Original Article

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Anaesthesia Section

Comparison of BPL™ Video Laryngoscope and Macintosh Laryngoscope Guided Throat Packing for Head and Neck Surgeries: A Randomised Controlled Study

MILON VASANT MITRAGOTRI[1], MADHURI KURDI[2], DHARMESH ARVIND LADHAD[3], PREMA RADDI[4], MAHESH D KURUGODIYAVAR[5]

ABSTRACT

Introduction: Evidence regarding throat packing for head and neck surgeries is limited. A video laryngoscope, an airway adjunct used for various diagnostic and therapeutic purposes, can also effectively pack the throat.

Aim: To compare the Time Taken for Throat Packing (TTTP) using a non-channeled video laryngoscope BPL™ versus the conventional Macintosh larynogoscope direct laryngoscope.

Materials and Methods: In this non-inferiority, randomised controlled, single-blind study, 72 patients undergoing head and neck surgeries requiring throat packing were recruited. The non-inferiority margin was set at 10 seconds between the two groups (n=36 each). Throat packing in Group-M and Group-V was performed using the Macintosh and video laryngoscopes with the assistance of Magill's forceps. The TTTP was recorded from the blade insertion to complete blade removal. A one-sided two-sample unpaired t-test was used to test non-inferiority hypothesis considered in this study.

Results: The mean age of patients in Group-M was 37.39 years and in Group-V was 33.65 years, with mean weights of 60.89 kg and 56.32 kg, respectively. The mean TTTP difference between Group-M and Group-V was found to be -12.6 seconds with a lower limit of the one-sided 95% Confidence Interval (CI) of -20.6s. The null hypothesis was accepted, concluding that video laryngoscope-guided throat packing took a longer duration. The ease of throat packing, haemodynamic stress response, and Postoperative Sore Throat (POST) were comparable between both groups.

Conclusion: Video laryngoscope-guided throat packing is inferior to conventional Macintosh throat packing in terms of TTTP. However, it is equivocal regarding the ease of throat packing and the stress response induced. POST was the same whether throat packing was performed using a video laryngoscope or a Macintosh laryngoscope.

Keywords: Glottis, Laryngoscopy, Sore throat

INTRODUCTION

Packing the pharynx to secure a sealed airway and prevent the aspiration of blood is a common practice in head and neck surgeries performed under general anaesthesia [1]. This practice inevitably involves laryngoscopy and the use of Magill's forceps to place the pack in the oral cavity, initiating a second wave of haemodynamic stress response similar to that which occurs after laryngoscopy and endotracheal intubation. The role of video laryngoscopes in airway management, especially in difficult cases, is well established compared to conventional laryngoscopy [1,2]. While many studies have assessed the efficacy of video laryngoscopy for intubation, none have evaluated its utility for throat packing [3-5]. Although research has been conducted on prevention of POST due to throat pack retention and the effects of different types of packing, few studies have examined the anaesthesiologist's technique of packing [1]. Nevertheless, nowadays, the video laryngoscope is being considered as the primary airway device in various scenarios. In such situations, it becomes crucial for the same video laryngoscope used for intubation to be employed for the nasopharyngeal packing that follows, particularly in head and neck surgeries [6].

The authors hypothesised that the use of a non-channeled BPL™ video laryngoscope [Table/Fig-1] would be an equivalent method for throat packing compared to conventional Macintosh laryngoscope-guided throat packing. Here, the clinicians designed a non-inferiority randomised controlled study to assess this, with the primary objective being the TTTP. Secondary objectives include evaluating the ease of throat packing, haemodynamic stress response, and POST.

[Table/Fig-1]: BPL Non-channelled Video laryngoscope.

MATERIALS AND METHODS

After obtaining approval from the institutional ethics committee (KIMS: ETHICS: COM: 299:2021-22) and written informed consent from patients, the authors conducted a two-arm, randomised, non-inferiority, single-blinded study between November 2021 and January 2023 at Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India. The study adhered to ethical standards and followed the Helsinki Declaration of 1975, revised in 2000.

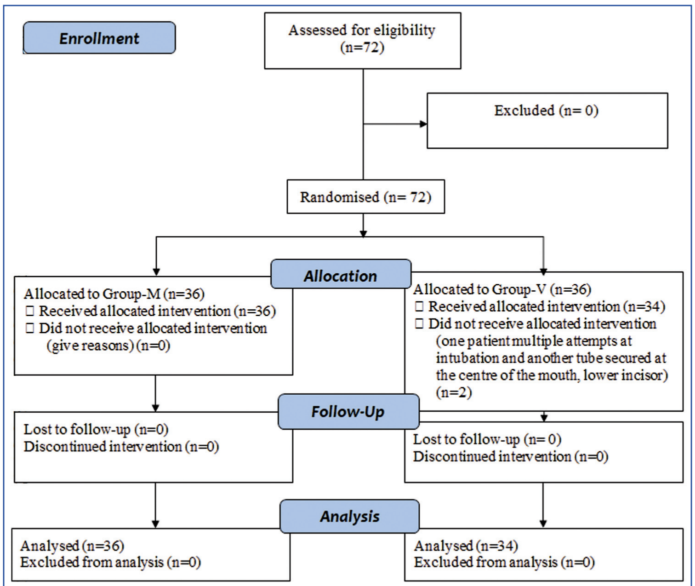
Inclusion criteria: Those consecutive adult patients aged 18 years and above undergoing elective head and neck surgeries requiring throat packing, such as endoscopic nasal surgeries, maxillary and mandibular surgeries, etc.

Exclusion criteria: Patients classified as American Society of Anesthesiologists (ASA) Grade IV and above, as well as those requiring nasal intubation, were excluded. The El Ganzouri risk index was evaluated in all recruited patients, and individuals with a difficult airway and an El Ganzouri risk index of >6 were excluded [7]. The sample size for the present non-inferiority study was determined with TTTP as the primary endpoint.

Sample size calculation: Based on a pilot study conducted at the study institution, with a non-inferiority limit of ten seconds, an anticipated standard deviation of 14 seconds, a one-sided type I error of 2.5%, and 80% power, the sample size was calculated to be 32 subjects in each group. Accounting for a 10% dropout rate, a final sample size of 36 subjects was considered in each group.

Procedure

The patients were blinded to the group allocation. The demographic data collected included age, gender, weight, and type of surgery. Following a thorough pre-anaesthetic evaluation, patients were instructed to fast for eight hours before surgery. Anxiolytic and antacid prophylaxis were administered in the form of a 0.25 mg tablet of alprazolam and a 40 mg injection of pantoprazole on the night before surgery. An intravenous injection of 40 mg Pantoprazole was repeated on the morning of the surgery. Randomisation was conducted using computer-generated random numbers [Table/Fig-2]. The numerical allocation of patients was sealed in an opaque envelope, which was opened when the patient was transferred to the operating theatre, revealing the allocated group for the patient.



[Table/Fig-2]: CONSORT flow diagram.

In the operating theatre, patients were monitored using an electrocardiogram, non-invasive blood pressure monitoring, pulse oximetry, and end-tidal capnography. Patients received pre-medication with an intravenous injection of glycopyrrolate 0.004 mg/kg, midazolam 0.05 mg/kg, and fentanyl 2 μg/kg. Five minutes later, patients were induced with intravenous injections of propofol 2 mg/kg and vecuronium 0.1 mg/kg. Subsequently, all patients were orally intubated with an appropriate-sized Endotracheal Tube (ETT) using a Macintosh laryngoscope, with the cuff inflated and connected to the anaesthesia machine, securing the ETT at the angle of the mouth. Anaesthesia was maintained with a 50% mixture of oxygen and nitrous oxide, along with 1-2% sevoflurane. Once a satisfactory minimum alveolar concentration of 1.3 was achieved, throat packing was initiated. Baseline Heart Rate (HR) and blood pressure (Systolic, Diastolic, and Mean BP-SBP, DBP, MAP) readings were recorded at this time as P1.

In the study, Group-M patients (n=36), the control group, were packed with a pre-defined size of 150 cm saline-soaked ribbon gauze around the ETT, ensuring complete sealing upto the anterior pillars of the tonsils using an appropriate size Macintosh laryngoscope and Magill's forceps. The proximal end was left exposed with a label indicating 'throat pack in.' Similarly, Group-V patients (n=36) were packed using a video laryngoscope with an appropriate blade size and Magill's forceps. The throat packing in both groups was performed by a single experienced anaesthesiologist proficient in using both scopes and having over a year of experience with the video laryngoscope. Assistance was only sought when necessary. The TTTP was recorded from the insertion of the blade through the packing process until the complete removal of the blade. Haemodynamic readings were taken immediately after throat packing as P2. The ease of insertion of throat packing was assessed by the performing anaesthesiologist using a Likert scale, where

0- Indicated smooth insertion without manoeuvering or assistance,

1- Indicated smooth insertion with mild manoeuvering and no assistance,

2- Indicated not smooth insertion with major manoeuvering but no assistance needed,

3- Indicated rough insertion requiring both manoeuvering and assistance.

4- Indicated unable to pack.

All parameters were documented by an Operating Theatre (OT) anaesthesia technician unaware of the study design.

After the surgery was completed, the throat pack was removed, and any complications such as injuries to the palate, pharynx, or tonsillar pillar were assessed. The patient was reversed with an intravenous injection of neostigmine 0.05 mg/kg and glycopyrrolate 0.008 mg/kg and extubated once all extubation criteria were met. Patients were followed-up for six hours postoperatively to monitor for any complications, especially POST. POST was graded as follows:

1 None if there was no throat pain or discomfort,

2 Mild if symptoms of throat irritation were present,

3 Moderate if mild throat pain and irritation were present,

4 Severe if there was throat pain with difficulty in swallowing.

STATISTICAL ANALYSIS

The statistical analysis was conducted using R software (version 3.1) for Windows [8]. Continuous variables were summarised as Mean ± standard deviation, while categorical variables were presented as frequencies and proportions. The authors hypothesised that videolaryngoscope-assisted throat packing was not inferior to Macintosh-assisted throat packing. Therefore, a non-inferiority margin (Δ) for TTTP was set at 10 seconds (Δ=-10) in this study (HO: Mean TTTP difference ≥ -10 sec, HA: Mean TTTP difference < -10 sec, Mean TTTP difference=Group-M-Group-V). A one-sided t-test was used to determine the difference between the groups. The haemodynamic stress values were not normally distributed; hence, the difference between the groups for changes in HR and BP was analysed using the non-parametric Mann-Whitney test. The level of significance was set at <0.05.

RESULTS

A total of 72 patients were recruited for the study, with 36 subjects in each group. Two patients were excluded from Group-V due to protocol violations. One patient was excluded because intubation was found to be difficult despite multiple attempts, and another patient was excluded because the tube needed to be secured in the center at the lower lip as desired by the surgeons.

The demographic variables were comparable in both groups. The mean age of patients in Group-M was 37.39 years, and in Group-V, it was 33.65 years, with mean weights of 60.89 kg and 56.32 kg, respectively. 44.28% of the patients underwent septoplasty [Table/Fig-3]. The majority of patients were in ASA class 1 and had an El Ganzouri Risk Index score of 0 or 1. Blade size 4 was used in four subjects in Group-M [Table/Fig-4].

Demographic variable		Group-M (n=36)	Group-V (n=34)
Age (years) (mean±standard deviation)		37.39±13.49	33.65±13.37
Weight (kg) (mean±standard deviation)		60.89±13.57	56.32±11.06
Gender	Female	11 (30.6%)	11 (32.4%)
	Male	25 (69.4%)	23 (67.6%)
Surgeries done	70		
Septoplasty	31 (44.28%)		
Functional Endoscopic Sinus Surgery (FESS)	18 (25.72%)		
Endonasal Dacrocystorhinostomy	3 (4.28%)		
Oral maxillofacial trauma surgery	9 (12.85%)		
Medial maxillectomy	2 (2.8%)		
Nasal endoscopy	2 (2.8%)		
Closed reduction of nasal bone	2 (2.8%)		
Miscellaneous	3 (4.28%)		

[Table/Fig-3]: Demographic variables and type of surgery.
Group-M: Oropharngeal packing done with Macintosh Laryngoscope; Group-V: Oropharyngeal packing done with video laryngoscope

		Group-M (N=36)	Group-V (Total N=34)
ASA physical status class* N (%)	ASA 1	27 (75%)	26 (76.5%)
	ASA 2	6 (16.7%)	6 (17.6%)
	ASA 3	3 (8.3%)	2 (5.9%)
Blade size N (%)	3	32 (88.9%)	34 (100%)
	4	4 (11.1%)	0 (0%)
EGRI# score N (%)	0	11 (30.6%)	12 (35.3%)
	1	11 (30.6%)	14 (41.2%)
	2	4 (11.1%)	5 (14.7%)
	3	7 (19.4%)	2 (5.9%)
	4	1 (2.8%)	1 (2.9%)
	5	2 (5.6%)	0 (0%)

[Table/Fig-4]: ASA grading, EGRI score and Blade size used.
*ASA: American society of anesthesiologists; #EGRI: El Ganzouri risk index

The mean TTTP difference between Group-M and Group-V was -12.6 seconds, with the lower limit of the one-sided confidence interval being -20.6 seconds, indicating that Group-V exceeded the non-inferiority margin of -10 seconds. The null hypothesis was accepted with a p-value of 0.995; hence, Group-V was found to be inferior to Group-M [Table/Fig-5].

The mean HR at baseline was 85.07 and 94.12, and after throat packing, it was 87.8 and 96.32 beats per minute in Group-M and Group-V, respectively. The mean BP at baseline was 88.7 mmHg and 85.76 mmHg, and after throat packing, it was 86.15 mmHg and 85.68 mmHg in Group-M and Group-V, respectively. Both groups were comparable in terms of ease of throat packing, haemodynamics, and POST [Table/Fig-6]. 58.8% (20/34) of patients

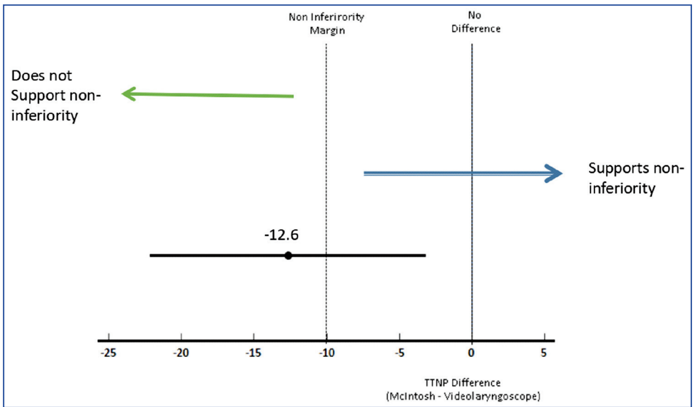
Group	TTTP* (seconds)		Mean difference	Lower 95% CI# for difference	One-sided t-test
	Mean±SD$	SE†			
M (n=36)	49.1±19	3.16	-12.6	-20.6	p=0.995
V (n=34)	61.7±20.8	3.57			

[Table/Fig-5]: Difference of Time Taken for Throat Packing (TTTP) between two groups.
*TTTP: Time taken for throat packing; #CI: Confidence interval; $SD: Standard deviation; †SE: Standard error

in Group-V and 41.66% (15/36) in Group-M experienced mild POST. 5.5% (2/34) in Group-V and 11.1% (4/36) in Group-M had moderate POST. Only one patient in Group-V had severe POST. No complications, including injuries to the tonsillar pillars, pharynx, or palate, were noted in either group. [Table/Fig-7] displays the TTTP difference between the Macintosh and video laryngoscope groups, with dashed lines at -10 seconds representing the non-inferiority margin.

		Group-M Median (IQR)	Group-V Median (IQR)	
Change in Heart Rate (HR)		2.5 (-1 - 6.5)	2 (-4 - 7)	p=0.846*
Change in systolic BP		0 (-2.01 - 6.5)	3 (-6 - 7)	p=0.972*
Change in diastolic BP		0 (-5 - 6)	0.5 (-4 - 6)	p=0.823*
Change in mean BP		1 (-6.5 - 5.5)	1 (-2 - 5)	p=0.934*
Ease of throat packing	0	16 (44.4%)	13 (38.2%)	p=0.166#
	1	16 (44.4%)	13 (38.2%)	
	2	1 (2.8%)	6 (17.6%)	
	3	1 (2.8%)	2 (5.9%)	
	4	2 (5.6%)	0 (0%)	
Post operative sore throat	Absent	17 (47.2%)	11 (32.4%)	p=0.204#
	Present	19 (52.8%)	23 (67.6%)	

[Table/Fig-6]: Comparison of haemodynamics, ease of throat packing and Postoperative Sore Throat (POST).
IQR: Interquartile range; BP: Blood pressure; *Mann-Whitney test used to compute p-value
#Chi-square test used to compute p-value



[Table/Fig-7]: Time Taken for Throat Packing (TTTP) difference between Macintosh versus video laryngoscope groups. The dashed lines at -10 seconds represents non-inferiority margin.

DISCUSSION

The video laryngoscope has become a ubiquitous device in the armamentarium of an anaesthesiologist. Its utility in managing a difficult airway is well known. Additionally, it plays a role in both diagnostic and therapeutic purposes and serves as an excellent tool for education and medicolegal recording [2]. Video laryngoscopes have been shown to improve glottis visualisation, facilitate intubation, reduce failed laryngoscopic attempts, and minimise airway trauma compared to direct laryngoscopes [9]. They are classified as channeled and non-channeled video laryngoscopes, and no single device among the plethora of video laryngoscopes has been found to be superior except for the C-MAC [2].

A multitude of studies have evaluated the role of the video laryngoscope for various indications such as placing nasogastric tubes, gastroscopes, endoscopes, etc., including rare indications like electromyographic tube placement for thyroid surgery [10-12]. However, it has not been studied for its utility for a common indication like throat packing for head and neck surgeries.

In fact, there is a lack of studies evaluating the effect of throat packing by direct laryngoscopy itself, even though it involves a second wave of haemodynamic stress response and can lead to morbidities such as oral injuries and POST. Karmarkar AA et al., studied the 'flange slide packing technique' of throat packing using a Macintosh laryngoscope as an alternative to the conventional technique of throat packing and observed an early and smoother placement of the throat pack and a lower incidence of POST and haemodynamic stress response [1].

Nevertheless, inadequate consensus on who should pack and when to pack the throat, removal issues, and problems due to failure to remove the pack were noted during the literature review. Therefore, the authors planned and conducted a non-inferiority design study comparing BPL™ video laryngoscope versus a laryngoscope in patients requiring throat packing. The BPL™ video laryngoscope is a portable, compact, and lightweight laryngoscope with disposable blades, 180-degree screen rotation, along with vertical movements for enhanced clinical assistance [Table/Fig-1]. The authors chose the BPL video laryngoscope because it was easy to use, cost-effective with disposable blades. The non-inferiority study design was selected as it is ideal for comparing two different interventions. The essence of this study design is the non-inferiority margin, which was pre-defined as 10 seconds in the present study [13,14]. Another advantage of a non-inferiority trial is the absence of a 'negative' result [13].

Throat packing is routinely performed in 30-70% of routine oral surgeries [15]. In the present study, it was mainly done for Ear, Nose, Throat (ENT) surgeries such as septoplasties and nasal endoscopic surgeries. Tonsillectomies, even though they required throat packing, were excluded due to the variability of ETT placement, such as nasal intubation or south pole ETT placement.

The mean TTTP with the use of the video laryngoscope was found to be inferior compared to direct laryngoscopy. This could be because the operator needs to change focus to pick-up and guide the throat pack with the Magill's forceps with each thrust. Many earlier studies have also noted that even though the video laryngoscope provides an excellent view of the glottis, it does not necessarily result in reduced intubation time [2,6]. Gupta A et al., state that the technique of throat packing has been a skill passed down through teaching, and there is no available evidence to indicate which method is superior. However, they mention that 66.2% used direct laryngoscopy and 21.8% used a video laryngoscope in their nationwide survey [15].

The ease of throat packing was similar in both groups, suggesting that the blade used was not the determining factor of the superiority of any particular method. The changes in mean HR and MAP in both groups were comparable. No significant changes were observed in the haemodynamic variables in the intra group analysis. Although throat packing does involve a stress response, the MAC value of 1.3 in the present study ensured that it did not occur.

POST is a well known occurrence following ETT insertion, and the incidence is higher if associated with female gender, mucosal injury, presence of a nasogastric tube, increased cuff pressure, prolonged duration of anaesthesia, and throat packing [1,16]. In the present study, 67.6% in the video laryngoscope group and 52.8% in the Macintosh group developed POST, but the difference was not significant, suggesting that the type of blade is not a factor in causing POST.

Limitation(s)

There were three limitations of the study that the authors noted during its conduct. The first limitation is the heterogeneous group of patients where the tube placement might vary from the right or left angle of the mouth. This is important because the Macintosh blade was inserted with an acute angulation towards the left of the mouth, while the insertion of the video laryngoscope was through the center of the mouth. Secondly, the secondary outcomes, such as ease of insertion, stress response, and POST, were not adequately powered, and therefore, further studies are needed for validation. Thirdly, the increase in TTTP in the video laryngoscope group did not translate into any disadvantage, such as haemodynamic stress response, in the present study. Further studies with a larger sample size and adequate power for the same can be conducted to analyse this effect.

CONCLUSION(S)

Although video laryngoscopy has been used as an excellent adjunct to intubation, it has not been utilised for throat packing. We hypothesised that videolaryngoscopy can serve as an alternative means to Macintosh guidance for throat packing. It is equivocal with respect to ease of packing, the stress response caused, and the incidence of POST. However, video laryngoscopy-assisted throat packing entails a longer duration to perform compared to Macintosh-guided throat packing.

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PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Anaesthesiology, Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India.
2. Professor, Department of Anaesthesiology, Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India.
3. Assistant Professor, Department of Anaesthesiology, Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India.
4. Assistant Professor, Department of Anaesthesiology, Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India.
5. Assistant Professor, Department of Community Medicine, Karnataka Institute of Medical Sciences, Hubballi, Karnataka, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Milon Vasant Mitragotri,
Assistant Professor, Department of Anaesthesiology, Karnataka Institute of Medical Sciences, Hubli-580021, Karnataka, India.
E-mail: milon.mitragotri4@gmail.com

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