ORIGINAL ARTICLE **DOI: https://doi.org/10.18502/fem.v6i3.9397**

Early clinical experience with a new Video Laryngoscope (SANYAR®) for tracheal intubation in adults: A comparison clinical study

Mohammad Reza Khajavi *, Rana Mohammadyousefi , Mohamadreza Neishaboury , Reza Shariat Moharari , Farhad Etezadi , Pejman Pourfakhr

Department of Anesthesiology, Tehran University of Medical Sciences, Tehran, Iran.

***Corresponding author:** Mohammad Reza Khajavi; **Email:** khajavim@tums.ac.ir

Published online: 2022-04-19

Abstract: **Objective:** SANYAR® video laryngoscope (S-VL) is a new video laryngoscope. We conducted a comparative clinical study to assess its ability to provide laryngeal exposure and facilitate endotracheal intubation (ETI) in adult patients.

Method: This comparison clinical study was conducted on adult patients undergoing elective general anesthesia. The patients were randomly divided into two groups of direct laryngoscopy (DL) or S-VL. The primary outcome was the time required for performing ETI. The glottic view and successful ETI on the first attempt was also compared between the two groups.

Results: Full and partial glottic visualization was achieved in 100% of the patients in the S-VL group, while the corresponding figure in the DL group was 90%. Cormack-Lehane III was observed in 5 patients of the DL group, and ETI was successfully carried out with S-VL. The first-pass success rate of ETI was significantly higher in S-VL group compared to the DL group (94% vs. 78%; P = 0.034). The mean times to ETI were 38.32±6.4 and 35.31±8.4 seconds in DL and S-VL groups, respectively (P = 0.650).

Conclusion: During ETI for general anesthesia, SANYAR® video laryngoscope compared with direct laryngoscopy improved glottic visualization and first-pass ETI rate.

Keywords: Device Approval; Intratracheal Intubation; Laryngoscopy; Video Laryngoscopy

Cite this article as: Khajavi MR, Mohammadyousefi R, Neishaboury M, Shariat Moharari R, Etezadi F, Pourfakhr P. Early clinical experience with a new Video Laryngoscope (SANYAR®) for tracheal intubation in adults: A comparison clinical study. Front Emerg Med. 2022;6(3):e35.

1. Introduction

In recent decades, different types of video laryngoscope (VL) were introduced into the clinical practice with the aim of improving the laryngeal view and the success of endotracheal intubation (ETI). Several clinical trials compared these devices with Macintosh Direct Laryngoscope and reported that utilizing VL had resulted in better glottic view, improved ETI success, and fewer complications (1-3). Successful use of VL depends on long-term training and practice and requires extensive practice to achieve expertise, even in those trained in direct laryngoscopy (4). The successful use of VL in the airway management of patients with the probability of difficult airway caused video laryngoscopy recommended in the guideline of patients with known or suspected difficult airway (5). In the corona era, the importance of using video laryngoscope in reducing the contamination of medical staff increased. On the other hand, due to the shortage of this device in the operating room and intensive care unit and reduction of device imports, SANYAR® video laryngoscope was made. In making this new video laryngoscope, researchers made innovations in its blade and how to transfer the image to the monitor. After making this video laryngoscope, its use on mannequins was evaluated and an experimental study was needed to evaluate its clinical efficacy. Therefore, the present study was designed and implemented.

2. Methods

2.1. Study design

This single-blind, randomized controlled trial was conducted from November 2020 until December 2021 at Sina Hospital, Tehran, Iran. The study protocol was reviewed and approved by the Ethical Committee of Tehran University of Medical Sciences (IR.TUMS.SINAHOSPITAL.REC.1399.060). The trial was registered prior to patient enrollment at www.irct.ir (IRCT20130304012695N8). Written informed consent was obtained from all participants prior to enrolment. Study was conducted in accordance with the Declaration of Helsinki on ethical principles for medical research involving human subjects.

2.2. Definition

This article introduces the capabilities of a novel portable VL that does not require a fixed monitor and transfers images to any mobile phones or tablets via Wi-Fi technology. SANYAR® Video Laryngoscope (S-VL) has a high-resolution

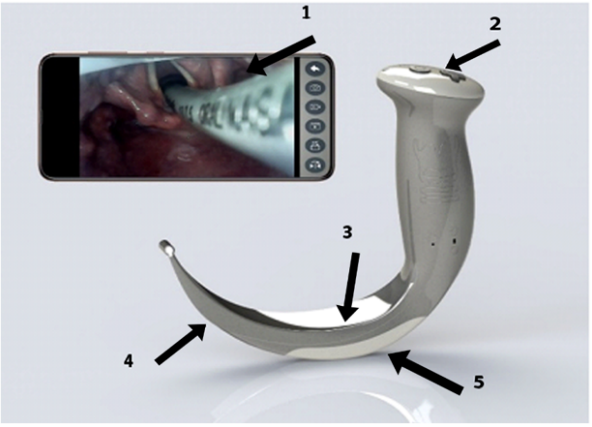

Figure 1 The SANYAR® Video Laryngoscope 1) Mobile LCD display; 2) handle with on / off button and battery charging connection; 3) blade with a 65° field angle; 4) 2 megapixel camera with an antifog lens; 5) bite lock

camera embedded into its blade, surrounded by eight LED lamps working as a light source. Inside the handle, there is a rechargeable battery and an electronic board that sends images via Wi-Fi to multiple mobile phones, tablets, or any device which have its application (Figure 1). The application allows the provider to record the received images on the phone without the need for external memory. This VL has ISO 13485:2016 standard and certification from national medical device directorate in IRAN.

2.3. Study participants

Inclusion criteria were as follows: Patients who were planning to undergo general anesthesia for elective surgery, aged over 18 years with ASA physical status I or II. Patients with a known history of airway pathology or previous neck fixation surgery were excluded. Morbid obese patients, defined as BMI of 40 or greater, were also excluded from the trial. Sample size required to compare time spent for ETI by using video laryngoscope or Macintosh laryngoscope calculated by according to a study by Sun et al. (6). The mean intubation time with video laryngoscope was 46 seconds and 30 seconds by direct laryngoscopy. We considering the study power of 80% and statistical error of 0.05, the required sample size for each of the study groups was 51 patients.

2.4. Randomization

Study participants were randomized into two groups (direct Laryngoscope or video laryngoscope) by employing randomized block design in block size of four. Individual randomization cards were placed in sealed envelopes. Just before the induction of general anesthesia, the randomization envelopes were opened to identify patients' groups. The Patients were blind to the type of laryngoscope for intubation.

2.5. Intervention

The preliminary data including gender, age, interincisive distance (cm), Mallampati score (I IV), and thyromental distance (cm) were recorded for all patients. Standard monitoring, including electrocardiogram, noninvasive blood pressure, and pulse oximetry, were performed for all patients via the anesthetic period. After preoxygenation in supine sniffing position, anesthesia was induced with midazolam 0.05 mg/kg, fentanyl 2 μg/kg, lidocaine 0.5 mg/kg, propofol 1.5 mg/kg, and atracurium 0.5 mg/kg. Four attending anesthesiologists carried out all intubation in both groups. Each of them had its own sequence for the laryngoscopy, which was assigned to two laryngoscopes equally. Prior to study enrollment, the necessary experience for working with S-VL was obtained by performing 60 laryngoscopies on the simulation manikin SimMan® (Laerdal Medical, Stavanger, Norway). Tracheal intubation was performed with S-VL, aided using GlideRite® Rigid Stylet.

2.6. Outcome measurement

When comparing DL to VL groups, the primary outcome was the time to ETI and the rate of successful first-pass ETI, as the secondary endpoint. Time of ETI was defined as the duration from the laryngoscope blade enters the patient's mouth until the first capnography wave is observed on the monitor. The Glotic View in both groups was evaluated and scored according to Cormack-Lehane scoring system. Based on the number of attempts needed to perform successful ETI, ease of ETI was defined as follows: 1) easy to intubate if the first try was successful 2) restricted if more than one attempt was need and 3) difficult to intubate if all attempts failed.

2.7. Statistical analysis

All analyses were performed using IBM SPSS (version 23.0). Categorical outcome variable such as first-pass success was tested using Pearson's chi-squared test. Continuous variables were tested using an independent t- student test. Continuous data were presented as mean ± standard deviation, while categorical data were presented as absolute values (numbers and percentages). A p-value of less than 0.05 was considered statistically significant.

3. Results

Flowchart of the study is presented in figure 2. A total of 100 eligible patients were enrolled in the final analysis (50 patients in each group). The patient's characteristics are described in Table 1.

In 45 patients from the DL group, the glottis visualization was complete or partial (Cormack-Lehane grade I and II), and in 5 patients (10%), the visualization of the glottis was not possible with DL (Cormack-Lehane grade III), and intubation was carried out by VL (Table 2). In the VL group, laryngeal view in all patients was full or partial (Cormack-Lehane grade I and II). Comparing the different glottic views between two arms of trial, full and partial views were more commonly encountered in the VL group with statistically significant differences (P = 0.039).

The first attempt intubation was achieved in 39 (78%) pa-

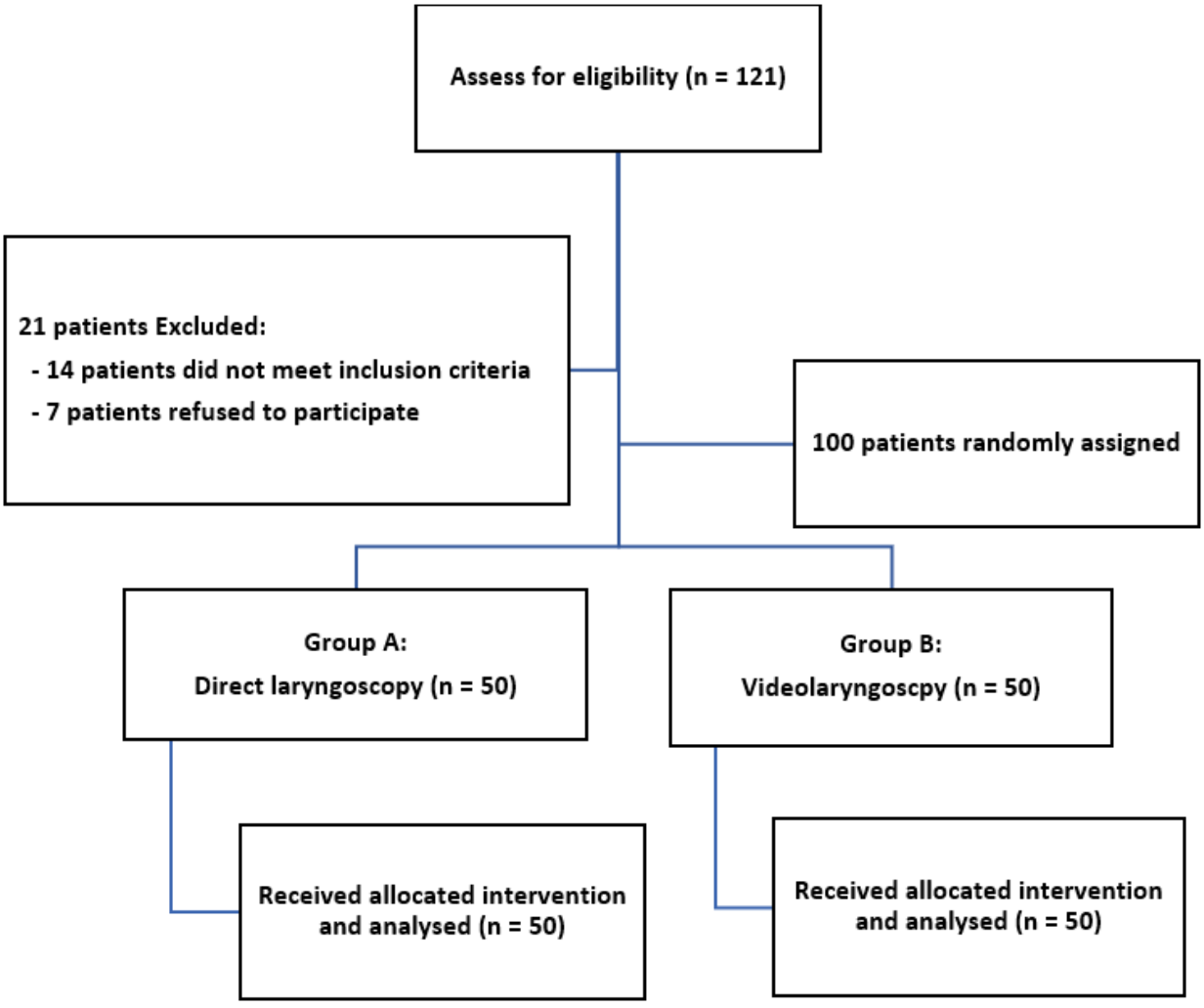

Figure 2 Flowchart of the study

tients in the DL group, and the six patients (12%), the second attempt was necessary to perform the intubation. As mentioned above, failed intubation was encountered in five (10%) patients in the DL group. In these patients, due to the prolongation of laryngoscopy and intubation time and the need for assistive devices for intubation, so their intubation time was not analyzed in the relevant group, but in the same group was considered only as a failure in intubation.

In 47(94%) patients in the VL group, the first attempt for intubation was successful, and in three patients (6%), intubation was performed in the second attempt. The corresponding figure showed a statistically significant difference comparing two groups (P = 0.034) (table 2).

The mean times to intubation were 38.32±6.4 and 35.31±8.4 seconds in DL and VL groups, respectively (P = 0.650).

4. Discussion

The current study describes the early experience with a new SANYAR® Video Laryngoscope (S-VL) at a single hospital involving 50 consecutive uses. The time of tracheal intubation was slightly longer in the direct laryngoscope group, but the difference was not statistically significant.

The main significant outcome of this study is the first-attempt success rate with S-VL (94%), which was higher than the success rate with direct laryngoscopy (78%) (P = 0.034). The higher quality views of the glottis with the S-VL were associated with intubation success. In 5 cases of unsuccessful DL, the patient was successfully intubated with an S-VL.

In video laryngoscopes, high-quality images of the glottis can be obtained by changing the blade curvature and using wide-angle and high-resolution cameras. GlideScope is the most commonly VL used in the clinic and it shows a full glottic view with successful tracheal intubation in 94.3% of cases, thus using video laryngoscopes in routine cases in clinical practice was gradually increasing over the past years (6-9). The first attempt success rate with S-VL was 94%, and its application in the management of difficult airways was shown in this study.

According to our preliminary data, SANYAR® Video Laryngoscope proved to be a valid option for tracheal intubation,

Table 1 Patients' characteristics

Variable	Direct laryngoscopy (n=50)	Video laryngoscopy (n=50)	P-value
Sex (Male/Female); number	26/24	21/29	0.380
Age (years); mean±SD	46.88±11.344	45.78±15.787	0.121
BMI (kg/m^2); median (IQR)	29.1 (22.3-34.2)	27.5 (25.3-36.1)	0.198
Inter-incisor gap < 3cm; n (%)	0 (0.0)	0 (0.0)	0.590
Mallampati score (III IV); n (%)	8 (16)	9 (18)	0.350
Thyromental distance < 6.5cm; n (%)	9 (18)	10 (20)	0.351
Neck extension < 50°; n (%)	7 (14)	6 (12)	0.351

Table 2 Comparisons of glottic views, feasibility and time of tracheal intubation in DL and VL groups

Variable	Direct laryngoscopy (n=50)	Video laryngoscopy (n=50)	P-value
	n (%) / mean±SD		
Cromack-Lehane grading			
Grade I	37 (74.0)	45(90.0)	0.039
Grade II	8 (16.0)	5 (10.0)	
Grade III	5 (10.0)	0 (0.0)	
Grade IV	0 (0.0)	0 (0.0)	
Ease of intubation			
Easy	39 (78.0)	47 (94.0)	0.034
Restricted	6 (12.0)	3 (6.0)	
Difficult	5 (10.0)	0 (0.0)	
Time of intubation (sec)	38.32±6.4	38.32±6.4	0.651

both in routine cases and in those predicted to be difficult. The mean time to intubation was not significantly different between the two groups, but in most studies, the total intubation time with VL was usually greater than DL (46-57 sec) (10-12).

Several reasons for improving the success rate and the time of tracheal intubation with S-VL were speculated. First of all, it has a low angulation blade with a camera near the tip of the blade which easily enters the mouth, and the surface of the blade has an angle of about 5 degrees to the left and easily directs the tongue to the left of the oral cavity and the glottis will appear quickly. Therefore, with a pre-formed stylet into the endotracheal tube, it can pass very easily through the vocal cords. This difference in intubation technique may account for improving the time taken to achieve successful intubation.

The glottis view score in video laryngoscopes depends on the operator's skill and experience, Mallampati score, thyromental distance, the blade shape, and the camera's angle of view. In our study, 50 (100%) patients in S-VL group had full and partial glottis view during laryngoscopy despite the possibility of difficult laryngoscopy according to its criteria (Mallampati score and thyromental distance) in some patients.

VL frequently provides a good glottic view but advancing the endotracheal tube via the vocal cords can sometimes be difficult, and a stylet is usually used to position the ETT tip at the glottic opening (13). To quickly insert the endotracheal tube into the trachea, the curvatures and the shape of the stylet are also important (14). We use a pre-formed GlideRite® Rigid Stylet that appears to align the tracheal tube better with the glottic opening and trachea.

The ease and speed of the endotracheal tube passing through the space between the laryngoscope blade and the right corner of the lip also affects the time of endotracheal intubation. In design of this model video laryngoscope, the distance between the tongue surface of the blade and its flange is 11 mm, therefore the endotracheal tube, which is properly shaped with a stylet, very easily enters the patient's mouth and placed in front of the glottis.

SANYAR® videolaryngoscope showed to be an effective, portable device for routine practice for tracheal intubation in surgical patients, even in those patients with predicted difficult airways.

5. Limitations

It is the first study performed on this new device and has some limitations. To find problems and improve the efficiency of video laryngoscope-assisted intubation, the components of the intubation time, such as glottic exposure and tube delivery, should be measured separately. Low sample size is also one of the limitations of the study. We hope that

in the future a study with a larger sample size and multicenter will be conducted.

6. Conclusion

Among the patients in the operating room requiring intubation, SANYAR® video laryngoscope compared with Macintosh direct laryngoscopy improved glottic visualization and first-pass ETI rate. There were no significant differences between the VL and the DL in terms of the mean time to intubation. More studies are needed to confirm our findings and verify its efficacy even in other settings such as intensive care units, emergency, and pediatrics, comparing S-VL with the most studied devices.

7. Declarations

7.1. Acknowledgment

We are indebted to the research and development center of Sina hospital for their support.

7.2. Authors' contribution

The conception and design of the work by MK; Data gathering by RM; Analysis and interpretation of data by FE; Drafting the work by RS; Revising it critically for important intellectual content by MN and PP; All the authors approved the final version to be published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work.

7.3. Conflict of Interest

The Authors declare that there is no conflict of interest.

7.4. Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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