were evaluated postoperatively by the attending physician at their private practice.

Exclusion criteria for the study were patients with obvious infection present, open fractures, history of prior ulcer, and case involving the rearfoot. Patients were analyzed in the following categories: age, sex, ASA status, length of surgery, number of procedures, hardware implanted, method of homeostasis, infections and bacteria causing infections. This information was extracted from the charts and reviewed.

## DEFINITIONS

*Infection.* The Centers for Disease Control and Prevention has developed standardized criteria for defining surgical site infections that have become national standard and are widely used by surgical personnel. These criteria define surgical site infections as infections related to the operative procedure that occur at or near the surgical incision within 30 days of an operative procedure. For this study we will follow patient postoperatively for 3 months. The clinical criteria used to define a surgical site infection for our study include:[27]

A purulent exudate draining from a surgical site that is culture positive
A positive fluid culture obtained from a surgical site that was primarily closed
The surgeon's diagnosis of infection with documented bacterial culture
A surgical site that requires reopening

*Clean wound.* Surgical wounds that have been made into tissue in which no inflammation is encountered, patient is without history of ulcer, nor are the respiratory, alimentary, or genitourinary tracts are entered. The wound was also closed primarily and there was no break in the sterile field during surgery. The surgery is not the cause of a traumatic event.[11]

*Postoperative antibiotics.* Patients may be given postoperative antibiotics by the attending physician but may still not deemed an infected wound. For the purpose of the study the guidelines stated above for an infection will be adhered to strictly. Patients may have increased erythema and edema may be placed on antibiotics, but an infection still may not be present. This data will be recorded and noted for the study.

## RESULTS

A total of 256 surgeries were reviewed for this study; 188 (73%) patients did not receive a preoperative antibiotic and 68 (27%) did receive a preoperative antibiotic. Of these 256 patients 4 (1.56%) patients had a documented infection. Three of the documented infections were Staphyloccocus aureus, the other one was Staphyloccocus epidermis. None of the 68 patients that received prophylactic antibiotics had a documented infection. four of the 188 patients that did not receive prophylactic antibiotics (2.1%) acquired a documented postoperative infection. Of the 68 surgeries that did not receive preoperative antibiotics the physicians felt that on 11 occasions (16%) that they should be given antibiotics postoperatively. In the group that did not receive prophylactic antibiotics 4 had documented infections and 16 additional patients received antibiotics postoperatively for a total of 20 of the 188 (10.6%).

The patients that received prophylactic antibiotics (group A) were 68 of the 256 patients enrolled into the study. Ancef was given to 64 of the 68 patients as the antibiotic, three received clindamycin, 1 received ciprofloxacin. None of the 68 patients had a documented infection, but 11 of the 68 (16%) had postoperative antibiotics. Soft tissue procedures were done 16% of the time (11/68). Bone work was done 84% of the time (57/68) and hardware was placed in 50/68 (74%) surgeries.

Group N is comprised of the patients that did not receive prophylactic antibiotics. Of the 256 enrolled into the study 188 patients were in this group (73%). Twenty of the 188 received antibiotics postoperatively (10.6%) with four of these becoming documented infection for 2.1%. A total of 38 out of the 188 (20%) were soft tissue procedures with 1 documented infection in this group (2.6%). Some form of bone work was done in 150 of the 188 cases with 3 documented infections for a 2% infection rate. Finally 92 of 188 involved hardware placement with 3 infections in that group for a rate of 3.3%.

If we take a look at the four patients that got infected we come up with the following data. None of patients that got infected received prophylactic antibiotics. All were in group N. All four infections were staph infections (three of them were Staphyoloccocus aureus and one was Staphyoloccocus epidermis) None of these infections were with bacteria resistant to first generation cephalosporin. Three required another surgery and IV antibiotics to resolve the infection. The fourth patient was given oral cephalexin (Keflex) and resolved without any further intervention. Three of the four surgeries involved hardware placement. Prolonged surgery was a risk factor for infection. In this study, all four infections were surgeries that took less than 100 minutes. Patients with severe systemic disease or immunocompromised patients are also at high risk for infection. In this study all four patients were ASA status of 2 or less and had ages of 33, 39, 43 and 76. The 76-year-old patient was the patient that resolved on a course of Keflex and did not require any further surgery. The four infected patients had the following surgeries: Austin bunionectomy, 2nd digit proximal interphalageal fusion with 5th metatarsal head resection, hallux interphalangeal fusion and 3rd-4th proximal interphalageal fusion, and tibial sesamoid excision.

## DISCUSSION

The data from our study may not answer the question about use of preoperative antibiotics. Of the 256 patients in the study four of them had a documented infection. All four were in group N (no prophylactic antibiotics). There was a strong bias for group N, of the 256 patients 188 were included in group N. Of the 188, (group N), 4 had documented infection (2.1%) which is the national average for infection. Whereas, the 68 patients that did receive prophylactic antibiotics (group A) none of them got infected. But the use of postoperative antibiotics was higher in group A, 11 (16%) of the surgeries compared with group N 20 (10%). The controversy continues as to the use of prophylactic antibiotic. Certain surgical procedures carry a higher risk of infection because of the nature and location. Most agreement regarding prophylaxis exists in the area of prosthetic implantation of the heart, and vascular tree, and surgery of the urinary tract. Also, there is no controversy when a patient has an open fracture, pre-existing infection, or catastrophic results would occur from an infection. But the controversy persists when the surgeon is performing a clean procedure. The data from this study may not answer the question with only 256 patients involved and a bias for patients not receiving antibiotics, 188 to 68 in group A.

It is important to look at the data from this study to see if age, pre-existing illnesses or ASA status, hardware placement, and surgical time influence the use of antibiotics or cause infections. Some studies have indicated that the older a patient gets, they are more likely to get infected. In our study there were 4 patients over the age of 81, 3 out of the 4 patients were in group A, none of them got infected. The 61-80 age group included 74 patients (34%), 53 of them didn't receive antibiotics (group N). Of this age group only one documented infection resuted and 50% of the patients were in the 41-60 age group. The age of the infected patients were 33, 39, 43, 76. The 76- year-old patient was the patient that resolved on a 10 day course of Keflex without any need for surgery. The conclusion we can draw is that there is no correlation between infection and increased age of patients and surgeons in our group are not likely to give prophylactic antibiotics with increase age until they are over the age of 81.

It is well documented that the longer the surgery the more likely the patient is going to get infected. It only makes sense that the longer the tissue is exposed to the open environment the more likely that an infection will occur. The data from this study does not support this idea that prolonged surgery is prediction for infection. Of the four infections the longest surgery was 100 minutes, and 32 surgeries lasted between 2-3 hours with no infections and only seven were in group A. There was no correlation between infection and length of surgery in this study.

Systemically sick patients or immunocompromised patients have historically deemed at high risk for infection. For this study, ASA status was used to assess patients overall health status. Did the higher the ASA status increase the risk of infection or the likelihood of get prophylactic antibiotics. All four of the documented infections had an ASA status of 2 or less. In group A 13 out of the 68 patients had an ASA status of 3 or higher (19%), where as the patients in group N 13 out of the 188 had ASA status of 3 or higher (7%). There was no correlation between higher ASA status or systemic disease and infection in this study, but physicians were more inclined to use prophylactic antibiotics in patients with ASA status 3 or higher.

There is strong support throughout the literature that when placing hardware in orthopedic surgery prophylactic antibiotic is indicated. There should be a distinction when defining hardware. There is a major difference between replacing a total knee joint and a screw for fixation of a bunion. For this study the following were considered hardware placement: screws, plates, Mitek anchors, stainless steel wire, absorbable pins or screws, and Kirschner wires. Sutures were not considered hardware unless steel was used. 142 of the 256 patients had some form of hardware placed during surgery. Three of the 142 had a documented infection for 2.1%. Group N comprised 92 of the 142 patients with all 3 infections coming from group N for 3.3% slightly higher than the gold standard of 2%. Is this an indication for prophylaxis if hardware is being placed in clean forefoot surgery?

There are many reasons to use prophylactic antibiotics with the consequences of infection being disastrous and expensive. But the overall consensus is that if antibiotics are going to be used peri-operatively they should be used effectively and timely. Burke in his classic studies evaluated prophylaxis and found that the greatest benefit

achieved by antibiotic prophylaxis occurs when the agent is present in adequate concentrations at the surgical site at the time of incisions. This is stated as the "decisive period" where in the size of the lesion is a determined and antibiotic level are high enough in the skin to inhibit infection.[2] The effective use of prophylactic antibiotic depends to great extent on the appropriate timing of their administration. Intravenous antibiotics in sufficient doses generally should be given within 1 hour before operation Fortman et al advocated 30 minutes prior to the tourniquet inflation.[33] Deacon et al did a study where they infused 1 gram Ancef 1 hour before inflation of tourniquet for bunion surgery. They then measured the antibiotic levels in the medial eminence of the metatarsal head that was removed. They found that the ancef levels were sufficient enough to be susceptible to the bacteria Staphylococcus Aureus. Through literature search there is no clear cut time when to administer prophylactic antibiotics although the prevailing idea is at least 20-30 minutes prior to incision or inflation of tourniquet.[4]

Another controversy is the duration of prophylactic therapy when used. The prevailing idea currently is less is better. Many studies are now suggesting single dose or 24-hour therapy.[3,8] Investigations of current surgical practice have repeatedly revealed a widespread misuse of antibiotics in the postoperative period. Continuation of an antibiotic regimen begun preoperatively through the third or even fifth postoperative day is unfortunately common. This occurs despite numerous reports documenting that routine prolongation of prophylaxis beyond the first postoperative day provides no additional benefit. In a recent article by Barie, the title of the article states the prevailing idea about antibiotic usage Modern Surgical Antibiotic Prophylaxis and Therapy – Less Is More.[3]

Many authors believe that there is no place for antibiotic prophylaxis in clean surgical operations.[1,5,24,25] They feel that the benefit of prophylaxis doesn't out way the risks. Knight et al states that prophylactic antibiotics are not indicated in clean general surgery cases with no statistical significant decrease in infection rate regardless of the patient past medical history and surgery performed.[5] Given the oft quoted infection rate of less than 2 percent following clean elective surgery, studies have to be fairly large to detect any significant differences in this low rate. For this reason little reliable work has been done in the area of surgical prophylaxis for podiatric procedures

Two articles in the literature discuss clean foot and ankle surgery and prophylactic antibiotics. Miller in 1983 in Foot and Ankle International gathered 20 years of information and 1841 cases of clean foot and ankle surgeries without prophylactic antibiotics. Infections occurred in 41 of those cases (infection rate of 2.2%). Thirty-seven healed without any further surgery. Three required further surgery and healed without complication. 1 patient developed permanent damage of ankle joint narrowing.[24]

Zgonis et al in a recent article had 555 patients that underwent clean foot and ankle surgery. A total of 306 patients received prophylactic antibiotics with 9 getting infected for 1.6%. Of the 249 patients that were without prophylactic antibiotics, 8 of them became infected for 1.4% infection rate. These two articles strengthen the argument against giving prophylactic antibiotics in clean forefoot surgery.[25]

## CONCLUSION

The results of this study have some limitations as there was a 3 to 1 ration of patients not getting prophylactic antibiotics. There were only 256 patients in the study. The results indicate that using prophylactic antibiotics doesn't lower the rate of infection. Although all four infections came from group N, the infection rate was at the gold standard of 2% (4/188 – 2.1%). Furthermore, the use of postoperative antibiotics was higher in group A (16%) than group N (10.6%). Remember, that a more significant (toxic) antibiotic would logically be required if the more benign antibiotic was used prophylactally. The only concern from the study may be that prophylactic antibiotics may be indicated when using hardware. (3/92 – 3.3%) However, this was not statistically significant due to low number of patients in this study. A larger study with more even distribution of patients may give a better indication of whether antibiotics are indicated in clean forefoot surgery. Ultimately it is important for us as foot and ankle surgeons to realize the indications and implications of using prophylactic antibiotics, to use them wisely. and not to just use them routinely.

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