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# Comparing hoarseness and sore throat after extubation at different endotracheal cuff pressures: A double-blinded clinical trial

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## Abstract:

**BACKGROUND:** Sore throat and hoarseness are two common complications of intubation in patients with general anesthesia. This research aimed to compare the effect of different endotracheal cuff pressures on sore throat and hoarseness after general anesthesia.

**MATERIALS AND METHODS:** The present double-blinded clinical trial was conducted on 45 patients who are candidates for surgery with general anesthesia in autumn and winter 2021. The participants were divided into three groups of 15 through a permuted block randomization. The 20–24 cm H<sub>2</sub>O (level of pressure) group was labeled as A, and the 25–29 cm H<sub>2</sub>O group B and the 30–34 cm H<sub>2</sub>O group was known as group C. All the patients were operated. The endotracheal intubation was done for men with tubes #8-8.5 and for women with tubes 7-7.5. The presence and severity sore throat and the hoarseness after operation were checked by a nurse after recovery. Data were recorded in a researcher-made checklist. The data were analyzed in SPSS 19.  $P < 0.05$  was considered.

**RESULTS:** The results revealed that the majority of participants suffered a slight hoarseness within the 1<sup>st</sup> hour (73.3%), 12<sup>th</sup> hour (91.1%), and 24<sup>th</sup> hour (100%) after recovery. Similarly, most participants experienced a slight hoarseness in the 1<sup>st</sup> hour (57.8%), 12<sup>th</sup> hour (71.1%), and 24<sup>th</sup> hour (91.1%) after recovery. Kruskal–Wallis test results showed no statistically significant correlation between hoarseness and the level of endotracheal cuff pressure in the three groups ( $P > .05$ ).

**CONCLUSION:** According to the results of the present study, despite the fact that the range of 20 to 34 cm of water is a safe and risk-free range in terms of causing sore throat and hoarseness, and there was no difference between the pressures in the three groups, but at higher pressure (groups 2 and 3), the amount of sore throat and hoarseness was more and there was a statistically significant difference at different times within group. Therefore, as much as possible, the amount of pressure should be adjusted according to the need and avoid applying excess pressure.

## Keywords:

Endotracheal cuff pressure, general anesthesia, hoarseness, sore throat

## Introduction

When respiratory problems or disorders occur, the best measure to take to improve a patient's ventilation state is the production and maintenance of a safe airway.<sup>[1]</sup> Endotracheal intubation is one

of the safe and secure methods of airway management for many patients,<sup>[2]</sup> and it is one of the common care techniques in special units.<sup>[3]</sup>

In the majority of cases when patients undergo a general anesthesia, endotracheal intubation is done to control the airway,

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facilitate ventilation, protect the airway, and prevent the potential aspiration.<sup>[4]</sup> In recent years, there have been more and more cases of using endotracheal intubation.<sup>[5,6]</sup> Overall, endotracheal intubation for those above 6 years of age is done using cuffed tubes, and for those below 6, is done with uncuffed tubes due to their narrow airway and the possibility of mucus injury.<sup>[7]</sup> If the endotracheal cuff pressure is increased, there may be more pressure on the anterior mucus wall, and it can induce ischemia. To prevent so, the cuff pressure should be less than the mean perfusion of mucus capillaries (i.e., 22 mm Hg). In some other studies, the recommended cuff pressure is <25 mm Hg, because higher pressures can induce endotracheal mucus ischemia or damages. Generally, the appropriate pressure to fill endotracheal cuffs is 20–30 cm H<sub>2</sub>O according to Miller's book "the basics of anesthesia." As suggested by Fink, the pressure can range between 27 and 34 cm H<sub>2</sub>O.<sup>[8–10]</sup>

Due to the increasing rate of endotracheal intubation, the adverse effects are more evident than before. Though low-pressure cuffed tubes are commonly used, the side effects still prevail.<sup>[11,12]</sup> The long-term extubation side effects are very well known and are mostly induced by the lowered blood pressure in the larynx mucus and more pressure on the walls. Injuries caused by the cuff pressure on the airway might not be clinically easily diagnosable. There is evidence that the endotracheal damages are caused by the cuff pressure. A high cuff pressure is put on part of the tracheal mucus. The duration of the pressure affects the development of tracheal damage. Some other research revealed that a higher than normal pressure for more than 15 minutes causes ischemic changes to the tracheal wall. Among the significant side effects are sore throat and gruffness. The short-term side effects of using cuffed endotracheal tubes among patients are sore throat and hoarseness.<sup>[13,14]</sup> The prevalence rate of endotracheal extubation sore throat among patients after surgery is 21–65%. Medically, this side effect is considered as the eighth most common adverse effects of an operation. Also the hoarseness of the voice is one of the common side effects after using the drug air way occurs at the rate of 14–50%. The results of studies indicate that it usually remains for 2–3 days which is effective on the level of patients' satisfaction with the treatment method and also their activities after discharge from the hospital.<sup>[15]</sup> Though many attempts have been made to reduce the incidence rate and severity of sore throat after an operation, it is still considered one of the most prevalent side effects of an operation.<sup>[14–17]</sup> A wide range of values have been suggested in the related literature for the safe level of the tube cuff. Though a pressure of 20–34 cm H<sub>2</sub>O is commonly suggested, and < 25 mm Hg in some other studies, no relevant study was found to report the rate of sore throat and hoarseness at different pressures. In this regard, different studies have reported

contradictory results. A study showed that there was no statistically significant difference in the amount of sore throat after extubation in different cuff pressures in the laryngeal mask.<sup>[18]</sup> While in another study, the low pressure of tracheal tube cuff decreased the incidence of moderate sore throat, but it did not affect the incidence of mild and severe sore throat.<sup>[19]</sup> Another study showed that cuff pressure of 25 cm H<sub>2</sub>O reduces the incidence of sore throat after surgery.<sup>[20]</sup> Calder *et al.* concluded with a study of 500 children that the incidence of sore throat is different at different pressures. In such a way that in uncuffed tracheal tubes, the rate of sore throat was 0–10%, at a pressure of 11–20 cm of water it was 4%, at a pressure of 21–30 cm it was 20%, and at a pressure of 31–40 cm it was 68%.<sup>[21]</sup> Ganason *et al.* showed in their study that the incidence of hoarseness and cough was significantly lower in the group whose tracheal tube cuff pressure was 25 than in the group whose cuff pressure varied from 18 to 30 cmH<sub>2</sub>O.<sup>[22]</sup> Considering the side effects of the pressure caused by endotracheal intubation, the present research aimed to compare sore throat and hoarseness at different tracheal tube cuffs (in the range of 20–34 cm H<sub>2</sub>O).

## Materials and Methods

### Study design and setting

The present double-blinded clinical trial (IRCT20190204042616N1) was conducted to explore sore throat and hoarseness caused by endotracheal cuff pressure compared across different pressures. The sample consisted of 45 patients who are candidates for surgery with general anesthesia in Allame Bohlool Gonabadi Hospital in autumn and winter 2021. The inclusion criteria were the patient's full consent to participate in the research, being enlisted for a general anesthesia, age range 18–60 years, having no surgery on head, face, and neck, no oral or nasal tube, no airway anomaly, sore throat or hoarseness (collaborated by an ENT specialist), absence of problematic intubation according to the Mallampati score, anesthesia classes I or II, no smoking, an age between 16 and 65, no history of respiratory or larynx disease, anesthesia duration of 0.5–2-hour length, and no consumption of drugs affecting sore throat and hoarseness, no use of anti-inflammatory drugs during two weeks before the operation, no history of upper airway infection and sore throat, and no drug addiction. Exclusion criteria included the occurrence of any condition that leads to re-intubation, failure of the first intubation, and prolongation of surgery.

### Data collection tool and technique

Initially, the patients were selected according to the inclusion criteria and purposive sampling. Then, they were divided into three groups of 15 people through a permuted block randomization. In this method, the 20–24 cm H<sub>2</sub>O pressure group was labeled as A, the one

with the 25–29 cm H<sub>2</sub>O pressure was labeled as B, and the group with the 30–34 cm H<sub>2</sub>O pressure was known as group C. Six states were conceivable for the three blocks, ABC, CBA, CAB, BCA, BAC, and ACB. Each block was coded specifically. Each time, one code was drawn randomly, and the patients were assigned to it. The demographic form enquired about the patients' age, sex, marital status, job, place of residence, weight, anesthesia class, duration of intubation, depth of intubation, duration of anesthesia, amount of bleeding during the operation, level of cuff pressure, and level of hoarseness. This information was completed by the researcher based on observation and the patients' medical records.

### All patients underwent general anesthesia in this way

Initially, the standard monitoring equipment was set up. Then, midazolam (0.03 mg/kg) and phenylethyl (2 mcg/kg) were injected as the premedication. The anesthesia was induced by intravenous thiopental (3–5 mg/kg). Next, atracurium (0.5 mg/kg) was prescribed to loosen the muscles (required for intubation). After about 3 minutes, the ventilation began with oxygen (100%) with tracheal tube no. 8-8.5 for male and 7-7.5 for female patients. For all patients, intubation was performed by one person to homogenize the time and pressure effects upon intubation. For all, the Macintosh laryngoscope blade was homogeneously used. Then, the standard VBN manometer was used by an anesthesia assistant, adequately trained to measure the cuff pressure. For each patient, the cuff pressure was set according to the group he/she belonged to. During the operation, the cuff pressure was measured every half an hour, and if there was any variation, it was readjusted. The type of position (supine) and the drug chosen to continue the anesthesia were chosen the same for all patients.

At the end of the operation, patients received oxygen (100%) and the residual anesthesia was reversed by atropine and neostigmine. Suctioning of secretions was done slowly, gently, and uniformly for all patients. The extubation was done next. When the patients recovered, they were transferred to the ward. The incidence and severity of sore throat and the hoarseness of voice after operation were checked by a nurse (the same nurse for all patients) blinded to the grouping of patients in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hours of recovery. These were marked in a researcher-made checklist developed to this aim. The visual analogue scale (VAS) was used to measure the sore throat. The severity and incidence of hoarseness were rated on a 4-point scale: 0 = no hoarseness, 1 = hoarseness during the interview as reported by the patient only, 2 = evident yet slight hoarseness, and 3 = evident and severe hoarseness. It is noteworthy that both the patients and the data collector were blinded to the intervention and the grouping.

### Ethical consideration

The research design code was A-10-1702-1, and the ethics code was IR.GMU.REC.1397.100. All ethical codes for clinical trials have been followed including: obtaining written informed consent, compensation for possible unwanted damage (in this research, no damage or complications occurred to patients), not using an intervention that causes physical or mental harm to people, understanding of information and intervention to the patient by the researcher and anesthesiologist, not including children and patients with psychological problems in the study, and blinding of patient and data collector.

### Data analysis

To analyze the collected data, SPSS 19 was employed. The descriptive statistics used were frequency distribution tables, mean, and standard deviation. Shapiro–Wilk test was used to determine the normality of quantitative variables. To compare quantitative data, analytical statistics were used including independent-samples *t*-test (to compare two groups) and ANOVA (to compare three groups). For nonparametric data and those without a normal distribution, the Chi-squared test, Kruskal–Wallis, and Friedman tests were used.

### Results

The mean age of the participants was  $43.77 \pm 11.27$  years. Among these, 30 (66.7%) were male and 15 (33.3%) were female. Furthermore, 73.3% were married and 66.7% had a diploma or lower degree of education. The mean and standard deviation of the participants' weight was  $69.31 \pm 11.90$ . The mean duration of the operation was  $92.44 \pm 11.70$  minutes. The mean duration of the anesthesia was  $97.44 \pm 16.90$  minutes. 66.7% of the patients belonged to class I and 33.3% to class II of anesthesia. The most frequent operations (42.2%) were general in type, and the least prevalent were women surgeries and laparotomy (4.4%). The majority of patients (64.4%) had a tracheal tube no. 8, and the minority (4.4%) had a tracheal tube no. 7.

It should be noted that all the research units were intubated in the first time (attempt). The Mallampati score of all was 1. No patient required blood transfusion, and 100% of patients were awake during the extubation. As the ANOVA test results showed, the groups were not significantly different in terms of age, weight, duration of operation, depth of intubation, tube size, and the mean time of anesthesia ( $P > 0.05$ ). Also, the Chi-square test did not show any difference between the groups in terms of gender and type of surgery ( $P > 0.05$ ). As the results revealed, 91.1% of patients experienced a slight hoarseness within the 1<sup>st</sup> hour, and 73.3% experienced in 12 hours. 24 hours after extubation, none of the patients

had hoarseness. Also, the results of the present study showed that the majority of the research units (57.8%) had a mild sore throat in the first hour and 20% of the research units experienced severe pain. The severity of sore throat decreased after 12 hours so that only 6.7% of patients had severe sore throat, 22.2% had moderate sore throat, and 71.1% had mild sore throat. After 24 hours, 91.1% had mild sore throat, 6.7% moderate, and 2.2% severe sore throat. The normality of the quantitative data was tested via the Shapiro–Wilk test. The sore throat and hoarseness scores were not normally distributed at different times ( $P = 0.0001$ ).

Friedman test results showed a decreasing rate of hoarseness through time in the three groups [Table 1]. In other words, in all three groups, the level of hoarseness decreased gradually after the surgery. This decrease was not significant in the first group where the cuff pressure was 20–24 cm of water. But there was a significant decrease in the other two groups. Perhaps the reason for the non-significant reduction of hoarseness in the first group is that this group had experienced a lower level of hoarseness from the beginning and in the first hour after extubation than the other two groups.

Moreover, as the Kruskal–Wallis test revealed, no statistically significant divergence was found among the three groups in terms of hoarseness in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hours of extubation [Table 2]. Also the present findings showed that the sore throat was gradually decreased through time. In the 1<sup>st</sup> hour of extubation, and 20% of the patients had a severe sore throat. In the 12<sup>th</sup> hour of extubation, 6.7% had a severe sore throat, and, within 24 hours, only 2.2% had a severe sore throat. As the Friedman test showed, the incidence rate of sore throat was significantly reduced through time [Table 3]. In other words, in all three groups, the level of sore throat decreased gradually after the surgery. This decrease was not significant in the first group where the cuff pressure was 20–24 cm of water. But there was a significant decrease in the other two groups. Perhaps the reason for the non-significant reduction of sore throat in the first group is that this group had experienced a lower level of sore throat from the beginning and in the first hour after extubation than the other two groups. Besides, Kruskal–Wallis test showed that the three groups did not differ from each other significantly in terms of the incidence rate of sore throat in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hours of extubation [Table 4].

## Discussion

The present findings showed that the majority of participants experienced a slight hoarseness after extubation at different points of time. Similarly, Khosravi *et al.* reported that 10% of patients experience

**Table 1: Comparison within groups of the rate of hoarseness in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> h of extubation in three groups**

Time Group	In 1 <sup>st</sup> h mean ranking	In 12 <sup>th</sup> h mean ranking	In 24 <sup>th</sup> h mean ranking	Friedman test result
Group 1	2.07	2.07	1.87	$\chi^2=2.667$ , Df=2, $P=0.264$
Group 2	2.38	1.84	1.78	$\chi^2=11.474$ , Df=2, $P=0.003$
Group 3	2.93	2.25	1.82	$\chi^2=6.500$ , Df=2, $P=0.039$

**Table 2: Comparison between groups of the rate of hoarseness in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> h of extubation in three groups**

Time Group	In 1 <sup>st</sup> h mean ranking	In 12 <sup>th</sup> h mean ranking	In 24 <sup>th</sup> h mean ranking	
Group 1	19.93	24.00	23.00	
Group 2	25.63	22.41	23.00	
Group 3	23.29	22.61	23.00	
Kruskal–Wallis test result	$\chi^2=2.475$ , Df=2, $P=0.290$	$\chi^2=0.544$ , Df=2, $P=0.762$	$\chi^2=0.000$ , Df=2, $P=1.000$	

**Table 3: Comparison within groups of the rate of sore throat in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hours of extubation in three groups**

Time Group	In 1 <sup>st</sup> h mean ranking	In 12 <sup>th</sup> h mean ranking	In 24 <sup>th</sup> h mean ranking	Friedman test result
Group 1	2.13	2.20	1.67	$\chi^2=4.471$ , Df=2, $P=0.107$
Group 2	2.53	2	1.47	$\chi^2=17.000$ , df=2, $P=0/0001$
Group 3	2.36	2.11	1.54	$\chi^2=7.943$ , Df=2, $P=0/019$

**Table 4: Comparison between groups of the rate of sore throat in the 1<sup>st</sup>, 12<sup>th</sup>, and 24<sup>th</sup> hours of extubation in three groups**

Time Group	In 1 <sup>st</sup> h mean ranking	In 12 <sup>th</sup> h mean ranking	In 24 <sup>th</sup> h mean ranking	
Group 1	21.13	24.03	22.33	
Group 2	25.75	22.34	23.56	
Group 3	21.86	22.64	23.07	
Kruskal–Wallis test result	$\chi^2=1.243$ , Df=2, $P=0.537$	$\chi^2=0.156$ , Df=2, $P=0.925$	$\chi^2=0.098$ , Df=2, $P=0.952$	

hoarseness after extubation.<sup>[13]</sup> Bennett *et al.* also compared hoarseness in two groups, one with cuffs filled with air and the other with saline. The former showed to experience 15.9% of hoarseness.<sup>[23]</sup> The potential different findings can be due to different methodologies and interventions.

The results of the present study showed that the majority of the research units experienced sore throat after extubation and the severity of sore throat decreased gradually over time. This finding is consistent with



Mahoori's study. He showed that the severity of sore throat was gradually reduced after extubation. However, Mahoori *et al.* investigated the effect of the lubricating gel on alleviating sore throat. Still, in their research, the severity of sore throat was reduced gradually in the control group.<sup>[17]</sup> In their research, Khosravi *et al.* indicated that 30% of patients experienced a sore throat after extubation.<sup>[13]</sup> Rakotondrainibi *et al.* showed that the majority of participants (31.6%) experience a slight sore throat after extubation.<sup>[24]</sup> In our study, most of the research units experienced mild sore throat. Kang *et al.* explored the effect of gargling ketamine on sore throat after extubation. They reported the prevalence rate of sore throat 18.20 in the control group and 17.20 in the intervention group. In this study, the prevalence of sore throat was much lower than our study. Maybe the reason for this difference in the results is different intubation, study population, and intervention technique. Kang *et al.* investigated only the prevalence of sore throat and not its severity.<sup>[25]</sup> In some other research, Gong *et al.* compared the effect of endotracheal intubation and laryngeal mask on sore throat and hoarseness. They concluded that 68.9% of patients experienced a sore throat in the 1<sup>st</sup> hour of extubation, 51.1% in the 24<sup>th</sup> hour, and 24.4% in the 48<sup>th</sup> hour of extubation. The results also showed that 57.8% of patients experienced hoarseness in the 1<sup>st</sup> hour of extubation. This rate was reduced to 28.9% in the 24<sup>th</sup> hour and 13.3% in 48 hours of extubation. In other words, both the sore throat and hoarseness had a decreasing trend, which is consistent with the present findings.<sup>[26]</sup> Nischala *et al.* explored the prevalence of sore throat and hoarseness with two methods, intubation with video laryngoscope (glide scope) and Macintosh laryngoscope blade. The results showed that in the Macintosh blade group (which is in accordance with the current research method), 86 of 100 patients did not have a sore throat 6 hours after extubation, and 10 had mild, 3 had moderate, and one had severe sore throat. After 12 hours, 97 people did not have sore throat and only three people had mild sore throat. As for hoarseness, in 6 hours after extubation, 95 patients had no hoarseness and only 5 reported hoarseness. In 12 hours after extubation, 98 patients had no hoarseness and only 2 reported a hoarseness. Within 24 hours, 100% of patients had no sore throat and hoarseness.<sup>[27]</sup> The decreasing rate of sore throat and hoarseness are consistent with the present research. But there is a difference in the prevalence of sore throat and voice harshness with the present study. In their study, the level of voice violence and sore throat was much lower. The difference might be due to differing methodologies and follow-ups. Nischala *et al.* did not categorize the severity of hoarseness.<sup>[27]</sup> Thus, no fair comparison is deemed possible. In their study, Yhim *et al.* explored the effect of benzydamine hydrochloride on sore throat after extubation in children. The rate of sore throat in their study was reported to be 49.3% in the control group (that received no medication), which is

consistent with the present finding. The majority of these patients (35%) had a slight sore throat. This study had no follow-up.<sup>[28]</sup>

The results of the present study showed that different tracheal tube cuff pressures in the range of 20–34 cm of water have no effect on the incidence and intensity of hoarseness and sore throat after extubation. This finding is consistent with the study of Javaherforoosh zadeh *et al.*,<sup>[4]</sup> the study of Weiss *et al.*<sup>[29]</sup> In their studies, they compared the prevalence of respiratory problems and stridor in tracheal tubes with and without cuffs in children. The results of their studies indicated that there was no relationship between the presence of a tracheal tube cuff and its inflation with the occurrence of respiratory problems, stridor, and voice harshness. Wang *et al.* in their study on adults undergoing gynecological surgery, concluded that in the range of tracheal tube cuff pressure between 18 and 22 mm Hg (approximately 24–30 cm H<sub>2</sub>O), the incidence of sore throat and harshness of voice and other complications are less. In their study, they did not examine pressure above 30.<sup>[30]</sup> In their study, Pula *et al.* concluded that the pressure of 20 cm H<sub>2</sub>O is an ideal pressure to reduce the complications of intubation, including sore throat and hoarseness.<sup>[31]</sup> Limitations and suggestions in this study include: the duration of anesthesia and intubation of the patient was the same, but due to the low number of surgeries in Bohlool hospital, the type of surgery was different. Only patients who had head and neck surgery were not included in the study. Therefore, in order to make a more accurate clinical judgment, it is suggested to conduct a study with a larger number of samples and in a type of surgery.

## Conclusion

The data analysis showed that the severity of sore throat and hoarseness did not differ significantly at different cuff pressures ranging from 20 to 34 cm H<sub>2</sub>O. Therefore, according to the various factors affecting the cuff pressure adjustment according to the patient's conditions, it is possible to adjust the cuff pressure in the range of 20 to 34 cm of water.

Although the majority of patients did not experience sore throat and hoarseness in high intensity, the point that should be noted is that the prevalence of sore throat and hoarseness after extubation was relatively high. Therefore, it is recommended to pay attention to the amount of cuff pressure and its precise adjustment, as well as pay attention to other factors affecting the occurrence of these two complications.

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### Conflicts of interest

There are no conflicts of interest.

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