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# A Prospective Double Blind Observational Study to Assess the Incidence and Risk Factors Associated with Endotracheal Intubation in Patients Undergoing General Anaesthesia

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## ABSTRACT

**Background:** To assess the incidence and risk factors of sore throat, cough and hoarseness in 180 patients undergoing general anaesthesia and endotracheal intubation.

Postoperative sore throat is one of the common adverse events after general anaesthesia and has a reported incidence from 21 to 71%. Though it is not a life threatening complication, it is an important cause of postoperative morbidity and patient dissatisfaction during the hospital stay.

**Methods:** A prospective observational study was conducted on 180 patients ASA PS 1 and 2, in the age group of 18-65 years of both gender, undergoing general anaesthesia and endotracheal intubation. Preoperatively h/o smoking and tobacco chewing were recorded. Intraoperatively number of attempts of intubation, duration of laryngoscopy, presence of throat pack and ryle's tube, position of head during surgery and duration of surgery were recorded. Post operatively complaints of sore throat, cough and hoarseness were recorded at 6hrs and 24 hrs using 4-point scale. Data were analysed with SPSS 22 version software, p value of <0.05 was considered

Data were analysed with SPSS 22 version software, p value of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

**Results:** The incidence of sore throat was 30.6%, hoarseness was 4.4% and cough was 2.8% in our study in patients undergoing general anaesthesia and endotracheal intubation.

**Conclusion:** The incidence of sorethroat was 30.6%, hoarseness 4.4%, and cough 2.8% in our study. Tube lubrication, position of head extension with pillow under shoulder and presence of throat pack shows higher incidence of POST.

Postoperative sore throat is one of the common adverse events after general anaesthesia and has a reported incidence of upto 21-71% [1]. Even after so much advances in anaesthesia and airway management, incidence of throat related complaints remain high. Apart from postoperative pain and nausea and vomiting, Postoperative sore throat (POST) is an important cause of postoperative morbidity and patient dissatisfaction during the hospital stay [2]. Various airway devices, insertion techniques and cuff designs have varied incidences of throat related complaints [3]. Although the etiology of POST is not clearly understood,

it appears to be due to irritation and inflammation of airway mucosa, compromised airway mucosal perfusion pressure due to high cuff inflation pressures [4].

NOVELTY: Whether technological advances in airway management, better training of residents for smooth intubation has reduced incidence of POST in recent times. Hence we studied 180 patients for incidence of postoperative sore throat and associated risk factors in our institute for a period of one year.

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# **Methods**

After obtaining institutional ethical committee approval and informed consent from patients, a prospective observational study was conducted on 180 patients of American society of anaesthesiologists physical status (ASA PS) grade 1 and 2, of either sex, aged between 18 to 65 years undergoing general anaesthesia with endotracheal intubation. Sample size was calculated based on incidence of POST in previous literature with confidence interval of 95% and power of 90%. All patients were counselled and educated to report any throat related complaints if they have after the surgery. Pre anaesthetic evaluation was done in all patients for any co-morbidities, history of smoking and tobacco chewing. Exclusion criteria were patients with recent or ongoing upper respiratory infection, airway surgeries, patients who could not be extubated after the surgery, patients on steroids or opioids preoperatively and those with pre-existing hoarseness due to vocal cord nodules or carcinoma. All patients received premedication with tab Ranitidine 50 mg PO, tab diazepam 10 mg PO night before surgery.

On the operating table, routine monitors like NIBP, SpO2 and ECG were connected. Patients were premedicated withinj Midazolam 0.05mg/kg, inj Fentanyl 2mcg/kg and inj Glycopyrolate0.04mg/kg. Anaesthesia was induced with inj propofol 2mg/kg. Muscle relaxation was obtained with inj Vecuronium 0.1mg/kg.

Female and male patients were intubated with 7 or 7.5, and 8 or 8.5 endotracheal tubes respectively.

Cuffs were inflated with 5 ml air or until obliteration of air leak. The endotracheal tubes were sterile polyvinyl chloride tubes with high volume low pressure cuffs (STERIMED PVC). All intubations were performed by an experienced anaesthesiologist after ensuring maximum neuro-muscular relaxation. Some patients received lubricated endotracheal tubes and some received non-lubricated endotracheal tubes. All intubations were performed in one or two attempts taking twenty to thirty seconds. Anesthesia was maintained with oxygen 33% with nitrous oxide 66% supplemented with sevofluorane 1-2%. All patients received injection diclofenac 75 mg iv infusion or paracetamol 1g iv infusion as part of multi modal analgesia. Presence of nasogastric tube and throat pack was noted.

At the end of surgery, gentle oral suctioning was done. After reversing residual neuro-muscular blockade with inj neostigmine 0.05mg/kg and inj glycopyrrolate 0.08mg/kg patients were extubated and shifted to post anesthesia care unit (PACU). After 6 hours, all patients were interviewed in a standard manner by directly asking questions about their throat related complaints.

POST was graded on a 4 point scale from 0-3.

• 0-no sore throat,

• 1-mild sore throat (complains of throat pain only on asking),

• 2-moderate sore throat (complains of throat pain on his or her own),

• 3-severe sore throat (change of voice associated with throat pain).

Assessment of cough

• 0 -no cough at any time since the operation,

• 1 -minimal cough or scratchy throat,

• 2 -moderate cough,

• 3 -severe cough.

Hoarseness

• 0-no evidence of hoarseness at any time since the operation,

• 1-no evidence of hoarseness at the time of interview, noted only by patient

• 2-hoarsenes that is readily apparent, but mild

• 3-hoarsenes that is readily apparent and severe.

Same assessments were repeated after 24 hours in PACU.

#### Statistical analysis

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. Independent t test was used as test of significance to identify the mean difference between two quantitative variables. Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram, pie diagram. P value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests. Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

## **Results**

The study was conducted on 180 patients who underwent surgery under general anaesthesia with endotracheal intubation. In this study we found that 55 patients (30.6%) had sore throat, 8 patients (4.4%) had hoarseness and 5 patients (2.8%) had cough. (Table 1).

 Table 1- Incidence of Sore throat, Hoarseness and Cough

|             | Yes   |       | No    |       |  |
|-------------|-------|-------|-------|-------|--|
|             | Count | %     | Count | %     |  |
| Sore throat | 55    | 30.6% | 125   | 69.4% |  |
| Hoarseness  | 8     | 4.4%  | 172   | 95.6% |  |
| Cough       | 5     | 2.8%  | 175   | 97.2% |  |

Patients were grouped into different age groups of < 20 years, 21-30years, 31-40 years, 41-50 years, 51-60years and > 60 years. Although patients between 21 – 30 years had higher incidence compared to other age groups, p value was 0.250 which was not statistically significant, hence age difference did not have any effect on incidence of sore throat (Table 2).

|      |                |       | P value |       |       |       |
|------|----------------|-------|---------|-------|-------|-------|
|      |                | Yes   |         | No    |       |       |
|      |                | Count | %       | Count | %     |       |
|      | <20 years      | 1     | 1.8%    | 14    | 11.2% | 0.250 |
|      | 21 to 30 years | 20    | 36.4%   | 34    | 27.2% |       |
| 1 ~~ | 31 to 40 years | 14    | 25.5%   | 29    | 23.2% |       |
| Age  | 41 to 50 years | 11    | 20.0%   | 20    | 16.0% |       |
|      | 51 to 60 years | 6     | 10.9%   | 15    | 12.0% |       |
|      | >60 years      | 3     | 5.5%    | 13    | 10.4% |       |

**Table 2- Age distribution** 

Multivariate logistic regression showed that lubrication of the tube, position of the head extension with pillow under the shoulder and presence of throat pack had statistically higher incidence of POST with P values 0.045, 0.05 and 0.01 respectively. Gender, tube size, cuff volume, number of intubation attempts, presence of ryle's tube and history of tobacco chewing and smoking did not show any statistically significant difference (Table 3).

| Table 3- Risk factors for Sore throa | Table 3- | Risk | factors | for | Sore | throat |
|--------------------------------------|----------|------|---------|-----|------|--------|
|--------------------------------------|----------|------|---------|-----|------|--------|

|                           |           | Sore throat |        |       |       | P value |
|---------------------------|-----------|-------------|--------|-------|-------|---------|
|                           |           | Yes         |        | Ν     | lo    |         |
|                           |           | Count       | %      | Count | %     |         |
| Sex                       | Female    | 37          | 67.3%  | 78    | 62.4% | 0.531   |
|                           | Male      | 18          | 32.7%  | 47    | 37.6% |         |
|                           | 6.0       | 0           | 0.0%   | 2     | 1.6%  | 0.339   |
|                           | 6.5       | 2           | 3.6%   | 3     | 2.4%  |         |
| Tube Size                 | 7.0       | 2           | 3.6%   | 14    | 11.2% |         |
| Tube Size                 | 7.5       | 35          | 63.6%  | 61    | 48.8% |         |
|                           | 8.0       | 3           | 5.5%   | 9     | 7.2%  |         |
|                           | 8.5       | 13          | 23.6%  | 36    | 28.8% |         |
|                           | 3         | 0           | 0.0%   | 2     | 1.6%  | 0.346   |
| Cuff Volume               | 5         | 55          | 100.0% | 123   | 98.4% |         |
|                           | 1         | 51          | 92.7%  | 119   | 95.2% | 0.312   |
| No of Intubation Attempts | 2         | 3           | 5.5%   | 6     | 4.8%  |         |
| *                         | 3         | 1           | 1.8%   | 0     | 0.0%  |         |
| 77 I I I ' ('             | No        | 18          | 32.7%  | 61    | 48.8% | 0.045*  |
| Tube Lubrication          | Yes       | 37          | 67.3%  | 64    | 51.2% |         |
|                           | 1         | 51          | 92.7%  | 119   | 95.2% | 0.312   |
| No of Intubation Attempts | 2         | 3           | 5.5%   | 6     | 4.8%  |         |
| L.                        | 3         | 1           | 1.8%   | 0     | 0.0%  |         |
|                           | Extension | 9           | 16.4%  | 6     | 4.8%  | 0.05*   |
|                           | Lateral   | 6           | 10.9%  | 24    | 19.2% |         |
| Position of Head          | Neutral   | 38          | 69.1%  | 91    | 72.8% |         |
|                           | Prone     | 2           | 3.6%   | 4     | 3.2%  |         |
|                           | No        | 43          | 78.2%  | 88    | 70.4% | 0.280   |
| Presence of Ryle's Tube   | Yes       | 12          | 21.8%  | 37    | 29.6% |         |
| Dressen of Threat Deals   | No        | 46          | 83.6%  | 119   | 95.2% | 0.01*   |
| Presence of Throat Pack   | Yes       | 9           | 16.4%  | 6     | 4.8%  |         |
| U/- T-h/0                 | No        | 46          | 83.6%  | 108   | 86.4% | 0.627   |
| H/o Tobacco/Smoking       | Yes       | 9           | 16.4%  | 17    | 13.6% |         |

Mean age among subjects with sore throat was  $38.25 \pm -13.583$  years and among subjects without sore throat was  $38.31\pm -15.41$  years. The p value was 0.819. The mean endotracheal tube size was  $7.709 \pm -0.5064$  in those with sore throat,  $7.720\pm -0.5902$  in those without sore throat with p value of 0.905. The mean cuff volume in those with sore throat was 5 ml and  $4.97\pm -0.252$  ml in those without sore throat (p value 0.3481). The mean number of intubations in those with and without sore

throat was 1.09+/-0.348 and 1.05+/-0.215 respectively with p value of 0.341. The mean duration of surgery in those with sore throat was 2.109+/-0.8427 hours and in those without sore throat was 2.149+/-0.8507 hours with p value of 0.773. Hence there were no statistically significant differences among patients with and without sore throat with respect to patients ane, endotracheal tube size, cuff volume, number of intubation attempts and duration of surgery as shown in (Table 4).

|                           | Sore throat | Ν   | Mean  | SD     | P value |  |
|---------------------------|-------------|-----|-------|--------|---------|--|
| Age                       | Yes         | 55  | 38.25 | 13.583 | 0.010   |  |
|                           | No          | 125 | 38.81 | 15.416 | 0.819   |  |
| Tube Size                 | Yes         | 55  | 7.709 | .5064  | 0.905   |  |
|                           | No          | 125 | 7.720 | .5902  |         |  |
| Cuff Volume               | Yes         | 55  | 5.00  | .000   | 0.348   |  |
|                           | No          | 125 | 4.97  | .252   |         |  |
| No of Intubation Attempts | Yes         | 55  | 1.09  | .348   | 0.314   |  |
|                           | No          | 125 | 1.05  | .215   |         |  |
| Dynation of Sympomy       | Yes         | 55  | 2.109 | .8427  | 0 772   |  |
| Duration of Surgery       | No          | 125 | 2.149 | .8507  | 0.773   |  |

Table 4- Distribution with respect to Sore throat

## Discussion

Supraglottic airway devices cause lesser incidence of sore throat than endotracheal tube. Face mask anaesthesia causes lesser POST than supraglottic devices [5-6].

Various risk factors are associated with sore throat like large size endotracheal tube [7], high cuff pressure [8], head and neck movement [9], number of attempts at intubation [10], use of succinyl choline [11], smoking [8], female gender [10,12], presence of throat pack, naso gastric tube, duration of intubation and duration of surgery [10,13], excessive suctioning, coughing and bucking on the tube, presence of blood on the endotracheal tube after extubation [14]. Various techniques have been used to decrease the incidence of sore throat like lignocaine spray [15], lubrication of endotracheal tube with lignocaine jelly [16-17], betamethasone gel application [18], ketamine gargle [19] and lozenses containing amyl-m- cresol, honey, azulene and dexpanthenol [20] etc. Hence a prospective observational study of incidence and risk factors for POST was conducted on 180 patients in our institute for a period of one year. In our study, the incidence of sore throat was 30.6%, hoarseness was 4.4% and cough was 2.8%. According to study by Efrem Fenta et al1, the incidence of sore throat was 48.8% and in a study by Biruk Melkamu Gemechu et al [10], the incidence of POST was 59.6%. Compared to these studies, incidence in our study was less which may be due to administration of non steroidal anti-inflammatory drugs (NSAID) as a part of multimodal analgesia.

Of the 180 patients 115(63.9%) were females and 65(36.1%) were males. Out of 115 females, 80(63%) patients did not have any sore throat, 26 patients had grade 1(22.6%), 7 had grade 2(6.1%) and 2(1.7%) grade 3 had sore throat at 6 hours. Among 65 males, 47(72.3%) patients did not have any sore throat, 13(20.0%) had grade1, 4(6.2%) had grade 2 and 1(1.5%) patient had grade 3 sore throat at 6hours. The p- value between male and female was 0.531, hence there was no statistically significant difference. A study by Jaensson M et al [12], also does not show any significant difference between

males and females. Unlike ours the study by Gemechu BM et al [10], shows significantly higher incidence in females than in males.

Among 180 patients, 101 were intubated with lubricated tube and 79 were intubated with non lubricated tube. 37 in lubricated group developed POST, 18 in non lubricated group had POST, the p-value was 0.045, hence we noticed the incidence among tube lubrication group was higher. In a study by Kori K et al [15] also found that lubrication of endotracheal tube caused higher incidence of POST. Lubrication of tube with water based lignocaine jelly is well known technique to reduce tracheal mucosal injury but contamination of tube while applying the jelly may explain the higher incidence of POST.

We studied the incidence of POST in different head positions like extension of head with pillow under the shoulder for thyroid surgeries, lateral, supine and prone positions. The incidence of POST was higher in patients with extension of neck with pillow under shoulder as p value is 0.05. Similar result was found in a study by A. M. Christensen et al [9] where they noted greater incidence of POST after thyroid surgery. Repeated head and neck movement while positioning for thyroid surgery may cause cause higher incidence of POST.

Among patients who had throat pack the incidence of POST was 60% and those without throat pack had 27% with p value of 0.01 which was statistically significant. Like our study, Jaensson M et al [21] also had higher incidence of POST in patients who had throat pack. Mechanical injury of airway mucosa while placing throat pack may cause higher incidence of POST.

# Conclusion

The incidence of sore throat was 30.6%, hoarseness 4.4%, and cough 2.8% in our institute. Tube lubrication, position of head extension with pillow under shoulder and presence of throat pack showed higher incidence of POST.

Limitations of the study: Intra-cuff pressure was not measured.

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#### Abbreviations

POST-Postoperative sore throat,

ASA PS- American society of Anaesthesiologists physical status

PACU- post anaesthesia care unit

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