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Original Research Article

I gel versus endotracheal intubation for percutaneous tracheostomies: a randomised study to ascertain amicable approach

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ABSTRACT

Background: Percutaneous tracheostomy or percutaneous dilation tracheostomy (PDT) is an airway management procedure routinely performed in critically ill patients, requiring prolonged ventilation. It is safely performed bedside by anaesthesiologist/intensivist in ICUs. Complications as endotracheal tube (ET) damage, loss of airway due to accidental extubation and piercing of guide wire through ET tube during procedure has led to exploration of safer/effective and viable airway alternatives while performing the procedures.
Methods: In this study we randomised 60 patients to group E (ET) and group I (I gel) 30 each and studied ease of carrying out procedure and associated complication rates in both groups.
Results: In ET group (group E), 9% of patients suffered with potentially catastrophic complications, e.g. loss of airway, inadequate ventilation of lungs, haemorrhage, airway leak due to ET tube cuff rupture and accidental extubation. In ETT group there was incidence of 18% cuff puncture by guide wire (p=0.025) and 3% accidental tracheal extubation. Group I witnessed lower incidence of haemorrhage (3%) and the incidence of guide wire piercing airway device was nil. Group I also demonstrated better hemodynamic stability attributed to lesser tissue trauma and airway manipulation.
Conclusions: This study demonstrates enhanced safety with usage of I gel for PCDT, with less complication, better hemodynamic stability and shorter procedure duration.

Keywords: Percutaneous dilation tracheostomy, Guide wire, I gel, Critical care

INTRODUCTION

Tracheostomy is defined as the process of creating an opening in the anterior wall of trachea.[1] A tracheostomy is a direct opening in the anterior trachea communicating with a stoma on the surface of the neck (Figure 1). This allows air to pass directly into the trachea below the vocal cords.

Tracheostomy can be divided in two subtypes depending on the adopted techniques like surgical tracheostomy (ST) refers to placement of a tracheostomy cannula after dissection of pre tracheal tissues and incision of tracheal wall under direct vision; PDT involves blunt dissection of pretracheal tissues followed by dilatation of trachea over the guidewire and subsequent tracheal cannulation using Seldinger technique. Both techniques differ with each other with respect to creation of initial stoma. Percutaneous tracheotomy involves gradual dilation of initial small hole by serial dilations. Percutaneous tracheotomy is usually carried out as bedside procedure.[2]

Tracheostomy was first described by Jackson in 1909 and is one of the oldest and most commonly performed procedures in critically sick patients.[3] It's use in intensive care unit (ICU) gained popularity during polio epidemic

in the 1950's. Ciaglia invented percutaneous dilatational tracheostomy in 1985. PDT has gained wide popularity among intensivists and now being adopted as standard of care in ICU.[4] However it is imperative to be aware of conditions where surgical tracheostomies may be favourable. Over the last few years, the original Ciaglia PDT technique has undergone modifications and multiple other techniques have also evolved.[4,5]

PDT is classically indicated in difficult to wean of patients to aid in trachea-bronchial toileting, airway protection in patients at risk of aspiration, prolonged ventilatory management and reduce sedation requirement. PDT is generally an elective procedure and avoided in emergency intervention, unless performed by an erudite operator. In case of difficult to intubate patients' emergency, cricothyrotomy is considered as the procedure of choice.[5] PDT now has been accepted as a bedside procedure in the management of critically ill patients. Various studies have demonstrated the superiority of the guidewire technique over conventional surgical tracheostomy. Inadvertent puncture of the endotracheal tube (ETT) cuff or impalement of ETT with the tracheal puncture needle is perhaps the greatest concern during PDT. The standard recommendation before conduct of PDT is that the ETT be withdrawn until the cuff lies immediately below the vocal cords.[6] In spite of this common practice, ET cuff punctures and impalement of ETT have been reported. The use of LMA (laryngeal mask airway) has been suggested as an alternative to ETT and has been used sporadically but no large study is available to compare its efficacy in providing safe and patent airway during the PDT.[7-9] The same goes with reference to usage of I gel (inter surgical gel airway device).

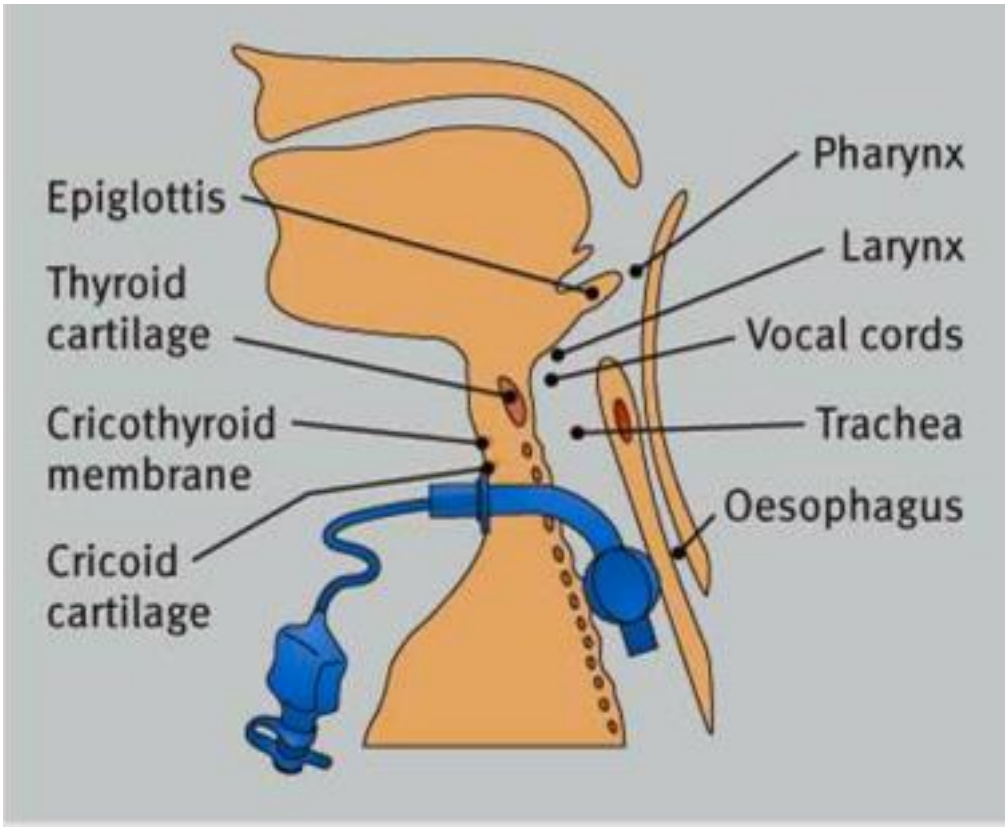

Figure 1: Anatomical sagittal section; description for tracheostomy.

Prolonged ventilatory requirement remains the fore most indication for carrying out tracheostomies, recommendation remains for patient requiring ventilator for more than 21 days and ETT is to be preferred if ventilator requirement is of less than 10 days. Various contraindications for the procedure are subdivided into absolute (infants, infection at insertion site, coagulopathies, cervical spine injuries) and relative (enlarged thyroid gland, pulsatile vessels, proximity to other injuries, difficult neck anatomy, high peep or FIO2 requirements).[10-13]

Recent years have witnessed extensive use of PDT in ICU, almost supplanting ST. This is secondary to easy execution of PDT at patient's bedside avoiding unnecessary and at times high-risk transfers to operation theater, and last but not the least, cost-effectiveness. A morbidity of 13-33% has been observed related to transport of critically ill patients, affecting management

significantly in 25% of patients.[15,16] Subsequently many studies have document minimally invasive nature of percutaneous tracheostomy.[17-19]

Percutaneous techniques were initially described in the mid-1980s by Ciaglia et al. Over the past decade multiple modifications and some other alternatives have also come up. The various percutaneous tracheostomy modality available are Ciaglia serial dilatational technique; Ciaglia single dilator tracheostomy; Griggs percutaneous technique; Fantoni translaryngeal tracheostomy; Frova's percutaneous tracheostomy; balloon dilatational tracheostomy (Ciaglia Blue Dolphin, Cook Medical); Ciaglia serial dilatational technique. Enough studies were lacking to advocate superiority of one PCDT technique over other.[20,21] Percutaneous tracheostomy is associated with lesser long term complications and immediate procedure related complications which can be attributed due to lesser trauma to targeted tissue.[22-24]

In our study we formulated to carry out Ciaglia serial dilatational technique. The choice was based on the extensive experience and comfort of the anaesthesiologist with the technique.

The main objectives were to analyse the effectiveness and safety profile of I gel over ET tube for conduct of percutaneous tracheostomies with minimal trauma and complications. Main concerns planned to be addressed after this study included incidence of guide wire piercing ET tube and other associated complications like subcutaneous emphysema, pneumothorax, haemorrhage, aspiration and accidental extubation.

METHODS

Total of 60 patients were included in study during the period January 2019 to January 2020 in our tertiary care center, after due approval of the study from institutional ethical committee. Patients were selected on the basis of pre formulated inclusion and exclusion criteria subsequently randomised by computerised draw. The procedure was carried out as elective procedure and the main operating anaesthesiologist and two help remained the same throughout the study.

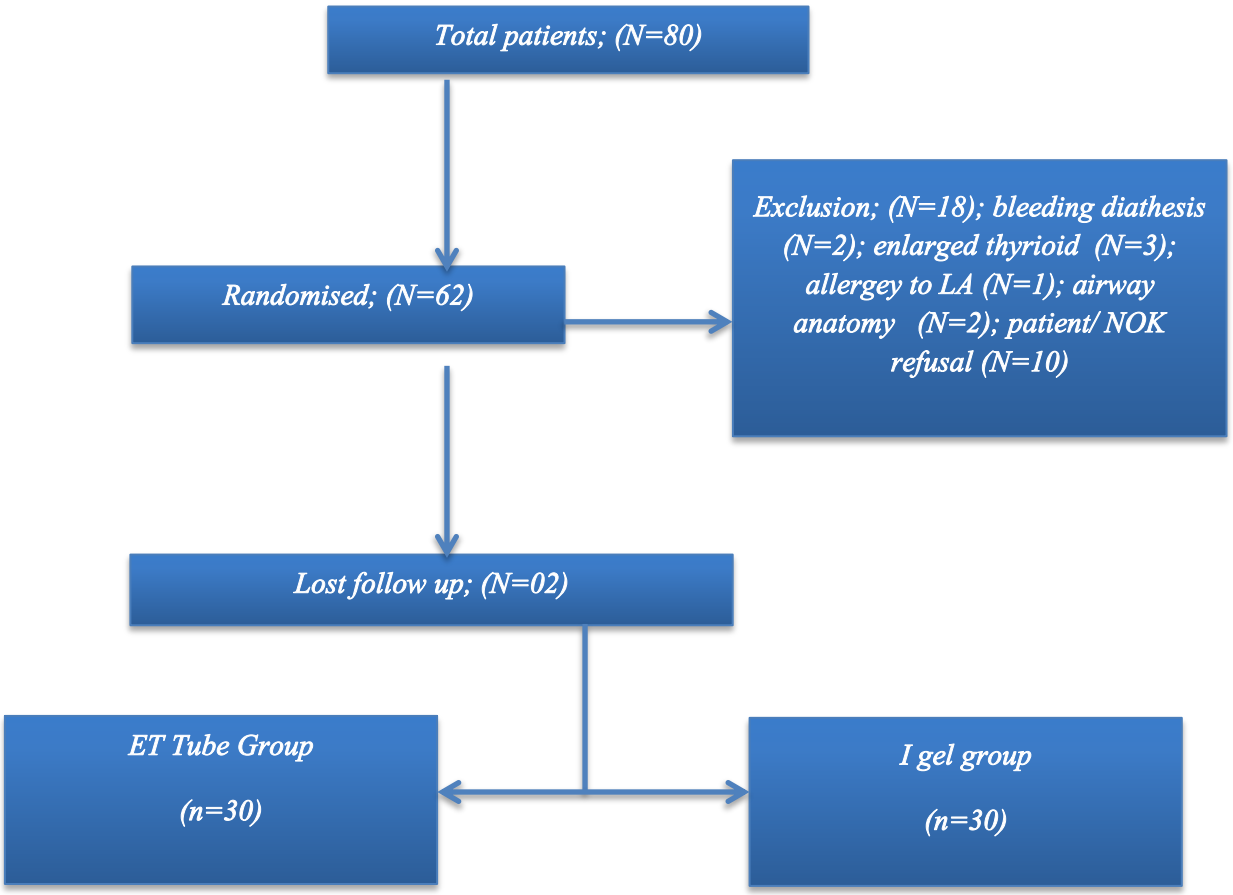

Figure 2: Flow of participants (CONSORT diagram).

Depending upon the variables planned for evaluation, primary and secondary endpoints sample size was calculated using SPSS software 2020.

Study design

This study was randomised, forward directional, interventional and analytic study. It included participation of patients with variable demography. This study was conducted with main focus on analysis of variable outcomes, which might follow a planned percutaneous tracheostomy. For analysis and validation of outcome, students paired t test and Chi 2 test were utilised.

Inclusion criteria

Patients requiring ventilation for more than 10 days were included in the study.

Exclusion criteria

Patients/nok unwilling to participate with known allergy to local anaesthetic, patients with bleeding diathesis, enlarged thyroid, distorted anatomy on USG evaluation and patients with potential full stomach status were excluded from the study.

The anaesthesiologist carried out the procedure in pair and findings were noted and tabulated by independent observer. The factors evaluated were, ease of carrying out the procedure, ease of manipulation of airway, haemorrhage, in advert puncture of ET tube by cannula/guide wire, hemodynamic stability, duration of procedure and post procedure complications.

The duration of procedure was noted from point of sedation to insertion of tracheostomy tube and removal of I gel/ET tube as per group profile.

Patients were randomised for I gel (group I) and ET tube (group E) as above. During the procedure all precautions and readiness was observed on the lines of difficult airway management. Standard steps were followed for conduct of percutaneous tracheostomy.

I gel was inserted in 30 of the patients of the group I, after their endotracheal tubes were removed. If ventilation was satisfactory as evaluated by adequate chest movement, tidal volume, minimal air leak and stable vital signs, PDT was performed with I gel alone.

30 patients were ventilated via ET during the procedure in group E. The cuff of the ET was deflated and was withdrawn slowly to lie just below the level of the vocal cords while ventilation was discontinued. Then the cuff was inflated enough to achieve the original tidal volume.

All patients were positioned with the neck extended over a pillow. After due confirmation of adequacy of ventilation, patients were sedated with injection fentanyl at 1 mcg/kg and paralysed with injection atracurium at 0.5 mg/kg. The neck and upper shoulders were cleaned with solution of povidone-iodine 10% and the operative area was draped. The sternal notch, thyroid and cricoid cartilages were identified. The procedure involved, ultrasound based evaluation of airway and subsequently carrying out of procedure. A 1 to 2 cm incision was made over the estimated level of the first and second or second and third tracheal ring and the insertion of the needle and guide wire was visualized by the ultrasound. PCDT was performed by the means of the Ciagla blue rhino percutaneous tracheostomy kit. The position of the tracheostomy tube was confirmed by physical examination, end-tidal CO_2, chest radiography and arterial blood gas parameters. Careful ultrasound examination and delicate handling of tissues ensured adequate hemostasis.

RESULTS

The study was extrapolated with reference to associated complications as haemorrhage, accidental piercing of ET tube by cannula/guide wire, duration of procedure, ease of manipulation of airway and hemodynamic stability.

Table 1: Demographical distribution.

Parameters	Group E	Group I
Age	56±14.6	58±13.6
Sex (F:M)	20:80	10:90
Weight	58±12.6	60±10.6

The demography profile of enrolled patients is tabulated below and was comparable in both groups. The distribution was equitable.

Table 2: Complication rate associated with procedure.

Sr. No.	Complications	Group E (N=30)	Group I (N=30)	Remarks
1.	ET piercing by GW/C (%)	6/18	Nil	In first attempt (p=0.025)
2.	Haemorrhage (%)	2/6	1/3	
3.	Subcutaneous emphysema	0	0	
4.	Pneumothorax	0	0	
5.	Aspiration	0	0	
6.	Airway leak	2	0	
7.	Accidental extubation (%)	1/3	0	

Table 3: Procedural observation for duration and ease of airway manipulation.

Sr. No.	Parameters	Group E (N=30)	Group I (N=30)	Remarks
1.	Durations	35±15	25±10	
2.	Ease of manipulations	Moderate	Easy	

Table 4: Hemodynamic parameter during procedure.

Groups	Parameters	10 min	15 min	20 min	25 min	30 min	35 min	40 min
E	Heart rate	78±7.8	80±8	85±8.5	80±8	78±7.8	89±8.9	70±7
	MAP	90±5	98±5	100±7	100±5	98±7	97±5	92±5
	SPO_2	99±1	99±1	98±1	99±1	97±1	98±1	99±1
I	Heart rate	68±12	70±7	72±7.2	68±6.8	68±6.8	70±7	65±6.5
	MAP	85±5	84±3	80±3	82±5	82±5	83±7	80±5
	SPO_2	99±1	99±1	99±1	99±1	99±1	99±1	99±1

The rate of complication was comparable in both groups (p=0.025) and group E demonstrated higher complication rates.

The procedural duration was significantly lower in group I with enhanced ease of airway manipulation.

Group I demonstrated better hemodynamic and oxygenation profile as compared to group E.

DISCUSSION

During performing PDT, the tracheal cuff puncture might cause loss of significant amount of tidal volume on controlled ventilation, which can be dangerous in patients having low arterial oxygen tension (PaO_2 <60 mm Hg). The withdrawal of the endotracheal cuff just below the vocal cords does not guarantee the prevention of tracheal cuff puncture. Even with such a practice cuff perforation and lacerations have been reported.[25-30] This was because the anatomic length of the adult human larynx varied from approximately 3.4-4.4 cm.[31] Since, the average length of the ETT (8.0-9.0 mm) cuffs for adults was about 3 cm and length of the tube beyond cuff also measures about 3 cm, it was possible that tracheal needle puncture can damage the endotracheal cuff or tube. Schwann had found useful to deflate the ETT cuff and reposition the tube so that the inflated cuff sits just below the level of the vocal cords. The cuff was re-deflated for the needle puncture and maintained deflated until the needle was withdrawn from the trachea, leaving only the J-wire *in situ*. However, again this technique did not eliminate cuff damage by the subsequent insertion of dilators.

In our study the overall complication rate was 27% in the ET group. Cuff puncture and accidental extubation, which accounted for 21% of the complications seen in the ET group. These complications were preventable by the use of I gel during PCDT. Moreover, these complications might have been prevented if different technique/adjuvants had been performed including appropriate fixation of the ET and fiberoptic guidance of the tracheal puncture site. Hemorrhage was noted in both group however patients, responded to local treatment. Although some studies have reported lower incidences of hemorrhages and wound infections with percutaneous tracheostomy.[29]

Various authors have performed bronchoscopic guided percutaneous tracheostomy. Using direct bronchoscope or bronchoscopic video imaging, the tip of the ETT was retracted to the level of the cricoid cartilage well above the proposed tracheostomy site. The advantage was that both the ends of ET tube as well as the needle puncture site in the midline of trachea can be visualised and PCDT under direct vision was performed. But again the maintenance of adequate minute ventilation to the patient was challenging due to leaks around the bronchoscope and ET tube adapter resulting into waste of ventilation and hypoxia. Apart from this, there was potential risk of damage to the bronchoscope optical fibres with the tracheal puncture needle or the dilators, which may not make the procedure cost effective.

In anaesthetic practice, the I gel had been used successfully for spontaneous as well as controlled ventilation of lungs for various surgical procedures. I gel had demonstrated adequate safety in maintaining airway seal pressure and against regurgitation.[32] In our experience, the I gel provided clear airway in significant number of patients and decreased incidence of guide wire piercing the ET tube or serial dilator damaging the ET tube. None of our patients had aspiration in either of the group.

There had been no or limited data available on usage of I gel for performing PCDT however studies using LMA has been conducted in past and didn't yield promising results. There had been potential threat against aspiration and loss of ventilation due to air leakage.

Brimacombe et al have successfully performed endoscopic percutaneous tracheostomy using size 3 LMA

in a sedated and paralysed adult female patient on controlled ventilation but they did not rule out the potential danger of regurgitation-aspiration, loss of airway (dislodgement of LMA) and inadequate ventilation.[33] It was well known that the LMA did not provide airtight seal around the glottis during controlled ventilation of lungs. Some of the air was likely to escape leading to waste of ventilation and subsequent hypoxia in susceptible patients.

I gel had got superiority over LMA in terms of better seal against airway leak and promising status against aspiration.[34] In our study we used I gel of size 4 and 5 as per the weight of the patient and were able to effectively ventilate patient. There was less air leak as compared to ET Tube group owing to the pharyngeal seal provided by the I gel. Adequacy of seal was decided on the basis of auscultation of anterior neck and ballottement of pilot balloon.

In this study, none of our patients of either group had gastric distension or regurgitation due to escape of air into the stomach. The ETT cuff got damaged while manipulating in 2 (6%) of the patients (group E) and air leak was noticed. In group I no air leak was noticed. I gel provided safe, patent airway in all patients.

This study was conducted as pilot study for assessing the benefits of using I gel over conventional ET tube *in situ*, for conduct of percutaneous tracheostomies in hospital set up. This study included a smaller population and sample size with safe inclusion profile. So as to make this practice universal further studies were recommended with larger sample size and wide inclusion criteria. This study can be a benchmark for future research for exploring safer techniques for percutaneous tracheostomies.

CONCLUSION

In absence of any study to demonstrate the efficacy of I gel over ET tube, this study was conducted at our tertiary care center and it showed significant hemodynamic stability and oxygenation status throughout the procedure. Patients randomised to I gel group for percutaneous tracheostomy had nil incidence of accidental ET tube puncture by guide wire, less incidence of haemorrhage and better hemodynamic stability due to least manipulation of airway and accentuation of airway reflexes.

In conclusion, the use of I gel during PCDT in critically sick patients provided effective, safe, quick and complication free procedure without e.g. hypoxia, airway loss or regurgitation/aspiration. In addition the safety profile ensured easy conduct of procedure by operator. Carrying out of PCDT with I gel will go long way in achieving higher success rate with least hemodynamic compromise and can provide a basis for further studies.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Frost EA. Tracing the tracheostomy. Ann Otol Rhinol Laryngol. 1976;85:618-24.
2. Veenith T, Ganeshamoorthy S, Standley T, Carter J, Young P. Intensive care unit tracheostomy: a snapshot of UK practice. Int Arch Med. 2008;1(1):21.
3. Szmuk P, Ezri T, Evron S, Roth Y, Katz J. A brief history of tracheostomy and tracheal intubation, from the bronze age to the space age. Intensive Care Med. 2008;34(2):222-8.
4. Ciaglia P, Firsching R, Syniec C. Elective percutaneous dilatational tracheostomy. A new simple bedside procedure; preliminary report. Chest. 1985;87(6):715-9.
5. Raimondi N, Vidal MR, Calleja J, Quintero A, Cortés A, Celis E, et al. Evidence based guidelines for the use of tracheostomy in critically ill patients. J Crit Care. 2017;38:304-18.
6. Bodenham AR. Percutaneous dilational tracheostomy. Completing the anaesthetist's range of airway techniques. Anaesthesia. 1993;48(2):101-2.
7. Tarpy JJ, Lynch L. The use of the laryngeal mask airway to facilitate the insertion of a percutaneous tracheostomy. Intensive Care Med. 1994;20(6):448-9.
8. Brimacombe J, Clarke G, Simons S. The laryngeal mask airway and endoscopic guided percutaneous tracheostomy. Anaesthesia. 1994;49(4):358-9.
9. Dexter TJ. The laryngeal mask airway: a method to improve visualisation of the trachea and larynx during fibreoptic assisted percutaneous tracheostomy. Anaesth Intensive Care. 1994;22(1):35-9.
10. Burrell T, Sampson B, Sundararajan K, Carter A. percutaneous dilatational tracheostomy consensus statement. ANZICS. 2014.
11. Pelosi P, Severgnini P. Tracheostomy must be individualized! Crit Care. 2004;8(5):322-4.
12. Huang CS, Chen PT, Cheng SH, Chen CK, Hsu PK, Hsieh CC, et al. Relative contraindications for percutaneous tracheostomy: from the surgeons' perspective. Surg Today. 2014;44(1):107-14.
13. Madsen KR, Guldager H, Rewers M, Weber SO, Kbke-Jacobsen K, Jensen R, et al. Danish Guidelines 2015 for percutaneous dilatational tracheostomy in the intensive care unit. Dan Med J. 2015;62(3):5042.
14. Plummer AL, Gracey DR. Consensus conference on artificial airways in patients receiving mechanical ventilation. Chest. 1989;96(1):178-80.
15. Insel J, Weissman C, Kemper M, Askanazi J, Hyman AI. Cardiovascular changes during transport

of critically ill and postoperative patients. Crit Care Med. 1986;14:539-42.
16. Smith I, Fleming S, Cernaianu A. Mishaps during transport from the intensive care unit. Crit Care Med. 1990;18(3):278-81.
17. Delaney A, Bagshaw SM, Nalos M. Percutaneous dilatational tracheostomy versus surgical tracheostomy in critically ill patients: a systematic review and meta-analysis. Crit Care. 2006;10(2):55.
18. Higgins KM, Punthakee X. Meta-analysis comparison of open versus percutaneous tracheostomy. Laryngoscope. 2007;117(3):447-54.
19. Putensen C, Theuerkauf N, Guenther U, Vargas M, Pelosi P. Percutaneous and surgical tracheostomy in critically ill adult patients: a meta-analysis. Crit Care. 2014;18(6):544.
20. Al-Ansari MA, Hijazi MH. Clinical review: percutaneous dilatational tracheostomy. Crit Care. 2006;10(1):202.
21. Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of ran- domised controlled trials: the QUOROM statement. quality of reporting of meta-analyses. Lancet. 1999;354(9193):1896-900.
22. Hazard PB, Garrett HE, Adams JW. Bedside percutaneous tracheostomy: experience with 55 elective procedures. Ann Thorac Surg. 1988;46:63-7.
23. Leinhardt DJ, Mughal M, Bowles B, Glew R, Kishen R, MacBeath J, et al. Appraisal of percutaneous tracheostomy. Br J Surg. 1992;79(3):255-8.
24. Winkler WB, Karnik R, Seelmann O, Havlicek J, Slany J. Bedside percutaneous dilational tracheostomy with endoscopic guidance: experience with 71 ICU patients. Intensive Care Med. 1994;20(7):476-9.
25. Friedman Y, Fildes J, Mizock B, Samuel J, Patel S, Appavu S, et al. Comparison of percutaneous and surgical tracheostomies. Chest. 1996;110(2):480-5.
26. Ambesh SP, Tripathi M, Kaushik S. Percutaneous dilatational tracheostomy: A prospective study in 45 Patients. J Anaesthesiol Clin Pharmacol. 1998;48(1):41-5.
27. Ambesh SP, Kaushik S. Percutaneous dilational tracheostomy: the Ciaglia method vs the Portex (correction of Rapitrach) method. Anesth Analg. 1998;87:556-61.
28. Crofts SL, Alzeer A, McGuire GP, Wong DT, Charles D. A comparison of percutaneous and operative tracheostomies in intensive care patients. Can J Anaesth. 1995;42(9):775-9.
29. Escarment J, Suppini A, Sallaberry M, Kaiser E, Cantais E, Palmier B, et al. Percutaneous tracheostomy by forceps dilation: report of 162 cases. Anaesthesia. 2000;55(2):125-30.
30. Day C, Rankin N. Laceration of the cuff of an endotracheal tube during percutaneous dilational tracheostomy. Chest. 1994;105(2):644.
31. Williams P, Warwick R. Gray's anatomy. 36th ed. London: Churchill Livingstone; 1980: 1229.
32. Kim YB, Chang YJ, Jung WS, Byen SH, Yi Y. Application of PEEP using the i-gel during volume-controlled ventilation in anesthetized, paralyzed patients. J Anesth. 2013;27(6):827-31.
33. Brimacombe J, Berry A. Cricoid pressure and the LMA: efficacy and interpretation. Br J Anaesth. 1994;73(6):862-5.
Jadhav PA, Dalvi NP, Tendolkar BA. I-gel versus laryngeal mask airway-Proseal: Comparison of two supraglottic airway devices in short surgical procedures. J Anaesthesiol Clin Pharmacol. 2015;31(2):221-5.

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