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Comparative Study between Trueview PCD Video Laryngoscope and Flexible Fiber Optic Bronchoscope for Awake Oral Intubation in Difficult Airway Patients

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Abstract

Background: Difficult airway leading to failed intubation are the foremost causes of anesthesia related morbidity and mortality. Newer developments in airway management has resulted in the pioneering of various optical and vedio laryngoscopes. In anticipated difficult airway patients, awake intubation using flexible fiber optic bronchoscope is the method of choice. Truview PCDTM laryngoscope is designed to help positioning of the endotracheal tube and also to record entry of the tube into glottis. *Aims:* To study and compare the effectiveness of fiber optic bronchoscope and Trueview PCDTM video laryngoscope in patients undergoing awake oral tracheal intubation in difficult airway situations. *Study design:* This was a prospective randomized study. *Methodology:* Sixty patients with ASA physical status classification I and II undergoing elective surgery under general anesthesia were randomized into two Groups; Group I (Trueview PCDTM video laryngoscope) and Group II (fiber optic bronchoscope). Intubation time, intubation attempts, Cormack and Lehane Grade (CLG), hemodynamic response, complications, were recorded. *Results:* Group II (88.10 ± 4.20 seconds) has significantly longer intubation time compared to Group I (58.00 ± 11.49 seconds). Intubation on first attempt observed in 76.7% patients in Group I compared to Group II (70%). CLG Grade I observed in 73.3% patients in Group I compared to Group II (80%). Better glottis visualization seen in Group II than Group I which is not significant. Hemodynamic parameters did not show significant difference among the two Groups. *Conclusion:* Trueview PCDTM video laryngoscope could be a suitable auxiliary to flexible fiber optic bronchoscope in difficult airway situations.

Keywords: Difficult airway; Flexible fiber optic bronchoscope; Oral intubation; Trueview PCD video laryngoscope.

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Introduction

During customary practice, airway management using direct laryngoscopy and endotracheal intubation remains a challenge for anesthesiologists in patients with difficult airway situations. We commonly experience problems like ineffective ventilation, difficult intubation or esophageal intubation which in turn increases the incidences of adverse respiratory events.[1] Failure of oxygenation leads to hypoxia followed by brain damage, cardiovascular dysfunction and finally death.[2]

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Morbidity and mortality related to anesthesia are most commonly due to debacle of airway management. Now-a-days, in awake, sedated, and anesthetized patients, flexible fiber optic bronchoscope (FFS) has become a boon for difficult airway management. At the annual meeting of the American Society of Anesthesiologists (ASA),[3] its use has been taught and recognized in guidelines for management of both anticipated and unanticipated difficult airways.[4–7] During awake fiber optic intubation, passage of endotracheal tube specially through nose is associated with intense painful stimulation. Sedation provides anxiolysis and amnesia and help to smooth the intubation process, but cannot adequately anesthetized the upper airway. Therefore, local anesthetics are needed for application in upper airway to suppress the gag and cough reflexes before awake fiber optic bronchoscope guided intubation for patient comfort and safety.[8] Glottic visualization using fiber optic endoscope is associated with less force, but the need of maneuvers or instruments to clear the airway result in hemodynamic response.[9] Video laryngoscopy guided intubation has been extensively used in the past due to several advantages: These are:

(1) In difficult airway situation there is improved laryngeal visualization without the need for aligning oral, pharyngeal and laryngeal airway axes.[10]

(2) Due to high quality and magnified view, it is easy to see the airway anatomical structures, anomalies, and easy manipulation of airway devices can be done if required.[11]

(3) Laryngoscopy and intubation can be seen by whole team on the monitor, this facilitates team communication and improve co-ordination between intubating person and other members of team, thus simply changes difficult airway management from "I" to "we".[12,13] At present, numerous Video Laryngoscopes (VL) are available, and the number constantly increasing. The prism and lens system in corporated in Truview PCD™ (Truphatek International Ltd., Netanya, Israel) provides indirect visualization of the larynx at an *angle of 46°* refraction.[14] The conclusion of the endotracheal tube through the glottis can be done with Opti-Shape™ (a pre-formed) stylet. In patients with restricted head and neck movements Truview PCD laryngoscope is one of the devices useful for tracheal intubation.[15,16] The use of stylet or laryngeal manipulations may increase the hemodynamic response. There are numerous studies available to compare vedio laryngoscopy to direct laryngoscopy in patients with one predictor of a difficult airway and observed increased success rate of endotracheal intubation in first attempt,[17–20] improved Cormack and Lehane Grade[19–22] and decreased intubation time.[19,20,22] Though fewer studies are available to compare the intubation time, intubation attempts, hemodynamic changes, Cormack and Lehane glottis view between Trueview PCD™ video laryngoscope and fiber optic bronchoscope. Hence, we decided to compare Trueview PCD™ video laryngoscope and flexible fiber optic bronchoscope for oral intubation in patients with difficult airway.

Materials and Methods

After approval of the institutional Ethics committee and informed consent of the patients, the study was conducted in prospective randomized manner in the Department of Anesthesia, Uttar Pradesh University of Medical sciences, Saifai, U. P., India, from *January 2018* to *December 2018*. Sixty patients of both sex, ASA physical status classification I and II, mallampati class 3 and 4, Body Mass Index (BMI) < *30 kg/m²* and aged *18–65 years*, posted for elective surgery under general anesthesia requiring endotracheal intubation were registered in the study. Patients with ASA physical status classification III and IV, allergic, restricted mouth opening, bleeding tendency, patient refusal, severe renal or hepatic disease, chronic hypertension, ischemic heart disease, left ventricular failure and major cardiac disorders were excluded from the study. After thorough pre-anesthetic evaluation, 60 patients were selected and divided into two Groups, Group I (Trueview PCD video laryngoscope) and Group II (fiber optic bronchoscope) of 30 each, using a computer generated random number table. Patients were administered tablet ranitidine *150 µg* and alprazolam *0.5 µg* orally one night before and in the morning *two hour* before surgery. After arrival in the operating room, peripheral intravenous (I.V.) access was achieved with 18 G cannula and Ringer's Lactate (RL) solution was started at $6\ \mu l/kg^{-1}$. Standard monitoring devices including pulse oximetry (SpO_2), Non-invasive Blood Pressure (NIBP), Electrocardiogram (ECG), and end-tidal partial pressure of carbon dioxide ($EtcO_2$) were applied and baseline parameters were recorded. In our study awake intubation was considered when sedation equivalent to a Ramsay sedation score 3 with spontaneous breathing was achieved. Topical anesthesia of mucosa of the tongue and oropharynx was done with lignocaine (10%) spray for *30 seconds* prior to sedation. Propofol infusion started at $100\ \mu g/kg^{-1}/minute^{-1}$ and increased gradually till target

Ramsay sedation score 3 (Grade I: Anxious or restless or both, Grade II: Co-operative, oriented and tranquil, Grade III: Responsive to commands, Grade IV: Brisk response to responsive to stimulus, Grade V: Sluggish response to stimulus, Grade VI: No response to stimulus) has reached. Pre-oxygenation done for *3 minutes* using 100% oxygen and the oral intubation was performed by well-trained anesthesiologist after Ramsay sedation score 3 with each of the devices being tested. In Group I, Truview PCD™ vedio laryngoscope was inserted from midline position and Cormack and Lehane Grade (CLG) as seen on the monitor was noted**.** Opti Shape™ stylet used for intubation by visualizing the glottis on the monitor. No laryngeal manipulation was done either to improve the CLG or to aid intubation. To avoid fogging, *10 liters/min* of oxygen was insufflated through the specified port. In Group II, under similar intubating conditions, fiber optic bronchoscope was inserted orally through bite block into the hypopharynx. After fiber optic bronchoscope entered into the trachea, the tube was advanced to the distal trachea and subsequently pulled to a distance of *3 cm* from the carina to prevent accidental selective intubation to the main bronchi. Finally, the cuff was inflated, bilateral entry checked, and general anesthesia was induced and maintained with 67% N_2O in 33% O_2 and isoflurane using controlled ventilation. The primary outcome measure was success of Endotracheal Tube (ETT) placement as evidenced by chest auscultation and appearance of capnograph waveform. Secondary outcome measures were intubation time (*seconds*) by using stopwatch **(**the time from start of insertion of VL or FFS till appearance of $EtcO_2$ waveform), intubation attempts (intubation time > *3 min* considered as failed attempt), Cormack and Lehane Grade, hemodynamic parameters *i.e.*, heart rate using ECG, systolic blood pressure, diastolic blood pressure were recorded before sedation (baseline) and then recorded after Ramsay sedation score 3, immediately after tracheal intubation, thereafter, every *one minute* till *5 minutes*. Trauma to the airway that occurred during manipulation regarding injury to gums and blood on the tube at extubation was noted. Once the airway was secured, anesthesia was conducted according to the choice of the attending anesthesiologist.

Sample Size

After discussion with our institutional statistician, on the basis of the previous studies[24] data, a sample size of 30 patients per group will attain 80% power to detect a relevant difference in successful intubation time between the two techniques with a significance level (a) of 0.05 using a sample t-test.

Statistical Analysis

The results are presented in frequencies, percentages and mean ± SD. To compare categorical variables between the Groups, Chi-square test was used. Unpaired t-test was used to compare the continuous variables between the groups. The repeated measures of analysis of variance was carried out to find the effect of time and time to group interaction in the change in continuous variables from prior to sedation to subsequent time periods. The result was considered significant with p-value < 0.05 and highly significant for p-value < 0.01. The data analysis was carried out on Statistical Package for Social Sciences (SPSS) 16.0 version (Chicago, Inc., USA).

Results

Sixty patients were recruited for the study, and none were excluded as shown in **Consort Chart 1**. Both Groups were comparable in terms of age, gender, anthropometric measurements, ASA physical status classification.

Discussion

In patients with difficult airway, traditional laryngoscope provides a poor view whereas Trueview PCD video laryngoscope was designed to provide better view of the larynx. It works on the optical principle of light refraction and show a more anterior view of larynx and makes an intubation to be performed under direct visualization more frequently compared to conventional laryngoscope. In recent years, flexible fiber optic intubation is an essential facility for an airway management specialist, as found useful in several situations like difficult airway, cervical spine risk, one-lung isolation, endotracheal tube exchange and tracheo-bronchoscopy. In our study, the demographic characteristics *i.e.*, age, sex, ASA classification, mallampati Grade, body mass index, were comparable among the Groups, shown in **Table 1**. Intubation time was found significantly shorter in Group I (58.00 ± 11.49 seconds) compared to Group II (*88.10 ± 4.20 seconds*) with p value < 0.0001, shown in **Table 2.** A similar study by Alhomary M *et al.*[23] who conducted a meta-analysis to compare the video laryngoscopy and fiber optic bronchoscopy for awake tracheal intubation and observed that intubation time was shorter in video laryngoscopy patients (seven trials, 408 participants, mean difference (95% CI) -45.7 (-66.0 to -25.4) s, $p < 0.0001$, low-quality evidence). Another study done by Essam Abd *et al.* Halim Mahran *et al.*[24] found that time to intubation was shorter in glidescope video laryngoscope (70.85 ± 8.88 S) than in flexible fiber optic bronchoscope (90.26 ± 9.41 S) which was significant. Our study has also been supported by R. Riveros *et al.*[25] where they studied 130 patients (*0* to *10 years of age*) the median tracheal time to intubation were *39 seconds*, *44 seconds* and *23 seconds* with Glidescope, Truview[PCD] vedio laryngoscope and direct laryngoscope respectively, with mean differences of *14 seconds* between Glidescope and direct laryngoscope and *17 seconds* between Truview[PCD] vedio laryngoscope and direct laryngoscope. They concluded that intubation time was more with Trueview[PCD] laryngoscopy compared to glidesocope and macintosh laryngoscopy. We also observed the number of intubation attempts, shown in **Table 2**. First attempt successful intubation observed in Group I patients (76.7%) compared to Group II (70%) and the difference was statistically not significant between the Groups (p = 0.38). Similar results were observed by Alhomary M *et al.*[23] on meta-analysis to compare the video laryngoscopy and fibre optic bronchoscopy for awake tracheal intubation and found no significant difference on first attempt success rate. Another study performed by Essam Abd *et al.* Halim Mahran *et al.*[24] observed that difference between success rate of the first intubation attempt was similar between the glidescope video laryngoscope group (22 patients, 81.5%) and fiber optic bronchoscope (21 patients, 78.8%). A study conducted by R Riveros

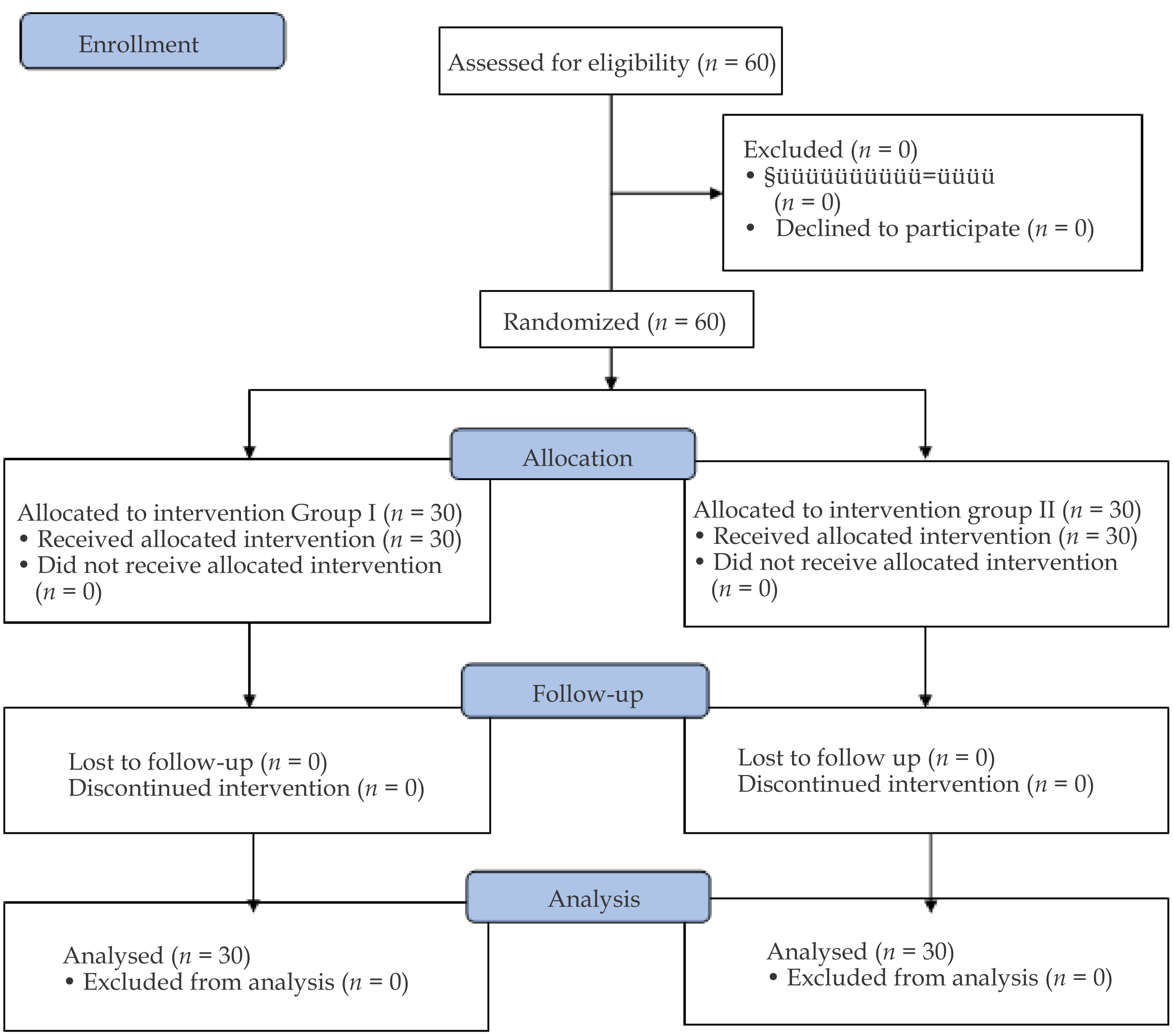

Chart 1: Consort Flow Diagram: Group I = Trueview PCDTM vedio laryngoscope; Group II = flexible fiberoptic bronchoscope.

et al.[25] observed no differences between the three randomization groups in either intubation success rate on the first attempt or in the occurrence of the complications. The success rates on the first attempt intubation were 95% for the Glide Scope group, 87% for the Truview PCD group, and 98% for the direct Laryngoscopy Group. Salama AK *et al.*[26] observed 100% success rate with video laryngoscope after first intubation attempt compared to fiberoptic laryngoscope (73.3%). But the difference observed was statistically significant (*p* value < 0.001). The reason for observed difference might be due to neuromuscular blocking agent used for intubation. In our study shows, Cormack and Lehane Grade I seen in 73.3% patients and Grade II seen in 26.7% in Group I while Cormack and Lehane Grade I was shown by 80% patients and Cormack Lehane Grade II was shown by 20% in Group II, shown in **Table 2,** displayed in **Chart 1**. But the difference observed was not significant (*p* = 0.54). Our findings have been supported by the study conducted by Essam Abd El Halim Mahran *et al.*[24] who found that in both the Groups (Glide scope Group and Fiber scope Group), Cormack and Lehane glottic score 1 and 2 showed no significant difference between the Groups (92.6% *vs* 96.3%). Another study conducted by Roya Yamul *et al.*[27] found that glottic view assessed using Cormack Lehane grading and POGO scoring was similar in C-mac video laryngoscope and fiber optic bronchoscope and difference observed was not significant in both the Groups (*p* value < 0.543). We observed for hemodynamic parameters and the analysis of variance shows no significant (*p* > 0.05) difference between the Groups at all the time periods, shown in **Table 3**. A similar study done by Abdelazim AT *et al.*[28] in obese patients on comparison of fiber optic bronchoscope and C-mac video-laryngoscope for awake intubation with predicted difficult airway and found no significant differences between both groups for hemodynamic parameters such as heart rate and mean blood pressure. Another study done by Aqil[29] who compared Glide Scope and flexible fibre optic bronchoscope for stress response to endotracheal intubation and observed no significant difference among hemodynamic parameters. We also observed for the complication such as sore throat, Group I had 10% cases and Group II had 16.7% cases and difference observed between the groups is non-significant (*p* = 0.44), shown in **Table 4**. Similar results were observed by Roya Yamul *et al.*[27] in patients undergoing cervical spine surgery and found that a very few numbers of patients had complain of sore throat after surgery, and this was non-significantly higher in the C-MAC Group (5 *vs* 1) compared with the fiber optic group. The current study has few limitations. This prospective randomized study was not performed in a blinded fashion; hence, there is a possibility of operator bias with respect to intubating conditions and

Table 1: Demographic characteristics of the patients

Parameters	Group I (*n* =30)	Group II (*n* =30)	*p*-value
Age (*years*) (mean ± SD)	36.33 ± 8.65	34.80 ± 9.02	0.50
Sex			
Male	4	5	0.71
Female	26	25	
Weight (*kg*) (mean ± SD)	56.43 ± 6.0	54.33 ± 5.98	0.18
Height (*centimeters*) (mean ± SD)	160.27 ± 4.46	163.57 ± 7.03	0.06
BMI (*kg/metre*^{2}) (mean ± SD)	22.02 ± 2.56	20.27 ± 1.24	0.07
ASA Grade			
I	27 (90%)	25 (83.3%)	0.44
II	3 (10%)	5 (16.7%)	

SD = Standard Deviation.

Table 2: Comparison of intubating time, intubation attempts and Cormack and Lehane Grade between the Groups

	Group I (*n* = 30)		Group I (*n* = 30)		*p* value
Intubating time (*seconds***)** (mean ± SD)	58.00 ± 11.49		88.10 ± 4.20		0.0001*
Intubation attempts	Numbers	Percentage (%)	Numbers	Percentage (%)	0.38
One	23	76.7	21	70	
Two	07	23.3	09	30	
Cormack Lehane Grade					
Grade I	22	73.3	24	80.0	0.54
Grade II	08	26.7	06	20	

SD = Standard Deviation.

Table 3: Comparison of hemodynamic parameters between the Groups

Time periods	Heart rate (beats per minute)			Systolic blood pressure (mm Hg)			Diastolic blood pressure (mm Hg)		
	Group I (n = 30) Mean ± SD	Group II (n = 30) Mean ± SD	p value	Group I (n = 30) Mean ± SD	Group II (n=30) Mean ± SD	p value	Group I (n = 30) Mean ± SD	Group II (n = 30) Mean ± SD	p value
Prior to sedation	84.50 ± 9.54	86.77 ± 9.02	0.56	127.40 ± 7.20	122.00 ± 18.65	0.14	78.20 ± 6.44	77.27 ± 7.64	0.61
Ramsay sedation score 3	82.50 ± 0.44	81.37 ± 8.01	0.63	114.27 ± 9.60	110.27 ± 9.91	0.11	73.40 ± 9.41	68.73 ± 9.75	0.06
Immediately after tracheal intubation	101.13 ± .04	97.03 ± 8.94	0.08	139 ± 10.15	138.00 ± 9.20	0.52	90.47 ± 8.99	85.73 ± 7.70	0.31
1st minute	97.20 ± 7.89	93.70 ± 10.67	0.15	123 ± 12.28	113.00 ± 12.78	0.21	82.60 ± 10.08	74.00 ± 11.30	0.31
2nd minute	91.50 ± 8.84	89.53 ± 9.95	0.42	114 ± 9.17	110.27 ± 10.82	0.08	76.80 ± 8.75	68.67 ± 11.16	0.32
3rd minute	88.00 ± 8.98	86.57 ± 12.63	0.61	114.60 ± 11.62	108.53 ± 10.52	0.31	75.20 ± 11.49	66.20 ± 12.36	0.5
4th minute	86.30 ± 9.52	85.10 ± 13.37	0.69	112.33 ± 12.92	107.60 ± 13.05	0.16	72.93 ± 13.36	66.53 ± 14.56	0.08
5th minute	85.53 ± 5.81	86.27 ± 12.35	0.76	117 ± 13.20	109.87 ± 12.63	0.022	78.00 ± 11.86	70.87 ± 14.67	0.41

SD = Standard Deviation.

Table 4: Comparison of complications between the Groups

Complications	Group I (n = 30)		Group II (n = 30)		p-value
	Number of patients	Percentage (%)	Number of patients	Percentage %)	
Sore throat	3	10.0	5	16.7	0.44
None	27	90.0	25	83.3	

possible adverse effects on the airway. Another limitation was that patients enrolled for study were mallampati airway class 2 and 3 only and other airway assessment parameters such as thyromental distance and neck mobility were not considered.

Conclusion

Our study concluded that the fiber optic bronchoscope when compared to Trueview PCD™ video laryngoscope had better glottis visualization and significant prolongation of time to intubation. However, the intubation related hemodynamic response and related complications were almost similar with the use of both Truview PCD™ vedio laryngoscope and flexible fiber optic bronchoscope.

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