Original Article

The VL3 videolaryngoscope for tracheal intubation in adults: A prospective pilot study

ABSTRACT

Background: Videolaryngoscopy (VLS) is recommended by international guidelines for the management of difficult airways. We conducted an observational prospective pilot study to assess the efficacy of the new VL3 videolaryngoscope for routine tracheal intubation (TI) in adults; in terms of success rate, the number of attempts, and maneuver duration, including both normal and difficult airways.

Methods: This prospective observational pilot study comprised a sample of 56 adult patients undergoing elective general anesthesia. For each patient, we performed VLS by VL3 recording the following data: successful TI rate, number of attempts, time of intubation, time to glottis visualization, Cormack-Lehane grade (CL), need for external laryngeal pressure, and presence of post-laryngoscopy side effects.

Results: TI was successfully carried out in the totality of patients. In only 4 out of 56 cases, the VL3 offered a CL II. The first attempt intubation was achieved in 48 patients (85.7%). In one case, external laryngeal pressure was needed. No CL III or CL IV were observed. We did not find any significant difference between the predicted difficult airways sample and the rest of the population.

Conclusion: VL3 videolaryngoscope showed to be an effective and safe device for routine TI, even in those patients with predicted difficult airway. More studies are needed to confirm our findings and verify its efficacy even in other settings.

Key words: Airway management; difficult airways; endotracheal intubation; videolaryngoscopy

Introduction

The incidence of difficult tracheal intubations (TIs) in the operating room constitutes about 1.2% to 3.8% of routine clinical practice, while in emergency conditions the percentage rises to 5.3%.[1]

It is estimated that up to 600 patients have died due to complications arising from TI.[2]

Direct laryngoscopy (DL) does not always allow optimal viewing of the glottis, especially in those patients with anatomical characteristics which can make tracheal intubation difficult.[3]

Videolaryngoscopy (VLS) is an airway management technique that facilitates the TI maneuver by visualizing the patient's larynx via a fiber-optic camera incorporated

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into the laryngoscope blade and displaying it on a monitor. The main advantage is the visualization of the target, as the operator's "eye" is now located at the tip of the blade 2 or 3 cm proximal to the aditus ad laringem. The alignment of the oral-pharyngeal-laryngeal axis, crucial to DL, is thus rendered nonessential in VLS. The number of attempts, and consequently the trauma to the airway, is also reduced.[4]

Several studies widely demonstrated the superiority of VLS compared to DL for glottic visualization, especially in cases of difficult TI,[5-7] so that its use is recommended by current international guidelines for the management of difficult airway, including the American society of anesthesiologists (ASA) 2013,[8] difficult airway society (DAS) 2015,[9] and DAS 2017.[10]

The VL3® videolaryngoscope (HugeMed®, Shenzhen) is a new portable device designed to perform indirect laryngoscopy in both routine and difficult airway intubations, in elective or in emergency settings.

It weighs 350 g and has a 3.5" display with a 2-megapixel sensor and an antifog lens; the blade has an angle of 66°, available in neonatal, pediatric, and adult sizes, in both reusable and disposable version [Figure 1]

We conducted an observational prospective pilot study to assess the efficacy of VL3 for routine TI in adults, in terms of success rate, the number of attempts and maneuver duration, including both normal and difficult airways.

Methods

The present study was approved by the Ethics Committee of University Hospital "Campus Biomedico of Rome" on 20 November 2018 (protocol number 82/18 OSS ComET CBM) and the study was conducted between December 2018 and April 2019, with total recruitment of 56 consecutive patients who met the eligibility criteria. The study protocol was registered on clinicaltrials.gov (NCT04252222).

Patients are eligible for general anesthesia in elective surgery, aged over 18 years with ASA physical status I-III was included. Pediatric population, ASA physical status IV patients, and emergency TI were excluded from the study. All the patients signed informed consent as part of the enrolment. We used the VL3 version with a reusable blade, which was sterilized after each use, as recommended by the manufacturer.

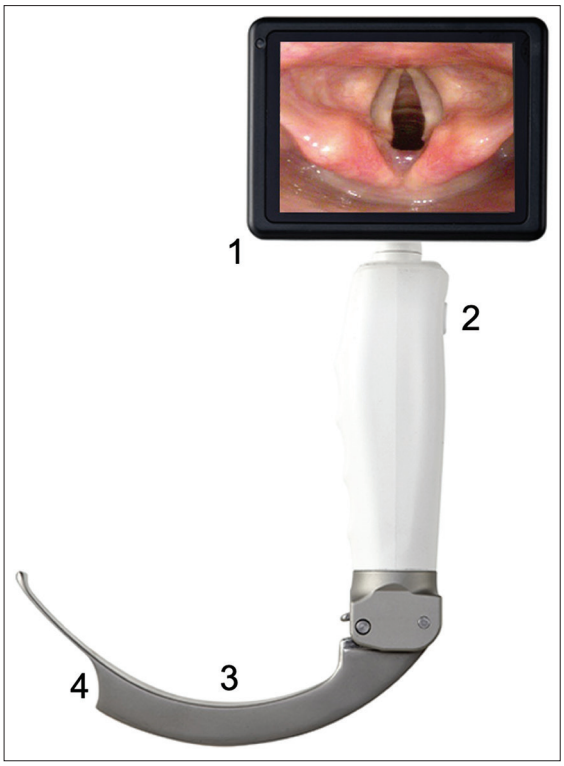

Figure 1: The VL3 videolaryngoscope. 1) 3.5" high-resolution display; 2) handle with recording button for pictures and videos; 3) Reusable blade with a 66° field angle; 4) 2-megapixel camera with an antifog lens

For each patient, preliminary data including difficult airway predictors were recorded:

- Age
- Body mass index (BMI) (kg/m^2)
- Interincisive distance (cm)
- Neck extension (°)
- Thyromental distance (cm)
- Mallampati score (I-IV)
- El Ganzouri Total Risk Index (EGRI).

Once in the operating room, and after induction of general anesthesia with propofol 3 mg/kg, fentanyl 200 mcg, and rocuronium 0.6 mg/kg, we performed TI with VL3, aided by the use of a 60° angulated flexible stylet.

Our study aimed to evaluate the VL3 efficacy in the adult population, including also patients with predicted difficult airways, to make it advisable as videolaryngoscope in every day clinical settings.

The following data were collected as primary outcomes:

- Successful TI rate
- Number of attempts
- Total time of intubation
- Time to glottis visualization

- Cormack-Lehane (CL) grade.

As secondary outcomes, we compared the above data among two subgroups: patients with predicted difficult airway and patients without prediction. Moreover, we reported, if present, the need for external laryngeal pressure during laryngoscopy and the presence of post-laryngoscopy side effects (bleeding, postoperative sore throat, and/or dysphonia).

Laryngoscopy performed with VL3 videolaryngoscope was carried out exclusively by experienced operators who had previous skills with VLS and completed the 1-month training on the simulation manikin SimMan ® (Laerdal Medical).

Statistical analysis

Continuous data were presented as mean ± standard deviation while categorical data were presented as absolute values (numbers and percentages).

A student's *t*-test has been used to compare continuous parametric data while Fisher's exact test has been used to compare categorical non-parametrical data among different groups. All analyses were performed using IBM SPSS (version 23.0). A *P* value of less than 0.05 was considered statistically significant.

Results

In our study, a total of 56 patients underwent TI with the VL3 videolaryngoscope. The patient's characteristics are described in Table 1.

About 10 patients had predictive indexes suggesting difficult intubation, including a total EGRI score greater than or equal to 4.

TI was successfully carried out in the totality of patients. The main outcomes are resumed in Table 2.

In only 4 out of 56 cases, the VL3 offered an incomplete visualization of the golttis (CL II) [Figure 2].

The 1st attempt intubation was achieved in 48 patients (85.7%). In 1 case, we needed to perform 3 intubation attempts with VL3 to successfully carry out the maneuvre. In 1 case, external laryngeal pressure was needed.

In all remaining patients, the VL3 showed a CL I. No CL III or CL IV were observed.

Furthermore, we performed a subsequent analysis comparing patients with predicted difficult airway (EGRI ≥4) vs. patients with no indexes of predicted difficult airway (EGRI <4). We did not find any significant difference regarding the total time of intubation, number of attempts, time to glottis-visualization, and CL grade [Table 3].

We did not observe adverse events during VLS. We recorded 1 episode of minor post-extubation bleeding and it was

Table 1: Patients characteristics

Sex (M/F)	27/29
Age (yrs)	49±17.9
BMI (kg/m^2)	28.6±6.2
Thyromental distance <6.5 cm	10 (17,9%)
Mallampati III-IV	6 (10.7%)
EGRI ≥4	10 (17.9%)

Table 2: Main outcomes

Successful TI	56 (100%)
Total time to intubate (sec)	46.6±21.2
Time to glottis visualization (sec)	16.2±5.6
1st attempt intubation	48 (85.7%)
CL I	52 (92.9%)
CL II	4 (7.1%)
CL III-IV	None

Table 3: Secondary outcomes

	EGRI <4	EGRI ≥4	*P*
Total time to intubate (sec)	46.3±21.5	47.6±20.6	0.86
1st attempt intubation	40 (87%)	8 (80%)	0.82
Time to glottis visualization (sec)	16.4±5.3	15.2±7	0.61
CL I	38 (83%)	8 (80%)	0.64
CL II	8 (17%)	2 (20%)	0.64
CL III-IV	-	-	-

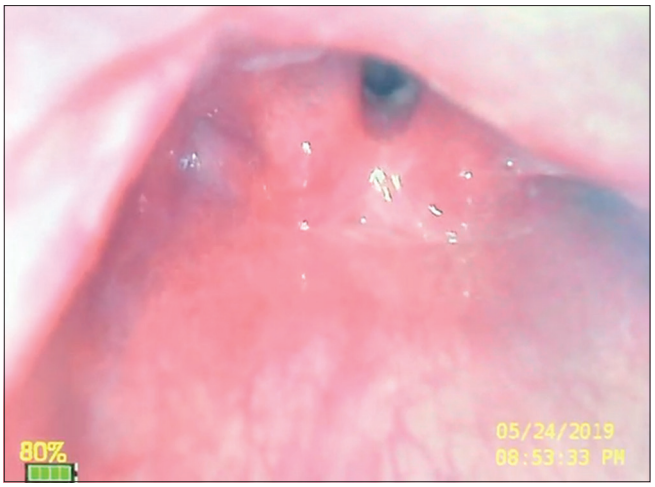

Figure 2: Patient with a Cormack-Lehane 2 grade visualized by VL3 videolaryngoscope

self-limiting. Postoperatively, we observed mild sore throat in 7 out of 56 patients.

Discussion

The international guidelines[6-8] recommend VLS as the main alternative in the event of unpredicted airway difficulties as it offers a higher rate of success.

In literature, VLS has widely been shown to be superior for difficult TIs compared to DL[11-15] but in most studies, DL times are shorter than those performed by VLS.[16-18] For this reason, and due also to the lack of adequate training, there are no current recommendations that advise the use of VLS in routinely TIs.[19]

In the panorama of VLS, the most commonly used device by far is the GlideScope.[15,16,20] A brief review of the data in the literature confirms the power of this tool: in 92% of cases, GlideScope shows a CL grade I with successful TI in 96.3% of cases, thus making it a recommended device for difficult airway management.[15,16,18] Moreover, 99% of rescue cases are successfully intubated via GlideScope after DL, with very high first-pass success rates compared to DL (93.6% versus 80.8%).[19,20]

The main studies analyzed[21-25] show the following TI times:

- Sun (2005): 46 s
- Jones (2008): 43.5 s
- Nouruzi-Sedeh (2009): 63 s
- Shimada (2010): 57 s
- Yeatts (2009): 69 s.

This results in terms of the first-pass success rate and average intubation times do not differ consistently by our findings on VL3. Moreover, in our study VL3 showed to be equally effective even in patients with a predicted difficult airway, with no significant differences in performing results.

Thus, by our preliminary data, VL3 proved to be a valid option for TI, both in routine cases and in those predicted to be difficult, proposing itself to be a recommendable device in the landscape of VLS. Such a kind of results suggests that videolaryngoscopes like VL3, in the presence of adequate staff training, should be used not only for unanticipated difficult airway but also for predicted difficulties. Moreover, performing VLS in routine daily practice could reduce the incidence of unpredicted difficulties avoiding the circumstance to intubate after one or more attempts by DL. However, there are still no official recommendations regarding the use of VLS in daily practice, maybe it's time for an update.

This study has some limitations. It is a pilot study, the first study performed on this new device. This pilot study aimed as a primary goal to verify the effectiveness of the device in terms of successful intubation. A huge limit of this study is the lack of a control group. However, comparing this new device to DL could have been redundant because the literature has widely demonstrated the superiority of video-devices, so we opted to analyze our results in terms of efficacy for successful TI, even in difficult predicted cases.

Conclusion

VL3 videolaryngoscope showed to be an effective and safe device for routine TI, even in those patients with predicted difficult airway.

More studies are needed to confirm our findings and verify its efficacy even in other settings such as emergency and pediatrics, comparing VL3 with the most studied devices.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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