

A New Personal Percutaneous Tracheostomy Approach: A Preliminary Animal Study

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Citation

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Abstract

Objectives: Percutaneous tracheostomy has been widely adopted for long-term airway management of critically ill patients. Currently, five different techniques are used; and the first two proposed, the original Ciaglia method and the Griggs forceps are still widely used. The aim of the study was to evaluate a new tracheotomy device and to determine possible advantages and complications.

Methods: Six male farm pigs weighing 25 – 35 Kg were used for this study. The experiments have been conducted in accordance with national and international Laws and policies. The animals were anesthetized and percutaneously tracheotomized with the kit Mini Invasive Tracheostomy (kitMIT; X-med; Modena, Italy). One hour after the procedure, pigs were sacrificed and the trachea was checked for lesions. We evaluated the length of procedure, the difficulties in performing the procedure (Frova and Quintel classification), bleeding during the procedure, posterior tracheal wall damage, kinking of guide-wire, tracheal rings fracture, and para-tracheal insertion.

Results: Mean time of procedure was 8.24 minutes. There were some difficulties in performing two procedures. Bleeding was absent in 4 pigs, and minimal in 2 pigs. There were no cases of posterior tracheal wall damage, no cases of tracheal rings fracture, and no cases of para-tracheal insertion of the device. In 2 cases, we observed kinking of the guide-wire.

Conclusions: In this experimental study, the kitMIT allowed safe and easy percutaneous tracheostomies. The next experimental step will be a perspective human study.

DISCLOSURE

Emilpaolo Manno has a financial interest in Mini Invasive Tracheostomy kit.

Luca Bertolaccini, Alessandro Berra, and Silvia Burchielli have no financial interest in Mini Invasive Tracheostomy kit. The study was performed with the financial support of X-med (Modena, Italy).

INTRODUCTION

Percutaneous tracheostomy has now been widely adopted for the long-term airway management of critically ill patients and represents one of the most frequently performed surgical procedure in Intensive Care Unit (ICU). Currently, five different types of percutaneous techniques are used [1, 2, 3, 4]; and the first two proposed, the original Ciaglia method [1] and the Griggs forceps [2] are still widely used despite new approaches. This fact can mean, only, that ICU physicians

are not completely satisfied with actually used techniques and the need for an improved dilatative technique is therefore obvious [5, 6, 7]. Actually, the percutaneous tracheostomies techniques do not use the available technologies as it has been done for example in cardiology, radiology, or endoscopy [8].

The aim of the study was to evaluate a tracheotomy device; witch comprises a cannula that passes from a contracted status, inside a peel-away introducer, to an expanded status to dilatate neck tissues performing a tracheostomy.

METHODS AND MATERIALS

The experiments has been conducted in accordance with national (Law n° 116/92, n° 8/July 94) and international Laws and policies (European Economic Community, Council Directive 86/609, December 1987). The animals were maintained in a pigpen for 1 to 3 days with free access

to water and food pellets before enrolment. They were fasting the night before the procedure.

All the procedures were performed by the authors, skilled in dilatative tracheostomy.

Animal Preparation: After an overnight fast, the animal were anesthetized by an intramuscular injection of Zolazepam and Tiletamine (Zoletil®, Virbac SA, Carros Cedex, France), 10 mg/kg and Atropine Sulphate (Atropine®, Fisiopharma S.r.l. Italia, Milano, Italy), 0.05 mg/Kg. Afterward, it was placed in dorsal recumbence and monitorized for electrocardiographic features. Anesthesia was maintained by intravenous infusion of Propofol (Diprivan®, Astrazeneca S.p.A., Basiglio (MI), Italy), 5 – 7 mg/kg/h.

Procedure: A 1.0 cm longitudinal incision on the skin was done among first and second tracheal ring. A 14 Gauge (G) needle was used to puncture the trachea; a guide-wire was placed inside the trachea and the needle was removed. A 14 French (F) Punch dilator was passed trough neck tissues and trachea. A 14 F Peel-away introducer was placed into the trachea. The introducer was peeled away (Figure 1), and the inside cannula was expanded, passing from the fully retracted status to expanded status.

Figure 1

Figure 1: Opening the peel-away.

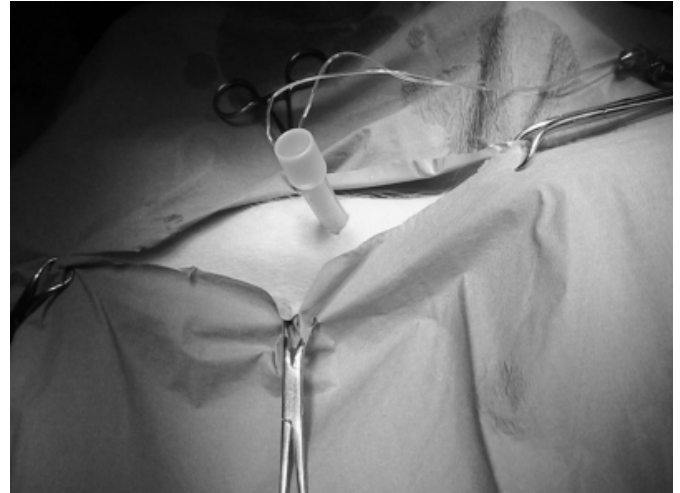


As a matter of fact, a color-coded filling channel was filled with saline under pressure (from 6 to 12 atmosphere (atm), [corresponding to 6079.5 – 12159 hectopascal (hPa)]) using QL® Inflation Device (Atrion Medical Products Inc., Arab, AL, U.S.A.). As it is preformed and made of not expansible material, the cylinder dilates the pig's tissues circularly and symmetrically, and assumes an expanded configuration typical of a tracheostomic cannula. After this, a second

color-coded filling channel was filled with saline under pressure (up to 4 atm [4053 hPa]) and a preformed balloon (Figure 2) reached a predetermined shape.

Figure 2

Figure 2: QL® Inflation Device filled to 6 atm.



The aim of balloon was to obtain an optimal dilatation of tracheal rings. 30 seconds later, the balloon was deflated and was removed together with the guide-wire. An inner cannula with an obturator was inserted, the obturator was removed, and air was fed into the airtight cuff of the cannula by means of a second color-coded inflation line (Figure 3).

Figure 3

Figure 3: Tracheal cannula in site.



The tracheostomy cannula was secured to the skin. The orotracheal tube was removed and the pig was ventilated trough the tracheostomy. Anesthesia drugs were stopped and pig awaked and begun spontaneous breathing. The animals were sacrificed one hour after the procedure, with intravenous injection of Propofol (Diprivan®, Astrazeneca

S.p.A., Basiglio (MI), Italy), 10 mg/kg and Potassium Chlorite, 20 mEq.

Data Collection: During the procedure, we collected data in a database, as shown in Table I.

Figure 4

Table 1: Data collection.

Data			
Length of the procedure (minutes)			
• Time a. Guide-wire into trachea – expansion of shape memory cannula			
• Time b. Insertion of inner cannula – ventilation of pig			
• Time c. Total time			
Difficulties in performing the procedure	Easy	Some	Impossible
Bleeding	Absent/Minimal (≤10 ml)	Medium (11 – 50 ml)	Serious (>50 ml)
Posterior tracheal wall damage	Yes	No	
Kinking of the guide-wire	Yes	No	
Tracheal rings fracture	Yes	No	
Para-tracheal insertion	Yes	No	

The length of procedure was evaluated in minutes, as the time from insertion of the guide-wire into trachea to expansion of shape memory cannula (time a), as the time from insertion of the inner cannula to pig ventilation (time b), and as total time (time c). We used the classification by Frova and Quintel (4) to evaluate difficulties in performing the procedure: (I) easy; (II) some difficulties, but possible; and (III) impossible. Bleeding, during the procedure, was classified as absent/minimal (≤ 10mL), medium (11 – 50 mL), and serious (≥50 mL). We evaluated also posterior tracheal wall damage, kinking of guide-wire, tracheal rings fracture, and para-tracheal insertion.

RESULTS

The results are shown in Table II.

Figure 5

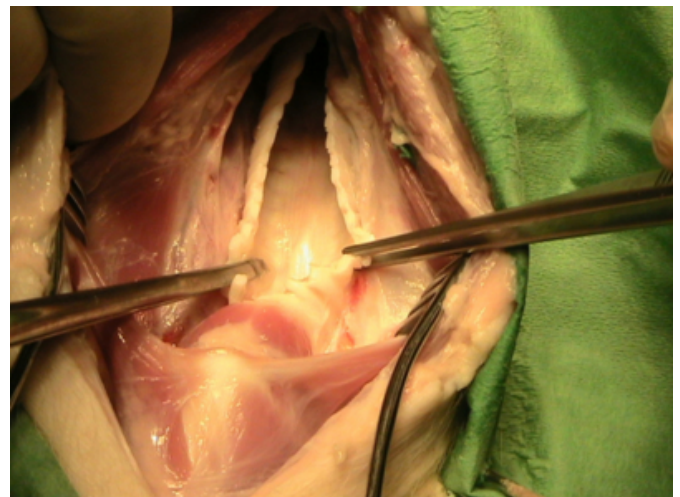
Table 2: Results.

	#1	#2	#3	#4	#5	#6
Length of the procedure (minutes)						
• Time a. Guide-wire into trachea – expansion of shape memory cylinder	6.50	6.10	7.30	6.30	5.50	5.10
• Time b. Insertion of inner cannula – ventilation of pig	2.20	2.30	2.10	1.50	1.40	1.55
• Time c. Total time	9.10	8.40	9.40	8.20	7.30	7.05
Difficulties in performing the procedure	Some	Easy	Some	Easy	Easy	Easy
Bleeding	Absent	Minimal	Absent	Absent	Minimal	Absent
Posterior tracheal wall damage	No	No	No	No	No	No
Kinking of the guide-wire	Yes	No	Yes	No	No	No
Tracheal rings fracture	No	No	No	No	No	No
Para-tracheal insertion	No	No	No	No	No	No

Mean time (± standard deviation [SD]) from insertion of the guide-wire into trachea to expansion of shape memory cannula (time a) was 6.20 ± 0.03 minutes. Mean time (± SD) from insertion of the inner cannula to pig ventilation (time b) was 2.04 ± 0.01 minutes. In addition, mean (± SD) total time (time c) was 8.24 ± 0.04 minutes. There were some difficulties in performing two procedures. Bleeding was absent in 4 (66.7%) pigs, and minimal (≤10 mL) in 2 (33.3%) pigs. There were no cases of posterior tracheal wall damage (Figure 4), no cases of tracheal rings fracture, and no cases of para-tracheal insertion of the device. In 2 (33.3%) cases, we observed kinking of the guide-wire.

Figure 6

Figure 4: No tracheal lesions shown after sacrifice.



DISCUSSION

In elective tracheotomy, fast procedure is not essential. Even if it is not possible to compare the procedure described in our paper with other human studies, too long a procedure could be a problem for ICU physicians. The mean time from guide-wire insertion to ventilation of the pig in our study was 8.24 ± 0.04 minutes. This time can be considered as satisfactory for an elective tracheotomy.

Literature described a learning curve for percutaneous tracheostomies, resulting in a decreased rate of complications and in a shorter procedure with appropriate experience [9]. The technique described in our paper has a simple learning curve. The range in length of procedure has oscillated between 9.10 minutes to 7.05 minutes.

Tracheal endoscopic examination is usually advocated for routine percutaneous tracheostomy, but we did not perform it in our study; nevertheless, we had only negligible complications, as minimal bleeding and kinking of the guide-wire. After sacrifice of pigs, we saw neither tracheal rings fracture, nor posterior wall lesions. These experimental evidences suggest that the progressive radial dilatation is protective against two complications that can lead to late tracheal stenosis [10, 11].

In conclusion, The Mini Invasive Tracheostomy kit is easy to perform and safe. The next experimental step for our device will be a perspective human study that will achieve the evaluation of the long term complications as excessive granulation tissue and the subsequent tracheal stenosis.

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