

## Cuff pressure manometer - a luxury or necessity?

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### Abstract

**Background:** It is recommended to maintain endotracheal tube cuff pressure within a range of 20 to 30 cm H<sub>2</sub>O to prevent complications.

**Objective:** To assess the ability of experienced anesthesiologists to inflate endotracheal tube cuffs to optimal range of cuff pressure by subjective assessment alone.

**Methodology:** An observational study was conducted to assess the ability of experienced anesthesiologists to inflate endotracheal tube cuffs to optimal range of cuff pressure by subjective assessment alone. 150 adult patients of either sex posted for elective surgeries were intubated and cuffs were inflated guided by subjective assessment alone. The pressure in these cuffs were then measured using a cuff pressure manometer and recorded. Statistical analysis was done using SPSS 18 (trial version). The primary outcome studied was the distribution of cuff pressures whether it was within or out of normal range (20 to 30 cmH<sub>2</sub>O). The relation of cuff pressure with age, sex, height, weight and nutritional status was looked for using Chi-square, Fischer Exact and Correlation tests.

**Results:** The anesthesiologists were able to inflate the cuff to an optimal cuff pressure only in 64% of cases. The cuff pressures were recorded as low in 17.3% while in 18.7% of cases the cuff pressure reached above the optimal range. No relation was established between cuff pressure and age, gender, height, weight or nutritional status.

**Conclusions:** Even experienced anesthesiologists are not able to inflate the endotracheal tube cuff up to optimal cuff pressure by using subjective assessment alone in all cases.

**Keywords:** Intubation, Endotracheal tube cuff pressure, Minimal Occlusive Volume, Intratracheal, cuff pressure manometer.

### Introduction

Endotracheal intubation is the gold standard of airway management which, according to documented history, was first described by Hippocrates. Endotracheal intubation is a procedure which is done extensively in different departments of a hospital mainly in operation theatres, intensive care settings and in emergency departments. It is also performed out of hospitals in trauma or medical emergencies. Most of the tubes used now are made of Poly Vinyl Chloride (PVC) with high volume low pressure cuffs which are inflated by injecting air through the pilot balloon. There are no clear cut guidelines regarding optimal cuff pressure, but several studies have suggested a cuff pressure within a narrow range of 20-30 cm H<sub>2</sub>O as optimal.

So, endotracheal intubation is a skill which should be mastered not only by anesthesiologists, but also by doctors and staffs of ICU settings, emergency departments and by paramedical personals. Even though, great efforts are being taken to train the above in intubation skills, not much importance is given to training them in generating and maintaining optimal endotracheal tube cuff pressure.

Most clinicians assess the adequacy of cuff pressure by palpating pilot balloon and inflating the cuff accordingly. Some prefer to use Minimum Occlusive Volume (MOV) that is the smallest volume of air needed to prevent any air leak during inspiration.

Cuffed endotracheal tube are now widely used, even in neonates, to ensure adequate delivery of tidal volume and to prevent aspiration of gastric contents and dislodgement of tubes. Since the advent of cuffed endotracheal tubes it has been presumed that experienced anaesthesiologists could inflate the cuff up to optimal range, guided by subjective assessment alone. Fernandez et al reported that difference in shape and volume of pilot balloon from different manufacturers make palpation of pilot balloon an unreliable technique for assessment of intra cuff pressure.<sup>(1)</sup>

Even though, cuff pressure manometers are now available for assessing the adequacy of cuff pressure, they are not widely used, as clinicians still depends on subjective methods like pilot balloon palpation or appreciation of audible or palpable leak disappearance for assessing the adequacy of cuff pressure. Ozer et al noticed no significant change in endotracheal cuff pressure when cuff inflation was guided by palpation of pilot balloon or by disappearance of leak.<sup>(2)</sup> Even though other studies have showed a lower cuff pressure with MOV technique, no change in the incidence of dysphagia or hoarseness of voice was seen.<sup>(3)</sup>

In this study, we are trying to find out whether subjective judgment skills of clinicians are enough for generating and maintaining an optimal cuff pressure or they should be replaced by objective methods like cuff pressure manometer.

## Methodology

An observational study was done in February 2016 with Institutional Ethics Committee approval (IEC/MES/01/2016). Assuming that in 59% of patients the cuff pressure will fall into a range of 20-30 cmH<sub>2</sub>O [Trivedi et al]<sup>(4)</sup> and with a 20% allowable error, the sample size was calculated to be 143. All adult patients of either sex, American Society of Anesthesiologists Physical Status (ASA PS) grade I and II, posted for elective surgery in different surgical specialties under general anaesthesia and intubated by anesthesiologists with minimum five years of experience were enrolled in the study. All emergency intubations, pregnant patients, patients with inadequate Nil per Oral status, trauma cases, anterior cervical spine surgeries, and patients with predicted difficult intubation, previous history of laryngeal surgery or known anatomical laryngo-tracheal anomalies were excluded from the study. Thus we recruited 150 patients who satisfied the inclusion – exclusion criteria during the one month study period.

All patients were anaesthetized according to institutional protocol using propofol for induction and vecuronium for muscle relaxation. Endotracheal tubes of sizes 7 and 7.5 were used in female patients and that of 8 and 8.5 in male patients. After intubation cuffs were inflated by injecting air through the pilot balloon and adequacy was assessed subjectively by the concerned anesthesiologists.

The anesthesiologists were not informed about the study to avoid Hawthorne effect. The use of cuff pressure manometer was not a routine in our institution as it was not available previously. Hence each of them carried out with their own disposition, either by palpating the pilot balloon or by inflating till the disappearance of palpable or audible leak.

After starting ventilation with 100% oxygen through Bain's circuit, cuff pressures were measured at the end expiratory phase using a cuff pressure manometer (Hand cuff pressure gauge, Mallinckrodt™, Covidien Inc., U.S.A.) and recorded. We used a simple aneroid manometer which measured cuff pressure in the range of 0-120cm H<sub>2</sub>O with increments of 2 cmH<sub>2</sub>O. To avoid bias, the same manometer was used in all the cases and the same person, who was trained to use the manometer, recorded the cuff pressure in all the cases.

Cuff pressure was considered high, if it was >30 cmH<sub>2</sub>O and low if <20 cmH<sub>2</sub>O. The pressure was adjusted to the normal range in required cases.

The primary outcome studied was the distribution of cuff pressures within or out of normal range. The relation between cuff pressure and gender was looked for using Chi-square test and that between cuff pressure and nutritional status was studied using Fischer Exact test. Correlation test was used to study the relation of cuff pressure with age (in completed years), height (in metres) and weight (in kilograms).

## Results

The mean age of the 150 patients included in the study was 38.53 years ( $\pm 14.4$ ) [range 18 -75 years]. About half of the study group (53.7%) was females. Table 1 depicts the basic anthropometric measurements of the participants. The mean weight of the patients was 62.31kg ( $\pm 10.04$ ) and mean height was 1.60m ( $\pm 0.09$ ). More than half of the study participants were malnourished with 5.3% underweight, 36.6% overweight and 18% obese.

**Table 1: Basic profile of participants**

	Minimum	Maximum	Mean	Standard. Deviation
Age	18	75	38.52	14.403
Weight	40	93	62.31	10.048
Height	1.41	1.90	1.6021	.09110
Cuff Pressure	10	46	24.91	6.642

In 64% patients the anesthesiologists were able to inflate the pilot balloon to a cuff pressure within the normal range of 20-30 cm H<sub>2</sub>O. In 17.3% the cuff pressure was recorded as lower than the normal range while in 18.7% cuff pressure was above the range (Table 2). The lowest cuff pressure recorded was 10 cm H<sub>2</sub>O while the highest was 46 cm H<sub>2</sub>O. The mean was 24.91( $\pm 6.642$ ) cm H<sub>2</sub>O.

**Table 2: Distribution of cuff pressure**

Cuff pressure	Frequency	Percentage
Low	26	17.3
Normal	96	64
High	28	18.7
Total	150	100.0

Low cuff pressure was recorded in 15.6% of male participants and 18.6% of female participants, whereas high pressure was seen in 12.5% males and 23.25% females (Table 3). No significant relation could be established between cuff pressure and gender (Chi square 3.945; p 0.139). No significant association was seen between cuff pressure and nutritional status (Fischer exact 5.234; p 0.564) (Table 4).

**Table 3: Gender- cuff pressure cross tabulation**

Gender	Cuff Pressure			Total
	Low	Normal	High	
Male	10	46	8	64
Female	16	50	20	86
Total	26	96	28	150

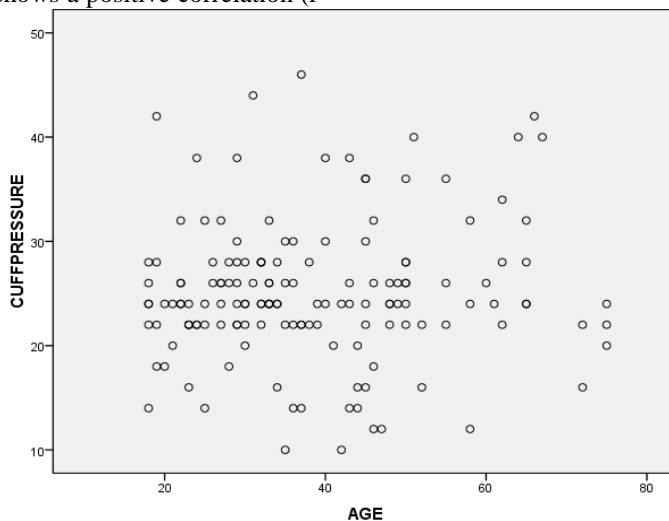
Chi-square: 3.544; p value: 0.171 (Not significant)

**Table 4: nutritional status – cuff pressure cross tabulation**

Nutritional status	Cuff pressure			Total
	Low	Normal	High	
Underweight	2	5	1	8
Normal	10	36	14	60
Overweight	9	40	6	55
Obese	5	15	7	27
Total	26	96	28	150

Fischer exact 5.234; p 0.564.

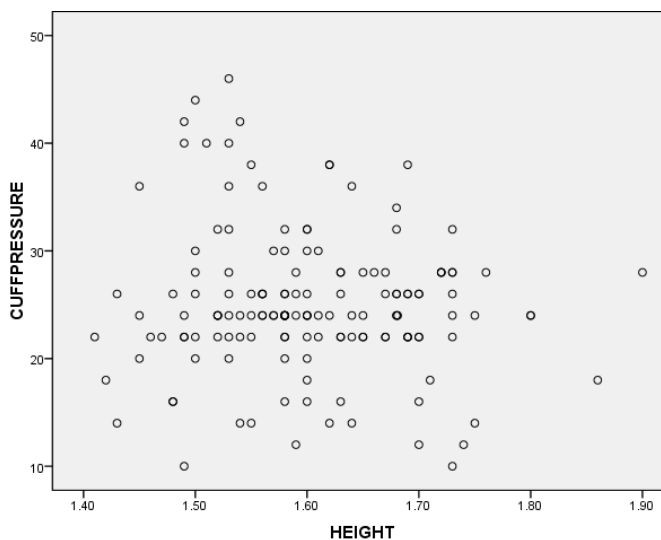
The Scatter plot depicting relation between cuff pressure and age (Fig. 1) shows a positive correlation (r



**Fig. 1: Scatter plot depicting relation between cuff pressure and age**

The Scatter plot shows a positive correlation (r 0.075) between cuff pressure and age but not significant (p 0.365).

Fig. 2 depicts a non-significant (p 0.251) negative correlation (r -0.094) was seen between height and cuff pressure (Table 5).



**Fig. 2: Scatter diagram depicting relation between cuff pressure and height**

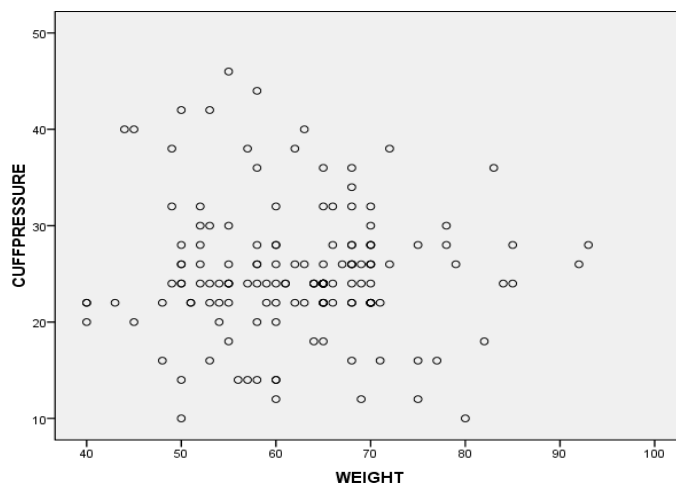
Scatter plot shows a non-significant (p 0.251) negative correlation (r -0.094) seen between height and cuff pressure.

0.075) but this finding was not significant (p 0.365) (Table 5).

**Table 5: Co-relation of age, height and weight with cuff pressure**

Correlations	Pearsons correlation	Significance
Age vs cuff pressure	0.075	0.365
Height vs cuff pressure	-0.094	0.251
Weight vs cuff pressure	-0.045	0.584

Similarly Fig. 3 too shows a negative correlation between weight and cuff pressure ( $r = -0.045$ ) but not significant ( $p = 0.584$ ) as seen in Table 5.



**Fig. 3: Scatter diagram depicting relation between cuff pressure and weight**

Scatter plot shows a negative correlation between weight and cuff pressure ( $r = -0.045$ ) but not significant ( $p = 0.584$ ).

### Discussion

Several studies have proved the effects of high cuff pressure, which varies from mild undesirable effects like sore throat, hoarseness of voice<sup>(5)</sup> and blood streaked expectoration to more serious effects like tracheal rupture,<sup>(6)</sup> vocal cord palsy,<sup>(7)</sup> tracheal stenosis and tracheo-esophageal fistula.<sup>(8)</sup> One of the earliest work to study the effect of cuff pressure on tracheal mucosal blood flow by Seegobin et al using endoscopic photographic method, showed that an intracuff pressure above 30cm H<sub>2</sub>O was associated with impairment of mucosal blood flow and that of 50cm H<sub>2</sub>O led to total obstruction of blood flow in mucosa overlying tracheal rings.<sup>(9)</sup> In anaesthesia practice, high cuff pressures can be further detrimental when nitrous oxide is used, during laparoscopic surgeries and when position of patients are changed intra operatively. Increased airway pressure associated with positive pressure ventilation also results in higher cuff pressure even with high volume low pressure cuffs.

Inflating cuff to below optimal range is also not desirable as there is potential danger of aspiration.<sup>(10)</sup> Sub inflation of endotracheal cuff, even for a short period, can cause aspiration of subglottic secretions facilitating entry of oropharyngeal bacteria into lower respiratory tract leading to ventilator associated pneumonia.<sup>(11)</sup> Adequate seal is needed to ensure delivery of set tidal volume. Under inflation of the cuff may also lead to eccentric positioning of the tube in the trachea, causing frictional mucosal erosion from the tip of the tracheal tube.

In our study, the mean cuff pressure was within normal range. But, almost equal percentage of patients had cuff pressures below (17.3%) and above (18.7%) the recommended range. A multi-centric study by Liu et al showed a mean cuff pressure of  $43 \pm 23.3$  mmHg

when cuffs were inflated by anesthesiologists, guided by pilot balloon palpation.<sup>(12)</sup> When similar studies were done by Jain et al and Al-metwalli et al the mean cuff pressures reached  $50.1 \pm 11.67$  and  $48.6 \pm 14$  cm H<sub>2</sub>O respectively, in the absence of objective measurement.<sup>(13,3)</sup> Sengupta et al studied cuff pressures generated routinely by anaesthesia providers in three different hospitals and found a mean recorded pressure of 35.3 cm H<sub>2</sub>O with 50% of patients having measured cuff pressure above 30 cm H<sub>2</sub>O.<sup>(14)</sup> In our study the mean cuff pressure measured was within the recommended range. This is similar to the study by Trivedi et al,<sup>(4)</sup> where the mean value of cuff pressure was within the normal range but 14.8% of cases showed values below optimum and 26.2% were above recommended range. In a similar study by Das et al, when cuff was inflated by minimal leak test, 64.7% patients had cuff pressure higher and 2.9% of patient had cuff pressure lower than the recommended range.<sup>(15)</sup> Compared to the above studies we got lesser percentage of patients with higher cuff pressure and more percentage of patients with lower cuff pressure.

This may be because anesthesiologists, being aware of the complications of high cuff pressure, are deliberately trying to maintain a lower pressure and in that effort are generating sub-optimal cuff pressures. This tendency cannot be entertained as the patients are prone to the complications of sub optimal cuff pressure.

It was found that in only 64% of patients, anesthesiologists were able to inflate the cuff up to recommended range based on subjective assessment alone. This suggests that cuff pressure manometer should be considered as a necessity for generating and maintaining optimal cuff pressure.

In the Sengupta et al study, no correlation was found between cuff pressure and demographic or

morphometric characteristics or tube size.<sup>(14)</sup> No association of endotracheal tube cuff pressure with age and BMI was found in a similar Danish study conducted in two hospitals.<sup>(16)</sup> This is in accordance to the results of our study, where we could not establish any relation of cuff pressure with age, gender, height, weight or nutritional status.

New devices like cuff pressure pop off valves are also available now which are intended to keep intra cuff pressure below 20 cm H<sub>2</sub>O.<sup>(17)</sup> Novel color coded syringe devices are available which allows optimal inflation of the cuff without using a separate manometer. The efficacy of these devices is being studied and the results seem promising.<sup>(18)</sup> But, compared to manometer, these devices may not be cost effective as they are for single use only.

### Conclusion

When their ability for optimal inflation of cuff was studied, it was found that in only 64% of patients, anesthesiologists were able to inflate the cuff up to recommended range based on subjective assessment alone.

Even though health care personals are now becoming more and more aware of the need for maintaining an optimal cuff pressure, the unavailability of manometers may be preventing them from using the same. We can hope that in near future objective measurement of cuff pressure would be made mandatory and status of cuff pressure manometer would be changed from luxury to necessity, just as pulse oximeter which was considered, initially, as a luxury.

### Limitations of the study

In this study we took only a single measurement of the cuff pressure and that too initially. No follow up measurements were done nor were post-op sequel studied.

It has been proved that connecting the pilot balloon to the manometer, itself can cause air leak and fall in cuff pressure which can make measurement inaccurate.

Correlation of cuff pressure with tube size was not studied.

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