Clinical Trial of a New Lightwand Device (Trachlight) to Intubate the Trachea

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Background: Transillumination of the soft tissue of the neck using a lighted stylet (lightwand) is an effective and safe intubating technique. A newly designed lightwand (Trachlight) incorporates modifications to improve the brightness of the light source as well as flexibility. The goal of this study was to determine the effectiveness and safety of this device in intubating the trachea of elective surgical patients.

Methods: Healthy surgical patients were studied. Patients with known or potential problems with intubation were excluded. During general anesthesia, the tracheas were intubated randomly using either the Trachlight or the laryngoscope. Failure to intubate was defined as lack of successful intubation after three attempts. The duration of each attempt was recorded as the time from insertion of the device into the oropharynx to the time of its removal. The total time to intubation (TTI), an overall measure of the ease of intubation, was defined as the sum of the durations of all (as many as three) intubation attempts. Complications, such as mucosal bleeding, lacerations, dental injury, and sore throat, were recorded.

Results: Nine hundred fifty patients (479 in the Trachlight group and 471 in the laryngoscope group) were studied. There was a 1% failure rate with the Trachlight, and 92% of intubations were successful on the first attempt, compared with a 3% failure rate and an 89% success rate on the first attempt with the laryngoscope (P not significant). All failures were followed by successful intubation using the alternate device.

The TTI was significantly less with the Trachlight compared with the laryngoscope (15.7 ± 10.8 vs. 19.6 ± 23.7 s). For laryngoscopic intubation, the TTI was longer for patients with limited mandibular protrusion and mentohyoid distance, with a larger circumference of the neck, and with a high classification according to Mallampatti et al. However, there was no relation between the TTI and any of the airway parameters for Trachlight. There were significantly fewer traumatic events in the Trachlight group than in the laryngoscope group (10 vs. 37). More patients complained of sore throat in the laryngoscope group than in the Trachlight group (25.3% vs. 17.1%).

Conclusions: In contrast to laryngoscopy, the ease of intubation using the Trachlight does not appear to be influenced by anatomic variations of the upper airway. Intubation occasionally failed with the Trachlight but in all cases was resolved with direct laryngoscopy. The failures of direct laryngoscopy were resolved with Trachlight. Thus the combined technique was 100% successful in intubating the tracheas of all patients. (Key words: Anesthetic techniques; laryngoscopy; tracheal intubation. Equipment: lightwand.)

TRACHEAL intubation is traditionally performed by direct vision using a laryngoscope. The success of laryngoscopic intubation depends largely on the experience of the intubator and the patient’s upper airway anatomy. Occasionally, even in the hands of experienced laryngoscopists, intubation by direct vision can be difficult or impossible. This difficulty with intubation has led to the development of alternate techniques. Transillumination of the soft tissue of the neck using a lighted stylet (lightwand) is one such technique. Several lightwands are commercially available, but these instruments have limitations, primarily related to the brightness of the light source and lightwand flexibility.

A newly designed lightwand (Trachlight, Laerdal Medical, Armonk, NY) addresses both of these deficiencies.1 The Trachlight consists of three parts: a reusable handle, a flexible wand, and a stiff retractable stylet (fig. 1). The wand consists of a durable, flexible plastic shaft with a bright light bulb affixed to the distal end. The retractable stylet is inserted into the wand to give sufficient stiffness to enhance maneuverability during intubation (fig. 2). When the stylet is partially retracted, the distal part of the wand becomes flexible, allowing

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the endotracheal tube to be advanced into the trachea. Although the brighter light source and the flexible wand of the Trachlight may enhance the effectiveness of intubation, there are no scientific data to confirm this. The goal of this study was to determine the effectiveness and safety of this device compared with conventional laryngoscopy in intubating the tracheas of elective surgical patients.

Materials and Methods

After the institutional review board had approved the study, we recruited 950 elective surgical patients. Informed consent was obtained from American Society of Anesthesiologists physical status 1 or 2 patients older than 16 yr who required orotracheal intubation. Excluded were patients who could not cooperate to allow adequate airway assessment during the preoperative visit, patients with a history of previous difficult intubation, patients with cervical spine fracture or cervical spine instability, patients with tumors, polyps, foreign bodies in the upper airway, patients with a history of gastroesophageal reflux, and patients scheduled for major cardiovascular and thoracic surgery.

During the preoperative visit, with the patient in the semisitting position, the airway was assessed, and the following measurements were made and recorded: (1) with the mouth widely open, the maximum distance between the upper and lower incisors or between the gingival margins in the edentulous; (2) the maximum distance of protrusion of the mandible relative to the maxilla; (3) the distance between the mentum and sternal notch with the neck in full flexion; (4) the distance between the mentum and sternal notch with the neck in full extension; (5) the distance between the mentum and hyoid bone; and (6) the circumference of the neck at the thyroid prominence. The pharyngeal structures were assessed with the patient's mouth widely opened as described by Mallampati et al.\textsuperscript{2} The demographics such as age, sex, weight, and height were also noted.

It is clear that experience has an influence on successful time to intubation (TTI). All the investigators in this study were experienced with the use of Trachlight and were also experienced laryngoscopists.

The patient's trachea was intubated orally using either a laryngoscope or the Trachlight determined by a coin toss. Intubations were performed with the patients' head and neck placed in a neutral position for the Trachlight and a conventional "sniffing" position for direct laryngoscopy. Endotracheal tubes with an internal diameter of 7 mm were used for female patients and 8 mm for male patients. After the induction of anesthesia and muscle relaxation, three attempts were allowed for each intubating technique by one of the investigators (all authors except R.D.S.). Oxygenation was permitted between each attempt. External manipulation of the larynx was used when necessary during laryngoscopy. Failure to intubate was defined as the inability to place the endotracheal tube into the trachea after three attempts. The alternative technique was used to intubate the trachea after a failed intubation (i.e., Trachlight in the laryngoscope group and laryngoscope in the Trachlight group). The duration of each attempt was recorded as the time from inserting the device (the Trachlight or laryngoscope) into the oropharynx to the time when the device was removed from the oral cavity.

The total TTI was defined as the sum of all intubation attempts. The use of the alternative intubating techniques were not included in the mean total TTI for either intubation, the oropharyngeal complications, such as lacerations, and dental injury. Analgesia and anesthesia, extubation, and extubation criteria, the postanesthesia care, and the intubating technique for patients for whom complaints of hoarseness before discharge were recorded. The data are reported as mean ± standard deviation.

Results

Nine hundred fifty patients in the Trachlight laryngoscope group and 950 patients in the Trachlight group are shown in Table 1. There were no significant differences in the study between the two groups. Intubation in every patient was successful. The total TTI in the Trachlight group was 14.0 ± 8.2 s, with a statistically significant difference (P < 0.05) after three attempts.

![Fig. 1. The Trachlight consists of three parts: a reusable handle, a flexible wand, and a stilet retractable stylet.](image1)

![Fig. 2. After the insertion of the wand of the Trachlight into the endotracheal tube, a 90° bend is made at the distal end of the tube to form the "field hockey stick" configuration.](image2)
The total TTI was defined as the sum of the durations of all intubation attempts (as many as three) before the use of the alternative intubating technique. Failed intubations were not included in the determination of the mean total TTI for either technique. After tracheal intubation, the oropharynx was examined for evidence of complications, such as, mucosal bleeding, lacerations, and dental injury. At the conclusion of surgery and anesthesia, extubation was carried out using routine extubation criteria. After extubation, the nurses in the postanesthesia care unit, who were unaware of the intubating technique, were instructed to ask the patients for complaints of dry throat, sore throat, and hoarseness before discharge from the unit. All complications were recorded.

The data are reported as means ± SD unless otherwise specified. All continuous data were analyzed using unpaired t tests. The nominal data were analyzed using the chi-squared contingency table. Correlation of variables were examined by linear regression for continuous data and Spearman’s rank-order correlation for ordinal data. Statistically significant difference was considered if P < 0.05.

Results

Nine hundred fifty patients were studied, with 479 patients in the Trachlight group and 471 patients in the laryngoscope group. The demographics of both groups are shown in table 1. There were no statistically significant differences in age, weight, and height between the two groups. The trachea was successfully intubated in every patient using either the laryngoscope or the Trachlight. The results and complications are summarized in table 2.

Of all the successful Trachlight intubations, 92% were successful after one attempt (mean TTI for one attempt was 14.0 ± 8.2 s) with a further 7.6% after two attempts and 0.3% after three attempts. Similarly, 89% of laryngoscopic intubations were successful with one attempt, 8.7% with two attempts, and 2.1% with three attempts (P not significant). There were 5 failures in the Trachlight group and 13 failures in the laryngoscope group with an overall success rate of 97.2% (P not significant).

The TTI was significantly less with the Trachlight compared with the laryngoscope (16 ± 11 vs. 20 ± 24 s). However, this difference became less evident when only the successful intubations after the first attempt were compared between the two groups. Close to 95% of all lightwand intubations were performed within 30 s (fig. 3) whereas approximately 85% of all laryngoscopic intubations were performed within 30 s (P not significant).

Using linear regression, the correlations between the TTI and different airway measurements are shown in figure 4 for the laryngoscope group. The TTI was inversely related to mandibular protrusion and mentohyoid distance. In addition, the TTI was directly related to the circumference of the neck. However, there was no obvious relation between the TTI and neck flexion, neck extension, mouth opening and body mass index. There was a direct relation between the TTI and Malampatti et al.’s classification (Spearman’s correlation coefficient = 0.25; P < 0.01) In contrast, there were no significant correlations between the TTI and any of the airway parameters for Trachlight (fig. 5).
Fig. 3. The percentage of patients intubated versus the intubation time between the two study groups. Approximately 95% of lightwand intubations (LW) were performed within 30 s, whereas 85% of laryngoscopic intubations (LG) were performed within 30 s (P not significant).

There was a significantly lower incidence of traumatic events in the Trachlight group compared with the laryngoscope group (10 vs. 37). Most of the trauma consisted of minor mucosal bleeding or mucosal laceration. One patient lost a tooth during laryngoscopic intubation. There was no dental injury in the Trachlight group. During postoperative assessment of throat discomfort, more patients complained of sore throat in the laryngoscope group than in the Trachlight group (25.5% vs. 17.1%). An additional 5% of the patients in both groups also complained of a dry throat. One patient in the laryngoscope group had significant sore throat and dysphagia that required admission to hospital for 24 h of observation.

Most intubations using the Trachlight (78.5%) were carried out successfully under ambient light. However, some patients who were either obese or had “thick” necks, required neck shaving or a reduction in ambient lighting from dimmed (8.7%) to dark (all lights off, 12.2%) to improve visualization of transillumination during the Trachlight intubation.

**Discussion**

Our data have shown that Trachlight is an effective and safe intubating device. Although there is a statistically significant difference in the total intubation time between Trachlight and laryngoscopic intubation, in experienced hands the small (4 s) difference is of no clinical significance. However, intubation using Trachlight is associated with fewer sore throat and traumatic events.

Although there were large variabilities, our data suggest that it will likely take longer to perform a laryngoscopic intubation in a neck, a small mouth opening, a restricted view of the pharynx or a difficult airway. Classification according to Mallampati class is not always an accurate method to reliably predict difficulty with tracheal intubation. Approximately 2.8% of laryngoscopic intubations required a second attempt. The incidence of laryngoscopic intubation in a neck, a small mouth opening, or restricted view of the pharynx is high. However, it is difficult to use a classification system to reliably predict difficult intubation. Approximately 2.8% of laryngoscopic intubations required a second attempt. The incidence of laryngoscopic intubation in a neck, a small mouth opening, or restricted view of the pharynx is high. However, it is difficult to use a classification system to reliably predict difficult intubation. Approximately 2.8% of laryngoscopic intubations required a second attempt.

**Fig. 4.** The relation between the total time to intubation (TTI) and various airway measurements for the laryngoscopic group.
COMPARATIVE LIGHTWAND AND LARYNGOSCOPIC INTUBATION

Fig 5. The relation between the total time to intubation (TTI) and various airway measurements for the lightwand group.

goscopic intubation in a large patient who has a thick neck, a small mouth opening, a small stiff jaw, or a restricted view of the pharyngeal structures (a higher classification according to Mallampati et al.2). However, it is difficult to use any of these airway parameters to reliably predict difficult laryngoscopic intubation. Approximately 2.8% of patients (13) in the laryngoscope group required an alternative technique for intubation. The incidence of unexpected “difficult laryngoscopic intubation” in this study is similar to that reported from other studies.4,5 However, the airway parameters among these 13 patients were indistinguishable from the remainder of the patients in the laryngoscope group. In other words, no airway parameter could reliably predict a patient with difficult laryngoscopic intubation in this study. Interestingly, in each of these patients the trachea was readily intubated by the Trachlight with one attempt with an average TTI of 13 s. Similarly, in the 5 patients in whom the trachea could not be intubated using the Trachlight, laryngoscopic intubation was successful with an average time of 11 s. The common features of these five patients were large tongue and long epiglottis. It is possible that these structures may obstruct the entrance of the tip of the endotracheal tube into the trachea. Several simple maneuvers are helpful in these cases. These include (1) a jaw lift; (2) use of the thumb of the nondominant hand to lift the tongue; (3) hyperextension of the head and neck; and (4) having an assistant to pull the tongue forward.

There was no correlation between the airway parameters and the time required to intubate using the Trachlight. In other words, intubation using the Trachlight was not influenced by anatomic variability in this population. This is consistent with the results of Ainsworth and Howells’s study, which demonstrated no apparent correlation between “difficult” laryngoscopic view and intubation success scores using a lighted stylet (TubeStat, Concept Corporation, Clearwater, FL).6 Intuitively, it would be expected that a longer time would be required to intubate an obese patient with a thick neck because transillumination might be reduced. However, this problem may be overcome by using a brighter light source and dimming the ambient light when necessary.

Successful intubation with earlier versions of the lighted stylet required a darkened environment for optimal transillumination. Ainsworth and Howells commented that “satisfactory conditions are met only when a darkened environment can be obtained and that transillumination in daylight may not be a reliable indicator of successful intubation.”7 This can be inconvenient at times and may even make the lightwand device unreliable in the “field environment” or in an ambulance. In addition, a darkened environment can be dangerous for patients with a high risk of reflux.
because regurgitation may not be easily detected during intubation. The enhanced brightness of Trachlight has significantly improved the transillumination of soft tissues of the neck compared with the earlier versions of lightwands. In fact, our data has shown that nearly 88% of intubations using the Trachlight can be effectively performed under ambient light with or without shading of the neck.

Intubation using the Trachlight is a light-guided technique without visualization of the laryngeal structures. There is a potential risk of trauma to the upper airway associated with its use. However, intubation using the Trachlight is a gentle technique. The tip of the tube is inserted and redirected when sensation is felt during the placement of the endotracheal tube. If sore throat is used as an indicator of airway manipulation, our data suggest that Trachlight intubation is less traumatic than laryngoscopic intubation. If sore throat is a function of the presence of an endotracheal tube, one would expect no difference between the two groups. Furthermore, the atraumatic nature of the technique is demonstrated by the lower incidence of mucosal injury compared with laryngoscopy. Because of these potential benefits, intubation using the Trachlight may be advantageous in patients with fixed dental appliances.

Although intubation using the Trachlight has been shown to be safe, there are other risks. Stone and colleagues reported disconnected laryngoscope from the lightwand (Fleximut, Concept Corporation) and migration into a major bronchus. However, with improved technology, the light bulb of this newly designed lightwand is firmly attached to the wand, significantly reducing the risk of its disconnection. Although it is extremely rare, subluxation of the cricoarytenoid cartilage has also been reported in a study using an older version of a lighted stylet (Tubesat). However, the retractable stylet may reduce the risk of traumatizing the arytenoid cartilage during Trachlight intubation. In testing the device, we have intubated the tracheas of more than 6,000 patients, and we have not encountered a single patient with symptoms and signs suggestive of cricoarytenoid subluxation.

In summary, we have demonstrated the Trachlight to be an effective and safe device when used by experienced personnel to intubate the trachea of elective surgical patients. Effective use of the Trachlight to intubate the trachea requires adequate preparation of the patient (e.g., preoxygenation) and proper training as well as regular use of the Trachlight. Although we did not demonstrate any clinically important difference in the TTI between the study groups, intubation using the Trachlight had significantly fewer complications than laryngoscopy. In contrast to laryngoscopy, the ease of intubation with the Trachlight did not appear to be influenced by anatomic abnormalities of the upper airway. Trachlight intubation may be difficult in patients with large tongue and long epiglottis, a problem readily overcome by direct laryngoscopy.

References


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