



A comparative study of the effects of tramadol and lidocaine gel on complications of orotracheal intubation

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ABSTRACT

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Background & Objectives: Endotracheal intubation (ETI) is usually required during general anesthesia, but has some complications associated with it. Prevention of these complications is essential for patient satisfaction. This study aimed to compare the effects of topical lidocaine gel and tramadol gel on complications of ETI.

Methodology: In this clinical trial, 200 patients scheduled for laparoscopic cholecystectomy were randomly divided into five groups. The endotracheal tube cuffs were applied different gels in the following order: Group P with 1 ml of a neutral gel, Group T1 with 1 ml of 2.5% tramadol gel, Group T2 with 1 ml of 5% tramadol gel, and Group L with 1 ml of 2% lidocaine gel. In the fifth group (Group C) no gel was used. At the end of the anesthesia, the incidence of bucking, coughing, laryngospasm and/or bronchospasm, and the intensity of sore throat were recorded and compared. Data were analyzed using SPSS 20 and Chi-square, ANOVA and Kruskal-Wallis tests. The significance level of tests was considered as $p < 0.05$.

Results: The use of 5% tramadol gel and lidocaine gel reduced the incidence of coughing ($p = 0.004$), but there was no significant difference between these two kinds of gels ($p = 0.108$). No cases of laryngospasm were observed. There was no significant difference between the incidence of sore throat, bucking, and bronchospasm in five groups ($p > 0.05$).

Conclusion: According to the results of this study, it seems that 5% tramadol gel decreases the incidence of coughing caused by the ETI and its impact rate is the same as with 2% lidocaine gel. But both gels don't have a significant effect on the incidence of bucking, sore throat, and bronchospasm.

Key words: Endotracheal tube; Tramadol; Lidocaine; gel; Cough

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INTRODUCTION

Endotracheal intubation (ETI) during general anesthesia is associated with some complications e.g., hemodynamic changes, increased intracranial pressure, increased

intraocular and blood pressure, and decreased arterial oxygenation and the anesthesiologists make every effort to prevent these to ensure patient satisfaction.¹ Coughing and bucking at the end of anesthesia and at extubation are other worrisome complications. Sore throat after ETI

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is a common side effect. To reduce these effects, different methods and drugs have been used.²

Several studies have evaluated different methods to reduce the complications of ETI, but no study has examined the effect of application of tramadol gel to the endotracheal tube (ETT) cuff for this purpose, although

many studies suggested local anesthetic effects of tramadol.^{1,2,3} The lidocaine gel has been the most commonly used gel on the cuff, but has been associated with systemic effect similar to its injectable form,⁴ but in the case of tramadol this issue has not been proven.³

We aimed to investigate the local effect of tramadol gel applied to the ETT cuff in decreasing the complications of ETI and compare it with placebo, lidocaine gel and with the control group.

METHODOLOGY

The study was approved by the Ethics Committee of Kermanshah University of Medical Sciences (KUMS.REC.1394.16). It is a randomized, double-blind clinical trial study. Convenient sampling technique was used. The sample was chosen from patients who were candidate for laparoscopic cholecystectomy surgery and referred to Imam Reza Hospital in 2015.

The study protocol was registered at the Iranian Registry of Clinical Trials website (IRCTID: IRCT201507114938N3). It was a prospective study, carried out over one year at Imam Reza Teaching Hospital, Kermanshah, Iran.

Inclusion criteria were 20-60 y age range, candidates for laparoscopic cholecystectomy surgery, ASA class I and II, mallampati grade 1 or 2, and TMD > 6 cm.

Exclusion criteria were the history of smoking or drug abuse, history of common cold during the previous two weeks, patients with COPD, asthma, and convulsions and those known to be allergic to the study drugs.

We selected 200 patients, scheduled for laparoscopic cholecystectomy, and distributed them to one of the five defined groups using random numbers tables.

All patients underwent a fixed general anesthetic technique employing 2 mg/kg propofol, 0.2 mg/kg sufentanil and 0.5 mg/kg atracurium, followed by laryngoscopy and intubation in all patients.

ETT cuff was treated in the following order:

Group P simple gel (placebo) one mL applied,

Group T1 tramadol gel (2.5%) one mL applied,

Group T2 tramadol gel (5%) one mL applied,

Group L lidocaine gel (2%) one mL applied,

And in Group C no drug was used.

Patients who needed greater than one attempt of laryngoscopy were excluded from the study.

To prepare 2.5% tramadol gel, 25 mg/ml of tramadol was dissolved in distilled water (double distillation) and the carbomer powder was slowly added to the drug solution at 40° C until the carbomer concentration reached to 1.5-2%. Finally, the gel was cooled and kept refrigerated in a sealed container until use. To prepare the placebo gel, 1.5-2% carbomer without any drug was used.

After the intubation, the ETT cuff was filled with air with pressure equivalent to 25 cmH₂O. Isoflurane gas was used to maintain anesthesia.

For all patients, surgery was performed by a single surgeon. At the end of anesthesia, all patients were reversed by 0.04 mg/kg neostigmine and 0.02 mg/kg atropine.

Patients were awakened and mouth suction was conducted with the pressure of less than 100 cmH₂O. The occurrence of bucking, coughing, laryngospasm and bronchospasm was noted and data were recorded. The patients were followed for the incidence of the sore throat using VAS at the first, sixth and twelfth hours after the extubation and findings were recorded. Patients with a VAS greater than 5 were treated with meperidine.

Table 1: Demographic features and the comparison of the incidence of cough in five studied groups

Variable	Group P	Group T1	Group T2	Group L	Group C	Test Statistics	P-Value
Age (mean \pm SD)	43.29 \pm 9.02	44.51 \pm 8.72	45.36 \pm 6.73	42.8 \pm 8.65	42.87 \pm 7.68	2.77	0.596
Male [n (%)]	8 (21.1)	15 (38.5)	13 (36.1)	17 (42.5)	14 (29.8)	4.92	0.295
Female [n (%)]	30 (78.9)	24 (61.5)	23 (63.9)	23 (57.5)	33 (70.2)		
Cough [n (%)]	17 (44.7)	21 (53.8)	9 (25)	17 (42.5)	27 (67.5)	15.4	0.004

Sample Size:

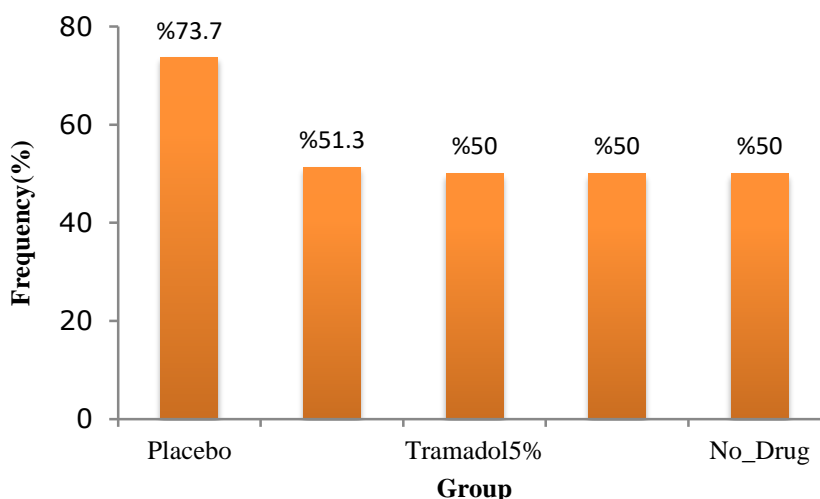
The sample size was considered to be 36 in each group with regard to 95% CI and statistical power of 90% based upon an earlier study, in which the incidence of cough with and without lidocaine gel was equal to $P_1 = 0.4$ and $= 0.31$) (1).

Data analysis:

Data were analyzed using IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.). Chi-square test was used to compare the qualitative variables between the two groups. For the quantitative dependent variables, one-way variance analysis (ANOVA) or Kruskal-Wallis test was used and in case of significance, the subsequent binary comparison tests were applied. The significance level of tests was considered as $p < 0.05$.

RESULTS**Descriptive features:**

Two hundred patients participated in this study. The minimum sample size was 36 in each group based on the PASS2011, and to increase the accuracy of the results in some groups, more participants were enrolled.

**Figure 1: Bucking incidence frequency in five studied groups of patients' candidate for laparoscopic cholecystectomy**

38 patients (19%) in the placebo group (Group P), 39 patients (19.5%) in 2.5% tramadol group (Group T1), 36 patients (18%) in 5% tramadol group (Group T2), 40 patients (20%) in the lidocaine group (Group L), and 47 patients (23.5%) in no drug group (Group C).

Patients were between 22 to 60 y old (43.71 ± 8.18 years). One hundred thirty-three patients (66.5%) were female and 67 patients (33.5%) were male.

Table 1 shows no significant difference between the mean age and the gender of patients in five groups ($p > 0.05$).

According to the results presented in Table 1, there was a significant difference between the

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incidence of coughing during extubation in five groups of patients ($p < 0.05$).

A dramatic decrease in coughing was observed in the 5% tramadol group. Although 5% tramadol decreases the coughing clinically more than 2% lidocaine group, the difference was statistically not significant ($p = 0.108$).

There was no significant difference between the frequency of bucking in 2.5% tramadol group and 5% tramadol group ($p = 0.897$), 2.5% tramadol group and lidocaine group ($p = 0.9$), 5% tramadol group and lidocaine group ($p = 0.8$) (Figure1).

There was no significant difference between the severity of sore throat at 1st, 6th, and 12th hours after extubation in between five groups ($p > 0.05$) (Figure 2).

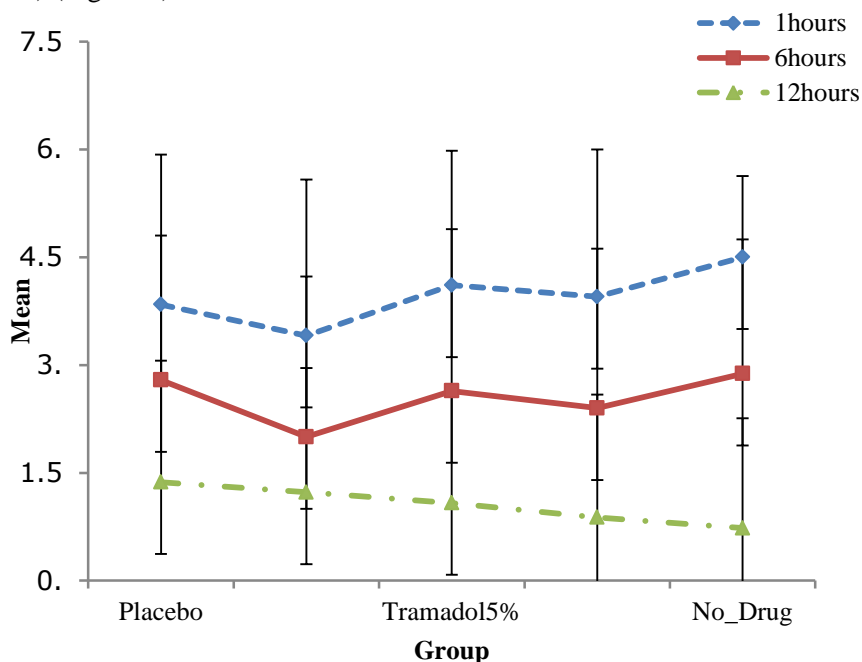


Figure 2: The average severity of sore throat in five studied groups

There was no significant difference between the frequencies of bronchospasm in five groups of patients ($p > 0.05$).

No cases of laryngospasm were noted in any of the five studied groups.

DISCUSSION

The results showed no significant difference between the mentioned groups in terms of age and gender of patients. In this study the effect of application of topical lidocaine gel and tramadol gel on ETT cuff on ETI related complications was evaluated. There was no significant difference between these five groups in terms of coughing, bucking, bronchospasm, laryngospasm and sore throat. The incidence of coughing was reduced in 5% tramadol group, but the frequency of bucking was increased in placebo group.

According to the results of this experiment, a significant difference was observed between the

ratios of coughing incidence in five groups of patients. So, 5% tramadol gel application led to a reduction in the incidence of coughing.

Sumathi et al. showed that the utilization of lidocaine gel in the ETI hadn't decreased the coughing incidence in comparison with the control group. This lack of consistency can be due to the variety of surgery, gel-forming substance, and extubation protocol.⁶

In our survey, the binary comparison revealed that bucking

incidence in placebo gel consumers is more than all other groups.

The results of the present study emphasized the effect of active drug in the gel on reducing the incidence of bucking. Some researchers demonstrated that tramadol has local anesthetic and analgesic effects like lidocaine.^{9,10}

Akbay et al. indicated that the pain of children with tramadol gel on ETT cuff for tonsillectomy was significantly lower than that of the normal saline group at 21 h and 7 days after surgery.

In Akbay and Heiba's studies, the positive effects of tramadol on reducing sore throat may be due to the systemic absorption of the drug in the high vascular region of inflamed tonsils. Tonsil's blood circulation is much greater than endotracheal mucosa and the tramadol dosage in this study was less than half of their used dosage.¹¹⁻¹² The results from other studies also confirm the possibility of systemic absorption.^{13,14}

In some studies, lidocaine gel has been used for reducing sore throat caused by the ETI in comparison with gels treated with other drugs such as betamethasone, beclomethasone gels. They also concluded that treating the ETI cuff with lidocaine gel had no impact on the reduction of postoperative sore throat compared to the control group;^{6, 15-16} even some of them have reported that the use of lidocaine gel can be worse.¹⁷

Mekhemar et al. obtained results in parallel with our survey and found that the use of 5% lidocaine gel in the ETI cuff does not prevent sore throat, however, it is better than 10% lidocaine or normal saline spray.¹⁸

According to the results of this study, no significant difference was observed between the ratios of laryngospasm or bronchospasm incidence in five groups of patients' candidates

for laparoscopic cholecystectomy surgery. In the literature, the rate of bronchospasm caused by the ETI has been mentioned to be 1%.¹⁹ It is similar to our study.

Since similar studies haven't compared the rate of bronchospasm incidence caused by the ETI treated with drugs such as tramadol and lidocaine, comparing the results of our study with other related studies was not possible.

CONCLUSION

According to the results of this study, application of 5% tramadol gel is effective in reducing the incidence of coughing caused by the endotracheal intubation, equivalent to the commonly used lidocaine gel. However, tramadol gel does not have an impact on the reduction of bucking, sore throat, bronchospasm, and laryngospasm caused by the endotracheal intubation.

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Competing interests:

The authors declare that they have no competing interests.

Authors' contribution:

HF: Design and literature review

MY: Concept and performing the study

GM: Literature review, drafting

MR: Statistical analysis, drafting

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