Effect of prophylactic intravenous Dexamethasone and Lidocaine on cough and sore throat after extubation in elective laminectomy surgery

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ABSTRACT
Context: In spite of advancement in anesthesia and surgery, major operative procedures are accompanied by post-operative complications. Some of them are due to intra-tracheal intubation an inevitable part of anesthesia for patient protection. At the post-operative period, sore throat, cough and hoarseness are more common and distress the patient. Objectives: The aim of this study is to compare the effect of prophylactic intravenous Dexamethasone and Lidocaine on cough and post-operative sore throat after elective laminectomy surgery. Methods and Materials: In this prospective analytic study, 90 adult patients undergoing elective laminectomy surgery were randomly allocated into three groups. The patients received either intravenous 0.1 mg/kg Dexamethasone (group D, n = 30) or 1.5 mg/kg Lidocaine (group L) or normal saline (group P, n = 30) after anesthesia induction and just before intubation with appropriate size of disposable reinforced endotracheal tubes. Follow up for the prevalence of cough and sore throat and its severity was done at 30 min, 1, 6 and 24 hours after extubation. Results: There were no significant differences in demographic data in three groups. In groups D and L, the prevalence of cough and sore throat and its severity were significantly less than placebo group (p<0.05). Regarding the prevalence of cough and sore throat, in comparison of group D with group L, no significant difference was seen (p>0.05). Conclusions: According to results of our study, we can conclude that both prophylactic intravenous Dexamethasone and Lidocaine can reduce the prevalence of post-operative cough, sore throat and its severity at the first 24 hours post-extubation period and can be used safely in selective patients.

Keywords: lidocaine; cough; pharyngitis; dexamethasone, laminectomy

1. INTRODUCTION
Major operations can be associated with inconceivable complications (Kolawole IK et al., 2008). Some of them are due to endotracheal intubation. Post-operative sore throat, cough and hoarseness are more common with incidence of 40 -100% that disturb patients under general anesthesia (Sumathi PA et al., 2008; Agarwal A et al., 2006; Jaensson M et al., 2012). Mucosal erosion and pharyngeal inflammation can cause severe respiratory distress especially when analgesia is insufficient during surgery and the patient suffers pain while coughing in post-operative period (Scuderi PE 2010; Tabari M et al., 2013). Different methods such as tracheal tube lubrication with Betamethasone gel (Kezemi A et al., 2007; El Hakim M 1993; Honarmand A et al., 2006) using small sizes of tracheal tubes, technical care during intubation, spraying Lidocaine on tracheal tube cuff, be assure of complete muscle relaxation before intubation, gentle suctioning the oral cavity and pharynx, checking cuff pressure during surgery, Aspirin and Ketamine gargling can reduce the incidence and severity of post-operative sore throat (Agarwal A et al., 2006; Rudra A et al., 2009). It is considerable that in spinal column operations in prone positioning, post-operative sore throat is more common. May be it is due to that in these surgeries it is recommended to use reinforced tracheal tubes which are flexible and more safe than routine tubes, but their external diameter is larger than normal. So this may result pharyngeal disturbance (Dimitriou VK et al., 2009). The intubation and extubation procedure may stimulate cough receptors, which will be resulted in hypertension, tachycardia, myocardial ischemia, bronchial spasm and hemorrhage after anesthesia emergence (Mahoori A et al., 2014; Hamill JF et al., 1981). Some studies have shown the efficacy of intravenous lidocaine (Saghaei M et al., 2005) and others demonstrate that the Dexamethasone is more effective than placebo for post-operative sore throat reduction (Bagchi D et al., 2012). We designed this study to compare the efficacy of lidocaine and Dexamethasone in decreasing of post-operative sore throat and cough in patients candidate for elective laminectomy under general anesthesia.

2. SUBJECTS AND METHODS
This prospective, randomized, double-blind study was conducted with the approval of the Scientific & Ethical Review Boards of Urmia University of Medical Sciences (ethical committee approval code: Ir.umsu.rec.1395.361) throughout the period from June 2018 until July 2019. After obtaining written informed consent, 90 patients who were scheduled for elective laminectomy surgery requiring general anesthesia with tracheal intubation in the prone position, using standard posterior approach, were enrolled in our prospective analytic study. All patients were ASA physical status I-II according to the ASA’s classification system. Patients with the history of preoperative hoarseness or sore throat, upper respiratory tract infection, psychiatric disorders, tracheal or laryngeal surgeries, use of corticosteroids, allergy to local anesthetics, anticipated difficult intubation, more than one attempts at intubation, impaired renal function, diabetes mellitus and morbid obesity were excluded from the study. Subjects were randomly assigned into
either Lidocaine group (L, n=30) or Dexamethasone group (D, n=30) or placebo group (P, n=30), using a computerized randomization table. Preoperative evaluation was performed in all patients.

Basic monitoring including electrocardiography, arterial saturation of oxygen (SPO2), heart rate and non-invasive blood pressure monitoring was done for all patients at the time of their entrance into operation room. All patients were premedicated with intravenous 1μg/kg of Fentanyl and 0.015mg/kg of Midazolam. General anesthesia was induced by an anesthesiologist, blinded to the patients' group allocation and it was done with 5mg/kg Sodium Thiopental and Atracurium 0.5 mg/kg was used for neuromuscular blockade. Study drugs were prepared as a 5 ml clear solution in syringes labeled 'study drug' by an anesthetic nurse who was not involved in the study and they were injected intravenously by an anesthesiologist blinded to the syringe contents. Before intubation, the patients received either intravenous 0.1 mg/kg Dexamethasone (group D, n = 30) or 1.5 mg/kg Lidocaine (group L) or normal saline (group P, n = 30). Direct laryngoscopy was performed by same anesthesiologist in all patients. For securing the airway, trachea was intubated with wire- reinforced tracheal tubes (Shiley Lo-Contour cuffed reinforced oral/nasal tracheal tube, Covidien TM, Mansfield, OH, USA) with a 7-mm ID for female and 8-mm ID for male. Positional change was done from supine to prone. During surgery, anesthesia was maintained with 1.0-1.2 vol.% isoflurane and 50% N2O in O2. Intra-cuff pressure was adjusted between 25 and 30 cm H2O with a noninvasive manometer and the end-tidal CO2 were kept between 25 to 30 mmHg. At the end of surgery, after reposition the patient from prone to supine, residual neuromuscular blockade was reversed with Neostigmine 0.04 mg/kg and Atropine 0.02 mg/kg. After suctioning oral secretion, the endotracheal tube was removed when the patient was able to obey commands and had adequate spontaneous lung ventilation. The prevalence of postoperative cough and sore throat and it’s severity were measured using direct interview by researcher who did not participate in this study at 30 minutes,1, 6, and 24 hours after extubation. The severity of postoperative sore throat was graded using a 4-point scale (0: no, 1: minimal, 2: moderate, 3: severe), (Bagchi D et al., 2012). In the patients who had severe cough and sore throat during first 24 hours after extubation, saline normal solution gargling and anti-congestive agents were administered and if it was needed, otolaryngology consultation was sent. Data was represented as numerical (continuous and discrete) and categorical (nominal and ordinal) data. They were analyzed by using SPSS for windows (version 20). Independent sample t-test, Chi-square test and ANOVA were utilized for analyzing data as appropriate. All follow-up analyses were corrected the Bonferroni adjustments. Values of P < 0.05 were considered statistically significant.

3. RESULTS
In this prospective analytic study, 90 ASA I-II patients were enrolled. Demographic and clinical characteristics were compared between three groups. The mean age was 50.1±12.9, 49.9±11.7 and 51.3±10.6 years in Lidocaine, Dexamethasone and placebo groups’ respectively (Table 1).

**Table 1** Baseline characteristics of the patients*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group L (n=30)</th>
<th>Group D (n=30)</th>
<th>Group P (n=30)</th>
<th>p. value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>9 (30%)</td>
<td>15 (50%)</td>
<td>14 (46.7%)</td>
<td>0.24</td>
</tr>
<tr>
<td>Female</td>
<td>21 (70%)</td>
<td>15 (50%)</td>
<td>16 (53.3%)</td>
<td></td>
</tr>
<tr>
<td>Mean age(y)</td>
<td>50.17±12.97</td>
<td>49.90±11.79</td>
<td>51.34±10.60</td>
<td>0.88</td>
</tr>
</tbody>
</table>

*Data are presented as n or mean value
Values are number of patients (%). Group P: Placebo group, Group L: Lidocaine group, Group D: Dexamethasone group.

According to table 2, at 30 min after extubation, there was no significant difference between three groups in cough prevalence (p=0.38). At 1, 6, and 24 h after extubation, the prevalence of cough was significantly lower in group L (1 h; 16.7%, p = 0.006 / 6 h; 10%, p = 0.002 / 24 h; 0%, p = 0.02 and group D (1 h; 16.7%, P =0.006 / 6 h; 13.3%, P = 0.005 / 24 h; 0%, P = 0.02) compared with group P (1 h; 50% / 6 h; 46.7% / 24 h; 16.7%), without significantly difference between group L and D(1 h; P = 0.63/ 6 h; p=0.6) (Table 2).
Table 2 prevalence of Cough among the Groups after Tracheal Extubation

<table>
<thead>
<tr>
<th>Time (h)</th>
<th>Group L (n=30)</th>
<th>Group D (n=30)</th>
<th>Group P (n=30)</th>
<th>p.value</th>
<th>p.value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P</td>
<td>D</td>
<td></td>
<td>L&amp;D</td>
<td>L&amp;P</td>
</tr>
<tr>
<td>0.5</td>
<td>1 (3.3%)</td>
<td>2 (6.7%)</td>
<td>4 (13.3%)</td>
<td>0.38</td>
<td>0.5</td>
</tr>
<tr>
<td>1</td>
<td>5 (16.7%)</td>
<td>5 (16.7%)</td>
<td>15 (50%)</td>
<td>0.004</td>
<td>0.63</td>
</tr>
<tr>
<td>6</td>
<td>3 (10%)</td>
<td>4 (13.3%)</td>
<td>14 (46.7%)</td>
<td>0.004</td>
<td>0.6</td>
</tr>
<tr>
<td>24</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>5 (16.7%)</td>
<td>0.005</td>
<td>--</td>
</tr>
</tbody>
</table>

Values are number of patients (%). Group P: Placebo group, Group L: Lidocaine group, Group D: Dexamethasone group.

The prevalence of sore throat at 30 min, 1, 6, and 24 h after tracheal extubation was significantly lower in group L (30 min; 20%, \( p = 0.02/1 \) h; 43.3%, \( p = 0.001/6 \) h; 50%, \( p = 0.001/24 \) h; 20%, \( p = 0.001 \)) and group D (30 min; 20%, \( p = 0.02/1 \) h; 53.3%, \( p = 0.001/6 \) h; 53.3%, \( p = 0.001/24 \) h; 30%, \( p = 0.01 \)) compared with group P (30 min; 46.7%; 1 h; 93.3%; 6 h; 96.7%; 24 h; 63.3%), without significantly difference between group L and D (30 min; \( p = 0.62/1 \) h; \( p = 0.3/6 \) h; \( p = 0.5/24 \) h; \( p = 0.27 \)) (Table 3).

Table 3 prevalence of Sore Throat among the Groups after Tracheal Extubation

<table>
<thead>
<tr>
<th>Time (h)</th>
<th>GROUP L (n=30)</th>
<th>GROUP D (n=30)</th>
<th>GROUP P (n=30)</th>
<th>P. value</th>
<th>P. value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P</td>
<td>D</td>
<td></td>
<td>L&amp;D</td>
<td>L&amp;P</td>
</tr>
<tr>
<td>0.5</td>
<td>6 (20%)</td>
<td>6 (20%)</td>
<td>14 (46.7%)</td>
<td>0.03</td>
<td>0.02</td>
</tr>
<tr>
<td>1</td>
<td>13 (43.3%)</td>
<td>16 (53.3%)</td>
<td>28 (93.3%)</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>6</td>
<td>15 (50%)</td>
<td>16 (53.3%)</td>
<td>29 (96.7%)</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>24</td>
<td>6 (20%)</td>
<td>9 (30%)</td>
<td>19 (63.3%)</td>
<td>0.001</td>
<td>0.27</td>
</tr>
</tbody>
</table>

Values are number of patients (%). Group P: Placebo group, Group L: Lidocaine group, Group D: Dexamethasone group

The Mean and Standard deviation of severity scores of post-operative sore throat are described in Table 4 and Fig 1. They were significantly less in the groups L and D than group P at 30 min, 1, 6 and 24 h after extubation (\( p =0.001 \)). But there was no significant difference among groups L and D (Table 4 and Fig 1).

Table 4 The Mean and Standard deviation of severity scores of sore throat

<table>
<thead>
<tr>
<th>Time (h)</th>
<th>GROUP L (n=30)</th>
<th>GROUP D (n=30)</th>
<th>GROUP P (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>( 0.40 \pm 0.20 )</td>
<td>( 0.40 \pm 0.20 )</td>
<td>( 0.67 \pm 0.60 )</td>
</tr>
<tr>
<td>1</td>
<td>( 0.72 \pm 0.56 )</td>
<td>( 0.77 \pm 0.60 )</td>
<td>( 1.63 \pm 0.71 )</td>
</tr>
<tr>
<td>6</td>
<td>( 0.72 \pm 0.56 )</td>
<td>( 0.72 \pm 0.50 )</td>
<td>( 1.63 \pm 0.71 )</td>
</tr>
<tr>
<td>24</td>
<td>( 0.40 \pm 0.20 )</td>
<td>( 0.40 \pm 0.20 )</td>
<td>( 0.76 \pm 0.67 )</td>
</tr>
</tbody>
</table>

Group P: Placebo group, Group L: Lidocaine group, Group D: Dexamethasone group
4. DISCUSSION

Despite many improvements in anesthesiology and surgical procedures, major post-operative complications may be occurred (Kolawole IK et al., 2008). Sore throat and hoarseness are the most common endotracheal complications during 24 hours after surgery (Kezemi A et al., 2007). The aim of this study is to compare the prophylactic effect of Lidocaine and Dexamethasone in reducing post extubation cough and sore throat in patients candidate for laminectomy. In this prospective analytic study, there was no significant difference in age and sex among participating groups (p>0.05). So age and sex are not confounding factors in our study. In this study we investigated the prevalence of cough and sore throat and its severity at 30 min, 1, 6 and 24 h after extubation in patients who had received Lidocaine or Dexamethasone or saline normal in laminectomy surgery. Cough prevalence was not significantly different in three groups at the first 30 min after extubation (p>0.05). But this difference was significant in other times of study among group L and D in compare with placebo group. We found that both of Lidocaine and Dexamethasone with no significant statistical difference (p>0.05), can reduce post-operative cough more than placebo. Saghaei et al. announced that prophylactic administration of Lidocaine prior to tracheal extubation may be ineffective to prevent but it is most effective for treatment of post-extubation cough. It means that Based on the results of this study, the Lidocaine efficacy is more in treatment than prophylaxis of post-extubation cough (Saghaei et al., 2005). However according to our study, the prophylactic administration of Lidocaine and Dexamethasone is more effective than placebo on post-extubation cough. Our findings showed that the prevalence of sore throat 30 min after extubation was significantly lower in groups L and D than placebo group (p<0.05). Although at times 1, 6 and 24 hours after extubation, this prevalence was lower in group L in compare with D, but was not significant. These finding showed that intravenous Lidocaine has more efficacy than Dexamethasone injection in reducing post-operative sore throat. The reason may be due to Lidocaine action in C nerve fibers stimulation and there upon decreasing the neurogenic impulse translation from airways and finally cough reflex suppression after extubation. But this prevalence was significantly more in placebo group than the two study groups. It would be justified that in mucosal part of airways, Dexamethasone has anti-inflammatory effect and Lidocaine has local anesthetic effect by sodium channel blockage and thus neural pathways inhibition (Saghaei et al., 2005; Bagchi D et al., 2012). Our findings correlate with the results of Sang Lee’s study in 2016, which explained that prophylactic Dexamethasone administration 0.1 mg/kg and 0.2 mg/kg in prone surgery reduces the incidence of postoperative sore throat and Dexamethasone 0.2 mg/kg decreases the incidence of hoarseness (Sang Ho Lee et al., 2016). In our study, we found that at times 0.5, 1, 6 and 24 h after extubation, the sore throat severity in groups L and D were similar to each other and significantly lower than placebo group.
According to Park et al. study, they demonstrated that prophylactic IV Dexamethasone 0.2 mg/kg significantly reduced the incidence and severity of post-operative sore throat and hoarseness in patients receiving a double lumen tube for one-lung ventilation during thoracic surgery (Park et al., 2008). The results of this study correlate with our findings in which we explained that Dexamethasone can reduce the prevalence and severity of post extubation sore throat and cough.

5. CONCLUSION
According to our results, it is recommended that prophylactic administration of Dexamethasone and Lidocaine will equally reduce the prevalence and severity of post-operative sore throat and cough and when one of these drugs is not available, we can use another one. In this research different dosages of Lidocaine and Dexamethasone were not compared. It is important to achieve to an optimal dose of intravenous Dexamethasone and Lidocaine to prevent their harmful side effects. So it is suggested that in further studies, different dosages of these drugs will be evaluated and so more study designing is needed.

Ethics approval and consent to participate
The study protocol was approved by Scientific & Ethical Review Boards of Urmia University of Medical Sciences (ethical committee approval code: Ir.umsu.rec.1395.361) throughout the period from June 2018 until July 2019. Participation was voluntary and all contributors received detailed information about the aims of this research and informed written consent was obtained from all patients.

Conflict of Interests
No conflict of interests was declared

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Authors’ contributions
All authors shared in this study design; they reviewed literature, and wrote the primary draft of the manuscript. All authors read and approved the final manuscript.

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