

A RANDOMISED CONTROLLED TRAIL ON EFFECT OF SMALLER ENDOTRACHEAL TUBE COMBINED WITH INTRAVENOUS LIGNOCAINE ON POST-OPERATIVE SORE THROAT

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ABSTRACT

BACKGROUND

Post-operative sore throat (POST) is one of the common complications of general anaesthesia (GA) with endotracheal tube, which may cause patient dissatisfaction after the surgery. Various methods to reduce POST have been tried, both pharmacological and non-pharmacological, with varying results. This study aims to compare the effectiveness of a combination of intravenous (I.V.) lignocaine and smaller endotracheal tube (ETT) on the occurrence of POST.

METHODS

Four hundred women between 18-70 years undergoing elective surgeries under GA with endotracheal tube satisfying the inclusion criteria were allotted into 4 groups: Group A: cuffed ETT size 7.0 with I.V. saline, Group B: cuffed ETT size 7.0 with I.V. lignocaine, Group C: cuffed ETT size 6.0 with I.V. saline and Group D: cuffed ETT size 6.0 with I.V. lignocaine. After extubation, the patients were assessed for occurrence and severity of sore throat at 1, 6 and 24 hours after surgery.

RESULTS

The incidence and severity of POST was statistically different among the 4 groups ($p < 0.001$ for overall incidence; $p = 0.001$, $p < 0.001$, $p = 0.002$ for incidence at 1, 6, and 24 hrs; $p = 0.027$, $p = 0.030$, $p = 0.622$ for different grades of POST at 1 hr, $p = 0.004$, $p = 0.044$ at 6 hrs., and $p = 0.008$, $p = 0.622$ at 24 hrs respectively). Inter group comparison showed statistical difference in incidence and severity between groups A and C; groups B and D; groups A and D.

CONCLUSIONS

The use of smaller ETT for GA reduces the incidence as well as severity of POST. Intravenous lignocaine has little effect in preventing the occurrence of POST, but the combination of smaller ETT and IV lignocaine appears to reduce POST more than when they are used individually.

KEYWORDS

Post-Operative Sore Throat (POST), Intravenous Lignocaine, Cuff Pressure.

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BACKGROUND

About 200 million major surgeries take place per annum world wide¹ and general anaesthesia is the anaesthetic technique given for the majority of cases. The assurance of a good quality of anaesthesia in the modern era has become increasingly important for improving the operative outcome. Post-operative sore throat (POST) can contribute to patient's dissatisfaction, discomfort and delay a patient's return to normal routine activities.² It is a won adverse effect after general anaesthesia with an endotracheal tube and its

incidence from 21% to 71.8%.^{3,4} The causes of sore throat is considered to be as a result of laryngoscopy, intubation damage, inflated cuff pressure on tracheal mucosa,⁵ size and shape of the tube, pre-existing tracheal disease, use of nasogastric tube during anaesthesia, type of surgery and the use of acetylcholine.⁶ There is a significantly higher occurrence of POST among female patients which may be attributed to the smaller size of female trachea and softer mucosal wall.⁷ Various methods^{3,5,8-10} are suggested by different authors to prevent sore throat which includes administration of various drugs like ketamine, NSAIDs, lignocaine intravenously or locally on the cuff as well as using a smaller endotracheal tube (ETT). The intravenous lignocaine prior to endotracheal intubation decrease the incidence of post-operative sore thorat and cough^{10,11} It has been proved that smaller endotracheal tubes (ETT) can alleviate sore throat and discomfort in women at the post anaesthesia care unit (PACU).⁹ When smaller sized ETT and intravenous lignocaine was combined together, it was found that the combination is better either of them alone when

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done on patients undergoing thyroidectomy.¹² There are no data concerning the effect of smaller sized ETT in combination with lignocaine on POST in women, undergoing surgery other than thyroidectomy. The hypothesis of this study is that the combination of physical (smaller sized ETT) and pharmacological (intravenous lignocaine) intervention together is better than either of them alone for reducing POST. Our present study was aimed at evaluating the occurrence of POST by combining both smaller ETT and intravenous lignocaine.

Aims and Objectives

The effect of smaller ETT and lignocaine on post-operative sore throat and Assessment of the severity of post-operative sore throat.

METHODS

A study titled 'Effect of smaller endotracheal tube combined with intravenous lignocaine on post-operative sore throat' - a randomised controlled trial was undertaken in GITAM institute of medical education and research Visakhapatnam, during the period October 2017 to August 2018. The study was undertaken after obtaining ethical clearance as well as after obtaining informed consent from all patients. Women of age group 18 to 70 years scheduled for elective surgeries under general anaesthesia were taken for the study.

Sample Size

The study conducted by Xu et al¹² showed that the incidence of POST among patients who received both smaller size ETT and intravenous lignocaine was 23% and without either of them was 62%. In our study, expecting similar results with 95% confidence, 90% power and considering 22% difference as clinically significant, the study requires a minimum of 95 subjects in each group. Four hundred female patients undergoing elective surgeries other than maxillofacial, oral cavity and neck surgeries under general anaesthesia, Women of age between 18-70 yrs., American Society of Anaesthesiology Physical Status (ASAPS) grade I-II and surgeries in supine position were included in the study. Patients who required more than 2 attempts of intubation, History of pre-operative sore throat or upper respiratory tract infection, Maxillofacial, intra oral and neck surgeries, Surgeries requiring nasogastric tube insertion Anticipated difficult intubation Use of succinylcholine during intubation, Smokers, and Patients with known allergy to lignocaine were excluded from study. Patients will be randomly allocated into four groups by the use of computer-generated random numbers. The grouping will be as follows:

Group A: Cuffed ETT size 7.0 with intravenous saline.

Group B: Cuffed ETT size 7.0 with intravenous lignocaine.

Group C: Cuffed ETT size 6.0 with intravenous saline.

Group D: Cuffed ETT size 6.0 with intravenous lignocaine.

Patients in group B and D will receive 1.5 mg/kg lignocaine intravenously that will be filled in syringe up to 10 ml; whereas patients in Group A and C shall receive equal

volume of 10 ml saline. All patients will receive premedication with tablet pantoprazole 40 mg and tablet ondansetron 8 mg before surgery. After connecting monitors and recording basal vitals, intravenous lignocaine or saline will be administered 3 minutes before induction. Anaesthesia will be induced with fentanyl 2 mcg/kg, propofol 2 mg/kg. Tracheal intubation will be facilitated with atracurium 0.5 mg/kg. In our study we have used only high-volume low pressure cuffed endotracheal tubes. The cuffed ETT will be inflated with air and the cuff pressure will be maintained at 20 to 25 cm H₂O, using a manometer. Cuff pressure will be monitored half hourly during surgery. Anaesthesia will be maintained by isoflurane, intermittent fentanyl (as and when required by the anaesthetist) and atracurium (when train-of-four/TOF >0.9) At the end of surgery, residual neuromuscular blockade will be antagonized by neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. All patients will receive ondansetron 4 mg for the prevention of post-operative nausea and vomiting at time of skin closure. After surgery, ETT will be slowly deflated and gentle suction of oral secretion will be done. Heart rate (HR), non-invasive blood pressure (NIBP), peripheral oxygen saturation (SpO₂), temperature and end-tidal CO₂ (EtCO₂) will be monitored throughout the surgery. Post operatively, all patients will receive paracetamol 1 g intravenous (i.v) infusion 8th hourly, and tramadol 50 mg slow I.V. will be administered as rescue analgesic until analgesia was adequately controlled. At 1, 6 and 24 hrs after extubation, the assessment of POST will be done based on a 4 point scale: 0-no sore throat, 1-mild (complaints of sore throat on enquiry), 2-moderate (complaints of sore throat on her own) and 3-severe (change of voice/hoarseness associated with sore throat).

If the score is 2, all patients will receive saline nebulisation 6th hourly. If the score is 3, all patients will receive saline nebulisation 6th hourly +injection diclofenac sodium 75 mg stat dose.

Statistical Analysis

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean \pm SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level 'significance. The following assumption on data is made. Dependent variables should be normally distributed, Samples drawn from the population should be random cases of the samples should be independent. Analysis of variance (ANOVA) has been used to find the significance of study parameters between three or more groups of patients and Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, non-parametric setting for qualitative data analysis. P value <0.001 is significant.

RESULTS

Age and Body Mass Index (BMI) Distribution

Majority of the patients in all the groups had BMI in between 18.5-25 with group A, B, C, and D having 53 (55.8%), 47 (49.5%), 51 (53.7%), 52(54.7%) respectively. The height, weight as well as the BMI distribution in all the 4 groups were matched with p= 0.317, 0.647 and 0.670 respectively.

Variables	Group A	Group B	Group C	Group D	Mean	P Value
Height (cm)	154.8 ±5.82	153.31 ±7.09	154.89 ±6.61	154.24 ±6.58	154.31 ±6.55	0.317
Weight (kg)	57.13 ±9.86	56.79 ±10.93	58.61 ±10.99	57.05 ±11.38	57.39 ±10.78	0.647
BMI (kg/m ² , mean ± SD)	23.71 ±3.04	24.00 ±3.35	24.25 ±3.23	23.79 ±3.45	23.94 ±3.27	0.670
Age Years	34.86 ±11.3	34.55 ±11.65	34.84 ±12.10	33.80 ±12.25	34.51 ±11.70	0.543

Table 1. Age and BMI Distribution in Study Group (mean ± SD)

Presence of Sore Throat at Different Intervals of Time

The occurrence of POST after 1 hr in group A was 30.5%, in group B it was 24.2%, whereas in groups C and D it was 11.6 and 10.5% respectively. The difference was found to be significant (p= 0.001) After 6 hours, the occurrence of POST in group A was 17.9% whereas in groups, B, C and D, it was 14.7%, 3.1% and 2.1% respectively, again being strongly significant with a P value <0.001 At 24 hours, 8.14% of patients in group A had sore throat, whereas in group B it was only 4.2%. However, no patients in group C and D had sore throat at 24 hrs. The reduction in POST was statistically significant with a p value of 0.002.

Duration after Extubation	Group A	Group B	Group C	Group D	p Value
1 hr	29(30.5)	23(24.2)	11(11.6)	10(10.5)	0.001
6 hr	17(17.9)	14(14.7)	3(3.1)	2(2.1)	<0.001
24 hr	8(8.4)	4(4.2)	0	0	0.002

Table 2. Incidence of Sore Throat after Extubation

The incidence of POST was reduced in group C when compared to group A at all times. It was found to be statistically significant at all points of time (p-values, 0.329, 0.556, 0.233)

The occurrence of POST was reduced in group D when compared to group C, but it was not statistically significant. (p-values, 0.001, 0.001, 0.004)

The incidence of POST was reduced in group D when compared to group A at all times and was found to be statistically significant throughout the time period (p-values, 0.817, 0.407, N/A)

The incidence of POST was reduced in group D when compared to group B at all times and was found to be statistically significant(p-Values, 0.001, <0.001, 0.004)

Comparison of Severity of POST

a. 1 Hour After Extubation

As per the protocol the POST was graded according to the severity and those patients with grade 2 sore throat were given saline nebulisation and those with grade 2 sore throat were given saline nebulisation and those with grade 3 POST were given diclofenac injection.

Post Severity Grading	Group A	Group B	Group C	Group D	p Value
1 hr					
1	23(24.2%)	16(16.8%)	10(10.5%)	10(10.5%)	0.027
2	4(4.2%)	6(6.3%)	1(1.1%)	0(0%)	0.030
3	2(2.1%)	1(1.1%)	0(0%)	0(0%)	0.622

Table 3. POST Severity in Different Groups at 1 Hour After Extubation (No. and Percentage)

At first hour, 24.2% patients in group A had mild sore throat while group B, C and D patients had 16.8%, 10.5% and 10.5% incidence of mild sore throat at 1st hour. The difference was found to be moderately significant with p= 0.027. In the same hour, 4 people (4.2%) in group A had moderate sore throat while group B, C, D had 6.3%, 1.1% and Zero percentage incidence of moderate POST, again found to be moderately significant with p value = 0.030. Similarly, 2 patients in group A (2.1%) and 1 patient in group B (1.1%) had severe sore throat requiring post op analgesia. No incidence of severe sore throat was found in group C and D. It was not found to be statistically significant.

b. 6 Hours After Extubation

Six hours post extubation, 13.7% of patients in groups A had mild sore throat while 10.5% patients in groups B had mild sore throat. 3 people (3.2%) and 2 people (2.1%) had mild sore throat in group C and D respectively. It was found to be strongly significant (p= 0.044). Also 3.2% people in group A and 4.2% people in group B had moderate sore throat after 6 hrs. None of the patients in the other 2 groups C and D developed moderate POST during this period. It was found to be statistically significant. (p= 0.044).

Only 1 patient developed severe POST in the 6th hr, in group A. It was not found to be significant.

Post Severity Grading	Group A	Group B	Group C	Group D	p Value
6 hr					
• 1	13(13.7%)	10(10.5%)	3(3.2%)	2(2.1%)	0.004
• 2	3(3.2%)	4(4.25)	0(0%)	0(0%)	0.044
• 3	1(1.1%)	0(0%)	0(0%)	0(0%)	1.000

Table 4. POST Severity in Different Groups at 6 Hours after Extubation. (in No. and Percentage)

C. 24 Hours After Extubation

After 24 hours of extubation, the severity of POST has come down, with only 6 patients in group A (6.3%) and 3 patients in group B (3.2%) developing mild sore throat, and none in group C and D. it was found to be strongly significant. (p= 0.008).

Two patients (2.1%) developed moderate sore throat in group A after 24 hrs while only 1 patient (1.1%) developed POST in group B and none in group C and D. It was not found to be statistically significant. (p= 0.622).

Post Severity Grading	Group A	Group B	Group C	Group D	p Value
24 hr					
• 1	6(6.3%)	3(3.2%)	0(0%)	0(0%)	0.008
• 2	2(2.1%)	1(1.1%)	0(0%)	0(0%)	0.622
• 3	0(0%)	0(0%)	0(0%)	0(0%)	

Table 5. POST Severity in Different Groups at 24 Hours after Extubation

Thus, the distribution of mild and moderate sore throat was statistically significant at 1 and 6 hrs after extubation among the 4 groups. At 24 hrs only the distribution of mild sore throat was statistically significant.

DISCUSSION

Many of the general anaesthetics in the modern anaesthetic practice are carried out with endotracheal intubation. POST is a well-recognized minor complication after GA rated by patients as one of the most undesirable outcomes in the post-operative period.¹² Prophylactic management for decreasing its frequency and severity is recommended to improve the quality of post anaesthesia care even though the symptoms resolve spontaneously without treatment. As non-pharmacological interventions, the effect of smaller sized tubes for reducing POST is also reported. The reduced occurrence of POST is probably due to lesser trauma to the airway while inserting the tube.^{9,12}

Intravenous lignocaine has been found to inhibit C fibres which carry pain from the pharyngeal mucosa thus reducing the perception of sore throat by reducing the release of neuropeptides followed by neuroplasticity in the airway and brainstem.^{13,14} Thus in the present study we utilized the advantages of the combination of smaller ETT and intravenous lignocaine for assessing the POST. The overall incidence of POST in our study was 24.7%. The incidence in group A was 41.05% and group B was 33.68%. These values correlate with the previous studies which have shown a range of 21% to 71.8%.^{3,6,12} The incidence of sore throat in group a in 1st hour was 30.5% while in group B,C and D it was 24.2%, 11.57% and 10.5% respectively. When the patients were analysed after 6 hrs the incidence of POST for groups A, B, C, D were 17.89%, 14.73%, 3.15% and 2.10% respectively. After 24 hours of extubation the POST had reduced to 8.42% in group A and 4.2% in group B respectively. No patients in group C and D complained of any grade of sore throat at 24 hours. In our study we found that difference in the incidence of POST was statistically significant in 4 groups. The severity of POST was also significantly different among the groups. There was significant reduction in severity in POST in group D compared to group A and in group C compared to group A at all points of time. When group B and group D were compared, the severity of POST was more in group B at 1 and 6 hrs. and was not significant at 24 hrs. Xu et al.¹² in

their study comparing lignocaine and smaller sized tube in patients undergoing thyroid surgery, found out that the incidence and severity of POST was more with the 7 mm ETT compared to 6 mm ETT, and the incidence was more at 6 hours. In our study we found similar results with the size of the tube, but the occurrence of POST was more in the first hour in all the 4 groups unlike their study. The patients in the previous study who had undergone thyroidectomy may not be able to differentiate between the surgical pain and the sore throat in the first hour.¹² In our study, the incidence of sore throat was maximum in the first hour for all the groups. Also, in all our cases we had excluded neck and oral surgeries for obtaining accurate results. In our study the mean surgical duration between different groups ranged from 103-106 min. The half-life of lignocaine is approximately 2 hours. Since I.V. lignocaine is given prior to study, it may be doubtful that lignocaine had analgesic effect post operatively. In another study by M. Jaensson, L. L. Olowsson and U. Nilsson⁹ compared the proportion of patients developing sore throat by using ETT of size 6 mm and 7 mm. They assessed the POST after, 2 and 24 hrs and found that the incidence as well as severity in sore throat was significantly higher in the ETT 7.0 mm group compared to 6.0 mm group. Similar results were obtained in our study. Smaller sized tubes are relatively easy to intubate and can probably cause less mucosal damage.⁹ In another RCT by Takakewa et al¹¹ which studied the effects of intravenous lignocaine prior to intubation on post-operative symptoms compared 2 different doses of lignocaine (1 mg/kg; 1.5mg/kg) and saline as control.(n= 80). They evaluated the symptoms after 24 hours of extubation. Even after 24 hrs they found significant differences in the incidences (p<0.01) and severity (p<0.01) of sore throat and cough between the groups. However, our study failed to show the isolated effect of intravenous administration of 1.5 mg/kg lignocaine on the occurrence of POST. In our study, the inter group comparison revealed incidence and severity of POST is statistically difference in incidence of POST when groups A and B; Group C and D were compared. Which shows that when compared to the tube size, lignocaine has little effect on the incidence as well as severity of POST.

CONCLUSIONS

The use of a smaller sized ETT for intubation prevents the incidence and severity of POST and the combination of smaller ETT together with intravenous lignocaine reduce the symptoms of POST when compared to separate use of the individual interventions.

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