

## ENDOTRACHEAL TUBE INSERTION AND POSITIONING APPARATUS

This application is a continuation of co-pending U.S. patent application Ser. No. 07/697,772, filed May 9, 1991, now abandoned.

### BACKGROUND OF THE INVENTION

This invention relates generally to the art of endotracheal tubes, and devices for facilitating implantation thereof.

Endotracheal intubation is a common medical procedure with over 55 million endotracheal (ET) tubes being sold annually. ET tubes are used in many situations for providing artificial airways for passages of respiratory gases to patients. ET tubes are used in both human and animal surgery to provide passageways for anaesthetic gases into lungs. They are used in emergency, life-threatening situations where patients have ceased spontaneous breathing (cardiac arrest, respiratory distress/arrest, seizures, and the like), thereby providing conduits for airway life support.

Normally ET tubes are flimsy plastic tubes which are difficult to manipulate. Thus, a more rigid malleable stylette is often placed into a central lumen of an ET tube for allowing an operator to better control the tube as it is implanted. That is, this added stiffness allows an operator to more easily manipulate a distal end of the ET tube between vocal cords and into a patient's trachea. Typically, such stylettes are firm, malleable rods made of metal and/or plastic. Normally, the stylette, or rod, is inserted the length of an ET tube's central lumen to a point just within a distal end thereof and then the ET tube is inserted into the trachea. In this regard, if such a firm-rod stylette were to extend beyond the distal end of the ET tube during insertion, its hard tip could potentially damage the vocal cords or other fine structures of a trachea, possibly even puncturing a hole through a trachea sidewall, or even through an esophagus sidewall, if mistakenly inserted thereinto.

To insert an ET tube into a patient, while he lies recumbent on his back, his neck is extended with his head tilted back. An operator, using his left hand to hold a laryngoscope, lifts the patient's tongue anteriorly, out of the way, thereby providing a line-of-sight, into a deepest portion of the patient's throat. This line-of-sight extends into the patient's esophagus. The esophagus is a large, wide, funnel-shaped structure. At an acute angle to the esophagus are an epiglottis and the patient's vocal cords, which define an entrance into the patient's trachea. Thus, an operator cannot actually view the trachea into which he is attempting to insert the ET tube.

In any event, with a stylette in the ET tube, the operator attempts to pass the ET tube between the vocal cords and into the trachea. However, due to the acuteness of the angle, poor lighting, poor visualization, and/or technical reasons, the ET tube may slide off the vocal cords and pass inadvertently into the esophagus. Should this occur, and not be recognized quickly, an unconscious patient will suffocate and die. This is a major problem in emergency situations and has multiple malpractice ramifications as well. Thus, it is an object of this invention to provide an endotracheal tube stylette apparatus which enables an operator to quickly and easily determine if an ET tube is mistakenly in an esophagus or is properly positioned in a trachea.

However, placement into a proper lumen (trachea rather than esophagus) at an appropriate depth is just a first technical hurdle to be overcome when properly implanting an ET tube. Assuming that an ET tube is properly inserted into a trachea, it is then incumbent on an operator to properly position the ET tube along the trachea. In this regard, the trachea is a relatively short tube, only 10-12 centimeters in length, and can be variable from one patient to another. The trachea divides into two distinct lumens at a carina, which is basically a bifurcation of the trachea. One of these lumens, a left mainstem bronchus, typically takes off at a very acute, nearly 90°, angle from the trachea, whereas the other, a right mainstem bronchus, takes off at a much shallower, oblique angle to the trachea. This anatomic fact is relatively constant. For this reason, if an ET tube is pushed too far into the trachea, it will inevitably track into the right main stem bronchus. This common complication of ET tube placement is called "endobronchial intubation". Should endobronchial intubation occur and should a retaining cuff of a standard ET tube be inflated in the right mainstem bronchus, this effectively seals the ET tube to the right lung only. This situation poses several mechanisms which produce potentially life-threatening problems for a patient. Firstly, if only the right lung is intubated, a left lung will not be ventilated or oxygenated. Therefore, efficacy of the entire procedure is reduced by 50%. Furthermore, since the operator does not realize he is operating in only one lung, he generates tidal volumes large enough for both lungs, all of which are forced into only the right lung. This presents the possibility of over-expansion and pneumothorax (explosive sudden collapse of a lung) of the right lung. This can rapidly cause compression of a heart leading to death by cardiac tamponade. Secondly, even in the absence of right lung collapse, the left lung will slowly collapse as stagnant gas is absorbed. This will eventually lead to a shift of the mediastinal structures and again, could lead to death by cardiac tamponade. For these reasons, it is another object of this invention to provide an endotracheal tube stylette apparatus which facilitates an operator determining when the endotracheal tube is in a proper position in the trachea, proximal to a carina. In this regard, it is a specific object of this invention to provide an endotracheal tube stylette apparatus with which an operator can space a distal end of an endotracheal tube a set distance from a patient's carina. Apparatus are described in Augustine et al U.S. Pat. No. 4,840,172 and Baum U.S. Pat. No. 4,449,522 for positioning distal ends of ET tubes anteriorly, or distally, of patients' carinas, however, the devices of these patents appear to be somewhat difficult to use in that they appear to require two hands, one hand to maneuver a positioning device and another hand to maneuver an endotracheal tube. Therefore, it is an object of this invention to provide an endotracheal tube stylette apparatus which allows an operator to properly position a distal end of an ET tube relative to a carina with one hand, that is, while maneuvering both the stylette apparatus and the ET tube with one hand.

Yet another difficulty with some positioning devices described in the prior art is that they do not allow tactile determination of fixed spacings of distal ends of ET tubes relative to carinas, but rather rely on operators determining proper positioning using sight. Such determinations are unduly complicated and require undue amounts of hand/eye coordination during emergency situations. Thus, it is another object of this invention to