Preface

My experience in tracheostomy started in 1957 at the University Hospital of Milan as general surgeon for the first two years and then as anaesthetist. At that time, the trend was a Björk method tracheostomy with an inferior skin-trachea bridge, that was usually followed by a high rate of incidence of late stoma complications, caused in part by the wide surgical opening and the difficult closure of the stoma, in part by the established habit of using rigid rubber cannulas of 12 mm I.D. or greater.

In 1966, as the head of a newly opened 16 bed general ICU, I had to face a massive influx of paediatric patients, from newborns with idiopathic respiratory distress syndrome (IRDS) to children with congenital or acquired airway obstruction, since specialized institutions in this field did not yet exist in our country. It was noted that in these small patients, with the use of smaller, softer and more flexible nasotracheal tubes and strong humidification of gases, the prolonged intubation resulted well tolerated and a preferable alternative to traumatic surgical tracheostomy (ST). Afterwards, similar outcomes were observed also in adults, so that the tracheostomy was restricted to the cases of irreversible respiratory failure or when it served for positioning a tracheal T-stent.

Later on, I greatly modified ST to make it less invasive and less painful by creating a sort of combination between the old opening and those that would have become the future dilatative methods. A rigid bronchoscope gave me the possibility to limit the neck incision through a protrusion of the neck wall, and to ensure an adequate ventilation during the entire procedure. The small opening of the anterior tracheal wall was then bluntly dilated with a three branches Laborde forceps. The result was a mixed technique, that had reduced some drawbacks of the standard surgical procedure. My previous professional experience as a surgeon allowed me to overcome the major technical difficulties arising from the stoma which was narrower than that of the traditional method and, above all, to be able to deal with a possible emergency, such as the rapid enlargement of the breach in the case of a haemorrhage, with the required expertise.

After carrying out a series of 300 surgical tracheostomies in adults and 50 in paediatric patients with satisfactory results over the period 1966-1990, I was attracted by the percutaneous technique of the Ciaglia multiple dilators method (1), that had achieved an initial large acceptance because launched as a minimally invasive bed site technique. In the years 1991-1992 I tried this method on 56 patients and published the relating results in the first Italian study on this subject (2).

Since we regularly had carried out ST at the bed site of patients, using the Ciaglia method a logistic advantage was not noticed. In addition, the lower invasivity of the new technique was widely reassessed by the need of a preliminary dissection of the pretracheal tissue to facilitate the needle centring and reduce the pushing efforts during the dilators and cannula insertion. Dissection, tearing and stretching of tissue provoked frequent haemorrhages, but the most alarming aspect was the high and always incumbent risk of the lesion of the posterior tracheal wall, caused by the forced insertion of dilators and cannula, an almost unknown complication with ST.

The awareness that this danger was indissolubly tied to the out/inside direction of inserting the tracheostomy tools, led me to search for a safer technique. With this purpose the translaryngeal tracheostomy was created, an extremely innovative technique, without even any minimal allusion in the past literature. Indeed, the dilation manoeuvre ran from the inside of the tracheal lumen to the outside of the neck (In/Out, no retrograde), in the exactly opposite direction of the dilational manoeuvre practiced in the Ciaglia method and other percutaneous tracheostomies afterwards proposed (Fig. 1).

And, just to highlight this crucial difference that entails important differences of clinical outcomes, we define OIT (Out/In Tracheostomy) all the other techniques.
Regarding the decision of creating this monograph, it originated from the fact we realized that there was a need to clarify some key points of the TLT technique, not always used in the best way, and suggesting tips for getting the most out of practicality and safety. A second reason was to have noticed that the system of evaluation and comparison of the various tracheostomy techniques was deeply wrong, and so the introduction of new, more reliable criteria appeared to be a non-deferrable requirement. It seems evident that the discussion of these important issues could not be compressed into the space of a simple article, so it was decided to discuss every aspect of the problems inherent to tracheostomy techniques in detail, with adequate space.

As for the on-line publication, we made this decision for obvious reasons of ensuring a broad and immediate circulation of the book and its content.

In addition, given its conceptual originality, many have been the requests for an explanation of where the idea of this process has come from. Therefore, we have thought it appropriate to dedicate a chapter of this book to the historical background of the technique.

Antonio Fantoni
**History of translaryngeal tracheostomy**

The influence of the practice of positioning tracheal stents

The origins of TLT go back to our activity on the conservative method to treat the obstructive airway lesions, that was illustrated in detail in one of our studies (3). After a gradual enlargement of the narrowed tract of the central airway with probes of increasing calibre, sometimes taking several days to be achieved, surgical tracheostomy was made. After a period of stabilization of the stoma, we proceeded with the insertion of a T-stent, according to the manoeuvres illustrated in figure 2.

![Fig. 2](Image)

**Fig. 2** The technique of enlargement of the laryngotracheal stenosis with probes and the T-stent positioning after surgical tracheostomy

With the same method were placed home-made T-stents with bronchial extension to correct distal obstructions of carina and bronchi (Fig. 3).

![Fig. 3](Image)

**Fig. 3** Home-made T-stents for distal airway narrowing

Many of these cases were paediatric patients in which the ST proved too invasive and loaded with complications, and then we started searching for a less damaging solution. The first advancement was to conceive that the diameter of the external branch of the commercial T-stent could be considerably reduced (Fig. 4), still respecting the function of fixing the body of the stent and providing an emergency route for the oxygen supply.
The new type of stent was prepared by gluing tubes of different calibre together. It allowed us to avoid the tracheostomy as it could be placed with a percutaneous procedure. After transoral dilation with probes of the restricted tract, a rigid metal bronchoscope was inserted. With the leverage of the instrument, a trocar was inserted in the bulging area. Being aware of the coarseness of the piercing manoeuvre, we avoided the risk of tracheal lesions by interposing the oblique opening of the bronchoscope as shown in figure 5A. The wire was then threaded through the trocar and the bronchoscope (Fig. 5B), and tied to the fixing branch of the T-stent. With the help of forceps, the wedging of the stent into the glottis was accomplished (Fig. 5C) and then, with a traction on the wire, the fixing branch was extracted and the final placement of the stent resulted accomplished (Fig. 5D).

The new original method to manage the insertion of the stent inspired the idea of the possibility of positioning a tracheal cannula with the same procedure, as illustrated in figure 6.
Needing a larger channel than that needed for the passage of the branch of T-stent and being biased by our experience on the multiple dilators technique of Ciaglia, we resorted to a series of six cones of increasing diameter, from 3 to 15mm, soldered along a metallic plait at an interval of 15 cm. The last cone was arranged to serve as a carrier of a flexible tracheal cannula (Fig. 7A).

A later modification was the substitution of the final metallic cone with a long cone of soft plastic to make more gradual the tougher ultimate step of the dilation (Fig. 7B).

In a paper in 1993 (4) we communicated the favourable results obtained from a first test of the new technique on six patients: easy performance and, above all, the main convincing advantage, the elimination of the risk of the injury of the posterior tracheal wall, the inherent weak point of all the OITs. The procedure went on to the separation of the cone from the cannula. The subsequent rotation of the cannula was controlled with a telescope inserted into the cannula, in accordance with the same method we still currently use.

The entire procedure was accomplished in apnoea, but the possibility to insert an endotracheal tube (ETT) in each span between two cones, offered enough margin of safety in case of any sort of emergency (Fig. 8).
A case of a 2 year old baby, requiring a tracheostomy for neurological respiratory insufficiency opened the way to a further evolution of the technique.

Realizing that the first 3 mm cone of the chain would have been enough for a small tracheal cannula and the dilation process too coarse, not gradual with a short cone, we thought to taper the plastic proximal end of a dilation artery catheter so as to make a long flexible cone, and to use its mouth for the inflating syringe like a connector for a tracheal cannula (Fig. 9).

This tracheostomy, carried out without difficulties, has taken on important meanings and consequences:
- It represented the first example of tracheostomy carried out by means of a single and flexible dilator. Some years later, Ciaglia adopted this concept in the Blue Rhino technique (5), but he settled only for a semi-rigid dilator, not being possible to use a completely flexible, less dangerous tool, with the Out/In dilation manoeuvre.
- The elimination of spurts of blood caused by the sequence of the removals of the cones, just criticized in multiple dilators technique, persuaded us to streamline our technique and to definitively abandon the cones chain system (Fig. 10).
An important consequence of this changeover was the obliged transition from apnoea to a continuous respiratory assistance during the whole procedure. The first solution was a small cuffed standard endotracheal tube, prolonged with a length of a suctioning catheter to consent the tube to reach the lower third of the trachea (Fig. 11). This passage occurred gradually. At first, this set for manual ventilation was used only in cases with more compromised respiratory function (6) and later it was routinely applied to all patients.

With the one-step dilation, we considered the trial stage of the technique ended and it was time to refine the home-made instruments until then used by entrusting an industry to prepare a kit of needed material.
The commercial kit of TLT

It is supplied by the Covidien Health Care Group in various sizes and its content includes (Fig. 12):

(A) Small Ventilation Tube (SVT)
(B) Reinforced tracheostomy cannula
(C) Cuff inflation line with pilot balloon
(D) Flexible guidewire
(E) Cuffed Rigid Tracheoscope (RTS)
(F) Tracheostomy tube flange
(G) Fixing strip
(H) Obturator
(I) Tracheostomy cannula connector
(J) Scalpel
(K) Respirator/cannula connector
(L) Pull handle
(M) Curved needle

![Fig. 12 The kit of tools](image)

The cannula, right-angle or straight type, is offered in sizes 5.5, 6.5, 7.5, 8.5, 9.5 mm I.D. It is armoured to offer the best O.D./I.D ratio, with a high flexibility to adsorb the traction from the respiratory circuit and to prevent decubitus on the trachea. It is moulded with a cone of soft plastic material which ends with a hollow metallic point (Fig. 13).

![Fig. 13 The cannula in detail. The insert highlights the absence of step between wire and metallic cone](image)

The location of the short cuff at the end of the cannula, besides being requested by the peculiarities of the technique, is very effective in preventing the obstruction of the tube opening in case of longitudinal displacement of the cannula.
The small ventilation tube (SVT), 40 cm long, has a large volume, low pressure cuff to create a perfect seal in the circuit and make possible the delivery of high PIP and PEEP, if requested.

The ventilation catheter is supplied in three sizes: 3, 4 and 5 mm I.D. accordingly to the size of the cannula.

The rigid tracheoscope is made in transparent plastic material with a black tip so as to increase contrast with tracheal mucosa, making its positioning extremely precise. A longitudinal black line indicates the shortest edge of the flute-shaped end.

The needle is curved to facilitate the retrograde insertion. Its tip is rounded to bluntly separate, instead of piercing, the highly vascularized tissues of the neck, and reduce the risk of haemorrhage.

The guide wire is a subtle steel plait with a short segment of steel thread, joining the J-shaped end, that can be cut without been frayed, so that to not compromise the passage of the guide wire through the metallic tip of the cone (Fig. 14).

Methods to perform TLT and division into phases

During the development period of the new technique, we had tested some different ways to carry it out, and, in the end, a method, the basic TLT (BTLT), was preferred and, since then, exclusively adopted and recommended by us. As often occurs in the medical field, and not only here, after the introduction a new technique, in no time modifications are proposed. The ST can be carried out with innumerable modifications, the percutaneous method of Ciaglia has been subject to variations with the aim to bring alleged improvements or, simply, to give a personal mark to the procedure. However, these modifications not always fulfil the requirements that in terms of safety and feasibility the inventor had intended to ensure to his technique.

Ciaglia, for instance, was concerned by the numerous reports of lesions of the posterior tracheal wall, that he referred to a non-strict observance of his original technique, so much so to be compelled, at various intervals, to refresh the basic principles to avoid a loss of credit of his procedure (7,8).

The same has happened to TLT. In fact, after the presentation of the final basic version (9), various modifications were presented. The advantages given by the common innovative method of dilation ensured to these variations a favourable clinical acceptance, but, at the same time, it became evident that they gave origin to some kinds of complications, like hypercapnia, desaturation and technical difficulties which were almost unknown with our basic technique (10).

To clarify this fact, we agreed on the need to analyze the various techniques by breaking them up into the three phases which can be identified in all percutaneous tracheostomies (11).
With this methodology the possibility is reached to carry out a more in-depth comparison, made for corresponding phases, which allows a clearer highlighting the differences, the advantages and disadvantages of each procedure (Table 1).

### Table 1 The phases of the percutaneous tracheostomies

<table>
<thead>
<tr>
<th>Phase</th>
<th>1</th>
<th>2</th>
<th>3</th>
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<tbody>
<tr>
<td>TLT</td>
<td>needle insertion</td>
<td>dilation</td>
<td>cannula rotation</td>
</tr>
<tr>
<td>OIT</td>
<td>needle insertion</td>
<td>dilation</td>
<td>cannula insertion</td>
</tr>
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OIT: Outside/Inside Tracheostomy  
TLT: Translaryngeal Tracheostomy

From this analysis, it has been pointed out that all the TLT practices have an identical phase 2, the In/Out dilation, that gives them substantial advantages over the other percutaneous techniques, whereas the remaining parts of the procedures, the phase 1, the phase 3 and the respiratory assistance, result performed in different ways, which are responsible for the different results and indications.

**The basic TLT technique (BTLT)**

**The phase 1**

A pillow is placed under the head to line up the oral, laryngeal and tracheal axes (Fig. 15).

![Airway alignment](image)
The neck is not hyperextended. With the help of a laryngoscope the rigid tracheoscope of the kit is advanced as far as the vocal cord, a side of the ETT. A light turning on the left of the head and a lateral retromolar entry make the manoeuvre easier (Fig. 16A).

Fig. 16 Retromolar entry (A) and safe exchange ETT/RTS, when a clear view of the glottis is achieved (B)

The change ETT/RTS is carried out when the end of RTS has reached a position adjacent to the vocal cords. With an optimal view of the anatomy (Fig 16B) and the certitude of an easy airway entering, the ETT is removed and RTS is advanced into trachea.

The ventilation is restarted with the cuff of the RTS partially deflated so as not to impede the adjustment of the tube but at the same time such as to allow satisfactory ventilation for the duration of phase 1 up to the replacement of the RTS with the small ventilation tube. Under the endoscopic control of a 0° degree telescope, the tip of RTS is advanced as far as its distal end has reached the space between the selected rings.

The leverage of the instrument, with its opening facing downwards (black longitudinal line downwards), in order to increase the perception outside (Fig. 17), indicates with high precision the external site of the needle puncture. In this way, the operator is not strictly dependent on transillumination and the localization of the external neck landmarks for a proper centring of the needle.

Fig. 17 The leverage of the instrument with the opening downwards
Afterward the RTS is turned 180° (black longitudinal line upwards) to facilitate the insertion of the needle and safeguard the posterior tracheal wall from puncturing. The wire is pushed into the lumen (Fig. 18).

The needle is slipped off, RTS removed and the ventilation catheter (SVT) inserted (Fig. 19A). The existent guide wire greatly helps to not lose the vision of the glottis (Fig. 19B), making easier and surer the insertion of SVT. It should be inserted into the trachea until the marks 24-25 cm, printed on the tube, come to coincide with the incisive dental arch. This corresponds, in the average of adult patients, to a cuff positioned half way between the site of the stoma and the carina. However the certitude of not incurring bronchial intubation is only given by ascertaining the symmetric, cyclical inspiratory expansion of the thoracic cage and the auscultation of bilateral respiratory sounds.

The J-segment of the wire is cut away, exactly at the middle of the connexion segment to avoid the fraying of the guidewire plait that would block the passage of the wire through the cone (Fig. 14). The wire is threaded through the cone and extracted from the lateral slot of the cannula to be joined to a length of suture material, the safety thread. The knot is than pulled inside the cannula (Fig. 20). The patient is ready for the dilation (phase 2).
The safety thread is joined to the guide wire. The knot is then brought into the cannula and stuck in the trap mechanism at the base of the cone.

**The phase 2**

By means of the pull handle, traction is made on the end of the wire and the cone-cannula is dragged through the larynx and neck layers. A pressure is exerted with the fingers tips against the cone coming out, *only to prevent the upward displacement of the neck wall* (Fig. 21).

After the metallic point surfacing, one or two short (2-3 mm) and shallow incisions are made on the ischemic ring of the skin surrounding the cannula, more than to smooth the subsequent rotation of the cannula than to make the exit of the cone easier. The pulling of the cone-cannula out is then continued until half of its length is outside the neck. The cuff inflation line is extracted from inside the cannula and then the cone is separated from the cannula at the lower point of the slot, between the arrows, to obtain a regular ridge of the cannula opening (Fig. 22). The patient is so prepared for phase 3.
The phase 3

A 0° angle telescope is inserted into the cannula as far as the bending of the cannula (shown in the insert of figure 23), permits.

A gradual extraction of the cannula is resumed making the cannula slide along the telescope which is maintained immobile and perpendicular to tracheal axis. When the red colour of the posterior wall appears at the bottom (see insert of figure 24), it means that the turning point has been reached, the cannula is fully straightened and can be rotated. The telescope must not enter the very soft, non-armoured final segment of the cannula for safety purposes.
The telescope is lightly tipped cranially and then the cannula, and only the cannula, is made to slide along the telescope, and advanced into the trachea. The telescope must not enter deeply the tracheal lumen, as it is clearly shown in figure 25. With a further tipping of the telescope the user can highlight the carina and adjust the position of the end of the cannula at a safe distance from the openings of the main bronchi.

The two segments of the cuff inflation line are then connected, the ventilation catheter is removed, the cuff of the cannula inflated and, after the application of the flange, ventilation is recommenced (Fig. 26). Finally, the two ends of the safety thread are knotted to make sure it stays in situ for a few days.
Respiratory assistance of the basic TLT technique

Mechanical ventilation with $\text{FiO}_2=1$, is provided without any interruption throughout the entire procedure, at first with ETT, then with RTS, afterwards with SVT (the small ventilation tube included in the tool kit), and finally, with tracheal cannula.

The small calibre of SVT requires a modification of the setting of the respirator. The increase of the respiratory resistances imposes a slight reduction of the respiratory rate and an increase of the inspiratory pressure to maintain an adequate tidal volume. The PEEP has to be adjusted to the need of each patient with careful control of PEEPi.

Variations of BTLT related to phase 1 and 3

Given the equality of phase 2 in all TLT techniques, in this chapter we describe the most common variations of the phase 1, the phase 3, the respiratory support, and compare them with the corresponding phases of BTLT.

The phase 1: With fibre flexible bronchoscope (TLT/FFB)

It is the most used variation. The FFB is inserted in the existing endotracheal tube (ETT) through the catheter mount access. After deflating the cuff, the ETT is withdrawn until the cuff is outside the vocal cords. Re-inflated, the cuff is moved against the glottis (Fig. 27) and the ventilation resumed.
Selected the point for the needle puncture with the palpation of the relevant landmarks (cricoid cartilage, tracheal rings, and jugular notch) and with the transillumination, the needle is inserted into the tracheal lumen under video guidance to ensure the optimal centring of the puncture and prevent an unintentional injury of the posterior tracheal wall. From this point, the procedure may follow two different ways:

**TLT/FFB Mode 1.** The cuff is deflated and the guide wire is made to run alongside the ETT as far as the oral cavity, from where it will be recovered (Fig. 28).

In figure 29 the sequence of steps is shown for the preparation of the patient to phase 2 of the dilation according to the variation TLT/FFB Mode 1. The advancement of the guide wire outside of the endotracheal tube is a largely chosen method because it offers the possibility to accomplish a more prolonged resistances free ventilation through the ETT, after the removal of FFB, during the period of time required for the connection of the wire to the cone-cannula (Mode 1: Figg.28,29).
1. The connection wire-cone-safety thread performed while the patient is ventilated through the ETT
2. The removal of ETT
3. The insertion of small ventilation catheter

**TLT/FFB Mode 2.** It consists in addressing the wire directly inside the ETT and recovering it at the catheter mount (Fig. 30).

In figure 31 is shown the sequence of steps in preparation of the patient to the phase 2 of the dilation with the variation TLT/FFB Mode 2.
The Mode 2 (Fig. 30, 31) avoids the need of researching the j-end of the wire in the oral cavity, is faster (12) but requires more ability. Indeed, it is not easy, especially in a stout neck, to thread the wire into the opening of the ETT, given that the distance existing between the needle tip and the end of ETT is greater than that between needle and RTS opening in the BTLT method (Fig. 32).

**Rigid vs. flexible bronchoscope**

The use of rigid instruments represents the main technical difference between BTLT and its variants. We advocate this method as it demonstrated substantial advantages in the previous our experiences in other techniques, in particular, at first, in the surgical tracheostomy and later in Ciaglia method.

- In the ST procedure, we had noticed that a rigid bronchoscope, by pushing up the trachea, enabled us to practice a shorter incision of the skin and a more limited dissection of the tissue, with following reduction of the local trauma and bleeding. This method proved to be essential in young patients.
- In the Ciaglia method the introduction of the tracheoscope has represented our unprecedented useful modification of the original Ciaglia technique. For this special indication, we prepared a tracheoscope by shortening a standard metallic bronchoscope and applying a rubber cuff (Fig. 33), the precursor of the plastic RTS of the TLT kit.

![Fig. 33](image)

**Fig. 33** Our tracheoscope: a shortened metallic bronchoscope with a reported cuff

Indeed, we discovered that, besides the advantages offered in the insertion of the needle, quite similar to those we would have noticed afterwards in TLT execution, in the Ciaglia technique the rigid scope proved to be very useful also in phases 2 and 3. In fact, it proved to be able to prevent the collapse of the trachea under the pressure of dilators and cannula insertion and the consequent risk of damaging the posterior tracheal wall. Some years later, the usefulness of rigid bronchoscope in the Ciaglia method, especially in the patients with expected difficult airway, high risk of bleeding and during the learning period of the technique, was confirmed and advocated also by others (13-16).

To better ensure these substantial advantages Klemm (17), Otolaryngologist of the Dresden Faculty, has built a particular bronchoscope suitable for all the percutaneous techniques.

- In BTLT, on the contrary, the usefulness of the rigid endoscope resulted limited to phase 1, because there are no indications for the remainder steps of the procedure but, nevertheless, its advantages are essential:

  - - the combination of the tracheoscope with a telescope connected to a video camera makes the centring of the needle easier by the stiffening and fixing of the trachea.
  - - RTS allows only one operator to accomplish both the endoscopy and the needle insertion.
  - - a levering manoeuvre on RTS (Fig. 17) facilitates the external location of where to insert the needle, that corresponds to the precise previously selected inter-cartilaginous space. In this way the proper site of the needle insertion can be found even in absolute no tracing of the external landmarks.
  - - in the short neck (cricoid-sternum notch distance ≤ 1 cm) with trachea deeply sunk in the chest, the levering manoeuvre allows the user to extract the trachea, for 1-2 rings and practice the needle insertion in a more suitable level. The RTS levering is the equivalent of the hook that allows in the ST to pull up the trachea.
  - - the leverage of the instrument reduces the thickness of the neck wall enhancing the transillumination.
  - - there is a complete protection of the posterior wall of the trachea by the long side of the opening of the RTS and the fact that the operator can precisely target the end of the needle inside the instrument (Fig.34A).
  - - with the RTS firmly wedged in the trachea and the wide gap between RTS lumen and the telescope, the continuity of airway control and the adequacy of ventilation are safeguarded.
- there is the possibility to quickly and thoroughly clean out large amounts of tracheal thick secretion which cannot be suctioned by the FFB.

Regarding the use of FFB some authors affirm that it has a peculiar indication in the cases of difficult airway approach and known, or potential, cervical spine instability because it does not require manipulation or movement of the neck (18). However, this flexible tool involves some drawbacks:
- unlike the widespread opinion of the easy of its use, FFB, non rarely involves difficult manoeuvres and unsatisfactory vision, which can not be solved except by long-running experts.
- the fiberscope does not ensure enough support to the anterior tracheal wall. The tracheal squashing predisposes to puncturing of the posterior tracheal wall (Fig. 34B).
- there is the risk of puncturing the cuff of ETT and the FFB itself.

![Fig. 34 Needle insertion protected by RTS (A) and tracheal squashing with FFB method (B)](image)

- in the cases in which the transillumination is not working and the external laryngeal marks are not traceable, the insertion of the needle becomes rather complicated.
- the trachea is mobile, shifting laterally and downwards. In this condition the retrograde insertion of the needle may raise technical difficulties (19). Many puncture attempts may be frequently required before reaching a proper centring of the needle.
- there are risks to lose the airway control.
- the FFB inside the ETT induces high flow resistances that hinder the ventilation as it has already been noticed in other percutaneous techniques (20).

**Contraindications to TLT/FFB**

All these above listed disadvantages may have significant consequences, as those of creating contraindications to TLT itself in some types of patients, when FFB is used, as:

- paediatric patients. With a small and very collapsible trachea, the probability that the needle rips up the posterior tracheal wall is so elevated that FFB variation must not be recommended, whereas RTS has an elective indication.
- the severe ARDS cases. The unstable sealing of the ETT cuff, barely leaning against the vocal cords, and the increase of the flow resistance from the FFB, make the circuit non fitting to supply high inspiratory pressures and PEEP during all the time necessary to the centring and insertion of the needle. Therefore, TLT/FFB is not advisable in the patients with severe lung damage, who don’t tolerate even short periods of inadequate ventilation and, especially, the fall of PEEP.
patients with short, stout necks and untraceable cricoid. TLT/FFB is equally non advisable for the predictable difficulties that the operator has to face in the needle insertion. It should be noted that this situation is shared by all other PDT when FFB is adopted. Indeed, in a study of 497 patients undergoing the Ciaglia method, of 33 cases of short neck, 9 were diverted to ST (21) largely for the difficulties created by the depth of the trachea from the skin surface that the authors consider an important factor in determining whether to proceed or not with PDT.

The weird resistance to the use of rigid instruments

Despite these drawbacks, we have to note that TLT/FFB is a very widespread system among the TLT users, first, because FFB is more traditional, being used in all the other percutaneous techniques, and second, because it is considered undemanding as it avoids one change of the tube, the substitution of ETT with RTS.

In our opinion, if a widespread concern of changing an endotracheal tube reigns in ICU, because it isn't considered a possible difficult manoeuvre but a potential dangerous procedure, it means that the medical staff does not have adequate competence in the airway control and cannot assure a sufficient protection to the in-patients in case of accidental decannulation or other respiratory emergencies. In truth, this situation has been highlighted by Walz (22) as a relatively common handicap of the intensive areas world-wide. In a study, he pointed out that, although in the intensive ward the respiratory emergencies are more severe than those that occur in an operating room, the caregivers are not always capable of adequately facing them. Therefore, he believes it would be more rational to entrust the anaesthetist for their more continuous and specific preparation on airway control.

But the main influential reason of the large preference for the FFB methods is a general reluctance to use rigid instruments due to the overrating of the difficulties connected with their use. In over four hundred cases of basic TLT, in which RTS is a fixed instrument of phase 1, we have not reported any complications. In 33 patients, we met some difficulties of insertion but not so insurmountable to impede the prosecution of the procedure. In some cases of cranio-facial distorted anatomy, RTS made the airway approach even easier. It is possible that these results are biased by our great familiarity with rigid instruments due to our vast experience in the conservative treatment with T-stent of airway obstruction (3), especially in smaller children, where the rigid instrument is mandatory.

On the other hand, also other TLT users favour employing the rigid endoscope. In the centres where both methods are used, the FFB results limited to about 20 % of the cases in which a difficult approach to the airways is founded (18,23,24).

It is obvious that to use rigid instruments one needs some training to acquire a suitable handling, but their use extends to so many other important applications that it is not acceptable that some experts are not present in an intensive ward. In fact, one wonders how to provide for a removal of a foreign body, a dilation of an unexpected narrowing of the central airways, a suction of a major bleeding without the use of a rigid bronchoscope.

Finally, the possible remark that telescopes are not always available in a smaller hospital is not acceptable today, seen the boom of endoscopic surgery and the opportunity to borrow instruments from other specialists.

This said, however, we wish to make clear that our advocation of the RTS is not to be interpreted like an attempt of the inventor of supporting his own technique. The phase 1 with RTS is not an exclusive peculiar part of TLT. Indeed, RTS, as above mentioned, proves to be very advantageous in all OITs so that its larger diffusion has to be expected also in these techniques, at least, for the treatment of the most challenging cases.
The phase 3: The variations

To facilitate the comparison, the most practiced methods of performing phase 3 of TLT are gathered in figure 35.

**A. With internal control, through a telescope inside the cannula**, the peculiar method of BTTLT, the sequence of which is illustrated in more detail in figures 23, 24, and 25.

**B. With the obturator and translaryngeal endoscopy**. The straightening and rotation manoeuvres are performed by using the obturator of the kit. All the shifting of the inside length of the cannula are checked with direct translaryngeal endoscopy. SVT is not always used.

The obturator is inserted perpendicularly in the cannula as far as the curvature permits. Making the cannula slide along the obturator, the extraction gradually is resumed until the cannula appears fully straightened at the translaryngeal endoscopic view which represents the turning point of B method, illustrated in the circle. The cannula is then rotated, and with a slight cranially tilt of the obturator, it is advanced into the trachea **while the obturator tip remains fixed outside the tracheal lumen**.

**C. With the obturator without endoscopy**. This method is rather widespread since it avoids the costs and loss of time of the endoscopy. The turning point is established when, during the extraction of the cannula along the obturator, the ridge of the cannula reaches the handle of the obturator (arrow).
Once straightened, the further adjustment of the cannula proceeds as in B variation. SVT is rarely used.

D. Without the obturator and with endoscopy. The arrangement of the cannula is made with bare hands, without instrumentation, according the method adopted by us in the tracheal stent insertion, illustrated in figure 2. Translaryngeal endoscopic control results to be mandatory. The turning point is similar to the one of method B, without the presence of obturator. The small ventilation tube is not cuffed.

The phase 3: Basic technique vs. variations

The internal control we have adopted in the basic TLT (Fig. 35A) offers some advantages. The telescope inside the cannula allows a more direct and millimetric control of the shift of the internal tract of the cannula and the avoidance of complications. The patient is properly ventilated by the SVT and the manoeuvres can be performed quietly and gradually. Another advantage consists in the possibility that a single operator accomplishes both the endoscopy and the adjustment of the cannula, with the video mode indicated for training and documentation.

On the contrary, the method with the obturator and FFB (Fig. 35B) requires two people, one for the moving of the cannula and a second one for the translaryngeal video endoscopy, indispensable to guide the operator. In addition, secretions, the movement of the vocal cords and laryngeal oedema may hinder the endoscopy.

The variation without endoscopy represented in figure 35C, although supported by someone (25), is not recommendable because the absence of a clear view of what is happening inside the trachea may expose the risk of accidental decannulation.

The D mode of figure 35, the placement of the cannula without inner stiffening tools, like the obturator or the telescope, follows the same pattern of our method of T-stent insertion (Fig. 2), and was proposed by Ferraro (26) with the aim to eliminate the risk of the inappropriate use of rigid tools. It can be considered acceptable, provided that the shifts of the internal segment of the cannula are thoroughly checked with trans-glottis endoscopy. However, in the cases of patients with abnormal thickness of the neck wall, this method may encounter some difficulties.

In summary, the A mode of the basic technique demands a more accurate execution but offers the complete control of the manoeuvres, that is, the thorough prevention of accidental decannulation and false passage.

Modes of respiratory assistance in BTLT variations

In phase 1 the type of respiratory support used in the TLT/FFB variations is similar to that adopted in the OITs. The existing ETT is withdrawn in order to clear the affected section of trachea at the stoma level and FFB, inserted in its lumen, ensures the endoscopic control of the manoeuvres. This method offers the advantage of avoiding changes of tubes as in BTLT, but involves several drawbacks:

- If the ETT must be withdrawn from the trachea and then the inflated cuff is leaned against the vocal cords, the seal of the respiratory system is very poor so that this procedure results unsuitable for the patients who need high PIP and PEEP.
- If the tube is not completely removed from the trachea, the cuff inflation provides a perfect fit, but the risk of cuff puncturing and the risk of piercing the end of the tube become rather high.
- The presence of the flexible bronchoscope inside the tube creates a considerable respiratory resistance and impairment of ventilation.
In phase 2 and 3 the respiratory support can be managed in different ways:

- Use of SVT (Fig. 29 and Fig. 31). The ETT is withdrawn and replaced by SVT which removes the above mentioned respiratory drawbacks. The patient therefore can be adequately ventilated till the insertion of the tracheal cannula.

- Partial use of SVT with its removal before phase 3. It is a practice to facilitate the rotation of the cannula and avoid possible stretching of the posterior tracheal wall due to the contemporary presence of the two tubes.

Indeed, with the more current combinations between SVT/cannula, like 4/7.5 I.D., 4/8.5, 5/8.5 there are no grounded reasons for the earlier removal of SVT. Stretch damages of the trachea have never been reported (27). For us, the removal could have a certain justification only in the case of use of 9.5 I.D. cannula and ventilation tube of 6 I.D. mm, adopted by someone (28). Theoretically, in these circumstances an overlapping of bigger devices could strain the pars membranacea, and in the unfortunate coincidence of the presence of asymptomatic narrowing of the trachea, even more severe injury might occur. But then, it is to wonder why to use a big cannula when Ciaglia (1) himself had advocated, already a few decades ago, the use of small cannulas, not superior than 8 mm I.D., which are more than enough for adults of any size. In addition, smaller cannulas have the advantage to prevent the complications deriving from a large hole in the neck, as infection, tissue breakdown and difficult spontaneous closure.

Even if some Authors have demonstrated that the interruption of ventilation does not involve great risks since the apnoea time, taken by the accommodation of the cannula, is less than a minute (12,29,30), the removal of SVT is not recommendable because, if a longer period of apnoea is accidentally required, deadly hypoxic complications occur. This risk is especially serious when an abnormal anatomy shuts off the possibility of a timely intubation. It is easy to guess the remarkable difference of risk existing in case of decannulation between patients with and without a full airway control. Milligan (31) is against the removal of SVT, precisely because the risk of not being able to quickly re-intubate a patient for the presence of laryngeal oedema, very frequent in subjects who have previously undergone prolonged tracheal intubation. Walder (25) reported two cases of decannulations, resolved uneventfully by a second TLT while the patients continued to be ventilated with SVT.

- Use of jet ventilation or tracheal open ventilation (TOV) (26) with non-cuffed catheter is a method with limited ventilatory performance as there is not a possibility to provide high PIP and PEEP. The jet support may be adopted only if there is the availability of appropriate equipment with efficient control of the respiratory parameters to prevent complications from hypoventilation and lung over-distension. Manually cycled method is not recommended for a high risk of pneumothorax as per our (9) and the experience of others (32).

- Use of laryngeal mask. TLT can be carried out as well also with the same airway device adopted in OITs in some centres. There are no published experiences on TLT, except communications on its use in cases of accidental decannulation or difficult approach to the airways (33,34).

From the analysis of ventilation methods used in TLT variations, it appears that, with the exception of the non-interrupted use of SVT, all remaining have certain weaknesses that prevent the practitioner from getting a full adequacy of respiratory support.

In BTLT, the RTS provides a ventilation without resistances and the subsequent use of SVT without interruption is able to satisfy the respiratory requirements in every moment and in every type of patient (9,18,23) including the most severe ALI/ARDS (35), provided of course that the parameters of the respirator are adapted to the presence of higher resistances, in line with the elementary concepts of respiratory physiology that each intensivist should well know (see page 16).

Adams (23) affirms that the only few episodes of desaturation observed in his cases studies, were due to a bronchial wedging of the SVT caused by the erroneous placement of the tube and negligence in ventilatory control.

In OITs, the small ventilation tube is not widespread, but some users have demonstrated its undoubted advantages. Fischer (36) found that the small catheter ensures a more stable control of the
airways and a more effective ventilation than the standard methods used in OITs, the endotracheal tube retracted at the vocal cords level or the laryngeal mask. This opinion is also shared by White who has defined this technique “Suspension Laryngoscopy-Assisted Percutaneous Tracheostomy (SL-PDT)” (37).

Since the small tube can offer undoubted advantages we cannot understand why FBB/TLT and OITs users may still accept the impending risk of desaturation and aspiration due to the unstable respiratory control, not to incur the risk of changing the tubes, indeed truly negligible for operators well trained in airway management, like all intensivist physicians should mandatory be.

Besides the useless risks which the patients are exposed to, our aversion to all sorts of unsuitable respiratory support is also justified by the feeling of insecurity in which the team is compelled to work: when a sudden emergency happens, hastening brings about anxiety, technical shortcutting, inaccurate manoeuvres and consequent complications.

**Advantages of the In/Out over Out/In dilation**

The unconventional mode of carrying out the stoma is the most exclusive technical feature of the TLT method that provides the following main advantages over OITs:

**First. The elimination of the risk of lesion of the posterior tracheal wall and carina during the dilation**

It was the first objective we had intended to achieve with a new safer technique, after having seen, in the course of our experience with the Ciaglia method (2), the continuous presence of the risk of this complication. Since the lesions of the rear tracheal wall are inherently tied to the Out/In mode of accomplishing the dilation, and therefore, expected to occur in all OITs also with skilful operators and endoscopic control (38-40) it should be considered as a kind of original sin of these techniques. The PercuTwist itself (41), promoted as technique with less risk of tracheal lesion than the other OITs, cannot be compared with TLT, because it is penalized by the presence of two weak points which make the difference. The first one, until the tip of the screw dilator is not held firmly between two tracheal rings, the pressure on the anterior tracheal wall, with consequent wall introflection and major risk of posterior wall damage, is unavoidable; the second, when at the end of dilation the screwing device is totally inside the tracheal lumen, its tip results in being too close to the posterior tracheal wall even with the elevation of the anterior tracheal wall (42). However, the most puzzling aspect of PercuTwist is the use of a rigid and strongly pointed dilator, even after the warning issued against them by Ciaglia in 1999 (43).

Another cause of the tracheal lesion in all OITs is the loss of visual control when the tracheostomy tube, loaded with the dilator, makes the anterior tracheal wall collapse and in this way facilitates the tear of the lower tract of the posterior tracheal wall and carina. Cases of this origin, with a lesion near the carina were noticed with PercuTwist (44) and with Blue Rhino (45), but it is possible in all OITs. This kind of more distal complication is especially detrimental because it impedes the possibility of trying a conservative treatment of the tear with simple intubation that in the higher lesion often avoids surgical repair.

On the contrary, TLT has reassessed this problem with the elimination of the risk of tracheal damage (19,46) that represents the most valuable advantage of this technique over other percutaneous tracheostomies (30,42). In fact, once the bronchoscopy confirms the correct positioning of the metal guide, in phase 2 the cone-cannula runs an obliged path (Fig. 21), so that the paratracheal misplacement is almost impossible (30) and the dilation becomes so sure that it does not even require endoscopic control.
In phase 3 the more delicate manoeuvre of adjustment of the cannula requires more prudence and carefulness, but the thorough observance of a few precautions is sufficient to avoid unwanted events. Large case series of patients don’t complain about any tracheal damage (18, 23). In over four hundred BTLTs we have never observed not even a single case of tearing but also, and even more significant, of simple abrasion of the posterior tracheal wall. Despite these favourable claims, the reporting of cases of tracheal lesions (47,48) goes to show that no technique can be considered without risks. However, these reported complications are attributable to modifications of the basic technique, the only one that assures their complete prevention thanks to the greater level of intrinsic safety compared to its variants. Among the most involved modifications, we find:

- The use of 9.5 mm I.D. cannulas. Besides the lack of its necessity, it considerably increases the danger of over-distension of the pars membranacea.
- The use of the rotation of the cannula with the obturator. It is a TLT variant which does not always ensure full endoscopic control of the manoeuvres, favouring the onset of complications.
- In certain cases the tracheal lesions may be traced back to the lack of SVT, or the inadequate reset of the respirator with consequent hypoxemia, as may be inferred from their occurrence reported in these studies (47,48). In emergency situations, that generate moments of tension and force the operator to rush manoeuvres, it is not surprising that tracheal lesions happen. Another point to make clear is that the major risk in the execution of phase 3 is inherent not so much to the straightening or rotation of the cannula, from which it can derive at maximum one accidental decannulation, as to the next caudal advancement of the cannula. As you can see in figures 25 and 35, only the cannula is to be inserted into the tracheal lumen, an absolute requirement that makes the BTLT simple and safe. On the contrary, if the whole obturator/cannula is forcibly pushed caudally, besides representing a completely unnecessary act, it means running the risk of injury of the posterior or lateral tracheal wall, depending on the inclination given to the tools. In these circumstances, TLT creates a paradoxical complication with a characteristic Out/In mechanism, in full contrast with the assumptions that have inspired the creation of our technique.

Second. The creation of two opposing pressures on peristomal tissue
The extraction of the cone-cannula necessarily demands a manual backpressure by the operator to avoid the upwards dragging of the neck wall and the consequent stretching of the anatomical structures. This juxtaposition of forces causes a strong compression of the neck tissue which results in a series of remarkable advantages:

- unlimited tractions can be practiced on the guide wire
Any degree of dilatational resistance can be overcome without incurring any side effect. Paradoxically, the higher are the resistances, the lower is the tissue stress and the more efficient is the haemostasis by compression. In contrast, in OITs, an abnormal toughness of the neck wall redoubles the likelihood of unwanted consequences.

- the local trauma is reduced to minimal levels
The cone-cannula, passing through a layer of peristomal tissue extremely compacted by two opposite pressures, forms a very regular channel, without lacerations and fringing. It is worth noting that this method is based on the same principle that craftsman has exclusively adopted since the dawn of time for making a clear-cut holes in the skin or other soft materials with a punch or similar tools (Fig. 36). And it is curious to note that if both the physician and the craftsman want to obtain the best result, they have no alternative methods.
- the maintenance of the integrity of the anterior wall of the trachea

The non-traumatic dilation of the anterior tracheal wall is one of the best inherent advantages of TLT over the Out/In percutaneous and surgical techniques (18), where luxation and disruption of the anterior tracheal wall heavily affect its barrier function. Indeed, in TLT, the integrity of the anterior tracheal wall ensures a complete and strong hold of the tracheal window on the cannula, with the following advantages:

- a wiping effect on the cannula surface during its extraction that averts the transfer of polluted secretions from tracheal lumen to the pretracheal space and the subsequent stomite. If one watches endoscopically the step of TLT dilation, it will be evident what extraordinary cleansing action the choking ring formed by the anterior tracheal wall can exert on the surface of the cone-cannula, before it enters the pretracheal space (Fig. 37).

To support this mechanism, there are large experiences that have shown that the risk of the increase of infectious complications of the channel from the oral passage of the cone-cannula, as one may be led to expect at first sight, is an unsupported worry. Indeed, the incidence of stomite in TLT procedures is similar or lower to the one of other current trachestomies (30,49-51).

- an effective barrier against the passage of pressurized gases and consequent emphysema of the neck.

It seems useful to highlight the essential role, strangely rather neglected so far, of the tightness of anterior wall in the prevention of some kinds of complications of the tracheostomies, especially if

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Fig. 36 The different results achieved with a hole-punch and with an awl on front (F) and rear (R) surfaces of a soft leather object

Fig. 37 The approach of the cone to the anterior tracheal wall (A), its wedging (B) and the cleansing effect on the cannula surface produced by the strangling rim of the anterior tracheal wall opening (C)
compared to the overestimation of the importance given to the barrier effect provided by the rim of the skin. If this topic is analyzed without the prejudice that the infection of the stoma comes from outside and should be prevented with a pack of gauze soaked with disinfectant, it would be evident that a strict sealing at skin level is only advantageous in TLT, whereas it represents a source of risk if not associated with the full sealing of the anterior tracheal wall, as occurs in both OITs and surgical technique (Fig. 38).

![Fig. 38](image)

**Fig. 38** The consequences of the strict adherence of the skin around the cannula in the presence of sealing (TLT) or leakage (ST-OITs) of the anterior tracheal wall

In fact, between the latter two techniques this risk is more pronounced in OITs as the skin opening in the ST is usually more gaping, so that the accumulation of infected material results less likely. When, conversely, ST is performed with small skin incisions or intentional narrowing of the stoma with sutures, this technique incurs an increase of the mentioned complications. In our experience with ST, on many occasions we had to widen the breach to drain peristomal abscesses, so that, at the end, we decided to prevent complications by systematically leaving a free outpouring of the secretion.

- **the pure divarication of the tracheal rings**
  The In/Out dilation and the application of an external counterpressure impede the deformation and fracture of tracheal rings (Fig. 39).
  The OITs are charged by a rather high rate of ring fractures, and it may not be otherwise because during the insertion of various dilators and cannula, a strong pressure is applied on the most critical part of the ring, the middle tract of convex surface of the cartilaginous bow. For Dempsey the percentage of this complication is underestimated (52).
  In autopsies, multiple comminute fractures of the tracheal rings, associated to severe mucosal injury of the anterior tracheal wall, were found by Van Heurn (53) in 11 of 12 cases of the Ciaglia method and by Hotchkiss (54) in 5 of 6 cases of Blue Rhino.
High percentage of ring fractures was found in Blue Rhino also by others (42,52). Rotating dilation procedure has the same damaging effect (42) and the problem is not negligible whether the inventors themselves denounce a frequency of 8% (41). The recent balloon dilatation tracheostomy seems not to be able to cause fewer complications in terms of ring buckling and injury in comparison with the other OITs (55).

Klemm (56) who thoroughly investigated this kind of complication affirmed that it is judicious to immediately reposition the bigger displaced fragments of rings to eliminate the risk that displaced fragments can be epithelialized and narrow the tracheal lumen. The smaller fragments and tissue debris should be removed.

A very low tissue trauma and the lack of a true insertion of the cannula are the substantial advantages of TLT which explain the absence in literature of ring fracture reports.

- **the blood vessels are not torn or avulsed**

With TLT the manual counter-pressure when pulling the cone-cannula through the stoma, reduces the shear forces and injury to other anatomic structures so that the dilation manoeuvre involves only a limited peristomal area of tissue.

In contrast, with OITs the strong pushing or rotating effort to insert dilators and cannulas generate straining of tissue which can be transmitted even far from the stoma. A case of death, caused by an avulsion of the right subclavian artery displaced cranially by a fibrosis that followed a previous right partial thyroidectomy, is described by Shlugman et al. (57) as a complication of a Blue Rhino tracheostomy. They attribute the incident to the above mentioned tractions acting on the vessel blocked in an anomalous position, and therefore, they highlight the hazard that PDT might incur in presence of vascular anomalies.

- **no obstruction on the venous return of the neck vessels**

It is an exclusive advantage of TLT, which eliminates one of the main causes of ICP (intra cranial pressure) or CPP (cerebral perfusion pressure) disturbances in the patient with intracranial pathologies (Fig. 39A). Combined with adequate and non-interrupted ventilation that prevents hypercapnia and hypoxemia, as ensured in the basic technique, TLT has proven not to alter ICP/CPP in the majority of patients with intra-cranial lesions (58). On the contrary, in OITs, the compression of the neck vessels during the dilation manoeuvres and tracheal cannulation, and the frequent impairment of the ventilation, especially in cases of critically ill respiratory patients, may create unfavourable conditions (Fig. 39B).
Third. The elimination of the traditional insertion of the cannula

The TLT mode of dilation extends its benefits also to phase 3, through the annulment of the usual insertion of the cannula and its complications, because at the end of dilation the cannula is already adjusted in the tracheal lumen. In this way, two important benefits are obtained:

- no additional tissue trauma

It is difficult to imagine what high resistance the small step of the rim of the cannula that does not fit tightly on the appropriate dilator, and the thickness of the deflated cuff may exercise when the cannula is pushed through the narrow channel in the neck wall. Consequently, very often in all OITs, firm pressures are required to advance the cannula-dilator complex into the tracheal lumen.

Difficult insertion of the cannula means the increase of the stretching of the neck layers, ring fractures, tracheal tear and hypoxemia when repeated attempts are required. This phase of the OITs is properly judged to be at risk (59).

In the Ciaglia method, difficult insertions are reported just in the presentation paper of the technique (1), and by others, especially in cases of subcricoidal stoma (29) and high tissue resistance (60). High incidence of these complications (9 out of 36 patients, with consequent 4 false passages), was observed also by Gysin et al. (13).

Hazard (61) thought to lower the resistances by means of cannulas with the distal end bevelled and sharply tapered, to allow it to fit closely against the obturator and to make the insertion easier. This measure was applied also in occasion of our experience with the Ciaglia method (Fig. 40).

![Fig. 40](image)

The rim of the cannula is tapered (arrow) to reduce the step on the dilator. The ends of the dilators show the effects of resistances encountered during the creation of the stoma

The Griggs technique, compared with the Ciaglia method, showed much higher difficulties of the cannula insertion (62).

With Blue Rhino, Bewsher (45) registered 12 difficult insertions and a case of rear wall tracheal tear out of 36 cases. To make this pitfall of the technique more acceptable he suggests accomplishing a blind dilation of the fresh channel by spreading the pretracheal tissues in both the vertical and in the horizontal planes with a forceps. However, he admits this manoeuvre reduces the resistances of the insertion but substantially increases the risk of damage to pretracheal structures and turns a simple dilatational procedure in a more complex two-stage one, with possible complications in both of them.

Always in Blue Rhino, also Fikkers (63) agrees on the need of a deep blunt dissection of the cervical tissue, anterior to the trachea. As a consequence of a difficult cannula insertion, even a tracheoesophageal fistula is reported (64).

PercuTwist involves difficult insertion as well, from 8 (41) to 25% (42). One of the possible reasons would be the greater force that the dilation in rotation requires for the complete dilation of the stomal passage, which makes the progress of the cannula difficult (65). Having discovered that a tear of the
posterior tracheal wall was provoked by a forced insertion of the cannula during a PercuTwist, Thant (44) recommends being cautious in performing this manoeuvre. Regarding Blue Dolphin, an almost five times greater incidence of difficulties than Blue Rhino was found by Cianchi (55).

In the figure 41 is showed the great difference of the invasivity of the two opposite methods.

Fig. 41 Different impact on the local trauma between TLT and OITs in phase 3

- the elimination of bleeding from the free channel interval between dilator extraction and cannula placement

It is the second benefit that consists in the elimination of possible splashes of blood that flow from the just formed stoma and free from the tools, which usually dab the haemorrhage. Since in a high percentage of cases, the insertion of the dilator causes tearing of blood vessels, sometimes of large diameter, it is clear the advantage, offered by TLT, of maintaining the tissue compression uninterrupted to avoid this source of bleeding. In our experience with the Ciaglia method, this occurrence was sometimes of substantial proportions and, if nothing else, always not aesthetically pleasing (Fig. 42).

Fig. 42 In OITs the free interval of the stoma between dilator’s removal (1) and cannula insertion (2) as cause of bleeding

In Table 2 it is shown the global view of the advantage offered by the In/Out dilatational manoeuvre which allows us to perform the technique even in some kinds of patients normally not recommended for OITs.
The wider range of indications provided by TLT dilation

- No limitation for the most severe cases of coagulopathies
Thanks to minimal trauma and the utmost adherence of tissue to the cannula, in TLT the blood losses are absent or negligible. When they occur they are calculated in drops. Numerous are the studies which evidence TLT as the method of choice in severe coagulopathies (18,25,66,67).
Since the first clinical TLT experiences described in literature, it was evident that there is a possibility to carry out the technique in severe coagulopathy without any previous attempts to correct it (68).
For Konopke (30), the gentle dilation of tissue, the blood vessels not torn but only pushed aside, and the strong and continuous compression of the pretracheal layers, make TLT particularly suitable for patients with an increased risk of haemorrhage.
Sharpe (18) in a study of 340 patients, of whom at least one half with bleeding diathesis, observed two cases with a loss of about 5 ml of blood during the dilation and rotation of the cannula, while the only larger bleeding, stopped with tissue compression, was provoked by the needle insertion, a phase non strictly peculiar to TLT as we mentioned previously.
However, better than a mere report of a series of undifferentiated cases, a detailed description of an example of extremely severe coagulopathy can sometimes give a more convincing idea of the effectiveness of a procedure. Byhahn (67) described the case of a patient with uncontrolled haemophilia who underwent TLT with an impressive absence of external and intratracheal loss of blood.
We too can cite a patient, judged unfeasible with ST by cardiosurgeons, who copiously bled after the accidental removal, during the disinfection of the operatory field, of a small crust, formed on the neck in the site of a previous subclavian vein cannulation, that required a prompt cauterisation. Afterward, the TLT procedure was completely bloodless. Only after two days, at the loosening of the tissue adherence on the cannula, some bleeding appeared that, however, was easily controlled with a compressive medication placed under the shield of the cannula.
This is an interesting case, since it faithfully reproduces the pattern of all other patients with similar pathology: possible minimal or no blood loss at the needle insertion, no bleeding in phases 2 and 3 thanks to the exclusive presence of blunt manoeuvres, a possible start of oozing that may occur after 24-48 hours with the release of the tight tissue adherence to the cannula, and easily stopped bleeding with local compressive medication. In other words, the TLT is always feasible, and this is a great
advantage for a patient in whom the tracheostomy cannot be deferred, whereas the post-procedural period does not bring significant problems of bleeding control thanks to the minimal intraoperative tissue trauma.

Given that “minor” bleeding (commonly defined as loss of 25-100 mL, 3-5 soaked swabs, or bleeding controlled by digital pressure) is the most frequent complication in percutaneous techniques (69), with an incidence ranging from 4 to 14% (52,63) in the Blue Rhino, as to mention the most widespread technique, it is very comforting to be able to rely on TLT, a bloodless procedure.

- **Children and young patients**
The high pliability of the trachea in children and young adults may result, in OIT techniques, in total compression of the tracheal lumen during needle puncture and dilation. Besides the temporary respiratory obstruction, the introflection of the anterior tracheal wall also increases the risk of damage to posterior tracheal wall. These problems can be avoided using TLT. However, we should point out that only the basic technique has all the prerequisites to provide a very reliable method for children, especially for the smaller ones, where the rigid instruments are mandatory. We performed TLT also on babies, using a metallic bronchoscope and small cone-cannulas, provided out of commerce by the industry, with favourable results in terms of low local trauma, no bleeding and negligible postoperative pain (70). We refer the reader to our study on surgical and percutaneous tracheostomies in children for wider acknowledgements (71).

- **Pretracheal thickness, obesity**
Among patients with a thick neck wall, the obese represent the great majority but it is to be reminded that obesity does not always involve pretracheal thickness and relevant major procedural difficulties, as we too have observed in our clinical experience. Dawson (73) points out that the neck circumference to height ratio is more revealing the difficulty of a tracheostomy than the BMI over 30 kg.m\(^{-2}\), a threshold commonly used to define the obesity condition. Therefore, the studies on this topic should make a diversification of the cases, so as not to incur statistically disguiding conclusions.

Nevertheless, an abnormal pretracheal thickness is a condition that increases 4.9 times the risk of complications in every type of tracheostomy (74). OITs are particularly challenged by this abnormal anatomy. There are great technical difficulties of giving direction and depth to the needle, dilator and cannula. The need of strong pushing efforts for increased resistances to the dilation manoeuvre and cannula insertion increases the risk of bleedings, false passages, and tracheal damage. The frequent obscured landmarks may constitute a supplementary problem. All together these drawbacks may make the need for the conversion OITs/ST more frequent.

Furthermore, one can consider the issue of difficult respiratory support. In obese patients there is the strong tendency to lung collapse, that can only be contrasted with high PEEP and an increase of the inspiratory pressure, which the usual systems adopted in OITs to ventilate, with the cuff of ETT only just leaning against the vocal cords or laryngeal mask, are not able to provide. The risks of the intervention in obese patients is highlighted by Morgan (75), that affirms the only way to reduce the risk of the percutaneous techniques (with reference to OITs) in patients with short fat neck and unidentifiable neck anatomy is to kindly ask an ENT (otolaryngologist) colleague for a surgical tracheostomy. That the problem is not immaterial, it is also shown by the proposal to practice even a preliminary removal of the fat mass that hampers the airway approach (76).

On the contrary, in patients with pretracheal thickness, TLT, especially the basic technique, proves to be the most appropriate method, for various reasons:
- once the needle is placed in the proper position and the guide wire is inserted, the rest of the TLT procedure becomes much easier than it might be in the case of an open tracheostomy (18).
- pivotal is the role of the mechanism of the two opposite pressures which compacts the neck layers, makes the neck wall thinner and reduces the tissue stretching and lacerations.
- the In/Out dilation does not need a preliminary evaluation of the thickness of the pretracheal layers and the particular nuances in the instrument handling demanded by OIT techniques, since the magnitude of the thickness of the neck wall does not influence dilation.
- in phase 3, the simple adjustment of the cannula helps to maintain the whole tissue trauma of the technique low. In particular, the opening on the anterior tracheal wall is able to supply, through a strong adherence on the cannula, an efficient sealing effect, which we quoted above (Fig. 37). This condition is particularly useful in obese patients because the contamination of the pretracheal space from tracheal secretions tends to spread easily and create pockets of infected material.
- regarding the respiratory support, SVT, steady fixed in the trachea and with a properly registered MV, can satisfy any sort of respiratory requirements, as we have pointed out before.
- the particular length of the shaft of the TLT cannula is more suitable than the traditional devices adopted by OITs to be subjected to an extra prolongation in patients with extreme thickness of the pretracheal anatomy (Fig. 43) (77).

![Fig. 43](image)

The way to prolong the standard TLT cannula. The lateral short slot is then closed with a round of tape

Therefore, for these reasons, TLT proves the most fitting technique for morbidly obese patients (30). To support these TLT advantages, cases of extreme thickness of the pretracheal tissue carried out easily and without complications are illustrated in figure 44.

![Fig. 44](image)

Infant with neurofibroma (A), adult with a large goitre (B), critically ill obese patient (C)
- **As temporary tracheostomy**
  The strong fitting of the anterior tracheal wall on the cannula, that blocks the passage of septic material from the trachea towards the neck layers, and the quick closure of the stoma put a clear indication to use TLT as a short-term procedure in maxillo-facial and laryngeal surgery to ensure the airway control in the immediate post-operative period (23). As a temporary procedure, TLT is adopted by Moon et al. (78) in cardiosurgical patients to overcome short periods of postoperative respiratory failure from cardiac insufficiency, after failed attempts of weaning.

- **Patients with previous neck surgery, radiotherapy or unclear surgical anatomy**
  In these cases, the indications to TLT are consequential to the fact that TLT does not create tractions at a distance from the stoma which, in OITs, may cause lacerations of the blood vessels, especially when they are blocked and displaced by scarring processes. In patients with these anatomical difficulties, it may be preferable to opt for an immediate surgical tracheostomy instead of attempting an Out/In PDT and to make a conversion if later needed (79).

- **Patients with tracheal stenosis**
  TLT can be practiced also through the stenotic tract of the tracheal lumen. The most demanding step is the needle insertion and centring in the middle of the stenosis. Afterwards, the remaining part of the procedure is limited to exert an adequate pulling on the wire, without unwanted effects at every level of effort (80).
  This type of tracheostomy was adopted by us in the conservative treatment of tracheal stenosis not amenable to surgical therapy as a bridge procedure before the placement of a T-stent (Fig. 45).

- **Patients with immune system insufficiency**
  The matchless minimal tissue trauma, the high sealing effect of the anterior tracheal wall, that acts as a barrier against the infiltration of tracheal contaminated secretions into the pretracheal space, make TLT the more indicated technique for these frail patients because it prevents deadly infectious complications. For the same reasons, TLT may also be practiced in close proximity of vast septic foci, as in the case of the breakdown of the neck wound that may follow the oesophageal surgery (81).

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**The evaluation of In/Out advantages in literature**

Taken together, the above mentioned advantages, related to the type of dilatation of TLT, have given rise to a series of claims favourable to the technique, which we list below:
- first choice technique for having eliminated the risk of tracheo-oesophageal fistula (19,30,46).
- the safest straightforward method with some advantages over the other puncture techniques (23).
- easily carried out and slightly invasive (82).
- suitable for the most challenging patients with underlying risk factors (31,49,67,68).
- easy, simple, the technique of choice in paediatric, obese, brachytype patients (83).
- especially suitable for children below the age of ten and associated with very few complications (72).
- being easily taught and performed (18,23,30).

Special technical aspects of TLT

Retrograde needle insertion

Since remarks have been made about the supposed greater technical difficulties of the retrograde insertion of the needle, compared with the traditional anterograde method (23), we believe it is appropriate to clarify some points on this debate.

In our basic technique, once RTS is positioned and the protrusion of the anterior wall of the neck is achieved (Figg. 17,18), the insertion of the needle into the RTS lumen, and the subsequent retrieval of the wire at the connector with respirator, makes the procedure quicker and safer than the anterograde way run in OIT techniques, especially in cases of stout necks and obscured external laryngeal marks. Kinking of wire, false route, repeated attempts, erroneous centring and posterior tracheal wall puncture, rather frequent in both OITs and TLT/FFB version (Fig. 27), are not part of basic TLT complications.

The marks on the cannula

Five black marks are printed on the external ridge of the curvature of the cannula to give, according to an initial purpose, a rough control of its position during the various steps of adjustment.

The following experience has showed they have a little technical importance in indicating the precise position of the end of the cannula because of the high variability of the distance skin/anterior tracheal wall that can be found between patient and patient.

In phase 3, when the strengthening and rotation require carefully planned manoeuvres, the movements of the inner segment of the cannula are controlled by the direct endoscopy so that the marks result completely superfluous.

Patients with difficult airway access

Before starting the tracheostomy, it is essential to perform an accurate laryngoscopy to highlight possible abnormal anatomy of the neck structures and prepare effective tactics for safe replacement of tubes.

With the premise that the problem of tube exchange in TLT technique has been magnified by superficial observers, it should be noted that in the case of patients with difficult airway, the substitution of the original endotracheal tube with the rigid tracheoscope or with the ventilation
catheter should be made in complete safety with the use of various types of tube exchangers. For instance, a thin probe, deeply inserted into the first endotracheal tube, may be a useful method to provide a safe ETT/SVT exchange (Fig. 46).

Fig. 46 The protected exchange of tubes

It may be noteworthy to point out that in cases of difficult airway approach it was possible to make a TLT with the aid of an intubating laryngeal mask (33). The authors of the report, however, advise that the method should be used only in selected cases, given the risk of gastric aspiration and the inability to ensure high inflation and end-expiratory pressures.

**Accidental decannulation**

**Intraprocedural decannulation.** This incident has different solutions according to the fact that the decannulation occurs in phase 2 or 3.
- **In phase 2.** It is very improbable, since the technique plans that the extraction of the cone-cannula should be stopped when half of its length is still anchored in the laryngotracheal tract (Fig. 47A).

Fig. 47 The correct position of the cone-cannula at the end of dilation (A) and after total extraction (B)
However, when it happens (Fig. 47B), being still intact, the cone-cannula can be reused. It is enough to connect the end of the guide wire to the oral end of the safety thread and re-insert the cannula by pulling the neck end of the safety thread (Fig. 48).

![Fig. 48 Reinsertion of the cone-cannula](image)

- **In phase 3.** This incident is more likely to occur because a small over-shift of the cannula, on the order of a few millimetres, is enough to drag its end off the trachea, into pretracheal layers of the neck. The decannulation proves more frequent with the obturator (Fig. 49) than with the telescope method due to the more precise control of the straightening and rotation manoeuvres provided by the internal vision of the cannula.

![Fig. 49 The partial decannulation in phase 3](image)

Therefore, this incident is always to be referred to inaccuracy in endoscopy and hurried manoeuvres. The remedy consists in a complete extraction of the cannula and the reinsertion of a new wire and a new cone-cannula with the help of the safety thread as in figure 48. Summarizing, in both cases, the safety thread gives a complete autonomy to TLT because it allows us to end the procedure easily and with no additional trauma, and thus, any conversion into OITs or ST is totally without justification.
With basic TLT technique, this event does not endanger the patient because the small ventilation tube ensures the reintroduction of the cannula without risks and worry. Instead, very risky situations may occur if a decannulation happens when the patient is subjected to TLT variations without the use of STV, especially when an immediate endotracheal intubation is not feasible. A case of this kind of respiratory emergency, was resolved with the use of a laryngeal mask but the authors remind us that this method does not always work in similar cases (34).

**Post-procedural decannulation.** It is a complication mostly connected to nursing carelessness, but the method of tracheostomy may play a role. TLT preserves the integrity of the anterior tracheal wall at the highest degree and thus, the tracheal window provides such a strong adherence to the shaft of the cannula that it makes decannulation, when the cuff is inflated, rather improbable. This effect could be compared to the fixing of the shield of the cannula with stitches adopted in OITs (84). As proof of this advantage, is the fact that in our ward prone-positioning is routinely applied in all patients subjected to MV (85) and, despite their continued mobilisation, the incidence of decannulation is negligible. Since the safety thread is usually left for 2 days, different solutions are adopted depending on the moment in which the decannulation occurs.

- **In the first 2 days.** As a rule, the patient is orally intubated and with the help of the safety thread a new cone-cannula is re-inserted, as illustrated in figure 48. An attempt of reintubation through the stoma, as it is suggested also for other techniques (42), is an acceptable practice if performed immediately, but it is an individual decision by the operator, that depends on his experience, the level of respiratory autonomy of the patient and the neck anatomy.

- **After two days.** The more prolonged stay of the cannula offers a longer-lasting stabilization of the stoma so that the above mentioned suggestion of a prompt and short attempt of reintubation through the stoma is even more appropriate. In case of failure, the absence of the safety thread imposes oral intubation and the repetition of the whole procedure, starting from the needle and wire insertion.

**The cuff inflation before the cannula rotation**

A mention should be reserved for the habit of some TLT users to practice a partial pre-inflation of the cuff before the straightening of the cannula, to make less likely the decannulation during the adjustment manoeuvre. Redundant in the basic technique, where the movement of the cannula is completely controlled by the telescope placed in its lumen (Fig.35A), it may be advantageous in the other three variants of figure 35, especially in the variant C that does not contemplate endoscopy.

**The usefulness of the safety thread**

TLT includes the placement of a safety thread which is very useful in the case of accidental perioperative decannulation (see Fig. 48). However, we have to admit that, on reviewing our experience, the only few cases of safety thread utilization could raise some doubts about the absolute indispensability of this procedure. But, our belief is that, since this precautionary act does not take time, does not involve unwanted effects and may resolve a delicate situation, it should always be adopted, if nothing else, like warding off an ill-luck measure.

**Infection of the stoma**

One of the first criticisms made to TLT has been the one addressed to the oral passage of the cone-cannula that could facilitate the infection of the stoma. Subsequently, greater experience showed these worries were unwarranted (49-51). Konopke (30) has lamented just one case of stomite in a patient severely obese out of 245 TLT.
A beneficial factor that contributes to prevent the infection of the stoma is represented by the extreme limitation of the local trauma, that ensures the maintenance of the whole defence capacity of the tissue, and the cleansing effect of the tight fitting of the anterior tracheal wall to the cannula, shown in figure 38.

**SVT- Guide wire entanglement**

Before beginning the procedure of dilation, the operator should verify that the guide wire does not wrap the SVT. In this regard, it is sufficient to take the precaution of keeping the two devices separate at the opposite sides of the mouth to prevent that the dilation manoeuvre be impeded.

**Right-angled or straight cannula?**

The request of a kit with a straight cannula was forwarded by a few TLT users with the intention of skipping the rotation of the cannula. Some considerations help to understand the unreason of this demand:
- phase 3 is formed by three basic manoeuvres, straightening, rotation and caudally advancement of the cannula.
- the accidental decannulation in phase 3, represented by the exit from the tracheal lumen into the pretracheal space of the end of the cannula, happens when the cannula is subjected to a further partial extraction to achieve its straightening.
- the rotation is performed by turning the cannula on a horizontal plane, and therefore it cannot influence the incidence of the decannulation, which, at this precise moment, has already occurred or not.

In a comparative study on three different methods of performing TLT, it is meaningful that the only two pulled-out, over of a series of 75 TLT, occurred in the straight cannula group (12).

In addition, the straight cannula, besides not being able to prevent decannulation, brings about three substantial drawbacks:
- at the end of rotation, the straight cannula needs an inducement with the telescope or the obturator to be pushed downwards, while the right angled one shows an automatic entering due to its tendency to regain the original curvature.
- the caudal advancement of the straight cannula has to be better controlled, to avoid the tip of the cannula going too far and entering a bronchus. This risk is less likely to occur with the angled cannula, thanks to the tactile sensation of the cannula settling down in its right position favoured by its angulation.
- the straight cannula must be changed early to avoid possible pressure lesions on the tracheal ring, proximal to the stoma, and the posterior tracheal wall, imposed by the unnatural curvature. Even if there is not a confirmation through post-mortem findings, this hypothesis is considered probable by the users of the straight cannula themselves (12).

In order to bring the problem of rotation to its real dimensions, it seems appropriate to point out that the extraordinary flexibility of the cannula allows its caudal progress even without a preliminary rotation, which can be delayed when the cannula is firmly located in the lumen of the trachea (Fig.50).
Topics of general interest

Post-procedural stenosis of the central airways

This is a topic of difficult debating, mainly due to the confusing identification of the alterations detected after a tracheostomy and in part due to the relative small number of patients submitted to long-term follow-up. Substantially, the more common sites of these lesions are:

- **Laryngotracheal.** The alterations at this level are caused by the previous prolonged intubation of the trachea, when it is not properly managed, or by extension of the stomal inflammatory process in case of high level tracheostomy. Endoscopic control before tracheostomy is essential so as to resolve doubts about the pathogenesis.

- **Suprastomal.** It is the main cause of failure of decannulation in paediatric patients (86) but can also be observed in adults, as Koitschev et al. (87) noted after percutaneous tracheostomy. This complication is interpreted by these authors as due to the pressure exerted by the oblique insertion of various dilators and cannulas on the suprastomal tract of the anterior tracheal wall, with a consequent weakening and intrusion of the cartilage structure. In support of this interpretation they bring the fact that in surgical technique, where the integrity of the cartilage frame is more highly respected, this type of complication is much less frequent. A variety of suprastomal stenosis related to percutaneous techniques, defined “corkscrew”, has been described by Jacobs et al. (88). As it relates to the TLT, there are no reports in literature of similar lesions, as was to be expected given that with the In/Out dilatational phase the causal mechanism of this complication is lacking.

- **At stoma level.** A recent review (89) has shown that the PDTs and ST are equal with regard to perioperative complications, but PDTs is featured by a higher incidence of tracheal stenosis. Even if there are no studies clearly demonstrating a direct connection between the level of local procedural trauma and stenosis, it is difficult to think that stumps of tracheal rings, hanging in the lumen of the trachea and large detachments of the mucosa cannot have any effect on the occurrence of scar retractions. Hotchkiss et al. (54) are of the opinion that every type of stomal traumatism contributes to the appearance of late tracheal narrowing. Van Heurn et al. (53) argue that, with the Ciaglia method, the only significant risk factor for the development of tracheal stenosis is the fracture of tracheal rings.
The study of Halum et al. (84), who found an association between obesity and use of cannula of size >7.5 mm I.D. and the development of airway stenosis, would support this connection since both these situations involve considerable peristomal tissue trauma and the consequent tendency to inflammatory processes.

The opposite view is backed by Higgins (90) who noticed that fractures of tracheal rings detected in 16 patients, subjected to the Ciaglia method or Blue Rhino, did not give rise to any tracheal complications later. Demsey (52), however, noted that this work was based on a small number of cases, such complications are not often detected, and the frequency of this type of tracheal lesion is too low not to exclude a possible coincidence. Therefore, he argues that in the Higgins research there was an over-interpretation of the data.

Regarding TLT we can make the same considerations set forth in respect to suprastomal complications. With the least invasivity among the percutaneous techniques, TLT should have fewer chances for tracheal damage and its consequences (24,66). Oeken (24) in 26 TLT patients examined at a distance, did not notice any narrowing. The same result was found in 63 patients by Konopke (30).

- **Below the stoma.** Stenosis of the trachea at this level is originated from the mucosal injury caused by cuff pressure, erosion of the ends of rigid cannulas, and prolonged trauma of the suction catheters. It is worth highlighting that at the origin of all the just mentioned complications an essential role may be played by the lack of conditioning of respired gases, a factor not taken into proper consideration despite the fact that the consequences of the respiration of dry gases can be devastating. Besides the cannula obstruction, the abrasion of mucosa by the tubes is strongly increased, the deposits of dried secretion may adhere to mucosa and, if they are not removed in the initial phase, they give rise to the narrowing of the tracheal lumen through successive layers of fibrinous material. Furthermore, if the cuff is maintained at full sealing inflation for a prolonged period, as a widespread measure of VAP prevention, the lack of the continuous removal of the secretions by the intermittent flow of air in the inspiratory phase, may give origin to a double stenosis (Fig 51A). For this reason, we prefer to avoid this complication by ensuring a small end-inspiratory gas escape (Fig. 51B) and entrust to the continuous supine-prone position change of the patient the task of preventing lung injuries.

**Fig. 51** Double stenosis at the proximal and at the distal end of the cuff due to prolonged dry gases respiration and full cuff sealing (A). The washing effect of physiologic humidification of gases and non-sealing of the cuff (B).

In extreme cases of adverse conditions, this complication may block the cannula, even to the point of preventing its removal. This complication has been reported in the study of Neri et al. (82), in six patients and erroneously misinterpreted as one of the specific drawbacks of TLT, whereas it should have to be attributed to coarse defects of post-procedural nursing. In other similar cases of double
tracheal narrowing after different tracheostomy techniques, sent to our centre for the dilatative recanalization, the same pathogenesis was detected.

Regarding our experience, we made an exhaustive investigation on late complications only on the first series of 96 TLTs (6). In twenty cases submitted to a long term follow-up by means of endoscopic control and/or computed tomography, we did not encounter any stenosis. In 9 patients subjected to autopsy at different intervals after tracheostomy, flat, non-infiltrated breaches, without torn tissues, were diagnosed.

In the second series of 297 patients (10), long term follow-up was made only in 32 cases. In one case the narrowing was found at the laryngotracheal junction and in the second one in the lower trachea, both far from the stoma and thus, not completely related to the tracheostomy technique.

Also on the basis of our experience we are of the opinion that the technique has its role in the pathogenesis of these complications, but that other factors have to be taken into consideration, like the level of post-procedural airway hygiene.

With regards the management of tracheal stenosis, we think that the surgical solution with partial or circumferential resection of the affected section could be in many cases avoided and replaced by a placement of a T-stent (Fig.4). Indeed, we have observed that these devices (with different calibre of the external branch, depending on the degree of a patient’s respiratory autonomy) are well tolerated in the long run and offer a high percentage of final recalibration of the tracheal lumen.

**Timing**

Early or late tracheostomy?. This debate arose from the concept that tracheostomy is generally practiced to avoid the complications of prolonged translaryngeal intubation (91), so that, as a logical consequence, the hypothesis had been raised that early tracheostomy within the first 3-4 days would have to bring to the patient more undoubted benefits than a late one, more than 10 days. Griffiths (92) observed that early tracheostomy reduces the duration of mechanical ventilation and hospital stay and Rumbak (93) noted a significant reduction of mortality as well. Subsequently, countless studies arrived at similar or completely opposite conclusions. In 2013 the randomized trial of Young (94), involving 73 critical care units in the United Kingdom, demonstrated that early tracheostomy does not reduce the sedative use, the duration of respiratory support, the length of stay in the critical care units, the antibiotic use and the mortality. For Terragni et al, the incidence of VAP and mortality are not lowered (95).

To find a way out of this confused situation of conflicting opinions, we have to make a few considerations dictated by our experience which can help clinicians, if by anyway, to resize the stressing proportions which seem to have reached the “early or late” dilemma:

- The major cause of the discordant results of the studies is the lack of a validated formula that allows clinicians to timely identify the patients who need prolonged mechanical ventilation for the following seven days among the population of intubated patients.
- In this situation, it seems obvious that if one opts for early tracheostomy in the first 3-4 days, he runs a high risk of subjecting the patient to unnecessary practice that is not without its own risk. Whereas, the majority of cases of acute respiratory failure, which receive mechanical ventilation for more than 12 hours, do not demand it for more than a week (96) with a very likely possibility, that the following day the patient could recover his breathing autonomy.
- On the contrary, if one chooses late tracheostomy, it is equally obvious that the patient may be unnecessarily exposed to an extended period of endotracheal intubation, with all the disadvantages that are usually attributed to this procedure.
- A minimally invasive technique, with fewer procedural risks, is prone to induce the physician to anticipate tracheostomy, for the simple reason that, in the case of an unexpected rapid regaining of respiratory autonomy, the minor trauma and the quicker and complete closure of the stoma would make the consequences of an unnecessary procedure much more acceptable.
A more dangerous technique drives physicians to delay the intervention so as to have the greatest confirmation of its indispensability. We can remember our reluctance to practice a tracheostomy when the only alternative to intubation was surgical tracheostomy.

- To tell the truth, all this wealth of investigations has always surprised us because in our department we never experienced this problem. The tracheostomy was done without delay when there was clear evidence of its necessity, for example, neuropathies which usually require more than 20 days of MV, while in a COPD case it could be postponed even for weeks, following several failed attempts of weaning. And just to the prevalence in our ICU of this genre of patients, our average timing is rather high, around 18 days (see page 51). And thus, it never crossed our mind that it was necessary to anticipate the intervention to be eligible for the benefits which usually are attributed to tracheostomy as compared to intubation, in particular, the prevention of VAP, a problem we have instead completely solved with the regular alternation prone-supine of the bedridden patients, through the prevention of alveolar collapse and the promotion of the drainage of bronchial secretions.

Other examples of very late timing due to repeated extubations and re-intubations are reported. Fikkers (63) complains a mean duration of tracheal intubation from ICU admission to tracheostomy of 21 days (range 1–62 days).

- With the premise that in prolonged treatments in MV, tracheostomy should be seen as an inevitable step, it must be taken into account that in cases where the tracheal intubation, for various reasons, has no alternatives, or should be continued for a long time, useful measures exist to improve its tolerability and reduce any possible drawbacks as the nasotracheal route, the use of small and flexible tubes, the physiological conditioning of inspired gases, double swivel devices to absorb the tractions on the tube from the respirator's connector, slight leakage of the cuff and PEEP to create an outward gas flow to prevent inflammatory reactions of the tracheal mucosa and fibrin deposits (see the chapter on post-procedural stenosis of central airways).

It is important to know that in paediatric patients the intubation is particularly tolerated and represents in a high percentage of cases a preferable alternative of tracheostomy (71,97).

In conclusion, if we start from the well-proven knowledge that the ability to timely identify which patients require prolonged MV does not exist, the huge amount of studies on a false topic appears disconcerting. They clearly show how the researchers may incur in phenomena of collective involvement about problems that could easily be solved with a bit of sound clinical thinking. In our view, the problem of the timing of tracheostomy, if so set, is insoluble and to keep discussing it is a pure, landlocked academic exercise.

**Training in one or many techniques?**

This question arises from the opinion of some researchers that the tracheostomy technique should be individualized (98). For Morgan and Bhatti (75,99) it is essential to make a precise choice of only one method, achieve a high degree of standardisation and maintain a thorough adherence to the protocols.

Sharpe (18) has a more restrictive interpretation of the problem. Not only dealing with various techniques but also with the different variations of the same technique (just the case of TLT) brings about confusion and precludes the operator from gaining sufficient experience in a single procedure. However, we see the problem from another point of view. The concept of having more techniques, each of which is more suitable to a particular type of patient, is very objectionable. All the techniques have some particular weak points which can generate problems if unexpected difficulties, not compatible with that type of procedure, occur.

We think that it would be preferable to adopt a technique fulfilling the widest possible range of patients. At the top of a hypothetical ranking, we find ST, to which all the patients who cannot be subjected to percutaneous tracheostomies arrive. Unfortunately, the widespread adoption of ST is hampered by the need for a thorough surgical preparation and by some specific drawbacks.
In second position we can place, among PDT, the basic TLT technique for having the widest range of indications. It can be demonstrated by our series that although it includes at least 25% of cases which, with a general consensus, are not recommended for OITs, we have never been forced to resort to other techniques as either completion or full replacement of TLT.

**Restricted team or generalized involvement of the staff?**

The opinion that all the personnel of an ICU should be prepared to perform a percutaneous tracheostomy is rather common. On the contrary, we believe the teaching should be restricted to a small number of individuals, simply because percutaneous methods are procedures which may lead to devastating complications if carried out without the necessary prudence and qualifications. For Bhatti (99), surgeons, anaesthesiologists, nurses and respiratory therapists must have a long common experience to be able to work as a team and to achieve significant expertise. Regarding anaesthetists, only 4 in a big centre would be enough. Each operator should have experienced an initial 20 procedures under supervision and then, independently, at least 30 procedures, to be able to re-intubate the patient, in case of accidental decannulation.

**Surgeon at hand?**

In consideration of the fact that life-threatening complications can happen also to operators with a large experience in the course of percutaneous tracheostomy, Massick (100) and Bhatti (99) believe that those who practice such techniques must be able to switch to the ST or have a sufficient surgical preparation to face a procedural emergency without delay. A deep haemorrhage in these non-invasive procedures requires the revision of the stoma that results much more challenging than in traditional open tracheostomies. The fresh channel is very narrow and should be promptly enlarged with manoeuvres which themselves may become very harmful if not skilfully performed.

If we consider that in the vast majority of ICU there are no physicians with a sufficient knowledge in surgery, it follows that when severe complications during tracheostomy occur in these areas, the intensivist should be limited to practice only the manoeuvres essential to survival and to call a surgeon or an otolaryngologist for more complete and definitive measures. However, in the organizational system of how to deal with major complications of percutaneous techniques, one must also take into account the type of tracheostomy adopted. In TLT, the absence of preliminary invasive manoeuvres and the small trauma of the neck structures minimize the need of asking for specialist help.

In OITs, the surgical component is not negligible. An adequate incision of the skin and a bluntly dissection of pretracheal tissue, formerly suggested by Ciaglia (1) for his technique, are usually adopted to make palpable the trachea, to help the centring of the needle and to reduce the pushing pressure on dilators and cannula. Given the rather high frequency of congenital or acquired aberrant vessels, these manoeuvres, added to the forced insertion of dilator and cannula from the outside to the inside remarkably increase the risk of complications, particularly vascular tears, which demand a surgical revision. For this reason, it is recommended to perform these types of tracheostomy during working hours only, when surgical expertise and theatre staff are readily available (57).

**The scheduled change of the cannula**

Percutaneous tracheostomies present more problems than the surgical technique during the change of the cannula because of the high tendency of the stoma to shrink.
Therefore, the cannula is not usually changed before the seventh day, the time required for a sufficient stabilisation of the channel.

It is also a widespread opinion that in TLT this waiting period has to be extended because of the exclusive tighter fitting of the tissue to the cannula and a more pronounced effect of narrowing of the stoma. Emphasising this effect, it has been affirmed that TLT is not advisable in patients who are addressed to the domiciliary respiratory care for the risk that a decannulation in a non qualified background could arise (82). This is another bit of nonsense that is going around in the field of tracheostomies, that makes a deeper analysis of the shrinking phenomenon indispensable. Making reference to our experience in dilatational treatment of laryngotracheal stenosis, we can affirm that after only two days of permanence of dilating devices, it is possible to obtain a stabilization of the tracheal lumen, sufficient to provide all the necessary time for the insertion of a stent in complete safety and without worry.

Therefore, it can be assumed that after 7 days from any percutaneous tracheostomy, the tendency to shrink, of the stoma, certainly less than that exerted by a scar tissue, should allow the replacement of the cannula without particular problems. Regarding the vaunted slower elastic return of the stoma in the PercuTwist method (59) compared with other OITs, even if no one ever bothered to check, this could be attributed to the fact that in PercuTwist, dilation takes more time than in Blue Rhino, not to a particular property of the technique. The advantage of this feature is very questionable if already at the time of the first introduction of the cannula, immediately after the removal of the screw dilator, one encounters more difficulty than in the Blue Rhino (42).

As regards the planned replacing of the cannula at a distance, there are no substantial differences of the stoma between the various techniques.

It is interesting to note that the Canadian group (66), with the justification that the TLT cannula has no inner cannula, change it with a traditional type after three or four days, a time that they proved to be sufficient to achieve a satisfactory stability to the stoma.

We too have performed numerous replacements of the cannula in the first days without complications and we interpret this possibility as an advantage of TLT due to the characteristic and exclusive regularity of the stoma that facilitates the sliding of the cannula into the tracheal lumen, a factor that after two days becomes predominant compared with the shrinking mechanism.

In OITs, this early substitution might be more hazardous owing to different conditions. Indentations and jagged pretracheal layers, due to the preliminary dissection and forced insertion of dilators and cannula, create the premises for a difficult advancement of the cannula and a high risk of false passages with the cannula wedging into pretracheal space.

As the high risk of the cannula exchange is universally recognized, it is appropriate to ask whether this procedure can not be delayed and made less frequent. Reducing the problem of encrustations with a correct humidification of gases and leaving a small leakage of air at the peak of the inspiratory phase to ensure a continuous removal of the secretions, are the key-steps that allow a long stay without obstructive complications to a cannula even without the inner cannula cleaner as in the case of the TLT device.

Thanks to these measures we are used to replacing the TLT cannula with a traditional one, equipped with the inner cannula, only at the time of transfer of the patient to a medical ward with lower levels of assistance.

Anyway, when the substitution of the cannula cannot be deferred, the procedure must be carried out with thorough measures of safety (tube exchangers, endotracheal intubation facilities or precautionary intubation in cases of short and stout neck or other predicted difficulties) usually adopted in all kinds of percutaneous tracheostomies. With the imperative purpose not ever to loose the airway control, we now are used to employing new cannulas, whose insertion is facilitated by a guide wire threaded through a drilled obturator.

In a recent paper, Kilic et al. (101) remember that the only way to avoid risks of serious respiratory complications in changing the cannula in patients with difficult anatomy of the neck is to practice a surgical tracheostomy according to the Biörk method. A "U-shaped" ST-skin connection with the lower edge of the front wall of the trachea provides a stable tract for easy tube reinsertion.
Endoscopic control: mandatory or optional

Despite a clear testimony to the effectiveness of the use of the bronchoscope in preventing serious complications of the Ciaglia method sustained by Marelli (102) many years ago, its utility is always under review and destined to fuel a never-ending debate. There are those who support its usefulness but admit that bronchoscopic guidance can minimize, but cannot completely eliminate, the risk of tracheal injury and false passage during PDT (25,39,40,103), and others who declare that bronchoscopy is not essential to an expert operator, except in cases of obesity and difficult anatomy of the neck (104). An extreme position was taken by Dennis (105) recently, after observing a very low incidence of major complications (0.38%) in a series of 3162 patients, with a percentage of 16% of cases with BMI > 35 who underwent Blue Rhino without endoscopic control. He felt able to say that such control even in the obese is not absolutely necessary.

It should, however, be recognized that one of the main reasons that deter the application of endoscopy, in addition to time and resources consumption, is the impairment of ventilation caused by the increase of the respiratory resistances induced by the presence of FFB (20) inside ETT. Anyway, to give a greater reliability to the for and against opinions, we think that the studies should take into consideration also the type of tracheostomy technique used. Indeed, the substantial difference of the potential risks of complications existing in the various tracheostomies requires a different level of endoscopic checking.

With a quick analysis, detailed per phases, we can see that:

- **in phase 1**, TLT and OITs have similar advantages from endoscopy. Blind insertion of the needle, promotes errors of correct centring and risk of perforation of the posterior tracheal wall. In OITs, a very widespread alternative to endoscopy (106) is to deepen the tissue dissection up to expose the trachea and directly select the site of the stoma. This is, however, a method somewhat questionable for the increased invasiveness of the procedure.

- **in phase 2**, the situation is remarkably different. In TLT the endoscopy is neither contemplated whereas in OITs, on one side, major complications are rather likely to occur because of the intrinsic less safety of the techniques, on the other side the effectiveness of endoscopy is impaired by antero-posterior tracheal collapse caused by the dilator pressure, the considerable hazard of any percutaneous technique (45). To these factors, it should be added the impairment of ventilation due to the obstruction of the tracheal lumen induced by the presence of the various dilating devices. Taken together, these unfavourable conditions explain why in OITs the effectiveness of endoscopy is not absolute.

- **in phase 3**, the endoscopy becomes indispensable again for both the methods, but while with TLT it can avoid a simple accidental decannulation, with OITs, the weight of the control is essential because the insertion of the cannula could involves the same complications of the dilatational manoeuvre. Two clinical experiences may shed light on the importance of taking into account the type of technique in the debate on whether or not to use endoscopy.

Berrouschot et al. (39) reported one death due to tension pneumothorax and two cases of perforation of the rear tracheal wall in 41 patients subjected to the Ciaglia method without bronchoscopy and two cases of minor haemorrhage in 35 patients of bronchoscopy group.

Walder (25) in 58 TLTs carried out without endoscopic control, reported only two plain decannulations, promptly and safely solved in well ventilated patients by repetition of the cannula positioning, according to the method described in figure 48. Therefore he felt justified in stating that TLT without endoscopy is an acceptable method.

We do not agree with this statement, because we believe that we should always try to eliminate even the slightest inconvenience. Therefore, with Craske (28), we consider bronchoscopy as an essential part of the TLT protocol.
Preliminary Ultrasound Scan

Already suggested by Sustic (107) fifteen years ago, Ultrasound Scan is becoming a more and more widespread procedure in percutaneous techniques, because it integrates bronchoscopy in the identification of the tracheal midline and the level of laryngotracheal cartilages. In addition, it proves to be an irreplaceable means to provide a detailed picture of the normally or abnormally located vessels of the neck. It should be mandatory adopted in all types of tracheostomy, ST included, in the cases of previous neck surgery, radiotherapy, and vascular pulsation over the tracheostomy site, in order to avoid complications induced by a distorted inner anatomy (57,79).

Also if in TLT the Ultrasound Scan does not play the key role that it takes in OITs, for the absence of those shear forces produced by the insertion of the dilator and cannula which, in OITs, can be transmitted far from the stoma and broaden the area at risk of vascular tearing, we think that the ultrasonography, like any other measure increasing the level of safety of a medical act, should be more frequently adopted, and therefore, we advocate it for TLT as well.

The duration of the procedure

This data is usually included in the group of criteria of evaluation of the tracheostomy techniques. However, we believe that taking a few extra minutes is not clinically significant, especially in a well ventilated-lung patient, when procedural safety is considered paramount. At most, the duration of the procedure could have a certain weight in affecting the overall score only in function of the debatable cost of the longer commitment of the staff. Furthermore, the differences among the various techniques are not remarkable and so they cannot condition the choice of a method. Compared with about 13 minutes of Blue Rhino (63) and of PercuTwist (108), the average length of the TLT reported in literature (12,30,46) and in our own experience varies between 5 and 12 minutes, depending on the technical variant adopted. In a review on TLT (23) it is stated that “TLT is no more time-consuming than most other PDT methods”.

We distrust super fast techniques, because they include manoeuvres necessarily more aggressive and therefore at greater risk. We must not forget that the first percutaneous techniques (109,110) that were carried out in a matter of seconds disappeared in a short time.

Soft or rigid cannula?

In all the techniques we experienced, we never used rigid cannulas during the patients stay in the ICU, but only flexible, armoured cannula for ST and PDT, and the ultra-flexible cannula of the kit for TLT. At the time of the transfer of the patient to other departments, the cannula was changed with a cannula with its inner cleaner. This approach has proved to offer some important advantages:

- the soft cannula is better tolerated, since in a moving patient it absorbs stresses (Fig. 52A).
- no life-threatening haemorrhages from erosion of large vessels as TIF (tracheoinnominate artery fistula) that instead is reported with a frequency of 0.35% after Blue Rhino (52), where the adoption of rigid cannulas exposes the patient to the risk of necrosis of the anterior tracheal wall (Fig. 52B).
- no pressure injury of the posterior tracheal wall, observed with rigid cannula (Fig. 52C).

Therefore in the case of use of rigid cannulas, the life-threatening nature of the haemorrhage and the tracheal decubitus require frequent inspections of the trachea to highlight the early stages of these lesions.
It is worth mentioning that it is widely believed that the flexible cannula would favour the decannulation, a consequence that would seem obvious at first sight, and that would diminish their advantages over the rigid one. Apart from the fact that the rigid cannula does not amortize external stress, the fact remains that the decannulation in our view substantially depends on everything what is considered behind this complication, first and foremost, the inadequate level of nursing. In our extensive experience with flexible cannulas, the increased incidence of decannulation has not been observed. And this is a fact, even more remarkable, when you consider that all of our patients on mechanical ventilation are systematically subjected to periodic change of prone-supine posture (85).

Our results compared to a Blue Rhino case series

In this chapter we have felt useful to make a comparison between the results obtained in our basic TLT case series and those reported by Dempsey (52) with Blue Rhino in a study that has many similarities to ours (Tables 3–5). Indeed, both studies were performed in a single centre and are based on a substantial number of patients. The tracheostomies were carried out by a small number of operators with proven experience, thus making possible the elimination of some of the most frequent disparities that usually affects the reliability of the comparisons. For basic TLT shall mean the version that includes the rigid tracheoscope, the use of small ventilation tube along all the duration of the procedure and the adjustment of the cannula with the endoscopy by means a telescope inserted into the cannula.

Table 3 Comparison between the case series of Fantoni and Dempsey

<table>
<thead>
<tr>
<th>Cases series</th>
<th>Fantoni</th>
<th>Dempsey</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU beds</td>
<td>8</td>
<td>19</td>
</tr>
<tr>
<td>Nº patients requiring tracheostomy</td>
<td>431</td>
<td>590</td>
</tr>
<tr>
<td>Selection</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Cases assigned to ST after selection</td>
<td>no</td>
<td>13</td>
</tr>
<tr>
<td>Total of patients tracheostomized</td>
<td>BTLT 431</td>
<td>Blue Rhino 577</td>
</tr>
</tbody>
</table>
Table 4  Comparison of the tracheostomized patients with BTLT and Blue Rhino

<table>
<thead>
<tr>
<th></th>
<th>BTLT</th>
<th>Blue Rhino</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>431</td>
<td>577</td>
</tr>
<tr>
<td><strong>Age yr</strong></td>
<td>67 (21-87)</td>
<td>58 (18-86)</td>
</tr>
<tr>
<td><strong>Male %</strong></td>
<td>61</td>
<td>59</td>
</tr>
<tr>
<td><strong>Score</strong></td>
<td>SAPS II 59±20.9</td>
<td>APACHE II 19±5.6</td>
</tr>
<tr>
<td><strong>Tracheostomy timing</strong></td>
<td>18 (1-64)</td>
<td>5 (1-21)</td>
</tr>
<tr>
<td><strong>Surgical patients %</strong></td>
<td>18</td>
<td>50</td>
</tr>
<tr>
<td><strong>Surviving to ICU discharge %</strong></td>
<td>67</td>
<td>69</td>
</tr>
<tr>
<td><strong>Mean length of ICU stay non-survivors in days</strong></td>
<td>50</td>
<td>18</td>
</tr>
<tr>
<td><strong>Mean length of ICU stay survivors in days</strong></td>
<td>36</td>
<td>20</td>
</tr>
<tr>
<td><strong>Mean length of hospital stay survivors in days</strong></td>
<td>72</td>
<td>42</td>
</tr>
<tr>
<td><strong>N° surviving to hospital discharge %</strong></td>
<td>50</td>
<td>63</td>
</tr>
<tr>
<td><strong>Duration of the procedure</strong></td>
<td>10 min</td>
<td>not reported</td>
</tr>
</tbody>
</table>

**Number of tracheostomies per year.** The significant difference between 29 and 98 procedures per year is to be related with the fewer number of beds of our ICU (8 vs. 19) and with our greater percentage of long-term stay patients, partly with respiratory insufficiency (COPD, cardiac failure), partly composed of post-surgical complex cases that required long periods of MV.

**Selection.** In our case series patients are unselected, while in the study by Dempsey, three different specialists have identified cases feasible with the Blue Rhino and sent to the ST cases contraindicated to OITs, according to well-known and universally accepted criteria. It follows that with the exclusion of the most challenging 13 cases, Blue Rhino comes to be considerably benefited.

**Timing.** Except for the cases in which the tracheostomy has been practiced in the first day of tracheal intubation for overt evidence of the need for a prolonged period of MV, our timing average was later with respect to that of the Blue Rhino study. This is due to the great majority of chronic patients who have a frequent alternation of improvements and worsening of breathing autonomy, that inevitably create continual tracheostomy postponements before reaching a sufficient reliability of the actual need of the procedure. Sometimes there are reasons that justify the non-habitual late timing, such as the desire to avoid creating the sensation in patients and relatives, that the point of no return has been reached in cases where the non perfect management of the patient before admission to ICU has sparked criticism and resentment against the caregivers. In extreme cases, see the patient with timing of 64 days, the delay is due to the stubborn refusal of tracheostomy that has led us to non-rational trade-off intubation/extubation until the obtaining of the consent given by absolute necessity. However, we must point out that in our department, late timing is certainly influenced by the excellent tolerance that patients show towards the intubation, achieved through the adoption of effective methods of prevention of complications attributed to it, already described in various portions of this paper. Among them, in first position, should be placed the change of prone/supine postures (85). This procedure proved to be useful both for the effective drainage of secretions and for the periodic re-expansion of gravitational atelectasis, two advantages that have been shown to be able to reduce the period of MV, both in cases with severe acute pulmonary pathology and in patients with neurological diseases with healthy lungs. For these reasons the timing was in many occasions delayed with the hope of avoiding the tracheostomy.
Duration of the procedure. It is not shown in the Blue Rhino series, most likely because it is not considered a fact that could affect the evaluation of a technique, in full agreement with our beliefs. The difference of a few minutes between techniques that should always require great care and prudence is certainly not to be taken as primary criterion. Significant is the fact that the techniques especially those most at risk for dangerous manoeuvres are those that are seen to be the fastest to do (go to the relevant chapter at page 49).

Our data must be understood as a mere completion of a table. The reported time, an average of 10 minutes is referable to a standard performance. For teaching requirements, the unavoidable increase in the duration proved well tolerated in patients in whom pulmonary ventilation was secured in the appropriate manner and throughout the entire procedure without interruptions.

Table 5  Complications

<table>
<thead>
<tr>
<th>Complications N°(%)</th>
<th>BTLT</th>
<th>Blue Rhino</th>
</tr>
</thead>
<tbody>
<tr>
<td>N° patients undergoing tracheostomy</td>
<td>431</td>
<td>577</td>
</tr>
<tr>
<td>Minor posterior wall injury</td>
<td>0</td>
<td>9 (1.55)</td>
</tr>
<tr>
<td>Posterior tracheal wall laceration</td>
<td>0</td>
<td>1 (0.17)</td>
</tr>
<tr>
<td>Minor bleeding*</td>
<td>3 (0.69)</td>
<td>25 (4.33)</td>
</tr>
<tr>
<td>Significant bleeding with surgical repair</td>
<td>0</td>
<td>6 (1.03)</td>
</tr>
<tr>
<td>Tracheal ring fracture visible at bronchoscopy</td>
<td>0</td>
<td>56 (9.70)</td>
</tr>
<tr>
<td>Oxygen desaturation **</td>
<td>4 (0.92)</td>
<td>17 (2.94)</td>
</tr>
<tr>
<td>Pneumothorax and or subcutaneous emphysema</td>
<td>0</td>
<td>4 (0.69)</td>
</tr>
<tr>
<td>Tracheal stenosis</td>
<td>2 (0.46)</td>
<td>2 (0.34)</td>
</tr>
<tr>
<td>Tracheo-innominate fistula</td>
<td>0</td>
<td>2 (0.34)</td>
</tr>
<tr>
<td>Infection of the stoma</td>
<td>4 (0.92)</td>
<td>not considered</td>
</tr>
<tr>
<td>Difficulties in needle insertion</td>
<td>20 (4.46)</td>
<td>not considered</td>
</tr>
<tr>
<td>Para-tracheal insertion of the cannula</td>
<td>0</td>
<td>4 (0.69)</td>
</tr>
<tr>
<td>Difficult cannula insertion (multiple attempts ≥3)</td>
<td>irrelevant to technique</td>
<td>57 (9.87)</td>
</tr>
<tr>
<td>Difficult cone-cannula extraction in TLT</td>
<td>3 (0.69)</td>
<td>irrelevant to technique</td>
</tr>
<tr>
<td>Difficult but not impossible RTS insertion ***</td>
<td>24 (5.56)</td>
<td>irrelevant to technique</td>
</tr>
<tr>
<td>Intra-procedural decannulation</td>
<td>6 (1.39)</td>
<td>irrelevant to technique</td>
</tr>
<tr>
<td>Cases converted to ST during tracheostomy</td>
<td>0</td>
<td>3 (0.51)</td>
</tr>
<tr>
<td>Cases abandoned, not tracheostomized</td>
<td>0</td>
<td>1 (0.17)</td>
</tr>
</tbody>
</table>

* In our cases minor bleeding is referred to a few drops or a few millilitres, in Blue Rhino cases it corresponds to 3-5 small soaked swabs

** In our cases the levels of desaturation was never lower than 92%, in Blue Rhino lower than 88%

*** In 5 cases we used a paediatric RTS (5.5 I.D.)

Posterior tracheal wall injury. If with the Blue Rhino only one case (0.17%) of laceration of the posterior wall of the trachea may be considered acceptable, the 9 cases of minor injury (1.55%) are absolutely not to be underestimate. In fact, the shallow lesions of the trachea are to demonstrate that the technique includes dangerous steps and that only the skill of the operator or a good dose of luck have allowed avoiding the worst. The lack in TLT of any degree of impairment of the tracheal wall is a testimony to the strong difference in safety between the two techniques.
Bleeding. Here we have the most noticeable difference between the two procedures. Indeed, while TLT can be defined as the bloodless technique (see page 33), Blue Rhino is prone to incur bleeding because of major tissue trauma, as confirmed by Fikkers (63) who reported 14 cases of 100 patients of peri-operative bleeding controlled by local pressure and 3 cases that required surgical exploration.

Tracheal ring fracture visible at bronchoscopy. The percentage of 9.7% given in Blue Rhino, is similar to that found in other OITs. The absence of this complication in TLT cases, which is also confirmed by the lack of reports in literature, is due to the In/Out direction of the dilation manoeuvre. The incidence of the ring fractures can be assumed as a very faithful index of local trauma of a tracheostomy, as we will explain later.

Oxygen desaturation. All percutaneous tracheostomies are ordinarily carried out in ventilation with 100% oxygen, so that the occurrence of severe desaturation (<88%) is synonymous of marked hypoventilation and/or insufficient PEEP caused by an inadequate system of respiratory support. In fact, in BTLT, where the use of SVT with an appropriate adjustment of the mechanical ventilator is systematic, this complication is avoided also in patients with severe acute lung damage. In OITs the usual methods of respiratory support are not able to ensure adequate ventilation, so that the patients with high ventilatory requirements (FiO\textsubscript{2} >80%, PEEP ≥15 cm H\textsubscript{2}O), are positioned between relative and absolute contraindications (111). Consequently, a higher percentage of desaturation of various degrees in this Blue Rhino study is not an unexpected data.

Pneumothorax and or subcutaneous emphysema. The first thing that one thinks of at the appearance of a subcutaneous emphysema of the neck after a percutaneous tracheostomy, especially if it is followed by detection of pneumothorax, is a lesion of the posterior tracheal wall. Other possible causes are the air leak due to pulmonary over-distension from an expiratory flow limitation and, in more frequent cases of simple emphysema of the neck, the infiltration of the pretracheal space by air coming from pressurized tracheal lumen. This last phenomenon is possible in a tracheostomy technique which does not ensure a strong seal of the front wall of the trachea around the cannula (Fig. 38).
In TLT, the adhesion of the tracheal window to the cannula shaft is enough to guarantee a complete separation between the two anatomical compartments, tracheal lumen and pretracheal space, so that emphysema of the neck of this nature is practically unknown.
Regarding the pneumothorax that we have reported in a previous study (9) the cause is to be attributed to air leak caused by pulmonary over-distension induced by jet ventilation with manual adjustment, applied in very few early patients and immediately abandoned after this incident.

Tracheal stenosis. Of our two cases, one is represented by a narrowing at the laryngotracheal junction, the other is located below the stoma and therefore not strictly attributable to the tracheostomy. However, the data is intended to be of little significance for the lowest percentage of cases referred to follow-up with respect to the series of Dempsey. See chapter: “Postprocedural stenosis of the central airways” for a wider dissertation on the subject.
Tracheo-innominate fistula (TIF). The mechanism at the origin of TIF is represented by the perforation of the anterior wall of the trachea by the end of rigid cannulas with subsequent erosion of large arterial vessels. In TLT the use of extremely flexible cannula with the cuff placed at the end that keeps the axis of the cannula centred in the tracheal lumen, prevents this complication in an absolute way.

Infection of the stoma. It is a rare and minor event in percutaneous techniques, so that often is overlooked as in the study by Dempsey. We have entered this data, simply to demonstrate that the transoral transition of cone-cannula does not necessarily cause the infection of the stoma, as some had hypothesised observing the atypical path followed by the dilator. Several studies confirm our results (see specific chapter).

Difficulties in needle insertion. With BTLT, the use of RTS in phase 1 assures a precise outside localization of the point where to insert the needle, a fast centring of the trachea and a safe advancement of the needle tip into the lumen of the trachea. On the contrary, the use of FFB in TLT variations involves frequent technical difficulties and increases the duration of phase 1. Since FFB is usually adopted in phase 1 of other percutaneous techniques, the failure to mention possible problems encountered during the introduction of the needle relative to the Blue Rhino cases of Dempsey, hardly surprised us, especially because these problems are not infrequently reported by studies on other OITs.

Para-tracheal insertion of the cannula. In OITs, the forced insertion of the cannula, a possible kinking of the guide wire or a wrong inclination of the tools may give rise to a para-tracheal advancement of the cannula, commonly defined as false passage. If the error is not readily identified, the resumption of ventilation is an additional cause of emphysema, sometimes massive and widespread. In TLT without endoscopic control, a false passage can be produced at the time of the straightening and inversion of the cannula, though with less probability given the absence of the three conditions mentioned above which penalize OITs. In our BTLT this incident is completely preventable, as our table data are demonstrating, thanks to the continuous and direct inspection of the movements of the distal portion of the cannula through the optics placed inside the cannula.

Difficult cannula insertion. It is a complication exclusive to OITs. In this study on Blue Rhino difficult cannula insertion is defined as multiple attempts ≥3 and results to have a rather high percentage (9.87). It must be considered on the light of the increase of the frequency of complications to which it may give rise, i.e. desaturation, ring fracture and posterior tracheal lesion.

Difficult cone-cannula extraction in TLT. It is the equivalent of the difficult insertion of the dilator in OITs. The main difficulties of the dilation manoeuvre are usually caused by the calcification of the trachea, particularly frequent in our series because of the high percentage of COPD patients with severe degenerative processes of the airways. Difficult dilation, however, is not a problem in TLT as
the resistances are overcome by a simple increase of traction on the wire, not only without any drawbacks but even with the possibility of obtaining, paradoxically, a more precise and regular stoma. Conversely, in OITs in these conditions the dilation involves a greater risk of complications.

**Difficult RTS insertion.** In some cases, in the presence of the usual well-known anatomic abnormalities which make the larynx access difficult, we met some difficulties in the introduction of RTS, but never insurmountable. In 5 cases we have reduced the difficulties by turning on the use of smaller diameter RTS. The retromolar entry remarkably facilitates the insertion as makes the approach to the larynx more direct (112).

**Intra-procedural decannulation.** It can be complete or partial in BTLT, as is elucidated in the chapter dedicated to it. We consider the decannulation a technical problem rather than a complication since it is not a risk in the patient under full respiratory control and its correction (repositioning of the cannula) is practiced with a particular fast and safe method (see chapter accidental decannulation). The situation is very different in the variations of BTLT that do not include the use of SVT or entail its early removal, so that this event may have severe consequences.

**Cases converted to ST during tracheostomy.** If we add the 3 cases of conversion Blue Rhino into ST to the 13 patients, not enrolled by the pre-selection, it is to admit that the number of the cases not suitable for Blue Rhino is relatively high. In particular, when it is compared with the absence of conversion in the unselected group of BTLT, where the obvious major percentage of difficult cases should have brought a higher incidence of this kind of complication. This greater capacity of BTLT to be usable in the entire range of patients, routinely admitted to an ICU, demonstrates very clearly the greater intrinsic safety of the technique. As evidence of this advantage, we could cite anecdotal experience on two patients, the first affected by uncontrollable coagulopathy (cited on page 33), the second with severe sepsis in an immunodeficiency state after heart transplant, which, refused by surgeons, were subjected to BTLT with no problems.

Regarding the conversions described in a few papers on TLT, this complication is to be referred to the adoption of personal modifications of the technique which, in the more demanding patients come to create operational difficulties that lead to interruptions of the procedure.

**Cases abandoned, not tracheostomized.** A case is reported in the Blue Rhino series, where the occurrence of a worsening of the patient's general condition forced operators to stop the procedure and, then, to definitively abandon the tracheostomy. Since there was not a detailed description of the event, it is impossible to determine what could have been the influence of the intervention and what could have been the influence of a trivial causality in the change in the clinical condition. Therefore, in our opinion, this event could not be called a true drawback of the technique.
Comparison of tracheostomies

The present situation

For a century surgical tracheostomy (ST) reigned unchallenged until the introduction of the Ciaglia method, the first acceptable percutaneous technique, created the need of comparing the different techniques. Subsequently, the appearance of further new methods has increased even more the interest to point out the best technique. Unfortunately, erroneous criteria of comparisons have been adopted so far and thus, the conclusions of the most part of studies on tracheostomy techniques result imprecise and misleading. Indeed, there is the habit of minutely reporting the data regarding age, gender, ASA class, severity score, number of days of tracheal intubation, for which any significant association with the rate of complications does not exist. On the contrary, and to make one of the most striking examples of evaluation absurdity, the fundamental data on the anatomical characteristics of the neck of each patient are not systematically taken into account, although they are essential to highlight the level of the real difficulties of the tracheostomy. In these conditions, we should not be surprised that techniques that had literally disappeared after a while, like the Shelden and Toye methods, at the beginning had been regarded as “simple, safe and recommendable”. For some time we have tried to draw attention to this problem but the situation of today is still very far from the radical modifications we have suggested, and that we propose here again, to achieve more reliable comparisons. Only recently some hints about the need for change have begun to be felt but the great majority of specialists are still anchored to the old criteria. Reviews and meta-analyses, which gather data from works methodologically in line with the requirements of EBM, but unreliable in content, can only provide questionable or useless results, as one can deduce also from a recently published review.

The main incongruities

1. The absence of data describing the neck anatomy as, at least:
   - the circumference and cricoid-sternal notch distance, correlate, with height and weight of the patient.
   - the thickness of the pre-tracheal tissue.
   - the traceableness of the neck landmarks.

2. The absence of any mention of the possible difficulties met in the airway approach, judged according to the difficulties encountered in the initial translaryngeal intubation, which can deeply influence the feasibility of the tracheostomy, tube exchange, and the endoscopic inspection.

3. The absence of data on the respiratory function, despite the remarkable difference existing between performing a tracheostomy in a normal and in ARDS patient.

4. The exclusion of the most challenging patients. Another senseless habit, a clear weak point of the comparisons, is the systematic exclusion from the studies of patients who are contraindicated to PDTs, according to a list introduced by Ciaglia two decades ago, and integrated more recently by Massick, that includes patients:
   - with overlying enlarged thyroid glands.
   - with marked obesity.
   - with obscured tracheal landmarks.
with abnormal coagulation profile, platelet count <50,000, PTT or PT greater than 1.5 times control levels.
- with untreatable coagulopathy.
- with severe acute respiratory failure, requiring PEEP higher than 10 cm H₂O.
- in paediatric age < 15 years.

These patients, if enrolled, would cause the worst complications, even after extensive experience is achieved (100). Referring to a study on the Ciaglia method and the Blue Rhino technique, Bhatti (99) says that suboptimal patient selection can lead to devastating results. Therefore, the only way to reduce the complications is to accurately exclude these most challenging cases. The consequence of the elimination of the test-bench cases is that any operator will be allowed to state that his technique is safe and advisable.

When a study regards the comparison between two techniques with the same number of contraindications, the pre-selection, putting both the procedures in the same favourable condition, will merely give an equal over estimation of the safety of both techniques. On the contrary, when two techniques with a significant difference of contraindications are compared, it is clear that the elimination of the most serious cases favours the less reliable method, for having excluded those patients who would have certainly encountered serious complications.

An example is offered by the comparative studies on ST/OITs that typically conclude with a false draw: the percutaneous techniques are more, or at least, equally recommendable than ST, when:
- ST has no contraindications.
- all the excluded cases are inevitably carried out with ST afterwards.
- in the course of OITs when technical difficulties compel the operator to stop the procedure even on selected patients, the conversion in ST reflects the usual practice.

The lack of major complications, specific to OITs, like the posterior tracheal wall breakthrough and especially the possibility of not having to impose restrictions on the acceptance of high-risk patients, explain why in certain hospitals preference is still given to the open technique (117). In addition, an increased competitiveness of ST is reached with its performance at the bed of the patient (as we were in the habit of doing) that equalizes the costs of PDT (119).

Another example of unsuitable researches is the comparison between TLT and OITs with the selection for a considerable wider range of indications of TLT.

5. Too coarse is the usual method to globally compare the various techniques. We have noticed that the subdivision of the percutaneous tracheostomies into phases (Table 1), according to the scheme we have been proposing for many years (11,115), is indispensable to perform more detailed, phase by phase comparison. In this way, it is possible to give a more reliable judgement of the feasibility, risk level, difficulties, duration of each phase, and their respective weight on the evaluation of the technique in its whole.

In figure 39, the importance of a single phase comparison, in this case limited to phase 2, is extremely evident. Indeed, the effects on the anterior and posterior tracheal wall, induced by different techniques of carrying out the dilation manoeuvres, and, in particular, the advantages due to the counter pressure mechanism, are clearly highlighted.

Within TLT itself, this division into phases is useful in showing how the variations are structured. All the methods of performing this technique share an identical phase 2, that gives them common exclusive advantages. Instead, the other phases (1 and 3) are very dissimilar in the TLT variations so that the comparison of the same phase of two different variations helps one to understand the reasons of different performances.

Furthermore, the list itself of complications, if timed according to the phases, would be more useful for a reader of a paper than the traditional one, because it permits him to go back automatically to the origin of a complication.

A bleeding in phase 1 is due to the needle insertion, a ring fracture in phase 3 is due to the insertion of the cannula (referable only to OITs), and so on, as shown in figure 53.
It might be of some interest to know the time taken by each phase in the different techniques: for example, phase 1 of the TLT is the longest and the one that causes the most frequent increases of the total duration, whereas the phase 2 is the shortest one among the percutaneous tracheostomies. Finally, the adoption of the division scheme helps to introduce new concepts in the comparative studies. In every technique one can spot a phase that characterizes the method, generally represented by the modality of the dilation manoeuvres. On the other hand, there are phases of different techniques quite overlapping. For instance, all the OITs recognize the same modality of the needle and the guide wire insertion and thus, in a hypothetical comparison between Blue Rhino and Griggs method (to cite a case), the complications of phase 1 should not be considered, since they depend exclusively on the expertise of the operator, not on the technique per se.

6. Non-objective and uniform evaluation of the complications. A shallow scratch or a superficial abrasion of the posterior tracheal wall are usually defined minor complications (113), without considering that they are there to show one that, without a great deal of good luck, they might be followed by much more severe events. In other cases there is not a uniformity of rating, like bleeding, from time to time estimated in millilitres, soaked gauzes, stopped with compression, needing transfusions or surgical repair.

An example of how a study may be influenced by too personal criteria and bias of the author to support its belief, (in this case, the superiority of Ciaglia method on ST), is demonstrated by the attribution to an allergic crisis the appearance of emphysema, pneumothorax and hypoxemia which had followed a difficult introduction of the cannula, and the subsequent overcoming of the emergency with the extraction of the cannula and endotracheal intubation (120).

Indeed, also the overall assessment of the technique is sometimes difficult to understand when, for example, in a study regarding 100 Blue Rhinos, 3 cases of bleeding, which required surgical exploration, 2 tension pneumothorax, 2 conversions and 1 false passage are reported and the technique is referred to as safe for the low incidence of major complications (63).

7. To take into account non–pertinent complications. Numerous are the unwanted events commonly described as complications of tracheostomy which, instead, are not strictly related to the technique and therefore should not be taken into account in the comparisons. According to our experience, we list the most common examples of erroneous attribution of some tracheostomies complications and their more frequent causes:

- Hypo/hypertension: too deep or too superficial anaesthesia, improper lung ventilation.
- Accidental post-procedural decannulation: inadequate nursing.
- Late haemorrhage: decubitus caused by the cannula, non periodic endoscopic surveillance especially in the case of the use of a rigid cannula, neck vessels with abnormal course.
- Cannula obstruction from encrustations: inhalation of dry gases, careless evaluation of secretions fluidity during suctioning.
- Cannula obstruction by displacement: failing shield fixation, lack of shock absorption of traction on the cannula.
This complication is more frequent with rigid cannulas, in particular the C shaped ones, because they are subject to lose alignment, already difficult to establish at the first adjustment. A particular consequence is represented by the embedding of the end of the cannula into the rear wall of the trachea and with the following obstruction of its opening (Fig. 54).

![Fig. 54 Cannula obstruction by its embedding into the tracheal wall](image)

This occurrence was studied by Polderman (121) and described as a new syndrome, defined TWISTED (Tracheal Wall Injury with intermittent Stoppage of Tracheal cannula and Episode of paroxysmal Dyspnoea). The merit of the author is to have drawn the attention to a rather frequent complication, not easily recognizable even with bronchoscopy, and potentially very dangerous. However, we think that it should not be defined as a specific complication of percutaneous tracheostomies because it is related to the rigid cannula and therefore it may occur also with surgical tracheostomy, as we have had the opportunity to detect in the past.

- Lock of cannula by scarring stenosis of the trachea. This complication was attributed specifically to TLT (82), and finds no other evidence in literature.
In 6 patients after months of prolonged home treatment the removal of the cannula was impossible because of the formation of a mass of inflammatory tissue around the cuff, which so firmly blocked the cannula that it was necessary to turn to surgical removing. In only one patient the original TLT cannula was still present, whereas in the others a Shiley cuffed cannula had been inserted at the discharge of the patients from the ICU. The surprising conclusion of the authors of the study (82) has been, that TLT: "is an easily carried out and slightly invasive procedure, plays a very important role in the management of the Intensive Care Unit patients, but should be reserved for the few cases requiring tracheostomy for limited periods of time, in low risk patients and within the first 18 days after the acute damaging event".

We invite the reader to go back to figure 51 to better understand the origins of this kind of complication that may occur with any other tracheostomy technique if the fundamental principles of tracheostomy care are not observed. It will be evident that these cases can not be defined TLT complications, but only unavoidable consequences of a wrong postoperative treatment. Our experience on tens of tracheostomized patients who underwent an uneventful prolonged domiciliary respiratory assistance, demonstrates the erroneous and misleading conclusions of the publication.
8. The non-definition of the level of experience of the operator. This is a parameter difficult to evaluate because it contains many components such as intelligence, manual dexterity, adaptability, learning ability, surgical preparation, and, of course, the size of personal case series, but unfortunately it is also one that has the greatest impact on the results. The influence of this parameter in the performance of ST, is huge and illustrative, since this technique gives the impression of establishing a genuine throat cutting if practiced by beginners, while if it is carried out by a skilful surgeon with a minimal tissue dissection and no bleeding, it appears to be the ideal technique. The level of experience is crucial also in the percutaneous methods, how one can infer from comparing the results obtained in two different studies on the same techniques (48,122) where TLT was evaluated in a completely opposite way.

9. Negligible report in the literature of the worst complications. A recent survey (123), organized with anonymity by the American Academy of Otolaryngology Head and Neck Surgery members, pointed out that each year in the US it is estimated the occurrence of about 1000 catastrophic events, following tracheostomy, with 500 cases of death or severe permanent disability. The percentage related to the various techniques, surgical or percutaneous, is not clarified but the important consideration that we can draw, is that these shocking numbers, compared with the paucity of those published, suggest a wide underreport of these complications. In fact, narrowing the field to percutaneous techniques, the opinion that most of the worst complications (fetal bleeding, tear of the posterior wall of the trachea, hypoxemia from loss of airway control) are not published is fairly widespread. The reasons are diverse and not limited to what apparently seems to be the most influential, namely the cover-up for fear of prosecution (38), but in great part result to be sustained by more ordinary conditions, as the lack of the propensity of a centre to make researches and to publish experiences. Not less influent are the difficulties that hinder the acceptance of the articles in medical journals, which dissuade possible authors. Furthermore, many unwanted events reported in publications with a low level of evidence, short communications, and clinical cases with misleading titles, which are ignored by reviews and meta-analyses, easily pass unnoticed. Therefore, it is not possible to know the figures of global mortality or the real incidence of the major complications associated with percutaneous tracheostomy.

Anecdotal reports and local experience suggest that fatal arterial bleedings during the performance of PDT are under-reported (124). Wise (125) said that in discussions between colleagues, “tales of horror” are often recounted by many of those who practiced PDT on complications that, later, are not always published. This author, with the intention of examining the incidence of severe acute complications such as bleeding, pneumothorax, hemothorax, dissection of the trachea and oesophageal rupture, distributed 60 anonymous surveys to those who routinely performed PDTs, largely Ciaglia or Blue Rhino, in a teaching hospital. It was discovered that out of 42 respondents, 50% incurred in one or more of these complications. The conclusions of this author are that these complications are rather common and, unlike a widespread trend, PDTs must be dealt with all the necessary precautions.

McCormick (126) considers the fact odd that in three meta-analysis on percutaneous tracheostomy (127-129) deadly haemorrhages are not counted not even in one episode. This perplexity is supported by the results of systematic review of the cases of the lethal complications from PDT published in the literature from 1985 to 2013, which shows that the haemorrhage, with 27 cases out of 71 deaths, represents the most frequent cause of death after tracheostomy (130).

Coming now in particular to the most exclusive complication of OITs, the posterior tracheal wall injury, there are many clues that lead us to believe that this type of complication is much more common than is published:

- Pothman (60) remembers that some cases of tracheal lesions, occurred in tertiary hospitals and not officially reported, came to his knowledge fortuitously through personal communications.
- We ourselves have come to learn directly about at least twelve cases after OITs, through consultancies made in other centres or because the patients were transferred to our specialized ward from small hospital or private institutions. All these incidents were not even published at a later date.

- Many cases of asymptomatic lesion may show spontaneous healing and are not noticed because a thorough endoscopy of the trachea is not always accomplished at the end of the tracheostomy or are non detectable at the control for being very small. Indeed, the endoscopy, to be quite revealing, is rather complex because it requires the removal of the cannula to provide the complete view of the entire length of the trachea and thus, the discontinuation of ventilation. However, some injuries are represented by a linear slot that is easily escaping the endoscopic view because it is hidden by the folds of the pars membranacea. In these circumstances, to achieve absolute security of the survey, the only effective system is that of introducing a cuffed endotracheal tube in the oesophagus so to obtain, by sliding up and down the inflated cuff, the distension of the posterior tracheal wall and, with it, the optimum condition to highlight even small injuries (Fig.55A). A positive finding requires the direct exploration of the oesophagus to detect its possible associated injury (Fig.55B).

![Fig. 55](image)

**Fig. 55** Method of checking a possible tracheal tear with oesophageal intubation

A: Tracheal exploration with intubation of the oesophagus to highlight minimal tears

B: Oesophageal exploration for detecting a tracheo-oesophageal fistula

- Taking into account that the reports of subcutaneous emphysema and pneumothorax following a percutaneous tracheostomy are relatively frequent in literature and that these complications may be related to breaches of the rear wall in a significant percentage, also Trottier (131), referring to his personal experience with the Ciaglia method, is of the opinion that the true incidence of perforation of the posterior tracheal wall must be held higher than that reported.

- The strange, almost incomprehensible repudiation of the multiple dilators by Ciaglia himself is very meaningful. Introduced in 1985, this method was extolled for fourteen years by innumerable publications as the easiest and safest method. Surprisingly in 1999, the inventor himself declared that his method should be abandoned since: "the risk of tracheal damage with the rigid dilators, especially in the case of high tissue resistances, is unacceptable. The day of the rigid dilators in PDT is over" (43).

To compel the inventor to make this disconcerting decision, there could be no other reason that the knowledge of an unacceptable incidence of tracheal injuries, provoked by his method. But, if we consider that the number of this kind of complications traceable in the most common specialized journals from the Ciaglia method introduction in 1985 till today, is only about twenty cases of tens of thousands tracheostomies, this should be esteemed a statistically excellent result, and justify the continuation of the method. It appears evident, therefore, that Ciaglia’s decision was taken under the pressure of the amount of not surfaced cases.
Based on these considerations, we can not be stunned by the fact that not only this technique is still used but that rigid and very pointed dilators are adopted in other methods.

- Many cases of tracheal lesions are not included in reviews because they are published in papers with titles that primarily draw attention to the treatment of the complication, as is the case quoted by Belcher (132). The title in fact highlights a peculiarity of the conservative method, (the intubation of both the main bronchi), to repair of an extensive carinal laceration, that only in the article and as an incidental information, the reader discovers to be caused by a Blue Rhino procedure.
Eleven other cases, not mentioned in the papers focused on the tracheostomy techniques but reported in a publication on the optimal mode of surgical treatment of the rupture of the posterior tracheal wall (133) bring additional credit to our beliefs.

- A further confirmation of the underestimation of this problem comes from a survey carried out in Germany on iatrogenic and non-iatrogenic tracheal injury of various origins (134). In this survey it appears that in the period from 2001 to 2005, 181 lacerations of the trachea caused by anonymous percutaneous tracheostomy were treated in various hospitals. Whereas the response to 323 forwarded questionnaires was 72%, this number should be even higher. Therefore, assuming an average of 200 cases every 5 years, it would reach the figure of 400 cases for the decade 2000 -2010. Given that in the world literature of the field, at least regarding the most widespread journals, the signalling of tracheal injuries from percutaneous tracheostomy does not exceed twenty cases up to the present time, even taking into account that some cases published in newspapers with more local circulation may escape the count, it seems logical to assume that the phenomenon of unreported complications is of huge proportions.

In conclusion, it can be taken for certain that:
- the major adverse events of percutaneous methods are quite frequent
- only a limited portion of them are brought to the surface in the relevant studies
- they would be even more numerous if the most challenging patients were not systematically excluded from the case series, for being afterward assigned to surgery.
It is intuitive that all percutaneous techniques fall into this situation but it is also obvious that the incidence of the complications is indirectly proportional to the intrinsic safety of each technique. Anyway, the non-reporting of negative outcomes has serious consequences because it creates a wrong picture of reality, and does not highlight the different levels of danger related to the various techniques.

10. The complexity of the procedure. Soon after its presentation, TLT was judged a complex technique, a criticism that deserves to be evaluated in the light of a deep analysis of the procedure. For these reasons we have set ourselves to describe the technique with extensive details and support it with many figures, almost at the limit of redundancy, to give the reader a complete picture of the basic TLT and its variants and the ability to make appropriate and comprehensive comparisons with other procedures.

But, first of all, it is crucial to define what is usually meant by complexity. If we examine the various manoeuvres carried out in percutaneous tracheostomies, we can see that none of them can be judged technically difficult to perform by an operator of medium preparation, ability and experience. The insertion of a dilating probe or the rotation of a cannula, in an experimental model of various kinds, can be theoretically quickly learned and done even by individuals not involved in the work. When the same manoeuvre is contraindicated in certain patients, this is not due to the fact that it is difficult by itself but is due to the risk of serious complications that it entails. Among all the components of the concept of complexity (time taking, feasibility, demanding manoeuvres, risk of complications) we have thus to turn on the one of the danger of a manoeuvre, and, willing to give a sound answer to this criticism, we think it advisable, once again, to take in comparison the single steps of the principal percutaneous tracheostomy techniques.
- In phase 1, with a thorough endoscopic control, the caudally and cranially insertion of the needle do not show substantial differences. This phase is critical for both OITs and TLT methods since the precise centring of the needle at the intended tracheal level affects the whole remaining part of all procedures.

- At phase 2, once the wire is positioned, TLT and OITs are not even comparable. The TLT dilation is the most simple, quick and safe of all the existing methods. *The simple, rough traction on the wire can be carried out by unskilled individuals in 30", and endoscopy is not needed.*

  In OITs, the dilation, practiced with the pulling or the rotating mode, is always a challenging procedure, that calls for a surgical dissection, a thorough endoscopy, experience and caution in order to avoid very severe complications. Yet, *the risks are not cancelled with the semi-flexible dilator of the Blue Rhino technique, as can be inferred from the list of ten "should and must" cautionary advices which the user finds in the manufacturer's instructions.*

  Nor is it simple in PercuTwist to keep the sharp tip of the screw dilator far from the rear wall with an upward traction, absolutely essential to prevent that the point of the dilator may come in contact with the posterior tracheal wall (108). Another inconvenience that makes this technique complicated is the frequent formation of a skin twisting, not always solvable with repeated lubrications (135).

- Phase 3 of OITs appears, compared with the one of TLT, simpler, since it consists of the traditional insertion of the cannula, but in reality, it does not prove easy and safe, as we explained in different chapters of this book.

  In TLT, the adjustment of the cannula (straightening and rotation) is undoubtedly an unusual manoeuvre and should be learned ex novo, but it is very far from being complex. To learn these manoeuvres quickly we recommend using a dummy of simple making (Fig. 56), very practical and effective, before starting the real training on the patient under the guidance of an expert colleague. When performed on a patient properly ventilated through the SVT, as in the basic TLT, the adjustment of the cannula may, at worst, run into an accidental decannulation, whose correction certainly does not present a problem (see page 38). Therefore the phase 3 can be managed with an extraordinary sense of tranquillity that is the essential condition for a safe and accurate performance.

  The opposite situation is to work on a non-ventilated patient, as happens in BTLT variations, when the rush leads to frantic manoeuvres. Indeed, some of the complications reported by certain publications derived from these unacceptable working conditions which transform phase 3 into a risky procedure.

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**Fig. 56** The period for learning the straightening and rotation of the cannula can be shortened with a particular type of dummy. The transparency of the silicon tube enables the learner to watch the movement of the cannula. The elastic diaphragm, obtained by the grinding of the tube wall (see insertion), mimicking the resistances of the tissue, makes the comprehension of the manoeuvres easier and faster, and allows one to carry out the procedure on the patient, safely.
- Regarding the respiratory assistance, TLT is criticized because it requires changes of tubes, such as the transition from primary ETT to the small ventilation tube (SVT), or, as in BTLT, the changes from ETT to rigid tracheoscope to the small ventilation tube.

At this point, we think that it is difficult to accept that a very advantageous procedure could be hindered by an exaggerated fear of having to accomplish it. The same consideration is made by Fisher about OITs (36), who noted that the resistance to the use of a small ventilation tube, and then giving up a secure better control of the airways, does not find any justification since, with the help of a simple elastic gum, he proved the exchange can be carried out fairly safely.

Ultimately, that the mentioned criticism of complexity of TLT was raised by a hurried and superficial examination of a very non-conventional method, is confirmed by outstanding studies showing that a few cases are enough to gain satisfactory experience, since each passage is driven by a logical sequence (24) and that there is not evidence of the limited practicability, occasionally described by others (23).

11. Missing precise explanation of the adopted technical variations. All the tracheostomy techniques, ST included (117), are feasible with numerous variations which may lead to improvements and drawbacks to the original version.

It is therefore essential that the authors of a given publication indicate with precision the technical changes they have introduced, in order to give the possibility to the reader to correctly interpret the results.

This advise is even more important in the case of studies which, later on, are selected for meta-analysis or reviews, because it avoids the risk of creating confusing and distorted generalisations, that occurred at the expense of the basic TLT technique, which has been involved in criticism regarding complications peculiar only to its certain variations.

12. The misleading influence of the RCT and meta-analysis. Meta-analysis is a technique for combining evidence from multiple trials, but, if the selected studies are not designed and performed appropriately, the conclusions will be necessarily erroneous and misleading. And, moreover, if the studies regard patients in intensive care, where the heterogeneity of cases reaches the highest levels among all other areas of medicine, we should not be surprised if they end up with false messages or the too frequent admission that “further investigations are necessary in order to achieve reliable results”.

A systematic analysis of the RCTs over the last 26 years published in 2002 (136) revealed that only 25% of the works were acceptable for randomisation, blinding, sample size, and that this alarming situation could be referred to all other medical journals. Vincent (137) highlighted that the most debated problems of this area of medicine are unresolved, an evident sign of the inability of RCTs and meta-analysis to achieve definitive conclusions.

Already about ten years ago, also Dreyfuss (138) admitted that this type of researches was not able to give concrete answers on the questions posed by the major themes of intensive care medicine, from the best treatment of ARDS and the optimal PEEP to the usefulness of the intestinal decontamination, from the albumin vs no albumin, to colloids vs. crystalloids, just to name a few.

This author added that many improvements in intensive care were produced more by observational studies and research, oriented on a sound physiological thinking, than by RCTs which several times resulted as being even harmful. He cited, supporting his affirmation, a polycentric study (139) that has hindered the diffusion of the prone positioning, denying its ability to reduce the mortality in ARDS patients.

He judged, this a big mistake, because he retained the technique very valuable and without unwanted effects as it was confirmed by its current wide use, and much more, by the admission of the same authors that denied the usefulness of the procedure in the past, to have lost 30 years of useful application.
Villar et al (140) point out that this situation leads to a distrust of RCT, induces caregivers not to accept their therapeutic addresses and take, as a foundation for the medical decisions, principles of care validated by a prolonged clinical acceptance and the opinion of experts. These authors cite, as an example of incorrect planning, the very celebrated ARDSnet trial (141), for having compared tidal volume of 6ml/kg with that of 12 ml, considered inappropriate because it did not meet real situations. Indeed, the average volume, used at the time of the study, was about 10 ml and, more, a tidal volume greater than 10 ml continues to be used by the same clinicians of the participating centres after the publications of the study (142). Besides the aspect of the usefulness of the RCT, Truog (143) draws the attention on the expenses of the polycentric trials: referring to the ARDSnet study, he highlights that facing no practical advantages, there is a cost of 15 million US dollars. Years later, we see that today the situation has not changed.

- after 60 years of the use of the mechanical ventilation it is still being discussed which is the best mode of applying it.
- after 50 years of PEEP, there is still no agreement about the Best PEEP.
- after 40 years larger studies are still required to determine if the selective decontamination of the digestive tract (144) or the pulmonary artery catheter in critical care and anaesthesia (145) are useful or not.

Recently, Sprung (146) draws attention to the need to avoid the major mistakes made so far in the planning of RCTs, first of all, because they influence the reliability of the guidelines.

Moving away from the general considerations about EBM to the specific aspects relating to the evaluation of the tracheostomy techniques, we can observe that, beyond the errors of statistical methodology, a significant contributing cause of unreliable results and misleading conclusions of the studies, is represented by a number of amazing inconsistencies with which evaluations and comparisons of the various methods have been and still are practiced.

A recent systematic review (118), performed with the aim of pointing out a likely superiority among the percutaneous techniques, is crowded with errors, typical of these studies. In fact, this review:
- is based exclusively on studies statistically correct but completely not reliable because performed according to the usual traditional criteria of comparison, whose incongruities and pitfalls have been widely pointed out previously in this chapter.
- it does not take into account the procedural variants of the selected techniques and hence the considerable diversity of results that they involve.
- it does not consider, in accordance with the EBM rules, a lot of papers (9,12,18,23,24,35), outstanding for the large case series and the authority of the Institutions, because they are not structured as RCT.

By sheer coincidence, these papers are in favour of TLT, one of the techniques included in the comparisons, so that it falls the support of a total of not less than one thousand cases.

Anyway, as an inevitable consequence of the above mentioned errors, the conclusions are, that given the relevance of the issue, there is an urgent need of adequately powered randomized studies. However, as a final compromise, the authors are of the opinion that all the examined techniques are acceptable.

Returning to the crucial issue of exclusions from the meta-analysis of publications without an adequate level of evidence, we underline that we have obtained a lot of useful information by reading conference papers, communications, posters and letters to the Editor. Therefore, we completely share the opinion of Ferguson (96) when he says that observational studies and case reports are to be considered very useful because they bring valuable information and play a vital role in the stimulation, development and support of the researches.

But then, at this point, one can not help raising the question of what is the meaning of rejecting these studies, when they have been approved for publication in major scientific journals by trustworthy colleges of peers, and that, precisely because of this approval, they can influence the therapeutic address of the lectors. It is alarming that this issue has never been raised by anyone, so far.
The shortcut comparisons

We realize that a comparison made in compliance with all the points listed above would require a lot of commitment and time, which are not always available. Moreover, the large articulation on which this new approach is structured could foster non strict observance of the various criteria, undermining its trustworthiness. For these reasons, we propose less complex solutions based on the account of easy definable indexes, but still sufficiently adequate to ensure reliable comparisons of the various tracheostomy techniques:

1. The index of the probability of posterior tracheal wall damage
A thorough examination of the procedure allows the physician to detect the steps, which, on the basis of the probability law, may be considered predisposing to cause the tracheal lesion in the three phases of a procedure:

- in phase 1, there is a similarity of a minor risk (needle puncture) between OITs and TLT.

- in phase 2, the difference becomes wider between the Out/In and In/Out dilation techniques. While TLT is literally at zero risk, in OITs the insertion of rigid dilators is always a dangerous manoeuvre, already highlighted by Ciaglia in 1999. However, also the semi-rigid device of Blue Rhino is not without risks of posterior tracheal wall injury (74).

- in phase 3, if the comparison is made between the basic version of TLT, performed in faithful compliance with the description given in this publication, and OITs, the difference remains large. Indeed, TLT may incur a simple decannulation in normally ventilated patients only in the case of absent or inadequate endoscopy, whereas in OITs the insertion of the cannula involves the same dangers of tracheal damage of the dilation phase.

2. The index of the severity of the trauma of the anterior tracheal wall
It is calculated on the basis of the percentage of the ring fractures detectable with the bronchoscopic examination. Although the visible fractures form only a part of the existing damaging, this index is without doubt the most reliable way to judge the magnitude of the damage of the local anatomy produced by a tracheostomy.

The difference between TLT and OITs is huge. In the first technique the problem does not even exist: the firm counter pressure on the neck surface, forces the rings only to spread themselves apart. In the other techniques the Out/In manoeuvres make the fracture inevitable so that, in fact, this event is signalled as one of the most frequent complications of this type of procedure. This OITs drawback deserves much more attention than what was pointed out so far, because it is usually matched with:
- Internal bleeding
- Obstruction of bronchi by clots or fragments
- Obstructive flaps of mucosa
- Loss of adherence of the tracheal window to the cannula
- Infection of the stoma
- Late tracheal stenosis.

3. The index of the effectiveness of endoscopic control
OITs and TLT are in a very different situation in all the three phases of the tracheostomy. In OITs not only the external compression by needle, dilator and cannula narrows the tracheal lumen but also the
presence itself of these devices obstructs the view of what is happening further down. Therefore, it is explainable why in OITs the endoscopic control is not able to completely eliminate the severe complications, like false passages and tracheal lacerations, also with experienced operators (38-40,44,52,100) (see the chapter on endoscopic control utility). All the manoeuvres performed without being able to visually inspect what one is doing, involve risks. We could mention, as a fitting analogy, the peridural anaesthesia, where everything is left to chance, since the expertise of the physician can not prevent the tip of the blindly inserted needle affecting blood vessels or nerve structures.

4. The index of respiratory support adequacy
A severe lung disease creates serious difficulties to the operator, but there is no doubt that even in the normal patient, episodes of hypoxemia and hypercapnia prove very common in the course of a tracheostomy without an adequate respiratory support. In a previous chapter, a large space has been reserved to the evaluation of the effectiveness of the various methods currently in use, applicable to both TLT variations and OITs. We concluded pointing out that the small ventilation tube, used in the basic TLT, is the only system capable of providing a stable, continuous ventilation, suitable for all kinds of patients.

5. The index of the inherent danger of a technique
It can be put in relationship with the number of contraindications attributed to the technique. Indeed, a contraindication always springs out from the observation that a certain technique frequently causes a certain type of complication when applied to a certain type of patient, even with wide-ranging experienced operators. Meaningful is the example of an expert operator who, wanting to verify if the Ciaglia method was feasible in paediatric patients, despite a precise warning of Ciaglia not to use it, was dissuaded from continuing the trial by two life-threatening accidents (147). From these considerations, one could make the assessment of the intrinsic safety of a technique just from the amplitude of its restrictions. A simple equation summarizes this concept: the more numerous are the contraindications for a technique, the more numerous are the critical steps it contains, the lower is the level of its intrinsic, non operator dependent safety. Due to the different levels of respective safety, TLT has wider indications among the ICU patients than OITs (18), as well as BTLT that has a greater range of indications when compared with its variations.

Conclusions

The TLT is a truly innovative technique because it relies on In/Out dilation direction, a method never taught before. Its main advantage is the elimination of the risk of injury to the posterior wall of the trachea, a complication that, as an original sin, is inherent in the techniques that push dilators and cannulas into the tracheal lumen from the outside of the neck by coarse and dangerous manoeuvres. A second advantage of the In/Out dilation is the extreme, unrivalled limitation of the local anatomical trauma that is obtained by the exclusive possibility of compressing the neck layers at the stoma level between opposing pressures, the only way to ensure a dilation manoeuvre without rips and tears of tissue, tracheal ring fractures and bleeding. It is interesting to note that the principle of the two face compression is also the technique that the artisan applies by means of a cutting die to practice perfect holes, without the fraying of the edges, in
plastic or leather items, and that, between artisan and physician, there is a singular analogy: both of
them have no viable alternative to obtain the best results.
Moreover, a significant contribution to the reduction of the tissue trauma is provided by the fact that
the cannula is dragged into the trachea following the cone during the dilation manoeuvre, and thus,
without the additional tissue damaging sustained by the traditional Out/In insertion of the cannula. This
advantage is not indifferent whether one considers that in OITs the insertion of the cannula is
generally regarded as a step at the same level of risk, or even higher, of the dilation phase, especially
when strong pushing efforts are to be practised.
This unique reduction of the anatomical trauma is materialized in an extreme reduction of
intraoperative and postoperative bleeding, so that TLT can be defined as the bloodless technique. If it
is true that bleeding is the most frequent complication in OITs (130), it is very comforting to know that
TLT users can rely on a technique in which blood loss, when it happens, is measured in drops. A
second remarkable benefit of the limited local tissue trauma is the minor risk of causing serious
complications, so that also the operator with limited surgical experience can enjoy greater
independence in comparison of the case of OITs, for which there is a closer need of availability of a
specialist for prompt surgical revision of the complication.
An important point to keep in mind when dealing with tracheostomy is that all the techniques, ST
included, can be performed with some variations. Consequently, if the procedure is not clearly
described in detail, the studies done on the different versions, by producing different results, create no
little confusion in the evaluation of a given technique.
For this reason we decided to divide the percutaneous tracheostomies in three stages (Table 1), in
order to make a more detailed evaluation of the different techniques, by comparing them not in the
usual global system but through the corresponding phases of each of them. In this way, the
differences and similarities, the weaknesses and advantages of the techniques, are easier highlighted
and more precisely located in the context of the procedure than what can be achieved with the
traditional comparisons.
In the case of the TLT technique, the division into phases highlights that all variants result in having in
common the mode of In/Out dilation, the main distinguishing and unmodifiable feature of the technique
that allows all of them to share the full set of advantages that TLT phase 2 offers over OITs. On the
contrary, between BTLT and its versions, substantial differences result in performing the other parts of
the procedures, with consequent different outcomes which explain why some kind of patients can not
be suitable for certain TLT variations and why we chose the basic technique as a standard method.
The BTLT superiority is due to the use of rigid devices: in phase 1, the tracheoscope greatly
facilitates the exact centring and the advancement of the needle into the tracheal lumen, while in
phase 3, a rigid optics inserted into the cannula makes the final settlement of the cannula quicker and
safer than what is achievable with the other variants. The remarkable advantages brought to the
Ciaglia method by the metallic tracheoscope (Fig. 33) used in the first Italian trials of this techniq
ue, allows us to say that the adoption of rigid instruments in all OITs, solving not a few of their problems,
certainly would increase their safety.
A second strength of BTLT is given by the absolute control of the ventilation during the entire length of
the procedure. This is a considerable advantage if one thinks that providing adequate ventilation
removes two of the main conditions, stress and hurry, that lead the operator to make mistakes and
cause complications.
In this book, a substantial space is also reserved to the numerous topics on tracheostomies that still
fuel heated debates. We reported the more recent and significant clinical trends which are not always
in line with our personal convictions, developed over years of experience in this specific field.
Eventually, we faced one of the most crucial issues regarding tracheostomies, the evaluation and
comparison of the current techniques.
It should be remembered that percutaneous tracheostomy represents an elective procedure and
therefore should not expose a patient to a high risk of hazardous complications (42). Therefore, the
reports of numerous serious accidents, the tales of who have suffered experience of near disaster (125), and a vast body of facts which lead to the conclusion that a large proportion of complications is not published, fully justify the studies which try to highlight the origin of these complications and to identify the technique that offers more guarantees of intrinsic safety. Unfortunately, up to date, there is very little good evidence dictating which PDT modality should be preferred (111), since the criteria commonly used are so absurd that they can not provide useful information about the superiority of one technique over the others.

What is more striking is the incredible absence of the systematic collection of the anatomical features of the neck of each patient, which are the only data that allow a precise assessment of the real difficulties of a tracheostomy. Other distortions are not to give weight to respiratory conditions, to compare techniques with different contraindications with the exclusion of the most challenging cases, and the non-uniformity of evaluation of the complications. It is disconcerting that these omissions have never raised strong criticisms with the exception of my papers on the need to changes the comparison methods (114-116) of many years ago. The first and heaviest consequence of this situation is represented by the fact that studies, even if accomplished in the strictest adherence to the rules of the evidence based medicine, are completely unreliable. Therefore, the surveys and meta-analysis, obtained from these kinds of studies, must be reconsidered and planned again on the new and sounder criteria to put an end to the open question of the superiority of a technique over another and to help the practitioner to perform sharp-witted choices. Given the great importance of the subject, ample documentation of opinions very sceptical about RCTs and meta-analysis in the scope of the intensive care, on which to ponder, is presented on page 64-65.

However, since the traditional methods of comparison are deeply rooted, the change of trend is not expected to be easy and immediate. Therefore, we propose the application of a series of simple indices, a sort of shortcut of more complex assessments, which give one the possibility of obtaining a clear picture on the levels of risk and invasivity of the various techniques. On the basis of these indices, the reliability of which can hardly be disputed because supported by simple criteria of clear clinical evidence and common sense, the translaryngeal technique, especially in its basic modality, has the least risk of complications, and consequently, the broader spectrum of indications. These advantages can not be even remotely diminished by a very questionable criticism that traded the great innovation of the technique for procedural complexity.

For this reason, we feel that we can conclude our work with the statement made by Oeken (24) that if TLT, with any version running, was more widely adopted in the ICUs, many dramatic complications of percutaneous techniques would be avoided.

References


22. Walz JM. Point: should an anaesthesiologist be the specialist of choice in managing the difficult airway in ICU? Yes. Chest 2012;142:1372-4


37. White HN, Sharp DB, Castellanos PF. Suspension laryngoscopy-assisted percutaneous dilatational tracheostomy in high-risk patients. Laryngoscope 2010;120:2423-9
44. Thant M, Samuel T. Posterior tracheal wall tear with PercuTwist. Anaesthesia 2002;57:501-21
54. Hotchkiss KS, McCaffrey JC. Laryngotracheal injury after percutaneous dilatational tracheostomy in cadaver specimens. Laryngoscope 2003;113:16-20
56. Klemm E. Dilatational tracheostomy using the Klemm tracheotomy endoscope. Straub Druck+Medien AG. D 78713 Schramberg, Germany 2005
63. Fikkers BG, Briedé IS, Verwiel JM, Van Den Hoogen FJA. Percutaneous tracheostomy with the Blue Rhino trade mark technique: presentation of 100 consecutive patients. Anaesthesia 2002;57:1094-7
89. Weissbrod PA, Merati AL. Is percutaneous dilatational tracheotomy equivalent to traditional open surgical tracheotomy with regard to perioperative and postoperative complications?. Laryngoscope 2012;122:1423-4
91. Durbin C, Perkins M, Moores LK. Should tracheostomy be performed as early as 72 hours in patients requiring prolonged mechanical ventilation? Respir Care 2010;55;76 83

94. Young DM, Harrison DA, Brian H, Cuthbertson BH, Rowan K, for the TracMan Collaborators. Effect of early vs late tracheostomy placement on survival in patients receiving mechanical ventilation the TracMan randomized trial. JAMA 2013;309:2121-9


98. Pelosi P, Severgnini P. Tracheostomy must be individualized! Crit Care Med 2004;8:322-4


109. Shelden CH, Pudenz RH. Percutaneous tracheostomy. JAMA 1957;157:2068-70


135. Fikkers BG, Venriel JM, Tillmans RJ. Percutaneous tracheostomy with the PercuTwist technique not so easy. Anaesthesia 2002;57:935-6
138. Dreyfuss D. It is better to consent to an RCT or to care? (“nothing in excess”). Intensive Care Med 2005;31:345-55
143. Troug RD. Will ethical requirements bring critical care research to halt? Intensive Care Med 2005;31:338-44
146. Sprung CL. Randomized controlled trials and practice guidelines: the good, the bad, and the ugly. Intensive Care Med 2012;38:1911-3