Original Article

A randomised comparative study on customised versus fixed sized pillow for tracheal intubation in the sniffing position by Macintosh laryngoscopy

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ABSTRACT

Background and Aims: The sniffing position has been most commonly used for positioning of the head and neck to facilitate tracheal intubation. However, the optimum degree of head elevation for the optimal laryngeal view is not well studied, especially in non-Western countries. The present study was aimed to compare the use of a fixed height pillow versus a customised pillow (CP) height for head elevation, in terms of glottis visualisation and time required for tracheal intubation. **Methods:** With research and ethics committee approval from the institute, this randomised study was conducted among patients of both sexes aged 16 years or more and American Society of Anesthesiologists physical Status I to IV. A total of 134 patients were randomly allocated into routinely used fixed-sized pillow (FP) and CP group (to achieve horizontal alignment of external auditory meatus [EAM] and sternal notch). Primary and secondary outcomes were Cormack–Lehane (C–L) grade of glottic visualisation and time required for tracheal intubation, respectively. They were compared using unpaired *t*-test and Fisher's exact test as applicable; $P < 0.05$ was considered statistically significant. **Results:** One hundred and nineteen patients completed the study. Both groups were similar in terms of demographic and external airway measurements. The mean ± standard deviation height of pillow required in Group CP was 6.26 ± 0.97 cm. Group FP had C–L Grade 3 view more often than Group CP (28.33% vs. 13.56%). In patients with modified Mallampati (MMP) Grade ≥3, the C–L grades and time required for intubation were both significantly lower in group CP. The time required for tracheal intubation was significantly lower in group CP ($P = 0.04$), even though the C–L grades were similar. **Conclusion:** Customising pillow for head elevation to horizontally align the EAM and the sternal notch gives better glottic visualisation and intubating conditions in patients with higher MMP grades.

Key words: Glottis, intubation, laryngoscopic view, laryngoscopy, time

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INTRODUCTION

Optimal positioning of the head and neck to facilitate tracheal intubation has been a matter of continuous debate, changing theories and varying explanations for the past few years. The most commonly used technique in this regard is the 'sniffing position' (SP), which consists of neck flexion of approximately 35° and atlanto-occipital joint extension of approximately 15°.[1,2] The three axis alignment theory is considered the most valid explanation for this position, while newer theories have yet to find widespread acceptance.[3]

The neck flexion component of the SP is generally achieved by elevating the head using pillows or a head

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ring. Studies have shown significantly better glottic visualisation with head elevation, although with varying amount of elevation required.[4,5] Others found no distinct advantage compared to simple extension of the head in routine practice.[6,7] Horizontal alignment of the sternal notch and the external auditory meatus (EAM) has been used as a marker of appropriate positioning, in terms of the head elevation. This is also the aim in 'ramping' which has an established role in obese patients.[8,9] This practice is however not routine for non-obese patients. The aim of the present study was to compare a fixed height obtained by routinely used ring versus a customised height by addition of sheets (for horizontal alignment of EAM and sternum) to achieve head elevation for tracheal intubation in terms of glottis visualisation and time taken for intubation.

METHODS

After obtaining approval from the institute ethics committee, the present prospective randomised study was conducted in a tertiary care teaching hospital in India from February 2017 to August 2017 [CTRI/2018/01/011222]. Patients of American Society of Anesthesiologists (ASA) physical Status I to IV, of both sexes, more than or equal to 16 years of age, coming for elective or emergency surgeries requiring endotracheal intubation were eligible for the study. Exclusion criteria included pregnant women, height <140 cm, mouth opening <3 cm, thyromental distance (TMD) <5.5 cm, any airway growth or obstruction, unstable cervical spine and any other contraindication to conventional Macintosh laryngoscopy and intubation of trachea. After identifying prospective study participants and taking appropriate consent from the patients, the patients were divided into two groups based on selection of a number by the patient from a chart of random numbers generated using an online open epidemiological tool – Open Source Epidemiologic Statistics for Public Health ('OpenEpi') (www.openepi.com). The two groups were fixed-sized pillow group (FP) and customised pillow size group (CP).

All study participants were evaluated thoroughly during pre-anaesthetic check-up and again before surgery. Data collected at the time of patient recruitment, before surgery commencement included demographic data such as age, sex, height and weight of the patient. ASA physical status class, modified Mallampati (MMP) grade, mouth opening, thyromental distance (TMD) measurement along with subjective assessment of the presence of short neck or not were noted. Management of pre-medication and general anaesthesia was standardised. Pillow for head positioning was used as per the randomly opted group by the patient. Group FP (FP height) received a 4-cm head ring (standard size used in the study set-up). Group CP received an additional layer of folded sheets in addition to the standard head ring, if required, so as to align the EAM and the sternal notch horizontally. The height required for alignment was noted in each case up to the nearest 0.5 cm.

Tracheal intubation was facilitated using either vecuronium 0.1 mg/kg or rocuronium 0.6 mg/kg, with a wait time of 3 min before attempting intubation. Succinylcholine or rocuronium 1.2 mg/kg was used in case of rapid sequence induction, with a wait time of 1 min before attempting intubation. Cricoid pressure was applied only in cases with <8 h nil by mouth status and cases with increased chances of regurgitation. Trachea was intubated by an experienced anaesthesiologist (minimum 2-year post-specialisation experience) using a standard appropriately sized Macintosh blade. The height of the operating table was adjusted so that the patient's EAM was at the level of the umbilicus of the anaesthesiologist intubating the trachea of the patient. Time taken for intubation was noted by a neutral observer (OT staff member or a resident) from the digitally displayed timer in the anaesthesia monitor. The time taken for tracheal intubation in the present study was defined as the duration from the insertion of laryngoscope blade into the oral cavity to its removal. Correct tube placement was confirmed by end-tidal CO_2 measurement. In case of multiple attempts, total time of all laryngoscopy attempts was noted. Glottic view was noted in terms of Cormack–Lehane (C–L) grade by the intubating anaesthesiologist. Other data collected at this time included number of attempts, any assistance used in the form of a bougie, stylet or use of external laryngeal pressure/manipulation. Change of pillow if required to facilitate successful intubation was also noted.

The present study was conducted as a pilot, as there were no such similar studies to guide us for sample size calculation. The sample size was calculated with an assumed 30% prevalence of C–L Grade 3 and more view in standard (FP group) and 10% with intervention (i.e., CP group). The two-sided significance ($1 - \alpha$) of 95% and a power ($1 - \beta$) of 80% were taken. Online tool OpenEpi (http://www.openepi.com/SampleSize/

SSCohort.htm) was used for calculating the sample which gave a sample of 62 (by Fleiss method) for each group taking exposed-to-non-exposed ratio of 1:1 and a design effect of 1. Five per cent dropouts were added to make the final sample as 65 participants per group (total 130). Therefore, we targeted recruitment of at least 65 patients in each group for the present study. A total of 150 random numbers were generated using Online tool OpenEpi (http://www.openepi.com/), and the patients were asked to choose any number of their choice from all the random numbers. The investigator then saw the group, in which the chosen number belonged and accordingly the group was allocated. Blinding and allocation concealment was not practically possible as the pillow size become obviously different. The primary outcome was to detect a difference in the C–L views between the two groups and the secondary outcome was time taken for tracheal intubations. The use of assistance, change of pillow height and number of attempts were also noted.

Data were presented as number, percentages, mean ± standard deviation (SD) or other as appropriate. Level of significance was ascertained using unpaired *t*-test and Fisher's exact test. Statistical analysis was carried out using INSTAT (GraphPad software Inc., La Jolla, CA, USA); a $P < 0.05$ was considered to be statistically significant.

RESULTS

138 prospective participants were counselled, 124 out of them were randomised and 119 (i.e., 60 patients of FP group and 59 patients of CP group) were finally analysed for comparison. The sampling tree (CONSORT) is presented in Figure 1. Only 3 (5%) of FP group and 2 (3.4%) of CP group patients were emergency cases ($P = 1.0$; Fisher's exact test).

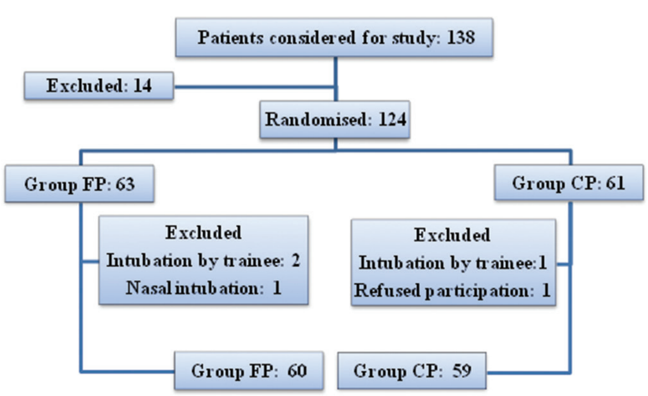

Figure 1: Sampling tree (CONSORT) of the participants of the study. FP: Fixed-sized pillow, CP: Customised pillow

The age of both the groups ranged between 16 and 70 years with median of 38 years (FP) and 16–65 years with median 40 years (CP) was not statistically different. The mean ± SD of age, sex, weight, height and body mass index distribution between two the groups was also comparable [Table 1]. The median ASA physical status for both the groups were 2 with interquartile range (q3-q1) were (3-1) versus (2-1); $P = 0.03$ in the group FP and CP, respectively. Although there were very few cases of ASA physical Status IV patients in the Group FP as compared to none in the Group CP, no statistical difference in the distribution of ASA physical status classes between the Group FP and CP (I [28.33% vs. 30. 51%], II [46.67% vs. 62.71%], III [16.67% vs. 6.78%]) were noted.

Mouth opening and TMD were similar between the two groups. The prevalence of MMP Grade 1 was higher in the FP group as compared to CP group (35% vs. 13.56%), but while comparing MMP ≤2 and ≥3, the differences between the two groups were not significant [Table 2].

The prevalence of C–L ≥3 in Group FP (28.4%) was higher than Group CP (13.6%), but the difference was

Table 1: Comparison of demographic and physical status profile

Parameters	Mean±SD		*P*
	Group FP (*n*=60)	Group CP (*n*=59)	
Age (years)	40.07±13.29	39.78±12.16	0.90*
Gender, *n* (%)			
Male	24 (40)	22 (37)	0.85#
Female	36 (60)	37 (63)	
Weight (kg)	60.58±12.49	58.91±11.93	0.46*
Height (m)	1.583±0.09	1.579±0.08	0.77*
BMI (kg/m²)	24.05±3.93	23.67±4.81	0.63*

*Unpaired *t*-test, #Fisher's exact test. BMI – Body mass index; SD – Standard deviation; FP – Fixed-sized pillow; CP – Customised pillow

Table 2: Comparison of external airway parameters assessed

Parameters	Group FP (*n*=60)	Group CP (*n*=59)	*P*
Mouth opening (cm), Mean±SD	4.17±0.72	4.11±0.70	0.66*
Thyromental distance (cm), Mean±SD	6.78±0.52	6.62±0.46	0.11*
MMP grade: Median (IQR)	2 (2-1)	2 (3-2)	0.03*
MMP 1, *n* (%)	21 (35.0)	8 (13.56)	0.009#
MMP 2, *n* (%)	25 (41.67)	34 (57.63)	0.100#
MMP 3, *n* (%)	14 (23.33)	16 (27.12)	0.677#
MMP 4, *n* (%)	0	1 (1.69)	0.495#
MMP ≤2, *n* (%)	46 (76.6)	42 (71.2)	0.54#
MMP ≥3, *n* (%)	14 (23.4)	17 (28.8)	0.54#

*Unpaired *t*-test, #Fisher's exact test. MMP – Modified Mallampati; SD – Standard deviation; IQR – Interquartile range; FP – Fixed-sized pillow; CP – Customised pillow statistically insignificant. The difference in the mean C–L grade between the two groups was also statistically comparable ($P = 0.172$), but the mean C–L grade in the subgroup of patients with MMP Grade ≥3 was lower in Group CP as compared to Group FP, $P < 0.05$ [Table 3].

The mean time taken for intubation was significantly less in Group CP ($P < 0.05$). In the subgroup of patients with MMP ≤2, both group FP and CP had comparable times. However, in subgroup of patients with MMP ≥3, Group CP required significantly lower time for tracheal intubation ($P < 0.05$). Mean time in subgroup with C–L ≤2 and ≥3 were also comparable between the two groups FP and CP [Table 4].

The pillow height for the FP group was fixed at 4 cm. The CP group required a pillow height which ranged between 4 cm and 8.5 cm with mean ± SD height of 6.26 ± 0.97 cm. There was no significant difference in the use of assistance in the two groups to facilitate tracheal intubation; 26% in Group FP versus 24% in Group CP ($P = 0.927$). Single attempt was successful in all the patients of both the groups and no change in pillow height was required in any of the patients.

Table 3: Cormack-Lehane glottic view grade distribution across the groups and categories

Category	Group FP (*n*=60)	Group CP (*n*=59)	P
C-L grade, Mean±SD			
In MMP Grade 1-4	1.93±0.79	1.745±0.68	0.17*
In MMP Grade ≤2	1.67±0.70	1.67±0.62	0.96*
In MMP Grade ≥3	2.79±0.43	1.94±0.83	0.002*
C-L grade, *n* (%)			
1	21 (35.0)	23 (38.98)	0.71#
2	22 (36.67)	28 (47.46)	0.27#
3	17 (28.33)	8 (13.56)	0.07#
4	0	0	

*Unpaired *t*-test, #Fisher's exact test. MMP – Modified Mallampati; SD – Standard deviation; FP – Fixed-sized pillow; CP – Customised pillow; C-L – Cormack-Lehane

Table 4: Comparison of time taken (s) for tracheal intubation

Category	Mean±SD		Two-tailed P*
	Group FP (*n*=60)	Group CP (*n*=59)	
All patients	13.22±5.49	11.25±5.01	0.04
MMP			
Grade ≤2	11.85±4.89	11.29±5.03	0.597
Grade ≥3	17.71±5.05	11.18±5.11	0.0013
C-L view			
Grade ≤2	10.79±2.79	11.69±4.36	0.298
Grade ≥3	19.35±5.95	15.38±5.29	0.118

*Unpaired *t*-test. FP – Fixed-sized pillow; CP – Customised pillow; SD – Standard deviation; MMP – Modified Mallampati; C-L – Cormack-Lehane

DISCUSSION

In the present study, head elevation was done in both the study groups, but the Group FP received a routinely practiced fixed ring-shaped pillow of 4 cm. We found that the occurrence of a higher C–L Grade ≥3 (poorer glottis visualisation) was lower in the Group CP, although statistically not significant. Furthermore, no difference was observed in the mean C–L grade between the two groups. These findings are in keeping with another study which concluded that the SP (7-cm cushion) did not significantly improve the glottic view in comparison to simple extension in routine tracheal intubation, except in those with restricted neck movements and obese patients.[6] Similar findings were also observed in the studies conducted in Australia and Japan.[7,10] In contrast, the SP and head elevation have been found to improve the glottic view in numerous studies. A study conducted on human cadavers recorded a significant increase in percentage of glottic opening score with progressive elevation of the head to as much as possible, increasing neck flexion.[11] A Malaysian study with 378 participants also reported better glottic visualisation scores and intubation success rates in head elevated (7 cm) SP versus simple head extension.[12] When the heads of adults were elevated with 0, 6 and 10 cm in each patient, it was found that the direct laryngoscopic (DL) views were better with increased elevation.[5] These results appear to be conflicting with respect to the present study, which reported no difference in glottic view between the two groups except in MMP Grade ≥3. The possible explanation for this is that the above-mentioned studies have compared head-elevated positions with no head elevation, whereas in the current study, the comparison was with a less head-elevated position (Group FP). Perhaps that is why no significant difference was appreciated in the overall C–L view.

Scientific literature has numerous studies regarding the most optimal position for DL and intubation, but there seems to be a large variation and conflicting opinions regarding the same, especially in terms of validity of the SP and the three axis alignment theory, height of pillow required and its use, other than in obese and difficult airway patients.[6,13] This issue is mainly attributed to the wide variation in assessment techniques and airway definitions, leading to subjective differences in prediction of the type and difficulty of the airway.[14,15]

The mean C–L grade in the subgroup of patients with MMP Grade ≥3 was however found to be lower in group CP, suggesting a better glottic view in Group CP in patients with a potentially difficult laryngoscopy and intubation. Elevation of the head and neck beyond the SP and ramped up position reported improvement in glottic visualisation and suggested even better intubation performance.[8,16] The present study findings also suggest so. Ramping position can be considered to be a modified SP, wherein both the head and the shoulder need to be elevated so as to align the EAM and sternal notch horizontally. This fact was concluded in both obese and non-obese patients.[4] In obese patients, only head elevated SP is not enough to achieve the alignment.[8,9,17] In the current study also, the sample population comprised of both obese and non-obese patients, although obese patients were only 7.5% of the total sample.

Another aspect of varied data is with respect to the height of pillow required for the best laryngeal view. Seven centimetre is most commonly encountered in literature, but studies have shown this height to be ranging from 6 cm to 12 cm.[5,6,8,18] The guideline prepared by experts for the All India Difficult Airway Association in 2016 for unanticipated difficult airway opine that optimum SP can be achieved by keeping a 10-cm thickness pillow under the patient's head.[19] The current study which comprised an Indian mixed population required a mean height of 6.2 cm to bring the EAM and sternum at same horizontal level, which is on the lower side of this range. These emphasise the fact that different races and ethnicities might require a customised pillow size, rather than a standard pillow for all patients.

In the current study, even though the overall mean C–L grade between Groups FP and CP was comparable, the mean time taken for intubation was significantly lesser in Group CP, perhaps due to better intubating conditions. Mean time taken was also lesser for Group CP in the subgroup of MMP Grade ≥3. This correlates with the better glottis visualisation observed in these patients. Most other similar studies have not evaluated the comparison of time taken for intubation. Another observation which supports Group CP over FP is that despite having significantly less number of MMP Grade 1 patients in Group CP, the C–L view was similar in the two groups, but the time taken for tracheal intubation was lower in group CP.

The laryngoscopy timing (i.e., 3 and 1 min) was predetermined based on the time required for maximal blockade rather than neuromuscular testing based. Both rocuronium 0.6 mg/kg and vecuronium 0.1 mg/kg take <3 min when used with isoflurane and/or opioids for 100% blockade,[20] whereas rocuronium 1.2 mg/kg and succinylcholine 2 mg/kg take <1 min when used with isoflurane and/or opioids.[20]

The present study was however limited by the fact that it was a single centre study with a relatively small sample size and limited scope. Inter-observer and even intra-observer variation in assessment of the glottis visualisation (C–L) is expected. This was, however, compensated to some extent by restricting the intubating anaesthesiologists to two in number. Large multicentric studies may provide strong findings and the present study can serve as the guiding pilot study. However, the present study clearly indicates that the routine pillow size used blindly should be under scrutiny for height customisation. The finding of the present and future such studies will help our indigenous bodies to prepare evidence-based guideline and recommendation for positioning of the head for tracheal intubation.

CONCLUSION

Horizontal alignment of the EAM and the sternal notch by customising the height of pillow is potentially beneficial in patients with higher MMP grades. CP was able to produce better glottis visualisation and required significantly lesser time for tracheal intubation in such patients. Indian population may require a lesser pillow height than the Western standard.

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Conflicts of interest

There are no conflicts of interest.

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