Innovative Journal of Medical and Health Science
Received 16 August 2022 | Revised 31 Augustt2022 | Accepted 22 Septt2022 | Published Online 30 Septembere2022

DOI: https://doi.org/10.52845/IJMHS/2022/12-9-4
Inno J of Med Health Sci 12 (09), 1973-1983 (2022)

RESEARCH ARTICLE

ISSN (P) 2589-9341 | (O) 2277-4939 IF:1.6

Comparative effectiveness of the video laryngoscope versus direct laryngoscopy in the predicted difficult airway

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Abstract

CONTEXT

Tracheal intubation using direct laryngoscopy(DL) is successful in the majority of patients, even when a line-of-sight view of the glottis is not possible. Poor glottic visualization is encountered between 1% and 9% of attempts.

This study was designed to determine the comparative effectiveness of the Videolaryngoscope compared with direct laryngoscopy in the predicted difficult airway. Our hypothesis was that using VividtracVideolaryngoscopy results in a higher intubation success compared with direct laryngoscopy in this challenging patient population.

Objectives of the study:

a. Primary objective – Intubation success at first attempt

b. Secondary objectives –

1. Best Cormack-Lehane laryngeal view,
2.laryngoscopy time,
3.use of external laryngeal maneuver,
4.arterial oxygen desaturation by pulse oximetry,
5.airway-related complications.

Methodology

The data for study is collected from subjects fulfilling inclusion/exclusion criteria and inpatients.

Study design: A hospital based prospective, randomized, two parallel arm clinical study.

Results:

VDL(94%) has more intubation success rate at first attempt than DL(78.7%),Laryngoscopy time for VDL took 49.21 seconds whereas DL was 32.99 seconds.External maneuvers were used only for DL (5.3%) whereas VDL did not require any(0%);videolaryngoscopeshowed better Cormack lehane view. Conclusion:A diverse group of anesthesia providersachieved a higher intubation success rate on first attemptwith the Vividtrac in a broad range of patients with predictorsof difficult intubation.Vividtrac laryngoscope offers a new approach to tracheal intubation of patients at increased risk for tracheal intubaton with lesser degree of hemodynamic stimulation compared to Macintosh laryngoscope.

Keywords: Difficult airway,Direct laryngoscopy,Vividtracvideolaryngoscopy.

1 | INTRODUCTION

Tracheal intubation using direct laryngoscopy(DL) is successful in the majority of patients, even when a line-of-sight view of the glottis is not possible. Poor glottic visualization is encountered between 1% and 9% of attempts, success can generally be achieved with additional force, external laryngeal manipulation, or the use of gum elastic bougies and stylets. Poor glottic exposure is more likely to require prolonged or multiple intubation attempts and, subsequently, may be associated with complications such as oxygen desaturation or airway and dental injuries. In recent years, videolaryngoscopy has begun to play an important role in the management of patients with an unanticipated difficult laryngoscopic intubation.

Videolaryngoscopy(VDL) made its introduction to airway management more than 10 years ago. As success rates for tracheal intubation utilizing direct laryngoscopy in experienced hands is very high, there does not seem to be added benefit beyond improvement of laryngeal view for the undifferentiated airway across all age groups1.As VL offers an improved laryngeal view relative to DL, it seems logical that the application of VL to the patient with a predicted difficult airway will improve intubation success. Although the majority of trials that have examined this issue have not been powered to determine this important outcome, a few have demonstrated the ability of VL to ease intubation[2]

Very few of clinical studies so far have sought to determine clinical effectiveness and defined intubation success as the primary end point for the comparison of VDL and DL. Based on the data, VL does seem to increase intubation success in patients with a predicted difficult airway. However, these studies require confirmation in our population and may or may not apply to all available VL devices, Very few of clinical studies so far have sought to determine clinical effectiveness and defined intubation success as the primary end point for the comparison of VDL and DL. Based on the data, VL does seem to increase intubation success in patients with a predicted difficult airway. However, these studies require confirmation in our population and may or may not apply to all available VL devices,

This study was designed to determine the comparative effectiveness of the Videolaryngoscope compared with direct laryngoscopy in the predicted difficult airway. Our hypothesis was that using Vivid tracVideolaryngoscopy results in a higher intubation success compared with direct laryngoscopy in this challenging patient population.

2 | AIMS AND OBJECTIVES OF THE STUDY

The aim of the present study was:-

To determine the comparative effectiveness of the Videolaryngoscope compared with direct laryngoscopy in the predicted difficult airway

The objective of the present study was :-

a. Primary objective –.

1. Intubation success at first attempt

b. Secondary objectives –

1. Best Cormack-Lehane laryngeal view,
2. Laryngoscopy time,
3. Use of external laryngeal manipulation or gum-elastic bougie,
4. Arterial oxygen desaturation by pulse oximetry,
5. Airway-related complications.

3 | MATERIALS AND METHODS

Source of data:

All surgical patientsadmitted to Rajarajeswari Medical College & Hospital who require tracheal intubation.

Method of collection of data: (including sampling procedure if any):

The data for study was collected from subjects fulfilling inclusion criteria/exclusion criteria and admitted as inpatients in RRMC&H

Regimens to be used for the study:

STUDY DESIGN: A hospital based prospective, randomized, two parallel arm clinical study. STUDY PERIOD: 12-18 months.October 2015- April 2017

INCLUSION CRITERIA:

1. ASA I and II patients of either sex.
2. Aged between 18 or older undergoing various surgical procedures who are deemed to be at increased risk for difficult laryngoscopy.
3. Reduced cervical motion either from pathologic conditions or cervical spine precautions (limited capacity to flex or extend the neck or managed with a cervical collar, but with negative imaging)
4. Mallampati classification score of III or IV.
5. Reduced mouth opening (less than 3 cm)
6. History of difficult direct laryngoscopy. The latter criteria was considered positive if previous anesthesia records demonstrated more than two direct laryngoscopy attempts until successful tracheal intubation, failed direct laryngoscopy rescued by another means, or if the patient received a written or verbal communication from an anesthesiologist that tracheal intubation had failed with direct laryngoscopy alone.

EXCLUSION CRITERIA:

1. History of relevant drug allergy
2. Risk factors for gastric aspiration
3. A documented easy tracheal intubation (success on first attempt);
4. A history of failed intubation and failed bag-mask ventilation;

5.Known unstable cervical spine injury;
6.Age younger than 18 years
7. Presentation for an emergency surgical procedure.

Methodology of Study:

The patients will be selected based on those satisfying the inclusion criteria.

They will undergo a detailed pre anesthetic checkup including history, clinical examination and all routine and relevant investigations like complete blood count, blood sugar, Liver Function Test, Renal Function Test, Serum electrolytes, ECG and Chest X ray.

After obtaining ethical committee clearance and taking an informed written consent, 300 patients will be included into the study.The subjects will be randomized into two study groups. Randomization will be done by computer based tables. The first Group is"VIDEOLARYNGSCOPY (VDL)" and the second group is "Direct Laryngoscopy"(DL).

Patints are kept nil per orally from 10 p.m on the night before surgery. On the night before surgery, all subjects will recieve tablet alprazolam 0.25mg. On the day of the surgery the patients will be premedicated with Inj. Glycopyrrolate 0.2mg, and Inj. Midazolam 1mg before the surgery.In the operation theatre the patient will be monitored with NIBP, pulse oximeter, PR, $EtCO_2$ probe during the course of the surgery.

Anesthetic Management

All patients were preoxygenated in the supine "sniffing" position with the exception of obese patients (body mass index more than 35) and those with cervical spine precautions. Obese patients were placed in a ramped position with a foam ramp or towels to a desired horizontal alignment of the sternal notch with the external auditory meatus. Those with cervical spine precautions were managed with manual in-line stabilization. Induction of anesthesia was at the discretion of the attending anesthesiologist, but included the use of neuromuscular blockade with succinylcholine or a nondepolarizing agent. Patients were deemed to be adequately relaxed with succinylcholine at resolution of fasciculations or after 90 s. Adequate relaxation after nondepolarizing neuromuscular blocking agent was determined at termination of twitches that were elicited by continuous repeat neurostimulation at the ulnar nerve at 1/s using Laryngoscopy was performed by attending anesthesiologists. During induction of anesthesia, a Vividtrac VDL device and conventional laryngoscopes were available. The selection of either a size #3 or #4 blade was at the discretion of the laryngoscopist.

Outcome Measures and data collection:

The primary outcome measure was intubation success at first attempt. Secondary outcome measures were

- Best Cormack-Lehane laryngeal view,
- Laryngoscopy time,
- Use of external laryngeal manipulation or gum-elastic bougie,
- Arterial oxygen desaturation by pulse oximetry, and
- Airway-related complications.

Intubation success was defined as confirmation of endotracheal tube placement by end-tidal carbon dioxide with a single blade insertion. Removal of the laryngoscope from the mouth constituted a failure. For patient safety, the failed attempt was subsequently managed at the discretion of the attending anesthesiologist with any device, and subsequent attempts were not controlled by the study design; however, the chosen technique was recorded. The provider reported their best laryngeal view obtained on the modified Cormack-Lehane scale.

GRADE 1: visualization of entire laryngeal aperture

GRADE 2: visualization of only posterior portion of laryngeal aperture

GRADE 3:visualization of only the epiglottis

GRADE 4:No visualization of epiglottis or larynx

For those randomized to VDL group, the provider reported the best view either directly (naked eye) or on the video screen. Laryngoscopy time was defined as the time between blade insertion into the mouth and inflation of the endotracheal tube cuff. We also recorded the following additional information: any oxygen desaturation below 90%, the number of laryngoscopy attempts, trauma noted by the laryngoscopist, use of a gum-elastic bougie, and the use of external laryngeal manipulation. External laryngeal manipulation was defined as any manual external manipulation of the glottis intended to improve laryngeal view or endotracheal tube passage. Further, we examined the patient's airway after successful tracheal intubation for lip or gum laceration, dental injury, pharyngeal injury, or bloody secretions.

Upon arrival to the recovery area we further examined the airway for any signs of trauma (lip/gum lacerations, dental injury, and pharyngeal injury), asked the patient if they noted a sore throat, and asked the patient to grade the intensity of the sore throat. The patient subjectively reported the intensity of the soreness on a three-point scale as mild, moderate, or severe. An assessment sheet was used to document the findings, Patients who remained ventilated at the end of surgery were evaluated by an intensive care doctor after extubation according to the same protocol.

4 | STATISTICAL ANALYSIS

A power analysis was conducted to determine sample size. From existing data in our hospital the incidence of multiple laryngoscopy attempts was found to be 15% in a patient population with predictors of difficult direct laryngoscopy, and 5% in patients with normal airways at our institution. The hypothesis of this investigation was that application of Vivid-Trac video-Laryngoscope could correct this difference. Based on that data and the aim of detecting the hypothesized difference (10%) with 80% power at 0.05 significance, 141 patients per treatment group were needed. Therefore, the study was designed to enroll a total of 300 patients.

Data were compiled into a MS Excel spreadsheet and statistical analyses were performed using SPSS VERSION 2.0 Descriptive statistics were performed on all patient variables. A chi-square or Fisher exact test was used to compare categorical variables, and a two-sample *t* test was used to compare continuous variables between the two laryngoscopy groups. Statistical significance for all measures was deemed at $P < 0.05$ based on two-sided tests

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data is made, **Assumptions: 1.**Dependent variables should be normally distributed, 2.Samples drawn from the population should be random, Cases of the samples should be independent Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven1s test for homogeneity of variance has been performed to assess the homogeneity of variance.

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. Fisher Exact test used when cell samples are very small.

Significant figures:

+ Suggestive significance (P value: 0.05<P<0.10)

* Moderately significant (P value:0.01<P ≤ 0.05)

** Strongly significant (P value: P≤0.01)

Statistical software: The Statistical software namely SPSS 18.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc**.**

OBSERVATION AND RESULTS

Study design: A Comparative two group clinical study

TABLE 1: INTUBATION SUCCESS AT FIRST ATTEMPT DISTRIBUTION IN TWO GROUPS OF PATIENTS STUDIED : n(%)

Intubation success at first attempt	Direct laryngoscopy n(%)	Video laryngoscope n(%)	Total
No	32(21.3%)	9(6%)	41(13.7%)
Yes	118(78.7%)	141(94%)	259(86.3%)
Total	150(100%)	150(100%)	300(100%)

P<0.001**, Significant, Chi-Square Test

VDL(94%) has more intubation success rate at first attempt than DL(78.7%) and it is statistically significant with p value of less than 0.001

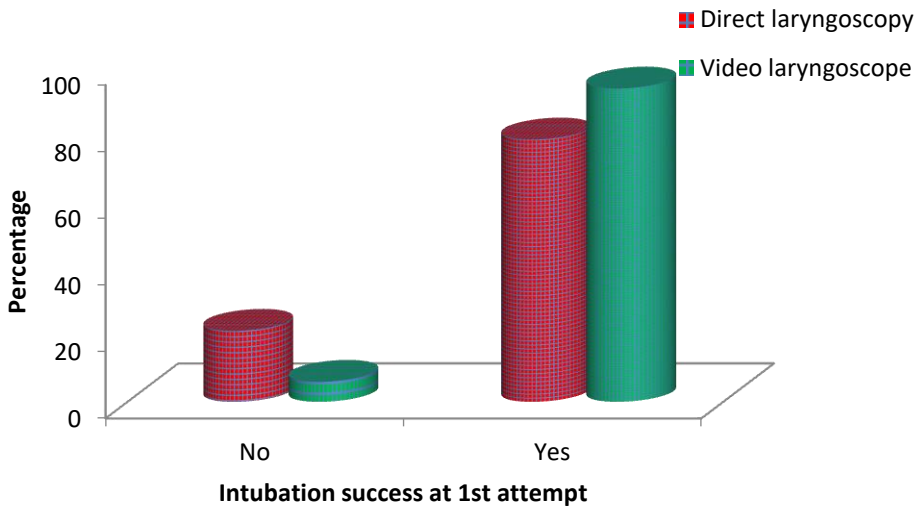

Figure 1: Comparison of Intubation success at first attempt between two groups

TABLE 2: LARYNGOSCOPY TIME DISTRIBUTION IN TWO GROUPS OF PATIENTS STUDIED: n(%)

Laryngoscopy time	Direct laryngoscopy n (%)	Video laryngoscope n(%)	Total
<30	18(12%)	0(0%)	18(6%)
30-50	132(88%)	93(62%)	225(75%)
>50	0(0%)	57(38%)	57(19%)
Total	150(100%)	150(100%)	300(100%)
Mean ± SD	32.99±4.96	49.21±4.18	41.10±9.33

P<0.001**, Significant, Student t test

Laryngoscopy time for VDL took 49.21 seconds whereas DL was 32.99 seconds and it is statistically significant with P value of less than 0.001. In other words VDL consumed more time than DL

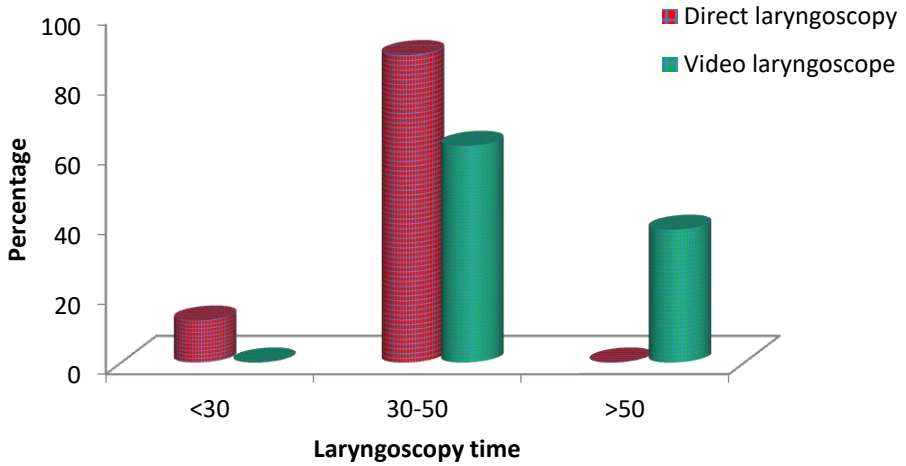

Figure 2: Comparison of Laryngoscopy time distribution between two groups

TABLE 3: EXTERNAL MANEUVERS (BOUGIE) DISTRIBUTION IN TWO GROUPS OF PATIENTS STUDIED: n(%)

External Maneuvers	Direct laryngoscopy n(%)	Video laryngoscope n(%)	Total
No	142(94.7%)	150(100%)	292(97.3%)
Yes	8(5.3%)	0(0%)	8(2.7%)
Total	150(100%)	150(100%)	300(100%)

P=0.004**, Significant, Chi-Square Test

External maneuvers were used only for DL (5.3%) whereas VDL did not require any(0%) and it is statistically significant with P value of 0.004

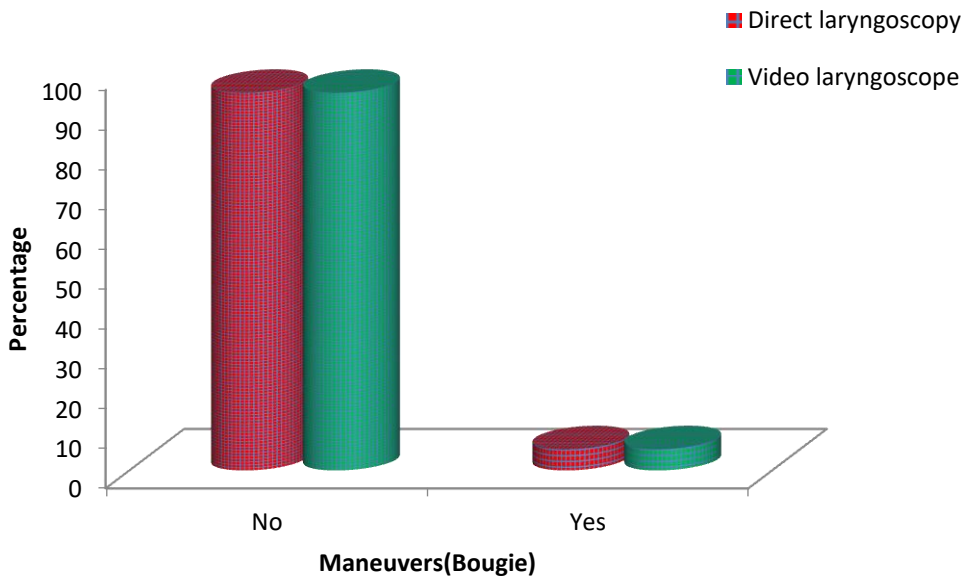

Figure 3: Comparison of external maneuvers (bougie) between two groups

TABLE 4: CL VIEW DISTRIBUTION IN TWO GROUPS OF PATIENTS STUDIED: n(%)

CL view	Direct laryngoscopy (n=150)	Video laryngoscope (n=150)	Total (n=300)	P value
I	0(0%)	150(100%)	150(50%)	<0.001**
II	26(17.3%)	0(0%)	26(8.7%)	<0.001**
III	77(51.3%)	0(0%)	77(25.7%)	<0.001**
IV	47(31.3%)	0(0%)	47(15.7%)	<0.001**

With respect to Cormack-Lehane view distribution between two groups. We observed that video laryngoscope showed better CL VIEW that is (100%) belonged to grade 1 than direct laryngoscope (0%) to grade 1, (17.3%) to grade II, (51.3%) to grade III and (31.3%) to grade IV it was statistically significant with P value of 0.001

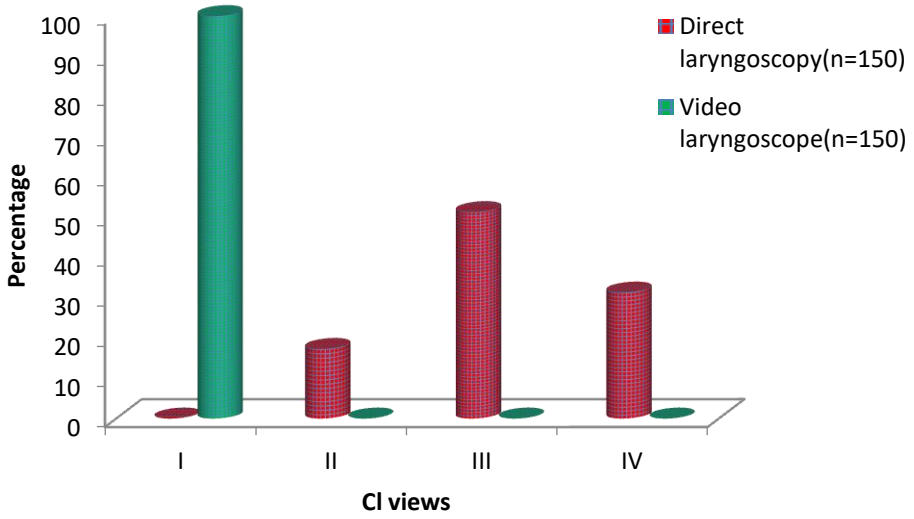

Figure 4: Comparison of CL VIEW distribution between two groups

5 | RESULTS

300 patients were approached for the proposed study and all chose to be enrolled. All patients of either sex belonging to ASA 1 AND ASA 2 had direct or vividtrac laryngoscope used successfully. 300 patients were randomized to receive either direct laryngoscope(150) or video laryngoscope(150).

VDL(94%) has more intubation success rate at first attempt than DL(78.7%)and it is statistically significant.(table 1)

Laryngoscopy time for VDL took 49.21 seconds whereas DL was 32.99 seconds and it is statistically significant. In other words VDL consumed more time than DL. (table 2)

External maneuvers were used only for DL (5.3%) whereas VDL did not require any(0%) (table 3) With respect to CL view distribution between two groups. We observed that video laryngoscope showed better CL VIEW that is (100%) belonged to grade 1 than direct laryngoscope (0%) to grade 1, (17.3%) to grade II, (51.3%) to grade III and (31.3%) to grade IV. And it is statistically significant.(table 4)

6 | DISCUSSION

Direct laryngoscopy using Macintosh laryngoscope has been used for laryngoscopy and intubation since 1943.Videolaryngoscope has been introduced to provide better laryngoscopic view on a video monitor and it can also potentially improve ease of intubation. The use of video laryngoscope in intubation is well established and has been extensively supported in the literature for managing the difficult airway. But its use for routine elective cases has not been studied in detail. Thus we prospectively evaluated the intubating conditions in 300 patients;150 in each group using Macintosh direct laryngoscope and Vividtrac Videolaryngoscope.

A hospital based prospective, randomized two parallel arm clinical study was done to compare intubation success with video laryngoscopy with direct laryngoscopy in a diverse predicted difficult airway patient population and among a large group of anesthesia providers.

In this routine clinical care environment, intubation success in the predicted difficult airway was higher with the vivid trac(94%) compared with direct laryngoscopy using a conventional Macintosh blade (78.7%). Laryngeal views were better and maneuvers to facilitate intubation were less with the Vividtrac. Laryngoscopy time was longer with the Vividtrac.

Haemodynamic stimulation and intubation-related trauma was lesser for vivid device. Management of the potential difficult airway remains a major clinical challenge. Unfortunately, despite predictive tests such as the Mallampatticlassification, mouth opening, and thyromental distance, no single factor reliably predicts these difficulties .[3]Consequently, many difficult intubations will not be recognized until after induction of anaesthesia. The rapid securing of the difficult airway, by means of tracheal intubation with an immediately available, easy-to-use alternative to the direct laryngoscope is a priority if complications are to be avoided. It has been previously demonstrated that the vividtrac possesses advantages over the Macintosh laryngoscopes when used by anesthetists,[4] inexperienced medical personnel [5], and novices [6] in simulated difficult laryngoscopy scenarios. Further support for the utility of the video laryngoscope in clinical settings likely to be associated with difficult airways, comes from reports of its effectiveness in facilitating tracheal intubation in a patient following traumatic asphyxia [7]. The video laryngoscope has also been demonstrated to be effective in morbidly obese patients presenting for surgery [8]. However, the utility of Vividtrac vs the

Macintosh laryngoscope has not been determined in a randomised clinical trial in patients at increased risk for difficult intubation.

In this study, parameters like interincisor gap, thyromental distance, modifiedmallampatti grade were taken into consideration to call it as predicted difficult airway.

Despite the limited exposure to the Vivid, its use resulted in a higher success rate while managing a difficult airway in our study population, which suggests easy adaptability of the Vividtrac system into routine clinical practice.

The higher intubation success rate noted in the Vividtracgroup is highly relevant. The success rate of direct laryngoscopy in this study (84%) was similar to our expected rate of success (85%) from database review. Reported first attempt success rates in case series for other video laryngoscopes in the setting of the predicted difficult intubation range from 72% to 99%. [9,10,11]

Two randomized controlled studies have compared videolaryngoscopy with direct laryngoscopy in the patient with apredicted difficult airway.[12,13]

In addition, the studies involved a smaller range of potential difficulty, and smaller provider groups of only two or three skilledvideolaryngoscopists. In contrast, the data discussed here represents a broad range of potential airway difficulties andcovered a broad surgical patient population. Moreover, the performance of 91 anesthesia providers was recorded in this study. Therefore, our study results have a high degree of validity as they reflect the performance of the two devicesunder routine anesthesia practice conditions, which involve adiverse group of providers treating a large variety of patients with predicted difficult airways. Improvement of laryngeal views as observed in this studyhas been described previously by the others.[14,15,16,17,18]

However, despite the repeated finding that video laryngoscopy improves view, a good laryngeal view does not always guarantee intubation success. For example, although they improve laryngeal views, video laryngoscopes with acutelycurved blades (*e.g.*, Glidescope®) still carry the risk of failure, likely because of difficulty with alignment of the endotrachealtube with the orotracheal axis.[19,20]

In other words, the chance of failingtracheal intubation despite an adequate laryngeal view wassimilar for both devices. Therefore, the overall higher success rate afforded by the Vividtrac in this study is likely related to the anterior extension and magnification of laryngeal view that is displayed on the screen, which is not available during conventional direct laryngoscopy.

In our study, following parameters were evaluated in adult patients in elective general anesthesia cases in our institute.

1.Cormack&Lehane grading of laryngeal structures
2.Number of attempts required
3.External manipulation
4.Duration of laryngoscopy and intubation.
5. Complications if any

Overall there was no statistical difference in demographics in 2 Groups. There were no significant differences in airway assessment using Cormack and Lehane grading and was comparable between 2 groups. This can be explained by the fact that the blades of Vividtrac and Macintosh are identical in design and the skills acquired using one device should be transferable to the other device and the two patient groups were of similar demographic. This study tested intubation success of two devices in a prospective randomized fashion and in a clinically relevant environment to demonstrate a success rate of 93% on first attempt utilizing the Vividtrac. The Cormack and Lehane grading system, although originally designed to compare glottic views at direct laryngoscopy,[21] provided a useful comparison of the direct and indirect laryngoscopic views achieved in this study. All patients intubated with the vividtrac had a grade 1 Cormack and Lehaneglottic view, compared to no patient in the Macintosh group. Fewer patients required additional maneuvers to improve glottic exposure with the vividtrac device.

However, the limitations of this latter measurement are acknowledged. All patients who sustained a significant arterial oxygen desaturation were in the Macintosh group. The lowest SaO2 values were seen in the situation where more than one attempt at tracheal intubation was required and where bag-mask ventilation had become suboptimal. The vividtrac resulted in less stimulation of heart rate and blood pressure post tracheal intubation in comparison with the Macintosh laryngoscope. In fact, the vivdtrac produced minimal haemodynamic stimulation in these patients. The relative contribution of laryngoscopy per se and insertion of the tracheal tube into the trachea to the degree of haemodynamic stimulation produced by the procedure of tracheal intubation is unclear. However, laryngoscopy alone has been demonstrated to produce similar increases in plasma adrenaline and noradrenaline to that seen with laryngoscopy followed by tracheal intubation.[22] Therefore, our finding probably reflects the fact that the vividtrac provides a view of the glottis without a need to align the oral, pharyngeal and tracheal axes, and therefore requires less force to be applied during laryngoscopy. The haemodynamic findings for direct laryngoscopy in our study were similar to those described previously.[23,24]In a recent study comparing the GlideScope (Verathon Inc., Bothell, WA) to the

intubating laryngeal mask airway, in which a near identical anaesthetic technique to that used in this study was utilized, no change was seen in heart rate, whereas blood pressure decreased slightly following tracheal intubation with both devices.[25] Taken together, these findings underline the potential for indirect laryngoscopes to produce less haemodynamic stimulation

In anticipated difficult airway, Vividtrac video laryngoscope has been shown to perform better in terms of shorter intubation time, higher success rate and less number

Of optimizing maneuvers.

Our data demonstrates that tracheal intubation with the vividtrac required less external laryngeal manipulation or use of a gum-elastic bougie, and suggests that better laryngeal view.

Existing case reports warn of the particular risk of oropharyngeal trauma associated with video laryngoscopy. We noted no pharyngeal injuries in this study although those

have been observed with other video laryngoscopes.[26,27,28,29,30,31,32,33]

The incidence of complications, such as lip trauma, dental trauma, pharyngeal injury, tracheal injury, or sore throat, were not different following the use of either the vividtracdevice or direct laryngoscopy.

Similar results to those seen with the Vividtrac have been demonstrated with other indirect laryngoscopes, such as the GlideScope[34] and video optical stylet.[35]Further comparative studies are needed to determine the relative efficacies of these devices

In conclusion, the vivid laryngoscope offers a new approach to tracheal intubation of patients at increased risk for tracheal intubation. It reduced the difficulty of tracheal intubation and the degree of haemodynamic stimulation compared with the Macintosh laryngoscope in these patients. These findings demonstrate the efficacy of the Vivid video Laryngoscope in this clinically important group of patients, and is a potentially useful device.

7 | CONCLUSION

A diverse group of anesthesia providers achieved a higher intubation success rate on first attempt with the Vividtrac in a broad range of patients with predictors of difficult intubation. Vividtrac laryngoscopy seems to be a useful technique for the initial approach to a potentially difficult airway. Vividtrac laryngoscope offers a new approach to tracheal intubation of patients at increased risk for tracheal intubaton with lesser degree of haeodynamic stimulation compared to Macintosh laryngoscope

VIVID TRAC VIDEOLARYNGOSCOPE

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