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REPORTS OF ORIGINAL INVESTIGATIONS

Topical lidocaine reduces the risk of perioperative airway complications in children with upper respiratory tract infections

La lidocaïne topique réduit le risque de complications périopératoires au niveau des voies aériennes chez les enfants souffrant d'infections des voies respiratoires supérieures

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Abstract

Purpose *To determine the effect of topically applied lidocaine on perioperative airway complications when using a laryngeal mask airway device (LMAD) in children either with or without a history of recent or ongoing upper respiratory tract infection (URI).*

Methods *In a randomized controlled double-blind trial, 34 children with a history of recent or ongoing URI and 32 non-URI children— all of whom were younger than age ten and scheduled to undergo minor surgical procedures— were randomly assigned to either a lidocaine or a placebo group. In the lidocaine group, an LMAD was lubricated with lidocaine gel before insertion, and a clear lubricating gel was used in the placebo group. The following data were recorded after standardized anesthesia induction and airway management: postoperative complications, such as coughing, desaturation, laryngospasm, and increased oral secretions, as well as length of stay in the postanesthetic recovery unit.*

Results *Children with URI had a lower overall perioperative complication rate if they received a lidocaine gel (35%) rather than placebo (94%) ($P < 0.01$). Also, the incidence of postoperative coughing was less (12% vs 53%; $P = 0.03$). In non-URI patients, lidocaine did not significantly reduce the rate of airway complications compared with placebo (17% vs 24%, respectively).*

Conclusion *Lubrication of the LMAD with lidocaine gel reduces the incidence of airway complications in children with an upper respiratory tract infection.*

Résumé

Objectif *Déterminer l'effet d'une application topique de lidocaïne sur les complications périopératoires au niveau des voies aériennes lors de l'utilisation d'un masque laryngé (LMAD) chez des enfants avec ou sans infection récente ou actuelle des voies respiratoires supérieures.*

Méthode *Dans une étude randomisée contrôlée à double insu, 34 enfants avec une infection récente ou actuelle des voies respiratoires supérieures et 32 enfants sans infection, tous plus jeunes que 10 ans et devant subir des interventions chirurgicales mineures, ont été randomisés à recevoir soit de la lidocaïne, soit un placebo. Dans le groupe lidocaïne, un LMAD a été lubrifié à l'aide de lidocaïne en gel avant l'insertion, et un gel lubrifiant clair a été utilisé dans le groupe placebo. Les données suivantes ont été enregistrées après une induction de l'anesthésie et une prise en charge standard des voies aériennes: les complications postopératoires, telles que toux, désaturation, laryngospasme et sécrétions orales accrues, ainsi que la durée de séjour dans la salle de réveil post-anesthésique.*

Résultats *Les enfants souffrant d'infection des voies respiratoires supérieures ont montré un taux global de complications périopératoires plus bas lorsqu'ils ont reçu de la lidocaïne en gel (35 %) plutôt que le placebo (94 %) ($P < 0,01$). De plus, l'incidence de toux postopératoire était moindre (12 % vs 53 %; $P = 0,03$). Chez les patients ne souffrant pas d'infection des voies respiratoires supérieures, la lidocaïne n'a pas réduit le taux de complications au*

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niveau des voies aériennes de façon significative par rapport au placebo (17 % vs 24 %, respectivement).

Conclusion *La lubrification du LMAD avec un gel de lidocaïne réduit l'incidence de complications au niveau des voies aériennes chez les enfants souffrant d'une infection des voies respiratoires supérieures.*

Since children suffer upper respiratory tract infections (URI) about six times a year,[1] it is not surprising that pediatric patients scheduled for routine surgical procedures often present preoperatively with a history of recent URI or even show signs or symptoms of an ongoing infection. Studies have shown that up to 70% of the pediatric patients have a history of URI within six weeks prior to surgery.[2-5] There have been reports of increased perioperative morbidity in children presenting to surgery with an actual or recent (< six weeks) URI.[2,4] An increased number of episodes of laryngospasm, desaturation, increased oral secretion, and coughing has been observed at induction, emergence, and throughout the postoperative phase period.

Lidocaine applied to the laryngeal mucosa or administered intravenously has been found to decrease the risk of laryngospasm in pediatric patients when administered before extubation[6,7] or prior to intubation[8]. Moreover, the use of a laryngeal mask airway device (LMAD) instead of tracheal intubation may reduce perioperative airway complications.[9] Furthermore, topically applied lidocaine[10] and intravenous lidocaine[11] have been shown to improve conditions for LMAD insertion. However, the application of a lidocaine gel to the LMAD to serve as lubricant is controversial, as results on sore throat and minor airway complications are diverging.[12,13]

To evaluate the effect of lidocaine gel lubrication of the laryngeal mask airway, we conducted a randomized controlled double-blind clinical trial to compare the rate of airway complications of lidocaine gel lubrication with that of placebo gel lubrication in children either with or without recent or ongoing URI who were undergoing minor surgical procedures with LMAD insertion (LMA Unique®, LMA Germany, Bonn, Germany).

After approval by the local Institutional Review Board of the Medical University of Vienna and after obtaining written informed consent from the participants' parents, we recruited 66 pediatric patients (American Society of Anesthesiologists' physical status I and II) scheduled for minor routine surgical procedures under general anesthesia. Children younger than one year, older than ten years, or taller than 130 cm were not included in the study. Other exclusion criteria included history of gastroesophageal reflux, hiatal hernia, body mass index > 35 $kg \cdot m^{-2}$, and patients with an ongoing severe URI. Patients undergoing airway related surgery, such as adenoidectomy or tonsillectomy, were excluded from the study. Data were collected from July 1, 2007 to March 1, 2008. All pediatric patients were cared for by one experienced anesthesiologist during this period.

At the preoperative visit, parents were asked whether their child experienced a URI within the previous six weeks and whether there were signs of runny nose, nasal congestion, recurrent sneezing, sore throat, hoarseness, coughing, fever > 38°C, or general malaise. Following the suggestions of other authors,[4,14,15] URI was defined as the presence of at least two of the mentioned symptoms or parents' confirmation of recent or ongoing infection. The anesthesiologist caring for the patient evaluated the presence of a severe URI on the basis of symptoms such as severe coughing, high fever, respiratory distress, and the clinical presentation of the child. Patients were assigned to either the non-URI or the URI group according to the above definitions. Additional conditions that could be linked to an increased risk of adverse respiratory events were assessed, including a history of allergies, passive exposure to cigarette smoke, or a medical history of asthma.

The anesthetic management was standardized. All patients received midazolam 1 $mg \cdot kg^{-1}$ (maximum 15 mg) rectally 15 min before arriving in the operating room. After preoxygenation via a facemask, anesthesia was induced using sevoflurane. Thereafter, a venous access was established and depth of anesthesia was increased using propofol 5 $mg \cdot kg^{-1}$ and fentanyl 3 $\mu g \cdot kg^{-1}$.

An assistant otherwise not involved in the anesthesia care prepared the LMAD (LMA Unique, LMA Germany, Bonn, Germany) by applying 0.3 $mL \cdot kg^{-1}$ of clear lidocaine-containing gel (2% Xylocain Antiseptic Gel; Astra Zeneca GmbH, Wedel, Germany) or the same volume of a gel of the same consistency and appearance containing no anesthetic (Vidisic Gel; Dr. Gerhard Mann Chem. Pharm. Fabrik, Berlin, Germany). The respective gel was chosen randomly according to a computer-generated stratified block randomization and sealed in an opaque envelope that was opened immediately after anesthesia induction. The appropriate LMAD size was chosen as recommended by the LMA manual[A] and was inserted after a trapezius squeeze test, as described by Chang *et al.*,[16] yielded no response. Anesthesia was maintained with fentanyl and sevoflurane (as needed to maintain mean arterial blood pressure within 20% of preinduction values) in 40% oxygen. Tidal volume was set at 8 $mL \cdot kg^{-1}$ ideal body weight.

[A] *The Laryngeal Mask Company Limited.* LMA Airway Instruction Manual. San Diego; 2005.

Fresh gas flow was limited to 1.5 $L \cdot min^{-1}$. Positive end-expiratory pressure (PEEP) was set at 3 cm H_2O in both groups. Ventilation frequency was set to achieve an end-tidal CO_2 partial pressure near 40 mmHg. The LMAD was removed during deep anesthesia at the end of the procedure after re-establishing spontaneous ventilation. The cuff of the LMAD was not deflated, and no suctioning of the upper airway was performed before airway removal.

Additional oxygen was applied as needed via a pediatric face mask in case of desaturation of more than 10% of preinduction value during transfer to the postanesthetic care unit (PACU). Rectal acetaminophen 40 $mg \cdot kg^{-1}$ was used for pain control in the PACU.

A blinded observer recorded the following adverse events from induction of anesthesia until discharge from the PACU: coughing, excessive oral and pharyngeal secretions, bronchospasm, laryngospasm, a > 10% decrease in oxygen saturation compared with the preinduction value, and the use of rescue maneuvers, such as infusion of parasympatholytic agents, deepening of anesthesia, and endotracheal intubation. Even a single episode of coughing was rated as an adverse event. Laryngospasm was defined as complete airway obstruction associated with missing or paradoxical thoracic movement throughout the respiratory cycle, and it was resolved primarily by applying PEEP and jaw-thrust maneuver in combination with stimulation of the mastoid. Bronchospasm was defined by the presence of increased respiratory effort, wheezes at auscultation, and a typical upsloping of the carbon dioxide curve. The need for rescue maneuvers, described above, and the presence of excessive secretions, laryngospasm or bronchospasm were identified by the anesthesiologist in charge of the case. An overall complication rate was calculated by including all patients who had at least one complication throughout the study period. Time was measured from arrival until discharge from the PACU.

Statistical analysis

The primary outcome measurement was the overall complication rate in patients with URI in both the treatment and placebo groups. Secondary outcomes were total complications and individual complications in URI and non-URI patients. After reviewing the current literature[9,17] and taking our own experience into account, we estimated that the complication rate would be 90% in patients managed without lidocaine. A reduction of 50% to 45% was considered clinically relevant. With these assumptions, 16 patients were needed in each treatment group with a power of 80% and an alpha error of 0.05.

For a stratified analysis of the overall complication rate including children with URI symptoms and children without URI, a Cochrane-Mantel-Haenszel (CMH) test was performed with URI as stratum. The analysis of specific complications and the CMH analysis (URI, non-URI) are not corrected for multiplicity and are hypothesis generating. For all other analyses, an unpaired two-tailed Student's *t* test and Chi square test with Yates' correction for continuity were used as appropriate. A $P < 0.05$ was considered to indicate statistical significance. We used the R 2.8.1 software for Mac (The R Foundation for Statistical Computing, Vienna University of Technology, Vienna, Austria) for statistical analysis.

Results

All 66 operations were performed successfully in a surgical fast track unit, and all 66 patients completed the study. The surgical procedures were urologic (36), orthopedic (11), general (11), ophthalmic (4), dermatologic (2), and ear, nose, and throat (2). Patients' demographic and pathophysiological data are displayed in Table 1. The

Table 1 Demographic and pathophysiological patient data for URI and non-URI patients

	URI		non-URI	
	Lidocaine (n = 17)	Placebo (n = 17)	Lidocaine (n = 12)	Placebo (n = 20)
Age (yr) (mean ± SD)	4.4 ± 1.8	3.8 ± 1.3	5.2 ± 2.0	4.1 ± 2.6
Height (cm) (mean ± SD)	105.0 ± 15.3	102.0 ± 8.0	106.4 ± 20.9	110.5 ± 3.4
Weight (kg) (mean ± SD)	16.8 ± 5.3	19.3 ± 6.7	16.4 ± 6.3	16.2 ± 5.9
ASA (I/II)	(15/2)	(17/0)	(12/0)	(20/1)
Asthma	0	0	0	0
Allergies	0	0	0	0
Passive smoker *n* (%)	9 (31%)	11 (30%)	8 (67%)	11 (55%)

SD = standard deviation; URI = children with ongoing or recent upper respiratory tract infection; non-URI = children without upper respiratory tract infection; ASA = American Society of Anesthesiologists' physical status classification

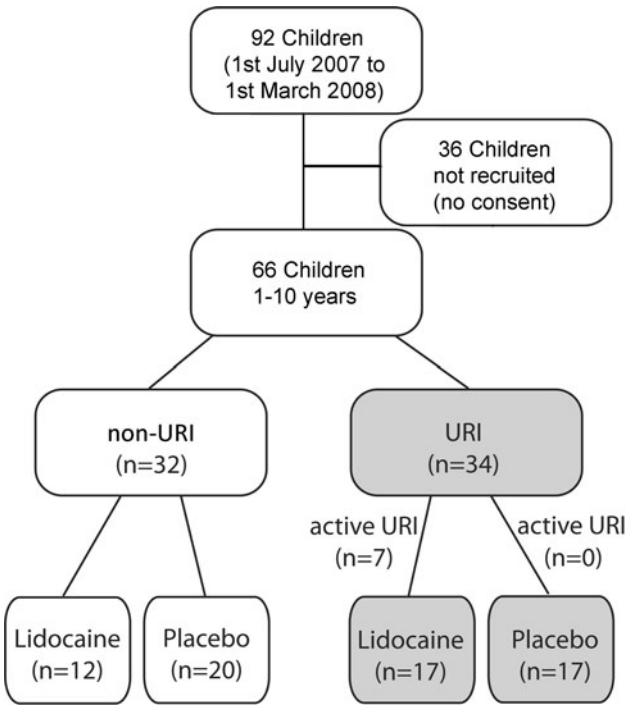

Figure Recruitment of patients

recruitment process and patient allocation are shown in the Figure.

Age distribution was similar in the lidocaine and placebo groups as well as in the subgroups (Table 1). In URI patients, no difference in the duration of PACU stay was found between the lidocaine and the control groups (lidocaine: 156 ± 25 min *vs* placebo: 158 ± 22 min; $P = 0.84$). In non-URI patients, duration of PACU stay was also similar between the lidocaine and placebo groups (lidocaine 165 ± 24 min *vs* placebo 182 ± 23 min; $P = 0.06$). In the lidocaine group, timing of URI was 2 ± 1 week before surgery compared with 3 ± 2 weeks in the placebo group.

In the URI patients, the overall perioperative complication rate was significantly less in the lidocaine group (35%) than in the placebo group (94%) (Table 2). Among the individual complications, the only difference found was for coughing in the postoperative period (lidocaine 12% *vs* placebo 53%; $P = 0.03$). In the intraoperative and postoperative phases, no difference between the lidocaine and placebo groups could be found in the URI patients in terms of intraoperative coughing and secretion, desaturation, bronchospasm, or laryngospasm. None of the children needed parasympatholytic agents and no endotracheal rescue intubation had to be performed.

In the non-URI patients, complications were less frequent (Table 2), and there was no statistically significant difference between the lidocaine and placebo groups. A detailed list of complications is provided in Table 3. Lidocaine related adverse events, such as seizures, arrhythmias or allergic reactions, were not observed in any patient.

Table 2 Rate of intraoperative and postoperative adverse events

	URI		non-URI	
	Lidocaine	Placebo	Lidocaine	Placebo
Intraoperative complications	5 (29%)	9 (53%)	1 (8%)	3 (15%)
PACU complications	6 (35%)*	13 (77%)	2 (17%)	3 (15%)
Overall complications	6 (35%)**	16 (94%)	2 (17%)	4(24%)

All values are *n* (%). *$P = 0.04$, **$P < 0.01$, Chi square test (lidocaine *vs* placebo in URI patients). URI = children with ongoing or recent upper respiratory tract infection; non-URI = children without upper respiratory tract infection; PACU = postanesthesia care unit

Table 3 Complications throughout the perioperative period

	URI		non-URI	
	Lidocaine (*n* = 17)	Placebo (*n* = 17)	Lidocaine (*n* = 12)	Placebo (*n* = 20)
Intraoperative				
Coughing	2 (12%)	2 (12%)	0 (0%)	1 (5%)
Secretion	2 (12%)	0 (0%)	1 (8%)	2 (10%)
Desaturation	2 (12%)	3 (18%)	0 (0%)	0 (0%)
Spasm	3 (18%)	7 (41%)	0 (0%)	2 (10%)
Postoperative				
Coughing	2 (12%)	9 (53%)*	0 (0%)	2 (10%)
Secretion	2 (12%)	2 (12%)	2 (17%)	1 (5%)
Desaturation	4 (24%)	4 (24%)	2 (17%)	1 (5%)
Spasm	3 (18%)	4 (24%)	0 (0%)	2 (10%)

All values are *n* (%). *$P = 0.03$, Chi square test (lidocaine *vs* placebo in URI patients). URI = children with ongoing or recent upper respiratory tract infection; non-URI = children without upper respiratory tract infection; Desaturation = drop in oxygen saturation of more than 10% of preinduction values; Spasm = bronchospasm and laryngospasm

Discussion

The present study shows that lidocaine gel applied to an LMAD leads to a marked reduction of respiratory adverse events in pediatric patients with a recent (< six weeks) history of URI or an ongoing URI. Coughing was the most frequent adverse event in the PACU. The overall complication rate was lower in the non-URI patients than in the URI group. Also, no effect of lidocaine lubrication was detected in the non-URI patients.

Topical or intravenous lidocaine has been shown to be effective in reducing airway reactivity in patients with induced bronchoconstriction.[18,19] Furthermore, lidocaine has been reported to reduce the risk of post-extubation

laryngospasm and stridor in adenoidectomy and tonsillectomy[8] and other surgical patients.[20] Lidocaine has also been used to break post-extubation stridor and laryngospasm in adult patients[19,21] and to decrease postoperative sore throat after extubation.[22] Although most of these studies refer to adult patients, the present results in pediatric patients are consistent with these findings.

Even though lidocaine is a relatively short-acting local anesthetic, we could show an effect of local application on the postoperative and overall complication rate. This may be due to the "depot" effect of the gel preparation, as it stays in the pharyngeal area for a relatively long period of time.

The incidence of perioperative complications was relatively high in the present study, probably because of a strict definition. In a large trial by Tait *et al.*,[4] the total airway-related complication rate was 30% in children with actual URI and 25% in those with a recent history of URI. In another study, von Ungern-Sternberg *et al.*[17] reported a complication rate of 19% in non-URI patients and nearly 32% in URI patients. In a large trial by Tait *et al.*, coughing occurred in up to 63% of children with URI managed with a laryngeal mask airway and in > 80% of those who were tracheally intubated.[9] In our trial, coughing in the PACU was observed in 32% of the children who presented with a history or signs of URI. In contrast to other studies,[4,9,17] the definition of airway complications in our trial was broad to reduce observer bias; therefore, even a single episode of coughing was recorded as an adverse event. The occurrence of laryngospasm that resolved without treatment was also considered an adverse event. According to the available literature, severe or sustained postoperative coughing in patients with active URI occurs in 4-15% of patients.[4,17] However, severity of coughing as well as occurrence of other airway complications are rather subjective parameters with a marked inter-observer variation. Thus, rather than including only "severe" events, we chose to record the incidence of these events regardless of severity.

In general, all airway-related adverse effects were included in the analysis regardless of their severity and frequency. However, to reduce the risk of bias by different experienced anesthesia providers, the patients were managed by a single anesthesiologist with extensive experience in pediatric ambulatory anesthesia. In the present study, various types of surgical procedures were included and only airway-related surgeries, such as tonsillectomy and adenoidectomy, were excluded. This wide variety of cases may have influenced airway reactivity. Since Schreiner *et al.* described an increased risk of airway complications in patients younger than one year of age,[23] we excluded this age group. The dose of lidocaine was calculated based on body weight to prevent side effects related to the toxicity of the drug. However, it is not possible to rule out that some airway complications related to the volume of the lubricant might have occurred.

In conclusion, this study shows that topical anesthesia of the airway—through the use of lidocaine gel as a lubricant for LMAD insertion—results in a clinically important reduction of the overall airway complication rate in children with ongoing URI or a history of recent URI.

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Competing interests None declared.

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