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CRITICAL CARE

Percutaneous tracheostomy: a 6 yr prospective evaluation of the single tapered dilator technique

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Key points

- A large single-centre service evaluation of percutaneous dilatational tracheostomies (PDTs) in a critical care unit over a 6 yr period.
- PDT was attempted in 576 patients and successfully completed in 572 patients.
- Early complication rate was 3%, late complications 0.7%, and directly attributable mortality 0.35%.
- The paper provides the largest single-centre evaluation of PDT and its safety/risk profile.

Background. The single tapered dilator (STD) percutaneous dilatational tracheostomy (PDT) technique now appears to be the single most common method of performing a tracheostomy in the critical care unit (CCU).

Methods. A single-centre, prospective evaluation of all PDTs performed in an adult mixed surgical and medical CCU between November 2003 and October 2009 was done. All procedures were undertaken by critical care physicians. A proforma recorded intraoperative complications and technical difficulties encountered during the procedure; all patients were followed up for a minimum of 3 months for delayed complications.

Results. A tracheostomy was performed on 589 patients during the study period. PDT was attempted in 576 patients and successfully completed in 572. PDT was abandoned in four patients due to bleeding, with three of these subsequently undergoing surgical tracheostomy (ST). ST was performed in 17 patients. Intraoperative technical difficulties were encountered in 149 (26%) cases. Sixteen (3%) procedures were deemed as having early complications. A further four (0.7%) cases had significant late complications including two tracheo-innominate fistulae (TIF). Both TIF patients died as a result of their complications giving a mortality directly attributable to PDT of 0.35%. There were no differences with respect to the occurrence of complications according to grade of operator.

Conclusions. PDT performed by the STD technique is a relatively safe procedure with more than 96% of procedures performed without any early or late complications. Using this technique, more than 97% of tracheostomies undertaken during the study period were performed percutaneously. Further audit at a national level is warranted to fully evaluate long-term complications after PDT.

Keywords: complications; dilatational; percutaneous; tracheostomy

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Percutaneous tracheostomy was first performed in 1955¹ after Seldinger's earlier description of a needle placement over a guidewire for arterial cannulation.² After Ciaglia's initial report of the dilatational technique in 1985,3 percutaneous dilatational tracheostomy (PDT) has become a commonly performed procedure in the critical care unit (CCU). It has largely replaced conventional surgical tracheostomy (ST) in critical care patients, with benefits in terms of cost, ease of performance, and reduced complications.4 5 In 2000, the first description of a modification of the technique was published (Blue Rhino® PercutaneousTracheotomy Introducer Kit; Cook Critical Care), whereby the series of dilators was replaced with a single, sharply tapered, dilator with a hydrophilic coating, permitting complete dilatation in one step.⁶ The single tapered dilator (STD) method has largely

supplanted the sequential dilatational procedure and now appears to be the single most common technique for performing a PDT.7-9

Several authors have published PDT case series using a variety of approaches. A number of papers have reported on complications of the STD technique; 10 11 further studies have compared it with other PDT techniques 12-14 or reported on its use across multiple centres.¹⁵ To our knowledge, we report the largest single-centre series solely utilizing the STD method.

Methods

This prospective service evaluation was carried out at Aintree University Hospital (AUH). The CCU at AUH is a 19-bedded mixed medical and surgical unit undertaking \sim 100 PDTs per year. The regional referral centre for head and neck cancer, the largest such unit in the UK, is also situated at AUH.

The need for PDT in any individual case was determined by the duty consultant intensivist. After the decision to proceed with a tracheostomy, all patients were fully evaluated and examined before operation. In all cases, when a tracheostomy is deemed appropriate, patients are assessed as to their suitability for a PDT. Patients undergoing ST as part of their surgical management for head and neck cancer were not included in the study.

From November 2003 to October 2009, data were prospectively collected on all PDTs performed at AUH. All PDTs were performed by critical care physicians at the bedside. All patients were over the age of 18 and each received i.v. general anaesthesia with neuromuscular block. Each procedure was undertaken with bronchoscopic guidance to ensure correct placement of the guidewire.

Before commencement of the procedure, the patient was positioned with the head extended and the lungs were ventilated with 100% oxygen. Throughout the procedure, heart rate, arterial pressure, and oxygen saturation were monitored continuously. After digital palpation of the neck, direct laryngoscopy was performed to position the tracheal tube (TT) above the site of the proposed PDT insertion point. Local anaesthesia and vasoconstriction were achieved using 2% lidocaine with 1:100 000 epinephrine administered s.c. to the pre-tracheal tissues. A 1 cm horizontal skin incision was made midway between the cricoid cartilage and the sternal notch. Pre-tracheal tissues were separated by blunt dissection. Tracheal puncture was performed with the standard 15 gauge needle and, after bronchoscopic confirmation of the position, the guidewire was passed into the tracheal lumen. A 4.5 cm 14 Fr gauge dilator was passed over the guidewire after which the STD was used to expand the tract between the skin and the tracheal lumen. The appropriate-sized tracheostomy tube was introduced into the tracheal lumen utilizing a loading dilator.

Perioperative data on each patient were recorded prospectively and included age, sex, reason for admission, admission APACHE II score, and intraoperative and postoperative complications as detailed below.

A PDT was considered 'technically difficult' if one or more of the listed events occurred during the procedure:¹⁶

- (i) oxygen desaturation (<88%);
- (ii) multiple attempts at tracheal cannulation (>3);
- (iii) bleeding (>3 soaked swabs);
- (iv) tracheal ring fracture evident on bronchoscopic examination;
- (v) posterior tracheal wall injury.

A PDT was considered to be 'complicated' if there was one or more of the following:

- (i) bleeding requiring surgical intervention;
- (ii) presence of surgical emphysema;
- (iii) malpositioning of tracheostomy tube;
- (iv) pneumothorax.

Table 1 Patient characteristic data of patients undergoing PDT (n=576). Data are mean (sp), mean (range), or numbers (percentage)

Age (yr)	58 (18-86)
Male (%)	340 (59)
Admission APACHE II score	19 (5.6)
Emergency admissions (%)	521 (91)
Days to PDT insertion from day of admission	5 (1-21)
Days to PDT insertion from initial tracheal	4 (1-14)
intubation	
Surgical patients (%)	288 (50)
Number surviving to ICU discharge (%)	395 (69)
Mean length of ICU stay non-survivors in days	18 (3-68)
Mean length of ICU stay survivors in days	20 (4-92)
Mean length of hospital stay survivors in days	42 (7-382)
Number surviving to hospital discharge (%)	360 (63)

Table 2 Rationale for opting for an ST rather than PDT (n=17). *Admission diagnoses for four patients with 'Reason not specified' for ST were pneumonia (three) and exacerbation of chronic obstructive pulmonary disease (one)

Reason for surgical tracheostomy	Number
PDT abandoned due to bleeding	3
Cervical spine fracture	3
Aberrant cervical innominate artery	2
Oesophagogastrectomy with cervical anastomosis	2
Soft tissue trauma to neck	1
Supraglottitis	1
Previous surgical tracheostomy with deep wound sinus	1
Reason not specified*	4

Routine post-procedural chest X-rays (CXRs) were performed after the first 384 PDTs. Thereafter, CXRs were limited to those PDTs considered technically difficult as defined above. 16

After critical care discharge, further surveillance was provided by the AUH Critical Care Outreach Service and after hospital discharge by the critical care follow-up clinic allowing identification of late complications.

Results

During the study period, 590 CCU patients required a tracheostomy. In 576 patients, a PDT was attempted, and in 572 (97%), the procedure was completed successfully (Table 1). In four patients, PDT was abandoned due to excess bleeding; three of these patients subsequently went on to have an ST. Consequently, a total of 17 (3%) patients underwent ST (Table 2). In the remaining patient, the procedure was abandoned and ST considered inappropriate due to worsening multiple organ failure. All PDTs were undertaken between the hours of 09:00 and 17:00 and 522 (91%)



Table 3 Adverse events encountered during 149 technically difficult PDTs. Note more than one technical difficulty occurred during some procedures, therefore the sum of technical difficulties exceeds 149

Difficulty	Number (% of all PDTs performed, n=576)
Minor posterior wall injury	9 (1.6)
Tracheal ring fracture visible at bronchoscopy	56 (9.7)
Multiple attempts (\geq 3) to cannulate the trachea	57 (10)
Minor bleeding (3–5 small soaked swabs)	25 (4.3)
Oxygen desaturation to ≤88%	17 (2.9)

Table 4 Technical difficulties by grade of operator; operator, person performing PDT, that is, not supervising or being supervised. *P*>0.05 Kruskal–Wallis

Grade of operator (number of PDTs performed by grade as a sole operator)	Technically difficult PDTs (% of number performed by relevant grade)
Consultant (149)	33 (22)
Fellow (151)	44 (29)
Registrar (120)	31 (26)

were performed on a weekday. Five hundred and twenty-one (91%) procedures followed an emergency critical care admission. In 406 (71%) cases, the most senior clinician present was a consultant. For the remainder, in 146 (26%) and 20 (3%) cases, the most senior clinician present was a senior critical care trainee (clinical fellow) and a specialist anaesthetic registrar, respectively.

According to the definitions described above, technical difficulties were encountered in 149 (26%) procedures (Table 3). Sixteen (3%) procedures were deemed as having early complications. These included six cases of significant bleeding (including four where the PDT was abandoned), four cases resulting in para-tracheal placement of the tracheostomy tube, three with significant surgical emphysema, one with a tension pneumothorax, one with significant posterior tracheal wall injury, and one case where the tracheostomy tube was sited in the cricothyroid membrane. Four cases (0.7%) were associated with significant late complications. Of these, two patients developed a tracheo-innominate fistula (TIF) and two patients developed a tracheal stenosis. In only one of these procedures was the initial tracheostomy regarded as being technically difficult (oxygen desaturation and a tracheal ring fracture in a patient subsequently developing tracheal stenosis). The two patients who developed TIF died as a result of massive haemorrhage whilst still patients on the CCU and represent a mortality directly attributable to PDT of 0.35%.

Table 5 Technical difficulties encountered by most senior physician present during PDT. *P*>0.05 Kruskal-Wallis

Grade of most senior physician present (number of PDTs)	Technically difficult PDTs (% of number performed by relevant grade)
Consultant (406)	107 (26)
Fellow (146)	38 (26)
Registrar (20)	4 (20)

There were no significant differences demonstrated between grade of operator and technical difficulties encountered when unsupervised procedures were excluded (Table 4). Similarly, seniority of supervising clinician had no bearing on outcome (Table 5).

Three hundred and sixty patients survived to hospital discharge. Thereafter, 25 patients died before their 3 month follow-up appointment, 36 patients were referred to AUH from outside our catchment area, eight patients were transferred to long-term care facilities for ongoing neuro-rehabilitation, and one patient remains an inpatient at AUH. Of the remaining 290 patients, 202 were seen in the critical care follow-up clinic, 59 have been seen in AUH in non-critical care clinics, four have had subsequent inpatient stays for conditions unrelated to their original critical care admission, and 25 had no evidence of follow-up.

Discussion

To our knowledge, this study is the largest single-centre evaluation of the STD technique to date. Earlier reports of STD PDT involve smaller numbers, 10 compared STD with other techniques, 12-14 were conducted in multiple centres, 15 or did not exclusively use the STD technique. 11 15 The practice within our unit, for the critically ill patient requiring a tracheostomy, is to almost exclusively perform PDT (97%). Despite this high rate of PDT, only four (0.7%) procedures were abandoned with three proceeding to ST. It is unclear from previous surveys of PDT practice as to what the ratio between ST and PDT is across UK CCUs. Although Krishnan and colleagues⁷ reported the results of a postal survey that stated that 173 (97%) of UK ICUs primarily performed percutaneous tracheostomy and only rarely, resorting to open ST, the ratio of PDT:ST was not reported. The authors also stated that clinicians would opt to perform an ST in the settings of a difficult airway, morbid obesity, and earlier failed PDT. In a later, similar study, Veenith and colleagues⁸ reported that 43% of UK units would perform a PDT of >95% of the time. It is, therefore, possible that a PDT rate of 97% is likely to be among the highest rates encountered within the UK. It is likely that this rate is influenced by the presence of the regional head and neck unit on site. Although the head and neck unit undoubtedly provides a level of support should a PDT become complicated this input is rarely required. We would not automatically resort to ST in the settings of a difficult airway and morbid obesity as described above. Indeed, where there is doubt over whether to perform an ST or a PDT, the decision as to which to proceed with would usually be a two-consultant decision. Additionally, as a group of intensivists, much of our practice involves head and neck patients which inevitably leads to an awareness that factors which are known to contribute to a difficult PDT are also likely to cause significant difficulties for the surgical operator.

Despite our collective willingness to take on more complex procedures, this does not appear to have resulted in an increase in complications. During an earlier study, assessing the use of routine chest radiography after PDT, we described the concept of a technically difficult but not necessarily complicated tracheostomy. 16 We felt that the incidence of postprocedural CXR changes was more likely if a procedure was technically difficult than if it were entirely straightforward. Consequently, we have utilized the same classification for the present study. The incidence of technical difficulties on initial examination of our data seems high at 26%. However, when we consider conventionally described complications, such as pneumothorax, significant bleeding, surgical emphysema, para-tracheal placement, and posterior tracheal wall injury, this figure reduces to 3% for early complications and to 0.7% for significant late complications. This is comparable with the published literature in both rate and type of reported complications. 10 11 15 Fikkers and colleagues¹⁰ reported a major complication rate of 6% due to bleeding, pneumothorax, and dilatation of a false tract. More recently, they have quoted rates of 1.4% for s.c. emphysema and 0.8% for pneumothorax. 17 Our rates for the corresponding complications were 0.5% (3 of 572) and 0.2% (1 of 572), respectively. Similarly, Kost¹⁵ reported a complication rate of 6.5% with the STD technique, the most significant being oxygen desaturation and bleeding. There were, however, no reports of either pneumothorax or pneumomediastinum which she attributed to the use of fibreoptic bronchoscopy. Although the use of fibreoptic bronchoscopy was used for all procedures in the current study, we have found that para-tracheal placement of the tracheostomy tube and barotrauma still occurred. In the absence of posterior tracheal wall injury, the most likely cause of the reported surgical emphysema is the use of a tracheostomy tube that is too short allowing air to escape into the s.c. tissues around the stoma. For each occurrence of malpositioning (excluding the case where the tube was passed through the cricothyroid membrane), a 7.0 mm TT was in situ. Although this allowed the passage of the bronchoscope to visualize the catheter and guidewire entering the trachea, effective mechanical ventilation with the bronchoscope in position was not possible. In each of these cases, therefore, the bronchoscope was removed after confirmation of wire placement and re-introduced to confirm tracheostomy tube placement whereupon the error was detected. We feel that this reiterates the importance of continuous bronchoscopic guidance throughout the procedure and if the TT is of insufficient calibre to allow ongoing mechanical ventilation during the procedure, the TT must either be

changed before commencing the PDT or a paediatric bronchoscope must be available.

The comparison of our data with the existing literature becomes more difficult when considering minor complications, or technical difficulties, as many such problems are not reported in comparable studies. Of the larger published series, 10 11 15 the reported rate of minor bleeding varies from $1.6\%^{11}$ to $14\%^{10}$ compared with our rate of 4.3% (25) of 576). It is possible that the bleeding rate may be affected by an operating technique. In our series, after skin incision, our practice was to divide the pre-tracheal tissues by blunt dissection in a manner similar to that described by Kost¹⁵ and as recommended by the manufacturers of the Blue Rhino® STD (www.cookmedical.com/cc/home.do). Some operators, however, prefer to proceed to the dilatational phase of the PDT immediately after skin incision. In the report by Fikkers and colleagues, 10 48 patients underwent STD PDT without blunt dissection of the pre-tracheal tissues, whereas 52 had pre-tracheal dissection. There was no difference in the bleeding rate between the two groups. There was, however, a significant increase in the difficulty of dilatation (requiring unusual force) when pre-tracheal dissection was not performed.

Minor posterior tracheal wall injury was only reported by Kost¹⁵ (0.6%) and Fikkers and colleagues¹⁰ (2%) in comparison with our rate of 1.6%. Oxygen desaturation during PDT was only reported by Kost¹⁵ with a rate of 2.8% (14 of 500) almost identical to our own of 2.9% (17 of 576). None of these authors 10 11 15 has reported rates of the tracheal ring fracture or number of attempts to cannulate the trachea. Other authors have, however, reported rates of the tracheal ring fracture in association with STD PDT with incidences varying from 5.3% to 36% 18-20 in comparison with our rate of 9.7%. Such a wide variation in the reporting of tracheal ring fracture rate is almost certainly related to how closely this complication is sought by the bronchoscopist during the PDT. Some authors have suggested that the incidence of the tracheal ring fracture is higher with STD PDT when compared with the Ciaglia technique. 19 20 However, it is likely that all clinical reporting of tracheal ring fractures represents an underestimate of the actual incidence. In a cadaveric study of 42 patients who had had a PDT by the Ciaglia method, Walz and Schmidt found 12 patients with tracheal ring fractures and 10 specimens where a cartilaginous defect was demonstrated at the tracheal stoma.²¹ The significance of the tracheal ring fracture after PDT with respect to long-term complications remains unclear. In the paper by Higgins and colleagues, 18 16 patients with tracheal ring fractures (four after STD PDT) were followed up until a mean time of almost 9 months after PDT. None of these patients developed a tracheal stenosis which led the authors to conclude that the tracheal ring fracture was not associated with subsequent development of tracheal stenosis. Given the small number of patients in the study, the likely under-reporting of tracheal ring fractures, and the rarity of tracheal stenosis after PDT, this seems to be an overinterpretation of the data. In the present study, one of the



two patients subsequently developing tracheal stenosis had a clinically evident ring fracture at the time of PDT (see below).

Long-term follow-up of this patient cohort may initially appear poor with only 202 patients out of a potential 360 attending the critical care follow-up clinic. Of these 360 patients, 25 died before follow-up could be arranged, 36 were transferred to AUH from other hospitals and were subsequently referred back to the referring hospital for ongoing care after discharge from the CCU, eight were transferred to neuro-rehabilitation facilities, and one patient remains as an inpatient at AUH. The actual number of patients, therefore, who we could realistically expect to follow up was 290. We have therefore managed to see almost 70% of these patients in our follow-up clinic with a further 63 (22%) patients being seen within the hospital in some other capacity after CCU discharge. In only 25 of these patients was there no evidence of follow-up. The problem facing critical care follow-up clinics with non-attendance is well recognized. In a review of seven studies of CCU follow-up clinics, Williams and Leslie found that among hospital survivors who had not been on a CCU, 67% attended clinic within 8 weeks, this figure decreased to 30% for patients discharged alive after a CCU stay.²² Nonattendance rates for critically ill follow-up patients varied from 10% to 30%. Placed in this context, achieving a postdischarge review rate of close to 70% is unusual. Additionally, one of the authors (T.M.J.) has a tertiary referral subspecialist interest in the management of tracheal stenosis. We are therefore confident that if any of the 36 patients repatriated to their base hospitals, within the locality, had subsequently developed a clinically relevant tracheal stenosis, they would have been referred back to AUH for further management.

Reports relating to late complications after PDT in large case series are again difficult to interpret due to the infrequency of most of these complications and the fact that many studies report predominantly early complications. ¹⁵ In the present series, there were four significant long-term sequelae—two TIF and two tracheal stenoses.

Our incidence for clinically evident tracheal stenosis: 0.35% (0.6% for those surviving to hospital discharge) is comparable with earlier series of both PDT 10 11 and ST. 23 The first case of tracheal stenosis was in a 41-yr-old male requiring admission to the CCU after an episode of near drowning. He underwent a PDT with no reported technical difficulties or complications. The tracheostomy remained in situ for 8 days. The second case was a 32-yr-old male admitted after a closed head injury. During his PDT, a tracheal ring fracture was noted at bronchoscopy; the procedure was otherwise complicated by a minor oxygen desaturation. His trachea remained cannulated for a total of 55 days. His critical care stay was complicated by a severe hospital acquired pneumonia and acute respiratory distress syndrome. It is likely that in the latter case, the factor of note is the prolonged duration of cannulation. As noted by Koitschev and colleagues,²⁴ the incidence of tracheal stenosis after PDT may be higher after prolonged

cannulation. In comparison, during the study period, we have had one case of tracheal stenosis associated with translaryngeal tracheal intubation in our unit.

Similarly, the incidence of TIF was also 0.35%. Again, in keeping with the published literature, where the rate is reported to be between 0.1% and 1%.²⁵ Each of these patients underwent essentially uneventful PDTs and was cannulated for 10 and 12 days, respectively, before the occurrence of their TIF.²⁶ Since both patients with TIF subsequently died of their complications, unlike earlier papers, we are able to report a death rate of 0.35% directly attributable to the PDT itself.

There remains a paucity of information pertaining to the occurrence of uncommon but significant long-term complications after PDT. The incidence of these complications may, at least in part, depend upon the clinical setting and duration of tracheal cannulation.²⁴ It is possible, in the scenario of closed head injury (given the differences in incidence of tracheal stenosis between PDT and ST) described by Koitschev and colleagues,²⁴ where prolonged cannulation will be required, that ST may be the most appropriate means of securing the airway. Given this dearth of information relating to longer term outcome after PDT, a more extensive audit of the role of PDT in critical care, to the standards set out by the Royal College of Anaesthetists,²⁷ is now justified at a national level.

Our low incidence of reported complications may also, in part, be due to the routine PDT practice within the unit. A majority of the current consultant body regularly anaesthetize for major head and neck surgery with its attendant problems of difficult airway management. All procedures are performed with a minimum of two experienced clinicians, one to manage the airway (including TT manipulations and bronchoscopy) and the other to perform the procedure. All procedures are carried out between the hours of 09:00 and 17:00, with in excess of 90% also occurring between Monday and Friday.

The timing of PDT in the current study is, compared with previous work, 10 11 15 somewhat early with a mean time to PDT of 5 and 4 days from CCU admission and tracheal intubation, respectively. Our practice of early PDT may, however, not be too different to UK practice with Krishnan and colleagues reporting that 50% of units perform a tracheostomy within the first week after admission and Veenith and colleagues reporting that 21% of units will perform the procedure within 5 days.

Optimal timing of PDT in the critically ill remains a subject of debate and considerable controversy within the literature with the indications and timing frequently based on personal preference. Indeed, even the definition of early/late tracheostomy is difficult to reach consensus on. There would be little doubt, however, that the vast majority, if not all, of PDTs described herein would fit in to the early category. Scales has recently reported the findings of a retrospective analysis of almost 11 000 patients over a 12-yr-period, using the Ontario health database, comparing the mortality of early (\leq 10 days) vs late (>10 days) tracheostomy in

critical care.³⁰ They reported modest reductions in 90 day and 1 yr mortality associated with early tracheostomy, along with faster weaning times and more ventilator free days. Another study in critically ill medical patients showed that early PDT was associated with reductions in duration of mechanical ventilation, CCU stay, morbidity, and mortality.³¹ More recently, a meta-analysis has challenged the positive beneficial effects of early PDT on the risk of developing pneumonia and mortality but did show a reduction in the duration of mechanical ventilation and length of CCU stay.³² It has always been our belief that the risks of early PDT were outweighed by the benefits accrued resulting from significant reductions or cessation of sedative drugs leading to the advantages described above and improved resource utilization.³³ The TracMan study in the UK reported no effects of early tracheostomy (days 1-4) compared with late tracheostomy (after day 10) on 30 day mortality.

In conclusion, we have performed the largest single-centre evaluation of the STD PDT technique to date. It would appear to be a relatively easy and safe technique when performed at the bedside. The complication rates described herein are similar to earlier reports of both PDT and ST. When taking into account the fact that the STD PDT was considered for all patients undergoing tracheostomy in our unit, with no absolute contraindications and with only four procedures being abandoned, the low complication rate is all the more remarkable. However, further large-scale audit on a national level is justified to fully evaluate the long-term outcomes after PDT.

Conflict of interest

None declared.

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