

Comparison of Post Extubation Complications In 3 Different States of Filling Endotracheal Tube Cuff With Lidoaine 4% In Elective Surgery Patients (This is the template – do not put these words about template in your paper)

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Abstract: post-extubation complications including coughing, sore throat, and hoarseness during emergence from general anesthesia common clinical problems. Some Clinical techniques used to decrease these complications. This aimed to assess post-extubation endotracheal tube complications in 3 different states of lidoaine 4% for filling endotracheal tube cuffs. This was a clinical trial study carried out in Iran. 200 candidates of elective surgery being and 2 ASA were randomly divided into 4 groups (N=50). The endotracheal tube cuffs of each group members were filled with (5-10ml) distilled water, lidoaine 4%, alkalized lidoaine 4% and warmed alkalized lidoaine 4%, respectively. The patients were observed for complications such as cough (for 6 hrs), sore throat, and hoarseness (for 24 hrs) after extubation. The data were analyzed by chi2, logistic regression using SPSS.

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1. Introduction

Endotracheal tubes (ETT) are extensively used as ventilatory and intubation devices in the management of anesthesia and critical care patients (Dollo et al., 2001). Nevertheless, the endotracheal tube as an external object can stimulate the patient's airway during the emergence from general anesthesia and create different reactions and complications (Hagberg et al., 2005). Techniques that have been used to diminish these reactions include deep extubation, administration of intravenous (IV) narcotics or IV lidoaine (Patrick J, 2010) as well as administration of lidoaine in various other methods (jell, spray, ointment) (Ali et al., 2009). Various studies have shown that there are problems in each of the above mentioned methods used to prevent the complications (Soltani and Aghadavoudi, 2002, Koga et al., 1999, Shizukuishi et al., 2001, Fagan et al., 2000).

In some studies, it was shown that lidoaine 4% diffuses across the semi-permeable cuff membrane of the endotracheal tube of Polyvinylchloride (PVC) material. Therefore, the endotracheal tube's cuff could serve as a potential reservoir with gradual release of lidoaine to retain and diffuse the drug and to make anesthesia in the region under the cuff (Sconzo et al., 1990, Huang et al., 1999).

Alkalinization and warming up the alkalized intracuff lidocaine leads to an increase of 63 times and 118 times of its diffusion across the cuff, respectively (Huang et al., 1998). Moreover,

alkalinization of lidocaine hydrochloride with sodium bicarb leads to a 65% lidoaine hydrochloride diffusion during 6 hours in comparison with its 1% diffusion without adding sodium bicarb (Estebe et al., 2005). The ability of lidoaine to diffuse across the cuff depends upon the concentration of the prescribed lidoaine and the operation period (the period in which the tube is in the trachea) (Estebe et al., 2005, Estebe et al., 2002a). So that leakage of lidoaine 14% across the cuff wall increases after 60-90 min (Soltani and Aghadavoudi, 2002, Fagan et al., 2000, Estebe et al., 2004, Shin et al., 2008, Estebe et al., 2002b, Hirota et al., 2000).

At present, endotracheal tube cuffs are filled mostly with air. Despite satisfactory initial sealing with air, nitrous oxide (N₂O) diffuses into the cuff during anesthesia, increasing the cuff volume and intracuff pressure (Karasawa et al., 2000, Miyashiro and Yamamoto, 2011, Navarro et al., 2007). This leads to pressure on the tracheal wall and damage to the tracheal mucous (Estebe et al., 2002a, Miyashiro and Yamamoto, 2011). To avoid the overinflation problem, liquid could be used instead of air to fill the endotracheal tube (Navarro et al., 2007). Use of liquid instead of air prevents the diffusion of nitrous oxide gas inside the cuff and its expansion (Navarro et al., 2007, Ali et al., 2009). Lidoaine, as a solution, can be a good alternative to air (Dollo et al., 2001). Besides the advantages mentioned above use of lidoaine in the cuff leads to limited contact of this drug with the mucous around the cuff and this prevents patient from

loosing protective supraglottic reflexes and vocal cords and at the same time, the patient tolerates the endotracheal tube well (Patrick J, 2010).

The use of endotracheal tube and consequently the possibility of complications due to various reasons are rising because of an increase in elective surgery or tracheostomy. Therefore the surgical team members including physician and nurses are responsible to reduce the possibility of any complications by providing care for patients and promoting their health in this regard.

In most studies, inflating endotracheal tube cuff with lidoaine had been compared with air (Estebe et al., 2004, Tanaka et al., 2009, Fagan et al., 2000, Dollo et al., 2001, Estebe et al., 2002b). This comparison of fluid like lidoaine with air seems to be inappropriate. Furthermore, there is little evidence supporting the effectiveness of using warmed alkalized lidoaine 14% in reducing post extubation complications. Therefore, this study is aiming at the comparison of post-extubation complications in three different states of lidoaine 4% used to fill the endotracheal tube cuff in patients undergoing elective surgery.

2. Methods

The design of this clinical trial study was approved by institutional ethics committee. Written informed consent were obtained from all patients involved in this study. 200 patients of class 1 & 2 American Society of Anesthesiologists (ASA) (18 to 60 years old) who were candidates for elective gynecologic, orthopedic, plastic, urology and general surgery (without nasal gastric tube) were selected randomly and allocated in 4 groups. Sample size was detected ($n=50$ for each group: the control (distilled water) and experimental (lidocaine 4%, alkalized lidoaine 4% and alkalized and warmed up at 38°C lidoaine)] based on previous studies (Fagan et al., 2000) considering $\alpha=0.05$, Power=80%, missing=20%.

Patients having each one of the following history or signs and symptoms were not included in this study: history of using narcotics or cigarette, with active upper respiratory tract infection, a history of head, neck, larynx surgery or anatomic disorders, history of allergy to drugs (such as amide anesthetics) or a special kind of food, complaints from sore throat before operation, with laryngitis, being exposed to the risk of aspiration of gastric contents, asthma, being at risk of intracranial or intraocular pressure, undergoing ocular or neurological surgeries, history of hypertension and/or cardiovascular diseases. The patient were excluded if they were not in supine position during operation, had bloody secretions during suction, received intravenous lidoaine during

operation, were under operation for less than 1 hours and were intubated with more than one trial.

All patients were anesthetized with the same method. They were preoxygenated with oxygen 100% via a face mask, received 1.5-2ml fentanyl, 0.05-0.1 mg/kg morphine, 0.03-0.06 mg/kg midazolam as premedicant and for induction of anesthesia 3-5mg/kg thiopental sodium, 1-2mg/kg propofol, 0.5-1 mg/kg atracorium (for relaxation of muscles). Then the patients were intubated with portex endotracheal tube (made in England) proportional to their size of trachea (7-7.5 mm and 8-8.5mm diameter for women and men, respectively). In all patients, curved blade laryngoscope was used for intubating. The appropriateness of endotracheal tube insertion was confirmed by observing symmetric, bilateral movement of the chest and bilateral auscultation of respiratory sounds as well as observation of water vapor build-up in the intratracheal tube during exhalation and displaying the percentage of the appropriate arterial oxygen in pulse oximetry. For maintenance of anesthesia in all patients 5-10 $\mu\text{g}/\text{kg}/\text{min}$ propofol, nitrous oxide (in a ratio of 50%) and oxygen (in a ratio of 50%) were used. During the operation, the ventilation of patients was made mechanically via a ventilator with constant volume of 6-10ml/kg. To maintain muscular relaxation during the operation atracorium with a dose of 1.3-1.5 the initial doses was used.

In order to prevent from the risk of allergic reactions, non allergenic intrathecal lidoaine containing preservative substance (amide group anesthetics) was used to prepare lidocaine 4% in this research.

In order to prepare lidocaine 4%, 1cc normal saline was added to each 4cc of lidoaine 5%. To prepare alkalized lidocaine 4%, 1cc of bicarbonate was added to each 4cc of lidoaine 5%. To prepare warmed alkalized lidocaine 4% the above alkalized lidocaine 4% was placed in the warmer for 1.30-2.30 hours to make its temperature up to 38°C.

Before starting the operation each of the above solutions was drawn in 10cc syringes and labeled appropriately. Each solution was chosen randomly for filling endotracheal tube cuff and a code was given to the information sheet depending on the type of solution used. All patients were observed for complications after extubation blindly.

The intracuff pressure was controlled [using endotracheal cuff pressure control device (figure 1) specifically made for this study] in a range of 10-20 cmH_2O (at a level lower than the capillary perfusion pressure of tracheal mucous of the patient with 5-10ml solution) to avoid the ischemia (Patrick J, 2010) and to decrease the possibility of the cuff rupture. To prevent toxicity with lidoaine in case of cuff rupture,

we used appropriate dose of lidoaine [(224mg±44mg) 5.6±1.1ml] according to studies in which, like this study no rupture in cuff or toxicity with lidocaine is reported (Fagan et al., 2000, Dollo et al., 2001, Ali et al., 2009, Sconzo et al., 1990, Huang et al., 1999, Huang et al., 1998, Estebe et al., 2002a, Estebe et al., 2004, Estebe et al., 2005, Hirota et al., 2000). External endotracheal tube cuffs were examined frequently during operation and the cuffs were checked after extubation to ensure the intactness of endotracheal tube cuffs. Based on these observations no rupture was seen in the cuffs.

Extubation was made when all the following criteria were met: appropriate spontaneous respiration, obeying verbal commands (opening the eye, lifting up to the head for 5 seconds and fisting the hand) or intentional movements (such as trying to extubate by him/herself).

After establishment of the above conditions, extubation was performed. All patients under study were observed for cough during the first 15 minutes, till 1 and 6 hours after extubation, sore throat and hoarseness were assessed during the first 1 hour and until 6 and 24 hours after extubation. To ensure the reliability of the observations all these variables were observed and recorded by one researcher.

The data were analyzed by SPSS using χ^2 and logistic regression tests.

3. Results

The chi-square test showed significant difference regarding cough, sore throat and hoarseness between groups under the study (table 1).

For recognizing the groups which have significant differences, the distilled water group has been compared with each lidoaine group by another χ^2 test. It revealed that the warmed alkalized lidoaine group significantly differed from the control group (distilled water) regarding cough (X^2 : 6.86, $P < 0.009$), sore throat (X^2 : 9.01, $P < 0.003$) and hoarseness (X^2 : 10.19, $P < 0.001$). Moreover, the results showed the significant difference in cough (X^2 : 6.86, $P < 0.009$) sore throat (X^2 : 7.48, $P < 0.006$) and hoarseness (X^2 : 6.83, $P < 0.009$) between the distilled water group and alkalized lidocaine 4%. A significant difference was found between the distilled water and lidoaine 5% only in sore throat (X^2 : 3.93, $P < 0.047$).

The frequency of each of the complications in different groups of study in relation to the period of the presence of the tube inside the trachea was evaluated using χ^2 . The results showed that except for hoarseness in warmed alkalized lidoaine group (X^2 : 4.764, $P > 0.05$) more complications are present when the period of the tube being inside the trachea is increased.

Based on the above result, logistic regression were used to find the odds ratio of the cough, sore throat and hoarseness (presence or lack of) in groups of distilled water, lidocaine 4% and alkalized lidocaine 4% on warmed alkalized lidocaine 4%. The results showed that for cough, sore throat and hoarseness only the odds ratio of distilled water was significant (table 2).

Similarly the multiple variable logistic regression were used for some more variables such as age, sex, weight, type of operation, intracuff pressure, duration of the presence of the tube inside the trachea in addition to different states of lidoaine for filling endotracheal tube cuff. The results showed that for cough, sore throat and hoarseness the odds ratio of both distilled water and lidoaine 4% was significant. Furthermore it was found that out of the new variables only duration of the tube inside the trachea was significant for them (OR: 1.10 - 1.11, $P < 0.0001$).

4. Discussions

Measures to prevent the complications of intubation are very important and should be considered by all members of therapeutic team.

In this study, post-extubation complications were investigated in 3 different states of lidoaine 4%.

Distilled water was used in this study instead of air to control confounding variables. As both distilled water and lidoaine, are liquid. They are similar in characteristic. The findings of previous studies show that the use of a liquid (lidoaine or saline) for filling the cuff had no harmful effects (Dollo et al., 2001, Soltani and Aghadavoudi, 2002, Fagan et al., 2000, Hirota et al., 2000, Estebe et al., 2002a, Navarro et al., 2007). Also, using lidoaine instead of air has been reported as a relatively easy and safe practice (Fagan et al., 2000).

A significant difference between distilled water group and each groups of warmed alkalized lidocaine 4% and alkalized lidocaine 4% was detected, but no significant difference was found between the distilled water group and lidoaine 4% regarding cough. In another study the frequency of the cough was significantly lower in 3 groups of warmed alkalized lidocaine 4% (8°C), alkalized lidocaine 4% and lidocaine 4% than the control group (normal saline) (Huang et al., 1998). Also the researchers showed that the prevalence of cough in 0-2 and 2-4 min for the groups of air, saline and lidocaine were not significant, but there was a significant difference between groups in 4-8 min regarding frequency of cough (Fagan et al., 2000). Most of these findings are in accordance with the findings of the present study. However, in our study lidoaine 4% was not effective in reducing post-extubation cough. These results show that the groups of warmed alkalized lidocaine 4%

and alkalized lidoaine 4% were more effective than the control group and lidoaine 4% in reducing post extubation cough.

A significant difference was found between the distilled water group and each group of warmed alkalized lidoaine4%, alkalized lidoaine4% and lidoaine4% regarding sore throat. This findings support the result of Haung and et al study (1998)(Huang et al., 1998), but is not in accordance with the result of porter and et al study (1999) in which there was no significant difference between the groups of lidoaine, normal saline and air (Porter et al., 1999). It should be considered that in this study we did not used air for filling the endotracheal cuff. In another study it was shown that lidoaine passed across the tracheostomy tube cuff to some extent that it significantly lowered the discomfort resulting from tracheostomy cuff (Hirota et al., 2000). These Findings show that use of lidoaine in 3 different states were effective in reducing the occurrence of post extubaton sore throat.

A significant difference between the distilled water group and each group of warmed alkalized lidoaine4% and alkalized lidocaine4% was found concerning hoarseness. But there was no significant difference between the groups of distilled water and

lidoaine4% in this regard. The findings of another study showed that the tolerance of hoarseness in the control group (air) was less than the lidoaine 4% and was less in the lidoaine4% than the alkalized lidoaine4% (Estebe et al., 2002a). However our findings show that the groups of warmed alkalized lidoaine 4% and alkalized lidoaine4% were more effective than the control group and the lidoaine 4% in reducing post extubation hoarseness. The increase in the ratio of uncharged lidocaine to charged lidoaine due to alkalization of lidoaine and warming up alkalized lidoaine results in better diffusion of lidoaine across the cuff wall (Huang et al., 1998)and lowers cough, sore throat and hoarseness.

An increase in post extubation cough, sore throat and hoarseness was seen regarding the period of the tube being inside the trachea, but an increase in hoarseness was not time related for warmed alkalized group. The complications were seen for shorter periods in lidoaine groups than the distilled water group. It seems that the diffusion of lidoaine have been enough to locally anesthetized patients' trachea. The complications observed during 24 hours after extubation was similar in all groups under the study.

Table 1. Distribution of patients regarding to status of post extubation cough, sore throat and hoarseness in groups under study.

Groups Under Study	Distilled water	Lidocaine4%	Alkalanized Lidocaine4%	Warmed Alkalanized Lidocaine4% (38 ^o c)	Statistical Finfings	
	Percent (Frequency)	percent (Frequency)	percent (Frequency)	percent (Frequency)	X ²	P
Lack of cough	29(58)	37(74)	41(82)	41(82)	9.98	0.12
Presence of cough	21(42)	13(26)	9(18)	9(18)		
Lack of sore throat	31(62)	40(80)	43(86)	44(8)		
Presence of sore throat	19(38)	10(20)	7(14)	6(12)		
Lack of hoarseness	33(66)	41(82)	44(88)	46(92)		
Presence of hoarseness	17(34)	9(18)	6(62)	4(8)		

Table 2. Logistic regression results for estimating of the odds ratio of different variables in cough, sore throat and hoarseness.

Complications & statistical measures Viriabies	Cough			Sore throat			Hoarseness		
	OR	95%C.I for OR	P	OR	95%C.I for OR	P	OR	95%C.I for OR	P
Distilled water	3.299	1.322-8.231	0.011	4.495	1.61-12.545	0.004	5/924	1.825-19.229	0.003
Lidocaine4%	1.601	0.613-4.176	NS*	1.833	0.611-5.502	NS*	2/524	0.723-8.818	NS*
Alkalanized Lidocaine4%	1	0.36-2.774	NS*	1.194	0.371-3.841	NS*	1/568	0.414-5.935	NS*
	Goodness of fit: p<0.022 X ² =9.609 df =3			Goodness of fit: p<0.008 X ² =11.947 df = 3			Goodness of fit: p<0.005 X ² =12.745 df =3		

NS*: Not Significant.

The odds ratio was not considered in any of studies available (Dollo et al., 2001, Ali et al., 2009, Estebe et al., 2005, Fagan et al., 2000, Sconzo et al., 1990, Estebe et al., 2002a, Estebe et al., 2004). So it was not possible to compare the result of this research

to others. Therefore, computation of the considered in further researches.

Overall it can be concluded that filling endotracheal tube cuffs with alkalized lidocaine4% and warmed alkalized lidoaine4% reduces the

occurrence of post- extubation cough, sore throat and hoarseness during emergence from general anesthesia. But lidocaine 4% is not effective in reducing these post extubation complications. Also, the chance of the occurrence of the complications under the study is less in the warmed alkalized lidocaine 4% than other groups.

It should be considered that this study was done on patients having predefined characteristics, therefore the results can not be generalized. To generalize the results, replication of the study on different patients specially those being under prolonged operation is suggested.

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