

Original Research Article

The Best Time to Prescribe Prophylactic Antibiotics before Spinal Anesthesia in Foot and Ankle Surgery and Its Effects on Hemodynamic Status during Anesthesia

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ABSTRACT

This study set out to determine the impact of a single dose of antibiotic prophylaxis on the incidence of SSIs following Foot and Ankle Surgery, which have the highest infection rate. The study looked at whether or not removing a Foot and Ankle Surgery in the lower leg would result in a lower rate of surgical site infections (SSIs) after a single prophylactic antibiotic dose. Patients undergoing removal of orthopedic implants to treat fractures below the knee were enrolled in the multicenter, double-blind, randomized Wound Infections Following Implant Removal trial. The trial was conducted in 17 teaching hospitals and 2 academic hospitals.

Cefazolin sensitivity was found in 14 microorganisms (74%) while it was absent in 5 (26%) of the microorganisms. No growth was found in the culture swabs taken from 2.7% of patients, and in 45.5% of patients with an SSI diagnosis, no culture swabs were taken. The identified microorganisms were cefazolin sensitive in 87.2% of the cases.

One intravenous dose of cefazolin given prior to surgery among patients having Foot and Ankle Surgery did not lower the risk of surgical site infection within 30 days of surgery.

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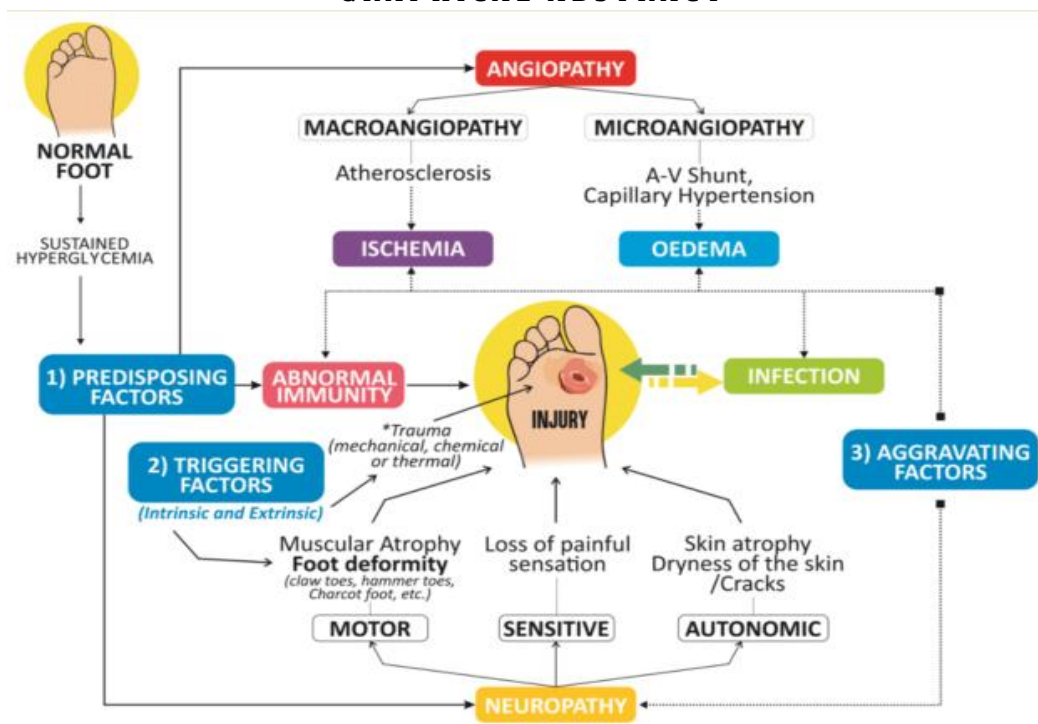
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GRAPHICAL ABSTRACT



1. INTRODUCTION

Surgical wound infection or SSIs is a common infection among patients with a history of various types of surgery. A surgical wound is a wound created in the surgical site by the surgeon. The surgical site is a place on the patient's body where the surgeon makes an incision to perform the surgery. Despite the many precautions and protocols done to prevent infection at the surgical site because it causes a break in the skin and loss of its integrity, there is still a 1 to 3% chance that a person will get this infection. If the surgery is without an implant, this usually happens in the first 30 days after the surgery, and if the implant is placed, the person will get this infection even up to a year after the surgery. Each year, surgical morbidity and mortality are significantly impacted by surgical site infection, which is an infection at or near surgical incisions within 30 days of an operation [1].

Many microorganisms live in or on our bodies or in our environment. Most of these microbes are harmless; few of them are even useful, for instance, the microbes in the gut help digest food and protect the body against harmful microorganisms. Human skin is a natural barrier against harmful microorganisms.

Spinal anesthesia is one of the methods of anesthesia in the operating room. Spinal anesthesia, like any other procedure, may be associated with side effects and problems. These problems can include headache, nausea and vomiting, low blood pressure, breathing disorder, and even infection caused by the anesthetics injection. The majority of nosocomial infections among surgical patients are surgical site infections (SSI), which make up 15% of all nosocomial infections. Postsurgical infection results in a lengthened hospital stay following surgery, dramatically increased costs, higher rates of hospital readmission, and compromised

health outcomes [2]. Creating resistance in microorganisms to antibiotics is one of the serious problems in the field of infectious medicine, the main cause of which is the inappropriate prescription of antibiotics by doctors [3]. According to a study, the excessive use of antibiotics in the United States imposes an additional cost of seven billion dollars on the healthcare system, and the control of resistant infections that have arisen involves an additional cost of four billion dollars [4]. The resistance of microorganisms to antibiotics causes the creation of resistance strains [5]. Infection is the most common complication of surgeries and surgical site infection is one of the most important causes of death and disability [6]. Antibiotics are drugs that treat infections caused by bacteria. Penicillin was the first antibiotic to become widely available in the 1940s. Before the discovery of antibiotics, infections such as pneumonia and tuberculosis were the leading causes of death in the United States.

Fortunately, we now have antibiotics as a treatment for these diseases. However, we should remember some tips to use them safely because these anti-infections can pose serious risks to you and thousands of other people who rely on them every day. The use of antibiotics to prevent infection of the surgical site is perfectly effective, provided that its principles and rules are followed, and this issue has been proven in various studies [7]. For proper prevention with antibiotics, the following points should be kept in mind: the necessity of prevention, type of antibiotic, appropriate dose, time to start its administration, route, duration of antibiotic use, and compliance with the time intervals of administration [8-10].

Gram-negative and gram-positive bacteria, including *Escherichia coli*, *Enterococcus*, and, sporadically, anaerobes like *Bacillus fragilis*, can enter hollow viscera and cause damage to the tissue there. Yeast species and viral pathogens are additional dangers [11-13]. Some people

recommend giving antibiotic prophylaxis prior to removing orthopedic implants because of the high SSI rates [14-16].

If the preventive prescription of antibiotics is not done according to the correct principles, several complications such as the loss of the body's natural microbial flora, the accumulation of more infections, the growth of antibiotic-resistant bacteria, and the creation of infections with these bacteria), increasing the risk of drug poisoning and increasing unnecessary costs will be created [17].

In general, unnecessary use of antibiotics (especially long-term use) does not benefit the patient in the best case, and is, in the worst case, completely dangerous [18]. Many researches have been conducted in the world, the results of which show that the use of antibiotics for the purpose of prophylaxis in surgery is not a favorable situation. For example, in France in 2000, only 41.7% of surgical patients had used antibiotics correctly [19]. In the same year, another study in France reported a 53% compliance with preventive antibiotic prescribing guidelines [20]. In India, the percentage of compliance with the guidelines was 51% in first-level hospitals and 64% in third-level hospitals [21]. In Italy, during a retrospective study in a 2,000-bed teaching hospital, it was found that antibiotics were used incorrectly in 63% of appendicitis surgeries and 75% of gallbladder surgeries [22]. In a Brazilian teaching hospital, compliance with national guidelines was observed at a very low level of 3%. On the other hand, in another study in the United States, this was not done in the cases of the need to prescribe antibiotics [23]. In 1990, the percentage of global sales of antibiotics was 12% of all drugs, and this index was 19% in developing countries. It was reported and it increased to 34% in 2000 that an amount of 40 billion dollars was spent on antibiotic treatment and about a third of this amount was spent by developing countries [24].

The occurrence and spread of infection with resistant strains of microbes such as *Staphylococcus aureus*, *Enterococcus*, *Enterobacteriaceae*, and *Pneumococcus* are all caused by the incorrect use of antibiotics in recent decades [25-27]. Antibiotics may be used to treat bacterial infections. These infections are diseases that:

- (1) They cannot be treated without antibiotics.
- (2) It can infect others.
- (3) If they are not treated, they remain in the body for a long time.
- (4) They have more serious complications [28].

Almost everyone knows that antibiotics or pus dryers are prescribed to eliminate the infection. First, it is necessary to make sure whether there is any infection in the body that requires antibiotics or not.

The diagnosis of this issue should be made by a doctor and ordinary people are not able to do this [29]. On the other hand, any type of antibiotic cannot eliminate all infections, so it should be initially determined that the cause of the disease is fungus, bacteria, parasites, or viruses. In general, antibiotics are not effective for treating colds and flu with a viral cause and using them will not make you better. It is recommended to let these types of viral diseases pass their course for 2 weeks and then see a doctor if there is no improvement. This study aimed to determine the impact of a single dose of antibiotic prophylaxis on the SSIs incidence following foot and ankle surgery which have the highest infection rate [30]. According to the mentioned materials, the present study was conducted with the aim of the best time to prescribe prophylactic antibiotics before spinal anesthesia in foot and ankle surgery and its effects on hemodynamic status during anesthesia.

2. EXPERIMENTAL

2-1-Materials and Methods

The current study was conducted as a randomized clinical trial with two parallel groups during the period of 2016 in Shohada and Imam Reza hospitals of Tabriz University of Medical Sciences. Patients undergoing removal of orthopedic implants to treat fractures below the knee were enrolled in the multicenter, double-blind, randomized wound infections following implant removal trial. The trial was conducted in 17 teaching hospitals and 2 academic hospitals.

2-2-Preparation before spinal anesthesia

For spinal anesthesia, a series of protocols and instructions must be followed. The first thing is to stop eating and drinking before the operation. Usually, depending on the type of operation for spinal anesthesia, patients are told to fast for 10 to 12 hours the night before and not to eat or drink. If you drink alcohol and smoke, you should avoid them the night before and the day of the operation.

2-3-Complications of spinal anesthesia

Spinal anesthesia may cause side effects that are temporary and will be resolved by following a series of prevention tips or simple treatments. Complications of back anesthesia include the following:

- ❖ Lower blood pressure,
- ❖ Headache,
- ❖ Dizziness,
- ❖ Nausea,
- ❖ Urinary retention, and
- ❖ Decreased heart rate.

2-4-Outcomes

It mainly includes mild gastrointestinal discomfort, nausea, diarrhea, or loose stools. Some antibiotics may cause sensitivity to sunlight. Call your doctor if you have the following side effects:

- ❖ Vomiting, severe watery diarrhea, severe abdominal pain, white plaques on the tongue, vaginal discharge, or itching (female genital area).

❖ 2-5-Allergic reactions

Some people are allergic to some groups of antibiotics (mainly penicillin group), in this case the doctor will not prescribe antibiotics of that group if he knows. Allergy symptoms include small red rashes, itching, hives, swelling of the lips, face, and tongue, and more severe cases such as difficulty in breathing and low blood pressure. In women, in addition to the above mentioned symptoms, the following points should be noted:

- ❖ Taking antibiotics may lead to fungal infection of the vagina, the reason for this is that as a result of taking these drugs, the usual bacteria that live in the vagina are killed, and thus the fungus grows rapidly. Symptoms include one or more of these conditions: itching, burning, pain during intercourse, and vaginal discharge

(1) Antibiotics may reduce the effectiveness of oral contraceptive pills, it may be necessary to use other contraceptive methods during the course of antibiotic treatment, in which case you should consult a pharmacist or doctor.

(2) In pregnant women, some antibiotics can cross the placenta and harm the fetus.

A case report form was used to record any SSI symptoms, such as warmth, redness, pain, swelling, wound dehiscence, purulent drainage, or a temperature greater than 38 °C. In the event that they noticed any symptoms of SSI, patients were advised to visit the emergency room or outpatient clinic as soon as possible. In the case of SSI, the proper treatment was started in accordance with local regulations.

2-6-Why do antibiotics have an hourly usage?

The answer to this question requires knowing some basic concepts in pharmacology. An important branch in the science of pharmacology is the study of the effect of drugs on the body,

that is, what happens to the drug in the body after taking it. In order for the drug to work, it must reach the desired place in the body that has a disorder or disease. For instance, when we take medicine, it must be absorbed from the digestive system, enter the blood stream, and reach the target organ with the blood. Some drugs are absorbed into the blood from the digestive tract, some are low, some are average, and some are very well absorbed, and their absorption speed is different, because factors such as the blood flow of the digestive tract and the food consumed affect the amount and speed of absorption.

Sometimes the drug enters the blood stream, initially its concentration is high, but gradually due to decomposition in the liver or other organs and some other factors, its concentration is low and it is excreted from the body through the kidney or other ways. This means that the concentration of the drug in the blood will subsequently decrease and reach a point where its effect is no longer noticeable, so it should be taken again. This is actually the reason for determining the time interval between administrations, which is different for different drugs, for example, one medicine should be taken once a day, another medicine should be taken twice, or another medicine should be taken 4 times a day. Antibiotics are used to treat bacterial infections, but are not suitable for viral infections such as colds, sore throats, and the flu. Smart use of antibiotics is the key to controlling the spread of antibiotic resistance. The main criteria for entering the study included patients who needed antibiotic prescription, and patients who were allergic to any of the antibiotics were excluded from the study process. All the drugs were prescribed by the orthopedic surgeon before and during the surgery and the main outcomes were recorded by him.

2-7-Not taking antibiotics by children

One of the most important problems threaten human health is the problem of microbial

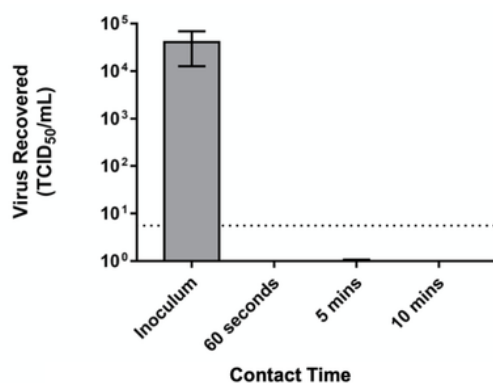
resistance, the main cause of which is the inappropriate, incorrect, insufficient, and incomplete use of antibiotics, so that the latest information published by the World Health Organization (WHO) in 2013 about microbial resistance is very shocking. Also, according to a recent report by the Centers for Disease Control and Prevention in the United States, antibiotic-resistant infections cause 2 million people and 23,000 deaths every year. In addition, this issue has imposed more than 20 billion dollars on the American budget. This issue is more serious in children. A recent study conducted at the University of Washington School of Medicine in the United States on American children showed that the harmless and symbiotic microbes in the

intestines of these children contain multiple genes resistant to antibiotics.

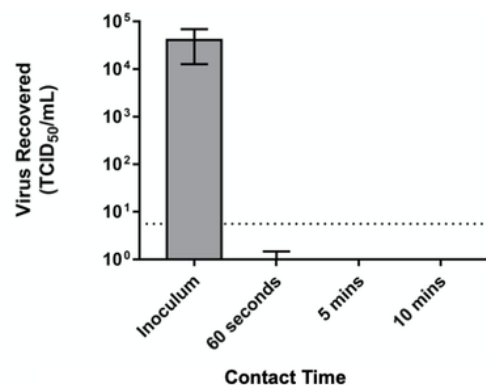
3. RESULTS AND DISCUSSION

Twenty-two patients received intravenous antibiotic prophylaxis (cefazolin group) and twenty-four patients received sodium chloride only (saline group) in a total of 19 Shohada and Imam Reza hospitals, out of which two were university hospitals. Eighty-eight patients received care in an academic facility. 7 patients were lost to follow-up after the randomization. There was a total of 27 patients available for analysis (24 in the saline group and 36 in the cefazolin group). 66 patients (14 %) experienced the development of an SSI (classification of SSI: superficial, 58; deep, 8) ([Fig 1](#)).

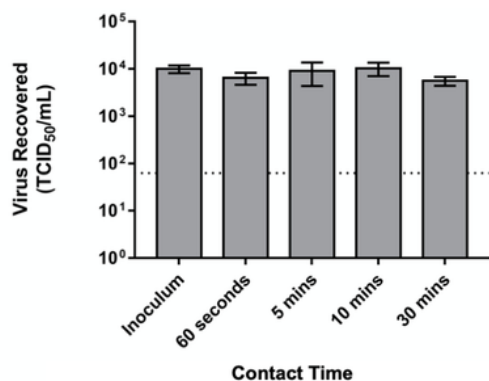
A Povidone-Iodine 5% w/v, 1:4 dilution



B Povidone-Iodine 5% w/v, 1:16 dilution



C Chlorhexidine Gluconate 0.1% w/v



D Chlorhexidine Gluconate 0.05% w/v

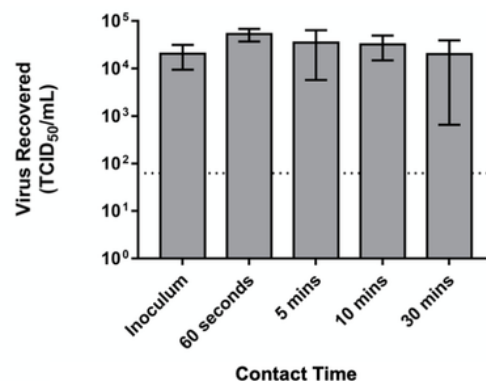
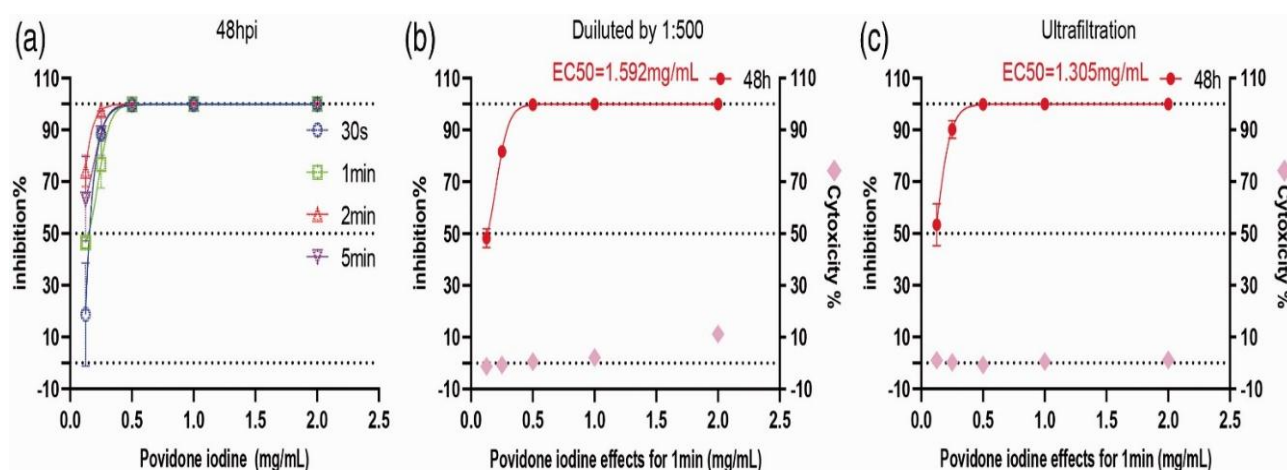


Fig 1.Rate of SSI after deference surgery

According to a study published on December 2nd in the Journal of the American Dental Association (JADA), dentists should stop prescribing antibiotics to patients with artificial joints before undergoing invasive dental treatments, because antibiotic prophylaxis is effective in reducing the infection risk and do not have any infection. The authors wrote that the continued use of antibiotic prophylaxis puts these patients at risk of drug side effects and increases antimicrobial resistance in the population. The study included more than 2,000 people in the United States who were hospitalized for late prosthetic joint infections (LPIs) [1].

Adjustment for center and diabetes did not change the odds ratios (ORs) for the association between cefazolin and risk of SSI for center to 0.854 for diabetes mellitus. In the cefazolin group, 30 patients (13.2 percent) developed an SSI compared to 36 patients (14.9 percent) in the saline group. All 8 patients with a deep SSI were admitted and received intravenous antibiotic therapy in 6 of the 8 patients, or 75% of the cases. In 4 of 5 patients (84.5%) with a superficial SSI, oral antibiotics were prescribed at the outpatient clinic or emergency department, and in 9 patients (15.5%), conservative treatment without antibiotics was used (Fig 2).

**Fig 2.**Infection response after Cefazolin treatment

Antibiotic prophylaxis (AP) should be discontinued to prevent late infections of the prosthetic joint and surrounding tissues, wrote the authors, led by Dr. Martin Thornhill, assistant professor in the Department of Oral Medicine at Carolinas Medical Center. The current study in the US population supports a study conducted in the UK (by many of the same authors) and published in January 2022 in JAMA Network Open. A UK study found no association between invasive dental procedures and subsequent LPIs, and therefore concluded that dentists would do

well to reconsider antibiotic prophylaxis. However, the issue of antibiotic prophylaxis for prosthetic joint patients undergoing invasive dental procedures is still a matter of debate. The findings of Dr. Thornhill and his team contradict the recommendations of the American Heart Association and the European Society of Cardiology, which recommend antibiotics for high-risk patients before invasive dental services. However, in August 2022, a study conducted in the United States and published in the American Journal of Cardiology showed a significant

association between dental extractions and oral surgeries with subsequent infective endocarditis in high-risk patients. Artificial joint infection is a serious complication associated with endocarditis. Seven of eight patients with a deep SSI were in the saline group. The incision was opened locally in two patients (3.4%). A mean EQ-5D-3L score of 0.72 preoperatively and 0.78 postoperatively was reported by patients for their health-related quality of life. After surgery, there was no statistically significant difference in the mean health-related quality-of-life score between the 2 study groups (0.78 in the cefazolin group vs. 0.79 in the saline group; absolute difference, 0.02). Preoperatively, the mean VAS score for the EQ-5D-3L's self-reported quality of life was 76 points, and postoperatively, it was 77 points.

After surgery, neither of the 2 study groups' mean VAS scores for self-reported quality of life (78 for cefazolin vs. 77 for saline; absolute difference, 1 point 16) statistically significantly differed from each other. The mean LEFS score for patients was 54 points preoperatively and 62 points after surgery. 62.3 in the cefazolin group vs. 62.2 in the saline group; absolute difference, 0.1), the mean LEFS did not statistically significantly differ between the 2 study groups postoperatively. On the VAS, the median patient satisfaction score with the course of treatment was 7 out of 7. Postoperatively, there was no statistically significant difference between the 2 study groups for this (7.5 in the cefazolin group vs. 7.8 in the saline group; absolute difference, 0.22) (Fig 3).

Numerous microorganisms were cultured from SSI patients. In the cefazolin group, 3 out of 23 patients (12.9%) had an SSI diagnosis, and 19 causative organisms were discovered in 19 cultures in this group.

The present study was conducted with the aim of the best time to prescribe prophylactic antibiotics before spinal anesthesia in foot and ankle surgery and its effects on hemodynamic

status during anesthesia. The significant and independent associations between a number of patient characteristics and SSI prediction have been demonstrated. Diabetes, smoking, being overweight, coincident remote site infections, and colonization are just a few instances. Although the relationship between diabetes and SSI is still debatable, significant correlations have been shown between high HgA1c levels and SSI rates as well as postoperative serum glucose levels greater than 200 mg/dL in populations undergoing cardiac surgery [15].

In a study in Switzerland, only 19% of patients received experimental treatment and only 22% of patients received inappropriate antibiotics [26]. The correct decision regarding the prescription of preventive antibiotics or its non-use was seen in our study at a high rate, which can be a sign of the high awareness of the surgical teams of the importance of antibiotics in preventing surgical site infection. This percentage is 81% in American surveys and 84% in Spain [26].

A noteworthy point in hospital is the inappropriate prescription of antibiotics for ear, nose, throat surgery, and laminectomy. Basically, according to the instructions, they should not be given antibiotic prophylaxis [19]. In laminectomy surgery due to increased surgical time (over 3-4 hours) and aftercare during hospitalization, as well as in otolaryngology surgery due to the presence of vformicrobes in the mouth and speeding up the healing of surgical site, only amoxicillin oral capsules in adults and ciprofloxacin syrup in children. It is used only for one dose after surgery. The doctor mentioned the reason for the prescription to treat middle ear infection and bronchitis by prescribing these drugs [20].

Furthermore, despite its link to diabetes, obesity carries a risk for SSI all on its own. Smoking prevents the primary healing of wounds, possibly as a result of the constriction of peripheral blood

vessels, which causes tissue hypovolemia and hypoxia [16].

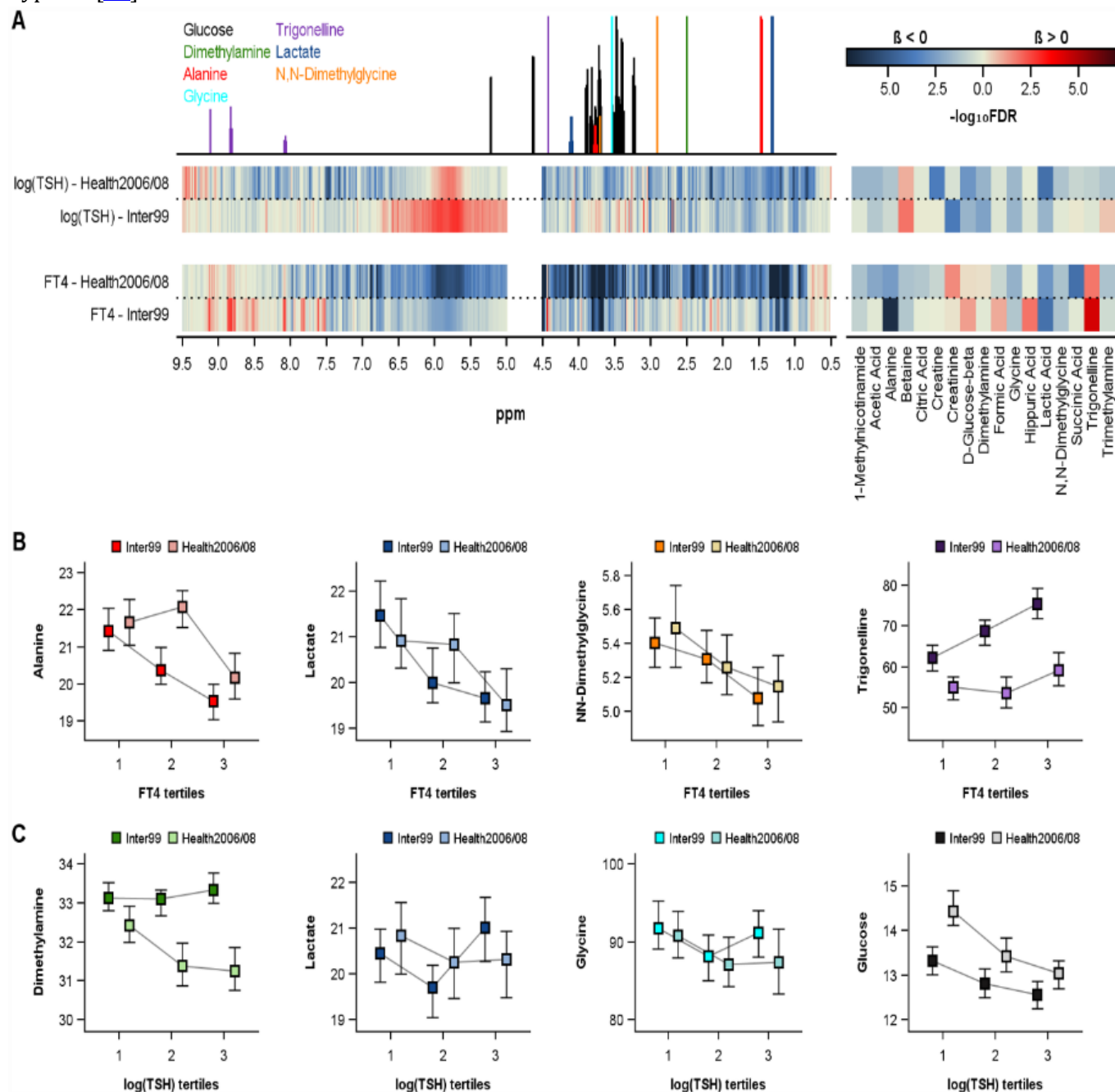


Fig 3.Log results after SSI in prophylaxis cefazolin

According to these findings, a 2003 randomized, controlled trial showed that quitting smoking for even just four weeks significantly lowers the risk of incisional wound infections [17]. It has been strongly suggested that *S. aureus* colonization, is

a strong predictor of SSI involving this organism [18].

Furthermore, obesity is a risk factor for SSI unrelated to its link to diabetes. Smoking prevents the primary healing of wounds, possibly as a result of the constriction of peripheral blood

vessels that causes tissue hypovolemia and hypoxia [19-21]. According to these findings, a 2003 randomized, controlled trial showed that quitting smoking for even just four weeks significantly lowers the risk of incisional wound infections [22]. *S. aureus* colonization has been strongly linked to SSI involving this organism and is present in the nares of 20% to 30% of healthy humans. A 2008 Cochrane Database review showed that mupirocin significantly decreased the incidence of *S. aureus*-associated SSIs through analysis of 8 randomized, controlled trials [23-25].

Overall, between January 2010 and December 2019, 2,344 patients were hospitalized with LPJI. Of these, 1,160 had commercial insurance or Medicare Supplement, and the remaining 1,184 were covered by Medicare. In the 15 months before the patients were hospitalized for LPJI, a total of 4,614 dental treatments, including 1,821 invasive dental treatments, had been performed on these individuals. Invasive procedures included oral surgery, endodontics, scaling, and tooth extraction. According to this study, among those who had invasive procedures, 333 patients (18%) were prescribed preventive antibiotics. Regardless of the type of insurance, the rate of performing invasive dental treatments during the three-month period before admission to the hospital for LPJI did not increase significantly compared to the 12-month control period. When the authors looked at rates of invasive dental treatments within one or two months prior to the hospitalization for LPJI, they again found no increase in rates of these treatments. When they analyzed invasive dental procedures in patients who received prophylactic antibiotics, the rate of these procedures increased in the three months before these people were admitted to the hospital for joint infections, but the increase was not significant. For patients who had undergone invasive dental procedures without antibiotics, they observed a small drop in the rate of these procedures in the three months before LPJI, they

wrote. However, this study was not without limitations, for example, while the databases used in the analysis included a large sample of the US employer-provided health insurance and Medicare enrollees, the authors only which had medical, dental, and prescription benefits were included in the analysis. Therefore, the results may not be generalizable to the entire US population, they wrote. Dr. Thornhill *et al.* wrote: "Prophylactic antibiotic discontinuation likely requires better communication between dentists and orthopedic surgeons and a collaborative effort to support evidence-based antibiotic stewardship practices."

3-1-Effective factors in surgical wound infection

Pathogenic factors depend on the surgical site. For instance, in heart, breast, eye, and orthopedic and vascular surgeries, the most common organism causing infection is *Staphylococcus aureus* and coagulase negative while in abdominal surgeries gram negative and anaerobic bacteria are more common. External sources of microorganisms include surgical instruments, operating room surfaces, air and personnel. Urinary tract infections and respiratory infections can occur after any surgery, but SSI can only occur after surgery that requires an incision. The most common exogenous bacteria are *Staphylococci* and *Streptococci*. Postoperative surgical wound infection is one of the common complications of surgery with a high mortality rate.

With the increase of antibiotic-resistant bacterial strains and the resulting mortality, the use of prophylactic antibiotics in dentistry has recently received attention. In spring 2021, the American Heart Association issued a statement on the prevention of infective endocarditis, noting that prophylactic antibiotic therapy before dental treatments may prevent a very small number of cases of endocarditis. Therefore, antibiotics are recommended only for patients who are at the

highest risk for adverse outcomes of infective endocarditis.

3-2-Epidemiology of surgical wound infection

The concept of asepsis or antisepsis was developed in the 19th century by Semmelweis, who used carbolic acid as a disinfectant and showed that washing hands before delivery reduced puerperal fever and the rate of surgical infections. He has seen a reduction in mortality from puerperal infection from 12% to 2%, which was significantly higher before the concept was developed. Today, it is difficult to provide accurate information for wound infection after surgery because this term covers a wide range of specialties, practices, patients, and geographic areas. Likewise, identifying wound infections has become more challenging due to the increasing prevalence of daily, outpatient surgeries, and the shortening of hospital stays.

Conclusion

Since the publication of the last review of the articles in the Cochrane Library in 2013, the authors of the recent study found no new, cohort, or randomized controlled studies that reported serious adverse events, including death, hospitalization, or cost outcomes evaluated treatment among individuals at risk of endocarditis who did or did not receive prophylactic antibiotic therapy after invasive dental procedures. However, they found a case-control study that included 48 people with bacterial endocarditis during a specific two-year period who had undergone a prophylactically indicated medical or dental procedure within 180 days before the study. These patients were matched with a similar group that did not have an infection. When evaluating the data, there was no significant effect of penicillin prophylaxis on the endocarditis incidence.

The researchers considered the above study to be weak in terms of design. For example, it is not

clear whether people who received antibiotics were worse off overall in terms of health than people who did not receive antibiotics, according to the review. They wrote that dentists should discuss with their patients the potential benefits and harms of antibiotic prophylaxis before deciding to prescribe antibiotics. Dr. Glenny *et al.* wrote: "It is unclear whether the potential harms and costs of prescribing antibiotics outweigh the benefits."

Arbitrary use of antibiotics causes some microbes and bacteria to become so resistant to these drugs that antibiotics no longer have an effect on curing the disease and antibiotic resistance occurs. In this case, the bacteria are not destroyed and their growth is not stopped, but they continue to grow and spread. With these interpretations, imagine that you get a simple infection that can be easily treated with an antibiotic, but because you have already used antibiotics incorrectly, your body has become resistant and you will not recover from the use of this medicine. To treat surgical site wound infection, a strategy appropriate to that site should be used because the microbial spectrum is often different. Furthermore, foreign bodies (mesh, implants, and metal work) should be removed due to biofilm formation. Controlling the source by choosing appropriate antibiotics based on the type of surgery and microbial causes is still important for the infection treatment. Most SSIs can be treated with antibiotics. Sometimes surgery and additional measures are needed to treat them. Often, initial surgical debridement is the preferred option to resolve the infection. In complex surgeries, re-operation of the surgical site causes significant complications.

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