Preemptive Nebulization of Lidocaine Epinephrine Before Anesthesia for Rigid Bronchoscopy in Pediatric: A Randomized Controlled Study

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ABSTRACT

Background: Foreign body aspiration in pediatrics is usually managed by rigid bronchoscopy, which is associated with plenty of adverse events. **Objective:** We tried to compare the effect of nebulized saline, lidocaine or combined lidocaine with epinephrine on postoperative respiratory complications.

Patients and methods: This prospective study included 90 children, who were divided into three groups according to the nebulized solution; NS group (normal saline 0.9%), L group (lidocaine 1% 4 $mg.kg^{-1}$) and LA group [4 $mg.kg^{-1}$ lidocaine 1% and adrenaline (1:1000) 3 mg). Our primary outcome was the incidence of post-operative respiratory complications, while the secondary ones included hemodynamic changes and the incidence of intraoperative cough or desaturation. **Results:** All pre-procedural data were insignificant among the three groups. The LA group expressed higher heart rates, while the L group showed a significant reduction when compared to NS group. Propofol consumption showed a significant decline in two studied groups compared to the NS group. Intraoperative cough was higher in NS group in comparison to L and LA groups. Although, intraoperative desaturation per case along with post-operative sedation showed no significant difference among the three groups, post-operative cough frequency attacks and severity were higher in NS group when compared to L and LA group and when L group were compared to LA group. Post-operative stridor was insignificant among the three groups.

Conclusion: Nebulized lidocaine/adrenaline combination is appropriate option to achieve proper intraoperative sedation and upper airway conditions with reduction of post-operative negative respiratory outcomes together with minor hemodynamic changes.

Keywords: Rigid bronchoscopy; Nebulization; Lidocaine; Epinephrine.

INTRODUCTION

Foreign body aspiration by children is a common problem that is frequently encountered in emergency pediatric practice. Impaction of the inhaled foreign body could lead to asphyxia, and it is the major cause of mortality in children aged less than four years [1]. Therefore, this serious entity should be immediately managed to avoid subsequent complications and irreversible lung damage [2]. It was managed by emetics and purges in the 19th century, but these management modalities were ineffective and were associated with a 23% mortality rate [3]. However, this rate dramatically decreased following the intervention of bronchoscopy[4].

For more than a century, rigid bronchoscopy has been a crucial tool in the diagnosis and treatment of various airway pathologies [5]. Despite the widespread use of flexible bronchoscopy, the rigid one is still used as the gold standard option for many complex airway diseases, including foreign body aspiration [6, 7]. It allows the operator to properly visualize and manipulate the aspirated object, with proper management of mucosal haemorrhage, if it occurred [8]. Although rigid bronchoscopy has a 95% success rate with a safe profile (less than 1% complication rate) [9, 10], multiple complications could be encountered, including bronchospasm, laryngeal oedema, pneumothorax, tracheobronchial lacerations, hypoxic brain damage, infection, bleeding and cardiac arrest [1, 11, 12]. Although early clinicians used topical anaesthesia for rigid bronchoscopy interventions [1], most anaesthetists prefer general anaesthesia nowadays, thanks to advances in anaesthetic delivery and the increased experience with rigid bronchoscopy procedures [7, 13]. During the procedure, anaesthetists usually try to maintain an adequate depth of anaesthesia to prevent cough and straining during the intervention. Stable hemodynamics and rapid post-procedural recovery are crucial needs as well [14, 15].

Lidocaine is an inexpensive, widely available anaesthetic agent with an excellent safety profile when nebulized. This contrasts the fact that topical anaesthetics are rapidly absorbed into the circulation following application onto mucosal surfaces, which increases the risk of systemic adverse events [15].

Epinephrine (adrenaline) is a potent adrenergic alpha and beta receptor stimulant. It is used during cardiopulmonary resuscitation. In addition, it could be nebulized in pediatric patients with airway inflammatory diseases like croup and bronchiolitis [16, 17]. Its potential positive impact on the airway is due to a decrease in airway secretions and oedema (alpha effect), together with airway dilatation and inhibition of inflammatory cascades (beta effect) [18].

Based on local anaesthetic effects of lidocaine and anti-edematous effects of adrenaline, our hypothesis is that preoperative nebulization of both

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drugs may improve outcomes after rigid bronchoscopy in the pediatric population.

Our primary outcome was to compare the incidence of post-operative respiratory complications (cough, stridor or desaturation) among the three studied groups. Secondary outcomes included hemodynamic changes and the incidence of intra-operative cough or desaturation (defined as oxygen saturation < 90%). Any change detected in MAP or heart rate more than 20% of its basal values were considered significant events.

PATIENTS AND METHODS

This prospective randomized trial was conducted at Mansoura University Anesthesiology Department in collaboration with the Pediatric Department. The study was conducted over a period of two years, from April 2017 till April 2019.

Sample size

Priori G power was done to calculate sample size, power of 80 % was used with α error of 0.05 and effective size 35 %, the total number of patients obtained was 85, a dropout of 5% was expected. Therefore, the total sample size was 90 patients. We included pediatric cases suspected of foreign body aspiration and scheduled for elective or emergency rigid bronchoscopy. Contrarily, we excluded children with known cardiovascular disorders or any congenital skeletal deformities.

Ethical considerations:

The study was approved by Institutional Review Board (IRB-MFM) of Mansoura University, Faculty of Medicine with Code number R/16.12.32, March 2017. We obtained informed written consent from the guardians of each participant after simple explanation of the indication, benefits, and possible complications of each intervention. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Using the sealed envelope method, the included 90 cases were divided into three equal groups according to the commenced preoperative nebulizer; NS group included 30 patients who received the nebulized solution containing only 0.9% saline, L group included another 30 cases who received nebulized solution containing 4 $mg.kg^{-1}$ lidocaine 1%, and LA group included the remaining 30 cases who received nebulized solution containing 4 $mg.kg^{-1}$ lidocaine 1% in addition to 3 mg of adrenaline (1:1000).

All patients were subjected to history taking, clinical examination and routine preprocedural investigations if needed. After planning the bronchoscope procedure, all patients were medicated with the nebulizer (according to the group allocation) about 15 minutes prior to the intervention. Then, all patients were monitored with AAGBI recommended basic monitoring on arrival to the operative theatre. Anaesthesia was induced by intravenous propofol (1.5 $mg.kg^{-1}$), dexmedetomidine (0.5 $\mu g.kg^{-1}$) and suxamethonium (1 $mg.kg^{-1}$) to facilitate the rigid bronchoscope passage through the vocal cords. Anesthesia was maintained by propofol infusion (150$\mu g.kg^{-1}.min^{-1}$) and dexmedetomidine (0.4 $\mu g.kg^{-1}.min^{-1}$). An additional dose of propofol 0.5 mg/kg was given to alleviate intraoperative coughing. The bronchoscopy procedure was then performed by the same experienced bronchoscopist. The heart rate, mean arterial pressure and SPO_2 were recorded at nebulizer intake, induction, bronchoscopy insertion and then at one, three, five, seven, and ten minutes during the procedure. Also, the number of cases who developed intra-operative cough, number of cough and desaturation attacks per every case were noted and recorded.

After the procedure, all patients were transferred to PACU and then to the internal ward, where all patients received humified oxygen for one hour. During the post-operative period, both MAP and heart rate were recorded at arrival, 15, 30 and 60 minutes after the procedure. Post-operative sedation was recorded according to the Richmond Agitation-Sedation Scale (RASS) [19]. Additionally, the incidence of post-operative stridor and cough was recorded. The severity of post-operative cough was graded using the VAS (a vertically marked scale of 1 to 10, with mild cough (< 4), moderate (4-6) and sever > 6).

Statistical analysis

IBM's SPSS statistics for MacOs (version 26) was used for the analysis of the collected and tabulated data. The Shapiro-Wilk test was done to ensure that the data distribution was normal. Continuous data with a regularly distributed distribution were expressed as mean ± SD, whereas categorical variables and those with an erratically distributed distribution were expressed as median and interquartile range or number and percentage (as appropriate). For normally and abnormally distributed continuous data, one-way ANOVA and Kruskal Wallis tests were utilized. The crosstabs function was used to run the Chi-square test on categorical data. All tests were carried out using a 95% confidence interval. A p (probability) value ≤ 0.05 was considered statistically significant.

RESULTS

Starting with demographic data of the included children, their ages had mean values of 35.9, 37.93, and 34.8 months in the NS, L, and LA groups, respectively. Regarding gender distribution, boys represented 60%, 60% and 70% of the included cases in the same three groups, respectively, while the remaining cases were girls. As regards the site of impacted foreign body, it was located in the trachea in 43.3%, 66.75%, and 76.7% of cases in the same three groups, while the right bronchus was the site of impaction in 30%, 20% and 10% of cases in the same groups respectively. The left bronchus was affected in the remaining cases. All of the previous parameters showed no significant differences among the three groups (p > 0.05), as shown in table (1).

Table (1): Demographic characteristics and foreign body site in the three groups

		NS group (n= 30)	L group (n= 30)	LA group (n= 30)	P	P1	P2	P3
Age (months)		35.90 ± 3.325	37.93 ± 5.192	34.80 ± 6.661	0.069	0.410	1	0.069
Gender (number & %)	**Male**	18 (60.0%)	18 (60.0%)	21 (70.0%)	0.650	> 0.05	> 0.05	> 0.05
	Female	12 (40.0%)	12 (40.0%)	9 (30.0%)				
Weight (kg)		16.03 ± 2.51	16.25 ± 1.83	17.04 ± 2.99	0.708	0.163	0.220	0.699
Site (number & %)	**Trachea**	13 (43.3%)	20 (66.7%)	23 (76.7%)	0.098	> 0.05	> 0.05	> 0.05
	Right bronchus	9 (30.0%)	6 (20.0%)	3 (10.0%)				
	Left bronchus	8 (26.7%)	4 (13.3%)	4 (13.3%)				

P1: NS group vs L group. P2: NS group vs LA group. P3: L group vs LA group.

As shown in table (2), no significant difference was noted between the three study groups regarding their basal heart rates. However, on nebulizer administration, the LA group expressed significantly higher heart rates, while the L group showed a significant decrease when compared to NS group, and this was noticed throughout the intraoperative and post-operative periods.

Table (2): Intra- and post-operative follow-up of heart rate in the three groups.

Heart rate (bpm)		NS group (n= 30)	L group (n= 30)	LA group (n= 30)	P	P1	P2	P3
Intra-operative	**Basal**	142.60 ± 11.106	136.67 ± 7.941	140.90 ± 10.203	0.061	0.065	1	0.298
	Nebulizer	142.67 ± 11.469	137.13 ± 7.969	152.27 ± 12.537	**< 0.001**	0.153	**0.003**	**< 0.001**
	Induction	140.87 ± 11.884	135.73 ± 7.847	152.00 ± 12.873	**< 0.001**	0.229	**0.001**	**< 0.001**
	Insertion	151.83 ± 12.804	140.87 ± 7.646	154.97 ± 13.005	**< 0.001**	**0.001**	0.873	**< 0.001**
	One minute	151.27 ± 12.795	140.33 ± 7.993	155.50 ± 13.054	**< 0.001**	**0.001**	0.475	**< 0.001**
	Three minutes	150.10 ± 12.848	139.40 ± 7.972	154.47 ± 12.995	**< 0.001**	**0.002**	0.436	**< 0.001**
	Five minutes	149.03 ± 12.931	138.57 ± 8.118	153.20 ± 13.158	**< 0.001**	**0.002**	0.507	**< 0.001**
	Seven minutes	149.50 ± 12.905	139.43 ± 8.054	154.33 ± 13.682	**< 0.001**	**0.004**	0.350	**< 0.001**
	Ten minutes	150.70 ± 13.233	140.57 ± 7.793	155.60 ± 13.768	**< 0.001**	**0.004**	0.344	**< 0.001**
Post-.	**PACU**	150.10 ± 12.992	140.10 ± 7.774	155.13 ± 14.058	**< 0.001**	**0.005**	0.317	**< 0.001**
	15 minutes	149.80 ± 13.376	140.00 ± 8.204	154.73 ± 14.059	**< 0.001**	**0.007**	0.360	**< 0.001**
	30 minutes	149.00 ± 13.478	139.70 ± 8.408	154.13 ± 14.347	**< 0.001**	**0.014**	0.334	**< 0.001**
	60 minutes	148.53 ± 13.930	139.23 ± 8.169	153.73 ± 14.727	**< 0.001**	**0.016**	0.342	**< 0.001**

P1: NS group vs L group. P2: NS group vs LA group. P3: L group vs LA group.

Basal MAP was statistically insignificant when compared among the three groups (p > 0.05). Nevertheless, the LA group showed significantly higher MAP values during nebulization and induction (p = 0.004 and 0.001 respectively) in comparison to the other groups. On subsequent readings, no significant difference was noted between the three groups regarding the same parameter (table 3).

Table (3): Intra- and post-operative follow-up of MAP in the three groups.

MAP (mmHg)		NS group (n= 30)	L group (n= 30)	LA group (n= 30)	P	P1	P2	P3
Intra-operative	**Basal**	63.53 ± 5.513	65.90 ± 6.127	63.83 ± 7.679	0.313	0.487	1	0.665
	Nebulizer	63.60 ± 5.587	65.53 ± 6.673	69.67 ± 8.384	**0.004**	0.858	**0.003**	0.073
	Induction	59.80 ± 5.845	61.70 ± 7.349	66.87 ± 8.341	**0.001**	0.939	**0.001**	**0.021**
	Insertion	69.67 ± 6.666	68.33 ± 7.893	72.37 ± 8.336	0.122	1	0.528	0.134
	One minute	70.03 ± 6.851	68.07 ± 8.056	72.60 ± 8.295	0.082	0.987	0.611	0.078
	Three minutes	69.17 ± 6.998	67.10 ± 7.761	71.33 ± 8.227	0.108	0.900	0.832	0.107
	Five minutes	68.37 ± 6.835	65.97 ± 7.668	70.27 ± 8.292	0.097	0.678	1	0.095
	Seven minutes	69.37 ± 6.851	67.13 ± 7.505	71.30 ± 8.575	0.115	0.789	0.996	0.115
	Ten minutes	70.13 ± 6.606	67.83 ± 7.557	72.37 ± 8.503	0.075	0.732	0.774	0.069
Post-.	**PACU**	68.73 ± 6.817	67.63 ± 7.416	71.53 ± 8.889	0.139	1	0.497	0.164
	15 minutes	68.20 ± 6.955	67.10 ± 7.640	71.20 ± 8.876	0.119	1	0.429	0.140
	30 minutes	67.77 ± 6.922	66.60 ± 7.837	70.43 ± 9.096	0.170	1	0.601	0.201
	60 minutes	67.67 ± 7.068	66.07 ± 7.570	69.90 ± 8.790	0.170	1	0.819	0.185

P1: NS group vs L group. P2: NS group vs LA group. P3: L group vs LA group.

SPO_2 showed no significant differences among all groups (table 4).

Table (4): Intra- and post-operative follow-up of SPO_2 in the three groups.

	SPO_2 (%)	NS group (n= 30)	L group (n= 30)	LA group (n= 30)	P	P1	P2	P3
Intra-operative	**Basal**	96.43 ± 1.25	97.00 ± 0.91	97.97 ± 0.85	0.354	0.188	0.561	0.302
	Nebulizer	95.70 ± 1.39	97.63 ± 0.99	97.00 ± 0.87	0.432	0.287	0.369	0.417
	Induction	96.27 ± 1.36	97.40 ± 1.16	96.93 ± 0.74	0.448	0.311	0.117	0.121
	Insertion	95.97 ± 1.43	97.30 ± 1.18	97.07 ± 0.69	0.441	0.255	0.295	0.326
	One minute	96.03 ± 1.42	97.50 ± 1.07	96.97 ± 0.89	0.286	0.511	0.388	0.523
	Three minutes	96.30 ± 1.44	97.60 ± 1.10	97.03 ± 0.76	0.128	0.367	0.184	0.415
	Five minutes	95.63 ± 1.22	97.67 ± 1.21	97.00 ± 0.87	0.312	0.322	0.328	0.295
	Seven minutes	96.53 ± 1.19	97.70 ± 1.24	96.77 ± 0.82	0.221	0.455	0.166	0.529
	Ten minutes	95.97 ± 1.49	97.63 ± 0.93	97.20 ± 0.66	0.342	0.398	0.173	0.612
Post-	**PACU**	96.33 ± 1.42	97.53 ± 1.04	97.10 ± 0.76	0.176	0.211	0.259	0.266
	15 minutes	95.97 ± 1.45	97.43 ± 0.97	96.90 ± 0.80	0.124	0.423	0.209	0.295
	30 minutes	96.17 ± 1.66	97.37 ± 1.16	97.13 ± 0.82	0.251	0.299	0.361	0.244
	60 minutes	96.40 ± 1.35	97.50 ± 1.19	96.96 ± 0.85	0.241	0.527	0.275	0.319

P1: NS group vs L group. P2: NS group vs LA group. P3: L group vs LA group.

Propofol consumption showed a significant decline in two drug groups in comparison with the NS group (p < 0.001). It had mean values of 61.83, 42, 45.67 mg in the NS, L, and LA groups, respectively. The number of cases who developed intraoperative attacks of cough were higher in NS group when compared to L and LA groups respectively, meanwhile it showed no differences between both L and LA groups. In contrast the incidence of intraoperative desaturation and cough was incomparable among the studied groups. Post-operative RASS had median values of 1.5, 2, and 2 in the same groups, respectively, with no significant difference between them (p = 0.074). Regarding the post-operative period, the incidence of cough showed a significant decline in the LA group (10% versus 43.3% and 33.3% in the NS and L groups, respectively). Similarly, cough severity was higher in NS group (sever cough) when compared to L (moderate cough) and LA (mild) group and when L (moderate) group were compared to LA (mild) group. However, the incidence of post-operative stridor was of no statistically significant values among the studied groups (p = 0.318) as shown in table (5).

Table (5): Intra-operative propofol requirements, cough, desaturation and post-operative recovery profile in the three groups.

	NS group (n= 30)	L group (n= 30)	LA group (n= 30)	P	P1	P2	P3
Propofol consumption (mg)	61.83 ± 14.94	42.00 ± 8.47	45.67 ± 10.32	<0.001	<0.001	<0.001	0.669
Intra-operative Cough (number & % of cases)	14 (46.67%)	9 (30%)	8 (26.67%)	0.028	0.011	0.261	0.374
Average cough/case (median & range)	3 (1-4)	2 (1-3)	2 (1-2)	0.106	0.667	0.212	0.245
Intra-operative desaturation (number & % of cases)	2 (6.67%)	1 (3.33%)	2 (6.67%)	0.630	1	1	0.964
Post-operative RASS (median & range)	1.50 (1-2)	2 (1.75-2)	2 (2-2)	0.014	0.018	0.096	0.732
Post-operative Cough (number & % of cases)	13 (43.3%)	10 (33.3%)	3 (10.0%)	**0.014**	> 0.05	**< 0.05**	> 0.05
Grade of Post-operative Cough (median & range)	7 (6-8)	5 (3-6)	3.5 (2-5)	**0.001**	**0.002**	**0.001**	**0.003**
Post-operative stridor (number & % of cases)	3 (10.0%)	0 (0.0%)	1 (3.33%)	0.318	> 0.05	> 0.05	> 0.05

P1: NS group vs L group. P2: NS group vs LA group. P3: L group vs LA group.

DISCUSSION

The removal of an aspirated foreign body is usually associated with prolonged manipulation of the upper respiratory tract, which leads to sympathetic overstimulation resulting in tachycardia, hypertension and cardiac arrhythmias [20]. Also, this manipulation is associated with airway oedema with subsequent narrowing [21]. This could be a risk of post-procedural respiratory adverse events [7]. Thus, it is essential to seek some maneuvers or interventions to decrease these complications.

Herein, we evaluated the effect of preoperative nebulization with lidocaine alone, compared to normal saline, and combined with epinephrine, regarding the incidence of post-operative respiratory complications.

Based on the previously mentioned results, it was noticed that there was no significant statistical differences between the three groups regarding all of the preprocedural parameters. This ensured the proper randomization technique, and this should also nullify any bias that might have skewed the results in favor of one group rather than the others.

In the current study, administration of nebulized lidocaine was associated with a significant decrease in heart rate compared to the NS and LA groups. This was evident from the time of intubation till the last follow up reading recorded. According to the existing literature, along with its local anesthetic action, the nebulized lidocaine could suppress the excitatory sensory C fibers present in the airway, leading to decreasing the stress response to laryngoscopy and bronchoscopy [22-24].

In our study, administration of nebulized lidocaine was associated with a significant decrease in propofol consumption compared to the other two groups. In another study that evaluated the role of nebulized lidocaine in non-sedation bronchoscopy, nebulized lidocaine was associated with a significant increase in intraoperative sedation ($p = 0.04$) compared to controls [25].

Our findings showed that the administration of nebulized lidocaine was associated with a significant positive impact on intra-operative cough, but no significant effect on intra-operative desaturation, post-operative sedation and stridor ($p > 0.05$) compared to controls. The incidence and severity of postoperative cough was higher in NS group when compared to L and LA group and when L group was compared to LA group. In a previous similar study, the incidence of intra-operative cough did not show any significant differences between the lidocaine and saline groups ($p = 0.18$). Also, the incidence of post-operative complications, including hypoxia and excessive cough, was statistically comparable with the nebulized saline group ($p = 0.41$) [25]. A previous Egyptian study reported that the nebulized lidocaine did not have any significant impact on the incidence of intraoperative cough or desaturation compared to controls who received only normal saline. However, nebulized fentanyl was associated with better hemodynamic response and decreased incidence of cough. Authors attributed these beneficial effects to the opioid characteristics of fentanyl. However, patients receiving fentanyl needed more time to full wakefulness [15]. On the other hand, **Palva *et al.*** [26] revealed the efficacy and improved patient acceptability in participants undergoing bronchoscopy with nebulized lignocaine. Following that, further studies have been conducted to assess the role of nebulized lignocaine in patients undergoing bronchoscopy.

When it comes to lidocaine adrenaline combination in the current study, its administration via nebulization was associated with significantly higher heart rates compared to the two groups. Also, MAP showed a significant rise during nebulization and anaesthetic induction. However, the post-hoc analysis revealed no comparable findings with the control group ($p > 0.05$) in most readings. In line with our findings, **Numa *et al.*** [27] reported a significant increase in heart rates after receiving nebulized epinephrine in the included 15 pediatric patients diagnosed with bronchiolitis. It was increased from 145 bpm (range, 94 – 177) before epinephrine, up to 164 bpm (range, 118 – 203) after it ($p = 0.0008$). The same authors also reported a subtle increase in MAP after epinephrine nebulization in their study ($p = 0.055$). It increased from 53 mmHg before the nebulizer up to 59 mmHg after it. The previous study reported a much stronger impact of epinephrine on the studies parameters, and we could attribute the weak effect in our study to its combination with lidocaine, which helped to attenuate the stress response associated with adrenaline injection. This could also explain the decreased propofol consumption in the LA group compared to controls.

In our study, although the LA group showed comparable results regarding intra-operative adverse events, there was a significant decrease in the incidence of post-operative cough in this group ($p = 0.014$). Adrenaline has a stimulant action for both alpha and beta receptors, which have a beneficial impact on both bronchial blood vessels and muscles. This, in turn led to the relief of airway obstruction resulting from bronchoscope manipulation [28]. Other studies also demonstrated the beneficial impact of epinephrine nebulization in children with bronchiolitis. It was associated with improved respiratory functions and lung mechanics [27, 28]. This could explain our finding.

Although our study revealed no significant difference between the three groups regarding post-procedural stridor, its incidence was higher in the NS group. In the same context, a recent report even stated that nebulized epinephrine (1:1000) could be used if patients developed stridor following bronchoscopy [29].

Our study had some limitations where it is a single-center study that included a relatively small sample size. More studies, including more cases with different nebulized drugs, should be performed to define the best-nebulized regimen that should be commenced for such cases before bronchoscopy.

CONCLUSION

Based on our findings, nebulized lidocaine/adrenaline combination can provide proper intraoperative sedation and upper airway conditions together with reduction in post-operative unwanted respiratory outcomes, with minor hemodynamic changes during pediatric rigid bronchoscopy procedures.

Declaration of interest

The authors have no conflict of interest.

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