RESEARCH

ANTIMICROBIAL PROPHYLAXIS IN NASOSEPTAL SURGERY

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SUMMARY

Aim of the study was to compare two different antimicrobial prophylaxis (AMP) regimens and obtain objective data about effectiveness of these regimens in nasal septal surgery (NSS) patients. One hundred-eight patients were randomized into 2 groups. Group one consisted 48 and the other 60 patients. Forty-eight patients in the 1st group were administered ampicillin/sulbactam 375 mg twice a day p.o. five days postoperatively and 60 patients in the 2nd group were administered a single dose of cefazolin 1gr/iv preoperatively. In both groups nitrofurazone ointment soaked extrafor packing material was applied after septoplasty. Preoperative and postoperative nasal flora was determined by microscopy and cultures. Preoperative and postoperative cultures of 1st group revealed *Staphylococcus aureus* in 20.8% (10/48) and 14.6% (7/48), and potential pathogenic bacteria (PPB) in 4.2% (2/48) and 14.6% (7/48), respectively. Preoperative and postoperative cultures of 2nd group revealed *Staphylococcus aureus* in 16.7% (10/60) and 18.3% (11/60), and PPB in 5% (3/60) and 20% (12/60). In analysis of growth rates of bacteria statistically insignificant pre and post-operative counts were found ($p=0.216>0.05$) in the 1st group, but significant ($p=0.015<0.05$) in 2nd group. One and two of the patients showed localized infection signs in 1st and 2nd group, respectively. Microbiologically postoperative five-day orally given AMP is superior but clinically there is no difference. According to clinical follow-up both AMP regimes are similarly effective. Compliance of patients to medical prescriptions should be taken in attention, therefore single dose preoperative iv AMP is more attractive to ensure patients adherence.

Keywords: Septal deviation, nasal septal surgery, septoplasty, antimicrobial prophylaxis, nasal packing

NAZOSEPTAL CERRAHİDE ANTİMİKROBİYAL PROFİLAKSİ

ÖZET

Bu çalışmanın amacı nazoseptal cerrahi hastalarında iki farklı antimikrobiyal profilaksi (AMP) protokolünü karşılaştırmak ve bu protokollerin etkinliğini objektif olarak değerlendirmektir. Toplam 108 hasta randomize olarak 48 ve 60 kişiden oluşan iki gruba ayrıldı. Kırksekiz kişiden oluşan birinci grubtaki hastalara postoperatif dönemde 5 gün boyunca oral yolla günde iki dozda 375 mg ampicillin/sulbactam preperatı verildi. Diğer gruptaki 60 hastaya ise ameliyattan 30 dakika önce tek doz cefazolin 1gr/iv yolla uygulandı. Her iki grupta ameliyat bitiminde nitrofurazone emdirilmiş ekstrafor tampon materyali uygulandı. Pre ve postoperative burun florası mikroskopi ve kültür ile değerlendirildi. Birinci gruptaki hastaların pre ve postoperative kültür sonuçlarında sırayla *Staphylococcus aureus* %20.8 (10/48) ve %14.6 (7/48), ve potansiyel patojenik bakteri (PPB) %4.2 (2/48) ve %14.6 (7/48), oranlarında üredi. Bu oranlar ikinci gruptaki hastalarda sırayla pre ve postoperative olarak *Staphylococcus aureus* %16.7 (10/60) ve %18.3 (11/60), ve PPB %5 (3/60) ve %20 (12/60) oranlarında üremiştir. Bakterilerin pre ve postoperative kültürlerde üreme hızları incelendiğinde birinci grupta istatiksel olarak anlamlı değilken ($p=0.216>0.05$); ikinci grupta ($p=0.015<0.05$) anlamlı idi. Birinci grupta 1, ikinci grupta 2 hastada postoperative dönemde lokalize enfeksiyon bulgusu görülmüştür. Sonuç olarak mikrobiyolojik bulgulara göre postoperative beş gün boyunca oral yolla uygulanan AMP protokolu daha başarılı iken klinik bulgulara dikkate alındığında iki protokol arasında fark görülmemiştir. Hastaların tedaviye uyumları ve ekonomik fayda da dikkate alınması gereken bir durum olduğundan preoperative tek doz AMP protokolü daha cazip hale gelmektedir.

Anahtar Sözcükler: Septum deviasyonu, nazoseptal cerrahi, septoplasti, antimikrobiyal profilaksi, nazal tampon

INTRODUCTION

Nasal septal surgery (NSS) is one of the most common operations that otorhinolaryngologist perform[1,2]. In addition, this type of surgery is often one of the earliest operations performed by a junior resident at a training clinic[1]. There are many different methods and techniques available. The postoperative management is also highly variable with no accepted guidelines for many issues such as nasal packing (NP) versus no NP, antimicrobial prophylaxis (AMP) versus no AMP[2].

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Surgical procedures on the upper aerodigestive tract are considered clean contaminated and may be associated with infectious complications. Sinonasal surgical procedures transgress mucosa that cannot be sterilized, but infectious complications are rare. When they do occur they contribute to morbidity and mortality. Although a consensus exists regarding the beneficial use of postoperative antibiotics in patients undergoing ablative procedures of the upper aerodigestive tract, there is no agreement regarding the use or value of antibiotics in patients undergoing sinonasal surgery[2].

Infections after NSS are uncommon and usually minor in nature. Nevertheless, serious complications, such as toxic shock syndrome (TSS)

or staphylococcal endocarditis, have been reported[1,3,4]. Although AMP has been regarded unnecessary by many authors[1,5,6], a wide diversity exists among surgeons' preferences. The routine use of antibiotics after septoplasty is preferred by 66% of physicians to prevent postoperative infections[2]. Moreover, the potential pathologic bacteria (PPB) in nasal flora plays crucial role in the induction of packing-associated infections. Therefore, a reduction of the PPB may diminish the incidence of postoperative infection[7].

In our clinic, NSS usually is performed with NP and AMP. The aim of this study was to compare two different AMP regimens and obtain objective data about effectiveness of these regimens in NSS patients.

MATERIAL and METHODS

The study involved 120 patients who underwent NSS in a single institution (Ministry of Health Ankara Numune Hospital, Department of 3rd Otorhinolaryngology) between January 2003 and August 2003. It was designed prospectively to evaluate two different AMP regimens in these patients. Growth of *Staphylococcus aureus* and other microorganisms and effectiveness of both AMP regimens were compared statistically.

The patients were chosen from a larger sample of patients who were performed NSS. One hundred twenty operated patients who had nasal packing were selected for this study. All the patients involved in the study had significant septum deviation; defined as deformities involving cartilaginous and/or bony parts. The deviations were impinged upon the OMC and/or lateral nasal wall causing objective obstruction on nasal endoscopy and CT scans. Mild septal deviations such as septal spurs, isolated anterior cartilaginous or posterior bony deviations were excluded. The patients who had systemic and/or infectious diseases, history of oral or systemic antibiotic application in the last 2 months or any history of sinonasal operations were also excluded.

NSS was performed under local sedation anesthesia. Cottle septoplasty was performed. Two days of nitrofurazone soaked extrafor was applied as NP and all patients were hospitalized on the day of surgery. AMP was given to all patients. The patients were randomly divided into two groups according to AMP type and taking into consideration the homogeneity of gender and age. First group (group-1) included 60 patients who were given no preoperative antibiotics but postoperatively 375 mg-bid ampicillin-sulbactam for 5 days. Second group (group-2) included 60 patients who were given cefazolin 1gr intravenously 30 minutes before surgery. No other antibiotics were allowed for this group postoperatively. Patients were distributed randomly between groups and written informed consent was obtained from patients.

Preoperatively nasal smears were obtained in a similar fashion in all patients. Since nasal vestibule and cavity floras may show differences, smears were taken from middle turbinate level. On the postoperative second day following removal of NP smears were repeated. Nasal smears were delivered for microbiological analysis in a sterile transport system. Specimens were cultured in 5% sheep blood and Mac Concey nutrient medium and incubated at 37 ºC for 48 hours. Microorganisms were identified according to microscopic appearance, growth on nutrient medium, colony morphology and acid production from carbohydrates (Api-system; BioMerieux, Genewa, Switzerland).

Normal and PPB were determined according to 7th (1999) edition of Manual of Clinical Microbiology[8]. Aerobic bacteria *Streptococcus pyogenes*, *Streptococcus pneumoniae, coagulase-negative staphylococci, corynebacterium species, stomatococcus, micrococcus, mycoplasma species* and *lactobacilli* and *anaerobic bacteria peptostreptococcus species, fusobacterium species, veillonella species, porphyromones, bacteroides species, prevotella species, actinomyces, bifidobacterium species* and *propionibacterium* species accepted as normal flora members.

Statistical analyses were carried out by using non-parametric Wilcoxon test. A “p" value less than 0.05 was accepted as significant.

RESULTS

One hundred-twenty patients, sixty patients in each group, were included in the study. But in group-1, 12 patients who didn't get antibiotics properly were excluded. Therefore, 48 and 60 patients were included in group-1 and group-2, respectively. Of the patient group excluded because of poor adherence to AMP, 2 (17%) patient had infection. One of them had sinusitis and 1 had vestibulitis, parenteral antibiotic treatment was applied to patients. In compare this poor adherent group to groups 1 and 2 infection rate was higher according to clinical observation.

In the 1st group, 62.5% (30/48) of patients were male and 37.5% (18/48) female, with an average age of 25 years (17-45). In the 2nd group, 63.3% (38/60) of patients were male and 36.7%

(22/60) female, with an average age of 26 years (18-48).

In 1st group, the most prevalent potential pathogen bacterium was *Staphylococcus aureus* [20.8% (10/48)] preoperatively. Other PPB were identified in 4.2% (2/48) of patients. Normal flora bacteria (NFB) found in 75% (36/48) of the patients. Postoperative cultures of the same group revealed *Staphylococcus aureus* in 14.6% (7/48), PPB in 14.6% (7/48) and NFB in 70.8% (34/48) of patients (Table). In analysis of growth rates of bacteria statistically insignificant pre and post-operative counts were found ($p=0.216>0.05$). One of the patients showed localized infection signs during the third day of surgery and parenteral antibiotic treatment was started.

In 2nd group, the most prevalent potential pathogen bacterium was *Staphylococcus aureus* [16.7% (10/60)] preoperatively. Other PPB were identified in 5% (3/60) of patients. NFB found in 76.7% (46/60) of the patients. Postoperative cultures of same group revealed *Staphylococcus aureus* in 18.3% (11/60), PPB in 20% (12/60) and NFB in 76.7% (46/60) of patients (Table). In analysis of growth rates of bacteria statistically significant pre and post-operative counts were found only on PPB group ($p=0.015<0.05$). One of the patients had signs of acute sinusitis and one had nasal vestibulitis. Parenteral antibiotics started for these patients.

DISCUSSION

The use of AMP may lead to confidence for the surgeon. Infectious complications are rare after NSS according to medical literature. Although major textbooks advocate AMP, according to the literature indications of AMP in NSS is questionable since microbiological investigations were not taken adequately in to account[2,4,7,8,9,10]. There is only a few report in English literature about AMP in nasal surgery as planned controlled and prospectively disagned. Rajan evaluated 200 patients prospectively and they concluded "a single dose AMP is sufficient for prophylaxis of postoperative surgical ınfections". They carried the study without looking alterations in nasal bacterial flora and just evaluated the cost effectiveness of two different AMP regimen and incidence of postoperative infections[11]. In a survey study conducted by Perrotti among plastic surgeons, questioning use of AMP in rhinoplasty, of the 1650 physicians 470 (28%) were not using antibiotics, 272 (16%) were using perioperative antibiotics; whereas 891 (55%) of the contributers were using antibiotics postoperatively 1-7 days. No significant difference was reported in infectious complications[12]. Hytonen reviewed their septoplasty patients and pointed that specialists were more prescribed antibiotics comparing to residents and concluded postoperative antibiotics don't appear to prevent development of postoperative infections[13]. Also they didn't investigated changes in nasal bacterial flora. In our study clinical signs of infections are very rare (2%). But statistical evaluations demonstrated significant benefit of AMP use on growth of PPB in 1st group. In analysis of growth rates of bacteria statistically insignificant pre and post-operative counts were found in 1st group, but statistically significant in 2nd group.

According to microbiological analysis long-term AMP has better preventive effect on *Staphylococcus aureus* and PPB. But single dose AMP group didn't show more postoperative infection than the other group. Also benefit to ensure better compliance of patients to a single dose AMP should be considered.

Group	MICROBIOLOGICAL RESULTS			
	Pre-operative		Post-operative	
	Potentially Pathogen Microorganisms, n (%)	Non-infectious Microorganisms, n (%)	Potentially Pathogen Microorganisms, n (%)	Non-infectious Microorganisms, n (%)
Group-1 n=48	*Staphylococcus aureus*,10 (20.8%) *Escherichia coli*, 1 (2.1%) *Pseudomonas aureginosa*,1 (2.1%) *Klebsiella pneumoniae*, 1 (2.1%)	Normal nasal flora, 36 (75%)	*Staphylococcus aureus*,7 (15%) *Citrobacter*, 1 (2%) *Pseudomonas aureginosa*, 1 (2%) *Enterobacter aerogenes*, 1 (2%) *Proteus mirabilis*, 1 (2%) *Klebsiella pneumoniae*, 2 (4%)	Normal nasal flora, 36 (75%)
Group-2 n=60	*Staphylococcus aureus*, 11 (18%) *Escherichia coli*, 2 (3%) Pseudomonas aureginosa, 1 (2%)	Normal nasal flora, 46 (77%)	*Staphylococcus aureus*, 11 (18%) *Escherichia coli*, 5 (8%) *Klebsiella pneumoniae*, 1 (2%) *Proteus mirabilis*, 1 (2%) *Enterococcus*, 1 (2%) *Enterobacter aerogenes*, 3 (5%) *Pseudomonas aureginosa*, 1 (2%)	Normal nasal flora, 46 (77%)

Table 1. Preoperative and postoperative microbiological results of patients.

There are some reasons given to justify the use of AMP in nasal surgery. First, the operative area is contaminated. Mucosal incisions are made in an area in which bacteria is abundant. While the preoperative disinfection of the outer nasal surface and vestibulum reduces bacterial germ count, number of bacterial count in nasal mucosal membranes don't diminish[14]. Second, nasal packing represent a foreign body which accumulates secretions and invokes an inflammatory reaction in the mucosa, predisposing the patient to infection of the surrounding mucous membrane, skin and cartilage. Third, the routine use of nasal packing leads to mucosal edema and occlusion of sinus ostiums. This subjects the patient to risk of rhinosinusitis. While these arguments have some theoretical merit, their practical significance may be questioned[10]. That AMP influence any of these factors has not been demonstrated adequately[1,2,10]. It may even be that the patients with an infection predisposing condition, such as diabetes or compromised immunity, should be considered for AMP[1].

Severe complications after nasal surgery, although rare, do occur and can be divided into the following four categories: Hemorrhagic, infectious, traumatic and miscellaneous[4]. Infectious complications is the second most common complication after hemorrhagic, ranging from 2 to 12%[1,4,6,7,10,15]. Because of the ubiquitous nasal flora and adjacent paranasal sinuses, there is always the potential for infections after nasal surgery. Most infections are at the surgical site, but sinusitis and intracranial infections have also been reported[3,4,6]. Local infections include cellulitis, abscesses and granulomas that involve the overlying skin, columella, nasal vestibule and septum. These infections respond rapidly to use of oral antibiotics and/or incision and drainage if indicated[2,4]. Reports of intracranial infections after nasal surgery were found in the pre-antibiotic era and were usually seen after NSS[13]. They include meningitis, cavernous sinus thrombosis, and dural and brain abscesses. Spinal osteomyelitis, septicemia and bacterial endocarditis have also been reported after NSS, as has TSS[3,4,6,12]. The majority of these infections are prevented by the prompt treatment of the initial minor local infection[2]. TSS is a potentially fatal and often serious multisystem disease caused by toxigenic *Staphylococcus aureus* infection[2,4,9,16]. The reported incidence of TSS after nasal surgery is an estimated two cases per 10 000 patients. TTS is rare and literature is absent suggesting that use of antibiotics to prevent TSS. However, its potential severity had led many otorhinolaryngologists to begin using AMP in nasal operations in an attempt to reduce the risk of this complication[2,16]. In this study, 2% (3/148) of patients have local infectious complications. With close follow-up, none of patients exhibit any infectious sequale. Any kind of TSS signs was not encountered.

The intranasal packing and the packing materials itself may have some influence on bacterial growth in the nose. Therefore, infection rate may be increased by causing foreign body reaction or via blocking sinus ostiums[7,20]. Complications also associated with intranasal packing include pressure necrosis of the nose, septum, mucosa and palate; allergy; aspiration; tetanus; septic blindness; meningitis; basisphenoid osteomyelitis; paraffinoma; and myospherulosis. However, in the postoperative period nasal packing is used to accomplish several goals. It is used to control bleeding and to maintain adhesion of the mucoperiosteal/ mucoperichondrial flaps to the remaining bony/cartilaginous septum or to the contralateral mucoperiosteum/ mucoperichondrium. This decreases postoperative edema, encourages stabilization of unstable fragments of the septum, and prevents septal hematoma. An additional goal of the nasal pack is to prevent the formation of synechiae[2,9,17,18]. AMP immediately before surgery can reach effective levels in the mucosa, cartilage and bone, while the inhibition of the PPB in the packed material is not achieved by AMP[7,15]. For this reason, in all our patients antibiotic-containing NP and AMP was applied together.

Pathogens are present mostly in the local nasal flora[4,7,15]. Staphylococcus aureus, is the most common and has been detected in the smears from the nasal mucosa in 18-50% of healthy subjects[7,20,21]. In 10-30%, *Staphylococcus aureus* produces TSS toxin 1 and enterotoxin[7,20,21]. Local organisms seem to be responsible in most of the postoperative wound infections, with the role of *Staphylococcus aureus* being of particular importance. Reducing the potentially infectious flora at the surgical site represent a crucial goal in any prophylactic regimen against infection[7,22]. In this study, the most prevalent potential pathogen bacterium was *Staphylococcus aureus* pre and postoperatively in both group. The use of AMP remains controversial in NSS. And also there is no agreement the applying of NP. A prospective randomized trial should be undertaken to answer these questions. In clinically practice, we use AMP routinely and usually apply NP. This study showed that postoperative five-day orally given AMP has more effective prophylactic affect if only microbiological analysis is taken in to account but no

difference was observed between to groups according to clinical signs. Since number of patients in our groups relatively low, studies with larger patients series may give more strong results.

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