



The Royal College  
of Anaesthetists

# The Faculty of Intensive Care Medicine

## **Regulation 28 Report to prevent future deaths**

**Helen Elizabeth Patton**

### **Comments from the Faculty of Intensive Care Medicine and Royal College of Anaesthetists**

The Faculty of Intensive Care Medicine and Royal College of Anaesthetists have reviewed the information received regarding the above Regulation 28 report. The Faculty and College noted that the clinical details were limited. Mrs Patton died from exsanguination either during or after a minitracheostomy was inserted for removal of secretions on an intensive care unit.

It was not stated who inserted the device or their level of experience or training in this or other modes of tracheostomy or front of neck airway (FONA). It is not stated at what level of the trachea this was inserted (or intended to be inserted) e.g. cricothyroidotomy or tracheostomy. It is not stated if the patient's condition rendered the procedure to be more difficult (obesity, short neck, limited neck movements) or more prone to complications (e.g. coagulopathy, anticoagulants, antiplatelet drugs, recent thoracic surgery). There is therefore inadequate data to answer this question definitively.

However, based on data from percutaneous tracheostomy, which is likely to be a higher risk procedure than minitracheostomy, routine use of ultrasound is not mandated prior to minitracheostomy and an appropriately equipped critical care unit would be a suitable setting, as timely management of potential complications can be undertaken (i.e. immediate intubation and management of bleeding). The Faculty and College would support the NCEPOD recommendation that insertion of any device in the front of the neck for access to the airway is classed as a surgical procedure. Appropriate patient assessment and planning should have taken place if the procedure was not urgent. As this is a surgical procedure it should have been undertaken by someone who was capable of weighing up all options and issues at the site, with responsibility for ensuring that appropriate support was available if needed and able to manage any complications (i.e. haemorrhage).

The Faculty and College would recommend:

- imaging for patients who have or are expected to have complications or abnormal anatomy.
- the presence of, or access to, an ENT specialist in these cases.
- a Seldinger technique as the default technique for minitracheostomy insertion. This will reduce the risk of bleeding at insertion.
- the cricothyroidotomy should be the default insertion site, which will reduce the risk of bleeding at insertion.
- that as the current evidence for minitracheostomy is limited, its use should be limited to specific circumstances.

It is not currently feasible to mandate the use of ultrasound for invasive airway access for a number of reasons. The Intensive Care Society and the Faculty of Intensive Care Medicine are developing ways to standardise ultrasound access training in order to make it more accessible. It should be noted that ultrasound is largely limited to pre-procedure planning and landmark identification as the footprint of

most available probes makes real-time scanning impractical. It should also be noted that bleeding can occur with or without prior use of ultrasound.

## **Background and rationale**

A minitracheostomy (Mini Trach) is a narrow uncuffed plastic tube (4mm internal diameter, 5.4m external diameter) intended to be placed through the cricothyroid membrane to 'access' the trachea and to enable clearance of secretions.

The 'mini-trach' and mini-trach II' devices are designed to be placed in the cricothyroid membrane but sub-cricoid use has been described (van Heurn LW, van Geffen GJ, Brink PR. Percutaneous subcricoid minitracheostomy: report of 50 procedures. *Ann Thorac Surg.* 1995; 59: 707-9.).

It has been used to assist sputum clearance most prominently after or during critical care admission and after thoracic surgery. It is likely its use has waned in the last decade or so. Its value compared to other techniques for sputum clearance (delayed extubation, tracheostomy, physiotherapy techniques) is likely unproven. In some parts of the country the use of mini tracheostomy in an ICU setting is rarely if ever used while in others the practice is more common.

In general a minitracheostomy will only be inserted in patients who have a high risk of sputum retention and respiratory failure. These are, by definition, a group of patients who are likely to have a high mortality in hospital with or without a minitracheostomy.

A minitracheostomy is most frequently inserted by an intensivist or an anaesthetist. In the past, ward doctors and occasionally physiotherapists have inserted them. Use by a surgeon outside elective prophylactic insertion for thoracic surgery would be less common.

Insertion is most commonly performed on an ICU/HDU (critical care area) but on occasions on a ward. The technique is usually performed in an awake patient using local anaesthetic. Reported and potential complications include failure of placement, misplacement (subcutaneous, oesophageal and pleural placement), granuloma formation, pneumothorax, oesophageal perforation, thyroid abscess and bleeding.

Ultrasound may be used to assist 'front of neck airway (FONA) procedures. It may improve identification of the trachea, of the level of insertion and identify blood vessels. This is an emerging technique for use in airway management and cannot be considered routine practice for any FONA. We are not aware of any data on its use for minitracheostomy.

The only comparative data would be for percutaneous tracheostomy on ICU. The NCEPOD report 'On The Right Trach' in 2014 estimates 12,000 tracheostomies are performed each year in the UK of which 70% are percutaneous procedures. While the report does not specify, almost all of these will be performed in a critical care setting rather than in an operating theatre. Tracheostomy – because of the lower location of the FONA, because of the size of the tube used, and because of the clinical state of the patients on whom it is performed would be anticipated to be a higher risk procedure for bleeding than minitracheostomy performed at the cricothyroid level.

NCEPOD states "...The use of real time ultrasound guidance has been advocated to assist in avoiding damage to vascular structures and to prevent misplacement of the tracheostomy tube. However, in a recent systematic review, the evidence of benefit over traditional landmark-guided techniques was limited (Rudas M and Seppelt I. Safety and efficacy of ultrasonography before and during percutaneous

dilatational tracheostomy in adult patients: a systematic review. Crit Care Resusc 2012; 14: 297-301). In the current study, ultrasound was used in 484/1471 (32.9%) of patients.”

The use of ultrasound (for percutaneous tracheostomy or open tracheostomy) is not included in any recommendation made by the NCEPOD report.

This report also noted that in percutaneous procedures “Although immediate complications were uncommon, they still occurred in 81/1482 (5.5%) patients. The most common complication was minor haemorrhage (46 cases).” (ie 3%).

The NAP4 report in 2011 collated data on major complications of airway management in the UK. Complications of tracheostomy in ICU were a significant contributor to airway related mortality but bleeding at tracheostomy was not [REDACTED] Major complications of airway management in the UK: results of the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 2 Intensive Care and Emergency Department.. British Journal of Anaesthesia 2011; 106: 632-42).

Bleeding from a tracheostomy may occur at insertion or after some delay. Performance of a FONA or tracheostomy procedure in an operating theatre does not preclude subsequent bleeding, including life-threatening bleeding.