

Validating the Pilot Balloon Method with a Manometer in Monitoring the Cuff Pressure in Dysphagia Individuals Secondary to Tracheostomy

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ABSTRACT

Aim: To validate the pilot balloon method with a manometer in monitoring the cuff pressure in dysphagia individuals secondary to tracheostomy.

Materials and methods: The study was conducted on $n = 25$ cuffed tracheostomized individuals. The cuff pressure was evaluated using the pilot balloon palpation method and manometer at four time intervals every 3 hours.

Results: The majority of the participants were rated with an underinflated cuff, followed by adequate cuff pressure and overinflation with the pilot balloon method. Fall of cuff pressure observed after 3 hours of duration. In the measurements made at time point 1, the manometric pressure and pilot balloon palpation methods exhibited a fair agreement; however, in further time points, this agreement decreased to almost none. This implies that the results of the pilot balloon palpation method do not match the manometric pressure results over time.

Conclusion: It is suggested to mandate the use of a manometer in monitoring the cuff pressure at least every 3 hours to avoid secondary complications related to cuff pressure of the tracheostomy tube.

Clinical significance: The pilot balloon method cannot be considered a reliable method, mandating the use of a manometer. It is important to frequently monitor with a manometer to improve the outcomes and reduce secondary complications.

Keywords: Cuff pressure, Dysphagia, Manometer, Palpation, Tracheostomy.

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INTRODUCTION

Tracheostomy is among the most performed surgical procedures in individuals with complex respiratory conditions.^{1,2} The choice of an appropriate tracheostomy tube is important to reduce trauma and subsequent stricture formation.³ The tubes could be either cuffed or cuffless. It is reported that the cuffed tubes may protect from aspiration of food, secretions, and gastric contents as compared to cuffless tubes.^{4,5} These tubes often arise as a matter of concern as they relate to swallowing.

It is important to investigate the impact of the cuff on swallow physiology to guide the clinical management of individuals with dysphagia.⁴ The cuff status of the tracheostomy tube may impact on swallowing mechanism, leading to dysphagia. Although no clear consensus to date, several studies are reporting that the deflated cuff status is more advantageous as compared to inflated cuff status in dysphagia individuals.⁶

It is essential to maintain adequate cuff pressure to prevent any secondary complications.⁷ The cuff pressure is considered one of the most common factors leading to tracheal injury and further tracheal stenosis.⁸ The recommended pressure is 15–25 cm H₂O.⁹ The underinflation being less than 15 cm H₂O and above 25 cm H₂O, an overinflated cuff. Literature has evidenced secondary complications of both overinflation and underinflation on the management of dysphagia, in addition to damage to the trachea, tracheal ulceration, dilatation, and perforation.⁶ The underinflated cuff is said to be associated with inadequate ventilation and microaspiration, resulting in several complications, including pneumonia.¹⁰

The two commonly used methods of measuring cuff pressure are pilot balloon palpation and the use of a hand-held

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manometer.⁹ Due to the various opinions existing between resources, it is important to understand the management of cuff and its potential impact. Therefore, the routine use of the objective technique with a manometer is suggested for tracheal tube cuff inflation and cuff pressure monitoring, especially in dysphagia individuals.⁷

MATERIALS AND METHODS

The study followed cross cross-sectional research design, and convenience sampling was adopted. The study was approved by the Institutional Research Committee and Institutional Ethics Committee (Ref IEC: 356/2022) at Kasturba Hospital, Manipal.



Fig. 1: Pilot balloon palpation method

The study was registered on the Clinical Trial Registry of India CTRI (Ref CTRI/2023/01/049019).

Participants

A total of $n = 25$ individuals aged 18–82 years with a mean \pm SD (50.7217.44) were enrolled. The demographic details of the participants were obtained from the medical records, and the cuff pressure was determined using two methods. The inclusion criteria included participants with a cuffed tracheostomy tube. The exclusion criteria included individuals who were unable to follow commands.

Procedure

Informed consent was obtained from the participants or their caregivers. The information about demographic details, cause of tracheostomy, types of tracheostomy tube, and other details was collected. The cuff pressure was documented initially using the pilot balloon palpation method (Fig. 1). This was performed by directly palpating or touching the pilot balloon between the fingers. This method of measurement was done by two clinicians (rater 1 and rater 2) to avoid subjective bias. The rating was done based on tactile sensation using a three-point rating scale (overinflated, adequate, and underinflated).

Secondly, the cuff pressure was evaluated using a handheld manometer (Fig. 2) (Smiths Medical Portex Cuff Inflator/Pressure Gauge). The attachment port of the manometer was connected to the Pilot balloon of the tracheostomy tube, and the cuff pressure was measured. If the cuff pressure was 15–25 cm H₂O, it was considered to be adequate. It was considered underinflated if the manometric pressure was less than 15 cm H₂O and overinflated if the cuff pressure was above 25 cm H₂O. The cuff pressure was evaluated using both methods at four time intervals every 3 hours.

Descriptive statistical analysis was carried out to measure the cuff pressure using the Pilot balloon palpation method and the manometer. The agreement between the raters and the two methods of cuff pressure measurement was determined using Kappa.



Fig. 2: Use of a handheld manometer

RESULTS

The current study aimed to validate the pilot balloon method with a manometer in monitoring the cuff pressure in dysphagia individuals secondary to tracheostomy. The objectives of the study were to measure the cuff pressure using the pilot balloon palpation method and the manometer and compare across different time points.

A total of $n = 25$ individuals (16 males and 9 females) aged 18–82 years, with a mean \pm SD of 50.72 \pm 17.44 years, with cuffed tracheostomy tubes, were recruited for the study.

In the current study, tracheostomy was performed due to prolonged mechanical ventilation in most of the participants. The types of tracheostomy tube included both single-lumen low-pressure cuffed tracheostomy tubes and double-lumen cuffed tracheostomy tubes of sizes 7, 7.5, 8, and 8.5 mm.

In the current study, the pilot balloon palpation method was done using a three-point rating scale (overinflated, adequate, and underinflated) at four-point intervals by two clinicians (rater 1 and rater 2) as depicted in Table 1. It was observed that the majority of the participants were rated with an underinflated cuff, followed by adequate cuff pressure and overinflation.

In the current study, the cuff pressure ranged from 8 to 72 cm H₂O, 2–48 cm H₂O, 2–34 cm H₂O, and 2–31 cm H₂O across the four intervals of time (Table 2). In addition, it was observed that there was a fall in cuff pressure after every 3 hours (3–4 cm H₂O).

DISCUSSION

Tracheostomy is a surgical procedure performed to determine a safe airway caused due to an airway obstruction and facilitate easy secretion clearing.¹¹ Despite their advantages, there is evidence on tracheostomy leading to complications in the upper airway, with dysphagia being one of the most associated complications post-tracheostomy.¹² The standard protocol in the ICU includes providing prolonged intubation with cuffed type of tracheostomy tubes that require mechanical ventilation, which was similar to the findings of the current study.⁸ The cuff pressure is considered one of the most common factors leading to tracheal injury and

further tracheal stenosis.⁸ It is essential to maintain adequate cuff pressure to avoid any secondary complications.⁷ The recommended pressure is 15–25 cm H₂O.^{9,13} There is evidence on abnormal cuff

pressure (increased-overinflated or decreased-underinflated) pressure leading to several complications. Increased pressure could cause necrosis, leading to damage in the tracheal wall.⁴ Decreased pressure, similarly, could lead to micro aspiration.¹⁰ In the current study, it was observed that most of the participants were underinflated or overinflated with the use of the pilot balloon method. This was in accordance with the study conducted by Faris et al.⁹ wherein they concluded that there is significant variability in the current clinical practice with respect to the monitoring of the cuff pressure. They also concluded that there could be inaccuracy in the pilot balloon method, even when performed with experienced specialists who are routinely involved in the management of tracheostomy individuals, similar to the findings of the current study. Hence, they stated that the clinical setups must advocate the mandatory use of a manometer in the ICU and otolaryngology wards for monitoring the cuff pressure of any patient with an inflated tracheostomy tube cuff. Morris et al.⁸ concluded that the pilot balloon method is inaccurate and recommend a reliable method, the use of a manometer, in monitoring the cuff pressure. In the current study, there was a fall in cuff pressure noted from one-time point to another which was also observed in Suryavanshi et al.¹⁴ where pressure was monitored using manometer every 6 hours over 24 hours for 4 days revealed a fall in cuff pressure at the end of 6 hours unlike in the current study, where the cuff pressure dropped after 3 hours. The similar findings were observed in a study by Faris et al.⁹ where the error in estimating with the pilot balloon method was observed to be 39%. The overall error was observed to be 50% if the pressure was double the recommended level. They also concluded that there could be inaccuracy in the pilot balloon method, even when performed with experienced specialists who are routinely involved in the management of tracheostomy individuals. Hence, they stated that the institute must advocate the mandatory use of a manometer. The authors suggested that frequent monitoring with a manometer is important to improve the outcomes. Monitoring the cuff pressure via the pilot balloon palpation method is inaccurate, and multiple authors have recommended the manometer as the only reliable method of cuff assessment.^{15,16} The use of a manometer to monitor cuff pressure in cuffed tracheostomy tubes is a good practice for clinicians with limited experience with cuffed tracheostomy tubes, and to avoid subjectivity. Such instrumental monitoring could also be used as a method of self-validation among clinicians.¹⁷

Table 1: Summary of pilot balloon palpation measured at four time points by two raters

Cuff pressures	Count (n = 25)	Percentage (%)
Pilot_balloon_palpation_C1_Time1		
Underinflated	13	52.0
Adequate	8	32.0
Overinflated	4	16.0
Pilot_balloon_palpation_C2_Time1		
Underinflated	15	60.0
Adequate	6	24.0
Overinflated	4	16.0
Pilot_balloon_palpation_C1_Time2		
Underinflated	15	60.0
Adequate	7	28.0
Overinflated	3	12.0
Pilot_balloon_palpation_C2_Time2		
Underinflated	17	68.0
Adequate	7	28.0
Overinflated	1	4.0
Pilot_balloon_palpation_C1_Time3		
Underinflated	18	72.0
Adequate	7	28.0
Overinflated	0	0.0
Pilot_balloon_palpation_C2_Time3		
Underinflated	21	84.0
Adequate	4	16.0
Overinflated	0	0.0
Pilot_balloon_palpation_C1_Time4		
Underinflated	21	84.0
Adequate	4	16.0
Overinflated	0	0.0
Pilot_balloon_palpation_C2_Time4		
Underinflated	22	88.0
Adequate	3	12.0
Overinflated	0	0.0

C1, clinician 1; C2, clinician 2

CONCLUSION

It is suggested to mandate the use of a manometer in monitoring the cuff pressure at least every 3 hours to avoid secondary complications related to cuff pressure of the tracheostomy tube.

Table 2: Summary of cuff pressure measured using a manometer at four time points

Descriptive statistics	Manometric_pressure Time1	Manometric_pressure Time2	Manometric_pressure Time3	Manometric_pressure Time4
n	25	25	25	25
Mean	24.64	20.68	17.32	16.60
Median	24.00	21.00	16.00	15.00
Std. deviation	14.003	11.506	9.245	8.347
Minimum	8	2	2	2
Maximum	72	48	34	31

Clinical Significance

The Pilot balloon method cannot be considered a reliable method, mandating the use of a manometer. It is important to frequently monitor with a manometer in order to improve the outcomes and reduce secondary complications.

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