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Original Article

Anaesthesia Section

Effect of Alkalinised Lignocaine in Reinforced Endotracheal Tube Cuff on Postextubation Cough and Sore Throat during Prone Percutaneous Nephrolithotomy: A Randomised Controlled Trial

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ABSTRACT

Introduction: Reinforced flexometallic Endotracheal Tube (ETT) is preferred in prone surgeries. Their large outer diameter, stylet use, and position related cuff pressure changes and laryngeal oedema may increase the risk of postoperative airway complications.

Aim: To evaluate the effect of intracuff alkalinised lignocaine on postextubation cough, and sore throat in patients undergoing Percutaneous Nephrolithotomy (PCNL) in prone position.

Materials and Methods: This randomised controlled study included 140 patients posted for PCNL at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh, India and were randomly allocated into two groups: intracuff air (Group A) and alkalinised lignocaine (Group L). Postextubation cough was assessed immediately, Postoperative Sore Throat (POST) and hoarseness were assessed postoperatively at one hour and 24 hours. Statistical analysis was done using Statistical Package for the Social Sciences 23.0 with Fisher's exact test and Independent t-test, p-value of <0.05 considered statistically significant.

Results: Demographic variables such as age, sex distribution, height, weight were comparable between the groups with p-value of >0.05. Mean duration of anaesthesia was comparable (114.6±13.44 minutes in Group A vs 113.71±13.95 minutes in Group L). There was significant reduction in postextubation cough in Group L compared to Group A (No cough: 61.4% vs 8.6%, p-value<0.001). At one hour postoperatively the incidence of sore throat was significantly lower in Group L than Group A (No sore throat: 75.7% vs 37.1%, p-value<0.001). Hoarseness was comparable between the groups.

Conclusion: Intracuff alkalinised lignocaine in reinforced endotracheal tube significantly reduced the incidence of postextubation cough, early POST in patients undergoing PCNL in prone position. This intervention reduces the postoperative airway morbidity, so it may therefore be considered an useful strategy for reducing postoperative airway related complications.

Keywords: Airway, Intracuff, Local anaesthetic, Positioning, Postoperative complication

INTRODUCTION

When administering general anaesthesia, tracheal intubation remains the standard technique for securing the airway of patients positioned prone for surgery [1]. Reinforced flexometallic are preferred in prone position surgeries because of their kink resistant coiled design and flexibility during positioning and extreme angulation of tube in prone position for maintaining the patency of airway [2]. However, despite large outer diameter, stylet use for intubation, may exert increased pressure on tracheal mucosa. Prone positioning has been shown to alter endotracheal tube cuff pressure due to thoracic compression and neck movements [3-5]. These factors may contribute to an increased incidence of postoperative airway complication. Postextubation cough, POST and hoarseness are among the most frequently reported airway complication after endotracheal intubation with incidence reported from 30-70% depending upon the intubation duration, patient position and cuff pressure [6-8]. These symptoms can significantly affect patient comfort, delay recovery and alter haemodynamic responses [9,10]. Various methods have been investigated to reduce postoperative airway complication. Arabkhazaie A et al., reported optimisation of ETT cuff pressure reduces the incidence of POST and hoarseness when maintained within the recommended range [7]. Park JH et al., found a significant reduction in POST in patients receiving intravenous dexamethasone during prone position surgeries [11]. Agarwal A et al., reported a significant reduction in POST with benzydamine hydrochloride gargle compared to aspirin and placebo due to its local analgesic and anti-inflammatory effect [12].

Intravenous lignocaine has also been evaluated by Yang SS et al., with meta-analyses and reported significant reduction in cough, sore throat because of its systemic analgesic and airway reflex suppressing effect [6]. Intracuff lignocaine has been widely evaluated because it provides the local anaesthetic effect at tracheal mucosa through diffusion of the drug across endotracheal tube cuff [13,14]. Estebe JP et al., showed that alkalanisation of lignocaine increases its non ionising effect which enhances diffusion across the cuff membrane [15]. Gaur P et al., reported 38% reduction in postextubation cough and 20% reduction in POST with intracuff alkalinised lignocaine when compared to air [16]. Meta-analyses by Chen ZX et al., and Peng F et al., reported reduction in postextubation cough by 60-70% and early POST by 65-80% in patient intubated with Polyvinyl Chloride (PVC) ETT using intracuff lignocaine [13,14].

While this approach has been described for conventional PVC tubes, with no prospective studies evaluating the use of intracuff alkalinised lignocaine with reinforced ETT tubes in prone position surgeries. Therefore, the present study was designed to evaluate the efficacy of intracuff alkalinised lignocaine in preventing postextubation cough, POST, hoarseness in patient undergoing

PCNL in prone position under general anaesthesia. The primary objective was to compare the incidence of postextubation cough between alkalinised lignocaine and air filled ETT cuff. The secondary objectives were to compare POST and hoarseness.

MATERIALS AND METHODS

This randomised controlled study was conducted at Department of Anaesthesiology, Sanjay Gandhi Postgradute Institute of Medical Sciences, Lucknow, Uttar Pradesh, India from February 2025 to November 2025. The study was conducted in single blinded manner, patients and observer assessing the outcome were blinded for group allocation. The study was approved by Institute Ethics committee vide approval number IEC code: 2024-243-IP-140, dated 22nd January 2025 and was registered with Clinical Trial Registry India (CTRI) vide registration number CTRI/2025/02/079948, Registered on: 04/02/2025. This study was conducted using the principles of the Declaration of Helsinki, 2013 and good clinical practice. Written informed consent from patients for participation in the study and use of patient data for research and educational purpose was obtained.

Inclusion criteria: Adult patients belonging to American Society of Anaesthesiologist (ASA) physical status 1 and 2 aged 18 to 65 years, patient scheduled for elective PCNL in prone position requiring Reinforced ETT for administering general anaesthesia with Cormack Lehane grading of 1 and 2 (a/b) were included in the study.

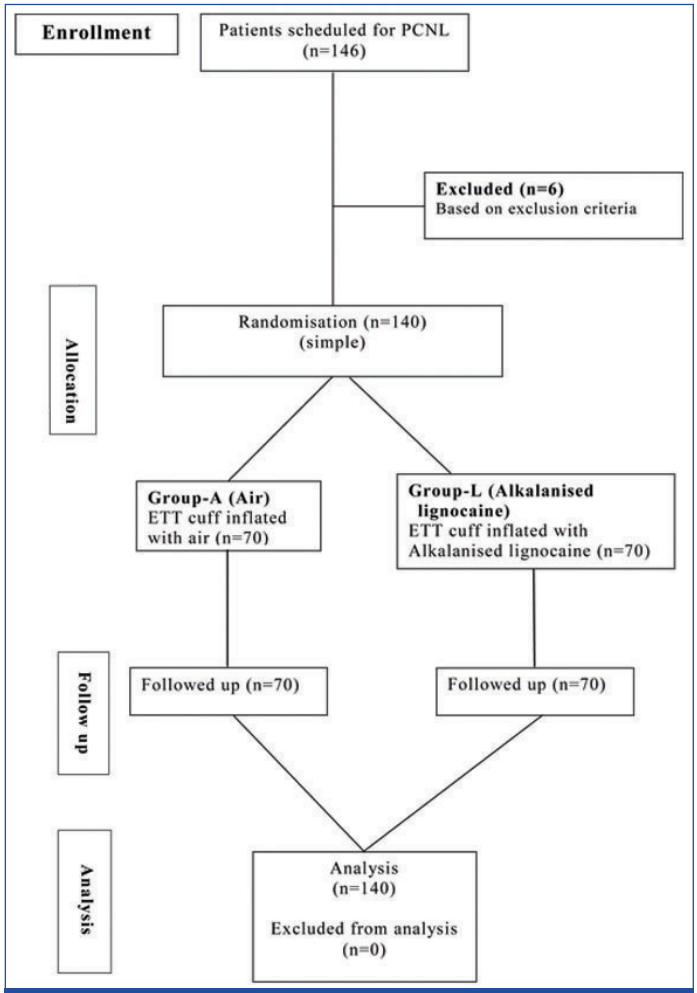
Exclusion criteria: Patients with ASA physical status 3 and 4, anticipated difficult intubation, active upper respiratory tract infections, bronchial asthma, Chronic Obstructive Pulmonary Disease (COPD), chronic cough, previous laryngeal or tracheal surgery, allergies to local anaesthetics, impaired cognitive ability and gastric tube insertion were excluded from the study.

Sample size calculation: The sample size was calculated using the standard two-proportion Z-test formula: $n=\{(Z_{\alpha/2}+Z\beta)^2\times\{p_1(1-p_2)+p_2(1-p_2)\}\}/(p_1-p_2)^2$, $Z_{\alpha/2}=1.96$ for a two-tailed significance level of 5% ($\alpha=0.05$), and $Z\beta=0.84$ for 80% statistical power ($\beta=0.20$) [17]. Based on the observed effect sizes reported by Gaur P et al., specifically a 38% difference in postoperative cough incidence ($p_1=0.54$ for the air group versus $p_1=0.16$ for the lignocaine group) and a 20% difference in POST at one hour incidence ($p_1=0.26$ versus $p_2=0.06$) the calculated sample size requirements were 25 patients per group for the cough outcome and 53 patients per group for the POST outcome, respectively [16]. During the study timeline, 70 patients were recruited in each group. A total of 146 were assessed for eligibility, six were excluded from study because of more than two attempt was required for intubation. So, 140 patients were enrolled and completed the study.

Study Procedure

All patients scheduled for surgery were evaluated by the attending anaesthesiologist a day before surgery premedication and Nil Per Oral (NPO) instruction were given according to standard protocol. On the day of surgery, patients were taken to operation theatre standard monitors baseline heart rate, blood pressure and oxygen saturation were connected and values recorded. Anaesthesia was induced with intavenous propofol (2 mg/kg), Fentanyl (2 µg/kg) with 100% oxygen, muscle relaxation was achieved with i.v. vecuronium 0.1 mg/kg followed by endotracheal intubation with an inner diameter of 7.0 mm or 8.0 mm reinforced ETT for females and males respectively. After intubation tracheal tube was inflated with air once and patient positioned from supine to prone. After prone positioning tracheal tube cuff was deflated and inflated with air adjusting the cuff pressure to 20 to 25 cm H_2O by Ambu® Cuff pressure gauge; Ambu Inc, Columbia, MD, USA, and the amount of air used for inflation was noted.

Simple randomisation using Microsoft Excel was employed to allocate patients to Group A or Group L, minimising selection bias by ensuring that each patient had an equal probability of assignment to either group. The random allocation sequence was generated by an anaesthesiologist who was not involved in patient enrolment, intraoperative management, or outcome assessment [Table/Fig-1].



[Table/Fig-1]: CONSORT flow chart of the trial.

In Group A cuff remained filled with air, whereas in Group L cuff was deflated and reinflated with equal volume of alkalnised lignocaine (19 mL 2% lignocaine: 1 ml 8.4% sodium bicarbonate) [18].

In both the groups anaesthesia was maintained with 1.5-2.5% sevoflurane, with mixture of air and oxygen fraction of 50% at a fresh gas flow of 2L/minute through closed circuit. Respiratory rate and tidal volume was adjusted to maintain end tidal carbon dioxide between 35 to 45 mmHg. After the completion of procedure patient was positioned to supine, residual neuromuscular blockade was antagonised with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg, followed by tracheal extubation after confirming adequate reversal. After assessing for postextubation cough patients were shifted to postanaesthesia care unit for observation and postoperative analgesia was maintained with intravenous paracetamol. In both the groups, postextubation cough was assessed immediately after extubation and upto five minutes thereafter. POST, hoarseness was recorded at one and 24 hours postoperatively by a blinded observer.

Cough was graded using modified Minogue scale [19] where

- Grade 1: No coughing or muscular stiffness,
- Grade 2: Coughing once or twice, or transient cough response to removal of tracheal tube that resolved with extubation,
- Grade 3: ≤ 3 coughs lasting 1~2 second, or total duration of coughing last ≤ 5 seconds,

- Grade 4: ≥4 coughs with each lasting > 2 seconds, total duration of coughing last > 5 seconds.

POST was graded as:

- Grade 0: No sore throat,
- Grade 1: Mild sore throat (patient complaining of mild irritation, scratching, and pain himself),
- Grade 2: Moderate sore throat (patient complaining of irritation, scratching, and pain himself),
- Grade 3: Severe sore throat (patient complaining of severe pain, difficulty in swallowing, coughing, or in distress) [12].

Hoarseness as:

- Grade 0: No hoarseness,
- Grade 1: Mild hoarseness (noticed by the patient only),
- Grade 2: Moderate hoarseness (noticed at the time of the interview by the personnel),
- Grade 3: Aphonia (inability to speak) [11]. Bias was minimised by standard anaesthesia protocol, uniform tube size, cuff pressure monitoring, blinding of outcome assessment and outcomes were evaluated by validated scoring system. The following parameters were recorded:

1. Demographic data (age, sex, height and weight)
2. Duration of anaesthesia, ASA (American Society of Anaesthesiologists) physical status and Cormack Lehane grading.
3. Postextubation cough immediately and upto five minutes of extubation
4. POST and hoarseness at one hour and 24 hours postoperatively

STATISTICAL ANALYSIS

Data was analysed using Statistical Package for the Social Sciences version 23.0. Categorical variables severity grades of postextubation cough, POST, and hoarseness were summarised as frequencies and percentages, and comparisons between Group A and Group L were performed using the Fisher's exact test. Continuous variables, including demographic parameters and duration of surgery, were expressed as mean±standard deviation and compared using the Independent t-test. A p-value <0.05 was considered statistically significant.

RESULTS

Demographic parameters including age, sex, height, weight, duration of anaesthesia, ASA status and Cormack Lehane grading were comparable among the groups, there was no significant difference [Table/Fig-2].

Postextubation cough: Following extubation and upto five minutes thereafter, the severity and incidence of cough was significantly lower in Group L compared to Group A, with higher proportion of cough grade 2 in Group A (p-value <0.001) [Table/Fig-3].

Postoperative Sore Throat (POST): POST at one hour was significantly (p-value <0.001) lower in Group L reporting no sore throat in 75.7% compared to 37.1% in Group A. Grade 1 sore throat was more common in Group A (55.7%) compared to Group L (24.3%). Grade 2 sore throat was only observed in Group A (7.1%). At 24 hours POST largely resolved in both the groups, with no significant difference (p-value =0.496) [Table/Fig-4].

Hoarseness: Hoarseness at one hour was not significantly (p-value =0.062) different between the groups though less frequent in Group L (1.4%) compared to Group A (10%) of Grade 1 [Table/Fig-5]. By 24 hours hoarseness incidence was similar in both the groups with nearly all patient reporting no hoarseness (p-value=0.496) [Table/Fig-5].

Variables	Group A	Group L	p-value
Age (years)			
Mean±SD	43.48±10.96	41.41±12.27	0.29
Sex n (%)			
Female	31 (44.3)	39 (55.7)	0.23
Male	39 (55.7)	31 (44.3)	
Height (cm)			
Mean±SD	166.87±7.87	165.98±7.61	0.50
Weight (kg)			
Mean±SD	69.60±9.13	68.47±8.99	0.46
Duration of Anaesthesia (minutes)			
Mean±SD	114.60±13.44	113.17±13.95	0.53
ASA physical status n (%)			
ASA I	40 (57.1)	48 (68.6)	0.22
ASA II	30 (42.9)	22 (31.4)	
Cormack Lehane Grading n (%)			
Grade 1	57 (81.4)	50 (71.4)	0.06
Grade 2a	8 (11.4)	18 (25.7)	
Grade 2b	5 (7.2)	2 (2.9)	

[Table/Fig-2]: Demographic characteristics.
SD: Standard deviation; Cm: Centimeters; kg: kilogram; ASA: American Society of Anaesthesiologists

Grading	Group A	Group L	p-value
Grade 1	6 (8.6%)	43 (61.4%)	<0.001
Grade 2	53 (75.7%)	27 (38.6%)	
Grade 3	11 (15.7%)	0 (0%)	
Grade 4	0	0	

[Table/Fig-3]: Cough grade after extubation and upto 5 minutes.
p-value <0.05 was considered statistically significant

Grading	Group A 1-Hour	Group L 1-Hour	Group A 24-Hour	Group L 24-Hour
Grade 0	26 (37.1%)	53 (75.7%)	68 (97.1%)	70 (100%)
Grade 1	39 (55.7%)	17 (24.3%)	2 (2.9%)	0 (0%)
Grade 2	5 (7.1%)	0	0	0
Grade 3	0	0	0	0
p-value	<0.001		0.496	

[Table/Fig-4]: Postoperative sore throat at 1 and 24-hour.
p-value <0.05 was considered statistically significant

Grading	Group A 1-Hour	Group L 1-Hour	Group A 24-Hour	Group L 24-Hour
Grade 0	63 (90%)	69 (98.6%)	68 (97.1%)	70 (100%)
Grade 1	7 (10%)	1 (1.4%)	2 (2.9%)	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
p-value	0.062		0.496	

[Table/Fig-5]: Hoarseness at 1 and 24-hour.
p-value <0.05 was considered statistically significant

DISCUSSION

Prone position surgeries under general anaesthesia with ETT are at increased risk of airway morbidity including postextubation cough, sore throat and hoarseness because position changes from supine to prone and repositioning back to supine which causes endotracheal tube displacement and change in cuff pressure leading to mucosal trauma [3,20,21].

This randomised controlled study aimed to evaluate the role of intracuff alkalinised lignocaine in reducing airway morbidity in patient undergoing PCNL in prone position with reinforced endotracheal tube. The present study demonstrated the significant reduction in

incidence and severity of postextubation cough and early POST suggestive of attenuation of airway reflexes triggered by the ETT and prone positioning. Conversely, the incidence of hoarseness at one hour was comparable between the groups, although 10% of patients in intracuff air group exhibited mild hoarseness. By 24 hours POST and hoarseness resolved nearly in all the patients.

In this study, in lignocaine group 61.4% of patients had no cough compared with only 8.6% of patients in air group. Present study finding are consistent with meta-analyses done by Chen ZX et al., of 12 radomised controlled trial included 1,175 patients reported 62% reduction in postextubation cough with intracuff alkalinised lignocaine compared to air and saline filled cuff [13]. Similarly, evidence based systemic review by Wallen SL et al., evaluated three RCTs and three meta-analysis found that intracuff alkalinised lignocaine reduce postextubation cough by 62-69% [22]. Although these studies were conducted with PVC tube in supine position, present study study showed the comparable effect in prone position with reinforced ETT extending the applicability in different clinical setting.

The present study showed significant reduction in early POST at one hour in lignocaine group while the difference was comparable at 24 hours. These findings were consistent with Chen ZX et al., reported 81% reduction in POST at 24 hour and signnificant reduction in early POST which was assessed by visual analogue scale [13]. Wallen SL et al., observed 69% and 91% reduction in early and late POST respectively [22]. The difference in present study at 24 hour may be because of self-limiting nature of sore throat and use of standardised cuff pressure monitoring.

In this study, there was no significant difference in hoarseness at one or 24 hour between the group while lower incidence in the lignocaine group (Grade 1 hoarseness at one hour: 1.4% in Group L vs 10% in Group A). Hoarseness is primarily caused by the mechanical trauma to vocal cord and laryngeal structure leading to mucosal oedema and vocal fold congestion rather than tracheal mucosal irritation alone which is also affected by laryngoscopy technique, tube size and number of intubation attempts [23]. Due to multiple factors which may act individually, differences in hoarseness outcome may occur.

Estebe JP et al., found that alkalinisation increases the non ionised fraction of lignocaine, enhancing its diffusion through ETT cuff which significantly reduces the postextubation cough and sore throat because of direct local anaesthetic action on tracheal mucosa, also allowing nearly ten-fold reduction in the effective dose of lignocaine improving both efficacy and safety [15]. For these advantages alkalinised lignocaine was adopted for cuff inflation in one group to be compared with standard method of inflation.

Previous studies evaluating intracuff lignocaine have been done in supine position using standard PVC ETT [13,14,16,18]. In contrast this study was done in patients undergoing PCNL in prone position using reinforced ETT.

Limitation(s)

Plasma concentration of lignocaine was not estimated and diffuses across the cuff. Cuff pressure after inflation with alkalinised lignocaine could not be measured by the manometer. Accurate evaluation of volume of lignocaine deflated at the time of extubation was not done.

CONCLUSION(S)

Intracuff alkalinised lignocaine in reinforced ETT significantly reduces the incidence of postextubation cough and early POST when compared to intracuff air in patients undergoing PCNL in prone position under general anaesthesia. The intervention was not associated with higher incidence of hoarseness. Findings of this study supports the use of intracuff lignocaine in reienforced endotracheal tube to reduce the postoperative airway morbidity in prone surgeries.

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