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Original Research Article

COMPARISON OF CONVENTIONAL ENDOTRACHEAL TUBE WITH PARKER FLEX-TIP TUBE FOR TRACHEAL INTUBATION THROUGH I-GEL TM

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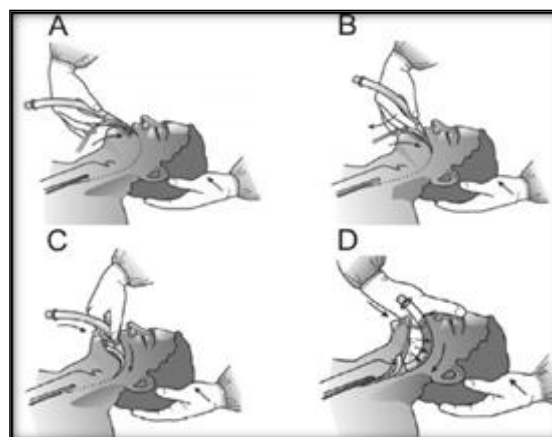[6]Department of Neurosurgery, Maharishi Markandeshwar Institute of Medical Science and Research, Mullana, Haryana, India.

Abstract

Background: Airway management is most crucial skill for any anesthesiologist. Significant morbidity and mortality in anaesthesia comes from inadequate knowledge and experience in airway management. A relatively new supraglottic airway device, I-gelTM is an alternative to ILMA to facilitate endotracheal intubation. The advantages of I-gelTM over ILMA are that the breathing tube of the device is shorter, wider so standard endotracheal tube (ETT) can also be easily placed. **Objective:** Comparison of conventional endotracheal tube with Parker flex-tip tube for tracheal intubation through I-gel[TM]. **Materials and Methods:** Single center hospital-based study at the Department of Anaesthesiology and Critical care, MAMC, Agroha. 100 patients of either sex, aged 18–60 years, belonging to American Society of Anesthesiologists (ASA) physical status class I and II presenting for elective surgery under general anaesthesia requiring endotracheal intubation were included in the study. **Results:** The success rate of intubation in conventional ETT group was 70% and in parker flex ETT group was 92%. The mean value of total time of intubation was significantly lower in parker flex tip. Occurrence of hoarseness of voice was significantly higher using conventional ETT as compared with parker flex tip ETT. **Conclusion:** we recommend to preferably use Parker Flex-tip ETT over conventional PVC ETT for blind intubation through I-gel[TM].

INTRODUCTION

Airway management is most crucial skill for any anesthesiologist. Significant morbidity and mortality in anaesthesia comes from inadequate knowledge and experience in airway management. The major breakthrough in difficult airway management was introduction of laryngeal mask airway (LMA).[1] In the last few years, many supraglottic airway devices (SADs) have been introduced in clinical practice. Supraglottic airway devices has changed the scenario from 'unable to intubate and ventilate' to 'unable to intubate but able to ventilate.[2] Specific Supraglottic airway Device, Classical laryngeal mask airway (cLMA) have been used as a conduit for tracheal intubation but it is not an ideal intubation aid because of its diameter and length limitations.[3]

Figure 1: Classic technique for insertion of a laryngeal mask airway (LMA) device (A).

255

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The inserting hand is positioned like a pen, with the index finger placed at the junction of the cuff and tube. The LMA tip is pushed up against the hard palate after verifying that it is lying flat against the palate and that the tip is not folded over. (B). As the mask moves in, the index finger maintains pressure against the posterior pharyngeal wall to avoid the epiglottis (C). The index finger is fully inside the mouth at the end of insertion (D). The other hand holds the LMA while the inserting finger is removed from the mouth. The cuff is inflated without holding the tube, permitting the device to position itself correctly. Adapted from Ramachandran et al.[3] (2004).

Later, intubating laryngeal mask airway (ILMA) was designed to overcome limitation of LMA. The ILMA was designed specifically to ease tracheal intubation. A relatively new supraglottic airway devices, I-gelTM is an alternative to ILMA to facilitate endotracheal intubation. The advantages of I-gelTM over ILMA are that the breathing tube of the device is shorter, wider so standard endotracheal tube (ETT) can also be easily placed.The I-gelTM is a single use supraglottic airway which does not have an inflatable cuff. It is composed of a soft, gel-like, non-inflatable cuff made of a thermoplastic elastomer. The stem of the I-gelTM is less flexible than that of the LMA-classic and has an integral bite.[4] I-gelTM has also been used in rescue airway management and as a conduit for tracheal intubation.[5-9] It is a latex free device and does not require digital insertion into patient's mouth, and it is cheaper than other supraglottic airways.

Figure 2: I-gel™

Polyvinyl chloride (PVC) tube and posterior beveled Parker flex tip tube are worth considering endotracheal tubes used for intubation. The study was conducted by Kanazi et al.[10] (2008) who compared silicone wire-reinforced tube with the Parker Flex Tip tube and conventional PVC tube for tracheal intubation through ILMA. These authors noted that minimal manipulation improved the success rate of intubation with the Parker Flex Tip tube through the ILMA and hence providing a possible alternative to the silicone wire-reinforced tube.[10]

Figure 3: Parker Flex Tube

The main purpose of this study is to compare the blind intubation success rate of posterior-beveled Parker flex tube with conventional PVC tube. Also, to compare the ease of intubation, total time required for successful intubation through I-gelTM, haemodynamic changes and incidence of complications if any.

Aims and Objectives
Comparison of conventional endotracheal tube with Parker flex-tip tube for tracheal intubation through I-gel™.

Objective
Primary
- To compare conventional tracheal tube and Parker flex-tip tracheal tube with regard to success rate.

Secondary
- To compare the ease of intubation, total time required for successful intubation through I-gelTM and incidence of complications if any

MATERIALS AND METHODS

Study setting: Single center hospital-based study at the Department of Anaesthesiology and Critical care, MAMC, Agroha.
Study duration: 1 year
Study design: Double arm, active group, single blind, randomized controlled trial.
Sample size:

$$\frac{(Z_{\alpha/2} + Z_{\beta})^2 \, [P_1 (1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2}$$

Type 1 error (Alpha, significance) /1.96 - 0 .05
Type 2 error (Beta, 1- Power)/1.282 - 0.10
Power - 90%
Success rate of blind intubation with Parker flex-tip TT, P1 - 0.86
Success rate of blind intubation with conventional PVC tube, P2 - 0.57
P1 and P2 are taken from previous study.[4]

$$= \frac{(1.96 + 1.282)^2 \, [0.86 \, (1-0.86) + 0.57(1-0.57)]}{(0.86-0.57)^2}$$

$$= 46$$

At least 46 patients in each group. Hence, we had conducted the study taking 50 patients in each group.

Inclusion Criteria
100 patients of either sex, aged 18–60 years, belonging to American Society of Anesthesiologists

(ASA) physical status class I and II presenting for elective surgery under general anaesthesia requiring endotracheal intubation were included in the study.

Exclusion Criteria

1. Obesity (body mass index ≥30 kg/m2)
2. Pregnancy
3. Known or predicted difficult airway
4. Reduced lung compliance
5. Mouth opening <2.5 cm
6. High risk for pulmonary aspiration (non-fasted, gastroesophageal reflux disease).

Method

Group allocation: Patients were randomly allocated to one of the two groups using computer-generated sequence of random numbers as follows.

Group A (n = 50): Blind intubation through I-gelTM LMA using conventional ETT.

Group B (n = 50): Blind intubation through I-gelTM LMA using Parker flex-tip ETT

Clinical examination: All the patients were examined during preoperative visit a day prior to surgery. Detailed clinical history along with physical examination had done. Routine investigations like hemoglobin (Hb), bleeding time (BT), clotting time (CT) and urine examination were carried out in all the patients. Other investigations were carried out as per requirements.

Preparation of the patient: The purpose and protocol of the study were explained to the patients and informed written consent had obtained for the same. Patient were kept fasting for 6 hours prior to the scheduled time of surgery. They were premedicated with tab. alprazolam 0.25mg and tab. ranitidine 150mg night before and in the morning 2 hours before surgery. Upon arrival in the operating room, all routine monitoring including heart rate, ECG, non- invasive blood pressure (NIBP), end-tidal CO_2(EtCO2) and pulse oximetry (SpO2) were established and baseline readings were recorded.

Intervention: After arrival in the operation theatre, the routine monitoring comprising of heart rate (HR), electrocardiography (ECG), pulse oximetry (SpO2), non-invasive blood pressure (NIBP), end-tidal CO_2(EtCO2), respiratory rate (RR) was set up. Baseline readings of these vital parameters were recorded. The patient was laid in supine position with the head resting in neutral position.

Peripheral intra venous line with 18-gauge cannula were secured. Glycopyrrolate 0.005 mg/kg, fentanyl 2 μg/kg were given as premedication. After pre-oxygenation with 100% oxygen for 3 minutes, induction of anesthesia was done with propofol 2 mg/kg. Additional propofol was given if required till loss of consciousness and loss of response to verbal commands was achieved. Then we checked the ability to mask ventilate the patient before giving neuromuscular blocking agent. Vecuronium 0.1 mg/kg had administered after confirming mask ventilation. Patients were ventilated for 3 min via facemask and anesthesia was maintained with 2% sevoflurane and 100% O2. An appropriate sized I-gelTM laryngeal airway was inserted after complete neuromuscular blockade. The external surface and the cavity ridges were lubricated with water-based gel. Patients were laid in supine position with head in neutral position. Patient's mouths were opened with mandible held upwards and forward. The frontal portion of the I-gelTM placed between the base of tongue and the palate. The I-gelTM introduced into the pharynx by applying gentle inward and downward pressure until a fixed resistance to forward movement was felt. Confirmation of correct placement of the airway was done by capnography, chest auscultation and adequate chest rise with no audible leak. In the event of complete or partial airway obstruction or air leak, the device was repositioned, or removed and reinserted. A maximum of three attempts were allowed, following which an alternative method to secure patient's airway was used and the patient were excluded from the study. Thereafter, ETT of appropriate size (I-gelTM size 3 - ETT 7 mm; I-gelTM size 4 - ETT 7.5 mm) were lubricated with water-based jelly and were passed through the airway tube of I-gelTM blindly. The cuff of the ETT were inflated and connected to the breathing circuit. Correct ETT placement were confirmed by capnography and presence of equal, bilateral breath sounds. After successful intubation via I-gelTM, the I-gelTM was removed over the endotracheal tube. For I-gelTM removal, we had used Magill forceps to hold the ETT in its position inside the trachea, disconnecting the universal 15mm ETT connector. After reconfirming the position, endotracheal tube was fixed. Oxygen saturation (SpO2), heart rate and mean arterial pressure were monitored continuously. Any haemodynamic fluctuations were managed as per standard ASA guidelines. Appropriate adjustment manoeuvres such as head extension and cricoid pressure were attempted in sequence to facilitate intubation.

Outcome measures: The following parameters were noted.

Insertion time of I-gelTM (T1): It is taken as the time from picking up the device till appearance of a capnograph waveform. The insertion time is the sum of all the attempts taken.

Number of attempts for ETT placement: An attempt is counted if a definite resistance is felt during the tube insertion or if esophageal intubation occurred. A maximum of 3 attempts are allowed.

Ease of TT placement:

Ease of placement is graded as

- Easy: Placement of TT in single attempt
- Difficult: More than one attempt required to place the tube
- Failure: Inability to secure the airway with TT

Insertion time of ETT (T2): It is taken as time from the picking up the tracheal tube till confirmation of correct placement.

Time taken for removal of I-gelTM (T3): It is taken as time from successful placement of ETT through I-gelTM to confirmation of ETT placement after removal of device from oral cavity.

Total time taken for successful intubation: It is taken as time from picking up the I-gelTM till removal of device from oral cavity after correct placement of ETT and is the sum of T1, T2 and T3.

Complications if any

Blood on ETT after removal and complications such as sore throat and hoarseness of voice were noted in both the groups.

Ethical issues: We confirmed that the procedures followed in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki declaration of 1975, as revised in 2000. We ensured the confidentiality of the subjects. There was no conflict of interest to declare. Informed written consent were taken from the patient at the time of enrolment.

Data collection: Data were collected from predesigned proforma, patients case sheet and clinical examination.

Data management: All the collected data in proforma were entered in excel master chart.

Statistical Analysis: Data were analyzed by using Statistical software SPSS 25.0. Data was represented in appropriate tables and charts. Qualitative categorical data were represented as frequency and proportion. Quantitative continues data were represented as Mean and SD. For comparison of continuous parametric data independent t-test was used and for categorical data Pearson's chi-square test was used. P value <0.05 was considered statistically significant.

RESULTS

Table 1 shows, 100 participants were selected based on the eligibility criteria and were divided in the ratio 1:1 into two groups conventional ETT and Parker flex tip ETT. The mean age of the patients in the conventional ETT group was 35.62 ± 12.45 years and in case of Parker flex tip ETT, the mean age was 35.24 ± 9.95 years. Upon carrying out Independent t-test, both the groups did not have any significant association with age; p value 0.866.

The mean weight of the patients in the conventional ETT group was 67.92 ± 6.45 kg and in case of Parker flex tip ETT, the mean weight was 69.92 ± 6.66 kg. Upon carrying out independent t-test, there was no significant difference in the weight between the two groups; p value: 0.130. Table 2 shows out of 50 participants 24(48%) participants were females and 26 (52%) participants were males. From the Parker Flex tip ETT group, out of 50 participants 19 (38%) participants were females and 31 (62%) participants were males. Upon carrying Chi-square test, both the groups did not have any significant association with gender; p value: 0.419

Table 3 shows, 32 (64%) patients belonged to ASA Grade-I and 18 (36%) patients belonged to Grade-II from the group Conventional ETT. From the parker

flex tip ETT group, 27 (54%) patients belonged to Grade-I and 23 (46%) patients belonged to Grade-II. Upon applying Chi-square test, both the groups did not have a significant association with ASA status; p value: 0.416

Figure 1 shows, Among the conventional ETT group, the success rate was 70% and failure rate was 30%. From the parker flex tip ETT group, the success rate was 92% and the failure rate was 8%. Upon applying Chi-square test, both the groups have a significant association with the success rate; p value: 0.0371

Figure 2 shows that out of 50 participants from the conventional ETT group, 27(54%) patients took 1 attempt 3 participants took 2 attempts and 5 participants took 3 attempts. From the Parker flex tip ETT, 43 (86%) participants took 1 attempt, 2 participants took 2 attempts, and 1 participant took 3 attempts. Upon applying Chi-square test, both the groups have a significant association with the number of attempts; p value: 0.0179.

Table 4 shows the ease of intubation was easy for 27 (54%) participants, difficult for 8(16%) participants whereas 15 (30%) participants failed. From the parker flex tip ETT group, the ease of intubation was easy for 43 (86%) participants, difficult for 3 (6%) participants whereas 4 (8%) participants failed. Upon applying Chi-square test, both the groups have a significant association with the ease of administration; p value: 0.002. In this study, it was observed that mean time taken for TT insertion through I-gelTM was found to be 23.42 ± 13.65 seconds in the conventional ETT group. In the Parker Flex tip ETT group, the mean time for the same was 12.24 ± 9.96 seconds. Upon carrying out the Independent t-test, there was a significant difference in the mean time taken for TT insertion among the two groups; p value <0.0001.

Table 5 shows that mean time taken for intubation was found to be 73.47 ± 11.64 seconds in the conventional ETT group. In the Parker Flex tip ETT group, the mean time for the same was $57.35\pm.96$ seconds. Upon carrying out the Independent t-test, there was a significant difference in the meantime taken for TT insertion among the two groups; p value <0.0001

Table 6 shows that it was observed that 4 (8%) participants had blood on device, 5 (10%) participants had sore throat and 3 (6%) participants had hoarseness of voice in the Conventional ETT group. In the Parker flex tip ETT group, 3 (6%) patients had blood on device, 4 (8%) participants had sore throat and 1 (2%) participant had hoarseness of voice. However, upon carrying the Chi-square test, there was no significant association found between the blood on device and sore throat in the two groups. But occurrence of hoarseness of voice was significantly higher with use of conventional ETT as compared with parker flex tip ETT.

Table 1: Age and Weight of patients

Age (in years)/Weight (in kg.)					
Descriptive		Conventional ETT	Parker flex tip ETT	Total	p-value
Age	N	50	50	100	0.866
	Mean	35.62	35.24	35.43	NS
	Std. Deviation	12.45	9.952	11.21	
Weight	N	50	50	100	0.130
	Mean	67.92	69.92	68.92	NS
	Std. Deviation	6.45	6.66	6.61	
Independent t-test					

Table 2: Gender Distribution

Gender	Conventional ETT		Parker flex tip ETT		Total	
	Count	Column N %	Count	Column N %	Count	Column N %
Female	24	48.0%	19	38.0%	43	43.0%
Male	26	52.0%	31	62.0%	57	57.0%
Chi-square test; p=0.419						

Table 3: ASA status

ASA status	Conventional ETT		Parker flex tip ETT		Total	
	Count	Column N %	Count	Column N %	Count	Column N %
ASA I	32	64.0%	27	54.0%	59	59.0%
ASA II	18	36.0%	23	46.0%	41	41.0%
Chi-square test; p=0.416						
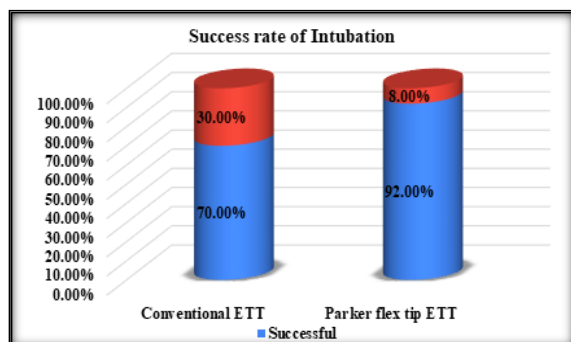
Figure 1: Success rate
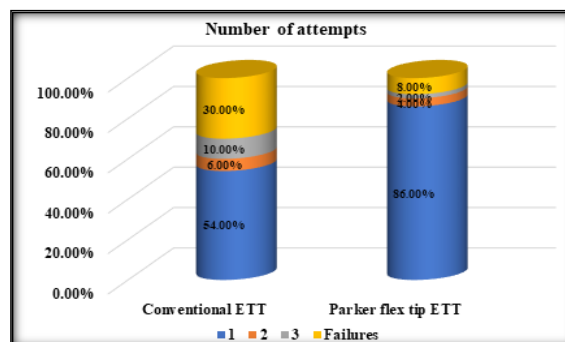
Figure 2: Number of attempts for intubation

Table 4: Ease of intubation through I-gel™

Ease of intubation	Conventional ETT		Parker flex tip ETT		Total	
	Count	Column N %	Count	Column N %	Count	Column N %
Easy	27	54.0%	43	86.00%	70	70.00%
Difficult	8	16.00%	3	6.00%	11	11.00%
Failures	15	30.00%	4	8.00%	19	19.00%
Chi-square test; p=0.002						

Table 5: Total Time taken for intubation

Total Time taken for intubation					
Descriptive		Conventional ETT	Parker flex tip ETT	Total	p-value
Time (in sec.)	N	35	46	81	<0.0001
	Mean	73.47	57.35	35.43	S
	Std. Deviation	11.64	8.82	11.21	
Independent t test					

Table 6: Complications

Complications	Conventional ETT		Parker flex tip ETT		P
	Count	Column N %	Count	Column N %	
Blood on device	4	8.00%	3	6.00%	0.455
Sore throat	5	10.00%	4	8.00%	0.653
Hoarseness of voice	3	4.00%	1	2.00%	0.021

DISCUSSION

The observation of our study was discussed under following sub-headings

- Demographic profile
- Success rate of intubation.
- Success rate at first attempt and Ease of intubation
- Time taken for TT insertion
- Total time for intubation

- Complications

Demographic profile. The two groups were comparable with regard to demographic profile.

Success rate of intubation. The success rate in parker flex tip ETT was significantly higher than conventional ETT (P=0.0371).

A study by Kanazi et al.[10] compared Silicone Wire-Reinforced Tube, PVC TT and Parker flex TT using ILMA as a conduit for blind intubation. They observed success rate of 90% with Silicone Wire-Reinforced Tube. Kanazi et al. used ILMA as a conduit, whereas I-gelTM was used in our study. Suzuki et.al.[11] compared Parker flex tube and standard PVC tube for intubation using bullard laryngoscope. They reported that the incidence of successful intubation at the first attempt (18/19 vs. 15/19) was higher in the parker flex tube group as compared with standard PVC tube group.

Success rate at first attempt and Ease of intubation

In our study, first attempt success rate of intubation was 54% in conventional ETT group and 86% in parker flex ETT group, difference was statistically significant. It depicts that intubation was easier using parker flex ETT than conventional ETT.

Similar results were shown by Jatin et al.[12] and Jafari et al.[13]

The results of the present study are in comparison with these studies showing higher first attempt success rate using Parker flex tube though different intubating methods were used. This could be due to special design of Parker flex tube which includes anterior flexible tip and posterior bevel.

Time taken for TT insertion.

In our study, the mean time of TT insertion was significantly lower in parker flex tip group as compared to conventional TT group (p<0.0001). This study is comparable with Jatin et.al. which showed that time taken for TT insertion through air‑ Q ILA was less with Parker flex‑ tip tube compared to PVC TT (P = 0.014). The mean time of TT insertion with conventional ETT in our study was 23.42±13.65 sec and it was 20.69±14.9 sec in study done by Jatin et al. The mean time of TT insertion with Parker flex tip ETT in our study was 12.24±9.96 sec and it was 13.6±8.5 sec in study done by Jatin et al.[12] Suzuki et.al. found that time required for intubation was 6 ± 2 s with the use of the Parker Flex-Tip tube and 14 ±6 s with the use of standard PVC tube (P < 0.01) using bullard laryngoscope.[11] In both of these studies, mean time for TT insertion was significantly reduced in Parker flex tube group, similar results were obtained in our study.

Total time for intubation

In our study, the mean value of total time of intubation was significantly lower in parker flex tip group as compared to conventional TT group (p<0.0001), which is comparable with Jatin et.al. that showed total time of intubation through air‑ Q ILA was less with Parker flex‑ tip tube compared to PVC TT (P = 0.043).[12] The mean value of total time of intubation with conventional ETT in our study was 73.47±11.64 sec and was 69.4±27.7 sec in the study done by Jatin et.al. while the mean value of total time of intubation with parker flex tip ETT in our study was 57.35±8.82 sec and it was 58.7±15.1 sec in study done by Jatin et al.[12]

Complications

In our study blood on device was reported among 8% cases in conventional ETT and 6% cases in parker flex ETT group (p=0.455), the difference in both the groups was not statistically significant. Jatin et al.[12] reported blood on device in 6.3% cases of conventional ETT and 4.2% cases of parker flex ETT group and the difference was not statistically significant and this is in correlation with our study. Sore throat was found among 10% cases in conventional ETT group and 8% cases in parker flex ETT group (p=0.653) in our study, the difference in both the groups was not statistically significant. Our study is in correlation with study by Jatin et.al.[12] who reported sore throat among 11.1% cases in conventional ETT group and 6.5% cases in parker flex ETT group.

We observed significant difference in hoarseness of voice when both groups were compared. 3 cases (4%) develop this complication in conventional ETT group and only 1 patient (2%) reported hoarseness of voice in parker flex tip ETT group (p=0.021).

Our results differ from the study done by Jatin et al.[12] who did not report any single case of hoarseness of voice. This could be due to the difference in technique and maneuvers employed, demographic and clinical profile of study population and experience of anaesthesiologist.

The Parker flex tip tube [PFT] group showed fewer vomiting reflexes and tube impingements than the Portex tracheal tube [PTT] group (p < 0.05) in the study conducted by Yamauchi et.al.[14]

Parker Flex Tip TT has a curved, centered, flexible and tapered distal tip that facilitates non-traumatic intubation. This leads to less incidence of complications with Parker Flex Tip TT as compared to conventional ETT.

However, there were certain limitations to our study. We did our study in patients with normal airway with no anticipated difficult intubation. The results may differ in patients with difficult airway. We had not assessed upper airway anatomy of failed cases in both the groups by fibreoptic bronchoscope so the reason for failed cases could not be commented on here. We had compared only two ETT having different designs. The results may vary with other available ETTs

CONCLUSION

To conclude, the rate of successful intubation and first attempt success rate is higher and total time required for successful intubation is lesser with Parker flex ETT as compared to conventional ETT while using I-gelTM as a conduit for intubation.

260

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Hence, we recommend preferably use Parker Flex-tip ETT over conventional PVC ETT for blind intubation through I-gel[TM].

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261

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