

EDITORIALS

The NCEPOD study: on the right trach? lessons for the anaesthetist

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Patients managed in our hospitals with temporary or permanent tracheostomies are exposed to a wide range of healthcare professionals and specialities, with the anaesthetist often pivotal in their inpatient journey. Since the widespread adoption of percutaneous procedures in the critically ill, the population of hospitalised patients with tracheostomy has changed.¹ It is surprisingly difficult to find national data on the number of patients managed with tracheostomy. What detailed data there are suggests that 7–19% of all patients admitted to an Intensive Care Unit (ICU) will be managed with a tracheostomy, and that up to 90% of these tracheostomies are currently performed by percutaneous routes.^{2–3} This figure varies with the admission diagnosis, individual units, and to some extent, the country.^{4–7}

The spotlight has turned onto tracheostomy care, after reports from around the world highlighting measurable harm in up to 30% of all acute hospital admissions involving temporary or permanent tracheostomy.^{1,8–12} The requirement for tracheostomy marks the patient out as one with high risk for morbidity and mortality. This is borne out by studies which demonstrate mortality rates during the index hospital admission ranging from 17–20%, rising to 40% in groups with significant comorbidities.^{10,11} Harm may occur that can be directly associated with the management of the airway device.^{8,9} Analysis of severe incidents has revealed common underlying themes, which include a lack of staff training, of basic bedside equipment, and inadequate environments and support mechanisms, compounded by poorly thought out care pathways and response to incidents. These findings were reinforced by the 2011 4th National Audit Project of the UK Royal College of Anaesthetists (NAP4), which reported similar

problems in a subset of major tracheostomy incidents, that occurred in the UK's critical care units.¹² Eleven out of the 14 dislodged ICU tracheostomies reported to NAP4 led to death or severe hypoxic brain injury. Competency deficiencies and a lack of capnography were consistent factors in these patients.

Anaesthetists will usually have first hand experience of dealing with routine and emergency care of neck breathing patients. They are also the professional group most likely to be involved acutely when care does not go well, as airway specialists, resuscitation experts and intensivists. These varied experiences alongside increasing awareness of avoidable harm, prompted the Association of Anaesthetists of Great Britain & Ireland (AAGBI) to propose a study specifically on tracheostomy care. The survey-based study was undertaken by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and is the largest study of its type to date.

The NCEPOD study: on the right trach?

The primary aim of this study was to explore factors surrounding the insertion and subsequent management of tracheostomies in both the ICU and ward environments. Typical NCEPOD methodology was used, recruiting appropriate leads to complete institution-level questionnaires and following the patient journey with detailed clinical data capture. Two complete sets of case notes were selected at random by NCEPOD from each of the 219 participating hospitals, and peer reviewed (along with associated questionnaires) by a panel of recruited expert advisors. Overall assessment of the quality of care in the patients subject to peer

review was felt to be good, in only around 40% of patients. Approximately 20% each of the patients were felt to have room for improvement at either clinical, organizational or both levels and this was consistent in both ward and ICU environments.

Over the 11 week study period, 2546 patients were included. Nearly 70% of tracheostomy insertions were percutaneous, with the majority of insertions occurring because of respiratory illness. Data were available for 1956 ICU discharges, describing a 17.5% ICU mortality. Detailed methodology, data analysis, results and recommendations can be viewed by downloading the full report from the NCEPOD website (www.ncepod.org.uk/2014tc.htm). Key messages for the anaesthetist are outlined below:

Tracheostomy insertion and equipment

The circumstances surrounding the insertion of tracheostomy tubes were examined in detail. Whilst most surgical procedures performed in operating theatre suites had a documented consent process, only 48.8% of percutaneous procedures (almost exclusively performed on the ICU) had such consent documented. A World Health Organisation surgical checklist was utilized in only 16% of these percutaneous patients. Tracheostomy insertion should be a carefully considered process for the patient and/or their family. Checklist driven preparation before high risk procedures has been demonstrated to reduce associated complications and improve safety, with anaesthetists playing a key role.¹³ In those patients that were reviewed in detail by looking retrospectively at case notes, final tube tip position was assessed after insertion using endoscopy in just 137/266 (51.5%) of patients.

Within this study, 20/217 hospitals with an ICU indicated that immediate access to a dedicated difficult airway trolley was not available. Only 162/209 hospitals had the equipment to perform bronchoscopy/fibreoptic laryngoscopy available immediately within the ICU. NICE published medical technology guidance concerning the provision of single-use endoscopes for emergency airway management in December 2013.¹⁴ Along with existing recommendations from the ICS and RCoA, this may serve to improve the availability of emergency endoscopy equipment. Encouragingly, most wards (380/396, 96%) were equipped with appropriate portable bedside tracheostomy equipment.

The UK Intensive Care Society (amongst others) has recently reinforced its guidance that inner cannulae should be used with tracheostomy tubes where possible.¹⁵ It was reassuring to find inner tubes were used in 1661/1931 (86%) of patients in the NCEPOD study.

Where records were available, capnography use was recorded in only 144 of 266 (54.1%) surgical tracheostomies. Whilst these findings may in part represent failure to document important procedures and parameters, there were also concerns from separate organizational data that capnography may not be universally available. The responses from 333 critical care areas in 198 hospitals revealed that capnography was available at 91.7% of ICU bed spaces, and used continuously in just 71.5%. These data are a reminder to all involved in airway management, that correct use of monitoring has been shown to improve safety, and endoscopy may be an increasingly important method of ascertaining the correct position of the tracheostomy tube tip.¹²

Airway management during surgical tracheostomy

Of the patients undergoing tracheostomy in the operating theatre, 14.4% had stridor and 29.1% were recognized as being potentially difficult to re-intubate, with concerns about oxygenation

before intubation in 13.4%. Mallampati scores were documented in 295 patients, with 29.8% grade III or IV. The vast majority of patients requiring surgical tracheostomy (565/662) underwent (or had previously undergone in ICU) endotracheal intubation. However there were 46 patients that had a surgical tracheostomy, that had their airway maintained with a simple face mask alone, and 5 patients with a laryngeal mask as the sole airway, immediately before tracheostomy. Of the patients who were intubated, 19.9% required the use of additional difficult airway equipment. In 6.1% of surgical tracheostomy patients, there was at least one failed attempt at intubation and in 3% of patients the anaesthetist was unable to intubate or ventilate at some point during the procedure. Finally, in 3.5% patients there were unanticipated complications on induction and in 5/561 patients there was prolonged hypoxia (SaO₂ <90% for >5 min). Whilst patients requiring elective or emergency tracheostomy might be expected to have a difficult airway, these data help to quantify this risk, and should serve as a timely reminder to anaesthetists who may be called upon infrequently to manage these situations.

The obese patient

Almost 30% of patients included in this study were classified as obese or morbidly obese. However, adjustable length tracheostomy tubes were used in only 96/510 (18.8%) of these patients and in 185/1825 (10.1%) of patients overall. It remains difficult to predict which size tracheostomy we should insert into the many different anatomically shaped necks that both surgeons and intensive care clinicians are confronted with. The population in the Western world is becoming increasingly obese¹⁶ and that a relatively small tube inserted into a 'large' neck, where the distance from anterior neck surface to trachea may be increased, would intuitively increase the risk of tube displacement (Fig. 1). Indeed, more than 50% of unplanned tube changes, occurring before 7 days post insertion occurred in the obese (BMI ≥30) in ICU, and in 38% of all unplanned tube changes. These are both disproportionately high ratios given the 29.1% of patients with BMI ≥30 in the dataset.

Complications

Complications occurred in 23.6% of ICU patients and 31.3% of ward patients and nearly 30% of patients that experienced one complication went on to experience further complications. In keeping with previous reports, tube displacement, obstruction,

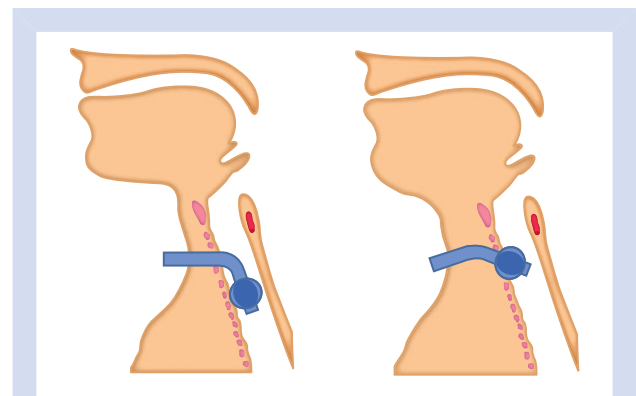


Fig 1 Standard tracheostomy tubes inserted into large necks may increase the risks of tube displacement.

pneumothorax and major haemorrhage were commonest themes, with accidental tube displacement in ward-based patients occurring more frequently than in ICU (6.3% vs 4.1%). It is important to note that ward patients with a tracheostomy who are intuitively expected to be more physiologically stable appear to suffer more complications. This was also seen in previous analyses of critical incidents, with the nature, frequency and severity of such incidents being greater in ward environments.^{8 9 17} Why should this be the case? In part it may relate to less close supervision of tracheostomy care in a ward as opposed to critical care environment. Whilst the NCEPOD report does not attempt to answer this question directly, there are also recurring themes of a lack of trained bedside staff, lack of equipment for both routine and emergency care and a lack of both leadership and a multi-disciplinary team working in some environments. For example only 174/216 hospitals (80.6%) had a policy for the management of blocked or displaced tubes, with 27.9% (48/172) of hospital sites not providing staff training in the management of blocked and displaced tubes. Just 54% of hospitals had resuscitation policies that routinely incorporated the care of the patient with a tracheostomy. Anaesthetists in particular are likely to be involved in resuscitation training for our own and other specialties and the deficiencies highlighted in this report may represent opportunities for anaesthetists to improve care. Resources for tracheostomy emergency management can be found via the National Tracheostomy Safety Project's website and smartphone Apps (www.tracheostomy.org.uk).¹⁸

Multidisciplinary care

The NCEPOD report found that the composition of multidisciplinary teams caring for tracheostomy patients varied and dietitians and critical care 'outreach' specialist nursing staff (who often provide a link between ICU and ward care) were relatively poorly represented. Only 57.1% of patients with a swallowing difficulty had an early referral (within 48 h) to Speech and Language Therapy. These are significant findings, given that there is increasing evidence that truly multidisciplinary team care can impact significantly on the quality of care delivered to this vulnerable cohort. Improvements in defined outcomes, such as ICU or hospital length of stay, reductions in untoward incidents, cost savings and improvements in what could be considered surrogate markers of the quality of care (such as time to first use of a speaking valve, decannulation time, and importantly improved perceptions of care by patients and their families), have all been demonstrated by groups working in a variety of exemplar institutions.^{19–23} Anaesthetists are well versed in managing complex teams, systems and situations, and can play a key role in leading, coordinating and contributing to multidisciplinary tracheostomy care. However NCEPOD found that only just more than a third of Trusts (34.4%) had medical leads for tracheostomy care.

In conclusion, this NCEPOD report is currently unique in documenting more than two and a half thousand new tracheostomy patient journeys, capturing a consecutive snapshot of 'real world' care for patients in the NHS. It reinforces some of what we knew already and adds new detail on the process of care and the current deficiencies which exist. Hospitals in England and Wales need to consider and act upon the report findings and recommendations. Fortunately there are extensive resources from exemplar institutions, national guidelines and global initiatives such as the Global Tracheostomy Collaborative (www.globaltrach.org), a global Quality Improvement Collaborative tasked with improving tracheostomy care.

Patients with altered airways present for routine and emergency procedures and anaesthetists should be knowledgeable and confident around the principles of safe tracheostomy care. Furthermore, this report highlights specific information relevant to the anaesthetist working in Head & Neck operating theatres or the ICU, and areas where our team working and systems can be improved.

Acknowledgements

The authors are extremely grateful to Marisa Mason (Chief Executive) and Mark Juniper (Lead Clinical Co-ordinator) at NCEPOD for advice and input when preparing this manuscript.

References

1. Wilkinson KA, Martin IC, Freeth H, Kelly K, Mason M. NCEPOD: On the right Trach? 2014. Available from www.ncepod.org.uk/2014tc.htm (accessed 20 October 2014)
2. Veenith T, Ganeshamoorthy S, Standley T, Carter J, Young P. Intensive care unit tracheostomy: a snapshot of UK practice. *Int Arch Med* 2008; **1**: 21
3. Young D, Harrison DA, Cuthbertson BH, Rowan K, TracMan Collaborators. Effect of Early vs Late Tracheostomy Placement on Survival in Patients Receiving Mechanical Ventilation. *JAMA* 2013; **309**: 2121–9
4. Nathens AB, Rivara FP, Mack CD, et al. Variations in rates of tracheostomy in the critically ill trauma patient. *Crit Care Med* 2006; **34**: 2919–24
5. Fischler L, Erhart S, Kleger GR, Frutiger A. Prevalence of tracheostomy in ICU patients. A nation-wide survey in Switzerland. *Intensive Care Med* 2000; **26**: 1428–33
6. Blot F, Melot C, Commission d'Epidémiologie et de Recherche Clinique. Indications, timing, and techniques of tracheostomy in 152 French ICUs. *Chest* 2005; **127**: 1347–52
7. McGrath BA, Ramsaran R, Columb MO. Estimating the number of tracheostomies performed in critical care in England. *Br J Anaesth* 2012; **109**: 662P
8. Thomas AN, McGrath BA. Patient safety incidents associated with airway devices in critical care: a review of reports to the UK National Patient Safety Agency. *Anaesthesia* 2009; **64**: 358–65
9. McGrath BA, Thomas AN. Patient safety incidents associated with tracheostomies occurring in hospital wards: a review of reports to the UK National Patient Safety Agency. *Postgrad Med J* 2010; **86**: 522–5
10. Halum SL, Ting JY, Plowman EK, et al. A multi-institutional analysis of tracheotomy complications. *Laryngoscope* 2012; **122**: 38–45
11. Shah RK, Lander L, Berry JG, Nussenbaum B, Merati A, Roberson DW. Tracheotomy outcomes and complications: a national perspective. *Laryngoscope* 2012; **122**: 25–9
12. Cook TM, Woodall N, Frerk C, on behalf of the Fourth National Audit Project. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia. *Br J Anaesth* 2011; **106**: 617–31
13. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med* 2009; **360**: 491–9
14. NICE medical technology guidance [MTG14]: Ambu aScope2 for use in unexpected difficult airways. 2013. Available from www.nice.org.uk/guidance/mtg14 (Accessed 3 January 2015)

15. Intensive Care Society. Standards for the care of adult patients with a temporary Tracheostomy. 2014. Available from www.ics.ac.uk/EasySiteWeb/GatewayLink.aspx?alid=2212 (Accessed 3 January 2015)
16. Ford ES, Maynard LM, Li C. Trends in mean waist circumference and abdominal obesity among US adults, 1999–2012. *JAMA* 2014; **312**: 1151–3
17. Templeton R, Webster K, McGrath BA. Patient safety incidents associated with displaced or obstructed tracheostomies: comparison of levels of harm between critical care and ward environments. *Br J Anaesth* 2011; **107**: 834–5
18. McGrath BA, Bates L, Atkinson D, Moore JA. Multidisciplinary guidelines for the management of tracheostomy and laryngectomy airway emergencies. *Anaesthesia* 2012; **68**: 1025–41
19. Cameron TS, McKinstry A, Burt SK, et al. Outcomes of patients with spinal cord injury before and after introduction of an interdisciplinary tracheostomy team. *Crit Care Resusc* 2009; **11**: 14–9
20. Pandian V, Miller CR, Mirski MA, et al. Multidisciplinary Team Approach in the Management of Tracheostomy Patients. *Otolaryngol Head Neck Surg* 2012; **147**: 684–91
21. Cetto R, Arora A, Hettige R, et al. Improving tracheostomy care: a prospective study of the multidisciplinary approach. *Clin Otolaryngol* 2011; **36**: 482–8
22. Speed L, Harding KE. Tracheostomy teams reduce total tracheostomy time and increase speaking valve use: A systematic review and meta-analysis. *J Crit Care* 2013; **28**: 216.e1–10
23. McGrath BA, Wallace S. The UK National Tracheostomy Safety Project and the role of speech and language therapists. *Curr Opin Otolaryngol Head Neck Surg* 2014; **22**: 181–7

British Journal of Anaesthesia 115 (2): 158–61 (2015)
Advance Access publication 3 June 2015 · doi:10.1093/bja/aev167

Haemostatic efficacy of fibrinogen concentrate: is it the threshold or the timing of therapy?

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Fibrinogen is the key substrate of thrombin in haemostatic clot formation, and its plasma concentration is highly susceptible to blood loss and haemodilution;^{1–3} therefore, it has been recognized as a primary target of coagulation therapy in the management of perioperative major bleeding.^{2–7} Human plasma-derived fibrinogen concentrate is convenient to use because it is lyophilized and quickly reconstituted for i.v. injection. In addition, it is simple to monitor the dose because fibrinogen concentrate increases plasma fibrinogen concentration in a dose-dependent manner⁸ and increases fibrin-specific clot formation (FIBTEM) on thromboelastometry.^{9–10} However, there is no consensus on the minimal fibrinogen concentration or FIBTEM value that is required for perioperative haemostasis,¹¹ and there are concerns regarding overuse and misuse.^{12–13} The value of FIBTEM-based fibrinogen interventions has been evaluated previously in both prospective studies and retrospective analyses (Table 1).^{14–17–19} However, it is yet unknown whether a low normal fibrinogen concentration (1.5 g litre⁻¹) is adequate for haemostasis in the perioperative setting or whether higher concentrations of fibrinogen might be required to reduce bleeding.

In this issue of the *British Journal of Anaesthesia*, Haas and colleagues¹⁵ shed new light on the perioperative fibrinogen replacement strategy. The authors performed a well-designed randomized controlled study in paediatric patients undergoing craniocynostosis and scoliosis surgery. Patients were randomized to receive therapy with fibrinogen concentrate based on a high (13 mm) or low target value (8 mm) of FIBTEM maximal

clot firmness (MCF). The authors found that intraoperative fibrinogen intervention using the higher threshold significantly reduced bleeding by ~67% and transfusion requirements by nearly 50% compared with the lower threshold value in craniocynostosis surgery. In scoliosis surgery, however, the extent of bleeding was similar between both groups, and only a trend for reduced transfusion with the higher threshold was found.

The two thresholds, 8 and 13 mm of FIBTEM MCF, used in this study represent the lower and upper target range in the European guidelines for the treatment of massive perioperative bleeding.⁶ They are also likely to correspond to the minimal fibrinogen concentration (1.5 g litre⁻¹) recommended by the European guidelines⁶ and the median concentration of fibrinogen (2.35 g litre⁻¹) for this age group.²⁰ Those who were randomized to the higher threshold received intervention early because their baseline FIBTEM MCF values were 10–11 mm (corresponding to plasma concentrations of about 1.8–2.0 g litre⁻¹).²¹ It can be speculated that plasma fibrinogen concentrations were maintained at above 2.0 g litre⁻¹ in the high-threshold group when intraoperative bleeding occurred. In the low-threshold group, however, plasma fibrinogen could be decreased to below 1.5 g litre⁻¹ as bleeding continued. It is thus important to consider the timing of therapy in addition to the optimal threshold. Nakayama and colleagues¹⁶ recently reported a prospective randomized study of conventional vs thromboelastometry-guided haemostatic intervention in paediatric cardiac surgery. In their study, the FIBTEM threshold was set rather low at 5 mm for