NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of translaryngeal tracheostomy

Tracheostomy using a breathing tube inserted from the windpipe to the outside of the neck

Some patients need the help of a machine (ventilator) to assist with breathing. This is normally done using a tube that passes into the windpipe (trachea) through the mouth. If a patient needs to be on a ventilator for more than a few days it is safer and more comfortable to have a breathing tube inserted directly into their windpipe through a hole in the front of the neck (a tracheostomy) rather than through the mouth. The translaryngeal tracheostomy procedure involves passing the breathing tube from inside the windpipe to the outside of the neck, as opposed to the usual technique where the tube is inserted from the outside inwards.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in February 2013 (date of literature search 28 November 2012).

Procedure name

- Translaryngeal tracheostomy

Specialist societies

- British Laryngology Association
- British Thoracic Society
- Faculty of Intensive Care Medicine
- Intensive Care Society.

Description

Indications and current treatment

Tracheostomy is commonly carried out for patients in intensive care to maintain their airway, to remove excessive airway secretions and to enable them to be weaned from mechanical ventilation. This may be performed surgically but anaesthetists and intensive care physicians usually perform the procedure using a percutaneous technique, inserting a tube from the outside of the neck into the trachea, using a various devices and, commonly under endoscopic guidance.

The translaryngeal tracheostomy technique may lead to lower rates of bleeding, trauma and infection to the tissues surrounding the insertion area, compared with surgical and other percutaneous techniques. It may also avoid the risk of damage to the posterior wall of the trachea and tracheal rings, because of a lack of external compression during insertion.

What the procedure involves

Translaryngeal tracheostomy is a method for inserting a tracheostomy tube, using direct endoscopic visualisation. It is usually carried out with the patient under general anaesthesia with muscle relaxation. The patient lies supine with the head extended, and the endotracheal tube is partially withdrawn to allow an endoscope to be passed into the trachea. A small introducer needle is inserted percutaneously between the second and third tracheal rings and visualised endoscopically as it enters the trachea. A metal guide wire is then passed through this needle into the trachea and pulled upwards and out through the mouth. The existing tubes are then temporarily replaced with a narrower ventilation tube for the remainder of the procedure. There are variations of the technique, for example the guide wire may be fed through the distal end of the endotracheal tube or a rigid tracheoscope and recovered at the tube connector.

The guide wire is attached to a special tracheostomy device consisting of a flexible plastic cone, with a pointed metal tip, joined to an armoured tracheal cannula. The tracheostomy device is then drawn back through, in turn, the oral cavity, the oropharynx, the larynx, the trachea and finally out to the surface of the neck, through the small stoma created by the introducer needle. Traction is applied to the guide wire with one hand, and counter pressure to the neck with the other hand. The cone is then separated from the

tracheostomy tube which is rotated 180° so the open end of the tube faces down towards the carina and bronchi. Correct placement of the tracheostomy tube is confirmed by auscultation of the lungs and endoscopy.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to translaryngeal tracheostomy. Searches were conducted of the following databases, covering the period from their commencement to 28 November 2012: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with respiratory problems needing mechanical ventilation. Patients undergoing surgical treatment to the head or neck for cancer.
Intervention/test	Tracheostomy insertion using the translaryngeal method.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 1206 patients from 2 randomised controlled trials (RCTs), 4 case series and 2 case reports[1-8].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on translaryngeal tracheostomy

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details

Antonelli M (2005)[1]

RCT (single centre) TLT vs. ST

Italy

Recruitment period: 2001-2002

Study population: Critically ill patients needing tracheostomy

Reason for ICU admission (n TLT/ST): Acute respiratory failure (17/25), Neurosurgery (23/24), cerebral ischemia/haemorrhage (11/7), sepsis (7/5), renal failure (0/2), metabolic disorders (3/2), cardiovascular diseases (6/6), Haemorrhagic shock (0/1).

Co-morbid conditions (TLT/ST): Hypertension (22/26), diabetes (6/9), COPD (4/7), leukaemia/lymphoma (3/2), solid tumours (6/6), alcoholism (1/0).

Mean SAPS ll score on admission: 43±13 points (associated with an estimated ICU mortality rate of 34%).

n=**139** (67 TLT vs. 72 ST)

Age: mean 64 years

Sex: 60% male

Patient selection criteria: Patients with verified difficulties weaning from mechanical ventilation, those that could not be weaned after 10 days,

Key efficacy findings

Number of patients analysed: **139 (67 TLT vs. 72 ST)**

Duration of procedure* (in minutes, mean ± SD)

TLT	ST	P value
17± 10	22±6	0.003

*measured from skin incision/needle insertion to final placement of tracheostomy cannula

Decrease in oxygen saturation <90%

TLT	ST	P value
3%	3%	0.66

Survival

	TLT group n	ST group n	Total
Survived to discharge	**33**	**34**	**67***
Survival at 1 year	18	18	37**

*discharged with open tracheostomies

** 45% (14/31) had open tracheostomies.

Patient's perceived quality of life* 1 year after tracheostomy

	TLT group n=18	ST group n=13	P value
Number of respondents	18 (94)	13(72)	0.08

Key safety findings

Mortality

	TLT % (n)	ST % (n)	Total	P value
Died in ICU	33 (22/67)	33 (24/72)	46	0.80
Died in hospital	18 (12/67)	19 (14/72)	26	0.46

Complications during procedure

	TLT group % (n=67)	ST group % (n=72)	P value
Tube dislocation	4 (3/67)	0	0.10
Subcutaneous emphysema	0	1 (1/72)	0.52
Major bleeding	0	0	0.99
Minor bleeding	1 (1/67)	3 (2/72)	0.99
Decreased oxygen saturation	3 (2/67)	3 (2/72)	.66

Complications after procedure (some patients had more than 1 complication)

	TLT group % (n=67)	ST group % (n=72)	P value
Stomal inflammation	10 (7/67)	15 (11/72)	0.29
Stomal infection	3 (2/67)	7 (5/72)	0.26
Severe stomal infection	1 (1/67)	1 (1/72)	0.72

Comments

Follow-up issues:

- Overall only 27% (37) patients were alive at 1 year follow-up. Of these 4 patients could not be contacted and 2 patients refused to participate in follow-up evaluation.

Study design issues:

- The method of randomisation was reported, there was allocation concealment and the outcome assessors were blinded.
- SAPS ll is a severity of disease classification and an ICU scoring system. Score is measured 24 hours after ICU admission. Range is between 0-163 points and equates to a predicted mortality

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details

and those with anticipated need of long-term ventilation for >10 days.

Technique: TLTs were performed at the ICU bedside by 2 ICU physicians (type of kit use was not reported). Patients received general anaesthesia, additional local anaesthesia and paralysing agents.

STs were performed in the operating room by a team of ENT surgeons. Anaesthesia protocol was the same one used for the TLT group.

Follow-up: **1 year**

Conflict of interest/source of funding: Not reported

Key efficacy findings

(% of survivors)			
Physical health subscore (range 6-20) mean (SD)	12 (5)	16 (5)	0.09
Emotional health subscore (range 6-27) mean (SD)	11 (3)	12(4)	0.27
Total score (range 12-47) mean (SD)	23 (8)	28 (9)	0.10

*assessed using the Short Form 12 Health Survey questionnaire, higher scores indicates better health and functioning.

Over half the patients in both groups, rated their quality of life as moderately or severely compromised. Ratings for patients with open tracheostomies were significantly lower than those who had closed tracheostomies (p<0.005).

Key safety findings

Major bleeding (>150 ml)*	0	8 (6/72)	0.03
Minor bleeding	3 (2/67)	3 (2/72)	0.26
Tracheomalacia	1 (1/67)	1 (1/72)	0.72
Total post-procedure complications	19 (13/67)	37(26/72)	0.02

*1 episode needed blood transfusion

	TLT group % (n)	**ST group % (n)**	**P value**
Bacteraemia (confirmed by culture of microbes previously isolated from pharynx or trachea)	9 (6/67)	8 (6/72)	0.56

In 8 patients (4 in each group) tracheostomy related bacteraemia resulted in severe sepsis.

Complications at 1 year follow-up (n=31)

	TLT survivors % (n=19)	**ST survivors % (n=18)**	**P value**
Open stomas	37 (7/19)	38(7/18)	0.58
Clinically evident tracheal stenosis *(narrowing >50%) – patient restored with laser treatment.	5 (1/19)	11 (2/18)	0.53
Need for stomatoplasty**	5 (1/19)	16 (3/18)	.48

*Stridor, cough or dyspnoea at rest or on exertion

** 3 of these patients had tracheal stenosis

Comments

between 0 and 100%.

Study population issues:

- There was no significant difference between arms at baseline.
- Length of endotracheal intubation before tracheostomy was not significantly different in the 2 groups.

Other issues:

- Experienced physicians performed the procedure.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details

Cantais E (2002)[2]

RCT (single centre) TLT vs. FDT

France

Recruitment period: 1999-2000

Study population: critically ill patients in ICU who were ventilated for a mean of 18±12 days.

Indications (TLT/FDT); stroke (11/11), head trauma (7/9), acute respiratory insufficiency (8/7), multiple trauma (5/6), subarachnoid haemorrhage (5/3), sepsis (3/4), low cardiac output (2/3), pneumonia (0/5), others (6/5). SAPS ll score (43±17/42±13).

n=**100** (47 TLT vs. 53 FDT)

Age: 58 years; Sex: 67% Male

Patient selection criteria: >18 years admitted to ICU for tracheostomy, expected to be ventilator dependent for >10 days when prolonged airway protection needed.

Technique: performed by the bedside in ICU, under general anaesthesia with paralysing agents and100% oxygen 15 mins prior to intervention TLT used Mallinckrodt kit; dilatation used percutaneous tracheostomy kit (SIMS LSSA portex). FDT used a modified Howard-Kelly forceps, tracheostomy was formed with a single or 2 dilations. Fibre-optic bronchoscopic guidance was used.

Follow-up: **Not reported**

Conflict of interest/source of funding: Not reported

Key efficacy findings

Number of patients analysed: **100**

Duration of procedure* in minutes (range)

	Mean operation time	P value
TLT	12.9 (1-48)	0.0018
FDT	6.9 (0.3-36)	

*the interval from puncture of the trachea to the connection of the tracheostomy cannula to the ventilator

Blood gas analysis

	Pre-tracheostomy mean ±SD	Post-tracheostomy mean ±SD	P value
PaO2 mmHg			
TLT	311±132	261±143	0.0069
FDT	289±120	284±127	NS
PaCO2 mmHg			
TLT	40±7	55±12	<0.001
FDT	37±9	53±17	<0.001
Arterial pH			
TLT	7.41±0.07	7.31±0.13	<0.001
FDT	7.44±0.08	7.32±0.10	<0.001

There was no significant difference in the increase in PaCO2 and decrease in arterial pH between the 2 groups.

Both groups had significant differences pre and post tracheostomy.

Key safety findings

Complications and technical difficulties

Complication	TLT group % (n=47)	FDT group % (n=53)	P value
Major	8.5 (4/47)	1.8 (1/53)	<.001
Death	0	0	-
Loss of airway with hypoxia (due to difficulties in re-intubating)	6 (3/47)	0	<0.001
Posterior tracheal wall injury with emphysema (in TLT case due to rotation of the intratracheal cannula and in FDT case due to dilation with the forceps being inserted too deep; surgical repair not needed)	2 (1/47)	2 (1/53)	NS
Unsolvable technical difficulties* (with retrograde passage of wire in 3 cases, rupture of guide wire in 3, accidental pull of cannula out of the neck in 5) needing conversion to FDT	23 (11/47)	0	<0.001
Minor			
Bleeding needing no treatment	4 (2/47)	23 (12/53)	<0.001
Loss of airway without hypoxia	9 (4/47)	0	<0.001
Posterior tracheal wall injury without emphysema (due to puncture)	2 (1/47)	0	NS

* Evenly spread throughout the trial period.

Comments

Follow-up issues:

- All participants were included in the analysis.

Study design issues:

- Single centre.
- Method of randomisation reported. There was no significant difference between arms at baseline.

Other issues

- Authors suggest that it must be performed by physicians who have experience in the technique and are skilled in the management of difficult airways.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details

Byhahn C (2001)[3]

Prospective comparative study

Germany

Recruitment period: 16 months (dates not reported)

Study population: critically ill adult patients (with ARDS, septic shock, pneumonia, low cardiac output, or neurological disorders) on long-term ventilation.

n=**100** (50 TLT vs 50 GWDF)

Age: 18-85 years

Sex: Not specified Patient selection criteria: patients undergoing elective tracheostomy at study centres.

Technique: All tracheostomies were performed at the patient's bedside under general anaesthesia with muscle relaxants.

TLT was performed using the Mallinckrodt kit. All manoeuvres took place under bronchoscopic visualisation. GWDF was performed using the Sims Portex kit. Tracheal puncture was bronchoscopically controlled for both techniques, a low pressure cuff was used to minimise the hazard of post tracheostomy stricture and the procedure completed with a final bronchoscopy.

Follow-up: **Not reported**

Conflict of interest/source of funding: Not reported

Key efficacy findings

Number of patients analysed: **100**

Duration of procedure in minutes

TLT mean ±SD (range)	**GWDF mean ±SD (range)**	**P value**
9.2±3.9 (4.0-30.0)	4.8±3.7 (0.5-15)	<0.05

Oxygenation variables

	Pre-op n=50 mean ±SD (range)	**Post-op n=50 mean ±SD (range)**	**P value**
FiO2 (TLT)	0.52±0.18 (0.21-1.0)	0.62±0.21 (0.3-1.0)	<0.05
FiO2 (GWDF)	0.58±0.21 (0.30-1.0)	0.63±0.26 (0.30-1.0)	NS
PaO2/FiO2 ratio (TLT)	222.9± 95.9	194.9± 107.3	NS
PaO2/FiO2 ratio (GWDF)	193.7±74.4	175.8±83.0	NS

Coagulation variables

Prothrombin time was longer in the TLT vs. GWDF group, 69.7±13.0 vs. 63.9±13.9 p value <0.05 respectively. Partial thromboblastin time (PTT), platelet count and heparin dose were not significantly different.

Key safety findings

Severe complications during tracheostomy

Technique	**N**	**Complication**	**Treatment**
TLT	1	Posterior tracheal wall perforation (4 cm with severe damage to second and third tracheal rings) during 180º rotation of tube, and massive mediastinal and subcutaneous emphysema developed, correct tube position could not be confirmed.	Endotracheal reintubation with endotracheal tube, the tube's end was placed distal to puncture site. Later a conventional surgical tracheostomy was performed by ENT surgeon. Emphysema resolved.
TLT	1	Tube pulled out too far. During 180º rotation the tube was rotated in the pretracheal soft tissues rather that the tracheal lumen.	Emergency conversion to percutaneous dilatational tracheostomy
GWDF	1	Massive bleeding (400 mls) form undetected subcutaneous vein	Administration of coagulation factors
GWDF	1	Mediastinal emphysema 4 hours after uncomplicated insertion	Resolved spontaneously within 72 hours

Minor bleeding (10-30 mls) was observed in 9 patients in the GWDF group. Transfusion or surgical intervention was not needed. (Not reported if this happened during or after procedure)

Comments

Follow-up issues:

- There were no reports of patients being lost to follow up.

Study design issues:

- Multicentre study.
- During the first 8 months of the study TLT technique was used, during the next 8 months GWDF technique was used.
- All tracheostomies were performed by experienced physicians.

Study population issues:

- There was no significant difference in the number of days of endotracheal intubation prior to tracheostomy between the 2 groups.
- TLT was done in 2 patients with pre-existing haemophilia A.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details

Divisi D (2009)[4]

Comparative case series

Italy

Recruitment period: 1998-2006

Study population: Patients needing prolonged mechanical ventilation (TLT/CBR) for; thoracic or cranial trauma (92/37), cerebral haemorrhage or ischaemia (116/28), Major vascular surgery or peritonitis (33/18), myocardial infarction or cardiomyopathy (15/17), COPD or motor neuron disease (94/20).

n=**470** (350 TLT vs. 120CBR)

Age: Mean 53 years; Sex: 60% Males

Patient selection criteria: not reported

Technique: All patients had a CT scan of the neck and thorax for morphologic and topographic evaluation of structures. Procedure was done in ICU under general anaesthesia with paralysing agents. Patients were ventilated with FiO2 <0.8 to maintain SaO2 between 95-100%. TLT was done using the Mallinckrodt Medical kit, CBR using the dilator/guiding catheter (William Cook Europe). A flexible bronchoscope was used at every stage of both procedures. Postoperatively patients were evaluated and followed up.

Follow-up: mean **100±3 months**

Conflict of interest/source of funding: Not reported

Key efficacy findings

Number of patients analysed: **470**

Mean procedure time in minutes

TLT **mean ±SD**	CBR **mean ±SD**
8±1	4±1

Pre-operative and post-operative oxygenation index

The comparative analysis of the 2 techniques did not find any pre-operative (p=0.65) or post-operative (p=0.83) significant differences in PaO2/FiO2.

The average time to decannulation was 20 days.

Survival

76.8% (361/470) patients were alive after 100±3 months.

Key safety findings

Complications during and after the procedure

23.2% (109/470) patients died within a mean of 20 ±5 days of intervention, (34) due to respiratory insufficiency, (57) of cerebral haemorrhage, (18) of myocardial infarction.

Complication	**TLT % (n) 4.5 (16/350)**	**CBR % (n) 2.4 (2/120)**	**Treatment**
Guide wire break (during traction)	0.6 (2/350)	0	extraction of tracheostomy tube from neck
Haemorrhage (on day 2 due to thyroid vessel injury)	0.3 (1/350)	0	Conversion to surgical tracheostomy
O2 Desaturation (SaO2 < 84% and PaO2 <80 mmHg)	0.9 (3/350)	0	FiO2 increased to 1.0
Increase in arterial pressure of PaCO2 to 50/55 mmHg	1.4 (5/350)	0	Acceleration of procedure
Lateral lesion to tracheal wall (due to 180º rotation of tube)	0.9 (3/350)		1 patient needed thoracotomy for suturing of a hole
Movable flap on posterior tracheal wall (noted on-optic bronchoscopy after 3 months)	0.6 (2/350)	0	Treated with laser therapy
Intraoperative subcutaneous bleeding	0	0.8 (1/120)	Resolved by single stitch
Tracheal stoma infection (at 35 days)	0	0.8 (1/120)	Antibiotics

Comments

Study design issues:

- Retrospective study
- Choice of tracheostomy technique was based on the operator's experience.

Study population issues

- There were no significant differences in post-operative coagulation profiles between the groups.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details	Key efficacy findings	Key safety findings	Comments
Konopke R (2006)[5] **Case series** Germany Recruitment period: 3.5 years (specific years not reported) Study population: Patients needing long-term ventilation due to pulmonary failure (pneumonia/ARDS (77.2%), airway obstruction (5.7%), head or neck surgery (6.5%), craniocerebral trauma (1.6%), facial and skull based injury (7.4%), laryngeal infections (1.6%) 10 days after endotracheal intubation. n=**245** Age: Median 61 years Sex: Not reported Patient selection criteria: not reported Technique: All patients received intravenous analgesia, sedation and paralysis. FiO^2 1.0 given 5 minutes before and during the procedure. Procedure done under bronchoscopic guidance (to ensure proper puncture location and cannula placement) using the Mallinckrodt Medical TLT kit. Lung auscultation and chest X-ray (in addition to bronchoscopy) to confirm correct placement. Fibre optic endoscopy in some cases to assess stability of anterior tracheal wall. Follow-up: **not reported** ('3317 days of cannula care'). Conflict of interest/source of funding: Not reported	Number of patients analysed: **245** TLT was successful in 99.2% (243/245) patients **Mean duration of procedure** Mean procedure time* (range): 7 (5–12) minutes Mean apnoea time (range): 40 (15–91) seconds *measured from tracheal puncture to ventilation by cannula, preparation time was 15–20 minutes. **Peri-procedural oxygen saturation levels** SaO2: Remained >92% in all patients pCO2: No significant pCO2 retention occurred **Decannulation** In 205 patients regular decannulation was possible after a median of 12 days (range 8-60). All stomas healed within 3-5 days without complications. Median time from regular decannulation until hospital discharge was 17 days. All patients were able to speak after decannulation and had no symptoms of hoarseness or dysphagia.	40 patients died from their primary disease after a mean of 29 days. 31/40 had autopsies, none of which revealed tracheal stenosis or lesions of the tracheal wall. **Peri and post procedure related complications** **Complication** / **Number of patients % (n)** Haemorrhage *: 0.8 (2/245) Injury of posterior tracheal wall: 0 Pneumothorax/mediastinal emphysema: 0 Subcutaneous emphysema: 0 Paratracheal placement of cannula: 0 Post procedural stomal infection (in an obese patient during 3317 days of cannula care, resolved with local therapy): 0.4 (1/245) Hypoxia: 0 Procedure related mortality: 0 *In 1 patient an endoluminal haemorrhage of a few millilitres of blood with aspiration occurred, needing bronchoscopic lavage during procedure. Bleeding stopped spontaneously. In the other case an enlarging haematoma was noticed immediately after procedure. The patient needed to undergo operative revision, where an injury of the brachiocephalic trunk was found, partly tamponaded by the tracheal cannula. This injury was repaired primarily and cannula was repositioned. Two patients who needed cranial MRI scans (on day 2 and 4 after procedure) needed decannulation, because of the metallic spiral contained in the cannula. Tracheostomy was redone at a later time using same procedure.	**Follow-up issues**: • Complete follow-up. • 10 patients were excluded prior to the study as their FiO2 requirements were >0.8. **Study design issues**: • Authors describe it as 'prospective analysis'. • A team of 5 surgeons performed all procedures. • 63 patients needed bronchoscopy after decannulation (unrelated to tracheostomy), none revealed any tracheal alteration or functional ability.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details

Adam H (2008)[6]

Case series

Germany

Recruitment period: '4 years' (details not reported).

Study population: Patients undergoing tumour surgery to the head, neck or maxillofacial area. Oropharyngeal SCC (33), floor of mouth SCC (49), other SCC (40), other oromaxillofacial tumours (23). 11 patients underwent a second TLT due to; tumour recurrence (5) or reconstructive procedures (6).

ASA scores were 1 (12 patients), 2 (87 patients), 3 (46 patients).

n=**145** (156 procedures performed)

Age: median 54 years (male); 60 years (female)

Sex: 79% Male

Patient selection criteria: Patients having head and neck surgery with anticipated need for prolonged mechanical ventilation, due to post-surgical oedema of the upper airways or who had poor respiratory function pre-operatively.

Technique: TLT was performed under general anaesthesia, immediately before tumour surgery. Using the Mallinckrodt TLT kit. Endotracheal intubation initially done using the rigid tracheoscope supplied with the kit, to

Key efficacy findings

Number of patients analysed: **145** (156 procedures)

Mean puncture and tracheostomy time in minutes

Mean puncture time*	10.1±4.8
Mean tracheostomy time**	15.4±8.4

*defined as puncture of the trachea to final positioning of the tracheal tube.

**defined as first intubation to completed fixation of the tracheal tube with a suture.

Endotracheal intubation with a 'rigid tracheoscope' was successful in 81.4% patients.

Oxygen saturation (with an of FiO_2 of 1.0)

	SaO2 before TLT % (±SD)	**Minimal SaO2 during TLT % (±SD)**
All patients (n=145)	98.4 (±1.29)	97.1 (±3.58)
Patient 1*	99	73
Patient 2*	96	80
Patient 3*	98	85
Patient 4*	96	87

*An oxygen saturation of less than 90% was recorded in 3% (4/145) patients. All cases of oxygen desaturation occurred due to single lung ventilation as a result of placement of the distal tube in the right bronchus (resolved after correction of tube position).

Key safety findings

Technical adverse events

Complication	% (n)	**Treatment**
Accidental pull-through of tube (due to inadequate pre-locking of the tube cuff in 2 cases and in 4 cases due to insufficient experience in performing the turning manoeuvre)	4.1 (6/145)	More experienced operator successfully placed TLT after second attempt without any problems.
Accidental pull-through of tube (unsuccessful 180º turn)	2.1 (3/145)	Changed to surgical tracheostomy
Bleeding 20 ml	1 (1/145)	No further treatment necessary
Displacement of tube	1.4 (2/145)	Not reported
Cuff defect	1(1/145)	Not reported
Infection originating from tracheostomy (after 17 days in 1 patient and 90 days in another)	1.4 (2/145)	1 patient needed surgical intervention and antibiotics. 1 resolved with antibiotics alone
Accidental tube removal by patients (on day 2 in 1 case and day 6 in another case)	1.4 (2/145)	In first patient emergency tracheostomy performed and in second, another tube was reinserted at puncture site.
Elective tracheal tube change by postoperative day 6	16 (24/145)	Performed without problems in all except 1 case there was

Comments

Follow-up issues:

- Period of follow-up was not reported. However, the median time tracheal tubes were in place was 9 days (min 2 days and max 113 days).

Study design issues:

- Study examined the suitability of TLT for airway management after surgery for oropharyngeal and maxillofacial tumours.
- ASA is a physical status classification system (from 1-5) for assessing the fitness of patients before surgery. 1= a normal healthy patient, 5=a moribund patient not expected to survive without surgery.

Study population issues:

- There were

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details	Key efficacy findings	Key safety findings	Comments
establish mechanical ventilation during tracheostomy insertion. Where this failed a conventional endotracheal tube was used. The procedure was performed under fibre-optic visualisation with all patients ventilated throughout the procedure with FiO2 of 1.0. Follow-up: **Not reported** Conflict of interest/source of funding: Not reported		due to severe crust formation with narrowing of tube lumen (n=19), leakage of cuff (n=3), dislocation of tube (n=2) / bleeding that ceased immediately on insertion of new tube.	considerably more men than women but little difference in demographic other data such as age, height and weight. **Other issues:** • The authors reported they observed no metastasis formation at the puncture site in any case.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details	Key efficacy findings	Key safety findings	Comments
Neri G (2004)[7] **Case report** Italy Recruitment period: 2 years (details not reported) Study population: Patients treated with TLT in ICUs of various hospitals and later discharged home with a bi-level positive airway pressure type of automatic ventilation (via tracheostomy). 3 patients had lung fibrosis with PCO2>50 mmHg, 2 had motor neurone disease, 1 had ependimoma. 5 patients had Shiley tracheostomy tubes in situ, 1 had the original TLT (Fantoni) tube. n=**6** Age: Mean 61 years Sex: 67% Female Technique: TLT, maintained with combined home treatment and automatic ventilator support system. Patients submitted to surgical review 3 months after TLT for preparation of a conventional tracheotomy to substitute the existing tube. All patients had a CT scan pre-operatively. 4 patients had loco-regional anaesthesia and 2 had general anaesthesia. Follow-up: **1 month** (after surgical tracheostomy /3 months after TLT insertion. Conflict of interest/source of funding: Not reported	Number of patients analysed: **6**	Patients presented with 'embedding of the tracheostomy tube in the tracheostomy opening'. During surgical replacement of tracheostomy the original tubes were found to be embedded because of a narrow stenosis of the surgical orifice, preventing its substitution without surgical intervention. Tracheostomy appeared to be stenotic and rigid, with a peristomal fibrosis in those with Shiley tubes. In the patient with conotube, besides fibrosis and stenosis, acute inflammation and crusted mucopurulent secretions were presented both on the border and within the tube. Histological examination of the peristomal tissue revealed, diffuse microerosive features of the epidermis with local-granulocyte infiltrations of the elastic derma associated with giant-cell reaction, epidermic parakeratosis with erosive features and marked scar fibrosis. Bacteriological examination demonstrated presence of colonies of coagulase-negative staphylococcus, while the assessment for mycetes was negative.	**Follow-up issues**: • All patients were followed up in the home setting, but were admitted to hospital for surgical tracheostomy substitution. **Study population issues**: • 5 patients had had their tracheostomy tube changed prior to discharge from ICU. 1 patient still had the original (TLT) tube at the time of surgical substitution. • 4 patients were autonomous from automatic ventilation for more than 1 hour, and 2 for less than 5 minutes.

Abbreviations used: ARDS, acute respiratory distress syndrome; ASA, American Society of Anaesthesiologists; CBR, Ciaglia Blue Rhino; COPD, chronic obstructive pulmonary disease; ENT, ear, nose and throat; FDT, forceps dilatational technique (Griggs); FiO2, fraction of inspired oxygen; GWDF, guide wire dilating forceps; ICU, intensive care unit; IV, intravenous; NS, non-significant; PaO2, partial pressure of oxygen in blood; PaCo2, partial pressure of carbon dioxide in blood SAPS, simplified acute physiology score; SaO2, saturated oxygen; SCC, squamous cell carcinoma; ST, surgical tracheostomy; TLT, translaryngeal tracheostomy.

Study details	Key efficacy findings	Key safety findings	Comments
Richter T (2011)[8] **Case report** Germany Recruitment period: Not reported Study population: Patient with intracerebral bleeding due to high flow arteriovenous malformation of the posterior inferior cerebral artery. Treatment with neuroradiological intervention and neurosurgical extirpation was carried out. n=**1** Age: 32 Sex: Female Patient selection criteria: not reported Technique: Translaryngeal tracheostomy Follow-up: **Not reported.** Conflicts of interest: Not reported		Due to prolonged ventilation TLT was performed. After 6 days oropharyngeal haemorrhage occurred. Source of bleeding could not be identified by an otorhinolaryngologist, who placed a nasopharyngeal, oropharyngeal and hypopharyngeal tamponade. Bleeding was reduced and had completely stopped after 15 minutes. Angiographic CT could not show the source of bleeding. After 2 hours a second massive haemorrhage occurred from the oropharynx beside the tamponade and tracheal tube. The tube was 'overblocked' extensively. A second attempt to identify the source of bleeding by angiography failed. The patient was transported to the operating theatre for revision of tracheostomy. Erosion in the dorsal wall of the brachiocephalic artery was found and closed. TLT was replaced by conventional tracheostomy. The following post-operative period was uneventful.	

Efficacy

Technical success

A case series of 245 patients undergoing translaryngeal tracheostomy (TLT) reported successful insertion in 99.2% (243/245) of patients[5].

Blood gas analysis results

An RCT of 139 patients comparing TLT (n=67) with surgical tracheostomy (n=72) reported no significant difference in oxygen desaturation, (saturated oxygen less than 90%) during tracheostomy insertion in the 2 groups (p=0.66)[1].

Duration of procedure

The RCT of 139 patients comparing TLT (n=67) with surgical tracheostomy (n=72) reported that the duration of TLT was significantly shorter than surgical tracheostomy (17 and 22 minutes respectively; p=0.003)[1].

Two studies compared TLT with other percutaneous methods. An RCT of 100 patients comparing TLT (n=47) against forceps dilatation tracheostomy (n=53) reported that TLT had a significantly longer duration (13 and 7 minutes respectively; p=0.0018)[1]. A comparative study of 100 patients comparing TLT (n=50) against guide wire dilating forceps (GWDF) tracheostomy (n=50) also reported that TLT had a significantly longer duration than GWDF (9 and 5 minutes respectively; p<0.05)[3]. The clinical significance of procedure time is uncertain.

Quality of life

The RCT of 139 patients reported no significant differences in quality of life between the TLT and surgical tracheostomy groups (assessed in 31 patients; using the SF-12 Health Survey questionnaire, higher scores indicate better health and functioning) at 1-year follow-up. Over half the patients in both groups rated their physical health as moderately or severely compromised. Quality of life ratings for patients with open tracheostomies were significantly lower than for patients who had closed tracheostomies (p<0.005)[1].

Safety

Death

Deaths were reported in the studies but none were attributed to insertion of tracheostomy.

Haemorrhage

Massive haemorrhage due to an erosive lesion in the dorsal wall of the brachiocephalic artery was reported in a single case report 6 days after TLT. After bleeding had been controlled a 'conventional' tracheostomy was performed[8].

Injury to the brachiocephalic trunk causing haematoma immediately after TLT was reported in 1 patient in the case series of 245 patients; this was repaired primarily and the cannula repositioned[5].

Haemorrhage due to injury to the thyroid vessel was reported in 1 patient 2 days after TLT in the case series of 470 patients. The patient was treated by conversion to surgical tracheostomy[4].

Minor bleeding (of less than 150 ml) was reported in 4% (3/67) of patients in the TLT group compared with 6% (4/72) in the surgical group in the RCT of 139 patients[1].

Loss of airway with hypoxia

Loss of the airway causing hypoxia was reported in 6% (3/47) of patients in the TLT group in the RCT of 100 patients because of difficulties re-intubating patients with the narrower type of endotracheal tube. Nine per cent (4/47) of patients in the TLT group were reported as having loss of airway without hypoxia[2].

Damage to tracheal wall

Tracheomalacia was reported in 1 patient each in TLT and surgical groups in the RCT of 139 patients (no further details were reported)[1].

Lateral tracheal wall lesions caused during the 180° rotation of the cannula, were reported in 3 patients in the case series of 470 patients; 1 needed thoracotomy for suturing the defect, the other 2 patients had a mobile flap on the posterior tracheal wall that needed laser therapy[4].

Posterior tracheal wall injury was reported in 2 patients in the TLT group (1 resulting in emphysema) in the RCT of 100 patients. Surgical repair was not needed in both cases[2].

A 4 cm perforation of the posterior tracheal wall with severe damage to the second and third tracheal rings and massive subcutaneous emphysema, which occurred during 180° rotation of the tube, was reported in 1 patient in the TLT group in the comparative study of 100 patients comparing translaryngeal tracheostomy (n=50) against guide wire dilating forceps tracheostomy (n=50). An emergency surgical tracheostomy was performed[3].

Infection

Stomal infection was reported in 3% (2/67)of patients in the TLT group compared with 7% in the surgical group in the RCT of 139 patients. Severe stomal infection was reported in 1 patient in each group. In the same study, 9% (6/67) patients who had TLT developed bacteraemia (confirmed by culture of microbes previously isolated from the pharynx and trachea) compared with 8% (6/72) of patients in the surgical group. Of these, 4 patients in each group developed severe sepsis (further details were not reported)[1].

Stomal infection was reported in 2 patients in a case series of 145 patients; 1 needed surgical intervention and antibiotics, the other resolved with antibiotics alone[6].

Problems with tube placement

Several studies reported technical difficulties with correct placement of the tracheostomy tube. The tube was accidently pulled completely out of the neck during insertion in 9 patients in the case series of 145[6]. In 6 of the 9 patients a second attempt at tube placement by a more experienced physician was successful; the other 3 patients were converted to surgical tracheostomy. The RCT of 100 patients reported problems with tube placement in 23% (11/47) of patients. These included the guide wire breaking in 3 patients, difficult retrograde passage of the guide wire in 3 patients and accidental pull of the tube out of the neck in 5 patients[1]. Other technical difficulties reported were guide wire fracture during traction (in 2 patients) and displacement/dislocation of the tube in 4% (3/67)[1] and 1% (2/145)[6] of patients.

Narrowing of tube lumen affecting tube changes

Narrowing of the tube lumen because of severe crust formation despite ventilator humidification was reported in 19 patients in a subgroup of 24 patients who needed a first tracheal tube change by post-operative day 6 in the case series of 145 patients[6].

Tracheal stenosis (narrowing of greater than 50%) was reported in 1 patient in the TLT group and 2 patients in the surgical group at 1-year follow-up in the RCT of 139 patients; this was resolved with laser treatment[1].

Other tube-related problems

Decannulation before a cranial MRI scan because of incompatibility of the metallic spiral in the cannula was reported in 2 patients in the first week after TLT in the case series of 245 patients. TLT was redone later[5].

Embedding of tube in stoma

Embedding of the translaryngeal tracheostomy tube because of stenosis in the tracheostomy opening was reported in a case report of 6 patients with long-term

tracheostomies cared for at home. This was treated by surgical replacement of the tracheostomy tubes. Histological examination revealed marked scar fibrosis. One patient had fibrosis and stenosis, as well as acute purulent inflammation[8].

Blood gas exchange

The RCT of 100 patients comparing TLT against forceps dilatation tracheostomy reported a significant decrease in post-procedural partial pressure of oxygen in blood in the TLT group (from 311 to 261 mmHg; p=0.0069) but not in the forceps dilatation tracheostomy group (from 289 to 284 mmHg; not significant). A significant increase in partial pressure of carbon dioxide in blood (p<0.001) and a decrease in arterial pH (p<0.001) was reported between pre- and post-procedure blood gas analysis in both groups[2]. The prospective comparative study of 100 patients comparing TLT (n=50) against GWDF tracheostomy (n=50) reported that patients in the TLT group needed significantly higher FiO_2 (fraction of inspired oxygen) levels after the procedure to maintain saturated oxygen above 92% compared with those in the GWDF group (FiO_2 levels in TLT went from 0.52 to 0.62, p<0.05; and in GWDF went from 0.58 to 0.63, not significant). The pre- and post-procedural arterial oxygen tension (partial pressure of oxygen in blood) and FiO_2 ratios did not vary significantly in both groups[3]. Deterioration of gas exchange was slight and temporary in both groups and no patient became hypoxic.

Validity and generalisability of the studies

- Most of the studies included critically ill patients needing long-term ventilation in an intensive care unit. Only one case series[2] included patients undergoing the procedure in conjunction with surgery for head and neck cancers.
- Only 1 RCT[1] compared TLT with surgical tracheostomy. Three case series[3,5,6] compared TLT with other percutaneous techniques.
- Most of the studies were of low quality and the studies had weaknesses in both methodology and reporting.
- The point at which patients were evaluated was often unclear. In studies that reported follow-up, duration of follow-up was relatively short (from 3 months to 1 year).
- None of the studies was carried out in the UK.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Rehabilitation after critical illness. NICE clinical guideline 83 (2009). Available from www.nice.org.uk/guidance/CG83

Technical patient safety solutions for ventilator-associated pneumonia in adults. NICE patient safety solutions pilot 2 (2008). Available from www.nice.org.uk/guidance/PSG002

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Mr Yakubu Karagama, Mr Guri Sandhu (British Laryngology Association)

Dr Andrew Bodenham, Dr Carl Waldman (Faculty of Intensive Care Medicine)

- All 4 specialist advisers stated they had adequate knowledge of the procedure and confirmed it was relevant to their speciality. One specialist adviser had never performed the procedure, 2 had performed it at least once, and 1 stated he performs it regularly.
- One adviser said translaryngeal tracheostomy was a minor variation on an existing procedure. But 2 (one of whom performs it regularly) said that it was definitely novel and of uncertain safety and efficacy. One specialist adviser said that it was established practice and no longer new.
- The comparator procedure was identified as percutaneous or open (surgical) tracheostomy.
- One specialist adviser was unable to give an estimate of the proportion of doctors in his speciality performing the procedure. The remaining 3 specialist advisers estimated fewer than 10% of specialists are engaged in this area of work.
- Theoretical adverse events listed were: bleeding, damage to the recurrent laryngeal nerve, infection, displacement of the tube, surgical emphysema,

blockage of the tube, technical difficulty, airway loss, directional misplacement or blockage of the tube, tracheal and thyroid injury.

- Anecdotal adverse events (known from experience) were directional misplacement of tube and difficulty in delivering the tube through the larynx. Another specialist adviser reported loss of airway during procedure leading to hypoxia and hypercarbia, airway obstruction form devices/blood, bleeding, pneumothorax, scarring and airway damage, and infection at the stoma site.
- Adverse events reported in the literature were: hypoxia, hypercarbia, acidosis, minor tracheal injury, bleeding and difficult tube changes. One specialist adviser cited the article by Cantais[5] (included in table 2).
- Key efficacy outcomes were identified as: reduced trauma, bleeding, infection, and good cosmetic outcome, and the technique's suitability in patients with coagulopathy, or those with neck masses or altered tracheal anatomy, as in these cases it is 'easier to find the airway from within'.
- Uncertainty or concerns about efficacy of the procedure were: the potential difficulty in urgently replacing the tube in the event of sudden blockage (resulting in airway loss), bleeding, lack of familiarity with novel tracheostomy tube and a long learning curve. One specialist adviser commented that the procedure is more complicated than other techniques, being harder to learn and harder to teach.
- Required training and facilities were identified as: prior knowledge of performing surgical tracheostomy and experience in assisting with or observing the procedure. One specialist adviser commented that training courses were essential and 'back up' ear, nose and throat services should be available.
- One specialist adviser responded that diffusion of the procedure was on the increase, but he could not presently predict the extent to which the procedure would be carried out. Another specialist adviser stated: "I do not foresee massive interest in this technique as it has only minor advantages in select cases over current percutaneous techniques." Another specialist adviser commented: "This procedure I believe is well used in Italy where it originated

around 1996/7, but had never really caught on in the UK and other countries where other [percutaneous] techniques are more widely used. It may have some application in children, unlike other kits which are only used in adults."

- Three specialist advisers thought this procedure would have a potentially minor impact on the NHS, the fourth suggested it would be moderate.

Patient Commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

References

1. Antonelli M, Michetti V, Di PA et al. (2005) Percutaneous translaryngeal versus surgical tracheostomy: A randomized trial with 1-yr double-blind follow-up. Critical Care Medicine 33: 1015–20

2. Cantais E, Kaiser E, Le-Goff Y et al. (2002) Percutaneous tracheostomy: prospective comparison of the translaryngeal technique versus the forceps-dilational technique in 100 critically ill adults. Critical Care Medicine 30: 815–19

3. Byhahn C, Wilke HJ, Lischke V et al. (2001) Bedside percutaneous tracheostomy: clinical comparison of Griggs and Fantoni techniques. World Journal of Surgery 25: 296–301

4. Divisi D, Altamura G, Battaglia C et al. (2002) [Translaryngeal tracheostomy using the Fantoni technique: report of 104 cases]. [French]

5. Konopke R, Zimmermann T, Volk A et al. (2006) Prospective evaluation of the retrograde percutaneous translaryngeal tracheostomy (Fantoni procedure) in a surgical intensive care unit: technique and results of the Fantoni tracheostomy. Head & Neck 28: 355–59

6. Adam H, Hemprich A, Koch C et al. (2008) Safety and practicability of percutaneous translaryngeal tracheotomy (Fantoni technique) in surgery of maxillofacial and oropharyngeal tumours--own results and review of the literature. Journal of Cranio-Maxillo-Facial Surgery 36: 38–46

7. Neri G, Angelucci D, Leone O et al. (2004) Fantoni's translaryngeal tracheotomy complications. Personal experience. Acta Otorhinolaryngologica Italica 24: 20–5

8. Richter T, Gottschlich B, Muller R et al. (2011) Late Life-threatening Hemorrhage after percutaneous Tracheostomy. International Journal of Otolaryngology 2011: 1–3

Appendix A: Additional papers on translaryngeal tracheostomy

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Byhahn C, Lischke V, and Westphal K. (2000) Translaryngeal tracheostomy in highly unstable patients. Anaesthesia 55:678-82.	N=2 Follow up= 91 days	Both patients died from causes un-related to tracheostomy insertion. Reported complications were minor bleeding episodes in a patient with haemophilia which were controlled promptly. Procedure was superior to other percutaneous techniques and was safe in patients with respiratory failure and coagulopathy.	Outcomes reported in table 2 and possible overlap with Byhahn 2001 study.
Byhahn C, Wilke HJ, Lischke V et al (2000) Translaryngeal tracheostomy: two modified techniques versus the basic technique--early experience in 75 critically ill adults. Intensive Care Medicine 26:457-61.	N=75 Follow-up=(Not reported)	Comparison of the basic versus the modified technique and technique using a newer set. The number of patients successfully decannulated or discharged was low; no death could be attributed to tracheostomy itself. There was complete pull-out of the straight cannula in 2 patients. Concluded modified technique was superior.	Possible overlap with Byhahn 2001 study. Complications reported elsewhere in table 2.

Cabrini L et al. (2012) Percutaneous tracheostomy, a systematic review. Acta Anaesthesiologica Scandinavica 56:270-281	Systematic review and meta-analysis of RCTs comparing different PDT techniques in critically ill adult patients. n = 1130 (13 RCTs)	Multiple dilators, single-step dilatation, guide wire dilating forceps, rotational dilation, retrograde tracheostomy, and balloon dilation techniques were always performed in the intensive care unit. The different techniques and devices appeared largely equivalent, with the exception of retrograde tracheostomy, which was associated with more severe complications and more frequent need of conversion to other techniques when compared with guide wire dilating forceps and single-step dilatation techniques. Single-step dilatation technique was associated with fewer failures than rotational dilation, and fewer mild complications in comparison with balloon dilation and guide wire dilating forceps (all $P < 0.05$). Among the six analyzed techniques, single-step dilatation technique appeared the most reliable in terms of safety and success rate. However, the number of available randomized trials was insufficient to confidently assess the best PDT technique.	Only 2 studies on TLT (Cantais 2002, Stocchetti N 2000) are included in this systematic review. Cantais 2002 is already included in table 2 and Stocchetti N (2000) is a small study with only 20 patients.
Fantoni A and Ripamonti D. (1997) A non-derivative, non-surgical tracheostomy: the translaryngeal method. Intensive Care Medicine 23:386-392.	N=95 Follow-up= (Not specifically reported)	Showed TLT was safer than other percutaneous techniques with reduction in apnoea times and suggested use was safe in children.	Complications were reported in other studies included in table 2.
Ferraro F, Capasso A, Troise E et al. (2004) Assessment of ventilation during the performance of elective endoscopic-guided percutaneous tracheostomy: Clinical evaluation of a new	N= 30 (15TLT) Follow-op	Three methods of percutaneous tracheostomy were compared. No significant intraprocedural complications were noted.	No new safety events were highlighted.

method. Chest.126 (1) : July 2004. 159-164.			
Giugliano G, Venturino M, DePaoli F et al. (2001) Learning curve for translaryngeal tracheotomy in head and neck surgery. Laryngoscope 111:t-33.	N=41 Follow up= 12 months	Major complications observed were mostly technical relating to occlusion of tracheostomy with mucous. TLT had a high proportion of complications and authors recommended the kit include a counter cannula and stylet.	Complications reported in other studies in table 2.
Katsaragakis S, Theodorou D, Drimousis P et al. (2007) A simplified technique for translaryngeal tracheostomy (TLT). A preliminary report. World Journal of Surgery 31:1854-1857.	N=14 Follow up	Study reported outcomes of a modification of the TLT technique. Nine patients died during hospitalisation, these deaths were unrelated to tracheostomy. One complication, related to rotation of the cannula. No post-operative complications were noted.	Complications were reported in other studies included in table 2.
MacCallum PL, Parnes LS, Sharpe MD et al. (2000) Comparison of open, percutaneous, and translaryngeal tracheostomies. Otolaryngology - Head & Neck Surgery 122:686-690.	N=100 Follow up= 6 months	Percutaneous methods had fewer complications than surgical methods. TLT had the greatest utility in patients with a coagulopathy.	Complications were reported in other studies in table 2.
Westphal K, Byhahn C, Wilke HJ et al. (1999) Percutaneous tracheostomy: a clinical comparison of dilatational (Ciaglia) and translaryngeal (Fantoni) techniques. Anesthesia & Analgesia 89:938-943.	N=90 (45TLT/45Ciaglia) Follow up=6 months	Comparative study of TLT and Ciaglia technique. 38% of patients died, no deaths were attributed to complications of tracheostomy. Both techniques were safe and unlikely to result in major complications when precautions are carefully observed.	Complications were reported in larger studies.
Westphal K, Byhahn C, Rinne T et al. (1999) Tracheostomy in cardiosurgical patients: surgical tracheostomy versus ciaglia and fantoni methods. Annals of Thoracic Surgery 68:486-492.	N=120 (40/40/40) Follow-up= 6 months	Comparative study of TLT, Ciaglia technique and surgical tracheostomy. TLT and Ciaglia techniques are attractive alternatives to surgical tracheostomy.	Complications were reported in larger studies and likely overlap with Westphal (1999) above
Zawadzka-Glos L, Rawicz M, and Chmielik M. (2004) Percutaneous tracheotomy in children.	N=3 Follow up=	TLT was done in 3 children age 5, 11 and 15 years. In 1 patient the tube was accidently	Larger studies reporting same outcomes.

International Journal of Pediatric Otorhinolaryngology 68:1387-1390.		pulled out during the rotation phase. TLT is especially suitable for children below 10 years and is associated with very few complications.	

Appendix B: Related NICE guidance for translaryngeal tracheostomy

Guidance	Recommendations
Clinical guidelines	**Rehabilitation after critical illness. NICE clinical guideline 83 (2009)** • Approximately 110,000 people (estimated from the UK Intensive Care National Audit and Research Centre [ICNARC] Case Mix Programme [CMP] Summary Statistics) spend time in critical care units in England and Wales each year, the majority surviving to be discharged home. The general perception among patients, families and most healthcare professionals is that these people undergo a rapid convalescence and recover to their previous life, in terms of both quantity and quality. • Until relatively recently, there was little understanding of what really happens to all of these people. In the United Kingdom, a handful of hospitals established specialist follow-up clinics, staffed initially by doctors and nurses who also worked in critical care, and who thus understood the context of the patients' clinical stories. Research on the longer-term consequences of critical illness has shown that significant numbers of patients surviving critical illness have important continuing problems. For many, discharge from critical care is the start of an uncertain journey to recovery characterised by, among other problems, weakness, loss of energy and physical difficulties, anxiety, depression, post-traumatic stress (PTS) phenomena and, for some, a loss of mental faculty (termed cognitive function). Family members become informal caregivers, and this itself can exert a secondary toll of ill-health; family relationships can become altered and financial security imperilled. Recovery from illness is highly

	individual, and few studies have been able to demonstrate a close relationship between features of the acute illness and longer-term impact. Logically, patients who have had prolonged episodes of critical illness are likely to have greater long-term difficulties, however patients with relatively short intensive care stays may also need substantial help.
Patient safety solutions pilot	**Technical patient safety solutions for ventilator-associated pneumonia in adults. NICE patient safety solutions pilot 2 (2008).** 1.1 Mechanically ventilated patients who are intubated should be positioned with their upper body elevated (in a semi-recumbent or seated position) for as much of the time as possible. For some patients this will not be appropriate (for example, those with spinal injuries). 1.2 Oral antiseptics (for example, chlorhexidine) should be included as part of the oral hygiene regimen for all patients who are intubated and receiving mechanical ventilation.

Appendix C: Literature search for translaryngeal tracheostomy

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	25/04/2013	April 2013	11
Database of Abstracts of Reviews of Effects – DARE (CRD website)	25/04/2013	April 2013	0
HTA database (CRD website)	25/04/2013	April 2013	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	25/04/2013	April 2013	3
MEDLINE (Ovid)	25/04/2013	1946 to April Week 3 2013	23
MEDLINE In-Process (Ovid)	25/04/2013	April 24, 2013	52
EMBASE (Ovid)	25/04/2013	1974 to 2013 Week 16	97
CINAHL (NLH Search 2.0 or EBSCOhost)	25/04/2013	N/A	12
JournalTOCS	25/04/2013	N/A	0

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

MEDLINE strategy

1 endoscopy/
2 endoscopes/
3 laryngoscopy/
4 laryngoscopes/
5 (endoscop* or laryngoscop*).tw.
6 or/1-5
7 tracheotomy/
8 tracheostomy/
9 intubation, intratracheal/
10 (trachea* or tracheo*).tw.
11 or/7-10
12 6 and 11

13 ((translaryngea* or endoscop* or retrograde*) adj3 (trachea* or tracheo*)).tw.	
14 12 and 13	
15 (TLT or fantoni or covidien).tw.	
16 14 or 15	
17 animals/ not humans/	
18 16 not 17	