
**“COMPARISON OF BUDESONIDE SPRAY
AND WATER BASED GEL AS AN
ENDOTRACHEAL TUBE CUFF LUBRICANT
ON INCIDENCE OF POSTOPERATIVE SORE
THROAT: RANDOMIZED CONTROL STUDY”**

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BELAGAVI, KARNATAKA**

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LIST OF ABBREVIATIONS

ETT	Endotracheal tube
POST	Post operative sore throat
ASA	American society of anaesthesiology
SPSS	Statistical package for social sciences
RCT	Randomized controlled trials
VAS	Visual analog scale
LMA	Laryngeal mask
NASIDs	Nonsteroidal anti- inflammatory drugs
NMDA	N- Methyl D-Aspartate
USG	Ultra sound guidance
COPD	Chronic obstructive pulmonary odema
HAI	Hospital acquired infection
DLT	Double lumen tube
KLE's	Karnataka lingayath education society

ABSTRACT

Background: Postoperative sore throat (POST) is a common complication following endotracheal intubation under general anesthesia. Various pharmacological interventions, including corticosteroids and lubricants, have been explored to minimize its incidence. This randomized controlled study compares the effectiveness of budesonide spray and water-based gel (K-Y jelly) as endotracheal tube (ETT) cuff lubricants in reducing POST.

Methods: A total of 178 patients, aged 18–60 years, undergoing elective surgery under general anesthesia were randomly assigned to two groups. Group B received 200 mcg of budesonide spray on the ETT cuff, while Group K had the cuff lubricated with 2 ml of K-Y jelly. The primary outcome was the incidence and severity of POST, assessed at multiple postoperative time points (immediately, 10 min, 1 hr, 6 hrs, and 24 hrs). Secondary outcomes included the incidence of postoperative cough and hoarseness.

Results: Both groups demonstrated a reduction in POST incidence. However, no statistically significant difference was observed between the budesonide and K-Y gel groups at most time points ($p > 0.05$), except at 1 hr ($p = 0.038$) and 24 hrs ($p = 0.0245$). The incidence of postoperative cough was similar between the two groups ($p > 0.05$).

Conclusion: Both budesonide spray and K-Y jelly are effective in reducing the incidence of POST, with K-Y jelly showing a marginally better outcome at certain time points. Given its ease of application and comparable efficacy, K-Y jelly may be a cost-effective alternative to budesonide spray for minimizing POST in patients undergoing general anesthesia with endotracheal intubation.

Keywords: Postoperative sore throat, endotracheal tube, budesonide spray, K-Y jelly, airway management, general anesthesia.

TABLE OF CONTENTS

SL.NO.	CONTENTS	PAGE NO.
1	INTRODUCTION	1-2
2	OBJECTIVES	3
3	REVIEW OF LITERATURE	4-7
4	BASIC SCIENCES	8-29
5	MATERIALS AND METHODS	30-35
6	RESULTS	36-45
7	DISCUSSION	46-50
8	CONCLUSION	51
9	SUMMARY	52-53
10	LIMITATIONS	54
11	REFERENCES	55-59
12	ANNEXURES	60-68

LIST OF TABLES

SL.NO	TITLE	PAGE NO.
1.	Table 1: : Factors causing POST	13-14
2.	Table 2: : Summary of preventive measures for postoperative sore throat	28-29
3.	Table 3: Post-operative Sore Throat Grading	34
4.	Table 4: : Cough Grading	34
5.	Table 5: Comparison of demographic variables over groups.	36
6.	Table 6: Comparison of ASA classification over groups	40
7.	Table 7: Comparison of duration of surgery over groups	41
8.	Table 8: Comparison of grading of POST over groups	42-43
9.	Table 9: Comparison of grading of cough over groups	44-45

LIST OF GRAPHS

SL.NO	TITLE	PAGE NO.
1.	Graph 1: Mean plot of age over groups	37
2.	Graph 2: Distribution of gender over groups	37
3.	Graph 3 : Mean plot of weight over groups	38
4.	Graph 4: Mean plot of height over groups.	38
5.	Graph 5: Mean plot of BMI over groups	39
6.	Graph 6: : Distribution of ASA classification over groups	40
7.	Graph 7: Mean plot of duration of surgery over groups	41
8.	Graph 8 : Distribution of grading of POST over groups	43
9.	Graph 9 : Distribution of grading of cough over groups	45

LIST OF FIGURES

FIGURE	TITLE	PAGE NO.
1.	Figure 1: : Anatomy of pharynx	9
2.	Figure 2: The laryngeal images before (A) and after (B) general anaesthesia with intubation.)	9
3.	Figure 3 : Budesonide AQ spray	17
4.	Figure 4 : Chemical structure of budesonide	18
5.	Figure 5 : Water based lubricant: K-Y GEL	24

INTRODUCTION

Endotracheal intubation is the most rapid, safe, and effective method for achieving all airway management objectives, and is considered the gold standard. However, the insertion of the endotracheal tube (ETT) can cause laryngeal trauma, leading to symptoms such as sore throat, pain, hoarseness, tachycardia, hypertension, and an increase in intracranial and intraocular pressure.

Postoperative sore throat (POST) is a common complication following general anaesthesia with endotracheal intubation occurs in 21% to 65% of patient (30). Postoperative sore throat usually subsiding on its own. However, in some cases, severe POST can result in difficulty breathing and swallowing, decrease patient satisfaction with anesthesia, and even extend hospital stays.

The causes of POST are multifactorial, While the exact cause of POST is not fully understood, it seems to be an inflammatory response, as the tracheal mucosa has been shown to release inflammatory mediators following local cell damage, which then affect the sensory nerves in the airways after intubation. However, the precise anatomical source of the sore throat remains unclear. With various mechanisms potentially contributing, such as airway trauma extended mucosal ischemia due to mechanical pressure, gastric content regurgitation, and the insertion of a gastric tube, among others.(15)

Several pharmacological methods have been suggested to reduce postoperative sore throat. Randomized controlled trials have indicated that anti-inflammatory treatments, including inhaled, topical, or systemic corticosteroids, and topical nonsteroidal anti-inflammatory drugs, can help prevent postoperative sore throat, includes Beclomethasone, applying lidocaine spray or lidocaine gel,

administering actions (3). Budesonide is long acting water soluble glucocorticoid that has been used topically for the treatment of inflammatory lesions of the oral mucosa, thus provide lubrication as well as anti-inflammatory effect. Pre induction Budesonide inhalation is effective in postoperative sore throat prevention. However, it requires inhaler equipment and patient's co-operation. Budesonide spraying on the endotracheal cuff is simple and can be performed on most patients requiring endotracheal intubation for the incidence of POST. Water based gel (k-y) using in this study is biologically inert also has an anti-inflammatory effect and contains no color or no odor, is shown to reduce the incidence of POST by applying on the ETT cuff. There are only few studies shows, the comparative effects of the agents, with respect to the incidence of post-operative sore throat, but they had small sample sizes. .

Hence an attempt is made in this study to examine the effects of budesonide and k-y gel in terms of the postoperative sore throat in patients undergoing general anesthesia.

AIMS AND OBJECTIVES

The objective of the present research work is “To compare the effects of budesonide spray and water based gel as an endotracheal cuff lubricant on the incidence and severity of post-operative sore throat”.

REVIEW OF LITERATURE

1. Hintong et al. (1) performed a randomised controlled trial with one hundred patients scheduled for elective noncardiac surgery, who were randomly assigned to either the budesonide group (n = 50) or the K-Y gel group (n = 50). In the budesonide cohort, 200 mcg of budesonide was administered by spray onto the cuff of the endotracheal tube. The ETT cuff in the K-Y gel group was lubricated with K-Y gel. A visual analogue scale was employed to evaluate the intensity of postoperative sore throat at 2, 6, and 24 hours post-surgery. Additional problems of tracheal intubation and harmful effects of budesonide were also documented. In comparison to the K-Y gel cohort, the budesonide cohort exhibited a markedly diminished overall incidence of POST (30% versus 54%, P = .032) and a 24% reduction in the risk of POST (relative risk reduction = 24%, 95% CI, 5.23-42.77, P = .012), alongside a lower incidence of hoarseness (8.6% versus 34%, P = .001) and cough (0% versus 8%, P = 0.041). No instances of drug-related adverse effects were observed in either group. Their findings indicated that administering budesonide on the endotracheal tube cuff markedly diminishes the occurrence and intensity of postoperative sore throat (POST).
2. Devi et al. (7) conducted a randomised double-blind controlled trial in the Department of Anaesthesiology at Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur, India, from September 2020 to December 2021. The study comprised 120 patients, regardless of sex, aged 20 to 60 years, classified as American Society of Anaesthesiologists (ASA) grade I and II, scheduled for elective surgery necessitating general anaesthesia with endotracheal intubation. The patients were randomly allocated into three

groups, each consisting of 40 individuals. Group M received nebulisation with 250 mg of magnesium sulphate, Group B with 250 mcg of budesonide, and Group S with normal saline, 15 minutes before the induction of anaesthesia. The incidence and severity of POST were recorded at 0 hours, 2 hours, 24 hours, and 48 hours post-extubation using a 0-3 scoring system. The obtained data was processed utilising Statistical Package for Social Sciences (SPSS) version 22.0, followed by statistical evaluation by Analysis of Variance (ANOVA) and the Chi-square test. The occurrence of POST was higher in the saline group compared to the budesonide and magnesium sulphate groups at all observation intervals (0 hr, 2 hours, 24 hrs, and 48 hrs). The saline group exhibited moderate severity of POST, whilst the other two groups demonstrated mild severity. This was statistically significant at 0 hours, 2 hours, and 24 hours (p-value)

3. A. Kuriyama, H. Maeda, et al (2) incorporated randomized controlled trials (RCTs) study that evaluated the effectiveness and safety of corticosteroids applied to tracheal tubes, comparing them to non-analgesic controls and analgesic agents in adults undergoing elective surgery under general anesthesia. The data were combined using a random-effects model, and trial sequential analysis was employed to assess the risk of random error. The primary outcomes included postoperative sore throat 24 hours after surgery or extubation, and adverse events. The evidence quality was assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) criteria. A total of 20 RCTs involving 2200 patients were included in the analysis. When compared to non-analgesic controls, the use of corticosteroids on tracheal tubes was associated with a lower incidence of postoperative sore throat, with a risk ratio (95% CI) of 0.39 (0.32–0.49) across

18 trials involving 1506 patients. Two RCTs did not report any adverse events. Additionally, when compared with lidocaine, corticosteroids applied to tracheal tubes also led to a reduced occurrence of postoperative sore throat, with a risk ratio (95% CI) of 0.42 (0.35–0.51) across nine trials involving 706 patients. Trial sequential analysis provided strong evidence that corticosteroids applied to tracheal tubes were more effective than both non-analgesic controls and lidocaine in preventing postoperative sore throat. The evidence for postoperative sore throat for both comparisons was rated as high quality. Only two trials assessed adverse events, and no adverse events were recorded. In conclusion, corticosteroids applied to tracheal tubes were found to be effective in decreasing postoperative sore throat when compared to both non-analgesic controls and lidocaine, with no adverse events reported in the included trials.

4. Sneha et al. (8) discovered that nebulisation of Budesonide at a dosage of 1 mg, administered 15 minutes prior to endotracheal intubation, diminished both the incidence and severity of sore throat, cough, and hoarseness of voice during the postoperative period for up to 24 hours in patients undergoing elective middle ear surgery under general anaesthesia. Budesonide nebulisation had no systemic side effects, and patient satisfaction was high.
5. Elnaggar et al. (10) conducted a study with 120 patients, who had physical examinations and assessments of vital signs (heart rate, blood pressure, and peripheral oxygen saturation), along with evaluations of cardiac and pulmonary diseases. All patients had evaluation for complete blood count, liver function tests, kidney function tests, and coagulation profiles. Patients were randomly allocated to one of three groups with computer-generated randomisation software. An impartial anaesthesiologist, blinded to the patient's group, will conduct perioperative patient management and data collecting. Their findings

indicated that pre-induction nebulised lidocaine and budesonide can avert post-extubation laryngospasm. Nebulised Budesonide (250 mcg) and, to a lesser extent, nebulised lidocaine (60 mg) can diminish the occurrence of post-extubation laryngospasm, cough, sore throat, and hoarseness.

6. Ajjapa A K , Anusha S et al(11). conducted study to evaluate the occurrence of postoperative sore throat (POST) after tracheal extubation in patients who had either betamethasone gel (Group 1) or KY jelly (Group 2) applied to the cuff of the tracheal tube during elective surgery under general anesthesia. POST was assessed at rest and during activities such as swallowing and talking at 1, 3, 6, 12, and 24 hours post-surgery. The findings revealed that the betamethasone group had a significantly lower incidence of POST compared to the KY jelly group. Additionally, the severity of the sore throat, measured using the Visual Analog Scale (VAS), was higher in the KY jelly group than in the betamethasone group. In conclusion, the study indicates that applying betamethasone gel to the cuff of the endotracheal tube helps reduce both the incidence and severity of POST after tracheal extubation

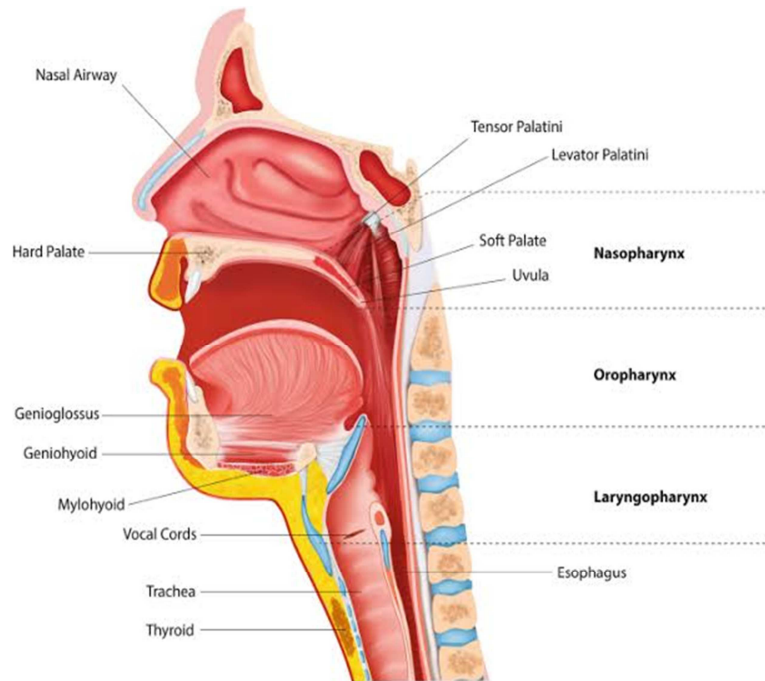
BASIC SCIENCES

POSTOPERATIVE SORE THROAT

Endotracheal intubation is a common operation that provides effective mechanical ventilation under general anaesthesia. Additionally, it may limit aspiration of upper airway content to the lower airways. However, endotracheal intubation is the prominent cause of airway mucosal injury, often resulting in postoperative sore throat. Although POST is typically transient and mild, it can be a distressing complaint for adult patients following endotracheal intubation. POST is typically resolves on its own. However, sometimes severe cases of POST can lead to dyspnea and dysphagia, reduce patient satisfaction with anaesthesia and even prolonged hospital stays.

- **CAUSES OF POST**

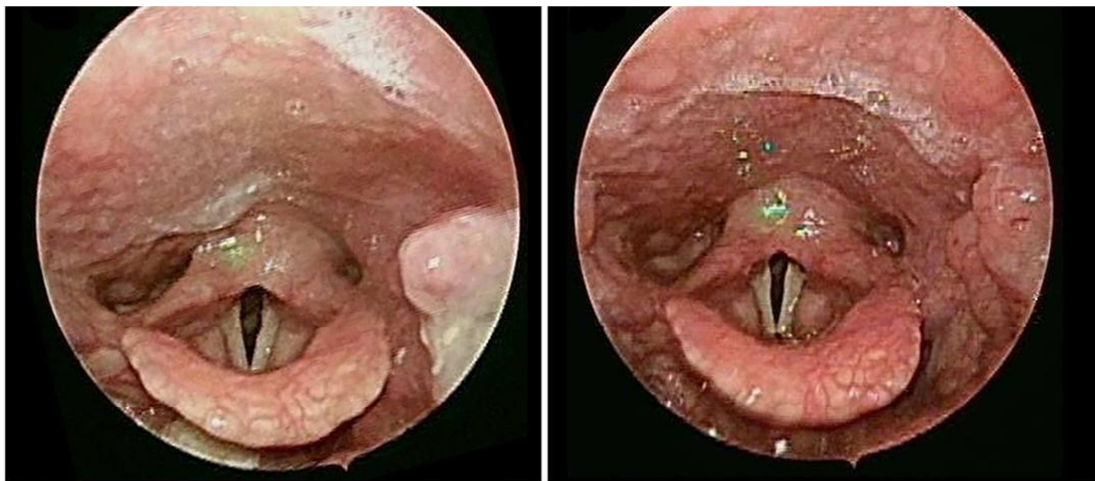
POST is nociceptive pain caused by larynx and tracheal mucosa damage during tracheal intubation under general anaesthesia. there are two primary sources of sore throat: pain originating from supraglottic structures, possibly caused by direct laryngoscopy and pain emerging from infraglottic structures presumably caused by the endotracheal tube or cuff. That leads to mucosal damage and inflammatory reactions triggered by leukocyte migration and cytokine secretion in the airways, mucosal thickening due to fibroblast proliferation, and ultimately, the occurrence of sore throat



(FIGURE 1: Anatomy of pharynx)

A

B



(Figure 2: The laryngeal images before (A) and after (B) general anaesthesia with intubation.)

- **RISK FACTORS**

Risk Factors for POST at present, various risk factors contribute to the occurrence of postoperative sore throat (POST). The main factors can be categorized into patient factors, operative factors and anaesthesia factors

➤ Patient factors

A study of risk factors for POST in tertiary care hospitals demonstrated that female patients were more prone to reporting sore throat compared to their male counterparts. Another study yielded the same result, suggesting that this disparity could be attributed to gender differences in reporting adverse outcomes, a tighter fit of the endotracheal tube in female patients and there may also be anatomical difference in the larynx between male and female.

The study also found that younger adults or those with lung disease were more likely to have POST. Patients' smoking history and the conditions surrounding tracheal intubation can influence the incidence of POST

➤ Operative factors

- Operative Time: The incidence of POST shows a positive correlation with the duration of the operation. Long-standing surgery lengthened the endotracheal intubation time and increased damage to the tracheal mucosa. The rise in cuff pressure over time, and the lateral contact pressure exerted by the cuff contribute to tracheal mucosa ischemia.
- -Type of Surgery: The surgical site and the surgical position significantly influence the occurrence of POST. The surgical often results in translocation of the tracheal tube in head and neck surgery, which will increase the incidence of POST. Taking thyroid surgery as an example POST after thyroidectomy reached up to 80%. Moreover, changes in the patient's position may also alter tracheal tube displacement or cuff pressure.
- Gastric tubes: gastric tubes from the nose in patients were an important predictor of POST. It has been feasible to remove the nasogastric tube with the advent of fast-track surgery, which may reduce the incidence of POST.

➤ Anaesthesia factors

The Size of the Tracheal Tube, Endotracheal Tube Shape and Cuff Pressure:

The size of the tracheal tube has been shown to play a significant role in POST, a smaller tracheal tube provided a better view of the tube through the larynx, reduced glottic damage which might decrease the damage associated with tube insertion.

Compared to an endotracheal tube with a cylindrical cuff, intubation using an endotracheal tube with a tapered cuff reduced the incidence and severity of POST, as well as the occurrence of hoarseness after surgery. This could be interpreted as diameters of tapered cuffs are smaller than those of cylindrical cuffs, and tapered cuffs have a smaller cuff and trachea contact area. It has been reported that the occurrence of cough and the tracheal tube cuff pressure ≥ 17 cmH₂O were both risk factors for POST

o Laryngoscope:

Difficult airways often result in challenging or repeated intubation due to limited visibility during direct laryngoscopy, leading to airway mucosal injury and an increased incidence of POST. In contrast, the glottis can be found quickly and accurately under the video laryngoscope, which avoids secondary damage to the patients indicated that the incidence of adverse events was lower with Glide Scope when comparing the application of the two kinds of laryngoscope in endotracheal intubation

o Fiberoptic bronchoscope:

Fiberoptic guided intubation resulted in less sore throat following nasotracheal intubation compared to Macintosh laryngoscope-guided intubation.

o Laryngeal Mask:

LMA produces less sympathetic stimulation than the tracheal intubation on insertion, and an overinflated ETT cuff after intubation might be a cause of POST. Furthermore, the use of the laryngeal mask airway improves the pharyngolaryngeal profile to a more favourable one. However, ETT were placed to more sensitive tissues of the larynx and the trachea which causes sensitization to pain, thus contributing to a postoperative sore throat.

o Double-Lumen Tube:

The larger diameter of the double-lumen endotracheal tube (ETT) can make intubation more difficult, potentially worsening throat mucosal damage and increasing the risk of postoperative sore throat.

o Suction Secretion:

Negative pressure sputum suction can sometimes cause congestion edema in the pharynx mucosa and sterile inflammation. sputum aspiration might affect the occurrence of POST

o Anaesthetic :

Intraoperative dexmedetomidine infusion reduced the incidence and severity of POST after thyroidectomy when compared to remifentanyl. Study revealed that sevoflurane was associated with less frequent sore throat than desflurane. Desflurane shows greater systemic and intrapulmonary proinflammatory response compared with sevoflurane during anaesthesia

Classification	Factor	Type of study	Purpose	Outcome
Patient factors	Sex	A prospective cross sectional study	Determine the incidence and explore associated risk factors contributing of POST at current hospital	Female patients were associated with increased postoperative sore throat rates
Operative factors	Operation time	A prospective randomized control study	Study the effect and safety of use of intracuff alkalinized lignocaine over conventional air and evaluated incidence of cough of coughing and POST after tracheal extubation	Duration of anaesthesia is another risk factor, which has significant impact on increase in cuff pressure consequently increased the incidence of coughing and POST in ETT cuff filled with air.
	Surgery type	A prospective randomized control study	Assess the effectiveness of a heated humidifier on the pattern of POST and cough occurrence following thyroidectomy	The incidence of POST varies according to different reports, with a range between 14.4% and 80%
Anaesthesia factors	The size of the tracheal tube, endotracheal tube shape and cuff pressure.	A randomized controlled trial	Analyse the rates of no, mild, moderate or severe sore throat 1 hr after surgery from participants	Sore throat 1 and 24 hr after surgery were less frequent and less severe after intubation with smaller tubes
	Laryngoscope	A double-blind A randomized controlled	To evaluate whether nasotracheal intubation using a fiberoptic	Fiberoptic bronchoscope guided intubation is associated with

		trial	bronchoscope reduces postoperative sore throat	less sore throat after nasotracheal intubation than Macintosh laryngoscope
	Laryngeal Mask	A randomized controlled trial	Compare the pharyngolaryngeal morbidities between endotracheal tube and Laryngeal mask airway	Sore throat with Laryngeal mask airway were found to be much reduced when compared with Ett
	Double-Lumen Tube	A systematic review & meta-analysis of randomized controlled trials	Compare the efficacy and adverse effects associated with a use of Branchial Blockers and DITs for lung isolation	DLTs were associated with a significantly incidence of airway injury
	Suction Secretion	Hospital based quantitative cross sectional study	Assess prevalence and factors associated with postoperative sore throat among patients who were operated under general anaesthesia with endotracheal intubation	Prevalence of POST in the study was higher, it might due to aggressive oropharyngeal suctioning
	Anaesthesia	A prospective randomized double blinded study	Assessed the effect of dexmedetomidine on POST	The study showed that he intraoperative dexmedetomidine infusion reduced the incidence and severity of post and hoarseness for 24 hours after thyroidectomy

(Table 1: Summary of Factors causing POST, reference- Na yang et al. 2023 from journal of anaesthesia and translational medicine)

- **PREVENTION OF POST**

Most laryngeal injuries caused by endotracheal intubation are mild, while moderate and severe injuries are less common. As long as laryngeal injuries can be detected and treated early, the patients can obtain the best potential outcomes. In recent years, numerous mechanical therapeutic interventions and pharmacological strategies have been investigated to prevent and treat POST in clinical practice.

- Local anaesthetics

Lidocaine is commonly used to prevent postoperative sore throat (POST) due to its analgesic and anti-inflammatory effects. Stabilizing the endotracheal tube (ETT) cuff pressure with alkalinized 2% lidocaine during nitrous oxide anesthesia can help reduce POST. The combination of lidocaine and dexamethasone is more effective in reducing POST than either treatment alone. Additionally, intratracheal dexmedetomidine with ropivacaine and 5% EMLA cream on the ETT cuff have both been shown to decrease POST severity without causing adverse effects.

- Nonsteroidal anti-inflammatory drugs (NSAIDs):

The use of Benzydamine hydrochloride spray on the endotracheal tube cuff decreased both the frequency and intensity of postoperative sore throat (POST) 12 hours following total thyroidectomy, with no notable side effects. Ketorolac tromethamine, applied along the 20-cm length of the cuff, also successfully reduced sore throat after intubation in patients undergoing general anesthesia.

- N-Methyl-D-Aspartate (NMDA) receptor antagonist:

Prophylactic use of nebulized ketamine, magnesium, and corticosteroids can effectively prevent POST. Among these, nebulized corticosteroids appeared to be the most effective approach for preventing POST.

➤ Neuromuscular blockade:

Nerve blocks enhance blood flow around nerves by interrupting pain signals, which may help reduce inflammation. Research has demonstrated that ultrasound-guided internal branch of the superior laryngeal nerve block (USG-guided iSLN block) is effective in alleviating postoperative sore throat (POST) after extubation.

➤ ETT Cuff pressure (CP):

Excessive tracheal tube cuff pressures have been linked to complications such as sore throat, tracheal mucosa ulcers, and tracheal rupture. To mitigate these risks, it is recommended to use suggested using a sensitive and accurate manometer to monitor cuff pressure and keep the cuff pressure at 20–25 cmH₂O. Gaur and colleagues conducted a study comparing cuff pressure inflated 38 Journal of Anaesthesia and Translational Medicine Na Yang et al. 2023, with air or alkalized 2% lignocaine under general anaesthesia with a N₂O-O₂ mixture. They indicated that cuff pressure was much higher and that the incidence of POST and cough at 1 hour and 24 hours postoperatively was significantly higher in the air group than in the lignocaine group. These findings highlight the beneficial role of alkalized 2% lignocaine played an important role in preventing elevated cuff pressure and reducing the occurrence of POST

➤ Glucocorticoid:

Preoperative intravenous dexamethasone effectively prevents tracheal intubation-related sore throat in adult surgical patients. Gargling with a 0.05% dexamethasone solution showed the same effect as intravenous injection of 0.1 mg/kg dexamethasone. POST at 24 hours were significantly decreased when the endotracheal tubes were lubricated up to the 15-cm mark with 2.5 ml of 0.05%

betamethasone gel. Additionally, when comparing triamcinolone paste with chlorhexidine gel, the application of the former to the tracheal tube and cuff was associated with a reduction in the incidence and severity of sore throat at 24 hours after extubation. Similarly, preoperative inhaled fluticasone and budesonide have also been helpful to reduce the incidence of POST.

- **Budesonide**

Budesonide is a high ratio of topical anti-inflammatory to systemic activity and is one of the most extensively used inhaled glucocorticoids. Budesonide decreases airway hyper responsiveness and reduces the number of inflammatory cells and mediators present in the airways of patient.



(Figure 3: Budesonide AQ spray)

▪ PHARMACODYNAMICS

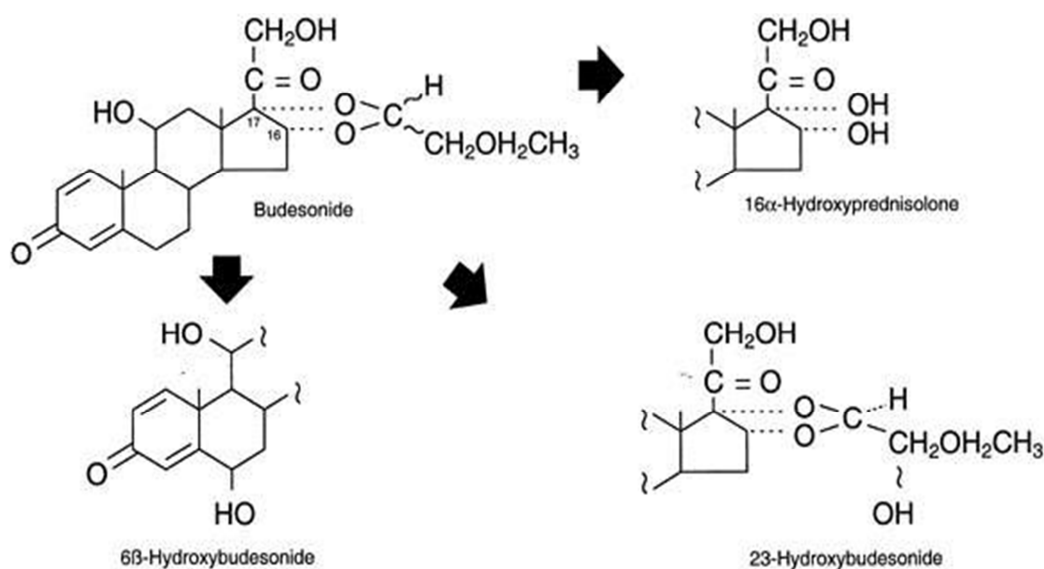
Budesonide ([RS]-1 β , 16 α 17, 21-tetrahydroxypregna1, 4-diene-3, 20-dione cyclic 16, 17-acetal with butyraldehyde) is a nonhalogenated corticosteroid that exhibits potent glucocorticoid activity and weak mineralocorticoid activity (figure4).

Corticosteroid actions are mediated by the glucocorticoid receptor, which is found in the cytoplasm of most cell types. Corticosteroids like budesonide have a

wide range of inhibitory activities against many cell types (eg, lymphocytes, eosinophils, mast cells, neutrophils, and macrophages) and mediators involved in allergic- and nonallergic-mediated inflammation (eg, cytokines, histamine, eicosanoids, and leukotrienes). In addition, corticosteroids increase the synthesis of antiinflammatory proteins, such as lipocortin-1, secretory leukocyte protease inhibitor, and IL-10, and increase the expression of β 2-adrenergic receptors.

- Receptor affinity

Compared with previously developed inhaled steroids, budesonide has a high relative affinity for the glucocorticoid receptor. In standard in vitro tests and animal models, budesonide has approximately a 200-fold higher affinity for the glucocorticoid receptor and a 1000-fold higher topical anti-inflammatory potency than cortisol. Budesonide is a 1:1 racemic mixture of 2 epimers, 22R and 22S, that do not interconvert. Both epimers exhibit high glucocorticoid activity, with the 22R epimer having 2-fold greater affinity than the 22S epimer.



(Figure 4 : Chemical structure of budesonide)

- Relative activity

Structure–activity studies demonstrate that the 16, 17-acetal side chain of budesonide(figure 4) confers highly potent topical anti-inflammatory activity¹⁵ with low systemic activity. Budesonide has demonstrated a high ratio of local anti-inflammatory activity to systemic activity in preclinical and clinical studies. which is explained by a potent anti-inflammatory effect, extensive first-pass hepatic metabolism of orally absorbed drug (85%-95%) and low potency of budesonide metabolites.

- Effects on inflammatory cells and mediators

In vitro evidence suggests that budesonide may phenotypically alter alveolar macrophages, reduce histamine release from basophils inhibit monocyte-mediated cytotoxicity and eosinophil activation, and induce the activity of neutral endopeptidase.

- Effects on airway hyperresponsiveness

Budesonide administered with the Turbuhaler has been shown in various challenge models (including histamine, methacholine, sodium metabisulfite, and adenosine monophosphate) to decrease airway reactivity in patients with hyperreactive airways.

- PHARMACOKINETICS

The human pharmacokinetics of budesonide have been evaluated by various routes of administration, including intravenous, oral, pulmonary, nasal inhalation, and rectal.

- Absorption: Budesonide is a nonproteolytic, moderately lipophilic compound with rapid uptake into airway mucosa. After oral administration of budesonide in healthy adults, peak plasma concentration was reached within approximately 1 to 2 hours, and the absolute systemic availability was 6% to 13%. A variable portion of inhaled corticosteroid is deposited in the oropharynx, and this potentially systemically available drug may result in unwanted systemic effects. The budesonide deposited in the oropharynx is assumed to be swallowed and eventually absorbed from the gastrointestinal tract; however, because of extensive first-pass elimination of oral budesonide (approximately 85%-90%), very little drug is systemically absorbed.
- Distribution: Budesonide is distributed widely into tissues and is 85% to 90% protein bound over the concentration range of 1 to 100 nmol/L, the latter exceeding the concentrations achieved with recommended doses. Budesonide shows little or no binding to corticosteroid-binding globulin and rapidly equilibrates with red blood cells with a blood/plasma ratio of approximately 0.8, which is independent of concentration. In children 3 to 6 years of age, budesonide has a mean volume of distribution at steady state of approximately 3 L/kg, which is similar to that observed in adults.
- Metabolism: In vitro studies with human liver homogenates indicate that budesonide is rapidly and extensively metabolized by the cytochrome P450 system, specifically by CYP3A enzymes.^{7,57} The resulting major metabolites of budesonide are 16 α -hydroxyprednisolone and 6 β -hydroxybudesonide, these metabolites have glucocorticoid-receptor and topical anti-inflammatory activities, which are only 1% or less than that of the parent drug. No important differences were detected between in vitro and in vivo metabolic patterns, and little metabolic inactivation was observed in human lung and serum studies.

Budesonide, fluticasone, and beclomethasone dipropionate were equally well taken up into airway tissue. Budesonide was shown to form lipophilic intracellular fatty acid esters (at the C-21 position) in the airway and lung tissue after topical application. In the large airways, approximately 70% to 80% of retained budesonide was conjugated 20 minutes after administration; conjugated budesonide was retained in the large airways longer than fluticasone or beclomethasone dipropionate, which do not form fatty acid conjugates. Conjugation of budesonide is reversible in vivo, and the conjugates gradually are hydrolyzed by intracellular lipases to free budesonide. The reversible conjugation observed with budesonide may enhance airway selectivity and prolong local anti-inflammatory effects. The formation of fatty acid conjugates in human lung tissues recently was demonstrated in vivo

- Systemic clearance : An important property of inhaled corticosteroids is rapid plasma clearance after absorption, which minimizes potential systemic effects. High plasma clearance of budesonide in this young population is advantageous to minimize potential systemic adverse effects associated with high-dose.
- Elimination: Budesonide is excreted primarily as metabolites in the urine and feces. Renal elimination of unchanged budesonide is low because of its extensive biotransformation in the liver. In healthy adults, 60% of an intravenous radiolabeled budesonide dose was recovered in urine, and no unchanged budesonide was detected.
 - Indication:
- Budesonide extended-release capsules are indicated for the treatment and maintenance of mild to moderate Crohn's disease.

- Various inhaled budesonide products are indicated for prophylactic therapy in asthma and to reduce exacerbations of COPD.
- A budesonide nasal spray is available over the counter for symptoms of hay fever and upper respiratory allergies.
- Extended-release capsules are indicated to induce remission of mild to moderate ulcerative colitis and a rectal foam is used for mild to moderate distal ulcerative colitis.
- Delayed-release capsule formulation of budesonide is indicated to reduce proteinuria in adults with IgA nephropathy at risk of rapid disease progression.
- Budesonide is indicated to treat eosinophilic esophagitis (EoE).
 - Adverse reactions :
 - Common adverse reactions from budesonide are nasopharyngitis, nasal congestion, pharyngitis, rhinitis allergic, viral upper respiratory tract infection, nausea, viral gastroenteritis, otitis media, conjunctivitis., toothache, oropharyngeal pain, cough, dysphonia, backpain, procedural pain, throat irritation, back pain, and headache.
- All types of budesonide formulations can give rise to hypersensitivity reactions.
 - Contraindication
 - Budesonide is contraindicated in any patients with a history of hypersensitivity to budesonide or any of the ingredients of the budesonide formulation.
 - Per Canadian labelling, additional contraindications are untreated bacterial, fungal, or viral respiratory infection, moderate-to-severe bronchiectasis, and active or quiescent pulmonary tuberculosis

➤ Others:

- Preoperative licorice lozenges have been verified to not only reduce the incidence of post-extubation cough in smokers undergoing general anaesthesia but also reduce the incidence and severity of sore throat 24 hours after extubation
- Additionally, perioperative use of strepsils tablets has been shown to reduce POST and hoarseness immediately and 24 hours after surgery and chewing gum for 2 minutes before the induction of general anaesthesia can significantly reduce POST within 24 hours after hysteroscopic surgery.
- **K-Y gel:** K-Y Jelly is a water-based, water-soluble, sterile, and widely used lubricant that has applications in both medical and personal settings. Initially developed as a surgical lubricant, it has gained prominence due to its inert nature, ease of use, and compatibility with medical devices and sensitive mucosal surfaces.



(Figure 5: Water based lubricant: K-Y GEL)

- Composition

The key ingredients in K-Y Jelly contribute to its unique properties. These include:

1. Water: Acts as the solvent, providing a smooth texture and non-greasy consistency.
2. Glycerin: A humectant that helps retain moisture, making the lubricant effective without excessive drying.
3. Hydroxyethylcellulose: A thickening agent that increases the viscosity and ensures uniform application.
4. Gluconolactone: A stabilizing and sequestering agent that helps maintain the consistency and efficacy of the product.
5. Chlorhexidine Gluconate: A broad-spectrum antimicrobial, which provides added protection against infections.
6. Methylparaben and Propylparaben: Preservatives that prevent microbial growth in the product during storage.

7. Sodium Hydroxide: Adjusts pH to make the product biocompatible with human mucosal surfaces.

This composition gives K-Y Jelly its odorless, colorless, non-staining, and non-irritating characteristics, which are critical for its use in sensitive clinical contexts.

- Physicochemical Properties
 - pH: K-Y Jelly is formulated to be pH-neutral, minimizing irritation when applied to mucosal surfaces.
 - Viscosity: The inclusion of hydroxyethylcellulose provides the ideal viscosity, enhancing the lubricating effect and preventing the product from dripping or drying out too quickly.
 - Water Solubility: The water-based formulation allows for easy cleaning and prevents residue build-up.
- Mechanism of Action

K-Y Jelly primarily works by reducing friction between surfaces. This is particularly important in medical procedures involving insertion of devices such as catheters, endotracheal tubes, rectal thermometers, and specula. The lubricant forms a thin film on the mucosal surfaces and instruments, decreasing mechanical trauma and irritation during procedures.

In addition, the presence of chlorhexidine gluconate imparts antimicrobial properties, which help in reducing the risk of infections associated with device insertion.

- Applications in Medical Practice

K-Y Jelly is extensively used in a variety of clinical and procedural settings:

1. Gynaecological and Urological Procedures: Used during pelvic examinations and the insertion of catheters to minimize discomfort and trauma.
2. Endoscopic Procedures: Facilitates the insertion of endoscopes by reducing friction between the scope and the mucosa.
3. Rectal and Anal Examinations: Assists in the insertion of rectal thermometers and anoscopes.
4. Intubation and Airway Management: Applied to endotracheal tubes and laryngoscope blades to reduce airway trauma.
5. Ultrasound Imaging: Occasionally used as a coupling gel for ultrasound probes.
6. Minor Surgeries and Wound Dressing: Used to ease the application and removal of wound dressings.

- **Antimicrobial Properties and Safety Considerations**

The inclusion of chlorhexidine gluconate provides K-Y Jelly with additional antimicrobial action. Studies have demonstrated its effectiveness against a broad spectrum of bacteria, reducing the risk of hospital-acquired infections (HAIs). However, prolonged use or use in specific scenarios (e.g., vaginal application) may disrupt the normal microbial flora, necessitating careful consideration of its application in certain patient populations.

- Potential Side Effects and Adverse Reactions

While K-Y Jelly is generally considered safe and non-irritating, certain adverse reactions may occur in rare cases, including:

- Allergic Reactions: Though uncommon, hypersensitivity to parabens or chlorhexidine may lead to localized irritation or rash.
- Alteration of Microbial Flora: Extended use in vaginal applications may disrupt the balance of normal flora due to its mild antimicrobial effect.
- Cytotoxicity: Some studies suggest that certain lubricants may exhibit cytotoxic effects on epithelial cells, though more research is required to understand the clinical significance.

- Advantages of K-Y Jelly

- Non-Greasy and Easy to Clean: Being water-soluble, it is easy to remove with water without leaving behind greasy residue.
- Safe for Use with Latex and Silicone Devices: Unlike oil-based lubricants, K-Y Jelly does not degrade latex or silicone, making it compatible with various medical and personal devices.
- Biocompatible: The formulation is gentle on sensitive tissues, making it suitable for a wide range of applications.

Intervention	Type of study	Purpose	Outcome
Glucocorticoids	Systematic review and meta-analysis	Assess the efficacy and safety of preoperative intravenous dexamethasone in preventing POST in adult patients	Preoperative intravenous dexamethasone alleviates POST more effectively than non-analgesis Methods
Local Anaesthetics	Prospective randomized double-blind controlled study	Investigate whether topical ropivacaine anaesthesia can facilitate early and rapid recovery of surgical patients post-thyroidectomy	Topical anesthesia with 0,75% ropivacaine before intubation can significantly reduce the incidence of POST without influence patients recovery.
NSAIDS	Randomized controlled trial	Compared the effects of benzydamine hydrochloride (BH), 10% lidocaine, and normal saline pray on preventing POST in patients who underwent total thyroidectomy	Application of BH spray on the ETT cuff reduced incidence and severity of POST at 1 hr after total thyroidectomy
NMDA receptor antagonists	Prospective randomized double-blind controlled study	Evaluate the effects of administration of zinc lozenges on POST	The administration of a single dose of 40-mg zinc lozenge 30 minutes preoperatively is effective to reduce the incidence and severity POST
Drug combination	Prospective randomized double-blind controlled study	Investigate whether intratracheal dexmedetomidine combined with ropivacaine reduces the severity and incidence of POST after tracheal intubation	The combined use of dexmedetomidine and ropivacaine for surface anaesthesia signifeanti reduced the incidence and severity of POST without side effects

Neuromuscular block	Randomized double blinded controlled study	Investigate the effectiveness and safety of ultrasound (US)-guided block of the Internal branch of the superior laryngeal nerve (iSLN) for alleviating POST after intubation of double-lumen endobronchial tubes (DLTs)	The use of US guided iSLN block can effectively reduced the incidence and severity of POST after intubation of DLTs on thoracic surgery
ETT cuff pressure	Prospective randomized double-blind controlled study	Compare the ETT cuff pressure inflated with air or alkalinized ligocaine during anaesthesia and evaluate POST following tracheal extubation	The use of alkalinized 2% lignocaine can significantly prevent rise of cuff pressure and incidence of POST

(Table 2: Summary of preventive measures for postoperative sore throat. Ref :

Na yang et al. 2023 from journal of anaesthesia and translational medicine)

MATERIALS AND METHODS

Source of Data: Patients between the age group of 18-60 years, of either gender, belonging to “American Society of Anaesthesiologists (ASA) grade I” & “II”, who underwent elective surgery with general anesthesia at KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehru Nagar, Belagavi

Study Design: Randomised control trial

Study Period: One year

Sample Size:

The formula used for sample size calculation is,

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1 - p_1) + p_2(1 - p_2))}{(p_1 - p_2)^2}$$

where p_1 and p_2 are the incidence of POST in Budesonide group and K-Y group respectively. For 95% confidence level, $Z_{\alpha/2}$ value is 1.96 and for 90% power Z_{β} value is 1.2816.

Ref: Hinton, Thanoo et al." A Randomized Comparison of effects of Budesonide Spray and K-Y Gel as Endotracheal Tube Cuff Lubricant on Incidence of Postoperative Sore Throat." Journal of PeriAnesthesia Nursing (2023)

Based on above reference,

The Budesonide group had a significantly lower overall incidence of POST (30%) compared to the K-Y gel group (54%). Considering similar incidence rate of POST in our study, at 95% confidence level and 90% power, minimum sample size required is $83.62593 \approx 84$ subjects for each group.

Considering 5% follow-up loss, the sample size required is 88 subjects per group. Total sample size required is $88 \times 2 = 176$ subjects. Larger the sample size, better the precision. In our study, 89 subjects were included in each group.

Sampling technique: Patients was assigned randomly to the Budesonide and K-Y GEL groups using a random method of allocation.

For this purpose, the first patient was assigned to one group using coin tossing and then, the next patient would be assigned to the other group. The distributions remained hidden to the patients

Inclusion Criteria:

- Age 18-60 years
- American Society of Anaesthesiologists classification Grade I and Grade II
- Surgery under general anaesthesia with endotracheal intubation not lasting for more than 3 hours.

Exclusion Criteria:

- Pre-operative sore throat
- Patients already on an analgesic or steroids (systemic/inhaled)
- Chronic lung disease
- Allergic to study drugs.

Study protocol:

Following approval from the Clinical Trials Registry of India, the Institutional Review Board, and the Institutional Ethical Committee, a total of one hundred and

seventy-nine patients undergoing general anaesthesia were enrolled in the study after meeting the inclusion and exclusion criteria and obtaining informed consent.

Patients were randomised into two groups:

In group B, the endotracheal tube (ETT) cuff was coated with a total of 200 mcg of budesonide spray, with 100 mcg applied to each side of the tube.

In group K, the endotracheal tube (ETT) cuff was lubricated with 2 ml of KY Jelly.

A thorough pre-anesthetic evaluation was conducted on the day before the surgery, and they were advised for 6 hours of nil by mouth as per institutional protocol.

On the day of surgery, the nil per mouth status was confirmed, and an intravenous cannula was placed in the forearm. Aspiration prophylaxis was administered to all patients with intravenous injection Pantoprazole 40 mg and Ondansetron 8 mg as part of the premedication regimen. Baseline blood pressure and heart rate were recorded as preoperative values. Standard monitoring was carried out with continuous measurements of non-invasive blood pressure, electrocardiogram, oxygen saturation, and EtCO₂ levels. All patients received premedication of IV inj Glycopyrrolate 0.005 mg/kg, inj Midazolam 0.05 mg/kg, and inj Fentanyl 2 mcg/kg. The patient was preoxygenated with 100% oxygen for 3 minutes, The study drugs were used to prepare the endotracheal tube (ETT) cuff. Patients under Group B, a total of 200 mcg of budesonide spray was applied to the endotracheal tube (ETT) cuff, with two puffs on each side of the tube, each puff delivering 100 mcg. Patients under Group K The endotracheal tube (ETT) cuff was coated with 2 ml of KY Jelly (82 gm) for lubrication. General anesthesia was induced with an intravenous injection of

Propofol 2 mg/kg, followed by IV Succinylcholine 2 mg/kg. Once adequate muscle relaxation was achieved, intubated with an appropriately sized, prepared endotracheal tube. After confirming bilateral air entry, the tracheal tube cuff was inflated with room air to maintain an intracuff pressure between 25 and 30 cm H₂O and securely fixed in place. The patient was then connected to mechanical ventilation and controlled ventilation with 6–8 millilitres per kg tidal volume, and the Normocapnia was attained by adjusting the breathing rate.

Anesthesia was maintained with a titrated dose of Isoflurane in oxygen and nitrous oxide. An intravenous bolus of Vecuronium 0.1 mg/kg or Atracurium 0.5 mg/kg was administered intermittently to sustain muscle relaxation. The endotracheal tube cuff pressure was monitored every 30 minutes and adjusted to maintain a pressure between 25 and 30 cm H₂O using a cuff manometer. At the end of the surgery, Isoflurane was discontinued, and neuromuscular blockade reversal was achieved with Neostigmine 0.05 mg/kg and Glycopyrrolate 0.01 mg/kg.

After regaining consciousness, the tracheal tube cuff was deflated, and the tube was extubated following oral suctioning. The patients were then shifted to the Post Anaesthetic Care Unit, where supplemental oxygen was provided via facemask for 30 minutes. Post-operative sore throat grading was performed.

Data collection procedure: Data collection was carried out by asking patients about the symptoms of a sore throat and any signs of coughing.

Post-operative Sore Throat Grading:

Grades	Severity of Post-operative sore Throat
Grade 0	No sore throat
Grade I	Mild (complained of sore throat only on enquiry)
Grade 2	Moderate (complained of sore throat only on his / her own)
Grade 3	Severe coughing (severe pain associated with marked change in voice)

(Table 3 : Post-operative Sore Throat Grading - Immediately,10mins, 1st hr, 6th hrs and 24th hrs after extubation.)

Cough grading :

GRADE	Severity of Cough
Grade 0	No cough
Grade I	Minimal cough (1-2 times)
Grade 2	Moderate cough (3-4 times)
Grade 3	Severe cough (more than 5 times)

(Table 4: Cough Grading: - Post-operative immediately, 10mins, 1hr, 6hrs and 24hrs after extubation.)

Data processing and analysis

Data is analysed using statistical software R version 4.4.2. and Microsoft Excel. Categorical variables given in the form of frequency tables. Continuous variables given in Mean \pm SD /Median (Min, Max) form. Chi square test is used to check the association of categorical variables. Normality of variable is checked by Shapiro Wilk test and QQ plot. If data follows normal distribution, parametric tests will be used. Otherwise, non-parametric tests will be used. Two sample t test is used to compare the mean of variables over groups. Mann Whitney U test is used to compare the distribution of variables over groups. P-value less than or equal to 0.05 indicates statistical significance.

RESULTS

The dataset consists of measurements from 178 subjects, evenly divided between the Budesonide group and the K-Y group. The following table gives the comparison of demographic variables over groups.

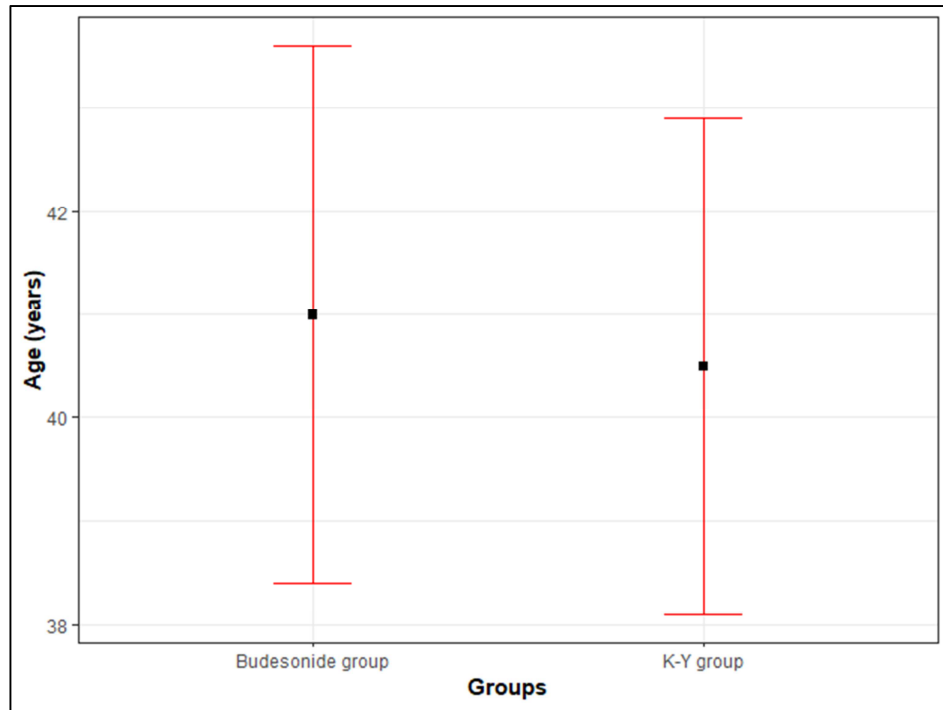
Demographic variables over Age, Gender, Weight, Height and BMI

The mean age was similar between the two groups with no statistically significant difference (p-value = 0.7051). The gender distribution was comparable (p-value = 0.4517), with 57.3% females in the Budesonide group and 51.69% females in the K-Y group. Weight, height, and BMI were also comparable, with no significant differences between the groups (p-values > 0.05).

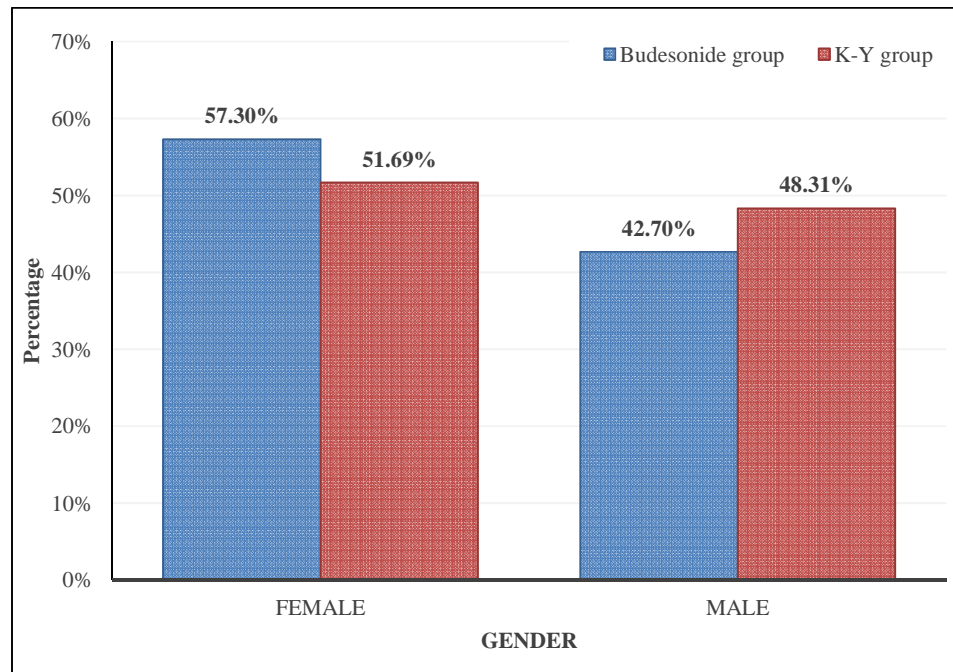
Table 5: Comparison of demographic variables over groups.

Variables	Sub Category	Budesonide group	K-Y group	Total	p-value
Age (years)	Mean \pm SD	41 \pm 12.71	40.54 \pm 11.77	40.77 \pm 12.22	0.7051 ^{MW}
	Median (Min, Max)	42 (2, 62)	42 (18, 60)	42 (2, 62)	
Gender	Female	51 (57.3%)	46 (51.69%)	97 (54.49%)	0.4517 ^C
	Male	38 (42.7%)	43 (48.31%)	81 (45.51%)	
Weight (kg)	Mean \pm SD	61.01 \pm 9.81	62.23 \pm 9.28	61.62 \pm 9.54	0.2742 ^{MW}
	Median (Min, Max)	59.9 (38, 94)	62 (43, 90)	61 (38, 94)	
Height (cm)	Mean \pm SD	152.87 \pm 7.55	154.27 \pm 7.02	153.57 \pm 7.3	0.2004 ^t
	Median (Min, Max)	152 (137, 173)	153 (139, 180)	153 (137, 180)	
BMI (kg/m ²)	Mean \pm SD	26.14 \pm 4.03	26.15 \pm 3.53	26.14 \pm 3.78	0.6870 ^{MW}
	Median (Min, Max)	25.81 (18.59, 41.78)	26.08 (17.97, 34.58)	25.88 (17.97, 41.78)	

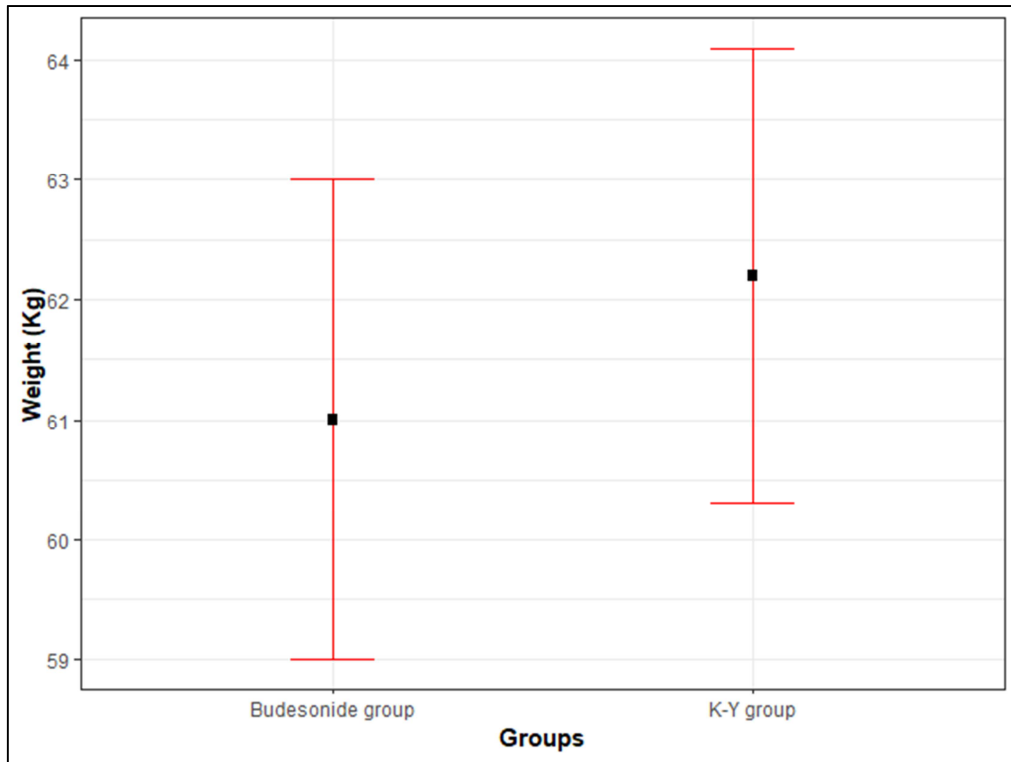
Abbreviation: *t* – Two sample *t* test, *MW* – Mann Whitney *U* test, *C* – Chi square test.



Graph 1: Mean plot of age over groups.



Graph 2 : Distribution of gender over groups.



Graph 3 :Mean plot of weight over groups.

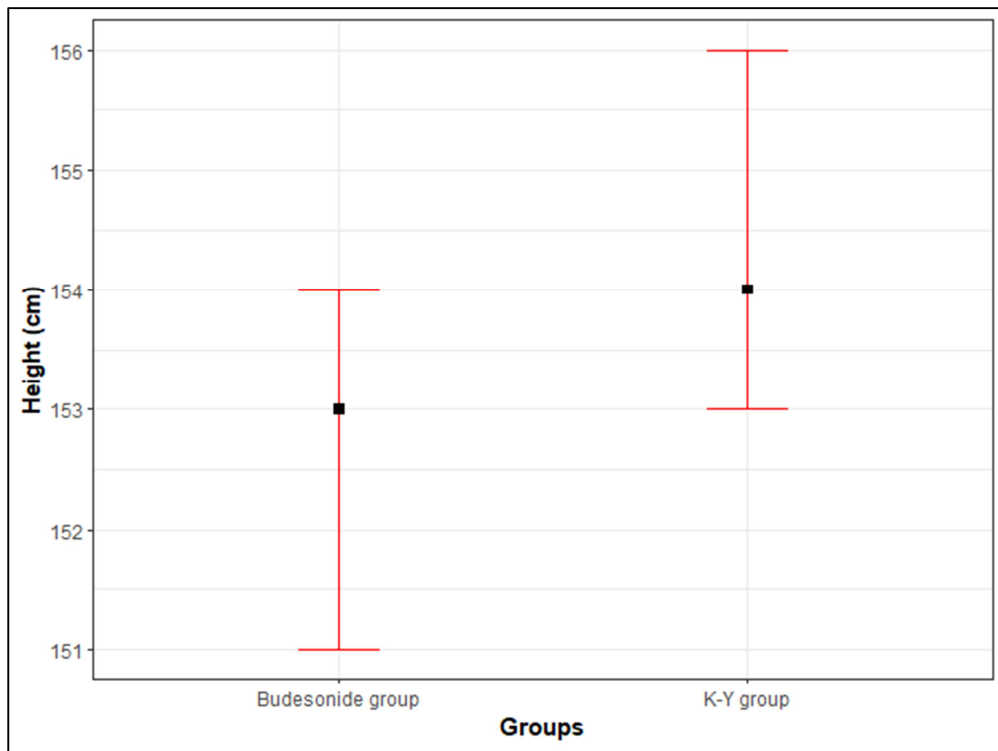
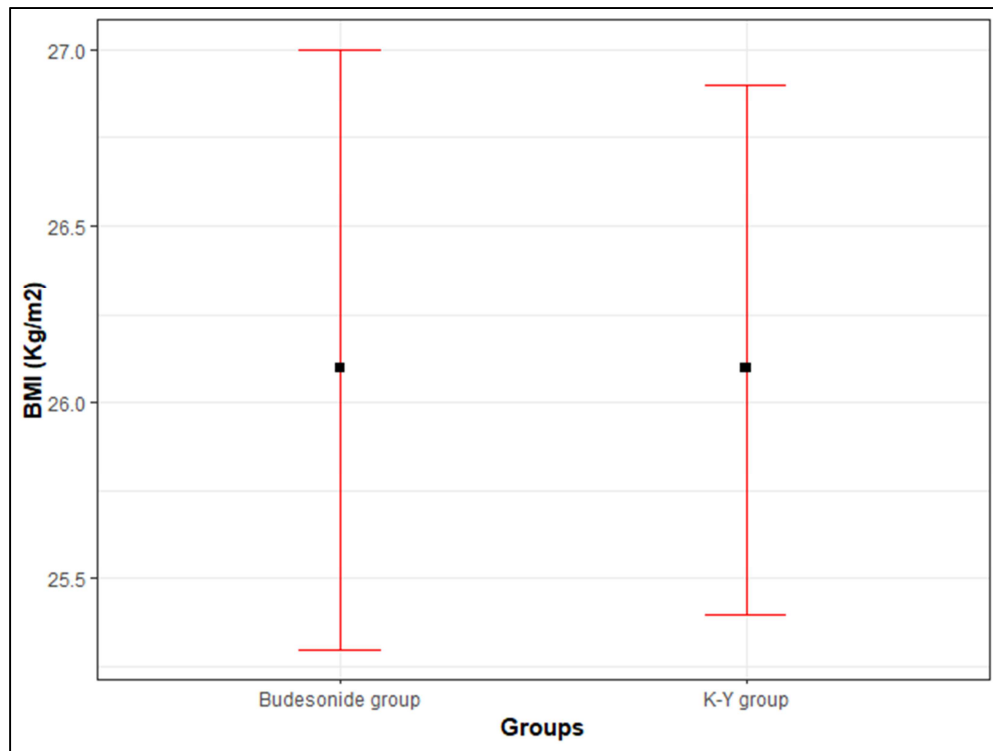


Figure Graph 4 : Mean plot of height over groups.



Graph 5: Mean plot of BMI over groups.

The following table gives the comparison of ASA classification over groups.

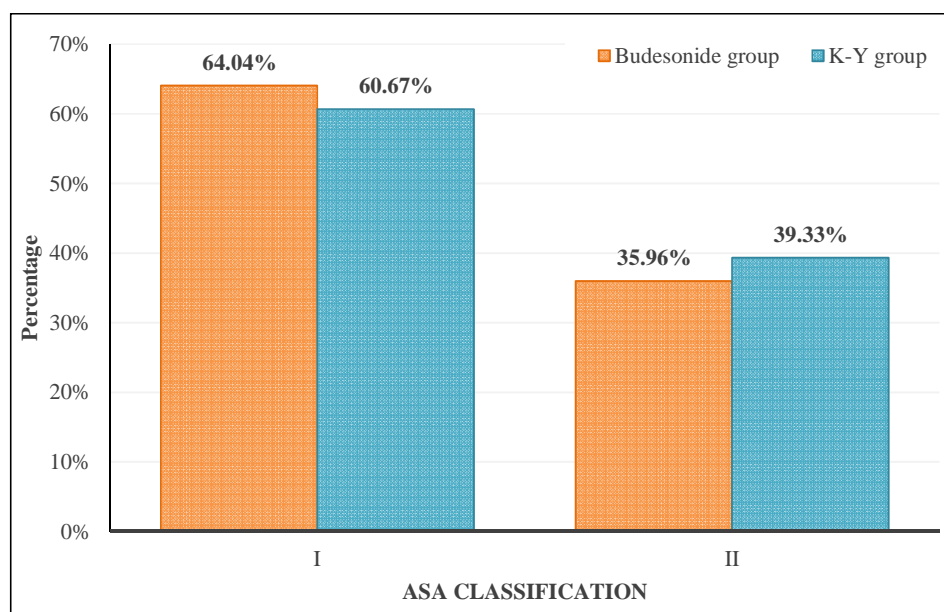
Distribution of ASA classification over groups

The majority of participants in both groups were classified as ASA I (64.04% in the Budesonide group vs. 60.67% in the K-Y group), while the remaining were ASA II (35.96% in the Budesonide group vs. 39.33% in the K-Y group). The difference between the groups was not statistically significant (p-value = 0.6426), indicating that both groups had a similar distribution of ASA classifications.

ASA classification	Budesonide group	K-Y group	Total	p-value
I	57 (64.04%)	54 (60.67%)	111 (62.36%)	0.6426 ^C
II	32 (35.96%)	35 (39.33%)	67 (37.64%)	

Table 6: Comparison of ASA classification over groups.

Abbreviation: C – Chi square test.



Graph 6: Distribution of ASA classification over groups.

Distribution over duration of surgery

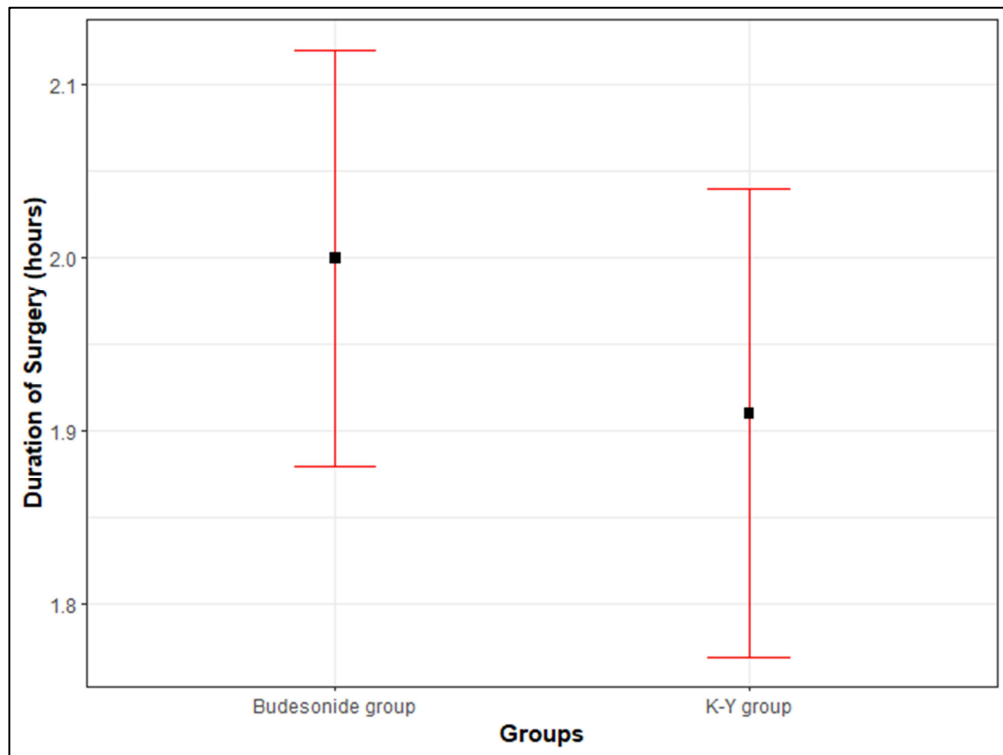
Duration of surgery showed no significant difference between the two groups (p-value = 0.4202).

The following table gives the comparison of duration of surgery over groups.

Variables	Sub Category	Budesonide group	K-Y group	Total	p-value
Duration of surgery (hours)	Mean ± SD	2 ± 0.58	1.91 ± 0.65	1.95 ± 0.62	0.4202 ^{MW}
	Median (Min, Max)	2.17 (0.63, 2.97)	1.95 (0.45, 2.98)	2.08 (0.45, 2.98)	

Table 7: Comparison of duration of surgery over groups.

Abbreviation: MW – Mann Whitney U test.



Graph 7 : Mean plot of duration of surgery over groups.

Comparison of grading of Post operative sore throat over 0min,**10 min,1hour,6th hour,24th hour**

At 0 min, 10 min, and 6 hours of extubation, there were no significant differences in POST grades between the groups (p-values > 0.05). However, at 1 hour (p-value = 0.0380) and 24 hours (p-value = 0.0245), a significantly higher percentage of patients in the K-Y group had Grade 0 (no sore throat) compared to the Budesonide group, suggesting that the K-Y group experienced less postoperative sore throat at these time points.

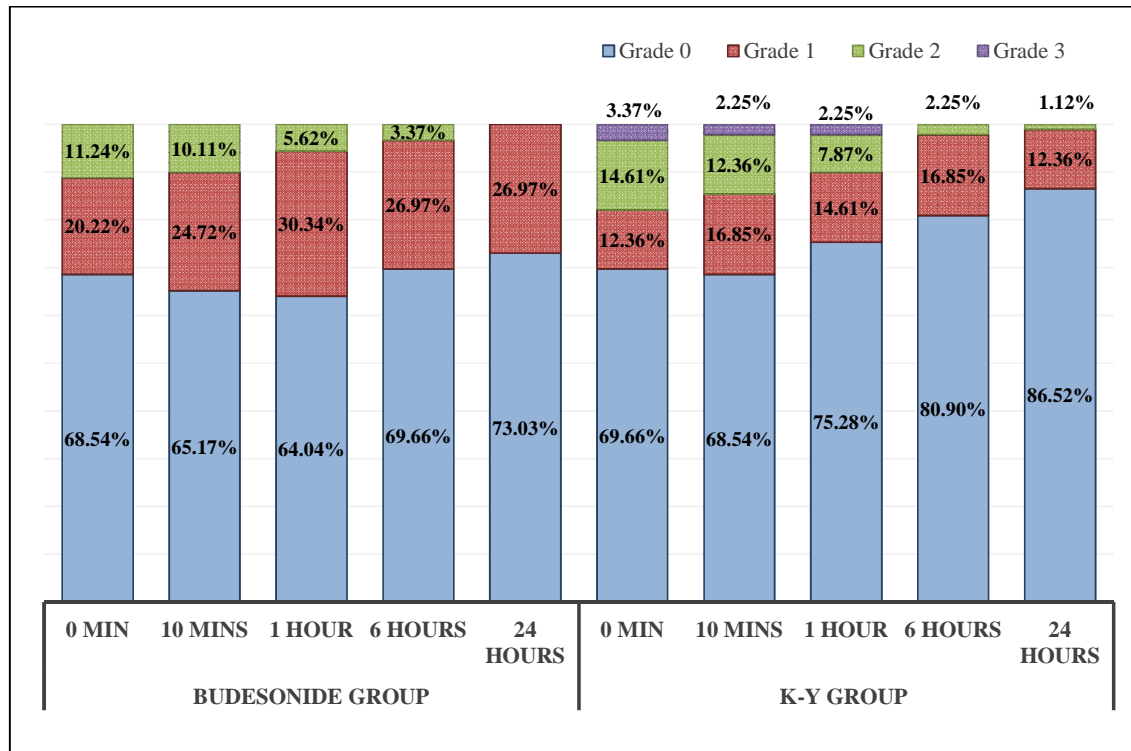
The following table gives the comparison of grading of POST over groups.

Table 8: Comparison of grading of POST over groups.

Time points	Sub Category	Budesonide group	K-Y group	Total	p-value
0 min	Grade 0	61 (68.54%)	62 (69.66%)	123 (69.1%)	0.1704 ^{MC}
	Grade 1	18 (20.22%)	11 (12.36%)	29 (16.29%)	
	Grade 2	10 (11.24%)	13 (14.61%)	23 (12.92%)	
	Grade 3	0	3 (3.37%)	3 (1.69%)	
10 mins	Grade 0	58 (65.17%)	61 (68.54%)	119 (66.85%)	0.3078 ^{MC}
	Grade 1	22 (24.72%)	15 (16.85%)	37 (20.79%)	
	Grade 2	9 (10.11%)	11 (12.36%)	20 (11.24%)	
	Grade 3	0	2 (2.25%)	2 (1.12%)	
1 hour	Grade 0	57 (64.04%)	67 (75.28%)	124 (69.66%)	0.0380^{MC*}
	Grade 1	27 (30.34%)	13 (14.61%)	40 (22.47%)	
	Grade 2	5 (5.62%)	7 (7.87%)	12 (6.74%)	

	Grade 3	0	2 (2.25%)	2 (1.12%)	
6 hours	Grade 0	62 (69.66%)	72 (80.9%)	134 (75.28%)	0.2144 ^{MC}
	Grade 1	24 (26.97%)	15 (16.85%)	39 (21.91%)	
	Grade 2	3 (3.37%)	2 (2.25%)	5 (2.81%)	
24hr	Grade 0	65 (73.03%)	77 (86.52%)	142 (79.78%)	0.0245^{MC*}
	Grade 1	24 (26.97%)	11 (12.36%)	35 (19.66%)	
	Grade 2	0	1 (1.12%)	1 (0.56%)	

Abbreviation: MC – Chi square test with Monte Carlo simulation, * indicates statistical significance.



Graph 8 : Distribution of grading of POST over groups.

Comparison of grading of cough over 0min, 10 min, 1hour, 6th hour, 24th hour

At all-time points (0 min, 10 min, 1 hour, 6 hours, and 24 hours of extubation), the majority of patients in both groups had Grade 0 cough (no cough). The distribution of cough grades was similar across groups, with no statistically significant differences at any time point (p-values > 0.05). This indicates that both treatments were comparable in terms of cough suppression over time.

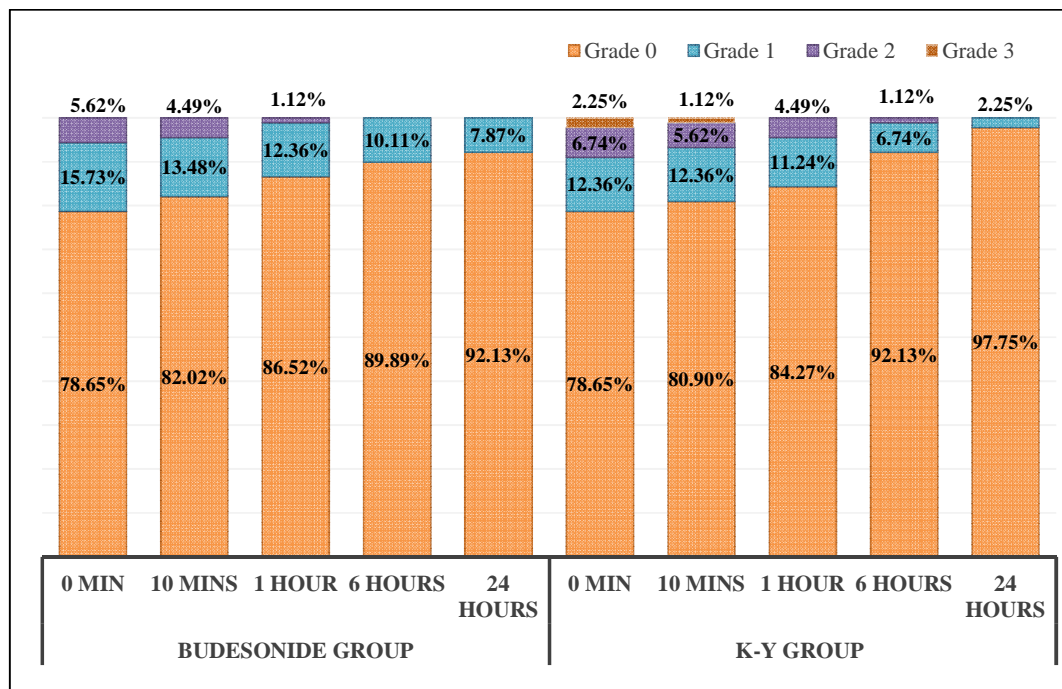
The following table gives the comparison of grading of cough over groups.

Table 9: Comparison of grading of cough over groups.

Time points	Sub Category	Budesonide group	K-Y group	Total	p-value
0 min	Grade 0	70 (78.65%)	70 (78.65%)	140 (78.65%)	0.5852 ^{MC}
	Grade 1	14 (15.73%)	11 (12.36%)	25 (14.04%)	
	Grade 2	5 (5.62%)	6 (6.74%)	11 (6.18%)	
	Grade 3	0	2 (2.25%)	2 (1.12%)	
10 mins	Grade 0	73 (82.02%)	72 (80.9%)	145 (81.46%)	0.9999 ^{MC}
	Grade 1	12 (13.48%)	11 (12.36%)	23 (12.92%)	
	Grade 2	4 (4.49%)	5 (5.62%)	9 (5.06%)	
	Grade 3	0	1 (1.12%)	1 (0.56%)	
1 hour	Grade 0	77 (86.52%)	75 (84.27%)	152 (85.39%)	0.4833 ^{MC}
	Grade 1	11 (12.36%)	10 (11.24%)	21 (11.8%)	
	Grade 2	1 (1.12%)	4 (4.49%)	5 (2.81%)	

6 hours	Grade 0	80 (89.89%)	82 (92.13%)	162 (91.01%)	0.5917 ^{MC}
	Grade 1	9 (10.11%)	6 (6.74%)	15 (8.43%)	
	Grade 2	0	1 (1.12%)	1 (0.56%)	
24 hours	Grade 0	82 (92.13%)	87 (97.75%)	169 (94.94%)	0.1824 ^{MC}
	Grade 1	7 (7.87%)	2 (2.25%)	9 (5.06%)	

Abbreviation: MC – Chi square test with Monte Carlo simulation.



Graph 9 : Distribution of grading of cough over groups.

DISCUSSION

The aim of this study was to compare the effects of budesonide spray and a water-based gel as lubricants for the endotracheal tube cuff on the incidence of postoperative sore throat. This randomized clinical trial was conducted at the Department of Anaesthesiology, KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre from March 2022 to April 2023, involving 178 patients aged 18 to 60 years, classified as ASA I or II, scheduled for elective surgery under general anaesthesia were selected and randomly divided into two groups: the group-B and group-K. Budesonide spray in Group B (200mcg), water based K-Y gel in the K group 82gm. An intracuff pressure of 20-30mmHg was maintained to provide an adequate seal. While few studies have indicated a statistically significant difference between budesonide spray and K-Y gel in this context, our findings reveal that there were no significant differences in outcomes between the two groups. The primary aim of the study was to examine the incidence of postoperative sore throat following the application of budesonide spray and water-based K-Y gel on the endotracheal tube cuff.

Compared with other studies, such as the one by Thanoo Hintong et al⁽¹⁾, which demonstrated that applying budesonide, particularly when sprayed on the ETT cuff, offers notable advantages over traditional methods like water-based lubricants, our findings did not show any significant difference between the budesonide spray group and the K-Y gel group. Hintong's study highlighted that this innovative technique provides a straightforward, efficient, and low-risk solution for preventing POST and other complications, such as hoarseness and cough, by effectively reducing the sensitivity of the tracheal mucosa and minimizing irritation and inflammation. However, in our study, both groups exhibited statistically similar results.

A study by DM Doukumo et al⁽¹⁶⁾ compared the effectiveness of lidocaine jelly (LJ) and K-Y jelly (KYJ) in reducing postoperative sore throat (POST), hoarseness, and cough after endotracheal anaesthesia. The results indicated that K-Y jelly was more effective than lidocaine jelly in preventing POST and reducing hoarseness and cough, with a statistically significant reduction in sore throat severity at 12 hours post-extubation. Although the differences in hoarseness and cough were not statistically significant, the trend favoured K-Y jelly. Additionally, a gender difference was noted, with females experiencing a higher incidence of POST when K-Y jelly was used compared to males. This finding aligns with previous research suggesting that females may be more prone to postoperative throat discomfort, potentially due to anatomical differences like smaller airway diameters. Further investigation into this gender-specific response is recommended to better understand the underlying factors.

In studies by Sneha S. and Nataraj MS et al⁽⁹⁾, the use of preoperative budesonide nebulization was evaluated for its efficacy in preventing POST, and it was observed that nebulization ensures the drug is evenly and effectively distributed across the pharynx and respiratory tract. It generates large particles that deposit in the mouth and throat, while smaller particles penetrate deeper into the airways, reaching the transition from the mouth to the airways. Despite these benefits, nebulization necessitates the use of a nebulizer and can be time-consuming, particularly in the preoperative period, potentially delaying procedures. On the other hand, inhalation forms present a more efficient and convenient alternative, as they are quicker and simpler to administer, making them a more suitable choice in time-sensitive clinical settings.

The effectiveness of budesonide and water based KY GEL as observed in our study can be explained by their pharmacological properties. Budesonide is a non-halogenated glucocorticoid with potent anti-inflammatory properties. It effectively alleviates congestion, reduces capillary permeability, and minimizes edema in the laryngeal mucosa.

The study conducted by Thanga P et al⁽²⁴⁾ aimed to evaluate the effect of intravenous diclofenac sodium on the occurrence and severity of postoperative sore throat (POST) in patients undergoing laparoscopic surgery. A total of 42 inpatients were randomized into two groups: one group received 75mg of intravenous diclofenac sodium in addition to standard treatment (such as intramuscular morphine 10mg or intramuscular pethidine 75mg intraoperatively), while the other group received standard treatment only. Patients were interviewed at 2, 6, and 18 hours postoperatively to assess the incidence and severity of sore throat using a Visual Analogue Scale (VAS). The results showed no statistically significant difference in the occurrence or severity of postoperative sore throat between the diclofenac and standard treatment groups at any of the time points. While intravenous diclofenac sodium may be effective for general postoperative pain management, it does not specifically address the root cause of POST. In contrast, lubricating the endotracheal tube cuff with substances like K-Y jelly or budesonide spray directly reduces mucosal irritation and inflammation, making it a more effective method for preventing POST. This suggests that local interventions, such as cuff lubrication, may be more beneficial in preventing postoperative sore throat compared to systemic treatments like intravenous diclofenac sodium.

In the present study, we used a budesonide spray to deliver the drug on endotracheal tube. Most of the studies which investigated the efficacy of various drugs on the incidence of POST have administered the drugs either intravenously, topically, as intracuff medication, nebulisation^(6,9,10) or gargle. Topical benzydamine hydrochloride^[23] intracuff and topical lidocaine^[3] magnesium sulfate^[26] ketamine⁽²⁸⁾, nebulisations of ketamine and magnesium sulfate^[7,31] and intravenous ketamine⁽²⁹⁾ are few examples.

In our study, we administered budesonide spray at a dose of 200 mcg, which is consistent with the approach used by Thanoo Hintong et al. This method was chosen because it is easy to administer, free from bitter or metallic taste, requires a smaller volume, eliminates the risk of aspiration if accidentally swallowed, and provides a cost-effective solution for reducing post-operative sore throat. K-Y jelly on the other hand a widely recognized and commonly used lubricant, functions by forming a thin, protective film on mucosal surfaces and medical instruments, which significantly reduces mechanical trauma and irritation that can occur during various medical procedures, thereby promoting smoother and more comfortable procedure for patients. Additionally, the presence of chlorhexidine gluconate within the formulation imparts antimicrobial properties that help to minimize the risk of infections associated with the insertion of medical devices into the body⁽³²⁾. As a result, K-Y Jelly is frequently employed in a wide range of medical procedures, including bronchoscopy, esophagoscopy, gonioscopy, and cryotherapy for odontogenic keratocysts, where both its lubricating and infection-prevention qualities are crucial to ensuring patient safety and procedure efficacy. In a randomized clinical study, K-Y lubrication of the tracheal tubes was found to be superior to lidocaine jelly in prevention of postoperative sore throat. Interestingly, one recent experimental study by Elgarhy A et al, highlighted the

value of this brand of jelly in inhibition of the increase in cuff pressure during general anaesthesia.³² The fact that this study is the first in India to compare budesonide spray and water-based gel for reducing POST is a significant strength, as it provides essential, localized data that could influence clinical practice, inspire future research, and contribute to improved patient outcomes in India.

CONCLUSION

The study showed that there was no significant difference in the effectiveness of budesonide spray and K-Y gel as lubricants for reducing the incidence of postoperative sore throat. However, both methods were found to be safe and effective for this purpose. Further research with larger sample sizes may be needed to confirm these results.

SUMMARY

Title: Comparison of Budesonide Spray and Water-Based Gel as an Endotracheal Tube Cuff Lubricant on Incidence of Postoperative Sore Throat: Randomized Control Study

Introduction: Endotracheal intubation is an essential technique for airway management during general anesthesia. However, it can lead to postoperative complications like sore throat (POST), which occurs in 21% to 65% of patients. POST is usually self-limiting but can lead to severe discomfort, difficulty swallowing, and a negative impact on patient satisfaction. The cause of POST is thought to be an inflammatory response triggered by trauma to the tracheal mucosa. Several strategies, including anti-inflammatory drugs, have been proposed to reduce POST. Budesonide, a corticosteroid with anti-inflammatory properties, and water-based gel (K-Y Jelly) are two lubricants tested in this study for their potential to reduce the incidence of POST when applied to the endotracheal tube cuff.

Objective: The objective of this study was to compare the effects of budesonide spray and water-based gel (K-Y Jelly) as endotracheal tube cuff lubricants on the incidence and severity of postoperative sore throat in patients undergoing elective surgery under general anesthesia with endotracheal intubation.

Methodology: This was a randomized controlled study involving 179 patients undergoing general anesthesia. The patients were randomized into two groups:

- **Group B (Budesonide Spray):** The endotracheal tube cuff was coated with 200 mcg of budesonide spray (100 mcg on each side of the tube).

- **Group K (Water-Based Gel):** The endotracheal tube cuff was lubricated with 2 ml of K-Y Jelly.

Pre-anesthetic evaluations were performed, and patients were required to fast for 6 hours before surgery. Standard anesthesia protocols were followed, including the administration of premedications and induction of general anesthesia with Propofol, neuromuscular blockade with Succinylcholine and vecuronium, and maintenance of anaesthesia with O₂, N₂O and isoflurane. The endotracheal tube cuffs were prepared as per the group assignments. The cuff pressures were monitored and adjusted to maintain a pressure of 25-30 cm H₂O throughout the procedure. The incidence of POST and cough severity were recorded at the following time intervals: immediately, 10 minutes, 1 hour, 6 hours, and 24 hours post-extubation.

Result and Conclusion: The study aimed to assess the incidence of POST following the use of budesonide spray versus water-based gel on the endotracheal tube cuff. The primary outcome was the occurrence and severity of POST postoperatively. The study found that there was no statistically significant difference between the two groups in terms of postoperative sore throat incidence. Both budesonide spray and water-based gel were found to be equally effective in reducing POST. Although the findings were inconclusive in terms of superiority between the two lubricants, both treatments provided a beneficial effect on reducing sore throat symptoms after endotracheal intubation.

LIMITATIONS OF THE STUDY

1. **Single-Center Study:** The study was conducted at a single institution, which may limit the generalizability of the findings to other settings with different patient populations or anesthetic practices.
2. **Short Follow-Up Period:** The assessment of postoperative sore throat (POST) was limited to 24 hours post-extubation. A longer follow-up could provide more insights into delayed-onset POST or other complications.
3. **Subjective Assessment:** The severity of POST was evaluated using patient-reported grading scales, which are inherently subjective and may introduce variability in the results.
4. **Limited Sample Size:** Although the study had an adequate sample size based on statistical calculations, a larger multicenter trial could provide more robust evidence and further validate the findings.

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ANNEXURE – I - INFORMED CONSENT FORM

"COMPARISON OF BUDESONIDE SPRAY AND WATER BASED GEL AS AN ENDOTRACHEAL TUBE CUFF LUBRICANT ON INCIDENCE OF POSTOPERATIVE SORE THROAT: RANDOMIZED CONTROL STUDY."

Name of Student/Principal Investigator

Name of Guide/CO Investigators:

Objectives: To compare the effects of Budesonide spray and water based gel as an endotracheal cuff Lubricant on the incidence and severity of post-operative sore throat.

Introduction: MR. MRS. _____ we are requesting you to enroll yourself in study titled "Comparison of Budesonide spray and water based gel as an endotracheal tube cuff lubricant on incidence of postoperative sore throat " conducted by Dr. _____ Post Graduate in MD Anaesthesiology under the guidance of Dr. _____, Professor, Department of Anaesthesiology, J.N. Medical College, Belagavi under KAHER, Belagavi.

Procedure: On the day of surgery, after being shifted to the operating room, surgery will be performed under general anesthesia with endotracheal tube intubation (for respiration purpose) wherein the cuff will be prepared with Budesonide spray or Water based gel to assess the incidence of post-operative sore throat in the time interval of 10 min, 1st hour, 6th hour and 24th hours after removal of endotracheal tube.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in study

"COMPARISON OF BUDESONIDE SPRAY AND WATER BASED GEL AS AN ENDOTRACHEAL TUBE CUFF LUBRICANT ON INCIDENCE OF POSTOPERATIVE SORE THROAT: RANDOMIZED CONTROL STUDY."

My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature of left thumb impression of the participant:

Name of the witness;

Signature or left thumb impression of the witness:

Name of the investigator:

Signature of the investigator:

ANNEXURE – II - PROFORMA

COMPARISON OF BUDESONIDE SPRAY AND WATER BASED GEL AS AN ENDOTRACHEAL TUBE CUFF LUBRICANT ON INCIDENCE OF POSTOPERATIVE SORE THROAT : RANDOMIZED CONTROL STUDY.

Group allotted :

Name : Age:

Gender : Weight:

Height : Date of Examination:

Address : Occupation :

BMI:

Pre examination evaluation

Past History

- HTN DM IHD
- Thyroid Disorder Respiratory Disorders
- Others (Specify)

- H/o previous surgery/(s) where airway difficulty will be encountered.

Yes No

General physical examination

Weight (Kg) : Temperature (⁰F) : Pallor:
Cyanosis : Pedal edema : Clubbing :
PR : BP : RR:

Musculoskeletal disorders:

Teeth:

Jaw movements:

Airway assessment:

Spine:

Investigations

Hb%:

Platelet Count:

TLC:

INR:

FBS:

Systemic examination:

CNS:

RS:

CVS:

GIT:

Preoperative physical status

American society of anesthesiologist

I II

Diagnosis:

Proposed surgery:

Monitors attached:

Pulse oximetry:

NIBP:

Duration of surgery:

Post-operative sore throat and Severity of Cough

Time	Immediately	10mins	1hour	6 hours	24 hours
Post-operative sore throat					
Severity of Cough					

> SIGNATURE OF THE ANAESTHESIOLOGIST.....

> SIGNATURE OF THE WITNESS.....

> SIGNATURE OF THE PRINCIPAL INVESTIGATOR.....

ANNEXURE – III - PHOTOGRAPHS



PHOTOGRAPH 1 :Budesonide AQ spray



PHOTOGRAPH 2 Water based lubricant: K-Y GEL

ANNEXURE - IV – KEY TO MASTERCHART

ASA	American Society of Anesthesiologists
BMI	Body mass index
POST	Post operative sore throat
Min	Minutes
Hr	Hour
F	Female
M	Male

ANNEXURE - V
MASTER CHART

No.	Group	Date	gender	AGE(year)	weight(kg)	Height(cm)	BMI(kgm)	ASA	Duration of surgery	Grading of POST					Grading of cough					
										0 MIN	10 MIN	1 HOUR	6th Hour	24th Hour	0 min	10 min	1 hour	6th hour	24th hour	
1	K	24-04-2024	F	24	47.9	150	21.28888889	I	02:18:00	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
2	K	20-08-2024	M	52	70	163	26.34649403	I	01:26	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
3	K	24-04-2024	M	42	69	158	27.63980131	II	01:24	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
4	K	24-04-2024	F	33	43	147	19.89911611	I	01:24	GRADE 2	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0
5	K	01-05-2024	M	32	66	150	29.33333333	I	01:15	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
6	K	01-05-2024		35	50	152	21.64127424	I	02:50	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0
7	K	16-04-2024	F	43	60	151	26.31463532	II	01:53	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0
8	K	16-04-2024	F	41	53	148	24.19649379	II	02:18	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
9	K	15-04-2024	F	32	56	152	24.23822715	I	01:37	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
10	K	20-07-2024	M	51	76	156	31.22945431	I	02:52	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
11	K	22-08-2024	F	34	60	152	25.96952909	I	01:20	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
12	K	22-08-2024	F	52	48	154	20.23950076	II	02:50	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
13	K	25-07-2024	M	40	54	157	21.90758246	II	01:58	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
14	K	25-07-2024	F	42	69	147	31.9311398	II	00:36:00	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
15	K	25-07-2024	F	47	66	150	29.33333333	I	02:17	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
16	K	24-07-2024	F	50	69	153	29.47584262	II	01:49	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
17	K	17-07-2024	F	24	57	153	24.34960912	I	02:10	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 0	GRADE 0
18	K	16-07-2024	F	39	60	142	29.75600079	II	02:36	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
19	K	27-07-2024	F	50	48.4	151	21.22713916	II	01:34	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
20	K	29-07-2024	F	55	72	151	31.57756239	II	01:13	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
21	K	31-07-2024	F	44	57.2	149	25.7646052	II	02:17	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
22	K	31-07-2024	M	23	62	155	25.80645161	I	02:06	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
23	K	01-08-2024	F	21	51.8	152	22.42036011	I	02:38	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
24	K	01-08-2024	M	60	71	162	27.05380277	I	01:24	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
25	K	24-08-2024	M	44	70	163	26.34649403	II	00:53:00	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
26	K	07-08-2024	M	33	60	153	25.6311675	I	01:49	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
27	K	07-08-2024	M	48	64	150	28.44444444	I	02:23	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
28	K	30-08-2024	M	38	61	146	28.61700131	I	02:23	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
29	K	13-08-2024	F	22	46	160	17.96875	I	02:53	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
30	K	07-06-2024	F	28	82	158	32.84730011	I	01:42	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
31	K	07-06-2024	M	32	58	156	23.8330046	I	02:20	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
32	K	16-06-2023	M	60	64	150	28.44444444	II	01:13	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 3	GRADE 3	GRADE 2	GRADE 0	GRADE 0	GRADE 0
33	K	13-04-2024	M	43	64	154	26.98600101	I	02:03	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
34	K	11-09-2023	F	57	67	149	30.17882077	II	01:43	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
35	K	13-08-2023	F	47	62	150	27.55555556	I	02:23	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
36	K	28-08-2023	F	52	60	148	27.39225712	I	02:48	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
37	K	01-09-2024	M	35	68	144	32.79320988	I	01:05	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
38	K	11-09-2023	F	19	44	139	22.77314839	I	02:02	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
39	K	25-08-2023	M	45	72	162	27.43484225	I	01:48	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
40	K	25-08-2023	M	40	58	143	28.36324515	I	00:48	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 2	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0
41	K	26-08-2023	F	46	69	152	29.86495845	I	02:22	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
42	K	26-08-2023	F	27	63	152	27.26800554	i	00:56	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
43	K	16-06-2023	F	28	54	149	24.32322868	I	01:18	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
44	K	14-06-2023	M	30	57	166	20.68515024	I	00:56	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
45	K	14-06-2023	M	58	52	160	20.3125	I	01:47	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0
46	K	14-06-2023	M	48	72	155	29.96878252	II	01:51	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0
47	K	14-06-2023	F	47	52	148	23.73995617	II	01:47	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
48	K	14-06-2023	M	40	66	158	26.43807082	II	00:47	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
49	K	14-06-2023	M	47	63	160	24.609375	I	02:21	GRADE 2	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1
50	K	13-06-2023	M	45	54	159	21.35991456	I	01:13	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
51	K	13-06-2023	F	54	67	155	27.88761707	II	01:51	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
52	K	13-06-2023	M	43	54	156	22.18934911	I	01:51	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0

53	K	13-06-2023	F	55	57	155	23.72528616	ii	02:21	GRADE 3	GRADE 3	GRADE 3	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1
54	K	13-06-2023	M	28	71	165	26.07897153	I	02:37	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
55	K	13-06-2023	F	48	57	153	24.34960912	II	02:17	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
56	K	12-06-2023	M	37	70	169	24.50894577	I	02:42	GRADE 3	GRADE 2	GRADE 2	GRADE 1	GRADE 0	GRADE 3	GRADE 2	GRADE 2	GRADE 1	GRADE 0
57	K	05-06-2023	F	55	52	150	23.11111111	I	01:22	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
58	K	05-06-2023	F	49	72	156	29.58579882	II	01:29	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
59	K	14-06-2023	M	40	48	145	22.82996433	I	02:14	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
60	K	14-06-2023	M	43	66	162	25.1486054	II	02:21	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
61	K	18-06-2023	F	19	48	145	22.82996433	I	02:27	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
62	K	14-06-2023	M	54	72	169	25.20920136	I	02:59	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0
63	K	15-06-2023	M	30	61	157	24.74745426	I	01:37	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
64	K	16-06-2023	M	54	67	160	26.171875	II	02:11	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
65	K	16-06-2023	F	52	62	139	32.08943636	II	02:17	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0
66	K	21-06-2023	M	26	60	152	25.96952909	I	02:37	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0
67	K	21-06-2023	F	55	67	152	28.99930748	II	02:49	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0
68	K	22-06-2023	M	44	62	159	24.52434635	II	02:48	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
69	K	21-06-2023	M	29	60	161	23.14725512	I	01:52	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
70	K	22-06-2023	M	26	67	160	26.171875	I	02:49	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 2	GRADE 2	GRADE 1	GRADE 0
71	K	22-06-2023	F	50	67	145	31.86682521	I	02:53	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
72	K	23-06-2023	F	35	59	149	26.57537949	II	00:56	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
73	K	22-06-2023	M	18	56	159	22.15102251	I	02:01	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
74	K	25-06-2023	M	54	61	158	24.43518667	II	02:39	GRADE 3	GRADE 3	GRADE 3	GRADE 2	GRADE 2	GRADE 2	GRADE 2	GRADE 2	GRADE 2	GRADE 0
75	K	25-06-2023	F	35	57	147	26.3778981	I	00:48	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
76	K	22-06-2023	F	20	51	147	23.60127725	I	00:58	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
77	K	23-06-2023	F	46	70	155	29.13631634	II	02:17	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0
78	K	23-06-2023	F	37	85	158	34.0490306	II	00:37	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
79	K	27-06-2023	F	19	49	153	20.93212012	I	01:19	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
80	K	27-06-2023	M	39	90	180	27.77777778	II	01:57	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
81	K	24-06-2023	F	22	68	160	26.5625	I	01:27	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
82	K	26-06-2023	F	53	78	162	29.7210791	II	01:09	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
83	K	27-06-2023	M	20	64	165	23.50780533	I	02:32	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0
84	K	27-06-2023	F	60	70	148	31.95763331	II	00:27	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
85	K	26-06-2023	M	39	63	162	24.00548697	I	01:28	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
86	K	26-06-2023	M	52	72	159	28.47988608	II	01:49	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
87	K	31-01-2024	M	32	82	154	34.5758138	I	02:04	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
88	K	26-12-2023	F	55	55	147	25.45235781	I	02:20	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
89	K	20-06-2023	M	56	63	163	23.71184463	II	02:59	GRADE 2	GRADE 2	GRADE 2	GRADE 1	GRADE 1	GRADE 1	GRADE 2	GRADE 2	GRADE 1	GRADE 0
1	B	28-09-2023	M	31	85	158	34.0490306	I	02:09	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
2	B	22-09-2023	M	40	58	150	25.77777778	I	02:06	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
3	B	28-09-2023	F	42	38	137	20.24615057	I	02:32	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
4	B	28-09-2023	M	41	76	155	31.63371488	II	02:41	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
5	B	28-09-2023	M	22	80	160	31.25	I	01:52	GRADE 0	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
6	B	2/1/2024	M	38	68	162	25.91068435	II	01:59	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
7	B	03-01-2024	F	42	72	163	27.09925101	I	01:32	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
8	B	02-01-2024	F	56	80	159	31.64431787	II	02:47	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
9	B	03-01-2024	F	51	46	148	21.00073046	I	00:47	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
10	B	22-09-2023	M	54	70	152	30.29778393	I	02:19	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
11	B	26-09-2023	M	27	69	159	27.29322416	I	02:14	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
12	B	26-09-2023	M	58	72	164	26.76977989	I	02:03	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
13	B	25-09-2023	F	45	63	144	30.38194444	I	2:17	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 0	GRADE 0	GRADE 0	GRADE 0
14	B	25-09-2023	M	29	74	159	29.27099403	I	02:10	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
15	B	22-09-2023	M	53	83	162	31.62627648	I	02:07	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0	GRADE 0
16	B	27-09-2023	M	56	72	164	26.76977989	I	01:39	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 1	GRADE 2	GRADE 1	GRADE 0	GRADE 0

