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Title of the article:
Endotracheal intubation in patients undergoing open abdominal surgery in the lateral position: a comparison between intubating video stylet and fiberoptic intubating bronchoscopy

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Running title: Endotracheal intubation in lateral position by intubating video stylet

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Dear chairman of the editorial board

Regarding the study entitled:

*Endotracheal intubation in patients undergoing open abdominal surgery in the lateral position: a comparison between intubating video stylet and fiberoptic intubating bronchoscopy*

This is to confirm that all authors have contributed intellectually in this manuscript, and the manuscript has been read, revised and approved by all authors. Moreover, the manuscript has not been published previously in total or in part, is not accepted for publication or under consideration by another journal.

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Highlights
• Airway management in unusual positions is considered one of the biggest challenges faced by the anesthesiologist intra-operatively.

• The intubating video stylet is considered one of the promising devices used in cases of uncommon positions including the lateral position.

• The use of intubating video stylet has shown a noticeably rapid intubation, unfortunately, it was accompanied by a higher incidence of sore throat compared to other means.
Endotracheal intubation in patients undergoing open abdominal surgery in the lateral position: a comparison between intubating video stylet and fiberoptic intubating bronchoscopy

Running title: Tracheal intubation in lateral position
Abstract

Background: We compared elective endotracheal intubation in lateral decubitus position using a video stylet device with fiberoptic bronchoscope device in patients undergoing laparotomy abdominal surgery.

Methods: Overall, 50 patients were enrolled in this prospective, randomised study. They were randomly classified into either video stylet (VS) intubation group or fiberoptic (FO) intubating bronchoscope group. After anaesthesia induction, patients were placed in lateral decubitus position, and a single investigator well versed in the use of the VS and FO bronchoscope performed the intubation. The primary outcome was the time taken for intubation. Secondary outcomes included intubation success rate, hemodynamic response at specific time points, overall user satisfaction and perioperative complications.

Results: The average time taken for intubation was significantly lower in the VS group than that in the FO group, with values of 39.5 ± 10 and 75.6 ± 16.2 s, respectively (P < 0.001). Incidence of successful first attempt intubation in the VS group was 88% vs. 100% in the FO group, which was statistically not different. There was a negligible difference in complications between the groups except sore throat, which showed a higher incidence in the VS group than that in the FO group (P = 0.013).

Conclusions In laterally positioned patients, elective endotracheal intubation with VS provides less intubation time and incidence of success rate for a single intubation trial [88%]; however, its use is accompanied by a significant increase in hemodynamic response after intubation and an increased incidence of sore throat.

Keywords: Abdominal surgery; Airway; Endotracheal intubation; Fiberoptic intubating bronchoscope; Intubating video stylet; Lateral position
Introduction

One of the most difficult tasks that confront an anesthetist is airway management, which is also one of the main causes of morbidity related to anesthesia [1]. Accordingly, it is crucial for any anesthetist to acquire the skills to handle the challenges encountered in the operating theater [2]. One of them is intubation in uncommon positions, such as the lateral position, when it is problematic to put the patient in a supine position such as in cases of accidental loss of the endotracheal tube midoperation, trauma patients, inefficient regional anesthesia, and neoplasms of the back, occiput, or sacral region [3, 4]. Recently, placing the endotracheal tube in a lateral position has been a huge concern for many researchers; moreover, several studies have been performed to determine the best means of lateral position intubation by using direct laryngoscopy, laryngeal mask airway, intubating laryngeal mask airway with and without the aid of a lightwand, and intubation with the lightwand [5, 6]. Unfortunately, these techniques are not free from drawbacks, as they are not only time-consuming, but they also put the anesthetist in an ergonomically challenging pose [7]. So, as a result, it was considered important to discover more ways that are both safe and successful. The Fiberoptic bronchoscope was believed to achieve the sought goals [8, 9]. However, it is a costly apparatus that requires thorough training. Thus, current studies are investigating the pros of using the video rigid intubation stylet. It is a novel device with several advantages, including easy mobility with a clear display screen for vocal cord visualization, easy to clean, lightweight, chargeable, reusable, durable, and less expensive. It has a red light source that is located at the far end of the stylet. Therefore, it is considered a more affordable choice than the fiberoptic [FO] bronchoscope in developing countries [10].

The aim of the present study was to compare the video stylet [VS] with the fiberoptic [FO] bronchoscope in laterally positioned patients undergoing laparotomy abdominal surgery.
Materials and Methods

This study was performed as a prospective randomised study at Theodor Bilharz Research Institute Hospitals and Cairo university hospital, after receiving permission from the Institutional Research Ethics Committee of Faculty of Medicine Cairo University [MD-53-2019] and Theodor Bilharz Research Institute Hospitals [No: 194471] with registered at ClinicalTrials.gov [NCT 04183959]. Written consent was obtained from each patient before being enrolled in this study, which was designed to recruit 50 patients between 18 and 60 year of age having the American Society of Anaesthesiologists [ASA] physical status of I or II, of either sex, with Mallampati Class I or II, scheduled for endotracheal intubation in lateral decubitus position under general anesthesia for open abdominal surgery.

Patients were excluded if they had pre-existing clinically significant cardiovascular or hypertensive problems, were aged under 18 or over 60 year, were ASA > II, had difficult intubation, were Mallampati > II, had limited neck mobility due to cervical spine pathology, had dental abnormalities, were obese [Body mass index [BMI] ≥ 40], or were at high risk of pulmonary aspiration. Before the start of the study, the enrolled patients were randomly allocated into two equal groups, using a computer-generated table of random numbers with an opaque and sealed envelope prepared by a research assistant not otherwise participating in the study, according to the device used in intubation, into a video stylet [VS] intubation group and a fiberoptic [FO] bronchoscope intubating group.

One day before surgery, the patients visited the anesthesia outpatient clinic for a history and assessment including electrocardiogram [ECG], complete blood count, and coagulation profile. The study protocol was explained to them and they were informed that they could drop out any time they desire. All patients fasted for 6 hours before the procedure. After demographic data was recorded, intravenous access was established with a 20-g IV [Intravenous] cannula over the forearm.
on arrival at the operating theater. At this time, the standard monitoring devices were attached, including an electrocardiograph, and noninvasive blood pressure and pulse oximeter.

All patients were premedicated IV with ondansetron 4 mg and pantoprazole 40 mg. The anaesthetic protocol was standardized in all the study groups. After pre-oxygenation for 5 min, induction of anesthesia was commenced by using propofol [1–2 mg.kg\(^{-1}\)] with IV fentanyl [1–2 mcg.kg\(^{-1}\)] until loss of verbal communication occurred. Thereafter, muscle relaxation was maintained by an initial loading dose of cisatracurium [0.15 mg.kg\(^{-1}\)] IV. After adequate oxygenation and muscle relaxation, patients were placed in a lateral position. Upon placing the patient in the lateral position an inflatable beanbag was used to achieve the anterior and posterior support needed. The dependant lower limb of the patient was flexed and a pillow was placed between both lower limbs to cushion the knees' bony protrusions. Moreover, the upper limbs were also protected using pillows to support the non-dependant upper limb, while the dependent one was rested on an arm board, while an axillary roll was used to prevent axillary vessels and brachial plexus injuries, by being positioned between the operating table and the patient's chest wall. As for the head and neck, they were kept in a neutral position by being supported using a firm 6-cm-high pillow formed of 2 separate parts, one made of foam on top of which another part made of a synthetic gel substance in the shape of a horse-shoe was placed to help fixate the head in a proper and correct way, with attention given to the dependant eye and ear to avoid pressure and ischemia. [5] Then they were randomly allocated to the two groups of 25 patients each.

**VS group:** The trachea was intubated using a laryngoscopic-assisted VS –[Red-Light Directive Video Rigid Intubation stylet [BD-SL-A, Besdata, Shenzhen, China]] by the consultant anaesthesiologist expert in the use of the VS wherein an endotracheal tube was placed over the device followed by introducing it into the mouth, and, on visualising the first one or two tracheal rings, the tube was slid into the airway.
**FO group:** Intubation was done using an FO [RBS, Series Portable Fiber Intubation Scope, Pentax F1-16BS 5.2 mm, Pentax, Montvale, NJ, USA] by the anaesthesiologist expert in the use of the FO. For the FO bronchoscope, the scope was inserted carrying the endotracheal tube until the carina was visualised, then the tracheal tube was slid into the airway. In both groups, a trained assistant was present to help perform the maneuvers such as lingual traction and anterior mandibular advancement to clear the airway; as each maneuver alone was proved beneficial, however they were more effective when performed together. The intubation process was thought to be a failure when not completed within either two trials or the patient’s saturation [SpO2] reached <90%. In case of intubation failure, the patient was then turned to the supine position and intubated using the conventional technique. After confirmation of a successful intubation by capnography and chest auscultation, the patient was connected to mechanical ventilation using isoflurane 2% to maintain anesthesia whilst the end tidal CO₂ was kept between 35 and 40 mmHg, muscle relaxation was maintained by 0.03 mg.kg⁻¹ IV of cisatracurium every 20 min, and surgery was continued in the required position [either supine or lateral], according to the type of operation. Upon completion of the procedure, the inspired anaesthetic was then stopped and neostigmine 0.05 mg.kg⁻¹ combined with atropine 0.02 mg.kg⁻¹ were used to reverse the effect of the muscle relaxant. Then extubation was performed after fulfilling the criteria for that procedure. Finally, the patient was taken to the post-anesthesia-care unit and duration of surgery was recorded.

The primary outcome of the current study was the time needed to intubate [defined as the time from the instrument’s introduction into the subject’s mouth until its removal following confirmation of the endotracheal tube [ETT] correct placement by witnessing the optimal waveform on the capnography]. The secondary outcome was the success of intubation. The anaesthesiologist who performed the intubation was asked to provide scores for ease of use [using a 4-point scale: 1 = difficult, 2 = moderate, 3 = fairly easy, and 4 = very easy], vital signs assessment based on systolic
arterial blood pressure [SBP], mean arterial blood pressure [MAP], diastolic arterial blood pressure [DBP], heart rate [HR], and oxygen saturation [SpO2]. The latter was measured at certain intervals [at baseline before anesthesia induction [BA], immediately after induction [AA], after induction of anesthesia but before intubation [T1], finally after a successful ETT placement [T2], and the occurrence of side effects including mucosal injuries [i.e., blood detected on the device], lip or dental trauma, postoperative nausea or vomiting, and desaturation [SpO2 < 92%]].

**Statistical analysis**

Sample size calculation was performed by comparing the intubation time between using the VS vs the FO maneuver in lateral position of open abdominal surgery cases. As previously reported [10], the mean ± SD of time of intubation in the VS group was roughly 19.7 ± 2.8 sec, whilst in the FO maneuver group it was approximately 38.2 ± 6.9 sec [SD was calculated from the given 95% CI]. Thus, the minimum proper sample size was calculated to be 22 participants in each group to enable detecting the real difference of 6 sec [15% of the control group] with 80% power at the α = 0.05 level when using Student’s *t*-test for independent samples. Sample-size calculation was performed using Stats Direct statistical software version 2.7.2 for MS Windows [Stats Direct Ltd, Cheshire, UK]. The number was increased to 50 patients [25 per group] to compensate for possible dropouts. All normally distributed continuous data is expressed as means [SDs]. Non-normally distributed continuous and ordinal data are presented as median [range]. Categorical data are expressed as number of patients and incidence. An unpaired *t*-test was used to compare continuous data in the two groups. Repeated measure ANOVA with post hoc Dunnett’s test was used to compare changes in continuous variables in relation to the baseline preoperative values, e.g., HR, SBP, MAP, and DBP within each study group. The chi square or Fisher exact test was used to compare categorical data. For all statistical comparisons, a *P*-value of <0.05 is considered significant. All data analyses and
graphical demonstrations are dose-dependent using the Statistical Package for Social Sciences SPSSv25.0 software for Windows.
Results

Fifty-three patients were assessed for eligibility. Three were excluded because of falling under the exclusion criteria, thus 50 patients were included in the study [Figure 1].

There were no statistically noticeable differences in patient characteristics or airway parameters among either group [patient age, BMI, and Mallampati score]. The number of successful VS intubation at the first attempt were 22 [88%], and using the FO bronchoscope were 25 patients [100%], with no differences between groups, but the average time needed for intubation was remarkably lower \( P < 0.001 \) in the VS group compared with the FO group, with values 39.05 ± 9.1 Second and 75.6 ± 16.2 Second, respectively. Three patients needed a second trial to accomplish a successful intubation when using the VS compared with none when using the FO bronchoscope; however, the difference was insignificant. At the end of intubation, we asked the anaesthesiologists about their satisfaction with the ease of using this technique of intubation. The result showed the anaesthesiologists’ becoming satisfied when using the VS for intubation compared with the FO bronchoscope [Table 1].

Hemodynamically, both groups were comparable regarding changes in SBP, MAP, DBP, HR, and SpO2, showing no statistically significant difference between groups in BA, AA, or T1. However, immediately after successful intubation, T2 showed significant increases in SBP, MBP, DBP, and HR in the VS group compared with the FO group. Also, the mean SpO2 showed a significant reduction in the FO group compared with the VS group [Figure 2,3].

Complications detected in the VS group included nine cases [36%] of sore throat, five cases [20%] of mucosal trauma, two cases [8%] of sore throat associated with nausea, one case [4%] of vomiting, and no case of desaturation. Whereas those detected in the FO group included one case [4%] of sore throat and another [4%] of mucosal trauma, no cases of nausea or vomiting were reported; however, one case [4%] of desaturation was announced. There was insignificant difference between groups
about complications except for the incidence of sore throat, which was noticeably higher in the VS group than in the FO group \( P = 0.013 \) [Table 2].
Discussion

Intubation is considered a fundamental step in the management of airway, especially when it is done in an unconventional position like the lateral position, or those with a restricted mouth opening or a restricted range of neck movement, as any deficiency in the airway management in these cases can lead to fatal outcomes. Recently, many researchers have developed means for airway management in unusual positions including FO bronchoscope, and rigid VS. The rigid VS proved to have many advantages in these extreme cases as preventing blind traumatic intubation and easy manoeuvre. Moreover, it is easy to master and is adaptable to shape for better adjustment in distorted anatomy. Unfortunately, some limitations have been found, including the inability to be used for nasal intubation, besides not having a suction channel or oxygen delivery port. Finally, it affords only a limited view, as it can be seen only as far as the proximal trachea [11, 12].

The current study concluded that the outcome of using the VS to intubate patients in a lateral position undergoing laparotomy abdominal surgery appeared to be faster, showing more than a 36-sec difference between the two devices, which can be explained by the more time needed to slide the endotracheal tube along the longer FO bronchoscope stylet. Furthermore, the need for more advancement of the FO bronchoscope up to the carina and the need of an assistant to uplift the patient’s chin whilst using the FO bronchoscope can all be considered reasons for such delay. Using the VS was also shown to yield a more favorable intubation condition compared with using the FO laryngoscope. However, despite having almost similar success rates, as successful intubation at the first attempt using the VS was shown to be 88% compared with the 100% found in the FO laryngoscope, the VS experienced higher failure rates, which can be attributed to several factors, including the difficulty in shaping its stylet after mouth insertion, poor image quality, and lack of a suctioning port [13,14].
Concerning the incidence of complications, despite the higher rates of hypoxia shown in the FO bronchoscope group mainly due to the longer time needed for intubation a higher increase in hemodynamic parameters, including blood pressure and HR, was measured in the latter group. This could be explained by a sympathetic stimulation as a result of jaw thrust performed during intubation using the VS; also, the more manipulations needed to centralize the vocal cords can lead to a catecholamine surge [15]. However, there was insignificant difference in the occurrence of complications between the groups except sore throat. This appeared to be higher when using the VS compared with the FO bronchoscope, which can be explained by the rigidity of its stylet.

Lee et al. conducted a study on 80 patients undergoing nasotracheal intubation to compare the use of the flexible FO bronchoscope with the VS in regards to the time needed for intubation and the complication incidence. The study showed a 36.4-sec delay when using FO bronchoscopy compared with the VS. However, there was a statistically insignificant difference when comparing both groups for complications [11].

Another study was performed on 60 patients undergoing elective procedures in a supine position with normal airway, to compare the time needed for intubation between the VS and the FO bronchoscope, showing an 18.5-sec difference between the groups with a greater delay when using the FO bronchoscope. Moreover, no statistically significant differences were found in hemodynamic response and complications [10]. A study conducted by Ong et al. was done to compare the VS and the Macintosh laryngoscope under four different conditions, which were normal airway, immobilisation of the cervical spine, tongue swelling with cervical spine fixation, and tongue edema. It was concluded that the use of the VS device appeared to have a superior outcome concerning time of intubation and learning time than did FO bronchoscopy [16]. Another study was done comparing intubation time with the incidence of complications when using the VS and FO bronchoscopy for patients undergoing thoracic surgery using a left-sided double lumen tube.
The result was a shorter time needed for intubation using the VS as well as a lower rate of hoarseness and sore throat [17]. A similar study was conducted on 200 patients using the VS OptiScope™, showed higher rates of success for a single intubation trial and fewer postoperative complications [18].

On the other hand, some authors claim that intubation time using the VS was not short compared with using a Macintosh manual blade [19]. Others claim that using the Optiscope™, which is a VS device, did not show any hemodynamic response modifications; however, it provided better vocal cord visualization than did the conventional laryngoscope for intubation [20].

Some limitations were found in our study. First, all participants had average BMIs and normal airways; therefore, our results may not be applicable for difficult intubation cases. Second, the VS does not have suction or oxygen supplementation outlets; these might be considered a drawback when secretions or blood accumulates in the nasopharynx or oropharynx. Finally, in the current study, the instruments were used by an expert anaesthesiologist, so the outcome of use by inexperienced personnel remains unknown.

**Conclusions**

In laterally positioned patients, elective endotracheal intubation with VS provides less intubation time and incidence of success rate for a single intubation trial [88%]; however, its use is accompanied by a significant increase in hemodynamic response after intubation and an increased incidence of sore throat. Nevertheless, more studies using a larger sample size are needed to decide its use in cases having a difficult airway, as well as the incidence of complications.
References


<table>
<thead>
<tr>
<th></th>
<th>VS Group</th>
<th>FO Group</th>
<th>P- Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age [year]</td>
<td>37.1 ± 10.5</td>
<td>34.6 ± 8.2</td>
<td>0.365</td>
</tr>
<tr>
<td>BMI [Kg.m(^2)-1]</td>
<td>25.7 ± 3.9</td>
<td>26.1 ± 4.8</td>
<td>0.773</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>9 [36%]</td>
<td>13 [52%]</td>
<td>0.393</td>
</tr>
<tr>
<td>F</td>
<td>16 [64%]</td>
<td>12 [48%]</td>
<td></td>
</tr>
<tr>
<td>Mallampatti Grades I</td>
<td>11 [44%]</td>
<td>13 [52%]</td>
<td>0.778</td>
</tr>
<tr>
<td>Mallampatti Grades II</td>
<td>14 [56%]</td>
<td>12 [48%]</td>
<td></td>
</tr>
<tr>
<td>Intubation time [Second]</td>
<td>39.5 ± 10 (^{*})</td>
<td>75.6 ± 16.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>No. of Intubation success</td>
<td>22 [88%]</td>
<td>25 [100%]</td>
<td>0.235</td>
</tr>
<tr>
<td>Anaesthesiologist satisfaction</td>
<td>4[1–4] (^{*})</td>
<td>3[1–4]</td>
<td>0.040</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SD, median [IQR] and No. [%]

VS Group: Video stylet intubation group

FO Group: Fiberoptic bronchoscope group

\(^{*}\) [P < 0.05]

Anaesthesiologist satisfaction scale; 1 = difficult, 2 = moderate, 3 = fairly easy, and 4 = very easy
Table 2. Comparison of complications in the two studied groups

<table>
<thead>
<tr>
<th></th>
<th>VS Group</th>
<th>FO Group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nausea</strong></td>
<td>2 [8%]</td>
<td>2 [8%]</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Sore throat</strong></td>
<td>11 [44%]*</td>
<td>1 [4%]</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>Vomiting</strong></td>
<td>1 [4%]</td>
<td>0 [0%]</td>
<td>1.00</td>
</tr>
<tr>
<td><strong>Mucosal trauma</strong></td>
<td>5 [20%]</td>
<td>1 [4%]</td>
<td>0.189</td>
</tr>
<tr>
<td><strong>Desaturation</strong></td>
<td>0 [0%]</td>
<td>1 [4%]</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Data represented as No. [%]

VS Group: Video stylet intubation group
FO Group: Fiberoptic bronchoscope group

Desaturation: decrease of SpO$_2$ < 92% after successful intubation.

* [*P* < 0.05]
Figure caption

Figure 1. Consort flow diagram
Figure 2. Comparison of the systolic, mean, diastolic blood pressures and mean heart rate of the two studied groups

Data represented as mean ± SD

VS: Video stylet intubation group

FO: Fiberoptic bronchoscope group

BA: [before anesthesia] before induction of anesthesia at baseline

AA: [after anesthesia] immediately after induction of anesthesia

T1: after induction of anesthesia but before tracheal intubation

T2: immediately after successful intubation [T2]

SBP: Systolic blood pressure
MBP: Mean blood pressure

DBP: Diastolic blood pressure

Bpm: beats per minute

* \[P < 0.05\]
Figure 3. Comparison of the mean oxygen saturation [SpO2] of the two studied groups

Data represented as mean ± SD

VS: Video stylet intubation group

FO: Fiberoptic bronchoscope group

BA: [before anesthesia] before induction of anesthesia at baseline

AA: [after anesthesia] immediately after induction of anesthesia

T1: after induction of anesthesia but before tracheal intubation

T2: immediately after successful intubation [T2]

* [P < 0.05]