Original Article

A randomised comparative study of "videoendoscope" with the Truview EVO2, C-MAC D blade videolaryngoscope and the Macintosh laryngoscope

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ABSTRACT

Background and Aims: Videolaryngoscopes are crucial components of a difficult airway cart. Issues of cost and availability, however, remain a problem. We compared the combination of an endoscope used in conjunction with the Macintosh laryngoscope with established videolaryngoscopes and the Macintosh laryngoscope using the intubation difficulty scale (IDS) score. **Materials and Methods:** A prospective randomised study including 120 adult patients, American Society of Anaesthesiologists (ASA) physical status I–III, with an anticipated difficult airway scheduled for elective surgery were randomly allocated to one of four groups: Truview EVO2 (group 1), C-MAC D Blade (group 2), videoendoscope (group 3), or Macintosh laryngoscope (group 4). The IDS score was the primary outcome. Secondary outcomes included the Cormack–Lehane grade, time to tracheal intubation, haemodynamic responses, and adverse events. **Results:** A significant proportion of patients in groups 2 and 3 had an IDS score of zero (73.3 and 70%, respectively). IDS scores were significantly lower in the C-MAC D blade and videoendoscope groups attributable to differences in parameters N4, N5 and N6 [C/L grades, lifting force and laryngeal pressure required] ($P < 0.001$). The C-MAC D blade and the Macintosh laryngoscope required less time for intubation as compared to the Truview EVO2 and videoendoscope. No differences were noted in post-intubation haemodynamic parameters and other adverse events. **Conclusion:** The performance of videoendoscope was comparable to C-MAC D Blade and superior to Truview EVO2 and Macintosh laryngoscope with respect to the IDS score and may thereby provide an effective alternative to commercial videolaryngoscopes in low resource settings.

Key words: Anaesthesia, endoscope, intubation, laryngoscopy, videolaryngoscope

INTRODUCTION

Observation of real-time passage of an endotracheal tube through the vocal cords is considered the gold standard for its placement. Alignment of the oral, pharyngeal, and laryngeal axes is essential for viewing the glottis with a direct laryngoscope. This line of sight visualisation may not be attainable due to some anatomic factors resulting in failure of direct laryngoscopy.[1,2] Videolaryngoscopes have come to occupy this crucial niche in the field of airway management as the alignment of these three axes is not a prerequisite for the successful placement of tracheal tubes. However, the issue of cost remains a critical impediment to the availability of these devices. To overcome this problem, we used an endoscope, an almost universally available component in the surgical suite due to the increasing popularity of laparoscopic and endoscopic surgery, to facilitate visualisation of the glottis. Anecdotal case reports have attested the usefulness of these

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devices in difficult airway scenarios, more so when commercially marketed devices were unavailable.[3,4] However, their performance has never been formally evaluated vis-à-vis the "standard" devices. Use of these endoscopes has real world applications, helping solve a major problem with the resources at hand.[5] Our "videoendoscope" consists of a 5 mm external diameter, 30° lateral illumination laparoscope used in conjunction with a Macintosh laryngoscope. We used the intubation difficulty scale (IDS) score, a function of seven parameters to determine intubation complexity.[6] This study evaluated the videoendoscope vis-à-vis established "videolaryngoscopes" [Truview EVO2 (Truphatek International Ltd., Israel) and C-MAC D Blade (Karl Storz, Germany)] and the standard-of-care "Macintosh laryngoscope." The primary objective was to compare and evaluate the IDS score with the different airway devices. Secondary objectives were the Cormack–Lehane (CL) grade, time to tracheal intubation (TTI) and time to best laryngeal view (TLV), haemodynamic responses and incidence of complications. We hypothesised that the videoendoscope was equivalent to the Truview EVO2, C-MAC D Blade videoendoscope and Macintosh laryngoscope with respect to the IDS score.

MATERIALS AND METHODS

After approval from our institutional ethics committee and registration with the Clinical Trial Registry of India (CTRI/2015/10/006254), written informed consent was obtained from 120 adult patients of American Society of Anaesthesiologists (ASA) physical status I–III requiring elective surgery under general anaesthesia with tracheal intubation having at least one of the following predictors of difficult intubation: history of difficult intubation in previous anaesthetic experience, thyromental distance ≤6 cm, sternomental distance ≤12 cm, limited neck extension and a modified Mallampati grade of III or IV.

Patients were excluded if an inter-incisor distance <3 cm, respiratory tract infection, cervical spine injury, or risk factors for gastric aspiration were present. Relevant observations were noted by an independent, unblinded observer.

The allocation sequence was generated using random number tables, and then concealed in sealed envelopes which were opened once patient's consent was obtained and the patient shifted to the operating room. Patients were randomised for tracheal intubation using one of the following four devices: Truview EVO2 (group 1), C-MAC D Blade (group 2), Videoendoscope (group 3), and Macintosh laryngoscope (group 4) [Figure 1].

Baseline data along with airway details (inter-incisor distance, modified Mallampati class, thyromental and sternomental distances and the subjective assessment of neck extension) were recorded. Standard monitoring including an electrocardiogram (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), end-tidal carbon dioxide, anaesthetic agent levels, and bispectral index (BIS; Aspect Medical Systems) were used in all patients. All patients received fentanyl citrate 2 mcg/kg IV prior to induction of anaesthesia. After preoxygenation, anaesthesia was induced with propofol (1.5-3 mg/kg) till loss of verbal response. Following the induction of anaesthesia, patients were manually ventilated with sevoflurane 0.6–1.5% in 100% oxygen and a non-depolarising neuromuscular blocking agent was administered. The choice of the neuromuscular blocker was left to the discretion of the attending anaesthesiologist. Laryngoscopy and tracheal intubation were then performed using the allotted device ensuring that the BIS was below 60. Propofol boluses were administered to maintain an adequate depth of anaesthesia when required. Following tracheal intubation, further management was as per the primary anaesthesiologist.

Tracheal intubation was performed in each patient by one of the two anaesthesiologists (A.P. or B.S.). When using the Truview EVO2, the tracheal tube was loaded onto the manufacturer provided preformed stylet. Oxygen was continuously insufflated via the side port.

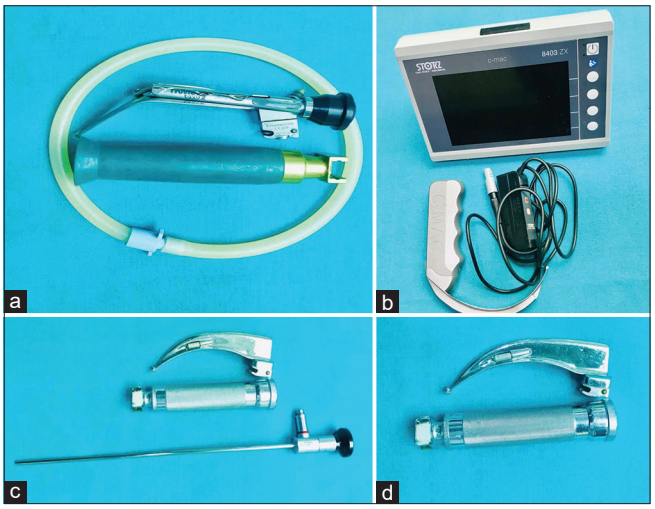

Figure 1: (a) Truview EVO2 with O_2 insufflation tube, (b) C-MAC D Blade with monitor, (c) Videoendoscope and, (d) Macintosh laryngoscope

Additionally, we warmed the blade with warm water and used defogging agents as appropriate to mitigate fogging. A stylet (bent into a J shape) was also used along with the C-MAC D-Blade.

The videoendoscope consists of a surgical endoscope (Jarit 600–780 autoclavable, 5.0 mm external diameter, 30° lateral illumination) used in conjunction with a Macintosh blade (size 3). The endoscope was attached to a standard light source (Karl Storz Xenon Nova 20131520) and a video camera (Olympus OTV-SX). Following introduction of the Macintosh laryngoscope in the oral cavity (in the standard manner), an assistant introduced the endoscope along the flange of the Macintosh blade (from the right side of the anaesthesiologist) approximately 3–4 cm till the glottis was visualised on the monitor. The light cord was kept at the 6 o'clock position during this manoeuvre and a stylet used to facilitate tracheal intubation. An oral endotracheal tube was then introduced from the right lateral corner of the mouth into the glottic aperture guided by the endovision display monitor.

The primary outcome was the IDS score described below.[6]

N1: Number of attempts >1
N2: Number of operators >1
N3: Number of alternative techniques used
N4: Cormack grade - 1
N5: Lifting force required
normal N5 = 0
increased N5 = 1
N6: Laryngeal pressure
not applied N6 = 0
applied N6 = 1
N7: Vocal cord mobility
abduction N7 = 0
adduction N7 = 1
Total IDS = Sum of scores (N1 - N7)

The degree of difficulty was graded as 0: easy, $0 < IDS \leq 5$: slight difficulty, $5 < IDS$: moderate to major difficulty, $IDS = \infty$ impossible intubation

Secondary outcomes included the CL grade, time to tracheal intubation, haemodynamic responses and complications (dental/mucosal trauma, postoperative sore throat or hoarseness), if any.

The duration of intubation was defined as the time taken from the insertion of the laryngoscope blade between the teeth till the appearance of the capnography trace confirming tracheal intubation. A maximum of three intubation attempts were permitted, following which the attempt was noted as a failure and intubation attempted using a device as per

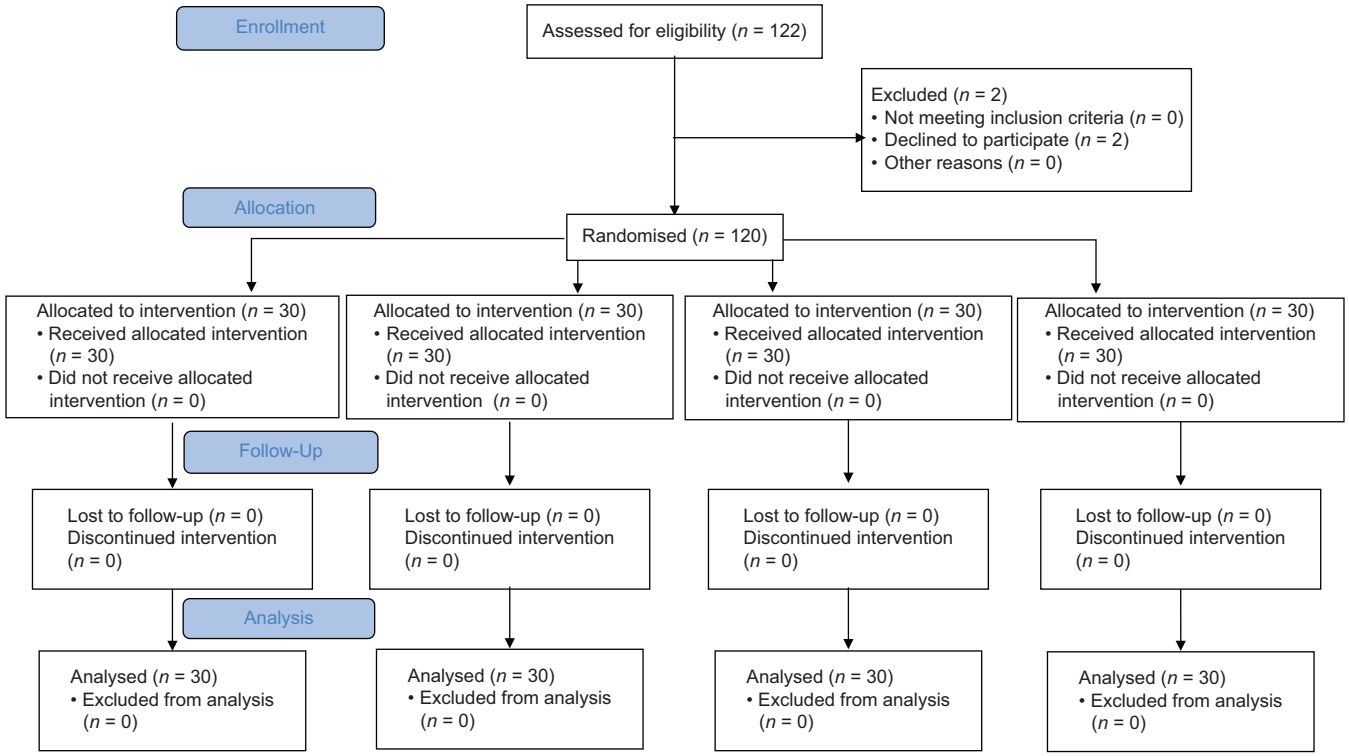

Figure 2: Consort flow diagram

the primary anaesthesiologist's discretion.

Statistical analysis

Sample size was estimated based on the IDS score. Based on previous studies,[7,8] we considered 2.0 as a clinically significant reduction in the IDS score. Using $\alpha = 0.05$ and $\beta = 0.2$, we estimated that we would need 29 patients for each of the four groups. We, therefore, enrolled 30 patients in each group anticipating possible losses.

Statistical analysis was performed using the Statistical Package for Social Sciences version 17.0 (SPSS 17.0). Continuous variables were presented as mean ± standard deviation (SD) or median and interquartile range. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using analysis of variance (ANOVA) with post-hoc analysis. Nominal categorical data between the groups was compared using Chi-square test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Kruskal Wallis test and further paired comparisons were performed using the Mann–Whitney U test. For all statistical tests, a *P* value less than 0.05 was taken to indicate a significant difference.

RESULTS

We recruited 120 patients who were randomised into four groups all of whom completed the study as shown in the CONSORT flow chart [Figure 2]. Patient characteristics and airway details of patients were comparable in all four groups [Table 1]. The median and interquartile range for IDS scores was significantly higher with the use of the Macintosh laryngoscope compared to the other groups and was significantly higher with the Truview EVO2 when compared to the C-MAC D-Blade and the videoendoscope [Table 2] [$P < 0.001$]. This significant difference in the IDS scores was mainly attributable to the differences in parameters N4, N5, and N6 (CL grade-1, lifting force required and laryngeal pressure respectively) [$P < 0.001$]. The Truview EVO_2, C-MAC D Blade and videoendoscope provided significantly better CL grade views as compared to the Macintosh laryngoscope. The C-MAC D Blade and videoendoscope required normal lifting force in 28 and 27 patients respectively; the other two devices requiring an increased lifting force in a higher proportion of patients. Laryngeal pressure was not applied in most patients in the C-MAC D Blade and videoendoscope groups. The other two groups required the application of laryngeal pressure in a significant number of patients. A significant proportion of patients in groups 2 and 3 had an IDS score of zero (73.3 and 70%, respectively).

The time required for optimal laryngeal view (TLV) and tracheal intubation (TTI) also differed significantly. The least amount of time for both endpoints was achieved with the use of the Macintosh laryngoscope or the C-MAC D Blade. The Truview EVO2 and the videoendoscope required a significantly longer time for both [Table 3].

No differences were noted in haemodynamic parameters following intubation. There were no differences in the incidence of complications between the groups, including postoperative sore throat, blood on the tracheal tube or laryngoscope blade.

Post-surgical intubation related adverse events were seen in a very small number of cases. There was no significant difference among the four groups. One

Table 1: Patient characteristics and airway details

	Group 1 (*n*=30)	Group 2 (*n*=30)	Group 3 (*n*=30)	Group 4 (*n*=30)	*P*
Age (years)	46.6±14.16	46.97±15.06	45.03±15.08	46.22±14.63	0.962
Weight (kg)	78.27±26.281	84.20±34.11	72.43±15.19	82.27±27.10	0.332
Height (m)	1.62±0.079	1.64±0.093	1.64±0.071	1.63±0.078	0.748
BMI (kg/m^2)	29.75±10.38	30.91±11.12	26.88±5.33	29.54±9.33	0.322
ASA physical status I/II/III	9/12/9	13/10/7	14/14/2	15/6/9	0.133
Previous difficult intubation (Y/N)	30/1	29/1	30/0	30/0	0.388
Inter-incisor distance (cm)	4.08±0.57	4.10±0.63	4.10±0.49	4.23±0.61	0.736
Modified Mallampati Class 1/2/3/4	0/0/18/12	0/1/18/11	1/2/15/12	1/0/21/8	0.538
Thyromental distance (cm)	6.95±0.968	7.05±1.093	7.05±1.093	7.07±1.006	0.971
Sternomental distance (cm)	11.78±1.649	11.90±1.561	11.98±1.506	11.68±1.50	0.886
Neck movement (normal/restricted)	10/20	17/13	18/12	15/15	0.167

Data reported as absolute numbers (*n*) or as mean±SD. *$P<0.05$ is considered statistically significant. Group 1: Truview EVO_2, Group 2: C-MAC D Blade, Group 3: Videoendoscope, Group 4: Macintosh laryngoscope

Table 2: Intubation Difficulty Scale (IDS) scores

IDS	Group 1 (*n*=30)	Group 2 (*n*=30)	Group 3 (*n*=30)	Group 4 (*n*=30)	*P*
Median (IQR)	1.5 (1-2)	0 (0-1)	0 (0-1)	2 (1-3.25)	<0.001*
Proportion of patients with IDS=0	6 (20%)	22 (73.3%)	21 (70%)	4 (13.3%)	<0.001*
N1 (0/1)	27/3	30/0	28/2	29/1	0.320
N2 (0/1)	28/2	30/0	30/0	29/1	0.288
N3 (0/1)	30/0	30/0	30/0	30/0	-
N4 (0/1/2)	19/11/0	25/5/0	26/2/2	6/18/6	<0.001*
N5 (0/1)	16/14	28/2	27/3	15/15	<0.001*
N6 (0/1)	13/17	27/3	23/7	11/19	<0.001*
N7 (0/1)	30/0	30/0	30/0	30/0	-

Data reported as absolute numbers (*n*), percentage (%), median and interquartile range (IQR). **P*<0.05 is considered statistically significant. Group 1: Truview EVO_2, Group 2: C-MAC D Blade, Group 3: Videoendoscope, Group 4: Macintosh laryngoscope

Table 3: Time taken for optimum view and intubation

	Group 1 (*n*=30)	Group 2 (*n*=30)	Group 3 (*n*=30)	Group 4 (*n*=30)	*P*
Time to intubation (s)	52.00±22.87	30.73±10.90	50.57±33.74	29.73±11.65	<0.001*
Time to optimum view (s)	21.28±11.97	11.10±4.06	21.37±14.35	13.00±7.89	<0.001*

Data reported as mean±SD. **P*<0.05 is considered statistically significant. Number (*n*), second (s). Group 1: Truview EVO_2, Group 2: C-MAC D Blade, Group 3: Videoendoscope, Group 4: Macintosh laryngoscope

case in each group reported sore throat following extubation. One case in the Truview EVO2 group had a tinge of blood on the tracheal tube following extubation.

DISCUSSION

It has been argued that videolaryngoscopes may supplant direct laryngoscopes in the foreseeable future, providing a visual and easily retrievable record of patients' airway parameters.[9] They are expensive devices however, and in the face of limited and often inadequate budgetary allocations, remain a distant dream in most public sector hospitals in the developing world.

Endoscopes, in their various avatars (forms), are increasingly being used to facilitate varied surgical procedures. Thus, they are relatively easier to obtain. In addition, they have been used to assist in a variety of difficult airway scenarios.[3,4,10,11] Prior studies have demonstrated improved glottic visualisation with their use.[12,13] However, their performance has never been evaluated in comparison with commercially available videolaryngoscopes in a difficult airway scenario.

The IDS score, devised by Adnet *et al.*, has been used as a quantitative retrospective indicator to gauge the degree of difficulty in intubation.[6] Our study found that the use of the videoendoscope resulted in consistently lower IDS scores, comparable to the C-MAC D Blade and better than those produced by the Truview EVO2 and the Macintosh laryngoscope. The major contributions to this difference in IDS scores were observed in parameters N4, N5, and N6 (CL grade - 1, lifting force required and laryngeal pressure respectively). The 30° angulation of the endoscope allows glottic visualisation sans the alignment of the oral-pharyngeal-laryngeal axes, thereby, reducing both, the required lifting force (N5) and the laryngeal pressure (N6) while concomitantly providing a better CL grade. Improvement in CL views has also been demonstrated in multiple other studies.[12,14,15] The improvement in glottic view also explains the reduced requirement of laryngeal pressure and an increased lifting force with the use of videolaryngoscopes. Barak *et al.* drew similar conclusions when comparing the Truview EVO_2 with the Macintosh laryngoscope in adult patients.[16]

Intubation using the Truview EVO2 and videoendoscope required a relatively longer time. In addition, the use of these devices also delayed glottic visualisation. This has been reported in earlier studies with the Truview EVO2, probably due to the unique blade design, refraction angle of the lens, and the differing laryngoscopy technique.[16,17] Fogging of the lens contributes to this problem, despite measures taken to prevent it. The use of the videoendoscope entails insertion of the Macintosh blade, following which the endoscope is introduced in the oral cavity and involves an assistant to position the endoscope. Additionally, the use of the videoendoscope requires not only good hand-eye coordination, but also the concerted effort of two individuals. These two factors

explain the relatively longer time required for both glottic visualisation and tracheal intubation when using the videoendoscope. The least amount of time was required when using the Macintosh laryngoscope, probably an indication of the level of comfort anaesthesiologists have when using the Macintosh laryngoscope. The C-MAC D Blade required only a slightly longer time. However, the increased time required when using the Truview EVO2 and the videoendoscope is unlikely to be clinically important as there were no significant differences in episodes of desaturation or trauma to the airway with the use of these devices.

While there have been case reports demonstrating the use of zero and 70° endoscopes to facilitate tracheal intubation, we used the 30° endoscope as it is most commonly used for laparoscopic surgical procedures.[3,10,11] Second, we believe a 30° endoscope allows insertion along the flange of the Macintosh blade. The Macintosh laryngoscope is a device that anaesthesiologists worldwide are familiar with, and as such considerably reduces the learning curve associated with using the videoendoscope. In addition, the 30° angle provides a visual axis that is more aligned with the direct line of sight facilitating insertion of the tracheal tube. This also allows the flange of the laryngoscope to be used as a guide while inserting the endoscope. The relatively easy learning curve allows proficiency in its use to be achieved after using the device just a few times.

While our study supports the use of a videoendoscope to aid in the management of difficult airways, a few drawbacks do exist. Videoendoscope use requires two individuals who need to be familiar not only with the technical aspects of device use but also need to communicate effectively. In addition, setting up the apparatus requires some amount of time, and may not be suitable in emergent situations.

A few limitations exist in our study. It was not possible to blind the anaesthesiologist to the device being used. Second, the measures used to assess a difficult airway are rather subjective, and as such not all patients enrolled in our study presented with difficulty on laryngoscopy/intubation. Further, we used a limited number of predictors that are routinely used at our institution to identify difficult airways. Also, there is some controversy as to the applicability of the IDS score when comparing indirect (video) laryngoscopes with direct laryngoscopes.[18] It is however, well accepted for comparisons between different videolaryngoscopes.

CONCLUSION

All three videolaryngoscopes facilitated relatively "easy" intubations in situations of anticipated airway difficulty. The performance of the videoendoscope was comparable to C-MAC D Blade and superior to Truview EVO2 and Macintosh laryngoscope with respect to the IDS score. The increasing popularity of laparoscopic procedures ensures the availability of an endoscope in most settings. The videoendoscope may thus offer an effective alternative to commercial videolaryngoscopes in low resource settings, providing a de facto videolaryngoscope when needed.

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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