IOSR Journal of Nursing and Health Science (IOSR-JNHS)
e-ISSN: 2320–1959.p- ISSN: 2320–1940 Volume 13, Issue 6 Ser.4 (Nov. – Dec. 2024), PP 05-71
www.iosrjournals.org

A STUDY TO ASSESS THE EFFECTIVENESS OF SALT WATER GARGLE VERSUS BETADINE GARGLE ON THROAT PAIN AMONG EXTUBATED PATIENTS IN A SELECTED HOSPITAL, BENGALURU.

BY

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Dissertation submitted to the

Rajiv Gandhi University Health Sciences, Karnataka, Bengaluru

In partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE IN NURSING

In

MEDICAL SURGICAL NURSING

(Neuroscience Nursing)

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2019-2021

ABSTRACT

Title: Effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients.

Background

Airway management is one of the important life support and especially tracheal intubations plays a major role in maintaining as well as restoring ventilation in a patient. This procedure is also indicated for patients undergoing general anesthesia. Tracheal intubations can cause throat pain, injuries to the tracheal tissues which results in discomfort for the patients. Therefore, in order to reduce the throat pain. Hence a study tilted "The effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital, Bengaluru" was undertaken by the investigator.

Objectives of the study

1. To compare the throat pain before and after salt water gargling.

2. To compare the throat pain before and after betadine gargling.

3. To compare the change in throat pain between the two groups after the intervention.

4. To determine the association of throat pain with the selected baseline variables in both the groups.

Methods

A comparative survey design was adopted and 60 patients admitted in MICU, SICU and EICU of St John's Medical College and Hospital, Bengaluru were selected by purposive sampling method. Numerical pain scale was used to assess the throat pain among extubated patients before and after the interventions. The data were analyzed using descriptive and inferential statistics.

Results

The findings of the study revealed that there is statistically significant difference in throat pain before and after the interventions in both the groups (p = <0.0001) In group 1 mean scores of throat pain before and after intervention is 3.27 and .63 respectively. In group 2 mean scores of throat pain before and after intervention is 3.37 and .10. And there was also significant difference between the two groups before and after the intervention (p = <0.013) with mean score difference in group 1 is 2.64 and in group 2 is 3.27. There is no significant association between pertest throat pain and selected baseline variables.

Conclusion

The study shows that salt water gargle and betadine gargle are effective in reducing throat pain among extubated patients and either of this intervention can be used to reduce the throat pain and make the patients comfortable.

Key words

Extubated patients, numerical pain scale, salt water gargle, betadine gargle.

1. INTRODUCTION

The availability of information and the growth of science have led to a significant improvement in health outcomes throughout the world. However, differences in outcomes, health inequalities and poorly performing health services continue to present a real challenge to all nurses. Half of the world's deaths could be prevented with simple cost-effective interventions but as the World Health Organization (2004) acknowledge not enough known about how to make these more widely available to the people who need them. Stronger emphasis needs to be placed not just on the discovery of the new products, drugs and diagnostics but on how we put the knowledge into practice; on how we close gaps between evidence and action.

Airway management includes evaluation, planning, and use of medical procedures and devices for the purpose of maintaining or restoring ventilation in a patient. These procedures are indicated in patients undergoing general anesthesia and in patients with respiratory failure or acute airway obstruction.[1] There are mainly two types of airway managements-Basic and Advance Airway Management. The Basic Airway Management includes head and neck maneuvers to optimize ventilation, abdominal thrusts, and back blows. The Advance Airway Management are tracheal intubation, cricothyrotomy, and tracheostomy[1].

Tracheal intubation is one of the most widely used methods to deliver anaesthesia. However, tracheal intubation is an invasive procedure. Placement of the tracheal tube can damage the vocal cords, tracheal mucosa. The space between the vocal cords, Rima glottides is narrowest part of airway and also the cricoid cartilage. Women has the narrower larynx than men [15]. Therefore, the inflated cuff in the trachea

for prolonged period leads to sore throat and hoarseness of voice. [2] According to American Pain Society, pain is an unpleasant sensation often experienced by the patients, and it has been referred to as the fifth vital sign. Pain is uniquely subjective individual experience, described as sharp, dull, burning, numbing, minor, major, acute, chronic, throbbing, aching, stinging, and so on. It can be the source from mild to severe states of discomfort and disquiet [3].

The International Association of Health defines the study of pain as "An unpleasant sensory and emotional experience associated with the actual or potential tissue damage or described in terms of such damage". Because pain is subjective and unique individual experience; Pain Management can pose challenges for the patients and health care providers. The higher intensity of pain particularly from longer duration of intubation may also lead to dysphagia and; also, in a study which shows that post-operative sore throat has been rated by patients as the 8th most undesirable discomfort in the postoperative period [16].

A study conducted in Greenland, showed that about 3% of intubated patients had complaints of throat pain lasting longer than one week and on laryngoscopy was found to have laryngeal lesions, pharyngeal haematomas or granulomas of the vocal cords [6]. The cause of throat pain is multifactorial. An evaluation from the studies states that using many different intubators, anestheisa methods were used to identify as many causal factors of post-operative throat complaints [6].

Post-operative throat pain is a major cause due to the intubation. There are various studies that have reported, that, patients who have undergone surgery under general anesthesia, experience throat pain postoperatively, which could become discomfort and uneasy, and this could be one of the factors. In a study done in Ethiopia among postsurgical patients with throat pain, it showed that about 27% of the patients had complaints of severity in pain, 43% had moderate pain and 59% of the patients had mild ache as indicated in the numerical pain scale [5]. Pain management is one of the main facets of nursing care. It is the alleviation of pain or reduction in pain to a level of comfort, that is acceptable to the client. Management of pain mainly comprises of pharmacological and non-pharmacological measures.

Salt water gargle has an effect of osmosis which draws out the fluid from the inflamed tissue as a result it decreases the inflammation and reduces the pain. And also, betadine has an effect of antiseptic which decreases the bacterial count. Therefore, the researcher with her own clinical experience has observed that the patients who are extubated develop pain, sore throat and hoarseness[3,4]. The central core of nursing is patient care and nurses have a special obligation to exercise competence in the field of practice. This study, thereby attempts to elucidate the impact and effect of salt water gargle versus betadine gargle on throat pain among extubated patients, and to apply this practice into nursing care setting.

NEED FOR THE STUDY

Tracheal intubation is done to prevent aspiration, reduction of dead space, accessibility of the airway for suction and controlled ventilation complications. An inflated endotracheal cuff has a risk for impairing tracheal capillary perfusion pressure. Sustained over inflation of ETT cuff leads to complications such as sore throat [1,2] hoarseness [1,2], pain [1,4] and nausea. These complaints have also been subjectively expressed by patients after tracheal intubation.[1] The incidence of sore throat among post-operative patients in a study were 56.6%, and 68% of participants had hoarseness of voice.[2]

Many of the critically ill patients are subjected to tracheal intubations as a life saving option to deliver mechanical ventilation and also the patients undergoing surgery under general anethesia, also needs tracheal intubations. According to American Journal on Anesthesia the incidence of sore throat after endotracheal extubation was found to be 90% and also the most common complaint of patients[8].

In a study, it shows that the incidence of coughing on emergence from general anesthesia, in the presence of an endotracheal tube, has been estimated between 38% and 96%; and it was observed that the delay in the extubation, aspiration of secretions, and blood in the ETT or blood during suctioning were the risk factors for post-operative sore throat. Therefore, the duration of extubation, coughing during extubation, and

suctioning before extubation would impact the incidence of post-operative sore throat. Also, several other factors, such as use of a muscle relaxant, neuromuscular monitoring, awake or deep extubation, timing of suctioning, suction pressure, and need for airway maneuvers immediately following extubation, could also significantly contribute to the frequency of post-operative sore throat [13].

A study done in Switzerland among 809 patients, highlighted that 40% of the patients developed sore throat following tracheal intubation. Salt water gargle is proved to have bactericidal and virucidal effect, and as it has the higher solute concentration which draws out the fluid from the inflamed tissue as a result which decreases the inflammation and reduces the pain. And betadine is known as Povidone Iodine, it is a Polymer Polyvinylpyrrolidone (PVP-I) well tolerated than other conventional antiseptic agent and completely soluble in cold and mild warm water has pharmacological role of strong anti-viral effect. Therefore, the researcher with her own clinical experience has observed that the patients who are extubated develop pain, sore throat and hoarseness[3,4].

Repeated attempts to place the intubation tube within the trachea can also damage the surrounding tissues of the mouth or throat. Inflammation caused by tissue damage can result in swelling of the injured body region, which is a side effect of intubation. And patients feel uncomfortable because of pain as a result they experience difficulty in speaking, and swallowing food. Nurses play an important role in assessing, managing, and providing care to the patients. The

investigator has seen the patients experiencing throat pain after extubation and to treat the pain, the investigator wanted to compare whether the salt water gargle or betadine gargle provides pain relief and which among this is more effective in intubation. These interventions are simple interventions which can be done easily by the nurses to reduce the pain and to make the patients more comfortable.

Hence, we see the importance for early assessment and providing care of the patients. Owing to the detailed background mentioned above, it is in the interest of the investigator to compare the effectiveness of betadine gargle versus salt water gargle on throat pain among extubated patients. The findings of the study will help the patients in the terms of reducing the throat pain after extubation. It also helps the nursing professionals to focus more on these neglected aspects and help in the implementing appropriate method to reduce the throat pain after extubation.

2. OBJECTIVES

STATEMENT OF THE PROBLEM

A study to assess the effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital, Bengaluru"

OBJECTIVES OF THE STUDY

1. To compare the throat pain before and after salt water gargling.
2. To compare the throat pain before and after betadine gargling.
3. To compare the change in throat pain between the two groups after the intervention.
4. To determine the association of throat pain with the selected baseline variables in both the groups.

OPERATIONAL DEFINITIONS

1. EFFECTIVENESS:

It refers to the capability of producing a desired result and the ability to produce desired output.

In this present study, effectiveness refers to the reduction of throat pain using salt water or betadine gargle which will be assessed by numerical pain scale.

2. SALT WATER GARGLE:

In this study, it refers to gargling done with salt water by mixing 3 grams of table salt in 100ml of normal water to form a salt solution, which the subjects will gargle the entire solution each time for two days in the morning and in the evening.

3. BETADINE GARGLE:

In this study, it refers to gargling done with betadine by mixing of 1ml of 2% of betadine in 100ml of normal water to form betadine solution, which the subjects will gargle the entire solution, each time, for two days in the morning and in the evening.

4. Throat pain among extubated patients:

It refers to the pain reported by subjects which is caused due to the insertion of endotracheal tube that is assessed by numerical pain scale.

ASSUMPTIONS:

1. Patients may experience intubation induced throat pain

2. Salt water gargle and betadine gargle may reduce intubation induced throat pain among patients.

CONCEPTUAL FRAMEWORK

The conceptual framework for the present study is based on the general systems theory as postulated by Von Ludwig Bertalanffy (1968) as explained by Newky (1996). According to this theory, a system is composed of both structural and functional components that interact within a boundary, and make each system distinct from the environment in which it is resolved into an aggregation of feedback circuits each as input, throughput and output. The feedback circuits helps in maintenance of an intact system.

Input

Is any form of energy, information, material or human that enters into a system through its boundaries. In this study, input refers to the Age, Gender, Education, Diagnosis, Duration on ventilator in hours, Use of analgesics, Number of attempts, Duration of extubation from ventilator, Pervious history of extubation.

Throughput

Is the process that occurs at some point between the input and output process which enables the input to be transferred as output in such a way that it can be readily used by the system. In this study, it refers to the assessment of pain in both the study groups and the intervention are carried out that is to see the effectiveness of salt water gargle versus betadine gargle among extubated patients.

Output

Is the energy, material or information transferred to the environment. In this study the output is the change in pain levels of both the groups.

Feed Back

Feedback is the information on environmental response to the system output, which is used by the system for adjustment, correction and accommodation to interact with the environment.

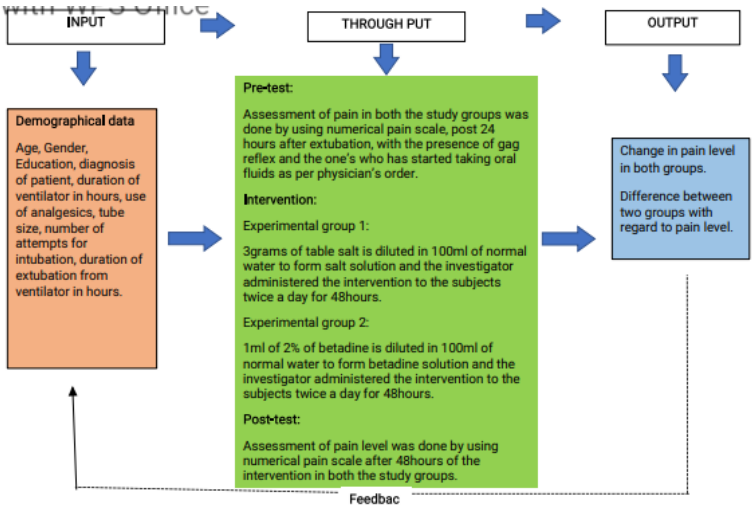


FIGURE 1: CONCEPTUAL FRAMEWORK BASED ON GENERAL SYSTEM THEORY BY BERTALANFFY IN 1968

DELIMITATION

The study is limited to patients admitted in MICU, SICU, EICU at St. John's Medical college Hospital, Bengaluru.

PROJECTED OUTCOME

- Findings of this study will help to identify the best method to reduce throat pain.
- The findings will serve as a basis for implementation of evidence-based practice.

HYPOTHESIS

H1: There will be a statistically significant difference in throat pain among extubated patients before and after salt water gargling at 0.05 level of significance.

H2: There will be a statistically significant difference in throat pain among extubated patients before and after betadine gargle at 0.05 level of significance.

H3: There will be a statistically significant difference in throat pain among extubated patients between both groups at 0.05 level of significance.

H4: There will be a statistically significant association of throat pain among extubated patients with selected baseline variables at 0.05 level of significance.

3. REVIEW OF LITERATURE

Review of literature is an essential step in a research. It provides basis for future investigations, justifies the need for the study, throws light on the feasibility of the study, reveals constraints of data collection and relates the finding from one study to another with the hope to establish a comprehensive study of scientific knowledge in a professional discipline, from which valid and pertinent theories may be developed [8].

The literature review for the present study has been discussed as follows:

1. Literature related to intubation induced throat pain.

2. Literature related to salt water gargle on intubation induced throat pain.

3. Literature related to effectiveness of betadine gargle on intubation induced throat pain.

1. Literature related to intubation induced throat pain

A comparative study was conducted in Sweden to assess the throat pain among the patients undergoing surgery. 82 patients above the age of 18 years were included in the study. They were randomly divided into two groups, each group consisting of 44 and 38 participants respectively. Group 1 of 44

patients were intubated with 6.5mm and the group 2 of 38 patients were intubated with 7mm.The results of the study showed that the 29.5% patients intubated with 6.5mm of ET tube developed sore throat whereas 39.5% patients intubated with 7mm ET tube developed sore throat. Therefore, there was a significant difference between tube size and self-rated pain scores among the two groups. It can be concluded that smaller tube sizes are associated with lesser pain [6].

A Cross sectional study was conducted in Ethiopia among 228 patients. Subjects were obtained through purposive sampling method. The interview was done between 12 and 24 hours post operatively after the patient is fully recovered from anesthesia and feels comfortable. The result of the study which showed that they had following symptoms that is about 129 (56.6%) participants had postoperative sore throat (POST), 68 (29.8%) of them developed hoarseness of voices and, sore throat was severe in 27(11.8%), moderate in 43(18.9%) and mild in 59(25.9%). And also, the participants complained of nausea and vomiting which was about 68.2%. The study concluded that majority of the patients experience sore throat after extubation and also difficulty in swallowing and speaking [20].

A descriptive study was conducted in North Korea on Incidence and Risk Factor, among postoperative patients with sore throat after endotracheal intubation. The study enrolled 207 patients by purposive sampling technique and after extubation post-operative

sore throat was assessed using a visual analogue scale which indicates that 0 score as no pain and 10 score as worst pain. The incidence of post-operative sore throat was 57.5% and the risk factors was found to be the intracuff pressure which was 17 cm H_2O and also the intracuff pressure above 17 cm H_2O resulted in hoarseness of voice. The study reveals that increase in intracuff pressure results in high incidence of sore throat[24].

A prospective study was conducted in Tamil Nadu, India. The study was to assess the adverse reactions of anaesthesia. The parameters for the study were hoarseness, throat pain and nausea the study was conducted for six months. Among 135 patients, the age group between 18 to 65 years were enrolled and 15 samples were excluded due to incomplete records. Adverse clinical outcomes of anaesthesia was assessed using verbal rating scale (VRS) score. Day of incidence of adverse outcomes was also monitored. The subjects had following symptoms such as headache, vomiting, hoarseness, pain, nausea, sore throat. The highest symptom experienced by patient was found to be sore throat with Chi-square value was 26.594 and $p<0.001$ which shows statistically significant. It can be concluded that tracheal intubation leads to complications such as hoarseness, nausea and pain.[7]

A cohort study was conducted in Saudi Arabia among 140 patients undergoing elective surgery. The patients were randomized into two groups. One group was intubated with glideslope

laryngoscope and the other group was intubated with Macintosh laryngoscope. Post-operative sore throat was assessed after the extubation using structured questionnaire which consists of 12 questions. The results of the study showed that the about 72% of the patients had severe pain intubated with Macintosh laryngoscope when compared to glideslope laryngoscope the study concluded that Macintosh blade is larger when compared to glideslope [17].

A descriptive study was conducted in Canada among 1325 patients, who had undergone surgery under general anesthesia the subjects for the study was selected through purposive sampling and the sore throat was assessed by using structured questionnaires. The incidence of sore throat was found to be 14.4%. And also the study showed that Multiple attempts of intubations which did not increase the incidence of sore throat, About 70.5% of the subjects complained of dryness of throat, 50% of patients had hoarseness, 18.5% had a cough. The findings of the study says that prolonged use of anesthesia can be the major cause for hoarseness and sore throat [31].

A Meta-analysis study was conducted in China among 509 female patients who had undergone surgery under general anethesia. The subjects for the study were selected using randomized control trail. And the details of study designs included, ETT insertion and anesthetic technique, ETT size, surgery duration, anesthesia maintenance, narcotic use. For meta-analysis three selected trials

were used among which one is a cohort study. Randomized sequence and allocation sequence were adequately conducted in two studies. The result of the meta-analysis study showed that smaller size of ETT reduce the incidence of post-operative sore throat p <0.0001 and the study concluded that there was difference in the level of sore throat between the 1[st] hour and 24 hours after the surgery [32].

2. Literature related to salt water gargle on intubation induced throat pain.

A experimental study was conducted in Malaysia to assess the effectiveness of thymol glycerine and salt water gargle on sore throat with nonbacterial pharyngitis for a period of 6 months. The participants for the study were 100 and they were randomized into groups of two, consisting of 50 participants in each group. Group 1 with 50 participants received salt water gargle for three times a day for one week. The other group with 50 participants received thymol glycerine for three times a day for one week. After 1 week sore throat questionnaire was filled. Salt water gargle has an anti-inflammatory property, the throat pain was reduced when compared to the patients who received thymol glycerine gargle. Therefore, the result of the study shows that there was a significant difference (p = < 0.005) the mean score of sore throat in group 1 before and after gargle is 5.22 and 1.32 respectively. In group 2 the mean score of sore throat before and after intervention is 6.00 and 4.22. The study concludes that gargling

with salt solution is natural and harmless it also helps to reduce the throat pain [8].

A case-control study was conducted in Mecca among 338 pilgrims, with all types of respiratory tract infections, with the symptoms of throat pain the purposive sampling method was used and the subjects were asked to wash their mouth and gargle their throat with salt water at least once a day. Structured interview method was used after the intervention to assess the effectiveness. The study concluded that lack of gargling with salt water increased the risk of respiratory infections by 2.3 times and the mean sore for throat pain was 7.01 which was high when compared with those who carried out the intervention with mean score 4.33 [21].

A prospective clinical study was conducted in Germany among 90 participants to assess the effectiveness of lozenges and salt water gargle on acute viral pharyngitis. The variables assessed were pain when swallowing, urge to cough and hoarseness. Hypertonic saline gargle was prepared ¼ of table salt was diluted in 1 glass of warm water. The participants were divided into 3 groups, in group one-35 participants received ectoine lozenges, in group two-35 participants received hyaluronic acid lozenges and in group three- 20 patients received hypertonic saline for gargling. Subjects were asked to keep the lozenges or tablets still , without sucking, until the first scintigraph image had been taken, after which they were asked to suck them normally. The throat spray was directed to the back of the throat and subjects were asked to

swallow before the first image was taken. With the gargle, subjects gargled with 15 ml of solution for 20–30 seconds and then expelled the solution before imaging. Scintigraphic images were used to analyse the amount and coverage of radioactivity in the mouth and throat. All the participants were asked to gargle for 7 days. And the subjects were assessed the greatest symptom reduction in the study was observed is 79.5% in the ectoine group, 72.2% in the hyaluronic acid lozenges group and 44.8% in the saline gargle group the interventions were found to be significant on throat pain in all the study groups. The results suggest that solid dose forms like lozenges and tablets are ideal interventions for the treatment of sore throat[9].

A comparative study was done in Egypt among group of children to assess the effectiveness of saturated saline rinse, alum mouth rinse and distilled water rinse on oral hygiene. 50 subjects were selected by using simple random sampling and the subjects were asked to gargle twice, daily for 21days and three saliva samples were taken from each individual on the 10th day and on the 21st day, and colony counts of Staphylococcus mutans were determined. Results showed that the children using saturated saline rinse and alum rinse showed statistically significant reductions in salivary Staphylococcus mutans counts after 10 days and also after 21 days. The results of the study revealed that there was statistically significant differences $p < 0.002$ in all the study groups but the mean score was high in saline gargle group it

was 5.33 when compared with the other study groups[22].

A comparative study was done in Indonesia among 93 subjects and were randomized into 3 groups to assess the effectiveness of Seawater, Chlorohexidine, and placebo among patients with plaque and gingivitis. The subjects were asked to do mouth rinse for 3 times a day for 4 weeks. Mouth rinses were given to the study group as blinded. The result showed that there was statistical significance difference between the groups with the p <0.05 and the mean score of sea water group before and after the intervention was 4.12 and 2.32 respectively. Therefore, the study concluded that the sea water was more effective when compared to other methods. [23]

3. Literature related to effectiveness of betadine gargle on intubation induced throat pain.

A comparative study was conducted in Republic of Korea to assess the effectiveness of betadine on oral health of the patients. The study was conducted for a period of one week. The participants for the study consisted of 20 patients. Participants were randomly selected and each group consists of 5 patients: Group one- 5 patients gargled with chlorhexidine, group two- 5 patients gargled with povidone iodine, group three- 5 patients gargled with sodium bicarbonate-normal saline and group four -5 patients gargled with sterile distilled water. All the patients were instructed to gargle for one week 3 times a day. Oral health was

assessed using the following indicators- pH, oral gas and exhaled gas, O'Leary method, Staphylococcus mutans and synder test. There was an increase in pH and change in oral gas of Staphylococcus mutans in the Chlorhexidine group and povidone iodine group before and after gargling. O'Leary index showed a statistical significance in all groups before and after gargling except in distilled water group. Among all the mouth washes used in this study, it was identified that povidone iodine caused most effective changes in the oral environment followed by chlorhexidine. [10]

A study was conducted in Japan to assess the effectiveness of betadine on patients with upper respiratory infections with the symptoms of sore throat. 130 subjects above 18 to 65 years were recruited for the study. The subjects were randomized into two groups with 65 subjects in each group. In group 1, patients gargled with betadine solution and in group 2 patients gargled with plain water. The interventions were carried out for two days and after the intervention the subjects were asked to rate their sore throat on 5-point Likert scale. The result of the study showed that there was a significant difference between the two groups with $p < 0.05$ and the mean score difference was found to be more in betadine group. Therefore, the study concludes that betadine has a antiseptic property and the reduction of sore throat is faster when compared with plain water gargle.[11]

A prospective study was conducted in Malaysia and 100 subjects for the study was recruited by using purposive sampling method and were diagnosed with tropical infectious diseases and had symptoms of throat pain was selected for the study. The patients were provided with betadine gargle thrice a day for 2 days. After the interventions an laboratory test was conducted by sending the oral swabs and also the interview was carried out for 30minutes with each subject. The results showed that about 99.9% of the virus was killed within 15 seconds of the gargle and it was statistically significant with p<0. 001. It also includes the Corona virus also therefore the study concludes that betadine has both bactericidal and virucidal effect [24.]

A comparative study was conducted in Japan to assess the effectiveness of topical povidone iodine among patients on mechanical ventilator the subjects for the study were 23 and was randomized into two groups. All patients received oral cleaning with 3% hydrogen peroxide, followed by irrigation with tap water and the patients in the experimental group received 10% povidone iodine applied topically to the oral cavity. The results showed that after irrigation of the oral cavity, the number of bacteria decreased, but increased again at 1 h after oral care in the control group and in the experimental group the concentration of bacteria was significantly lower. And the growth of all bacterial counts was decreased in 3 hours of given time in experimental group when compared to control group [25.]

A comparative study was conducted in Malaysia among 20 patients diagnosed with COVID 19 with the symptoms of sore throat. Subjects for the study was obtained by using purposive sampling method. The study has 4-arms in which the 1st arm is gargling with 1% betadine, 2nd arm is use of essential oils and the 3rd arm is use of tap water and the 4th arm is a control group with no intervention After the interventions the patient were given a chart to write down the frequency of gargling and symptoms and were monitored for 7 days, Nasopharyngeal and oropharyngeal swabs were taken at day 4,6 and 12 days of the intervention. The result of the study showed that there was significant difference between the study groups $p<0.001$. The study also concluded that there is a difference between the study groups and the interventions such as gargling with 1% PVP-I and essential oils shows a great potential to be part of the treatment and management of Stage 1 COVID-19 [34].

A experimental study was conducted in Germany to assess the effectiveness of Povidone against the Klebsiella pneumoniae and Streptococcus pneumoniae According to bactericidal quantitative suspension test was done against severe acute respiratory syndrome and Middle East respiratory syndrome coronaviruses rotavirus strain and influenza virus A subtype H1N1. The povidone was used in this study was PVP-I 7% the results showed that gargle and mouthwash diluted in the ratio 1:30 showed effective

bactericidal activity against Klebsiella pneumoniae and Streptococcus pneumoniae and rapidly inactivated SARS-Co virus , influenza virus A H1N1 and rotavirus after 15 seconds of exposure. Therefore, the study proves betadine had bactericidal and virucidal effect [33].

A comparative study was conducted in United Kingdom among 66 patients diagnosed with URTI. The subjects were randomised into intervention group (n=32) and control group (n=34). The intervention group made hypertonic saline at home and performed hypertonic saline nasal irrigation and gargling for 12times/day which was carried out for 14days. And control group carried out routine care, Nose swabs collected in the morning on four consecutive days. Both groups kept a diary and were assessed by using the Wisconsin Upper Respiratory Symptom Survey-21 questionnaire. The symptoms were reduced in experimental group then control group [36].

A experimental study was conducted in Saudi Arabia to assess the effectiveness 1 % povidone iodine and 3.0% of hydrogen peroxide on chronic periodontitis. Sixteen patients were randomized into three groups. Group 1 received ultrasonic scaling and root planning plus irrigation with 1% povidone iodine and 3.0% hydrogen peroxide mixture, Group 2 received ultrasonic scaling and root planning plus irrigation with 1% povidone–iodine and Group 3 received ultrasonic scaling and root planning plus irrigation with normal saline and Group 4 served as a control group.

After the interventions the subjects were assessed using examiner calibration, plaque scoring, probing depth. Results showed 67% in group 1 had decreased in the symptoms such as bleeding upon probing, suppuration, gingival recession and there was no significant difference between the study groups p >0.005. Hence the study findings showed that 1% of povidone iodine was more effective when compared with other methods [38].

A study was conducted in Japan to assess the effectiveness of tap water gargle, saline gargle and betadine gargle on patients with common cold with symptoms of throat pain. Subjects for the study were 130 and were randomly divided into three groups. 20ml of each solution was given to gargle for 15 seconds for 3 days in all the study groups. Later the patients were assessed by using self-administered questionnaire. The results showed that betadine gargle reduced the incidence of throat pain by 56% and the mean score before and after the intervention was found to be 6.44 and 2.48 respectively. Therefore, the betadine gargle was more effective when compared to other methods[27].

CONCLUSION

The reviews have shown the importance of gargling on throat pain among extubated patients. The studies also demonstrates that various interventions have been helpful to improve the well-being of the patients. Thus, the reviews also had given inputs into various intervention and tools that can be used to assess the throat pain of extubated patients.

4. METHODOLOGY

This chapter deals with the methodology adopted for the proposed study and the different steps under taken after gathering and organizing data for investigation. It includes research approach, research design, setting, population, subjects and sampling techniques, description of tool, development of teaching strategy, data collection procedures and plan for data analysis [28] .

RESEARCH APPROACH

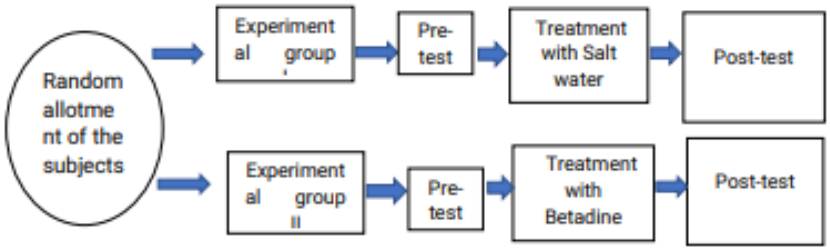
The research approach indicates the procedure for conducting the study. In view of nature of the problem selected for the study and the objectives to be accomplished. The research approach used in this study is quantitative research approach and it is considered as appropriate for this study.

RESEARCH DESIGN

Research design refers to the overall plan for obtaining answer to the research questions and it spells out the strategies that the researcher adopts to develop information that is accurate, objective and interpretable[31].

The present study assessed the effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital. The research design used for this study Comparative survey design.

REPRESENTATION OF COMPARATIVE SURVEY DESIGN



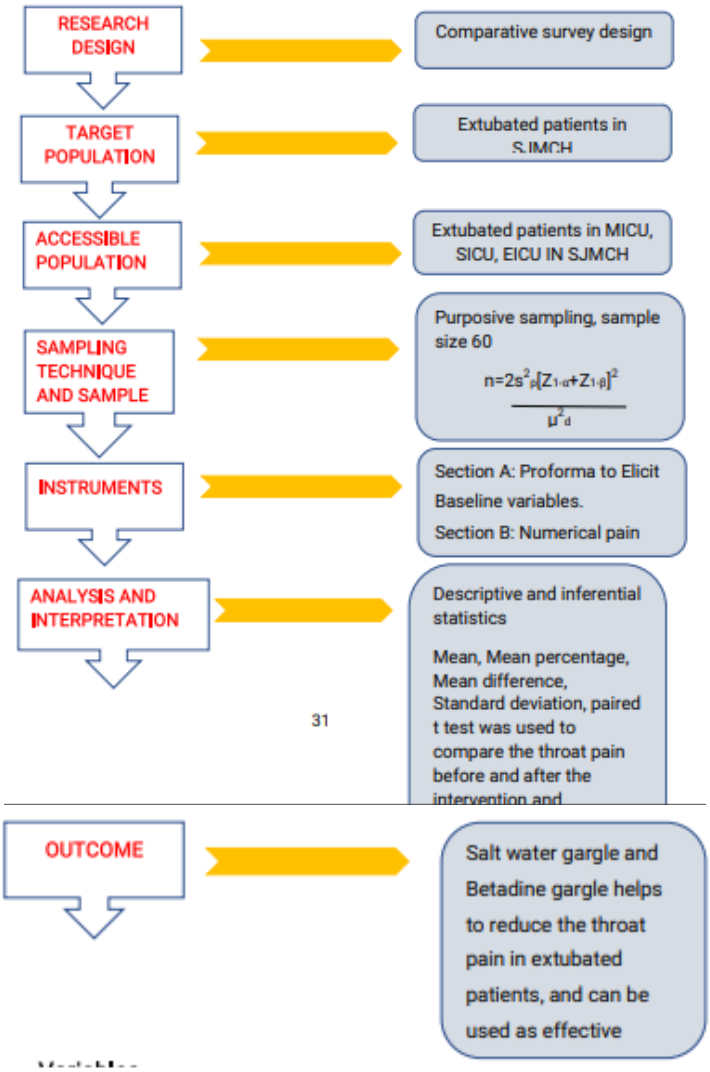


FIG 2: SCHEMATIC REPRESENTATION OF THE STUDY DESIGN

Independent variable: Salt water gargle and betadine gargle

Dependent variable: Throat pain

Baseline variable: Age, Gender, Education, diagnosis of patients, duration on ventilator in days, use of analgesics, number of attempts for intubation, duration extubation from ventilator in hours, history of Re-intubation.

Setting of the study

The study was conducted in MICU, SICU AND EICU of St. John's Medical College Hospital, Bengaluru. St John's Medical College Hospital is a 1350 bedded multispecialty tertiary care Hospital with 80-85% bed occupancy on a average 10 to 15 patients are on ventilator per day in the ICU.

Population

Population for this study is all the patients who will be intubated in St. John's hospital. Bengaluru.

Sample size

In this study, the sample comprised of 60 subjects, which is calculated based on an average change of 2.36 in pain score in both the study groups and standard deviation of 2.47 and 1.86 respectively at 80% power and 1% level of significance.

Sampling technique

Purposive sampling technique and the subjects were randomly allotted by lottery method into experimental groups.

Sampling criteria

Inclusion criteria

1. Patients who are conscious, oriented and post 24 hours after extubation.

2. Patients with the presence of gag reflex and who has started taking oral fluids as per physician's instructions.

3. Patients age >18years.

Exclusion criteria

1. Patients with no report of throat pain as evidenced by numerical pain scale.

Description of the tool

- Section A: Proforma to Elicit Baseline variables
- Section B: Numerical pain scale.

Content validity

The tool was sent to 15 experts out of which 10 of them responded, modifications were made according to the expert's opinion.

- Experts suggested to add on the pervious history of extubation in the baseline variables and modifications was done.

Reliability:

- Reliability for numerical pain scale was established by inter rater reliability method and it was administered to 6 subjects. The reliability was calculated using Spearman's rank correlation and obtained the value of r=1 which indicate that the tool is reliable.

Ethical clearance

Ethical clearance was obtained from the Institutional Ethics Committee (IEC). (Copy is attached in Annexure – 2)

Pilot study details

The pilot study was conducted in the intensive care units of SJMCH from 11/01/2021-16/01/2021 among 6 patients with throat pain, after extubation who were divided into two groups and

intervention was carried for two days, the results showed that the betadine group had reduction pain more when compared to salt water group. The study was found to be feasible.

DATA COLLECTION METHOD

- Formal administrative permission was obtained from St. John's Medical College Hospital.

- Ethical clearance was obtained from Institutional Ethics Committee.

Data collection was carried out between 18/1/2021 to 4/02/2021

- The subjects were selected according to inclusion and exclusion criteria.

- Subjects were selected by using non probability purposive sampling technique with lottery method which were randomly assigned into two groups.

- Throat pain among extubated patients were assessed by using the numerical pain scale rating from 0-10 (Score of 0 is no pain and score of 10 is severe pain) in both the study groups before the intervention.

- For salt water gargle, 3 grams of table salt was diluted in 100ml of normal water to form the salt solution. The investigator made the subjects to sit upright and the subjects were asked to gargle the entire salt solution by taking small sips of the solution. After gargling, the subjects were asked to spit out the contents into a

plastic basin, which was discarded into the sluice tank of the ward. The investigator was present throughout the gargling to ensure the safety of the subjects. Gargling was done for two days in the morning and evening. Then, the throat pain was assessed by using a numerical pain scale

- For betadine gargle, 1ml of 2% of betadine was diluted in 100ml of water to form betadine solution. The investigator made the subjects to sit upright and the subjects were asked to gargle the entire salt solution by taking small sips of the solution. After gargling, the subjects were asked to spit out the contents into a plastic basin, which was discarded into the sluice tank of the ward. The investigator was present throughout the gargling to ensure the safety of the subjects. Gargling was done for two days in the morning and evening. Then, the throat pain was assessed by using a numerical pain scale.

DATA ANALYSIS PLAN:

The following steps were taken to analyse the data:

- The data was organized in MS Excel worksheet for tabulation and statistical processing
- The data analysis and the interpretation of the study included Descriptive and Inferential Statistics.
- The frequency and percentage distribution were used to describe the baseline variables.
- Mean, Mean percentage, Mean difference, Standard deviation, paired t test was used to compare the throat pain before and after the intervention and independent t test was used to compare in between the two groups after intervention.
- Independent t test and ANOVA was used to determine association of throat pain with the selected baseline variables.

5. SAMPLE SIZE OF ESTIMATION

STATEMENT:

To observe an average change of 2.36 in pain score in both the study groups and standard deviation of 2.47 and 1.86 respectively at 80% power and 1% level of significance, the minimum sample size required is 20 per group. A sample size of 30 patients per group was taken considering attrition.

Average change in pain score	2.36
Experimental group 1 SD	2.47
Experimental group 2 SD	1.86
Power of the test	80%
Confidence Interval	99%
Required sample size	20

Formula: $n = \frac{2s^2_p[Z_{1-\alpha}+Z_{1-\beta}]^2}{\mu^2_d}$ $S^2_p = \frac{s_1^2 + s_2^2}{2}$

Where,

S^2_1 = Standard deviation in the first group

S^2_1 = Standard deviation in second group.

μ^2_d = Mean difference between the samples

α = Significance level

$1-\beta$= Power

6. RESULTS

This chapter deals with the analysis and interpretation of data gathered, to compared the effect of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital, Bangalore. The result of the study are computed using descriptive and inferential statistics.

Objectives of the study

1. To compare the throat pain before and after salt water gargling.

2. To compare the throat pain before and after betadine gargling.

3. To compare the change in throat pain between the two groups after the intervention.

4. To determine the association of throat pain with the selected baseline variables in both the groups.

Statistical methods:

The data was organized in MS Excel work sheet for tabulation and statistical analysis.

- The data analysis and the interpretation of the study included Descriptive and Inferential Statistics.
- The frequency and percentage were used to describe the baseline variables.
- Mean, Mean percentage, Mean difference, Standard deviation, paired t test was used to compare the throat pain before and after the intervention and independent t test was used to compare in between

the two groups after interventions.

- Independent t test and ANOVA was used to determine association of throat pain with the selected baseline variables.

Organization of findings:

The data is analyzed and presented under the following sections:

- SECTION 1: Description of baseline variables of both the groups
- SECTION 2: Comparison of the throat pain before and after salt water gargling in group 1
- SECTION 3: Comparison of the throat pain before and after betadine gargling in group 2
- SECTION 4: Comparison of the change in throat pain between the two groups after the intervention.
- SECTION 5: Association of throat pain with the selected baseline variables in both the groups.

Section 1: Description of Baseline variables of both the groups

Table 1a: Frequency and percentage distribution of the subjects according to age and gender.

n = 60

Sl No	Baseline variable	Group 1 (Salt) F	%	Group 2 (Betadine) F	%	Chi-Square test	P value
1	Age						
	18-37	7	23.3	9	30		
	38-57	15	50	15	50	.536	0.750
	58& above	8	26.7	6	20		(NS)
2.	Gender						
	Male	14	46.7	13	43.3		0.795
	Female	16	53.3	17	56.6	0.067	(NS)

Table 1 (a) shows that

The highest number of subjects belong to the age group of 38 – 57 years, in both the groups it is 15(50%) and very few are from 18 -37 years in group 1 7 (23%) and in group 2, 58 and above 6 (20%). Female are highest in both the groups in group 1, 16(53.3%) and in group 2, 17(56.6%).

Table 1b: Frequency and percentage distribution of the subjects according to Education.

n=60

Sl. No	Baseline variable	Group 1 (Salt)		Group 2 (Betadine)		Chi-Square test	P value
		F	%	F	%		
1.	Education						
	Professional Degree	1	3.3	2	6.7	6.940	0.364 (NS)
	Graduation	7	23.3	8	26.7		
	Higher Secondary school	1	3.3	5	16.7		
	High school certificate	5	16.7	4	13.3		
	Middle school certificate	3	10	0	0		
	Primary school certificate	1	3.3	2	6.7		
	Illiterate	12	40	9	30.0		

Table 1(b) shows that

The highest number of samples belong to illiterate, in both the groups it is 12(40%) in group 1 and in, group 2 it is 9(30%) and very few are from higher secondary and primary school in group 1, 1 (3.3%), in group 2, primary school 2 (6.7%).

Table 1(c): Frequency and percentage distribution of subjects according

Sl. No	Baseline variable	Group 1 (Salt)		Group 2 (Betadine)		Chi-Square test	P value
		F	%	F	%		
1.	Diagnosis						
	Neuro	6	20	5	16.7		
	Cardiac	1	3.3	1	3.3	3.510	0.971 (NS)
	Respiratory	8	26.7	8	26.7		
	Gastro Intestinal	5	16.7	3	10.0		
	Genito urinary	3	10.0	3	10.0		
	ENT	1	3.3	0	0		
	Poisoning	1	3.3	3	10.0		
	Burns	1	3.3	1	3.3		
	Musculo Skeleton	4	13.3	6	20.0		

diagnosis.

n=60

Table 1(c) shows that

The highest number of subjects belong to respiratory system diagnosis, in both the groups it is 8(26.7%) and very few belong to burns, poisoning, ENT, cardiac system in group 1, 1 (3.3%) , in group 2, burns and cardiac system 1(3.3%).

Table 1(d): Frequency and percentage distribution of subjects according duration of ventilator in days and use of analgesics.

Sl. No	Baseline variable	Group 1 (Salt)		Group 2 (Betadine)		Chi-Square test	P value
		F	%	F	%		
1.	Duration of ventilator in days						
	< 2 days	6	20	9	30.0		
	3-5 days	19	63.3	20	66.7		
	5- 10 days	5	16.6	1	3.3	3.119	0.238 (NS)
	>10 days	0	0	0	0		
2.	Use of Analgesics						
	Yes	8	26.6	5	16.7		
	No	22	73.3	25	83.3	.884	0.532 (NS)
						n=60	

Table 1(d) shows that

The highest number of samples had 3-5 days duration on ventilator in both the groups it is 19(63.3%) in group 1, 20(66.7%) in group 2 and very few samples had duration of 5-10 days in both the group, in group 1, 5(16.6%), in group 2, 1(3.3%). Use of analgesics the highest number of samples in both groups were No, group 1, 22(73.3%) and in group 2, 25(83.3%).

Table 1(e): Frequency and percentage distribution of subjects according to number of intubations attempts and duration of extubation in hours.

Sl. No	Baseline variable	Group 1 (Salt)		Group 2 (Betadine)		Chi-Square test	P value
		F	%	F	%		
1	Number of intubation attempts						
	1	29	96.6	27	90.0		
	2	1	3.3	2	6.7	1.417	0.612(NS)
	>2	0	0	1	3.3		
2.	Duration of extubation in hours						
	24-27	17	56.6	16	53.3		
	28-31	9	30	13	43.3	2.627	0.426(NS)
	32-35	3	10	1	3.3		
	≤36	1	3.3	0	0		

Table 1(e) shows that

The highest in number of intubations attemtps is 1 in both the groups; group 1 29(96.6%) and in group 2, 27(90.0%) and duration of extubation in both the groups is 24-27 hours in group 1, is 17(56.6%) and in group 2, is 16(53.3%).

Table 1(f): Frequency and percentage distribution of subjects according to the history of reintubation.

Sl No	Baseline Variable	Group 1 F	%	Group 2 F	%	Chi-square test	P value
1.	History of reintubation						
	Yes	1	3.3	2	6.7	.351	1.000 (NS)
	No	29	96.6	28	93.3		

n=60

Table 1(f) shows that

The highest number of subjects had no history of reintubation in both the groups, in group 1, it is 29(96.6%) and in group 2, 28(93.3%).

Section 2: Comparison of throat pain before and after salt water gargling in group 1.

Objective 1: To compare the throat pain before and after salt

water gargling.

H1: There will be statistically significant difference on throat pain among extubated patients before and after salt water gargling.

Table 2: Maximum Score, Range, Mean, Mean %, Mean Differences, Standard Deviation t test, p value of pain scores before and after the salt water gargling.

n=60

	Maximum score	Range	Mean	Mean %	Mean difference	SD	Paired t test	P value
Pre test	10	2-6	3.27	32.7	2.64	1.159	29.457	<0.0001 * (S)
Post test	10	0-4	.63	6.3		1.042		

*Significant

Table 2: Shows that there was statistically significant difference between throat pain before and after salt water gargle with p value (<0.05). Therefore, the hypothesis is accepted.

Section 3: Comparison of throat pain before and after betadine gargling in group 2.

Objective 2: To compare the throat pain before and after betadine gargling.

H2: There will be statistically significant difference on throat pain among extubated patients before and after betadine gargle.

Table 3: Maximum Score, Range, Mean, Mean %, Mean difference, Standard Deviation, t test, p value of pain scores before and after the betadine gargling.

n=60

	Maximum score	Range	Mean	Mean %	Mean difference	SD	Paired t test	P value
Pre-test	10	3-8	3.37	33.7	3.27	1.159	14.891	<0.0001* (S)
Post Test	10	0-4	.10	1		0.305		

*Significant

Table 3: Shows that there was statistically significant difference between throat pain before and after betadine gargle with p value (<0.05). Therefore, the hypothesis is accepted.

Section 4: Comparison of the change in throat pain between the two groups after the intervention.

Objective 3: To compare the throat pain between the two groups after the intervention.

H3: There will be statistically significant difference on throat pain among extubated patients between both groups.

Table 4: Maximum score, Mean, Mean difference, standard deviation, independent t test, p value of change in the level of throat pain between two groups after intervention.

n =60

	Maximum score	Pre-test Mean SD	Post-test Mean SD	Mean Difference	Independent t test	P value
Group 1	10	3.27 .9 44	.63 1.066	2.64	2.634	0.013 *(S)
Group 2	10	3.37 1.159	.10 0.305	3.27		

*Significant

Table 4: Shows that there was statistically significant difference between two groups after the intervention with p value (<0.05). Therefore, the hypothesis is accepted.

Section 5: Association of throat pain with the selected baseline variables in both the groups.

Objective 4: To determine the association of throat pain with the selected baseline variables in both the groups.

H4: There will be statistically significant association of throat pain among extubated patients with selected baseline variables.

Table 5a: Mean, Standard deviation, test of significance and p value of association of pre-test throat pain with selected baseline variables in group 1.

Sl no	Baseline variables	Mean	SD	Test of significance	P value
1.	Age				
	18-37	3.43	1.272	1.303#	0.288(NS)
	38-57	3.00	0.535		
	Above 57	3.63	1.188		
2.	Gender				
	Male	3.13	1.025	-0.875$	0.389(NS)
	Female	3.43	0.852		
					n=30

#- ANOVA

No Significant: NS

Table 5a: Shows that there is no statistically significant association of throat pain with age, gender. Therefore, hypothesis is rejected.

Sl no	Baseline variables	Mean	SD	Test of Significance	P value
1.	Education				
	Professional Degree	3.00			
	Graduation or Post-Graduation	3.29	1.380		
	Higher Secondary School	3.00		0.131#	0.991(NS)
	High School Certificate	3.00			
	Middle School Certificate	3.33	0.577		
	Primary School Certificate	3.00			
	Illiterate	3.42	1.084		

Table 5b: Association of pre-test throat pain with selected baseline variables in group 1.

n=30

No Significant: NS

#- ANOVA

$- Independent t test

Table 5b: shows that there is no statistically significant association of throat pain with education. Therefore, hypothesis is rejected.

Table 5c: Association of pre-test throat pain with selected baseline variables in group 1. n=30

Sl no	Baseline Variable	Mean	Standard deviation	Test of significance	P Value
1	Diagnosis				
	Neuro	3.00	0.632		
	Cardiac	2.00			
	Respiratory	3.63	1.188	0.527#	0.823(NS)
	Gastrointestinal	3.00			
	Gastro urinary	3.33	0.577		
	ENT	3.00			
	Poisoning	4.00			
	Burns	3.00			
	Musculoskeletal system	3.50	1.732		
2	Duration on ventilator in days				
	<2	2.67	0.516		
	3-5	3.42	1.017	1.575#	0.226 (NS)
3	Use of analgesics				
	Yes	3.25	1.165	-0.057$	0.955 (NS)
	No	3.27	0.883		
4.	Number of attempts				
	1	3.17	0.805	-3.454$	0.07 (NS)
	2	6.00			

No Significant: NS #- ANOVA, $- Independent t test

Table 5c: shows that there is no statistically significant association of throat pain with diagnosis , duration on ventilator, use of analgesics and number of attempts . Therefore, hypothesis is rejected.

Table 5d: Association of pre-test throat pain with selected

Sl no	Baseline variable	Mean	Standard deviation	Test of significance	P value
1.	Duration of extubation from ventilator in days				
	24-27	2.67	0.516	1.575#	0.226(NS)
	28-31	3.42	1.017		
	32-35	3.40	0.894		
2.	History of reintubation				
	Yes	4.00			
	No	3.24	0.951	0.785$	0.439(NS)

baseline variables in group 1.

n=30

No Significant: NS #- ANOVA, $- Independent t test

Table 5d: shows that there is no statistically significant association of throat pain with duration of extubation from

ventilator and history of reintubation. Therefore, hypothesis is rejected.

Table 5e: Association of pre-test throat pain with selected baseline variables in group 2. n=30

Sl no	Baseline variable	Mean	Standard deviation	Test of significance	P value
1	Age				
	18-37	3.33	0.866		
	38-57	3.67	1.397	1.675#	0.206(NS)
	Above 57	2.67	0.516		
2.	Gender				
	Male	3.44	1.413	0.352$	0.727(NS)
	Female	3.29	0.825		
3.	Education				
	Professional Degree	4.50	0.707		
	Graduation or Post-Graduation	3.00	0.535	2.312#	0.075(NS)
	Intermittent or Post High School	3.20	0.837		
	High School Certificate	4.50	2.380		
	Primary School Certificate	2.00	0.000		
	Illiterate	3.33	0.707		

No Significant: NS #- ANOVA, $- Independent t test

Table 5e: shows that there is no statistically significant association of throat pain with age, gender and education. Therefore, hypothesis is rejected.

Table 5e: Association of pre-test throat pain with selected

Sl no	Baseline variables	Mean	SD	Test of significance	P value
1.	Diagnosis				
	Neuro	3.40	0.894		
	Cardiac	2.00			
	Respiratory	3.13	0.835	0.998 #	0.459 (NS)
	Gastro intestinal	3.33	0.577		
	Genito urinary	4.67	2.887		
	ENT	-	-		
	Poisoning	2.67	0.577		
	Burns	4.00			
	Musculo skeletal system	3.50	0.837		
2.	Duration on ventilator in days				
	<2	3.44	1.944		
	3-5	3.35	0.671	0.068#	0.935(NS)
	5-10	3.00			
3.	Use of analgesics				
	Yes	3.60	0.894	0.487$	0.630(NS)
	No	3.32	1.215		
4.	Number of attempts				
	1	3.33	1.177	0.394$	0.697(NS)
	2	3.00	0.000		

baseline variables in group 2. n=30

No Significant: NS #- ANOVA, $- Independent t test

Table 5f: shows that there is no statistically significant association of throat pain with diagnosis, duration on ventilator, use of analgesics and number of attempts. Therefore, hypothesis is rejected.

Table 5g: Association of pre-test throat pain with selected

baseline variables in group 2. n=30

Sl no	Baseline variables	Mean	Standard deviation	Test of significance	P value
1.	Duration of extubation from ventilator in hours				
	24-27	3.44	1.944		
	28-31	3.35	0.671	0.068#	0.935(NS)
	32-35	3.00			
2.	History of Reintubation				
	Yes	3.00	1.414	-0.457$	0.651(NS)
	No	3.39	1.166		

No Significant: NS #- ANOVA, $- Independent t

Table 5g: shows that there is no statistically significant association of throat pain with duration of extubation from ventilator and history of reintubation. Therefore, hypothesis is rejected.

7. DISCUSSION

This study is aimed to evaluate the effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital, Bengaluru. This chapter presents findings of the study, and discuss them in relation to the similar studies conducted by other researchers. The sample size included 60 extubated patients admitted in SJMCH. Numerical pain score was used to assess the throat pain.

Objectives of the study

1. To compare the throat pain before and after salt water gargling.

2. To compare the throat pain before and after betadine gargling.

3. To compare the change in throat pain between the two groups after the intervention.

4. To determine the association of throat pain with the selected baseline variables in both the groups.

The findings of the study are discussed and organized under the following headings:

Findings related to:

- Description of baseline variables in both the experimental groups
- Comparison of throat pain before and after salt water gargling.

- Comparison of throat pain before and after betadine gargling.
- Comparison of the change in throat pain between the two groups after the intervention.
- Association of throat pain with the selected baseline variables in both the groups.

Discussion related to the description of baseline variables of both the study groups.

The study subjects in the present study consisted of 60 patients. The baseline variables of the extubated patients were elicited to find its influences in throat pain. In the present study 50% of subjects in both the groups belonged to age group of 38-57 years. Majority of the subjects were females (In group 1 53.3 % and in group 2 were 56.6%). 26.7% of the subjects were intubated for respiratory cases. Subjects belonged to duration on ventilator was between 3-5 days (In group 1 63.3% , and in group 2 66.7%) . Subjects were not on any analgesics usage. (In group 1 73.3% and in group 2, 83.3%). In this present study subjects were intubated with only 1 attempt in both the groups (group 1, 96.6% and in group 2, 90.0%). Duration of extubation is found to be between 24-27 hours in both the groups (In group 1, 56.6% and group 2, 53.3%).

It revealed that the patients on prolonged duration on ventilator had more pain and the number of attempts for intubation also proved that patients experience moderate to severe pain. This may be because of mucosal damage due to repeated attempts or

continuous pressure on the trachea.

These findings were supported by a study conducted in Madagascar which showed about 43.5% of patients belonged to age group of 28-58 years. And 90% of the subjects were not on any of the analgesic after extubation. Another study done in Switzerland showed that 40% of female had sore throat and about 73% of the subject's duration of extubation was in between 12 to 26 hours. A similar study in Ethiopia showed that 78 patients were intubated with only 1 attempt. Whereas a study in Republic of Korea showed that 100% of the patients were intubated with 1 attempt[3].

Discussion related to the comparison of pain before and after salt water gargling.

In this present study, the throat pain of the subjects was assessed using numerical pain scale before and after the intervention by the investigator, and the subjects were given the intervention for 2 days and after 2days of intervention post test was carried out. Results revealed that the throat pain was reduced from 3.27 to 0.63 (mean) and it was found that there was statistically significant difference in throat pain before and after salt water gargle ($p<0.001$). Therefore, the reduction in throat pain is due to the intervention which the patients received and also it has helped the patients to recover from throat pain.

These findings were supported by a study conducted in Malaysia

to assess the effectiveness of salt water gargle versus thymol glycerin on throat pain, revealed that there was a significant difference in throat pain before and after salt water gargle at ($p < 0.001$) with the mean score of throat pain reduced from 6.22 to 2.14. The effectiveness of the salt water gargle is proved to have bactericidal and virucidal effect. Another study in Pune was conducted to assess the effectiveness of salt water gargle on throat pain, revealed there was significant difference ($p<0.005$). (pretest mean score was 7 and post test mean score is 1.320). The significant difference is found because salt water gargle has an effect of osmosis which draws out the fluid from the inflamed tissue, and as a result there is a decline in the inflammation and eventually the pain diminishes[8].

Discussion related to the comparison of pain before and after betadine gargling.

In this present study, the throat pain of the subjects was assessed using numerical pain scale before and after the intervention by the investigator, and the subjects were given the intervention for 2 days and after 2days of intervention post test was carried out. Results revealed that the throat pain was reduced from 3.37 to .10 (mean) and it was found that there was statistically significant difference in throat pain before and after betadine gargle ($p<0.001$). Therefore, the reduction in throat pain is due to the intervention which the patients received. Therefore the result shows that betadine gargle was effective for throat pain as the

betadine has the property of antiseptic and henceforth it reduces the throat pain and makes the patient comfortable.

These findings were supported by a study conducted in Malaysia to assess the effectiveness of betadine gargle among the patients with throat pain and the study revealed that there was statistically significant difference in throat pain before and after betadine gargle ($p<0.001$) and the pre test mean score is 5.27 and post test mean score is 3.01. The mean scores of throat pain before and after interventions proves that the betadine has an effect of pain reduction as it has the property of antiseptic and decreases the bacterial count. As a result, it reduces the pain [10]. Thus, helps the patient in reduction of throat pain and improves the patients well being.

Discussion related to the comparison in the change of throat pain between the two groups after the intervention.

In this present study, the comparison was done between the two groups revealed that there was statistically significant difference between the two groups before and after intervention ($p<0.005$). And the mean score difference of betadine group was greater when compared to salt water group (group 1 -2.64, group 2-3.67).This may be because betadine has an antiseptic property which reduces the pain when compared with salt water gargle.

These findings were similar to the study conducted in Korea to

compare between salt water gargle and betadine gargle showed that there were statistically significant difference between the two groups ($p<0.005$), and the betadine gargle mean difference was greater when compared to salt water group (group 1- 3.33, group 2- 4.65) [24]. The study emphasizes that the betadine is a medication which has iodine that helps in the reduction of inflammation and also decreases the bacterial count [24]. Another study was conducted in Japan to compare between the effectiveness of tap water gargle, saline gargle and betadine gargle revealed that betadine gargle reduced the incidence of throat pain by 56% and the mean score before and after the intervention was found to be 6.44 and 2.48 .

Discussion related to association of throat pain with the selected baseline variables in both the groups.

In the present study association was done with selected baseline variables like age, gender, education, diagnosis, duration on ventilator in days, use of analgesic, number of attempts, duration of extubation in hours and the history of reintubation.

The study findings revealed that there is no statistically significant association of throat pain with selected baseline variables. Although no statistically significant association was found with selected baseline variables but it was observed that the prolonged duration on ventilator, and more than 2 attempts for intubation cause moderate to severe pain in patients undergoing tracheal intubations.

These were supported by a study conducted in Sweden which showed that there was no significant difference in Age, gender, and duration of extubation with the p value >0.005 at the level of significance [4].

8. CONCLUSION

This chapter deals with the conclusions drawn based on the findings of the study. The main aim of the study was to assess the effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital, Bengaluru. 60 patients were recruited for the study. The throat pain was assessed using numerical pain scale before and after the intervention. The interventions were carried out twice a day for 2 days. And post test was done after two days of the interventions.

Major findings of the study.

- There is statistically significant difference in throat pain before and after salt water gargle, which is statistically significant at 0.001 level.
- There is statistically significant difference in throat pain before and after betadine gargle, which is statistically significant at 0.001 level.
- There is a statistically significant change in throat pain in between two groups after the intervention, which is statistically significant at 0.013.
- There is no statistically significant association of pre-test score with age, gender, education, diagnosis, duration on ventilator in days, use of analgesics , number of attempts, duration of extubation in hours and history of reintubation.

NURSING IMPLICATIONS

Nursing practice

Findings of the study will enable the nurses to improve the patients outcomes with early assessment of sore throat and implementation of appropriate intervention.

Nursing education

The findings of the study reinforce the need for educating the nursing students on the use of appropriate interventions based on an early assessment and from evidenced based knowledge.

Nursing administration

The findings of the study throw light on the need to improve evidenced based interventions and in designing protocols while caring for mechanical ventilator patients.

Nursing research.

The findings of the study will provide database for future research and it will benefit in utilization of the best evidences.

LIMITATIONS

- Physiological parameters were not assessed during the research study.
- Number of gargles were only twice a day, if the frequency for gargling was more than the effectiveness for pain would be better.
- Objective evaluation of oral cavity was not done by the investigator.

RECOMMENDATIONS

- Qualitative study can be undertaken to explore patients experience and preferences for different interventions.
- Study can be conducted on a larger sample to generalize the findings.

9.SUMMARY

This chapter presents a brief summary of the study.

This study aimed to evaluate the effectiveness of salt water gargle versus betadine gargle on throat pain among extubated patients in a selected hospital, Bengaluru.

Objectives of the study

1. To compare the throat pain before and after salt water gargling.

2. To compare the throat pain before and after betadine gargling.

3. To compare the change in throat pain between the two groups after the intervention.

4. To determine the association of throat pain with the selected baseline variables in both the groups.

ASSUMPTIONS:

1. Patients may experience intubation induced throat pain

2. Salt water gargle and betadine gargle may reduce intubation induced throat pain among patients.

The conceptual framework for the study was based on General System Theory by Bertalanffy in 1968. The theory facilitates the investigator to conduct the study in a comprehensive and

systematic way.

The review of literature was organized and presented under the following headings:

1. Literature related to intubation induced throat pain.

2. Literature related to salt water gargle on intubation induced throat pain.

3. Literature related to effectiveness of betadine gargle on intubation induced throat pain.

4. Literature related to comparison of salt water gargle with betadine gargle.

The review has shown the importance of early assessment and to provide care to the patient by reducing the throat pain. And the studies have also demonstrated that various interventions have been helpful to reduce the throat pain among extubated patients. Thus, the review has given the evidences to use either of the methods to reduce throat pain.

The instruments used consists of two sections.

Section A: Proforma to elicit baseline variables of the extubated patients.

Section B: Numerical pain scale to assess the throat pain.

Content validity was established by sending the tool to experts seeking their valuable suggestions and; the reliability was

established by using inter rater reliability method. The pilot study was conducted on 6 samples and the study was found to be feasible.

The final study was conducted for the period of 1 1/2 months. Pre-test was conducted by assessing the throat pain and interventions were carried out for two days, after the interventions post-test was carried out. The data obtained was analyzed in view of the objectives of the study using descriptive and inferential statistics.

The results showed that the post-test scores for throat pain were lower when compared to pre- test scores among extubated patients, the mean score of throat pain before and after interventions in group 1 is 3.27 and .63 and in group 2 is 3.37 and .10 respectively. It indicated that the interventions were effective. It revealed that the gargling provided was an effective method to reduce the throat pain among extubated patients and there was statistically significant change at 0.05 level. There was no statistically significant association between throat pain and selected baseline variables. The process of the present study provided a benefiting experience to the investigator as if helped to understand the importance of gargling for extubated patients with throat pain and found that there is need for the patients for gargling after extubation in order to provide comfort to the patients.

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