

Percutaneous Tracheostomy in Critically Ill Patients

Giuseppe Servillo
Paolo Pelosi
Editors

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Foreword

I am honored to have been invited to write the foreword for this book, which provides comprehensive coverage of all the aspects associated with tracheotomy in critically ill patients, from its history as one of the oldest surgical procedures, through the different insertion techniques to current recommendations and clinical management.

When considering this topic while preparing this preface, three elements struck me in particular. Firstly, it is quite amazing to see how much progress has been made in this procedure in just a few decades. When I was a medical student, tracheotomy was a surgical procedure, performed almost exclusively in the operating room. It was considered a rather ‘major’ intervention and needed a referral to the surgical team, which often meant a wait until a surgeon was available. The introduction of percutaneous techniques in 1985 made tracheotomy easier, faster and safer to perform. Tracheotomy is now often performed by an intensivist at the bedside, without the need for a surgeon or an operating room! Secondly, Italian doctors have contributed by far the most to the progress in this field, following the lead set by the Italian physician, Antonio Musa Brasavola, who performed the very first documented successful tracheotomy back in 1546! More recently, our Italian colleagues have contributed by developing simpler systems for percutaneous procedures. Finally, there has been prolonged debate about the optimal timing of tracheotomy in patients receiving mechanical ventilation: “early” versus “late(r)”. But we were naïve to think that the problem could be resolved by a prospective randomized controlled trial (RCT), or indeed several! In these trials, some patients who were randomized to the early tracheostomy group did not actually need a tracheostomy at all, and a number of patients randomized to the late tracheostomy group never received it. Critically ill patients are all different and it is impossible to predict who will need prolonged mechanical ventilation – such decisions need to be personalized to the individual patient.

Maybe up to 10% of critically ill patients will receive a tracheostomy at some point during their stay in the intensive care unit, largely as a result of prolonged mechanical ventilation. It is, therefore, important to have up-to-date, detailed

information regarding this frequent procedure, and this book will be of interest to all those who perform percutaneous tracheotomies, as well as those involved in caring for such patients. I congratulate the editors on this valuable addition to the available literature.

We have indeed come a long way since the very first tracheotomy, and made substantial progress... primarily thanks to our Italian colleagues!

Brussels, Belgium

Jean-Louis Vincent, MD, PhD

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Chapter 1

Tracheostomy: From Surgical to Percutaneous Techniques

G. Servillo and P. Pelosi

Abstract The first known description of tracheostomy is from 3600 BC, on Egyptian tablets. The first scientific reliable description of successful tracheostomy by the surgeon who performed it was by Antonio Musa Brasavola in 1546, for relief of airway obstruction from enlarged tonsils. From the early nineteenth century, medical literature reported a widespread use of tracheostomy. In 1869 Trousseau reported the use of tracheostomy in patients with diphtheria. The recent history of tracheostomy of the last 50 years is notable for major developments to make this technique safer. The recent percutaneous dilatational tracheostomies were initially developed by Ciaglia in 1985. From this point, different techniques have been developed.

According to legend, the first known description of tracheostomy is from 3600 BC, on Egyptian tablets. In the fourth century BC, Alexander the Great used his sword to open the airway of a soldier choking from a bone lodged in his throat. Both Aretaeus and Galen, in the second century AD, wrote that Asclepiades of Bithynia performed elective tracheostomy in around 100 BC. The first scientific reliable description of successful tracheostomy by the surgeon who performed it was by Antonio Musa Brasavola in 1546, for relief of airway obstruction from enlarged tonsils. At the same time, Fabricius ab Aquadependente performed a tracheostomy on a patient with a foreign body in the larynx, as well as on several other occasions [1]. Sanatorius, in 1590, first used a trocar for tracheostomy and reported leaving a cannula in place for 3 days. Tracheostomy was proposed also for George Washington,

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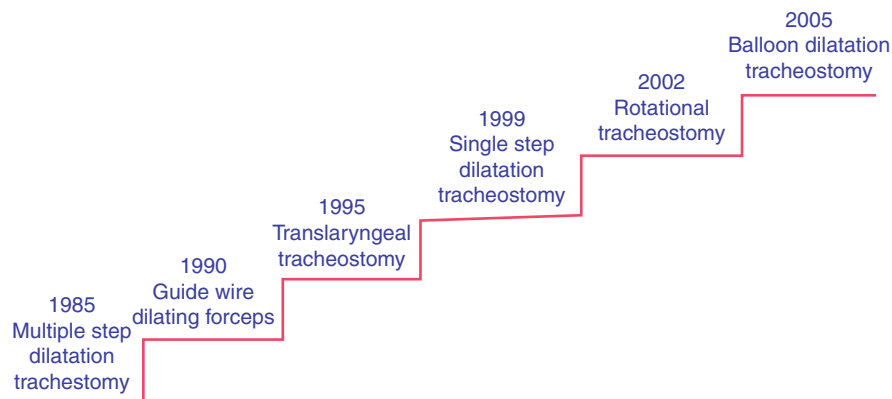
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who died in 1799 for a progressive upper-airway obstruction due to an acute epiglottitis [1]. The prominent physician Elisha C. Dick, who examined the former president, recommended tracheostomy but was overruled by the other physicians in attendance.

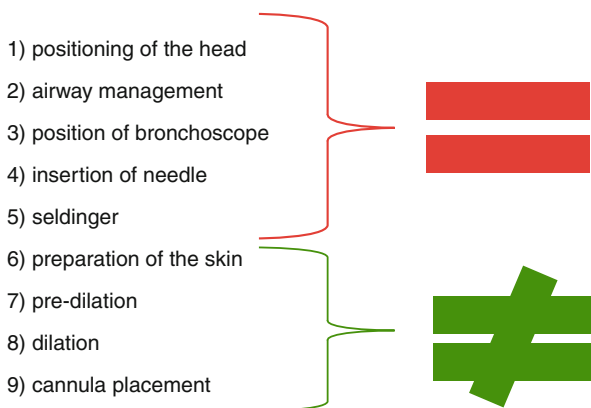
From the early nineteenth century, medical literature reported a widespread use of tracheostomy. In 1869 Trousseau reported the use of tracheostomy in patients with diphtheria [1]. In 1909 the famous surgeon Chevalier Jackson described in detail the technical aspects of the procedure. The recent history of tracheostomy in the last 50 years is notable for three additional major developments [2]. The first progress of tracheostomy was due to the development of intermittent positive-pressure ventilation along with the evolution of intensive care units following the devastating poliomyelitis epidemics in the 1950s [2]. Second, among the last half-century's, the introduction of less injurious, low-pressure cuffs for endotracheal and tracheostomy tubes permitted safer and more widespread use of tracheostomy for long-term mechanical ventilation [2]. Third, the most recent step in the history of tracheostomy has been the development of the percutaneous dilatational technique. First reported by Toye and Weinstein in 1969, the introduction of this technique has brought a revolution of sorts with respect to tracheostomy and its use in critical care [2]. In the 1985 Ciaglia introduced, the use of the Seldinger technique and preassembled kits, such as those that had previously been available for percutaneous nephrostomy, to make tracheostomy simpler and available at bedside [3].

The primary "Ciaglia technique" of a percutaneous subcricoid tracheostomy describes a multistep dilatation procedure using tapered dilators. Following the guide wire, dilators of increasing size progressively enlarge the opening in the tracheal wall [3]. In the 1990 Griggs proposed a new percutaneous technique with a modified Howard Kelly forceps to dilate the soft tissue and then the trachea or both at once. After passing the guide wire through the hole in the tip of the forceps and advancing it until it is inside the tracheal lumen, the forceps is opened and withdrawn with both hands [4]. In 1997, Fantoni proposed a technique consisting of an insertion of tracheostomy tube by use of a J guide wire inserted through a cannula into the tracheal lumen. The Fantoni technique or translaryngeal tracheostomy is the only percutaneous technique with retrograde passage of the tracheal lumen. This method uses a specific "cone-cannula", a special device formed by a flexible plastic cone with a pointed metal tip joined to an armoured tracheal cannula. This "cone-cannula" is acting as dilator and tracheostomy tube at once. Additionally, the translaryngeal technique necessitates a rigid tracheoscope and a specific, 40 cm long, 4 mm inner diameter, cuffed endotracheal catheter serving to oxygenate and ventilate the patient [5]. In 1999, a new modified Ciaglia method was proposed: the single-step dilatational tracheostomy. This technique used a curved dilator and a (tracheostomy tube) loading dilator. Following the guide wire, a single tapered, horn-shaped dilator enlarges the opening in the tracheal wall [6]. In 2002, Frova et al. proposed the rotational dilatational tracheostomy [7]. The controlled rotating dilation used a specially designed screw-type dilator with a thread to facilitate

dilation of soft tissue and tracheal wall. After complete dilatation, the dilator is twisted back and removed and the tracheostomy tube is advanced over the guide wire into the trachea [7]. In 2005, the balloon dilatational tracheostomy was proposed as a development of the first Ciaglia technique [8]. This method uses an assembly consisting of a balloon-tipped dilatation-catheter, an inflation device and a (tracheostomy tube) loading dilator [8].



Despite each technique has specific characteristics, all PDT are carried out during general anaesthesia using modified Seldinger technique (with the exception for TLT technique that uses a translaryngeal approach) and performed under continuous bronchoscope control. The dilatational techniques recognise essentially nine procedural steps. The first five, the positioning of the head, the airway management, the position of bronchoscope, the insertion of needle and Seldinger, are shared with all the techniques currently available, while the preparation of the skin, the pre-dilatation, dilatation and the cannula placement vary according to the technique.



At this time, percutaneous dilatational tracheostomies are largely used in ICU. PDT is easy to be performed with a faster learning curve [9]. PDT is a safe

alternative to ST [10]. The percutaneous approach was also a skill in the training of intensive care physicians, whereas surgeons largely performed open tracheostomies [11]. The preference, background and training of physicians were responsible of the choice of the tracheostomy technique in critically ill patients.

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Chapter 2

Anatomical and Sonographic Landmark

M.G. Valerio and P. Pelosi

Abstract During percutaneous dilatational tracheostomy (PDT), the physician cannot directly see the anatomical structures involved which are located between the skin and the tracheal lumen.

To perform a safely PDT is useful taking into account the anatomy of structure involved.

In PDT, ultrasound may help to easily identify the right tracheal ring and the anatomical structures involved in the procedure. In this chapter, we describe: (1) the neck anatomy focusing on the region usually involved in the procedure, (2) a brief introduction of ultrasonography and (3) the ultrasound-assisted PDT.

2.1 Rationale

Ultrasound-assisted PDT has a larger success rate, is faster to perform [1], is safer and is more precise than conventionally procedure [2–7]. The ultrasound-assisted PDT could be safely performed also in obese patient [8]. Actually, in a recent study, the ultrasonography replaced the broncoscopic guidance of PDT [9]. Neck ultrasounds as screening before PDT may help to visualise anatomic anomalies that may complicate the procedure. For example it has been reported a case in which the brachiocephalic artery was located before the trachea.[2].

2.2 Anatomy

At the neck midline, from the surface to the deeper layers, we found:

- Epidermis
- Dermis
- Hypodermic fatty layer

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- Superficial cervical fascia
- Middle cervical fascia
- Deep fatty layer
- Isthmus of the thyroid gland
- Tracheal wall

The thickness of fatty layer is variable according to body mass index, but even in thin layers, some vascular abnormalities can be found.

2.2.1 Structure of the Trachea

The trachea is a fibrous hollow organ made of 12–20 cartilaginous rings. The trachea is nearly but not quite cylindrical, flattened posteriorly. In cross section, it is D-shaped, with incomplete cartilaginous rings anteriorly and laterally, and a straight membranous wall posteriorly.

This structure starts from the inferior part of the larynx (cricoid cartilage) in the neck, opposite to the 6th cervical vertebra, to the intervertebral disc between T4 and T5 vertebrae in the thorax, where it divides at the carina into the right and left bronchi. The length of the trachea is different, being shorter in children rather than adults. According to the position of the head, when the neck is in a neutral position, the cervical portion of the trachea is made of five to six rings. The surface of the trachea is covered, from above downward, by the isthmus of the thyroid gland, the inferior thyroid veins, the arteria thyroidea ima (Neubauer or ima artery, if it exists), the sternothyroid and sternohyoid muscles, the cervical fascia and, more superficially, the jugular venous arch between the anterior jugular veins. The thyroid isthmus usually is in front of the 2nd and 3rd tracheal cartilages. Laterally, in the neck, the trachea is in relation with the common carotid arteries, the right and left lobes of the thyroid gland, the inferior thyroid arteries and the recurrent nerves. Posteriorly, it is in contact with the esophagus and behind it, to the vertebral column in the neck and thorax [10, 11].

2.2.2 Vascularisation

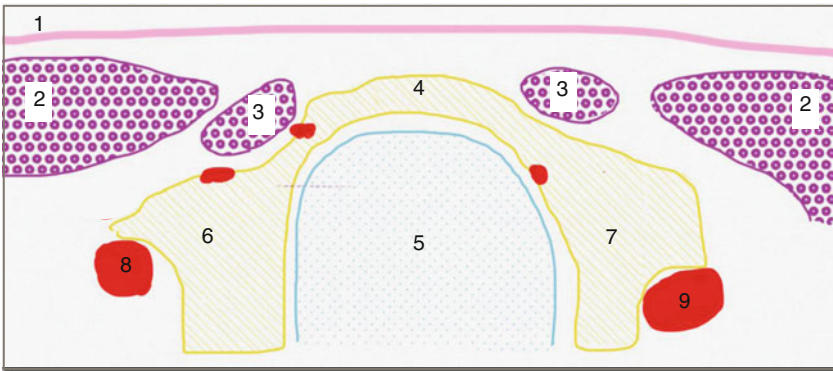
In the hypodermic fatty layer, some small veins may be found, and their size, distribution and shape are very variable. The fasciae are made of fibrous tissue with very little vascularisation.

In the deep fatty layer, it is common to find some veins tributary to the thyroid veins, and seldom an artery running vertically along the midline from the arch of the aorta to the thyroid isthmus can be found (Neubauer or ima artery) [10].

The trachea is vascularised by inferior thyroid vessels. Four principal arteries supply the thyroid gland: upper and lower and left and right thyroid arteries. The thyroid ima artery comes from aortic arch and ascends vertically on the anterior vsurface of the trachea, supplies both the trachea and thyroid and may terminate as a single trunk or as multiple bifurcations.

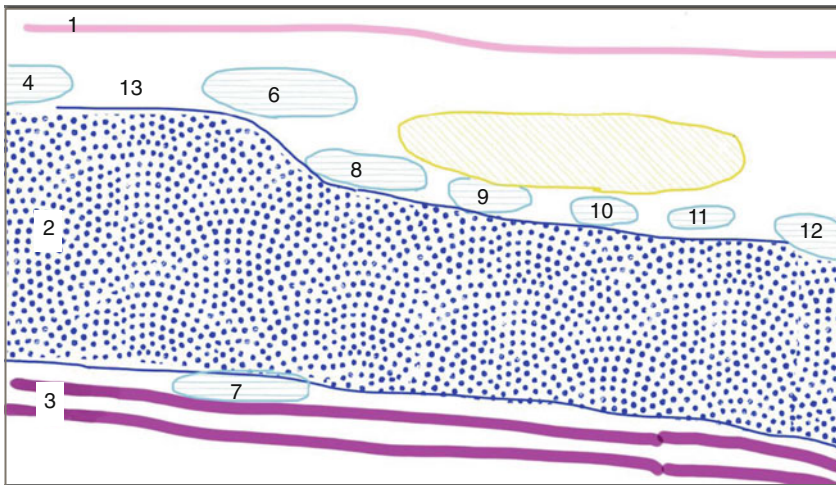
The thyroid is drained by several different veins that may be grouped in six groups (upper middle and inferior thyroid veins on both sides), and these vessel may increase their size in case of respiratory distress. The inferior thyroid veins may be organised in a complex plexus in front of the trachea going downwards into the brachiocephalic vein, and these vessels also may cause complications during operative procedures on the cervical portion of the trachea such as tracheostomy [10, 11].

2.2.3 Transverse Section of the Neck



1 Skin, 2 Sternocleidomastoid muscle, 3 Sternohyoid muscle, 4 Thyroid (isthmus), 5 Trachea, 6 Thyroid (right lobe), 7 Thyroid (left lobe), 8 Right carotid artery, 9 Left carotid artery. In red are depicted other blood vessels of the thyroid capsule

2.2.4 Longitudinal Section of the Neck



1 Skin, 2 Trachea, 3 Esophagus, 4 Lower portion of laryngeal cartilage, 5 Isthmus of the thyroid, 6 Anterior portion of the cricoid, 7 Posterior portion of the cricoid, 8 II tracheal ring, 9 III tracheal ring, 10 IV tracheal ring, 11 V tracheal ring, 12 VI tracheal ring, 13 Cricopharyngeal membrane

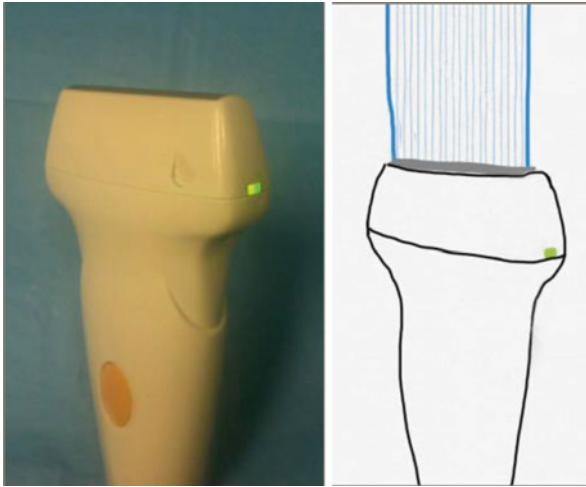
2.3 Principles of Ultrasonography

2.3.1 Introduction

In this paragraph, we describe the principles of ultrasonography.

The ultrasound scanner is made of one or more probes.

The probes emit a short burst of ultrasound and then receive the echoes back, such sequence is repeated several times per second.



When the ultrasound passes through the body of the patients, it may encounter anatomical structures that partially or completely reflect them, and hence, an echo is generated.

The ultrasound scanner measures the time elapsed from the emission of the ultrasounds and the detection of the echoes, and then it calculates the distance between the probe and the structure that generated the echoes. The intensity of the echo is also measured and a dot is plotted on the screen. The intensity of white is proportional to the intensity of the echo received. A black and white image will be plotted several times per second on the screen representing the echoes received back from the tissues of the patients originated from the probe.

Structures that produce few or no echo are represented as black or dark grey and defined hypoechogenic. Structures that reflect the ultrasound more are represented as white lines and are described as hyperechogenic. If most ultrasound is reflected back, little or no further echoes will be produced underneath the hyperechogenic structure.

In some cases, it is possible to measure the frequency shift of the echoes produced by moving objects, such frequency shift is named Doppler effect. When this function is activated (usually called Duplex mode), the dots are plotted in red or

blue according to the direction and speed of the body who generated the echo. The Doppler effect is useful to visualise the movement of blood in vessels.

The ultrasounds cannot pass through air. A gel should be smeared on the skin of the patient, and more important, when the ultrasound beam encounters a structure full of air (e.g. the trachea), it will be completely reflected back, and no echoes will be received (and plotted) from the area below, on the screen arises a dark “shadow”, which is an artifact effect not corresponding to any actual anatomical structure. In case of subcutaneous emphysema, ultrasonography will be very difficult.

2.3.2 Hardware

There are many different ultrasound scanners available.

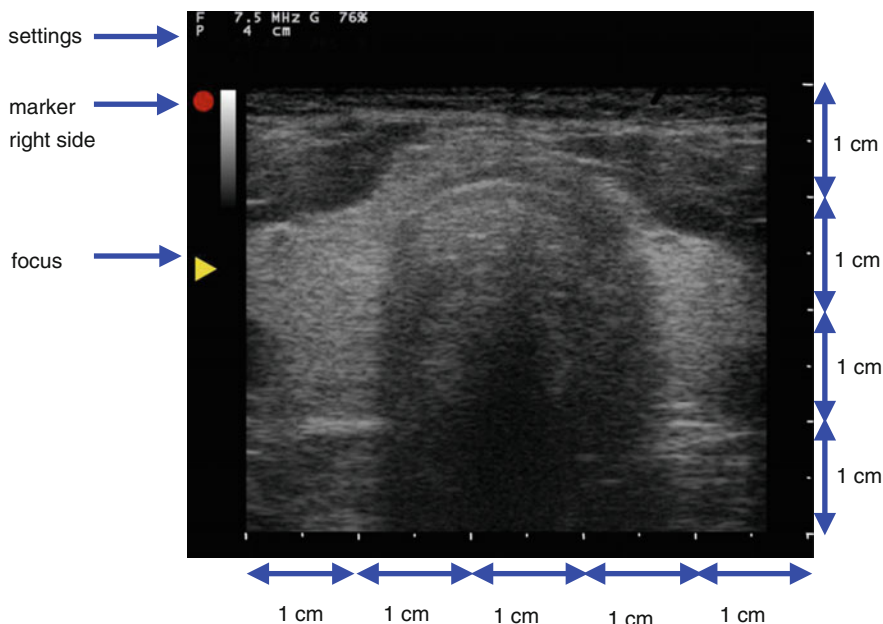
Among the several different probes available on the market, the best one to perform neck ultrasounds is the linear probe. This one emits a thin layer of parallel ultrasound wave. Usually the frequency of the ultrasounds ranges from 7.5 to 12 MHz; the small length of wave will provide a sharp image 1–7 cm away from the probe.

On any ultrasound probes, there is a marker of orientation, in the picture is a green light, and in other devices, it may be a notch or a small knob on the side of the probe. It is very important to keep the marker on the right side of the patient during transverse scan or on the cranial side of the patient during longitudinal scan. If the orientation of the probe is not known by the user, ultrasonography may be very confusing and even harmful for the patient.

On the ultrasound scanner, there are usually many different knobs and buttons, which may puzzle the inexperienced user. For the ultrasound-assisted PDT, only very few functions as on-off switch, probe selector, depth, gain, focus and freeze are really needed. The “depth” control sets the maximum distance from the probe which is plotted on the screen, and it is suggested to set it at 5 cm or less. The “gain” control sets the intensity of the screen, and the user should set it according to his/her capability to recognise anatomical structures. The “focus” control improves the quality of the image at a given distance from the probe, and it is suggested to keep the focus at 1 or 2 cm from the probe, in the area that will be affected by the procedure. The freeze button is used to stop ultrasonography and leave the last image plotted on the screen to observe it or to print it.

Modern ultrasound scanners have many functions to improve the quality of the image that are extremely useful when performing a diagnostic exam. In case of ultrasound-assisted PDT, such features are useless, and they should be disabled if they slow the updating on frameworks on the screen. It is better to have a smooth-flowing real-time movie of the neck rather than a razor-sharp static image.

The ultrasonography provides many information not properly required for an ultrasound-assisted PDT. On the side of the screen, a marker followed by several dots similar to the notches on a ruler represents the depth and is very useful to esteem the size of any structure seen on screen.



2.4 Ultrasonographic Anatomy

Four tissues can be easily identified in an ultrasound of the anterior part of the neck: muscles, vessels, thyroid and trachea. The shape changes according to the plane of section, for example, a vessel may seem round when observed by a transverse section and long and rectangular when observed on a longitudinal section.

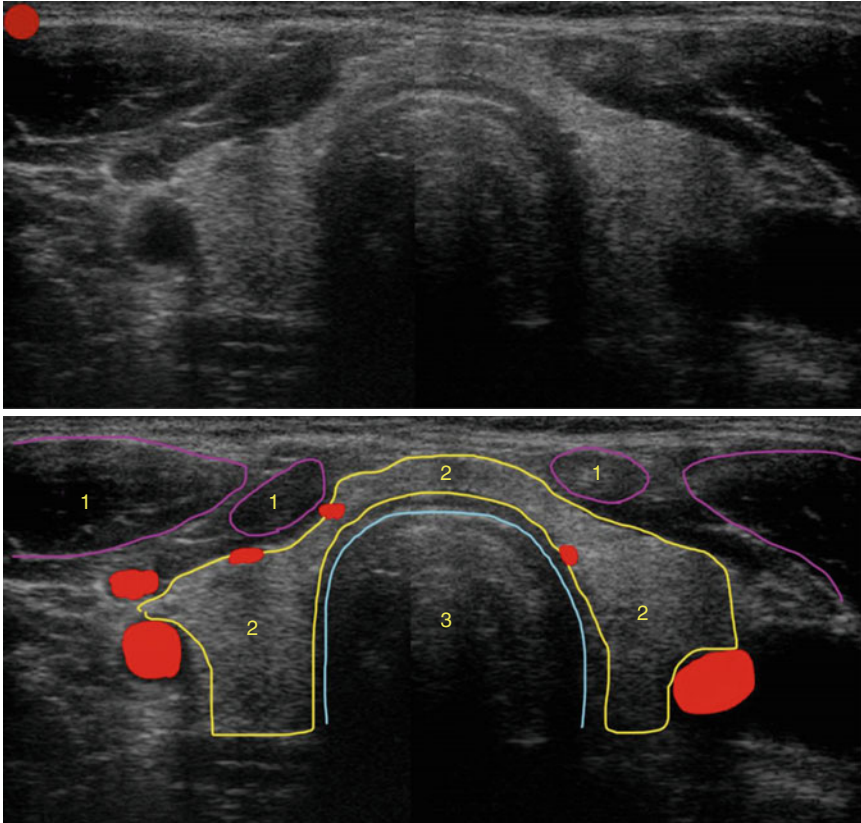
Vessels are hypoechogenic (black) and dynamic: arteries, according to the systolic pulse; veins according to the venous pressure and volemic status, breathing and Trendelenburg position [13]. A gentle pressure of the probe on the skin of the patient may collapse the underlying veins.

Thyroid is quite echogenic, and it can be easily recognised due to its clear grey and smooth ultrasound pattern. Muscles are hypoechogenic and appeared as dark grey with slightly irregularity due to the septa between fibres.

By ultrasonography, you can see the most superficial part of the trachea that appears as strong hyperechogenic line. Air has been considered enemies of ultrasonography. Due to the differences in velocity and acoustic impedance of ultrasound between normal tissue and air-filled lumen, a total reflection of ultrasound occurs.

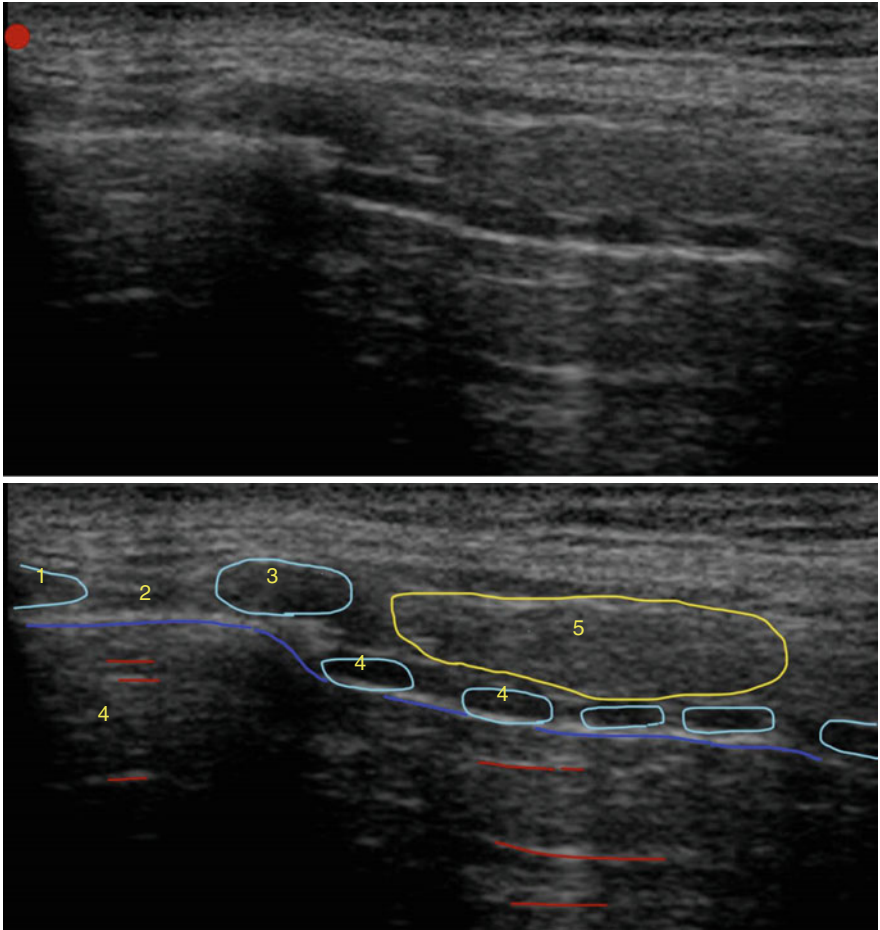
Several artifacts parallel white lines are visible in the trachea, representing a reverberation of ultrasound trapped between the trachea and the probe structures deeper to the trachea can't either be visualized due to the echographic shadow. In a longitudinal scan of the trachea, you can easily recognise the rings that are hypoechogenic.

2.4.1 *Transverse Scan of the Neck*



1 Muscles, 2 Thyroid, 3 trachea, in red are depicted some blood vessels

2.4.2 Longitudinal Scan of the Neck



1 Lower portion of the laryngeal cartilage, 2 Cricolaryngeal space, 3 cricoid, 4 tracheal rings, 5 thyroid, Blue line tracheal mucosa. Red lines artifact

2.5 Ultrasound-Assisted Percutaneous Tracheostomy

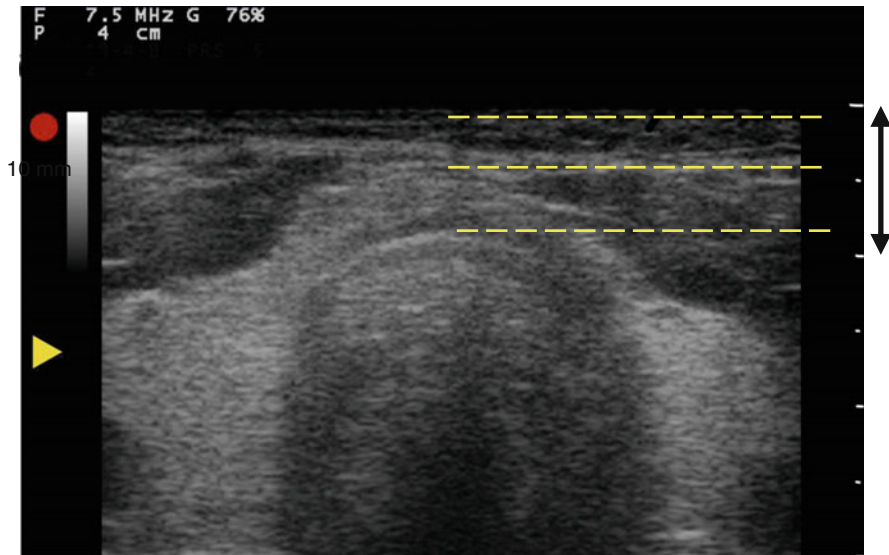
Echography can be very useful to assist percutaneous tracheostomy, in three different steps:

1. Evaluation of the anatomy of the neck between the skin and the trachea
2. Marking the right level of the trachea to perform tracheostomy
3. Guiding the needle closely to the top of the tracheal arch

2.5.1 Anatomical Study

It is advisable to perform transverse scans of the anterior region of the neck at different levels to get the following information:

- Depth of the trachea
- Thickness of the thyroid isthmus
- Aberrant vessels that may cause complications
- Deviation of the trachea from the midline



In this case, the trachea is located at less than 10 mm from the surface, and the isthmus has a thickness of about 4 mm.

2.5.2 Location of the Right Level to Perform Tracheostomy

A longitudinal scan of the neck is performed. Holding the probe with nondominant hand, you slide between the probe and the skin of the patient a straightened paperclip. This paperclip will produce a black shadow on the screen, and when the shadow is located on the tracheal ring where you plan to do the procedure, remove the probe and mark the skin with the dermatographic pen (Figs.2.1, 2.2 and 2.3).

This part of the procedure can be also performed in a sterile manner. You will need a sterile sheet for the probe, sterile gel and instead of the paperclip a long spinal needle, and be careful to not accidentally wound the patient with the sharp tip of the needle.

Fig. 2.1 Longitudinal scan of the neck, on a healthy volunteer: the paperclip sweeps up and down to locate the proper level for tracheostomy

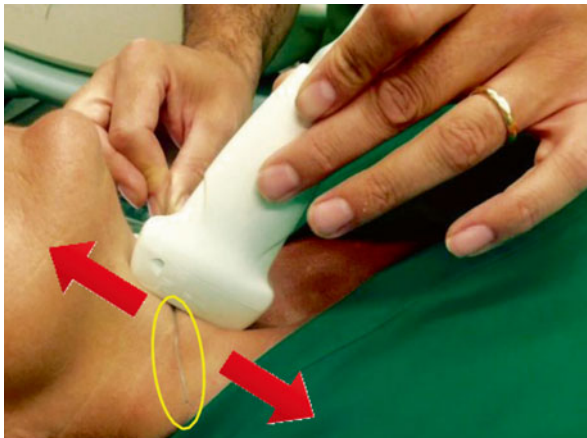


Fig. 2.2 Longitudinal scan of the neck: the shadow of the paperclip (red arrow) is too cranial and should be swept slowly downwards

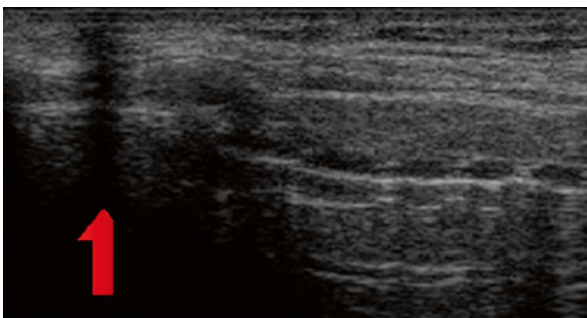
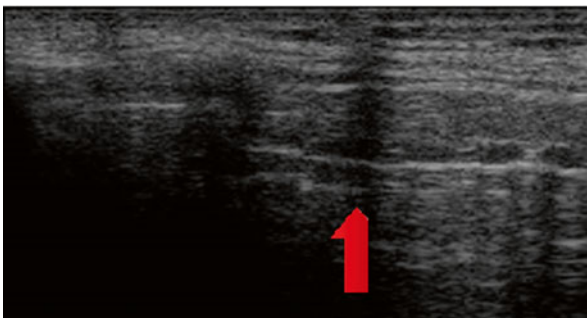


Fig. 2.3 Longitudinal scan of the neck: the shadow of the paperclip is on the 3rd tracheal ring



2.5.3 Puncture of the Trachea

In this case, it is mandatory that orientation of the probe is correct (markers on the probe and on the screen on the same side, usually right) and the position of the

screen is comfortable for the operator. You should perform a transverse scan of the neck at the level you previously selected; the probe must be held with the nondominant hand, very steadily and always perpendicular to the trachea; and the dominant hand handles the needle. During the transverse scan, you should be able to estimate with accuracy the depth of the trachea, then you will enter the skin with the needle caudally to the probe at a distance from the probe equal to the depth of the trachea from the skin with an angle of 45° , and doing so, the sharp tip of the needle will reach the part of the trachea visualised on the screen. When the needle has positioned in the trachea, the ultrasound is less useful because the tracheal lumen is full of air and no echoes will be produced (Fig. 2.4).

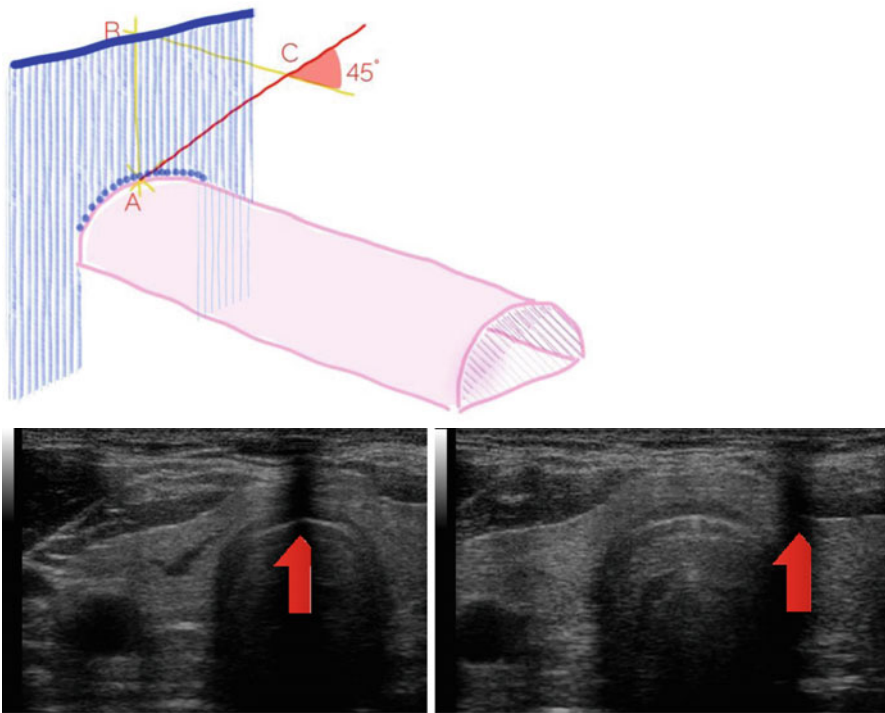


Fig. 2.4 (a) Trachea, pink; ultrasound beam, blue; A tracheostomy site. AB, depth of the trachea from skin; C, needle entry point in the skin. Needle direction (*red line*). The distance between ultrasound probe and needle entry point on the skin (*BC*) should be the same of the depth of the trachea (*AB*), and with an angle of 45° , the point where the needle is expected to touch the trachea will fall in the ultrasound beam and be easily visualised. The shadow cast by the needle is located on the middle of the trachea (b). The shadow cast by the needle is too lateral and should be changed (c)

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Chapter 3

Indication and Timing

Andrea Cortegiani, Vincenzo Russotto, and Cesare Gregoretti

Abstract Tracheostomy is performed in patients requiring prolonged mechanical ventilation aiming at avoiding the potential detrimental effect of a sustained translaryngeal intubation (e.g. laryngeal oedema, mucosal ulcerations). Potential benefits of tracheostomy in critically ill patients are improved comfort and reduced need for sedation, easier clearance of secretions and oral hygiene, and a possible faster weaning from mechanical ventilation. Controversy exists over optimal timing (early, tracheostomy placement compared with later time points) in patients with respiratory failure. Among the published randomised controlled trials, two large studies did not report a significant advantage of an early tracheostomy compared to a late procedure for the primary outcomes of incidence of ventilator-associated pneumonia and all-cause of mortality at 30 days from randomisation. In non-head injured blunt trauma patients with prolonged respiratory failure, tracheostomy placement after 7–10 days seems appropriate. This timing would avoid the potential procedural complications of an unnecessary procedure in patients with a possible shorter period of mechanical ventilation. Further investigations are needed for giving proper indication and timing of tracheostomy in selected populations (e.g. traumatic and non-traumatic neurologic injuries).

Overview

Tracheostomy is the most common procedure performed in patients admitted to the intensive care unit (ICU) and requiring mechanical ventilation [1]. For most indications and potential benefits of tracheostomy, high-quality evidence is lacking as it comes from clinical experience, observational studies and few controlled studies [1]. The best timing during the ICU stay for tracheostomy

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performance has been better investigated. Appropriate selection of patients and time for tracheostomy may enhance the potential benefits associated with this procedure [2].

This chapter will focus on indication and timing of tracheostomy, providing the clinician information on the current level of evidence about the decision of whether and when to perform a tracheostomy in a critically ill ICU patient.

3.1 Indication for Tracheostomy

The requirement of prolonged mechanical ventilation is the leading indication for tracheostomy [3]. Patients with difficult airway management (e.g. upper airway obstruction due to cancer, trauma, burn, surgery) are a small proportion of patients receiving tracheostomy in either emergency or elective setting. A greater proportion of ICU patients undergo elective tracheostomy after considering the potential adverse events related to prolonged translaryngeal intubation [4]. Although manufacturing and material of endotracheal tube (ET) and its cuff technology evolved during years, leading to reduced injuries and better tolerance [5], laryngeal complications following laryngeal intubation (e.g. laryngeal oedema, mucosal ulcerations) is still a matter of concern [6–8]. Different potential benefits of tracheostomy have been advocated and may represent the reason for tracheostomy performance in selected individuals [2]. In a recently published nationwide survey investigating the indication, timing and preferred technique of tracheostomy, a prolonged mechanical ventilation was the leading indication for tracheostomy, followed by provision of airway protection in neurological, surgical or traumatic disorders [9]. Table 3.1 summarises the indication and potential benefits of tracheostomy in the ICU setting.

Table 3.1 Indications and potential benefit of tracheostomy in critically ill patients

Indications
Need for prolonged mechanical ventilation
Upper airway obstruction
Potential benefits
Patient's comfort and reduced need for sedation
Improved clearance of airway secretions
Faster weaning from mechanical ventilation
Avoidance of (or recovery from) laryngeal injuries due to prolonged translaryngeal intubation and better long-term laryngeal function
Improved oral hygiene
Oral intake
Easier communication
Easier airway management in non-ICU settings
Possible reduction of ventilator-associated pneumonia

Patients with both traumatic and non-traumatic neurological injury may benefit from tracheostomy since it provides airway protection and facilitates pulmonary clearance. In this group of patients, long-term ventilatory support may not be necessarily required [10].

Patients' undergoing tracheostomy in an elective setting should have their clinical status optimised in order to reduce the risks associated with its surgical or percutaneous dilatational procedure (i.e. hemodynamic instability, risk of delivering a low ventilatory support, metabolic and haemostasis alterations) [1].

3.2 Benefits of Tracheostomy

3.2.1 *Patient's Comfort*

It is a common belief that tracheostomy is associated with improved patients' comfort and consequently less need for sedation [10]. In a retrospective study with the primary aim of assessing the effect of tracheostomy on sedation level requirements, tracheostomy was performed in 72 out of 312 patients requiring mechanical ventilation during the study period. The cumulative doses of fentanyl and midazolam decreased after tracheostomy. This observation was associated with a reduced time on sedation without any increase in agitation. Of note, during the 7 days following tracheostomy, almost half of patients started to have oral alimentation [11].

In a randomised study of early tracheostomy compared to prolonged translaryngeal intubation in unselected critically ill patients, participants were asked to answer a subjective questionnaire assessing the degree of comfort through a 10-point rating scale. For most investigated criteria (e.g. mouth discomfort, feeling of better mouth hygiene, patient's perception of better well-being, overall feeling of comfort) resulted in favouring tracheostomy. Of note, all patients who received both translaryngeal intubation and early or late tracheostomy considered the latter the most comfortable technique. [10] The potential conclusion is that improved patient's comfort may be enough to justify the indication for tracheostomy in patients with an anticipated prolonged intubation.

3.2.2 *Weaning from Mechanical Ventilation*

It is a common belief that tracheostomy may hasten the liberation from mechanical ventilation and facilitate transfer outside the ICU [12]. The reduced dead space of tracheostomy has been traditionally included among the advantages of the procedure contributing to a higher weaning success rate [13]. However, the contribution of a smaller dead space seems to have a negligible effect on ventilatory mechanics and gas exchange [14].

Tracheostomy may reduce resistances to airflow if compared to endotracheal tube. Indeed, airways resistance and associated work of breathing is increased in the presence of turbulent airflow, tube length and smaller tube diameter [15]. Therefore, a theoretical benefit in terms of resistance may be attributed to tracheostomy, given its shorter length, rigid design and a possible presence of an inner cannula, which allows an easier and effective clearance of secretions. Reduced airflow resistance and associated work of breathing was studied both in a mannequin model [15] and in several case series of patients undergoing tracheostomy. A significant reduction of baseline work of breathing in endotracheally intubated patients was reported after tracheostomy performance in most, but not all, studies [13, 16–18]. However, in tracheostomised difficult to wean subjects, the decrease of the tracheostomy tube size was associated with an increased diaphragm effort and worse weanability indices (pressure-time product per minute, the ratio of breathing frequency to tidal volume, and tension-time index of the diaphragm) that were otherwise normal, using a higher diameter. An *in vitro* study showed that resistances increased similarly for tracheostomy tube and endotracheal tube, decreasing the diameter and increasing the flows [19]. The benefit of tracheostomy in terms of reduced duration of mechanical ventilation has been investigated as a secondary outcome of recently performed randomised studies designed with the primary aim of assessing the role of early tracheostomy for mortality or ventilator-associated pneumonia (VAP) reduction if compared to a late tracheostomy approach [20, 21], showing a higher ventilator-free days and ICU-free days in one of them [20]. A major difficulty in assessing the direct effect of tracheostomy on weaning is the need to anticipate prolonged mechanical ventilation for patients' inclusion in trials. For this reason, Sugerman et al. [22] highlighted the possibility of selection bias among the limitations of a multi-centre study investigating the use of early tracheostomy in trauma patients. In this study, attending surgeons or residents may have prevented patient's entry into the study according to their strong clinical belief of performing an early extubation. Moreover different weaning protocols and even weaning success criteria have been adopted in different trials. It has also been emphasised that the clinician's management of patients needing ventilatory support may be modified if patients are endotracheally intubated or tracheostomised [3]. Tracheostomy allows the maintenance of a patent airway and the ease of suctioning in a patient who may be ready for discontinuation from ventilatory support. These advantages may lead to an early liberation from the ventilatory support compared to a more cautious approach reserved to endotracheally intubated patients, who would be exposed to an increased risk of reintubation in case of failure [23]. In a cohort of reintubated patients, patients who received tracheostomy had an outcome similar to those without tracheostomy [24].

Finally, in many hospitals, patients with a tracheostomy can be discharged from the ICU to different facilities where, eventually, the ventilatory support may be continued by trained staff. The presence of a stable airway with ease of suctioning by non ICU staff is perceived as a safe policy by most clinicians [3]. This fact should be considered if length of ICU stay is a secondary outcome variable of a study investigating the benefits of tracheostomy in terms of duration of mechanical ventilation.

3.2.3 *Incidence of Ventilator-Associated Pneumonia*

No definitive evidence has been reported about the role of tracheostomy for prevention of VAP. Pathogenesis of VAP largely relies on the interplay between the endotracheal tube, risk factors, virulence of bacteria and patient's immune status [25]. The endotracheal tube may play a major role because of the disruption of natural defence mechanisms (i.e. cough reflex, mucociliary clearance) and the risk of tracheal soiling due to micro-aspirations from the pooling of secretions above the ET. The theoretical advantage of tracheostomy comes from the preservation of glottic function and the avoidance of other potential pathogenic mechanisms associated with translaryngeal intubation. Nevertheless a high-quality, multi-centre study investigating the advantage of early tracheostomy compared to late tracheostomy for the primary outcome of VAP showed no statistically significant difference in VAP incidence among the two groups [20].

Most of data about VAP incidence came from studies investigating tracheostomy timing [20, 26]. However, a potential bias could arise when comparing an early versus late approach since the incidence of VAP is clearly related to the length of intubation.

3.3 **Timing of Tracheostomy**

Timing of tracheostomy in critically ill patients refers to the time at which tracheostomy is performed during the clinical course. Even though indications and advantages of tracheostomy have been largely described in the critical care setting, timing remains controversial. More than 25 years ago, a consensus conference on artificial airways in patients receiving mechanical ventilation produced the following recommendation: "The appropriate duration of translaryngeal intubation cannot be defined at present. Clinical consideration or complications may dictate changing the artificial airway to another route. However, no data exist that give adequate direction as to when it is routinely advisable to change from a translaryngeal intubation to a tracheostomy" [4]. Nowadays, some uncertainty remains about this topic. A strong indication for tracheostomy arises when there is the need for prolonged endotracheal intubation for mechanical ventilation. The concept of "prolonged" intubation has changed over time, starting from an older approach with indication for tracheostomy given after several days of the course of the critical illness (usually after 15 days or more of endotracheal intubation) to more recent approaches considering tracheostomy earlier (e.g. after 3–10 days). Moreover, other aspects have influenced this trend. In 1960s, ETs were made of rigid and inflexible material with low-volume, high-pressure cuff. [27] Consequently, it was common to perform tracheostomy "early" during the clinical course to minimise injuries to upper airways, larynx and trachea resulting from translaryngeal intubation. During the following decades, progress in materials and equipment leads to less injuries and complications. In 1981 Stauffer et al. [28] reported data about risks associated with tracheostomy describing a significant increase in morbidity (stomal haemorrhage and

infection rates >30 %, rate of tracheal stenosis >50 %) and a significant increase in mortality (4 %). Thus, the trend started to change leading to a progressive delay of the procedure. During the last 25 years, advances in techniques and equipment caused great improvement in the safety of the procedure that became easily performable at bedside [3, 29, 30]. Generally, the different approaches in timing have been defined as *early* and *late*. However, no consensus exists about what exactly constitutes early vs late tracheostomy. The question about tracheostomy timing is complex because several factors should be considered: (1) an estimate of the probability of prolonged mechanical ventilation, especially for certain categories of critically ill patients (e.g. neurological or trauma patients), and (2) the best time for tracheostomy during the course of the critical illness. In the case of patients considered at risk of prolonged mechanical ventilation, early tracheostomy strategy would expose them to an unnecessary procedure if the prediction failed. On the other hand, patients considered to have unduly relatively short mechanical ventilation during their stay in the ICU may undergo an unnecessary prolonged exposure to translaryngeal endotracheal intubation. This fact may increase potential complications, without the advantages of tracheostomy in terms of weaning, and other aspects of care.

A recent analysis [31] of seven national surveys performed in France [32], Germany [33], Italy [9], the Netherlands [34], Spain [35], Switzerland [36] and the UK [37] demonstrated that the presence of a shared clinical practice across Europe about tracheostomy timing (from 7 to 15 days from ICU admission). A review of the Project IMPACT database (109 ICUs) reported that tracheostomy was performed at a median of 9 days after ICU admission with an interquartile range of 5–14 days [38]. From many years, evidence to guide the decision about tracheostomy timing came from observational, retrospective and relatively small and/or single-centre randomised trials [10, 22, 39–42]. Several factors may have reduced the quality of evidence from studies: variable protocols quality, sub-optimal sample size, heterogeneity in populations enrolled and patients' characteristics, lack of standardised protocol for co-interventions and inconsistency in outcomes selection across studies. Many of these studies supported the concept that early tracheostomy was beneficial, generating the hypothesis to be confirmed by larger studies. Recently, two large prospective multi-centre randomised trials enrolling general ICU population [20, 21] and two meta-analyses [43, 44] have investigated early versus late strategy for tracheostomy, adding robust data and new insight about this topic.

In 2010, Terragni et al. [20] reported data from a multi-centre randomised trial performed in 12 Italian ICUs from June 2004 to June 2008 enrolling 600 adult patients without pneumonia (clinical pulmonary infection score, CPIS <6), ventilated for 24 h, who had a Simplified Organ Failure Assessment score between 35 and 65 and a Sequential Organ Failure Assessment (SOFA) score of 5 or more. Patients were randomised after 72 h (48 h after the enrolment) if having $\text{PaO}_2 < 60$ mmHg ($\text{FiO}_2 = 0.5$, $\text{PEEP} = 8$ cmH₂O), SOFA score ≥ 5 and no pneumonia. The two arms of the study were: (1) early tracheostomy (6–8 days of laryngeal intubation, 209 patients assigned) and (2) late tracheostomy (13–15 days of laryngeal intubation, 210 patients assigned). The primary outcome of the study was the incidence of VAP; secondary outcomes during the 28 days immediately following ran-

domisation were number of ventilator-free days, number of ICU-free days and survival. VAP were diagnosed using the simplified CPIS (CPIS score >6) at study entry, at randomisation and every 72 h until day 28. The study included medical patients (40 % of the early group and 36 % of the late group), scheduled surgical patients (8 % vs 10 %), unscheduled surgical patients (41 % vs 45 %) and trauma patients (11 % vs 9 %) without significant difference between groups. Many randomised patients (31 % in the early group vs 43 % in the late group) did not undergo tracheostomy due to proximity to extubation or death. All tracheostomies were performed bedside with percutaneous techniques (Griggs technique in 72 % in early group and 73 % in late group, PercuTwist technique in 25 % in early group and 22 % in late group). Adverse events occurred in 39 % of both groups. The incidence of VAP was not significantly different between groups (14 % early vs 21 % late; $P=0.07$). The number of ventilator-free and ICU-free days and the incidences of successful weaning and ICU discharge were significantly greater in patients randomised to the early tracheostomy group compared with patients randomised to the late tracheostomy group; there were no difference between the groups in survival at 28 days. The authors concluded that early tracheostomy did not result in a significant reduction in incidence of VAP compared to late tracheostomy. They also underlined that long-term outcomes did not differ and that more than one-third of patients experienced adverse events related to the tracheostomy. Basing on these findings, they suggest that tracheostomy should not be performed earlier than 13–15 days. One limitation of this study was the use of CPIS score for the diagnosis of VAP since its diagnostic performance in this setting was not high, especially in surgical and trauma patients [45]. Another limitation was related to some exclusion criteria (such as chronic obstructive pulmonary disease, active pneumonia, anatomic deformity of the neck, lung cancer) partially limiting the clinical applicability of the results to general ICU population.

The TracMan trial [21] was an open multi-centre randomised trial published in 2013. It was conducted in 13 university and 59 non-university hospitals in the UK from 2004 to 2011 and enrolled 909 patients. Subjects were enrolled if identified to require at least 7 days of mechanical ventilation by treating physician. The investigators randomised patients to receive early (within 4 days from ICU admission and immediately after randomisation) or late tracheostomy (after 10 days or later if still indicated). The primary outcome was all-cause mortality 30 days from randomisation. Secondary outcomes were mortality at critical unit, hospital discharge and, at 1 and 2 years, length of stay in the critical care unit and in hospital, antimicrobial-free days in critical care up to 30 days from randomisation. Most patients were medical (79.6 %), with respiratory failure as the most common primary diagnosis, whereas 20.6 % were surgical. Almost 90 % of tracheostomies were performed bedside with single-tapered dilator as the most common technique (77.3 %). In the early group 91.9 % of patients received tracheostomy; in the late group, only 45.5 % of subjects received tracheostomy since many were liberated from mechanical ventilation without tracheostomy. There was no difference in 30-day mortality (30.8 % early vs 31.5 % late); no difference was noticed also in 2-year mortality, ICU stay, hospital stay, duration of mechanical ventilation and antibiotic use up to 30 days

after randomisation. The median number of days on which patients received any sedatives was significantly different between groups (5 days early vs 8 days late; $P < 0.001$). The lead investigator explained well the results at the 29th International Symposium of Intensive Care and Emergency Medicine: “if you had 100 patients requiring tracheostomy, doing it early results in 2.4 days less sedation overall, but you would performed 48 procedures more, with 3 more procedural complications and no effect on mortality or ICU stay”.

A recent systematic review for the Cochrane Collaboration (updated to August 2013) [44] evaluated the effectiveness and safety of early (≤ 10 days after tracheal intubation) vs late tracheostomy (> 10 days after tracheal intubation) in critically ill adults predicted to be on prolonged mechanical ventilation with different clinical conditions. Authors included all randomised and quasirandomised controlled trials. They included 8 trials enrolling globally 1977 participants. Of note, 4 trials were identified as ongoing. The authors found a significant difference in term of mortality at longest follow-up time available in the studies in favour of early tracheostomy (relative risk 0.83, 95 % CI 0.7–0.98 – moderate quality of evidence). Results concerning the time spent on mechanical ventilation suggested benefits associated with early tracheostomy (very low quality of evidence). Two studies show a significantly higher probability of discharge from the ICU at 28 days of follow-up in the early tracheostomy group (high quality of evidence) and no significant differences for pneumonia (very low quality of evidence).

In 2015, Szakmany et al. [43] published a systematic review and meta-analysis of randomised controlled trials in patients allocated within 10 days of start of mechanical ventilation compared with placement of tracheostomy after 10 days if still required. Fourteen trials were identified enrolling globally 2406 patients. Tracheostomy within 10 days was not associated with any difference in mortality (risk ratio, RR: 0.93–95 % CI 0.83–1.05). There were no differences in duration of mechanical ventilation, ICU stay or incidence of VAP. However, duration of sedation was reduced in the early tracheostomy groups. More tracheostomies were performed in patients randomly assigned to receive early tracheostomy (RR: 2.53–95 % CI 1.18–5.40).

Beyond the “timing per se” a careful balance between risks and benefits of tracheostomy in a patient should be always done. As a matter fact, other aspects should be considered such as patient’s comorbidities and capability to clear the airway, anatomy of the upper airway and respiratory system, vascular anatomy of the neck, type of technique to be performed (surgical vs dilatational) and experience of the operator. It should be also taken in mind that a tracheostomy in place may have an important impact on patients’ discharge destination from an ICU rising logistic problems.

3.3.1 Timing of Tracheostomy in Neurocritical Patients

Trauma and neurologic damage from stroke and traumatic brain injury represent groups of patients generally considered to benefit of an early tracheostomy. Potential points in favour of tracheostomy in these populations are the need to minimise any

increase in intracranial pressure due to coughing and the need for airway protection or suctioning [23].

Several studies investigated specifically benefits of early tracheostomy in these population but large high quality randomised trials are lacking.

Of note, recent large multi-centre randomised trials enrolled only small number of trauma or neurocritical care patients without giving insight on this subgroup of patients. Several nonrandomised studies evaluated tracheostomy timing in terms of mortality, length of stay in ICU and in hospital, duration of mechanical ventilation, sedation and costs. Only few single-centre randomised studies addressed this topic. In 2006, Barquist et al. [46] published the most recent data from a randomised single-centre trial enrolling 60 trauma patients older than 15 years and either a Glasgow coma scale (GCS) >4 with a negative brain computed tomography or a GCS >9 with a positive head computed tomography. Patients were randomised to receive tracheostomy before day 8 or after day 28. No difference in mortality, ICU-free days, ventilator-free days or rates of VAP was identified. Of note, the study was halted after the first interim analysis. In 2009, the Eastern Association for the Surgery of Trauma published guidelines on tracheostomy timing in trauma patients after reviewing available literature [47]. Authors stated three recommendations. Firstly, it was stated that no mortality difference between patients receiving early tracheostomy (3–7 days) and late tracheostomy or extended endotracheal intubation exists (Level I). Secondly, it was underlined that patients with a severe head injury should receive an early tracheostomy since it decreased the total days of mechanical ventilation and ICU length of stay. Of note, this is a level II recommendation supported by class II data that included observational, cohort, prevalence and case-control studies. The third recommendation stated that early tracheostomy should be considered in all trauma patients who are anticipated to require mechanical ventilation for >7 days, such as those with neurologic impairment or prolonged respiratory failure. Notably, this is a level III recommendation suggesting only that the majority of practitioners consider it reasonable. Recently, a single-centre pilot randomised study evaluated timing of tracheostomy in ventilated patients with severe stroke. Sixty patients expected to receive at least 2 weeks of mechanical ventilation were randomised to receive percutaneous tracheostomy within 3 days from intubation or between day 7 and 14 if extubation was not possible. No difference was observed with regard to the primary outcome length of stay in the ICU and adverse effects. Instead, use of sedatives, ICU mortality and 6-month mortality were significantly lower in the early group than in the standard group. The authors claimed the need for a larger multi-centre randomised trial to confirm these results.

3.4 Conclusion

For a general ICU population, not involving neurocritical patients, there are consistent data that early tracheostomy is not associated with improved survival. Data also demonstrated that clinicians cannot accurately predict which patients will require

prolonged mechanical ventilation. So, it seems reasonable to wait at least 7–10 days to be sure that a patient still needs mechanical ventilation and ensure good respiratory care via endotracheal tube before considering tracheostomy.

For trauma patients with and without brain injury and for patients with non-traumatic neurologic injuries, more robust data from large randomised trials are needed to confirm the potential benefit in terms of ICU length of stay, mechanical ventilation duration, sedation and mortality.

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Chapter 4

Surgical Tracheostomy

G. Dell'Aversana Orabona, M. Iannuzzi, and L. Califano

Abstract Tracheostomy is the only surgical procedure that completely bypasses the upper airway. This procedure consists of making an incision on the anterior aspect of the neck and opening a direct airway through the trachea to allow the placement of the tracheostomy tube. Through the tracheostomy tube, a patient can breathe without the use of upper airway. In the early twentieth century, when physicians began to use tracheostomy in the treatment of patients afflicted with paralytic poliomyelitis who required mechanical ventilation, the primary indication for surgical tracheostomy shifted from emergent relief of upper airway obstruction to elective airway support in prolonged ventilator dependence. Toy and Weinstein first, and Ciaglia after, introduced the concept of percutaneous tracheostomy. Surgical tracheostomy is among the oldest described procedures and it is preferred to percutaneous techniques when this approach can be difficult or risky.

4.1 Introduction

Tracheostomy, from the Greek tracheo plus stoma, is a surgical procedure that consists of making an incision on the anterior aspect of the neck and opening a direct airway through the trachea to allow the placement of the tracheostomy tube. Through the tracheostomy tube, a person can breathe without the use of upper airway. Since 1950, when mechanical ventilation and intensive care unit started to develop, the primary indication for surgical tracheostomy shifted from emergent relief of upper airway obstruction to elective support of the airway in prolonged ventilator dependence.

Even though surgical tracheostomy has been flanked by percutaneous tracheostomy in airway management, the procedure is still performed in many cases.

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4.2 Anatomy

In order to perform a correct procedure, an excellent knowledge of the anatomical district is surely mandatory.

Adult trachea measures 10–13 cm in length from the larynx to the carina, depending on the individual. Topographical anatomic representations describe the trachea with half the length above the thoracic inlet. Due to neck position and patient body habitus, the trachea can present a high variability in planar orientation and can slide in cephalocaudal direction. In patients affected by obesity or by severe skeletal deformations, the trachea can reside in part or entirely in the bony part of the thorax.

The trachea presents a C shape, anteriorly and laterally described by incomplete cartilaginous rings and posteriorly delimited by a flat posterior membranous wall strictly related to the oesophagus. At the thoracic inlet, the trachea is directed caudally on an anterior to posterior direction passing behind the thymus, the innominate vein and the innominate artery. The angle can approach 90° in the elderly, making tracheotomy difficult [1, 2].

A midline dissective anterior approach to the trachea unveils the platysma muscle, the superficial cervical fascia, the anterior jugular veins, the sternohyoid and sternothyroid muscles, the thyroid isthmus (3–4th tracheal ring) and pretracheal fat pad which can englobe the inferior thyroid veins and occasionally thyroid artery.

4.3 Indications

Nowadays scientific evidence proves that prolonged tracheostomy ventilation is preferable to the translaryngeal one. Major benefits comprehend improved patient comfort, safety and hygiene, less need for sedation, lower work of breathing, phonation recovery, oral intake, faster weaning from mechanical ventilation, lower risk of ventilator-associated pneumonia and shorter hospitalisation [3–5].

Surgical tracheostomy is preferred to percutaneous techniques in those situations in which the percutaneous approach can be difficult or risky: cervical spine lesions, problematic necks (i.e. obese, short, limited extension, masses, post-irradiation), anatomical abnormalities of the trachea, problems with the stoma site (i.e. vessels, masses, infections) [6]. As every surgical procedure, surgical tracheostomy carries an amount of complications related to the surgical performance itself during the intra- and post-operative period: bleeding, sub-obstruction of the airways, bronchospasm, perforation of the oesophagus, infection, pneumothorax, gastric aspiration, vocal cord damage, tracheal stenosis and laryngeal injuries [6].

4.4 Surgical Technique

The surgeon attempting the procedure should be able to explore the neck anatomy with his fingers before proceeding.

By running the index finger down the neck midline, the body of the hyoid bone can be palpated at C3 level, while at C4, the thyroid notch at the laryngeal prominence of the thyroid cartilage can be felt.

Sliding below, thyroid isthmus with the depression of the cricothyroid junction can be encountered.

At C6 level, the cricoid cartilage is felt and is encountered below the trachea with its cervical rings. The thyroid isthmus crosses the trachea over the third/fourth ring, but it is difficult to recognise under the fingertips.

Surgical tracheostomy is routinely performed under general anaesthesia in the operating room; it can be done in some cases at the bedside in the intensive care unit (e.g. high-dependency patient that cannot be moved to the operating theatre safely).

Before starting the surgical procedure, a correct patient position is essential; the shoulders are elevated and the head and the neck are extended by the use of rolled towels positioned between the shoulder blades. This position allows to identify the anatomic landmarks of the neck. Hyperextension of the neck can elevate up to half of the trachea into the operative field (Fig. 4.1).

An iodine-based solution was used to prepare the surgical field and sterile drapes are placed, leaving an opening over the surgical site.

Local anaesthesia with 1 % lidocaine and epinephrine is performed, in order to reduce bleeding. A 2–3 cm transverse skin incision is created; it is very important to pay attention during the dissection of the deep layers to prevent lacerating the superficial vein or thyroid isthmus (Fig. 4.2). Then by means of a vertical dissection, the infrahyoid muscles were retracted to access the trachea (Fig. 4.3).

Hemostasis is achieved progressively with bipolar forceps. At this stage when the thyroid isthmus appears, it is carefully cut and tied (Fig. 4.4). The isthmus of the



Fig. 4.1 Preoperative patient's position. Rolled towels are positioned between the shoulder blades to obtain neck hyperextension

Fig. 4.2 The skin incision should be conducted carefully to avoid damaging the subcutaneous vessels that join the anterior jugular veins in the midline

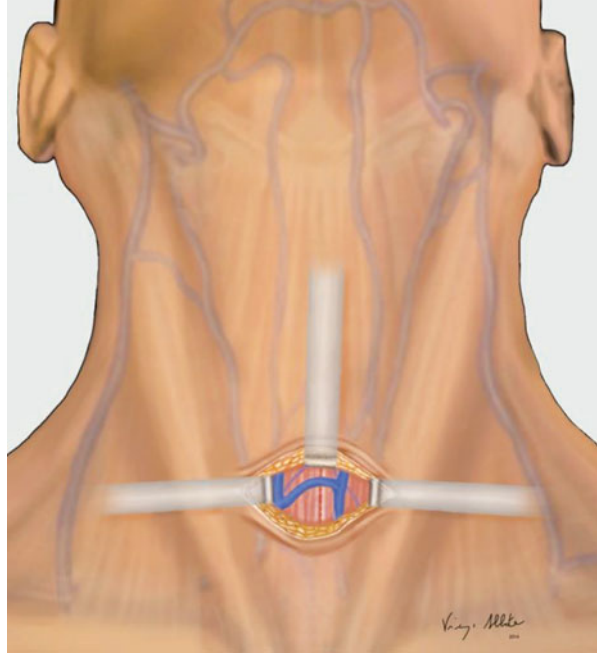


Fig. 4.3 Subcutaneous vessels must be highlighted and tied to access the pretracheal muscle

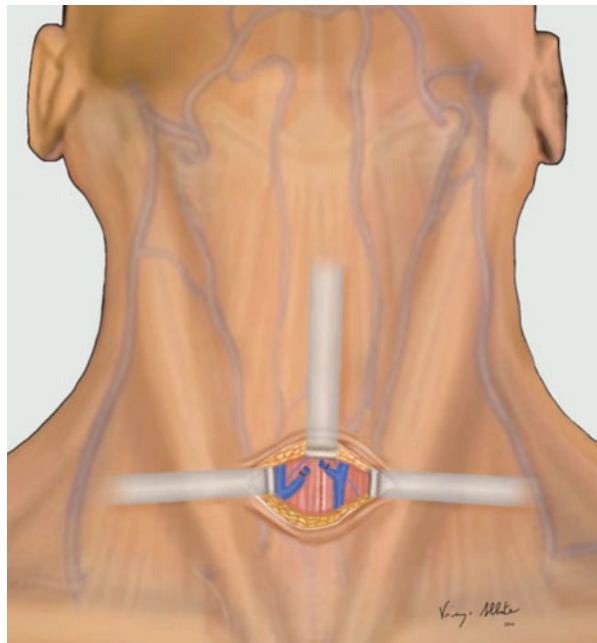
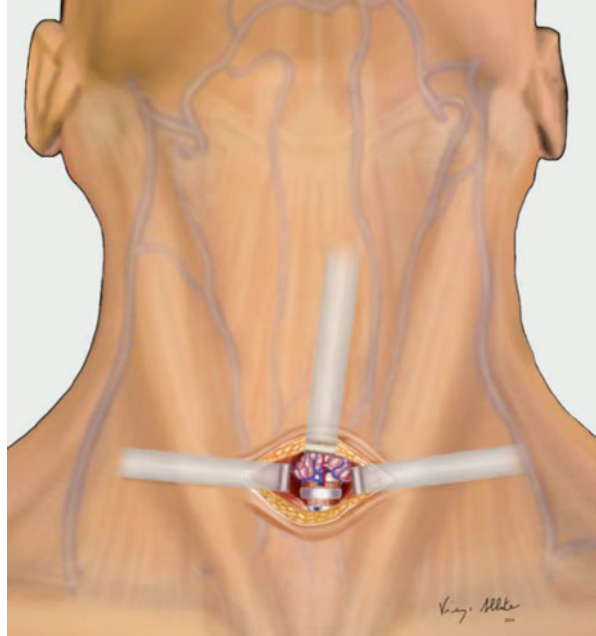


Fig. 4.4 The thyroid isthmus appears after infrahyoid muscles retraction



thyroid may be divided. Tracheostomy through the divided isthmus provides direct access to the anterior surface of the trachea. However this makes the procedure much more invasive and the risk of haemorrhage is greatly increased. An alternative consists of retracting the isthmus downward (supra-isthmic approach) or upward (infra-isthmic approach).

An intact isthmus may increase the risk of secondary haemorrhage from erosion of small vessels in the isthmus by tracheostomy cannula; in addition the isthmus may move and obstruct the tracheal orifice, making it more difficult to change the cannula.

Furthermore, in terms of choice, the optimal site for the opening of the trachea is located in the normotype adult between the second and the fourth tracheal ring [7]. Whether the tracheostomy is infra-isthmic or supra-isthmic, one should be careful not to incise the trachea too low or too high, respectively, noting that if the tracheal incision is too high, the risk of subglottal stenosis may be run [8].

Therefore the trachea can be engraved. The dissection is continued through the peritracheal fascia and the second ring can be identified (Fig. 4.5).

There are two types of access to the trachea.

One is the complete removal of the anterior part of the ring to create the stoma and one is the creation of a U-shaped flap still anchored to the ring (Figs. 4.6 and 4.7).

Once access to the trachea is created the tracheostomy tube over a guide can be easily inserted.

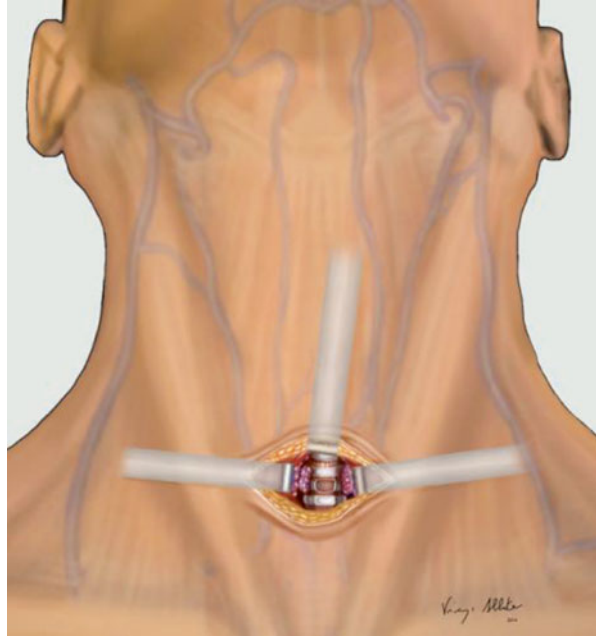
After the tracheostomy tube is in place, the guide catheter is removed and the tracheostomy cuff is inflated.

Fig. 4.5 The thyroid isthmus is cut end tied. Thus the peritracheal fascia and the second ring can be identified



Fig. 4.6 Complete removal of the rectangular flap



Fig. 4.7 U-shaped flap

Correct positioning of the tube will be assessed by means of bilateral lung ventilation on auscultation and capnography. Finally the sutures are performed [1, 2].

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Chapter 5

Percutaneous Tracheostomy: The Ciaglia Techniques

Christian Byhahn

Abstract The principle technique of contemporary percutaneous tracheostomy was introduced by surgeon Pasquale Ciaglia in 1985 (“Basic Ciaglia technique”) and further refined in 1999 (“Ciaglia Blue Rhino”) and 2005 (“Ciaglia Blue Dolphin”). After tracheal puncture and guidewire insertion, tissues and anterior tracheal wall are dilated using either up to seven progressively larger dilators (basic technique), a curved, hydrophilic-coated single-step dilator (Blue Rhino), or a fluid-filled high-pressure balloon (Blue Dolphin). The procedure concludes with the insertion of a tracheal cannula. Regardless of the technique chosen, continuous bronchoscopic surveillance of the entire procedure is strongly recommended.

Percutaneous tracheostomy in intensive care medicine is commonly associated with the name of a New Yorker with Italian roots: Pasquale Ciaglia. He invented the first “modern” technique of percutaneous tracheostomy in the early 1980s, and when this technique hit the market in 1985 [1], it was not only a huge commercial success but first of all a cornerstone in the management of critically ill patients on long-term ventilation.

Based on his own experiences and the input he received from clinicians all over the world, he extensively modified the basic technique in 1999 [2], and at the age of 87, Ciaglia became the father of the Blue Rhino technique. After his death in 2000, his spirit lived on, and his preliminary visions were further refined by pulmonologist Michael Zgoda. Five years later, the final modification was launched: the Ciaglia Blue Dolphin technique [3].

All three techniques have some common elements. The patient is deeply sedated, his neck was extended, and a non-depolarising muscle relaxant has been given to avoid coughing during the procedure, which may result in tracheal injuries.

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Thereafter, the endotracheal tube in place is either removed, and a laryngeal mask airway is inserted, or the endotracheal tube is pulled back to a level just below the vocal cords. Either technique is comparable in terms of patient's safety [4].

A flexible fibrescope is inserted through the endotracheal tube or the laryngeal mask airway, and the first few tracheal rings need to be identified. Upon puncturing the trachea, the tip of the puncture needle becomes visible. If the tip of the needle is not in the midline (i.e. between 11 and 1 o'clock), the puncture should be repeated and the position of the needle adjusted. After withdrawal of the puncture needle and insertion of a flexible J-tip guidewire, a small 14 F punch dilator is used to widen the puncture channel. The guidewire is now armed with a Teflon catheter to prevent kinking (basic and Blue Rhino techniques only).

5.1 Skin Incision

A 15 mm transverse skin incision is mandatory for the Blue Dolphin technique – the balloon cannot dilate the skin. With the basic and the Blue Rhino techniques, the decision to perform a skin incision is made on an individual basis and depends on a number of factors, such as patient's age (the younger a patient is, the more elastic and difficult to dilate is his/her skin), coagulopathy and use of antiplatelet drugs. Both techniques do not require a routine skin incision, and it is often recommended to perform skin incision according to demand, i.e. if the skin is too elastic to allow for gentle insertion of the dilators and force is required, and the skin should be incised in very small increments, just that much to allow dilation without significant force.

Another topic being debated is whether a local anaesthetic combined with a vasoconstrictor should be injected prior to skin incision, particularly when a 15 mm incision is mandatory for the Blue Dolphin technique. The advantage of using vasoconstrictors is less intraoperative bleeding, which improves surgical exposure and reduces the risk of blood aspiration. On the downside, however, bleeding from small vessels that were initially constricted occurs hours later when the vasoconstrictive effect is gone.

5.2 Dilation

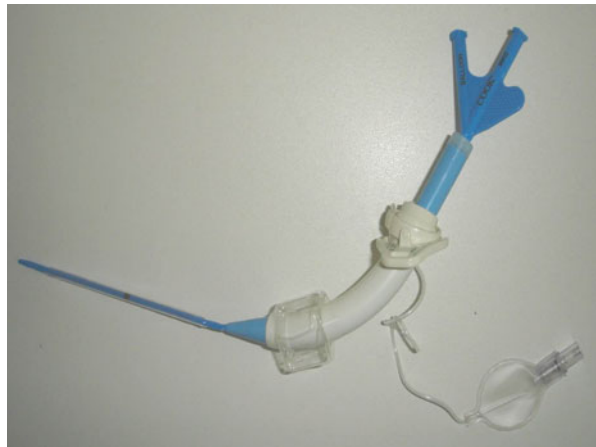
The basic Ciaglia technique of percutaneous tracheostomy consists of seven stiff, progressively larger dilators to dilate the trachea to 36 F. Thereafter, the tracheal cannula is then inserted over a smaller dilator that fits best into the cannula.

The Blue Rhino dilator is a flexible, hollow tube of hard rubber with a special hydrophilic coating. To increase the dilator's external smoothness, it was wetted with a few millilitres of saline solution or distilled water. The dilator is then advanced over the guidewire and guiding catheter through the soft tissues and into the trachea up to its marking of 38 F external diameter (Fig. 5.1). Because of the dilator's smoothness, dilation required a minimum of force. The set contains three hard rubber stylets of different sizes with cone-shaped tips. As a result, once the tracheos-

Fig. 5.1 Ciaglia Blue Rhino technique



Fig. 5.2 Ciaglia Blue Dolphin dilating assembly



tomy tube is armed with its corresponding stylet, tube and stylet form a perfectly fitting unit, in particular at the interface of tube and stylet. This unit is advanced over the guidewire into the trachea, and once the stylet has been withdrawn and the correct position of the tracheostomy tube is confirmed bronchoscopically, the cannula is connected to the respirator.

The Blue Dolphin technique is novel, using a combined dilator-tube introducer assembly, which uses a high-pressure balloon to dilate the stoma. The unique feature of this technique is the balloon-tipped catheter with tube-loading dilator assembly (Fig. 5.2). The balloon measures 70 mm total with a 54 mm central section and 16 mm (48 Fr) in diameter when fully inflated. The loading dilator size varies between 24 and 30 F. The final component of the set is a manual inflation device with a pressure gauge. The balloon device and inflator are modified from standard and well-established radiology equipment used for angioplasty and other interventions. The balloon is factory tested and is not test inflated before use.

Fig. 5.3 Fully inflated balloon



After withdrawal of the 14 F punch dilator, the compressed balloon in the distal portion of the balloon-tube assembly is advanced over the guidewire until the distal 1–2 cm of the balloon is seen in the tracheal lumen.

A manual inflation device with aneroid pressure gauge, containing 20 ml of saline solution, is connected to a side port of the balloon-tube assembly, and the balloon is inflated with saline solution to 11 atm/bar (Fig. 5.3). Care needs to be taken to position the functional part of the balloon so it extended from the skin into the trachea, with a portion of balloon seen outside the skin and the distal portion seen inside the trachea.

The balloon needs to be kept inflated for 5–15 s. Thereafter, all fluid is evacuated from the balloon, and the balloon-tube assembly carrying the tracheostomy tube is further advanced into the trachea under endoscopic control, until the tracheostomy tube is within the trachea. The balloon-catheter assembly and guidewire are then withdrawn together, leaving the tracheostomy tube in place.

5.3 Which Ciaglia Technique Should I Use?

Simply said, all Ciaglia techniques are equally safe. The basic technique has been widely replaced by the Blue Rhino technique, mainly because the latter is more simple to perform and fewer steps are necessary to dilate the stoma, thereby reducing the risk of bleeding and airway loss. Although being introduced ten years ago, very little data is available regarding the Blue Dolphin technique [5–7]. In theory, because radial dilation is performed with a high-pressure balloon, no pressure at all needs to be applied from the anterior. The tracheal lumen is not compressed during

dilation, and the risk of posterior tracheal wall injury is virtually eliminated. Furthermore, dilating the tissues with 11 bar results in temporary ischemia, during which the tissue loses its ability to accommodate. The dilated stoma stays open for approximately 15 s after dilation, allowing for gentle cannula insertion. Once the wound edges are reperfused, circumferential tissue contraction results in an extremely tight fit around the tube.

Many clinical studies are available for the Blue Rhino technique. Serious, potentially life-threatening complications occur in less than 0.5 % of cases. Most of such events are injuries to the posterior tracheal wall and intraoperative airway loss. In the postoperative period, the main reason for harm is premature decannulation and subsequent hypoxia [8]. It is important to know that after decannulation within the first 7–10 days after percutaneous tracheostomy – regardless of the technique used – immediate orotracheal intubation is required for airway control. Although the stoma stays open at skin level, deeper tissue layers contract immediately, rendering cannula reinsertion impossible. Intensivists from Australia and New Zealand therefore recommend to place warning signs at the beds of patients with tracheostomies, providing immediate information regarding date and technique of tracheostomy (i.e. surgical or percutaneous) [9].

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Chapter 6

Balloon Dilation Tracheostomy

E. De Robertis, F. Cirillo, G.M. Romano, and G. Servillo

Abstract Inflatable balloon dilation system tracheostomy can be considered the latest evolution of Ciaglia technique of single-step cone dilator for percutaneous tracheostomy. Balloon dilation tracheostomy (BDT) is the first device for percutaneous tracheostomy that uses a pneumatic dilation to create the tracheal stoma. BDT is a relatively recent technique. Initial experiences have showed that this new technique can be considered safe, feasible and easy to perform.

6.1 Introduction

Inflatable balloon dilation system tracheostomy can be considered the latest evolution of Ciaglia technique of single-step cone dilator for percutaneous tracheostomy, which has been considered as the dilatational technique of choice, being easy and fast to perform.

The innovation of this technique is that dilation is not given by the introduction of a single dilator with a progressive increasing diameter but is made by an inflatable balloon dilation system which, positioned over a guide wire, is directly inflated into the trachea under bronchoscopic vision. Furthermore, as tracheal tube flows directly around the dilation system, insertion occurs immediately after the deflation of the balloon, with the benefit that dilation and tracheal tube insertion are combined in one single operative step.

Initial experiences have showed that this new technique can be considered safe, feasible and easy to perform.

6.2 Why Pneumatic Dilation

Balloon dilation tracheostomy (BDT) is the first device for percutaneous tracheostomy that uses a pneumatic dilation to create the tracheal stoma.

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Due to their relative simplicity, safety and cost-effectiveness, Ciaglia techniques gained popularity and widespread acceptance by medical community.

The first Ciaglia percutaneous techniques performed the dilation by the multiple insertions of several consecutive dilators of different sizes over a guide wire [1]. This procedure is not free from risks. A prospective observational study on 24 patients of a medical-surgical ICU treated with Ciaglia multiple dilation technique revealed, in 3 patients, posterior tracheal wall lesions with tension pneumothorax, 2 accidental extubations, 1 case of obstruction of tracheal tube and 1 case of tracheal tube misplacement [2]. Based on observations on swine and cadaver models, the authors argued that posterior tracheal injury may happen if guide wire and guiding catheter are not well stabilised during the insertion.

In order to avoid the use of serial dilations, in 1998 a single-step dilation tracheostomy (SSDT) was introduced as a modification of the previous technique. SSDT creates the tracheal stoma by the insertion of a single hydrophilically coated curved dilator with an increasing progressive diameter [3]. Although the use of a single dilator technique under routine bronchoscopic guidance has led to a lower percentage of adverse events with respect to the multiple dilators technique, posterior tracheal wall perforation, bleeding [4] or tracheal ring fracture [3, 5] are still possible.

A systematic review of 1963 articles [6] examined 71 cases of death related to Ciaglia percutaneous tracheostomy (both multiple dilators and SSDT). The main problems found in the analysis of the literature were haemorrhage related to tracheostomy (38 %, 27 patients) and airway complications (29.6 %, 21 patients). Most part of bleeding incidents (75 %) happened between 3 days to 6 weeks from the procedure, with a median time of 5 days. Among airway complications, the most frequent were displacement of tracheal cannula (52.4 %), airway loss during the procedure (19 %) and paratracheal dislocation of tracheal cannula (14.3 %). Tracheal perforation occurred in 11 patients, accounting to 15.5 % of deaths. Other causes were pneumothorax (5.6 %), bronchospasm (4.4 %), cardiac arrest (4.4 %) and sepsis due to mediastinitis (1.5 %).

Posterior tracheal wall injury and tracheal ring fracture could lead to the formation of granulation tissue, depicting the so-called subglottic suprastomal stenosis, with obstruction of the airways [7].

While the correlation between dilator and posterior tracheal wall perforation is easily deducible, tracheal ring fracture needs some consideration. Basically, this accident is caused by two factors, one related to the dilator and the other one related to the intrinsic anatomy of the trachea.

First of all, Ciaglia single curved dilator, in spite of its curved profile and hydrophilically coated surface, fails to dilate equally trachea tissue [3], but, during the change of orientation from perpendicular to caudal direction, generates high compressive and torque forces that press on the adjacent superior tracheal cartilage, mostly on longitudinal direction. Considering the anatomy of smooth muscle of trachea, it has to be pointed out that there is a preponderance of longitudinal fibres in comparison with circumferential fibres. Therefore, in longitudinal direction, there is less elasticity than in the transverse direction [8, 9], and the compression made by the dilator could facilitate a fracture in that portion of tracheal ring.

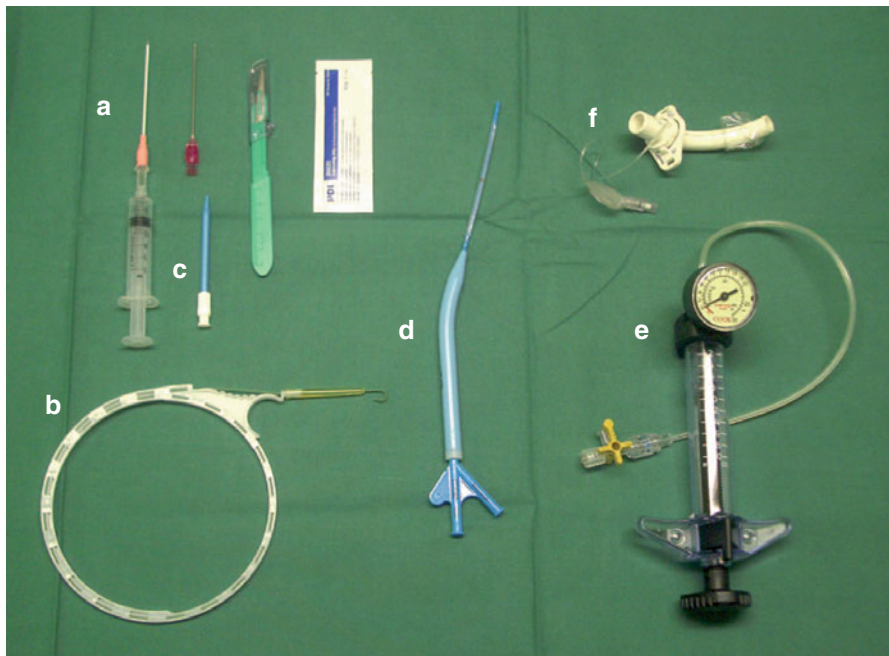
Thus, the pneumatic outward radial dilation given by an inflatable balloon seems to be a convincing alternative. Furthermore, it is arguable that pressure of the inflated balloon on the wall of the new created tracheal stoma has a clear mechanical haemostatic effect, which can stop possible bleeding from small vessels.

6.3 Procedure

Before the beginning of the procedure, it is extremely important to prepare the patient and all needed materials.

In order to guarantee the safety and facilitate the operation, patient has to be sedated and curarised, with head and neck completely extended. The mechanical ventilator through the endotracheal tube already in place supplies ventilation. Accordingly, there is no need to replace the tracheal tube, avoiding a manoeuvre that can be risky and can expose the patients to inhalation and subsequent infection. The tracheal tube must be pulled back at the vocal cord level and eventually cut to facilitate the procedure and the bronchoscopy. Fiberoptic bronchoscopy (better if of a paediatric size) has to be placed at the distal extremity of the tracheal tube to follow all the procedure.

When patient is prepared, all components of balloon dilation tracheostomy (BDT) set must be exposed and organised. These components are: an introducer needle (a), a guide wire (b), a 14-French dilator (c), a catheter with the pneumatic balloon dilation system (d), the balloon inflation device (e) and a tracheal cannula (f).



The balloon dilation system (d) is a modified nylon-made angioplasty balloon 5.4 cm long, with an external diameter of 16 mm, when totally inflated (it is designed to reach a maximum pressure of 11 atm), mounted at the tip of a small dilator over which, before the beginning of the operation, a tracheal cannula (f) is loaded (it is important a good lubrication of the internal and external walls of the tracheal cannula). The pneumatic balloon has two channels, one, in the middle, for the guide wire, and the other to be connected with the balloon inflation device (e). Before the procedure, the balloon inflation device (e) has to be filled with about 20 ml of saline solution and connected to the pneumatic balloon through the dedicated channel with a lower-lock connection.

To avoid injuries to superficial structures, neck ultrasound can be performed to identify aberrant blood vessels and the anatomy of thyroid gland and to estimate the distance from the skin to the trachea [10].

The procedure should follow the following steps:

1. After disinfection of the skin and identification of tracheal rings below cricothyroid membrane, under bronchoscopic vision, the operator penetrates with the introducer needle (a) and reaches the trachea, through, preferably, the second tracheal space.
2. A guide wire (b) is inserted through the introducer needle, and its position in trachea bronchoscopically controlled.
3. A little transverse incision of the skin and a preliminary dilation with a 14 Fr dilator (c) are performed.
4. The balloon dilation system with behind the loaded tracheal cannula (d + f) glides over the guide wire (b), across the different structures to be positioned in trachea. Approximately half balloon is inserted in trachea over the guide wire to reach the correct position to be inflated (a black marker line is visualised through bronchoscopy at the level of the internal anterior wall of trachea).
5. When correctly positioned, the pneumatic balloon is inflated with the saline solution, loaded in the inflation device (e), by screwing the piston of the inflation device to reach and maintain a pressure not greater than 11 atm for 25–30 s. This manoeuvre will also make a compressive mechanical haemostasis of the small cutaneous and subcutaneous bleeding.
6. After the dilation, the pneumatic balloon is quickly deflated and the preloaded tracheal cannula inserted in the trachea through the hole created by the dilation of the balloon (the tracheal stoma).
7. After the insertion of tracheal cannula, balloon dilation system and guide wire are gently removed through the tracheal cannula.
8. It is strongly recommended to check the correct position of the cannula through direct bronchoscopic vision.

During the procedure, one sign of a successful dilation is the loss of strength of the tissues that can be visible at the pressure gauge of the inflation device as a slight decrease in pressure. In this case, it must be compensated with an additional increase of pressure by screwing the piston of the inflation device. Usually, in old patients this loss of strength is well rendered. In young patients with stronger tissue, the dilation procedure may require few seconds more.

6.4 Balloon Dilation Tracheostomy in Literature

BDT is a relatively recent technique, and there is not a large body of study on it. Feasibility and efficacy have been shown, but, despite theoretical hypothesis, a real superiority compared to the most used and widespread SSDT is far to be demonstrated.

Preliminary report appeared in 2005, with the experimental study of Zogda and Berger on seven pigs [11]. In this work, the authors showed that percutaneous dilation by a balloon was feasible and safe; no tracheal damage on posterior wall was found on post-procedure dissection; no visible bleeding observed. Median time of execution was 5.5 min from tracheal puncture.

An initial documented clinical experience was published in 2009, with the work of Gromann in a cardio-surgical ICU [12]. Tracheostomy was made in 20 patients, always under bronchoscopic vision. Authors did not observe neither bleeding nor posterior tracheal perforation. There was one fracture of a single tracheal ring and, in one patient, subcutaneous emphysema during the dilation that did not require any treatment. Median time of procedure was around 3 min.

A randomised controlled trial compared BDT with SSDT in a medical and trauma ICU [13]. Thirty-five patients were randomly allocated to have BDT or SSDT. All procedures were made by the same three physicians and always under fiberoptic bronchoscopic vision. They found SSDT significantly faster than BDT (1.5 min vs. 4 min). Unexpectedly, bronchoscopic vision after 6 h from procedure revealed unapparent bleeding in 24 patients in BDT group (68.6 %) and in 12 patients of SSDT group (34.3 %) that did not require any treatment. Authors reported tracheal ring injury in 2 patients of SSDT group and in 3 patients of BDT group. Tracheal buckling affected 1 patient in SSDT group and 3 patients in BDT. No patient experienced major complication (pneumothorax, posterior tracheal wall perforation, tracheal tube misplacement). Difficulty in tracheal tube insertion was more frequent in BDT group (ten patients) than SSDT (three patients). However, BDT is more recent, and intensivists were less experienced with this technique. They argued also that the outward radial force of pneumatic dilation is not enough to facilitate tracheal tube insertion.

In a prospective observational study [14] of 70 patients tracheostomised with BDT under bronchoscopic vision, the authors reported difficulty in the insertion of the cannula in ten patients, small bleeding in seven patients, partial atelectasis for three patients and rupture of tracheal tube cuff in two patients. In one patient, it was impossible for them to continue with BDT, so they switched to SSDT technique. Serious complications were observed in only two patients: one case of severe haemorrhage, which required an open surgical approach and one case of tracheal tube misplacement with desaturation.

In conclusion, in current literature, BDT appears feasible, easy to perform and safe, also in patients who need anticoagulation [12]. There are some concerns about the dimension of the dilation. In particular, Cianchi et al. argued that dilation of the balloon was right on diameter, but not enough to enable the easy insertion of the trachea cannula [13].

With regard to our experience over the last years, we have noticed that this technique is handy and allows to complete a percutaneous tracheostomy very quickly. The training time required to master the technique is quite short, and no special skills are required. The technique can be performed by a single operator with the aid of a physician dedicated to the bronchoscopy; however, inflating the pneumatic balloon with the dedicated device while keeping the balloon in place during the first moment of insufflation can be simplified by a second operator dedicated to this task.

BDT results effective and safe, especially during dilation. Furthermore, in our opinion, balloon accomplishes a perfect haemostasis of possible small bleeding; operating field after procedure remains usually without visible blood. Differently from the study of Cianchi et al. [13], in our experience cannula insertion has never resulted difficult not requiring any kind of effort. However, 10 s for balloon inflation are too short to get a valid tracheal stoma; in our clinical experience, it needs no less than 25–30 s. It has to be clarified the clinical importance and impact of possible phases of hypoventilation during balloon inflation. In fact, expansion of the balloon can occupy a large portion of the trachea in those patients with a trachea of small size. However, the time of balloon inflation is usually short, and we believe that this brief moment of hypoventilation does not have significant clinical effects. However, more study are needed to clarify this aspect especially in those patients characterised by tissues with high tensile strength, in which the duration of the inflation can be slightly prolonged in order to get an optimal dilation.

6.5 Conclusion

In conclusion, BDT is an effective and safe technique to perform a fast bedside percutaneous tracheostomy, free from major adverse events.

Further studies need to assess if there is a real superiority of BDT compared with other percutaneous procedures, regarding effect on gas exchange and ventilation during the procedure, incidence of post-procedure infections and major side effects. Moreover, it should be better investigated the effects of the different typology of forces applied to dilate a trachea. In fact, BDT exercises outward radial forces created by the balloon dilation, which could be more advantageous in several conditions (i.e. cervical spine injury, recent cervical surgery) with respect to the coaxial forces exercised by SSDT.

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Chapter 7

Percutaneous Tracheostomy: The Guide Wire Dilating Forceps Technique

Christian Byhahn

Abstract When percutaneous tracheostomy was steadily gaining acceptance in the community of intensivists worldwide, the Australian surgeon William Griggs invented another tracheostomy technique – the guide wire dilating forceps technique (GWDF). The stoma is created with a modified Howard Kelly forceps, in which the guidewire passes through a central hole in the tip of the closed forceps. Spreading the forceps by pulling the handles apart dilates pretracheal tissues and the anterior tracheal wall. The final step consists of inserting a lubricated tracheostomy tube with its obturator into the tracheal lumen. The entire procedure requires continuous bronchoscopic surveillance.

When Ciaglia's basic technique of percutaneous dilational tracheostomy was steadily gaining acceptance in the community of intensivists worldwide, the Australian surgeon William Griggs invented another tracheostomy technique based on Seldinger's technique – the guide wire dilating forceps technique (GWDF) [1].

As with any other antegrade percutaneous technique, the patient is deeply sedated, paralysed and ventilated with 100 % oxygen in a pressure- or volume-controlled mode. The neck is then hyperextended, the surgical area disinfected and draped, and the endotracheal tube in place is withdrawn into the larynx. Alternatively, the tube may be removed and a laryngeal mask airway inserted. Continuous bronchoscopic surveillance of the entire procedure is mandatory.

The GWDF kit consists of an introducer needle with cannula, a flexible J-tip guidewire, a 14 F punch dilator and the dilating forceps. The latter is a modified Howard Kelly forceps, in which the guidewire passes through a central hole in the tip of the closed forceps, thus leading them in the right direction. Spreading the

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forceps by pulling the handles apart dilates pretracheal tissues and the anterior tracheal wall.

First, the trachea is punctured in midline between the first and second or second and third tracheal rings with a fluid-filled syringe. Correct intratracheal placement is confirmed by bronchoscopy and double checked by aspirating air bubbles. Relying on aspiration alone is not sufficient. The needle is withdrawn, leaving the Teflon cannula in place through which the guidewire is inserted. Thereafter, a 10 mm transverse skin incision is made, and the 14 F punch dilator is used to widen the puncture channel. Then, the closed Howard Kelly forceps are passed over the guidewire, and by pulling the handles apart, pretracheal tissues are dilated. The forceps are now removed in open position. For final dilation, the forceps are passed over the guidewire again in closed position until the tips of the blades can be seen entering the tracheal lumen. Again, the blades are opened by pulling the handles, and the anterior tracheal wall is now dilated until the desired degree. The final step consists of removing the forceps in open position, leaving the guidewire in place, and inserting a lubricated tracheostomy tube with its obturator into the tracheal lumen. The obturator and the guidewire are now removed, and correct intratracheal position of the cannula is confirmed bronchoscopically before the tube is connected to the ventilator.

7.1 Pros and Cons of the GWDF Technique

Regarding fatal and potentially life-threatening complications, the GWDF technique is as safe as any percutaneous tracheostomy technique. It is the fine print, however, that contributed to the fact that GWDF nowadays is a rarely used technique.

There are two major things on the downside of GWDF: blindness and force. When the forceps is used to first dilate the pretracheal tissues, the user does not have any visual control about this step. The degree of dilation remains unclear, and an unsatisfactorily degree of dilation has been reported, resulting in multiple dilation attempts and problems during cannula insertion. Furthermore, at each stage of the dilation process, significant force is required to pull the handles apart and open the blades. Dilation is blunt and violent and cannot be controlled. Therefore, GWDF is associated with a higher rate of perioperative bleeding episodes requiring even transfusion [2–5]. In patients prone to bleeding or with pre-existing coagulopathy, another technique should be used for percutaneous tracheostomy. When GWDF was used in patient with severe thrombocytopenia, no significant episodes of haemorrhage were observed. However, most patients did receive platelet transfusion immediately prior to GWDF tracheostomy, thus their platelet function must be considered normal during tracheostomy [6].

7.2 Late Outcome

Many studies report on a significant incidence of fractures of tracheal cartilages during dilation with the GWDF device, which is attributed to the high and sudden force exerted on the tracheal rings during opening of the blades. There is good evidence that tracheal ring fractures are not associated with poor outcome, i.e. late tracheal stenosis [7]. The results from this post-mortem study are confirmed by a number of clinical studies which examined the patients' tracheas a few months after decannulation using computed tomography or magnetic resonance imaging [5, 8, 9]. Modest tracheal narrowing was seen in some patients but no radiologically or even clinically significant tracheal stenosis. In some patients, tracheal dilation was observed as a long-term result after GWDF, which was attributed to particular forceps technique [9].

Fig. 7.1 Guide wire dilating forceps



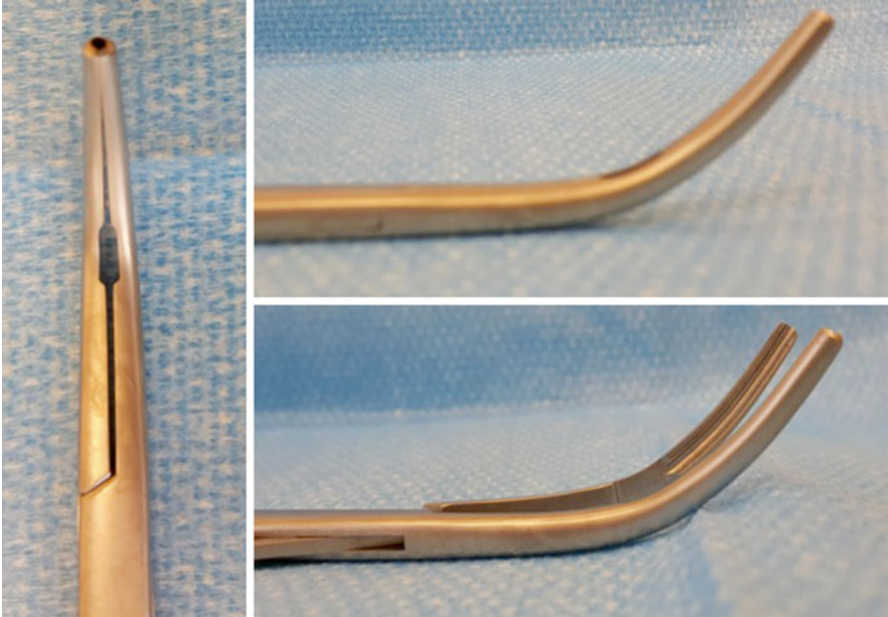


Fig. 7.2 Guide wire dilating forceps: particular findings

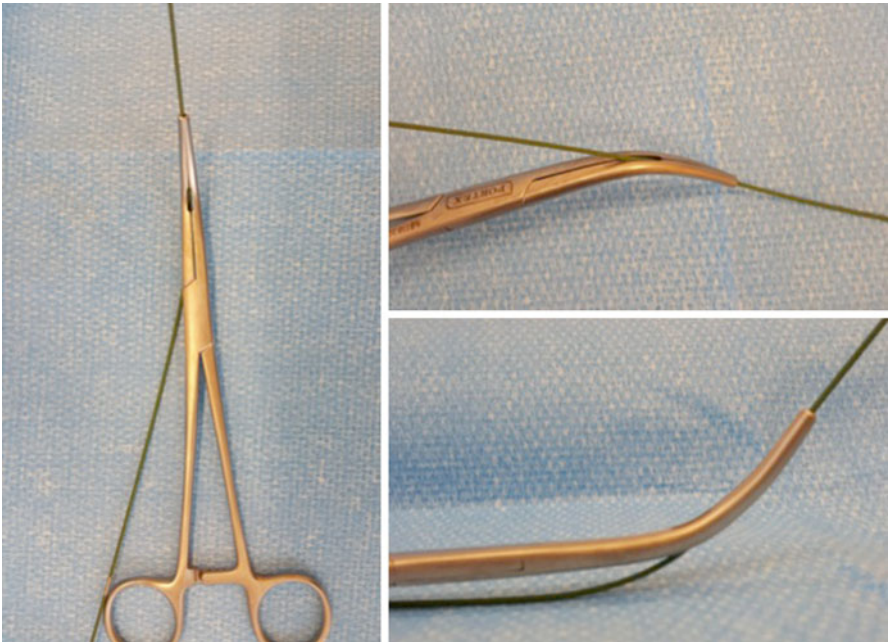


Fig. 7.3 Guide wire dilating forceps: particular findings with seldinger insertion

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Chapter 8

Frova's Rotational Technique and Fantoni's Translaryngeal Tracheostomy

I. Brunetti and P. Pelosi

Abstract The percutaneous dilatational tracheostomy (PDT) is a frequently used technique to perform a tracheostomy in long-term ventilated patients in intensive care. The PDT has proven to be safe as the conventional surgical approach and, moreover, shows many advantages such as a decreased incidence of wound infections, a smaller scar, best aesthetic results and economic advantages with saving of medical personnel and resources of the operating room (Delaney et al., *Crit Care* 10(2):R55, 2006; Brotfain et al., *Crit Care Res Pract* 2014:156814, 2014).

Although each technique has its specific characteristics, the PDT are all carried out under general anaesthesia with modified Seldinger technique and transcervical approach (except for the TLT technique that uses a translaryngeal approach) and performed under continuous bronchoscope control to make the procedure easier and safer.

In this chapter, we describe two techniques: (1) translaryngeal tracheotomy (TLT) and (2) rotational technique (RT).

8.1 Translaryngeal Tracheotomy

The set for the TLT appeared, at the beginning, as a series of metallic cones assembled together on a metal wire, every 20 cm, with an increasing diameter from 3 to 15 mm and a length from 1 to 2.5 cm. A tracheostomy tube was joined to last cone and dragged from inside to the outside of the trachea through the neck wall [3–5]. By the evolution of this first version came the final prototype presented in 1997.

The basic principle of this technique is that the stoma is obtained by passing the dilator between the vocal cords and pushing out through the neck (retrograde

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tracheostomy). This technique is different from all the others, and it is considered the only “non-derivative” method.

8.1.1 Procedural Steps

The first step of the procedure is the positioning of the patient, that lies supine, with the head extended and raised to line up the oral, larynx and trachea axes. After that, the endotracheal tube (ETT) is replaced by a rigid tracheoscope (RTS), included in the kit, and advanced at the level of the vocal cords.

The advantage to use the rigid tracheoscope, allowing bronchoscopy, is that it can be used to protrude the trachea forward, consequently stiffening and immobilising the trachea with thinning the overlying tissues (Figs. 8.1 and 8.2).

If the operator chooses to use a standard ETT (a variation of the classic technique), this must be partially withdrawn until the vocal cord to allow a good endoscopic view.

To facilitate the insertion of the curved needle, between the second and third tracheal rings (the best site in the original description), the longitudinal black line on RTS must be upwards (Fig. 8.3).

Fig. 8.1 Rigid Tracheoscope (RTS)



Fig. 8.2 Transillumination of the neck





Fig. 8.3 Curved needle



Fig. 8.4 The figure does not show the counterpressure to highlight the hole around the cannula

A metal guide wire is then passed through this needle, directed cranially and pulled upwards and out through the mouth. The needle is slipped off and the RTS temporarily replaced with a narrower ventilation tube (external diameter 5 mm).

Then, on the guide wire, is placed the armoured tracheostomy cannula (right-angle or straight type), moulded with a flexible plastic cone which ends with an hollow small metal tip (Fig. 8.4). This device is then drawn back through the oral cavity, larynx, trachea and the neck tissue by the pull handle, while a pressure is applied with the fingertips of operator's non dominant hand against the cone output.

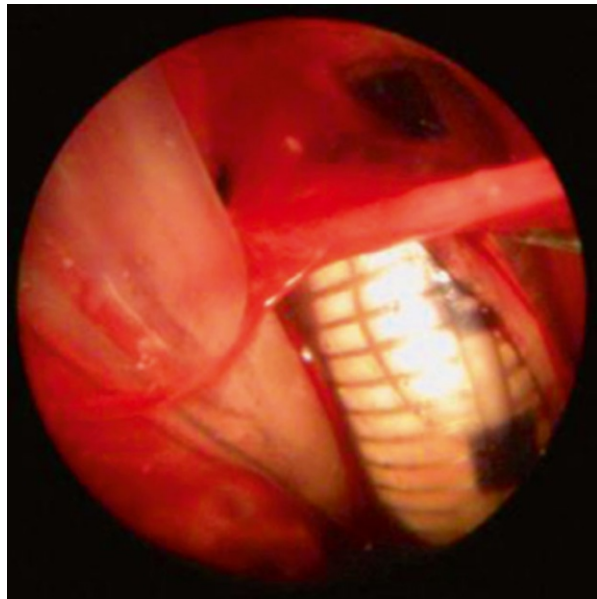
After the tip of the cannula has appeared on the surface, an incision (Fig. 8.5) is made on the skin and pre-tracheal tissue, to facilitate the exit of the cannula and perform the subsequent rotation of the cannula easier.

The pull out of the cannula is continued until the black marker appears on the surface of the neck, and the cuff inflation line is extracted from the inside the

Fig. 8.5 The cannulad is pulled out from the neck



Fig. 8.6 Insertion of the cannula before extraction of tracheal tube (endoscopic view)



cannula. Then, the cone is separated from the cannula by cutting between the two arrows, drawn on the surface of the cannula.

The tracheostomy tube is then rotated 180° on a horizontal plane by the insertion, as far as possible, of a plastic obturator on which the cannula slide along, after it has been retracted and advances into the trachea. The obturator is perpendicular and immobile to tracheal axis until the open end of the cannula faces down towards the carina. Using the tip of tracheoscope is possible to facilitate this step pulling down the cannula (Fig. 8.6).

Finally, we have to connect the two segments of the cuff inflation line, to apply the flange and to verify the correct placement of the tracheostomy cannula.

8.1.2 Translaryngeal Tracheotomy Advantages

- TLT overcomes the needs of external dilation of the trachea with less pressure on the trachea and pre-tracheal tissue and, thus, limiting the risks of compression of the tracheal lumen and injury of the posterior tracheal wall. For the same reason, the TLT may be used in children and young adults with highly elastic trachea [6].
- TLT may be particularly useful in patients with bleeding disorder [11, 12]. This is very important if we consider that bleeding is the most important cause of death during and after percutaneous tracheotomy [9]. In a randomised controlled trial [7] comparing TLT vs. surgical tracheostomy (ST), the authors reported major bleeding 0/67 in TLT group vs 8/72 in ST group ($p < 0.03$). Another randomised controlled trial [8] compared TLT vs forceps dilatational technique (FDT) showing minor bleeding in 4 % of patients in TLT group vs 23 % in FDT ($p < 0.001$). Only one massive haemorrhage, due to an erosive lesion in the posterior wall of the brachiocephalic artery, was reported in a single case report, 6 days after translaryngeal tracheostomy. Once bleeding was controlled, a “conventional” tracheostomy was performed.
- TLT technique shows an optimal adaptation of the stoma to the cannula, leading to less stomal bleeding and less infectious complications [10].

8.1.3 Translaryngeal Tracheotomy Disadvantages

- TLT standard technique requires that the patient is intubated twice: the first time to position the rigid tracheoscope and the second one to replaced it with the narrow ventilation tube. These two manoeuvres could be risky in patients with difficult airways management, although the substitution of the original endotracheal tube could be made with tube exchangers. Cantais et al. [8] reported 9 % of loss of airways in TLT against 0 % in FDT ($p < 0.001$) without hypoxia and 6 % in TLT against 0 % in FDT ($p < 0.001$) with hypoxia. Nani et al. [14] in series of 220 reported four cases of hypoxemia (2.1 %) due to technical difficulties, even more in TLT in the rotational manoeuvres.
- The gradual retraction of the cannula during the rotation phase can hesitate in a decannulation due to a small over shift of the cannula with the risk to put the cannula into pre-tracheal layers of the neck. According to Fantoni [15], complication is more frequent when the obturator is used while the telescope method (variant of the standard technique that uses telescope inside the cannula

to provide the rotation manoeuvres) prevents it. Fantoni [15] reported 6 decannulations (1.39 %) out of 431 procedures. Adam et al. [13] reported an accidentally loss of tracheostomy tube, completely pulled out of the neck, in 9 patients (6.2 %). In 6 of the 9 patients, a second attempt, by an experienced physician, successfully placed the tracheostomy tube. A randomised controlled trial of 100 patients [8] reported problems with tube placement in 23 % (11/47) of cases. These included the guide wire breaking in 3 patients, difficult retrograde passage of the guide wire in 3 patients and accidental pull of the tube out of the neck in 5 patients. Other technical difficulties were ring fracture during traction and displacement/dislocation of the tube. Nani et al. [14] described accidental decannulation in 8/220 patients.

- Another critical moment could be the change of the cannula. The maximal hyperextension of the neck, required to optimise the procedure, might promote a misalignment of the anatomical plans between the trachea and the stoma when the neck resumes its physiological position. Moreover a case report [16] described the embedding of the cannula in the tracheostomy opening that required surgical treatment. Therefore, as in all PDT, the first tracheostomy tube exchange should be performed in ICU with staff well trained in airway management. Finally, TLT, due to needs of some specific technical skills, requires a longer learning curve compared to other PDT techniques.

8.2 Rotational Technique

In 2012 Frova and Quintel [17] proposed a new method of percutaneous dilatational tracheotomy (PDT) performed through a controlled rotation obtained with a dedicated screw dilator of variable calibre (rotational technique).

8.2.1 Procedural Steps

The rotational technique (RT) is performed under bronchoscopy visualisation of the trachea.

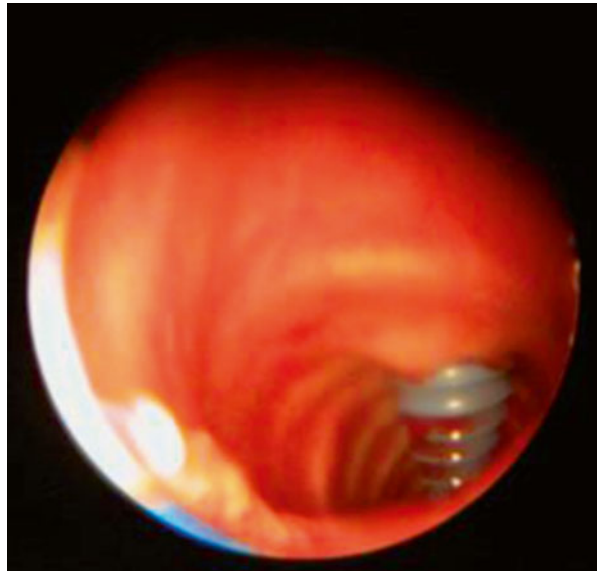
The ETT in place is withdrawn at the level of vocal cords.

Transillumination was used to facilitate the identification of the puncture site and to identify unexpected larger vessels at the planned place of cannula insertion. After careful disinfection of the skin, in asepsis, the trachea was punctured in the midline. The puncture was performed between the cricoid and first tracheal ring or in one of the intratracheal ring spaces between the first and the third tracheal ring. After successful fiberoptic-controlled puncture of the trachea, the J-guide wire was introduced into trachea and advanced in the direction of the carina. After the removal of the needle, a small vertical skin incision, not larger than 8–10 mm, was performed. A

Fig. 8.7 Rotational device and guidewire in place



Fig. 8.8 Endoscopic view of the rotational device fully inserted



hydrophilically coated dilation screw, either suited for the insertion of an 8 or 9 mm inner diameter tracheal cannula, was then dropped into sterile water to activate coating. The rotational technique device has a central inner lumen that allows the passage of the guide wire. Using the guide wire, the dilator was guided towards the skin incision. Under slight pressure, the dilator was turned clockwise until the first threads were advanced into the pre-tracheal tissues.

As soon as the thread catches hold, elevation is applied until the greatest possible degree of dilatation has been achieved (usually eight threads are visible inside the tracheal lumen). After a complete dilatation (Figs. 8.7 and 8.8), the dilator is twisted back and removed. Then, the tracheostomy tube is advanced, over the guide wire, into the trachea.

8.2.2 *Rotational Technique Advantages*

- Hyperextension of the neck is not mandatory in RT, differently from other technique (e.g., TLT). This prevents the increase of intracranial pressure [20] and avoids a non-rectilinear skin- tracheal route that represents the first cause for difficult cannula exchange.
- The rotational motion avoids pressure and lesions against posterior tracheal wall and allows the tracheal lumen to be held up, during the dilatation process, by gentle elevation of the anterior tracheal wall, using the screw already inserted in the tracheal tissues. As a consequence, the endoscopic view is always adequate during every step of the intervention. A recent study [25] comparing Griggs and RT, the duration of the procedure was significantly shorter in the RT group compared with other groups. RT was easier to perform and was associated with minimal complications.

8.2.3 *Rotational Technique Disadvantages*

- The frequently debated topics of rings fractures during PDT involved RT.
- Ferraro et al. [19] reported in a series of 290 tracheostomies 9.6 % of tracheal rings fractures, 76.2 % of these during rotational technique. The rings fractures should be minimised by a sufficient deep skin incision and by a slow and smooth initial rotation of the dilator [21].
- In a retrospective analysis on 348 RT [22], Frova et al. showed the complete absence of major complications and 5.4 % tracheal rings fractures as minor complications. Many authors reported a difficulty in rotation [7, 8]. Byhahn et al. [23] in an observational clinical trial reported the difficulty or impossibility to insert cannula in 8 out 30 patients (26 %). Rodriguez et al. [24] reported difficulty to insert the cannula in 16 of 57 patients (28.1 %).
- The rotational technique is easy and safe, with rapid learning curve, but the choice of technique must consider both individual and ward experience and risk factors for bleeding [18, 26].

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Chapter 9

Choice of the Appropriate Tracheostomy Technique

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Abstract Only 16 randomised controlled trials (RCTs) compared the different PDTs in mixed low-risk population: the meta-analyses evaluating their results showed that single-step dilation technique (SSDT) and Griggs dilating forceps technique (GDFT) are superior in terms of procedural efficacy and safety; moreover, SSDT appeared the best one for short-term complication rate, while no difference was present for midterm and long-term complications. Similar findings come from nonrandomised studies.

Few, low-quality data are available for high-risk groups. SSDT is the only technique evaluated in obese patients: it appeared safe, but the risk of complication could be higher compared to non-obese patients. In patients at higher risk of bleeding, SSDT could be the safest choice, while GDFT seems associated with a higher incidence of bleedings. In hypoxaemic patients, SSDT could be the technique of choice due to its easiness, but a careful ventilator setting is needed as SSDT might increase the incidence of pneumothorax. In neurosurgical patients, GDFT is the best evaluated technique: intracranial pressure can increase during the procedure, but cerebral perfusion pressure seems preserved with GDFT.

Finally, long-term outcomes are difficult to evaluate, as few survivors are commonly available at follow-up. Tracheal stenosis incidence seems not different between SSDT and GDFT; however, SSDT causes more tracheal ring fracture, an injury suspected to predispose to stenosis. Hoarseness and disturbing symptoms (but not vocal cord paralysis) are more common with SSDT, while cosmetic problems seem to be minimised using SSDT.

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9.1 Introduction

A recent meta-analysis [1] demonstrated that percutaneous dilatational tracheostomy (PDT) is superior to surgical tracheostomy performed in the operating theatre in terms of reduction in wound infection and suggested that it might reduce clinically relevant bleeding and mortality. Even though at least six different techniques/devices are commercially available and each one has a different risk profile and can probably offer different advantages, PDT is often considered as a unique entity. Few randomised controlled trials (RCTs) comparing the various PDT techniques are available, and most of these comparisons were performed in low-risk patients. Nonetheless, the results of these comparisons can be helpful when choosing the best technique for a specific patient. Observational prospective and retrospective studies offer further information on this issue, in particular on the use of PDT in high-risk patients. The aim of this chapter is to summarise the best evidence on safety and efficacy of the different PDT techniques.

9.2 Results from RCTs

To the best of our knowledge, so far only 16 RCTs comparing at least two PDT techniques have been published in peer-reviewed, indexed journals [2–17]. Three meta-analyses recently compared the commercially available PDT techniques [18–20].

Data are limited in most cases, with five RCTs comparing single-step dilation technique (SSDT) and Griggs dilating forceps technique (GDFT), four RCTs comparing GDFT with multiple steps technique (MST) and with all other comparisons based on two or less studies. No technique was compared to all the others, and, as a consequence, in many cases, we must rely on indirect comparisons.

All RCTs took place in intensive care units (ICU), but inclusion/exclusion criteria were heterogeneous. All RCTs but one [17] were performed in a mixed population, generally excluding high-risk conditions like coagulopathy and anatomical distortion.

The two meta-analyses that included and compared all six existing PDT techniques [18, 20] showed that three techniques (GDFT, SSDT, MST) are largely equivalent, while the other three (rotational technique, RT; translaryngeal technique, TL; and pneumatic dilation technique, PT) are more dangerous and/or less effective. Among the three best techniques, SSDT resulted slightly superior to GDFT causing less mild complications. It should be underlined that the three “worst” techniques were evaluated together in only six RCTs, that in most cases the ICU staff was at the beginning of the learning curve for these relatively “new” techniques, while it was already expert in older techniques and that only short-term outcomes were analysed (failure rate, intraoperative mild and severe complications).

Even though the findings of the RCTs showed equivalence between MST and SSDT, SSDT has now commercially replaced its predecessor MST, and the best PDT technique is therefore to be identified between GDFT and SSDT. This was

the aim of a recent meta-analysis that also attempted to compare midterm and long-term outcomes [19]. The pooled comparison of the five available RCTs showed that the incidence of intraoperative technical problems (the sum of difficult cannula insertion and failures) was statistically significantly higher with GDFT (15.5 % with GDFT vs. 4.9 % with SSDT, OR 2.6, CI 1.14–6.00, P for effect=0.02, P for heterogeneity=0.4). Interestingly, all the five GDFT failures were completed crossing to SSDT technique, and the only SSDT failure was completed using a surgical approach. Mild and severe bleeding was also more common with GDFT (19.3 % with GDFT vs. 7.6 % with SSDT, OR=2.31, CI 1.15–4.61, P for effect=0.018, P for heterogeneity=0.5). No other statistically significant differences were observed for intraoperative complications, even if a non-significant trend was present for stoma overdilation (7 cases with GDFT vs. 1 with SSDT, OR = 1.89, CI 0.39–9.32, P for effect=0.4, P for heterogeneity =0.6) and tracheal ring fracture (1 case with GDFT vs. 12 with SSDT, OR=0.33, CI 0.08–1.37, P for effect=0.13, P for heterogeneity=0.7). A non-significant trend ($P=0.3$ in both cases) was reported for midterm complications (bleeding episodes while cannulated were 4 in GDFT group vs. 9 in SSDT group OR=0.58, CI 0.20–1.65) and for late disturbing symptoms after decannulation (27 in GDFT, 39 in SSDT, OR=0.7, CI 0.37–1.33).

We underline again that such comparison was based on a limited number of cases (less than 400 patients randomised) and that considering the low incidence of most complications, all the RCTs were underpowered to identify differences. This is particularly true for midterm and long-term outcomes, as many patients die while cannulated or shortly after decannulation before hospital discharge, further reducing the power of the analyses. However, these data constitute the best evidence available so far. Unfortunately, no data on cost-effectiveness were reported.

9.3 Comparisons in Non-RCT Studies

Few studies compared the PDT techniques with a retrospective or prospective (but not randomised) design [21–23]. Three [21–23] out of six studies came from the same German centre, in Frankfurt, in which also some of the RCTs took place.

Three studies compared TL (or “Fantoni”) to GDFT or MST. When compared to GDFT, TL required more time (9.2 vs. 4.8 min) and no other significant differences and with two (4 %) major complications in each group [21]. In the two studies comparing TL and MST [22, 23], the only reported significant difference was a better post-procedural PaO₂/FiO₂ ratio in the TL group with similar procedure time and technical problems with guide wire advancement observed in one-third of TL cases.

One nonrandomised study compared RT (or “PercuTwist”) and SSDT [24]. RT required a longer procedure time (12 vs. 8 min), and 3/24 (12.5 %) patients in the RT group vs. 2/116 (1.7 %) in the SSDT group presented an erosion of the posterior tracheal wall; all differences were not statistically significant.

One study [25] compared GDFT and MST in neurosurgical patients. No statistically significant difference was reported with a trend towards more overall complications and longer procedural time in the MST group.

Finally, one relatively large nonrandomised prospective study compared GDFT and SSDT [26], including midterm and long-term outcomes. Difficult stoma dilation (0 % vs. 13.5 %) and total number of intraoperative minor complications were more common in the SSDT group, while all the three failed procedures were in the GDFT group. The only significant differences at the long-term follow-up were a higher incidence of voice changes and hoarseness in the SSDT group (22 % vs. 8.5 %) and a higher incidence of cosmetic problems with GDFT (9.4 % vs. 2 %).

In conclusion, results of nonrandomised studies confirm that PDT is generally a safe procedure and that GDFT and SSDT are slightly superior to the other techniques, even if also non-RCTs appeared underpowered to reliably detect differences in complications.

9.4 Current Practice

Two national surveys assessed current practice of tracheostomy. Kluge et al. [27] found that SSDT was the preferred technique in Germany (69 % of respondents). In a recent survey in Italy, Vargas reported that SSDT was the most commonly used PDT technique (33 %) [28]. Finally, SSDT was recommended in the guidelines on tracheostomy published by the Belgian Association of Pneumology and the Belgian Association of Cardiothoracic Surgery [29]. SSDT was the chosen technique in a multidisciplinary PDT programme at the Johns Hopkins Hospital [30].

9.5 Choosing the Best Technique for High-Risk Subgroups

Even if PDT was traditionally contraindicated in obese patients, in those with elevated risk of bleeding and with hypoxic respiratory failure, in recent years these conditions have become relative rather than absolute contraindications (along with a growing number of studies showing a higher than expected safety of PDT in these patients) [31].

Since no RCT comparing two PDT techniques was performed in high-risk patients and no retrospective or observational study aimed at comparing the safety and effectiveness of different PDT techniques in these subgroups exists, the choice of PDT is based on a low level of evidence, and only a prudential suggestion, with the strength not higher than that of an expert opinion, can be formulated.

9.5.1 Obesity

Obesity is a growing problem in most western countries and is associated with a high incidence of complications during surgical or percutaneous tracheostomy [32, 33]. Obesity is also the main risk factor for PDT-related deaths associated with airway complications [34]. More recently the incidence of major complications during PDT in this challenging situation was reported to range from 0 to 12 % [35].

SSDT is the only technique that has been specifically evaluated in obese patients. Romero et al. [36] in a prospective study found no difference in complication rate between obese and non-obese patients; nevertheless, a trend towards a higher incidence of postoperative complications (tracheostomy tube displacement) was present in the obese group. Heyrosa et al. [37], in a retrospective study in 89 obese patients, reported a complications rate of 5.6 % in the SSDT group, identical to the incidence reported in the surgical tracheostomy group. The five patients with complications in the SSDT group (loss of the airway, bleeding, malpositioning or difficult insertion of the cannula) required conversion to surgery in four cases. McCague et al. [38] did not find significant differences between obese and non-obese patients while using the SSDT in 426 cases. The same findings had been reported by Rosseland in 1000 PDTs [39]. Finally, Dennis et al. [35] in the largest retrospective study on more than 3000 PDT analysed almost 1000 overweight-obese patients reporting a complication rate of 1 % and no conversion to surgery. The complication rate in the overall population was 0.38 %.

SSDT proved safe and successful in obese patients in a limited number of nonrandomised studies. In the absence of comparative studies, we don't know if other techniques are better or worse, and actually some authors preferred TL [40]. However, in comparative RCTs in unselected patients, SSDT demonstrated to be technically the easier method [18, 19]. On the basis of available data, choosing SSDT in obese patients seems reasonable. An expert team adequately equipped is mandatory. Ultrasound evaluation and guidance could also be of help in limiting risks [41].

9.5.2 Patients at Higher Risk of Bleeding

In this subgroup, we include patients affected by coagulopathy or thrombocytopenia and patients under treatment with anticoagulant or antiplatelet drugs. The issue is of relevance, as post-procedural haemorrhage is the main cause of death PDT related as recently reported by Simon et al. [34]: coagulopathy was found in 5 out of 27 patients who died.

Despite being traditionally considered a relative contraindication, coagulopathy did not result to increase the risk of bleeding in a retrospective analysis of 483 PDTs [42]. In line with this finding, Veelo et al. reported that the correction of subclinical disorders (abnormal platelet count or prothrombin time or single antiplatelet

therapy) did not further reduce the already low incidence of bleeding [43]. In another study, abnormal partial thromboplastin time or low platelet count was associated with chronic bleeding [44].

Again, as observed in obese patients, we lack prospective or retrospective studies comparing different PDT techniques, and we must rely on case series describing only one technique in this high-risk population.

Barton et al. found no association between coagulation values or prophylactic anticoagulation or antiplatelet therapy and risk of bleeding in 352 MST, while platelet count was significantly lower in patients experiencing bleeding events [45]; however, all episodes of bleeding were of mild severity.

Using GDFT in patients with severe thrombocytopenia treated with preoperative platelets transfusion, Kluge observed a 5 % major bleeding episodes requiring sutures in patients who had an elevated APTT due to heparin infusion [46]. In a prospective study including patients at higher risk of bleeding or obese, Rosseland found that SSDT was associated with a low risk of bleeding; increased INR was the most important risk factor for bleeding, followed by low platelet count [39]. In a small prospective study including 32 patients with coagulopathy or thrombocytopenia, after correction with fresh frozen plasma (FFP) and/or platelet transfusion, only one major bleeding (requiring surgery) and three minor bleedings were reported [47]. Auzinger et al. evaluated 60 patients with severe liver disease, 25 of whom had secondary coagulopathy refractory to FFP and platelets transfusion: SSDT was used in 43 cases and MST in 18. Only one patient in the refractory group suffered from major bleeding requiring further transfusion, and no significant difference was present among refractory and not refractory coagulopathy groups [48]. SSDT was also applied uneventfully in two patients under ongoing double antiplatelet therapy [49]. Finally, SSDT was used in 118 patients on extracorporeal lung support [50]; preventive treatment with FFP or platelets transfusion was administered in a minority of cases, while heparin infusion was stopped 1 h before the procedure. Two major bleedings (1.7 %; one requiring surgery) and 37 minor bleedings were observed; no clotting complication of the extracorporeal devices happened.

SSDT is the most evaluated technique in patients at high risk of bleeding, and it seems relatively safe. An expert team and correction of severe coagulopathy help reduced risks. SSDT also showed a significantly lower incidence of intraoperative bleeding events when compared to GFDT in RCTs [19]. In conclusion, on the basis of indirect comparisons with a low-level evidence and despite some expert preference for other techniques like the TL [40], SSDT is likely the best technique in patients at high risk of bleeding.

9.5.3 Severe Hypoxaemia

Severe hypoxaemia is likely one of the strongest contraindications to PDT, even if expert groups can adopt more limited exclusion criteria as $FiO_2 > 0.8$ and $PEEP > 15$ cmH_2O [30].

Only one manuscript specifically addressed PDT in hypoxaemic patients. A prospective nonrandomised case series by Beiderlinden et al. compared 88 patients requiring PEEP >10 cmH₂O with 115 patients treated with lower PEEP: PDT was uneventful in both groups, and oxygenation was not jeopardised.

Hypoxaemia in patients that were not hypoxaemic before the procedure was seldom reported in RCTs, and only one study identified a significant difference, with MST being worse than GDFT [5]. No difference was found between the two “best” techniques, GDFT and SSDT [19]. Among nonrandomised studies, MST resulted worse than TL in one study [22].

In our opinion, in the absence of robust data, when PDT must be performed in hypoxaemic patients, SSDT could be considered the technique of choice as it is easily accomplished, with a low risk of intratracheal bleeding and a low risk of failure. However, SSDT was found to be associated to a non-significant higher incidence of pneumothorax when compared to other techniques [19, 26], maybe due to a valve mechanism trapping the air distally to the dilator [8]: a cautious approach is therefore recommended, and periprocedural PEEP reduction should be performed whenever possible. Innovative solutions like the use of a double-lumen endotracheal tube could improve the safety of PDT in hypoxaemic patients [51].

9.5.4 Neurosurgical Patients

Stocchetti et al. compared two different PDT techniques and the surgical technique in a RCT with no significant increase of intracranial pressure (ICP) at the time of cannula placement in every technique [17]; however, an ICP >20 mmHg was more common with MST than with GDFT. Cerebral perfusion pressure (CPP) dropped below 60 mmHg in one-third of patients, mainly in the surgical group. A significant increase of arterial CO₂ was present in all groups. In another RCT comparing RT and MST in a mixed population, a significant increase of the ICP was observed for the GFDT group, but the ICP after tracheostomy and the CPP were not different between the groups [52]. Noteworthy, mean post tracheostomy ICP was >30 mmHg. Finally, in an observational study in 14 neurosurgical patients, no increase in ICP was noted during PDT (5 MST, 9 GDFT).

In conclusion, few contradictory data on this issue are available. A relevant increase in ICP during the procedure is possible, and the decision to perform PDT should be carefully evaluated when CPP must be preserved. GDFT is the best evaluated technique, might be the less dangerous in this subgroup and could be considered the technique of choice in the absence of major risks of bleeding. Unfortunately no data on SSDT performance in neurosurgical patients were found.

9.5.5 Long-Term Outcomes

Long-term outcomes are difficult to evaluate or compare, as few survivors are commonly available at follow-up; this is particularly true with small studies. Moreover, in most cases it is not possible to attribute a complication like swallowing

dysfunction or tracheal stenosis to the PDT instead of the previous endotracheal intubation. Long-term outcomes can be of major relevance in young patients, due to their life expectancy. In the following paragraphs, we will consider three relatively common complications and their potential relationship with the PDT technique; for rare, severe complications like trachea-innominate fistulae, no association can be reliably hypothesised at the moment.

9.5.5.1 Tracheal Stenosis

The incidence of symptomatic tracheal stenosis is <1 % for PDT in hospital survivors, and it is not different from surgical tracheostomy [53]. However, asymptomatic stenosis after PDT could be much more common, with an incidence up to 24 % and higher than that observed after surgical tracheostomy [54]. In a recent report on nine consecutive cases of tracheal stenosis, endoscopy revealed damage of the anterior tracheal wall in all cases [54]. Five of the PDT procedures were performed using SSDT, the others using MST. A cause-effect relation between tracheal ring fracture and late stenosis is suspected, but not yet demonstrated. Tracheal stenosis seems quite uncommon after GDFT, while tracheal dilatation seems more likely [55]. A recent meta-analysis found no difference in the incidence of tracheal stenosis between SSDT and GDFT [19]; however, a trend towards more frequent fracture of tracheal rings was observed for SSDT (6.5 % vs. 0.5 %). It has been reported that most ring fractures during SSDT occur half-way of the insertion of the dilator, maybe due to excessive speed in dilation [3, 8]. No data are available on other techniques. Hence, on the basis of the weak evidence on the association between ring fracture and tracheal stenosis, a slow dilatation with the SSDT technique or the use of GDFT might be the best choice.

9.5.5.2 Hoarseness, Disturbing Symptoms and Vocal Cord Paralysis

Hoarseness and disturbing tracheal symptoms reported by patients are not rare. In a prospective study on 342 patients, Fikkers reported an incidence of 9 % with GDFT and 22 % with SSDT ($P < 0.01$) [26]. Consistent with these findings, the meta-analysis comparing SSDT and GDFT reported a trend towards a higher incidence with SSDT (21 % vs. 15 %) [19]. On the contrary, the incidence of vocal cord paralysis was similar (1.6 %). Many relevant issues are simply totally unknown: among others, how long the symptoms last, if they are related to tracheal rings or mucosal damages, and the incidence with other PDT techniques. At the moment GDFT seems the best technique if the risk of voice changes must be minimised.

9.5.5.3 Cosmetic Issues

Also for this topic, few data are available and limited to two techniques, GDFT and SSDT. Cosmetic problems were noted by Fikkers in 9.4 % of patients after GDFT vs. 2 % after SSDT ($P < 0.05$) [26]. In the meta-analysis, there were 4 (2 %, referred

to the patients undergoing the PDT, and not to survivors) cases with GDFT vs. 4 with SSDT, a non-significant difference; however, three patients in the GDFT group required a surgical scar correction, vs none in the SSDT group. Based on this limited data, SSDT seems the best technique when cosmetic outcome is of great relevance.

9.6 Conclusions

Even if PDT is a common procedure, few RCTs compared the existing techniques. Moreover, high-risk patients have usually been excluded from RCTs. Finally, all studies were singularly underpowered to reliably detect differences in midterm and long-term outcomes.

Available data suggest that SSDT could be considered the technique of choice in most cases, due to its superior success rate and low incidence of complications. National surveys confirm that SSDT is the preferred technique. However, SSDT might be associated with a higher incidence of pneumothorax, voice changes, disturbing symptoms and tracheal stenosis. GDFT is likely the best alternative and might be the technique of choice in neurosurgical patients while it might be best avoided in patients at higher risk of bleeding or when cosmetic consequences are relevant.

Knowledge of the pros and cons of each PDT techniques and above all of SSDT and GDFT should help in choosing the right technique and in the optimisation of the procedure. Other interventions, like the use of a bronchoscope or of ultrasound or preliminary correction of coagulation disorders, could likely further enhance safety. Finally, as a recent study clearly showed [30], staff experience and a standardised approach are crucial in improving the quality of care of PDT in a cost-effective manner.

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Chapter 10

Complications of Percutaneous and Surgical Tracheostomy in Critically Ill Patients

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Abstract Percutaneous tracheostomy is more widely used in intensive care unit. In critical patients, it has many potential advantages over endotracheal intubation including reduction of respiratory resistance, work of breathing, length of mechanical ventilation, laryngeal injury and a better clearance of airway secretions. From a practical point of view, percutaneous tracheostomy is a safe and cost-effective technique performed at bedside, but it is not without risks and complications. The reported incidence of significant complications for PDT is about 1–10 %, including both short-term and long-term complications.

Percutaneous tracheostomy is more widely used in intensive care unit. Different percutaneous tracheostomy techniques have been proposed: (1) single-step dilatational techniques [Ciaglia Blue Rhino (CBR), Ciaglia Blue Dolphin (CBD), PercuTwist (PT)], (2) multiple step dilatational technique [Ciaglia multiple dilator], (3) guide wire dilating forceps technique [Griggs technique – GWDF] and (4) retrograde translaryngeal tracheostomy [Fantoni technique – TLT]. In critical patients, it has many potential advantages over endotracheal intubation including reduction of respiratory resistance, work of breathing, length of mechanical ventilation, laryngeal injury and a better clearance of airway secretions [1, 2]. Furthermore, tracheostomy has been reported to reduce the need of sedation, to improve patient comfort and communication as well as to facilitate nursing work. From a practical point of view, percutaneous tracheostomy is a safe and cost-effective technique performed at bedside, but it is not without risks and complications [3]. The reported incidence of significant complications for PDT is about 1–10 %, including both short-term (such as bleeding, loss of airway and infection) and long-term (tracheal stenosis, tracheomalacia, tracheocutaneous fistula and so forth) complications. Many of these complications are potentially

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preventable and may be related to technical and procedural factors. Attention to the level of placement may have an impact on the risk of tracheal stenosis, trachea-innominate fistula and dislodgment [4]. Selection of the appropriate tube size and puncture site may decrease the risk of early dislodgement [4]. Avoidance of vascular structures may decrease the risk of bleeding [4]. Accurate assessment of endotracheal tube (ETT) tip position may decrease the risk of airway loss [4]. These procedural considerations may be particularly relevant in patients with high-risk factors, which may increase the technical difficulty of the procedure and the risk of complications. These high-risk factors include coagulopathy, morbid obesity, cervical spine immobilisation (CSI), repeat tracheostomy and the ongoing need for high levels of respiratory support. Most of the literature consists of observational data or small prospective studies; therefore debate still continues as to which method is preferred. Early complications of tracheostomy include bleeding, wound infection, false route or early tube displacement, subcutaneous emphysema and pneumothorax [5]. Late complications include swallowing problem, tracheal stenosis, tracheo-innominate artery fistula [5]. In the literature, there is no agreement on the definition of complications. Some authors divided complications in: (1) early or late complications if they occur, respectively, within or a week after tracheostomy placement; (2) perioperative or postoperative complications if they occur during the first 24 h or after 24 h from the procedure [6], in addition to intraoperative complications; and (3) minor and major complications. Minor complications are defined as clinically irrelevant when no patient harm occurred, while major complications were classified as potentially life threatening or with the need of an intervention. According to different tracheostomy techniques developed during the last 30 years, many published studies compared different percutaneous tracheostomies to each other or to surgical procedures. Four meta-analysis compared surgical to percutaneous multiple and/or single dilatational tracheostomy (PDT). In 1999, Dulgerov et al. performed a meta-analysis to compare percutaneous tracheostomy technique, introduced in 1985, with a historical control group of surgical tracheostomy performed from 1960 to 1996 [7]. In this study, 55 randomised clinical trials were included; perioperative and postoperative complications were further subdivided in serious, intermediate and minor subgroups according to the severity. Percutaneous technique was associated with more perioperative but less postoperative complications than surgical tracheostomy. Another meta-analysis of prospective clinical trials to compare PDT and surgical technique in critically ill patients was performed by Freeman et al. including 5 studies and 236 patients [8]. In this study, PDT showed advantages compared to ST including ease of performance, lower incidence of peristomal bleeding and postoperative infection [8]. In 2006, Delaney et al. performed a systematic review and meta-analysis comparing PDT and surgical tracheostomy, to investigate the possible differences in the incidence of wound infection, bleeding, perioperative and long-term complications as well as mortality [9]. Seventeen randomised clinical trials,

published between 1996 and 2005 involving 1212 ICU patients, were eligible for this meta-analysis. Clinically important wound infection occurred in 6.6 % of patients; PDT was associated to less infection compared to surgical tracheostomy. Overall incidence of bleeding was 5.7 %, mortality rate 37 % and major complications 2.6 % with no statistical difference in the subgroup analysis. These results showed that PDT was associated to a reduction of infection and was equivalent to surgical tracheostomy in the mortality and perioperative and long-term complications [5]. Higgins and Punthake performed another meta-analysis to compare complications rates of PDT versus surgical tracheostomy in mechanically ventilated patients involving 15 RCTs including 973 patients [10]. Pooled analysis revealed infection, unfavourable scarring and overall trend of complications, but no difference in false passage, minor haemorrhage, major haemorrhage and subglottic stenosis [10]. Information regarding long-term complications of surgical or percutaneous tracheostomy are astonishingly scanty. This is likely due to difficulties to monitor patients who underwent tracheostomy because of high mortality and poor neurological outcome and patient collaboration which makes difficult planned post-procedural evaluation. In 2005, Antonelli et al. in a randomised clinical trial with 1-year double-blind follow-up assessed short-term and long-term complications of translaryngeal tracheostomy (TLT) and surgical technique [11]. One hundred and thirty-nine patients were enrolled, 67 in TLT group and 72 in the surgical technique group, but only 31 patients were contacted for the follow-up. TLT showed many advantages compared to surgical technique, it was more rapid and associated to less perioperative bleeding, but infection complications and bacteraemia were similar between the groups. Follow-up evaluation showed that stomatoplasty or evident tracheal stenosis occurred more frequently in the surgical group, but quality of life didn't differ between them [11]. Among long-term complications, tracheal stenosis is the most serious and life threatening. Raughuraman found that tracheal stenosis caused by PDT was significantly closer to the vocal cord and associated with early onset and with more difficult surgical correction compared to surgical technique [12]. While there is support in the literature of equivalent early complication rates between open and percutaneous techniques, there is less evidence about their equivalency with regard to late complications such as tracheal stenosis. For this reason, there is still debate about which method provides superior patient outcomes. The incidence of symptomatic tracheal stenosis following OT or PT ranges in the literature from 0 to 10 %. The true incidence of tracheal stenosis is difficult to ascertain because it is often subclinical in nature. Kettunen et al. in 2014 compared incidence of, and factors contributing to, tracheal stenosis following percutaneous tracheostomy (PT) or open tracheostomy (OT). Of 616 patients, 265 underwent OT and 351 underwent PT. Median injury severity score was higher for PT (26 vs. 24, P 5.010) [13]. Overall complication rate was not different (PT 52.3 % vs. OT 52.6 %, P 5.773). There were nine tracheal stenosis, four (1.1 %) from the PT group and five (1.9 %) from the OT group (P 5.509). Mortality was higher in OT

patients (15.5 % vs. 9.7 %, P 5.030). Numerous and variable risk factors for tracheal stenosis following intubation have been suggested in the literature and include trauma and inflammation at the endotracheal tube cuff site, excess granulation tissue around the tracheal stoma site or over a fractured cartilage, high tracheostomy site, prolonged intubation, traumatic intubation or previous intubation or tracheostomy [13]. The authors demonstrated that patients who developed tracheal stenosis tended to have longer mechanical ventilator requirements (26.7 vs. 16.1 days, P 5.055), with patients developing stenosis being on the ventilator on average 11 additional days [13]. It could be hypothesised that additional ventilator days meant more time with an inflated tracheal cuff causing tracheal ischemia and stenosis. They did identify that younger age and longer length of ICU stay were associated with increased rate of tracheal stenosis; however, the reason for these findings is unclear, and these findings were not observed in similar studies [13]. Other studies compared different percutaneous techniques to each other. Divisi et al. in a retrospective study reported similar complication rates in TLT and CBR [14], but the latter was associated with fewer iatrogenic complications, less procedural time and less complex execution [14]. In a prospective randomised clinical trial, Cianchi et al. compared Ciaglia Blue Rhino with Ciaglia Blue Dolphin tracheostomy in ICU. Seventy patients with no difference in baseline characteristics were enrolled, 35 assigned to CBR group and 35 to CBD group. CBD was more frequently associated to a presence of blood drain on tracheal and bronchial mucosa, tracheal ring buckling and injury, cutaneous bleeding and resistance to tracheal tube passage [15]. Fikkers et al. compared single-step dilatational tracheostomy versus (SSDT) guide wire dilating forceps technique (GWDF) in a randomised clinical trial involving 120 patients [6]. Overall complications were higher in the GWDF than in SSDT, in particular, minor or major blood loss, difficult cannula insertion and difficult dilation, and conversions in another technique were more frequent in the guide wire forceps technique [6]. GWDF was compared with PercuTwist (PT) in a prospective randomised trial by Montcriol et al. In this study 87 patients were enrolled, 45 randomised in PT group and 42 in the GWDF group [16]. Whereas there was no statistical difference in complications, the authors identified two trends. Griggs technique was associated to more bleeding complication due to its dilatational procedure; probably in PT the rotational dilatation with the screw provided a tight closure of the stoma. The second trend concerned cannulation difficulties, because PT technique required a more physical strength for a complete dilation so cannula placement is often difficult [16]. Different percutaneous tracheostomies result in a different pattern of complications due to the main practical features of the technique. Cabrini et al. performed a meta-analysis of randomised clinical studies to evaluate if one PDT technique is superior to another with regard to minor and major intraprocedural complications [17]. Thirteen randomised clinical studies were finally included in the review involving 1030 patients and six techniques. The main result of this study was that GWDF, SSDT

and multiple dilatational techniques were equivalent in safety, and SSDT was superior to GWDF for mild complications. In 2014 Putensen et al. conduct a meta-analysis to determine whether PT techniques are advantageous over ST and if one PT technique is superior to the others [18]. Computerised databases (1966–2013) were searched for randomised controlled trials (RCTs) reporting complications as predefined endpoints and comparing PT and ST and among the different PT techniques in mechanically ventilated adult critically ill patients [18]. According to the authors, available evidence from RCTs including adult critically ill patients tends to show that PT techniques are performed faster and reduce stoma inflammation and infection but are associated with increased technical difficulties when compared with ST. Among PT techniques, MDT + SSDT are associated with the lowest odds for intraprocedural technical difficulties and major bleeding, while GWDF accounts for increased odds for intraprocedural major bleeding [18].

While bronchoscopic guidance is routinely used during PDT, bedside ultrasound has, more recently, received attention as a potentially useful tool to improve the safety of PDT. The potential advantages of US include the ability to identify the cervical vasculature [4], assist with tube size and length selection [19], help identify the most appropriate location for the tracheal puncture site and guide needle insertion into the trachea. Several studies have demonstrated the value of preprocedural cervical US to improve the safety of PDT [12, 20, 21]. In 1999, the first real-time US-guided PDT was described [22], followed by the publication of several reports, including a systematic review [23–26]. Preprocedural assessment with ultrasound was described several years ago, as was the use of ultrasound during the procedure to facilitate tracheal puncture at the appropriate level, without real-time visualisation of needle passage [12, 20, 27, 28]. Rajajee et al. in 2015 reviewed all percutaneous dilatational tracheostomies performed in an 8-year period in a neurocritical care unit [4]. Bronchoscopic guidance was used for all procedures with addition of real-time ultrasound guidance at the discretion of the attending physician. Real-time ultrasound guidance was used to guide endotracheal tube withdrawal, guide tracheal puncture, identify guide wire entry level and confirm bilateral lung sliding. The primary outcome was a composite of previously defined complications including (among others) bleeding, infection, loss of airway, inability to complete procedure, need for revision, granuloma and early dislodgement [4]. Propensity score analysis was used to ensure that the relationship of not using real-time ultrasound guidance (RUSG) with the probability of an adverse outcome was examined within groups of patients having similar covariate profiles [4]. A total of 200 patients underwent percutaneous dilatational tracheostomy during the specified period, and 107 received real-time ultrasound guidance. Risk factors for percutaneous dilatational tracheostomy were present in 63 (32 %). There were nine complications in the group without real-time ultrasound guidance: bleeding ($n=4$), need for revision related to inability to ventilate or dislodgement ($n=3$) and symp-

omatic granuloma ($n=2$) [4]. There was one complication in the real-time ultrasound guidance group (early dislodgement) [4]. The odds of having an adverse outcome for patients receiving real-time ultrasound guidance were significantly lower (odds ratio=0.08; 95 % confidence interval, 0.009–0.811; $P=0.032$) than for those receiving a standard technique while holding the propensity score quartile fixed [4]. In this study the use of RUSG during PDT was associated with a significantly lower rate of procedure-related complications in a propensity score-matched analysis and may be particularly useful when performing PDT in patients with risk factors, such as coagulopathy [4]. Gobatto et al. in 2015 analysed all patients who were submitted to PDT after the standardisation of US-guided PDT technique in their institution [29]. Sixty patients who had been submitted to PDT were studied, including 11 under bronchoscopy guidance and 49 under US guidance. No surgical conversion was necessary in any of the procedures, and bronchoscopy assistance was only required in one case in the US group. The procedure length was shorter in the US group than in the bronchoscopy group (12 vs. 15 min, $P=.028$). None of the patients had any major complications. The minor complication rates were not significantly different between the groups nor was the probability of breathing without assistance within 28 days, intensive care unit length of stay or hospital mortality. In this study ultrasound-guided PDT is effective, safe and associated with similar complication rates and clinical outcomes compared with bronchoscopy-guided PD [29]. In the same way Ravi et al. evaluate the efficacy of ultrasound-guided percutaneous tracheostomy (USPCT) and bronchoscopic-guided percutaneous tracheostomy (BPCT) and the incidence of complications in critically ill, obese patients [30]. Seventy-four consecutive patients were included in a prospective study and randomly divided into USPCT and BPCT. The overall complication rate was higher in BPCT than USPCT patient group (75 % vs. 32.1 %, $P<0.05$). Most complications were minor (hypotension, desaturation, tracheal cuff puncture and minor bleeding) and of higher number in the BPCT. Ultrasound-guided PCT was possible in all enrolled patients, and there were no surgical conversions or deaths. Real US-guided PCT is a favourable alternative to BPCT with a low complication rate and ease, thus proving more efficacious [30].

In conclusion, in critically ill patients: (1) percutaneous might be considered as the technique of choice for tracheostomy performed in ICU. Surgical tracheostomy should be reserved for patients when percutaneous tracheostomy is contraindicated. (2) Among different percutaneous dilatational techniques, single-step dilatational tracheostomy was easy and safe to perform and associated to less complication than the other techniques. Minor bleeding is the most common complication with the Griggs technique, while puncture of endotracheal tube, cannula displacement or difficult dilatations are more frequently observed with the other commonly percutaneous tracheostomy techniques (Table 10.1).

Table 10.1 Meta-analyses on PDT in critically ill patients

Author, year [ref]	Number of studies	Type of included studies	Population	Searching strategy until (years)	Statistical analysis	Number of patients	Main outcome	Conclusions
Dulguerov et al. (1999) [7]	65 articles	RCT, PT, RT	ST vs. PT	1960–1984 1985–1996	No OR, RR or RD calculated	9514	Serious complications: death, cardiopulmonary arrest, pneumothorax, pneumomediastinum, tracheocephalic fistula, mediastinitis, sepsis, intratracheal postoperative haemorrhage, cannula obstruction and displacement, tracheal stenosis Intermediate complications: intraoperative desaturation, lesions of the posterior tracheal wall, cannula misplacement, switch of a PT procedure to a surgical technique, aspiration pneumonia, atelectasis, lesion of the tracheal cartilages Mild complications: intraoperative haemorrhage, false passage, difficulty with tube placement, subcutaneous emphysema, postoperative wound haemorrhage, infections, delayed closure of tracheostomy tract, keloids, anaesthetic scarring	Higher incidence of perioperative complications, perioperative death and serious cardiorespiratory events in the PT group Higher incidence of postoperative complications in ST group

(continued)

Table 10.1 (continued)

Author, year [ref]	Number of studies	Type of included studies	Population	Searching strategy until (years)	Statistical analysis	Number of patients	Main outcome	Conclusions
Freeman et al. (2000) [8]	5 articles	PT	MDT vs. ST	1985–2000	MD; OR	236	Length of procedure; operative complications; intraoperative bleeding; postoperative complications; postoperative bleeding; stoma infection; mortality	PT shorter length and greater ease of procedure PT lower incidence of overall postoperative complications, intraprocedural and post-procedural bleeding and stoma infections
Delaney et al. (2006) [9]	17 articles	RCT	PT vs. ST	Inception to 2005	OR	1.212	Wound infection, bleeding, mortality	Compared with ST, PT has a lower incidence of wound infections Compared with ST, PT is not associated with a higher incidence of clinically significant bleeding, major periprocedural or long-term outcomes When comparing open ST performed in the ICU, PT has a lower incidence of relevant bleeding

Higgins and Punthake (2007) [10]	368 abstracts; 15 articles	RCT	PT vs. ST	1991–2005	OR	973	Minor haemorrhage; major haemorrhage; false passage; wound infection; unfavourable scar; decannulation/dislodgment; subglottic stenosis; mortality	PT higher incidence of false passage and accidental decannulation PT lower incidence of wound infection and unfavourable scarring PT performed faster and with more cost effectiveness Overall complications did not differ between groups When comparing open TT performed in the OT vs. PT performed in the ICU, PT has a lower overall complication rate
Cabrini et al. (2012) [17]	13	RCT	Within PT	2000–2010	RD	1130	Conversion to other method; any mild complications; any severe complications	SSDT lower incidence of mild complications than BDT and GWDF SSDT lower frequency of failure than RDT GWDF lower incidence of severe complications and frequency of failure than TLT No differences between MDT and SSDT MDT lower incidence of mild complications than GWDF; same incidence of severe complications and conversion rate

(continued)

Table 10.1 (continued)

Author, year [ref]	Number of studies	Type of included studies	Population	Searching strategy until (years)	Statistical analysis	Number of patients	Main outcome	Conclusions
Putensen et al. (2014) [18]	14	RCT	PT vs. ST; within PT	1966–2013	OR	973	Complications during the procedure: major and minor bleeding, technical difficulties, false route, subcutaneous emphysema, pneumothorax and oxygen desaturation Complication after the procedure: major and minor bleeding, stoma inflammation or infection, tracheomalacia and tracheal stenosis	PT techniques are performed faster and reduce stoma inflammation and infection PT are associated with increased technical difficulties when compared with ST MDT + SSDT are associated with the lowest risk for intraprocedural technical difficulties and major bleeding GWDF is associated with increased risk for intraprocedural major bleeding

RCT randomised controlled trials, *PT* prospective trials, *RT* retrospective trial, *ST* surgical tracheostomy, *PT* percutaneous tracheostomy, *OR* odds ratio, *RR* relative risk, *RD* risk difference, *MD* weighted mean difference, *OT* operating theatre, *TT* tracheostomy, *MDT* multiple dilatation tracheostomy, *SSDT* single-step dilatation tracheostomy, *GWDF* guide wire dilating forceps, *BDT* balloon dilatation tracheostomy, *RDT* rotational dilatation tracheostomy

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Chapter 11

Emergency Percutaneous Tracheotomy

S. Schmitz and M. Hamoir

Abstract Percutaneous tracheotomy (PT) is a standard procedure for airway establishment in selected indications. It is not considered a standard technique for the management of emergency airway situations despite more and more reports highlighting its use in this setting. In this chapter, we compare PT with other emergency airway access techniques and describe a new approach to manage patients with major airway obstruction leading to “no ventilation, no intubation” situations under general anaesthesia.

11.1 The Emergency Airway: Definition

The American Society of Anesthesiology (ASA) [1, 2] defined a difficult airway as a situation in which facemask ventilation or tracheal intubation of the upper airway is not adequate or unsuccessful. Many new airway devices have been created to manage these conditions safely. However, if both ventilation and intubation are impossible, invasive airway access has to be considered either by tracheotomy or emergency percutaneous airway access, including cricothyroidotomy and percutaneous tracheotomy (PT). Risk factors for a “no ventilation, no intubation” situation include difficult mask ventilation [3], difficult direct laryngoscopy [4] and multiple attempts at tracheal intubation by an experienced anaesthesiologist. Furthermore, diagnosed and undiagnosed obstructive disease of the upper airway frequently leads to this situation.

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11.2 Invasive Airway Access

11.2.1 *Cricothyroidotomy*

Cricothyroidotomy is the technique frequently selected in emergencies and consists of percutaneous tracheal access through the cricothyroid membrane. The main advantage of this technique is related to the accessibility of the cricothyroid membrane – as it is located superficially to the skin, minimal dissection is required. Cricothyroidotomy can be performed by puncture with a narrow-bore cannula-over-needle (ID ≤ 2 mm), a wide-bore cannula-over-trocar (ID ≥ 4 mm) or a wire-guided (Seldinger) technique. The cricothyroid membrane can also be approached surgically.

The cricothyroidotomy procedure is reported to be associated with less complications, is faster than surgical tracheotomy and requires less surgical skills [5, 6]. Cricothyroidotomy with a narrow-bore cannula over needle allows jet ventilation, but appropriate output after each jet delivery is essential to avoid pneumothorax and hypercapnia. This is compromised in several clinical situations, particularly when severely obstructing tumours are present [7]. Even with modern jet ventilation (incorporating a cut off system and alarms in case of overpressure), ventilation remains challenging in patients with upper airway obstruction. Ventilation systems with larger diameters, while improving ventilation, carry a greater risk of posterior tracheal wall injuries due to the higher pressure required to insert such devices [8]. Furthermore, as the cricothyroid membrane is small, damage to the cricoid cartilage may occur inducing irreversible long-term injuries of the upper trachea such as subglottic stenosis, scars or voice changes [9]. Laryngeal fracture and bleeding, secondary to the insertion of a small tube (6 mm in diameter), are also possible with a surgical approach. Due to the limited ventilation possibilities and potential complications, cricothyroidotomy should be considered a temporary procedure that often requires subsequent conversion to a tracheotomy [6].

Cricothyroidotomy is generally performed in emergency situations, whereas PT is routinely used in selected indications. The latter is therefore generally preferred by medical staff. Failure to identify the cricothyroid membrane occurs frequently and is the principal cause of failed cricothyroidotomy [10]. Different cricothyroidotomy techniques have been tested on human cadavers with the finding that anatomical-surgical techniques were associated with a higher success rate, a faster tracheal tube insertion time and a lower complication rate than puncture techniques in inexperienced healthcare personnel, underlining the impact of operator experience on the success of a given technique [11].

11.2.2 *Tracheotomy*

Surgical tracheotomy has the advantage of providing a definitive and stable airway and is considered to be the golden standard. This technique is, however, time consuming and relies on the surgical expertise of the medical staff. Furthermore, the

complication rate is reported to be five times higher in an emergency than in an elective situation [6, 7]. Tracheotomy is, therefore, not the best option for rapid airway control.

The role of emergency percutaneous tracheotomy (PT) is not currently well established. PT is largely used in elective situations and as an attractive alternative to a surgical approach, being significantly faster and more cost-effective [12, 13]. The list of contraindications for PT has shrunk progressively over the last few years as users have gained more experience and adjuncts, such as bronchoscopy and ultrasound imaging, have increased the security of the procedure. The use of PT has been reported in clinical conditions described previously as relative contraindications including obese patients [14], patients with injuries to the head and neck area [15] and in emergency airway situations. The most used PT technique described in the emergency setting is the Griggs wire-guided forceps method.

A laboratory comparison of the Ciaglia wire-guided dilators method versus the Griggs wire-guided forceps method showed benefits in terms of time of placement in favour of the Griggs technique, mean 217 s versus 89 s, respectively. The Griggs technique should therefore be the technique of choice if PT is to be performed as an emergency procedure [16]. Furthermore, in a meta-analysis, Powell et al described a 1.2 % perioperative complication rate and a 2.0 % postoperative complication rate for the Griggs method, which is lower than the complication rate induced by other PT techniques (7.6 %–22.9 % and 5 %–6.5 %, respectively) [17].

The largest retrospective study on the use of PT in emergency conditions involved 18 patients. Indications for emergency PT included respiratory failure associated with anaphylaxis, supraglottic oedema, cardiac arrest and blood or oedema blocking the airway preventing intubation. Among the 18 patients, 9 had a body mass index that fell within 30–112 kg/m². The authors described successful placement of PTs in all patients. No complications were documented after the procedure. Of interest, two patients had previously undergone cricothyroidotomy which did not function adequately [18].

The second largest retrospective study of emergency PT using a modified Griggs technique involved ten patients with cervical spine fractures, maxillofacial trauma, head and neck burns and inhalation injuries [19]. The mean time from skin incision to intubation was 5.5 min including the oxygen insufflation period. There was no failure, no complications related to the procedure and no conversion to an open technique. Long-term follow-up did not reveal any other complications. Smaller reports showed similarly encouraging results with the Griggs technique in different clinical situations including upper airway obstruction due to haematoma [20], angiooedema [21], cardiogenic shock [22], altered neck anatomy due to severe burn [23] and cancer [24]. The technique is described as safe and feasible, and, in experienced hands, emergency PT is faster than open tracheotomy [25]. Given that the Griggs method of emergency PT is safe and rapid, some centres have implemented it as the procedure of choice for emergency airway access [26].

11.2.3 *PT to Assess the Airway of Patients with an Expected “No Ventilation, No Intubation” Situation*

Recently, we published a modified PT technique for major upper airway obstruction, as tested in 13 patients [27]. We combined the Griggs dilatation technique with the insertion, inside the trachea, of a narrow-bore cannula-over-needle (Ravussin catheter, VBM Medizintechnik GmbH, Germany), generally used for cricothyroidotomy. The Ravussin was placed under local anaesthesia, and its correct placement was confirmed by the presence of air bubbles (by aspirating into a syringe filled with water) and capnograph CO₂ readings taken directly out of the catheter (Fig. 11.1). PT was then performed under general anaesthesia by passing the guide wire through the Ravussin cannula. After removing the Ravussin cannula, the classical Griggs dilatation technique was performed in less than 1 min. This technique is particularly useful in patients with major airway obstruction secondary to extended head and neck tumours leading to a predictable “no ventilation and no intubation” status.

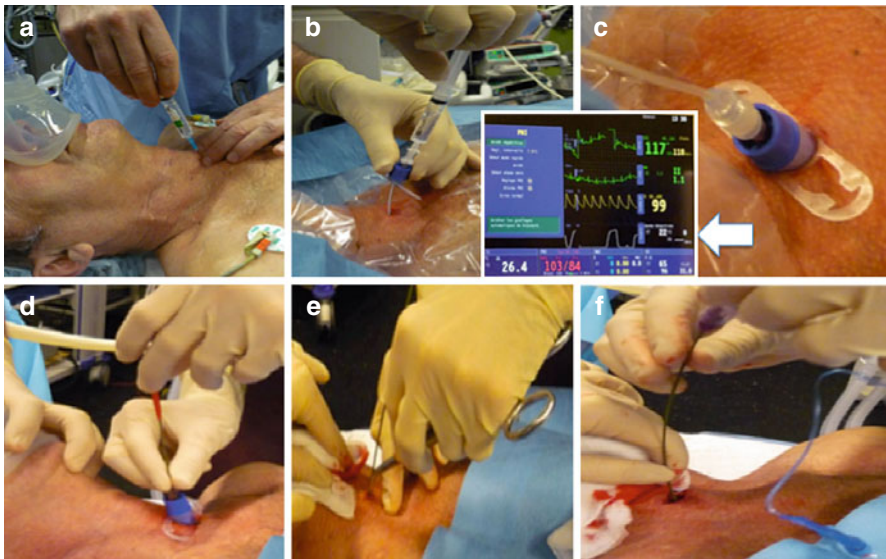


Fig. 11.1 (a) Local anaesthesia of the skin, the subcutaneous tissue and the trachea. (b) Air bubbles observed into the syringe after aspiration confirm the position in the airway. (c) The capnograph also confirms the position of the catheter in the airway. (d) Insertion of the guide wire into the transtracheal catheter. (e) The use of the dilating forceps after first dilatation (not shown). (f) Insertion of the cannula

11.3 Conclusions

Emergency PT using the Griggs technique is feasible and safe. In experienced hands, it may be even easier and faster than open surgical tracheotomy. It can be performed as rapidly as cricothyroidotomy and has the advantage of providing a definitive approach to the airway. There are several factors that influence the choice of technique to manage the emergency airway including anatomical, user experience and available devices. All techniques should be performed and practiced in non-emergency settings so that medical teams can learn to rapidly and successfully manage emergency airway conditions.

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Chapter 12

Tracheostomy Tube

Types and Criteria of Choice

E. Arditi, G. Russo, and P. Pelosi

Abstract Tracheostomy tubes are now available with different materials as silicone or PVC. Tracheostomy tubes are now equipped with low-pressure cuff to help protect sensitive tracheal tissue. In the last 30 years, the development of different kit for percutaneous tracheostomy imposed the change in of tracheostomy tube especially in distal tip and in introducer set.

As follows, different characteristics of tracheostomy tube are reported.

12.1 Introduction

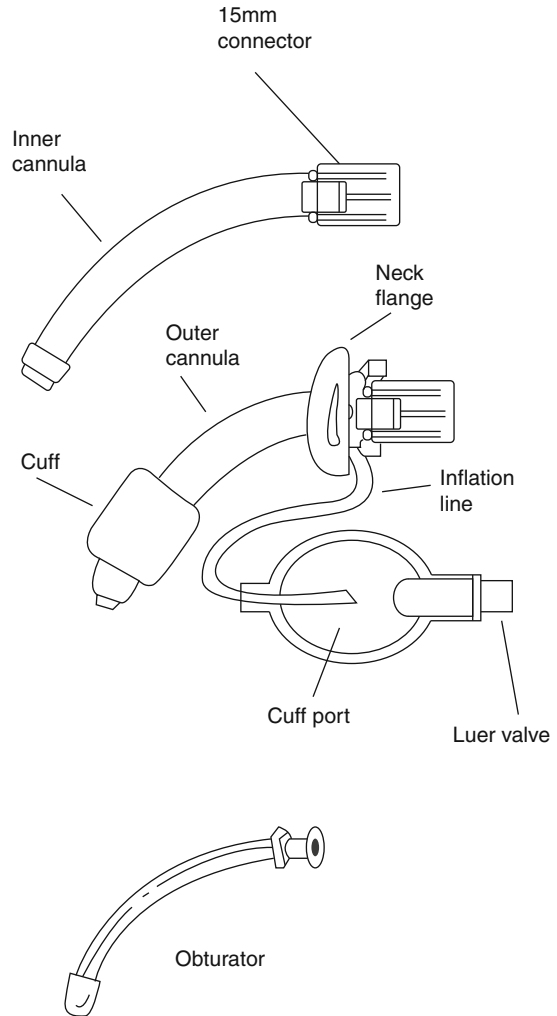
Tracheostomy tubes are now available with different materials as silicone or PVC. Tracheostomy tubes are now equipped with low-pressure cuff to help protect sensitive tracheal tissue. In the last 30 years, the development of different kit for percutaneous tracheostomy imposed the change in of tracheostomy tube especially in distal tip and in introducer set.

Tracheostomy tubes are available in a variety of sizes and styles from several manufacturers. The inner diameter, outer diameter and any other distinguishing characteristics (percutaneous, extra length, fenestrated) are marked on the flange of the tube as a guide to the clinician. Some features are relatively standard among typical tracheostomy tubes (Fig. 12.1).

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Fig. 12.1 Main Features of tracheostomy tube



Actually, two types of tracheostomy tube are now available: (1) the cuffed tracheostomy tube frequently used for patients ventilation and (2) the uncuffed tracheostomy tube frequently used to keep the stoma.

According to materials used, tracheostomy tube may be divided in

1. Rigid tracheostomy tube – Shiley like (Fig. 12.2).
This rigid tracheostomy tube has an inner cannula, and it is especially useful in prolonged and home mechanical ventilation. Furthermore, the adult size of this tracheostomy tube is often used in surgical tracheostomy.
2. Polyvinyl chloride tracheostomy tube softens at body temperature (thermolabile) (Fig. 12.3).
Most used cannula that conforms itself to patient anatomy and centring the distal tip in the trachea.



Fig. 12.2 Rigid tracheostomy tube



Fig. 12.3 Polyvinyl chloride tracheostomy tube

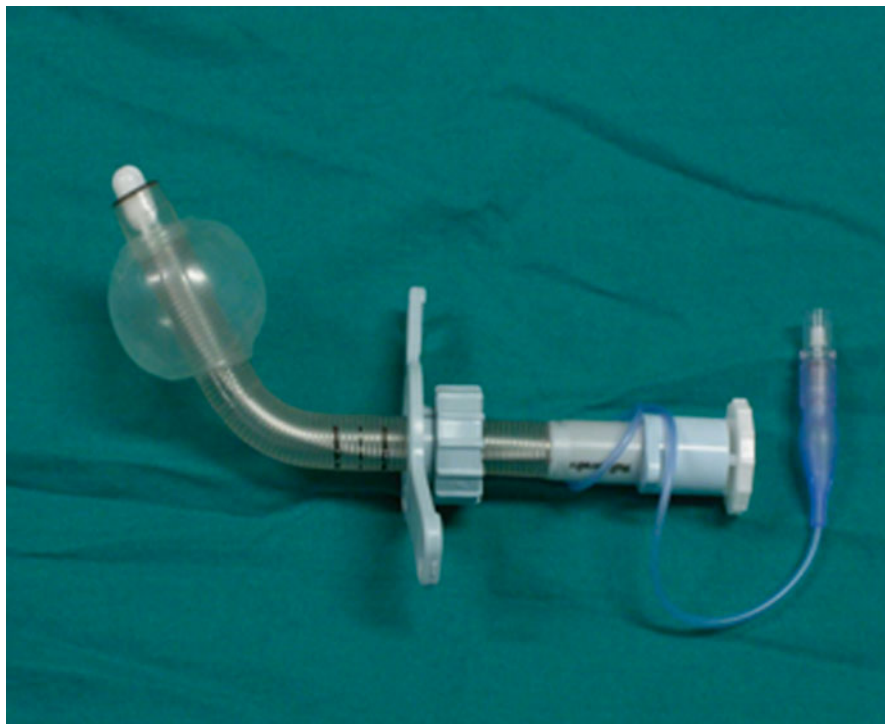


Fig. 12.4 Reinforced tracheostomy tube with metallic spiral

3. Reinforced tracheostomy tube with metallic spiral (Fig. 12.4).

This tracheostomy tube has an adjustable neck flange to allow bedside adjustments to meet patient needs. Because the locking mechanism on the flange tends to deteriorate over time, this tube is easily deployable. The use of these tubes should be considered a temporary solution.

4. Silicone tracheostomy tube (Fig. 12.5).

This tube is made of soft biocompatible silicone intended to be gentle on sensitive tracheal tissue. When a seal is no longer needed, the cuff can be deflated, and it will rest tight to shaft, reducing the risk of trauma to the trachea and allowing airflow around the tube supporting the ability to speak.

According to curvature, tracheostomy tubes may be divided in angle or curved tubes
This feature can be used to improve the fit of the tube in the trachea.

1. Angled tracheostomy tube (Fig. 12.6)

This tracheostomy tube has a horizontal and a vertical part of different length. This cannula may be safely positioned but fits less with the anatomical shape of the trachea.



Fig. 12.5 Silicone tracheostomy tube



Fig. 12.6 Angled tracheostomy tube



Fig. 12.7 Curved tracheostomy tube

2. Curved tracheostomy tube (Fig. 12.7)

In this tracheostomy tube, the angle formed by the line passing through the horizontal part of the tube that intersects the line passing through the vertical part of the tracheostomy tube has variable curvatures between 88 and 105° . This tube is the most used during percutaneous tracheostomy because it fits well with the stoma.

12.2 Tracheostomy Tube with Special Function

12.2.1 Fenestrated Tracheostomy Tubes

The fenestrated tracheostomy (Fig. 12.8) tube is similar in construction to standard tracheostomy tubes, with the addition of an opening in the posterior portion of the tube above the cuff. This opening may be a large hole or smaller multiple holes. The fenestration, like a large hole, may become obstructed by the formation of granulation tissue, resulting in airway compromise. Proper position of the fenestrations in the airway should be inspected regularly. However, when possible, it is to use fenestrated tracheostomy tube with multiple holes. Fenestrated

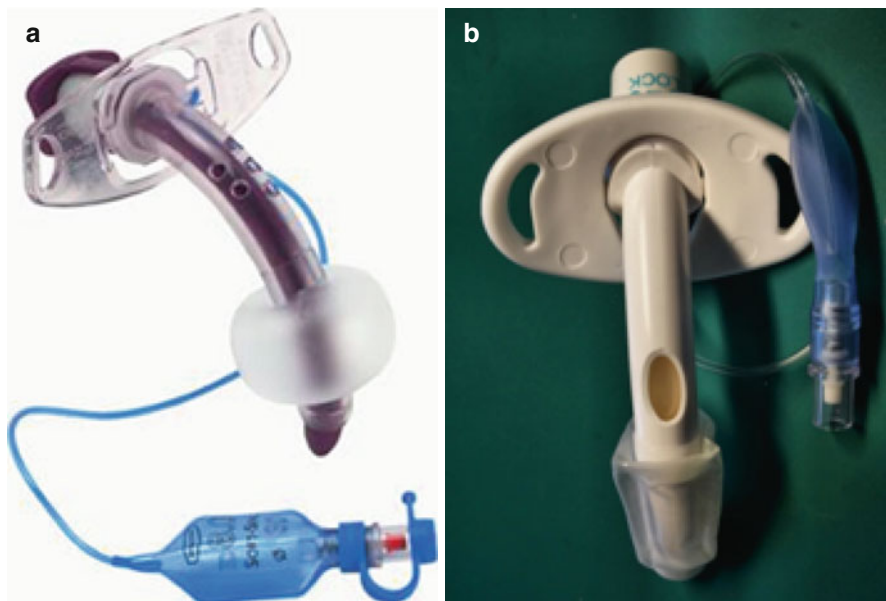


Fig. 12.8 Fenestrated tracheostomy tube with multiple and single holes

tracheostomy tubes are equipped by a non-fenestrated inner cannula allowing mechanical ventilation and fenestrated inner cannula allowing spontaneous ventilation and speaking.

12.2.2 Tracheostomy Tube with Subglottic Suction

Tracheostomy tube with subglottic suction has a posterior aspiration opening above the cuff and an additional lumen to remove the secretions above the cuff.

12.2.3 Extra-Long Tracheostomy Tube

Extra-long tracheostomy tube has length of 90–125 mm. This type of tracheostomy tube is useful in case of obese patients allowing to overcome the neck tissue thickness. Two types of this cannula are commercially available:

- Tyco, Tracheosoft (Fig. 12.9) – a flexible, angled tracheostomy tube with inner cannula
- Smiths Medical, Uniper (Fig. 12.10) – a reinforced tracheostomy tube with metallic spiral and adjustable flange



Fig. 12.9 Extra long tracheostomy tube

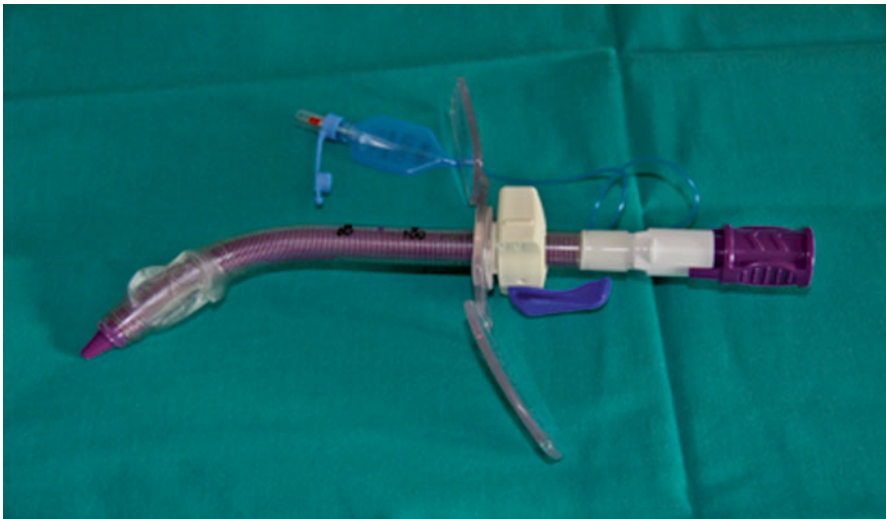


Fig. 12.10 Extra long tracheostomy tube

12.2.4 *Speaking Valve*

Speaking valves (Fig. 12.11) enable easier vocalization for alert, awake patients who are independently breathing. This valve keeps an end-expiratory positive pressure useful for respiratory rehabilitation.

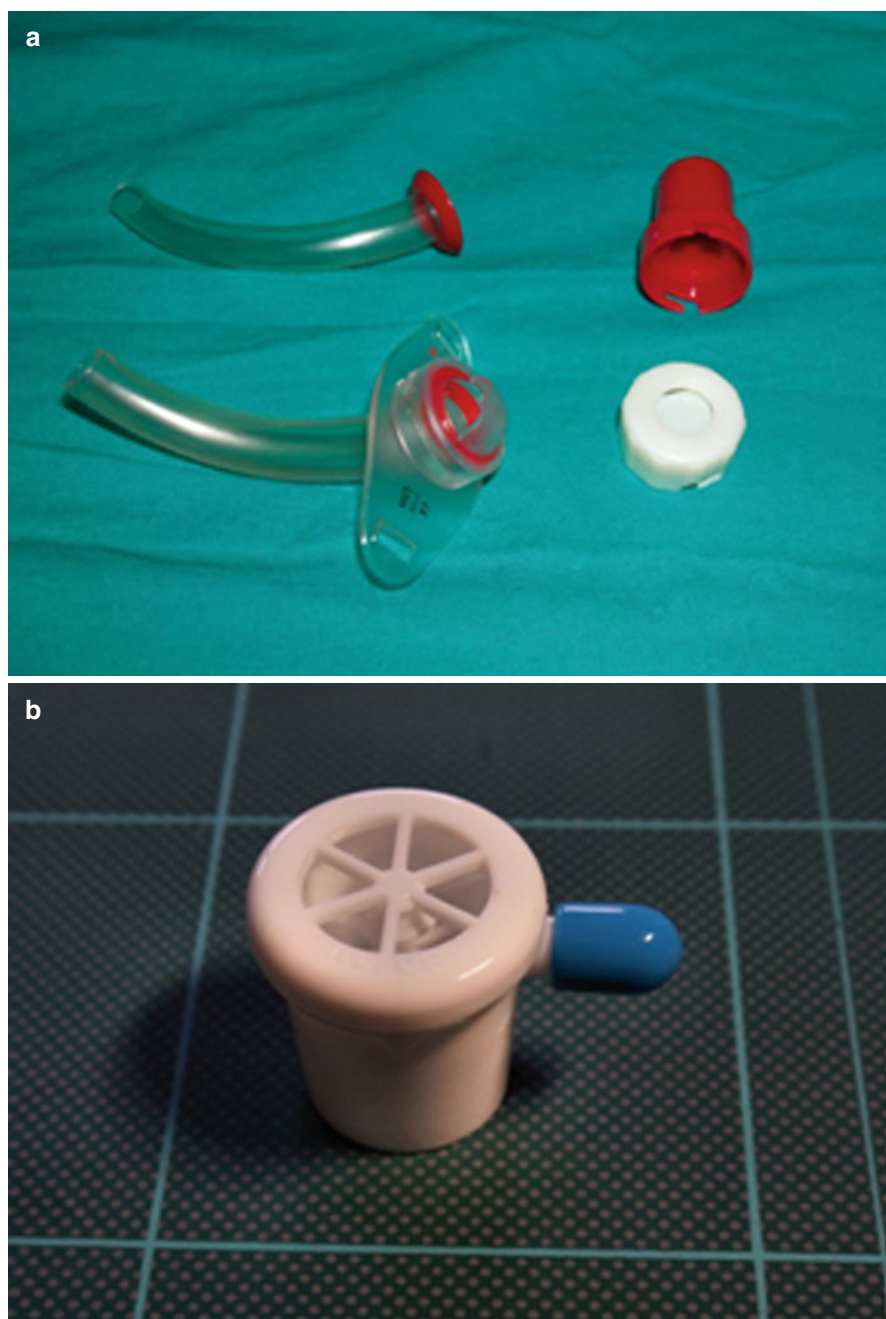


Fig. 12.11 Speaking valves

12.3 Tracheostomy Tube for Percutaneous Tracheostomy

Several tracheostomy tubes are designed specifically for insertion as part of the percutaneous dilatational tracheostomy procedure. Different tracheostomy tubes for PDT are tapered to reduce the insertion force during this procedure. Furthermore, this tube has a reduced thickness. A tracheostomy tube with an internal diameter (ID) of 8 mm, most used in adult patients, may have an external diameter (ED) between 10.3 and 11.8 mm. The table below shows a comparison between the most used tracheostomy tubes for PDT.

	Portex Blue line 8	Cook Versatube 8	Rusch Tracheofix 8	Shiley FlexTra 8
ID	8	8	8.5	8
ED	11.9	11	10.3	10.8
Length	75.5	86	78	74
Inner cannula ID	6.5	7	7	6.5

Tracheostomy tubes for PDT are made of thermoplastic soft materials gently conform to patient anatomy. This tube has a tapered distal tip that creates a smooth transition from loading obturator/introducer to tracheostomy tube outer diameter, minimizing insertion force and the potential for tracheal wall trauma (Figs. 12.12 and 12.13).

The obturator/introducer of this tracheostomy tube passes above a Seldinger. This is a proper characteristic of this tube that allows a safe introduction of the cannula during the procedure and a safe cannula exchange (Fig. 12.14).

Tracheostomy tubes for PDT (Figs. 12.15 and 12.16) are also available with a reinforced metallic spiral and adjustable neck flange. Also in this case the obturator/introducer passes over a Seldinger. This tube may be useful in case of tracheal deviation or malformation. The reinforced tracheostomy tubes for PDT are extra-long but without an inner cannula.

12.3.1 Inner Cannula

The integrated inner cannula (Fig. 12.17) has a 15 mm and Luer-lock connector to connect the patient to mechanical ventilator. Optional inner cannula (Fig. 12.18) is available for different tracheostomy tubes; however, this kind of cannula reduces the internal diameter of this tube increased the resistance to flow.

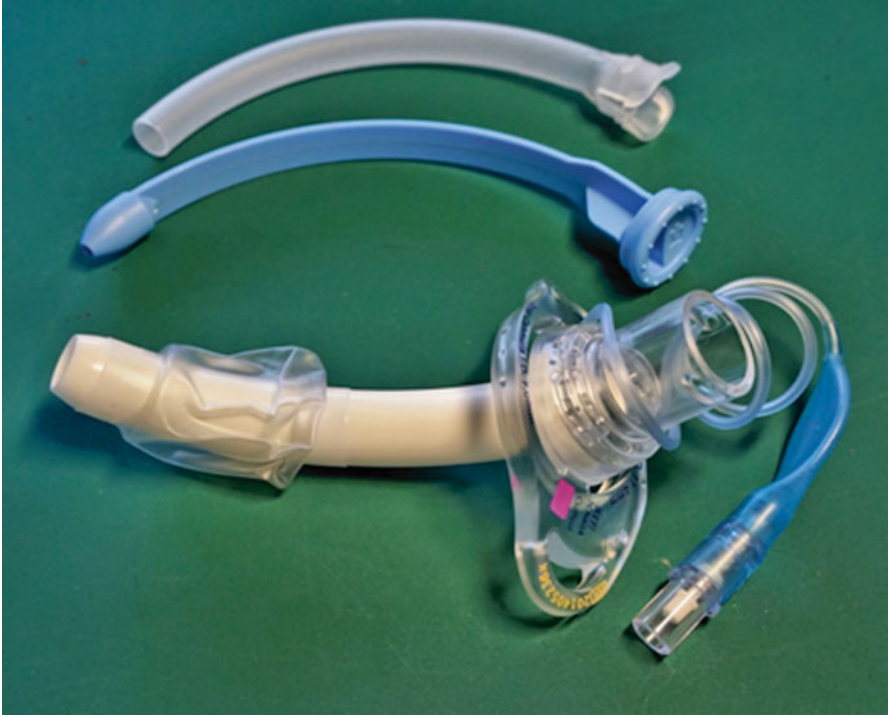


Fig. 12.12 Tracheostomy tube for PDT



Fig. 12.13 Feature of tracheostomy tube for PDT

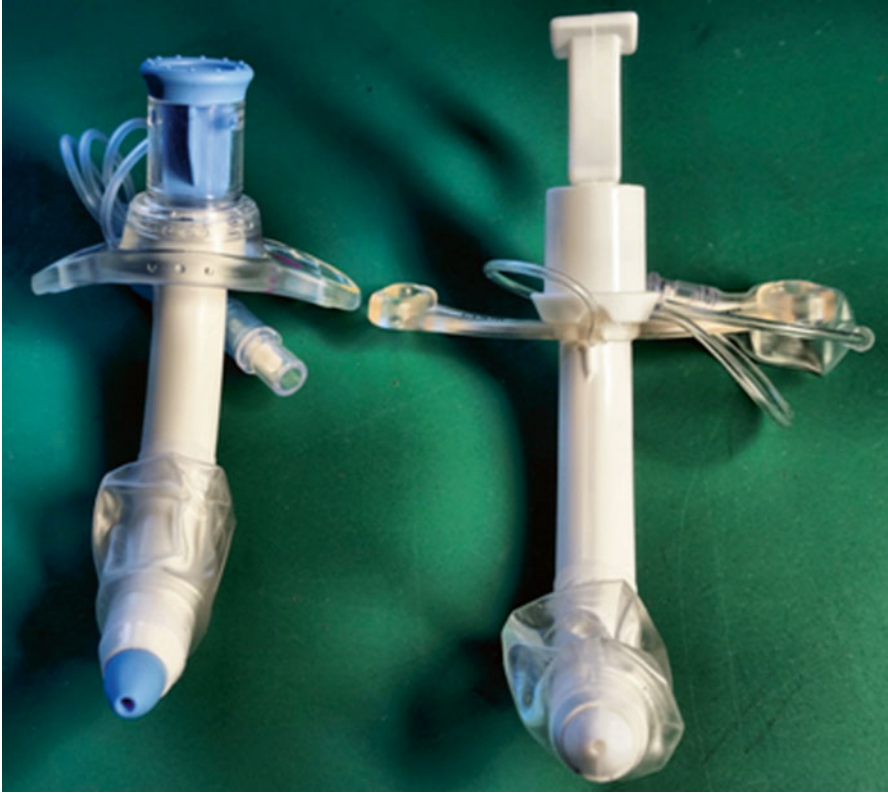


Fig. 12.14 Obturator/introducer of tracheostomy tube for PDT



Fig. 12.15 Tracheostomy tube for PDT with reinforced metallic spiral

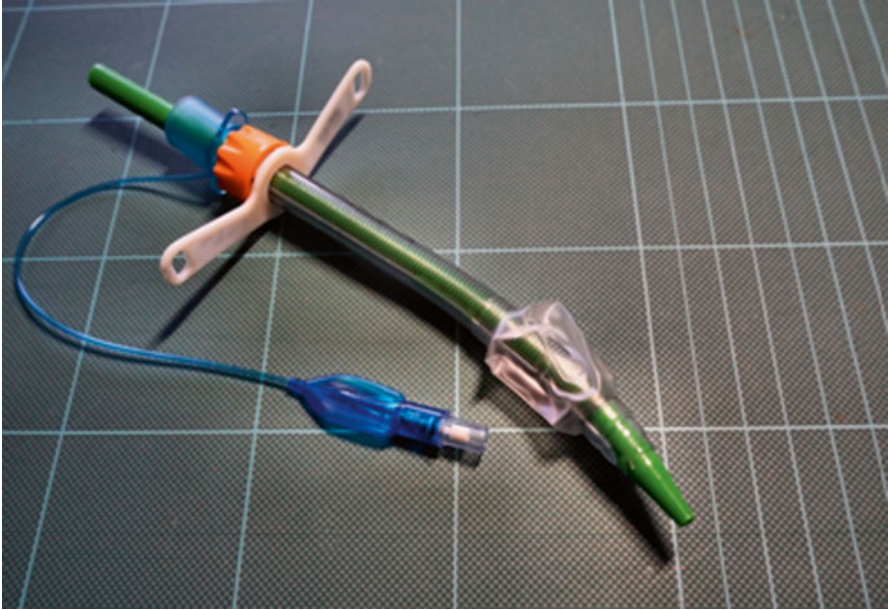


Fig. 12.16 Tracheostomy tube for PDT with reinforced metallic spiral and its obturator/introducer



Fig. 12.17 Inner cannula for tracheostomy tube



Fig. 12.18 Inner cannula for tracheostomy tube

12.4 Conclusions

Tracheostomy tubes have different characteristics. In clinical practice it could be useful to have different models. According to this, we suggested to have in ward different tracheostomy tubes in PVC with or without inner cannulas and with different adult sizes (7, 8, 9 mm). Furthermore, it is important to have extra-long reinforced cannula with adjustable neck flange in case of tracheal damage or obese patients.

Chapter 13

Airway Management During Tracheostomy

Conventional Device

Laryngeal Mask Airway

Double Lumen Endotracheal Tube

M. Vargas, A. Perrone, and G. Servillo

Abstract A number of percutaneous tracheostomy (PDT) techniques have been developed across the years. The different techniques and devices appeared largely equivalent, with the exception of retrograde tracheostomy. Conventionally, the airway management during PDT has been managed by a single lumen endotracheal tube (ETT). PDT may be performed with laryngeal mask airway (LMA) if the operators are confident with this procedure. LMA may overcome the problem of accidental extubation during PDT because it is stably cuffed during the procedure. Double-lumen endotracheal tube (DLET) for PDT has been recently proposed by literature. DLET is divided in an upper channel, for placement of bronchoscope, and a lower channel exclusively dedicated to patients' ventilation.

13.1 Conventional Device

A number of percutaneous tracheostomy (PDT) techniques have been developed across the years. The different techniques and devices appeared largely equivalent, with the exception of retrograde tracheostomy [1]. Conventionally, the airway management during PDT has been managed by a single lumen endotracheal tube (ETT). In a recent Italian survey, PDT is performed in 83 % of ICU patients with the ETT in place, while it was replaced with a larger or smaller one in 10 and 7 % of ICU patients [2]. Also fiberoptic bronchoscopy during PDT was used in 93 % of Italian

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ICU patients [2]. In a summary analysis of seven international surveys about PDT including 1195 ICUs, the airway management during PDT was obtained with the ETT in place, and the bronchoscope-guided procedure is largely used [3].

The presence of bronchoscope in the ETT (1) reduces the inner diameter of the ETT available for patients' ventilation and (2) alters the gas exchange [4]. According to Hsia et al. all bronchoscope/ETT combinations reduce the tidal volume (V_T) and increase the peak inspiratory pressure (PIP) [5]. For example, putting a 5 mm bronchoscope in a 8 mm ETT reduces the V_T of 46 % and increase the PIP of 11 cm H₂O [5]. Furthermore, the reduction of inner diameter of ETT increases the airway resistance. Hsia et al. reported that during the performance of flexible bronchoscopy through an ETT in patients receiving mechanical ventilation, airflow resistance across the ETT dramatically increases from 2- to 63-fold [5].

PDT performed with conventional ETT is associated with a decrease of PaO₂ and increase of PaCO₂. Reilly reported that the use of fiberoptic bronchoscope during PDT is the most important factor responsible for hypercapnia development during this procedure [6]. In our experience, to reduce airway resistance and to limit the alteration of gas exchange, we recommended to perform PDT with a bronchoscope less than 50 % of inner diameter of ETT.

During PDT, the ETT is withdrawn at the level of the vocal cord, and the procedure is guided by a bronchoscope within the ETT. In this way the airway is not fully protected and may be lost during the procedure. Airway complications and vascular injuries are the main reasons of catastrophic events during PDT [7]. Simon et al reported that deaths related to airway complication during PDT are due to dislocation of tracheal cannula and lost airway during procedure [7]. We suggest that airway during PDT should be managed by a skilled operator in difficult airway to minimise risky events.

13.2 Laryngeal Mask Airway

PDT may be performed with laryngeal mask airway (LMA) if the operators are confident with this procedure. LMA may overcome the problem of accidental extubation during PDT because it is stably cuffed during the procedure. Linstedt et al successfully used the LMA for PDT in a cohort of 86 patients even if 4 patients required reintubation [8]. LMA is also associated to a better protection of bronchoscope from accidental puncture and to a better visualisation of tracheal structure. However, LMA do not offer a better ventilation and gas exchange compared with conventional ETT. Linstedt et al. reported a similar decrease in oxygenation and an increase in PaCO₂ when using LMA or ETT [9]. A recent meta-analysis compared the use of LMA versus ETT during PDT in terms of effectiveness and safety [10]. This meta-analysis included eight randomised controlled studies and 467 PDTs. The authors reported no differences in mortality and serious adverse events comparing LMA with ETT [10]. However, the use of LMA reduced the duration of procedure and optimised the visual condition of PDT [10]. In our opinion the LMA reduces the duration of PDT because it may be simply positioned outside the vocal cords while the ETT should be repositioned

between the vocal cords. The correct repositioning of the ETT may require time to find the correct position without hindering the bronchoscope, while the LMA do not have this problem. We suggest that LMA should be used during PDT by a skilled operator in its routine use. While using LMA for PDT, the equipment for a prompt intubation should be available at bedside.

13.3 Double-Lumen Endotracheal Tube

Double-lumen endotracheal tube (DLET) for PDT has been recently proposed by literature [4, 11].

DLET is divided in an upper channel, for placement of bronchoscope, and a lower channel exclusively dedicated to patients' ventilation (Fig. 13.1).

The upper lumen should be positioned at the level of the vocal cords, while the lower lumen to the level of carina. The lower lumen has: (1) an elliptical shape to better lean on the posterior tracheal wall without taking up too much space of the trachea and (2) a distal cuff to be cuffed at the carina. PDT with DLET in place may be performed with the same step of a conventional PDT. The intubation with the DLET may be safely achieved with a proper tube exchanger under a direct laryngoscopy. The correct positioning of DLET with the upper lumen at the level of vocal cords and the lower lumen at the carina has to be checked with the bronchoscope. Once the correct position of the DLET is confirmed and the distal cuff is inflated, the PDT should be conventionally performed. The DLET is now available for single-step tracheostomy and for guide wire dilating forceps technique, both with a proper cannula (Fig. 13.2).

The puncture of anterior tracheal wall, Seldinger insertion, dilatation and cannulation are performed with the DLET placed in trachea (Figs. 13.3, 13.4, and 13.5).

DLET has been tested in in vitro and in vivo studies [4, 11]. In a lung model, DLET showed the lower resistance, according Rohrer equation, during an increasing continuous flow [4]. The Rohrer equation, $\Delta P_{ETT} = K_1 F + K_2 V F^2$, describes the resistive properties of an ETT. DLET showed the lower resistance when compared with conventional ETT also in inspiratory and expiratory phases of

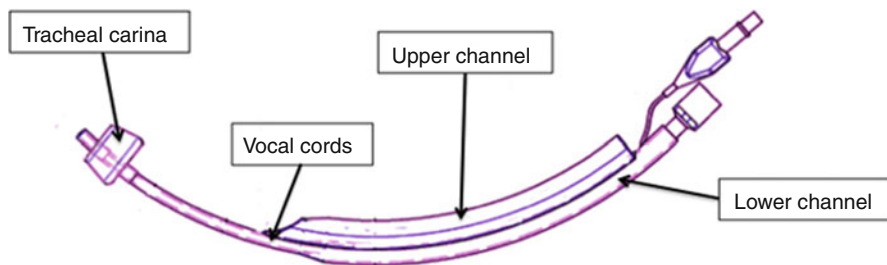


Fig. 13.1 Characteristics of double-lumen endotracheal tube (DLET). The figure shows the upper channel dedicated for bronchoscopy, the lower channel for patient's ventilation



Fig. 13.2 Different available kits with double-lumen endotracheal tube (DLET). (a) Kit for Ciaglia single-step tracheostomy. (b) Kit for Griggs guide wire dilating forceps tracheostomy. (c) Tracheostomy tube for DLET

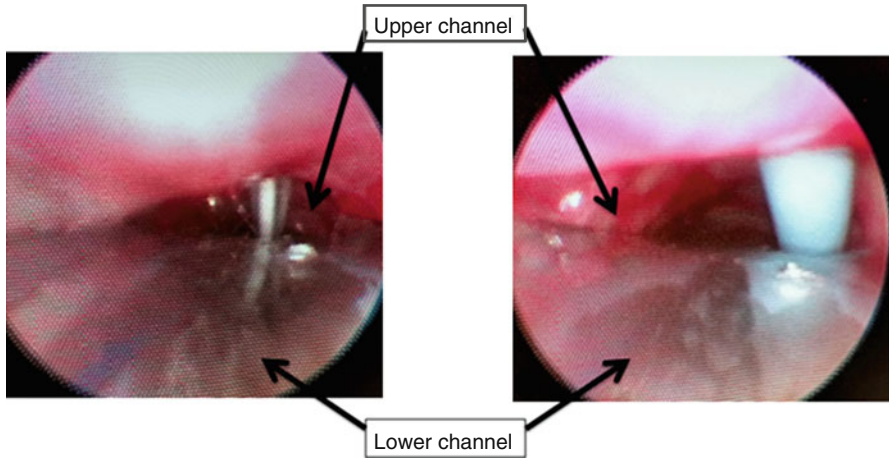


Fig. 13.3 Double-lumen endotracheal tube procedural steps. (a) Puncture of anterior tracheal wall with DLET placed on the posterior tracheal wall. (b) Pre-dilation of anterior tracheal wall with DLET placed on the posterior tracheal wall

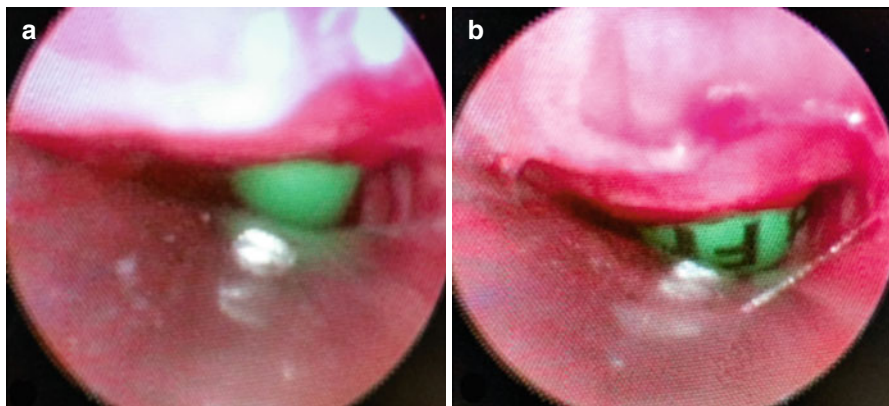


Fig. 13.4 Double-lumen endotracheal tube procedural steps. (a) Initial dilation with DLET placed on the posterior tracheal wall. (b) End of dilation of anterior tracheal wall with DLET placed on the posterior tracheal wall

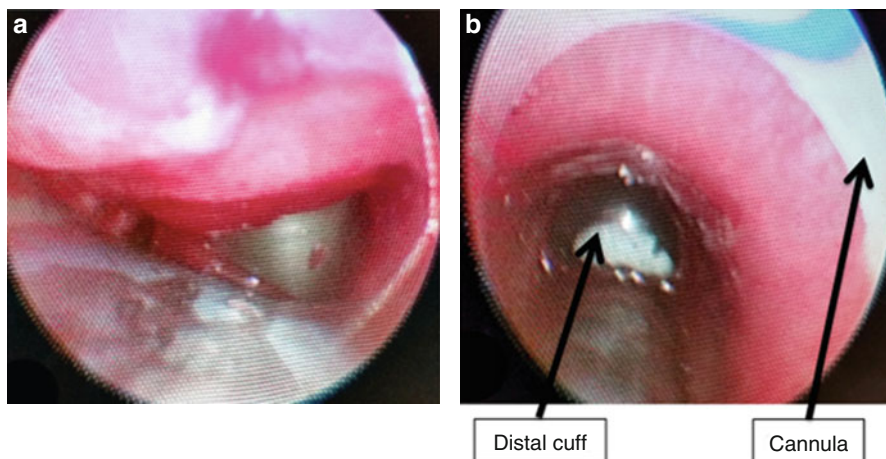


Fig. 13.5 Double-lumen endotracheal tube procedural steps. (a) Cannula placement with DLET placed on the posterior tracheal wall. (b) Control of correct cannula placement with DLET still placed on the posterior tracheal wall

volume-controlled ventilation [4]. These results are consistent with the fact that DLET is the first device that allows a ventilation independent from bronchoscopy.

In further unpublished *in vitro* evaluation, DLET compared with ETT showed the lower resistance also in a setting of volume-controlled ventilation with airway resistance was calculated as pressure drop/flow across each ETT (Fig. 13.6). Volume-controlled ventilation was set with V_I of 500 mL, PEEP 5 cm H_2O and inspiratory to expiratory ratio 1:1 and 1:2.

In the *in vivo* evaluation, DLET can be safely used for PDT without complication limiting the procedure [11]. Furthermore, the use of DLET during PDT resulted in more stable gas exchange, airway pressures and ventilation than PDT with the conventional ETT [11]. PDT with conventional ETT is associated to an alteration of gas exchange. Kaiser et al. reported an increase of 20 mmHg $PaCO_2$ and a decrease of 1 point PH during PDT performed with Ciaglia single step and Griggs dilating forceps techniques [12]. The same results were reported by Montcriol et al. comparing rotational PDT with Griggs dilating forceps techniques [13]. DLET do not impair the gas exchange keeping it stable during the entire procedure [11]. Indeed, PaO_2 and $PaCO_2$ level remained stable in PDT with DLET while markedly varied with a trend towards respiratory acidosis and hypoventilation in PDT with ETT [11].

DLET may add additional safety to PDT. Using DLET during PDT (1) may ensure airway control avoiding the risk of accidental extubation and protection of the distal airway and lung parenchyma from bleeding and aspiration owing to the presence of a distal cuff and (2) may protect the fiberoptic bronchoscope from accidental damage as a result of puncture or inappropriate dilation by the presence of the upper tube. With the DLET in place, the posterior tracheal wall is protected during the entire PDT.

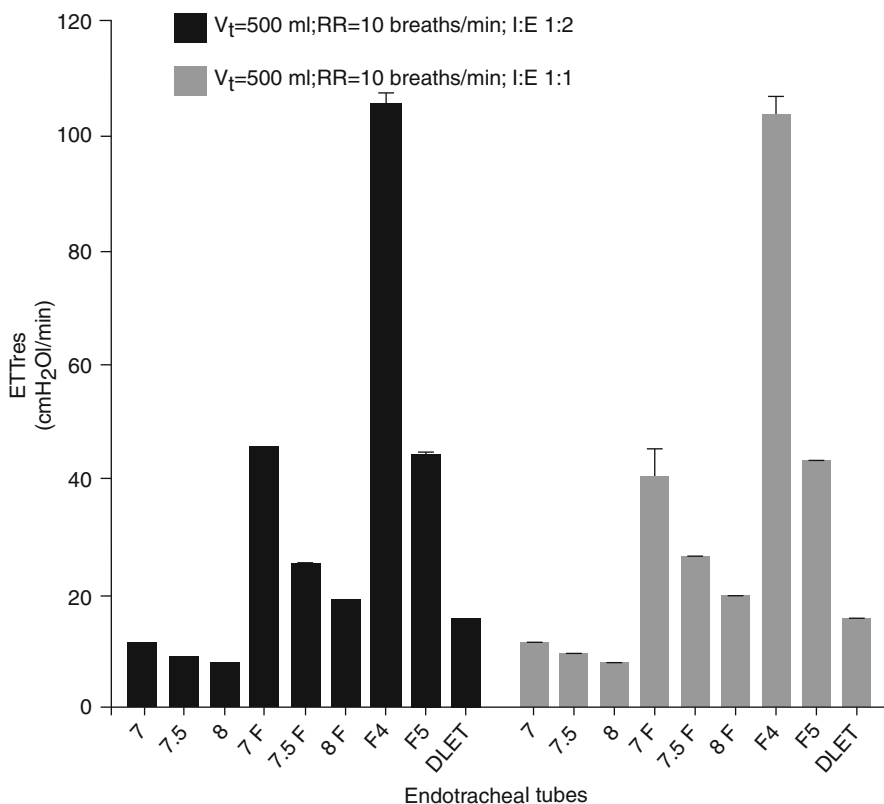


Fig. 13.6 Endotracheal tube resistance measured during the inspiratory phase of volume-controlled ventilation. Data are expressed as mean and standard deviation. Endotracheal tubes refer to the tube's inner diameter measurement; tubes denoted with *F* refer to tubes with a 4.5 mm external diameter fiberoptic bronchoscopy inserted; *F4* and *F5* refer to 4 and 5 mm inner diameter ventilation tubes of Fantoni techniques; *DLET* refers to double-lumen endotracheal tube, with 7.5 mm inner diameter

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Chapter 14

Medical and Nursing Management of Tracheostomy

A. Negro, M. Greco, and L. Cabrini

Abstract Tracheostomy is a common procedure in critically ill patients and after ENT surgery. It is essential for both physician and nurses: (1) to have good knowledge and understating of tracheostomy management and (2) to be able provide routine care to these patients and deal with complications and emergencies.

When approaching a patient with tracheostomy, the type of cannula, the indication, the time since tracheostomy and, if the procedure is recent, the technique for tracheostomy should be ascertained. The purpose of this chapter is to report the medical and nursing management of tracheostomy in intensive care unit, in hospital ward and at home.

14.1 Introduction

Tracheostomy is a common procedure in critically ill patients and after ENT surgery [1]. It is a frequent experience for physician and nurses to care for patients that underwent a recent procedure or with a long-standing tracheostomy admitted to a standard ward, and a small proportion of these patients may be discharged at home or to a nursing home with this condition.

Thus, it is essential for both physician and nurses to have good knowledge and understating of tracheostomy management and to be able provide routine care to these patients and deal with complications and emergencies.

When approaching a patient with tracheostomy, the type of cannula, the indication, the time since tracheostomy and, if the procedure is recent, the technique for tracheostomy should be ascertained.

Two large categories of tracheostomy techniques exist: surgical and percutaneous techniques. The former are conducted using a classical scalpel or electrocautery

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and often (but not necessarily) in a full operatory room environment. The latter are normally conducted at bedside in the intensive care, using one of the several techniques available (i.e. Ciaglia technique, Fantoni technique, Griggs, technique, Ciaglia modified technique) [2–5]. Percutaneous procedures are nowadays more common in critically ill patients, due to reduced complications and costs.

In the early days after tracheostomy (<7 days), some differences in management between surgical and percutaneous technique should be noted. This is related with bleeding (more common in percutaneous procedures) and consequences of cannula dislodgment [6].

Regardless of the procedure adopted, the care and the complications in a patient with tracheostomy are the same when it has been in place for at least 5–7 days.

Due to the acute risk dislodgment, bleeding and pneumothorax immediately after the procedure, special care and monitoring are necessary for the first 24 h after tracheostomy, and patients are normally admitted to ICU or PACU for monitoring for at least 24 h after tracheostomy. Routine thoracic x-ray is no longer deemed necessary after percutaneous procedures [7].

Another distinction that should be made before approaching a patient with tracheostomy is whether the cannula is in place for long-term ventilation, for secretion/loss of airway protection or for upper airway obstruction. In the latter case, securing tracheostomy for immobility is of paramount importance, as early displacement can be life threatening.

14.2 Clinical Assessment of the Airway in a Patient with Tracheostomy

Assess all the patients with tracheostomy for airway patency, which include:

- Respiratory rate
- Respiratory distress
- Inability to cough
- Abnormal breathing sounds
- Cyanosis
- Deterioration in oxygen saturation
- Bleeding within or around tracheostomy cannula
- Check cannula for evidence of dislodgement
- Check cuff (deflation or inflation according to prescription)

Any abnormality detected in these risk factors should prompt for rapid and complete evaluation of cannula patency and displacement, including suctioning, a procedure that should elicit cough reflex in the awoken patient. When suctioning is difficult or airway patency cannot be established or cannula position cannot be confirmed, rapid evaluation by fibroscopy or expert advice should be immediately sought.

14.3 Emergencies in Patients with Tracheotomy

Tracheostomy is a common and relatively safe procedure. However, there are several complications that should be well known, as their consequences can be life threatening.

These complications can be divided in early and late, as their consequences differ according to time since tracheostomy.

- **Cannula displacement:** displacement of tracheostomy cannula may lead to respiratory arrest, pneumomediastinum or air trapping in the ventilated patient. In patient on mechanical ventilation, recognition of this complication should be immediate. The effect of this complication is related with timing from procedure and with technique: in the early days after percutaneous tracheostomy, cannula displacement can have more serious consequences, as the stoma can collapse and it can be difficult to achieve correct placement of a new cannula. Extreme care should be adopted if replacing a dislodged tracheostomy after percutaneous technique, to avoid the risk of creating a new false route in the mediastinum. Displacement after surgical tracheostomy is generally related with lower risk, due to easier repositioning of the cannula. After 5–7 days, the risks are parallel. If in doubt about repositioning, patients should be reintubated by orotracheal route and the tracheal cannula repositioned under direct fibroscopy. In patient with upper airway obstruction hindering orotracheal intubation, further care is required to avoid tracheostomy displacement.
- **Obstruction:** secretions can partially or completely obstruct the cannula. This will hamper ventilation and may lead to respiratory arrest. If the cannula has an inner cannula, this should be removed and changed. Patient should be suctioned. If this does not restore ventilation, the cuff should be deflated. Finally, if obstruction is unresolved or if it was not possible to complete suctioning, dislodgement should be suspected, and cannula should be removed and replaced.
- **Air trapping:** the presence of secretion or partial displacement of the cannula in a patient on mechanical ventilation may lead to a valve effect, with inspiratory volume completely delivered to the lungs due to the pressure from the ventilator, but with no effective expiratory volume. This condition may lead to a rapid increase in intra-alveolar pressure, leading to pneumothorax, pneumomediastinum and subcutaneous emphysema that can rapidly become life threatening. If suspected, the cuff should be immediately deflated, and in case of dislodgement cannula should be removed and replaced.
- **Bleeding:** early bleeding after tracheostomy is generally from a small vessel from the stoma, related with direct surgical incision or laceration from percutaneous technique. Bleeding is usually benign and can be generally be controlled by compression or, in some cases, by surgical cauterisation. Late bleeding from tracheostomy on the contrary can be life threatening, as it can derive from tracheal granulomas (developed in the tracheal mucosa as result of irritation), or from erosion of artery nearby leading to arterial fistula. The most known of these due to its high mortality rate is tracheoinnominate artery fistula, which has a peak incidence between 7 and 14 days after tracheostomy.

- **Infection:** infection of the stoma can lead to serious complication, including mediastinitis. Moreover, oesophageal fistula may develop early (due to procedural complications) or later (due to compression and necrosis of the pars membranacea of the tracheal wall by the cuff or cannula). Prompt recognition of these conditions is necessary, and surgical advice should be sought.

In all cases, when approaching a patient with tracheostomy for an urgent/emergent condition, some steps should be conducted: remove unnecessary element from the cannula (speaking valve, humidifiers), remove inner cannula (when present), extend patient head, assess airway patency through suctioning and deflate the cuff if obstruction is unresolved. Finally, if these manoeuvres are unsuccessful, cannula should be removed if obstruction or displacement is suspected.

14.4 Suctioning

According to the American Association for Respiratory Care Clinical Practice Guidelines 2010, endotracheal suctioning is a necessary procedure for patients with artificial airways. Most contraindications are relative to the patient's risk of developing adverse reactions or worsening clinical condition as result of the procedure. There is no absolute contraindication to endotracheal suctioning, because the decision to withhold suctioning in order to avoid a possible adverse reaction may, in fact, be lethal.

It is recommended to evaluate the presence of secretion and to perform endotracheal suction only if necessary, not routinely, in order to avoid the risk of complications [8].

If inserting a suction catheter is difficult, a tracheostomy evaluation should be requested, even if the patient is in no distress. Recognising potential problems before an emergency develops is important [9]: difficult endotracheal suction should be considered as possible airway obstruction for secretion or cannula displacement until proven otherwise. In a patient not on mechanical ventilation or alternating spontaneous breathing and mechanical ventilation cycles, mechanical ventilation should not be resumed until cannula patency and placement is confirmed.

14.5 Cuff Management

The tracheostomy cuff provides a seal to enable positive pressure ventilation and provides some protection against aspiration of secretions. The maximum acceptable tracheostomy tube cuff pressure is 25 mm/Hg. Tracheal capillary perfusion pressure is normally 25–35 mm/Hg; higher pressure exerted by the inflated cuff can produce tracheal ischemia and mucosal injury. Cuff pressure management is an important aspect of care to prevent complications associated with incorrect cuff pressures;

persistent low cuff pressure (<20 cm H₂O) predisposes patients to pneumonia, presumably by predisposing to aspiration of oropharyngeal secretions and/or refluxed gastric contents [10].

Low cuff pressure can lead to silent aspiration of secretion. Silent aspiration can be defined as foreign material entering the trachea or lungs without an outward sign (coughing or respiratory difficulty). High cuff pressure could lead to tracheal erosion or fistula. A common reason for high cuff pressure is a tube that is too small in diameter, resulting in overfilling of the cuff to achieve a seal in the trachea. Another common cause of high cuff pressure is malposition of the tube. The use of a manometer to assess the pressure of the cuff every eight hours is mandatory, and it is a good practice to document cuff pressure; indirect assessments by palpation of the external pilot balloon or determination of minimal leak are considered inaccurate [11]. To minimise aspiration of pooled secretions from above the cuff, subglottic suctioning through hypopharynx is recommended prior to cuff deflation [12].

Cuff Myth!

Does not prevent aspiration!

Bolus already aspirated (below the vocal cords) before it reaches the inflated cuff.

Bolus, particularly fluids, can still slide past an incomplete cuff seal to the lungs.

Aspirated materials may pool above the cuff and be aspirated on cuff deflation. Tracheal suctioning of most types of t-tubes will not remove food sitting on cuff.

Bacterial colonisation may occur if food/saliva continues to accumulate above the cuff, which may make its way to the airway.

Tracheostomy guidelines. St Georges Healthcare NHS Trust [13].

14.6 Stoma Care

In the immediate postoperative period, the tracheal stoma needs to be assessed regularly. Nurses must undertake care of the stoma site at least once a day or more frequently as required to reduce the risk of skin irritation and peristomal infection. Secretions that collect above the cuff ooze out of the stoma site producing a moist environment leading to excoriation and infection. Tracheostomy ties should be changed when wet or soiled and routinely at least once a day. Patients with copious secretions often require frequent dressing changes to keep the skin dry and prevent maceration of tissue and skin breakdown.

Tracheostomy tubes sutured in place require daily cleaning with 0.9 % saline; do not use cotton wool. Always use gauze for tracheostomy dressings using an aseptic nontouch technique. In the event the patient's skin is red, excoriated or exuding, it

is suggested to send microbiology swabs for culture, and a skin barrier cream should be applied, i.e. soft paraffin or Cavilon [14, 15]. When the tracheostomy ties require changing, i.e. wet, soiled or routine, in order to avoid inadvertent dislodgement of the tracheostomy tube, one person should securely hold the tube in place, while a second person performs the tie exchange, leaving one finger space between ties and patient's neck. The tube should be secured carefully, ensuring that the chosen method minimises the risks of pressure sores. All tracheostomies are at risk of displacement, of greatest significance in the first few days following insertion, as it takes around 4 days for an open surgical stoma and 7–10 days for a percutaneous stoma to become established [16]. The care of the stoma includes accurate documentation of redness, swelling, exudate, evidence of granulation tissue, pain, increased amount of secretions or skin breakdown.

The tracheostomy tube should be kept in a neutral position. Traction forces should be removed and the tube supported as necessary by using the ventilator support arms or a strategically placed towel roll [9].

14.7 Mobilisation of Secretions and Humidification

One of the most important aspects of care for any patient with a tracheostomy is mobilisation of secretions. Mobilisation consists of three primary factors: adequate hydration, physical mobility and removal of secretions [9]. As the upper airway of a patient with a tracheostomy has been bypassed, the natural warming and humidification of the air are affected. Inadequate humidification of respiratory gases may lead to life-threatening blockage of the tracheostomy with tenacious sputum, keratinisation and ulceration of the tracheal mucosa, sputum retention, atelectasis, impaired gas exchange and secondary infection [16].

For hospitalised patients, humidity can be provided by using a heat and moisture exchanger, suitable for stable patients who are well hydrated or heat humidifiers suitable for unstable, dehydrated patients or with tenacious secretions. The level of humidification required by patients will change depending on their clinical state, level of respiratory support required and their degree of hydration. If the current degree of humidification is inadequate, then the patient should be 'stepped up' to the next level. Patients with tracheostomies and laryngectomies are very vulnerable to complications due to inadequate humidification, and its importance cannot be overemphasised. This becomes even more important if the patient is unwell and dehydrated and has purulent secretions [16].

It is well reported that deconditioning is a common problem in ICU patients; obviously it affects also patients with a tracheostomy. A programme of early and progressive mobility, combined with range-of-motion exercises, will prevent deconditioning damages and help mobilise secretions. It is very important for patients to be mobilised out of bed, or at least dangling to gain a favourable position to breathe and cough.

14.8 Mouth Care

Adequate hydration of the oral mucosa is important as dry gases and the inability to take oral diet or fluids can lead to oral drying and discomfort. This can in turn increase the susceptibility of the individual to infection [17]. Because oral hygiene has an important role in preventing ventilator-associated pneumonia (VAP), the American Association of Critical Care Nurses recommends to develop and implement a comprehensive oral hygiene programme for patients in critical care and acute care settings who are at high risk for ventilator-associated pneumonia (VAP):

- Brush teeth, gums and tongue at least twice a day using a soft paediatric or adult toothbrush.
- Provide oral moisturising to oral mucosa and lips every 2–4 h.
- Use an oral chlorhexidine gluconate (0.12 %) rinse twice a day during the peri-operative period for adult patients who undergo cardiac surgery.

Oral discomfort can also have psychological effects, which need to be considered as part of the holistic care of the patient.

14.9 Cleaning and Replacing the Inner Cannula

The primary purpose of the inner cannula is to prevent tube obstruction by allowing regular cleaning or replacement. Many episodes of tube obstruction can be prevented with simple inspection and cleaning or changing of the inner cannula. It is important to check manufacturers' instructions for cleaning tracheostomy tubes. No studies have been done to determine the optimal frequency for cleaning the inner cannula; however, the cannula should be inspected regularly, perhaps at least 3 times per day, depending on the volume and thickness of the patient's secretions [9].

14.10 Nutrition and Swallowing

Nutrition is an important aspect of tracheostomy care as well. The tracheostomy tube may impair swallowing and compromise the patient's nutritional status. He may also have a loss of appetite due to his altered airway, which affects his sense of smell.

An assessment of swallowing function is required prior to the commencement of oral feeding in patients, identified as being at risk of dysphagia. This is to reduce the risk of aspiration, which may lead to aspiration pneumonia [18]:

“If the complex interrelation between deglutition (prolonged artificial feeding) and respiration is disrupted, significant impairment can result. Additionally, due to

the shared functions of the hypopharynx and the larynx, the impact of dysphagia is often heightened for the individual with respiratory compromise” [19].

14.11 Communication and Reduced Need for Sedation

Tracheotomised patients are able to communicate orally, even during mechanical ventilation. Oral communication improves quality of life and can facilitate interaction in elderly patients and safety.

Normally patients that are weaned from mechanical ventilation at least for some hours a day can be able to speak when cuff is deflated. However, a phonation valve is often necessary in patients that have been for several days on mechanical ventilation and had lost muscular strength.

The first application of a phonation valve should be conducted with care, monitoring the respiratory rate and looking for signs of breathing distress, as some patients may not tolerate it or may need a period of training.

Oral communication in the ICU can reduce the incidence of agitation and delirium. Moreover, tracheostomy cannula is not painful, as orotracheal or nasotracheal intubation, thus it is well tolerated and sedation can be reduced after tracheostomy.

14.12 The Importance of Tracheostomy Progression and Replacement of Tracheostomy Cannula

Tracheostomy cannulas that have no definitive indication should be considered for progression as soon as patient insufficiencies are reversed. In patients that underwent tracheostomy for prolonged mechanical ventilation, tracheostomy should be considered for progression after 24 h of successful weaning from mechanical ventilation.

The first step to begin to wean a patient from tracheostomy is generally to deflate the cuff. If this step is well tolerated, with ability to clean secretion, further progression to cuffless lower diameter tube can be attempted. The process of tracheostomy progression is completed upon decannulation and complete respiratory autonomy. This process can last for weeks and can be safely completed by trained personnel on a standard ward.

A checklist for tracheostomy progression is as follows [9]:

- Is the patient free from mechanical ventilation from >24 h?
- Is the original indication for tracheostomy resolved?
- Is the cuff deflated?
- Can the patient manage secretion?

When all these factors are positive, tracheostomy progression can be started.

14.13 Ward Management of the Patient with Tracheostomy

The number of tracheostomies being performed in ICU has been increasing significantly over the last 5–10 years [20]. Routine care of an established tracheostomy was in the past considered a basic ward skill, but unfamiliarity with tracheostomies and their routine care means that this can no longer be considered true. Tracheostomy care has been identified as a “high risk, low incidence” skill [21]. Wards receiving tracheostomy patients must have the appropriate skills to care for them, and this will require additional training and assessment of competence. The management of patients with a tracheostomy had been identified as one area that requires considerable investment, in terms of education and training and direct practical support from Critical Care Outreach Teams or Medical Emergency Teams [22].

Regular review, comprehensive documentation and good communication are keys to avoidance of problems and effective treatment [16].

Improvements in care have been described by institutions adopting a hospital-wide multidisciplinary tracheostomy team. Critical care has an increasing role, increasing expertise and also a degree of responsibility in ensuring that safe care is delivered for patients managed both within the ICU and following discharge. Tobin and Santamaria in their study concluded that the institution of a tracheostomy team to manage tracheostomy care of patients discharged from ICU with a tracheostomy was associated with improvements in decannulation rates and length of stay, and this may potentially lead to financial savings for the health [23]. Pandian et al demonstrated that safety and efficiency improved after the development of a multidisciplinary percutaneous tracheostomy team (MPTT) [24].

The Intensive Care Society Standards for Tracheostomy Care in 2014 stated that on discharge from critical care, a dual cannula tube should be in situ; ideally this would be uncuffed, but only when the patient’s condition enables it [16]. There should be a clear plan of care for weaning, communication, swallow and tube changes documented and actioned. Ideally a multiprofessional team should visit the patient on a regular basis to review and progress the patients care. Initially the patient should be followed up by critical care for at least 48 h; this may be part of the outreach team or follow-up role.

The American Academy of Otolaryngology Head and Neck Surgery recently published consensus statements for tracheostomy care and provide important suggestions in an area where randomised clinical trials are lacking [25].

Table 14.1 provides some of these important statements.

14.14 Home Management of the Patient with Tracheostomy

Patients discharged at home with tracheostomy are patients with long-term or irreversible conditions. In patient not requiring mechanical ventilation, this condition is achieved with an uncuffed long term tracheostomy cannula, that may be provided

Table 14.1 Summary of the consensus statements for tracheostomy care [25]

1. Humidification should be used during the immediate postoperative period and as necessary thereafter.
2. Humidification should be used if a patient requires mechanical ventilation.
3. Humidification should be used for patients with a history of thick secretions.
4. In a clinical setting, after the initial tube change, replacement of a tracheostomy tube should be supervised by experienced medical or nursing staff.
5. During hospitalisation and at home, the inner cannula should be cleaned regularly.
6. While at home, the tracheostomy tube should normally be replaced using a clean technique.
7. The stoma and tracheostomy tube should be suctioned when there is evidence of visual or audible secretions in the airway.
8. The stoma and tracheostomy tube should be suctioned if airway obstruction is suspected.
9. The stoma and tracheostomy tube should be suctioned before and after the tracheostomy tube is changed.
10. If there is a blockage in the tracheostomy tube, the tube should be replaced.
11. If the tracheostomy tube is malfunctioning, the tube should be replaced.
12. Tracheostomy tube cuff pressure should be checked routinely and adjusted as necessary.
13. A patient should not use a swallowing or speaking valve while the tracheostomy tube cuff is inflated.
14. Prior to cuff deflation, the tracheostomy tube and stoma should always be suctioned.
15. In the absence of aspiration, tracheostomy tube cuffs should be deflated when a patient no longer requires mechanical ventilation.
16. Utilisation of a defined tracheostomy care protocol for patient and caregiver education prior to discharge will improve patient outcomes and decrease complications related to their tracheostomy tube.

with a inner cannula (with or without speaking valve) that can easily removed and cleaned from secretion.

It is essential to organise home assistance, according to the resources made available by the health system or health insurance, as tracheotomised patients will need daily care for their tracheostomy.

Patients can be divided in:

- Autonomous patients that can care for themselves or that have a supportive family environment that can provide help and care. This category of patients will in any case need frequent nursing or medical evaluation.
- Patients that need daily community support by nurse with expertise in tracheostomy, but that can live in their home.
- Patients that should be placed in a nursing home.

Before discharge, education on stoma and cannula care should be provided for patient and caregivers. Training on emergencies and simple algorithms to alert ambulance service should be prevue. Provision of supplies and emergency equipment should be available [16].

In patients with long-term use of tracheostomy, psychological surveillance should be provided, as tracheostomy tube can be associated with lower self-esteem and self-image.

All patients with tracheostomy should be scheduled for follow-up ambulatory care before discharge, to detect late complications (including granulomas, fistula and infections) of tracheostomy and slowly developing consequences as tracheal stenosis. The family physician in charge should be informed in advance about the discharge of a patient with tracheostomy and provided with necessary information or training and hospital contact for referral [16].

14.15 Conclusions

Tracheostomy is a common procedure generally carried out in the intensive care or surgical setting. However, management of a patient with tracheostomy is more ample, because it involves nurses and physician from standard ward, nursing home and the territory in patients discharged at home. Management of routine care and major complication should be known to all actors involved in the process of care and to the patient himself and his caregivers in case of discharge at home. With training, information, checklist and algorithm for management of emergencies, tracheostomy care can be safely taught and achieved.

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Chapter 15

Quality of Life and Complications After Percutaneous Tracheostomy

Giuseppe Bello, Francesca Di Muzio, and Massimo Antonelli

Abstract Subjects with chronic respiratory failure who receive invasive mechanical ventilation through a tracheostomy outside an acute care facility usually express a high level of satisfaction with their lives, despite severe physical limitations. A proper assessment of health-care quality of life may help in deciding whether to give or withhold therapeutic interventions in these subjects. Percutaneous tracheostomies may be accompanied by a number of complications, which may be associated with considerable morbidity and mortality. Health-care professionals of patients with tracheostomy should be aware of the risk factors for developing complications after tracheostomy and the impact of these complications on clinical outcomes. Multidisciplinary strategies are needed to optimize the clinical management of persons with a tracheostomy, preventing early or late complications.

15.1 Introduction

Percutaneous dilatational tracheostomy (PDT), an alternative to surgical tracheostomy, is the placement of a tracheostomy tube without direct visualization of the trachea. It is usually performed for airway management in critically ill patients who require long-term mechanical ventilator support. PDT is a minimally invasive procedure that can be achieved safely at the patient's bedside. It can be performed in different ways. Most are variants of the method described by Ciaglia et al. [1] which is accomplished via a modified Seldinger technique, typically with the aid of bronchoscopy.

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PDT is carried out by intensive care unit (ICU) physicians rather than surgical staff and without the need to transfer the patient to the operating theatre. Consequently, the proportion of PDTs in the ICU has markedly increased compared to open surgical tracheostomies (STs) [2].

The use of home invasive mechanical ventilation has increased considerably over the last few decades due to the advances in technology and the improvement of home care [3]. With the spread of tracheostomies within the community, special attention has been devoted to the quality of life and life satisfaction of tracheostomized persons. Also, abundant literature has been published on the short- and long-term complications associated with tracheostomy.

This document will review the information regarding the impact of PDT on patients' quality of life (QoL) and the complications that may occur after PDT.

15.2 Quality of Life

QoL is a broad multidimensional concept that includes subjective evaluations of both positive and negative aspects of life [4]. The concept of health-related QoL has been introduced to comprehend those aspects of overall QoL that can strictly affect health, either physical or mental [5, 6]. Health-related QoL is an assessment of how the well-being may be influenced over time by a disease, disability, or disorder. Health-related QoL is not merely limited to direct measures of individual health, but it focuses on the impact that health status has on QoL. It describes how subjects put their actual situation in relation to their personal expectations.

15.2.1 Measurement of Quality of Life

Individual physical and mental perception of health can vary over time, depending on several external factors, such as social support and severity and length of illness. Moreover, patients' and physicians' rating of the same objective situation can differ significantly. Consequently, health-related QoL has been assessed using carefully designed and validated instruments including questionnaires or semi-structured interview schedules. These measures are often multidimensional and cover physical, social, emotional, cognitive, and job-related aspects. Particularly, QoL measures take into account disease-related symptoms, therapy-induced side effects, and even the financial impact of medical conditions. QoL questionnaires not only serve to establish the actual patient-perceived life satisfaction but may be also useful instruments for increasing QoL of patients, helping them in reducing anxiety, improving feelings of autonomy, and enhancing participation in therapeutics and healthcare decision-making. A common limitation of reports on health-related QoL is that the studied population is representative of only a self-selected group predisposed to accepting a QoL assessment.

15.2.2 Factors That May Affect Quality of Life

Opinions provided by persons living with a tracheostomy are various. A polio survivor stated that she valued the mobility and freedom that tracheostomy afforded, and she was grateful that tracheostomy kept her alive and able to experience what gave meaning, satisfaction, and serenity to her life [7]. On the other hand, there is a common opinion that tracheostomy is a viable option for some subjects, but not for everyone [7].

Several factors may affect practical life of tracheotomized persons:

- Individual physical inability
- Suitable place to live
- Adequate in-home services
- Availability of care in a long-term facility
- Assistance from family members and friends
- Assistance from volunteers
- Availability of a trustworthy care coordinator
- Dimensions and weight of ventilation equipment
- Need for suctioning
- Access to buildings
- Transportation systems
- Bureaucratic obstacles
- Personal financial resources
- Health insurance benefits

Additionally, tracheostomized subjects may suffer from a lot of emotional symptoms, including distress, anxiety, anger, shame, or fear of being a burden to family and society. Therefore, it may be useful in these subjects to receive psychological support as well as to be involved with disability organizations or religious communities that may provide a constant source of strength to face their psychological difficulties.

Factors that may affect emotional life of persons with a tracheostomy are the following:

- Change of body image perception
- Loss of autonomy
- Loss of mobility and participation in external activities
- Loss of verbal communication
- Swallowing disorders
- Loneliness
- Physical vulnerability
- Public stigma
- Lack of society understanding of disability

A survey on the perceptions of users of mechanical ventilation about their own health-related QoL was conducted in two Canadian cities over a 2-year period [8].

An interview instrument was used to elicit information of all the significant life domains: somatic sensations, physical function, emotional state, and social interaction [5, 6]. In this survey, interview participants reported to feel well and healthy, with a high QoL, thus countering societal assumptions about use of mechanical ventilation. These participants perceived mechanical ventilation as a benefit to independent living, increasing energy and overall health. However, some areas of dissatisfaction did emerge. Firstly, dimensions of ventilator were often considered cumbersome and noisy, especially at night. Also, the need of suctioning and the size of suctioning equipment were felt as an obstacle to getting out of the house. Furthermore, a multitude of physical barriers were reported to have a constant, negative impact on the daily life. Interview participants of the Canadian study gave a number of suggestions to improve their QoL. These included the following:

- Designing smaller and quieter ventilators
- Increasing accessibility to public buildings and recreation opportunities
- Improving health systems with more trained professionals
- Promoting respect for persons who have disabilities, using public educational programs
- Reducing bureaucracy in social services

A further issue of the survey was the psychological trauma in ventilator users. A previous admission to the ICU was described as a major cause of emotional trauma. Some of the participants stated that they experienced the sensation that life-and-death decisions were being made on their behalf by healthcare professionals who believed they should have allowed dying because of their poor QoL. They were sure that they would have died if their family had not decided for ventilatory intervention. Other emotional problems reported by this study population were those derived from loss of employment or loss of speech. Particularly, the ability to talk may be crucial in difficult situations such as a respiratory crisis when verbal communication is helpful to explain symptoms and necessities.

15.2.3 Evidence Base on Quality of Life

In a study on life satisfaction in patients with Duchenne muscular dystrophy receiving mechanical ventilation, Bach et al. [9] found that the majority of patients were satisfied, whereas healthcare professionals significantly underestimated the patient's life satisfaction and overestimated their degree of precariousness due to their chronic ventilator dependence.

In a study on the outcomes and complications of PDT and ST in 139 critically ill patients who required a tracheostomy, Antonelli et al. [10] interviewed study patients who had been discharged from the hospital 1 year after tracheostomy using the Short Form 12 Health Survey model questionnaire [11], rating the subjective perceptions of health and QoL. Patients also underwent a physical examination to identify possible tracheostomy-related complications including incomplete

stomal closure, objective respiratory or speech impairments, and clinical signs of tracheal stenosis (stridor, cough, or dyspnea at rest or exercise), and they were eventually scheduled for bronchoscopy and laser treatment, if needed. In all three patients (one PDT patient, two ST patients) with clinical signs of tracheal stenosis, subsequent bronchoscopy revealed granulomas that reduced the tracheal diameter by >50 % so that argon laser treatment was needed to restore full patency of the trachea. Also, 38 % of PDT patients and 33 % of ST patients ($p=.53$) reported subjective phonetic or respiratory problems. There were no significant intergroup differences in QoL, as reflected by Short Form 12 Health Survey scores. Over half of the interviewed survivors rated their physical and emotional health as moderately or severely compromised. QoL ratings for patients whose tracheostomies were still open at the 1-yr follow-up were significantly lower than those of the patients whose stomas had been closed.

In a Swedish study on the QoL of 91 patients with neuromuscular disorders and skeletal deformities receiving home mechanical ventilation administered noninvasively ($n=60$) or through a tracheostomy ($n=31$), patients of both groups reported a quite good QoL, despite severe functional limitations [12]. In this study, tracheostomized patients with post-polio dysfunction or scoliosis perceived the best health, compared with those patients with the same diagnoses who were treated with non-invasive ventilation.

Subjects with different types of chronic respiratory disorders may have different perceptions of QoL. Also the severity of the disease responsible for tracheostomy might play a role in determining QoL. Among 19 patients with neuromuscular diseases and on domiciliary ventilation for a mean duration of 54 months, more than two thirds of patients were satisfied with their lives and 84 % reported they had made the right choice when they accepted to be ventilator users [13]. In this study, patients with amyotrophic lateral sclerosis (ALS) were somewhat more negative or ambiguous toward assisted ventilation and had lower life satisfaction scores as compared with Duchenne muscular dystrophy patients.

Other reports observed a positive concept of life among patients with ALS. In a study on QoL and degree of depression in 13 patients with ALS who underwent tracheostomy for respiratory failure, only two patients (15 %) could be considered as severely depressed [14]. That would support the view that life satisfaction may not only depend on physical function but also be related to sociodemographic characteristics as education, social life, and income. Another finding of this study was that life satisfaction was comparable with that reported for the reference population group and it was not affected by the presence of tracheostomy, since the scale used did not show any difference between the tracheostomized patients and control subjects. Also, 11 patients (85 %) reported a positive view of the ventilator treatment and said that they would want to undergo tracheostomy if they could make the decision again. Finally, in these patients, tracheostomy showed good acceptance although administered at the time of a respiratory crisis without being discussed in advance. That is in contrast with previous reports showing that when not informed in advance about the option of tracheostomy in their terminal phase, patients with ALS are poorly satisfied with their QoL after tracheostomy [15].

Pandian et al. [16] developed a novel instrument for measuring health-related QoL in awake and cooperative patients admitted to the ICU and undergoing mechanical ventilation, using a questionnaire administered at three time points (5 days, 10 days, and 15 days after tracheal intubation). QoL was investigated by evaluating a number of items including the following: overall comfort, airway comfort, comfort of breathing, body image, activity, bedside recreation, swallowing, speech, saliva control, mood, anxiety, sleep, and autonomy. Qualitative assessment of results from item analyses revealed that the variance of QoL at 10 days respect to 5 days after intubation was small, probably because of minimal clinical changes during the first days of mechanical ventilation. Instead, the mean scores of all items, except for body image, improved at 15 days after intubation, probably because at this time, some of the patients who underwent tracheostomy were able to speak and swallow. Interestingly, in this study, QoL scores improved with the performance of a tracheostomy, specifically with a tracheostomy that was placed early, within 10 days of intubation. Another notable finding of this study was the correlation between the arterial oxygen partial pressure to inspired oxygen fraction ($\text{PaO}_2:\text{FiO}_2$) ratio and the comfort of breathing, in the sense that the comfort of breathing decreased as the oxygenation decreased.

15.3 Complications

PDTs are associated with a variety of possible complications that are best grouped by the time of occurrence and may be divided into early (within the first 24 h) and late (after the first 24 h) complications. Early complications include intraoperative and immediate postoperative adverse events and they are generally closely related to the expertise of operators.

Early complications usually include:

- Hypoxemia
- Bleeding
- Hemodynamic instability
- Loss of airway
- Difficulty in tube placement
- False passage
- Tracheal ring fracture
- Pneumothorax
- Pneumomediastinum
- Subcutaneous emphysema
- Skin or deep tissue infection
- Posterior tracheal wall injury
- Esophageal injury

The most common late complications include:

- Tracheal stenosis
- Tracheomalacia

- Vascular erosion
- Tracheoesophageal fistula
- Pneumonia
- Aspiration
- Tube obstruction
- Accidental decannulation
- Vocal injury
- Keloid scar

The risks of PDT in ICU patients are difficult to be predicted, as they depend on a number of factors, such as the patient anatomy, the technique used to accomplish the procedure, the level of experience of operators, and the presence of comorbidities.

Before dealing with complications associated with tracheostomy, it would be worth making some initial considerations. Recognizing tracheostomy-related complications may be often challenging. Indeed, adverse effects of tracheostomy are not usually detectable until when they become clinically evident. Moreover, it is frequently difficult to differentiate the direct effects of tracheostomy from those of a preceding translaryngeal endotracheal intubation. In fact, some of the consequences of tracheostomy on the trachea, e.g., tracheal stenosis or tracheomalacia, may also be caused by prolonged endotracheal intubation itself [17]. Furthermore, the extent of airway injury may depend on patients' comorbidities, such as shock conditions that may compromise mucosal blood flow and favor mucosal ischemia [18]. Finally, the supposed increased safety of patients discharged to the ward with a tracheostomy in place is still an active subject. Martinez et al. [19] conducted a prospective observational study on the relationship between the presence of a tracheostomy at ICU discharge and hospital mortality and found that lack of decannulation before moving to the general ward in conscious tracheostomized patients was associated with higher mortality. Other factors associated with ward mortality in this study were obesity and tenacious sputum. Lack of proper monitoring or inadequate speed in giving treatment of tube-related problems might explain the increased mortality in patients who were not decannulated at ICU discharge.

The decision to perform a PDT in a critically ill patient is done by clinical consensus of ICU staff that should specifically give the indications adopted. In this decision, a balance of the risks and benefits of PDT should be used to establish whether the procedure is actually needed.

15.3.1 Evidence Base on Complications

A meta-analysis performed by Freeman et al. [20] suggested potential advantages of PDT over ST, including ease of performance, and lower incidence of peristomal bleeding and postoperative infection. In contrast, a long-term follow-up of critically ill patients conducted by Norwood et al. [21] by means of fiberoptic bronchoscopy and computed tomography identified a 31 % rate of >10 % tracheal stenosis after PDT. In this study, symptomatic tracheal stenosis after decannulation was detected

in 6 % of patients. Melloni et al. [22] provided a 6-month follow-up in 50 patients undergoing ST or PDT, showing that early postoperative complication rates were 36 % ($n=9$) for ST patients (one minor bleeding, seven stomal infections, and one accidental decannulation) and 4 % ($n=1$) for PDT patients (minor bleeding). In this study, there were no late tracheal complications in the surgical group, whereas two late tracheal complications (one segmental malacia and one stenosis at the level of the stoma) were observed in the PDT group. In two prospective randomized controlled studies, PDT was showed to be effective, safe, and superior to conventional surgical approach, as complications were fewer and of less severity [23, 24].

In a multicentric trial on early versus late PDTs in 264 patients, Terragni et al. [25] found that more than one third of patients (39 % of the overall population) experienced an adverse event related to tracheostomy. In this study, intraoperative adverse effects associated with tracheostomy included minor bleeding (2 %), tube dislocation (2 %), and hypoxemia (5 %). Postoperative complications were stoma inflammation (15 %), stoma infection (6 %), minor bleeding (5 %), major bleeding (2 %), pneumothorax (<1 %), subcutaneous emphysema (<1 %), tracheoesophageal fistula (<1 %), and cannula displacement and need for replacement (<1 %).

The following sections deal with the main complications associated with PDT.

15.3.2 *Tracheal Stenosis*

Tracheal stenosis refers to abnormal narrowing of the central airways. Narrowing can occur at different anatomical locations: at the level of the stoma, above the stoma, or at the site of the cuff or the distal tip of the tube [17, 18].

A first location for tracheal stenosis is at the level of the stoma. Risk factors for stomal stenosis include sepsis, stomal infection, hypotension, advanced age, male sex, steroids, tight-fitting or oversized cannula, excessive tube motion, prolonged tube placement, and disproportionate opening of anterior tracheal cartilage during tracheostomy procedure [17]. Stomal granulation tissue often develops at the site of the tracheostoma, obstructing the airway and potentially causing bleeding at the time of replacing the tracheostomy tube. Granulation tissue is initially soft and vascular, frequently starting at the cephalic aspect of the stoma. Subsequently, it becomes fibrous and covered with a layer of epithelium. At this time, stenosis develops while the anterior and lateral aspects of the tracheal wall become narrowed [26].

A second location for tracheal stenosis is above the stoma, below the vocal cords. Suprastomal stenosis has been described as a complication of tracheostomies, particularly when they are accomplished with the percutaneous dilational approach [27–29]. Suprastomal injury may occur following a puncture- or guidewire-related damage of the posterior tracheal wall and may be complicated by the development of hematoma or granulation tissue. Furthermore, the dilators used to enlarge the percutaneous dilational tracheostomy stoma can cause harm to the anterior tracheal cartilage, with possible tracheal ring fracture. The deformed tracheal wall structures may

protrude into the tracheal lumen and cause obstruction [27, 29]. In a retrospective study of 19 patients undergoing percutaneous tracheostomy performed using the Griggs approach, 12 patients (63 %) had tracheal stenoses >10 %, 2 patients had tracheal stenoses >25 %, and 7 patients had the cricoid cartilage affected by the PDT site [30]. In contrast, tracheal stenosis seems to be less frequent when the Ciaglia's technique is used [31].

A third location for tracheal stenosis is at the site of the tracheal tube cuff, where mucosal ischemia can occur. Risk factors for the development of cuff-site stenosis include female sex, older age, prolonged tube placement, and excess cuff pressure [17, 18]. During intubation with cuffed tubes, ischemic injury to the trachea is least likely when the lateral wall pressure exerted by the cuff does not exceed the mean capillary perfusion pressure of the tracheal mucosa. Although the balloon cuff may be easily distensible in open air, when confined within the trachea, small increments in the inflation volume may produce high pressures. In a study on the relationship between inflation pressure and distention of the cuff with eight different commercially available soft cuff tracheal tubes, low-volume high-pressure cuffs were shown to decrease major tracheal complications tenfold and eliminate complications specifically related to the cuff, compared with high-volume low-pressure cuffs [32]. A study on 96 mechanically ventilated ICU patients reported that the most common tracheal ischemic lesion was frank ischemia (68 %), followed by hyperemia (54 %), ulcer (10 %), and tracheal rupture (1 %) [33]. In this study, overinflation of the tracheal cuff, i.e., >30 cmH₂O, was shown to be the main risk factor for ischemic tracheal lesions [34]. Other risk factors for tracheal ischemia have been described, including hypotension, hypoxemia, inflammation, and incautious subglottic secretion drainage [35]. A study on tracheal perfusion in 40 patients intubated with a high-volume low-pressure cuffed tracheal tube showed important reduction in mucosal capillary blood flow at a wall pressure above 30 cmH₂O and a total obstruction above 50 cmH₂O. Cuff pressure can be influenced by several factors, such as the quantity of air injected in the cuff, the ratio between cuff and tracheal diameter, cuff physical characteristics, patient temperature, airway pressure, and patient position [35]. After severe tracheal ischemic lesions, several complications may occur, including tracheal stenosis, tracheal rupture, tracheobronchomalacia, tracheoinnominate artery fistula, and tracheoesophageal fistula [35]. Cuff pressure should be checked and maintained between 20 and 25 cmH₂O, if possible using a device allowing continuous control or, alternatively, using a manometer at least twice a day. The finger method is inaccurate in estimating cuff pressure. If cuff pressure is not adequately checked, patients are at risk to spend long periods of time with underinflation or overinflation of the cuff [36]. When cuff-site ischemia occurs, abnormal traction forces from the respiratory circuit may exacerbate the damage to the mucosa. After prolonged ischemia, tracheal wall ulceration, chondritis, and cartilaginous necrosis may occur, resulting in the development of granulation tissue. Subsequently, fibrous narrowing and circumferential stenosis may develop. Pooled secretions over the tracheostomy cuff or gastroesophageal reflux disease can aggravate this process [37].

A further location for tracheal stenosis is near the distal tip of the tracheostomy tube. This lesion may develop on either the anterior or posterior wall of the trachea, depending on the positioning of the tube.

Tracheal stenosis may produce no symptoms until the lumen has been reduced by 50–75 % [17]. Then, cough and difficulty clearing secretions may appear. Manifestations of severe stenosis include exertional dyspnea when the tracheal lumen has been reduced to <10 mm and dyspnea at rest or stridor when the lumen is narrowed to <5 mm.

Symptoms may present weeks to months after decannulation or occur early while the patient is still under mechanical ventilation, thus preventing weaning from ventilator or delaying decannulation. Rumbak et al. [38] retrospectively reviewed 37 patients requiring prolonged mechanical ventilation (mean endotracheal/tracheostomy time =3/12 weeks) and having tracheal obstruction. Patients presented with failure to wean, intermittently high peak airway pressures, or difficulty in passing the suction catheter and were treated by placement of a longer tracheal tube or a tracheal stent. Based on these findings, the authors suggested that patients requiring prolonged mechanical ventilation and failing ventilator weaning should all undergo fiberoptic bronchoscopy.

Fiberoptic laryngotracheoscopy is the main diagnostic approach to define the cause of tracheal stenosis as well as its localization and extension. Imaging examinations for tracheal stenosis include chest X-ray, tracheal CT scan, or magnetic resonance.

In symptomatic patients with web-like tracheal stenosis, laser resection with rigid bronchoscopic dilation remains the preferred therapeutic approach [28]. If this approach is not feasible and proves ineffective, stenting of the airway and tracheal sleeve resection are the next recommended options [28].

15.3.3 Tracheomalacia

As with ST, also PDT may be complicated by tracheomalacia. This is a pathological condition of the central airways characterized by flaccidity of the tracheal supporting cartilage which leads to airway collapse. Malacia may involve segments of the trachea, the entire trachea, or even the trachea and the left and right mainstem bronchi (this condition is termed tracheo-bronchomalacia). In normal subjects, the airways dilate and lengthen during inspiration, whereas they narrow and shorten during expiration. Weakening of the tracheal wall accentuates this physiologic process, causing excessive changes in tracheal diameter. In patients with tracheomalacia, tracheal narrowing is most prominent during forced expiration, cough, or the Valsalva maneuver, when intrathoracic pressure becomes considerably greater than intraluminal pressure. Various degrees of airway obstruction can result from tracheal narrowing. A diagnostic criterion of >50 % reduction of the cross-sectional area of the trachea during expiration has been widely used in both bronchoscopy and CT scan studies on tracheomalacia [39].

Narrowing of the airways can result in expiratory airflow limitation, air trapping, and retained respiratory secretions. Generally, in patients with a history of previous tracheostomy, tracheomalacia presents as breathing difficult, whereas in patients on mechanical ventilation, it presents as failure to wean from ventilator. Fiberoptic findings of tracheomalacia usually include loss of normal semicircular shape of tracheal lumen, forward ballooning of the posterior membranous wall, and antero-posterior narrowing of the trachea. If conservative treatment (humidified air, chest physical therapy, and control of infection and secretions) fails, placement of a longer tracheostomy tube to bypass the region of expiratory collapse is usually sufficient. With more severe cases, therapeutic options include tracheal stenting, continuous positive airway pressure, and surgical techniques, such as tracheal resection or tracheoplasty [39].

15.3.4 Innominate Artery Erosion

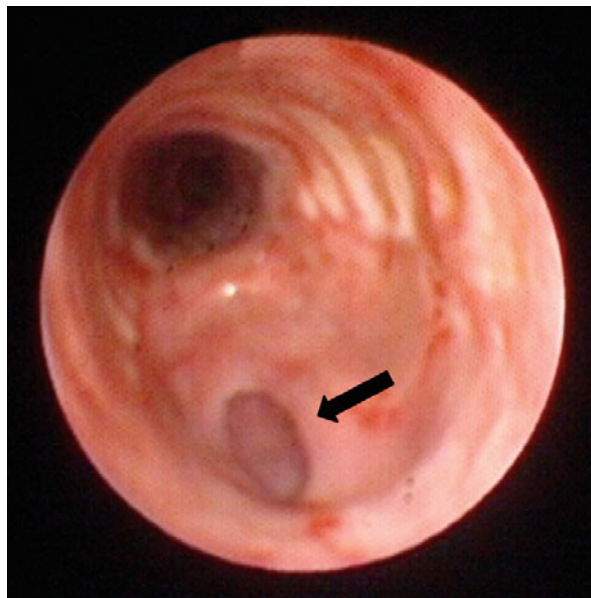
An infrequent complication of PDT is the development of a tracheo-innominate artery fistula which presents with bleeding around the tracheostomy tube or massive hemoptysis usually at 3–4 weeks of tracheostomy placement [17]. Generally, the tip of the tracheostomy tube or an overinflated tracheostomy cuff balloon can severely damage the tracheal mucosa, leading to necrosis and erosion into the innominate artery. Risk factors for the development of trachea innominate fistula are aberrant innominate artery position, tracheal infection, corticosteroid therapy, overinflated cuff, excessive movement of the tracheostomy tube, or a tube that has been placed too low. Prevention of tracheo-innominate artery fistula is crucial because of the extremely high mortality associated with this complication. Prevention starts with avoiding placement of the tracheostomy tube below the third tracheal ring and avoiding prolonged or exaggerated hyperextension of the neck. Further efforts consist of avoiding excess mechanical traction of the trachea by using swivel adapters and ventilator tubing support.

Management of active bleeding from tracheo-innominate artery fistula includes emergency digital compression of the fistula and transport to the operating room for immediate surgical interruption of the innominate artery [40].

15.3.5 Tracheoesophageal Fistula

Tracheoesophageal fistula (Fig. 15.1) is the development of an abnormal connection between the trachea and the esophagus [41], generally resulting from injury to the membranous tracheal wall. In patients undergoing PDT, tracheoesophageal fistula can be secondary to posterior tracheal wall injury that may occur during the tracheostomy placement or be caused by the tip of the tube or an overinflated cuff. High cuff pressure and excessive angulation of the tube are risk factors for tracheoesophageal fistula [42]. The presence of a nasogastric tube may also contribute to

Fig. 15.1 Endoscopic view of tracheoesophageal fistula. The arrow indicates the solution of continuity between the membranous wall of the trachea and the adjacent esophageal wall



the development of the fistula [42]. Symptoms of tracheoesophageal fistula include copious production of secretions, recurrent aspiration of food, increasing dyspnea, persistent air leak, or gastric distention [17]. Barium esophagography, computed tomography of the chest, or endoscopic tracheal or esophageal studies are commonly used to make the diagnosis. Treatment consists of placement of a double stent, i.e., in esophagus and trachea, or surgical repair in selected patients [42]. Definitive therapy by bronchoscopic application of a sealing agent to occlude tracheoesophageal fistulas may be used, particularly in poor surgical candidates [43].

15.3.6 Infections

Data on possible advantages of tracheostomy over translaryngeal tube in lowering the risk for ventilator-associated pneumonia are controversial. In a prospective study on ventilator-associated pneumonia in 880 patients receiving mechanical ventilation at a non-teaching community hospital, Ibrahim et al. [44] found that 15 % of these patients developed pneumonia. Logistic regression analysis showed that tracheostomy, together with multiple central venous line insertions, reintubation, and use of antacids, was independently associated with the development of pneumonia.

In contrast, a 4-year period trial performed in 12 Italian ICUs on the effectiveness of early tracheostomy (after 6–8 days of laryngeal intubation, $n = 145$) versus late tracheostomy (after 13–15 days of laryngeal intubation, $n = 119$) in reducing the incidence of ventilator-associated pneumonia showed that pneumonia was present in 14 % of patients in the early tracheostomy group and in 21 % of patients in the late tracheostomy group ($p = 0.07$) [25].

Fig. 15.2 Tracheostomy stoma infection



Skin and soft tissue infection of the anterior aspect of the neck (Fig. 15.2) is usually circumscribed, but it may be complicated by local or systemic dissemination.

15.3.7 Aspiration

Aspiration may be a complication in tracheostomized subjects, particularly if the cuff is left inflated while the patient is eating [45]. A number of studies have investigated the influence of tracheostomy on the swallowing reflex in patients with tracheostomy. Physiologically, subjects with tracheostomy are more likely to aspirate because the tracheostomy tube partially blocks laryngeal movements, preventing its elevation during deglutition. Tracheostomy tubes, particularly when the cuff is inflated, may compress the esophagus and interfere with swallowing [45]. Additionally, prolonged translaryngeal intubation can result in swallowing disorders even after the tracheal tube is converted to a tracheostomy [46].

Elpern et al. [47] found that 50 % of 83 patients receiving long-term mechanical ventilatory support had evidence of aspiration. In 77 % of these patients, aspiration was clinically silent. Advanced age was found to be a risk factor for aspiration in this population.

In non-ventilated patients, some small studies have investigated the role of tracheostomy cuff inflation on aspiration. In 12 ICU patients who had been weaned from mechanical ventilation, Amathieu et al. [48] showed that the swallowing reflex was progressively more difficult to elicit with increasing cuff pressure and, when activated, the resulting motor swallowing activity and efficiency at elevating the larynx was depressed. In 12 tracheostomized patients who undergone fluoroscopic swallowing studies after ventilator weaning, Davis et al. [49] showed that when the cuff was inflated, the aspiration rate was 2.7 times higher than when the cuff was deflated. In this study, logistic regression analysis revealed that the cuff status and

the type of substance ingested were both predictors of aspiration, suggesting that feeding with the cuff deflated may be the preferred method and that solid foods are safer than liquids. Conversely, different findings were reported by Suiter et al. [50] in a study on the effects of tracheostomy cuff status and use of one-way speaking valve on the physiology of swallowing in 14 spontaneously breathing patients under three conditions: cuff inflated, cuff deflated, and one-way valve in place. Aspiration was not significantly affected by cuff status, i.e., inflation or deflation, whereas one-way valve placement significantly reduced aspiration for the liquid bolus.

In the light of these findings, in non-ventilated patients with tracheostomy, the evidence is inconclusive as to whether the cuff status predisposes to aspiration of food or fluids at the level of the larynx. However, performing swallowing studies may be a useful method for assessing which substances will be better tolerated by an individual patient. Clinicians who perform swallowing studies in tracheostomized patients should also include evaluations with a one-way speaking valve in place before making any decisions regarding the use of the valve as a means to reduce aspiration.

15.3.8 Tracheostomy Tube Occlusion

Obstruction of the tracheostomy tube is a life-threatening emergency. Usual manifestations of respiratory distress due to an obstructed tracheostomy tube include agitation, dyspnea, tachypnea, accessory muscle use, hypoxemia, or hypercapnia. The most common cause of tracheostomy tube obstruction is dried mucous plug. For preventing tube obstruction from mucous plugs, airway suctioning should be performed when indicated. Further, inhaled humidification and a proper patient hydration are essential for maintaining a patent airway. Finally, the use of tracheostomy tubes with an inner cannula can prevent tube obstruction by allowing regular inspection and cleaning or replacement of the inner cannula. Managing subjects having a tracheostomy without an inner cannula outside of an ICU may be hazardous (Fig. 15.3).

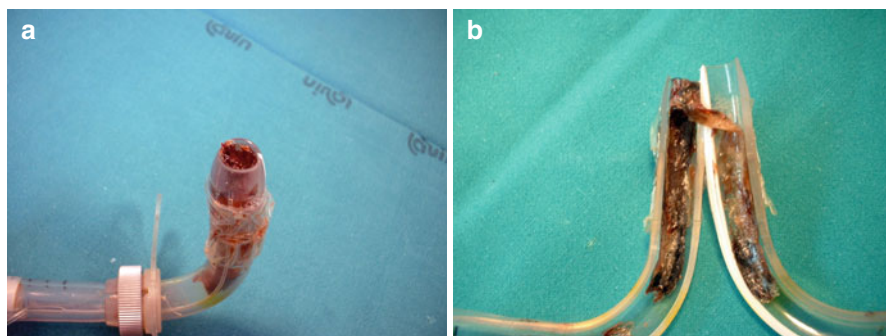


Fig. 15.3 Obstruction of a tracheostomy tube from mucus plug. (a) Tracheostomy tube after being removed from the patient. (b) Tracheostomy tube cut lengthwise to better show mucus plug

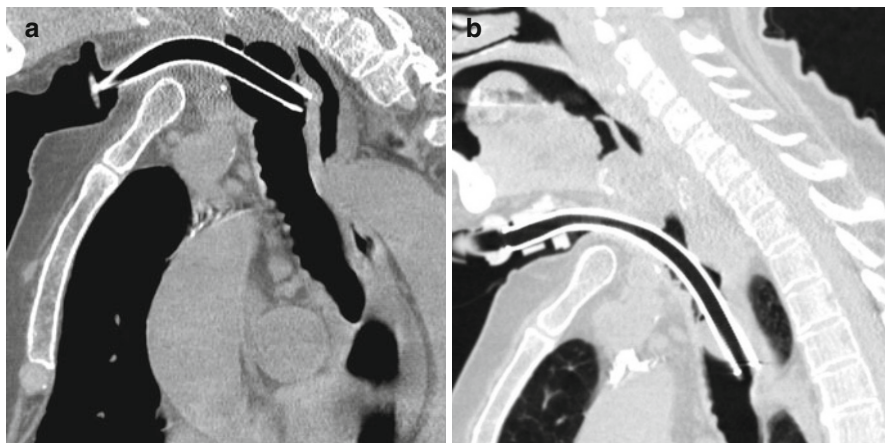


Fig. 15.4 Inappropriate tracheostomy tube occluded against the posterior tracheal wall. (a) Computed tomography scan of the neck and chest, sagittal plane. The distal end of the tracheostomy tube lies against the membranous tracheal wall, in the upper third of the trachea, and oriented posteriorly. (b) A new tracheostomy tube with different characteristics has been positioned. The distal opening of the new tube appears more patent compared with the previous tube

Use of an inappropriate model of tracheostomy tube could lead to the occlusion of the tube against the tracheal wall (Fig. 15.4a). Generally, a tracheostomy tube should extend at least 2–3 cm beyond the stoma and lie in the center of the tracheal lumen, at least 2 cm above the carina. The selection of a proper tube should be individualized and the angulation selected to avoid problems of tube occlusion (Fig. 15.4b).

15.4 Conclusion

Persons living with a tracheostomy generally express a high level of satisfaction with their lives. However, various areas of dissatisfaction have been identified among ventilator users. A proper assessment of healthcare quality of life may be helpful to better understand the needs of tracheostomized persons and improve their types of life. Healthcare professionals should be aware of early and late complications that may develop in these persons and use a multidisciplinary strategy to optimize their clinical management.

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Chapter 16

Clinical Practice of Informed Consent for Percutaneous Tracheostomy

M. Vargas, A. Marra, G. Servillo, and P. Pelosi

Abstract Informed consent (IC) is the process through which patients understand and agree to medical procedures. The informed consent process needs to fulfil two main purposes: (1) the moral and ethical right of autonomy and freedom of choice and (2) the legal authorisation for the proposed treatment. The IC is not simply a legal and ethical obligation; it is central factor in decisional process helping the patient arrive at a treatment decision. The competence is the most important element to obtain a valid informed consent. The majority of critically ill patients are naturally incompetent and not legally incompetent. This kind of patients has a temporarily or partially mental incapacity that requires a surrogate decision maker. The purpose of this chapter is to report the problems of IC in critically ill patients and to show the different national legislation about it.

16.1 Informed Consent: Definition

Informed consent (IC) is the process through which patients understand and agree to medical procedures. The informed consent process needs to fulfil two main purposes: (1) the moral and ethical right of autonomy and freedom of choice and (2) the legal authorisation for the proposed treatment [1]. The IC is not simply a legal and ethical obligation; it is central factor in decisional process helping the patient arrive at a treatment decision [1]. The IC needs to fulfil five criteria:

1. Competence defined as the ability to understand and decide
2. Disclosure of information consisting in the communication about the procedure, risks/benefits and possible alternatives

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3. Understanding that is the comprehension of the information
4. Voluntariness consisting by a decision free from coercion
5. Decision to proceed due to the selection of goal, treatment or therapy regimen

16.2 Informed Consent for Critically Ill Patients

The competence is the most important element to obtain a valid informed consent. Competence/capacity refers to the ability of patients of making choices [2]. As a consequence, an incompetent patient doesn't have the mental faculty to consent to medical procedure or therapy. The incompetent patient needs of a representative, identified by law, to give a valid consent [2]. Patients in intensive care are substantially different than in general acute care. The majority of critically ill patients are naturally incompetent and not legally incompetent [3]. This kind of patients has a temporarily or partially mental incapacity that requires a surrogate decision maker [4]. Figure 16.1 summarises the characteristics of competent and incompetent critically ill patients.

The rules of IC and the way to design the surrogate for critically ill patients differ across countries [5]. Many countries recognise the figure of a designated surrogate or proxy, while the other countries give the legal right to the relatives. Furthermore, different countries recognise the legal validity of the advanced directives of treatment. However, the types and the contents of the advanced directives of treatment vary across countries. The most common advanced directives of treatment are the living will and the power of attorney or healthcare proxy. The living will is a document designed to control future healthcare decision or treatment when patients become incompetent. The living will describes the type of medical treatment the person would want or would not want in state of unconsciousness. The power of attorney, also called healthcare proxy, is a legal document in which the patient names a person to be his proxy to make all your healthcare decisions if he/she becomes unable to do so. The person indicated in this document has the right to consent to medical treatment (Table 16.1).

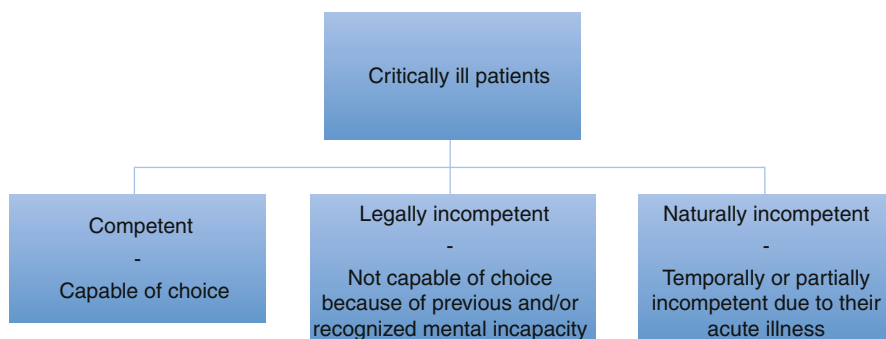


Fig. 16.1 Critically ill patients divided according the mental status

Table 16.1 Summary of the legislation about informed consent and surrogate designation in different countries

	Competent patient	Incompetent patients	Advanced directives of treatment
Austria	Validity of self-assessment and decisional capacity	Validity of decisional power of a relative	Validity of living will and power of attorney
Belgium	Validity of self-assessment and decisional capacity	Validity of decisional power of a relative	Validity of living will and power of attorney
Bulgaria	Validity of self-assessment and decisional capacity	Validity of decisional power of the closest relative	No legal availability of living will and power of attorney
Denmark	Validity of self-assessment and decisional capacity	Validity of decisional power of a relative or friend	Validity of living will and power of attorney
Finland	Validity of self-assessment and decisional capacity	No possibility to appoint a surrogate. Consultative role of relatives	Still debating
France	Validity of self-assessment and decisional capacity	Consultative role of relatives	Consultative role
Germany	Validity of self-assessment and decisional capacity	Validity of designed surrogate. Lacking this, consultative role of relatives	Validity of living will and power of attorney
Hungary	Validity of self-assessment and decisional capacity	Validity of decisional power of a proxy	Validity of living will and power of attorney
Italy	Validity of self-assessment and decisional capacity	No possibility for patients to appoint a surrogate. Only a judge may appoint a support administrator	No legal availability of living will and power of attorney
The Netherland	Validity of self-assessment and decisional capacity	Consultative role of relatives	Validity of living will and power of attorney
Norway	Validity of self-assessment and decisional capacity	Consultative role of proxy	Legal authority still debating

(continued)

Table 16.1 (continued)

	Competent patient	Incompetent patients	Advanced directives of treatment
Spain	Validity of self-assessment and decisional capacity	Validity of decisional power of a relative	Validity of living will and power of attorney
Switzerland	Validity of self-assessment and decisional capacity	Validity of decisional power of a surrogate	Validity of living will and power of attorney
Turkey	Validity of self-assessment and decisional capacity	Still debating	Still debating
UK	Validity of self-assessment and decisional capacity	Validity of decisional power of a surrogate	Validity of living will and power of attorney
USA	Validity of self-assessment and decisional capacity	Validity of decisional power of a surrogate	Validity of living will and power of attorney

Critically ill patients more often required invasive procedure. Although a valid consent may be obtained by a proxy, this introduces more uncertainty. There is poor agreement between surrogate decision makers' and patients' decision in intensive care unit [6]. Two conditions are required to fulfil the role of the surrogate decision maker. First, the surrogates should be informed in order to fully understand the procedure, but often relatives as surrogate decision makers lack important information [5]. Second, the surrogates should be informed of the patients' wishes expressed before the critical illness. More often relatives as surrogate have a little knowledge of patients' wishes [5]. Furthermore, the surrogates collaboratively consent to clinical trial with the purpose to help the loved one to recover faster and not according to the patients' wishes [7]. Last but not least, critical illnesses have a rapid pace leaving to the surrogate few time for evaluating proposed treatment and possible alternatives.

Informed consent for critically ill patients is a complex procedure of everyday practice. Physicians have the role to show clinical data and medical information as well as possible to help patients and relatives in complex decisions.

16.3 Informed Consent for Tracheostomy

Critically ill patients required invasive procedure for diagnosis and therapy. Different invasive procedures required an informed consent, but this practice varies from different countries.

Table 16.2 Most common invasive procedures performed in intensive care unit

Airway	Endotracheal intubation, cricothyrotomy and percutaneous and surgical tracheostomy
Diagnostic and/or therapeutic procedures	Lumbar puncture, thoracentesis, paracentesis, chest tube insertion, percutaneous gastrostomy insertion
Endoscopic procedure	Gastrointestinal endoscopy, bronchoscopy
Vascular procedures	Central venous catheter, peripherally inserted central catheter arterial catheterization, pulmonary arterial catheterization, extracorporeal membrane oxygenation

Table 16.2 shows the most common invasive procedure performed in intensive care unit.

The clinical practice of informed consent for invasive procedure in critically ill patients has been poorly investigated. In a US survey performed in intensive care units, the informed consent was more requested for medical research, gastrointestinal endoscopy, thoracentesis and paracentesis while less request for endotracheal intubation and foley catheterizations [8]. Interestingly in this survey, the consent for medical research was required >95 % of participating units, while consent for arterial and femoral catheterizations was not obtained in more than half of institutions [8]. Davis et al. described the nature in critically ill patients [9]. The informed consent was more obtained for central vascular catheter insertion, blood transfusion and tracheostomy placement. In the US survey by Stuke et al., the informed consent for tracheostomy was obtained in 97 % of respondents [10]. The first national survey investigated the clinical practice of informed consent for tracheostomy was performed in Italy [11]. This survey which evaluated the practice of informed consent for tracheostomy related the state of consciousness of critically ill patients. As results, the authors reported that the informed consent for tracheostomy: (1) in conscious patients was obtained in 82 % of participating units and (2) in unconscious patients was obtained by 62 % of participating units [11]. Percutaneous tracheostomy in critically ill patients is an elective procedure, even if some reports exist about tracheostomy in emergency situation [12]. As invasive procedure with potential risk and complications, tracheostomy needs informed consent and risk/benefit information.

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Chapter 17

Tracheostomy in Intensive Care Unit: The Need of European Guidelines

A. Marra, M. Danzi, M. Vargas, and G. Servillo

Abstract Surgical or percutaneous tracheostomies have become one of the most frequently performed procedures in intensive care unit. Over the past years, different percutaneous tracheostomy techniques have been proposed. Surveys conducted in different European Countries showed that tracheostomy techniques, procedural features as well as complications are markedly heterogeneous among European ICUs and might differ even within ICUs from one country to another. Lacking clinical guidelines to provide the best available scientific evidence and to reduce inappropriate variation in PT practice, a careful analysis of different surveys suggested to physicians the most common practice associated with PT.

17.1 Tracheostomy in Intensive Care Unit: The Need of European Guidelines

Surgical or percutaneous tracheostomies have become one of the most frequently performed procedures in intensive care unit (ICU). Over the past years, different percutaneous tracheostomy techniques have been proposed. Surveys conducted in different European Countries showed that tracheostomy techniques, procedural features as well as complications are markedly heterogeneous among European ICUs and might differ even within ICUs from one country to another [1]. Lacking clinical guidelines to provide the best available scientific evidence and to reduce inappropriate variation in PT practice, a careful analysis of different surveys suggested to physicians the most common practice associated with PT.

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Only a consensus conference was found as general guideline on tracheostomy, recognised from the American college of chest in 1989, which began to indicate some features associated with the tracheostomy [2]. The authors stated that tracheostomy is a valuable adjunct to continued mechanical respiratory support. Ideally, tracheostomy should be performed or directly supervised by an experienced surgeon with an anaesthesiologist in attendance in an operating room or appropriately equipped critical care setting [2]. Personnel should be experienced in its performance and knowledgeable in tracheostomy after care to minimise complications [2].

Currently, the first document comparable to a guideline on the tracheostomy in the ICU was prepared by the Danish Society of Intensive Care Medicine (DSIT) and the Danish Society of Anaesthesiology and Intensive Care Medicine (DASAIM) in 2010 [3]. This guideline describes the indications and contraindications, timing, complications compared to surgical tracheostomy, anaesthesia and technique, decannulation strategy as well as training and education [3]. In 2015, they have been updated [4]. The Danish national guideline, in addition to the previous guidance, added indications for use of fibre bronchoscopy and ultrasound guidance [4]. No randomised, controlled trials concerning indications for PDT were found. In experienced hands, PDT seems to be a safe procedure. The risk/benefit and timing of PDT should be evaluated on an individual patient basis. Usually PDT is an elective procedure, and all reversible risk factors should be corrected in advance. The number of relative contraindications to PDT declines with increasing operator experience. Randomised clinical studies of anaesthesia for PDT were not identified, so this recommendation relies primarily on expert opinion and case reports [4]. Sedation to tube tolerance is not sufficient for surgical anaesthesia [4]. Thus, real doses of anaesthetics are used. As regards the choice of the type of tracheostomy, the Danish guidelines state that the procedure differs slightly with choice of kit, but this suggestion is based on expert opinions and rules of thumb [4]. To minimise complications, guidelines recommend that each institution chooses one kit and gains familiarity with this specific kit to appreciate its advantages and drawbacks [4]. No RCTs of PDT with bronchoscopic guidance versus no bronchoscopic guidance were identified. However, a systematic review of all published deaths related to PDT identified lack a bronchoscopic guidance as a serious risk factor [4]. For timing of PDT, in prolonged mechanical ventilation, authors suggest that optimal timing of tracheostomy be determined on an individual patient basis (2B) [4]. There is insufficient or conflicting evidence to make a general recommendation of early versus late tracheostomy.

Key recommendations of Danish guidelines 2015 are summarised in Fig. 17.1.

The first step to build a standardised approach to percutaneous tracheostomy was to understand the real size and extent of the problem. Therefore, Vargas et al. in 2012, in collaboration with Italian Society of Anaesthesia Analgesia and Intensive Care (SIAARTI), carried a survey that was intended to assess the most common procedures associated with tracheostomy in Italian ICU [1]. The aim of the study was to evaluate the frequency of different techniques, indications, timing as well as procedural features, sedation and ventilation protocols and early and late complica-

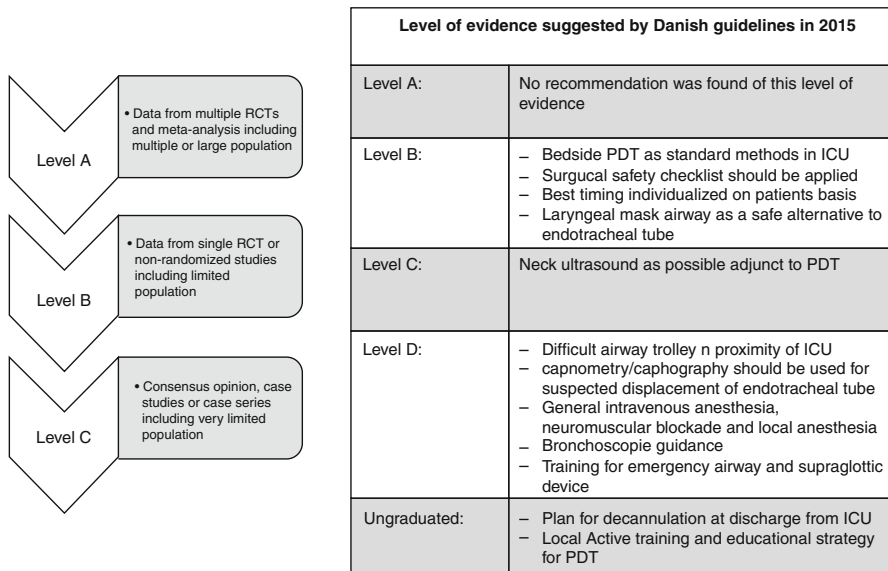


Fig. 17.1 Key recommendations of Danish guidelines 2015 for percutaneous dilatational tracheostomy in the intensive care unit

tions of tracheostomy in intensive care unit [1]. It was a retrospective survey on data collected in 2011. A questionnaire was mailed to all members of the Italian Society of SIAARTI.

The questionnaire was organised in two main sections. The first section included questions about hospital and ICU demographics as well as the number of beds, ICU admissions and number of tracheostomies performed in 2011. The second section aimed to evaluate the type of tracheostomy technique applied, timing, indication, procedural features, sedation and ventilation protocol and early and late complications [1]. In this national survey investigating the most frequent clinical practice to perform the tracheostomy in the Italian ICUs, the authors found that (1) the most commonly used tracheostomy was Ciaglia Blue Rhino and the main indication was prolonged mechanical ventilation. CBR was the most popular technique reported in previous surveys in Germany and the UK. On the contrary, GWDF was the most used in Spain, while ST in Switzerland, the Netherlands and France. TLT technique was the third technique performed in the Italian ICUs, while it was used in only 13 % of the German and 1.2 % of the Spanish ICUs and not evaluated in other published surveys. The popularity of CBR, GWDF and ST is likely due to the fact that they are easier to be performed with a faster learning curve. However, the TLT, a technique developed in Italy, is a more complex tracheostomy with less potential damage for anterior and posterior tracheal wall and requiring a specialised training. In this survey, the most important reported indication for tracheostomy was prolonged mechanical ventilation followed by neurological/surgical/traumatic disorders for which the physician does not expect a

resumption of airway protective reflexes and consciousness in a short time, prolonged or difficult weaning and inability to airway protection as also reported by the previous surveys performed in Switzerland and France. (2) The tracheostomy was performed between 7 and 15 days after ICU admission, followed by a similar distribution of the first week (<7 days) and the third week (15–21 days), as reported in the previous European survey. These data do not follow the most common published recommendations on tracheostomy timing [1]. A consensus conference in 1989 recommended endotracheal intubation in the first 10 days of mechanical ventilation and to perform tracheostomy after 3 weeks of endotracheal intubation. In 1992, the French Society of Intensive Care Medicine recommended that the decision to perform a tracheostomy should be taken within the first 5–7 days, if the duration of mechanical ventilation longer than 15 days is expected [5]. In 2000, it has been suggested that the optimal timing should be chosen according to the patient conditions [6]. In a randomised controlled trial, Terragni et al. failed to demonstrate any beneficial effects of early (6–8 days) versus late (13–15 days) tracheostomy [7]. More recently, Freeman et al. suggested that tracheostomy should be performed at least 2 weeks after the onset of acute respiratory failure but neurological patients might benefit from an earlier tracheostomy [8]. Most of the Italian participating ICUs had a dedicated tracheostomy team made up of more than one intensive care physician and a nurse [1]. In other surveys, different specialists were involved in performing surgical or percutaneous tracheostomy in ICU, in Switzerland mainly by the surgeon, followed by the intensive care or ENT physician, in the Netherlands by the surgeon and the intensive care physician and in France, equally by the surgeon, the intensive care or ENT physician [1]. More similar to Italy, in Germany percutaneous tracheostomy was mainly performed by intensive care physicians, while ST by surgeons [1]. A previous survey in the UK reported that doctors were more frequently involved to perform tracheostomy in ICU. (3) In the ICUs participating to this survey, the sedation-analgesia and neuromuscular blocking protocol was more frequently implemented than a ventilation protocol. The finding that the ventilation protocol was less common than a sedation protocol was unexpected because tracheostomy involves the airway management, potentially leading to hypoxia and alveolar derecruitment [1]. Volume-controlled protective mechanical ventilation with an inspiratory oxygen fraction of 100 % was more often used during the procedure; (4) tracheostomy was frequently guided by fibre-optic bronchoscope, as reported in the German and the UK survey, while neck ultrasounds were used as a screening procedure to assess at-risk structure; (6) bleeding controlled by local pressure was the most common early and late complication in line with data reported in both the Swiss and the UK surveys. Previous studies showed higher risk of post-procedural major bleeding in surgical compared to percutaneous tracheostomy techniques [1].

A careful analysis of different surveys may suggest to physicians the most common practice associated with PT. This analysis evaluated the shared clinical practice for PT from seven national surveys performed in France (where 152 intensive care

units participated in the survey), Germany (505), Italy (130), the Netherlands (63), Spain (100), Switzerland (48), and the UK (197) [5]. This analysis found that:

1. The most common indication for PT was the long-term mechanical ventilation.
2. The most used techniques were Ciaglia single-step dilator.
3. The most common timing was 7–15 days after ICU admission.
4. Ventilation and sedation protocol were largely used as fibre-optic bronchoscopy.

The Danish guideline and the international surveys showed a shared clinical practice for PT. In our opinion, they may be the first step towards the production of a standardised and international guidelines about this procedure [1].

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