

COMPARISON OF THE EFFICACY AND SAFETY OF EACH OF LEVITAN AND SHIKANI OPTICAL STYLETS EITHER USED ALONE OR WITH DIRECT LARYNGOSCOPY FOR TRACHEAL INTUBATION

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ABSTRACT

Background: New intubating optical stylets that facilitate visualization have been developed to overcome obstacles faced with management of the difficult airway.

Objective: The aim of the study was a comparison of the efficacy and safety of each of Levitan and Shikani optical stylets either used alone or with direct laryngoscopy for tracheal intubation.

Methods: This study was carried out on two hundred ASA physical status I & II of both sex adult patients who were scheduled for elective surgery under general anesthesia with tracheal intubation. Patients were randomly classified according to the used aid for endotracheal intubation into four equal groups (each one consisted of fifty patients). In group I (L/A), Levitan optical stylet was used alone for tracheal intubation with manual chin lift and in group II (L/L), Levitan optical stylet was used with a Macintosh laryngoscope aid to retract the base of the tongue. In group III (S/A), Shikani optical stylet was used alone and in group IV (S/L), Shikani optical stylet was used with the aid of Macintosh laryngoscope. Intubation success rate, intubation time and intubation related complications were recorded in each group.

Results: Statistically, the patients of the four groups were similar in demographic data (age, sex, weight, height, mallampati grade, thyromental distance and interincisor gap). The overall intubation success rates of the four groups were statistically similar. The intubation time and the degree of difficulty in group I (L/A) were significantly lesser than in group III (S/A) and in group II (L/L) were significantly lesser than in group IV (S/L). Also the intubation time and the degree of difficulty in group II (L/L) were significantly lesser than in group I (L/A) and in group IV (S/L) were significantly lesser than in group III (S/A) (Table – 2). The incidence of the various intubation related complications are statistically similar in the four groups.

In conclusion: Levitan optical stylet with or without the aid of direct laryngoscopy is more effective than Shikani optical stylet with or without the aid of direct laryngoscopy for tracheal intubation with similar incidence of intubation related complications.

Key words: Levitan, Shikani, optical, stylet, intubation.

INTRODUCTION

The management of the difficult airway remains one of the major challenges in anesthesia. It is a leading cause of anesthetic morbidity and mortality (1). It is well known that the greater the difficulty in tracheal intubation the greater the trend to use physical force, which can result in direct trauma, dental damage and exaggerated cardiovascular response (2). These critical situations arise mainly because of poor visualization of the larynx on direct laryngoscopy (3).

In the last few years, several improvements have been made to overcome obstacles faced with management of the difficult airway (4). New intubating stylets that facilitate visualization have been developed. Similarly to the classic stylet currently used for intubation, the new stylets are inserted into the endotracheal tube and maintain a preformed shape, usually that of a hockey stick. However, there are a lens at their distal end and a fiberoptic cable inside. In comparison to the classic stylet whereas intubation may be a blind or semi blind technique, the seeing optical stylets permit continuous monitoring of the airway during intubation (5).

The Shikani Optical Stylet (Clarus Medical, Minneapolis MN, USA) is a new device that has recently been developed for difficult tracheal intubations. It combines the advantages of a light wand and a fiberoptic bronchoscope. It consists of a high resolution endoscope within a malleable stain less steel sheath, in a preformed J shape and an eyepiece attachment that does not have a focus adjustment. The eyepiece can be used as a stand-alone device, or with a video camera and monitor. The stylet can be used with several light sources such as a portable battery-operated light source handle or an AC-powered light source connected via a fiberoptic light cable. A practical feature is an "Adjustable Tube Stop" which fits the tube firmly to the stylet and allows oxygen delivery through the interior of the tracheal tube (6).

The Levitan FPS (First Pass Success) Stylet (Clarus Medical, Minneapolis MN, USA) is a short bendable seeing stylet designed to be integrated into a first pass laryngoscopy strategy. It has a shorter tube length than the Shikani Optical Stylet. The shorter length which resembles a standard stylet makes it useful in every laryngoscopy, handling and shaping of the tracheal tube, while offering a fiberoptic-guided

intubation and an immediate visual confirmation of intra-tracheal placement (7).

The aim of this study was a comparison of the efficacy and safety of each of Levitan and Shikani optical stylets either used alone or with the aid of direct laryngoscopy for tracheal intubation.

METHODS

This prospective randomized clinical trial study was conducted at Zagazig University Hospitals, during the period from April 2011 to January 2013.

This study was approved by the Local Ethics Committee of Zagazig University Hospitals. The approval was on November 2010. A written informed consent was obtained from all enrolled patients. This study was carried upon two hundred ASA physical status I – II of both sex adult patients who were scheduled for elective surgery under general anesthesia with tracheal intubation.

Patients with history of previous difficult intubation or expected to have difficult intubation were excluded from the study.

Sample size calculation: Using the G*power 3 software, a priori power analysis based on data published in previous studies (4,8,9,10) of the differences between means and standard deviations of the time needed for tracheal intubation as a primary endpoint for the efficacy of either Levitan FPS or Shikani optical stylets revealed an effect size 0.24. With an effect size 0.24, a sample size of 50 patients per group (total 200 patients) would be required for a statistical power 80% at a two tailed level of significance of $P < 0.05$.

Randomization: patients were randomly allocated into one of the four groups according to block randomization using research randomizer program.

All patients were pre-medicated by atropine, (0.01 mg/kg IM) 30 min before induction of general anesthesia. In the operating room, venous access to the median cubital vein was established with an 18-gauge cannula. Electrocardiogram electrodes, non-invasive blood pressure cuff, and pulse oximeter probe were applied for continuous monitoring of ECG, heart rate and rhythm, blood pressure and SPO2 throughout the surgery.

All patients were pre-oxygenated with 100% oxygen for five minutes then anesthesia was induced intravenously by 1 ug/kg fentanyl, 2-3 mg/kg Propofol and 0.1 mg/kg rocuronium. Patients were placed in classic sniffing position and ventilated with 3% isoflurane in 100% oxygen for 3 minutes.

The procedure was carried out by anesthesiologists with over 3 years experience, each one of them had practiced the assigned scope for at least 20 successful intubations on a training manikin and 5 successful elective intubations under supervision on a regular patients.

Before usage, each of the optical stylets should be slightly lubricated and an anti-fogging agent should be applied to the distal lens. The optical stylet was positioned inside the tracheal tube approximately 1 cm within the distal end of the overlying tracheal tube. The short length of the Levitan scope necessitates that tracheal tubes be trimmed to 28 cm for the scope tip not to protrude past the end of the tube to achieve the correct scope position.

Then, according to the study design, patients were randomly divided into four equal groups; each group consists of fifty patients. In group I (L/A), the Levitan optical stylet was used alone for tracheal intubation with manual chin lift. Whereas the operator used his left hand to distract the jaw, while his right hand manipulates the scope down to the larynx following a strict midline approach and the eyepiece is used continuously from initial insertion. In group II (L/L), the Levitan optical stylet was used with the aid of a Macintosh laryngoscope to retract the base of the tongue. The tip of the scope is positioned under direct vision until it is close to, but below and away from the tip of the epiglottis, the operator then switches his head to bring his dominant eye to the eyepiece and under fiberoptic view, directs the stylet under the epiglottis edge into the trachea. In group III (S/A), the Shikani optical stylet was used alone with manual chin lift and in group IV (S/L), the Shikani optical stylet was used with Macintosh laryngoscope as prescribed before with Levitan scope. With the use of either optical stylet in conjunction with direct laryngoscopy, the optical stylet was bend at 35° angle at the tubal cuff. An extreme bend angle of 70° was applied in order to use the scope alone without direct laryngoscopy aid. As the Levitan stylet is designed in shorter length the operator stands in his usual position at the head of the patient. The Shikani optical stylet is long, therefore depending on the height of the stretcher and the operator's height, the head of the bed can be lowered or the operator can position himself on a stool. Alternatively, the operator can face the patient's head and roll the device partially into the mouth before moving to a position more directly above the supine patient.

Once the stylet passes through the vocal cords under fiberoptic vision, the left hand slides the tube off the stylet into the proper depth by

rotating the tube clockwise off the stylet. After the tube is advanced to the correct depth, the stylet is withdrawn, the cuff inflated, and the tube secured in the usual manner and proper intubation is confirmed by conventional capnogram and auscultation.

The success rate of intubation was recorded, whereas failure was considered to have occurred if intubation was not succeeded in 2 attempts, the maximum number of allowed attempts per patient. An intubation attempt either ended with successful intubation, fall of oxygen saturation on pulse oximeter to 93% or withdrawal of the optical stylet from the mouth for any otherwise reason. Bag/mask ventilation with 100% oxygen was done for 90 seconds between attempts. Whenever the two intubation attempts failed, the third one was accomplished with traditional direct laryngoscopy. The total time to intubation was recorded by an independent observer with stopwatch. The intubation time was the sum of the time the optical stylet was inside the patient's mouth during attempts. The

stopwatch was started when the preloaded optical stylet entered the mouth and was suspended between attempts. The degree of difficulty of tracheal intubation with assigned scope was rated by conducting anesthesiologist on a visual analogue scale with zero value is the least difficulty and ten value is the highest difficulty encountered. Postoperatively, the incidence of intubation related complications as oropharyngeal trauma, sore throat and hoarseness of voice were also reported.

Statistical analysis: The collected data from patients were verified prior to computerized data entry. The Statistical Package for Social Sciences (SPSS for Windows, Version 13) was used for statistical analysis. All data are presented as mean \pm standard deviation or number (percentage). Statistical analysis was done using one-way analysis of variance (ANOVA) with adequate pos hoc tests or Chi square analysis with Bonferroni's correction whenever appropriate. All tests of significance were two-tailed with P values < 0.05 were considered statistically significant.

RESULTS

Statistically, the patients of the four groups were similar in demographic data (age, sex, weight, height, Mallampati grade, thyromental distance and interincisor gap) (Table – 1).

Table (1): Demographic data of the four groups' patients.

	Group I (L/A)	Group II (L/L)	Group III (S/A)	Group IV (S/L)
Age (Year)	43 \pm 10.5	45 \pm 8.8	44 \pm 12	44 \pm 10.3
Sex:				
Males	29(58)	28(56)	26(52)	28(56)
Females	21(42)	22(44)	24(48)	22(44)
Weight (Kg)	83 \pm 8.7	81 \pm 9.8	81 \pm 8.3	79 \pm 9.7
Height (cm)	173 \pm 7.4	172 \pm 7.2	171 \pm 5.9	171 \pm 7.7
Mallampati class:				
Class I	33(66)	30(60)	32(64)	36(72)
Class II	17(34)	20(40)	18(36)	14(28)
Thyromental distance (cm)	7.4 \pm 0.7	7.6 \pm 0.6	7.4 \pm 0.6	7.5 \pm 0.5
Interincisor gap (cm)	4.6 \pm 0.5	4.5 \pm 0.6	4.3 \pm 0.5	4.4 \pm 0.6

- Data are presented as mean \pm standard deviation or number (percentage).

- L/A (Levitan optical stylet alone), L/L (Levitan optical stylet with Macintosh laryngoscope aid), S/A (Shikani optical stylet alone), S/L (Shikani optical stylet with Macintosh laryngoscope aid).

The overall intubation success rate of Levitan optical stylet when used alone was 90% and reached 96% with the use of laryngoscope aid. While the Shikani optical stylet overall success rate was 86% when used alone and 90% with the aid of direct laryngoscopy. Statistically, the overall intubation success rates of the four groups were similar (Table – 2).

However, the intubation time in group I (L/A) was significantly shorter than in group III (S/A) and in group II (L/L) was significantly shorter than in group IV (S/L). Also the intubation time in group II (L/L) was significantly shorter than in group I (L/A) and in group IV (S/L) was significantly shorter than in group III (S/A) (Table – 2).

The degree of difficulty in group I (L/A) was significantly less than in group III (S/A) and in group II (L/L) was significantly less than in group IV (S/L). Also the degree of difficulty in group II (L/L) was significantly shorter than in group I (L/A) and in group IV (S/L) was significantly shorter than in group III (S/A) (Table – 2).

Table (2): The success rate, intubation time and degree of difficulty in the four groups.

	Group I (L/A)	Group II (L/L)	Group III (S/A)	Group IV (S/L)
Success rate:				
- After the 1 st attempt success	32(64)	34(68)	27(54)	32(64)
- after the 2 nd attempt success	13(26)	14(28)	15(30)	13(26)
- Failed	5(10)	2(4)	8(16)	5(10)
Intubation time(Second)	81±35*	44±24*	99±40*	63±30*
# Degree of difficulty	5.8±1.7*	2.9±2*	6.9±1.8*	4.6±2.3*

- Data are presented as mean ± standard deviation or number (percentage).

- L/A (Levitan optical stylet alone), L/L (Levitan optical stylet with Macintosh laryngoscope aid), S/A (Shikani optical stylet alone), S/L (Shikani optical stylet with Macintosh laryngoscope aid).

- # Visual analogue scale with (0) value is the least difficulty and (10) value is the highest difficulty.

- * Significant in comparison to each one of the other three groups, P < 0.05.

The incidence of the various intubation related complications are statistically similar in the four groups (Table – 3).

Table (3): The incidence of the various intubation related complications in the four groups.

	Group I (L/A)	Group II (L/L)	Group III (S/A)	Group IV (S/L)
Trauma	3(6)	2(4)	4(8)	3(6)
Sore throat	4(8)	3(6)	5(10)	3(6)
Hoarseness of voice	3(6)	2(4)	4(8)	2(4)

- Data are presented as number (percentage).

- L/A (Levitan optical stylet alone), L/L (Levitan optical stylet with Macintosh laryngoscope aid), S/A (Shikani optical stylet alone), S/L (Shikani optical stylet with Macintosh laryngoscope aid).

DISCUSSION

The present study showed that the success rate on using the Levitan and Shikani optical stylets either with or without the aid of a laryngoscope for elective tracheal intubation was high and similar with no significant differences. The overall success rate of Levitan optical stylet when used alone was 90% and reached 96% with the use of laryngoscope aid. While the Shikani optical stylet overall success rate was 86% when used alone and 90% with the aid of direct laryngoscopy. In accordance with our results, Turkstra et al. (8) showed 91.3% success rate of Shikani optical stylet. In addition, Mihai et al. (11) found in their meta-analysis study a total overall success percentage 94.9% of Shikani optical stylet. Also, Aziz and Metz (10) showed a

success rate 99.7% of Levitan optical stylet with modified curve to be used alone without direct laryngoscopy. Moreover, Greenland et al. (9) found a success rate of 91% with Levitan optical stylet with the aid of direct laryngoscopy. This high success rate and failure to detect significant differences between the two optical stylets could be attributed to the easiness to master the both optical stylets because of its rigid design and similarity to the ordinary familiar intubating stylet.

On the other side, the intubation time in seconds showed significant differences among the groups in this order: Levitan optical stylet with laryngoscope aid (44±24) < Shikani optical stylet with laryngoscope aid (63±30) < Levitan without laryngoscope aid (81±35) < Shikani without

laryngoscope aid (99 ± 40). This means that Levitan optical stylet with or without the aid of direct laryngoscopy is more effective than Shikani optical stylet with or without the aid of direct laryngoscopy for tracheal intubation. These results were also reflected on the anesthetists rated degree of difficulty of intubation which showed the same order of significance. In consistence with these findings, Phua et al. (12) found the time to intubation of Shikani optical stylet to be 58 ± 26 seconds. Greenland et al. (9) showed an intubation time 19.9 ± 6.2 seconds for Levitan optical stylet with direct laryngoscopy. In the study of Aziz and Metz (10) the mean intubation time was 23 ± 24 seconds with Levitan scope when used alone without direct laryngoscopy.

In contrast, Young and Vadivelu (13) in a small study suggest that the Shikani optical stylet can be used with a laryngoscope as efficiently and effectively as used alone.

Indeed, the net outcome results of such procedures depend on the level of operators' experience. However, the learning curve for many optical scopes was found to be approximately 20 to 25 uses (14, 15). Thus, the procedure in our study was conducted by anesthesiologists who had practiced the assigned optical stylet for at least 20 successful intubations on a training manikin and 5 successful intubations under supervision on elective patients.

Intentionally, The Levitan FPS is offered for use as laryngoscopy adjunct to achieve the first pass success. For most of the laryngoscopies in which the laryngeal view is easily seen the Levitan FPS stylet and overlying tube are introduced like any other stylet into the trachea. Additionally, immediate intratracheal placement can be fiberoptically verified. In difficult laryngoscopy, when fiberoptic visualization is needed for intubation, the Levitan FPS tip is positioned under direct vision until it is close to the epiglottis. The operator then moves his head to bring his dominant eye to the eyepiece, directing the stylet into the trachea under fiberoptic view (7).

For the scope to be used in conjunction with direct laryngoscopy, it has been recommended to be kept straight along the length of the tracheal tube with a 35° bend at the proximal tube cuff to resemble a hockey stick (7). The recommendation of a 35° bend angle is based on the optimal scope bend angle that allowed tip visualization and maneuverability without compromising the passage of the tracheal tube due to impaction of the scope tip on the anterior tracheal rings (16). Alternately, the optical stylet can be bend to an approximately 70° angle at the

proximal tube cuff. With this more extreme bend angle, it can be used alone without laryngoscope aid (7).

Furthermore, the incidence of complications related to tracheal intubation was low and comparable with both Levitan and Shikani optical stylets either used alone or with direct laryngoscopy aid. In comparison of the Shikani optical stylet as an alternative to the GlideScope videolaryngoscope in simulated difficult intubations, it was noted a higher incidence of airway mucosal injury in patients intubated with the GlideScope videolaryngoscope compared with the Shikani optical stylet (5 versus 0 respectively) (12). Aziz and Metz also found that the modified Levitan optical stylet can be used without direct laryngoscopy as an effective, rapid and relatively atraumatic tool for intubation, even in difficult airway, whereas only three patients (1%) of their 301 studied patients suffered minor trauma (10).

The limitation of this study was the difficulty of using double blind technique.

In conclusion, Levitan optical stylet with or without the aid of direct laryngoscopy is more effective than Shikani optical stylet with or without the aid of direct laryngoscopy for tracheal intubation with similar incidence of intubation related complications.

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