INTUBATION SYSTEM

BACKGROUND OF THE INVENTION

1. Field of The Invention

Applicant's invention relates to endoscopy and to instruments and methodologies which are useful in the performance of intubation procedures.

2. Background Information

Intubation is the process by which an endotracheal tube is inserted into the trachea of an individual who requires assistance in breathing. The need for intubation often arises from a cardiac and/or pulmonary arrest, or from trauma when the patient is unable to breath without outside intervention. Alternatively, elective intubation may be involved in preparing a patient for surgery under general anesthesia when the capacity for independent breathing will be interrupted.

Intubation is a well-established procedure for obtaining an artificial airway, but is often difficult for the medical professional, and potentially dangerous (or, at least, ineffective) for the patient. Properly negotiating the anatomy of the pharynx and larynx to ultimately place an endotracheal tube in the trachea for a proper intubation necessarily requires that the endotracheal tube pass through a patient's vocal cords, not a structure that is always visible at the time of intubation, and thus intubation is often a partially blind procedure that relies on imperfect, indirect methods for confirming proper endotracheal tube placement.

A laryngoscope is an instrument held with the left hand during intubation, and is used to divert the patient's tongue and epiglottis, thereby distorting the anatomy to expose the vocal cords. Exposing the vocal cords makes an intubation (where the endotracheal tube must pass through the vocal cords and enter the trachea) at least possible. Often, however, even with the laryngoscope in an optimal position, the vocal cords cannot be visualized due to a small mouth opening, inability to flex the neck due to trauma or other reasons, or an anterior position of the larynx, and, therefore, placement of the endotracheal tube becomes a partially blind procedure. In fact, the most critical phase of intubation is that where the endotracheal tube is seen passing through the vocal cords and into the trachea. Without seeing this, an intubation becomes more difficult and may even be impossible.

In any event, absolute certainty of the proper placement of the endotracheal tube in the trachea is an indispensable requirement of every intubation. Thus, even if the vocal cords can be visualized and the endotracheal tube is seen passing through the vocal cords and into the trachea, indirect methods for verifying proper placement of the endotracheal tube are required to assure that the endotracheal tube is in proper position within the trachea, that being 2.5 to 3.0 cm above the carina.

Methods for insuring proper endotracheal tube placement, and thereby excluding an esophageal intubation (where the endotracheal tube extends into the esophagus, rather than the trachea) are not always reliable. Even the most reliable indirect methods for verifying a tracheal intubation are undesirably time consuming, expensive, and can be associated with incidental risks (such as by radiation exposure).

The most commonly employed indicator for proper placement of an endotracheal tube involves listening to the upper abdomen and chest for breath sounds as the patient is ventilated. Such apparent indications of proper endotracheal tube placement have, however, been reported in cases which ultimately turned out to involve esophageal intubations.

Another indirect method for verifying proper placement of an endotracheal tube involves measuring carbon dioxide emissions from the endotracheal tube (to indicate that the endotracheal tube is in communication with the patient's lungs and, therefore, in a position for exhausting the carbon dioxide of respiration). The carbon dioxide detection method involves the expense of a disposable carbon dioxide sensor, and is susceptible to both "false positives" and "false negatives" under certain circumstances relating to the patient's gastric state and/or cardiac function at the time of intubation.

Another method of determining proper placement of an endotracheal tube is by xray verification. This involves radiation exposure which should be avoided when non-radiation methods are equally efficacious. Moreover, xray verification of proper endotracheal tube placement is time consuming and involves additional expense.

In light of the limitations to indirect, post-intubation indication of proper endotracheal tube placement, it is highly desirable to insure that proper tracheal intubation has occurred in the first place, and even more desirable to confirm proper placement as the intubation is proceeding. Absolute assurance of correct endotracheal tube placement is only possible when the medical professional can actually watch the tube pass through the vocal cords and into the trachea, and see its position in the trachea.

Visualization of the path through which an endotracheal tube must pass in connection with an intubation is known (See *Fiberoptic Endoscopy and the Difficult Airway*, Ovassapian, Andranik (Lippincott-Raven)). However, no existing instrument permits visualization of the intubation process itself, as it proceeds. Also, existing endoscopes are not specifically or exclusively designed for intubation and can be difficult to use by other than highly trained and experienced practitioners of intubations. According to Dr. Ovassapian, two methods for so called fiberoptic endoscopy are presently available: (1) the "tube-first" approach, and (2) the "scope-first" approach.

In the tube-first approach to fiberoptic intubation, an intubating airway (a temporary device that is placed in the patient's mouth to guide an endotracheal tube generally toward its intended target) is placed, and an endotracheal tube is then inserted into the passageway of the intubating airway. While a second person supports the endotracheal tube, which is now held in position by the intubating airway, the fiberscope is advanced (using both hands) through the endotracheal tube through the vocal cords and into the trachea. Using the fiberscope as a guide wire, one of the medical professionals then advances the endotracheal tube over the fiberscope and (hopefully) into the trachea. The long fiberscope insertion cord is then withdrawn while holding the endotracheal tube in place.

The tube-first approach to fiberoptic intubation using presently available apparatuses is not without its limitations. A common problem may occur when the fiberscope is advanced through the endotracheal tube. As the distal tip of the fiberscope nears the distal end of the endotracheal tube, the fiberscope tip may (and often does) pass through the "Murphy's eye" of the endotracheal tube. The Murphy's eye is a lumen which opens through the side of the endotracheal tube near its distal end which is provided for preventing complete blockage of the endotracheal tube, even if the distal opening somehow becomes blocked. When the fiberscope tip does pass though the Murphy's eye, withdrawing the fiberscope after placement of the endotracheal tube is often impossible, unless the endotracheal tube is also with-