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Evaluation of Conventional Cuffed Polyvinyl Chloride (PVC) Tube for Intubation through Intubating Laryngeal Mask Airway (LMA)

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Abstract
The rationale of the study is to evaluate the feasibility of conventional cuffed polyvinyl chloride (PVC) endotracheal tube for intubation through intubating laryngeal mask airway. The design was a prospective, randomized study enrolling eighty patients of either sex, ASA grade I & II, MPG grade I & II posted for various elective surgeries under general anaesthesia. Two groups of patients were randomly selected to compare the clinical performance of conventional cuffed PVC with FTST for tracheal intubation through ILMA.Continuous variables were compared between 2 groups by performing un-paired t-test. Categorical variables were compared by using Pearson's chi-square test. For small numbers, Fisher's exact test was applied wherever applicable. Statistical software STATA version 13.1 was used for statistical analysis. Mean time required for insertion of ILMA in group I (FTST) was comparable statistically with group II (PVC). Incidence of successful intubation in first attempt was more in FTST group as compared to PVC group but it was not statistically significant. PVC group more frequently required maneuvers for successful intubation than FTST group. However overall success rate of intubation and time required for intubation in both the groups was comparable. The laryngopharyngeal complications observed in the present study were comparable in both the groups. The present study concluded that conventionally used cuffed PVC tube can be a feasible alternative to routinely used FTST with comparable success rate, time required for insertion and laryngopharyngeal complications.

INTRODUCTION

Tracheal intubation is considered to be the 'gold standard' for airway management during administration of general anaesthesia and critical care settings to provide positive pressure ventilation. In case of difficult intubation it may not be possible to visualize the cords after laryngoscopy [1]. In spite of a plethora of intubating aids and difficult airway algorithms[2] failed or difficult tracheal intubation is the most important cause of mortality and morbidity in anaesthesia.[3]

The standard laryngeal mask airway, first described in 1985 by Brain,[4] has been shown to play an important role in rescue ventilation[5] in difficult airway management but its role in facilitating tracheal intubation is limited. Intubating laryngeal mask airway (ILMA) is an

airway device which can also be useful as superior conduit for blind or fiberoptically guided tracheal intubation in difficult airway cases.[6]

A specially designed wire-reinforced silicone (WRS) endotracheal tube (ETT) is advocated for intubation through the LMA-Fastrach ™.[7] The unique characteristics of this tube are the straight alignment, wire reinforcement, and presence of a conical Touhy-like tip, which is less traumatic than conventional ETT. However, the low volume, high-pressure cuff of this tube makes it less suitable for prolonged use. Also, it is very expensive and not so easily available. Moreover, wire reinforcement may be disadvantageous, as ventilation may be hampered due to distortion of the lumen if the patient bites on the tube.[6], [8]

A polyvinyl chloride conventional tracheal tube is disposable, less expensive and readily available. Successful tracheal intubation via the ILMA using the conventional PVC tube has been reported by many authors.[7]-[14] However, there are certain disadvantages associated with their use like decreased chances of entry into the glottis and airway trauma, due to its relative stiffness, partly which can be rectified by warming the tube.[15] Despite these concerns, the conventional PVC tube has been used successfully for tracheal intubation through the ILMA .[8],[16]-[18]

We deliberate this study to evaluate the use of conventional PVC cuffed endotracheal tube for intubation through intubating LMA as an alternative to silicon FTST tube. The present study was designed to compare the ease of insertion through the ILMA of LMA-Fastrach™ ETT with the conventional PVC tube to evaluate the feasibility of PVC tube through the ILMA. The ease of insertion was evaluated by comparing the number of attempts, time taken and maneuvers employed to accomplish tracheal intubation using conventional PVC tubes versus LMA-Fastrach™ wire-reinforced silicone tubes(FTST). In the present study problems encountered during insertion, time required and associated laryngo-pharyngeal morbidity was studied.

MATERIALS & METHODS

This is a prospective, randomized comparative study carried out in the department of anesthesiology at Tertiary care hospital. Before starting the study ethical approval has been obtained from the Hospital Ethical Committee. The power of study is kept 90% with confidence interval 95% and α 0.05. The minimum sample size required for this is calculated to be 30 in each group. Pre-operative explaining of the procedure done and written consent taken. The present study included total 80 patients belonging to ASA grade I & II, MPG grade I & II of either sex with the age and weight between 20-60 years and 30-60 Kgs respectively. The patients were randomly divided using the sealed envelope technique into two groups according to the tube used for intubation through intubating LMA as-

Control Group (I): Specially designed FTST tube no 7/7.5 and

Study group (II): Conventional cuffed PVC tube no 7/7.5.

Patients are kept NBM for 6 hours prior to the operation. Exclusion criteria included- patient not NBM, Patient posted for emergency surgery, ASA grade III & IV, Patients with respiratory tract pathology (oropharynx & larynx), Mouth opening <3cms, Malampatti grade III & IV, Loose/Artificial dentures, Patients at risk of aspiration- Morbidly obese patients with H/O-Hiatus hernia, Esophageal reflux, Previous upper gastrointestinal tract surgery.

All patients are given oral diazepam 0.2 mg/kg, ranitidine 150 mg and metoclopramide 10 mg on previous night. In the operation theatre standard multipara monitor with electrocardiogram, NIBP and pulse-oximeter applied to the patient and baseline parameters like pulse rate, blood pressure and SPO_2 recorded. Intravenous infusion started with normal saline. After routine premedication with ranitidine 1 mg/kg, glycopyrrolate 4 µg/kg, metoclopramide 0.15 mg/kg and sedation with midazolam 1mg, pentazocine 0.5 mg/kg, pre-oxygenation done for 3 minutes in all the patients. Anesthesia induced with Propofol 2 mg/kg

intravenously (IV) and after confirming adequacy of ventilation on mask muscle relaxation facilitated with vecuronium 0.1 mg/kg. When patient is fully relaxed, with head in neutral position, an appropriate sized ILMA inserted with cuff deflated. Cuff inflated with air as per recommendations after insertion of ILMA. Proper placement of ILMA determined by chest inflation, auscultation of breath sounds, a square wave capnography and no oropharyngeal leak with peak airway pressures > 20 cm H_2O.

If any one of the criteria is not satisfactory, ILMA repositioned with either technique e.g. Chandy's maneuvre, removal and insertion or changing the size of ILMA. If ventilation continues to be a problem due to malpositioning of ILMA, those patients are excluded from the study and intubation done with conventional laryngoscopy.

Thereafter, according to group allotment either FTST or PVC tube selected for intubation and lubricated well with water soluble jelly. If PVC tube is to be used, it is softened by immersing it into sterile water bath (heated to 50^{o}C) for 1-2 minutes. While intubating with PVC tube it is passed into the ILMA with its inherent curve facing backwards. However in case of FTST it is ensured that the black vertical line on the tube is facing the handle of ILMA before insertion. Both the tubes inserted till 15cm depth and gently advanced into trachea without applying undue force. Cuff inflated and position of the tube confirmed by capnography and presence of bilateral breath sounds after connecting to the circuit. ILMA is then removed by standard described method using stabilizing rod.

All ILMA placement and intubation are performed by the same anaesthesiolgist having experience in ILMA placement. When intubation is not successful after two attempts with PVC tube, intubation is done either with FTST or with conventional laryngoscopy.

Ease of intubation is judged by- 1] Success rate of intubation.

2] No. of attempts required for successful intubation.

3] Maneuvers required for successful intubation.

4] Time required for intubation i.e. from disconnection of breathing circuit from ILMA till confirmation of tracheal tube placement.

5] Failure to intubate.

Any critical incidence such as accidental extubation or tube displacement, bronchospasm, SPO_2 <90% during the procedure are recorded. The incidence of trauma in successfully intubated patients as evidenced by blood on the tracheal tube or ILMA after removal noted. The post intubation laryngopharyngeal morbidity is assessed on verbal analog scale (0-10) and score >3 considered as positive.

Statistical Analysis:

All the observational data in the present study was subjected to statistical analysis. Continuous variables were compared between 2 groups by performing un-paired t-test. Categorical variables were compared by using Pearson's chi-square test. For small numbers, Fisher's exact test was applied wherever applicable. P<0.05 was considered as statistically significant. Statistical software STATA version 13.1 was used for statistical analysis.

RESULTS

Demographic data were comparable in both groups [Table 1]. Placement of the ILMA was successful in all patients (100% success rate) and there were no immediate adverse events. The number of attempts and maneuvers required for ILMA insertion in both the groups were shown in Table 2 and 3. Mean time required for insertion of ILMA in group I and group II were Found to be 35.15±10.56 and 35.05±9.16 respectively, which were comparable statistically (p>0.05).

The successful intubation in first and second attempt in group I patients 34 (89.47%) and 4 (10.53%) was comparable to 31 (83.78%) and 6 (16.22%) in group II patients, the difference was not statistically significant (p>0.05). Maneuvers required to accomplish successful endotracheal intubation was 21.05% in group I and 45.94% in

group II respectively (p<0.05). The overall success rate for FTST in the present study was 95% while that for PVC tube was 92.5% which was statistically not significant (p>0.05). The mean duration for endotracheal intubation through ILMA using specially designed FTST was observed to be 13.10 ±11.32 while that in PVC tube was 14.54 ±7.34, which was statistically comparable (p>0.05). Mean time required for ILMA removal in FTST group was 16.65 ± 5.55 and in PVC group was 17.56 ± 7.03, the difference was statistically comparable (p>0.05). Total time required for ILMA insertion to removal in FTST group was 210 ± 55.79 and that in PVC group was 198.64 ± 43.35, when compared it was found to be statistically not significant (p>0.05). Evidence of trauma was seen in13.16% of patients in group I and 18.92% of patients in group II & was comparable (p>0.05).

None of the patients from both the groups had esophageal intubation in the present study. In 2 (5%) patients of group I and 3 (7.5%) patients of group II intubation was not possible within 2 attempts irrespective of maneuver used and were excluded from the study. The laryngopharyngeal complications were minimal and found to be statistically not significant (p>0.05).

Table No. 1: Distribution of patients according to Age, Weight, Sex, ASA grading and Malampatti classification

Group	Age (yr)		Weight (Kg)		Sex (%)		ASA grading (%)		Malampatti classification (%)	
	Range	Mean ± SD	Range	Mean ± SD	Male	Female	Grade I	Grade II	Grade I	Grade II
Group I	21-57	39.15 ±9.25	35-60	51.07 ± 6.49	26 (65 %)	14 (35 %)	28 (70%)	12 (30%)	27 (67.5%)	13 (32.5%)
Group II	20-58	39.6 ± 10.83	40-60	51.67 ± 6.00	21 (52.5%)	19 (47.5%)	27 (67.5%)	13 (32.5%)	21 (52.5%)	19 (47.5%)
p-value	0.7530, NS		0.669 , NS		0.256, NS		0.809, NS		0.171, NS	

Both the groups were comparable statistically with respect to age, mean weight, sex, ASA grade and malampatti class. (p>0.05)

Table No. 2 Attempts required for ILMA insertion and ETT intubation

Attempts	ILMA INSERTION Number of patients (%)		ETT INTUBATION No. of patients (%)	
	Group I	Group II	Group I	Group II
1st attempt	30 (75%)	28 (70%)	34 (89.47%)	31 (83.78%)
2nd attempt	10 (25%)	12 (30%)	4 (10.53%)	6 (16.22%)
Failed	00	00	02 (5%)	03(7.5%)
Total	40 (100%)	40 (100%)	38 (100%)	37 (100%)
p-value	0.617, NS		0.516,NS	

The table shows number of attempts required for ILMA insertion and ETT intubation in both the groups which was not statistically significant. (p>0.05).

Table no 3: Maneuvers required for ILMA insertion and intubation

Maneuver	ILMA INSERTION Number of patients (%)		ETT INTUBATION Number of patients (%)	
	Group I	Group II	Group I	Group II
Required	15 (37.5%)	16 (40%)	8 (21.05)	17 (45.94%)
Not required	25 (62.5%)	24 (60%)	30 (78.95%)	20 (54.05%)
TOTAL	40 (100%)	40 (100%)	38 (100%)	37 (100%)
p-value	0.818,NS		0.022, S	

The table shows maneuvers required for successful ILMA insertion which was statistically comparable (p>0.05) and intubation which was statistically significant (p<0.05)

DISCUSSION

The standard technique of insertion of ILMA as described by Brain et al. (1997)[7] was followed in the present study as well as in other studies.[7],[9]

The mean time for insertion of ILMA in present study in group I and group II was 35.15±10.56 sec. and 35.05 ± 9.16 respectively, this finding correlates well with the observations of the Timmerman et al [19] who noted it to be 35.6 ± 80. Brain and colleagues[7] reported a 99.3% success rate in their preliminary clinical trial in 1997 when they have used silicone wire-reinforced tube for intubation through the ILMA. However, none of the subsequent studies could achieve the same success rate as Brain and colleagues (89–98%).

Success rate of intubation with FTST was 95% and with PVC was 92.5% in the present study which correlates with the findings of Pankaj Kundra et al[8], Megha U Sharma et al[17] and Veena R Shah et al[18]. Special designing of FTST and softening of PVC tube by adequate prewarming attributed for the success rate in present and all other studies. Also the technique of insertion using reverse curve technique helps to decrease the angle of emergence as close to silicon tube increasing the chances of successful intubation. However when compared the first and overall success rate of intubation with FTST was more than PVC tube clinically though not statistically significant ($p>0.05$).

Also the attempts and maneuvers required for successful intubation with PVC tube were significantly more than with FTST group in the present study as well as other studies[8,17,18] ($p<0.05$). Stiffness of PVC tube as well as more obtuse angle of emergence from LMA causing impringement of tip of tube against anterior part of larynx might have contributed for it.

The mean time required for intubation with FTST (13.10 ± 11.32) and PVC (14.54 ± 7.34) as well as the total time required for insertion of ILMA, intubation and removal of ILMA in FTST group (210 ± 55.79) and PVC group (198.64 ± 43.35) was statistically comparable ($p>0.05$) in the present study.

Learning curve in acquiring expertise and anatomical variations in individual patients can be the cause for failure rate of intubation i.e. 5% in FTST and 7.5% in PVC in the present study as well as other studies[8],[17],[18].

The overall incidence of trauma and post operative tracheal morbidity was minimal i.e. 13.16% & 10.53% in FTST group & 18.92% & 16.22% with PVC group in the present study and was comparable statistically ($p>0.05$) as observed by others[8],[17],[18].

The limitations of our study is that patient population consisted of patients with normal airway which might not apply to patients with difficult airway, lack of blinding during intra operative period, a good mask larynx relationship was ascertained only clinically and not with fiberscope.

CONCLUSION

We concluded that the conventionally used cuffed PVC tube can be a feasible alternative to routinely used FTST for insertion through ILMA with comparable success rate, time required for insertion and laryngopharyngeal complications. The study recommends the use of cuffed PVC tube for intubation through ILMA in patients with normal airway when FTST is not available.

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