Archives of Anesthesiology and Critical Care (Summer 2024); 10(3): 210-215.

Available online at http://aacc.tums.ac.ir

Research Article

A Non-Inferiority Study of the Speed and Success of Nasotracheal Intubation in Maxillofacial Surgeries Using Macintosh Direct Laryngoscope versus Sanyar® Video Laryngoscope

Pejman Pourfakhr[1], Mehran Sadeghi[1], Farhad Etezadi[1], Parisa Kianpour[1], Azam Biderafsh[2], Mohammad Reza Khajavi[1]*

[1]Anesthesia, Critical Care, and Pain Management Research Center, Tehran University of Medical Sciences, Tehran, Iran.

[2]Department of Epidemiology and Biostatistics, School of Public Health, Tehran University of Medical Sciences, Tehran, Iran.

ARTICLE INFO

Article history:
Received 15 October 2023
Revised 08 November 2023
Accepted 29 November 2023

Keywords:
Nasotracheal-endotracheal intubation;
Airway management;
Direct laryngoscopy;
Sanyar® video laryngoscopy;
Maxillofacial surgery

ABSTRACT

Background: The recently developed blade design of the Sanyar® video laryngoscope yields an exceptionally precise visualization of the larynx, thereby easing the process of tracheal intubation.
Objectives: A non-inferiority clinical investigation, to assess the efficacy of the Sanyar® as compared to the Macintosh® direct laryngoscope for nasotracheal intubation in the context of maxillofacial surgeries.
Methods: 78 patients for maxillofacial surgery were divided randomly into two groups and intubated through the nose using either the Sanyar® or Macintosh® laryngoscope after anesthesia was induced. The study measured intubation time and secondary objectives included success rate, attempts, and hemodynamic changes in two groups.
Results: 40 eligible patients in the Sanyar® and 38 in the Macintosh® group were involved. Of all, 42(53.8%) were men and 36(46.2%) were women. The average age of patients in the Sanyar® and Mackintosh groups was (31.62±13.41) and (30.81±10.89), respectively. 39(98%) of the Sanyar® group and 33(86%) of the Macintosh® group had successful laryngoscopy and intubation, with a P-value<0.034. Sanyar® group had a significantly shorter intubation time than Macintosh® (P-value<0.001). Hemodynamic changes before and after laryngoscopy and intubation had no significant differences between the two groups.
Conclusion: The Sanyar® video laryngoscope reduced the time of nasal tracheal intubation in maxillofacial surgery compared to direct laryngoscopy and improved the success rate of the first intubation attempt.

Introduction

Airway management is very important and vital to maintain lung oxygenation and ventilation in emergency and elective surgery patients. Many techniques and tools have been invented in the field of airway security, and its training is considered one of the main subjects of clinical medicine courses [1-2]. Nasotracheal intubation (NTI) is very necessary in patients who are candidates for maxillofacial surgery. In nasal intubation, the tracheal tube is passed through the nasal cavity blindly through the path that has the least resistance. In this method, laryngoscopy will help a lot to see the glottis and guide the tracheal tube correctly in

The authors declare no conflicts of interest.
*Corresponding author.
E-mail address: khajavim@tums.ac.ir

passing between the vocal cords and entering the trachea. Laryngoscopy is performed with two direct and indirect techniques [3].

A direct laryngoscope (DL) with the Macintosh® blade is a conventional and common device in daily practice. Video laryngoscopes (VL) are equipped with a camera blade that allows indirect observation of the glottis on a monitor [4]. These devices improve glottis observation and facilitate tracheal intubation in patients with normal and difficult airways [5-6]. Many studies have been done comparing two methods of direct laryngoscopy and types of VL in terms of intubation success and intubation time [7]. Specifically, the use of the GlideScope has previously been shown to increase the success rate, without the use of McGill forceps, for nasotracheal tracheal intubations [8].

This device appears similar to the GlideScope, but the Sanyar® is an innovative wireless VL, that does not require a fixed screen and transmits images to any mobile phone or tablet via Wi-Fi technology and records all patients' information in high resolution. This laryngoscope (Figure 1-2) has a hyper-angulated blade, and a high-resolution camera with strong LED lights, which is placed near the tip of the blade and easily enters the patient's mouth. The blade surface is angled about 11 degrees to the left, so, easily guides the tongue to the left side. Also, the distance between the blade and the body is about 10 mm, which creates a suitable space without resistance for the passage of the tracheal tube, and a trained operator can easily pass the tube through this space and the tip of the tracheal tube will be in front of the glottis. Usually, in the first attempt, the tracheal tube will easily pass between the vocal cords and enter the trachea, and the oral cavity and the glottis appear quickly and well.

Objectives

In our previous study, we compared the performance of a VL with the new blade design (Sanyar®) in oral intubation with the Macintosh laryngoscope [9], and it was comparable with Macintosh® DL in tracheal intubation in the term of the meantime to intubation. In the present study, our aim was to evaluate the efficacy of Sanyar VL compared to a DL in NTI.

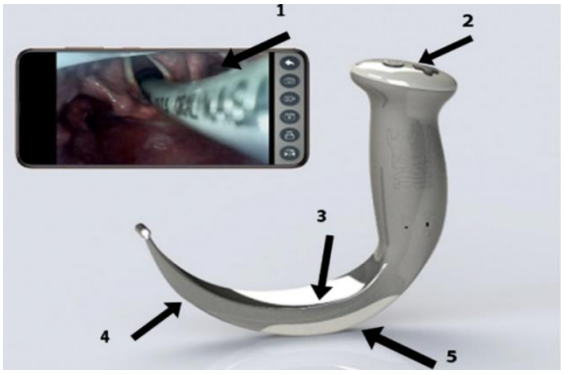

Figure 1- Sanyar® Video-Laryngoscope [9]

1) Movable LCD screen;
2) Handle with an on/off button and battery charging port;
3) Blade with field angle of 65◦;
4) 2-megapixel camera with anti-fog lens;
5) Bite lock

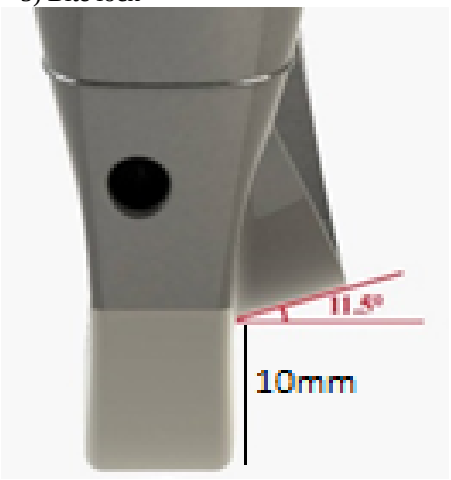

Figure 2-Posterior view of the Sanyar® laryngoscope blade

Methods

This study was a non-inferiority, randomized, controlled, two-arm with parallel groups, single-center clinical trial in which the success rate and time of NTI of the Sanyar® VL were evaluated in comparison to the Macintosh® DL in maxillofacial surgeries.

The present study was authorized and registered with the Anesthesia Department Research Division associated with the Tehran University of Medical Sciences and obtained an ethics code from the Ethics Committee of Sina Hospital (IR.TUMSSINAHOSPITALREC1400055).

Subsequently, the protocol was prospectively recorded in the Iranian Registry of Clinical Trials (https://irct.behdasht.gov.ir/) with the trial registration number IRCT20130304012695N11.

Eligible patients who were candidates for elective maxillofacial surgeries and NTI over the age of 18 were included in the study from the date of 2021 August until 2022 March.

Patients with any airway pathology, Body Mass Index (BMI) above 40, restriction of neck movement due to recent surgery, history of difficult intubation, and presence of cervical masses were excluded from the study. As well, patients with severe limitations of opening the mouth that prevented laryngoscopy and required intubation through fiber optics or other methods of establishing the airway were excluded. Before participating, written, free, informed consent was obtained from the eligible patients.

Eligible patients for NTI were divided into two groups (Sanyar® VL, and Macintosh® Direct DL), using the

block-balanced randomization technique. Then, basic information and physical assessment of the airway including sex, age, inter-incisive distance (cm), Mallampati score (I- IV), neck extension, and thyromental distance (cm) were recorded.

After standard monitoring, induction of anesthesia was done with the following drugs: fentanyl 2 μg/kg and midazolam 0.05 mg/kg as premedication, lidocaine 0.5 mg/kg and propofol 1.5 mg/kg as hypnotics, and atracurium 0.5 mg/kg as muscle relaxant. Neuromuscular monitoring was performed to ensure complete muscle relaxation for laryngoscopy and intubation in both groups. Thirty seconds after all responses to the train of four stimulations disappeared, NTI was performed.

The hemodynamic status of the patients, mean arterial pressure (MAP), and heart rate (HR) one minute before and after intubation was documented in case report forms (CRF); also, duration of the laryngoscopy (from the time the laryngoscope blade enters the patient's mouth until the first capnography curve is seen on the monitor), observed view during the laryngoscopy based on the Cormack-Lehane criteria were recorded. NTI was performed with spiral and flexible tracheal tubes of sizes 6, 6.5, or 7 according to the weight and gender of the patients.

A nurse anesthetist who was not a member of the research team recorded all the data of each patient. The primary outcome of this study was intubation time and secondary outcomes included the first attempt success, overall success, Cormack-Lehane grade, hemodynamic response to laryngoscopy, and intubation maneuvers required for intubation. Laryngoscopy was performed in both groups by two anesthesiologists familiar with ten years of experience and familiar with the use of both laryngoscopes.

Ease of NTI was defined based on the number of attempts required by the operator to successfully perform NTI, as follows: 1) If the first attempt (without the Magill forceps) was successful, intubation was easy, 2) If more than one attempt was needed (with Magill forceps), intubation was considered restricted, 3) If 3 consecutive failures in NTI happened (even with Magill forceps), intubation was considered difficult and fail.

Sample size

The sample size in the present study according to the study of Ambulkar et al [10] considering the minimum difference between the two groups with clinical significance equal to 17 seconds and statistical power of 90%, the sample size for each of the studied groups is 38 people and a total of 76 patients is required.

Statistical analysis

An independent t-test was used to compare mean values for continuous variables and the chi-square test and Fisher exact test for nominal variables between the two groups (Sanyar® vs. Macintosh® group). Analysis of Covariance (ANCOVA) was used to compare the mean values for outcomes in two groups of Sanyar® and Macintosh® while controlling for the effects of at least one continuous covariate. All statistical analyses were performed at a significance level of 0.05 using IBM SPSS software version 24 with $P < 0.05$ considered to indicate significance.

Results

In this study, 78 people were included, 40 people in the Sanyar® VL group and 38 people in the Macintosh® DL group (Figure 3).

The mean age of patients in the Sanyar® and Macintosh® groups was (31.62±13.41) and (30.81±10.89) respectively.

There were no significant differences between the participants in the two groups in terms of gender, age, and airway examinations (Table 1).

Data are presented as mean ± standard deviation or n (%).

In the Macintosh® DL group, 33 patients, 86.8%, were intubated in the first term of laryngoscopy, and 3 patients (7.8%) were intubated with the help of Magill forceps in the second attempt. Two patients could not be intubated with this device, so the overall intubation success rate with the Macintosh® blade laryngoscope was 94.7%.

Within the Sanyar® VL group, a total of 39 (97.5%) patients were successfully intubated upon the first attempt. However, one patient (2.5%) required the assistance of a Magill device during the intubation.

The observation of the larynx according to the Cormack-Lehane classification in two groups is shown in (Table 2).

The intubation time in the patients of the Sanyar® VL group (27.1 ± 6.8) was significantly less than that of the Macintosh® (36.47 ± 7.14) DL group (P-value < 0.001).

There were no statistical differences between the two groups' perioperative hemodynamic responses to laryngoscopy and intubation (mean arterial pressure and Heart Rate) (Table 2).

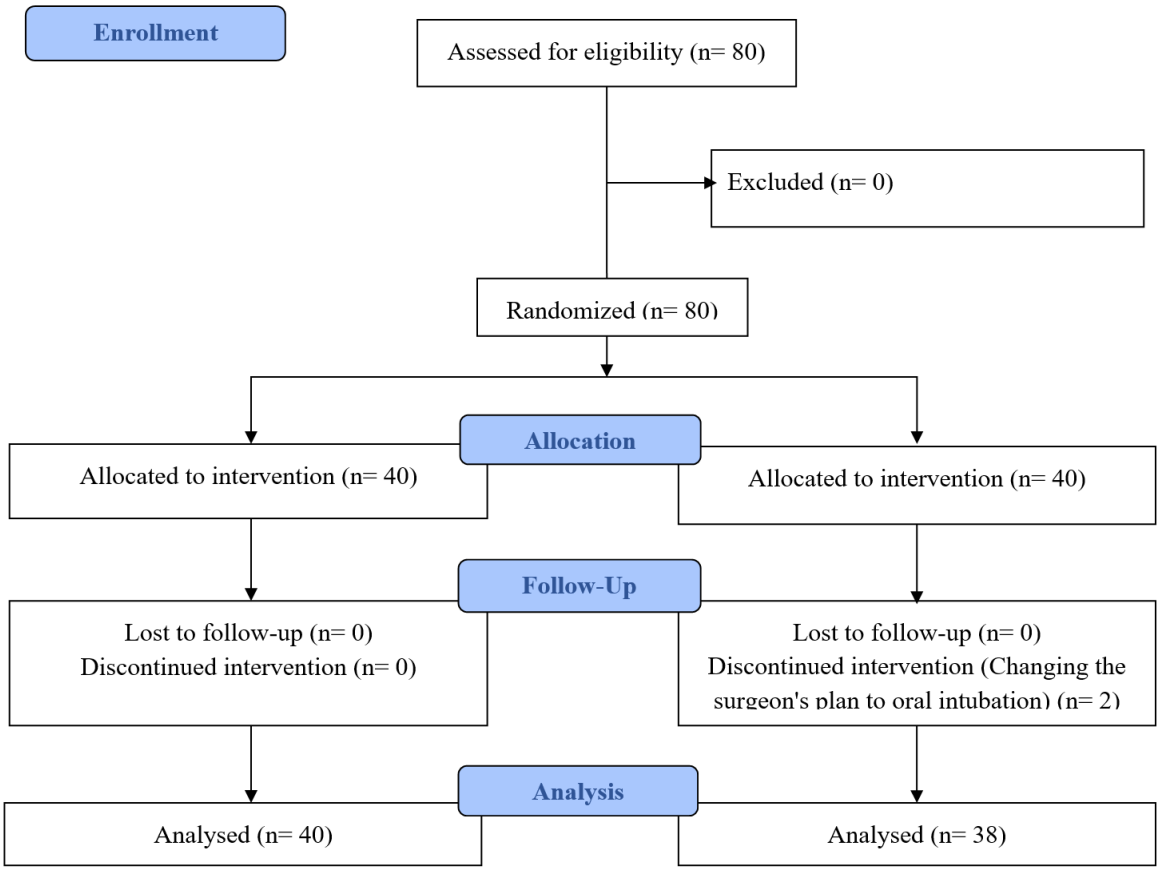

Figure 3- CONSORT Flow Diagram of the participants in the study group: Sanyar® and Macintosh® group

Table 1-Demographic characteristics of the Sanyar® VL and Macintosh® DL group

Variable	Macintosh® DL (n=38)	Sanyar® VL (n=40)
Sex (M/F)	21/17	22/18
Age (years)	30.81±10.89	31.62±13.4
Inter-incisor gap (cm)	5.05±0.65	4.52±0.78
Inter-incisor gap<3cm	0	0
Mallampati score (III-IV).	6(16%)	7(17%)
Thyromental distance (cm)	7.11±0.57	7.15±۰.66
Thyromental distance<6cm	6(16%)	7(17%)
Neck extension<50º	4(10%)	3(7.5%)

Table 2-Comparison of glottis view (using the Cormack-Lehane classification), ease, success, and time of NTI in two groups

Variable		Macintosh® DL (n=38)	Sanyar® VL (n=40)	P value#
View of glottis	Full view (I-II)	24(63.2%)	31(77.5%)	0.024
	Partial view (III)	12(31.5%)	9(22.5%)	0.45
	None view (IV)	2(5.3%)	0	0.001
Ease of NTI	Easy	33(86.8%)	39(97.5%)	0.001
	Restricted	3(7.8%)	1(2.5%)	0.048
	Difficult	2(5.2%)	0	0.001
Intubation Success Rate		94.7%	100%	0.034
Time of intubation(min)		36.51±۷.11	27.05±٦.08	0.001
MAP (mmHg) before		90.76 (4.34)	92.05 (7.99)	0.37

	after	93.89 (8.77)	91.60 (12.67)	0.35
Heart rate	before	78.97 (9.53)	79.65 (11.17)	0.77
	after	80.84 (7.96)	78.95 (9.80)	0.4

Data are presented as mean ± standard deviation or n (%)

Statistics: a: T-test & Fishers Exact test, as appropriate

Full view of glottis: Cormack-Lehane class I and II; Partial view of glottis: Cormack-Lehane class III; non-view of glottis: Cormack-Lehane class IV.

NTI: nasotracheal intubation; MAP: mean arterial pressure

Discussion

The preliminary results of the present study indicate the success of using the new VL (Sanyar®) in the NTI of maxillofacial surgery patients. The success of the first nasal intubation attempt by Sanyar® VL was 97.5%, which was significantly higher than DL (86.8%) (P<0.001). The Sanyar® VL created a complete and high-quality view of the glottis, which led to an increase in the percentage of intubation and a high success on the first attempt. In 2 patients from the DL group, the view of the glottis was not visible at all, and intubation was successfully performed with the help of the Sanyar®. In most studies, the intubation success rate on the first attempt for all VL was more than DL (94.8% vs 84.2%) [11].

In our study, the use of the Sanyar® VL improved the glottis view and CL grading and required fewer optimization maneuvers to observe the glottis. This is like the findings of previous studies [12-14].

These VLs, by changing the curvature of the blade and using wide-angle and high-resolution cameras, create very high-quality images of the glottis for intubation, as a result, these devices are used as an alternative in patients who have difficult intubation.

Several studies have demonstrated the suitability and advantage of VL for routine NTI in oral and maxillofacial surgery, resulting in significantly faster intubation times and reduced use of Magill forceps compared to traditional DL [15-17]. The results of our study also confirm the findings of previous studies and suggest that in patients requiring NTI, Sanyar® VL provides superior performance compared to DL.

The average time of nasal intubation with the Sanyar® VL was 9.5 seconds, shorter than a DL with the Macintosh® blade.

The speed of intubation and ease of passage through the larynx in nasal intubation is faster and easier than oral intubation. After passing the tracheal tube through the nasal cavity and nasopharynx, the tip of the tube is usually located in front of the entrance to the larynx, and if the tip of the laryngoscope blade ‹lifts the epiglottis from the glottis, the tip of the tracheal tube will easily pass between the vocal cords and enter the trachea.

This study had certain limitations. We could not blind the operator or assessor to the type of laryngoscope used, this is a common challenge in all Clinical trials associated with VL. The evaluator objectively measured the intubation time and tried to record the operator's observations during laryngoscopy without bias. Our study was conducted by using a single type of VL (Sanyar®) which has a hyperangulated blade; Therefore, the results of this study may not be extrapolated to other VLs.

Conclusion

The evidence based on the results of this study shows that the Sanyar® VL leads to a shorter time for NTI, a higher first-attempt success rate, and a reduced need for the use of Magill forceps compared to the Macintosh DL in maxillofacial surgeries.

Acknowledgments

The authors would like to thank the statistics consultants of the Research and Development Center of Sina Hospital for their technical assistance.

References

[1] Etezadi F, Najafi A, Pourfakhr P, Moharari RS, Khajavi MR, Imani F, et al. An assessment of intubation skill training in novice anesthesiology residents of Tehran University of medical sciences with the use of mannequins. Anesth Pain Med. 2016; 6(6).

[2] Pourfakhr P, Mirzaie MA, Etezadi F, Shariat Moharrari R, Khajavi MR. Evaluation of the success rate and quality of teaching of tracheal intubation to medical students by using video laryngoscope. Tehran University Medical Journal TUMS Publications. 2022; 79(12):951-7.

[3] Collins SR. Direct and Indirect Laryngoscopy: Equipment and Techniques Discussion. Respiratory care. 2014; 59(6):850-64.

[4] Niforopoulou P, Pantazopoulos I, Demestiha T, Koudouna E, Xanthos T. Video-laryngoscopes in the adult airway management: a topical review of the literature. Acta Anaesthesiol Scand. 2010; 54(9):1050-61.

[5] Paolini JB, François Donati MD, Drolet P. video-laryngoscopy: another tool for difficult intubation or a new paradigm in airway management?. Can J Anaesth. 2013; 60(2):184-91.

[6] Ghodki P, Kulkarni P, Prabhu A, Dhamdhere A. Comparison of Truview® Video Laryngoscopy with Conventional Macintosh Direct Laryngoscopy for Orotracheal Intubation: A Randomized Controlled

Trial. Arch Anesth & Crit Care. 2022; 8(Supplement):370-376.

[7] Su YC, Chen CC, Lee YK, Lee JY, Lin KJ. Comparison of video laryngoscopes with direct laryngoscopy for tracheal intubation: a meta-analysis of randomised trials. European Journal of Anaesthesiology| EJA. 2011; 28(11):788-95.

[8] Jones PM, Armstrong KP, Armstrong PM, Cherry RA, Harle CC, Hoogstra J, et al. A comparison of GlideScope® videolaryngoscopy to direct laryngoscopy for nasotracheal intubation. Anesth Analg. 2008; 107:144–8

[9] Khajavi MR, Mohammadyousefi R, Neishaboury M, Moharari RS, Etezadi F, Pourfakhr P. Early clinical experience with a new video laryngoscope (SANYAR®) for tracheal intubation in adults: a comparison clinical study. Frontiers in Emergency Medicine. 2022; 6(3):e35.

[10] Ambulkar R, Ranganathan P, Savarkar S, Divatia JV. A randomized controlled trial comparing McGRATH series 5 videolaryngoscope with the Macintosh laryngoscope for nasotracheal intubation. J Anaesthesiol Clin Pharmacol. 2020; 36(4):477-82.

[11] Gupta N, Gupta A, Sarma R, Batra A, Madan K. Video laryngoscopy vs. direct laryngoscopy for nasotracheal intubation in oromaxillofacial surgery: a systematic review and meta-analysis of randomized controlled trials. Korean J Anesthesiol. 2021; 74(5):439-48.

[12] Roh GU, Kwak HJ, Lee KC, Lee SY, Kim JY. Randomized comparison of McGrath MAC videolaryngoscope, Pentax Airway Scope, and Macintosh direct laryngoscope for nasotracheal intubation in patients with manual in-line stabilization. Can J Anaesth. 2019; 66(10):1213-20.

[13] Ho CH, Chen LC, Hsu WH, Lin TY, Lee M, Lu CW. A Comparison of McGrath Videolaryngoscope versus Macintosh Laryngoscope for Nasotracheal Intubation: A Systematic Review and Meta-Analysis. J Clin Med. 2022; 11(9):2499.

[14] Altaiee AH, Hassen HA, Fadeel SJ. Video laryngoscopy versus direct laryngoscopy on time of orotracheal intubation in normal adult in elective surgeries. Medical Science. 2020; 24(106):4264-9.

[15] King BJ, Padnos I, Mancuso K, Christensen BJ. Comparing Video and Direct Laryngoscopy for Nasotracheal Intubation. Anesthesia Progress. 2020;67(4):193-9.

[16] Zhu H, Liu J, Suo L, Zhou C, Sun Y, Jiang H. A randomized controlled comparison of non-channeled king vision, McGrath MAC video laryngoscope and Macintosh direct laryngoscope for nasotracheal intubation in patients with predicted difficult intubations. BMC anesthesiology. 2019; 19:1-9.

[17] Mishra G, Philip VM, Kumar VR, Sivashanmugam T. Suitability of nasotracheal intubation using King Vision and TruviewPCD video laryngoscopes: A randomized clinical trial. Anesth Essays Res. 2018; 12(2):581-5.