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A Comparative Study of Tramadol Gargle and 2% Lidocaine Plain Solution for the Prevention of Postoperative Sore Throat Following General Anesthesia with Endotracheal Intubation in Patients Undergoing Cesarean Section

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Abstract*—Background: postoperative sore throat has reported incidence of up to 12% following General anesthesia .in adults undergoing tracheal intubation, female sex, younger age preexisting disease of larynx and trachea, prolonged duration of anesthesia, traumatic intubation and the presence of a blood -stained tracheal tube on extubation are associated with greatest risk **Aim of study**: To compare between tramadol gargle and 2% lidocaine plain solution as regard their efficacy for controlling the postoperative sore throat after General Anesthesia with Endotracheal intubation. **Patient and methods**: 90 patient ASA class Il, Female, Age between (18-40), scheduled for Cesarean Section C/S requiring General Anesthesia with endotracheal intubation were randomly recruited into 3 groups: group A (tramadol), group B (2%xylocain plain solution), group C (tape water 30cc). Group A received tramadol gargle [100 mg in 30 ml tape water] for 2min, while group B received 2% plain solution lidocaine(2mg/kg) in 30 ml tape water gargled for 2min and group C received 30ml tape water was gargled for 2 min before induction of anesthesia. The incidence and severity of Postoperative sore throat were graded at 0,1,6 hr after surgery using four point -scale. **Result**: the incidence and severity of POST was significantly less in group A (tramadol group) in compared with group B (2% xylocaine plain solution) and group C (tap water) at grade zero,1hr. No statistically significant association (P= 0.108) between study groups and development of postoperative sore throat after six hours. **Conclusion**: study demonstrated that preoperative gargling with tramadol will decrease the incidence and severity of POST in compared to gargling with 2%xylocain plain solution in patient undergoing cesarean section during general anesthesia with endotracheal intubation in the early postoperative period.*

***Keywords*—** *Post-operative sore throat, tramadol gargling, xylocaine 2% plain solution.*

I. INTRODUCTION

Tramadol used as a sole drug cannot be considered the drug of choice after moderately painful surgical procedures. The doses needed to relieve pain in 80% of patients are much larger than the usual dose of 100 mg (1). Tramadol added to lidocaine for intravenous regional anesthesia provided a shorter onset time of sensory block (2) Trama- dol added to 1.5% mepivacaine for brachial plexus block enhances the duration of analgesia in a dose-dependent manner with acceptable side effects (3). Intraarticular tramadol was also used for management and prevention of pain after arthroscopic knee surgery (4). The intraarticular admixture of tramadol 100 mg with 0.25% bupivacaine provides pronounced.

Lidocaine is an amide local anesthetic that is also used to control ventricular tachyarrhymias. It has class Ib anti-arrhythmic actions.

Mechanism of action: Local anesthetic appears to work primarily by inhibiting the movement of sodium through channels in the plasma membrane of a neuron. By doing this, they inhibit the transmission of nerve impulses. Local anesthetics are relatively selective for sodium channels that are open or in the activated state. Local anesthetics attach to a binding site inside the channel itself accessed from the intracellular side of the membrane. Local anesthetics are far more effective on nerves that are repeatedly firing than on nerves that are not firing. They are also more effective on smaller diameter nerves such as C fibers which are easier to penetrate. Typically, local anesthetic tends to effect pain sensation first, then other sensations and finally, motor function.

Aim of study:

To compare two different methods as regard their efficacy for controlling the postoperative sore throat after General Anesthesia with Endotracheal intubation in patients undergoing cesarean section.

II. PATIENT AND METHODS

This study is prospective randomized double blind clinical trial was conducted at Baghdad teaching hospital, medical city, Baghdad, Iraq, which started in February 2018 to September 2018.

Inclusion criteria:

1. Age 18 40years.
2. Patient of ASA class Il
3. Weight BMI < 35

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Exclusion criteria:
1. Patient refusal.
History of allergy to studied drug.
History of preoperative sore throat.
History of asthma.
Mallampati grades >2.
HX of tonsillectomy.

After approval of the local ethical committee, and the consent was obtained from all patients before included them in the study. A detailed history was taken from each patient's clinical examination was
performed pre operatively.

Anesthetic protocol: All patients prepared properly to the operation, wide bore IV cannula inserted, sedative premedication was not given to patient. All patient received 50mg ranitidine, 10mg metoclopramide. The patients were randomly allocated into three equally divided groups (30 patients each), the anesthetist who administered study drugs and performed laryngoscopy and intubation were to the study groups.

Group (A): Patients were asked to gargle for 2min with 30ml tap water containing tramadol hydrochloride 100mg.

Group (B): Patients were asked to gargle for 2min with 30ml tap water containing 2% xylocaine plain solution. (2mg/kg).

Group (C): Patients were asked to gargle for 2min with 30ml tap water only.

the monitors including (pulse rate (PR), non-invasive BP, SPO2, electrocardiogram (ECG), end tidal CO2 (ET CO2).

Anesthesia was induced with 0.5 mg /kg ketamine, propofol up to 2mg/kg, and tracheal intubation (with size 6.5 ID endotracheal tube) was facilitated with a muscle relaxants suxamethonium 100mg (1 mg /kg).

Anesthesia was maintained with halothane 0.6_1.0 % in 100% oxygen. Neuromuscular blockade was maintained with a muscle relaxant rocuronium (0.6mg\kg) and Analgesia was maintained by IV paracetamol 1000mg for all patients.

At the end of surgery, patients oropharynx was gently suctioned with as minimal instrumentation as possible, residual neuromuscular blockade was antagonized using neostigmine 2.5mgqg and atropine 1.2mgq. Each patient trachea was extubated on return of spontaneous respiration and the following ability to obey verbal command or have a sustained head lift for 5 second.

After extubation, each patient was transported to the recovery room for further observation and monitoring of vital signs. Patients were asked for the presence of pain on swallowing as a symptom of postoperative sore throat or throat pain when patients fully awake, prior to discharge toward. Patients were instructed on the four-point grades of postoperative throat pain as shown in Table 1

TABLE 1: Four-point scale

1	No sore throat.
2	Mild sore throat (complains of sore throat only on asking).
3	Moderate sore throat (complains of sore throat on his or her own).
4	Severe sore throat (change of voice or hoarseness, associated with throat pain).

Statistical Analysis: The data analyzed using Statistical Package for Social Sciences (SPSS) version 25. The data presented as mean, standard deviation and ranges. Categorical data presented by frequencies and percentages. Analysis of variances (ANOVA) (two tailed) was used to compare the age among study groups accordingly. Pearson's Chi-square test was used to assess statistical association between study groups and postoperative sore throat development. A level of P — value less than 0.05 was considered significant.

III. Results

The total number of study patients was 90. All of them were undergone elective caesarean section under general anesthesia. Before induction, 30 patients were received tramadol gargle (Group A), other 30 patients were received xylocaine 2% plain solution gargling (Group B) (for prevention of postoperative sore throat), and the other 30 patients received 30 cc tab water gargle (Group C).

Age: Study patients age was ranging from 18 — 40 years old with a mean of 28.22 years and standard deviation of + 7.35 years. We noticed that there was no statistically significant difference (P= 0.066) in mean of age between study groups as shown in table (1).

TABLE 1: Comparison in age between study groups

Study Group	Age (Years) Mean ± SD	P - Value
A	28.43 ± 7.81	0.066
B	25.82 ± 5.16	
C	30.41 ± 9.08	

Postoperative sore throat: At zero time: The comparison between study groups by postoperative sore throat complain at zero time is shown in figure (1) and table (2). In this study, 93.3% of patients in control group (Group C) were complained from postoperative sore throat at zero time with a significant association (P= 0.003) between study groups and development of postoperative sore throat at zero time.

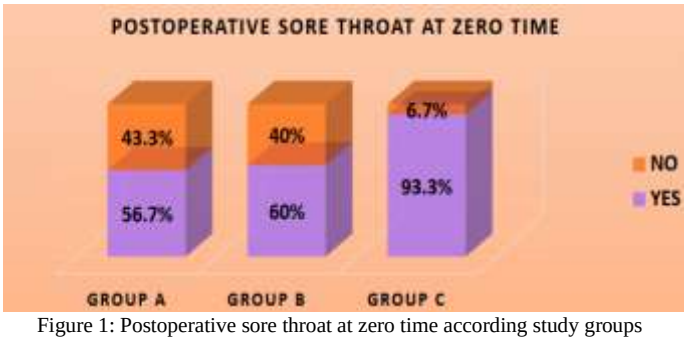

Figure 1: Postoperative sore throat at zero time according study groups

TABLE 2: Comparison between study groups by postoperative sore complaint at zero time

Study Group	Postoperative sore throat at zero time		Total (%) n= 90	P-Value
	Yes (%) n= 63	No (%) n= 27		
A	17 (56.7)	13 (43.3)	30 (33.3)	0.003
B	18 (60.0)	12 (40.0)	30 (33.3)	
C	28 (93.3)	2 (6.7)	30 (33.3)	

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After one hour: The comparison between study groups by postoperative sore throat complain after one hour is shown in figure (2) and table (3). We noticed that 86.7% of patients in control group (Group C) were complained from postoperative sore throat after one hour with a significant association (P= 0.028) between study groups and development of postoperative sore throat after one hour.

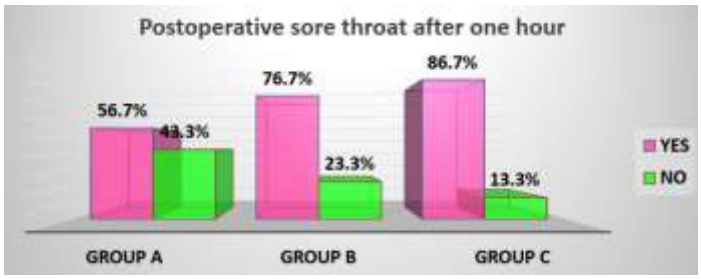

Figure 2: Postoperative sore throat after one hour according to study groups

TABLE 3: Comparison between study groups by postoperative sore throat complain after one hour
Postoperative sore throat

Study Group	Postoperative sore throat after one hour		Total (%) n= 90	P-Value
	Yes (%) n= 66	No (%) n= 24		
A	17 (56.7)	13 (43.3)	30 (33.3)	0.028
B	(76.7)23	(23.3)7	30 (33.3)	
C	26 (86.7)	4 (13.3)	30 (33.3)	

The comparison between study groups by postoperative sore throat complain after six hours is shown in figure (3) and table (4). No statistically significant association (P= 0.108) between study groups and development of postoperative sore throat after six hours. Postoperative sore throat after six hours

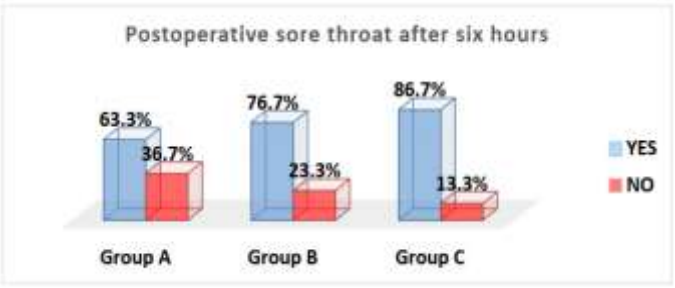

Figure 3: Postoperative sore throat after six hours according to study groups

TABLE 4: Comparison between study groups by postoperative sore

Study Group	Postoperative sore throat after six hours		Total (%) n= 90	P-Value
	Yes (%) n= 68	No (%) n= 22		
A	19 (63.3)	11 (36.7)	30 (33.3)	0.108
B	(76.7)23	(23.3)7	30 (33.3)	
C	26 (86.7)	4 (13.3)	30 (33.3)	

Severity of postoperative sore throat after six hours: The comparison between study groups by severity of postoperative sore throat after six hours is shown in figure (4) and table (5). In comparison between groups B and C, we noticed that 38.5% of patients in control group were complained from moderate sore throat with a significant association (P= 0.017) between xylocaine 2% plain solution and severity of postoperative sore throat after six hours.

No statistically significant differences (P > 0.05) were shown between groups A and C and between groups A and B regarding severity of postoperative sore throat after six hours.

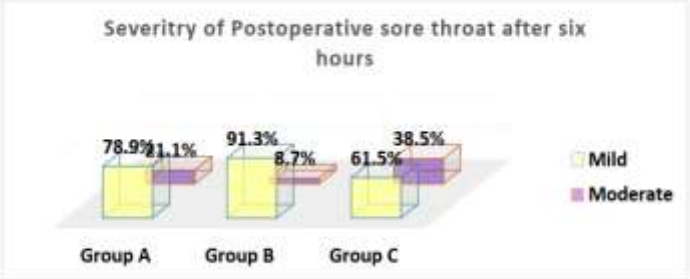

Figure 4: severity of postoperative sore throat after six hours according to study groups

TABLE 5: Comparison between study groups by severity of postoperative sore throat after six hours

Study Group	Severity of Postoperative sore throat after six hours		Total (%)	P - Value
	Mild (%)	Moderate (%)		
Between groups (A & C)	n= 31	n= 14	n= 45	
A	15 (78.9)	4 (21.1)	19 (42.2)	330.
C	16 (61.5)	10 (38.5)	26 (57.8)	
Between groups (B & C)	n= 37	n= 12	n= 49	
B	21 (91.3)	2 (8.7)	23 (46.9)	0.017
C	16 (61.5)	10 (38.5)	26 (53.1)	
Between groups (A & B)	n= 36	n= 6	n= 42	
A	15 (78.9)	4 (21.1)	19 (45.2)	0.243
B	21 (91.3)	2 (8.7)	23 (54.8)	

IV. Discussion

Post-operative sore throat [POST] related to endotracheal tube might be caused by aseptic inflammation, edema, congestion, pain. It suggested that NMAD antagonists decrease the incidence and severity of POST because of their analgesic and anti-inflammatory effects.

The study showed the preoperative gargling of 100mg of tramadol for five minutes prior to endotracheal intubation has more beneficial effects when compared to gargling with 2% xylocain plain solution and control group (tap water gargling) in the prophylaxis of post-operative sore throat attributable to endotracheal intubation at zero and 1hr. In this study, 93.3% of patients in control group (Group C) were complained from postoperative sore throat at zero time with a significant association (P= 0.003) between study groups and development of postoperative sore throat at zero time, after that we noticed that 86.7% of patients in control group (Group C) were complained from postoperative sore throat after one hour with a significant association (P= 0.028) between study groups and development of postoperative sore throat after one hour. No significant association (P= 0.108) between study groups regarding severity of postoperative sore throat after six hours.

Direct questioning technique was used in this study with less emphasis on pain from operative site. Also, proper grading of severity of postoperative sore throat may have

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contributed to the measured outcome in this study.

In this study we found that the contribution of age to the development of postoperative throat pain was not significant, p-value (0.066). Were study of Higgins et al, (5) age in 10 year increments was significantly associated with postoperative sore throat pain ,p- value (< 0.05) . This implied that older patients have higher incidence of post-operative sore throat, in our study it was noted that there is no significant risk associated with development of post-operative throat pain in mean of age between 18 40 years (6). Another mechanism of action of tramadol could be involved in the explanation of its reducing effect of POST, is its local anesthetic effect was evidenced in several studies ; AK bay et al .showed that topical 5% tramadol applied to the tonsillar fossa provides good analgesia after tonsillectomy (7), Tekelioglu et al found that topically applied tramadol and ketamine to tonsillar fossa for 5 min after tonsillectomy reduce postoperative pain (8, 9), Kargi et al showed that local infiltration with 5% tramadol was similar to 2% lidocaine in tendon repair surgery of the hand (10).

Therefore, used the studies of other NMDA antagonists, the study of Canbay et al (11) and the study of Shrestha et al (12) they found that preoperative gargling with ketamine 40mg or 50mg respectively reduced the incidence and severity of POST after endotracheal intubation similar to our study. This could be explained by Zhu et al that found that locally administrated ketamine inhibits the inflammatory response as NMDA receptors are present in the CNS and peripheral nerves (13).

Another NMDA antagonist, magnesium sulfate, has anti-inflammatory effect and decreases the inflammatory mediators as histamine and leukotriene (14) and it's found to be effective in reducing the severity of POST as show in study of Gupta et al (15), he found that preoperative Mg nebulization reduce the incidence of POST.

In study of Agarwal et al (16) found the efficacy of dispersible aspirin gargle with benzamine hydrochloride gargles for reduction of POST. They found that aspirin and benzamine hydrochloride gargles reduce incidence of POST.

V. CONCLUSION

Study demonstrated that preoperative gargling with tramadol will decrease the incidence and severity of POST in compared to gargling with 2%xylocain plain solution in patient undergoing cesarean section C/S during general anesthesia with endotracheal intubation in the early postoperative period.

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