Original Article

To compare the efficacy of the between-the-fingers grip with the conventional pen-holding grip to hold an endotracheal tube for orotracheal intubation: A randomised controlled trial

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ABSTRACT

Background and Aims: Correctly holding the endotracheal tube (ETT) is essential for successful tracheal intubation. The study's primary objective was to compare the between-the-fingers grip with the conventional pen-holding grip regarding the number of attempts required for orotracheal intubation and usage of external aids. **Methods:** Three hundred patients undergoing elective surgeries under general anaesthesia were randomised according to the method to hold the ETT to Group C (conventional grip) and Group M (modified, between-the-fingers grip) during oro-tracheal intubation. A designated anaesthetist blinded to the groups performed laryngoscopy in all the patients, and difficult Cormack-Lehane grade 3b and 4 (n = 24) were excluded. Then, the group was revealed to the anaesthetist, and intubation was done accordingly; the number of attempts, use of backward upward rightward pressure (BURP), and time taken were noted. The sample size was estimated using the software G*Power version 3.1.9.2. Statistical Package for Social Sciences, version 23 (SPSS-23, IBM, Chicago, USA) was used for data analysis. **Results:** Single-attempt intubation was comparable between the groups (99.3% versus 97.2%, $P = 0.197$). In contrast, the external assistance as BURP (0.75% versus 6.99%, $P = 0.009$) and the time taken for intubation ($P = 0.008$) were reduced in group M significantly. **Conclusion:** The between-the-fingers grip seems as effective as the standard grip to hold the ETT during intubation. However, it proved to be better as it can reduce the requirement for external assistance in BURP.

Keywords: Endotracheal intubation, endotracheal tube, general anaesthesia, glottis, grip, laryngoscopy

INTRODUCTION

Airway management is the cornerstone of anaesthetic practice. Various methods of tracheal intubation described in the literature include blind intubation, digital intubation, via direct laryngoscopy, through an intubating supraglottic device, and flexible fibreoptic laryngoscopy.[1-5] There is no evidence of the best technique for holding the endotracheal tube (ETT) to facilitate orotracheal intubation.

A different grip to hold the ETT was described over two decades ago.[6] This modified grip allowed the operator to change the curvature of the ETT as it neared the glottic opening in a dynamic fashion during laryngoscopy; thus, the tip can be manoeuvred anteriorly while aligning with it. It was claimed to provide better control and less external assistance use

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during ETI than the conventional method of holding the ETT [Figure 1].

Therefore, this trial aimed to compare the success rate of the modified grip with the standard grip with the primary objective of comparing the number of attempts and the comparison of the requirement of external assistance in the form of the backward upward rightward pressure manoeuvre (BURP) to perform endotracheal intubation (ETI). The secondary objectives were to compare the time taken for ETI for each grip and the haemodynamic parameters (heart rate (HR) and mean arterial pressure (MAP)) in the two groups.

METHODS

This is a randomised, interventional single-centre study. After clearance from the institutional ethics committee (vide approval number IEC Code 2021-9-MD-118, dated 23 January 2021), the trial was registered as the 'BETI trial' (Between the fingers grip to hold ETT for Intubation) on the Clinical Trials Registry-India (vide registration number REF/2021/02/040654, accessible at www.ctri.nic.in/). The study was carried out according to the principles of the Declaration of Helsinki (2013) and good clinical practice. After obtaining written and informed consent for participation in this study and use of their data for research and educational purposes, the study was conducted on patients between 18 and 60 years who were posted for elective surgeries under general anaesthesia (GA) with ETI at a tertiary care centre. The recruitment of patients was from 1 May 2021 till 1 September 2022. The primary inclusion criteria to participate were patients with Mallampati grades (MPG) 1, 2, and 3[7] and Cormack-Lehane (CL) grades 1, 2a, 2b, and 3a on laryngoscopy.[8] The exclusion criteria were refusal to participate in the study, patients with an anticipated difficult airway, history of difficult airway in previous documents, head and neck pathology, and haemodynamic instability.

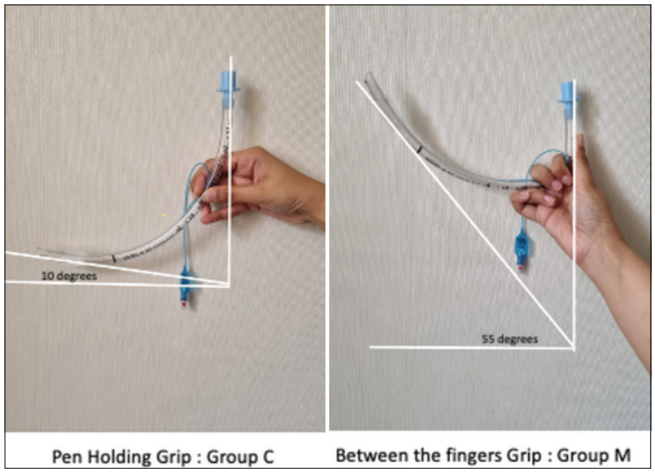

Figure 1: Endotracheal tube curvature in the pen-holding grip and the between-the-fingers grip

The patients were explained the study protocol, and once they understood the procedure and gave informed written consent for inclusion in the study, they were randomised to Group M (modified, between-the-fingers grip) or Group C (conventional pen-holding grip) according to the computer-generated randomisation table [Figure 2].

The patient was wheeled in, and the monitors were attached in the operation room; peripheral intravenous access was taken, and the left radial arterial line (indicated for surgery) was inserted with full aseptic precautions under local anaesthesia for beat-to-beat blood pressure monitoring. The choice of ETT was polyvinyl chloride (PVC), 7.5-mm internal diameter for adult women and 8.5-mm internal diameter for adult men (Smiths Medical Portex, Smiths Medical ASD, Inc. Minneapolis, USA). Anaesthesia was induced with intravenous (IV) fentanyl (1–2.5 μg/kg), midazolam (0.005–0.01 mg/kg), and etomidate (0.2–0.6 mg/kg) combination along with 100% oxygen with a mask. IV vecuronium (0.08–0.1 mg/kg) was used for neuromuscular blockade for ETI. After 3 minutes of bag-and-mask ventilation with the patient in the sniffing position, a single anaesthesiologist (with more than ten years of experience) performed the direct laryngoscopy and intubation. CL grading after laryngoscopy was assessed for inclusion in the study. Patients with CL grades 3b and 4 were announced and excluded. After that, as per group allocation, the grip for holding ETT was decided, and orotracheal intubation was done. Another anaesthesiologist (with more than five years of experience) applied the BURP manoeuvre whenever needed. A trained technician (with ten years of experience) noted the time required for the orotracheal intubation [defined as the time from insertion of the tip of the ETT between the open lips till the first end-tidal carbon dioxide ($EtCO_2$) upstroke on the monitor] in all the patients throughout the study. After intubation, the circuit was connected to the ventilator and surgery was started. After completion of the surgery, the patient was shifted to the postoperative area for further care until discharge, as per our hospital protocol.

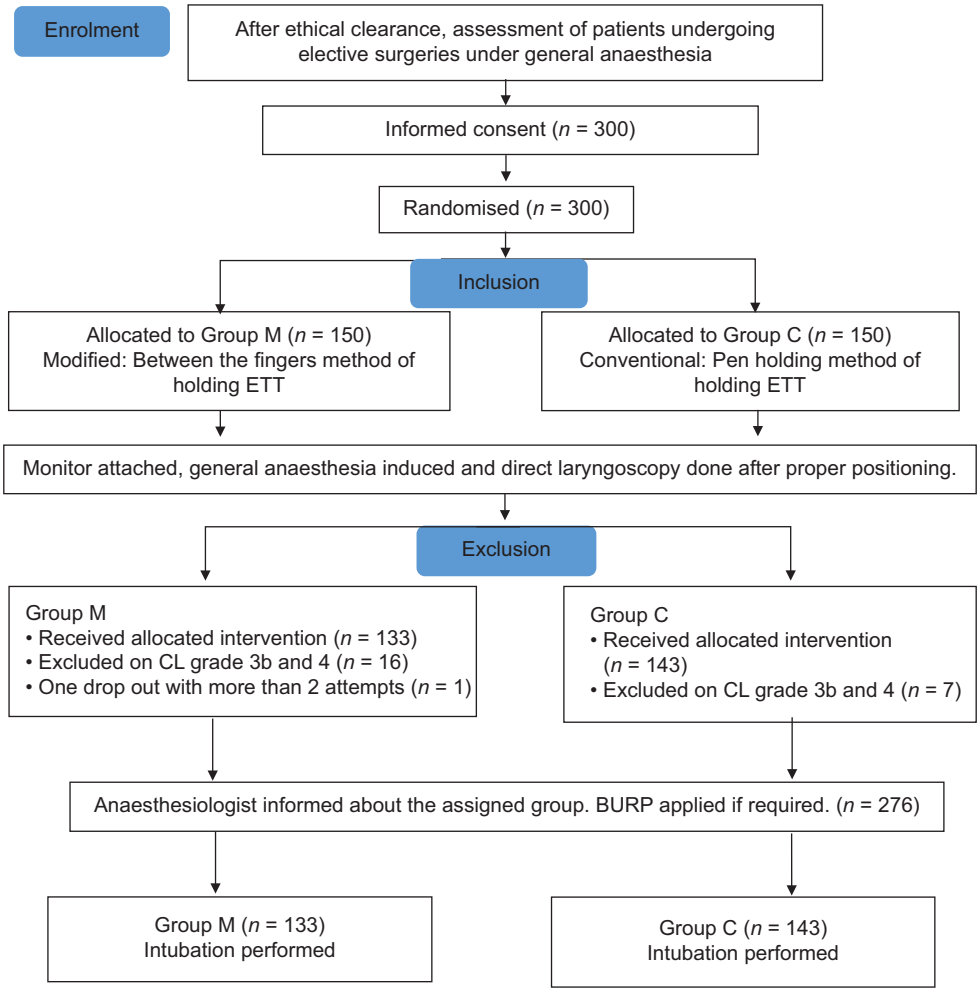

Figure 2: Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the flow of participants. Group M: Modified group, Group C: Conventional group, OT: Operation Theatre, CL grade: Cormack-Lehane grade, ETT: Endotracheal tube, BURP: backward, upward, rightward pressure, ASA: American Society of Anesthesiologists physical status, n= number of patients

As primary outcome measures, the number of attempts (one or two) and any external assistance required during the procedure in the form of BURP were documented. If the attempts were more than two or any use of stylet or bougie during intubation, then that patient's data were excluded from the statistical analysis. The secondary outcome measures included the time required for the completion of tracheal intubation by either of the two methods and change in HR and MAP as haemodynamic parameters at assigned time points as baseline readings (before induction of anaesthesia, at the time of introduction of the ETT tip into the mouth, and at the time of appearance of the 1st $EtCO_2$ upstroke on the monitor). These data were collected from the electronic charting and data management system (Innovian® © Drägerwerk AG and Co. KGaA, 2023) used with the anaesthesia workstation (Primus Drägerwerk AG and Co. KGaA) at the mentioned time points.

Even after proper selection based on various classifications of airway difficulty, the success rate of unaided single-attempt ETI is less than 100%. In a trial of intubation in an emergency area where there may have been a lack of appropriate aids and trained personnel to help with the ETI, the success rate was only 70%.[9] Therefore, considering a difference of 15% in the success rate (in the first attempt between the modified group and standard control group, where the assumed success rate is up to 85% and 70%, respectively) at a minimum two-sided 95% confidence interval (CI) and 80% power of the study, the required sample size in each group (1:1 ratio) was 121. The sample size was estimated using the software G*Power version 3.1.9.2. After accounting for the possible exclusions on the operating table after laryngoscopy based on their CL grade, 300 patients were randomised between the two groups using the computer-generated block randomisation method.

Statistical Package for Social Sciences, version 23 (SPSS-23, IBM, Chicago, USA) was used for data analysis. Data of the continuous variables, such as age, height, weight, HR, MAP, and time taken, are presented as mean [standard deviation (SD)], while categorical variables, such as airway variables, number of attempts, requirement of BURP, are presented as frequency (percentage). An independent *t*-test was used to compare the means between the two groups. The Chi-square or Fisher exact test (when in any cell, the expected count was <5) was used to compare the proportions between the two study groups. A 95% CI was calculated for the proportions and the mean of the measurements. The effect size was calculated for the mean differences by using the formula, mean difference/pooled standard deviation, whereas, for the proportions, the absolute difference in % was used. The degree of freedom (DF) was calculated for independent samples *t*-test, whereas for the Chi-square test/Fischer exact test, was calculated using the formula (Number of rows − 1) × (number of columns = 1). A *P* value of <0.05 was considered statistically significant.

RESULTS

A total of 276 patients completed the study, and in the final analysis, 143 patients in Group C and 133 in Group M were included. The number of attempts during ETI of more than two and the requirement of shape-changing aids such as stylet and bougie resulted in one dropout (CL grade 4), and that patient was also not included. The demographic distribution of the study patients that is, age, sex, weight, height, body mass index (BMI), and airway variables, that is, mouth opening, Mallampatti grading, neck movement, temporomandibular distance, and dentition, were comparable between the two study groups ($P > 0.05$) [Table 1]. There were 49.6% and 56.6% patients with CL grade 1 and 8.3% and 10.5% with CL grade 3 in Group M and Group C, respectively ($P > 0.05$) [Table 1]. The number of patients with a single attempt for intubation was 97.2% versus 99.3% in Group C and Group M, respectively ($P = 0.197$). The requirement of assistance, in the form of BURP, was one in 133 in Group M and 10 in 143 in Group C (0.75% versus 6.99%) ($P = 0.008$) [Table 2]. Time taken for tracheal intubation was less in Group M than in Group C ($P = 0.009$) [Table 2]. The haemodynamic parameters, including HR and MAP, were compared using an independent *t*-test, and results were statistically comparable in both groups ($P > 0.05$) [Table 3]. The patients in both groups who did not require BURP during intubation were separately compared for the mean (SD) time taken, 12.72 (4.74) in Group M and 13.89 (4.44) in Group C ($P = 0.038$) [Table 3].

DISCUSSION

We observed that the between-the-finger grip is as good as the standard grip, where the number of attempts required for successful intubation remained the same. It seems better that less external assistance is needed and less time is necessary to accomplish the ETI. The patients remained haemodynamically stable, where the HR and MAP remained statistically similar in whatever grip was used.

The changed grip works uniquely with the fingers and the thumb, each playing a crucial role.[6] The modified grip allows the operator to change the curvature of the ETT as it nears the glottic opening dynamically and align it on the go. This is possible because the ring and the little finger are placed at the lowest, where the ETT rests on them, making this point the fulcrum. The thumb on top and the index and middle fingers in the middle surround the tube so that when pressed, the counter forces manoeuvre the ETT tip upwards and forwards. The tip can be manoeuvred forward and anteriorly during intubation according to the glottic opening seen during laryngoscopy, thus providing better control and alignment than fixed curvature in the conventional method.

This method has shown that external assistance in the form of BURP is less needed than the standard technique of ETI. Direct laryngoscopy with a Macintosh blade requires the blade to enter the oral cavity from the right side and sweep the tongue and the glottis to the left, upwards, and caudally. This procedure might result in a partial view of the glottis or an inability to align the ETT to the glottic opening.[10] The external laryngeal manipulation countering this action by applying BURP results in better conditions for ETI.[4]

The use of BURP requires a second assistant, who is guided by the anaesthesiologist performing the laryngoscopy. This assistant has no visualisation of the inside of the oral cavity and is only guided by verbal cues to change and align the glottis with the manoeuvre, thus causing unnecessary delay in the visualisation. It also requires understanding how to apply proper external pressure so that further deterioration in the view does not occur. In the between-the-fingers

Table 1: Demographic and airway variables

Variables	Group M (*n*=133)	Group C (*n*=143)
Age (years)	39.85 (13.64)	41.45 (12.9)
Gender (male)	72 (54.1%)	85 (59.4%)
Height (cm)	162.13 (6.45)	162.66 (6.34)
Weight (kg)	60.48 (8.25)	61.32 (8.07)
Body Mass Index (Kg/m^2)	22.97 (2.53)	23.17 (2.73)
Mouth opening (>3 Fingers)	133 (100%)	143 (100%)
Neck movement (adequate extension and flexion)	133 (100%)	143 (100%)
Thyromental distance (>6 cm)	133 (100%)	143 (100%)
Dentition (Adequate)	131 (99.3%)	143 (100%)
Mallampatti Grading 1/2/3	41 (30.8%)/85 (63.9%)/7 (5.3%)	45 (31.5%)/90 (62.9%)/8 (5.6%)
Cormack-Lehane Grade 1/2a/3a/3b	66 (49.6%)/35 (26.3%)/21 (15.8%)/11 (8.3%)	81 (56.6%)/36 (25.2%)/11 (7.7%)/15 (10.5%)

Data expressed as mean (standard deviation) or numbers (percentages). Group C: Conventional group, Group M: Modified group. DF=Degree of freedom, n: number of patients

Table 2: Haemodynamic changes – heart rate and mean arterial pressure

Variables	Group M (*n*=133)	Group C (*n*=143)	Effect size	DF	*P*
HR at baseline	86 (20) (84,89)	83 (22) (80, 87)	0.140	274	0.298
HR at the insertion of the ETT into the mouth	89 (21) (85,93)	89 (24) (85,93)	0.010	274	0.931
HR at 1st $EtCO_2$ read	91 (22) (87,94)	94 (25) (90,98)	0.137	274	0.258
MAP at baseline	97 (18) (93,100)	97 (18) (94,100)	0.001	274	0.991
MAP at the insertion of the ETT into the mouth	82 (19) (79,85)	82 (21) (79,86)	0.028	274	0.813
MAP at 1st $EtCO_2$ read	89 (19) (86,92)	88 (21) (84,91)	0.052	274	0.669

Data expressed as mean (standard deviation) (95% confidence interval). HR: Heart Rate, MAP: Mean Arterial Pressure, ETT: Endotracheal Tube, $EtCO_2$: End-tidal carbon dioxide, Group C: Conventional group, Group M: Modified group. DF: Degree of freedom, n: number of patients

Table 3: Comparison of the two groups in terms of the number of attempts, requirement of BURP, and time taken for intubation

Variables	Group M (*n*=133)	Group C (*n*=143)	Effect size	DF	*P*
Number of patients with single-attempt intubation	132 (99.2%) [95%, 100%]	140 (97.9%) [94%, 99%]	1.3%	1	0.623
BURP required (number of patients)	1 (0.75%) [0.4%, 0.99%]	10 (6.99%) [3.61%, 12.81%]	6.24%	1	0.008
Time taken in all patients (s)	12.7 (4.7) (11.9, 13.6)	14.3 (4.9) (13.5, 15.1)	0.325	1	0.007
Time taken in patients without the requirement of BURP (s) [132, 133]	12.7 (4.7) (11.9, 13.5)	13.9 (4.4) (13.1, 14.6)	0.255	1	0.038

Data expressed as mean (standard deviation) (95% confidence interval) or number (%) [95% confidence interval). Group C: Conventional group, Group M: Modified group. DF: Degree of freedom, BURP: Backward, upward, rightward pressure, n: number of patients

grip, in this trial, it was conclusively found that the movement of the tip occurs in the direct vision of the person performing the intubation. Therefore, the requirement for external assistance may be reduced. This also becomes evident in the time taken, which was significantly less to complete the ETI with this new grip as the requirement for aids and their use was reduced. However, this new grip significantly reduces the time taken for ETI when even external assistance is not used, as the subset analysis of only patients where BURP was not used clearly showed.

The findings of this study have to be seen in light of certain limitations, the primary being a single-centre trial with a total of 276 patients in the adult population. Furthermore, being the first study evaluating this new grip, there was a lack of available literature to guide the sample size calculation. Another important aspect of this trial was avoiding observer bias, accomplished by assigning roles for different tasks throughout the study. The patients with anticipated difficult airways were excluded from our research, which can be further evaluated in future trials.

CONCLUSION

We conclude that the between-the-fingers grip proved to be an equally good method to hold the endotracheal tube for orotracheal intubation as compared to the standard method.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' Institution policy.

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Conflicts of interest

There are no conflicts of interest.

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