"AIRWAY NERVE BLOCKS VS AIRWAY TOPICALIZATION FOR AWAKE FIBEROPTIC BRONCHOSCOPE ASSISTED NASOTRACHEAL INTUBATIONS"

By

Dr. JALA USHASREE

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

Under the Guidance of

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ABBREVIATIONS

FOI	Fiberoptic intubation
ASA	American Society of Anaesthesiologists
SLN	Superior laryngeal nerve
GPN	Glossopharyngeal nerve
RLN	Recurrent laryngeal nerve
LAST	Local anaesthetic systemic toxicity
FNATI	Fiberoptic bronchoscope-assisted awake nasotracheal intubation
LA	Local anaesthesia
EtCO2	End tidal carbon dioxide
ECG	Electrocardiogram
GA	General anaesthesia
HR	Heart rate
MAP	Mean arterial pressure
RR	Respiratory rate
BP	Blood pressure
SpO2	Peripheral capillary oxygen saturation
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
INR	International normalized ratio

ABSTRACT

Introduction: To avoid potentially fatal situations such as "can't intubate, can't ventilate," it is essential to confirm a stable airway before administering general anaesthesia, particularly to patients who have trouble with their airways. Awake fiberoptic bronchoscope-assisted nasotracheal intubation (FOI) is recommended for such cases but requires thorough patient preparation to ensure cooperation and comfort. Adequate sedation and opioid use are essential to maintain comfort while keeping the airway patent. Mild sedation combined with local anaesthetics offers excellent hemodynamic stability, although anxiety can complicate the process by triggering autonomic responses. Effective anaesthesia during intubation relies on comprehensive knowledge of airway anatomy and innervation, using various topical and regional techniques to desensitize specific regions. Topical anaesthesia methods include sprays and nebulizers, while nerve blocks, though more challenging, provide superior anaesthesia when performed by experienced anaesthesiologists.

Materials and Methods: A single blinded randomized controlled trial was performed from September 2022 to February 2024 with 50 adult patients (>18 years) undertaking elective surgeries under general anaesthesia requiring

fibreoptic bronchoscope assisted nasotracheal intubations at R. L. Jalappa Hospital and Research Centre, Tamaka, Kolar. Randomization done on 50 patients with 1:1 allocation using block randomization with unequal block size into nerve block (N) group and topicalization (T) group. The study was started after Institutional Ethical Clearance (IEC). Standard pre-, intra-, and post-operative care was taken for both the groups. A t-test for independent samples was employed to compare the continuous variables of the two groups. For all statistical tests, a p-value less than 0.05 was deemed to indicate statistical significance.

Results: The groups were clinically alike terms of gender, age, comorbidity (DM, hypertension, and hypothyroidism), INR status, heart rate, MAP, SpO2, and respiratory rate (p>0.05). The variance in MAP between the two clusters was high by 8 mm HG (95% CI: 1 to 14 mm HG; p=0.03) at 12 minutes and 10 mm HG (95% CI: 4 to 15 mm Hg; p=0.006) at 15 minutes. The mean respiratory rate at 15 minutes was meaningfully different (Mean difference 4 min; 95% CI: 1 to 9; p=0.03) between the two groups. The cough and GAG score was relatively high (score 3) in the T group (n=10, 40%) than the N group (n=3, 12%) (p=0.02). The intubation score, comfort score, ease of intubation was better in the N group and the variance was statistically noteworthy. While 16 patients (64%) in the group N took 6 minutes or less for intubation, only 7

(28%) patients took 6 minutes or less for intubation in the T group (p=0.04). All the members in both the clusters had airway complications in relations of mouth opening. Nonetheless, zero adverse reports were made by patients in either group.

Conclusion and recommendation: The current research emphasizes the relative merits of topicalization and airway nerve blocks as upper airway anaesthetics for awake fiberoptic bronchoscope-assisted nasotracheal intubations, as well as their respective safety profiles. Both techniques were effective in achieving adequate intubation conditions. However, airway nerve blocks demonstrated superior outcomes in relations of patient comfort, ease of intubation, duration for intubation, and control of cough and gag reflexes, along with a more stable hemodynamic profile.

Keywords: Airway nerve block, airway topicalization, airway management, awake fiberoptic bronchoscope.

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INTRODUCTION

INTRODUCTION

Anaesthesiologists face a formidable obstacle while administering general anaesthesia: safeguarding the airway, especially in individual who are known to have trouble with this procedure. [1, 2] Effective management of the airway is critical to avoid life-threatening scenarios such as “can’t intubate, can’t ventilate”. [3] Awake fiberoptic bronchoscope-assisted nasotracheal intubation (FOI) is often recommended in these situations to ensure optimal operating conditions for various head, neck, and upper respiratory tract surgeries. [4]

However, the prospect of awake nasotracheal manipulations can be highly intimidating for patients, necessitating thorough mental and pharmacological preparation. [5,6] Adequate sedation and opioid use are essential to maintain patient comfort while keeping the airway patent. [7] Patient cooperation, achieved through detailed procedural explanations, is vital for the success of awake FOI. [8]

Several studies have documented excellent hemodynamic stability with FOI when mild sedation and local anaesthetics are used in combination. [9] Nonetheless, anxiety can trigger undesirable autonomic responses, complicating the intubation process through elevated heart rate (HR), blood pressure (BP), excessive secretions, and heightened protective reflexes. [6,7] Comprehensive knowledge of airway innervation and anatomy is crucial for effective anaesthesia during intubation.

To reduce these reflexes by desensitizing certain areas of the airway, researchers have used a variety of topical and regional approaches. [10] Topical anaesthesia can be achieved via sprays, nebulization, atomization, gargles, and direct application. [10] Ultrasonic nebulizers, which produce a fine mist with a lower dose of medication, offer uniform distribution but carry a risk of systemic toxicity if dosages exceed recommended limits (British Thoracic Society Bronchoscopy Guidelines Committee, 2001). Additionally, inadequate topical anaesthesia can lead to laryngospasm, jeopardizing airway patency during FOI. [10]

On the other hand, when done by skilled anaesthesiologists, airway nerve blocks provide better airway anaesthetic despite the increased risk of problems including bleeding and nerve injury. [7] The transtracheal injections for the recurrent laryngeal nerve, the glossopharyngeal nerve (GPN), and the superior laryngeal nerve (SLN) are the usual components of an effective airway block. [10]

AIMS & OBJECTIVES

AIMS & OBJECTIVES OF THE STUDY

Primary objective:

- To check efficacy of airway topicalization to achieve upper airway anaesthesia for awake fiberoptic bronchoscope assisted nasotracheal intubations.
- To compare airway topicalization with airway nerve blocks to achieve upper airway anaesthesia for awake fiberoptic bronchoscope assisted nasotracheal intubations.

Secondary objective:

- To compare the hemodynamical response between airway nerve blocks group and airway topicalization group.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Airway anatomy:

Stimulating the nasal and/or oral canals is a common approach to anaesthetize the upper airway. Nasal sensory innervation is supplied by the trigeminal nerve, also known as cranial nerve V. A branch of the trigeminal nerve known as the lingual nerve, supplies the front three-quarters of the tongue with sensory input, while the glossopharyngeal nerve, which is cranial nerve IX, controls the back third. Both the glossopharyngeal nerve (IX) and the vagus nerve (cranial nerve X) offer sensory info to the pharynx. The superior laryngeal nerve, which is a branch of the vagus nerve, is responsible for innervating the region above the vocal cords. On the other hand, the recurrent laryngeal nerve is responsible for innervating the region below the vocal cords as well as the trachea. Additionally, the vagus nerve (X) is responsible for supplying the trachea with vascular supply. [(11)]

When it comes to anaesthesiology, the management of the airway is one of the most significant processes, and it plays a crucial role in ensuring that patients get safe treatment throughout diagnostic and surgical procedures. [(12)] Fiberoptic bronchoscope-assisted Awake Nasotracheal Intubation (FNATI) is a common technique used in cases where spontaneous ventilation is desired, e.g. difficult airway management or when general anaesthesia carries high risk. [(13,14)] The upper airway needs to be effectively anaesthetized before performing the MCTs, as severe complications could follow otherwise. [(11)]

The two primary techniques in upper airway anaesthetics are;

- Airway topicalization: targeted absorption of LA drugs to the mucosal boundaries into the airway and
- Airway nerve blocks- targeted to a specific general sensory of the air mucous area for regional anaesthesia. [11, 15-18]

Each of the two methods has its strengths and weaknesses. [11, 18, 19]

Airway Topicalization:

In this technique, the mucosal surfaces of the airway are directly treated with local anaesthetic medicines delivered directly to them. During surgical procedures, this method is used in situations when naturally occurring breathing is essential. [20]

- **Historical Development and Evolution:**
  - The use of LA for airway management dates back to the early 20th century.
  - In the initial days, simple topical applications like using cotton swabs and were used.
  - In the recent days, LA has been advanced significantly in terms of the potency of the drugs and their delivery methods. [21]
  - The newly developed LAs confer high efficacy and safety. [22]

- **Techniques and Agents Used:**

  The methods can be used for airway topicalization are as follows-

- Nebulization: inhalation of an anaesthetic aerosol, provides a uniform distribution of the anaesthetic agent across the airway [23]
- Sprays: Similar to nebulization but the distribution is comparatively low.
- Gels: Provides anaesthesia in a localized place only.
- "Spray-as-you-go": Applied during bronchoscopy, drug is sprayed directly to the airway mucosa. It is more effective than the other techniques and also easy to apply. [24]

- **Drugs used:**
  - Commonly used local anaesthetic agents include lidocaine (Also known as lignocaine), tetracaine, and benzocaine.
  - Lidocaine's effects have a modest duration and a fast start when administered at 2% or 4% concentrations. [6]
  - Tetracaine has the ability to produce effects that are felt for a longer amount of time. As a result, it is used in situations when persistent anaesthesia is essential. [25]

- **Efficacy in Clinical Settings:**
  - Effective airway topicalization for providing adequate anaesthesia for awake fiberoptic intubation is a critical part of upper airway surgical procedures.
  - According to the findings of a randomized controlled experiment conducted by Xue and colleagues, a comparison was made between 2% and 4% lidocaine that was provided using the spray-as-you-go method. They found that both the dosage is effective. However, 4% concentration provided a higher success rate for intubation. [26]
  - Similar finding was noted for nebulized lidocaine use. The nebulized form was effective in reducing patient discomfort and improving overall procedure tolerance. [27]

- **Advantages and Limitations**

  Airway topicalization has the following advantages:

  - Its administration is simple,
  - It starts working immediately,
  - It is a non-invasive technique.
  - It allows for continuous assessment of airway reflexes and patient cooperation during the procedure. [28]

On the other hand, it might be dangerous to use too much and cause local anaesthetic systemic toxicity (LAST) or inadequate anaesthesia in sensitive individuals. [29]

In summary, airway topicalization is a versatile and effective method for achieving upper airway anaesthesia. Its proper application can significantly enhance the safety and comfort of patients undergoing awake fiberoptic intubation.

Airway Nerve Blocks:

One strategy to establish regional anaesthetic of the upper airway is using an airway nerve block, which involves inhibiting particular nerves that are responsible for feeling. This technique is particularly useful for procedures like awake fiberoptic intubation, where complete anaesthesia of the airway is essential to prevent discomfort and reflex responses. [30]

- **Overview of Nerve Blocks Relevant to Upper Airway Anaesthesia**

Several key nerves innervate the upper airway, and blocking these nerves can provide effective anaesthesia:

1. **Glossopharyngeal Nerve Block:** The oropharynx and portions of the nasopharynx, as well as the back third of the tongue, are innervated by this

nerve. This nerve is blocked due to the injection of a local anaesthetic that is administered close to the base of the palatoglossal arch. (21)

2. **Superior Laryngeal Nerve Block:** It is responsible for providing feeling to the laryngeal inlet and epiglottis, two layers of mucosa located above the voice cords. A local anaesthetic injection that is administered in close proximity to the greater cornu of the hyoid bone has the potential to obstruct it. (Figure 1). (11)

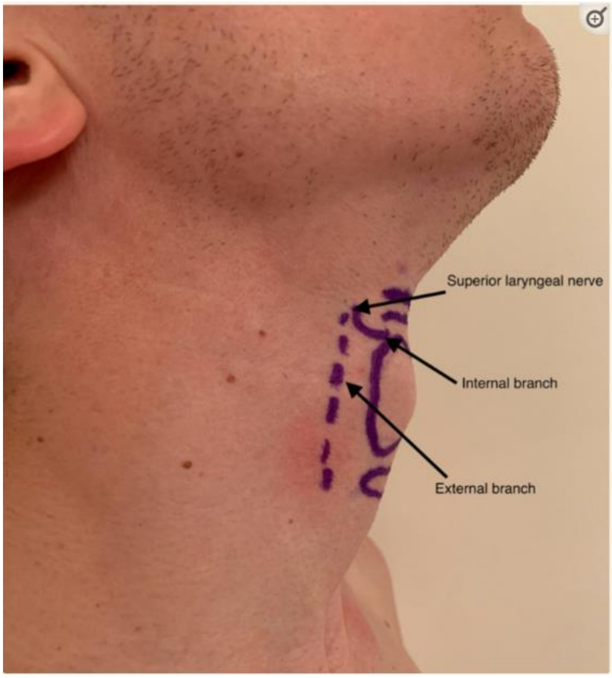


Figure 1: Superior laryngeal nerve anatomy

3. **Recurrent Laryngeal Nerve Block:** This nerve supplies the mucosa below the vocal cords. Blocking it typically requires transcricoid injection, known as the transtracheal block. (32)

- **Anatomical Considerations**

The administration of a nerve block successfully requires a thorough understanding of the anatomy of the upper airway as well as the path that these nerves take. The glossopharyngeal nerve can be reached via the mouth cavity, the superior laryngeal nerve can be addressed by the lateral neck, and the recurrent laryngeal nerve can be reached through the cricothyroid membrane in the back of the neck. (Figure 2) [11]

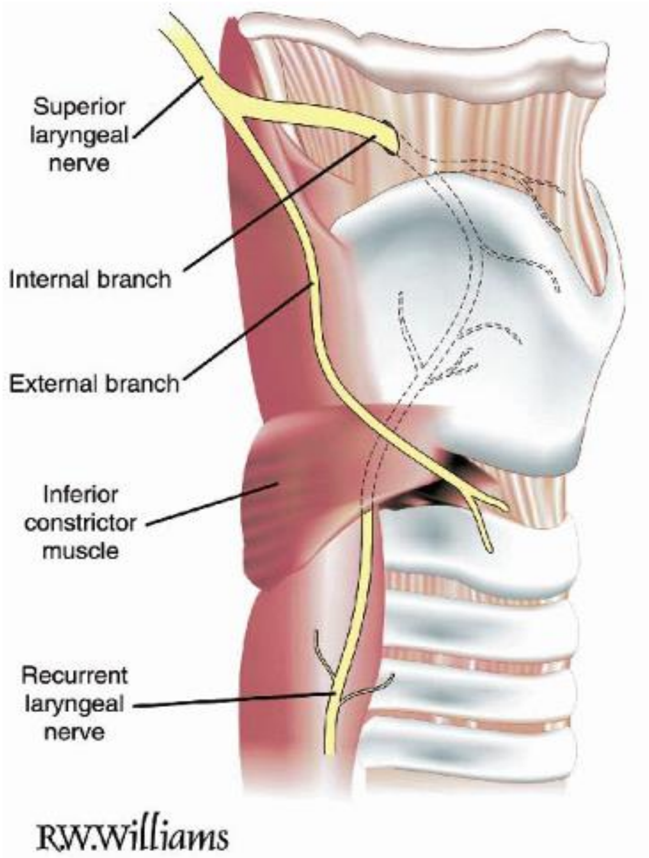


Figure 2: Applied functional anatomy of the upper airway

- **Techniques and Procedural Details**

1. Glossopharyngeal Nerve Block - This block is created by injecting one or two milliliters of lidocaine between the palatoglossal arches. The injection is made after identifying the anatomical landmarks and ensuring negative aspiration to avoid intravascular injection. [33]
2. Superior Laryngeal Nerve Block - An injection of 2-3 milliliters of local anaesthetic is administered behind the larger cornu of the hyoid bone to accomplish this. Proper technique involves palpating the hyoid bone and injecting at the junction of the thyrohyoid membrane. [34]
3. Recurrent Laryngeal Nerve Block (Transtracheal Block) - For the purpose of administering 2-4 milliliters of local anaesthetic directly into the trachea, the cricothyroid membrane is used during this block. To ensure that the anaesthesia is distributed evenly throughout the body, the patient is told to take a deep breath while the needle is being placed. [11]

- **Clinical Applications and Efficacy**

Airway nerve blocks are widely used in clinical practice for achieving effective anaesthesia of the upper airway. Studies have shown that these blocks can significantly reduce patient discomfort, prevent gagging and coughing, and facilitate smoother intubation compared to topical anaesthesia alone. [35] The precision of nerve blocks often results in better patient tolerance and cooperation during awake intubation procedures. [35]

- **Advantages and Limitations**
  - Intubation of the upper airway, full anaesthesia,
  - Enhanced patient comfort and better reflex thresholds.

Disadvantages

- This method requires a good anatomical knowledge and expertise.
- Complications: Intravascular injection (likely), hematoma, and nerve injury. [11]

Airway Topicalization vs Airway Nerve Blocks

Given the various factors that can guide the selection of either IA or AN as local anaesthetic techniques for attaining UA anaesthesia in AFOI, no definitive conclusion about superiority of one over another is possible. This was followed by a literature search comparing these two methods.

Upper airway anaesthesia adequacy

Despite its usefulness, topicalization—the direct administration of local anaesthetics to airway mucosa—is insufficient for effective anaesthesia, particularly at locations where the anaesthetic agents do not penetrate well. [33]

Alternatively, nerve blocks interrupt the nerves of specific areas that supply sensation to all or part of a portion of an airway and thus can yield more segmental/somewhat total anaesthesia.. [36]

Comparative Studies and Findings

a) Anaesthesia quality and patient comfort:

Nerve blocks have been shown to offer more predictable and profound anaesthesia in comparison with topicalization. For instance, in comparison to topical anaesthetic, Xue et al. found that superior laryngeal nerve blocks resulted in reduced pain and fewer reflex reactions during intubation. [23]

b) Procedure Success Rates:

Nerve blocks do provide more consistent anaesthesia and case series have reported a higher incidence of successful awake fiberoptic intubation than we typically observe. Collins et al. noticed that nerve blocks resulted in a crisper intubation with less stop and go due to patient squirming or reflexes. [21]

c) Patient Tolerance and Cooperation:

Nerve blocks have a higher degree of patient comfort and cooperation compared to Airway topicalization techniques. Hence, the risk of inadequate anaesthesia due to anaesthesia drugs being more patchy or incomplete, such as is often the case with topicalization, is reduced. [19]

Advantages and Limitations

Airway Topicalization:

Advantages: One major benefit of airway topicalization is that it is a non-invasive procedure that is both simple to do and very well-tolerated by patients. It is especially beneficial when nerve block execution is complicated due to anatomical differences or when it is unwarranted. [22]

Limitations: Despite the advantages mentioned above, however, it has an unclear rate of incomplete anaesthesia. This rate is reasonably high, particularly in less accessible regions of the airway, and the technique in question requires careful and often clumsy administration. [37]

Airway Nerve Blocks:

Airway nerve blocks, on the other hand, guarantee relatively complete and predictable anaesthesia. As one of the primary benefits, this results in a high degree of comfort and tolerance for the patient. This technique is especially beneficial for any procedure that necessitates deep anaesthesia of a specific region of the airway. [31] At the same time, the procedure is more technically precise, more sophisticated, and more disorderly, with a higher chance of unintentional intravascular drug injection, hematoma, or nerve damage. Consequently, a skilled doctor and an intuitive grasp of airway anatomy are necessities. [38]

A systematic review and meta-analyses provided the information necessary to recommend clinical practice. According to the analysis, while both methods were effective, patient satisfaction and adverse procedural frequency were higher for nerve blocks. [27] In addition, Xue et al. [33] listed nerve blocks as better partly because the procedure allows providers to control unwanted reflexes. Conclusively, the choice between airway topicalizations and nerve blocks should rely on patient’s willingness to collaborate, procedural complexity, and acumen. Topicalization is preferred for faster, simpler procedures, while larger anaesthesia depth requires nerve blocks. Similarly, the techniques are sufficient for safe and efficient airway management during awake fiberoptic intubation.

Hemodynamic Responses During Awake Intubation

When performing airway management procedures, it is essential to achieve optimal hemodynamic responses. This is particularly true in the context of an awake intubation, when it is essential to maintain the patient's safety and comfort. A number of responses, such as changes in blood pressure and heart rate, and even arrhythmias, may be brought on by the stress of pain that occurs during a medical procedure. [1]

Knowledge of these responses is important in deciding about the type and method of anaesthesia used to better outcome.

Physiological Basis of Hemodynamic Responses

The insertion of an endoscope and the process of intubation stimulate the autonomic nervous system reflex which results in hemodynamic changes. The sympathetic and parasympthetic nervous system primarily mediate these responses. (36) The mechanical stimulation of the airway can elicit reflexes such as coughing, gagging and laryngospasm leading to significant hemodynamic perturbation. (24)

Comparison of Hemodynamic Responses: Topicalization vs. Nerve Blocks

a) Airway Topicalization:

Mechanism: Physiology Mechanism: When direct local anaesthetics are applied to the mucosa, it reduces the sensory input locally. However, its ability to blunt hemodynamic responses depends on the completeness of the anaesthesia. (33) In hemodynamically stable patients, topicalization reduces the changes in BP and HR associated with awake intubation. However, the effects are less compared to nerve blocks. (27)

b) Airway Nerve Blocks:

Mechanism: Nerve blocks act by inhibiting the nerves responsible for airway sensation. It results in excessive gag reflexes, coughing and bronchospasm during general anaesthesia. [21]

Hemodynamic Impact: Nerve blocks offer a better haemodynamic control compared to topicalization. Patients usually have more stable hemodynamic parameters in awake intubation with nerve blocks, showing a decrease rate of tachycardia, hypertension, and arrhythmias. [7]

Clinical Studies and Evidence

Patient Outcomes

Xue et al. compared hemodynamic responses in patients undergoing awake fiberoptic intubation either with topical anaesthesia or inferior laryngeal nerve block. The authors found that the latter group demonstrated a significantly more hemodynamically stable profile, as evidenced by lower maximum heart rates and blood pressures during the study. [27]

Meta-Analysis Findings

Systematic review by Siddik-Sayyid et al summarized several studies that compared hemodynamic responses during awake intubation with various anaesthetic techniques. The analysis showed that nerve blocks were superior to topical anaesthesia in controlling the haemodynamic response to intubation, which indicates blunting of stress responses following definite method (e.g., autonomic and cognitive effects) versus local anaesthetic approach. [33]

Case Reports and Clinical Trials

The effectiveness of nerve blocks in the maintenance phase against hemodynamic responses has been demonstrated through many case reports and clinical trials. When compared to topical anaesthetic alone, for instance, research that was done by Kristensen and colleagues shown that a combination of superior laryngeal and recurrent laryngeal nerve blocks that were administered prior to awake intubation resulted in a reduction in the amount of hemodynamic instability. [38]

Practical Implications

An appropriate anaesthetic technique should be chosen with consideration of the patient's baseline cardiovascular status and likelihood for hemodynamic compromise. Because of nerve block hemodynamic stability benefits, GA may be less preferred in patients with cardiovascular comorbidities or at high risk for hemodynamic fluctuation. [34] Nevertheless, the technical complexity of nerve blocks and potential morbidity should be balanced in favour against these advantages.

Conclusion

Hemodynamic responses are one of the major contributors associated with awake intubation which is important to keep in mind for better patient safety and comfort. Airway topicalization and nerve blocks serve as effective methods of providing anaesthesia, however use of the latter results in better control over hemodynamic responses ultimately producing stable patient outcomes. As such, the choice between different techniques for gastric access based on an individual patient's needs and procedural requirements is likely best made by clinicians with careful consideration of their specific advantages and drawbacks.

Safety and Complications

Both airway topicalization and nerve blocks are usually safe in clinical practice. However, notably, both the techniques carry separate risks of complications.

Airway Topicalization

Safety: Airway topicalization appears to be a conduit that permits upper airway anaesthesia and is simple, minimally invasive technique. Direct delivery of local anaesthetics to the airway mucosa via swabs, nebulizers, or sprays is the goal of this approach. [11]

Complications of topicalization [6, 11]:

- Incomplete Anaesthesia may lead to patient discomfort and reflex responses during intubation.
- Local Anaesthetic Toxicity: particularly when higher concentrations or a large volume of anaesthetic agent is used.
- Airway Irritation: Possible irritation or damage to the mucosal surfaces may take place, which in turn can cause coughing or bronchospasm. This side effect is uncommon.

Airway Nerve Blocks

Safety: Nerve blocks provide targeted anaesthesia by injecting local anaesthetics near specific nerves. This technique requires anatomical knowledge and precision.

Complications of nerve block [6,11]:

- Technical Difficulty: This method needs a lot of anatomic insights and acumen.
- Intravascular Injection: Inadvertent intravascular injection may cause local anaesthetic toxicity as well several cardiovascular issues.
- Hematoma Formation: Hemorrhage and hematoma at the injection site, particularly in patients with coagulopathies.

- Nerve Injury: Risk of nerve injury with resulting prolonged numbness, or neuropathic pain.

Comparative Safety

In general, airway topicalization is easier to administer and carries only a few complications but it provides less consistent anaesthesia. Nerve blocks are more reliable with better patient comfort. However, it requitres higher technical demands and risks of serious complications if not performed correctly.

Head-to-head comparison:

Mathur et al. [39] Through the use of awake fiberoptic bronchoscopy-guided intubation, the preferable method for treating problematic airways was explored. The primary objective of this investigation was to ensure that the patient was comfortable while receiving adequate airway anaesthetic. Conducted as a randomized single-blind prospective study, it compared lignocaine nebulization with airway nerve blocks. During the course of the research project, both groups consisted of sixty adult patients who were scheduled to have surgery while under general anaesthesia. In one of the groups, jet nebulization was performed using 10 milliliters of 4% lignocaine. Individuals in the other group were administered bilateral superior laryngeal and transtracheal recurrent laryngeal nerve blocks, each of which contained 2 milliliters of 2% lignocaine. Procedural sedation with dexmedetomidine was administered to all patients. Time to intubation, intubating circumstances, vocal cord placement, cough intensity, and patient satisfaction were all variables examined in the research. Student's t test for parametric data, Mann-Whitney U test for non-parametric data, and Fisher's test for categorical data were the statistical tests that were used in the study. P values that were less than 0.05 were deemed to be statistically noteworthy. Group B had a much shorter intubation time than Group N, with a difference of 115.2 (14.7) seconds compared to 214.0 (22.2) seconds (P = 0.029). This difference was statistically noteworthy. The conditions under which the intubation was performed in Group B were better, and the patients in that group reported higher levels of overall satisfaction and comfort. The researchers concluded that airway nerve blocks are the best alternative for airway anaesthetic, even if lignocaine nebulization may be used in cases when nerve blocks are not possible.

Researchers Chandra et al. [40] set out to evaluate two methods for sedation-free diagnostic fiber optic bronchoscopy—trans cricoid injection and "spray as you go"—while keeping an eye out for potential problems. Group I consisted of sixty patients ranging in age from twenty to seventy who were undergoing diagnostic bronchoscopy with a single 3 ml transcricoid puncture of 4% lignocaine; group II consisted of two ml of 4% lignocaine administered via the bronchoscope onto the vocal cords and one ml of 2% lignocaine administered into each main bronchus. Extra lignocaine was given to both groups as required. Nebulization with 3 ml of

4% lignocaine and intramuscular atropine 0.6 mg were administered to all patients 20 minutes before the surgery. Groups were compared based on the total lignocaine dosage and the time it took to get from nasal bronchoscope insertion to the carina. The study examined pre- and post-operation systolic blood pressure, heart rate, and cough episodes, and 30 minutes after the treatment, participants were asked to rate their level of pain on a 0–10 visual analogue scale (VAS). Compared to group I, group II had a longer time to reach the carina, more cough episodes, less stable vitals, and a greater total lignocaine dosage. The groups did not differ in their VAS ratings. The research found that bronchoscopists had less difficulties and pain, used a lower dosage of local anaesthetic, and maintained more stable vitals while doing diagnostic bronchoscopy without sedation via trans cricoid puncture.

Mohanta et al. [41] recognizing the importance of administering an adequate amount of anaesthesia to the upper airway in situations when it is anticipated that the airway would be difficult to access, when awake fiberoptic guided intubation is often the technique of choice. They conducted an evaluation of the efficacy of lignocaine- and ultrasound-guided airway nerve blocks, as well as ultrasonic nebulization, with the purpose of providing airway anaesthetic prior to the implementation of awake fiberoptic-guided intubation. Sixty adult patients scheduled for surgery due to an expected difficult airway were involved in this prospective, randomized research. Although the group that got bilateral superior laryngeal and transtracheal recurrent laryngeal nerve blocks received airway nerve blocks guided by ultrasound, the group that underwent ultrasonic nebulization with lignocaine received lignocaine in the form of a nebulization. Time to intubation was the main endpoint, with secondary outcomes including gastric reflex, cough reflex, hemodynamic changes, attempts to intubate, and comfort score during intubation. It was observed that the intubation time for the group that had nebulization was significantly longer than the intubation time for the group that got ultrasound-guided airway nerve blocks (69.27±21.85 seconds vs 92.43±42.90 seconds, $p = 0.015$). No noticeable difference could be seen between the groups, despite the fact that there were variations in hemodynamic markers during the course of the operation. No significant differences between the two groups could be reported; comfort ratings, the number of attempts, and responses to coughing and gagging did not show any statistically significant difference. A review of the study indicated that the technique of using ultrasound-guided airway nerve blocks for awake fiberoptic intubation is preferable than the technique of ultrasonic nebulization.

Singh et al. [(42)] conducted a study on studied patients who had cervical spine injuries where a contrast was made between the airway anaesthetic that is administered through nerve blocks and the one administered using the local anaesthesia atomizer with regard to Fiberoptic intubation while the patients are awake. This is very necessary and helpful in maintaining neurological, especially during intubation and surgical implantations. After the randomization process was completed, awake fiberoptic intubation was carried out on thirty patients who were scheduled to have elective surgery and for whom an airway-directed local anaesthetic approach was deemed necessary: Group N which received nerve block with transtracheal injection of lignocaine and bilateral superior laryngeal blocks or Group A which received atomized lidocaine. The authors compared intubation time and patient discomfort as assessed by cough and gag scores. In comparison to the atomizer group, the nerve block group saw a considerably quicker time until intubation, with a time of 90.2-11.7% compared to 210.4-10.6 seconds (p=0.041). A larger number of patients in the atomizer group also had coughing and gagging during exploration (11 in total) as compared to one patient with these complications, who was assigned to the nerve block-group (p=0.006). Patients were also intubated, in which it was found that the ease of intubation and comfort on part of patient group receiving nerve block was noteworthy. The study found that nerve blocks provided more efficient airway anaesthesia without increased patient discomfort or time of intubation compared with topical anaesthesia.

NEED FOR THE STUDY

The most effective method for treating individuals with airway difficulties is awake fiberoptic intubation. Airway anaesthetic, whether via topical numbing agents or regional nerve blocks, has a major impact on intubation time, patient comfort, and ease. In cases of anticipated difficult airways, such as cervical instability, oro-mandibular fractures, head and neck tumors, facial anomalies, and obesity, fiberoptic bronchoscope-assisted oral or nasal endotracheal intubation is commonly performed. Various techniques, including airway blocks, gargles, sprays, atomization, and nebulization, with or without mild sedation, have been used to facilitate this process. While ultrasonic nebulizers provide optimal conditions with minimal systemic toxicity, there remains a risk of laryngospasm due to inadequate topical anaesthesia. Alternatively, the McKeinze Technique using low-flow oxygen to spray local anaesthetic is another approach. Airway blocks, although effective, are technically challenging and carry risks such as nerve damage and accidental intravascular injections, especially for the inexperienced. To facilitate nasal intubation, a comprehensive block of multiple nerves is recommended. This research is necessary because there is a significant paucity of comparative studies on the efficacy of airway nerve blocks vs topical anaesthetic for awake fiberoptic intubation. This lack of similar studies highlights the necessity for this investigation.

MATERIALS &
METHODS

METHODS

Study Design: Single blinded randomized controlled trials

Study Duration: From September 2022 to February 2024

Study Participants: The study looked at 50 people at the R. L. Jalappa Hospital and Research Centre in Tamaka, Kolar, who were going to have planned treatments while under general anaesthesia and were expected to have trouble breathing.

Sampling Method: Universal sampling. Randomization will be done by software with 1:1 allocation using block randomization with unequal block size.

Sample Size: The sample size is estimated as 25 per each group

The sample size is calculated through G power 3.1.9.6 software by taking the Ease of Intubation Score in patients with Airway Nerve block and Airway topicalization for awake fibreoptic bronchoscope assisted Naso-tracheal intubation as reported in a study done by the input values taken for the calculation are,

Number of groups = 2

Calculated Mean (as reported in the study) Group UAB = 2.64

Calculated Mean (as reported in the study) Group LA = 5.96

Standard deviation for Group UAB= 1.25

Standard deviation for Group LA= 1.27

α error probability = 0.05

Power (1-β power probability) = 0.95

Allocation Ratio = 1:1

Effect size f = 1.10

The minimum sample size needed for the study amounted to be = 45 (including both groups)

So, for this study we considered 50 patients in total, and divided them 25 per each group for better statistical representation.

INCLUSION CRITERIA: Patients over 18 years old, over 50kg, and ASA grade I II and III planned for elective procedures under general anaesthesia with expected airway difficulty.

EXCLUSION CRITERIA:

- Uncooperative patients
- Local anaesthetic allergy
- Pregnancy
- Deranged coagulation
- Skull base fracture
- Epilepsy

- Raised Intracranial pressure and Intraocular pressure

Study procedure:

The study was started after Institutional Ethical Clearance (IEC). Prior to the treatment, the patients were given thorough explanations in their native language and informed permission was acquired.

The study was conducted on adult patients more than 18 years of age and requiring fiberoptic bronchoscope assisted nasotracheal intubations. A detailed preoperative evaluation was performed on each patient. This evaluation comprised a thorough check of their airway, which included a dental inspection, mouth opening, Mallampati grade, thyromental distance, and neck movements. Additionally, the standard operating procedure for fasting was included in this evaluation. In the preoperative room the following medications was administered after securing IV cannula half an hour before intubation:

- Inj. Ranitidine 50mg IV
- Inj. Ondansetron 4mg IV
- Inj. Glycopyrrolate 0.2mg IV.

Inside the operating room, standard monitors are connected to monitor i.e., electrocardiogram (ECG), HR, BP and oxygen saturation. Continuous end tidal carbon dioxide ($EtCO_2$) will be monitored following intubation.

Airway nerve block (N) and airway topicalization (T) were the two groups that patients were assigned to using a computer-generated random sequence of numbers and the closed-envelope technique.

Nerves supplying the nose are blocked using nasal packs soaked with 2% lignocaine with 1:200000 adrenaline in both the groups.

Group N (n-25): Patients received following nerve blocks

1. Bilateral Superior Laryngeal Nerve block - with 2ml of 2% lignocaine (each side) injected approximately 2-4 mm inferior to the greater cornu of the hyoid bone.
2. Recurrent laryngeal nerve block – trans laryngeal injection with 2ml of 4% Lignocaine injected after aspirating air at the level of cricothyroid membrane.

Group T (n-25):

1. Patients receive 10ml of 4% Lignocaine for topicalization using Modified McKeinzie Technique with infant feeding tube.

Both the groups receive 4- 5 liters of supplemental oxygen through nasal cannula throughout the procedure.

Appropriate size flexometallic endotracheal tube was loaded on to Fibre Optic Bronchoscope.

The following parameters are recorded:

- The length of time required for intubation, measured in seconds, beginning with the insertion of the fiberoptic scope into the nose and ending with the confirmation of tracheal intubation via capnography
- Ease of intubation – cough and gag score, intubation score
- Cough and gag reflex
- Any other complications.

After securing the airway, general anaesthesia was delivered by intravenous administration of fentanyl at a rate of 2 mcg/kg, propofol at a rate of 2 mg/kg, and vecuronium at a rate of 0.06 mg/kg. For maintenance, isoflurane, 50% oxygen, and 50% nitrous oxide were supplied.

Methods of data collection

Data was collected using a pre-tested proforma after taking the informed consent from the participants.

Study variables

Hemodynamics – Heart rate, blood pressure, oxygen saturation, respiratory rate.

Cough and gag score

1 = None,

2 = Minimal coughing and gagging, <3 times,

3 = Mild cough and gag lasting for <1 min,

4 = Persistent coughing and gagging

Intubation score

1 = no reaction

2 = slight grimacing

3 = severe grimacing

4 = verbal objection

5 = defensive movement of head, hands, or feet

Ease of intubation – quality of awake fiberoptic intubation

Grading of the score was done as below: -

1-2 score – grade 1 (excellent)

3-4 score – grade 2 (good)

5-6 score – grade 3 (satisfactory)

7-9 score – grade 4 (poor)

Comfort score

1 = Good

2 = Moderately comfortable

3 = Poor, uncomfortable

Lignocaine toxicity – ECG changes, seizures, bronchoconstriction

Time taken for intubation (minutes)

Airway complications - The following are examples of airway complications: sore throat, throat spasms, hoarse voice, inflammation, hematoma of vocal cords, epistaxis, symptoms similar to influenza, tracheal perforation, and changes in ETCO2 before and after intubation.

Gastric complications – aspiration

Drug complications – lignocaine toxicity

Statistical considerations:

Collected data was coded and entered into an excel data base. The data was analyzed in Stata version 18.0.

All the quantitative measures were provided in either the mean and standard deviation (SD) or the median and inter-quartile range (IQR), depending on the distribution of the variable. The categorical variables were provided in the form of frequency and percentage (%), together with the corresponding confidence interval (CI).

To compare the two groups, independent sample t-test was done for the continuous variables.

In the case of categorical variables, the Mann-Whitney U test, the chi square test, and Fisher's exact test will be deemed suitable for the purpose of interpreting the findings.

A p-value < 0.05 was considered as statistically noteworthy for all statistical tests.

Ethical considerations:

It was necessary to acquire authorization from the institutional ethics committee before beginning the research. Consent to participate was sought from each and every participant in a prospective manner.

RESULTS

RESULTS

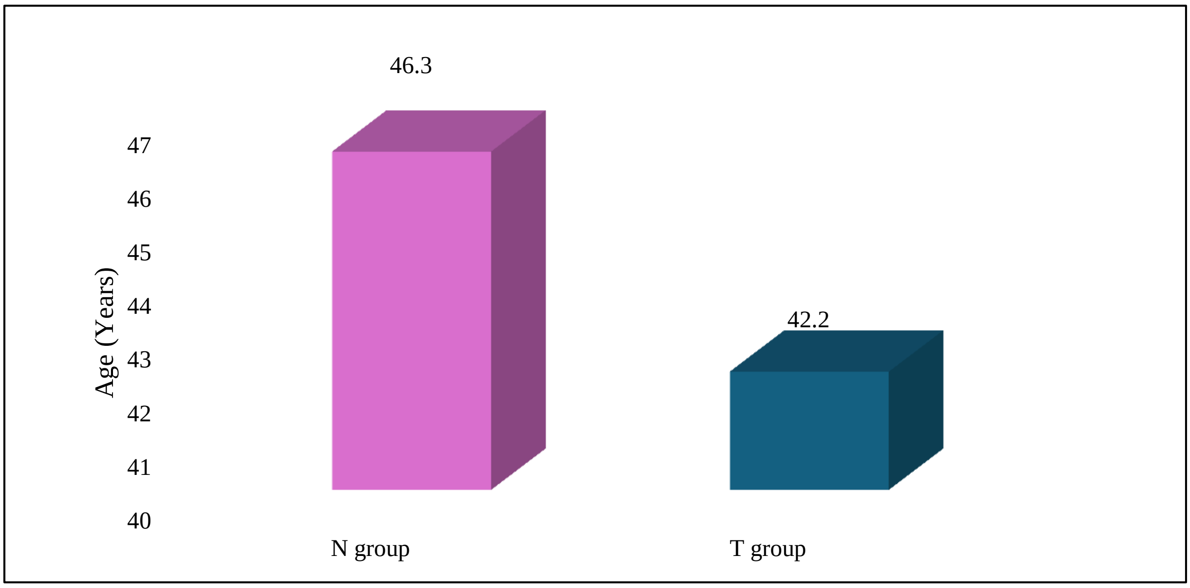
We recruited a total number of 50 participants in the study. The mean age of the participants was 44.3 years (SD 15.6 years).

Baseline characteristics of the two groups

The following table illustrates the differences between the two groups:

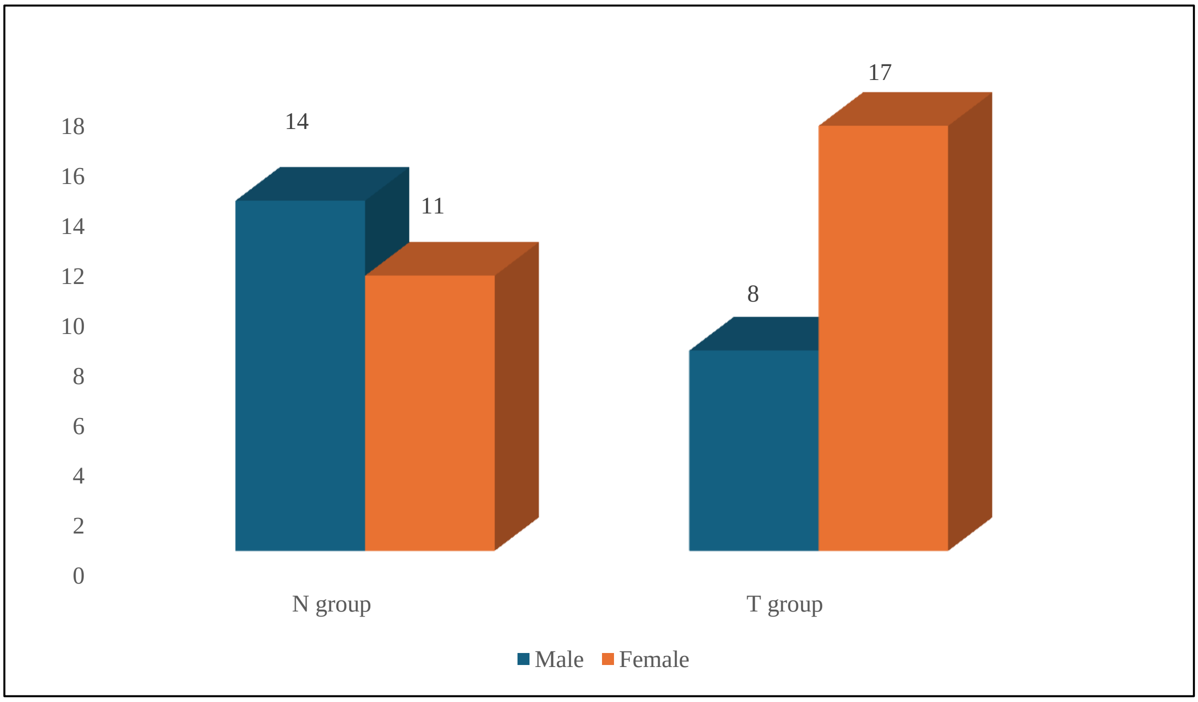
Age distribution: In the T group, the average age was 46.2 years old, with a standard deviation of 15.4 years. In the N group, the average age was 46.3 years old, with a standard deviation of 13.9. Table 1 and Figure 3 both show that statistical analysis did not find any noteworthy differences (p = 0.36).

Figure 3: Age distribution of the two groups



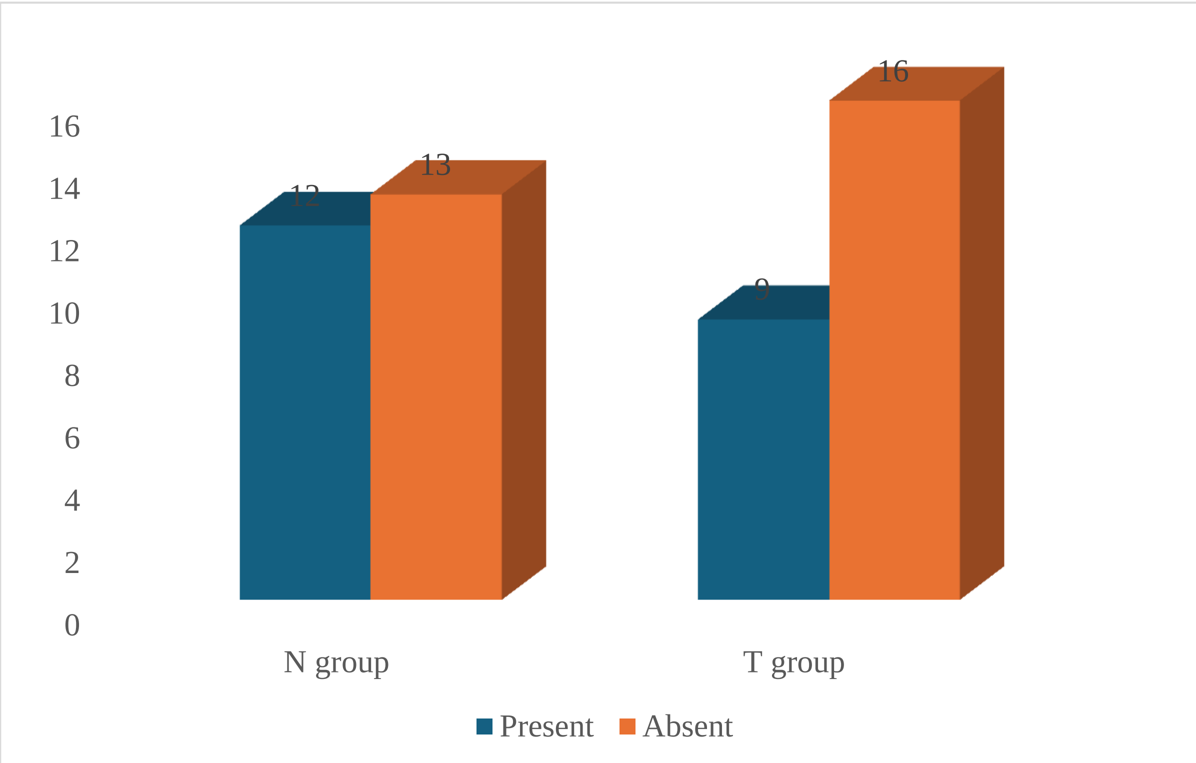
Gender distribution: Overall, there were 22 (44%) males and 28 (56%) females. There were 14 men and 11 ladies in group N, making it 56% male and 44% female. Eight (13.2%) men and seventeen (68.0%) ladies made up the T group. With a p-value of just 0.08 (Table 1, Figure 4), the disparity passed muster.

Figure 4: Gender distribution of the two groups



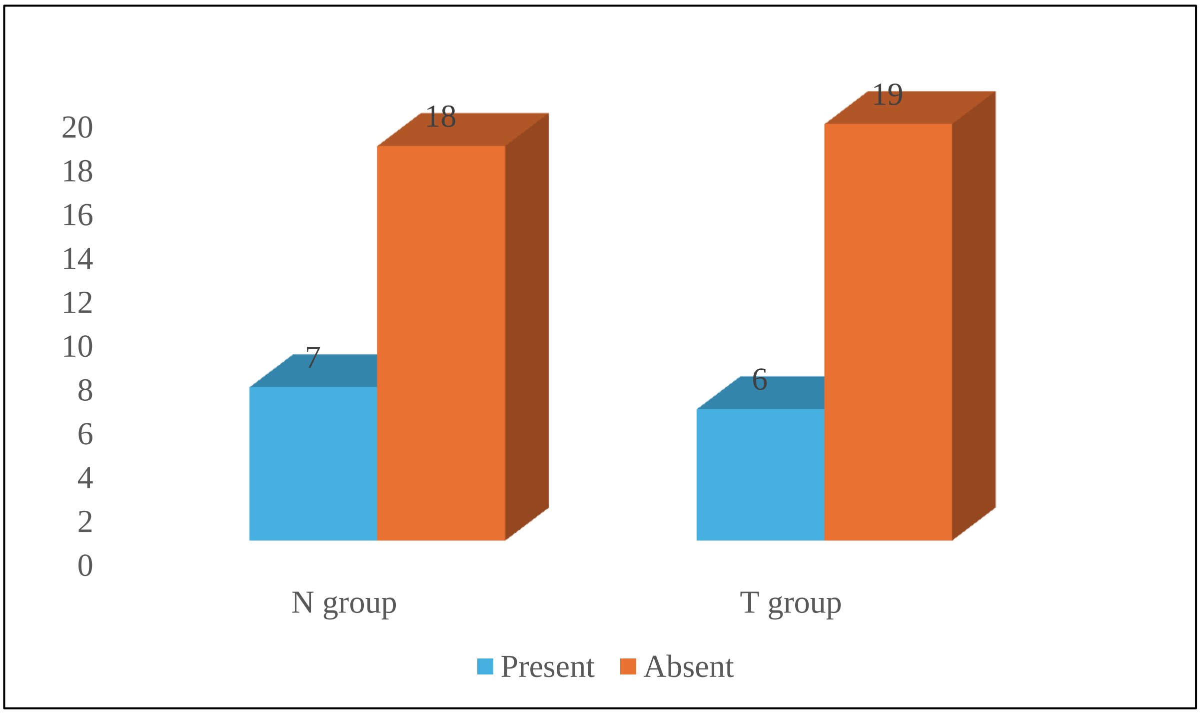
Distribution of comorbidity: As a whole, there were 12 (48%) patients in the N group had any comorbidity, while 9 (36%) patients in the T group was diagnosed with any comorbidity. The variance was not statistically noteworthy (p=0.73) (Table 1, Figure 5).

Figure 5: Comorbidity distribution of the two groups



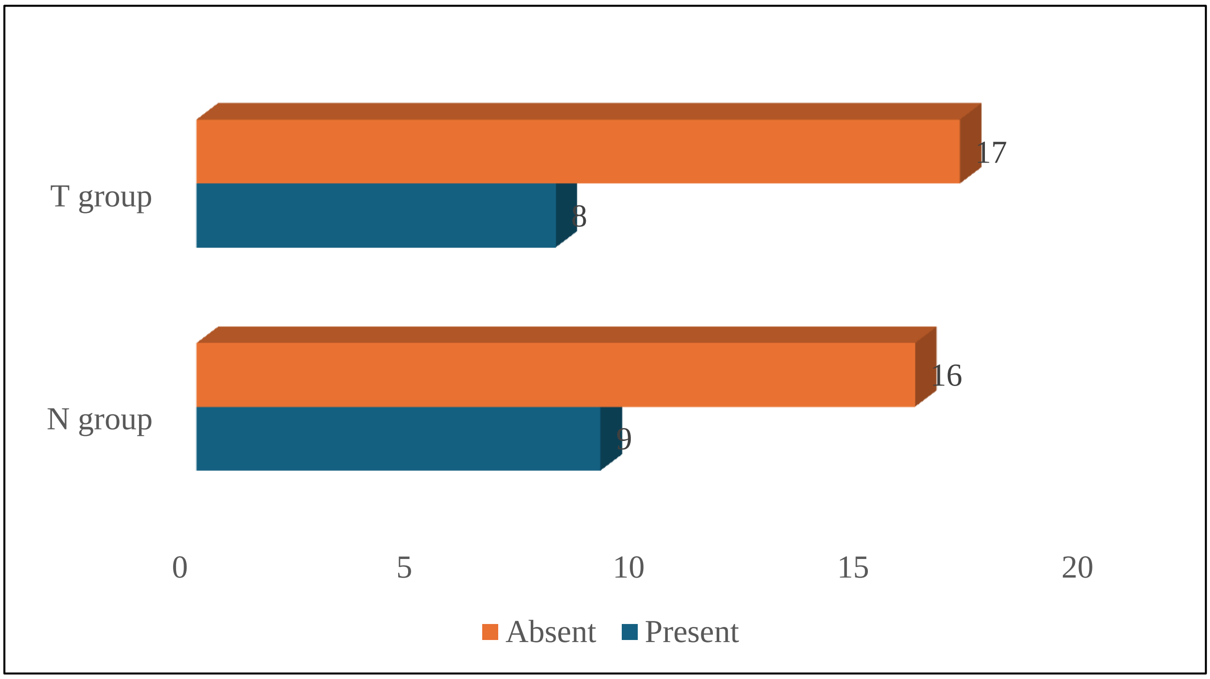
Distribution of diabetes mellitus (DM): While 7 (28%) patients in the N group had DM, 6 (24%) patients in the T group was diagnosed with DM. There was no statistically noteworthy change (p=0.1) (Table 1, Figure 6).

Figure 6: DM distribution of the two groups



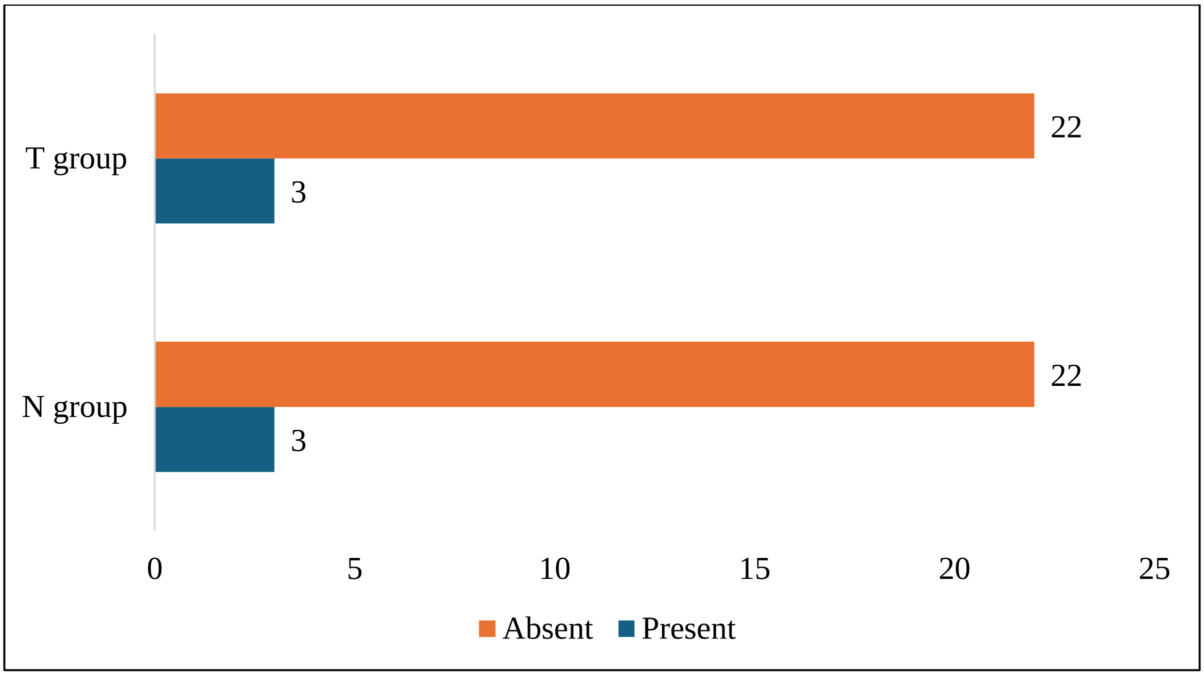
Distribution of hypertension: While 9 (36%) patients in the N group had hypertension, 8 (32%) patients in the T group was diagnosed with hypertension. With a p-value of just 0.1, there was no statistically noteworthy change. (Table 1, Figure 7)

Figure 7: Hypertension distribution of the two groups



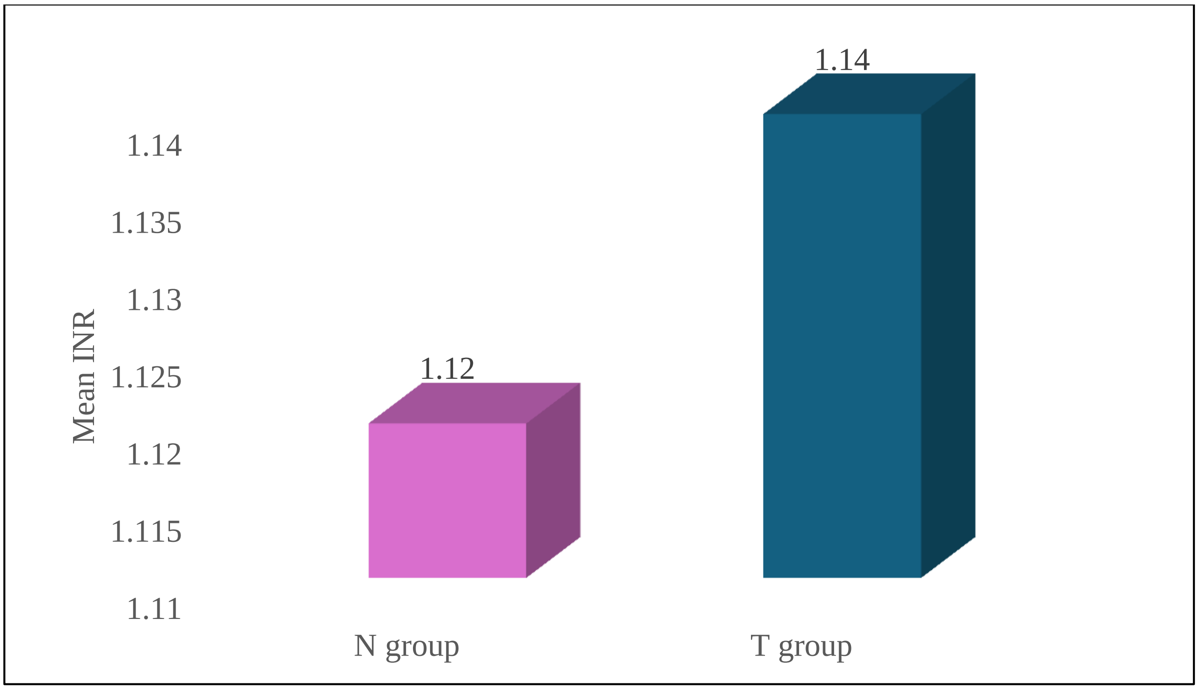
Distribution of hypothyroidism: 3 (12%) patients in each groups had hypothyroidism. There was no variance of the groups in terms of hypothyroidism proportion (p=1.0) (Table 1, Figure 8).

Figure 8: Hypothyroidism distribution of the two groups



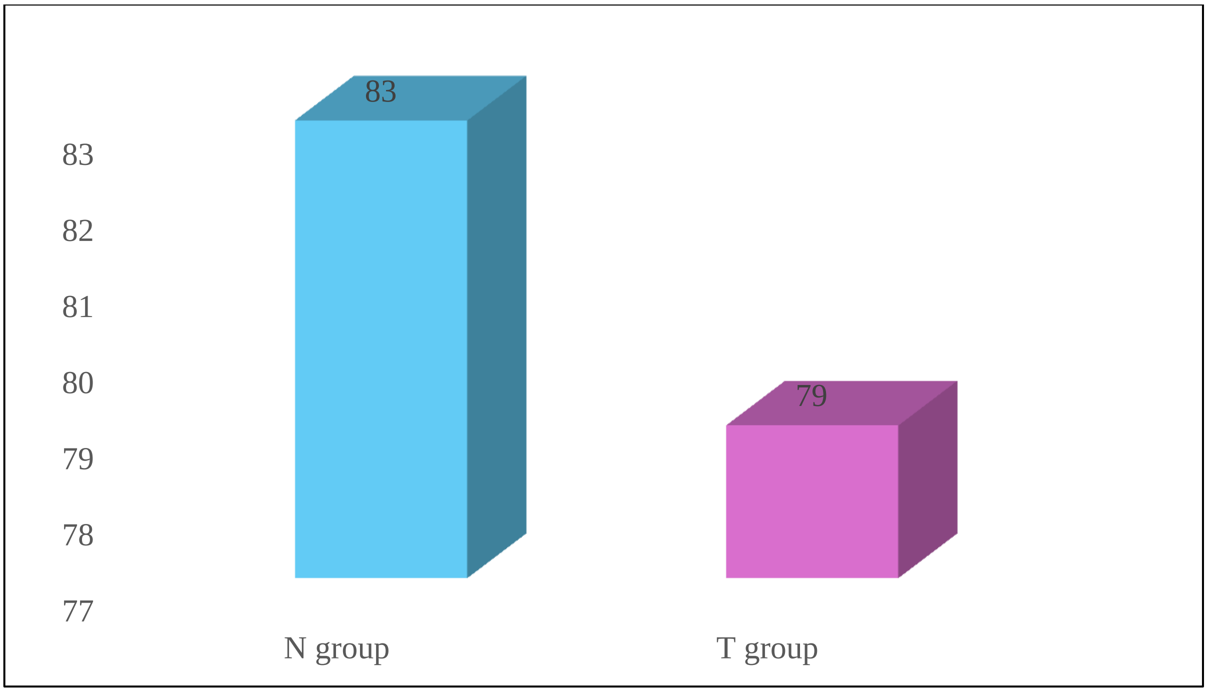
INR distribution: The mean INR of group N was 1.12 (SD 0.14) in the N group and 1.14 (SD 0.11) in the T group. The variance was not statistically noteworthy (p=0.53) (Table 1, Figure 9).

Figure 9: INR distribution of the two groups



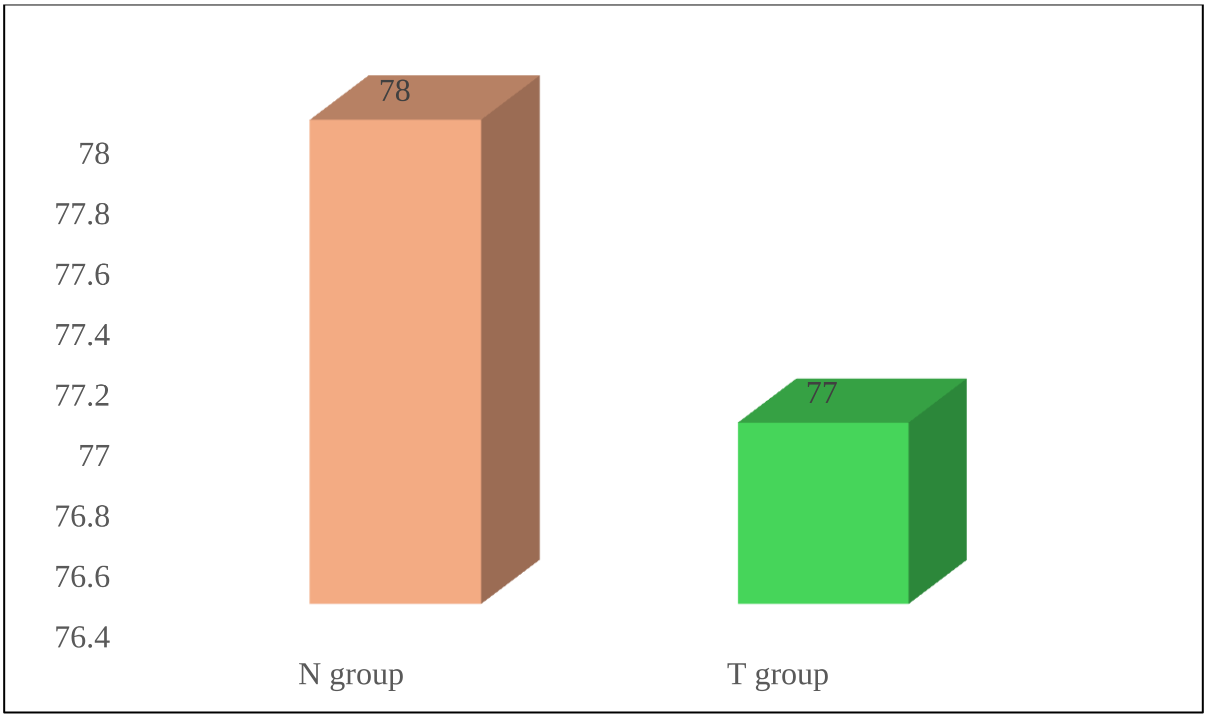
Pre-operative heart rate distribution: In the group N, the mean pre-operative HR was 83 beats per minute (standard deviation: 12 beats per minute), whereas in the group T, the mean heart rate was 79 beats per minute (standard deviation: 15 beats per minute). Due to the fact that the change was statistically insignificant (p=0.3), (See Figure 10 and Table 1)

Figure 10: Pre-operative heart rate distribution of the two groups



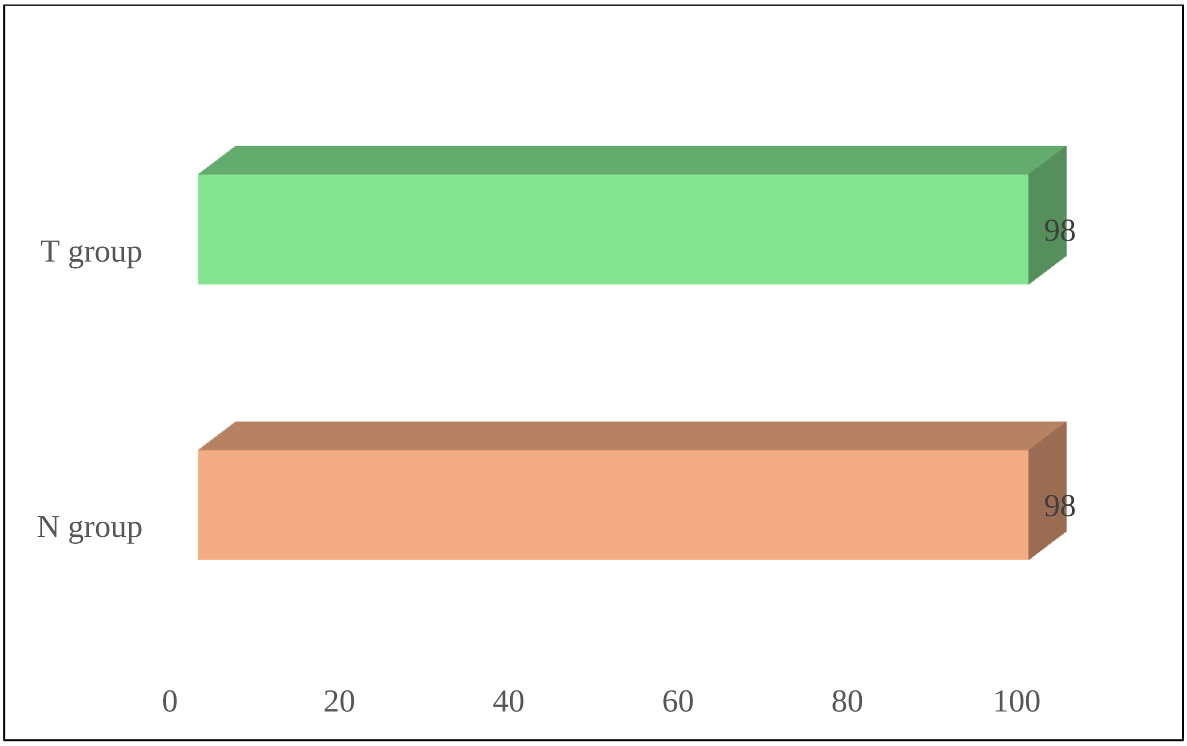
Pre-operative MAP distribution: The pre-operative mean arterial pressure (MAP) of group N was 78 mm Hg (standard deviation: 9 mm Hg), whereas the MAP of group T was 77 mm Hg (standard deviation: 10 mm Hg). The deviation did not meet the criteria for statistical significance (p = 0.65; see Table 1 and Figure 11).

Figure 11: Pre-operative MAP distribution of the two groups



Pre-operative SpO2 distribution: The mean pre-operative SpO2 of group N was 98% (SD 1%) in the N group and 98% (SD 2%) in the T group. Statistically, the change was insignificant (p=0.39). (Table 1, Figure 12).

Figure 12: Pre-operative SpO2 distribution of the two groups



Pre-operative respiratory rate (RR) distribution:

The mean pre-operative RR of both the groups was 18/min (SD 2/min). There was no variance between the groups (p=0.42) (Table 1, Figure 13).

Figure 13: Pre-operative RR distribution of the two groups

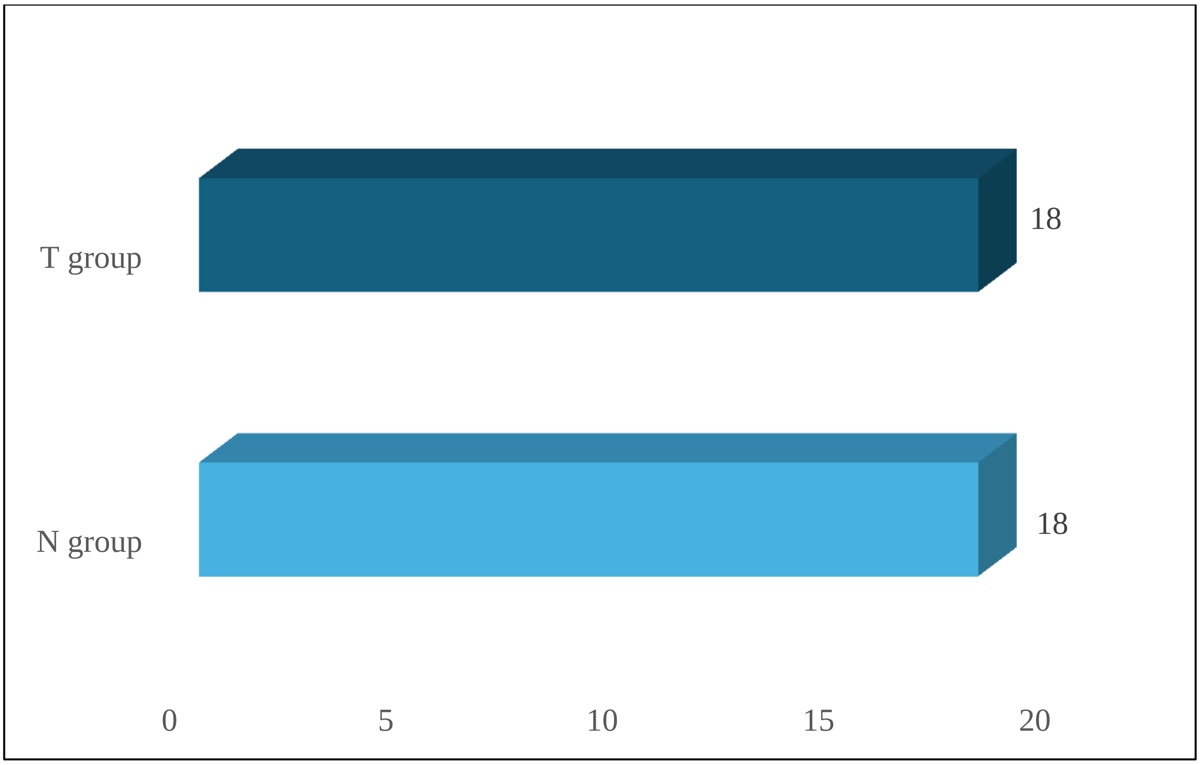


Table 1: Baseline characteristics of the two groups

Variables		Estimate		p-value
		Group N (n=25)	Group T (n=25)	
Mean age, years (SD)		46.3 years (SD 15.9 years)	42.2 years (15.4 years)	0.36
Gender, n (%)	Male	14 (56%)	8 (32%)	0.08
	Female	11 (44%)	17 (68%)	
Comorbidity (All)	Present	12 (48%)	9 (36%)	0.73
	Absent	13 (52%)	16 (64%)	
DM	Present	7 (28%)	6 (24%)	0.1
	Absent	18 (72%)	19 (76%)	
Hypertension	Present	9 (36%)	8 (32%)	0.1
	Absent	16 (64%)	17 (68%)	
Hypothyroidism	Present	3 (12%)	3 (12%)	1.0
	Absent	22 (88%)	22 (88%)	
Mean INR (SD)		1.12 (SD 0.14)	1.14 (SD 0.11)	0.53
Mean pre-operative heart rate		83/min (SD 12/min)	79/min (SD 15/min)	0.3
Mean pre-operative MAP		77 mm Hg (SD 10 mm Hg)	77 mm Hg (SD 10 mm Hg)	0.65
Mean pre-operative SpO2		98% (SD 1%)	98% (SD 2%)	0.39
Mean pre-operative RR		18/min (SD 2/min)	18/min (SD 2/min)	0.42

Intra-operative clinical differences between the two groups

Difference in heart rates (HR):

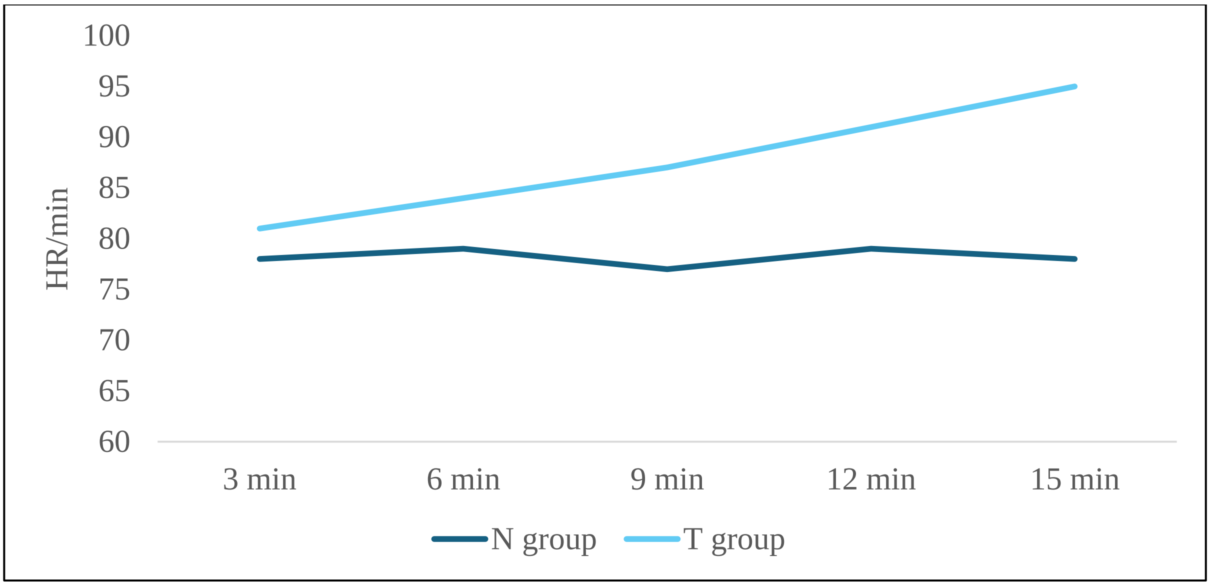
The mean HR was 78/min (13/min) in the N group, while it was 81/min (SD 11/min) in the T group at the end of 3 minutes. The variance was not statistically noteworthy (p=0.43). While the heart rate remained static for the N group over the time till the end of 15 minutes, the heart rate steadily increased for the T group. The difference in mean HR was 10 (95% CI: 4 to 15; p=0.02) at 9 minutes, 12 (95% CI: 6 to 18; p=0.001) at the end of 12 minutes, and 17 (95% CI: 8 to 25; p=0.001) at the end of 15 minutes between the two groups (Table 2, figure 14).

Table 2: Distribution of intra-operative in HR between the two groups

Duration (min)	Hear rate/ min		Mean difference (95% CI)	p-value
	N group (n=25)	T group (n=25)		
3 min	78/min (13/min)	81/min (SD 11/min)	3 (-10 to 4)	0.43
6 min	79/min (10/min)	84/min (11/min)	5 (-2 to 6)	0.08
9 min	77/min (8/min)	87/min (9/min)	10 (4 to 15)	0.02*
12 min	79/min (10/min)	91/min (10/min)	12 (6 to 18)	0.001*
15 min	78/min (8/min)	95/min (8/min)	17 (8 to 25)	0.001*

*Statistically significant

Figure 14: Distribution of intra-operative in HR between the two groups



Difference in MAP:

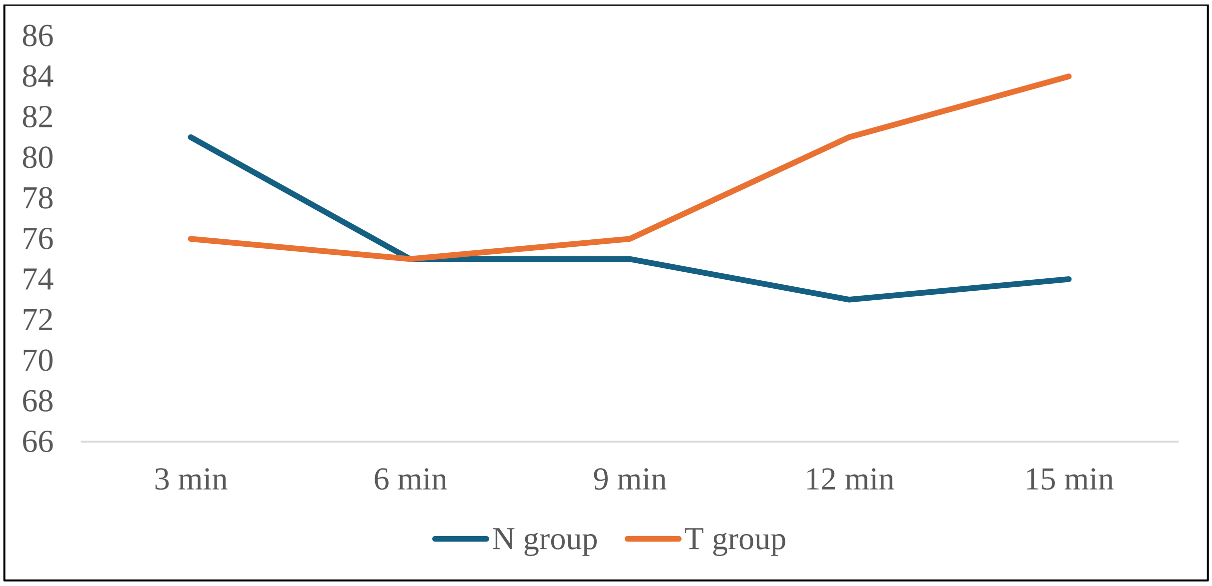
The mean MAP was static for the N group. The MAP was static for the T group till 9 minutes, but surged marginally after that. The difference between the two groups was not noteworthy till 9 minutes; however, the MAP was high by 8 mm HG (95% CI: 1 to 14 mm HG; p=0.03) at the end of 12 minutes and 10 mm HG (95% CI: 4 to 15 mm Hg; p=0.006) at the end of 15 minutes. (Table 3, figure 15).

Table 3: Distribution of intra-operative MAP between the two groups

Duration (min)	MAP (mm Hg)		Mean difference (95%CI)	p-value
	N group (n=25)	T group (n=25)		
3 min	81 (8)	76 (10)	-5 (-10 to 1)	0.09
6 min	75 (8)	75 (9)	0 (-5 to 4)	0.84
9 min	75 (10)	76 (9)	1 (-5 to 6)	0.84
12 min	73 (8)	81 (9)	8 (1 to 14)	0.03*
15 min	74 (8)	84 (8)	10 (4 to 15)	0.006*

*Statistically noteworthy

Figure 15: Distribution of intra-operative MAP between the two groups



Difference in SpO2:

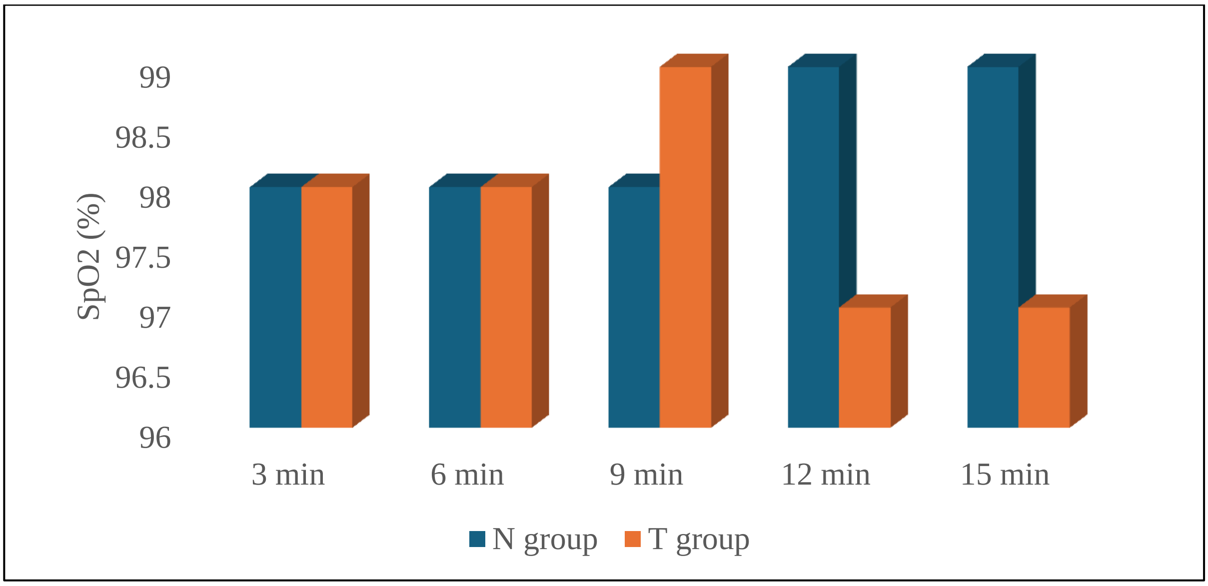
The mean SpO2 was static for the both groups till 9 minutes. For the T group, SpO2 reduced marginally at 12 and 15 minutes. However, the difference was not statistically noteworthy. (Table 4, figure 16).

Table 4: Distribution of intra-operative SpO2 between the two groups

Duration (min)	SpO2 (%)		Mean difference (95% CI)	p-value
	N group (n=25)	T group (n=25)		
3 min	98 (1)	98 (1)	0 (0 to 1)	0.96
6 min	98 (1)	98 (2)	0 (-1 to 1)	0.84
9 min	98 (1)	99 (2)	1 (-5 to 6)	0.84
12 min	99 (1)	97 (2)	2 (-1 to 3)	0.13
15 min	99 (2)	97 (2)	2 (-1 to 3)	0.12

*Statistically noteworthy

Figure 16: Distribution of intra-operative SpO2 between the two groups



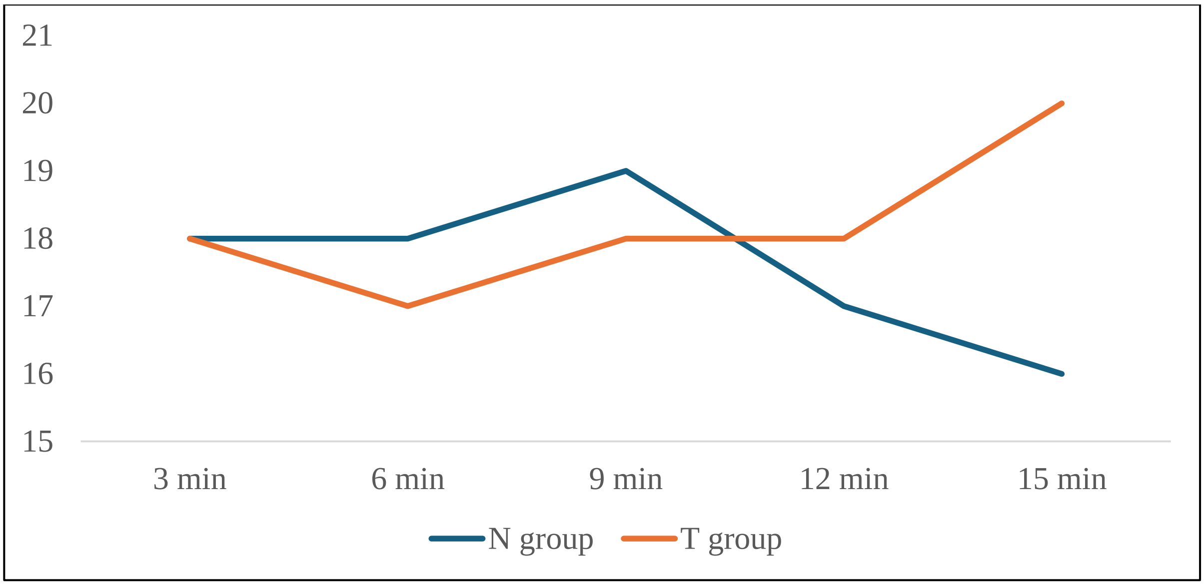
Difference in RR: (Table 5, figure 17).

Table 5: Distribution of intra-operative RR between the two groups

Duration (min)	RR (%)		Mean difference (95% CI)	p-value
	N group (n=25)	T group (n=25)		
3 min	18 (3)	18 (3)	0 (1 to 2)	0.72
6 min	18 (3)	17 (2)	1 (-1 to 3)	0.76
9 min	19 (3)	18 (2)	1 (- to 2)	0.47
12 min	17 (3)	18 (3)	2 (-1 to 3)	0.13
15 min	16 (3)	20 (4)	4 (1 to 9)	0.0.03*

*Statistically noteworthy

Figure 17: Distribution of intra-operative RR between the two groups



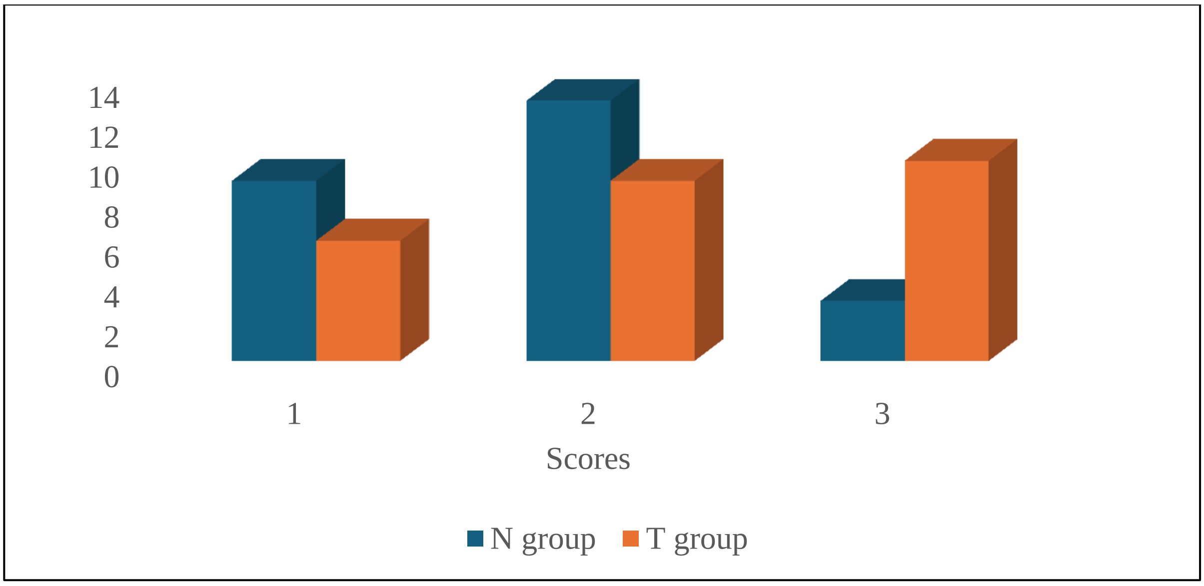
Cough GAG score: The cough and GAG score was relatively high (score 3) in the T group (n=10, 40%) than the N group (n=3, 12%). The difference was statistically noteworthy (p=0.02) (Table 6, figure 18)

Table 6: Cough GAG score distribution among the two groups

Score	Group N, n (%)	Group T, n (%)	p-value
1	9 (36)	6(24)	0.02*
2	13 (52)	9 (36)	
3	3 (12)	10 (40)	

*Statistically significant

Figure 18: Cough GAG score distribution among the two groups



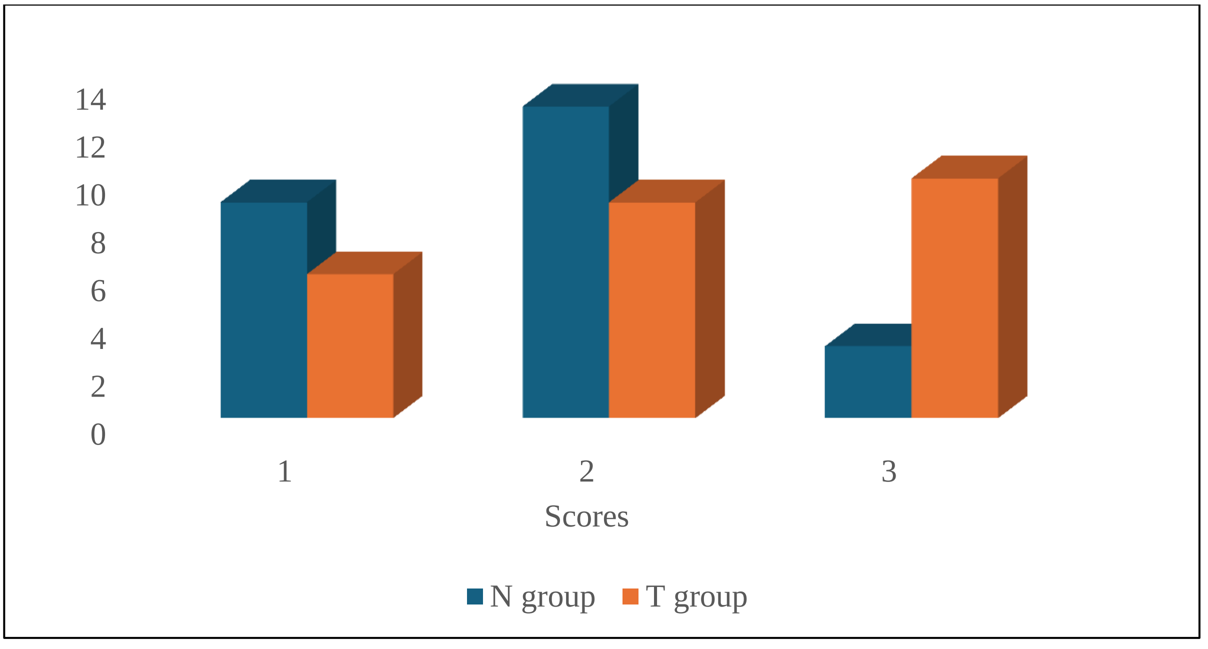
Intubation score: According to the intubation score, group T had a higher score than group N. Only two patients, or eight percent, obtained a score of three in the N group, while nine patients, or thirty-six percent, received a score of three in the T group. There was a variation that was statistically noteworthy (p = 0.03). (See figure 19 and table 7).

Table 7: Intubation score distribution among the two groups

Intubation Score	Group N, n (%)	Group T, n (%)	p-value
1	8 (32)	3 (12)	0.03
2	15 (60)	1 3 (52)	
3	2 (8)	9 (36)	

*Statistically significant

Figure 19: Intubation score distribution among the two groups



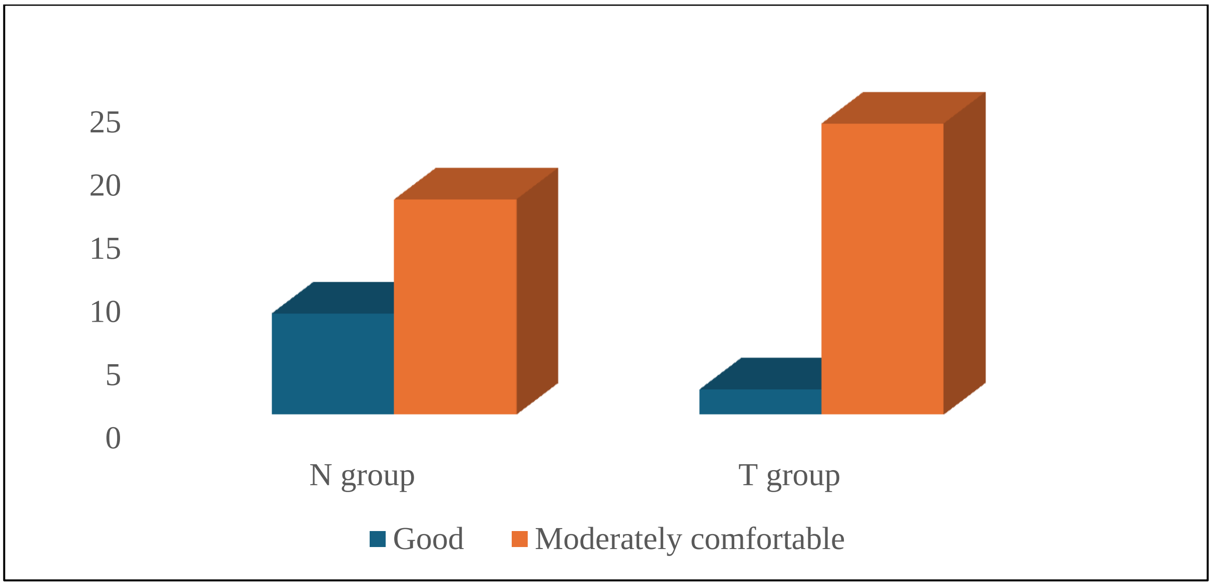
Comfort score: While 8 (32%) patients had a good comfort score in the N group, only 2 (8%) patients in the T group had a good comfort score. The disparity was identified via statistical analysis (p=0.03). (Table 8, figure 21).

Table 8: Comfort score distribution among the two groups

Comfort Score	Group N, n (%)	Group T, n (%)	p-value
Good	8 (32)	2 (8)	0.03*
Moderately comfortable	17 (68)	23 (92)	

*Statistically significant

Figure 20: Comfort score distribution among the two groups



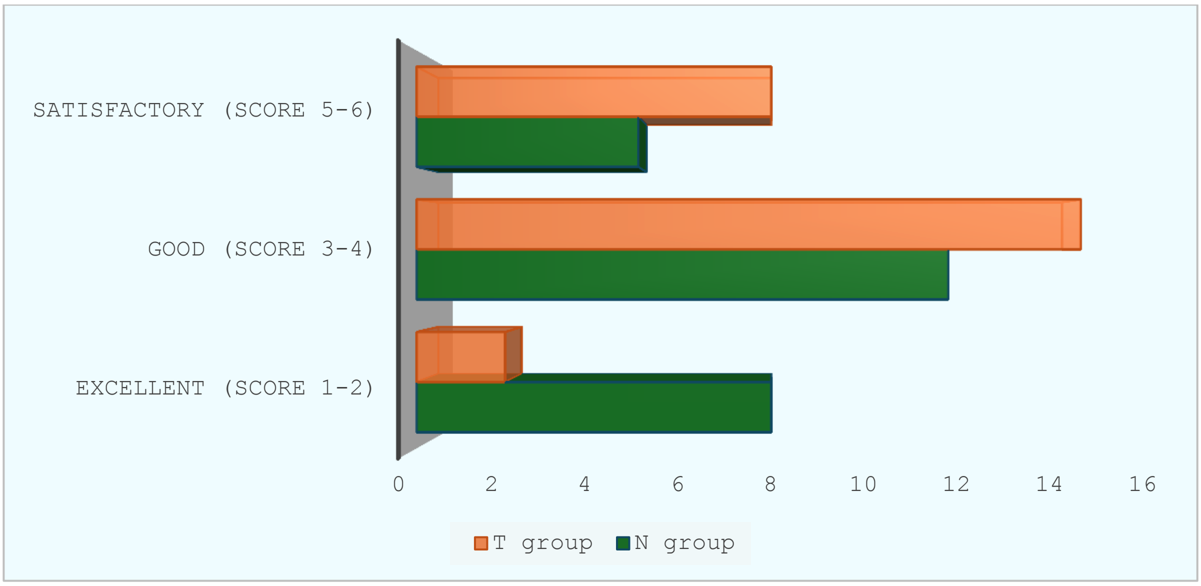
Ease of intubation: The median ease of intubation score Only 8% of patients in group T reported intubation ease of 2 or higher, but 32% (n=8) of patients in group N said the same. A statistical test revealed a noteworthy difference (p=0.03). (Table 9, figure 21).

Table 9: Ease of intubation among the two groups

Ease of intubation grade	Group N, n (%)	Group T, n (%)	p-value
Excellent (Score 1-2)	8 (32)	2 (8)	0.03*
Good (Score 3-4)	12 (48)	15 (60)	
Satisfactory (Score 5-6)	5 (20)	8 (32)	

*Statistically significant

Figure 21: Ease of intubation among the two groups



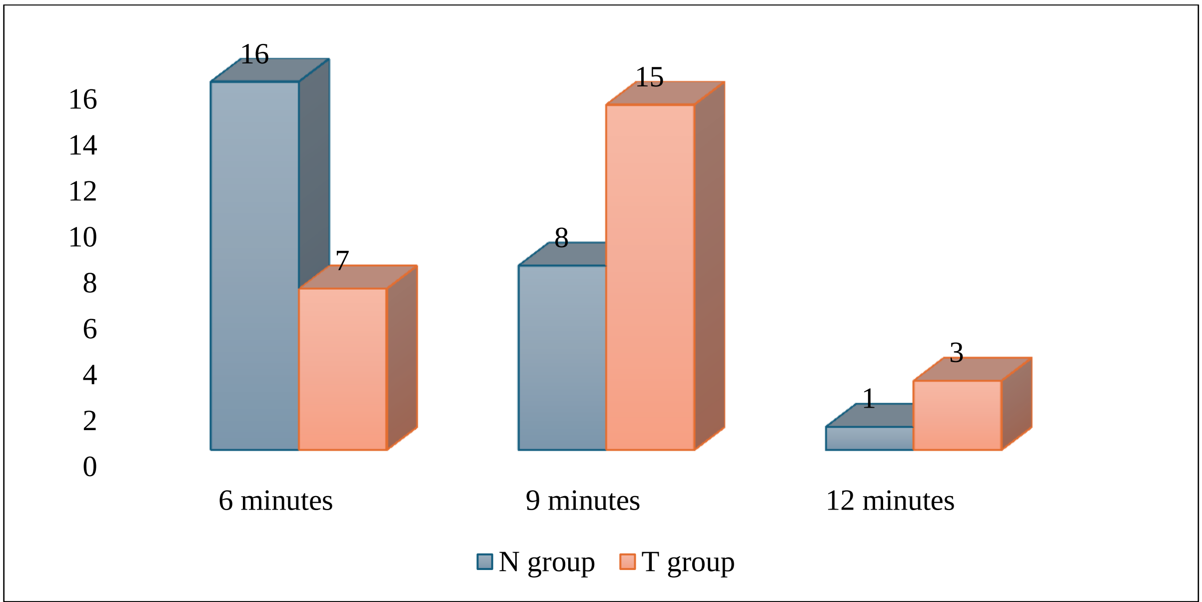
Intubation time: While 16 patients (64%) in the group N took 6 minutes or less for intubation, only 7 (28%) patients took 6 minutes or less for intubation in the T group. On the other hand, one patient (4% of the N group) required twelve minutes for intubation, while three patients (12%) in the T group required twelve minutes. A statistical test revealed a noteworthy difference (p=0.04).

Table 10: Time taken for intubation among the two groups

Time taken	Group N, n (%)	Group T, n (%)	p-value
6 minutes	16 (64)	7 (28)	0.04*
9 minutes	8 (32)	15 (60)	
12 minutes	1(4)	3 (12)	

*Statistically significant

Figure 22: Time taken for intubation among the two groups



Lignocaine toxicity: The administration of lignocaine did not cause any adverse effects in either group of patients.

Gastric complication: No patients in either group had gastrointestinal toxicity, including aspiration, according to the reports.

Airway complication: When it came to opening their mouths, every single patient in both groups had difficulties with their airways. Eighteen patients in the N group had one finger opening, whereas nineteen patients in the T group had such a condition. The N group included 18 patients with this issue. The difference did not meet the criteria for statistical significance (p = 0.53) (see Table 11).

Table 11: Airway complications in both the groups

Airway complications	Group N, n (%)	Group T, n (%)	p-value
<one finger opening	7 (28)	6 (24)	0.53
One finger opening	18 (72)	19 (76)	

Drug complications: None of the patients in either group reported to have any drug-related complications.

DISCUSSION

DISCUSSION

Fifty people were included in this randomized controlled experiment to see if airway topicalization was effective in achieving upper airway anaesthetic for awake fiberoptic bronchoscope-assisted nasotracheal intubations. The trial was blinded. Our study also compared the hemodynamic response between airway nerve blocks group and airway topicalization group.

Baseline characteristics:

Age Distribution: The mean ages of the participants in the airway nerve block (N) group and the airway topicalization (T) group were 46.3 years and 42.2 years, respectively, with no statistically noteworthy difference (p=0.36).

Gender Distribution: Gender distribution between the two groups did not show a noteworthy difference (p=0.08), with 56% males in the N group and 32% males in the T group.

Comorbidity Distribution: Co-morbid conditions can have a marked effect on the response to anaesthesia as well as procedure safety. The distribution of comorbidities including DM, hypertension (HTN), and hypothyroidism was similar in both groups (p>0.1 for all). This equivalence balanced the health between participants, which provided fair comparison of their efficacy and safety in two techniques.

INR Distribution: International Normalized Ratio is a measure of blood clotting. Mean INR values of 1.12 for the N group and 1.14 in the T group (P =.53) suggest comparable coagulation profiles This is important because it dilutes the risk of bleeding complications associated with these interventions.

Pre-operative Vital Signs: Pre-operative HR and MAP are similar in the two groups of patients, as well SpO2 %. The respiratory rate was also not statistically significantly different between both groups. These are basic indices for physiological status and possibly anaesthetic response. These data also confirm the absence of differences between conditions prior to intervention, and thus demonstrates that any changes observed post-intervention are more likely a result of the interventions as opposed to previously established baseline levels.

The two groups in this study were homogeneous at baseline without noteworthy differences in their characteristics (Table 1). This shows the randomization process was adequate, and ensured that the groups are equally balanced at intervention baseline. This comparability is important for the interpretation of the results, as it will decrease potential confounding variables that might impact on its measurements. In summary, baseline characteristics establish no major differences between groups that subsequently allows a strong basis for comparison in the efficacy and hemodynamic effects of airway topicalization vs airway nerve blocks to achieve upper airway anaesthesia for awake fiberoptic bronchoscope-assisted nasotracheal intubations; This ascertains the internal validity of findings and helps to establish a reliability for later results.

Clinical differences:

Heart rate: Results show that there was no noteworthy variance in the HR between the two groups at the end of three minutes. A noteworthy difference was noticed subsequently. Initially, the mean HR was 78 beats per minute (bpm) in the N group and 81 bpm in the T group (p=0.43), indicating similar baseline heart rates.

After this period, HR in the N group showed little extra variation until time of shock emerged but progressively increased within T group. By minute 9 of there was a mean HR difference between groups by 10 bpm (95% CI:4-15; p=0.02) that widened to 12bpm (6-18; p=0.001) at minute-12and17bpm (8-25, p =0.03) at end-exercise. This suggests that over time, the T group has a noteworthy increased change in heart rate compared to the N group.

While in Group N emerging findings imply that airway nerve block is superior than the conventional technique of awake fiberoptic nasotracheal intubation using topicalization with respect to peak-to-peak heart rate. That the increase in HR is progressive in T group may suggest that this stress response, or discomfort experienced during procedures. The later time points are also consistent with the statistical significance, suggesting again that nerve blocks offer a benefit relative to topicalization in maintaining cardiovascular stability during these procedures.

Mean Arterial Pressure (MAP) Analysis: Mean Arterial Pressure (MAP): Both nerve block group and topicalization experienced different trends of mean arterial pressure throughout the procedure.

Initially, there was no noteworthy difference in MAP between the two groups up to 9 minutes. However, as the procedure progressed beyond this point, significant differences emerged. At the end of 12 minutes, the MAP in the T group was 8 mm Hg higher than in the N group (95% CI: 1 to 14 mm Hg; p=0.03). By the end of 15 minutes, this difference increased to 10 mm Hg (95% CI: 4 to 15 mm Hg; p=0.006).

Interpretation:

The observed static MAP in the N group suggests a more profound or sustained anaesthetic effect, leading to better overall hemodynamic stability. In contrast, the static MAP followed by a marginal surge in the T group indicates that airway topicalization might not provide the same level of hemodynamic control, especially in the later stages of the procedure. The statistically significant higher MAP in the T group at 12 and 15 minutes reinforces the notion that nerve blocks could be more effective in maintaining lower and more stable blood pressure during awake fiberoptic bronchoscope-assisted nasotracheal intubations.

The stable HR and gradually declining MAP in the N group suggest that airway nerve blocks provide better overall cardiovascular stability during the procedure. The stability for our participants is likely due to the sustained anaesthetic effect that reduced stress and discomfort. Reduction in stress and dyscomfort in turn minimizes sympathetic stimulation. As a result, both HR and MAP were maintained at a lower level ensuring effective hemodynamic control.

On the other hand, participants in the T group exhibited a progressively increasing HR with a slightly increasing MAP. These changes suggest that airway topicalization may be less effective in maintaining the hemodynamic stability. The increase in HR and MAP could be indicative of a higher stress response and inadequate anaesthesia, leading to greater sympathetic nervous system activation. The significant differences in HR and MAP at later time points reinforce the notion that patients in the T group experience more cardiovascular stress as the procedure progresses.

The results of this study align with findings from previous research, further highlighting the differential hemodynamic responses between nerve block and topicalization techniques during awake fiberoptic bronchoscope-assisted nasotracheal intubations.

Yadav et al. [43] found that there were no statistically significant changes in heart rate, SBP, DBP, or oxygen saturation before sedation and after obtaining a Ramsay sedation scale of 2 in both the nerve block and atomization groups. Nevertheless, as the scope penetrated beyond the vocal cords, both groups had increases in heart rate, systolic blood pressure, and diastolic blood pressure. These increases occurred during and shortly after intubation at the same time. These alterations were just temporary and returned to their usual state after five minutes of the intubation. Particularly noteworthy is the fact that the atomization group had a greater rise in both SBP and DBP in comparison to the nerve block group. Similarly, Kundra P et al. [(44)] found that all patients saw a gradual rise in their heart rate and mean arterial pressure (MAP) from the beginning of the treatment. On the other hand, the nebulization group experienced a rise that was both more substantial and more protracted than the block group. During the operation, patients who were in the block group had higher hemodynamic stability than those in the control group.

Vasu et al. [(46)] reported comparable baseline HR and MAP values when comparing atomized lignocaine nebulization and transtracheal injection of lignocaine. However, they noted a significant increase in HR after sedation during the transtracheal injection. Despite this, the HR was comparable in both groups overall.

Singh et al. [(42)] recorded a significant rise in HR in nebulization-treated patients, with measurements taken one and three minutes after awake fiberoptic intubation. Subsequent measurements after intubation showed that this rise had reverted to around baseline. Nevertheless, there were no statistically noteworthy variations between the groups in terms of changes in heart rate in comparison to the baseline measurements at any point throughout the intubation process.

Mohanta et al. [41] discovered that the variations in hemodynamic profile between both group were similar. Based on the hemodynamic stability that was seen in both groups throughout the current investigation, it seems that both airway nerve blockages and topicalization procedures were successful in achieving appropriate airway anaesthetic. The lack of significant intergroup differences aligns with Gupta et al.'s and Vasu et al.'s findings, indicating that both techniques are comparable in maintaining stable HR and MAP during the procedure. [45,46]

The current study corroborates these findings, as it also demonstrated more stable HR and MAP in the nerve block group compared to the topicalization group.

Difference in SpO2

In this study, the oxygen saturation (SpO2) was unchanged with time during 9 min in N and T groups. The only change we observed was a small reduction of SpO2 at 12 and 15 min in the T group. However, this lower rate did not reach statistical significance. The sustained stability of SpO2 for up to 9 minutes in both the group suggests that airway nerve block and topicalization are effective maneuvers especially during initial phases. With respect to SpO2, it can be deduced from the results that both approaches are largely similar in terms of oxygenation preservation as the variance was not statistically noteworthy. The slight decrease in SpO2 for the T group at latter stages is not clinically important enough to be of concern and as such, both anaesthetic techniques are overall effective in preserving respiratory function throughout this procedure. Similarly, there were no large and clinically meaningful changes in SpO2 after rebreathing other than posttreatment sedation of around 91% that is insignificant. The absence of an important imprecision supports the effectiveness of airway anaesthesia established by both procedures ensuring patient safety and a reduction in anxiety. Similarly to our study, Yadav et al. concluded that the SpO2 at many points in time during their cases was not significantly different between million IPC and standard care. [43]

Difference in Respiratory Rate (RR)

In the current study, overall mean respiratory rate (RR) remained constant for both groups nerve block N and topicalization T till 12th minute. After 15 minutes the mean RR increased significantly in group T to 20 breaths per minute (SD=4), compared with N at just16 breathes/min (SD-3)]; P<0.05). This difference was statistically noteworthy, with a mean difference of 4 bpm (95% CI:1 to 9; P=0.03).

The stability in RR for both groups up to 12 min indicates that effects of airway nerve blocks and topicalization are well maintained, providing effective control over the rate of respiration during awake fiberoptic bronchoscope-assisted nasotracheal intubations. Since the variable RR significantly increased at 15 minutes in the T group, patients may experience more discomfort or respiratory stimulation as it goes on than those treated with N.

The high RR observed at the 15th minutes in the present study reflects a potential disadvantage of topicalization which has revealed inability to sustain, respiratory stability during procedure. The increased RR might represent hyperventilation, assuming patients may be experiencing stress or that the anaesthetic effect of sevoflurane is not fully optimal. In contrast, the stable RR in the N group suggests that airway nerve blocks provide better control over respiratory parameters, contributing to greater overall stability and patient comfort during the intubation process.

Most other studies have not reported on respiratory rate outcomes specifically. However, the consistent stability in other hemodynamic parameters, such as HR and MAP, observed in previous studies aligns with the current findings.

Cough and Gag Scores: The incidence of higher cough and gag scores (score 3) was notably higher in the T group, with 40% of patients (n=10) experiencing severe responses compared to only 12% (n=3) in the N group. This difference was statistically noteworthy.

Comfort Scores: Patient comfort was rated as good in 32% (n=8) patients within the N group compared to only 8% (n=2) within the T group. The variance was not statistically noteworthy (p=0.03).

The difference in observed cough and gag scores as well as patient comfort suggests that the ability of a specific anaesthetic technique to block airway reflexes more successfully correlates with how comfortable the procedure is for this particular patient. Among the T group, a higher incidence of severe cough and gag per device and lower comfort scores all indicate greater discomfort/stress. On the other hand, better suppression of airway reflexes in N group is accompanied by higher comfort score that indicates more favourable and less trouble situation for patients. Results show that airway nerve blocks are better at reducing cough and gag response compared to topicalization, consequently leading to improved patient comfort during awake fiberoptic bronchoscope assisted nasotracheal intubations. This association underlines the desire for airway anaesthetic approaches that not only lead to anatomical debilitation and are a factor of general patient ease but furthermore enhance procedural will yield.

Yadav et al. [43] It was revealed that the decrease of cough and gag reflex was considerably lower in nerve block groups (28 percent of patients compared to 92 percent for atomization at a significance level of 0.001). The researchers hypothesized that the raining-down effect of local anaesthesia into the trachea during atomization would have resulted in less effective topical anaesthesia, which led to greater cough and gag ratings in the atomization group, which in turn led to poorer comfort scores.

Gupta B et al. [45] compared to the group that had an airway nerve block, it was shown that a significantly higher percentage of patients in the ultrasonic nebulization group reported experiencing choking and coughing throughout the operation ($p = 0.004$).

Singh J et al. [42] reported higher cough and gag scores in patients receiving atomized local anaesthesia compared to airway nerve blocks, with a p-value of 0.006.

Vasu BK et al. [46] noted that patients in the atomized lignocaine group had higher cough and gag scores compared to those in the transtracheal injection group (p=0.001).

Chandra A et al. [40] found that the number of coughs was significantly lower in the group receiving nerve blocks compared to the atomization group ($p<0.05$).

Mohanta et al. [41] reported better patient comfort scores in the group receiving airway nerve blocks, supporting the present study's findings. They found that better patient comfort scores and fewer intubation attempts in the nerve block group indicated superior quality of airway anaesthesia. This aligns with the present study's observation of significantly better comfort scores in the N group compared to the T group.

Mathur et al. [39] measured patient comfort before, during, and after intubation by comparing ratings on measures of cough severity and intubation comfort. It was discovered that patients in the nerve block group reported far greater levels of comfort.

Intubation Score, Ease of Intubation, and Intubation Time: The present study evaluated the intubation score, ease of intubation, and intubation time in both the nerve block (N) group and the topicalization (T) group, revealing distinct differences between the two groups.

When compared to the T group, the intubation score seen in the N group was shown to be significantly higher. There was a statistically significant difference between the groups according to the p-value of 0.03.

Thirty-two percent (n=8) of patients in the N group were judged as having an exceptional level of ease of intubation (Score 1-2), but only eight percent (n=2) of patients in the T group had this level of ease. There was a statistically significant difference between the two groups ($p = 0.03$), which suggests that intubation was less difficult for the N group than it was for the T group.

The median intubation time for the N group was comparatively lower- as time required for intubation was 6 minutes or less for two thirds (64%) of the patients. On the contrary, for the T group, intubation was achieved within this time for only 7 (28%) of the patients. For most of the patients (72%) in the T group, time taken was 9-12 minutes.

The combined analysis of these three parameters highlights the nuanced outcomes of the two anaesthetic techniques:

Intubation Score: The high intubation scores in the T group clearly suggest that airway nerve block is superior in achieving adequate conditions for intubation over topicalization.

Ease of Intubation: As reflected from the intubation score, intubation was significantly better in the nerve block group, indicating that nerve blocks facilitate a smoother intubation process, potentially reducing the stress and effort required by the clinician.

Intubation Time: The less intubation time for the nerve block group suggests that the duration of the procedure is an additional advantage for the nerve block group apart from the understanding that ease of performing the intubation is better with nerve blocks.

Unlike the present findings, studies such as Gupta B et al. [(45)] and Singh J et al. [(42)] have reported that both nerve blocks and topicalization can achieve effective conditions for intubation, even though other parameters like comfort and reflex suppression may vary.

Mohanta et al. [(41)] found that patients in the nerve block group had a significantly better ease of intubation score compared to those in the atomization group, supporting the present study's findings. They concluded that airway nerve blocks offer better quality of airway anaesthesia, contributing to easier intubation.

Intubation Time:

Previous studies have reported varying intubation times depending on the specific anaesthetic technique used, but the present study's finding of similar intubation times across both groups aligns with the understanding that both techniques can be equally efficient in terms of procedure duration. The majority of the other studies came to the conclusion that the group that received an ultrasound-guided nerve block had a significantly lower average time needed for intubation as compared to the group that received an ultrasonic nebulization intervention. [41 45, 46, 47] On the other hand, research conducted by Kundra and colleagues found that the amount of time required by both groups seemed to be comparable. The researchers Vasu BK et al. [46] discovered that the duration of intubation was much less when transtracheal topical anaesthesia was used (48.5±38.6 seconds) in comparison to atomized local anaesthetic (88.8±36.3 seconds), with a statistically significant difference (p=0.019). When comparing the mean intubation periods for airway nerve blocks (115.2±14.7 seconds) to lidocaine nebulization (214.0±22.2 seconds), Mathur PR et al. found that the latter had a shorter duration. Singh J et al. [42] also indicated that the time necessary for FOB-guided intubation was much reduced in the nerve block group (90.2±11.7 seconds) compared to the atomizer group (210.4±10.6 seconds). This was verified by comparing the respective times.

The combined analysis of intubation score, ease of intubation, and intubation time underscores the advantages of airway nerve blocks over topicalization. While both techniques are effective in achieving successful intubation, nerve blocks significantly enhance the ease of the procedure, and shortens the intubation time contributing to a more favorable experience for both patients and clinicians. These findings highlight the importance of considering not just the effectiveness but also the ease and comfort of the intubation process when selecting an anaesthetic technique for awake fiberoptic bronchoscope-assisted nasotracheal intubations.

Complications: In the present study, none of the patient reported lignocaine toxicity, and gastric Complications. However, airway complications in terms of mouth opening were observed in almost all the patients, with no significant difference (p=0.53).

Similar to the present study, Yadav et al. [(43)] did not report any cases of lignocaine toxicity in their study. No gastric complications were noted, aligning with the findings of the present study. The authors observed a lower incidence of airway complications in the nerve block group compared to the atomization group. This contrasts with the present study, where the incidence of airway complications was high but comparable between the two groups.

Gupta B et al. [(45)] did not report lignocaine toxicity, consistent with the current study's findings. No significant gastric complications were noted, similar to the present study. They reported fewer airway complications in the nerve block group compared to the nebulization group, suggesting a better safety profile for nerve blocks. This differs from the present study's finding of similar airway complication rates between the groups. Singh J et al. also did not find any lignocaine Toxicity or gastric Complications.

Vasu BK et al. [46] reported a higher incidence of airway complications in the topicalization group compared to the nerve block group, which contrasts with the present study where both groups had a high and similar incidence of airway complications.

While the present study found no cases of lignocaine toxicity or gastric complications, and similar rates of airway complications between the nerve block and topicalization groups, other studies generally reported fewer airway complications in the nerve block group. This discrepancy could be due to differences in study designs, patient populations, and techniques used.

According to the results of Webb et al. [48], Graham et al. [49], and Sethi et al. [50], the intubating circumstances in Group B were much better than those in Group N. This finding is in line with the findings of our own research. On the other hand, Reasoner et al. [47] and Gupta et al. [45] stated that there was no material difference in the circumstances of intubation between their respective groups. It is essential to keep in mind that earlier research did not use a standardized scale for assessing the circumstances of intubation. Consequently, the direct comparison of our findings with those of the prior studies is restricted.

SUMMARY

SUMMARY

- With regard to age, gender, comorbidities (including diabetes, hypertension, and hypothyroidism), INR status, heart rate, mean arterial pressure, spirometry, and respiratory rate, the two groups were clinically comparable to one another. ($p>0.05$) The p-value did not meet the criteria for statistical significance.
- The N group had a mean heart rate that remained constant, but the T group saw a rising heart rate during the course of the study. However, the mean arterial pressure (MAP) was elevated by 8 mm Hg (95% confidence interval: 1 to 14 mm Hg; $p = 0.03$) at the end of 12 minutes and 10 mm Hg (95% confidence interval: 4 to 15 mm Hg; $p = 0.006$) at the end of 15 minutes. The difference between the two groups did not become statistically significant until 9 minutes.
- The mean SpO_2 was similar in both the groups and the difference was not statistically significant.
- The mean RR was static for both groups till 12 minutes. For the T group, the mean RR increased to 20/min (SD 4/min) compared to mean RR of 16/min (SD 3/min) at 15 minutes. The difference was statistically significant (Mean difference 4 min; 95% CI: 1 to 9; $p=0.03$).

- The cough and GAG score was relatively high (score 3) in the T group (n=10, 40%) than the N group (n=3, 12%). The difference was statistically significant (p=0.02)
- The intubation score was high for group T than group N. similar in both the groups. The difference was statistically significant
- While 8 (32%) patients had a good comfort score in the N group, only 2 (8%) patients in the T group had a good comfort score. The difference was statistically significant (p=0.26)
- The ease of intubation was excellent (Score 1-2) for 32% (n=8) of patients in group N compared to only 8% (n=2) of patients in group T. The difference was statistically significant (p=0.03)
- While 16 patients (64%) in the group N took 6 minutes or less for intubation, only 7 (28%) patients took 6 minutes or less for intubation in the T group. The difference was statistically significant (p=0.04)
- None of the patients in either group reported to have any lignocaine toxicity.
- None of the patients in either group reported to have any gastric toxicity.
- All the patients in both the groups had airway complications in terms of mouth opening. While 18 (72%) patients had one finger opening in the N group, 19 (76%) of the patients in the T group had such a complication. The difference was not statistically significant (p=0.53).

- None of the patients in either group reported to have any drug-related complications.

In short, this study demonstrates that both airway nerve blocks and topicalization are effective techniques for achieving upper airway anaesthesia during awake fiberoptic bronchoscope-assisted nasotracheal intubations. However, nerve blocks emerge as less invasive to the patient, easier intubation, time to intubation and control of cough and gag reflexes. Comparing both techniques, nerve blocks give less variability in the hemodynamic status and, overall, the outcome of a better quality of the patient's experience during the procedure. Clinicians should use nerve blocks in order to enhance the procedural effectiveness and reduce patients' discomfort in particular when the case involves the necessity of airway management.

CONCLUSION

CONCLUSION AND RECOMMENDATIONS

The present study focuses on the effectiveness and complications of airway local anaesthetic nerve blocks in comparison with topicalization during awake fibre-optic bronchoscope naso-tracheal intubation. Both techniques were useful in creating optimal intubation conditions for the patients. Airway nerve blocks had better results in terms of patient's tolerance, intubation process, time for intubation, and cough and gag reflexes, as well as less variability in the patients heamodynamics.

Recommendations

Preferred Technique: For awake fiberoptic nasotracheal intubations, nerve blocks should be preferred over topicalization because they are associated with more comfort to the patients and better procedure control.

- Training and Practice: It is recommended that clinicians receive adequate training on the correct methods of performing nerve blocks to that more benefits can be accrued and the safety of the patients preserved.
- Monitoring: Supervision of the patient's heart rate, MAP, SpO2, and respiratory rate is crucial for early identification of any complications throughout the process of intubation.

- Further Research: Future research should focus on the long-term results of these approaches and attempt to identify how the occurrence of airway issues could be reduced even more.
- Patient Selection: Awareness of patient's factors and clinical situations should inform the selection of the type of anaesthesia to provide the best results.

Implementing these suggestions enables clinicians to enhance the safety and effectiveness of awake fiberoptic intubations, enhancing patients' perceptions and clinical results.

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ANNEXURE

ANNEXURE

PROFORMA

Personal Details:

NAME: AGE: SEX:

ADDRESS:

OCCUPATION:

HEIGHT: IBW:

TELEPHONE NO: UHID NO:

ASA Grading:

Co-Morbidities:

General physical examination:

Height: Weight: Pulse rate: BP:

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

- **Systemic examination:**

RS - **CVS -**

CNS - **P/A -**

- **Investigations:**

Platelet count -

Prothrombin time -

INR -

aPTT -

Clinical Diagnosis:

Proposed operation:

- **Group N (n- 25)** : Patients receive following nerve blocks

  1) Bilateral Superior Laryngeal Nerve block - with 2ml of 2% Lignocaine (each side) injected approximately 2-4 mm inferior to the greater cornu of the hyoid bone and

  2) Recurrent laryngeal nerve block with 2ml of 4% Lignocaine injected through cricothyroid membrane.

- **Group T (n-25)** : Patients receive 10ml of 4% Lignocaine for topicalization using Modified McKeinzie Technique with infant feeding tube.

OBSERVATIONS:

1) Hemodynamics during intubation

	0 min	3 min	6 min	9 min	12 min	15 min
HR						
BP						
MAP						
$Sp0_2$						
RR						

2) Cough and gag score –

1	None	
2	Minimal coughing and gagging, <3 times	
3	Mild cough and gag lasting for <1 min,	
4	Persistent coughing and gaging	

3) Intubation score –

1	no reaction	
2	slight grimacing	
3	severe grimacing	
4	verbal objection	
5	defensive movement of head, hands, or feet	

4) Comfort score –

1	good	
2	moderately comfortable	
3	poor, uncomfortable	

5) Ease of intubation –

1-2 score	grade 1 (excellent)	
3-4 score	grade 2 (good)	
5-6 score	grade3 (satisfactory)	
7-9 score	grade 4 (poor)	

6) Lignocaine toxicity –

Ecg changes :
Seizures :
Bronchoconstriction :

7) Time taken for intubation –

8) Airway complications –

9) Gastric complications -

10) Drug complications -

INFORMATION SHEET

TITLE: AIRWAY NERVE BLOCKS VS AIRWAY TOPICALIZATION FOR AWAKE FIBEROPTIC BRONCHOSCOPE ASSISTED NASOTRACHEAL INTUBATION.

I, **DR. USHASREE JALA** Post graduate in the department of Anaesthesiology, Sri Devaraj Urs Medical College, Kolar . We are carrying out above mentioned study at RLJH, Tamaka, Kolar. The study has been reviewed and approved by the institutional ethical review board. We will be checking the effectiveness of airway topicalization during fiberoptic bronchoscope assisted nasotracheal intubations.

Participation in this study doesn't involve any added cost to the patient. There is no compulsion to participate in this study and you will not be affected with regard to patient care, if you wish not to be part of this study.

All the information collected from the patient will be kept confidential and will not be disclosed to any outsider, unless compelled by the law. The information collected will be used only for this study. I request your kind self to give consent for the above-mentioned research project.

For any further clarification you are free to contact,

Dr. USHASREE JALA

(Post Graduate in Anaesthesiology)

Mobile no: 8500149057

Dr. SURESH KUMAR.N.

(Professor in Anaesthesiology)

Mobile no: 9008222550

INFORMED CONSENT FORM

AIRWAY NERVE BLOCKS VS AIRWAY TOPICALIZATION FOR AWAKE FIBEROPTIC BRONCHOSCOPE ASSISTED NASOTRACHEAL INTUBATIONS

Date:

I, ____ aged ____________ ,after being explained in my own vernacular language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for performing airway nerve blocks and airway topicalization for awake fiberoptic bronchoscope assisted nasotracheal intubations. The nature and risks involved have been explained to me to my satisfaction. I have been explained in detail about the study being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereby give consent to provide my history, undergo physical examination, undergo the procedure, undergo investigations and provide its results and documents etc., to the doctor / institute etc. For academic and scientific purpose the operation / procedure etc., may be video graphed or photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc., responsible for any untoward consequences during the procedure / study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

________________ ________________

(Signature & Name of Pt. Attendant) (Signature/Thumb impression

(Relation with patient) & Name of patient)

Witness 1: ____________________

Witness 2: (Signature & Name of Research person /doctor)

ಸಮ್ಮತಿಗಾಗಿ ವಿಷಯವನ್ನು ತಿಳಿಸಿದೆ

ರ್ ವೇ ನರ್ವ್ ಬ್ಲಾಕ್ಸ್ ವಿರುದ್ಧವಾಗಿ ಏರ್ ವೇ ಟೋಪಿಕಾಲೈಸೇಷನ್ ಅವೇಕ್ ಗೆ ನಾಸೋಟ್ರಾಕೆಯಲ್ ಇಂಟುಬೇಷನ್ಸ್ ಸಹಾಯದಿಂದ ಫೈಬರೋಆಪ್ಟಿಕ್ ಬ್ರೊಂಚೋಸ್ಕೊಪ್
ದಿನಾಂಕ :

ನಾನು, –
ವಯಸ್ಸು

ನನ್ನದೇ ಆದ ಭಾಷೆಯಲ್ಲಿ ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶವನ್ನು ವಿಶದವಾಗಿ ವಿವರಿಸುತ್ತೇನೆ ಅಲ್ಲದೆ ನಿರ್ವಹಣೆಯ ದುಷ್ಪರಿಣಾಮ ಮತ್ತು ತೊಡಕುಗಳನ್ನು ಬರಹ ರೂಪದಲ್ಲಿಬಲವಂತವಾಗಿ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹ ಪೀಡಿತಕ್ಕೆ ಒಳಗಾಗದೆ ಏರ್ ವೇ ನರ್ವ್ ಬ್ಲಾಕ್ಸ್ ಮತ್ತು ಏರ್ ವೇ ಟೋಪಿಕಾಲೈಸೇಷನ್ ಅವೇಕ್ ಗೆ ನಾಸೋಟ್ರಾಕೆಯಲ್ ಇಂಟುಬೇಷನ್ಸ್ ಸಹಾಯದಿಂದ ಫೈಬರೋಆಪ್ಟಿಕ್ ಬ್ರೊಂಚೋಸ್ಕೊಪ್ ನ್ನು ನೆರವೆರಿಸುತ್ತೇನೆ.
ಇದರ ಸ್ವಭಾವದಲ್ಲಿ ಒಳಗೊಂಡಿರುವ ಅಪಾಯ ಮತ್ತು ದುಷ್ಪರಿಣಾಮ ಗಳನ್ನೂ ನನಗೆ ತೃಪ್ತಿಯಾಗುವಂತೆ ವಿವರಿಸಿದ್ದಾರೆ. ಈ ಅಧ್ಯಯನವನ್ನು ನಡೆಸಿರುವುದ ಬಗ್ಗೆಯೂ ಸಹ ವಿಶದವಾಗಿ ತಿಳಿಸಿದ್ದಾರೆ . ನಾನು ರೋಗಿಯ ತಿಳುವಳಿಕೆಯ ಮಾಹಿತಿಯನ್ನು ಓದಿ ತಿಳಿದುಕೊಡಿದ್ದಲ್ಲದೆ ರೋಗಿಯನ್ನು ಏನು ಬೇಕಾದರೂ ಪ್ರಶ್ನೆ ಕೇಳುವುದಕ್ಕೆ ಅವಕಾಶವಿತ್ತು. ಯಾವುದೇ ಪ್ರಶ್ನೆ ಕೇಳಿದರೂ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ನಾನು ಈ ಅವಿಷ್ಕಾರದಲ್ಲಿ ಸ್ವಇಚ್ಛೆಯಿಂದ ಒಬ್ಬ ಸದಸ್ಯನಾಗಿ ಪಾಲ್ಗೊಳ್ಳಲು ನಾನು ಸಮ್ಮತಿಸಿದ್ದೇನೆ . ನಾನು ನನ್ನ ಚರಿತ್ರೆಯನ್ನು ಭೌತಿಕ ಪರೀಕ್ಷೆ, ಎಲ್ಲಾ ಅನ್ವೇಷಣೆ ಮತ್ತು ನಿಯಮಗಳಿಗೆ ಅನುಸರಿಸಲು ಒಪ್ಪಿ ಮತ್ತು ಆ ಫಲಿತಾಂಶ ಮತ್ತು ಪ್ರಮಾಣ , ದಾಖಲೆಗಳನ್ನು ಸಂಬಂಧ ಪಟ್ಟ ವೈದ್ಯರಿಗೆ ಅಥವ ಪ್ರತಿಷ್ಠಾನಕ್ಕೆ ಕೊಡಲು ಒಪ್ಪಿರುತ್ತೇನೆ. ಶೈಕ್ಷಣಿಕ ವ್ಯಾಸಂಗ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶದಿಂದ ಚಿಕತ್ಸೆ /ನಿರ್ವಹಣೆ ಯನ್ನು ಛಾಯ ಚಿತ್ರ ಮತ್ತು ವಿಡಿಯೋವನ್ನು ಉಪಯೋಗಿಸ ಬಹುದು. ಎಲ್ಲ ಮಾಹಿತಿಯನ್ನು ಪ್ರಕಟಿಸ ಬಹುದು. ಮತ್ತು ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ ವ್ಯಾಸಂಗಕ್ಕೆ ಉಪಯೋಗಿಸಬಹುದು. ಯಾವುದೇ ಎಡವಟ್ಟಿನ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರಾಗಲೀ ಸಂಸ್ಥೆಯಾಗಲ್ಲಿ . ಹೊಣೆಯೆಂದು ಒಪ್ಪವುದಿಲ್ಲ. ಈವಿಷಯ ಸಮ್ಮತಿಯ ಒಪ್ಪಿಗೆಯನ್ನು ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ದಾಖಲೆಯನ್ನು ಭಾಗವಹಿಸುವವರಿಗೆ ಒದಗಿರುಸುತ್ತೇನೆ

ರೋಗಿಯ/ಸೇವಕ ಹೆಸರು ಮತ್ತು ಸಹಿ
ರೋಗಿಯ ಹೆಬ್ಬೆಟ್ಟು ಗುರುತು, ರೋಗಿಯ ಸಂಭದಿಕರು

ಸಾಕ್ಷಿ ೧ .
ಸಾಕ್ಷಿ ೨

ಪರಿಶೋದಕರ /ವೈದ್ಯರ ಸಹಿ

MASTER CHART

KEY TO MASTER CHART

HR	Heart rate
MAP	Mean arterial pressure
RR	Respiratory rate
BP	Blood pressure
SpO2	Peripheral capillary oxygen saturation
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
INR	International normalized ratio

sl no	Group	Age	Gender	comorb_DM	comorb_htn	Comorb_hypothyroidism	comorbidity	INR	Heart rate_0	Hear rate_3	Heart rate_6	Hear rate 9	Hear rate 12	Heart rate_15	MAP_0	MAP_3	MAP_6	MAP_9	MAP_12	MAP_15	SpO2_0	SpO2_3	SpO2_6	SpO2_9	SpO2_12	SpO2_15	RR_0	RR_3	RR_6	RR_9	RR_12	RR_15	Cough_GAG score	Intubation score	Comfort score	Ease of intubation score	Lignocaine toxicity	Itubation time	Gastric complication	Airway complication	Drug complication
1	1	24	2	0	0	0	0	1.17	98	71	64	93	86	72	78	89	70	65	72	61	99	98	96	99	97	100	15	17	18	20	15	20	2	1	1	5	2	2	2	1	2
2	1	67	1	1	1	1	1	1.18	79	88	93	95	81	88	81	81	75	64	77	84	98	98	100	98	99	98	19	16	15	20	15	17	1	2	1	6	2	2	2	1	2
3	1	65	1	1	1	0	1	1.07	89	84	80	94	80	98	87	78	75	77	80	90	98	100	96	99	98	100	22	14	17	18	20	22	3	2	2	4	2	2	2	1	2
4	1	65	1	0	1	0	1	1.31	66	68	68	74	65	78	60	91	69	91	91	85	100	98	99	99	96	97	17	21	14	20	15	22	1	2	2	4	2	2	2	1	2
5	1	42	2	0	0	0	0	1.34	75	92	97	74	97	71	73	84	71	66	84	89	97	99	99	98	99	100	17	18	20	14	18	16	1	3	1	3	2	3	2	1	2
6	1	21	1	0	0	0	0	0.92	95	87	61	83	81	91	92	79	91	69	88	65	96	97	100	96	98	100	17	21	18	19	22	19	3	1	2	4	2	2	2	1	2
7	1	69	1	1	1	1	1	1.28	59	68	69	73	82	88	79	83	68	73	73	66	98	96	100	99	100	97	22	14	19	15	14	20	2	1	2	2	2	3	2	1	2
8	1	60	1	0	1	0	1	1.27	102	66	80	87	84	94	83	81	83	87	80	67	99	99	99	100	98	98	20	21	21	18	16	22	1	2	2	3	2	2	2	2	2
9	1	48	2	0	0	0	0	1.00	88	63	74	64	67	62	79	88	79	75	78	63	96	97	96	98	100	98	15	22	18	19	21	16	2	1	2	4	2	2	2	1	2
10	1	54	2	0	0	0	0	1.20	96	93	61	91	94	74	68	93	81	61	67	67	97	99	99	97	100	98	20	22	14	15	16	22	1	2	1	4	2	2	2	2	2
11	1	21	2	0	1	0	1	1.19	93	76	93	78	90	88	88	87	62	73	80	87	98	99	98	100	99	96	17	21	16	19	22	15	3	2	2	2	2	3	2	1	2
12	1	41	1	1	0	0	1	1.20	89	63	60	82	75	60	64	92	77	90	65	65	98	97	97	96	99	99	19	20	22	18	14	19	2	2	2	4	2	2	2	1	2
13	1	50	1	0	1	1	1	1.07	92	71	63	61	66	60	64	69	88	60	60	62	96	98	96	99	100	98	19	19	19	20	14	15	1	2	2	6	2	3	2	2	2
14	1	25	2	1	0	0	1	1.24	84	62	98	78	86	98	82	86	64	81	65	73	99	97	100	100	99	96	16	16	15	21	18	21	1	2	2	4	2	2	2	1	2
15	1	64	2	1	1	0	1	0.84	57	98	79	95	92	87	66	71	72	79	86	80	98	98	100	97	97	96	19	14	22	14	21	21	2	2	2	3	2	2	2	2	2
16	1	22	1	0	0	0	0	1.30	97	63	91	70	81	80	69	93	77	87	67	64	100	99	99	99	99	98	17	18	14	21	16	18	2	1	2	4	2	2	2	1	2
17	1	37	2	0	0	0	0	1.20	81	89	59	98	84	81	86	62	73	88	78	62	99	97	96	97	98	99	17	19	22	18	17	20	3	1	2	3	2	3	2	1	2
18	1	60	2	1	0	0	1	1.08	88	74	64	93	66	63	90	78	66	73	79	83	97	100	99	97	96	96	20	22	19	16	22	17	3	1	2	4	2	2	2	1	2
19	1	49	1	0	0	0	0	0.88	71	98	72	67	75	60	79	73	86	62	65	66	96	100	97	98	100	100	18	16	20	22	16	21	1	1	2	3	2	2	2	1	2
20	1	36	2	0	0	0	0	1.10	72	97	96	68	98	61	70	81	75	69	60	66	98	96	99	96	96	98	20	15	18	20	20	14	2	2	1	3	2	2	2	1	2
21	1	52	2	0	0	0	0	0.97	82	65	84	89	72	80	79	78	87	89	65	83	99	100	96	99	99	96	14	19	16	15	17	18	2	2	1	6	2	2	2	2	2
22	1	51	1	0	0	0	0	1.07	79	91	81	92	60	67	72	66	70	72	73	69	98	98	99	99	97	97	19	22	17	22	17	22	3	2	1	5	2	2	2	1	2
23	1	34	1	0	0	0	0	1.18	84	96	61	63	75	60	82	73	75	80	70	73	100	99	100	99	97	96	22	18	15	20	16	21	3	2	2	4	2	3	2	2	2
24	1	38	1	0	1	0	1	0.93	66	63	81	95	65	86	93	85	71	70	90	72	96	98	98	97	100	98	19	20	21	22	15	14	2	2	1	3	2	2	2	1	2
25	1	63	1	0	0	0	0	1.12	93	67	79	86	91	76	88	84	67	87	89	90	96	99	99	97	100	99	22	14	22	20	19	20	1	3	2	4	2	2	2	1	2
26	2	37	1	0	0	0	0	1.15	56	74	94	85	69	73	91	70	63	92	71	87	96	99	99	100	99	96	21	22	16	14	16	19	2	3	2	2	2	3	2	1	2
27	2	34	2	0	0	0	0	1.20	78	90	60	76	74	70	87	63	73	62	61	84	96	96	98	99	96	98	17	14	16	19	20	18	2	2	2	2	2	3	2	1	2
28	2	67	1	1	1	0	1	1.04	59	94	96	73	72	73	79	76	71	88	74	69	99	100	100	97	98	98	20	18	16	19	15	14	2	1	2	6	2	2	2	2	2
29	2	41	2	0	0	0	0	1.08	101	63	74	66	66	82	84	85	87	69	74	69	98	98	99	96	99	100	14	18	18	14	20	21	2	1	1	2	2	3	2	1	2
30	2	61	2	1	1	1	1	1.10	68	96	90	95	77	80	81	80	69	64	87	69	99	100	99	96	97	96	17	21	22	20	19	20	3	2	2	4	2	2	2	1	2
31	2	50	2	0	1	0	1	0.98	96	79	70	95	90	80	61	92	79	74	75	70	99	96	97	100	100	98	18	22	14	14	18	21	1	1	2	6	2	2	2	1	2
32	2	18	2	0	0	0	0	1.07	97	84	60	61	64	79	74	92	62	70	84	77	99	98	98	97	99	99	15	21	20	16	15	21	1	2	2	4	2	3	2	1	2
33	2	36	2	0	0	0	0	1.35	65	86	80	63	75	88	67	62	80	66	77	62	96	99	96	98	97	99	16	16	18	14	14	15	2	2	2	2	2	2	2	1	2
34	2	27	2	0	0	0	0	1.29	79	67	64	64	70	81	69	76	83	67	88	90	99	100	96	100	98	99	20	19	18	21	21	15	2	3	2	3	2	3	2	1	2
35	2	67	2	1	1	1	1	1.12	85	83	87	61	59	92	66	83	61	69	68	66	99	97	99	97	97	100	18	14	20	20	15	21	2	1	1	2	2	2	2	2	2
36	2	47	2	0	0	0	0	1.10	102	86	85	76	60	90	70	66	84	93	61	78	99	97	99	100	100	100	19	20	19	22	22	18	2	2	2	4	2	2	2	2	2
37	2	41	1	0	0	0	0	1.26	88	90	91	98	64	76	91	72	87	86	61	89	100	96	97	100	100	96	17	19	15	17	16	16	1	2	2	3	2	3	2	1	2
38	2	45	2	0	0	0	0	1.25	101	93	75	76	62	85	72	63	69	82	62	83	98	100	99	100	96	98	21	15	20	21	21	17	2	1	2	3	2	3	2	1	2
39	2	44	2	1	0	0	1	0.93	59	86	81	62	78	91	89	83	70	60	76	78	97	98	96	99	98	97	15	15	14	14	15	20	2	1	2	4	2	2	2	2	2
40	2	28	2	0	0	0	0	1.17	93	73	73	79	94	77	60	78	80	89	85	64	96	96	96	100	96	99	18	17	18	19	15	21	3	2	2	3	2	3	2	2	2
41	2	57	2	0	1	0	1	1.10	73	87	78	82	79	91	85	74	74	82	80	69	96	97	100	100	96	99	19	22	17	14	22	15	1	2	2	4	2	2	2	2	2
42	2	20	2	0	0	0	0	1.14	94	75	81	70	83	71	90	77	77	85	84	65	97	100	99	98	98	100	18	15	14	21	21	19	2	2	2	5	2	3	2	1	2
43	2	63	2	1	1	1	1	1.22	68	86	68	60	74	66	80	89	85	81	65	78	99	96	98	97	98	98	21	15	15	19	14	22	2	2	2	3	2	2	2	1	2
44	2	60	2	1	1	0	1	1.33	86	96	88	75	89	93	67	66	89	73	67	73	96	96	99	98	96	99	19	19	14	18	20	17	1	2	2	4	2	3	2	2	2
45	2	21	1	0	0	0	0	1.23	84	71	93	94	89	75	76	79	63	68	74	83	100	100	98	99	96	99	14	19	15	18	18	18	1	2	2	5	2	2	2	1	2
46	2	19	1	0	0	0	0	1.08	64	78	61	75	77	94	72	63	71	60	66	89	100	97	99	100	100	96	17	18	15	21	18	19	3	3	2	6	2	2	2	1	2
47	2	41	2	0	0	0	0	0.97	76	64	69	87	98	81	86	90	72	89	91	77	97	96	96	99	96	98	17	22	14	20	16	14	1	2	2	4	2	2	2	1	2
48	2	27	1	0	0	0	0	0.98	62	91	61	94	87	72	83	92	62	73	79	74	100	97	98	100	99	98	22	20	14	14	18	16	2	2	2	4	2	3	2	2	2
49	2	50	1	0	0	0	0	1.27	60	69	97	81	97	80	78	60	92	88	60	67	100	96	100	98	100	97	20	14	15	22	20	20	1	2	2	5	2	3	2	1	2
50	2	54	1	0	1	0	1	1.16	79	60	88	76	64	84	63	80	81	72	65	87	100	97	100	96	99	98	16	17	20	21	18	22	1	1	2	6	2	2	2	1	2