



Original Research Article

Comparing intracuff alkalinised lignocaine and normal saline for reducing postoperative sore throat: A prospective, double-blinded, randomised trial

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Abstract

Background and Objective: Postoperative sore throat (POST) is a frequent and distressing complication of endotracheal intubation, impacting patient comfort and recovery. Alkalinised lignocaine, by diffusing through the cuff and exerting a topical anaesthetic effect on the tracheal mucosa, may help mitigate POST. This study aimed to compare the efficacy of intracuff alkalinised lignocaine with normal saline (NS) in reducing POST in adult patients undergoing elective surgery under general anaesthesia (GA).

Materials and Methods: This prospective, randomised, double-blinded, comparative study included 120 adult patients undergoing elective surgery under GA. Patients were randomly assigned to two groups (n = 60 each): Group A received 6 mL of 2% alkalinised lignocaine for ETT cuff inflation, while Group B received 6 mL of NS. POST was assessed at 0, 2, 12, and 24 hours using a four-point scale. Statistical analyses were performed to compare outcomes between groups.

Results: Postoperative sore throat (POST) scores were significantly lower in Group A at 2 hours (1.72 ± 0.45 vs. 1.90 ± 0.48 , $p = 0.033$), 12 hours (0.90 ± 0.40 vs. 1.65 ± 0.52 , $p < 0.001$), and 24 hours (0.28 ± 0.45 vs. 1.02 ± 0.57 , $p < 0.001$) compared to Group B. However, no significant difference was observed at 0 hours (2.23 ± 0.46 vs. 2.18 ± 0.47 , $p = 0.559$).

Conclusion: Intracuff alkalinised lignocaine significantly reduces the incidence and severity of POST compared to Normal Saline in patients undergoing elective surgery under GA.

Keywords: Postoperative sore throat, Intracuff alkalinised lignocaine, Cuffed endotracheal tube.

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1. Introduction

Securing and maintaining a patent airway remains one of the primary responsibilities of anaesthesiologists. Despite the introduction and popularisation of supraglottic devices, cuffed endotracheal tubes (ETTs) remain the gold standard for this purpose. However, while cuffed ETTs are outstanding for ensuring effective ventilation and preventing aspiration, their use is associated with various complications.¹ These complications range from severe, albeit rare, ones like tracheomalacia and tracheoesophageal fistula to minor, but more common, ones like postoperative sore throat (POST).²

Postoperative sore throat (POST) is a common and uncomfortable side effect associated with the use of cuffed ETTs. Although minor and self-limiting, it has an incidence as high as 62% in patients undergoing general anaesthesia (GA).³ Additionally, 40–90% of patients may experience post-extubation coughing, hoarseness and dysphagia.^{4,5} The proposed mechanisms for POST are mechanical injury while airway instrumentation, mucosal damage due to cuff pressure, mucosal dehydration and bucking during extubation.⁶ The pressure exerted by ETT cuff is the most crucial factor in the development of POST, highlighting the importance of monitoring and maintaining an optimal cuff pressure of 20 – 30 cmH₂O throughout the surgery.⁷

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While air inflation has remained the most common mean of cuff inflation, studies suggest that the use of liquids to inflate the cuff, especially during nitrous oxide based anaesthesia techniques, may reduce the incidence of POST.⁸ One of the probable reasons is that use of liquids prevents nitrous oxide from diffusing inside the cuff and increasing the cuff pressure intraoperatively. Lignocaine may offer additional advantage by diffusing out of the cuff and exerting its topical anaesthetic action on the tracheal mucosa.⁹ Alkalinising lignocaine may further enhance this effect by increasing the non-ionised form of lignocaine which has higher permeability through the polyvinyl cuff walls.¹⁰

Although the effect of alkalinised lignocaine on POST has been studied in the past, limited data exist on its efficacy in reducing POST at various time intervals in the postoperative period. This study aimed to compare the efficacy of alkalinised lignocaine and normal saline (NS) in reducing POST in adult patients undergoing elective surgery under GA.

2. Materials and Methods

This prospective, randomised, double-blinded, comparative study was conducted on 120 patients undergoing elective surgery under GA. Ethical clearance was obtained from the institutional ethics committee (F. No. TP MD/MS 40/2020/IEC/ABVIMS/RMLH/327), and written informed consent was secured from all participants for both trial participation and subsequent publication in a scientific journal. The study adhered to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

The sample size was estimated based on data from a previous study by Rakhi et al., which reported a 20% baseline incidence of postoperative sore throat (POST) in the normal saline group. A clinically relevant difference of 15% in POST incidence between the two groups was considered.¹¹ Based on these values, a minimum of 59.08 patients per group was required to achieve 80% power at a 95% confidence interval. Accordingly, 120 ASA I and II patients, aged 18 years and above, scheduled for elective surgery under GA with an anticipated duration of 2–3 hours, were included in the study.

Exclusion criteria included patients with a sore throat or a history of sore throat within the last 72 hours, those with rhinitis, chronic obstructive pulmonary disease, or asthma, individuals with a BMI over 30 kg/m², patients with an anticipated difficult airway, and pregnant or lactating women.

The selected patients were randomly divided into two groups of 60 each using the sealed envelope technique. A computer-generated randomisation list was prepared, and corresponding study drug details were placed inside opaque, sealed envelopes. These envelopes were sequentially opened on the day of surgery before the patient entered the operation

theatre (OT). The endotracheal tube (ETT) cuffs in Group A were inflated using 2 mL of 2% lignocaine mixed with 4 mL of 8.4% sodium bicarbonate solution, while those in Group B were inflated using 6 mL of NS.

The patients were reassessed on the morning of surgery and written informed consent was taken. All standard ASA monitors were attached after shifting the patients inside the OT and GA was induced following standard institutional protocol. Intubation was carried out using unlubricated, cuffed (high volume, low pressure), soft seal, sterile, polyvinyl ETT with 7.0 mm internal diameter for female and 8.0 mm internal diameter for male patients. The cuffs of these tubes were inflated and inspected for any potential leaks prior to patient being taken inside the OT. After insertion, ETT cuffs were inflated using 2 mL of 2% lignocaine + 4 mL of 8.4% sodium bicarbonate solution in group A patients, and 6 mL of NS in group B patients. To ensure blinding, the investigator responsible for opening the sealed envelope and preparing the drug solution was blinded to subsequent intraoperative proceedings, while the investigator responsible for intraoperative conduct was blinded to the contents of drug solution.

The ETT position was confirmed by auscultating the lung fields and any potential air leaks were carefully assessed. In case of appreciable air leak, the ETT cuff was further inflated using 8.4% sodium bicarbonate in group A or NS in group B patients, till the leak was resolved. The patients were mechanically ventilated and anaesthesia was maintained as per the standard institutional protocol. After completion of the surgery and reversal of residual neuromuscular blockage, ETT cuff was deflated and tube was removed once the patients were fully awake and had regained adequate muscle power.

After extubation the patients were shifted to the post anaesthesia care unit (PACU) and were assessed for presence and severity of sore throat at 0, 2, 12 and 24 hours. Assessment was made using a four-point scale for POST (Table 1).¹²

Table 1: Postoperative sore throat (POST) Score – A four-point scale to assess POST

Post Score	Category	Clinical Features
0	No sore throat	No complain of sore throat, even when asked
1	Mild sore throat	Complains of sore throat, only when asked
2	Moderate sore throat	Spontaneously complains of sore throat
3	Severe sore throat	Sore throat associated with voice changes, hoarseness, or cough with throat pain

The collected data were presented as mean \pm standard deviation for quantitative variables and as frequencies with percentages for categorical variables. Nominal categorical data were compared using the Chi-square test, while quantitative data were analysed using Student's t-test for normally distributed variables and Fisher's exact test for non-normally distributed variables. Data were entered and coded using MS Excel (v. 2021, Microsoft Corp., Redmond, WA, USA), and statistical analyses were performed using SPSS software (v. 21, IBM Corp., NY, USA). A p-value of <0.05 was considered statistically significant for all analyses.

3. Results

All 120 patients enrolled in the study successfully completed the trial and were included in the final analysis (**Figure 1**).

The demographic characteristics of the two groups were comparable, with no statistically significant differences observed between them (**Table 2**).

Postoperative sore throat (POST) was assessed using a standardized four-point scale at multiple time intervals. A statistically significant difference in POST scores was observed between the two groups at 2 hours (1.72 ± 0.45 vs. 1.90 ± 0.48 , $p = 0.033$), 12 hours (0.90 ± 0.40 vs. 1.65 ± 0.52 , $p < 0.001$), and 24 hours (0.28 ± 0.45 vs. 1.02 ± 0.57 , $p < 0.001$), with lower POST scores recorded in Group A (alkalinised lignocaine) compared to Group B (normal saline) (**Table 3, Figure 2**).

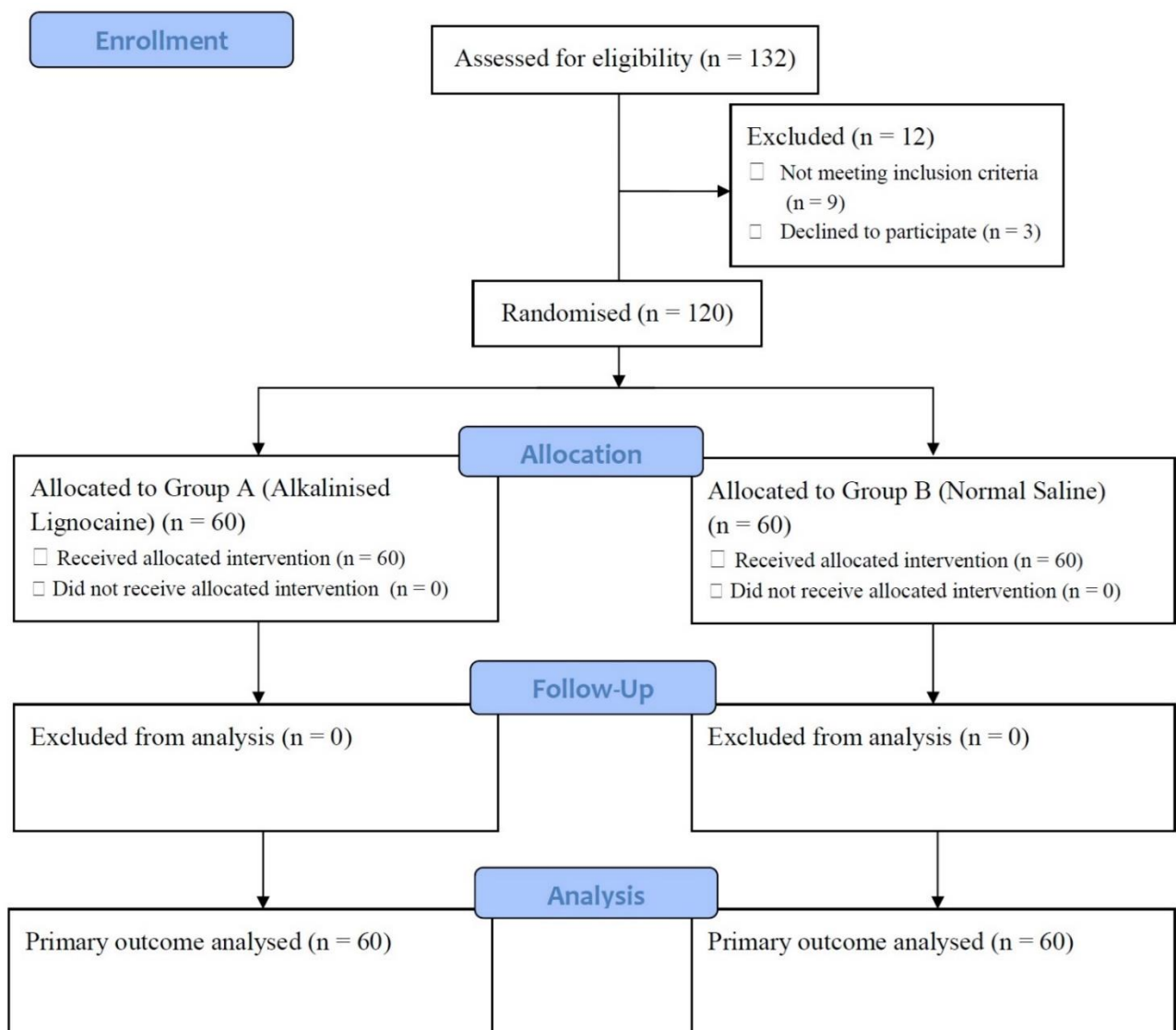


Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram, n = number of patients

Table 2: Comparison of demographic parameters between the groups

Parameter	Group		p value
	A (Alkalinised Lignocaine)	B (Normal Saline)	
Age (years) (Mean ± SD)	42.55 ± 12.80	44.88 ± 16.87	0.395
Weight (Kg) (Mean ± SD)	66.48 ± 7.04	66.32 ± 7.20	0.898
Height (cm) (Mean ± SD)	163.88 ± 6.39	163.58 ± 8.06	0.822
BMI (Kg/m ²) (Mean ± SD)	24.71 ± 1.77	24.84 ± 2.22	0.720
Gender			
Female n (%)	36 (60.0%)	27 (45.0%)	0.100
Male n (%)	24 (40.0%)	33 (55.0%)	

SD: Standard Deviation, BMI: Body mass index, n: Frequency, %: Percentage

Table 3: Comparison of postoperative sore throat (POST) scores between the groups

Time (h)	POST Score (Mean ± SD)		p value
	Group A (Alkalinised Lignocaine)	Group B (Normal Saline)	
0	2.23 ± 0.46	2.18 ± 0.47	0.559
2	1.72 ± 0.45	1.90 ± 0.48	0.033*
12	0.90 ± 0.40	1.65 ± 0.52	< 0.001*
24	0.28 ± 0.45	1.02 ± 0.57	< 0.001*

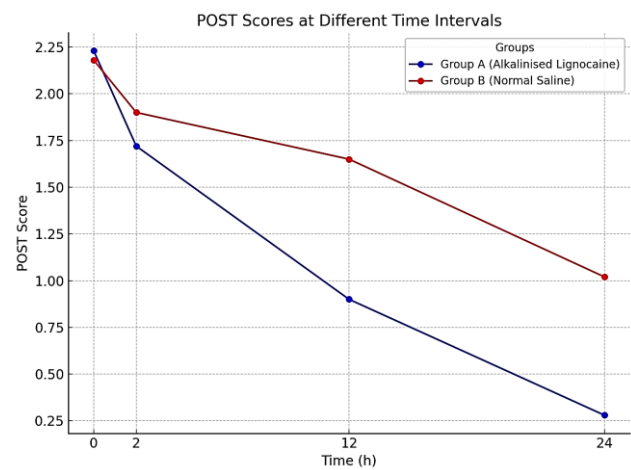


Figure 2: POST scores at different time intervals for both Groups

4. Discussion

Postoperative sore throat (POST) is a common but often underemphasised complication of endotracheal intubation using cuffed ETT. Although a self-limiting condition, it significantly impacts patient’s comfort and satisfaction in the postoperative period.¹³ The current study was aimed to evaluate the effect of intracuff alkalinised lignocaine versus NS on reducing POST in patients undergoing elective surgery under GA. The study’s findings indicate a statistically significant reduction in POST scores at 2, 12 and 24 h post extubation in patients whose ETT cuffs were inflated with alkalinised lignocaine compared to those whose ETT cuffs were inflated with NS.

Several mechanisms have been implicated in the development of POST, including mucosal irritation caused by the inflated ETT cuff, mucosal injury during airway instrumentation, mucosal dehydration, among others. Lignocaine mitigates these effects by exerting its protective anaesthetic action over the tracheal mucosa. Topical lignocaine may be administered through various methods. Previous work by Soltani et al. demonstrated the superiority of ETT cuff inflation by lignocaine over application of lignocaine jelly (2%) or spray (10%) on the cuff, as well as to spraying lignocaine (10%) on the laryngopharyngeal structures.¹⁴ Another advantage of using liquids like lignocaine to inflate ETT cuff is the inability of nitrous oxide to diffuse inside the liquid filled cuff. This prevents the over inflation of cuff during nitrous oxide-based anaesthesia, thereby keeping the cuff pressure and hence, POST under check. Alkalinised lignocaine offers advantage over non-alkalinised lignocaine by offering a faster onset, superior quality and longer duration of action.¹⁵ The pH of commercial preparations of lignocaine ranges from 3.9 to 6.5. Alkalinisation increases the lipid soluble fraction of lignocaine, leading to enhanced diffusion through barriers. Estebe J et al. reported a 60-fold increase in the fraction of lignocaine diffusing through the ETT cuff over a 6-hour period.¹⁶

Rajegowda S et al. conducted research on 400 patients undergoing elective surgery under GA. They randomly divided them into four groups of 100 patients each, and used air, normal saline, 4% lignocaine and 2% hydrocortisone to inflate ETT cuff, respectively. They observed significantly

lower incidence of sore throat in lignocaine group compared to other groups at 0, 6, 12 and 24 h interval.¹⁷ Rakhi T et al. compared ETT cuff inflation using saline, 2% lignocaine and 4% lignocaine in 3 randomised groups of 60 patients each and observed significantly less instances of POST in both, 2% and 4% lignocaine groups, as compared to normal saline at 0, 2, 4 and 24h intervals. No significant difference was observed between the two concentrations of lignocaine.¹¹ Sony S et al. conducted a study on 120 patients undergoing elective surgery under GA, randomising them in to two groups of 60 patients each. Normal saline was used for ETT cuff inflation in one group and 2% lignocaine in the other. They also reported similar results with less incidence of sore throat in lignocaine group at 0, 4, 8, 16 and 24h intervals.¹⁸ Nath P et al. compared cuff inflation with 2% lignocaine and normal saline in 200 patients receiving GA and observed less incidence of cough in the lignocaine group at the time of extubation.¹⁹

Consistent with previous studies, the present trial found that patients in the lignocaine group experienced significantly lower POST scores compared to the normal saline (NS) group at 2, 12, and 24 hours post-extubation. This supports the hypothesis that intracuff alkalinised lignocaine can reduce the incidence and severity of POST. However, an interesting observation in the current study was the lack of a significant difference in POST scores at the 0-hour interval, immediately after the patients were transferred to the Post-Anaesthesia Care Unit (PACU).

Several factors may explain this initial similarity between the two groups. In the immediate postoperative period, patients are often disoriented and uncomfortable due to the lingering effects of anaesthesia, which can amplify their perception of airway irritation. This heightened sensitivity to discomfort may result in uniformly high POST scores across both groups, thereby obscuring the early effects of lignocaine. Additionally, airway irritation could be exacerbated by the generalised discomfort experienced by patients during this phase, which is commonly accompanied by other postoperative symptoms such as throat dryness, hoarseness, and difficulty swallowing. As the anaesthetic effects wear off and patients regain orientation, the influence of psychological factors on their perception of postoperative discomfort diminishes. At this point, the protective effect of lignocaine becomes more evident, as reflected in the significant differences in POST scores observed at 2, 12, and 24 hours post-extubation.

The results of this study emphasise the importance of considering both the physiological and psychological factors that can influence the perception of postoperative symptoms. Future studies with more frequent postoperative assessments during the first few hours may offer additional insights into the early effects of intracuff alkalinised lignocaine in reducing POST.

The results of current study are further supported by findings from Wang et al., who demonstrated that inflating ETT cuff with 2% lignocaine reduces tracheal mucosal injury and postoperative airway complications compared to normal saline or air.²⁰ The proposed mechanism behind this benefit is that lignocaine diffuses out of the cuff and exerts a topical anaesthetic effect on the tracheal mucosa. This process alleviates irritation caused by cuff pressure and mechanical trauma during intubation and extubation. These findings not only align with the results observed in the present study but also shed light on the underlying mechanism by which lignocaine helps in preventing POST. By preventing mucosal injury and reducing irritation, lignocaine potentially offers a protective effect that is evident in the lower POST scores observed in our study, particularly at the later time intervals post-extubation.

While this study provides valuable insights, there are certain limitations which also need to be acknowledged. Firstly, the study was limited to ASA 1 and 2 adult patients undergoing elective surgeries. This restricts the generalisability of the results to paediatric or high-risk patients or patients undergoing emergency surgeries. Secondly, the study did not include long term follow up of the patients to assess the persistence of benefits or any long-term complications. Lastly, the study was conducted at a single centre, which may limit its applicability to populations with different geographical profile. Future multicentric studies with broader patient profile could provide more generalisable results.

5. Conclusion

Inflating endotracheal tube cuffs with alkalinised lignocaine significantly reduces postoperative sore throat when compared to normal saline in patients undergoing elective surgery under general anaesthesia. The simplicity, safety, efficacy, and cost-effectiveness of intracuff lignocaine make it a valuable strategy for improving postoperative airway comfort and enhancing patient satisfaction. Incorporating this practice into routine anaesthetic management could help reduce airway-related morbidity and contribute to improved perioperative outcomes.

6. Source of Funding

Nil.

7. Conflict of Interest

Nil.

8. Acknowledgement

Nil.

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