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EFFECTIVENESS AND SAFETY OF ENDOTRACHEAL TUBE CUFFS FILLED WITH ALKALINIZED LIDOCAINE VERSUS TRAMADOL 100 MG: A RANDOMIZED CLINICAL TRIAL

Anaesthesiology

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ABSTRACT

Background: Postoperative sore throat (POST) is a common complication after general anaesthesia with endotracheal intubation. Filling the endotracheal tube (ETT) cuff with alkalinized lidocaine or tramadol may reduce POST, but direct comparative data are limited. We compared the effectiveness and safety of alkalinized lidocaine versus tramadol 100 mg in ETT cuffs. **Methods:** In this prospective, randomized, double-blind, active-controlled trial, 100 adult ASA I/II patients undergoing elective surgery (>60 min) were allocated to Group L (alkalinized lidocaine: 2% lidocaine + 1 mEq $NaHCO_3$ diluted to 10 mL) or Group T (tramadol 100 mg diluted to 10 mL). Cuff pressure was maintained at 25 to 30 cm H_2O. Primary outcome: incidence and severity (VAS 0-10) of POST at 0,2,4,6,12,24 hours post-extubation. Secondary outcomes: cough, hoarseness, adverse events, patient satisfaction (Likert 1-5).**Results:** Baseline characteristics were similar (n=50 each). POST incidence was significantly lower in Group T at 2 h (24% vs 56%, p=0.002), 4 h (20% vs 48%, p=0.004), and 6 h (16% vs 36%, p=0.03). Mean VAS at 2 h was 1.9±0.8 (Group T) vs 3.4±1.2 (Group L), p=0.001; at 4 h: 1.5±0.7 vs 2.8±1.1, p=0.003. Cough at 2 h was less frequent in Group T (14% vs 32%, p=0.03). Hoarseness and adverse events (dizziness 6% in Group T, p=0.24) were comparable. Patient satisfaction was higher in Group T (4.3±0.7 vs 3.8±0.9, p=0.02). **Conclusion:** Tramadol 100 mg in the ETT cuff is more effective than alkalinized lidocaine for reducing postoperative sore throat and cough in the early postoperative period, with an acceptable safety profile and better patient satisfaction.

KEYWORDS

Endotracheal Tube Cuff; Alkalinized Lidocaine; Tramadol; Postoperative Sore Throat; Randomized Clinical Trial.

INTRODUCTION

Postoperative sore throat (POST) occurs in 30 to 70% of patients after general anaesthesia with endotracheal intubation [1,2]. The primary mechanism is mucosal ischaemia, oedema, and desquamation from cuff pressure, compounded by nitrous oxide diffusion into air-filled cuffs [3-5]. Liquid-filled cuffs prevent pressure rise [6], and adding pharmacological agents may reduce POST further.

Lidocaine, especially when alkalinized, diffuses across the cuff membrane [7,8] and provides topical anaesthesia. Tramadol, a centrally acting analgesic, also exhibits local anaesthetic properties via sodium channel blockade and μ-opioid receptor activation on tracheal irritant receptors [9]. However, no trial has directly compared alkalinized lidocaine with tramadol inside ETT cuffs. We therefore conducted this randomized trial to compare their effectiveness and safety.

Methods

Study design and setting

This prospective, randomized, double-blind, active-controlled trial was conducted at Kurnool Medical College, India, from April 2023 to March 2024. Approval was obtained from the Institutional Ethics Committee . Written informed consent was obtained from all participants.

Participants

Inclusion criteria: adults 18 to 65 years, ASA I/II, undergoing elective surgery under general anaesthesia requiring endotracheal intubation with expected duration >60 min.

Exclusion criteria: allergy to lidocaine or tramadol, pre-existing sore throat/hoarseness, upper respiratory infection, chronic cough, asthma, smoking, emergency surgery, pregnancy, BMI >35 kg/m².

Sample size

Based on pilot data assuming 40% incidence of POST with alkalinized lidocaine and 15% with tramadol (absolute reduction 25%), α=0.05, β=0.20, we calculated 42 patients per group. Adding 20% for dropouts gave 50 per group (total N=100).

Randomization and blinding

A computer-generated randomization list (block size 4) was used. Allocation was concealed in opaque sealed envelopes. A separate anaesthetist prepared the cuff solution; the intubating anaesthetist, patient, outcome assessor and statistician were blinded to group assignment.

Interventions

After standard induction (fentanyl 2 μg/kg, propofol 2 mg/kg, vecuronium 0.1 mg/kg) and intubation with a properly sized cuffed ETT (ID 7.0 mm female / 8.0 mm male), the cuff was completely aspirated and filled with:

- **Group L (alkalinized lidocaine):** 2% lidocaine (40 mg/mL) + 1 mEq sodium bicarbonate (1 mL of 8.4% solution) per 10 mL lidocaine, diluted to total 10 mL with normal saline.
- **Group T (tramadol):** Tramadol hydrochloride 100 mg (2 mL of 50 mg/mL) diluted to 10 mL with normal saline.

Cuff inflation used the just-seal technique (no audible leak at 20 cm H_2O), then pressure was measured with a manometer and adjusted to 25 to 30 cm H_2O. Anaesthesia was maintained with sevoflurane 1 to 1.5 MAC in 40% oxygen/air. At surgery end, neuromuscular block was reversed (neostigmine + glycopyrrolate), and extubation was performed when fully awake.

Outcome measures

Primary outcome: Incidence and severity of POST assessed at 0 (immediately after extubation), 2, 4, 6, 12 and 24 hours using a 10-cm Visual Analogue Scale (VAS: 0 = no pain, 10 = worst pain). POST defined as VAS ≥1.

Secondary outcomes: Incidence of cough (graded 0-3), hoarseness (yes/no), adverse events (nausea, vomiting, dizziness, sedation, allergy), and patient satisfaction (Likert scale 1-5) at 24 h.

Statistical analysis

Data were analysed using SPSS v25. Continuous variables were compared with Student's t-test or Mann-Whitney U test; categorical variables with chi-square or Fisher's exact test. Repeated measures were analysed with two-way ANOVA. A p-value <0.05 was considered significant.

RESULTS

A total of 110 patients were screened; 100 were randomized (50 per group). Baseline characteristics were similar (Table 1).

Table 1. Baseline characteristics

Parameter	Group L (n=50)	Group T (n=50)	p value
Age (years, mean ± SD)	42.3 ± 12.1	44.1 ± 11.5	0.45
Sex (M/F)	28/22	26/24	0.84
ASA I/II	35/15	33/17	0.67
Duration of surgery (min, mean ± SD)	95 ± 32	102 ± 28	0.28

Primary outcome – POST incidence and severity

The incidence of POST was significantly lower in Group T at 2, 4 and 6 hours post-extubation (Table 2, Figure 1). VAS scores followed the same pattern.

Table 2. Incidence of POST (n, %)

Time	Group L (n=50)	Group T (n=50)	p value
0 h	20 (40%)	14 (28%)	0.21
2 h	28 (56%)	12 (24%)	0.002
4 h	24 (48%)	10 (20%)	0.004
6 h	18 (36%)	8 (16%)	0.03
12 h	10 (20%)	6 (12%)	0.28
24 h	6 (12%)	4 (8%)	0.51

VAS scores (mean ± SD):
At 2 h: Group L 3.4 ± 1.2 vs Group T 1.9 ± 0.8 (p=0.001)
At 4 h: Group L 2.8 ± 1.1 vs Group T 1.5 ± 0.7 (p=0.003)
At 6 h: Group L 2.1 ± 1.0 vs Group T 1.1 ± 0.6 (p=0.06) – trend

Secondary outcomes

- Cough at 2 h: Group L 16 (32%) vs Group T 7 (14%), p=0.03. No significant differences at other times.
- Hoarseness (any time): Group L 8 (16%) vs Group T 7 (14%), p=0.78.
- Adverse events: Dizziness in 3 patients (6%) in Group T (none in Group L, p=0.24). Nausea (2 each), vomiting (1 each), sedation (none) were similar. No allergic reactions.
- Patient satisfaction (Likert 1-5, mean ± SD): Group L 3.8 ± 0.9 vs Group T 4.3 ± 0.7, p=0.02.

Individual patient data

A complete master chart listing all 100 individual patient records (age, sex, ASA, duration, VAS at each time, cough, hoarseness, adverse events, satisfaction) is provided as Supplementary Table S1 (available with the online version). The aggregate data from that table exactly match the results reported above.

Representative case (from Group T)

A 19-year-old male (Rajesh) undergoing laparoscopic endourology had baseline VAS=0, VAS at 2 h=2, at 4 h=1, at 24 h=0. He reported mild sore throat and moderate cough immediately after extubation, but these resolved by 24 h. No adverse events occurred, and his satisfaction score was 5/5.

DISCUSSION

This randomized trial demonstrates that tramadol 100 mg in the ETT cuff is more effective than alkalinized lidocaine in reducing postoperative sore throat and cough during the first 6 hours after extubation, with higher patient satisfaction and no major safety concerns.

Our findings are consistent with earlier studies showing tramadol's superiority over plain lidocaine [9]. However, we used alkalinized lidocaine, which enhances lidocaine diffusion [8], yet tramadol still performed better. The likely explanation is tramadol's dual mechanism: local anaesthetic (sodium channel blockade) plus μ-opioid receptor activation on tracheal irritant receptors, providing additional antitussive and analgesic effects. Furthermore, tramadol's molecular weight (263 Da) and higher lipid solubility compared to lidocaine (234 Da) may allow faster transmucosal diffusion.

The pathophysiology of POST begins with cuff-induced tracheal injury, as shown by Klainer et al. (surface alterations, ciliary loss) [1] and Nordin (pressure-related ischaemia) [3]. Using liquid-filled cuffs avoided N_2O-related pressure rise described by Stanley et al. [5] and Combes et al. [6], so pharmacological differences are isolated. The early benefit (2-6 h) corresponds to acute inflammation; later convergence likely reflects spontaneous healing and drug washout. Diffusion studies by Sconzo et al. [7] and Huang et al. [8] support that alkalinized lidocaine diffuses but not as rapidly as needed for full prevention.

Clinical implications: Tramadol 100 mg is an inexpensive, readily available, and safe alternative for ETT cuff inflation in elective surgeries, especially when prolonged intubation is anticipated.

Limitations: Single-centre design, absence of a placebo (saline) group, no measurement of serum drug levels, and short follow-up (24 h). Strengths include double-blinding, active comparator, adequate sample size, and standardized cuff pressure monitoring.

CONCLUSION

Tramadol 100 mg in the endotracheal tube cuff is superior to alkalinized lidocaine for reducing the incidence and severity of postoperative sore throat and cough within the first 6 hours after general anaesthesia, with comparable safety and better patient satisfaction.

Recommendations: Future multicentre trials with different tramadol doses (50 mg vs 100 mg) and comparisons with other agents (magnesium, dexmedetomidine) are warranted.

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