Guidelines for Percutaneous Dilatational Tracheostomy (PDT) from the Danish Society of Intensive Care Medicine (DSIT) and the Danish Society of Anesthesiology and Intensive Care Medicine (DASAIM)

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This guideline has been approved by the Danish Society of Anesthesiology and Intensive Care Medicine (DASAIM) and the Danish Society of Intensive Care Medicine (DSIT) Oct 14 2011

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Dan Med Bull 2011;58(12):C4358

Summary:
Percutaneous dilatational tracheostomy is a common procedure in intensive care. This guideline from the Danish Society of Intensive Care Medicine (DSIT) and the Danish Society of Anesthesiology and Intensive Care Medicine (DASAIM) describes indications and contraindications, timing, complications compared to surgical tracheostomy, anaesthesia and technique, decannulation strategy, as well as training and education.

Limitation: Applicable only for patients aged > 15 years

Last literature review: December 6, 2010

Topic update: December 18, 2010

Next update: January 2014

1. INTRODUCTION

Tracheostomy is a common procedure in the critically ill. In an international one-day prevalence-survey, twenty-four percent of all mechanically ventilated ICU patients were ventilated via a tracheostomy [1]. Since 1985 [2], PDT has gained popularity over surgical tracheostomy which, however, remains the back-up method in difficult cases.

2. PDT – INDICATIONS AND CONTRAINDICATIONS

Indications for PDT:
Prolonged mechanical ventilation
Airway protection against pulmonary aspiration (e.g. laryngeal incompetence due to critical illness, polyneuropathy, or bulbar dysfunction)
Prolonged need for intratracheal suction
Upper airway obstruction (e.g. tumor, bilateral recurrens paresis)
Trauma or infection in oral cavity, pharynx or larynx.
Minimisation of sedation

Contraindications against PDT:
Unstable fractures of the cervical spine
Severe local infection of the anterior neck
Uncontrollable coagulopathy

Relative contraindications:
Controlled local infection
Coagulopathy
High PEEP or FiO2 requirements
Difficult anatomy (e.g. morbid obesity, short thick neck, reduced neck extension, excessive goiter, tracheal deviation)
Proximity to extensive burns or surgical wounds
Elevated intracranial pressure
Haemodynamic instability
Previous radiotherapy to the neck

No randomized, controlled trials concerning indications for PDT were found. In experienced hands, PDT seems to be a safe procedure. The risk/benefit and timing of PDT should be evaluated on an individual patient basis. Usually PDT is an elective procedure, and all reversible risk factors (e.g. coagulopathy or excessive PEEP/FiO2 requirements) should be corrected in advance.
The number of relative contraindications to PDT declines with increasing operator experience. A case series with 207 patients showed that PDT can be performed safely as an emergency procedure by experienced clinicians [3]. Also PDT has been

performed with few complications in spite of coagulopathy [4] or high PEEP/FiO2 requirements [5]. Some small studies and case reports have reported fewer laryngeal complications with tracheostomy as compared with prolonged translaryngeal intubation [6].
Overweight patients (BMI > 27,5) have a 5 times higher risk of perioperative complications with PDT than normal-weight patients [7].

Potential advantages with tracheostomy compared to prolonged translaryngeal intubation:
Less sedation needed for tube acceptance
Higher patient comfort (mobilisation, oral hygiene, fonation)
Reduced risk of laryngeal damage in long-term intubation
Reduced airway resistance and respiratory work
More efficient cough
Faster weaning from mechanical ventilation
Shorter ICU-stay

3. TIMING OG TRACHEOSTOMY IN THE CRITICALLY ILL - EARLY VERSUS LATE?

Recommendation:
In prolonged mechanical ventilation, optimal timing of tracheostomy should be determined on an individual patient basis. There is insufficient evidence to make a general recommendation of early versus late tracheostomy. (Grade A, level 1b)

Background:
In the literature, definitions of early tracheostomy vary from 2-10 days from start of mechanical ventilation. Until 2004, conflicting evidence from only four randomised, controlled trials were found. All studies were either small, quasi-randomised or carried out in selected non-generaliseable populations such as burn or head trauma patients [8-10]. In 2004, Rumbak et al [6] found significant effect with early (<48 h) as opposed to late (day 14-16) tracheostomy in terms of mortality, duration of mechanical ventilation and ventilator-associated pneumonia (VAP).
On this background a metaanalysis [11] from 2005 found early tracheostomy resulting in fewer days in the ventilator and shorter length of stay in the ICU, but no significant difference in mortality or VAP.
An Italian multicentre study [12] from 2010 compared early (day 6-8) to late (day 13-15) tracheostomy. No significant difference in mortality or VAP was found.
The results from a British multicentre study (www.tracman.org.uk) have not yet been published, but preliminary data did not show any mortality difference [13].
On this background, we find insufficient evidence to support a general recommendation of early versus late tracheostomy. Optimal timing of tracheostomy should be determined individually with daily clinical assessment.

4. PDT VERSUS SURGICAL TRACHEOSTOMY – INCLUDING COMPLICATIONS

Recommendation:
Bedside PDT should be the standard method for tracheostomy in intensive care patients, since
- bedside PDT is logistically simpler and has fewer or equally few complications compared to surgical tracheostomy (Grade A, level 1b)
- bedside PDT is less expensive than surgical tracheostomy in the operating room (OR) (Grade C, level 4)

Surgical tracheostomy in the operating room remains the back-up method in difficult cases. (Grade D, level 5).

Background:
In controlled studies, clinically important complications are infrequent following both PDT or surgical tracheostomy. Most serious or fatal complications such as uncontrollable bleeding or irreversible loss of airway have only been published in case reports. Table 1 shows reported complications of both PDT and surgical tracheostomy.

Table 1. Complications of tracheostomy (both PDT and surgical tracheostomy) [14].

Immediate/early	Late
Bleeding Hypoxia / loss of airway Tracheal lesion; posterior wall perforation or tracheal ring fracture. Oesophageal lesion Displaced tracheal tube / via falsa Obstruction of tracheal tube by blood clot Hypercapnia Raised intracranial pressure Simple or tension pneumothorax Pneumomediastinum Surgical emphysema Atelectasis Needle damage to fibre bronchoscope (PDT)	Stomal infection Displaced tracheal tube / via falsa Bleeding from erosion into blood vessels (including innominate artery) Subglottic or tracheal stenosis Delayed healing after decannulation Tracheo-oesophageal fistula Permanent voice changes Scarring of the neck Dysfagia

A metaanalysis [14] from 2006 of 17 randomised, controlled studies including 1212 patients found a significantly reduced wound infection rate of 2,3 % after bedside PDT versus 10,7 % following surgical tracheostomy either bedside or in the OR. A possible cause is the minimally invasive surgical technique with PDT. Bleeding requiring transfusion or subsequent surgical haemostasis was seen in 5-6 % in both groups. A subgroup analysis of bedside PDT versus surgical tracheostomy in the OR revealed a significantly lower risk of bleeding and lower mortality with bedside PDT. This finding could reflect the risk of intrahospital transport of a critically ill patient. Also the financial cost of bedside PDT is lower than that of surgical tracheostomy in the OR [15].
The most significant study in the above-mentioned metaanalysis [14] is an Australian, controlled trial [16] from 2006 randomizing 200 ICU patients to either bedside surgical or percutaneous tracheostomy. No significant difference was found in the combined primary endpoint (bleeding, infection, pneumothorax, accidental decannulation, other major operative complication, or death). The total complication rate was low: 3,5 %. However, there were fewer stomal infections in the PDT group at day 7. Also time from randomization to tracheostomy was shorter in the PDT group. The latter could reflect the logistical advantage of the intensivists themselves performing the procedure.

Presumably, clinically relevant long-term complications following tracheostomy in the critically ill are infrequent. Tracheal stenosis is common, but mostly subclinical. The paucity of long-term follow-up studies impedes conclusions about PDT versus surgical tracheostomy.

5. ANAESTHESIA FOR PDT

Recommendation:
Anaesthesia for PDT should routinely consist of intravenous general anaesthesia. Neuromuscular blockade is recommended. Usual fasting rules are applicable. Prepare for a difficult airway. PDT can also be carried out in local analgesia.
(Grade D, level 5)

Background:
Randomised, clinical studies of anesthesia for PDT do not exist, so this recommendation relies solely on expert opinion and case reports.
Sedation to tube tolerance is not sufficient for surgical anesthesia. Thus, real doses of anaesthetics are used [17]. Neuromuscular blockade optimises surgical conditions and eases controlled ventilation. Inhalational anaesthesia is avoided, since the procedure implies gas leakage. In this procedure, managing the airway is the anaesthesiologist's greatest challenge [18]. To facilitate the surgical procedure, the upper part of the back is elevated and the neck hyperextended which makes direct laryngoscopy more difficult. Prior prolonged intubation constitutes a risk for airway oedema [19].
The oro-tracheal tube can be retracted under direct laryngoscopy until the cuff is just distal to the vocal cords, before the trachea is punctured [20]. Still there is a risk that the introducing needle hits the tracheal tube if the tip of the tube is not proximal to the puncture site. An alternative is to extubate the patient and insert a laryngeal mask, where the risks are pulmonary aspiration, air leakage and compromised ventilation. The exact choice of method depends on clinical evaluation and personal preference. Equipment for managing the difficult airway should be available.

6. PDT: TECHNIQUE AND PROCEDURE
Several commercial kits are available for PDT. The basic contents, however, remain similar: an introducing needle, one or more dilatators and possibly a forceps for the initial penetration of the tracheal wall. To minimize complications, we recommend that each institution chooses one kit and gains familiarity with this specific kit to appreciate its advantages and drawbacks. No strong evidence supports one specific kit or technique. The following suggestions for PDT technique and procedure are based on expert opinions and rules of thumb.

Suggested PDT procedure:
The procedure differs slightly with choice of kit, but some basic steps remain common [21] (Grade D, level 5)

Staff:
One experienced physician can perform PDT safely, if assisted by an experienced intensive care nurse. In case of increased risk of complications or a less experienced operator, at least two doctors should participate, one of whom should be experienced in PDT.

Preparation:
• If the patient is competent: informed consent must be obtained directly from the patient.
• If the patient is temporarily incompetent: The patient's next of kin are informed if possible.
• If the patient is permanently incompetent: informed consent must be obtained from the patient's guardian.
• Nil per os: Common rules for NPO apply. Vomitus can be provoked by direct tracheal or indirect pharyngeal or eosophageal stimuli.
• Anti-coagulation should be paused according to institutional practice.
• Intubation and anaesthesia: see *section 5: Anaesthesia for PDT*.

Instruments:
• PDT-kit.
• Laryngoscope, intubation tray, equipment for difficult airway management should be immediately available.
• Optional fibre bronchoscope.
• Optional ultrasound machine.

The procedure itself:
• Operator position, two possibilities:
- operator at patient's side. Advantage: direct access to surgical field without moving patient or bed.
- Operator at head end of patient's bed. Advantage: Easier management of airway complications such as accidental extubation.
• Patient positioning for optimal presentation of anterior neck anatomy, usually with a pillow under the shoulders and maximal cervical spine extension.
• Direct laryngoscopy with retraction of the tracheal tube until the cuff is placed just under the vocal cords. At the same time the laryngoscopy difficulty grade is evaluated in case of need of oro-tracheal re-intubation.
• Marking: The cricoid and tracheal rings are palpated. The optimal site for tracheostomy is determined and marked, always under the cricoid cartilage and ideally between the second and third tracheal ring. More proximal placement increases the risk of tracheal stenosis, whereas a more distal placement increases the risk of erosion of the great vessels in the mediastinum. The choice of tracheostomy site can be guided with fibre bronchoscopy (light through the anterior tracheal wall) and/or ultrasound.
• Antiseptic and sterile preparation according to institutional guidelines.
• Infiltrational analgesia with a local analgetic containing adrenalin (to reduce bleeding) from skin to trachea.
• Skin incision: 8-12 mm horizontal incision at the chosen level. The incision must be as short as possible to reduce risk of bleeding and infection and to provide a tight-fitting stoma.
• Introduction of guidewire: The cuff of the tracheal tube is deflated, the trachea is punctured in the midline, and the guidewire is introduced. Clinical confirmation of intra-tracheal placement: Ventilation-synchronous oscillation through introducer needle/catheter, unhindered passage of guide wire until bronchial stop at expected anatomical depth. Optionally, fibreoptic guidance through the orotracheal tube.
• Stomal dilatation with one or more dilators, possibly with the use of a dilating forceps.
• Control of intra-tracheal placement:
- Ventilation-synchronous air escape (through open stoma with guidewire in situ or through dilator with removed guidewire).
-optionally, fiberbronchoscopic control through oral tube.

• Choice of tracheal cannula: according to clinical judgement. A few rules of thumb:
- use tube with adjustable flange for patients with deeply-located trachea.
- use wire tube in patients with risk of kinking of tube (short neck, obesity, caudally placed stoma).
Perioperative bleeding:
• Minor bleeding (no transfusion requirement):
- manual compression.
- subcutaneous infiltration with adrenaline containing local analgesic circumferentially to the tracheal stoma.
- compress soaked with adrenalin-solution (1 mg adrenalin, 4 ml sterile water) wrapped around the tube between the flange and the skin.
• Major bleeding (transfusion requirement or continued bleeding in spite of the above measures)
- consult an ENT specialist (exploration, suture, cautery)

Bronchoscopy:
If a bronchoscope is available, we recommend bronchoscopic guidance as a minimum if :
the operator is in training.
in case of difficult neck anatomy or other clinically complicated situations.
With the bronchoscope the following can be ascertained:
- correct tracheostomy site (midline placement, level at tracheal rings, light at the anterior tracheal wall).
- intra-tracheal guidewire placement.
- intratracheal dilator placement without tracheal damage.
- position of tracheal cannula.

Ultrasound:
If ultrasound machinery is available, a skilled operator can evaluate
- the anatomy of major vessels and the thyroid gland in relation to tracheostomy site.
- localise level of tracheal rings and identify midline, puncture, depth etc.

7. DECANNULATION

Recommendation: (all Grade D, level 5)
The patient should be decannulated as soon as possible when
- cough is sufficient
- inspiratory fraction of oxygen is reasonably low
- suctioning is rarely needed
- mechanical ventilation has not been needed for more than 24 hours
- the airway is spontaneously patent

At discharge from ICU to the ward with a tracheal cannula in place:
- the tracheal cannula should be without cuff (to avoid risk of total airway occlusion). An individual plan for decannulation should be presented.

Background: Recommendations about decannulation suffer from lack of solid evidence and are largely based on expert opinions. An international survey demonstrated considerable variability in the decannulation practices of intensive care doctors [22]. A prospective observational study showed that discharge from ICU to the ward with a tracheal cannula in place was an independent risk factor for mortality – especially in case of a high BMI [23]. An intensivist-led, post-ICU tracheostomy follow-up team has been associated with earlier discharge from hospital [24].

8. TRAINING AND EDUCATION

To minimise complications, PDT should be performed by doctors able to maintain their routine in this procedure, presumably 100-150 physicians in Denmark, most of them specialists in anaesthesiology and intensive-care medicine.
Training a procedure, in this case PDT, involves both knowledge (indications, contraindications, complications), practical management (preparation, dexterity, technique) as well as communication and teamwork (consent, modesty, knowing when to call for senior assistance) [25].

When a colleague is training a procedure, the following steps are suggested [26]:
1) **Demonstration**: The supervisor demonstrates the procedure at a normal pace, but without comments.
2) **Deconstruction**: The supervisor demonstrates and simultaneously describes the steps of the procedure.
3) **Understanding:** The supervisor demonstrates the steps of the procedure, but this time with the trainee talking the supervisor through the steps.
4) **Management:** The trainee demonstrates and describes the steps of the procedure.

In this way the procedure is split into manageable steps, and the trainee is asked to describe each step. The repetition reinforces the learning process, and possible mistakes are corrected. Also, different learning styles are possible, because the trainee sees, hears, describes and performs the procedure, whereby the learning outcome is optimised.
We recommend that the supervisor and the trainee meet two times as a minimum to ensure that all 4 steps are carried out.
Step 1 is demonstrated on a clinical patient, or a teaching video. It is important that the trainee has the possibility to identify fully through a thorough demonstration.
Step 2-4 can be trained theoretically, but preferably on a mannequin. These steps are repeated until the supervisor finds the trainee ready to perform the procedure on a clinical patient under supervision (step 4). It is individually decided when the colleague is ready to perform PDT without supervision.

We recommend the following structure for every learning session [27]:
• **Introduction:** The trainee's basic knowledge of PDT? Consider the placement of the trainee: Next to you or opposite? Left- or right-handed?
• **Dialogue:** Have you broken down the PDT procedure into clearly defined steps? Do you give positive feedback to the trainee? ("What went well?", "What would you do differently next time?") Avoid too much talk. Often too many details are given.
• **Conclusion:** Can the colleague safely perform PDT? How will he or she continue the learning process? Take home messages.

9. CONTRIBUTORS, SEARCH STRATEGY, AND LEVEL OF EVIDENCE

Upon open call for contributors to the guideline in the member magazine of DASAIM (Danish Society of Anesthesiology and Intensive Care Medicine), a group of doctors dedicated to intensive care and PDT was constituted. Subtopics were formulated

and delegated to individual authors within the group, who in turn handed in a draft for internal peer review. Emphasis was put on randomised clinical trials and well performed metaanalyses, but no formal predefined criteria were applied. Cross references, personal communication, and expert opinions were also used. When possible, each topic is introduced with a recommendation followed by a background, but not all topics allow this in a meaningful manner.
The Guideline was presented and accepted with minor revisions at the annual symposium of the Danish Society for Intensive Care at Hindsgavl, Denmark, January 26 2011, and finally accepted by the Danish Society for Anesthesiology and Intensive Care Medicine on October 14 2011.

Search Stategy:
Pubmed search: ("tracheostomy"[MeSH Terms] OR "tracheostomy"[All Fields]) AND ("critical care"[MeSH Terms] OR ("critical"[All Fields] AND "care"[All Fields]) OR "critical care"[All Fields]). Similar search on CINAHL, EMBASE, Cochrane.

Level and grade of evidence: If possible and meaningful, Oxford Evidence Based Medicine criteria were applied (Table 2):

Table 2.

Grade	Level	
A	1a	Systematic review or metaanalysis of homogenous, randomised, controlled trials
	1b	Randomised, controlled trial
	1c	Absolute effect (all or none)
B	2a	Systematic review of homogeneous cohort studies
	2b	Cohort study
	2c	Database studies
	3a	Systematic review of case-control studies
	3b	Case-control studies
C	4	Case series, case reports
D	5	Expert opinion or based on patophysiology, laboratory research or rules of thumb.

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