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The Effect of Intracuff Low Dose Alkalinized Lidocaine With and Without Dexamethasone on Extubation Response: A Prospective, Double-Blind, Randomized Control Trial

Dr. Divya Dinakar A¹, Dr. Arun Kumar HD^{2*}, Dr. Shaji Mathew³, Dr. Laxmi Shenoy⁴, Dr. Madhu Rao⁵

¹Assistant Professor, Department of Critical Care Medicine, St Johns Medical College and Hospital, Bangalore, Karnataka, India, 560034

²Additional Professor, Department of Anesthesiology, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, India, 576104

³Professor, Department of Anesthesiology, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, India, 576104

⁴Associate Professor, Department of Anesthesiology, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, India, 576104

⁵Specialist Anesthesia, Department of Anesthesiology Bhurjeel Day surgery centre, Abu Dhabi - United Arab Emirates

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Abstract: Background: Intubation with a cuffed endotracheal tube is the gold standard for securing a definitive airway. Bucking over the tube during extubation can result in a potentially dangerous hemodynamic response. Tracheal tube cuff can be used as a reservoir for drugs to blunt this response. Lidocaine, a local anesthetic can achieve this by anesthetizing the airway. Dexamethasone has been known to potentiate the effect of lidocaine and has an intrinsic anti-inflammatory property. Methods: A prospective double-blind randomized control trial was conducted in a tertiary hospital for patients undergoing elective surgeries under general anesthesia requiring endotracheal intubation. Sixty patients were randomized equally into one of three groups. Cuff was inflated with saline (Group-S), 40 mg alkalinized lidocaine (Group-L), 40 mg alkalinized lidocaine with 8 mg dexamethasone (Group-LD). Heart rate, blood pressure and bucking were recorded during extubation, and post-operative sore throat were assessed. Results: All groups were comparable with regard to demographics, quantity of drug instilled in the cuff, duration of extubation and baseline hemodynamics. Group-L had the lowest incidence of hemodynamic changes during extubation, even lower than Group-LD. (p=0.020). Group-L and Group-LD had a lower incidence of bucking when compared to placebo (p < 0.001). Both Group-L and Group-LD revealed a lower grade of sore throat in the early post-operative period. Conclusion: Instilling endotracheal tube cuff with 40 mg alkalinized significantly blunts hemodynamic response and bucking during extubation, and sore throat in the early post-operative period compared to placebo. Addition of 8 mg dexamethasone does not improve hemodynamic extubation response.

Keywords: Intracuff, extubation, emergence, alkalinized, lidocaine, dexamethasone.

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INTRODUCTION

Intubation with a cuffed endotracheal tube is the gold standard for securing a definitive airway for patients undergoing surgery under general anesthesia. It facilitates positive pressure ventilation and the cuff prevents aspiration. However, the tracheal tube can also lead to a range of unwanted effects from coughing over the tube, sore throat, dysphagia, bronchospasm to even tracheal stenosis when used for a prolonged period of time.

Coughing over the tube can complicate emergence from general anesthesia resulting in a potentially dangerous haemodynamic response during extubation. Such response includes hypertension, tachycardia, dysrhythmia, increased intraocular pressure/ increased intra-cranial / intra-thoracic / intraabdominal pressures, bronchospasm and wound

*Corresponding Author: Dr. Arun Kumar HD

Additional Professor, Department of Anesthesiology, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka, India, 576104

dehiscence [1]. Hence, blunting this hyperdynamic response becomes useful.

Options for reducing the unwanted emergence effects include use of parenteral and /or topical medications. The parenteral route entails higher doses with likely increase in side effects, which could be detrimental to a subset of patients and scenarios. The topical use of drugs in lower doses to achieve the benefits could be an advantage for these reasons.

Use of the endotracheal tube cuff as a reservoir for drugs has been established by a number of studies [2, 3]. Lidocaine has been extensively studied in invitro studies. By diffusing out of the cuff, lidocaine blocks the local receptors of the tracheal mucosa and could decrease the undesirable side effects of bucking and thereby the hyperdynamic response. Lidocaine administered locally in various forms has also shown to have a decreased incidence of post-operative sore throat and other airway related morbidities like dysphagia and hoarseness of voice. The dose as well as the concentration required for achieving this effect has not been standardised at the present. Alkalinizing lidocaine facilitates its diffusion out of the cuff even at low concentrations [2].

Dexamethasone is a potent corticosteroid with anti-inflammatory, anti-emetic and analgesic properties. The use of intravenous dexamethasone to reduce airway inflammation is a standard of care. By combining dexamethasone and lidocaine we may potentiate the local action of lidocaine which has been studied in peripheral nerve blocks, as well as achieve an additive benefit in decreasing airway related morbidity [4].

It is thus useful to study drugs, dosages and combinations for endotracheal cuff instillation as there is inadequate standardization of the same. Therefore, this study was done to compare the effects of filling of endotracheal tube cuff with normal saline as control, alkalinized lidocaine (40mg) and alkalinized lidocaine (40mg) with dexamethasone (8 mg) in suppressing the extubation response.

MATERIALS AND METHODS

This was a prospective, randomised, doubleblind interventional study that was conducted after receiving the institutional ethics committee approval. The study was registered under Clinical Trial Registry-India (CTRI/2018/03/012730).

60 adult patients between the age of 18-65 years of either gender belonging to ASA physical status I/II scheduled to undergo tympanoplasties or mastoid surgeries expected to last longer than 2 hours were enrolled in the study. Patients were randomly allocated into one of the 3 groups using computer generated table of random numbers and allocation concealment was ensured using sequentially numbered, opaque sealed envelopes. Group S (saline), Group L (40 mg alkalinized lidocaine) and Group LD (40 mg alkalinized lidocaine with 8 mg dexamethasone). Exclusion criteria included patients on medications known to alter hemodynamic parameters, compromised cardiorespiratory functions, known history of smoking, an anticipated difficult airway and history of sensitivity to study drugs.

All observations were done by an anesthesiologist observer blinded to the groups. This included heart rate and blood pressure pre-induction and at extubation, incidence of bucking at extubation and post-operative sore throat. All patients were followed up for a period of 24 hours. Primary outcome included the hemodynamic extubation response and secondary outcomes included bucking and postoperative sore throat.

All patients were assessed a day prior to surgery and a patient information sheet was given to them, after which a written informed consent was taken. They were premedicated with tablet pantoprazole 40mg and metoclopramide 10 mg, and oral alprazolam (\leq 50 kg received 0.25 mg tablet, >50 kg received 0.5 mg tablet) on the night prior to and on the morning of day of surgery. All were kept nil per orally, at least 6 hours for solids and 3 hours for clear fluids.

On the day of surgery, the patient was shifted to the operating room and monitored with 5-lead electrocardiogram, pulse oximeter & non-invasive blood pressure monitor. Baseline heart rate and noninvasive blood pressure reading was noted. Intravenous line was secured and induction of anesthesia was with intravenous fentanyl 2µg.kg⁻¹ and propofol 2mg.kg⁻¹. Additional doses of propofol were given in titrated doses until loss of response to verbal commands was achieved. After ensuring adequate mask ventilation, muscle paralysis was ensured with IV vecuronium 0.1 mg.kg⁻¹. Bag and Mask ventilation was continued with 2% isoflurane in 100% oxygen to achieve a MAC of 1.0 - 1.3. A peripheral nerve stimulator was attached to stimulate the ulnar nerve at wrist and was set to deliver a Train-of-four (TOF) stimulus of 40 mA. Ventilation was continued until the TOF count of zero was achieved. Direct laryngoscopy was done with Macintosh blade (#3 or #4) by consultant anesthetist with experience, who was blinded to the study drugs. Endotracheal intubation achieved using 7.0 mm internal diameter (in female patients) or 8.0 mm internal diameter (in male patients) polyvinyl chloride endotracheal tube (Portex[®] Smiths Medical Australia Pty.Ltd) having high-volume low-pressure cuff and cuff was inflated with study drug as per randomization.

Study drugs were prepared by a trained anesthesia technician as per randomization. Group S received 5 ml of saline. Group L received 40 mg alkalinized lidocaine (2 ml of 2% lidocaine with 1 ml of 8.4% sodium bicarbonate) and 2 ml of saline. Group LD received 40 mg alkalinized lidocaine and 8 mg dexamethasone (2 ml of 2% lidocaine, 1 ml of 8.4% sodium bicarbonate and 2 ml of dexamethasone). Each solution was a minimum of 5 ml. Cuff was inflated to achieve a seal just enough to prevent leak at volume-controlled ventilation. Any additional requirement of solution was achieved by instilling 1.68 % alkalinized saline from a separate syringe. This was prepared by adding 1 ml of 8.4% sodium bicarbonate to 4 ml of normal saline. Once this is achieved no solution was allowed to be instilled or removed from the cuff. Solutions from Group L and LD had a pH of above 7 when checked using a universal indicator paper.

Anesthesia was maintained using isoflurane in a mixture of oxygen & air, with use of additional boluses of vecuronium as required. Intraoperative analgesia was provided with 2% lidocaine with adrenaline as local infiltration before surgical incision as well as 1 gm of intravenous paracetamol. No additional use of opioids was administered. Once the surgeon started closure of the surgical incision, IV ondansetron 0.1 mg.kg⁻¹ was administered. Adequate antagonism of residual neuromuscular blockade was ensured with appropriate dose of neostigmine and glycopyrrolate prior to extubation. Pharyngeal secretions were gently aspirated only once just before extubation. With patient still on the operating table extubation was performed when all the following criteria were met: regular spontaneous respiration with adequate tidal excursion of chest, full return of consciousness. adequate return of deglutition movements and ability to follow verbal commands. The following parameters were noted, heart rate, systolic, diastolic and mean arterial blood pressure measured every 2 minutes after reversal. The highest hemodynamic value observed was taken and compared with the baseline. The difference was expressed as a percentage. Rate pressure product is an index that acts as a marker for myocardial workload and is known to increase in times of stress. It incorporates both heart rate and blood pressure and is given by the formula $HR \times SBP \div 1000$. This was calculated. Incidence of bucking was also noted at the same time points (Bucking or coughing during suctioning was not

included in data). Sore throat was assessed once the patient was shifted to a post-anesthesia care unit at intervals of 15 minutes, 1 h, 2 h and 24 h using a 4-point grading scale starting from grade 0 to 3 (Grade 0: no sore throat, Grade 1: mild discomfort or itchy sensation in throat, Grade 2: pain on swallowing/attempts at swallowing, Grade 3: pain at rest). Grade 2 and 3 were considered severe sore throat.

Sample size was calculated based on a pilot study of 15 participants. To achieve a clinically significant difference of 30% of heart rate between the groups at the rate of 5% level of significance to achieve 80% power of the study we required 17 participants in each group. 20 participants in each group were enrolled in the study.

Data was analysed using SPSS v20 for windows. For quantitative normally distributed variables group comparisons were done with one-way ANOVA followed by Post-Hoc Tukey when significance was detected. Skewed data group comparisons were done with Kruskal-Wallis followed by Mann-Whitney U when significance was detected. Categorical variables like proportions were analysed using Chi-Square test. A *p*-value < 0.05 was considered statistically significant.

RESULTS

Demographic data were comparable between the three groups. There was a significantly lower difference in heart rate at extubation in the lidocaine group when compared to the saline group. Systolic blood pressure was also lower at extubation in the lidocaine group even though the difference from baseline was not significant. Post-Hoc analysis of both showed the difference to be between the lidocaine and saline group only. Rate pressure product was lowest in the lidocaine group (Table 2). Frequency of bucking at extubation and severity of post-operative sore throat is represented in Table 3. Bucking was significantly lower in both the lidocaine groups when compared to saline. Sore throat was lower in both the lidocaine groups in the early post-operative period. At 24 hours none of the patients had a severe grade of sore throat.

Variable	Group S	Group L	Group LD	p value
Age (yrs.)	38.55 ± 11.88	38.4 ± 9.40	34.3 ± 9.76	0.355 ^a
Weight (kg)	9/11	5/15	10/10	0.233 ^b
Sex(male/female)	22.22 ± 2.40	22.54 ± 2.42	23.21 ± 1.51	0.344 ^a
BMI (kg.m ⁻²)	22.22 ± 2.40	22.54 ± 2.42	23.21 ± 1.51	0.344 ^a
Duration of surgery (hrs)	3.00 ± 0.93	3.12 ± 0.66	3.07 ± 0.63	0.871 ^a
Volume of drug (ml)	5.55 ± 0.88	5.40 ± 0.88	5.55 ± 0.88	0.826 ^a
Duration of extubation(min)	8 (6.00 - 11.50)	8 (6.00-12.00)	7 (4.50-8.00)	0.078°

 Table 1: Baseline characteristics (data represented as mean ± SD, median (IQR) or proportions as applicable)

¹One-way ANOVA test ^b Chi square test^c Kruskal-Wallis test



Figure 1: Consort flow diagram

Table 2: Her	nodynamic pa	rameters at baseline, e	extubation with the va	ariation. (data is repre	esented as mean ± SD
_		or medi	ian (IQR) as applicab	le	

	Group S	Group L	Group LD	p value		
Heart rate; beats.min ⁻¹						
Baseline	77.65 ± 9.33	83.80 ± 14.58	85.75 ± 12.23	0.101 ^a		
At extubation	103.70 ± 18.56	97.9 ± 11.18	105.95 ± 15.51	0.241 ^a		
% Variation	33.76 (21.15-44.12)	12.56 (9.85-27.05) *	18.70 (9.64 - 39.24)	0.015 ^b		
Systolic blood pressure; mm Hg						
Baseline	135.25 ± 19.59	130.50 ± 12.44	137.35 ± 11.99	0.346 ^a		
At extubation	158.25 ± 29.31	$141.35 \pm 17.27 \#$	150.60 ± 12.50	0.045^{a}		
% Variation	17.11 (3.68 - 30.37)	7.35 (0.70 - 16.17)	8.70 (3.67 - 14.95)	0.243 ^b		
Diastolic blood pressure; mm Hg						
Baseline	80.05 ± 8.50	81.00 ± 8.92	81.85 ± 8.32	0.803 ^a		
At extubation	92.05 ± 17.91	82.75 ± 13.46	87.75 ± 8.14	0.111 ^a		
% Variation	13.81 (0.00 - 28.62)	2.49 (-3.58 - 14.57)	4.78 (-0.87 - 18.69)	0.107 ^b		
Mean blood pressure; mm Hg						
Baseline	100.4 ± 11.30	99.2 ± 10.09	102.2 ± 8.70	0.641 ^a		
At extubation	116.35 ± 20.37	106.60 ± 13.68	115.40 ± 7.72	0.082^{a}		
% Variation	15.23 (6.10 - 28.09)	4.46 (0.00 - 15.76)	11.49 (2.79 - 23.61)	0.129 ^b		
Rate pressure product						
Baseline	10.54 ± 2.21	10.89 ± 1.90	11.79 ± 2.06	0.153 ^a		
At extubation	16.51 ± 4.35	$13.74 \pm 1.62 \pounds$	15.98 ± 3.00	0.020^{a}		

^a One-way ANOVA test ^b Kruskal-Wallis test

*p=0.015 vs Group S (Mann Whitney U test) *p=0.035 vs Group S (Post Hoc Tukey) p=0.022 vs Group S (Post Hoc Tukey)

Variable	Group S	Group L	Group LD	p value		
	n=20	n=20	n=20			
Frequency of bucking	6 (4.25 to 10.00)	1 (0.00 to 3.50)	1 (0.25 to 2.00)	< 0.001 ^a		
Severe sore throat						
15 minutes	13(65%)	4(20%)	7(35%)	0.013 ^b		
1 hour	11(55%)	3(15%)	2(10%)	0.002 ^b		
2 hours	5(25%)	0(0%)	0(0%)	0.003 ^b		
24 hours	0(0%)	0(0%)	0(0%)			

 Table 3: Frequency of bucking at extubating and incidence of severe sore throat was compared between the three groups. Bucking is represented as median (IQR) and sore throat is represented as number (proportion)

^a Kruskal-Wallis test, ^b Chi-Square test

DISCUSSION

Hemodynamic instability is an undesirable side effect of emergence and extubation in patients recovering from anaesthesia and endotracheal intubation. Management of these complications are of varied complexity and can have adverse effects in special populations of patients. Meng *et al.*, in 2014 published a study stating the benefit of anesthetising the local airway in attenuating hemodynamic response. They found a reduced requirement of anti-hypertensives at extubation when airway was anesthetised [5].

The use of endotracheal tube cuff as a drug delivery system has been studied by many in-vitro studies that have shown that lidocaine diffuses out of the cuff [2, 3, 10, 11].. The pH of the medium has a great influence on the speed of onset and diffusion of drug as only uncharged molecules enter the nerve endings. The pKa of lidocaine is approximately 7.7 [12]. This property of higher diffusion of lidocaine at physiological pH of 7.4 accounts for its rapid onset of action. This property can therefore be used in hastening diffusion across non-nerve media by altering the pH of the medium by bringing it closer to its pKa. Estebe et al showed that 40mg of lidocaine can diffuse out of the cuff when it is alkalinized. They demonstrated this invivo. However, they used a high volume of 10ml for cuff inflation using 8ml of sodium bicarbonate. The average volume used for cuff inflation in our study was 5.5 ± 0.87 ml which has shown to be effective in supressing cough as well as in attenuating hemodynamic response. The quantity of drug, its concentration and addition of an alkalinizing agent have all been studied separately but there are no standard recommendations at present regarding the dose, amount, concentration or pH of the drug that can be used in the cuff. Hence we standardised these factors.

Dexamethasone is a glucocorticoid that has analgesic, anti-inflammatory and anti-emetic properties. It reduces the airway oedema that follows endotracheal intubation. It has also been shown to reduce cough when given intravenously [7-9]. The addition of dexamethasone to lidocaine has also been shown to be effective in prolonging the sensory duration of action [4]. The mechanism of this property of dexamethasone is poorly understood. Some of the theories put forward include local vasoconstriction, anti-inflammation both local and systemic and absorption into nerve endings and prevention of signal transmission. Although intracuff dexamethasone alone and with lidocaine has been studied in clinical trials, alkalinisation of dexamethasone has not been studied previously [13]. There are also no in-vitro studies available for the diffusion of dexamethasone outside the cuff. It is interesting to note that in our study, addition of dexamethasone to alkalinised lidocaine lowered the effect of lidocaine in attenuating haemodynamic extubation response. It is also worth noting that addition of dexamethasone to the solution caused a change in colour from clear to a turbid solution, indicting precipitation of the drugs. In combination with additional dilution of the drug this is probably responsible for lowered effect of the combination in attenuating haemodynamic responses to extubation. Its action on sore throat and bucking remained unchanged probably due to the decreased concentration of drug required for this action. Further biochemical analysis of this solution would add to more clarity on the reasons for reduced efficacy

Sore throat after intubation with low-pressure high-volume cuffs have been mainly attributed to the cuff area in contact with the mucosa when normal sealing pressure is used. Seegobin et al looked at fibreoptic images of the trachea at various cuff pressures and noted that there was an increase area of contact between the tracheal mucosa and the cuff when high-volume low-pressure cuff were used [14]. They also noticed that a clinical seal is achieved with pressures as low as 20 cm of H₂O which does not compromise the tracheal blood flow. We used sealing pressures for cuff inflation in our study, and noted that in all patients the tactile feel of the endotracheal tube cuff was acceptable with 5-7 ml of the test drug. No nitrous oxide use was permitted in our study and thereby we assumed there would be no further change in the cuff pressure. There was no leak noted in any of our patients throughout surgery. Continuous intracuff pressure monitoring would have given us more accurate results and is a limitation of this study.

Soares *et al.*, studied the effect of 0.5% and 1% lidocaine in attenuating hemodynamic response when compared to air and saline in paediatric patients

[15]. They found a decrease in hemodynamic extubation response in both lidocaine groups. However, the dose of drug was dependant on the volume used for cuff inflation, which varied. If an increased volume was used for cuff inflation a higher concentration of drug would be used. They measured the plasma lidocaine levels in both groups 30 minutes after intubation and found the systemic levels of lidocaine to be minimal and well within the toxic limit. Although we did not measure the lidocaine levels in our study a dose as low as 40 mg in the cuff is unlikely to have any systemic or toxic effect in adults. Furthermore, our study has standardised the dose of drug irrespective of the concentration.

Soussi et al., found a dose of 160 mg of alkalinized lidocaine to be effective in suppressing cough in N₂O free general anaesthesia [11]. They compared saline v/s lidocaine after confirming in an invitro study the effectiveness of diffusion of lidocaine at this dose. The in-vitro study compared 3 doses of lidocaine 40 mg, 80 mg and 160 mg showed a mean dose of 25.2 mg, 40.1 mg, 49.3 mg diffused out of the cuff respectively after 8 hours. They stated the importance of duration of surgery to be greater than 2 hours to allow adequate time for the drug to diffuse out which was followed in our study as well. They did not however standardise the concentration of sodium bicarbonate that was added. They tested only 160 mg in their clinical trial assuming the highest diffusion across the cuff in this group. The in-vivo concentration of lidocaine diffusing out of the cuff was not studied. They also did not study the hemodynamics at extubation. They looked at sore throat at 15 minutes, 1 hour and 24 hours after surgery and found no significant difference between the groups. This could be because they included smokers in their study and there was a significant increase in use of Guedel's airway in the lidocaine group that could have caused an upper airway irritation resulting in comparable results. In our study, a dose as low as 40 mg of lidocaine with 1.68% of sodium bicarbonate was sufficient to be effective in attenuating haemodynamic response, bucking during extubation, as well as severity of sore throat in the early postoperative period. This can be done with 2 ml of commercially available 2% lidocaine. Thus, a smaller dose of lidocaine may be instilled into the cuff without risking harmful effects of high cuff pressure or potential risk of lidocaine toxicity in the unlikely event of cuff rupture.

CONCLUSION

Using 40 mg of intracuff alkalinised lidocaine to attenuate hemodynamic response during extubation, bucking and sore throat in early postoperative period is a feasible and safe option. Addition of 8 mg of dexamethasone reduces this benefit on haemodynamic response to extubation with no added benefit on frequency of bucking or severity of sore throat.

Disclosures

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