One dose of preoperative, intravenous, prophylactic antibiotics þÿ s i g n i f i c a n t l y l o w e r s p o s t o p e r a t i v e i n f e c t i o n r a t e study of 772 operations

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One dose of preoperative, intravenous, prophylactic antibiotics significantly lowers postoperative infection rate in septoplasty – a study of 772 operations

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RUNNING TITLE: Prevention of septoplasty infections

ABSTRACT

Objectives Postoperative infection is the most common complication after septoplasty. Pre- or postoperative prophylactic antibiotics are commonly used, although no official guidelines exist.

Design We retrospectively collected data on postoperative infections from 772 septoplasties performed in 2015, 2016, and 2018 and classified the infections according to surgical-site infection (SSI) criteria by the Centers for Disease Control and Prevention (CDC). We evaluated the infections according to antibiotic use (preoperative or postoperative, both, or none) and accounted for patient and surgical confounding factors. We compared the results with three previous studies from our department to find out the trend in the occurrence of postoperative infections and in the use of antibiotics.

Results Twenty-nine cases (3.8%) fulfilled CDC infection criteria. Any kind of antibiotic prophylaxis reduced the risk of SSI (p=0.018). One dose of intravenous cefuroxime before incision was the most effective preventive measure (p=0.045). We found no significant effect of postoperative antibiotics. However, postoperative antibiotics lowered the infection rate to 1.8% compared with 6.1% among those not treated with any antibiotics. The only

other factor reducing the risk of SSI was local anaesthesia compared to general anaesthesia.
Conclusion Preoperative antibiotic prophylaxis effectively reduced postoperative infection rate after septoplasty.

KEYWORDS Antibiotic prophylaxis, Complication, Nasal septum, Surgical wound infection, Surgical-site infection

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INTRODUCTION

Postoperative infections form a common problem that affects millions of people every year and can contribute to increased hospital stay, higher costs, and antibiotic resistance [1,2]. Although septoplasty is one of the most common otorhinolaryngologic surgeries, there are no generally accepted recommendations on the use of prophylactic antibiotics. Reported infection rates vary considerably (0.5 to 12%) [3-9]. The World Health Organization (WHO) guidelines generally recommend antibiotic prophylaxis in clean-contaminated surgeries such as septoplasty [1]. The administration should occur prior to, but no earlier than 120 minutes before incision. Use of prophylactic postoperative antibiotics is not recommended [1,10].

Surgical site infections (SSIs) are classified according to the Centers for Disease Control and Prevention (CDC) criteria into superficial, deep, and organ/space SSIs. Criteria of the two first mentioned are presented in Table 1 [10,11].

We have previously reported the rate of postoperative infections after septoplasty at our institution in 2000, 2005, 2011, and in 2019 [3-5,9]. In the first two studies, the infection rate was 12% and 4.2%, with 21% and 41% of the patients having received prophylactic postoperative antibiotics orally, respectively. In 2011 in a prospective, double-blind, placebo-controlled study, we observed fewer deep infections after one dose of preoperative cefuroxime intravenously (i.v.) than in the placebo group [3]. Our current aim was to assess the trend of the use of prophylactic antibiotics and how different regimens affect the infection rate in a real-world setting.

MATERIAL AND METHODS

Material

In this study, we included all 959 septoplasties and septo-columelloplasties (both with ICD-10 code DJD20) performed in 2015, 2016, and 2018 at the Helsinki University Hospital (HUS). Additional inferior turbinate surgery was not an exclusion criterium, but all patients with other concomitant procedures, were omitted from the

series. Thus, 772 operations on 767 patients were included as five patients had two surgeries each. There were no other exclusion criteria.

Methods

Information on patient-related factors (including age, gender, body mass index [BMI], smoking status, and American Society of Anesthesiology [ASA] score) and operation-related factors (including anaesthesia [local or general anaesthesia] and performing surgeon [rhinologist, ENT specialist, or resident]), methods of closure (splints, stapler, tamponade, or combinations thereof), and possible pre- and postoperative antibiotics were collected from electronic case records. All postoperative contacts that reported symptoms suggestive of infection were registered. Two experienced rhinologists re-reviewed the possible infections and classified them as non-infectious or as infection according to the CDC SSI guidelines [(11)]. Disagreements were resolved by discussion with a third rhinologist until consensus was reached. We also determined if the patient had redeemed the prescribed antibiotics for an infection from the pharmacy.

Patients with superficial SSIs often presented with mild fever (<38°C), crusting, tenderness, and flush and were diagnosed and treated as SSI by the doctor on call. If pus was drained or aspirated, the infection was categorized as a deep SSI.

Statistical analysis

A professional statistician performed data analysis and statistics with NCC 8 (NCSS. LLC. Kaysville, Utah, USA). For numeric values, Student's T-test was used with Box-Cox analysis if values were not normally distributed. An Aspen-Welch T-test was used for comparison of groups with different sizes. Mann-Whitney U-test was used for comparisons of ordinal variables. Pearson's Chi-Square test or Fisher's Exact test were used in the analysis of categorical data. A p-value <0.05 was considered statistically significant.

Ethical considerations

The data were based on patient records and therefore no approval from a research ethics committee was needed. An institutional study permission was granted.

RESULTS

Patients

Most (80.2%, n=615) of the 767 patients were men. Mean age was 40.6 years (range 5-84, median 39.0). There were two patients <16 years and two over 75. The patients were generally healthy; of the 658 patients with a registered ASA score, only 66 (8.5%) had an ASA score 3-4. Mean BMI was 26.5 (range 15.9-47.8, median 25.9; n=630); 177 (22.9%) patients were smokers and 180 (23.3%) were ex-smokers (total n=651) (Table 2).

Surgery

During the years 2015, 2016, and 2018, 772 septoplasties or septocolumelloplasties were performed. Thirty-nine (5.1%) were revisions. One third (30.3%, n=234) of the patients received radio frequency ablation (RFA) to the inferior turbinate(s) in conjunction to septal surgery.

The operations were mainly (74.2%, n=573) performed as day surgery procedures and under local anaesthesia (68.1%, n=526), usually with cocaine (200 µg)-adrenaline surface analgesia and septal lidocaine-adrenaline infiltration. In our hospital, an overnight stay is required if the patient has sleep apnoea, severe or uncontrolled diseases or substantive functional limitations, increased risk of bleeding, or no adult company at home during the first postoperative night. General anaesthesia (GA) is used in more complicated cases, in teaching sessions, and in selected cases, for example of patient wish. The operations were typically performed by rhinologists (47.4%, n=366, Table 2). The surgery duration from start of local anaesthesia to closure was on average 1 hour 18 minutes.

For closure, 438 patients (56.7%) had silicone splints (200 patients also had packing) and 200 (25.9%) were closed with stapler (76 patients also had packing). Packings were removed on the first day after surgery and the splints on average 6.8 days after surgery (range 1-13) (Table 2). Only three patients had splints less than five days, two were removed because of acute infection and one because of pain. None of the patients with splints more than ten days had an infection.

In 61.0% (n=471) of the operations, the patient received prophylactic antibiotics preoperatively. All but seven cases were administered cefuroxime 1.5 g i.v. 30-60 minutes before the incision. The other seven got amoxicillin 2 g orally (n=3), clindamycin i.v. (n=3), and doxycycline starting one week preoperatively for sinusitis (n=1). Postoperatively, 115 (14.9%) cases were given planned antibiotics, mostly cephalexin 1500 mg a day for an average of 7.2 days (range 3-21). Fifty-nine (7.6%) cases got both pre- and postoperative antibiotics whereas one third (31.7%, n=245) no prophylactic antibiotics was given (Table 3).

Surgical-site infections

In retrospective analysis, we found 61 cases (7.9%) that contacted healthcare services with some symptom suggestive of infection. After re-evaluating patient histories, three rhinologists (M.H., M.Li., M.Lu.) agreed that 29 (3.8%) of the cases fulfilled the aforementioned SSI criteria. These patients were mainly treated with cephalexin orally and had superficial pus or crusting in the incision (n=12) but were not drained. Three of them had fever ≥38°C. Although not diagnosed having an SSI by the consulting doctor, 19 of the remaining 32 patients were prescribed antibiotics 'in case it gets worse'. These patients did not fulfil any type of SSI. The 13 patients who were not pharmacologically treated did not contact the hospital again and were not prescribed antibiotic treatment according to the national pharmacy records.

Four patients were classified as having a deep SSI and all had local swelling and tenderness. In three patients an obvious abscess developed; one of these patients did not have fever. In the fourth case, there was a suspicion of an abscess, but no pus was found after drainage. However, *Staphylococcus aureus* and *Staphylococcus agalactiae* were cultured from the incision and the patient had high fever, thus fulfilling criteria for deep SSI. Two of the patients had a *Methicillin-resistant Staphylococcus aureus* (MRSA) infection and were treated with i.v. clindamycin combined with either vancomycin or cefuroxime. The two others were treated with cephalosporines.

An infection developed on average in 8.8 days (range 1-30) days. Deep SSIs developed slightly sooner (mean 4.8 days). However, three of the four cases of deep SSI developed within 3 days. For the superficial SSIs the mean was 9.4 days.

Factors affecting postoperative infection risk

The only factor that increased the risk of SSI was GA (p=0.00001). None of the factors related to the patients, the operation, or postoperative care affected the risk of SSI, not even a concomitant RFA.

The effect of antibiotics on SSI

To compare the effect of prophylactic antibiotics on the risk of developing SSI, we divided the cases into four groups: only preoperative antibiotics, only postoperative antibiotics, any kind of prophylactic antibiotics, or no antibiotics (Table 3). The last group was used for comparison. Antibiotics prescribed for complications were excluded.

Treatment with antibiotics pre- or postoperatively reduced the risk of developing SSI to 2.6% *vs.* 6.1% in the non-antibiotic group (p=0.018) compared to the no antibiotic group. Three out of the four documented deep SSIs were found in the non-antibiotic group (p=0.034, Table 3).

The results were confirmed in the group receiving preoperative antibiotics, where antibiotics administered 30-60 minutes prior to the incision significantly reduced the risk of SSI (n=400, 2.9%, p=0.045). The SSI percentage was even lower in the postoperative antibiotic group (n=55, 1.8%), however, the result was not significant (p=0.320, Table 3).

Comparison over the years

We compared our results with previous results from our hospital [3,5,9] (Table 4). Patient age was similar in all studies. The use of splints and simultaneous RFA, and GA were more common in the current series than in 2011, whereas packing was less used. In 2000 and 2005, postoperative prophylactic antibiotics were administered in 21% and 41% of cases, respectively. No patients received preoperative antibiotics. The practice changed towards one dose of preoperative prophylaxis, which was administered in 48.9% and 61.0% in 2011 and 2015-2018, respectively. Correspondingly, the use of postoperative antibiotics decreased to 14.9%. We observed a simultaneous reduction in infection rate from 12.0% in 2000, 4.2% in 2005, 5.3% in 2011 to the current 3.8% and an evident reduction in deep infections (8.0% to 0.5%).

DISCUSSION

In this study, we observed that the use of 1500 mg of cefuroxime administered i.v. 30-60 minutes before surgery significantly reduced SSIs. The SSI percentage was also reduced in the postoperative-prophylaxis group, although the result was statistically insignificant. The infection rate of 3.8% in was comparable with previous reports [3-8], but in the group without antibiotics the rate was as high as 6.1%. In the comparison over time, infection rates, and especially the potentially dangerous deep SSIs reduced with the increased use of prophylactic antibiotics [3-5,9], advocating the use of prophylaxis.

Some studies recommend the avoidance of antibiotics in septoplasty [12,,13] whilst others advocate postoperative courses even though the data on efficacy are controversial [6,7,14,15]. According to an American survey, 66% of doctors prescribe postoperative antibiotics [14] for the prevention of SSIs and the extremely uncommon toxic shock syndrome [12,16]. However, the disadvantages of long antibiotic courses are numerous, including bacterial resistance, risk of adverse drug reactions, and high costs [13,17]. In a study by Ritter et al. postoperative antibiotics did not hinder bacterial colonization but instead 16% of bacterial strains had turned resistant when comparing samples taken during surgery and after one week of postoperative splinting [6]. In large review of nasal packings, no benefits for the use antibiotics after septoplasty were found [12].

Although many studies report infection rate, very few describe the precise infection criteria used [13], which makes comparisons difficult. In this study, we used the SSI criteria defined by CDC [11]. The criteria were not easily adapted for septoplasties. However, the deep infections stood out from the others. They were fast developing, deliberately opened abscesses with pus, the patients had fever and/or microorganisms cultured, two of which were MRSA. In this study, 32 (4.1%) of cases patients sought help for symptoms that did not fulfil SSI criteria. These symptoms were slight rash or pain, a slightly elevated temperature, sinusitis, or a wound caused by splints. However, 19 of these were prescribed antibiotics 'in case it gets worse', without any clear SSI signs. The uncertainty of verifying infection retrospectively is a weakness of this study that we sought to mitigate by asking two independent rhinologists to evaluate all suspected infections. This highlights the challenges of differentiating a postoperative complication from normal healing. Although a modest increase in body temperature is not uncommon as septoplasty is prone to bacteraemia, it often resolves without antibiotics [18]. To reliably determine the need for prophylaxis and the possible risk with splints or packing, consistent definitions of normal healing and complications are needed.

We acknowledge that factors such as advanced age, nutritional status, glycaemic control, tobacco use, and intraoperative technique can influence the development of SSI [1,19]. Patient age was similar in all our studies, and as smoking rates and ASA score were generally low, it is unlikely that these factors explain the results. Perioperative washing and operative technique have not changed considerably in the last 10 years, whereas more splints and less packing are used. However, closure or packing did not affect infection rate in this study, nor in a review on packings [12].

The form of anaesthesia was the only statistically significant factor besides prophylactic use of antibiotics that was related to reduced risk of SSI. This does not explain the SSI reduction over time, as more GA was more frequent in 2015-2018 than in the previous studies [3,5,9]. The reason for this finding is unclear. The most common reason for GA in our institution is patient's request. Also, more difficult or longer procedures, such as revisions or resident's surgery, are performed in GA, but in analyses, none of these factors were associated with infections.

The heterogenous material of this study is a limitation we acknowledge. The wide age-range, different co-morbidities, the large group of performing surgeons, and

varying postoperative schemes might cause bias. This, however, is a real-life study presenting data largest in this category. As septoplasty is a common surgery, the question of antibiotic prophylaxis remains an important factor to be included in guidelines.

CONCLUSION

SSI is a present risk in all surgery, which can cause both human and financial costs. This study shows that prophylactic antibiotics, and specifically one dose of i.v. cefuroxime 30-60 minutes preoperatively, significantly lowers the risk for SSIs in septoplasty in a large material of 772 cases. This regimen is consistent with global guidelines and causes less side effects than longer courses of postoperative antibiotics.

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	SSI criteria
Superficial incisional SSI	Occurs within 30 days after surgery Involves only skin or subcutaneous tissue and at least one of the following a) purulent drainage from the incision b) organism(s) isolated from an aseptically obtained culture from the incision c) superficial incision deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; redness or heat d) diagnosis of superficial incisional SSI by a doctor. Stitch abscesses should not be reported as SSIs.
Deep SSI	Occurs within 90 days after surgery Involves the deep soft tissues of the incision (fascia, muscle) and at least one of the following: a) purulent drainage from the deep incision. b) a spontaneously ruptured or deliberately opened, or aspirated wound AND - organisms are identified through microbiological testing AND - the patient has at least one of the following signs or symptoms: fever >38°C, localized pain or tenderness. c) An abscess or other evidence of infection involving the deep incision that is detected clinically or radiologically.

Table 1. Centers for Disease Control and Prevention criteria for superficial and deep Surgical Site Infection (SSI).

Table 2. Patient demographics and operative details in the groups with and without postoperative infection in a series of 772 septoplasties.

	No infection N = 743 (96.2%)	Postoperative infection N =29 (3.8%)	p-value
Age (mean), years	40.7	38.2	N.S.
Body mass index (mean), kg/m^2	26.5	26.3	N.S.
Smoking			N.S.
Yes	171 (23.0)	6 (20.7)	
Ex-smoker	172 (23.1)	8 (27.6)	
No	283 (38.0)	10 (34.5)	
Unknown	117 (15.7)	5 (17.2)	
ASA score I-II	567 (98.9)	24 (82.8)	N.S.
ASA score III-IV	64 (8.6)	2 (7.0)	
Unknown	110 (14.8)	5 (17.2)	
Local anaesthesia	517 (69.5)	9 (31.0)	0.0001
General anaesthesia	226 (30.4)	20 (69.0)	
Rhinologist	353 (47.5)	13 (44.8)	N.S.
ENT-surgeons	272 (36.6)	7 (24.1)	
Residents	118 (15.9)	9 (31.0)	
Postoperative packing			N.S.
Yes	369 (49.6)	15 (51.7)	
No	374 (50.3)	14 (48.3)	
Postoperative splints			N.S.
Yes	423 (56.9)	15 (51.7)	
No	320 (43.0)	14 (48.3)	
Stapler			N.S.
Yes	191 (25.7)	9 (31.0)	
No	552 (74.2)	20 (69.0)	
RFA			N.S.
Yes	222 (29.8)	12 (41.3)	
No	521 (70.1)	17 (58.6)	

SSI= Surgical site infection, N.S. = Not significant, ASA = American Society of Anesthesiology score, RFA= radio frequency ablation. p-value indicates risk of postoperative infection.

	No infection n =743 (%)	Postoperative infection n=29 (%)	Superficial SSI n=25 (%)	Deep SSI n=4 (%)	p-value
Only pre-operative antibiotic n=412 (53.3%)	400 (97.1)	12 (2.9)	11 (2.7)	1 (0.2)	0.045
Only postoperative antibiotic n=56 (7.3%)	55 (98.2)	1 (1.8)	1 (1.8)	0 (0.0)	0.320
Pre- and/or postoperative antibiotic n=527 (68.3%)	513 (97.3)	14 (2.6)	13 (2.5)	1 (0.2)	0.018
No antibiotic n=245 (31.7%)	230 (93.9)	15 (6.1)	12 (4.9)	3 (1.2)	-

Table 3. Description of prophylactic antibiotic treatment as compared to postoperative infections among 772 cases.

p-values describe the comparison of prescribed antibiotic treatment to no antibiotics.

	Mäkitie A et al. 2000	Hytönen M et al. 2005	Lilja M et al. 2011	Lundberg M et al. 2021
Number of patients	100	167	188	772
Average age, years	40	44.3	41	40.6
Infection rate, total Superficial SSI Deep SSI	12 (12.0) 4 (4.0) 8 (8.0)	7 (4.2)	10 (5.3) 7 (3.7) 3 (1.6)	29 (3.8) 25 (3.2) 4 (0.5)
Preoperative antibiotics	0 (0)	0 (0)	92 (48.9)	471 (61.0)
Postoperative antibiotics	21 (21.0)	68 (40.7)	0 (0.0)	115 (14.9)
Local anaesthesia	100 (100.0)	154 (92.2)	172 (91.5)	526 (68.1)
RFA	0 (0.0)	0 (0.0)	48 (25.5)	234 (30.2)
Splints	No data	40 (24.0)	57 (30.3)	438 (56.7)
Postoperative packing	No data	164 (98.2)	188 (100.0)	384 (49.7)

Table 4. Comparison on septoplasties published in 2000, 2005, 2011, and 2020.

N (%), SSI= Surgical site infection, RFA= radio frequency ablation.