의학석사 학위논문

How clean is the rhinoplasty field?:

Can chlorhexidine pretreatment prevent bacterial contamination?

클로르헥시딘 전처치가

코성형 수술 부위의 세균 오염에 미치는 영향

2015년 2월

서울대학교 대학원

의과대학 임상의과학과

김신혜

A thesis of the Degree of Master

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지도 교수 진홍률

이 논문을 의학석사 학위논문으로 제출함

2014년 10월

서울대학교 대학원

의과대학 임상의과학과

김신혜

김신혜의 의학석사 학위논문을 인준함

2015년 01월

위 원 장 _____ (인)

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ABSTRACT

Introduction: Postoperative infection can occur following rhinoplasty and poses significant cosmetic and functional problems. This study investigated the bacterial contamination of the rhinoplasty field and examined the effect of preoperative chlorhexidine treatment in decreasing bacterial contamination in the rhinoplasty field.

Materials and Methods: Thirty patients who underwent rhinoplasty were enrolled. Patients with an active *Staphylococcus aureus* (*S. aureus*) infection, chlorhexidine allergy, antibiotics treatment within 30 days from the surgery, acute sinusitis, or previous rhinoplasty history were excluded. Patients were block randomized into a chlorhexidine, regular-soap, or control group comprising of 10 participants each. The chlorhexidine group was subject to chlorhexidine showering, shampooing, and facial-cleansing 12 hours prior to the operation, the regular-soap group was subjected to showering, shampooing, and facial-cleansing with regular soap, and the control group did not have any skin pretreatment. Bacterial cultures were done at 12 hours preoperatively from the nasal cavity and perinasal skin, immediately

preoperatively from the perinasal skin and at 1 and 2 hours intraoperatively from the operation field. Culture results were compared between the three groups, according to operation time, or whether invasive procedures were undertaken.

Results: The bacterial species and numbers of Colony-forming unit (CFU) at preoperative nasal cavity and perinasal skin were similar. In all three groups, *Coagulase-negative staphylococcus* (*CNS*) was the most commonly found bacteria in the rhinoplasty field. The CFU numbers of *S. aureus* and *Corynebacterium* decreased rapidly less than 0.01 times after preoperative chlorhexidine treatment. The number of CFU for *CNS* showed a steady decline in all three groups. There was higher bacterial count (converted to percent) with the use of more invasive procedures, but this was not statistically significant. In all three groups, there was no postoperative infection during a follow-up period of 6 months.

Conclusions: This study identified that rhinoplasty surgical field is not sterile and continuously exposed to bacterial floras of perinasal skin and nasal cavity. Chlorhexidine pretreatment showed some effect in

decreasing the number of *S. aureus* and *Corynebacterium* on the perinasal skin but its effect on the prevention of postoperative infection needs further study.

Keywords: rhinoplasty, pretreatment, chlorhexidine, culture, infection

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LIST OF TABLES AND FIGURES

LIST OF ABBREVIATIONS

Staphylococcus aureus: *S. aureus*

Colony-forming unit: CFU

Coagulase-negative staphylococcus: *CNS*

Surgical site infection: SSI

Methicillin resistant S. aureus: MRSA

Introduction

Asepsis was first introduced in 1860 into the practice of surgery. It revolutionized the practice of surgery from frequent infection and death to prolonging life and improving quality of life.[1] Since then, it has become an intensive pursuit to eliminate surgical site infection (SSI) which could result in undesired complication and morbidity that hinders the surgeon's best effort to obtain a good result, especially in the case of rhinoplasty. Rhinoplasty is considered for a clean contaminated operation.[2,3] SSI in rhinoplasty could result in failure of implant and severe scarring of the nose, resulting in possible cosmetic and functional disaster.

Currently in the practice of rhinoplasty, the risk of SSI varies depending on the implant materials, status of reoperation and surgical techniques and is reported to be under 1%.[2,4,5] The prevention of infection is even more important in Asian rhinoplasty that is more vulnerable to infection due to frequent use of alloplastic implant.[4,6] Although antibiotics administered pre and post operatively can reduce SSI rate in rhinoplasty patients,[2] there is still a substantial rate of infection. Due to the severe consequences of SSI in rhinoplasty and increasing antibiotics resistance, it is pertinent to investigate on additional ways to reduce bacterial load intraoperatively.

One of the ways to achieve this is to administer preoperative skin sterilization. Skin pretreatment, among others, is an important step to decrease SSI rate in rhinoplasty as the main source of infection is likely to be direct inoculation of the patients' own microflora, especially from the skin and the manipulated site.[7,8] Antiseptic agents such as povidone-iodine, chlorhexidine

gluconate and alcohol are the most commonly used for skin pretreatment.[9]

Several studies comparing the effects of chlorhexidine gluconate and povidone-iodine has been mainly in orthopedic, gastrointestinal or gynecologic surgery. Most meta-analysis studies about efficacy of chlorhexidine and povidone-iodine on bacterial contamination suggested that chlorhexidine had significantly better efficacy than povidone-iodine.[9,10] On the contrary, there was a study that povidone-iodine may be superior to chlorhexidine in general surgery.[11]

So far there has been no study performed to characterize the bacterial population in the rhinoplasty surgical field and bacterial contamination before and after skin pretreatment. The purposes of this study are to characterize the bacterial population preoperatively and intraoperatively in the rhinoplasty surgical field and to examine the effect of preoperative chlorhexidine treatment in decreasing bacterial contamination and postoperative infection.

Materials and methods

Qualifying patients receiving rhinoplasty in the department of otolaryngology at Boramae Medical Center between June 24, 2013 and December 2, 2013 were evaluated. Thirty hospitalized patients who provided informed consent were included in this study, 10 each in the chlorhexidine group, the regular-soap group and the control group. Patients who had active *Staphylococcus aureus* (*S. aureus*) infection, chlorhexidine allergy, antibiotics

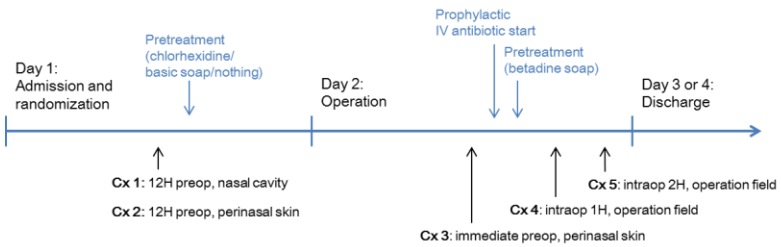
treatment at least 30 days before surgery, acute sinusitis or previous rhinoplasty were excluded from the study. This was approved by the Institutional Review Board of Boramae Medical Center (IRB No: 26-2013-6).

To prevent selection bias, block randomization was performed to determine the sequence of the chlorhexidine, regular-soap, and the control group. The patients were assigned to the groups based on the order of hospitalization. The chlorhexidine group was subject to shampooing, showering, and facial-cleansing with chlorhexidine gluconate solution (Hexidine®, Microshield 4, Johnson & Johnson Medical, North Ryde, Australia, 4% chlorhexidine gluconate with detergent, emollient, and moisturizer) 12 hours prior to the surgery. The regular-soap group was subject to pretreatment with regular soap provided by the hospital (Hair and body soap, LG Household & Care, Korea). The control group did not receive any pretreatment preoperatively.

Five bacterial swabs were taken from one subject at 4 different timings (Fig. 1). Twelve hours prior to the surgery, bacterial swab was taken using a sterile cotton swab from the nasal cavity and perinasal skin in all 3 groups before skin treatment (Culture at nasal cavity (Cx1), Culture at perinasal skin (Cx2)). In the following day, swab was repeated at the perinasal area immediately before povidone-iodine (Betadine®) pretreatment and draping in the operation room (Cx3). At 1 and 2 hours intraoperatively, bacterial swab was taken again from the nasal dorsum in the operative field (intra-dorsum, Cx4 and Cx5). Immediately before surgery, the patients were administered intravenous cefotetan 1 g (Yamatetan®) and it was given twice a day after surgery until they were discharged from the hospital. Patients were prescribed 7 days of

oral cefpodoxime (Banan®) 200 mg every 12 hours upon discharge.

Fig.1. Schematic diagram of bacterial cultures over time



The samples were stored in a conical tube containing 1 mL of 0.9% saline. The samples were cultured within 6 hours of collection. Two hundred microliter aliquots of each sample were inoculated onto blood agar, MacConkey agar and Sabouraud dextrose agar plates, and then these plates were incubated aerobically for 48 hours at 37°C. After 48 hours of incubation, the numbers of colony-forming units (CFU) on each plate were recorded, and the bacterial species were identified (VITEK II). When the identified bacteria exceeded 300 CFU, it was simply recorded as more than 300 CFU.

Bacterial identification was performed according to microbial examinations standards for categorization; a small population of common nasal cavity species was categorized as normal flora.[9] Any large bacterial population including typically normal residents were reported as pathogenic flora. Bacterial species and numbers of CFU were analyzed and compared between the groups according to the time sequence. The number of operative procedures which connect to nasal cavity (septoplasty, osteotomy, septal

extension graft and spreader graft) and graft material used (rib cartilage, temporalis fascia or allofascia) were counted from medical records. Especially, the number of invasive operative procedures such as osteotomy, use of rib cartilage or temporalis fascia was counted and the relation between that numbers with bacterial recovery rates was analyzed. Postoperative infection was investigated for 6 months postoperatively.

Statistical analyses were performed using SPSS 18.0 for Windows (SPSS Inc., Chicago, IL). Non-parametric independent t-test and ANOVA compared the continuous variable among the experimental, regular-soap, and control groups. Non-continuous variables were compared using the Chi-square test or Fisher's exact test. The association of pathogen identification was estimated by calculating the relative risk and 95% confidence interval; the *p*-values less than 0.05 were considered significant.

Results

The number, mean age, sex ratio and operation time of the 3 groups were showed in Table1. There was no significant difference in operation time between the 3 groups. Cx1 and Cx2 showed similar species and numbers of bacteria (Fig.2). Quantification of the CFU for the bacteria cultured is shown in Fig.3 to Fig.5. *Coagulase negative staphylococcus* (*CNS*) was the most prevalent bacteria in all three groups. Among all the pathogens identified, gram-positive pathogens including *CNS, S. aureus,* and *Corynebacterium* were the main pathogens around the rhinoplasty surgical site. Gram-negative pathogens including *E. aerogenes,* and *E. coli* were rarely observed in all 3

groups.

Table1. Demographics of the patients

Groups	Chlorhexidine	Regular-soap	Control
Number	10	10	10
Mean age (year)	25.4	30.2	35.0
Sex ratio (male:female)	9:1	4:6	6:4
Operation time (minute)	168.9	172.3	151.1

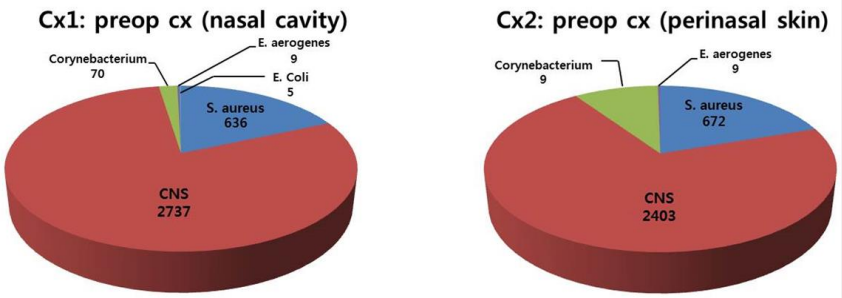


Fig.2. Culture results showing the numbers of CFU at preoperative nasal cavity and perinasal skin in thirty patients before skin pretreatment

In the chlorhexidine group, the numbers of *S. aureus* and *Corynebacterium* at Cx3 decreased compared to Cx2 but it was not statistically significant (Fig.3). In the regular-soap group, CFU number of *CNS* showed a steady decline but it was not statistically significant. The CFU numbers for other

bacteria did not differ much between Cx3 and intraoperative cultures (Cx4 and Cx5) (Fig.4). In the control group, the number of *CNS* and *S. aureus* slightly decreased but the numbers of *Corynebacterium* and *E. aerogenes* increased in Cx3 compared to Cx2 (Fig.5).

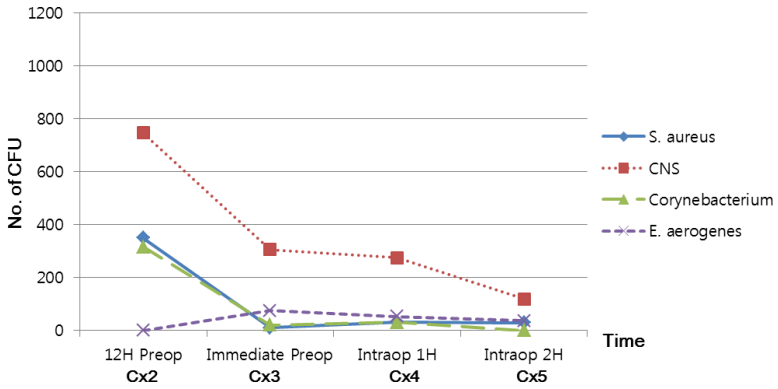


Fig.3. Culture results showing the numbers of CFU in the chlorhexidine group

No. of CFU: sum of ten patients: less than the same

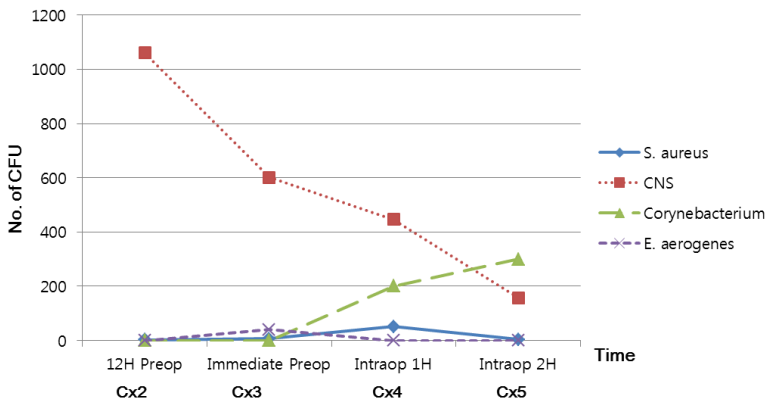


Fig.4. Culture results showing the number of CFU in the regular-soap group

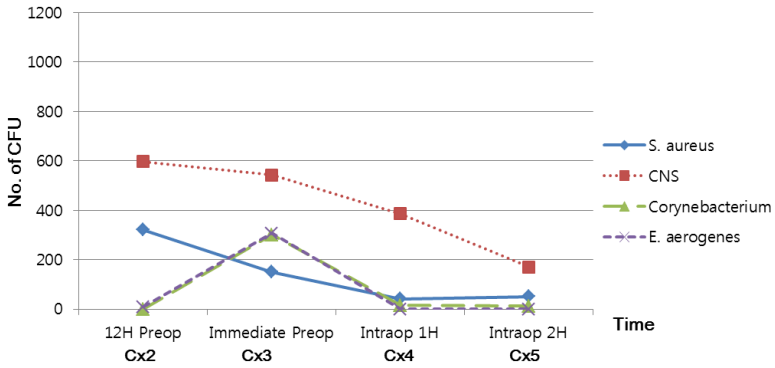


Fig.5. Culture results showing the number of CFU in the control group

The number of operative procedures (septoplasty, osteotomy, septal extension graft and spreader graft) and graft material used (rib cartilage, temporalis fascia or allofascia) were similar among the 3 groups (Table 2). Invasive operative procedures such as osteotomy, use of rib cartilage or temporalis fascia were associated with increased bacterial CFU (converted to %) over time during the operation, but it was not statistically significant (Fig.6). There was no postoperative infection in all 30 patients during a follow up period of 6 months.

Table2. Operative procedures and graft materials used in the chlorhexidine, regular-soap and control groups

Groups	Septoplasty	Osteotomy	SEG	SG	RCG	T.f.	Allofascia

Chlorhexidine	10	7	5	5	3	1	0
Regular-soap	10	5	3	4	3	1	2
Control	10	9	2	7	0	0	3

SEG: septal extension graft; SG: spreader graft; RCG: rib cartilage graft; T.f.: temporalis muscle fascia

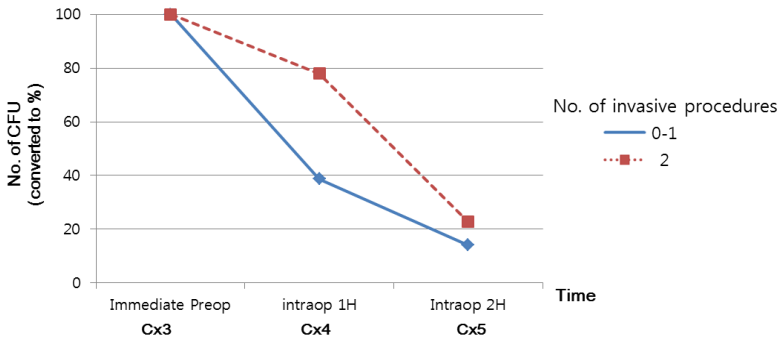


Fig.6. Culture results according to the number of invasive procedures

No. of CFU: converted to %

Discussion

There have been some reports about the SSI during septoplasty or rhinoplasty,[12-14] but there has been no study about the bacterial colonization at the rhinoplasty surgical field itself. The fact that *CNS*, *S. aureus*, *Corynebacterium*, *E. aerogenes* and *E. coli* were found in considerable amount in this study shows that rhinoplasty surgical field is not sterile and continuously exposed to bacteria.

Povidone-iodine is commonly used as an iodophor antiseptic by destroying microbial proteins and DNA.[15] It can be safely used on mucous membrane

surfaces, but its activity is limited by the amount of time the agent is in contact with the skin. Chlorhexidine has been used recently as a skin antiseptic. Chlorhexidine works by disrupting bacterial cell membranes and it has more sustained antimicrobial activity than other local antimicrobials because its resistance to neutralization by blood products than the iodophors.[16,17]

There was a study comparing bacterial contamination by whether chlorhexidine pretreatment or not. In plastic surgery such as breast reconstruction or liposuction, the surgical site of subjects randomly assigned to receive either a preoperative chlorhexidine shower, regular-soap shower, or no shower, then bacterial contamination of the site decreased with preoperative chlorhexidine shower.[18] However, unlike our study, this study only identified and compared bacteria CFU after respective pretreatments without including pre-sterilization and intraoperative bacterial CFU.

There have been studies supporting that chlorhexidine is more effective than povidone-iodine in decreasing SSI or bacteremia. In a study comparing the SSI rates between patients receiving chlorhexidine-alcohol or povidone-iodine pretreatment prior to a clean-contaminated procedure such as abdominal, thoracic or gynecologic surgery, the chlorhexidine-alcohol group experienced a significantly lower SSI rate of 9.5% compared to the 16.1% of the povidone-iodine group.[10] In a precedent randomized controlled clinical trial that compared the bacteriostatic and bactericidal effects of povidone-iodine and chlorhexidine on neonates weighing greater than 1500 g at birth, the 1% chlorhexidine more effectively reduced the bacteremia rate than did 10%

povidone-iodine, and no contact dermatitis was observed.[19] A meta-analysis study with 9 prospective, randomized controlled clinical trials suggested that the use of chlorhexidine for skin antisepsis, instead of povidone-iodine, would result in significant reduction in hospital-acquired infections and hospital costs.[20] In detail, cost-effectiveness analyses examining the use of chlorhexidine for all surgical site antisepsis suggested savings of $13 per case, or annual hospital savings of $285,298 and preventing of 68 SSIs annually in comparison with povidone-iodine.

Many studies have compared the individual antiseptic activity of chlorhexidine and povidone-iodine, but few studies have evaluated the activity of the compounds in combination. There were two studies investigating the combined effects of chlorhexidine and povidone-iodine when used sequentially. Langgartner et al concluded that skin disinfection with chlorhexidine followed by povidone-iodine was superior to either regimen alone in preventing central venous catether colonization,[21] and Guzel et al found that cleaning the skin with 15% chlorhexidine followed by 10% povidone-iodine was safe and effective for skin antisepsis prior to neurosurgical intervention.[22]

Nowadays while chlorhexidine is continues to be used as a skin pretreatment agent, it has gained popularity as a hand-scrubbing and showering antiseptic prior to surgery.[23] In this study, all patients had povidone-iodine preparation immediate before surgery regardless of chlorhexidine pretreatment to determine the effect of preoperative chlorhexidine in decreasing bacterial contamination and postoperative

infection. Furthermore, this is because the patients in control group get povidone-iodine preparation before surgery is ethical.

The perinasal skin was selected as a representative culture site proving the effect of chlorhexidine pretreatment because perinasal skin is a routinely exposed site that might contaminate the operation field during rhinoplasty. It is also an area where chlorhexidine pretreatment can easily implement its effect. The fact that the culture results from the nasal cavity, which can be another source of rhinoplasty field infection, showed similar result with the perinasal skin also supports our choice.

In this study, the decreased CFU numbers of *S. aureus* and *Corynebacterium* at the perinasal area in chlorhexidine group compared to other groups shows that the chlorhexidine pretreatment is effective in reducing the *S. aureus* and *Corynebacterium* contamination. The significance is not statistically maybe due to a small sample size. It is difficult to judge the effect of chlorhexidine for regular-soap to *S. aureus* and *Corynebacterium* because the CFU of *S. aureus* and *Corynebacterium* at 12 hours prior to surgery in regular-soap group was very low. However, the effect of chlorhexidine for no chlorhexidine treatment in reduction the *S. aureus* and *Corynebacterium* can be meaningful because *S. aureus* is a commonly found and virulent organism in postoperative wound infection. *S. aureus* is found in about 50% of all healthy persons in the nasal vestibule,[24] and the incidence of *methicillin resistant S. aureus* (*MRSA*) colonization is reported as approximately 0.8% of the US population and 0.7% in Australia community, and 3% in Pakistani community.[25]

From Cx3 to Cx5, all bacterial including *CNS* showed a steady decline in CFU except for *Corynebacterium* in regular-soap group. The reason for this intraoperative decline is considered to be caused by the effect of intravenous antibiotics or the irrigation of the operation field during the surgery. Preoperative and postoperative antibiotics and povidone-iodine preparation of the face and nasal cavity are routinely implemented procedures in our practice of rhinoplasty. Even though our study showed decrease in the perinasal skin colonization of *S. aureus* after chlorhexidine pretreatment, its preventive effect on postoperative infection is difficult to determine because there were no clinical infection case in all 3 groups.

In this study, there was a hypothesis that the more invasive procedures such as osteotomy, use of rib cartilage or temporalis fascia in rhinoplasty, higher remaining bacteria. It may because bacterial colonies of nasal cavity, chest, or scalp move to rhinoplasty surgical field, that is, intradorsum. The result at Fig.6 seemed likely that there is association between numbers of invasive operative procedures and remaining bacterial CFU. However, it was not statistically significant because this difference was to be masked by the effect of intravenous antibiotics or the irrigation of the operation field during the surgery.

Although this study is a prospective, randomized, and controlled study, the size of each group was not large enough to deduce statistically significant results. Future study with a larger numbers of patients will be necessary to elucidate the effect of chlorhexidine pretreatment in the prevention of SSI in rhinoplasty. In conclusion, authors found that rhinoplasty surgical field is not

sterile and continuously exposed to bacterial floras of perinasal skin and nasal cavity. Chlorhexidine pretreatment 12hours before the surgery showed some effect in decreasing the number of *S. aureus* and *Corynebacterium* on the perinasal skin but its effect on the prevention of postoperative infection needs further study.

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초 록

Introduction: 코성형 수술 후 감염은 흔하게 발생하며, 수술 후 감염은 중요한 문제가 될 수 있다. 코성형 수술부위의 오염 정도를 알아보고 수술 전 chlorhexidine 전 처치가 수술부위의 오염을 줄이는데 도움이 되는지를 알아 보고자 한다.

Material and Methods: 코성형 수술을 받은 30명의 환자를 대상으로 하였다. *Staphylococcus aureus* 활성 감염, chlorhexidine 알러지, 수술 전 한달 이내 항생제 복용력, 급성 부비동염, 이전의 코성형술의 기왕력을 가진 환자는 제외하였다. 환자들을 무작위 추출을 통해 각 10명 씩 chlorhexidine군, regular-soap군, 대조군의 세 군으로 나누었다. chlorhexidine군은 수술 12시간 전 chlorhexidine으로 샤워, 샴푸, 세안을 하였고, regular-soap군은 병원에서 제공한 일반 제품으로 샤워, 샴푸, 세안을 하였으며, 대조군은 아무런 피부 전처치도 하지 않았다. 모든 환자에서 4번의 시기에 총 다섯 번의 균배양이 시행되었다. 수술 전날 피부 전처치 하기 전 비강 내, 코 옆 피부에서 첫 번째, 두 번째 균 배양을 하였고, 수술실에서 povidone-iodine soap 도포 직전에 코 옆 피부에서 세 번째 균 배양을 시행하였다. 수술 시작 한 시간, 두 시간 후 수술 부위인 비배 내측 부위에서 네 번째, 다섯 번째 균 동정을 시행하였다. 세 군에서 시기에 따른 균 동정 결과를 비교, 분석하였고, 수술 술기에 따른 균 동정 결과를 추가 분석하였다.

메모 [B1]: 수술후 감염에서는 infection을, 수술 부위 오염에서는 contamination이 어울릴 것 같아 '오염'으로 기술 하였습니다.

메모 [B2]: Inclusion criteria보다, exclusion criteria가 중요해서, '---인 경우가 없는 환자를 대상으로 하였다 보다', '---는 제외하였다'로 기술 하였습니다.

Results: 수술 12시간 전 비강과 코 옆 피부에서 시행된 첫 번째와 두 번째의 균 동정 결과, 그 균 종과 균 수에서 통계적 의미 있는 차이는 없었다. 세 군 모두에서 *Coagulase-negative staphylococcus* (*CNS*)가 코성형 수술 부위에서 가장 흔하게 동정된 균이었다. Chlorhexidine 전처치 후 *S. aureus*와 *Corynebacterium*의 CFU수가 0.01배 이하로 급격히 감소하는 것을 볼 수 있었으나, 통계학적으로 유의하지는 않았다. 세 군 모두에서 *CNS* 의 수는 일정 비율로 감소하는 것을 볼 수 있었다. 침습적 술기를 많이 시행할수록 동정된 균의 수가 높은 경향을 볼 수 있었으나, 통계적으로 유의하지는 않았다. 세군 모두에서 6개월간 경과 관찰을 하여도 술 후 감염은 보고되지 않았다.

Conclusions: 코성형 수술은 수술 부위에서 피부 상재균이 동정되는 clean contaminated operation이며, Chlorhexidine 피부 전처치를 통해 코 옆 피부에서 *S. aureus*와 *Corynebacterium*의 수를 줄이는데 도움이 되었다. Chlorhexidine 의 수술 부위 오염을 줄이는 효과가 수술 후 감염을 줄일 수 있는지에 대해서는 좀 더 많은 환자를 대상으로 추가 연구가 필요할 것이다.

Keywords: rhinoplasty, pretreatment, chlorhexidine, culture, infection

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