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Original Research Article

A PROSPECTIVE RANDOMISED CONTROL STUDY ON INTRACUFF ALKALIZED LIGNOCAINE REDUCES SEDATIVE/ANALGESIC REQUIREMENTS FOR MECHANICALLY VENTILATED PATIENTS IN A TERTIARY CARE HOSPITAL

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Abstract

Background: Endotracheal tube (ETT) is a source of discomfort and pain in postoperative mechanically ventilated intensive care unit (ICU) patients who have to keep the ETT for a long time. Endotracheal tube discomfort is primarily caused by cuff irritation that enhances airway secretions, exacerbating cough and producing more discomfort. Sedatives and analgesics are usually administered to keep the patients comfortable, especially in the first few postoperative days. **Materials and Methods:** A prospective randomised control study was conducted to evaluate the effect of intracuff alkalinised lidocaine on sedative/analgesic requirements for mechanically ventilated patients in a tertiary care hospital. Fifty patients were included in the study and were randomly assigned to two groups: Group A (intervention group) received intracuff alkalinised lidocaine, and Group B (control group) received normal saline. The primary outcome was the total dose of propofol and fentanyl required during the first 24 hours of mechanical ventilation. Secondary outcomes included the frequency and severity of cough and the number of ineffective triggering events. **Result:** There was a significant reduction in the total dose of propofol and fentanyl required in the intervention group compared to the control group ($P < 0.001$). The frequency and severity of cough were also significantly lower in the intervention group ($P < 0.001$). The number of ineffective triggering events was also significantly lower in the intervention group ($P < 0.001$). **Conclusion:** These results suggest that intracuff alkalinised lidocaine can reduce sedative/analgesic requirements and improve patient-ventilator interaction in mechanically ventilated patients.

INTRODUCTION

Endotracheal tube (ETT) is a source of discomfort and pain in postoperative mechanically ventilated intensive care unit (ICU) patients who have to keep the ETT for a long time. Endotracheal tube discomfort is primarily caused by cuff irritation that enhances airway secretions, exacerbating cough and producing more discomfort.[1,2] Sedatives and analgesics are usually administered to keep the patients comfortable, especially in the first few postoperative days. Hans Von Euler-Cheplin discovered lignocaine, and isogramine was synthesised by Holger Erdtman and Nils Lofgren. Bengt Lundqvist found it to be active and longer lasting than procaine.[3] Lignocaine has many different clinical uses; Lignocaine transdermal patch (Lidoderm) is used for relief of pain associated with post-herpetic neuralgia, an oral patch (Dentipatch) is also available for application to accessible mucous membranes of the mouth before superficial dental procedures.[4]

The combination of lignocaine (2.5%) and prilocaine (2.5%) in an occlusive dressing (EMLA) is used as an anaesthetic agent before venipuncture, skin graft harvesting, and infiltration of anaesthetics into genitalia. Other uses of lignocaine include; the treatment of Cardiac dysrhythmias, Ventricular fibrillation, a 5% ointment and 2% jelly for surface application and lubrication of endotracheal tube and oscopy instruments. It is given topically on the cornea, and it causes mydriasis, vasoconstriction and cycloplegia. Used in the management of neonatal convulsions and for the treatment of chronic pain syndrome in adults, it also possesses anti-inflammatory and anti-thrombotic activity.[5,6]

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Guedel experimented with rubber tube items to construct the first endotracheal tube cuff 1926. The cuff should completely seal the trachea and prevent oropharyngeal secretions from entering the trachea, allowing adequate perfusion of tracheal mucosa.[7] Usage of Lignocaine hydrochloride with or without the addition of sodium bicarbonate (i.e., alkalisation) for inflating the endotracheal tube cuff instead of air has been studied during general anaesthesia.[2] Continuous diffusion of intracuff Alkalized lignocaine across the cuff wall, anaesthetising the tracheal mucosa, and reduction in the ETT-induced emergence phenomena have been documented. The present study analyses the effect of intracuff instillation of Alkalized lignocaine instead of air on the analgesic requirement for postoperative patients on ventilator support and monitors the patient-ventilator interaction.

MATERIALS AND METHODS

This prospective randomised control study was conducted at the Institute of Anesthesiology and critical care, Madras Medical College, Chennai, for three months. The study protocol was approved before the commencement of the study by the Institutional Ethics Committee, and informed consent was obtained from all the patients.

Inclusion Criteria

Patients of age 18 years and above, patients with body mass index (BMI) < 35 kg/ m2, American Society of Anesthesiology physical status: I, II, III, and patients posted for both elective and emergency surgery were included.

Exclusion Criteria

Post-cardiac arrest patients, patients with ventilation through a tracheostomy, a history of seizures, pregnant women and other neurological deficits were excluded.

Fifty patients were included (25 in ETT Cuff and Alkalized Lignocaine Group and 25 in ETT Cuff and Normal Saline Group). Patients in group A (Intervention group) were administered 2% lignocaine with 8.4% sodium bicarbonate (Alkalized Lignocaine) at a ratio of 1:1ml to inflate the ETT cuff before connecting to the ventilator to maintain an intra-cuff pressure of 20-25mmHg. Patients in group B (Control group) were administered normal saline to inflate the ETT cuff, who were also connected to the ventilator.

Endotracheal tubes with 7-7.5 mm inner diameter were used for women and 7.5-8mm for men. Both patients were connected to a ventilator on Synchronised Intermittent Mandatory ventilation (SIMV). The ventilator settings were adjusted to obtain a tidal volume of 6-8ml/kg and delivered with an inspiratory flow rate of ≥60 l/min. Positive End Expiratory Pressure (PEEP) was fixed to maintain PaO2 >90mmHg with FiO2 <0.6. A Fentanyl infusion of 75µg/hr was given to the patients as a postoperative analgesic to maintain a score of <5 on the Behavioral Pain Scale (BPS). The level of analgesia was monitored hourly using Behavioral Pain Scale. If the score was ≥ 5 (outside the target level), the patients were administered Fentanyl bolus 25µg and were monitored. For each patient in both the groups, the control (Group A) and intervention (Group B), the number of bolus doses of fentanyl required for the first 24 hours was recorded and compared between both groups.

This Behavioral Pain Scale and scoring system assesses three aspects of a patient's condition: fascial expression, upper limb movements, and compliance with mechanical ventilation. The scores range from 1 to 4, with higher scores indicating more severe symptoms. For facial expression, a score of 1 represents a relaxed expression, while a score of 4 indicates grimacing or severe facial tightening. Regarding upper limb movements, a score of 1 means no movements, while a score of 4 indicates permanent retraction or limited mobility. Regarding compliance with mechanical ventilation, a score of 1 suggests that the patient can tolerate movement during ventilation. A score of 4 means the patient cannot control ventilation or is struggling with the ventilator.

Statistical Analysis

The data were entered into MS Excel and analysed by using SPSS. The data were presented in frequency and percentage. The chi-square, Independent T, and Fisher Exact tests were used to compare categorical variables, and a p-value of <0.05 was considered statistically significant.

RESULTS

The study population included fifty postoperative patients who required ventilator support.

The majority of the ETT Cuff + Alkalized Lignocaine group patients belonged to the 41-60 years age class interval (n=14, 56%) with a mean age of 44.88 years, and this also includes the patients belonging to the female gender class interval (n=13, 52%). In the ETT Cuff + Normal Saline group patients, the majority belonged to the same age class interval (n=14, 56%) with a mean age of 45.32 years and the same gender class interval (n=13, 52%).

Patients in the 151-160 cms height class interval (n=9, 36%) with a mean height of 148.80 cm were a large part of the ETT Cuff + Alkalized Lignocaine group. In the ETT Cuff + Normal Saline group patients, the majority belonged to the same height class interval (n=8, 32%) with a mean height of 148 cm.

Patients in the ETT Cuff + Alkalized Lignocaine group, with a mean weight of 55.08 kg, belonged to the 51–60 kg weight class interval (n=13, 52%). Patients in the ETT Cuff + Normal Saline group, with a mean weight of 55.48 kg, tended to fall into the same weight class interval (n=12, 48%).

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Most patients in the ETT Cuff + Alkalized Lignocaine group (n=12, 48%) had an average BMI of 25.00, placing them in the overweight BMI class range. Most patients in the ETT Cuff + Normal Saline group (n=13, 52%) had a mean BMI of 25.08 and belonged to the same BMI class interval.

The mean total Fentanyl dose in patients in the ETT Cuff + Alkalized Lignocaine group was 40 micrograms. The mean total dose of fentanyl in the ETT Cuff + Normal Saline group is 71 micrograms, which is statistically significant.

The mean cough incident measurement in the ETT Cuff + Normal Saline group is 5.04 times. The average number of cough incidents per patient in the ETT Cuff + Alkalized Lignocaine group was 3.32 times. The ETT Cuff + Alkalized lignocaine group had a lower mean cough incident measurement than the ETT Cuff + Normal Saline group, which is statistically significant.

In patients with ETT Cuff + Alkalized Lignocaine group, the mean ineffective trigger measurement was 3.12 times. In ETT Cuff + Normal Saline group, the mean ineffective trigger measurement is 4.96 times. The decreased mean ineffective trigger measurement in ETT Cuff + Alkalized Lignocaine group compared to the ETT Cuff + Normal Saline group, which is statistically significant. [Table 1]

Table 1: Frequency distribution for numeric variables with Independent T-test analysis

Variables		ETT Cuff + Alkalized Lignocaine N=25	Mean	SD	ETT Cuff + Normal Saline N=25	Mean	SD	P-value
Age Distribution (Years)	≤ 20	2 (8)	44.88	13.39	1 (4)	45.32	12.52	0.905
	21-40	8 (32)			9 (36)			
	41-60	14 (56)			14 (56)			
	> 60	1 (4)			1 (4)			
Height Distribution (Cms)	≤ 140	7 (28)	148.8	10.48	8 (32)	148	10.87	0.792
	141-150	6 (24)			6 (24)			
	151-160	9 (36)			8 (32)			
	161-170	3 (12)			3 (12)			
Weight Distribution (Kgs)	≤ 40	1 (4)	55.08	7.27	1 (4)	55.48	7.7	0.851
	41-50	6 (24)			6 (24)			
	51-60	13 (52)			12 (48)			
	61-70	5 (20)			6 (24)			
BMI Distribution	Underweight (≤ 18.49)	0 (0)	25	2.84	0 (0)	25.08	2.84	0.921
	Normal (18.50 to 24.99)	11 (44)			10 (40)			
	Overweight (25 to 29.99)	12 (48)			13 (52)			
	Obese	2 (8)			2 (8)			
Total Fentanyl Dose (Micrograms)	25	15 (60)	40	20.41	2 (8)	71	21.26	0.000
	50	5 (20)			5 (20)			
	75	5 (20)			13 (52)			
	100	0 (0)			5 (20)			
Cough Incident	≤ 3 times	16 (64)	3.32	1.22	2 (8)	5.04	1.31	0.000
	4-5 times	7 (28)			14 (56)			
	6-7 times	2 (8)			9 (36)			
Ineffective Trigger	≤ 3 times	17 (68)	3.12	1.3	4 (16)	4.96	1.34	0.000
	4-5 times	7 (28)			12 (48)			
	6-7 times	1 (4)			9 (36)			

Table 2: Frequency Distribution for categorical variables with Fisher Exact analysis

Variables		ETT Cuff + Alkalized Lignocaine N=25	ETT Cuff + Normal Saline N=25	P-value
Gender Distribution	Male	12 (48)	12 (48)	1.000
	Female	13 (52)	13 (52)	
ASA Classification	ASA II	20 (80)	19 (76)	0.748
	ASA III	5 (20)	6 (24)	

Most of the patients in the ETT Cuff + Alkalized Lignocaine group (n=20, 80%) fell within the ASA II class interval. Most patients in the ETT Cuff + Normal Saline group (n = 19, or 76%) belonged to the same ASA class interval. There is no significant difference in gender and ASA classifications between the groups.

Table 3: Frequency distribution for heart rate and blood pressure with independent T-Test analysis

Heart Rate				Systolic Blood Pressure			Diastolic Blood Pressure		
Rate	ETT Cuff + Alkalized Lignocaine N=25	ETT Cuff + Normal Saline N=25	P value Unpaired t-Test	ETT Cuff + Alkalized Lignocaine N=25	ETT Cuff + Normal Saline N=25	P value Unpaired t-Test	ETT Cuff + Alkalized Lignocaine N=25	ETT Cuff + Normal Saline N=25	P value Unpaired t-Test
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
0 hr	75.88	76.8	0.738	118.6 (13.92)	123.4 (12.41)	0.204	72.8 (7.46)	78.56	0.011

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	(8.66)	(10.58)						(8.01)	
1 hr	73.4 (7.08)	78.92 (9.54)	0.025	119.08 (12.7)	123.44 (12.65)	0.230	73.96 (6.12)	80.2 (7.62)	0.003
2 hr	75.92 (7.8)	81.76 (8.87)	0.017	121.52 (13.21)	126.12 (13.36)	0.227	74.44 (6.44)	80.24 (8.62)	0.010
3 hr	77.36 (8.18)	82.44 (9.12)	0.044	124.16 (11.96)	127.48 (11.26)	0.317	76.12 (6.13)	83.12 (7.89)	0.001
4 hr	76.12 (7.81)	81.6 (8.32)	0.020	122.48 (11.25)	127.88 (9.49)	0.053	75.56 (7.07)	81.72 (5.31)	0.001
5 hr	75.44 (8.32)	80.72 (7.76)	0.025	124.2 (9.7)	121.52 (24.73)	0.617	76.12 (7.3)	80.88 (5.64)	0.013
6 hr	77.24 (7.5)	81.84 (6.52)	0.025	123.6 (9.3)	127.6 (9.83)	0.146	76.2 (5.95)	81.72 (6.45)	0.003
8 hr	75.88 (7.93)	80.52 (7.93)	0.044	123.16 (9.91)	125.84 (10.55)	0.359	74.68 (6.85)	81.12 (5.33)	0.001
10 hr	75.08 (7.94)	80.12 (6.65)	0.019	124.36 (8.63)	127.44 (9.19)	0.228	75.2 (6.95)	82.08 (6.18)	0.001
12 hr	75.16 (6.86)	79.64 (6.67)	0.023	124.12 (9.2)	124.92 (9.47)	0.763	75.48 (7.95)	79.32 (6.12)	0.062
16 hr	75.24 (8.01)	79.72 (6.39)	0.034	124 (7.31)	127.64 (9.41)	0.134	75.32 (7.05)	80.56 (5.61)	0.006
20 hr	74.84 (6.71)	80.12 (7.53)	0.012	123.92 (7.99)	128.4 (8.44)	0.060	75.04 (7.01)	83 (5.28)	0.000
24 hr	75 (5.92)	78.92 (6.85)	0.035	123.56 (7.79)	125.52 (5.94)	0.323	74.92 (7.04)	78.8 (4.37)	0.024

Table 4: Frequency Distribution for Mean Arterial Pressure and Behavior Pain Scale variables with Independent T-Test analysis

Mean Arterial Pressure				**Behaviour Pain Scale**		
Rate	**ETT Cuff + Alkalized Lignocaine N=25**	**ETT Cuff + Normal Saline N=25**	**P value Unpaired t-Test**	**ETT Cuff + Alkalized Lignocaine N=25**	**ETT Cuff + Normal Saline N=25**	**P value Unpaired t-Test**
	Mean (SD)	**Mean (SD)**		**Mean (SD)**	**Mean (SD)**	
0 hr	102.92 (11.62)	93.4 (8.75)	0.002	3 (0)	3 (0)	1.000
1 hr	103.84 (10.2)	94.48 (8.66)	0.001	3 (0)	3.36 (0.49)	0.0012
2 hr	89.92 (8.24)	95.52 (9.45)	0.030	3.4 (0.65)	3.96 (0.54)	0.0017
3 hr	91.84 (7.72)	97.72 (8.06)	0.011	3.64 (0.64)	4.4 (0.82)	0.0006
4 hr	91 (8.21)	96.92 (5.7)	0.005	3.8 (0.41)	4.24 (0.97)	0.0445
5 hr	91.8 (7.41)	94.28 (9.25)	0.301	4.24 (0.72)	3.84 (0.85)	0.0797
6 hr	91.68 (6.3)	96.76 (5.66)	0.004	4.12 (0.78)	4.2 (0.82)	0.7249
8 hr	90.56 (7.11)	95.84 (6.19)	0.007	3.72 (0.84)	3.8 (0.76)	0.7266
10 hr	91.4 (6.72)	97 (6.03)	0.003	3.88 (0.93)	4.4 (0.96)	0.057
12 hr	91.6 (7.76)	94.28 (5.8)	0.173	3.8 (1.08)	3.8 (0.91)	1.000
16 hr	91.44 (6.21)	96.04 (5.46)	0.008	3.84 (1.03)	4.4 (1)	0.0567
20 hr	91.28 (6.49)	97.84 (5.16)	0.000	3.64 (0.64)	4.28 (0.89)	0.0055
24 hr	90.96 (6.05)	94.08 (3.03)	0.027	3.76 (0.44)	3.84 (0.37)	0.4897

In patients belonging to ETT Cuff + Alkalized Lignocaine group, the mean heart rate measurement was 75.76 bpm. In ETT Cuff + Normal Saline group, the mean heart rate measurement is 80.53 bpm. The decreased mean heart rate measurement in ETT Cuff + Alkalized Lignocaine group is statistically significant compared to the ETT Cuff + Normal Saline group.

In patients with ETT Cuff + Alkalized Lignocaine group, the mean systolic blood pressure measurement was 123.18 mm Hg. In ETT Cuff + Normal Saline group, the mean systolic blood pressure measurement is 126.15 mm Hg. The increased mean systolic blood pressure measurement in ETT Cuff + Alkalized Lignocaine group is statistically significant compared to the ETT Cuff + Normal Saline group.

In patients with ETT Cuff + Alkalized Lignocaine group, the mean diastolic blood pressure measurement was 75.25 mm Hg. The mean diastolic blood pressure measurement in the ETT Cuff + Normal Saline group is 81.06 mm Hg. The decreased mean diastolic blood pressure measurement in ETT Cuff + Alkalized Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant. [Table 3]

In patients with ETT Cuff + Alkalized Lignocaine group, the mean arterial pressure measurement was 92.28 mm Hg. The mean arterial pressure measurement in the ETT Cuff + Normal Saline group is 95.90 mm Hg. The decreased mean arterial pressure measurement in ETT Cuff + Alkalized Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant.

In patients with ETT Cuff + Alkalized Lignocaine group, the mean behaviour pain scale measurement was 3.46 points. In ETT Cuff + Normal Saline group, the mean behaviour pain scale measurement is 3.99 points. The decreased mean behaviour pain scale measurement in ETT Cuff + Alkalized Lignocaine group compared to the ETT Cuff + Normal Saline group is statistically significant between 1-4 hours, 10th hours and 16 to 20hrs.

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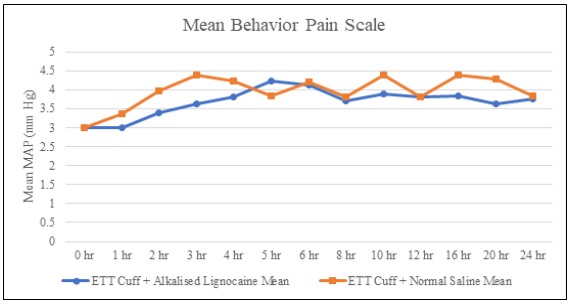

Figure 1: Frequency Distribution for Mean Behavior Pain Scale between both groups

DISCUSSION

In our study, the mean heart rate in the ETT Cuff + Alkalized Lignocaine group was consistently lower by 4.97 bpm compared to the ETT Cuff + Normal Saline group. The ETT Cuff + Alkalized Lignocaine group had significantly lower diastolic blood pressure measurements, with a 7% decrease or a difference of 5.81 mmHg compared to the ETT Cuff + Normal Saline group. The mean arterial pressure measurements were also significantly lower in the ETT Cuff + Alkalized Lignocaine group, showing a 4% decrease or a difference of 3.62 mmHg compared to the ETT Cuff + Normal Saline group. Furthermore, the mean behaviour pain scale measurements indicated a significant and consistent decrease of 13% or a difference of 0.53 points in the ETT Cuff + Alkalized Lignocaine group compared to the ETT Cuff + Normal Saline group. The mean total Fentanyl dose was significantly lower by 40% or a difference of 31 micrograms in the ETT Cuff + Alkalized Lignocaine group compared to the ETT Cuff + Normal Saline group.

Out of the 25 patients (n=25) in Group A (Intervention group), 15 patients required 25µg of fentanyl, five patients required 50µg, and another five patients required 75µg of fentanyl. In Group B (n=25) (Control group), two patients required 25µg of fentanyl, five patients needed 50µg of fentanyl, 13 required 75µg and five were given 100 µg of fentanyl. This study documented a 40% reduction in the Fentanyl requirement during the first 24 hours in patients with intracuff Alkalized lignocaine.

Mallick et al. has reported a 35% reduction in Fentanyl requirement in patients with intracuff Alkalized lignocaine.8 Basuni Ahmed Sobhy had also documented a 30% reduction in fentanyl and propofol requirement in patients with intracuff lignocaine.[2] This study's results were comparable to those of the above-quoted studies. 2% lignocaine and 8.4% sodium bicarbonate were used in a ratio of 1:1ml. Various studies have shown that variation in the concentration of sodium bicarbonate injected into the cuff did not affect the diffusion of lignocaine. Lignocaine is known to be absorbed rapidly from tracheobronchial mucosa. However, for systemic lignocaine to be effective in reducing ETT discomfort, a very high plasma concentration of lignocaine is required (IV Lignocaine 2mg/kg give plasma Lignocaine level >3µg/ml) than that attained in case of Lignocaine diffusion with 8.4% sodium bicarbonate (<0.08µg/ml) suggesting that improved ETT tolerance after intracuff Alkalized lignocaine is local rather than a systemic effect.

The present study also documented a significant reduction in the incidence of cough and restlessness in the intervention group than the control group. The frequency of ineffective triggers was lower in patients who received intracuff Alkalized lignocaine than in the control group. This is attributed to the increased ETT tolerance and patient comfort associated with intracuff Alkalized Lignocaine.[9,10]

An ineffective trigger occurs when patients' effort fails to reduce airway pressure below ventilator trigger sensitivity. However, the ineffective trigger occurs particularly due to improper ventilator settings (inappropriate trigger sensitivity) or abnormal pulmonary mechanics.[11-13] Also, sedatives and analgesics have been shown to depress the inspiratory drive and decrease the inspiratory muscle effort, thereby increasing ineffective triggers.[14,15]

Singh et al. reported that using saline or 2% Lignocaine without alkalisation as liquid media for inflating the ETT cuff reduced post-extubation reaction.[16] Lignocaine and sodium bicarbonate mixture could be irritative in cuff rupture. However, in vitro and vivo studies showed no cuff obstruction or rupture.[9,17,18] Similarly, this study had no events of cuff rupture or obstruction. Some incidents of cuff rupture have been reported when lignocaine was used as a lubricant or for local anesthesia.[19]

CONCLUSION

The study concluded that using intracuff Alkalized Lignocaine results in a significant decrease in the sedative/ analgesic requirement and frequency of ineffective trigger when compared to using intracuff saline and hence have better ET tube tolerance and improves patients' compliance.

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