

CUSTOMIZED VERSUS FIXED SIZED PILLOW FOR TRACHEAL INTUBATION BY USING MACINTOSH LARYNGOSCOPY - A RANDOMISED COMPARATIVE STUDY

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Abstract

Background: Best laryngeal views are obtained when oro-pharyngo-laryngeal axes come in a straight line. This linear axis is formed when the patient's head and neck are placed in "sniffing position". Since years it is most commonly advocated for tracheal intubation but even then, many practitioners still find difficulty in intubation. **Objective:** Our study was aimed at comparing the use of fixed height pillow versus a customized pillow height for head elevation, to know the time taken for intubation and glottic view. **Materials and Methods:** The present study, to compare the use of fixed sized pillow and customized pillow height for head elevation, in terms of laryngeal view and time required for tracheal intubation, was conducted in department of Anaesthesiology, SDM College of Medical Sciences and Hospital, Dharwad. **Result:** The C-L grade in both the groups was observed to be statistically insignificant, (p value >0.05). The mean time taken was found to be more in the group CP (13.37secs vs 16.59secs) than group FP irrespective of the C-L grade and Modified Mallampati score. **Conclusion:** Our study concluded that head elevation by customizing the height of pillow as compared to the standard height of 4cm, does not show any clinically significant improvement in the Cormack-Lehane grade and overall duration of laryngoscopy and intubation.

INTRODUCTION

Securing an airway forms a key skill in an anesthesiologists' repertoire during general anaesthesia or in emergency resuscitations. For that, optimum positioning of the head and neck is of utmost importance. The sniffing position is widely accepted as the standard position for direct laryngoscopy and tracheal intubation.^[1] It consists of neck flexion of approximately 15⁰ and atlantooccipital joint extension of approximately 35⁰. Neck flexion is achieved by the elevation of the head which aligns the laryngeal axis and the pharyngeal axis. Extension at the atlantooccipital joint brings the visual axis of the mouth into better alignment with those of the larynx and pharynx.^[2] The most valid explanation for this position is the "The threeaxis alignment theory", where as newer theories have yet to find widespread recognition. The neck flexion is achieved by elevating the head using a pillow. No advantage of the "sniff" position over simple head extension was found in one

study,^[3] except in presence of obesity or limited head extension. Thus, proper positioning of a patient before direct laryngoscopy is a key step.

Horizontal alignment of the sternal notch and the external auditory meatus [EAM] has been used as a marker for appropriate positioning in terms of head elevation. This is known as 'Ramping' or Head elevated laryngoscopy position [HELP], coined by Levitan^[4] Many objective clinical reports support placing the obese patients in a ramped position prior to induction of anaesthesia. This position yields outstanding outcomes in obese patients, but more research is needed to determine why these secondary markers are related to changes in airway structure with different head and neck positions. Are these markers also applicable to non-obese patients? When caring for an airway of non-obese patients, the concept of aligning the three airway axes in preparation for intubation has been taught at anaesthesia teaching colleges. Even after advocating the "sniffing position", some anaesthesia care givers still encounter unanticipated difficult airway issues

intraoperatively. In such cases of difficult laryngoscopy, application of external laryngeal pressure, changing of laryngoscope blade and use of bougie are equally important.^[5]

Since the development of the “three axis alignment” theory, other studies have provided little objective evidence for the sniffing position being optimal for direct laryngoscopy. There were few observations made that questioned the validity of the sniffing position in a series of papers,^[6-8] but more studies are needed to establish a new conceptual framework to understand the mechanisms of laryngoscopy

Lastly, a good glottic view minimizes the rate of tracheal injury, duration of the procedure, repeated attempts at laryngoscopy and ultimately overall rate of trauma and further complications. Good positioning will also facilitate all methods of airway management.

Therefore, this study was designed to compare the use of a fixed height pillow versus a customized pillow (for horizontal alignment of EAM and sternum) for tracheal intubation in terms of glottic view and time taken for intubation.

MATERIALS AND METHODS

After obtaining the Institutional Ethical Committee approval, This Prospective randomized single blinded comparative study was conducted among 160 ASA grade I, II and III patients in the age group of 16 - 65 years, scheduled for various elective surgeries at SDM College of Medical Sciences and Hospital, requiring general anaesthesia with endotracheal intubation were enrolled in this prospective study. Duration of study was December 2019 to May 2021

In this study, comparison between fixed sized pillows versus customized pillow was done to evaluate the glottic visualization and the time taken for tracheal intubation.

Inclusion Criteria

- Patients of either sex in age group 18 years - 65years.
- ASA physical status 1, 2 and 3.
- Elective cases requiring tracheal intubation.

Exclusion Criteria

- Pregnant women
- Patient refusal
- Height < 140 cm
- Mouth opening < 3 cm
- Any difficult airway [Ex: airway growth, obstruction, unstable cervicals spine]

Pre-anesthetic evaluation

All patients were examined a day prior to surgery. Demographic variables were collected. A detailed history and systemic examination was done to rule out any of the above-mentioned exclusion criteria and informed consent was obtained. Airway assessment was done and the following parameters were recorded.

1. Samssoon and Young modification of Mallampati grading was assessed with patient sitting and head in neutral position with mouth opened widely and tongue protruded without phonation and examiner’s eye at the level of patient’s mouth.

Class I is visualisation of the hard palate, soft palate, fauces, uvula and pillars.

Class II is visualisation of hard palate, soft palate, fauces and base of the uvula. **Class III** is the visualisation of hard and soft palate

Class IV is visualisation of only hard palate

2. Mouth opening was assessed by interincisor distance (cm) which was measured from upper central incisor to lower central incisors while the patient’s mouth is fully opened.

- > 4cm – classified as easy laryngoscopy
- < 4cm – classified as difficult laryngoscopy

None of the patients were given any solid food for 6 hours and clear liquids for 2 hours before induction of anesthesia. Patients were given tablet pantoprazole 40 mg HS and early morning next day as preanesthetic medication.

Pre-operative ward

Patients were randomly categorized into 2 groups

Group F: Fixed pillow height group received a pillow of height 4 cm

Group C: Customized pillow height group received an additional layer of folded sheets, if required, to align the EAM and the sternal notch horizontally.

Operating room

After adequate preoxygenation using face mask of appropriate size induction of anesthesia was done using injection Fentanyl 2mcg/kg and injection Propofol 2mg/kg. Neuromuscular blockade was achieved using Vecuronium 0.1mg/kg, with a wait time of 3 min before attempting intubation. Direct laryngoscopy was performed in the ‘sniff’ position on fixed sized non compressible pillow or a customized pillow depending upon the group the patient was allotted to.

All laryngoscopies were performed by an experienced anesthesiologist (minimum 2-year post-specialization experience).^[9] The height of the operating table was adjusted so that the patient’s forehead was at the level of the xiphoid process of the anesthesiologist intubating the trachea.^[10] Direct laryngoscopy was performed with the proper size Macintosh blade to provide the best image of the glottis. In the current study, the time required for tracheal intubation was defined as the time from the insertion of the laryngoscope blade into the oral cavity and securing the endotracheal tube until its withdrawal. End-tidal CO₂ measurements indicated proper tube placement. In the case of multiple attempts the average of the total time spent on laryngoscopy was taken into account.

The intubating anesthesiologist assessed the C-L grade of laryngeal view. Any use of help, such as

external laryngeal manipulation, the use of a bougie or stylet, a change in pillow height, and the number of attempts, was also recorded. The above parameters were recorded by an unbiased observer.

Sample Size Estimation

Using the above mention formula, at 95% confidence interval and 80% power of the study, the sample size was found to be 77 in each group. Therefore, 80 patients were included in each group to compensate for dropouts.

Sampling Procedure

All patients fulfilling the inclusion criteria were divided into two groups randomly using the chit method.

Study Instrument

A pre-designed and pre-tested proforma was used to collect information.

Statistical Analysis: The mean time taken for intubation and CL grade in both the groups was compared using unpaired *t*-test and chi-square test respectively. The data was presented as number, percentages, mean \pm standard deviation (SD) or other as appropriate. Data analysis was done using SPSS software trial version.

RESULTS

One sixty (160) consenting and eligible adult patients belonging to ASA physical status I, II, and III, undergoing elective surgery under general anaesthesia being planned for tracheal intubation were included the study. All patients were successfully intubated in both the groups.

Table 1: Comparison of Group F and Group C by age groups

Age Groups	Group F	%	Group C	%	Total	%
18-30yrs	23	28.75	25	31.25	48	30.00
31-40yrs	22	27.50	23	28.75	45	28.13
41-50yrs	23	28.75	19	23.75	42	26.25
51-60yrs	12	15.00	13	16.25	25	15.63
Total	80	100.00	80	100.00	160	100.00
Mean age	37.90		38.63		38.26	
SD age	11.27		10.20		10.72	

Chi-square=0.5270, p=0.9130, NS

P value was > 0.05 for mean age comparison and hence no significant difference existed between both the groups.

There was no significant difference in distribution of male and female patients among Group F and Group C, p value > 0.05.

ASA Physical Status

No statistical difference was observed in the distribution of ASA physical status between the group F and C, p value = 0.4260 by Chi-square test.

External Airway Parameters

Mouth opening was assessed by Interincisor gap (in cm) and the prevalence of Modified Mallampati Grade was measured in percentages among both the groups.

Table 2: Comparison between Group F and Group C by external airway parameters

Parameters	Group F N = 80	Group C P N = 80	P Value
Mouth opening (cm), Mean \pm SD	5.85 \pm 0.50	5.66 \pm 0.51	0.0158, S
MMP Grade, n (%)			
Grade 1	36.25	35	0.8410, NS
Grade 2	51.25	55	
Grade 3	12.50	10	

Table 3: Comparison of Group F and Group C by Modified Mallampati Grade

MMP Grade	Group F	%	Group C	%	Total	%
Grade 1	29	36.25	28	35.00	57	35.63
Grade 2	41	51.25	44	55.00	85	53.13
Grade 3	10	12.50	8	10.00	18	11.25
Total	80	100.00	80	100.00	160	100.00

Chi-square=0.3460, p=0.8410, NS

Mouth opening was comparable between both the groups (>5 cm), even though it was statistically significant. MMP grades were not statistically significant between both the groups.

The Cormack- Lehane grade of laryngeal view as observed by the intubating anesthesiologist was as follows:

Table 4: Comparison of Group F and Group C by Cormack- Lehane grades

Cormack-Lehane grade	Group F	n%	Group C	n%	Total	%
Grade 1	41	51.25	43	53.75	84	52.50
Grade 2A	24	30.00	25	31.25	49	30.63

Grade 2B	13	16.25	11	13.75	24	15.00
Grade 3	2	2.50	1	1.25	3	1.88
Total	80	100.00	80	100.00	160	100.00
Chi-square=0.5680, p=0.9040, NS						

The primary outcome of the study which was the Cormack- Lehane grade was found to be comparable in both the groups and was also statistically insignificant, p value = 0.904 by Chi-square test.

Table 5: Comparison of Group F and Group C with mean Cormack-Lehane grade in each MMS score

MMS	Group F		Group C		t-value	p-value
	Mean	SD	Mean	SD		
Grade 1	1.45	0.69	1.61	0.79	-0.8139	0.4192, NS
Grade 2	1.78	0.91	1.48	0.66	1.7648	0.0813, NS
Grade 3	2.10	0.74	2.50	0.76	-1.1307	0.2749, NS

We can conclude that irrespective of the Modified Mallampati Score, the difference in the mean C-L grade between the two groups was statistically comparable by unpaired t-test

Time taken for intubation

In our study, the time taken for intubation was defined as the duration of insertion of laryngoscopic blade in the oral cavity and securing the endotracheal tube to its removal. Overall, the mean time taken (secs) for tracheal intubation was found to be more in customized sized pillow than fixed height pillow, 16.59 versus 13.37 secs respectively, though was statistically significant, p value = 0.0001 (unpaired t- test) but not clinically significant.

Table 6: Comparison of Group F and Group C with mean time taken (in secs) in each C-L grades by independent t-test

CL grades	Group F		Group C		P-value
	Mean	SD	Mean	SD	
CL grade 1	12.37	1.96	15.72	1.30	0.0001, S
CL grade 2A	14.07	4.58	17.26	1.91	0.0024, S
CL grade 2B	15.35	3.43	18.49	3.18	0.0307, S
CL grade 3	12.42	0.31	16.20	0.00	0.0640, S

The mean time taken for intubation was significantly more in the group C irrespective of the C-L grade and it was statistically significant, p value < 0.05 but clinically insignificant.

Number of attempts

An "Attempt" in our study was defined¹¹ as a single advanced airway maneuver i.e., beginning from the insertion of the laryngoscope into the patient's mouth and ending with its removal. We noted the number of tracheal intubation attempts as one attempt, two attempts, and '3 or more attempts.

Majority of the patients were intubated in first attempt of which 78 patients were from Group F and 73 patients from group C. 7 patients in the C group required two intubation attempts, whereas only 2 patients in the F Group required two intubation attempts, but the data analysis was statistically insignificant. No patient required more than three attempts at intubation.

Need of assistance

The use of assistance to facilitate tracheal intubation with the help of bougie, external laryngeal maneuver/ manipulation, change of pillow was noted in each patient.

4 patients in Group C required bougie assistance whereas only 2 patients required bougie in group F. Majority of the patients required ELM (n= 104) to improve Cormack- Lehane grade and to facilitate intubation out of which 54 were from group C and 50 were from group F. Overall, the need of assistance to facilitate intubation was more in Group C than in Group F, but the data was statistically

insignificant, p- value > 0.05, as well as clinically insignificant. No change of pillow was required in any of the groups.

DISCUSSION

Even though the sniffing position is routinely approved for intubation in large number of cases, approximately 1% to 4% of patients, laryngoscopic examination may still be difficult.^[11] In our prospective comparative study, head elevation was given in both the study groups, with the help of fixed sized pillows. We tried to discover that whether increasing the head elevation in addition to the use of a fixed sized pillow of height 4 cm (group F), was capable of improving the glottic view.

Patient characteristics across the groups

There was no significant difference in patients of both the groups with respect to age, gender, ASA physical grade, Modified Mallampati score and mouth opening.

Cormack – Lehane Grade

In the present study, the laryngeal view was observed by the intubating anesthesiologist and graded based on the Cormack-Lehane grading scale. It was seen that the prevalence of C-L grade was found to be statistically comparable between group F and group C. In addition, there was no difference in the mean C–L grade between the two groups, p - value was statistically insignificant.

Our results were in line with the study conducted by Ju Hong et.al,^[12] that found no differences in the glottic view while performing laryngoscopy on a 4 cm height pillow and an 8 cm height pillow. On the contrary many studies prove that increasing the head elevation helps in improving the laryngeal visualization. El-Orbany et.al,^[13] found that direct laryngoscopic (DL) views were found to be better with greater elevation when the heads of adults were elevated by 0, 6, and 10 cm in each patient. Park et.al,^[14] in 2010 had shown that laryngoscopic view with a 9 cm pillow was significantly superior to that with 3 cm, 6 cm pillows and without a pillow (p-value < 0.001). In a study on seven human cadavers, Levitan^[4] and authors reported that as the head elevation and neck flexion increased, the POGO score improved. All of the above findings appear to be at odds with the findings of the current study, which found no differences in glottic vision between the two groups.

Time taken for intubation

Mean duration for laryngoscopy and intubation in Group F was 13.37 secs and in Group C was 16.59 secs and the difference was highly significant statistically, p value = 0.001, as assessed by unpaired t-test. Though in our study, the intubation response was not recorded, this data is clinically insignificant as only few seconds more were required for intubation in Group C. Our results were conflicting with the study done by Dhar et.al^[9] who observed that the time necessary for intubation was significantly lesser in Group CP in patients with Mallampati grade III. They correlated this result with better glottic visualization observed in Group CP patients. We came to conclusion that even though the overall mean C-L grade between Group F and Group C was comparable in the current study, the mean time taken for intubation was significantly more in the Group C but it was not significant clinically. This was in line with the study by Ju Hong et.al^[12] where they found that increasing the head elevation by placing 8 cm height pillow, instead of a routine 4 cm height pillow, did no improvement in the C-L grade but increased the anesthesiologist discomfort score. The authors reported that the limited head extension in the 8 cm group made it harder to open the patient's mouth and insert the laryngoscope and suggested this reason for the higher discomfort score in the 8 cm group. Although the duration of intubation was not evaluated in their study the increased time taken for intubation in our study Group C could be attributed to the reason stated above. The tracheal intubation was successful in both the groups as expected as most of the anesthetists would exert their maximum effort to secure the airway. The efforts might have contributed to the increased duration of laryngoscopy and intubation.

Number of attempts

Two intubation attempts were required by 7 patients in the group C and by 2 patients in group F but the statistical difference was insignificant, p value=

0.86. A study conducted by Hafiizhoh et.al,^[15] on 378 patients undergoing elective surgery were intubated in sniffing position and simple head extension after dividing into group A and group B respectively. After intubation, the success rate of first attempt intubation was compared between the two groups. Group A had 156 (3.5 percent) successful intubations on the first try (p = 0.05), while Group B had 121. (64.0 percent). In the present study, our results showed that Group C required more number of intubation attempts than in Group F. The data analysis is statistically and clinically insignificant.

CONCLUSION

We concluded that improved laryngeal view does not guarantee facilitated and easy intubation. Head elevation by customizing pillow height as compared to the standard height of 4 cm doesn't make clinically significant improvement in laryngoscopy and intubation.

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