EGYPTIAN JOURNAL OF ANAESTHESIA
2020, VOL. 36, NO. 1, 1–6
https://doi.org/10.1080/11101849.2020.1723330

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RESEARCH ARTICLE



# The Effect of preoperative nebulized: Magnesium sulfate versus lidocaine on the prevention of post-intubation sore throat

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**ABSTRACT**

**Background**: Different agents have been used to control postoperative sore throat after general anesthesia with variable success. The aim of this study was to compare the effect of preoperative-nebulized magnesium sulfate versus lidocaine on the prevention of post-intubation sore throat.

**Methods**: A prospective double-blind randomized controlled study. Seventy-eight8 patients were divided randomly into three equal groups: Group (M) ($n$ = 26): received nebulized magnesium sulfate 250 mg (2.5 ml) plus 2.5 ml normal saline. Group (L) ($n$ = 26): received nebulized lidocaine 2% 100 mg (5 ml). Group (C) ($n$ = 26): received nebulized normal saline 5 ml. So total volume (5 ml). Patients nebulized by compressor nebulizing for 15 min before the induction of anesthesia.

**Results**: At 0 and 2 h postoperative, the severity and incidence of sore throat were statistically significantly lower in group M and L compared to the C group ($P < 0.001$). However, at the same time interval, both groups M and L were comparable ($P > 0.05$). At 4, 8, 12, 24 h postoperative, the severity and incidence of sore throat were statistically significantly lower in group M compared to L and C groups ($P < 0.001$). However, at the same time interval, both groups L and C were comparable ($P > 0.05$). The hemodynamics was statistically significantly reduced in group L compared to M and C groups. However, group M showed statistically insignificant changes in hemodynamics compared to groups L and C.

**Conclusions**: Preoperative 250 mg nebulized magnesium sulfate has more protection against post-intubation sore throat than 100 mg nebulized lidocaine lasting up to 24 h after the operation.

**ARTICLE HISTORY**
Received 10 January 2020
Accepted 25 January 2020

**KEYWORDS**
Sore throat; magnesium sulfate; lidocaine and post-intubation

## 1. Introduction

One of the most common complications after endotracheal intubation is sore throat. It represents 18–65% of all postoperative endotracheal intubation complications, which usually lasts 12–24 h after surgery [1,2].

Magnesium sulfate is an N-Methyl- D-Aspartate (NMDA) receptors antagonist with local analgesic and anti-inflammatory effects. NMDA receptors antagonist found in central and peripheral nervous system. Magnesium sulfate is administered as gargles, lozenges or nebulization before surgery for control of postoperative sore throat (POST). The nebulized route ensures equivalent and effectual distribution of magnesium sulfate all over the pharynx till the beginning of the upper respiratory tract. Also, the nebulized rout prevents user variability companies with gargling and discomfited the matter of taste of the medications [3].

Lidocaine is an amino amide local anesthetic, used to decrease airway reflexes, bronchial hyperreactivity and suppress hemodynamic response of intubation because of its analgesic and anti-inflammatory actions by decreasing the excitation of airway sensory C fibers plus the release of sensory neuropeptides. The incidence of POST may increase with the use of lidocaine gel or ointment by irritating or damage the tracheal mucosa. Nebulized lidocaine is easily found with decreasing cost, easily administered, acts immediately with short duration, minimal side effects and no term residual side effects [4–6].

The current study was undertaken to find the ideal agent to either reduce or relieve the throat pain after tracheal intubation. So, the aim of this study was to compare the effect of preoperative-nebulized magnesium sulfate versus lidocaine on the prevention of post-intubation sore throat.

## 2. Patients and methods

This study was approved by our University's Institutional Review Board (ref: 4915/14-10-2018) and written informed consent was obtained from all subjects participating in this trial. The trial was registered prior to patient enrollment at clinicaltrial.gov (ref: NCT03729973 and the date of registration: 15 November 2018). The first patient was enrolled on 1 December 2018.

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Dr. Olfat Abdelmoniem Ibrahem Amin: this author helped in data collection, analyzing and approving the final manuscript.

A prospective comparative controlled double-blind randomized clinical study was conducted from December 2018 to September 2019 on 78 patients of either sex, age between 21 and 45 years, belonging to American Society of Anesthesiologist (ASA) I, II physical status undergoing elective lower abdominal and lower limb surgeries around 2-h duration under general anesthesia and endotracheal intubation with insertion of epidural catheter for administration of postoperative analgesic regimen. So, the patients could estimate postoperative throat pain if it was present. Patients with a history of previous sore throat, using steroids or analgesia in the last 48 h, with chronic obstructive airway disease (COPD) or asthma, neuromuscular disease, allergy or hypersensitivity to the drugs used in this study, risk index of El-Ganzouri for difficult tracheal intubation $\geqslant 4$, with Body Mass Index (BMI > 35 kg/m$^2$), pregnant women, mental disease and subjects who cough or bucked before extubation were excluded from this study.

The primary aim of the current study was to compare the effect of preoperative magnesium sulfate versus lidocaine on the incidence and severity of POST and the secondary aims were to compare changes in hemodynamics and any related side-effects among groups.

This was a double-blind study as the patient and the outcome assessor (the anesthesiologist not sharing in the study who assessed the primary and secondary outcomes) did not know the nebulized solutions.

In the preparation room, under local anesthesia intravenous line was inserted and standard monitors were connected (Electrocardiogram – ECG, non-invasive blood pressure and pulse oximetry) and baseline parameters such as heart rate (HR), systolic & diastolic BP and peripheral oxygen saturation were noted. Changes in HR, systolic & diastolic BP and peripheral oxygen saturation were recorded just after nebulization and before induction of anesthesia.

Before induction of general anesthesia, seventy-eight patients were divided randomly by computer-generated randomization table into 3 groups each was 26:

Group (M) ($n$ = 26): patients nebulized with magnesium sulfate 250 mg (2.5 ml) plus 2.5 ml 0.9% normal saline.

Group (L) ($n$ = 26): patients nebulized with lidocaine 2% 100 mg (5 ml).

Group (C) ($n$ = 26): patients nebulized with 0.9% normal saline 5 ml (control group).

So total volume (5 ml). Patients nebulized by compressor nebulizing for 15 min.

After nebulization, the patient was transferred to the operating room, standard monitors were applied (ECG, noninvasive blood pressure and pulse oximetry) and an epidural catheter was inserted under complete aseptic condition by 18 gauge Tuohy needle, at the level desirable for surgical incision. After negative aspiration, 3 ml lidocaine 2% as a test dose was injected and confirmation of the negative response to the test was done. Then, bolus of 6-ml lidocaine 2% was injected and the dermatome level of the block was carried out.

Patient was pre-oxygenated with 5 L/min oxygen ($O_2$) 100% for 3–5 min. Induction was done with fentanyl 2 µg/kg and propofol 2 mg/kg. Endotracheal intubation was facilitated by atracurium 0.5 mg/kg and intubation was performed by an experienced anesthesiologist using cuffed soft seal sterile polyvinyl chloride tracheal tube of 7-mm inner diameter for female and 8 mm for male patients, the cuff was inflated with air and the pressure in the cuff was maintained between 20 and 22 cm $H_2O$ using a pressure manometer. To prevent the mucosal dryness we used heat and humidifier moisture exchanger (HME). Maintenance of anesthesia was done using isoflurane 1.2% in oxygen 100%, tops up doses of atracurium 0.15 mg/kg every 20 min and fentanyl 0.5 µg/kg/h.

At the end of the surgery and before turning off inhalational anesthetic, post-operative analgesic regimen was begun by continuous epidural infusion of 0.125% bupivacaine with 2 µg/ml fentanyl at a rate of 4–6 ml/h then the muscle relaxant was reversed by administration of neostigmine 0.05 mg/kg, and atropine 0.01 mg/kg then the patient was extubated.

The intensity of sore throat was recorded at 0 h (on arrival to post-anesthesia care unit (PACU)), 2, 4, 8, 12 and 24 h postoperative.

(1) Sore throat was measured on a 4-point scale (0–3) [6]: 0 = no sore throat; 1 = mild sore throat (complaint of sore throat only on asking); 2 = moderate sore throat (complaint of sore throat on his/her own); 3 = severe sore throat (change in voice or hoarseness associated with throat pain).

Patients with sore throat score = 2 or 3 were treated with IV diclofenac 1 mg/kg every 8 h.

### 2.1. The sample size

Assuming that the incidence of POST at fourth hour in nebulized magnesium sulfate group is 53.3% and control group is 86.7%, case to control ratio: 2/1 [7]. So sample size was calculated by OPENEPI to be 78 cases in 3 groups (26 cases in each group) with confidence interval 95% and power of test is 80.

### 2.2. Statistical analysis

All data were collected, tabulated and statistically analyzed using SPSS 20.0 for windows (SPSS Inc., Chicago, IL, USA 2011). Quantitative data were expressed as the mean ± SD, and qualitative data were expressed as

absolute frequencies (number) & relative frequencies (percentage). One-way analysis of variance test (f) was used to compare between more than two groups. Post hoc test was used to provide means are significantly different from each other when F-test was significant. Percent of categorical variables were compared using Chi-square test or Fisher's exact test when appropriate. All tests were two sided. *P*-value < 0.05 was considered statistically significant (S), p-value < 0.001 was considered highly statistically significant (HS), and *p*-value ≥0.05 was considered statistically insignificant (NS).

## 3. Results

Seventy-eight patients were prepared for the study. There were no excluded cases. So, 78 patients were randomly divided among the three groups (26 patients for each) (Figure 1).

- The age, sex, BMI, ASA I, II and duration of surgery were comparable among the groups (Table 1).
- At 0- and 2-h postoperative, the severity of POST was statistically significantly lower in groups M and L compared to the C group ($P < 0.001$). However, at the same time interval, there was no statistically significant difference between groups M and L ($P > 0.05$) (Table 2).
- At 4, 8, 12, 24 h postoperative, the severity of POST was statistically significantly lower in group M compared to L and C groups ($P < 0.001$). However, at the same time interval, both groups L and C were comparable ($P > 0.05$). (**Table 2**).
- The incidence of POST was statistically significantly lower in M group compared to L and C groups all over the postoperative follow-up time ($P < 0.05$). Also, the incidence of POST was statistically significantly lower in group L compared to group C at 0- and 2-h postoperative. While at 4, 8, 12 and 24 h both groups L and C were comparable ($P > 0.05$) (Table 3) (Figure 2).
- HR, systolic and diastolic blood pressure were statistically significantly reduced in group L after nebulization and before induction compared to the

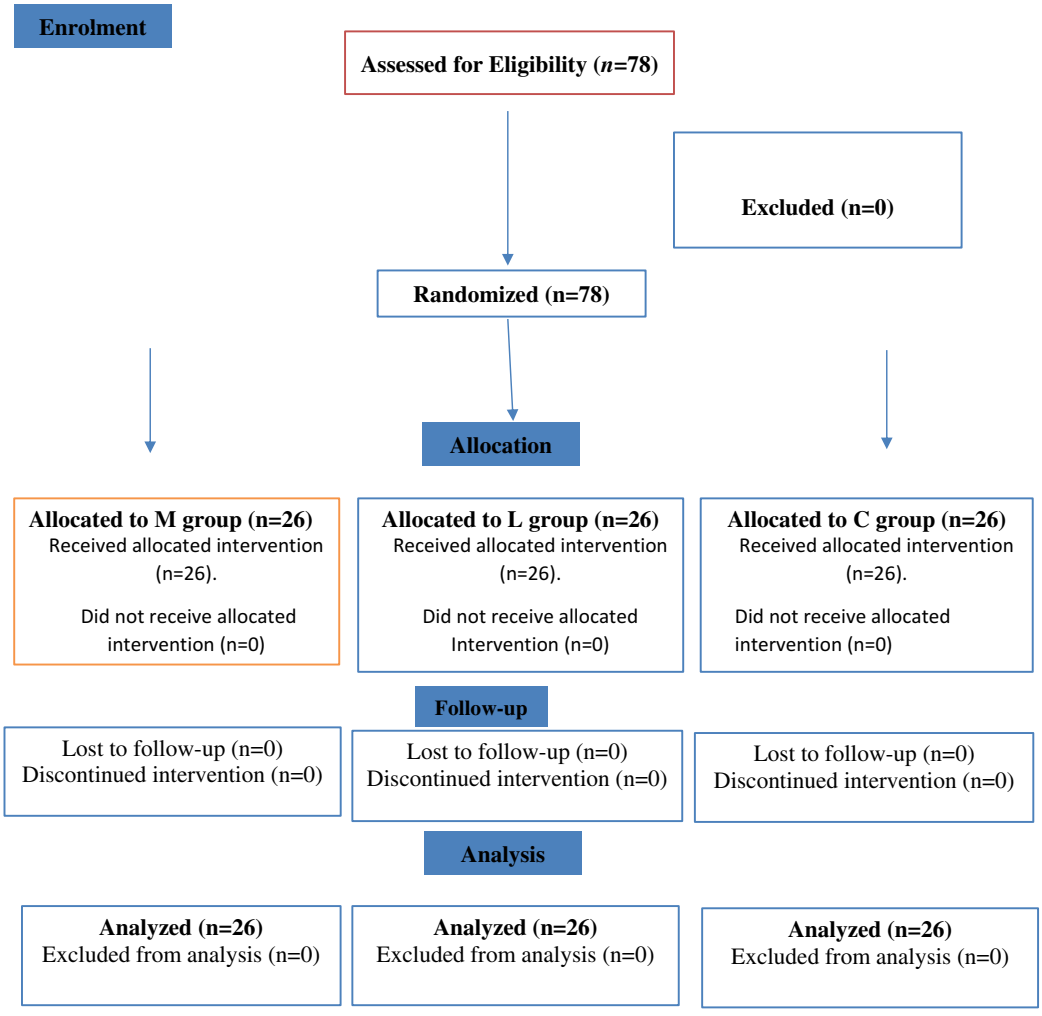



**Figure 1.** Consort flow diagram.

**Table 1.** Patient's characteristics and duration of surgery among studied groups.

| | Group C | Group M | Group L | | *p* |
|---|---|---|---|---|---|
| Age (years) | 31.5 ± 6.9 | 30.8 ± 8.3 | 33.1 ± 6.4 | *f*= 0.68 | 0.50 |
| Sex ***n*** (%) | 12(46.2%) | 12(46.2%) | 11(42.3%) | $\chi^2$ = 0.103 | 0.95 |
| Female | 14(53.8%) | 14(53.8%) | 15(57.7%) | | |
| Male | | | | | |
| BMI (kg/m2) | 29.7 ± 2.9 | 29.4 ± 1.8 | 28.4 ± 2.4 | *f* = 2.07 | 0.133 |
| ASAIII | 19(73.1%) | 21(80.8%) | 18(69.2%) | $\chi^2$ = 0.94 | 0.62 |
| | 7(26.9%) | 5(19.2%) | 8(30.8%) | | |
| Duration of surgery (min) | 121.7 ± 23 | 119.9 ± 21 | 120 ± 19.8 | *f* = 0.059 | 0.943 |

Data were expressed as mean ± SD, or No (%). $P < 0.05$ was significant. $\chi^2$ = Chi-square test.
ASA = American Society of Anesthesiologist. *f* = one-way analysis of variance.
BMI = Body Mass Index.

**Table 2.** Sore throat score among studied groups at preset time postoperatively.

| Time | Sore throat score | Group C | Group M | Group L | $\chi^2$ | P | C_M | C_L | M_L |
|---|---|---|---|---|---|---|---|---|---|
| At 0h(on arrival to PACU) | 0 | 0 | 21(80.8) | 20(76.9) | 49.4 | <0.001 | <0.001 | <0.001 | 0.34 |
| | 1 | 10(38.5) | 5(19.2) | 4(15.4) | | | | | |
| | 2 | 13(50) | 0 | 2(7.7) | | | | | |
| | 3 | 3(11.5) | 0 | 0 | | | | | |
| At 2h. | 0 | 0 | 20(76.9) | 19(73.1) | 42.6 | <0.001 | <0.001 | <0.001 | 0.38 |
| | 1 | 10(38.5) | 6(23.1) | 5(19.2) | | | | | |
| | 2 | 12(46.1) | 0 | 2(7.7) | | | | | |
| | 3 | 4(15.4)) | 0 | 1(8) | | | | | |
| At 4h. | 0 | 3 (11.5) | 21(80.8) | 8(30.8) | 35.9 | <0.001 | <0.001 | 0.06 | <0.001 |
| | 1 | 8(30.8) | 5(19.2) | 12(46.1) | | | | | |
| | 2 | 14(53.8) | 0 | 6(23.1) | | | | | |
| | 3 | 1(3.8) | 0 | 0 | | | | | |
| At 8h. | 0 | 3(11.5) | 16(61.5) | 4(15.4) | 33.8 | <0.001 | <0.001 | .52 | <0.001 |
| | 1 | 4(15.4) | 10(38.5) | 8(30.8) | | | | | |
| | 2 | 16(61.5) | 0 | 12(46.1) | | | | | |
| | 3 | 3(11.5) | 0 | 2(7.7) | | | | | |
| At 12h. | 0 | 1(3.8) | 19(73.1) | 2(7.7) | 41.7 | <0.001 | <.001 | .86 | <0.001 |
| | 1 | 14(53.8) | 7(26.9) | 15(57.7) | | | | | |
| | 2 | 9(34.6) | 0 | 8(30.8) | | | | | |
| | 3 | 2(7.7) | 0 | 1(3.8) | | | | | |
| At 24h. | 0 | 2(7.7) | 19(73.1) | 2(7.7) | 37.9 | <0.001 | <0.001 | 0.96 | <0.001 |
| | 1 | 14(53.8) | 7(26.9) | 15(57.7) | | | | | |
| | 2 | 10(38.5) | 0 | 9(34.6) | | | | | |
| | 3 | 0 | 0 | 0 | | | | | |

Data were expressed as number, percentage (%). $P < 0.05$ was significant.
$\chi^2$ = Chi-square test. Post-anesthesia care unit = PACU.

**Table 3.** Incidence of sore throat among studied groups at follow-up time.

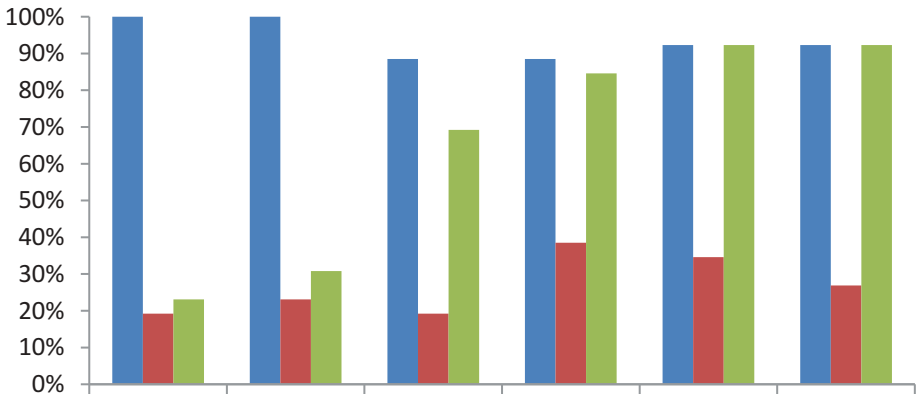
| Hour (h) | Group C | Group M | Group L | $\chi^2$ | *p* | C_M | C_L | M_L |
|---|---|---|---|---|---|---|---|---|
| **0** | 26(100%) | 5(19.20%) | 6(23.10%) | 43.3 | <0.001 | <0.001 | <0.001 | 0.73 |
| 2 | 26(100%) | 6(23.10%) | 8(30.80%) | 37.4 | <0.001 | <0.001 | <0.001 | 0.53 |
| 4 | 23(88.50%) | 5(19.20%) | 18(69.20%) | 27.5 | <0.001 | <0.001 | 0.09 | <0.001 |
| 8 | 23(88.50%) | 10(38.50%) | 22(84.60%) | 19.4 | <0.001 | <0.001 | 0.99 | <0.001 |
| 12 | 25(96.20%) | 7(26.90%) | 24(92.30%) | 38.9 | <0.001 | <0.001 | 0.99 | <0.001 |
| 24 | 24(92.30%) | 7(26.90%) | 24(92.30%) | 35.6 | <0.001 | <0.001 | 1 | <0.001 |

Data were expressed as number, percentage (%). $P < 0.05$ was significant.
$\chi^2$ = Chi-square test.

**Table 4.** Changes in heart rate, systolic & diastolic blood pressure and peripheral oxygen saturation (Spo2) among studied groups.

| variables | Group C | Group M | Group L | *f* | *p* | C_M | C_L | M_L |
|---|---|---|---|---|---|---|---|---|
| Heart rate (beat per minute) | 81 ± 10.1 | 82.9 ± 9.6 | 81.9 ± 9.5 | 0.76 | 0.47 | | | |
| At baseline | | | | | | | | |
| After nebulization | 80.9 ± 9.6 | 81.8 ± 9.4 | 63.8 ± 7.8* | 33.24 | 0.0001 | 0.73 | <0.001 | <0.001 |
| Before induction | 81.1 ± 9.2 | 81.3 ± 8.3 | 64.7 ± 6.2* | 36.87 | 0.0001 | 0.93 | <0.001 | <0.001 |
| Systolic blood pressure (mmHg). | 125.2 ± 14.8 | 120.4 ± 14.5 | 121.6 ± 10.8 | 0.89 | 0.414 | | | |
| At baseline | | | | | | | | |
| After nebulization | 126.7 ± 13.7 | 121.2 ± 14.4 | 103.6 ± 9.6* | 23.31 | 0.0001 | 0.16 | <0.001 | <0.001 |
| Before induction | 125.7 ± 13.3 | 122.5 ± 12.6 | 107.1 ± 7.8* | 19.45 | 0.0001 | 0.38 | <0.001 | <0.001 |
| Diastolic blood pressure (mmHg). | 83.6 ± 7 | 81.3 ± 5.8 | 81 ± 9.3 | 0.933 | 0.39 | | | |
| At baseline | | | | | | | | |
| After nebulization | 83.1 ± 6.2 | 80.3 ± 5.7 | 64.6 ± 7.9* | 58.16 | 0.0001 | 0.096 | <0.001 | <0.001 |
| Before induction | 82.6 ± 7.8 | 81.1 ± 7.3 | 66.4 ± 8.6* | 33.23 | 0.0001 | 0.72 | <0.001 | <0.001 |
| SPo2 (%) | 97.8 ± 1 | 97.8 ± 1 | 97.8 ± 1 | - | | | | |

Data were expressed as mean ± SD. $P < 0.05$ was significant.
*f* = One-way analysis of variance *significant.




| | 0h | 2h | 4h | 8h | 12h | 24h |
|---|---|---|---|---|---|---|
| C | 100% | 100% | 88.50% | 88.50% | 92.30% | 92.30% |
| M | 19.20% | 23.10% | 19.20% | 38.50% | 34.60% | 26.90% |
| L | 23.10% | 30.80% | 69.20% | 84.60% | 92.30% | 92.30% |

**Figure 2.** Incidence of sore throat among groups at follow up times.

other groups ($P = 0.0001$). M group showed statistically insignificant changes in hemodynamics compared to other groups ($p$-value > 0.05) and SPO2 was comparable between the studied groups all over the time 97.8 ± 1 with no statistically significant difference (Table 4).

## 4. Discussion

Modern anesthesia is multifaceted, secure, and requisite to the patient; therefore, the anesthesiologists doing their efforts, and research to minimize the occurrence, and severity of anesthesia-related complications such as POST [1].

Many pharmacological agents and non-pharmacological methods have been used to decrease (POST). The pharmacological agents such as gargling with magnesium sulfate and ketamine, nebulized lidocaine, inhalation of beclomethasone and intracuff lignocaine gel. Among non-pharmacological methods; airway instrumentation, smaller size endotracheal tubes, gentle suction, and minimizing intracuff pressure < 20 mmHg [8].

So, the aim of this study was to compare the effect of preoperative-nebulized magnesium sulfate versus lidocaine on the prevention of post-intubation sore throat.

In the current study, nebulized lidocaine was comparable to nebulized magnesium sulfate in early reduction of the severity and incidence of POST during the first 2-h postoperative. However, nebulized magnesium sulfate had been showed statistically significant reduction in the severity and incidence of POST lasts up to 24-h postoperative. Which was in a correlation with a meta-analysis done by Singh et al. [9] reported that the use of magnesium sulfate pre-operative was effective in decreasing incidence of POST during the first 24 h without any significant side-effects.

In the present study, Nebulized lidocaine group showed statistically significant reduction in the severity and incidence of sore throat during the first 2 h post-operative when compared to control group. However, both groups were comparable at 4, 8, 12 and 24 h post-operative.

Rao et al. [6] reported improvements in the severity of POST in the lignocaine nebulization group compared to control group at 0, 1 and 2 h and this was in line with us. Also, Valera-Rodríguz et al. [10] concluded that nebulized lidocaine was more effective to control the post-intubation laryngeal-tracheal pain with less risk of hemodynamic changes than intravenous lidocaine.

In the current study, group L showed statistically significant reduction in HR, systolic and diastolic blood pressure after nebulization and before induction compared to the other groups. However, M group showed statistically insignificant changes in hemodynamics compared to other groups.

Venus et al. [11] reported that mean blood pressure and HR after intubation in inhaled nebulized lignocaine group were significantly less than that of their control group of patients who received normal saline spray. Also, Jokar et al. [12] concluded that the mean arterial blood pressure and pulse were significantly lower in group inhaled nebulized lignocaine than that of intravenous lignocaine group and the inhaled nebulized lignocaine can control the hemodynamic changes of intubation better than intravenous lignocaine. While Agrawal et al. [13] revealed that changes in HR, SBP, DBP and MAP were comparable between nebulized and intravenous lidocaine and the return of MAP to baseline value was earlier in nebulized group. These findings were in correlations with the present study.

Yadav et al. and Blitz et al. [1,14] reported no significant systemic effects of nebulized magnesium sulfate and explain that due to very low dose they used, in the form of nebulization and systemic absorption of which is 10% compared to the doses used in pre-eclampsia and eclampsia and this was in agreement with the current study as the same dose was investigated.

The systemic side effects were not noted for the studied drugs as well as no statistically significant changes in SPo2 between studied groups all over the 24 h. Borazan et al. [15] reported that Magnesium sulfate, in alkaline PH, is highly concentrated in inflamed tissue with minimal systemic absorption which leads to minimal systemic side-effects with prolongation of its action.

### 4.1. Limitation of the study

In the current study, there were no excluded cases. The reasons were first, we have used epidural analgesia as post-operative pain control regimen for the site of surgery in order not to mask throat pain. Second, all intubation had been done by experienced anesthetist. Lack of data that compare between nebulized lidocaine and magnesium sulfate is the second limitation of this study as this is the only study that compares between both drugs. So, we recommend further studies.

## 5. Conclusion

Preoperative 250 mg nebulized magnesium sulfate has more protection against post-intubation sore throat than 100 mg nebulized lidocaine lasting up to 24 h after the operation.

## Disclosure statement

No potential conflict of interest was reported by the authors.

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