Danish Guidelines 2015 for Percutaneous Dilatational Tracheostomy in the Intensive Care Unit

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This 2015 revised edition of the 2011 edition has been approved by the Danish Society of Anesthesiology and Intensive Care Medicine (DASAIM) and the Danish Society of Intensive Care Medicine (DSIT) on January 22 2015

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Summary: Percutaneous dilatational tracheostomy is a common procedure in intensive care. This updated Danish national guideline describes indications, contraindications and complications, and gives recommendations for timing, anaesthesia, and technique, use of fibre bronchoscopy and ultrasound guidance, as well as decannulation strategy, training, and education.

Limitation: Applicable only for patients aged ≥ 15 years

Last literature review: November 2014

Next update: January 2019

List of abbreviations:
ICU = intensive care unit
PDT = percutaneous dilatational tracheostomy
ST = surgical tracheostomy
RCT = randomized controlled trial
PICO = population, intervention, comparator, outcome
DASAIM = Danish Society of Anesthesiology and Intensive Care Medicine
DSIT = Danish Society of Intensive Care Medicine
OR = operating room

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. Since 1985, PDT has gained popularity over surgical tracheostomy which, however, remains the back-up method in difficult cases.

2. CONTRIBUTORS, METHODS, SEARCH STRATEGY, AND LEVEL OF EVIDENCE
Contributors
Upon open call to the members of DASAIM, the authors of the 2011 version of this guideline were supplemented. Thus a group of Danish ICU doctors with special interest and expertise in PDT was constituted.

Research questions
Where possible formal research questions were formulated, all concerning tracheostomy in mechanically ventilated adult critically ill patients in the ICU:
Which indications, contraindications, and complications should be appreciated?
What is the optimal timing of tracheostomy?
Should PDT be preferred as standard method over ST?
Should fibrescopic guidance be used?
Should ultrasonic guidance be used?
Which form of anaesthesia is preferable?
How is training and education for PDT best organized?

PICO questions
Subtopics and PICO questions were formulated and delegated to individual authors within the group, who in turn handed in a draft for internal peer review.

Population: adult critically ill patients in the ICU
Intervention: percutaneous tracheostomy
Comparator: any
Outcome: mortality, morbidity, bleeding, pneumonia, length of mechanical ventilation, length of stay, and serious adverse events

Search strategy
PubMed and Cochrane Library were searched for literature. In addition, we hand-searched reference lists of relevant publications. No study designs were per se excluded but emphasis was put on RCTs and well performed recent meta-analyses.

Inclusion criteria
Adult critically ill patients in the ICU undergoing mechanical ventilation.

Exclusion criteria
Validation and grading of evidence

We evaluated trial data using the GRADE approach (www.gradeworkinggroup.org). The GRADE system does not grade the quality of single studies but sequentially assesses the quality of evidence from the best available data for the outcomes of interest followed by assessment of the balance between benefits versus risks, burden, and cost. Literature identified by the search strategy was considered to represent the best-quality evidence. The quality of the evidence was quantified (high, moderate, low or very low) and potentially downgraded in the domains 1) risk of bias, 2) inconsistency of results, 3) indirectness of the evidence, 4) imprecision of results, and 5) other considerations including suspicion of publication bias, and was downgraded based on the number of domains with concerns (Table 1).

Recommendations

The recommendations were agreed upon in the group, and if total agreement could not be obtained, the group voted; 4/6 of the votes were needed to issue a strong recommendation. Strong recommendations (marked 1) were given the wording ‘we recommend’ and weak recommendations (2) ‘we suggest’. The level of evidence was graded high (marked A), moderate (B), low (C) or very low (D) based on the number of domains that were downgraded in adherence to GRADE.

Table 1. Rating the quality of evidence according to GRADE.

<table>
<thead>
<tr>
<th>Study design</th>
<th>Quality of Evidence</th>
<th>Lower if</th>
<th>Higher if</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trial</td>
<td>High (A)</td>
<td>Risk of bias</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate (B)</td>
<td>Inconsistency</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td></td>
</tr>
<tr>
<td>Observational study</td>
<td>Low (C)</td>
<td>Indirectness</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Very low (D)</td>
<td>Publication bias</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Likely</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very likely</td>
<td></td>
</tr>
</tbody>
</table>

Danish External Quality Standards in Intensive Care (DASAIM) on …… 2015. Denmark, January 2015, and finally accepted for publication by DASAIM on …… 2015.

Table 2. Key recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>We suggest that optimal timing of tracheostomy be determined on an individual patient basis. There is insufficient or conflicting evidence to make a general recommendation of early versus late tracheostomy (2B)</td>
</tr>
<tr>
<td>We recommend bedside PDT as the standard method for tracheostomy in intensive care patients (1B)</td>
</tr>
<tr>
<td>We recommend that surgical tracheostomy in the operating room remains the back-up method in difficult cases (ungraded best clinical practice)</td>
</tr>
<tr>
<td>We suggest that anaesthesia for PDT should consist routinely of intravenous general anaesthesia and neuromuscular blockade (2D)</td>
</tr>
<tr>
<td>We suggest that PDT can also be safely carried out in local analgesia (2D)</td>
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<tr>
<td>We suggest the laryngeal mask airway as a safe alternative to retraction of an endotracheal tube during PDT (2B)</td>
</tr>
<tr>
<td>We suggest bronchoscopic guidance for PDT (2D)</td>
</tr>
<tr>
<td>We suggest ultrasound as a possible adjunct to PDT (2C)</td>
</tr>
<tr>
<td>We recommend that the Surgical Safety Checklist, as developed by WHO, and with local modifications, should be routinely applied to the surgical procedure of PDT (1B)</td>
</tr>
<tr>
<td>We recommend capnometry/ -graphy should be used in cases of suspected tracheal tube displacement (1D)</td>
</tr>
<tr>
<td>We suggest that all clinical staff who work in ICU should be trained in interpretation of capnometry/graphy (2D)</td>
</tr>
<tr>
<td>We recommend the presence of a difficult airway trolley in close proximity to the unit (1D)</td>
</tr>
<tr>
<td>We suggest the establishment of an algorithm to be used in the clinical scenario where there is suspicion of a displaced tracheostomy (2D)</td>
</tr>
<tr>
<td>We suggest that all ICU doctors receive ongoing training in the use of supraglottic devices and are familiar in the techniques of advanced airway management (2D)</td>
</tr>
<tr>
<td>We suggest that an individual plan for tracheostomy management and decannulation should be presented at patient discharge from ICU to the general ward with a tracheal cannula in place (ungraded).</td>
</tr>
<tr>
<td>We recommend an active training and education strategy for PDT, with local modifications (ungraded).</td>
</tr>
</tbody>
</table>

2. PDT – INDICATIONS AND CONTRAINDICATIONS

Indications for PDT:
- Prolonged mechanical ventilation
- Airway protection against pulmonary aspiration (e.g. laryngeal incompetence due to critical illness, polynuropathy, or bulbar dysfunction)
- Prolonged need for intratracheal suction
- Upper airway obstruction (e.g. tumor, bilateral recurrencs 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
3. TIMING OF TRACHEOSTOMY IN THE CRITICALLY ILL - EARLY VERSUS LATE?

**Population:** Mechanically ventilated adult critically ill patients in the ICU

**Intervention:** early tracheostomy

**Comparator:** late or no tracheostomy

**Outcome:** mortality, pneumonia, duration of mechanical ventilation and ICU or hospital stay

**Recommendation:**
In prolonged mechanical ventilation, we suggest that optimal timing of tracheostomy be determined on an individual patient basis (2B). There is insufficient or conflicting evidence to make a general recommendation of early versus late tracheostomy.

**Background:**
Definitions of early tracheostomy vary from 2-10 days from start of mechanical ventilation. Thirteen RCTs with mortality data comparing early versus late tracheostomy were identified (table 2).

<table>
<thead>
<tr>
<th>Tracheostomy timing:</th>
<th>Early</th>
<th>Late or none</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths/total</td>
<td>133/448</td>
<td>132/445</td>
<td>1.00 (0.75-1.33)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>3/30</td>
<td>14/30</td>
<td>0.13 (0.03-0.51) *</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>19/58</td>
<td>32/61</td>
<td>0.44 (0.21-0.93) *</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>9/50</td>
<td>7/50</td>
<td>1.35 (0.46-3.96)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>24/109</td>
<td>26/107</td>
<td>0.88 (0.47-1.66)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>108/209</td>
<td>128/210</td>
<td>0.69 (0.46-1.01)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>12/61</td>
<td>15/62</td>
<td>0.77 (0.33-1.81)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>2/29</td>
<td>5/31</td>
<td>0.39 (0.07-2.16)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>19/60</td>
<td>37/60</td>
<td>0.29 (0.14-0.61) *</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>12/31</td>
<td>7/31</td>
<td>2.17 (0.71-6.57)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>4/21</td>
<td>6/23</td>
<td>0.67 (0.16-2.79)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>13/53</td>
<td>11/59</td>
<td>1.42 (0.57-3.51)</td>
</tr>
<tr>
<td>Deaths/total</td>
<td>9/51</td>
<td>13/55</td>
<td>0.69 (0.27-1.79)</td>
</tr>
</tbody>
</table>

**Source:** Siempos et al 2014

Thus only three of these individual trials showed a statistically significant survival benefit with early tracheostomy, on the other hand none showed statistically significant harm. Recently the largest RCT to date failed to show any mortality reduction with early tracheostomy21. However the study did not achieve its intended sample size. In fact all RCTs so far have been underpowered to detect a possible small yet clinically relevant benefit of early timing of this widespread procedure in the ICU. Correspondingly, meta-analyses22 have returned non-significant results on outcomes such as mortality, pneumonia, duration of mechanical ventilation, and length of intensive care or hospital stay, however with the most recent meta-analysis being in favour of early tracheostomy23. On this background, we find insufficient evidence to support a firm recommendation of early versus late tracheostomy in routine clinical practice. Optimal timing of tracheostomy should be determined individually with daily clinical assessment.

4. PDT VERSUS SURGICAL TRACHEOSTOMY

**Population:** Mechanically ventilated adult critically ill patients in the ICU

**Intervention:** PDT

**Comparator:** ST

**Outcome:** mortality, bleeding, infection, pneumothorax, other major complications, accidental decannulation, tracheal stenosis, indication to procedure time, financial cost.

**Recommendation:**
We recommend bedside PDT as the standard method for tracheostomy in intensive care patients (1B), since
- bedside PDT is logistically simpler and has fewer or equally few complications compared to ST (B)
- bedside PDT is less expensive than ST in the operating room (C)

We recommend that surgical tracheostomy in the operating room remains the back-up method in difficult cases (ungraded best clinical practise).
Background:
In controlled studies, clinically important complications are infrequent following both PDT or ST. Most serious or fatal complications such as uncontrollable bleeding or irreversible loss of airway have only been published in case reports. Table 3 shows reported complications of both PDT and surgical tracheostomy.

Table 3. Complications of tracheostomy (both PDT and surgical tracheostomy)

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

A meta-analysis from 2006 of 17 RCTs 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.

The most significant study in the above-mentioned meta-analysis randomized 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:

We suggest that anaesthesia for PDT should consist routinely of intravenous general anaesthesia and neuromuscular blockade (2D).

We suggest that PDT can also be safely carried out in local anaesthesia (2D).

We suggest the laryngeal mask airway as a safe alternative to retracting an endotracheal tube (2B).

Usual fasting rules are applicable. Prepare for a difficult airway (ungraded)

Background:
Randomised clinical studies of anaesthesia for PDT were not identified, so this recommendation relies primarily on expert opinion and case reports. Sedation to tube tolerance is not sufficient for surgical anaesthesia. Thus, real doses of anaesthetics are used.

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. 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. 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. 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.

However one randomized clinical trial concludes that the laryngeal mask airway has significant advantages over withdrawing an endotracheal tube. 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 dilators 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 firm evidence supports one specific kit or technique, though single-step dilatation is gaining popularity due to fewer minor complications and ease of insertion compared to forceps dilatation, multiple dilatation, screw like dilatation, balloon dilatation or translaryngeal techniques. The following suggestions for PDT technique and procedure are based on expert opinions and rules of thumb.

Suggested PDT procedure: (ungraded)

The procedure differs slightly with choice of kit, but some basic steps remain common.

Staff:
In most cases two doctors should participate to allow bronchoscopic guidance, safe management of any complications, and clinical teaching. However, we appreciate than in very experienced hands, PDT can be performed safely by one doctor, if assisted by an experienced intensive care nurse. Physician assistance and bronchoscopic guidance should be readily available.

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 pro-voked by direct tracheal or indirect pharyngeal or oesophageal 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 and equipment for difficult airway management should be immediately available.
• 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 orotracheal 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 adrenaline circumferentially to the tracheal stoma.
• Manual compression.
• Minor bleeding (no transfusion requirement):
• Intratracheal guidewire placement.
• Correct tracheostomy site (midline placement, level at tracheal rings, light at the anterior tracheal wall).
• Intratracheal guidewire placement.
• Intratracheal dilator placement without tracheal damage.
• Position of tracheostomy cannula postprocedurally.

7. BRONCHOSCOPIC GUIDANCE
Recommendation:
We suggest bronchoscopic guidance for PDT (2D)

Background: No RCTs of PDT with bronchoscopic guidance versus no bronchoscopic guidance were identified. However, a systematic review of all published deaths related to PDT identified lack of bronchoscopic guidance as a serious risk factor. 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 postprocedurally.

8. ULTRASOUND GUIDANCE
Recommendation:
We suggest to use ultrasound as a possible adjunct to PDT (2C).

Background:
Prior to the procedure, ultrasound allows evaluation of the anatomy of major vessels and the thyroid gland in relation to tracheostomy site.
- any small vessels anterior to the tracheostomy site.
- the position of the tracheal rings and the midline.
- even in obese patients.

In skilled hands real time ultrasound is associated with even fewer complications. Thus ultrasound guidance may even obviate the need for bronchoscopy. In one minor study with 16 patients the use of ultrasound was associated with less hypoxia and shorter procedure time than the use of bronchoscopy, but the majority of studies with ultrasound has used both adjuncts.

9. PATIENT SAFETY
Recommendation: In intensive care units caring for tracheostomized patients:
- We recommend that the Surgical Safety Checklist, as developed by WHO, and with local modifications, be routinely applied to the surgical procedure of PDT (1B).
the decannulation practices of intensive care doctors

An international survey demonstrated considerable variability in

Background:

- the tracheal cannula should be without cuff (to avoid risk of displacement (1D)
- We recommend the presence of a difficult airway trolley in close proximity to the unit (1D)
- We suggest the establishment of an algorithm to be used in the clinical scenario where there is suspicion of a displaced tracheostomy (2D)
- We suggest that all ICU doctors receive ongoing training in the use of supraglottic devices and are familiar in the techniques of advanced airway management (2D)

Recommendations about decannulation suffer from

When a colleague is training a procedure, the following steps are suggested:

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:

• 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.

References:

34. Lavery GG, McCloskey BV. The difficult airway in adult critical care. Critical care medicine 2008;36:2163-73.