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Intracuff alkalinized lidocaine and the incidence of cough and postoperative sore throat after anesthesia in children: A randomized clinical trial

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ABSTRACT

Background: Uncuffed tracheal tubes (TT) have historically been used in children under 8 years for fear of airway mucosal injury. Cuffed tubes are however useful for several surgeries and have been showed suitable.
Objective: To study the effect of intracuff alkalinized lidocaine (2%) in reducing airway morbidity compared to intracuff air in children.
Methods: This prospective randomized clinical trial was conducted at the University of Nigeria Teaching Hospital, July 2016 and July 2017 and involved 100 ASA I & II patients randomly divided into two groups. All cases were done under general anesthesia lasting less than 60 min. In fifty patients, air was used to inflate the TT cuff and in the remaining patients, alkalinized lidocaine (2%) 2 ml was used. The cuff pressure was maintained between 20 and 22 mmHg. Postoperative airway morbidities were compared between the two groups. The data obtained was analysed using Prism 6 statistical software.
Results: The study showed a significant decrease in the incidence of postoperative sore throat and cough in the Lidocaine group compared to the Air group.
Conclusions: Intracuff alkalinized lidocaine is effective in reducing postoperative sore throat and cough related to the use of cuffed TT in children.

1. Introduction

Historically, uncuffed tracheal tubes were preferred in children up to the age of 8 years due to fears of mucosal injury post extubation [1,2]. This was based on studies of the larynx of infants and children conducted on cadaveric specimens [3-5] Later studies using cuffed tubes showed no association with airway injury in children [6,7]. These studies employed various measures to minimize tracheal injury caused by cuffed TT including tracheal extubation in the deep plane of anesthesia, topical local anesthetic cream applied on TT, intravenous (IV) narcotics, esmolol, lidocaine, topical lidocaine via sprays, or direct instillation into the TT [8]. Intracuff lidocaine was shown to block cough receptors in adults [9]. Estebe et al., demonstrated that alkalization of intracuff lidocaine enhanced its diffusion across the cuff membrane and allowed lower effective non toxic dosage to be used [10].

The aim of this study was to determine the efficacy of intracuff alkalinized lidocaine in diminishing the incidence of coughing at extubation and postoperative sore throat in children.

2. Methods

This prospective randomized clinical trial was conducted at the University of Nigeria Teaching Hospital, Enugu between January 2016 and January 2017. After obtaining institutional ethical clearance and parents/patients' informed consent, 100 American Society of Anesthesiology (ASA) physical status 1 or 2 children aged 5–12 years were recruited for this double blinded, prospective study. All the patients were scheduled for elective abdominal laparotomy under nitrous-oxide free general anesthesia with tracheal intubation at a tertiary hospital located in South East Nigeria. The inclusion criteria were elective abdominal laparotomy lasting less than 1 h, Mallampati Status 1 or 2, and aged between 5 and 12 years. Patients were excluded if they had a history of allergy to lidocaine,

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asthma and previous laryngeal or tracheal surgery or pathology; were predicted to have difficult intubation; active upper respiratory infection, more than 1 attempt at tracheal intubation.

Routine preoperative fasting was observed, and all patients were premedicated with temazepam 1–2 h before surgery to allay their anxiety. In the theatre, standard monitors were attached to the patients to measure heart rate (HR), non-invasive blood pressure (NIBP), mean arterial pressure (MAP), electrocardiograph (ECG) and oxygen saturation (SpO_2) The vital signs were recorded at 5 min interval. Intravenous access was established with wide bore cannula and maintained with normal saline. Antisialogogue (atropine 0.02 mg/kg) and antiemetic (metoclopramide) were administered intravenously as a prophylaxis against excessive secretions and post operative nausea and vomiting respectively. An anesthetist who was blinded to the study design conducted anesthesia. Patients were pre-oxygenated with 100% oxygen via face mask. Anesthesia was induced with fentanyl 2 μg/kg and propofol 2.5 mg/kg. Nasotracheal intubation was facilitated with pancuronium bromide 0.1 mg/kg, using nasal RAE-tube (Ruschelit™ Rüsch GmbH, Kernen, Germany) with an inner diameter calculated according to the Cole's formula (I.D. = age/4 + 4) [11]. Correct placement was confirmed by chest auscultation for equal breath sounds on both lung fields, and by capnography. Patients were randomly assigned by envelope randomization to belong to either Lidocaine (L-group) or Air (A group) groups 1:1.

Two identical syringes were coded by an assistant for cuff inflation. The TT cuff was completely aspirated and then inflated with a syringe loaded with either a mixture of 2 ml of 2% lidocaine/8.4% sodium bicarbonate (L group) or 2 ml air (A group). The cuff was inflated to prevent air leaks and its pressure was measured using a handheld manometer P-V gauge (Mallinckrodt Medical, St. Louis, USA).

Anesthesia was maintained with isoflurane 0.8% in oxygen via a circle breathing system and intermittent positive pressure ventilation. Depth of anaesthesia was monitored using vital signs. Ventilation was adjusted to maintain therapeutic hypocapnia of 28 mmHg. Analgesia was maintained with intravenous morphine 0.1 mg/kg. Muscle relaxation was achieved with pancuronium bromide, 0.05 mg/kg and assessed using Train-of-Four stimulation.

At the end of surgery, isoflurane was discontinued and residual neuromuscular blockade antagonized with neostigmine 0.04 mg/kg and glycopyrrolate 0.2–0.4 mg, pre-extubation HR, NIBP, $Sp0_2$ were recorded. Gentle pharyngeal suctioning was performed. The cuffed TT was aspirated and the volume of aspirate, (Air or Lidocaine), recorded. Extubation was carried out when the following criteria were met: spontaneous ventilation, ability to respond to verbal command or demonstration of purposeful movement. The duration of surgery and intubation were recorded. The number of episodes of coughing from the time spontaneous ventilation began, to 30 min post extubation was recorded in the recovery room. Post extubation coughing was graded and recorded based on the modified four point scale as follows; Grade 0 = No cough; Grade 1 = (Mild) single bout of cough; Grade 2 = (Moderate) more than one episodes of unsustained (≤5 s) coughing and Grade 3 = (Severe) sustained (>5 s) bouts of coughing.

Sore throat was evaluated at the time of discharge from recovery room and 24 h post extubation using a modified visual analogue scale (0–100 mm) for children. We examined all patients for signs of lidocaine toxicity.

The data collection form was used to document patients' characteristics.

3. Statistics

Based on our pilot study, we calculated our sample size by estimating a 45% decrease of postoperative cough and sore throat using alkalinized lidocaine at a significance level of 0.05 with a power of 80%.

Analysis was performed using Prism 6 software. Fifty subjects were needed in each group. The Students t-test was used to compare parametric data between the groups while the chi square test was used to compare categorical data. Man-Whitney U-tests compared non-parametric data. Statistical significance was defined as $P < 0.05$. Data are presented as mean and SD.

4. Results

Fifty patients were recruited and completed the study in each group and patient characteristics without significant difference between the groups are in Table 1.

We found a significant reduction in the incidence of cough in the alkalinized Lidocaine group, n = 15 (30%) compared to the Air group, n = 30 (60%). Table 2.

The incidence of sore throat at the recovery room was 26% in the alkalinized Lidocaine group and 36% in the control group ($P < 0.05$), Table 3. After 24 h, sore throat occurred in 13 patients (16%), and 16 patients (32%) in the alkalinized lidocaine and Air groups respectively. ($P = 0.71$). We found no clinical signs of lidocaine toxicity in the patients.

5. Discussion

The findings in this study were a significant decrease in the incidence of postoperative cough, and sore throat in the first hours after extubation when alkalinized Lidocaine was used to inflate the TT-cuff. This findings are in line with other reports from adults [10,12,13]. Fagan et al., proposed that this decrease was due to diffusion of lidocaine across the polyvinyl chloride membrane of the cuff and anaesthetizing the local area of contact with the trachea [9]. Wetzel et al., carried out similar studies in smokers comparing alkalinized lidocaine with air in the TT-cuff [14]. Although their study was in surgeries lasting less than 90 min, their

Table 1
Patient characteristics and operative data.

	Lidocaine group(n = 50)	Air group (n = 50)	P value
Age (years)	7.4 ± 4	7.0 ± 3	0.9
Weight (kg)	25 ± 9	28 ± 6	0.67
Female n (%)	25 (50)	26 (52)	0.46
Duration of surgery (min)	128 ± 55	124 ± 43	0.40
Duration of anesthesia (min)	144 ± 23	155 ± 30	0.75
Intracuff volume (ml)	1.5 ± 0.2	1.4 ± 0.4	0.45
ASA status n (%)			
1	27 (54)	26 (52)	
2	23 (46)	24 (48)	

Table 2
Postoperative Cough: data are presented as number (percentage) with significance level.

GROUPS	YES	NO	TOTAL
Air group	29 (58%)	21(42%)	50(100%)
Alkalinized Lidocaine Group	15 (30%)	35 (70%)	50(100%)
Total	44 (44%)	56 (56%)	100

P = 0.006.

Table 3
Postoperative sore throat: data are presented as number (percentage) with significance level.

	recovery room		after 24 h	
	YES	NO	YES	NO
Air group	18(36%)	34(68%)	16(32%)	34(68%)
Lidocaine Group	13(26%)	37(74%)	13(16%)	37(84%)
Total	31(31%)	71(74%)	29(29%)	71(71%)

findings demonstrated also protective properties of intra cuff lidocaine [15].

The incidence of cough in the control group was 60% in our study which is within the range of 38–96% of earlier reports [13,15] but lower than the 76% demonstrated by Souissi. et al. [13] This may be because of the difference in the type of cuff in the tracheal tube used in their study. They used the high pressure, low volume cuff in contrast to low-pressure high volume used in our study. With the high pressure low volume, the pressure transmitted from the TT–cuff to the tracheal mucosa will be more, resulting in a more likelihood of tracheal mucosal damage.

The use of alkalinized lidocaine resulted in 30% greater reduction in the incidence of cough in our study. Lais et al., showed 44% incidence in their control group and 8% in the alkalinized lidocaine group, that is a 36% reduction [16]. Their higher incidence could be because N_2O was used to maintain anesthesia in that study. N_20 diffuses into the TT-cuff causing an increase in cuff pressure, which results in an increase in post extubation laryngeal morbidity [17].

There was no significant difference in the mean duration of anesthesia in all groups and this was well above the 60 min period required for sufficient amount of 40 mg alkalinized lidocaine to diffuse through the TT-cuff [9]. Soares et al. studied the effects of tracheal tube cuffs filled with air, saline or alkalinized lidocaine on postoperative laryngotracheal morbidity in children. They concluded that filling the tracheal tube cuff with alkalinized lidocaine reduces postoperative laryngotracheal morbidity in children [18]. Similar finding was obtained from our study.

Our study has some limitations. The serum levels of lidocaine in patients whose TT cuff was inflated with alkalinized lidocaine was not measured due to the unavailability of high performance liquid chromatography in the study center. No local anesthesia toxicity was however observed in the patients. Another limitation was that the study was confined to surgeries lasting less than 150 min. Surgeries lasting longer than this may have effects not observed in our study and we cannot generalize the results to younger children or neonates.

In conclusion, alkalinized intracuff lidocaine is effective in reducing the incidence of cough and sore throat related to intubation after general anesthesia in children of 5–12 years.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tacc.2018.10.003.

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