RESEARCH PROTOCOL

THE PILOT STUDY OF THROAT PACKS SOAKED IN GENGIGEL SPRAY IN PATIENTS UNDERGOING ELECTIVE SURGERY UNDER GENERAL ANAESTHESIA

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INTRODUCTION

Throat packs are commonly used in many surgical procedures involving the oral cavity and pharynx, primarily to prevent blood, saliva, and other debris from entering the lower respiratory tract, thereby maintaining a clear airway and reducing the risk of aspiration and respiratory complications (Anderson et al., 2020; Smarius et al., 2018). Traditionally, these packs are moistened with saline or used in a dry state, with the choice often depending on the surgeon's preference and specific surgical requirements. However, despite their widespread usage, the exploration of alternative substances to moisten throat packs, particularly those with additional therapeutic benefits, remains limited in medical research (Alfiky et al., 2018; Pabst et al., 2022; Athanasoglou et al., 2018). This pilot study introduces Gengigel spray as an innovative alternative to saline for moistening throat packs. Gengigel, a hyaluronic acid (HA)-based product, is known for its healing properties and anti-inflammatory effects, which are beneficial in oral care (Beecham, Nessel, & Goyal, 2022). Gengigel provides a non-anesthetic approach that promotes tissue repair and reduces inflammation. This makes it particularly advantageous in the context of surgical procedures where reducing postoperative inflammation and promoting mucosal healing are crucial.

The rationale for using Gengigel-soaked throat packs stems from its unique properties that have not been previously applied in this context. By leveraging its anti-inflammatory and healing effects, Gengigel has the potential to not only maintain airway patency but also enhance patient comfort by reducing postoperative throat pain and irritation, common complaints associated with the use of throat packs during intubation (Bahar & Yoon, 2021; Beecham, Nessel, & Goyal, 2022; Eipe, Gupta, & Penning, 2016). As this is a pilot study, it aims to explore the feasibility and potential benefits of Gengigel as a new standard for throat pack application, setting the foundation for further research in this area.

Postoperative throat pain is a common and distressing complication following elective surgeries involving the oral cavity and pharynx. Throat packs are routinely used in these procedures to prevent the aspiration of blood and other debris, but they can contribute to postoperative discomfort and pain. The approach of using gengigel soaked throat pack could potentially transform standard postoperative care practices by addressing one of the most frequent postoperative complaints. However, despite these promising prospects, there remains a significant knowledge gap in the literature regarding the safety, efficacy, and overall impact of gengigel-soaked throat packs, with existing studies focusing mainly on its general use in other medical applications and not specifically on its use in throat packs during surgical procedures.

In contrast, Gengigel spray, which contains HA known for its healing properties and anti-inflammatory effects, presents a novel and potentially superior alternative to saline in throat packs. Gengigel's unique formulation may not only reduce postoperative throat pain but also promote mucosal healing, thereby addressing both pain and tissue recovery. This pilot study aims to investigate the use of Gengigel-soaked throat packs in patients undergoing elective surgery under general anesthesia. It is a practice that has not been explored in existing literature. Emphasizing Gengigel's healing and anti-inflammatory properties, this research seeks to fill the current knowledge gap and evaluate the potential benefits of this innovative approach. By conducting this study, we aim to provide preliminary evidence that could pave the way for new postoperative care practices, ultimately enhancing patient outcomes and comfort during recovery.

While Gengigel spray, known for its healing and anti-inflammatory properties, has found use in various medical applications, its potential role in moistening throat packs for surgical settings has not been explored. Gengigel has not been examined in the context of throat packs during surgeries involving the oral cavity and pharynx. Existing literature on throat packs primarily focuses on their use with saline or as dry packs, and there is an absence of comprehensive research evaluating the healing and analgesic benefits of Gengigel-soaked throat packs. Specifically, there is no data on how Gengigel might influence the duration and extent of pain relief, enhance mucosal healing, or impact overall patient recovery and satisfaction post-surgery.

Moreover, the literature does not address the potential advantages of using a substance like Gengigel, which could offer both anti-inflammatory and healing properties, over traditional saline or lignocaine-soaked packs. The absence of studies examining possible complications, such as local tissue reactions or the efficacy of Gengigel in comparison to lignocaine, further underscores the need for detailed investigation. Comprehensive studies, including randomized controlled trials, patient-reported outcomes, and clinical assessments, are essential to fully understand the implications of using Gengigel in throat packs. In summary, while Gengigel is recognized for its therapeutic properties in wound care and inflammation management, its specific application in throat packs during surgeries is inadequately studied. Addressing this knowledge gap through targeted research could potentially revolutionize postoperative care, enhancing both pain management and tissue recovery in surgical procedures involving the oral cavity and pharynx.

Initial observations from a pilot study indicate a promising reduction in postoperative throat pain among patients who received Gengigel-soaked throat packs compared to those with standard saline-soaked packs. Patients not only reported lower pain scores but also experienced improved mucosal healing and a quicker return to normal swallowing function. These early results suggest that Gengigel-soaked throat packs may provide dual benefits: significant analgesic effects due to their anti-inflammatory properties and enhanced tissue recovery, potentially improving overall patient comfort and speeding up recovery times.

To support these preliminary findings, we can consider Gengigel's established effectiveness in wound healing and inflammation management in various medical contexts. Although the use of Gengigel in throat packs is novel, its known benefits in promoting mucosal health and reducing inflammation align with the observed outcomes in this pilot study. The existing literature, such as a systematic review by Athanassoglou et al. (2018), has highlighted the potential harms and benefits of throat packs in surgeries but noted the absence of specific studies focusing on substances like Gengigel. This underscores the necessity for more targeted research to fully understand the implications and potential advantages of using Gengigel-soaked throat packs in surgical procedures.

This study design is robust and comprehensive, ensuring that the impact of Gengigel-soaked throat packs is thoroughly evaluated. By employing a randomized controlled trial (RCT) methodology, the study aims to provide high-quality evidence on the analgesic benefits, anti-inflammatory effects, and safety profile of Gengigel in this specific application. The systematic recording and analysis of postoperative throat pain, mucosal healing, complications, and patient satisfaction will offer crucial insights into the potential advantages of Gengigel-soaked throat packs. This approach addresses a significant knowledge gap in the medical field and has the potential to guide future clinical practice by improving postoperative care and patient outcomes.

PROBLEM STATEMENT

Using throat packs is a standard practice in surgeries involving the oral cavity, pharynx, and upper airway to prevent the aspiration of blood and other debris, which could lead to postoperative complications such as aspiration pneumonia. Traditionally, these throat packs are moistened with saline or left dry. However, this conventional approach has been associated with postoperative throat pain and discomfort, which are common and often distressing complications for patients undergoing surgery under general anesthesia. The discomfort caused by these packs can delay recovery, extend hospital stays, and negatively impact overall patient satisfaction with the surgical experience.

Gengigel presents a novel alternative with distinct advantages. Gengigel, which contains HA, is recognized for its anti-inflammatory and healing properties, making it a promising candidate for improving postoperative outcomes when used in throat packs. Despite Gengigel's established use in other medical applications, such as wound care and oral health, there is currently no research exploring its effectiveness in moistening throat packs during surgical procedures. This represents a significant knowledge gap, as the combination of Gengigel's healing and anti-inflammatory effects could potentially address both pain and mucosal recovery.

Addressing this gap is crucial for advancing postoperative care, as current literature does not adequately explore the potential benefits or risks associated with using Gengigel in throat packs. Furthermore, there is a lack of data on patient outcomes, including the extent of pain relief, the speed of mucosal healing, potential complications, and overall patient satisfaction when Gengigel is utilized in this context. The absence of such data limits the ability of healthcare providers to make evidence-based decisions that could improve patient care.

To bridge this gap, this study proposes a randomized controlled trial (RCT) to compare the outcomes of using Gengigel-soaked throat packs versus traditional saline-soaked packs in patients undergoing surgery under general anesthesia. The study will systematically assess postoperative throat pain levels, evaluate the degree of mucosal healing, monitor for any adverse effects, and measure overall patient satisfaction. By conducting this comprehensive evaluation, the research aims to provide robust evidence that could guide the use of Gengigel in throat packs, potentially setting a new standard in postoperative care. Ultimately, the findings could lead to enhanced patient comfort, faster recovery times, and a higher quality of care for patients undergoing surgeries involving the oral cavity and pharynx.

LITERATURE REVIEW

The use of oropharyngeal packs in surgical procedures has been extensively researched, particularly for their potential to reduce postoperative throat pain, hoarseness, and throat irritation. Various studies have explored the efficacy of different substances used to moisten these throat packs, including lignocaine, dexamethasone, and triamcinolone acetonide. However, there is limited research on alternative substances like Gengigel, known for its healing and anti-inflammatory properties, which could offer additional benefits beyond traditional options. The potential of Gengigel to enhance mucosal healing and provide analgesic effects presents a promising area for further investigation in the context of postoperative care.

The therapeutic use of HA in various medical applications has garnered significant attention due to its anti-inflammatory, healing, and tissue-regenerative properties. Recent studies have explored its

efficacy in different clinical settings, including dental care, postoperative pain management, and treatment of chronic inflammatory conditions of the pharynx. This literature review critically examines the findings of three studies that investigate the effects of HA in treating gingivitis, reducing post-tonsillectomy pain, and managing chronic pharyngitis, highlighting both the potential and limitations of HA as a therapeutic agent.

For example, Sapna and Vandana (2011) conducted a clinical and histopathological evaluation of the anti-inflammatory effects of 0.2% hyaluronan gel in patients with gingivitis. Their study employed a comprehensive approach, comparing the effects of scaling alone, scaling combined with topical hyaluronan gel, topical hyaluronan gel alone, and topical plus intrasulcular hyaluronan gel. The results demonstrated significant reductions in clinical parameters and inflammatory markers, particularly with the combined use of topical and intrasulcular hyaluronan gel, which was found to be as effective as scaling alone. This study underscores the potential of HA as an adjunctive treatment for gingivitis, particularly in cases where traditional mechanical therapy may not be sufficient or feasible. However, the study's reliance on a relatively small sample size and the short duration of observation may limit the generalizability of the results. Further research with larger cohorts and extended follow-up periods is necessary to validate these findings and explore the long-term benefits of HA in periodontal therapy.

Meanwhile, the study by Al-Baidhani and Abdulameer (2021) evaluated the efficacy of high molecular weight hyaluronic acid (HMW-HA) spray in reducing postoperative pain following tonsillectomy. Conducted as a cross-sectional study with 60 patients, the research found that HMW-HA significantly reduced pain levels between 3 to 7 days post-surgery compared to the control group, suggesting its potential as an effective pain management strategy in the postoperative period. However, no significant pain reduction was observed within the first 24 hours post-surgery, indicating that HMW-HA's analgesic effects may be more pronounced in the medium-term recovery phase. A notable strength of this study is its focus on a common postoperative complication in otolaryngology, where pain management is critical. Nevertheless, the study's limitations include its cross-sectional design and relatively small sample size, which may not fully capture the variability in patient responses. Moreover, while the study emphasizes the safety of HA use, it does not delve into potential long-term effects or the optimal dosage and frequency of application, which are crucial for standardizing clinical protocols.

On the other hand, Leone et al. (2015) explored the efficacy and safety of high molecular weight sodium hyaluronate (SH) in treating chronic pharyngitis, a condition characterized by persistent inflammation of the pharyngeal mucosa. Their open, randomized controlled trial revealed significant improvements in symptoms and cytological parameters among patients treated with SH compared to the control group. The study highlights SH's role in enhancing mucociliary clearance, tissue hydration, and defense against microorganisms, which are critical functions for maintaining mucosal integrity in chronic pharyngitis. The absence of adverse events and good patient compliance further underscore the potential of SH as a therapeutic option in chronic inflammatory conditions. However, the study's limitations include a small sample size and the lack of a double-blind design, which may introduce bias. Additionally, the study does not compare SH's effectiveness with other standard treatments, making it difficult to ascertain its relative efficacy. Further research involving larger, double-blind, placebo-controlled trials is necessary to confirm these findings and establish SH as a viable treatment option for chronic pharyngitis.

Apart from that, Hanci and Altun (2015) conducted a prospective, double-blind, controlled clinical study to evaluate the effectiveness of HA in alleviating post-tonsillectomy pain and promoting wound healing. The study included fifty patients, with HA applied to one side of the tonsillar bed while the

other side served as a control. This within-subject design minimized individual bias by allowing the same patient to evaluate and score pain on both sides. The results indicated significantly lower pain scores on the HA-treated side ($p < 0.001$) and faster wound healing compared to the control side, with almost complete healing observed on the HA-treated side at the end of the two-week follow-up period ($p < 0.001$). The study concluded that HA could be recommended as an effective treatment for managing post-tonsillectomy pain and enhancing wound healing.

Besides, Sahayata, Bhavsar, and Brahmbhatt (2014) investigated the clinical and microbiological effects of HA in the treatment of chronic plaque-induced gingivitis. In this longitudinal, randomized, placebo-controlled trial, 105 patients were divided into three groups: a negative control group, a placebo control group, and a test group receiving HA gel adjunct to routine oral hygiene. Clinical parameters, including Plaque Index (PI), Gingival Index (GI), and Papilla Bleeding Index (PBI), were assessed at intervals of one, two, and four weeks, with microbiological parameters monitored at the four-week mark. The study found significant improvements in GI and PBI in the HA-treated group compared to the other groups, although reductions in PI were not statistically significant. Additionally, the HA group showed a statistically significant reduction in anaerobic gram-negative bacilli and an increase in gram-positive coccoid cells at four weeks compared to baseline, though pairwise comparisons between groups were not statistically significant. The findings suggest that HA gel can be a beneficial adjunctive treatment in non-surgical periodontal therapy, specifically in improving clinical outcomes related to inflammation and bleeding. However, the lack of significant changes in plaque levels and the microbiological findings' limited statistical significance highlight the need for further research. The study's randomized design and the comprehensive assessment of both clinical and microbiological parameters are strengths; however, the variability in response among different clinical parameters suggests that HA's effectiveness may be context-dependent and influenced by other factors such as patient compliance and baseline oral hygiene practices.

However, there are notable limitations across these studies that warrant consideration. The relatively small sample sizes and short follow-up periods limit the ability to fully understand HA's long-term efficacy and safety. Additionally, while the studies provide promising results, they also reveal variability in HA's effectiveness across different clinical parameters and patient populations. This suggests that HA's benefits may not be universally applicable and may depend on specific clinical contexts or patient characteristics. Future research should focus on larger, multi-center trials with extended follow-up periods to confirm these findings and explore HA's broader applicability. Studies comparing HA with other standard treatments, such as corticosteroids or other anti-inflammatory agents, would provide valuable insights into its relative efficacy and cost-effectiveness. Moreover, exploring the molecular mechanisms underlying HA's effects could help optimize its clinical use and identify patient populations most likely to benefit from its application. While HA shows considerable promise as an adjunctive treatment for postoperative pain management and periodontal care, further investigation is required to fully establish its role in clinical practice. The current evidence supports its safety and efficacy in specific applications, but more comprehensive studies are needed to guide its integration into standard therapeutic protocols and maximize its potential benefits for patients.

There are other studies done previously using other substances such as lignocaine, dexamethasone, and triamcinolone acetonide. In one study, Talapatra et al. (2024) examined the effects of fluticasone-impregnated throat packs versus saline-soaked packs in nasosinus surgeries. This randomized, double-blinded trial found no significant difference in the incidence and severity of postoperative throat pain

and voice hoarseness between the groups. While the fluticasone group showed a trend towards reduced postoperative throat pain and hoarseness, the results were not statistically significant, indicating the need for further research to validate these findings.

Moreover, Agrawal et al. (2021) focused on the efficacy of lignocaine and dexamethasone in oropharyngeal packs. Their retrospective study of 70 patients indicated that combining lignocaine and dexamethasone significantly reduced the incidence of postoperative throat pain, hoarseness, and throat irritation, corroborating the findings of Sarswataskar et al. (2018). This research stated no significant differences in hemodynamic parameters, reinforcing the safety of this combination for postoperative care.

Meanwhile, Sultan et al. (2020) explored the usage of triamcinolone acetonide in reducing postoperative throat pain. Their comparative and prospective study on patients undergoing Functional Endoscopic Sinus Surgeries (FESS) discovered that throat packs soaked with triamcinolone acetonide significantly reduced postoperative throat pain scores in comparison to those soaked with lubricating gel. The study also indicated lower incidences of dysphagia and hoarseness in the triamcinolone group, suggesting its potential as an efficient intervention for postoperative throat pain management.

Moreover, several studies explored the use of anti-inflammatory agents like tenoxicam and corticosteroids. These studies found that when throat packs were impregnated with these agents, patients reported lower levels of postoperative sore throat and related symptoms. The anti-inflammatory properties help reduce the swelling and irritation in the throat tissues, thereby providing relief.

The collective findings from these studies underscore the importance of targeted interventions in managing POST. By incorporating anti-inflammatory agents into clinical practice, there is a significant potential to improve postoperative patient comfort and satisfaction. However, further research is needed to refine these methods, determine optimal dosages, and establish standardized protocols to maximize the benefits and minimize any potential risks associated with these treatments. This body of research points towards a promising direction in perioperative care, where patient-centered approaches can significantly enhance recovery outcomes and overall patient experience.

RESEARCH QUESTIONS

1. How does the use of gengigel-soaked throat packs compare to standard saline-soaked packs in terms of reducing the incidence and severity of postoperative sore throat among patients undergoing elective surgeries?
2. What are the differences in patient-reported satisfaction and the presence of hoarseness of voice between those who receive gengigel-soaked throat packs and those who receive standard saline-soaked packs?

HYPOTHESIS

H1: The use of gengigel-soaked throat packs significantly reduces the incidence and severity of postoperative sore throat compared to standard saline-soaked packs in patients undergoing elective surgeries.

H2: Patients who receive gengigel-soaked throat packs report higher levels of satisfaction and lower incidence of hoarseness of voice compared to those who receive standard saline-soaked packs.

OBJECTIVE(S)

1. To evaluate the impact of using gengigel -soaked throat packs on the incidence of postoperative sore throat compared to standard saline-soaked throat packs in patients undergoing elective surgeries.

2. To assess the severity of postoperative sore throat, hoarseness of voice, and patient satisfaction in patients who receive gengigel-soaked throat packs versus those who receive standard saline-soaked throat packs.

MATERIALS AND METHODS

Study Design

This research is designed as a randomized controlled trial (RCT) aimed at evaluating the effects of gengigel-soaked throat packs on postoperative outcomes. The study will span four months and will be conducted at the Department of Anaesthesiology, UMMC. Prior to commencement, the study protocol will be reviewed and approved by the research ethics department to ensure compliance with ethical standards and patient safety regulations.

Study Population

The target population for this study includes patients scheduled for elective surgical procedures requiring the use of throat packs. The inclusion of both male and female patients aged 18 to 60 years, who are classified under the American Society of Anesthesiologists (ASA) physical status I-II, ensures a broad yet specific demographic that is representative of the general surgical population.

Inclusion Criteria

Patients will be eligible to participate in the study if they meet the following criteria:

1. Classified as ASA I-II, indicating a relatively low risk of complications from anesthesia
2. Aged between 18 and 60 years, which represents a typical adult surgical population
3. Both male and female patients, ensuring gender inclusivity and representation in the study findings

Exclusion Criteria

The study will exclude patients who present any of the following conditions, as these could confound the results or pose additional risks:

1. Existing sore throat prior to surgery, which could affect the baseline measurement of postoperative sore throat.

2. Anticipation of a difficult airway, as these patients may require specialized intubation techniques that are not standardized across the study.
3. More than two attempts at endotracheal tube (ETT) insertion, as multiple attempts could cause additional trauma and skew the study outcomes.
4. Any trauma occurring during intubation, which could independently contribute to postoperative sore throat and other complications

This comprehensive approach to the study design, population, and criteria ensures the reliability and validity of the research outcomes. The selection criteria are meticulously defined to create a homogeneous study group, facilitating a clear assessment of the specific impact of gengigel -soaked throat packs on patient recovery and postoperative comfort.

Sample size

As this is a pilot study, 30 patients will be in the intervention group and 30 patients will be in the control group. The sample size for this study was estimated using OpenEpi (Version 3), an open-source calculator for epidemiological studies. The calculation was based on a similar study comparing saline versus lignocaine. Given that our study compares saline versus Gengigel, we adopted the same methodology with appropriate modifications.

A two-sided significance level (α) of 0.05 (95% confidence level) and a power of 80% (1-β) were used. The assumed proportions of outcome occurrence in the exposed and unexposed groups were derived from previous literature and adjusted for our study parameters. The sample size was calculated using the Kelsey, Fleiss, and Fleiss with continuity correction methods, with the final sample size determined based on the most appropriate estimate.This sample size is considered to provide a statistically sound comparison.

Primary/Secondary outcome measurements

Primary Outcome Measurements

The primary outcome of this study is the incidence of postoperative sore throat.

Secondary Outcome Measurements

The secondary outcomes include the severity of postoperative sore throat, patient satisfaction, and the presence of hoarseness of voice, cough.

Incidence and severity of POST, hoarseness of voice and presence of cough- This will be assessed with Scoring System of Harding and McVey(Table 1)

Patient Satisfaction: This will be assessed with a yes/no question regarding their overall satisfaction with the postoperative care.

Instruments/Procedures

This study employs a rigorous randomized controlled trial (RCT) design to assess the effectiveness of gengigel-soaked throat packs in elective surgeries. Patients scheduled for surgeries that necessitate the use of throat packs will be recruited and randomly assigned to one of two groups: one group receiving gengigel-soaked throat packs and the other receiving saline-soaked throat packs. The randomization process ensures that each participant has an equal chance of being assigned to either group, thereby minimizing selection bias and enhancing the reliability of the results.

Intervention

Gengigel-Soaked Throat Packs: Throat packs soaked in a gengigel solution (5mls and soaking time standardized).

Saline-Soaked Throat Packs: Throat packs soaked in normal saline solution (5mls and soaking time standardized).

Data Collection

Incidence and severity of POST, hoarseness of voice and presence of cough- This will be recorded at multiple time points - 1-hour post-surgery and 24 hours post-surgery using Scoring System of Harding and McVey.

Complications: Any adverse effects or complications (e.g., bleeding, infection, allergic reactions) will be documented.

Patient Satisfaction: Patient satisfaction and overall comfort will be assessed at discharge.

Table 1

Scoring system of Harding and McVey

Sore throat	
	Score
No sore throat at any time since the operation	0
Minimal sore throat (Complains of sore throat only on asking)	1
Moderate sore throat (Complains of sore throat on his / her own)	2
Severe sore throat (Complains of throat pain)	3
Cough	
	Score
No cough at any time since the operation	0
Minimal cough or scratchy throat (Light or single episode of cough)	1
Moderate cough (more than one episode of non-sustained cough)	2
Severe cough (Sustained and repetitive cough with head lift)	3
Hoarseness	
	Score
No evidence of hoarseness at any time since the operation	0
No evidence of hoarseness at the time of interview	1
Hoarseness at the time of interview noted by patient only	2
Hoarseness that is easily noted at the time of interview	3

Table 1 Scoring system of Harding and McVey

Procedures

This prospective interventional comparative study will be performed after approval of the Research Ethics Committee. This study will be performed at UMMC. Written informed consent will be obtained from all patients prior to performing the procedure.

Patients who are undergoing dental procedures, Functional Endoscopic Sinus Surgeries, and any other procedures requiring throat pack insertion will be enrolled in this double-blinded, randomized controlled trial. Participants will be randomly assigned to the gengigel group or the saline group using a computer-generated randomization schedule.

In the operation theatre, patients will be attached to a vital sign monitoring device as per standard procedure. The same standardized anaesthesia technique will be used for all patients, which includes induction with fentanyl (1mcg/kg), propofol (2mg/kg), and Atracurium(0.5mg/kg) or Rocuronium(0.6mg/kg) and maintenance with sevoflurane in O_2/air mixture. Endotracheal intubation will be performed using disposable, well-lubricated tubes with internal diameters of 7mm for females and 7.5mm for males. The cuff will be inflated with air until it reaches a pressure of 25mmHg. The number of attempts for intubation will be recorded.

A standard length of throat pack 60cm will be placed under direct visualisation using Magill forceps and positioned around oropharynx. Intubaters will also be standardized, which are two chosen anaesthesia lecturers. Time of throat pack insertion and removal will be recorded.

Based on a random-number table, each patient was randomly assigned via sealed envelope to either the Gengigel-soaked throat pack group(Throat pack is soaked with gengigel spray 5mls) or the Saline-soaked throat pack group (Throat pack is soaked with saline 5mls). The anaesthetic doctor will position the soaked pack, and they will be blinded regarding the solution used to soak the throat pack.

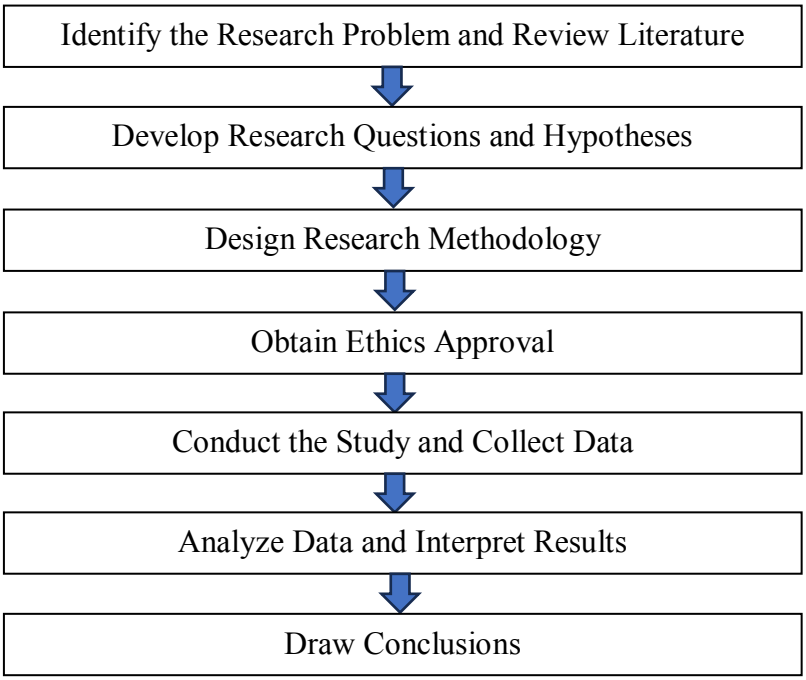
Intraoperatively, IV Paracetamol 1000mg and IV Dynastat 40mg will be given if there are no contraindications. As per standard practice, IV metoclopramide 10mg and IV Dexamethasone 8mg will also be given.

Postoperatively, the throat pack will be removed. The patient will be extubated and sent to recovery. Patients will be unaware of the solution used for the throat pack. At 1 hour and 24 hours, they will be interviewed regarding any incident and severity of sore throat, hoarseness of voice, cough and satisfaction.

Statistical analysis plan

Data will be analyzed using Statistical Package for Social Science (SPSS Inc., Chicago, IL, USA, version 23.0 for Windows). The quantitative parametric data will be presented as mean, standard deviations (SD), and ranges then compared using an independent t-test. The quantitative data will be presented as mean, SD, median, and inter-quartile range (IQR) and then compared using the t-test or Mann-Whitney U-test, whichever is applicable. Qualitative variables will be presented as numbers and percentages and then compared with the Chi-square test or Fisher test whichever is ever applicable. The confidence interval will be set to 95%, while the margin of error accepted will be set to 5%. Accordingly, the p-value will be considered statistically significant when it is less than 0.05.

FLOW CHART


Identify the Research Problem and Review Literature
Develop Research Questions and Hypotheses
Design Research Methodology
Obtain Ethics Approval
Conduct the Study and Collect Data
Analyze Data and Interpret Results
Draw Conclusions

GANTT CHART

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	J	A	S	O	N	D	J	F	M	A	M	J
Define research problem												
Literature review												
Develop research questions												
Formulate research hypotheses, design and methodology												
Research proposal preparation												
Proposal defence												
Ethics committee/authorities approval												
Protocol preparation												
Performing study and data collection												
Data entry												
Data analysis												
Report preparation and submission												

FUNDING
Self funding

EXPECTED OUTCOME(S)

The findings of this study are expected to provide substantial insights into the risks as well as benefits of using gengigel-soaked throat packs. If proven effective, this practice could be broadly employed, leading to enhanced patient satisfaction and comfort, and has potential in setting new standards in anaesthetic care. Additionally, the study aims to fill the existing knowledge gap and make way for future research in this area.

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