Comparative Analysis of Peak Air Pressure and Oxygen Flow between Conventional and Modified Endotracheal Tube for Retromolar Intubation (PUNTUBE)- *An In Vitro* Study

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Abstract

Introduction: In conventional practice for retromolar intubation, endotracheal tube (ET) is bent. This leads to compression of the inner diameter of the tube which in turn reduces airflow. Furthermore, conventionally ETs are stabilised in position using inflated tracheal cuff. Elastic sticky tapes around the exit pose hindrance for surgical procedures on the face. Surgical manipulation and maxillomandibular fixation may lead to compression, damage or accidental extubation of ET. We have developed a modified ET dedicated to retromolar intubation with innovative means for tube stabilisation to solve these problems. **Materials and Methods:** To study the efficacy of the tube, a comparative *in vitro* study was done on mannequins. Null hypothesis of no change in air pressure and oxygen concentration in bent conventional ET versus modified ET was formulated. Comparison was done on the basis of the peak air pressure (PEP) and oxygen concentration, which was checked using air–gas monitor. **Results:** The mean PEP was found to be 24.29 psi with standard deviation (SD) of 9.54 in sequentially bent conventional tube. This was found to be only 10.35 psi with SD of 3.22 in modified ET. Oxygen delivery was found to be 3.96 L/min in bent conventional tube, which was 5.22 L/min in modified tube. Both the findings were statistically significant. **Discussion:** Modified retromolar tube (PUNTUBE) has been found to be efficient in maintaining low PEP while delivering more oxygen as compared to bent conventional tube. Novel mode of tube stabilisation in the form of PUNSTAB is an easy and effective way of tube stabilisation.

Keywords: Air pressure, airway, airway extubation, anaesthesia, endotracheal intubation

INTRODUCTION

For placement of endotracheal tube (ET), oral route is easier when compared to nasal route. Oral intubation does not irritate the nasal mucosa and is the immediate first choice in cases where nasal intubation is contraindicated. Nasal intubation has few contraindications involving nasal bone fracture, naso-orbito-ethmoid complex fractures, cerebrospinal fluid leak, nasal injuries, etc., Oropharyngeal passage is much wider as compared to nasal passage. This makes the oral intubation relatively easy with minimum trauma to nasopharyngeal soft tissues.^[1]

Option to bypass the oral passage is a sub-mental route of intubation, which imparts additional extraoral wound and post-operative scar. Hernandez Altemir first described an alternative for tracheostomy in 1986. The sub-mental route for

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endotracheal intubation consists of pulling the free end of an ET through a submental incision, after the usual orotracheal intubation has been performed. Risk of surgical damage to lingual nerve and submandibular gland duct adds to the post-operative morbidity.^[2] Maxillofacial surgeries require the manipulation of facial structures. Forces used for such

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manipulation vary as per degree of displacement and type of procedure performed. This manipulation may displace the oral ET.

Retromolar intubation provides an effective option to bypass the nasal passage. Although it is in use in contemporary practice for many years, no modifications in conventional design of the tube were done for its specific use. Conventional tube, when used for retromolar intubation, needs to be bent in transverse direction to adapt the tube in the retromolar region. This has a risk of kinking the tube which in turn reduces the lumen of the tube affecting the airflow.^[2] Kinking increases significantly when intermaxillary fixation is done due to reduction in the retromolar area. Furthermore, damage to the tube may occur due to heavy intermaxillary fixation forces or due to sharp cusps of adjacent teeth. Conventional tubes are stabilised in position using tracheal cuff inflation which will be pressed on tracheal walls avoiding any movement of the tube during the surgery.^[2] Furthermore, the tube is stabilised around the tube exit from the oral cavity using elastic stretchable tape. There is no additional stabilisation mode present in conventional practice. Conventional tubes rely solely on air pressure in the tracheal cuff for retention of the tube. If the tracheal cuff is breached, it can compromise the tube stabilisation which can lead to life-threatening complications.^[2]

Bending of the tube leads to compression of the lumen is well known. To confirm the impact of this on the airflow through

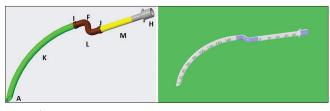


Figure 1: Diagrammatic representation of modified endotracheal tube for retromolar intubation (PUNTUBE). A: Bevel tip, K: part 1, L: part 2, M: part 3, I: connector 1, J: connector 2, F: bend in tube, H: adapter

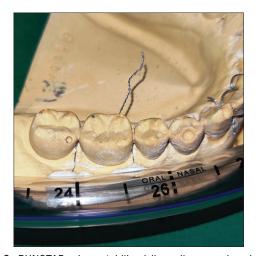


Figure 3: PUNSTAB wires stabilised lingually around molar tooth (representative image on plaster cast just for understanding concept)

the tube, and to quantify the level of airway compromise with respect to the magnitude of bending, we have designed this study. In order to overcome these limitations of retromolar intubation, we have modified the design of the conventional tube and inculcated PUNSTAB as an additional mode of tube stabilisation method, both of which are patented in India.

Study design

Ethical clearance for this *in vitro* study was taken from the institutional ethical committee with letter number KIMSDU/ IEC/06/2023 with protocol number 693/2022-23. *In vitro* design for this comparative study was adapted to check the effect of bending conventional ET sequentially. Before describing the study, brief description of the innovative new design [Figure 1] and non-cuffed, rigid prototype made up by fused deposition modelling technique which is 3-D printed for the *in vitro* study [Figure 2]. For *in vivo* use, the tube will be made in flexible polyvinyl chloride material.

Lateral curvature in the design

This lateral curvature is designed to match the distobuccal line angle of mandibular second molar. This adapts the tube well behind the last erupted molar. The level of this bend was adjusted at a distance of 12–14 cm from the outer end of the tube. This distance was decided just to exceed the distance between last erupted molar and oral commissure. Furthermore, this bend is kept at 16–18 cm away from bevel of the tube, which was decided based on marking on conventional tube during routine oral intubation and various sizes of the tube.

Ligature wires for oral stabilisation of tube

After placement of the tube, these wires are to be tied to the adjacent molar teeth [Figure 3]. The tube has three parts connected to each other with threaded connections for tight airproof connectors. The first part runs from tracheal bifurcation to the oral cavity (Part 1). The second part extends from the posterior part of the oral cavity to the buccal vestibule (Part 2).



Figure 2: PUNTUBE prototype (non-cuffed, rigid for in vitro study)



Figure 4: Mannequin model used for the study

The third part extends from the lateral side of molar teeth to the exterior of mouth (Part 3).

Part 2 can be rotated in horizontal direction as per the side of placement of the tube as per the choice of the operator. Different sizes of the tube will vary according to gender of patient and jaw size. This can be easily achieved by changing the length of Part 1 and Part 3 only. Part 2 can be uniformly used with changed Part 1 and Part 3 as per size required. Diameter of the tube can be set while manufacturing as per conventional tube diameters available in market during *in vivo* studies. During flexion and extension of the neck, the part of the ET tube to get affected is the part which extends into the trachea from the oropharynx. Considering the same, this part of the tube in this innovation (Part 1) is kept identical to conventional ET tubes. Thus, the effect of flexion-extension of the name will be same as conventional.

Intubation process

For *in vivo* use, standard intubation process for oral placement of ET tube is to be followed. After confirming bilateral synchronous air entry into lungs, tracheal cuff is inflated to secure the tube primarily. Then, the tube is shifted to either of the sides towards the retromolar region as per the choice of operator. After placing the intermediate part in the retromolar region, bilateral equal air entry into lungs will be rechecked. Then, the PUNSTAB wires are mobilised from walls of intermediate part of the tube. These wires will be passed around adjacent molar teeth and tied around the same by twisting on each other over the lingual aspect. Care should be taken to avoid damage to lingual soft tissues.

METHODOLOGY

The study was conducted in the Skill Lab of our institution. As this is an *in vitro* study, no human or animal participants were used. Equipment used were mannequin model for endotracheal intubation training manufactured by Simulaids [Figure 4], air–gas monitor, conventional ET and modified ET. The tube manufactured for this *in vitro* study was non-cuffed tube due to no need of cuff in simulation model. Peak air pressure (PEP) and mean oxygen flow (OF) per min were parameters which were evaluated in this study. Null hypothesis of no effect on tube bending over PEP and mean OF per min (L/min) was formulated. The two groups that were compared were the sequentially bent conventional tube versus modified tube for retromolar intubation. After placing the conventional tube and connecting the same with monitor, the tube was bent in the retromolar region by 10° sequentially. PEP and OF values were recorded and tabulated. Single operator was chosen to bend the tube and sequential blinded data collection was done on monitor. This was continued till 90° of the bend angle to match the bend angle of PUNTUBE. Five readings of PEP and OF were recorded on PUNTUBE. Mean of the readings was compared with the findings of conventional tube readings. All readings were tabulated and subjected to statistical analysis.

RESULTS

All analysis was done on Statistical Package for the Social Sciences (Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp) was used. Unpaired *t*-test was used as a test of significance. PEP was compared in comparison to the tube bend angle. In Group I, i.e., conventional tube, PEP ranged from 9 to 39 with mean of 24.29 with standard deviation (SD) of 9.54. Pressure increased gradually in direct relation to the tube bend angle. In Group II, i.e., modified tube, PEP was recorded as 10.35 with SD of 3.22. The difference was found to be statistically significant using unpaired *t*-test [Table 1].

In Group I, OF was found to be in the range of 1.1 L to 6 L with mean of 3.96 with SD of 1.36 L. OF decreases in direct proportion to that of bend angle. In Group II, OF was found to be 5.22 L with SD of 0.44. The difference was found to be statistically significant using unpaired *t*-test [Table 2].

DISCUSSION

Improper positioning of the patient may lead to intraoperative kinking of the oral endotracheal tube. Also the temperature changes during the surgery can also lead to the same.^[3] These temperature changes are more relevant in maxillofacial surgical procedures which generate heat like drilling or cutting the bone in proximity to the tube. At oral temperature, the ET softens and kinking occurs at astonishingly low angles. The kinking typically occurs where the cuff line exits, 18 cm from the tube's tip, a spot usually hidden in the oral cavity. The outer side of the ETT's

Table 1: Peak pressure of air when compared on the basis of tube bend angle									
Tube bend angle	Mean	SD	Mean difference	Unpaired t-test value	Р				
Group I-positive air pressure (conventional tube)	24.29	9.54	-13.94	5.71	0.001*				
Group II-positive air pressure (PUNTUBE)	10.35	3.22							

*P=0.001. SD: Standard deviation

Table 2: Oxygen flow when compared on the basis of tube bend angle									
Mean	SD	Mean difference	Unpaired t-test value	Р					
3.96	1.36	1.259	3.638	0.001*					
5.22	0.44								
	Mean 3.96	Mean SD 3.96 1.36	Mean SD Mean difference 3.96 1.36 1.259	MeanSDMean differenceUnpaired t-test value3.961.361.2593.638					

*P= 0.001. SD: Standard deviation

bend, usually marked by the manufacturer, should face nasally. Manufacturers should ideally consider changing the ETT's design, so that the cuff line exits the tube outside the oral cavity.^[3] Nishikawa and Fujita compared four methods of ET passage in simulated airways. They showed a need for improved techniques to enhance ET design for better local airflow in the human airways induced by artificial mechanical ventilation.^[4] According to the study, the pressure loss due to a bend is dependent on the ratio of the radius of curvature of the bend to the diameter of the pipe. They surmised that the discrepancies in pressure loss through the tubular part of tubes between measured and predicted values are mainly due to the sharp bend of the tubes, and that the pressure losses due to the bend increase in the preformed tubes with smaller diameter. In this study, the pressure losses through the slip joints constituted 20%-35% of the total pressure losses through uncompressed preformed tubes. These additional features in tube, such as sharp bends and slip joints, cause obvious increases in the pressure loss.^[5] According to Hagberg, wire ligature when used to secure the ET externally can deform the tube by compressing the inner diameter of the tube.^[6] Most common oral tube stabilising methods include tube fastener or adhesive tapes placed around the tube. They occupy facial structures hindering access to surgical field.^[7,8] Facial surgical procedures such as Weber-Fergusson incision, open sky approach for naso-orbito-ethmoidal complex fractures and Abbe-Estlander flap would not be possible with tapes occupying most of the perinasal and perioral regions. Furthermore, due to pre-operative painting of the surgical field with antiseptic solutions, these tapes become wet and subsequently leave their stickiness. This leads to failure of tube stabilisation. Stability of the tape is not reliable to withstand extreme forces of manipulation in cases of severely displaced fractures. PUNTUBE is tied on the lateral side of teeth using ligature wires, and this will prevent tube interruption while doing intermaxillary fixation. Previously ligature wires were used to stabilise the tube by passing them around the tube.^[9] This will compress the lumen of polyvinyl tubes and tightening may also lead to cuts on the tube. Incorporating wires in the wall of the tube prevent both these risks as wires will be maintained outside the tube. Ligature wires (PUNSTAB) are incorporated in front of the curvature. These ligature wires will be passed interdentally and tied around the molar tooth after final stabilisation of the tube. This will ensure proper tube placement and will avoid accidental extubation during the surgical manipulation of the jaws. PUNSTAB is a patented novel feature of incorporating thin ligature wires attached to the outer wall of the tube. After securing the tube through tracheal cuff, these ligature wires are freed from the walls, passed around the adjacent teeth and then twisted. We advocate passing these thin wires below the arch bar to keep arch bar loops away from the tube. This secures the tube with molar teeth without compressing the lumen of the tube. This also secures the tube to teeth below the cementoenamel junction level, keeping it free from occlusal surfaces. This eliminates the periodic hindrance of the tube during maxillomandibular fixation. Wire stabilisation provides a more firm and reliable mode of stabilisation which can be checked easily during the procedure than to rely on tracheal cuff tension indirectly through pressing

the unsterile pilot balloon during the surgery. Limitation of this innovative design is the need for time and expertise needed to place the tube. Connectors need to be tightened completely to prevent air leak at junctions and dislodgement during manipulation. Single-piece tube without any need of connectors is the aim for version 2.0. Furthermore, evaluating factors such as difficulties in intubation, stabilisation and extubation could not be checked *in vitro*. These need to be checked in further *in vivo* studies. Further study is aimed to compare the stabilisation forces of PUNSTAB ligature wires with conventional methods.

CONCLUSION

This comparative study proved that bending the conventional tube reduces the OF as well as increases the PEP. Modified ET certainly provides a superior option for safer, uninterrupted oxygen delivery to patients while keeping the pressure low. PUNSTAB wires provide an easy, firm and direct mode of tube stabilisation which is more reliable than conventional methods of stabilisation. We advocate the incorporation of PUNSTAB feature in all the routine oral ETs irrespective of using retromolar intubation.

Further *in vivo* studies with good sample size are planned after certification to evaluate the efficiency as well as *in vivo* limitations of PUNTUBE in order to modify the structure for development of future versions of the same.

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Conflicts of interest

There are no conflicts of interest.

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