ORIGINAL ARTICLE

Effect of applying lignocaine gel, diclofenac gel or their combination on endotracheal tube on the hemodynamic response and incidence of postoperative complications in patients undergoing CABG surgery

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ABSTRACT

Objectives: Hoarseness of voice, cough and sore throat are well known complications of endotracheal intubation. Many pharmacological strategies are used to reduce the incidence of these complications post surgery. We conducted this study to see the effectiveness of local application of diclofenac sodium gel, lidocaine gel or the effect of these two drugs when applied in combination on tracheal tube during intubation, regarding hemodynamic response and the incidence of postoperative sore throat, hoarseness of voice and cough.

Methodology: In this prospective, randomized single blind trial, 150 patients undergoing coronary artery bypass graft (CABG) surgery at Chaudhry Pervaiz Elahi Institute of Cardiology from January 2016 to March 2016, were selected. The patients were divided into three groups; Group X (control Group) in which endotracheal tube (ETT) was lubricated with 2% lignocaine gel. Group D: ETT was lubricated with diclofenac sodium gel (2%). And Group XD: where a mixture of lignocaine and diclofenac sodium gels was used to lubricate ETT before insertion. Data were analyzed in SPSS V16. One way ANOVA and chi-square test was used for analysis of quantitative and qualitative variables respectively taking p-value < 0.05 to be significant.

Results: There was no difference in the age and gender of patients between groups. Post intubation HR increased more in Group D (108.94 ± 7.40 beats/min.), and least in Group XD 96.62 ± 3.84 beats/min and 100.72 ± 6.98 beats/min in group X ($p < 0.0001$). HR returned back to baseline value in group X and Group XD within five minutes after intubation but remained higher in diclofenac group ($p < 0.0001$). The rise in blood pressure after intubation was highest in Group D (162.46 ± 5.05 mmHg), then 157.34 ± 5.43 mmHg in Group X, and least in Group XD (154.12 ± 6.07 mmHg) ($p < 0.0001$). Similarly blood pressure after five minutes of intubation was still high in Group D and was least in Group XD ($p < 0.0001$). The time of return of HR and systolic blood pressure to baseline value was 9.00 ± 1.33 min in Group D, 4.59±1.03 min in Group X and 3.43 ± 0.81 min in group XD ($p < 0.0001$). Incidence of sore throat, hoarseness of voice and cough was highest in Group X and less in Group D and was least in Group XD (p-values 0.039, 0.025 and 0.002 respectively).

Conclusion: Local application of a combination of lignocaine and diclofenac sodium gels over the endotracheal tube before intubation is associated with better hemodynamic control and significantly lower incidence of postoperative sore throat, hoarseness of voice and cough.

Key words: Anesthetics, Local; Lidocaine; Diclofenac sodium gel; Lignocaine; Lignocaine Gel; Postoperative; Complications; Sore throat; Coughing

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INTRODUCTION

Hoarseness of voice, cough and sore throat are well known complications of endotracheal intubation. All of these conditions are distressing and uncomfortable and leave the patient with unpleasant memories of the surgical procedure.[1,2] The pathophysiology of these conditions is believed to be local irritation, traumatization and inflammation of the airway during intubation.[3,4]

Both non-pharmacologic and pharmacologic strategies are used to reduce the incidence of these complications after surgery. Use of smaller sized endotracheal tube (ETT), lubrication of tube with water soluble gel, low intra-cuff pressure and removal of ETT after full deflation are well known non-pharmacologic measures reported to reduce the incidence of these complications.[3,5,6] Pharmacologic therapies include the use of lignocaine gel, intravenous or local application of steroids, non-steroidal anti-inflammatory drugs and ketamine gargles.[7-1]

Some studies have shown the effectiveness of intravenous diclofenac sodium and diclofenac epolamine patch (NSAIDs) in reducing the incidence of postoperative sore throat.[14,15] In our search we did not come across any study comparing the efficacy of diclofenac gel application for lubrication of ETT prior to intubation on the incidence of postoperative sore throat, hoarseness of voice or cough. We conducted this study to see the effectiveness of local application of diclofenac sodium gel, lignocaine gel and a combination of these two gels on the ETT prior to intubation regarding hemodynamic changes and incidence of postoperative sore throat, hoarseness of voice and cough during the first six hours of postoperative period.

METHODOLOGY

This was a prospective, randomized single blinded trial. Ethical approval was taken from the department of academic affairs, Ch. Pervaiz Elahi Institute of Cardiology, Multan before starting this research work. The study was conducted in the cardiac surgery unit of the hospital. One hundred and fifty patients undergoing any type of CABG surgery (off pump or on pump) under general anesthesia were recruited. There were three equal groups of patients (50 patients in each group); Group X (control Group) in this group of patients ETT was lubricated with lignocaine gel 2% (Xylocaine Jelly 2% 15g, Barrett Hodgson Pakistan (Pvt) Ltd), our routine method of intubation. Group D: in this group ETT was lubricated with diclofenac sodium gel 2.0 % (Motaar, Standpharm Pakistan (Pvt) Ltd.) and Group XD: in this group a mixture of lignocaine and diclofenac sodium gel was used to lubricate ETT before insertion. We lubricated all portions of ETT that were to come in contact with the patient's pharyngeal wall, vocal cords and trachea. Randomization was done using lottery method. Patients were asked to pick up a folded paper containing name of groups, and the patient was placed in that group according to the folded paper chosen by him. An informed consent was taken from the patients after briefing them about the research project.

Patients with previous history of respiratory disease e.g. chronic obstructive airway disease and asthma, gastro-esophageal reflex syndrome taking pre-operatively anti-inflammatory and analgesic drugs and with prolonged ventilation in the postoperative period (tracheal intubation time more than 10 hours) were excluded.

Invasive blood pressure monitoring, pulse oximetry, capnography, and electrocardiography monitoring was used in every patient before and after intubation until the ETT was removed. Anesthesia technique was standardized by using midazolam (0.02 to 0.05 mg/kg) fentanyl (10 to 15 μg/kg), and atracurium bromide (0.2 to 0.4 mg/kg). ETT was inserted in first attempt in all patients by a senior consultant with the help of an appropriate sized laryngoscope blade. The cuff pressures were maintained at approximately 20 mmHg and were measured using Smiths Medical Portex cuff manometer after every 20 min of intubation. Heart rate (HR) and mean systolic arterial blood pressures were measured and noted in every patient by the assistant anesthetist before insertion of ETT, immediately after insertion and five minutes after. The time period for return of systolic blood pressure to baseline value i.e. equal to blood pressure before insertion of ETT was also noted. The severity of postoperative sore throat, hoarseness of voice and cough was noted at 6 hours after removal of ETT (extubation). Patients were extubated when they were hemodynamically stable with minimum inotropic support and arterial blood gases were in the normal range. Ventilator support was weaned off gradually and when patient tolerated continuous positive airway pressure (CPAP) trial for 20 min and had normal ventilatory parameters and were obeying commands with normal power of all limbs. Decision of extubation was made by the consultant anesthesiologist. Total intubation

time was noted at the time of removal of ETT in the Intensive Care Unit (ICU) by the anesthetist who extubated the trachea. The scoring system used for the assessment of sore throat, hoarseness of voice and cough used was described by Harding CJ et al[16] and Park et al. [17] The assessment of these complications was done by an intensivist who was unaware of the patient's group.

Table 1: Scoring system for assessment of postoperative sore throat, hoarseness of voice and cough

Score*	Description
Sore throat	
0	No sore throat
1	Mild sore throat
2	Moderate sore throat
3	Severe sore throat
Hoarseness of Voice	
0	No hoarseness of voice
1	Hoarseness of voice noted by patient
2	Mild readily apparent hoarseness of voice
3	Severe readily apparent hoarseness of voice
Cough	
0	No cough
1	Mild cough
2	Moderate cough
3	Severe cough

**Patients with a score 2 or 3 were labeled to have complications; patients with 0 or 1 score were labeled as normal*

Collected data were analyzed in SPSS V16. One way ANOVA and chi-square test was used for analysis of quantitative and qualitative variables respectively taking $P \leq 0.05$ as significant.

RESULTS

Demographic and hemodynamic characteristic of patients of each group are shown in Table 2. There was no difference in the age and gender of the patients in all groups.

HR before intubation was equal in all groups. HR rise was more in diclofenac group and the rise in HR was least in diclofenac plus lignocaine group ($p < 0.0001$). The HR returned back to baseline value in Group X and Group XD within five minutes but remained high in the diclofenac group ($p < 0.0001$). There was no significant difference in baseline systolic blood pressure in patients of all groups. There was a sudden rise in systolic blood pressure immediately after intubation. The rise in blood pressure was highest in diclofenac group and least in Group XD. Similarly blood pressure after 5 min of intubation was still high in diclofenac group and was least in lignocaine plus diclofenac group ($p < 0.0001$).

There was no significance difference in the intubation time of patients of three groups. Incidence of sore throat, hoarse of voice and cough was highest in lignocaine group, less in diclofenac group and least in lignocaine plus diclofenac group ($p = 0.039$, 0.025 and 0.002 respectively).

DISCUSSION

Incidence of postoperative sore throat, hoarseness of voice and cough varies between 6.6 to 90% according to different studies.[2,9,17-20] Diameter of ETT, cuff pressure, intubation procedure, movement of the tube during surgery and excessive suctioning during extubation are some known factors which are considered responsible for the above mentioned conditions.[2,21,22] All these factors cause local irritation, trauma and inflammation of the laryngeal mucosa which are responsible for the development of all these complications.[3,23]

We found four prior studies relating to the use of NSAIDs in reducing the incidence of post-op sore throat.[14,15,24,25] But none of these studies have observed the effects of NSAIDs (either gel or IV formulation) on hemodynamic parameters and the incidence of hoarseness of voice and cough after surgery. In our study, we investigated the effect of local application of diclofenac sodium on ETT before and after intubation on hemodynamic parameters and postoperative sore throat and, hoarseness of voice and cough. Our study is also different from previous studies in that we applied the diclofenac gel on ETT but in other studies they used intravenous NSAIDs, transdermal patches and gargles. In previous studies involving local application of NSAIDs there was a significant reduction in the incidence and severity of postoperative sore throat. In these studies, the investigators used epolamine patch.[15]) and ketoprofen patch[25] on the anterior surface of the neck and aspirin and benzydamine hydrochloride gargles.[24] One investigator evaluated the effect of intravenous diclofenac sodium on postoperative sore throat but saw no significant effect of diclofenac sodium on the occurrence and severity of postoperative sore throat.[14] From these studies it appears that local application of NSAIDs is more effective because of close proximity with the site of action but may result in high concentrations

Table 2: Comparison of demographic and hemodynamic characteristics

Variable	Group X (Lignocaine Group)	Group D (Diclofenac Group)	Group XD (Lignocaine + Diclofenac Group)	P-value
Age (Years)	55.84 ± 8.82	55.02 ± 9.50	53.74 ± 9.67	0.53
Male Gender N (%)	42 (84.0)	41 (82.0)	46 (92.0)	0.31
HR before Intubation (Beats/min)	75.96 ± 6.62	74.82 ± 6.68	75.88 ± 6.78	0.63
HR immediately after Intubation (Beats/min)	100.72 ± 6.98	108.94 ± 7.40	96.62 ± 3.84	< 0.0001
HR after 5 min of Intubation (Beats/min)	76.06 ± 6.47	84.64 ± 5.32	74.84 ± 5.13	< 0.0001
Systolic Blood Pressure before intubation (mmHg)	124.24 ± 7.42	122.20 ± 9.26	125.53 ± 7.54	0.15
Systolic Blood Pressure Immediately after Intubation (mmHg)	157.34 ± 5.43	162.46 ± 5.05	154.12 ± 6.07	< 0.0001
Systolic Blood Pressure after 5 min of Intubation (mmHg)	124.68 ± 6.66	137.86 ± 8.15	123.28 ± 5.55	< 0.0001
Time to Return to base line (mins.)	4.59 ± 1.03	9.00 ± 1.33	3.43 ± 0.81	< 0.0001

Age, HR (heart rate) and Systolic blood pressure are presented as mean ± SD

Table 3: Incidence of sore throat, hoarseness of voice and coughing between groups

Variable	Group X	Group D	Group XD	P-value
Total Intubation Time	7.62 ± 1.67	7.48 ± 1.65	7.60 ± 1.97	0.913
Sore Throat n (%)	12 (24.0)	07 (14.0)	3 (6.0)	0.039
Hoarseness of voice n (%)	6 (12.0)	2 (4.0)	0 (0.0)	0.025
Coughing n (%)	11 (22.0)	3 (6.0)	1 (2.0)	0.002

of drug in the pharyngeal mucosa. When diclofenac is given intravenously the bioavailability is 100% but the concentrations achieved in the pharyngeal mucosa may be less as compared to the local application. This difference in the concentrations may be responsible for reduced incidence of postoperative sore throat in our study as compared to the study of Thanga's et al.

We also found that local application of diclofenac sodium gel was associated with less incidence of sore throat, hoarseness of voice and cough (14.0%, 4.0% and 6.0% as compared to the lignocaine gel group, where the incidence was 24.0%, 12.0% and 22.0% respectively. Combined application of these two drugs further reduced the incidence of these complications to 6.0%, 0.0% and 2.0% and p-values were 0.039, 0.025 and 0.002 for sore throat, hoarseness of voice and cough respectively. However, diclofenac gel did not provide good control on hemodynamic parameters (e.g. systolic blood pressure and HR) immediately after intubation and 5 min after intubation. Time of return of HR and mean systolic blood pressure to baseline value was 9.00 ± 1.33 min in diclofenac group (Group D), 4.59 ± 1.03 min in lignocaine group (Group X) and 3.43 ± 0.81 min in Group XD (P < 0.0001). Systolic blood pressure was still high in diclofenac group i.e. 137.86 ± 8.15 mmHg as compared to 124.6.68 ± 6.66 in lignocaine group and 123.28 ± 5.55 mmHg in diclofenac plus lignocaine group (p < 0.0001). Similarly HR was also high in diclofenac sodium group, 84.64 ± 5.32 beats/min as compared to 76.06 ± 6.47 beats/min in lignocaine group and 74.84 ± 5.13 beats/min in lignocaine plus diclofenac group (Group XD) with p < 0.0001. We concluded that lignocaine usage was associated with better hemodynamic control, while diclofenac provide better relief for sore throat, hoarseness of voice and cough. And combined effect of these is associated with good hemodynamic control and less postoperative complications. We recommend diclofenac to lubricate the ETT before intubation. This better control of hemodynamics in lignocaine group is perhaps due to its local anesthetic actions, which reduces the local irritation immediately by anesthetizing the intubation tract thereby reducing the sympathetic response.

applying lignocaine or diclofenac gel or both on endotracheal tube

LIMITATIONS

The main limitation of our study is the small sample size. A large scale trial should be conducted.

CONCLUSIONS

Local application of lignocaine gel plus diclofenac sodium over the endotracheal tube before intubation is associated with better hemodynamic control and significantly reduces the incidence of postoperative sore throat, hoarseness of voice and cough.

Conflict of interest: None declared by the author.

Author contribution: All of the authors contributed in the concept, conduct of the study, literature search, data analysis and manuscript preparation, and accept full responsibility for the material presented.

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