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# Comparative analysis of pre operative Chlorhexidine and povidone iodine oral rinses in prevention of Surgical site infection in high-risk group oral cancer patients- A randomised clinical Trial

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# **ABSTRACT**

#### Introduction

Following head and neck surgery, surgical site infections (SSIs) are a significant contributor to morbidity and mortality. Patients undergoing flap reconstruction have reported wound infection rates ranging from 20% to 40%, even with perioperative systemic antibiotic therapy. Pre-operative surgical site preparation lowers the incidence of surgical site infections (SSIs) and the microbial burden on the surgical site. Currently, the most often used preoperative skin antiseptics are povidone-iodine (PI) and chlorhexidine (CH). However, information about the frequency of mucous adverse events and the avoidance of surgical site infections (SSIs) is not consistently available. In order to lower surgical site infection in these high-risk patients undergoing head and neck surgery, our study sought to ascertain the effectiveness of preoperative topical decolonisation.

#### Materials and methods

This study was conducted among 60 patients of high-risk group presenting oral squamous cell carcinoma requiring surgical intervention. Our study inclusion criteria were high risk group patients having ASA III, Tumour staging IV, Undergoing flap reconstruction. Patients were randomised into three groups. Group A - No use of any preoperative topical anti-microbial decolonization method, Group B - Chlorhexidine mouth wash, Group C -

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Povidone iodine rinses. Pre-operatively for 1 week with standard perioperative systemic antimicrobial prophylaxis. The main outcome was the incidence of SSIs.

#### Results and discussion

Out of 60 patients involved in study 20 developed surgical site infection- 10 patients of the control group, 3 patients of the CHX group, and 7 patients of the povidone-iodine group. The results of our study indicated that the Chlorhexidine group had a significantly lower infection rate, and that topical decolonisation prior to surgery is a useful strategy for lowering surgical site incidence.

#### Conclusion

The frequency of surgical site infections following head and neck surgery is greatly reduced when antiseptic mouthwashes, such as those containing 0.2% chlorhexidine and 10% povidone iodine, are used before surgery. However, occurrence of surgical site infection is multifactorial.

**Keywords:** Surgical site infection, Pre-operative, Chlorhexidine, Povidone iodine, Oral cancer,

#### INTRODUCTION

After head and neck surgery, surgical site infections (SSIs) can lead to a worsening prognosis, an extended hospital stay, and unsatisfactory cosmetic outcomes. They are also a significant cause of morbidity and mortality. 8% to 45% of cases occur even with routine antibiotic prophylaxis. [1,2] The majority of surgical site infections (SSIs) following head and neck surgery result from endogenous flora that is either skin or aerodigestive tract-resident. [3,4] Although the term "postoperative surgical site infection" is not well defined, it is generally agreed upon that superficial and deep wound infections (SSI) within 30 days after surgery [5,6,7]. Preoperative antibiotics, aseptic operations, rigorous hand antiseptics, and other measures are some of the ways that postoperative surgical site infections can be avoided. Preoperative skin antiseptic use is one of the most important risk factors for postoperative surgical site infections, according to updated guidelines for the prevention of postoperative surgical site infections from the World Health Organisation (WHO) [8], the Centres for Disease Control (CDC) [9], and the National Institute for Health and Care Excellence (NICE) [10]. Patients undergoing flap reconstruction have reported wound infection rates ranging from 20% to 40%, even with perioperative systemic antibiotic therapy. [16] An agent with broad antibacterial activity, chlorhexidine is used in several therapeutic contexts. [11] Both povidone-iodine (PVP-I) and chlorhexidine (CHX) have broad-spectrum bactericidal actions, keeping microbial counts low, which may help oral or cutaneous wounds heal. [12,13] Chlorhexidine and povidone iodine is typically found in topical solutions and mouthwashes, gels, and toothpaste designed to treat plaque and gingivitis. However, research has shown that both are cytotoxic and genotoxic to fibroblasts and osteoblasts in vitro, which may slow down the healing process even if they have broad-spectrum germicidal effects. [14,15]

In clinical settings, povidone-iodine is the most often utilised preoperative skin antiseptic. Nonetheless, a number of studies conducted in the last few years have demonstrated that, when it comes to preoperative skin antiseptic, chlorhexidine works better than povidone-iodine. For doctors, selecting preoperative skin disinfectants is a perplexing issue. The majority of research on decolonization's efficacy in reducing surgical site infections (SSIs) relates to orthopaedic and cardiac surgery; head and neck surgical patients have not been the subject of this research. Our study aimed to determine the efficacy of preoperative topical decolonisation before head and neck surgery in reducing surgical site infection in these high-risk patients.

## MATERIALS AND METHODS

This study was conducted in Department of Oral and maxillofacial surgery of Saveetha Dental college and Hospital, Vellapanchavadi, Chennai, Tamil Nadu, India. Among 60 patients of high-risk group presenting oral

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squamous cell carcinoma requiring surgical intervention. Our study inclusion criteria were high risk group patients having ASA III, Tumour staging IV, Undergoing flap reconstruction. Patients were randomised into three groups. Group A - No use of any pre-operative topical anti-microbial decolonization method, Group B – Chlorhexidine mouth wash, Group C – Povidone iodine rinses. Pre-operatively for 1 week with standard perioperative systematic antimicrobial prophylaxis. We excluded the patients who are allergic to chlorhexidine and povidone iodine. Patients were evaluated for any developing signs of infection as per guidelines by US centres for disease control and prevention. The main outcome was the incidence of SSIs. Swab culture was taken from the infected site and sent for culture and sensitivity as a confirmatory for growth of pathogenic microorganisms. Ethical clearance was taken from the Saveetha Dental College & Hospital institutional Human Ethical committee (SDC-IHEC), IHEC-Reference Number: IHEC/SDC/OMED-2303/24/159.

### Statistical analysis

Demographic variables were documented. Data entered into Microsoft Excel was verified. SPSS software was used for statistical analysis. Frequency analysis, percentage analysis, and mean & standard deviation were utilised for continuous variables, while categorical variables were described about the data using descriptive statistics. The significance of categorical data was determined using the Chi-Square test. The probability value of 0.05 is regarded as the significant level in all of the statistical tools mentioned above.

#### RESULTS

In our study, based on the age distribution of the study population 3.3% of the patients are in 31-40 years age category, 25% of the patients are in 41-50 years age category, 36.7% of the patients are in 51-60 years age category and 35% of the patients are in greater than 60 years age category. This indicates young adults are less prone in developing surgical site infection and oral carcinomas. Majority of the patients fall under the age category of more than 60 years old. The mean age of our study population is  $56.1 \pm 9.6$ . Gender distribution, more than three quarters (76.7%) of the patients are male and rest (23.35) of them are female. Based on our study results male are more prone to get SSIs. Though P value showed noteworthy statistical significance.

Among the 60 patients selected, 40 patients show no signs of surgical site infection or wound dehiscence, 20 of them developed SSI postoperatively. The incidence of SSI among oral cancer patients between three groups were; SSI developed in 10 patients of the control group, 3 patients of the CHX group, and 7 patients of the povidone-iodine group. The difference in the incidence of SSI among oral cancer patients between the three groups was statistically significant (p=0.041). Our study results also suggest Gender, ASA classification, Reconstruction with flap is directly associated with surgical site infection.

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| Age in years | No of patients (n=60) | Percentage (%) |
|--------------|-----------------------|----------------|
| 31-40        | 2                     | 3.3%           |
| 41-50        | 15                    | 25%            |
| 51-60        | 22                    | 36.7%          |
| >60          | 21                    | 35             |

Table 1- Demographic details – Age

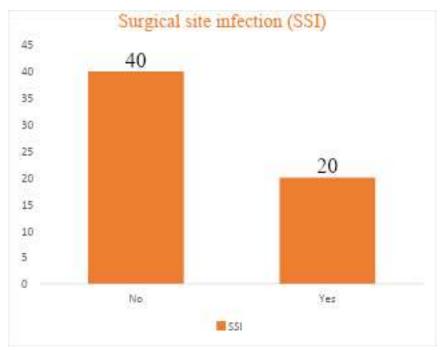


Figure 1: Incidence of Surgical site infection

Table 2: Comparison of incidence of SSI among three groups

| Developed SSI |   | Control (A) | CHX (B) | PI(C) | p-value |
|---------------|---|-------------|---------|-------|---------|
| No            | N | 10          | 17      | 13    | 0.041   |
|               | % | 25%         | 42.5%   | 32.5% |         |
| Yes           | N | 10          | 3       | 7     |         |
|               | % | 50%         | 15%     | 35%   |         |

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#### **DISCUSSION**

The most common cause of nosocomial infections in surgical patients is surgical site infection. [17] The rate of postoperative surgical infections was startlingly high before to the development of the germ theory of infection and the realisation of antisepsis's preventative effectiveness. Our findings point to a tendency in head and neck surgery patients' SSI incidence declining with preoperative oral rinses decolonisation. The use of alcohol-based antiseptic solutions during head and neck surgery is contraindicated because to the increased risk of surgical fire caused by the anatomic proximity to the airway and oxygen The ideal way to apply new findings about the efficacy of various surgical site antiseptic treatments to head and neck surgery is still up for debate. Chlorhexidine is a member of the bisbiguanide class of antimicrobials. The most common oral preparation is 0.2% water-soluble chlorhexidine gluconate, which dissociates at physiological pH to produce a molecule with a positive charge. The antibacterial properties of chlorhexidine gluconate (CHG) arise from its ability to destabilise bacterial cell membranes. The cytoplasmic (inner) membrane is harmed by CHG when it first destroys the outer cell layers and passes through the cell wall or outer membrane. Cell death and intracellular component leakage result from this. [18,21] Povidone iodine is a water-soluble iodine compound including polyvinylpyrrolidone. The most popular formulation of free iodine is a 10% solution, which releases the bactericidal component gradually and contains 1 ppm of free iodine. Targeting proteins, nucleotides, and fatty acids in the cytoplasm and cytoplasmic membrane, iodine enters bacteria and inactivates components that are essential for survival, eventually resulting in the death of bacterial cells. [19-21]

The mean age of our study subjects is  $56.1 \pm 9.6$ . The preoperative and operational checklists must be followed consistently in order to reduce the incidence of surgical site infections. In our study among the 60 high-risk oral carcinoma patients, 20 patients developed SSI. A study conducted by Swenson BR et al (2009) [23] 6.7% of the patient treated with Chlorhexidine and 6% of the patient treated with povidone iodine developed SSI. According to our research, ASA and the onset of SSI are directly correlated. Numerous studies examining the connection between ASA and SSI are lacking. 33.4% of the total study population developed SSI who underwent flap reconstruction. The flap recipient site influences the incidence of SSI. According to reports, it can happen in as many as 16.5% of head and neck reconstruction surgeries. [22]

In our study the incidence of SSI among oral squamous cell carcinoma patients between three groups. SSI developed in 10 patients of the control group, 3 patients of the CHX group, and 7 patients of the povidone-iodine group. Researchers Wu yan [24], Patrick [25], Guo [26], and Culligan et al. [27] examined the effects of povidone-iodine and chlorhexidine on local bacteria and discovered that the former considerably inhibited the growth of bacteria more than the latter. Research conducted by Kulkarni and Awode [28] revealed that povidone-iodine had a longer-lasting effect than chlorhexidine. However, Study conducted by Andrew G Shuman in 2012 [29] indicates that there was no significant change in the number of SSIs following perioperative topical antibiotic decolonization, even if there was a tendency toward a decrease.

This study underscores the effectiveness of Chlorhexidine in the pre-operative decolonisation of high-risk oral carcinoma patients for the prevention of surgical site infection its complications and adverse effects.

#### Conclusion

Pre-operative use of Anti-septic mouth wash example- 0.2% chlorhexidine, 10% povidone iodine significantly decrease the incidence of surgical site infection after head and neck surgery. It can be considered for high-risk groups despite the lack of statistically significant evidence confirming efficacy. According to this study, povidone-iodine was not as effective as chlorhexidine in reducing surgical site infections after surgical management in oral squamous cell carcinoma patients.

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