Tracheal Intubation Using Trueview® Videolaryngoscopy Versus Direct Macintosh® laryngoscopy: An observational, Case-control Study

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ABSTRACT

Background: The main objective of this study is to evaluate the effectiveness of videolaryngoscopy, performed with the help of Trueview® device, for routine oro-tracheal intubations compared with visualization by direct laryngoscopy, performed with McIntosh laryngoscope.

Material and method: The study enrolled 237 patients, aged between 4 weeks and 87 years, who underwent surgery under general anaesthesia with oro-tracheal intubation. Patients were randomized into two groups: videolaryngoscopy group VL (n=139) and direct laryngoscopy group DL (n= 98). Preoperative, for prediction of difficult airway, the following were evaluated: Mallampati score, thyro-mental distance, body mass index (BMI). During surgery, hemodynamic and respiratory parameters were monitored and also the peripheral oxygen saturation. The intubation time, the number of attemps and the success rate were recorded.

Results: The success rate on first intubation attempt, was higher In the VL group, than the DL group, 96.4% and 86.7% respectively, without statistically significant differences between the two groups, $p>0.05$.

Conclusion: The videolaryngoscope Truphatek TrueView® PCD is a useful device for the management of the patients with difficult intubation.

The video-assisted techniques should be included in the protocol of difficult airway management of every anesthesia and intensive care compartment.

Keywords: Difficult airway, difficult intubation, direct laryngoscopy, videolaryngoscopy

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BACKGROUND

Difficult airway and hence failed intubation represents one of the most stressful situation to the anesthetist and life-threatening to the patient whose protective reflexes and responses are abated.

The American Society of Anesthesiology (ASA) definition of difficult airway is: the clinical situation in which a trained anesthetist encounters difficulties in mask ventilation, oro-tracheal intubation or in both techniques applied to a patient (1).

According to the ASA, the respiratory airway prosthetics related events (incorrect intubation, esophageal intubation or the impossibility of intubation) represent approximately 32% of the total number of intubations (2). Difficult intubation represents 6.4% of the total number of intubations, and 57% of these suffer serious complications such as hypoxic encephalopathy and death (2). It is the opinion of some authors that the incident of serious complications is underreported and therefore is much higher (3).

Videolaryngoscopy has some advantages over direct laryngoscopy. It is easier to handle and to manipulate, and it offers a high quality image of the vocal cords. It is easier to assess the effect of Sellick maneovre (cricoid pressure) and hence enable succesfull intubation. It also enables visulization of the cuff of the tracheal tube passing through and beyond the vocal cords, and hence should prevent endobronchial intubation (4).

The aim of this study was to compare the effectiveness of videolaryngoscopy (VL) with DL for intubation of patients who underwent elective surgery under general anaesthesia with tracheal intubation.

MATERIAL AND METHOD

Approval for this study was obtained from the Ethics Committee of the Clinical County Emergency Hospital of Tirgu- Mures. Written informed consent was obtained from either the patient or the legal guardian. Randomization was done on a daily basis, the theaters were randomly chosen for the use of VL or DL. Two hundred and thirty seven (237) patients were recruited. The study was carried out in the Clinical County Emergency Hospital, Tîrgu Mureş between October 2011 and March 2012.

The study enrolled 237 patients aged between 4 weeks and 87 years who underwent elective surgery (abdominal and plastic surgery) and who required oro-tracheal intubation.

The study population included only patients who were undergoing elective surgery under general anaesthesia with tracheal intubation.

Patients were divided in two groups:

- The VL group (n=139) - patients which received oro-tracheal intubation by videolaryngoscopy
- The DL group (n=98) - patients which received oro-tracheal intubation by direct laryngoscopy with the McIntosh laryngoscope

At the pre-anesthetic assessment, age, height, weight, medical history, mouth opening degree, cervical spine mobility, Mallampati score and thyro-mental distance were recorded. During surgery, patients were hemodynamic and respiratory monitored. Reactions during endotracheal intubation (coughing, movements and tachycardia) were also recorded.

Patients over 18 years received premedication with midazolam 2 mg and atropine 0.5 mg i.v. Children less than 18 years received no premedication. All patients were oxygenated for 3 minutes, after that anesthesia was induced with fentanyl 2 μg/kg and Propofol® 2 mg/kg. The muscle relaxant administered was either Rocuronium (0.4 – 0.5 mg/kg) or Atracurium (0.5

mg/kg). Manually assisted ventilation was performed until the patients were fully paralyzed, after which VL or DL was performed.

Intra-operative monitoring and documentation of the hemodynamic parameters (ECG – lead II, heart rate, non-invasive blood pressure) monitoring of the inhaled and exhaled gases (capnography, inspiratory oxygen fraction, volatile minimum alveolar concentration) and pulseoxymetry. Monitoring was done using the included Drager Infinity Delta anaesthetic machines (Drägerwerk AG & Co, Lubeck, Deutchland).

In VL group the videolaryngoscopy was performed with a Trueview® device (Truphatek Holdings Limited, Netanya, Israel).

The videolaryngoscopy kit comprises different blades (0 to 5), two handles (long and short), different sized and shaped guide wires for the tracheal intubation tube and the display monitor, where the image from the tip of the blade can be visualized. The blades are equipped with a port for oxygen connection, which enables continuous delivery of oxygen at the tip of the blade. Direct laryngoscopy was performed using a McIntosh laryngoscope with different sized curved blade.

The VL and DL intubations were performed by senior residents, certified as competent in skill of intubation and by consultants assigned to the surgical list.

BACKGROUND

Difficult airway represents one of the most urgent situations which can occur in the operating room or anywhere else the airway control is necessary. This situation requires fast and efficacious management because otherwise can jeopardize the patient's life.

The A.S.A. (American Society of Anesthesiology) definition of difficult airway is: the clinical situation in which a trained anesthetist encounters difficulties in mask ventilation, oro-tracheal intubation or in both techniques applied to a patient (1).

According to ASA, the respiratory airway prosthetics related events (incorrect intubation, esophageal intubation or the impossibility of intubation) represent approximately 32% of the total number of intubations (2). Difficult intubation represents 6,4% of the total number of intubations, out of which 57% show fatal consequences leading to hypoxic encephalopathy or death (2). In reality these incidents and accidents have a higher incidence because of their underreporting (3).

Videolaringoscopy presents some advantages over direct laringoscopy, because it can be very helpful thanks to it s possibility of delivering high-quality images of vocal cords. Also, if any supplemental manevres are necessary, such as Sellick manevre, the person which intubates can reasses the procedure as necessary in order perform a successfuly intubation. With videolaringoscopy the endotracheal tube can be visualised until it passes the vocal cords and it s secured in the trachea.(4)

The aim of this study was to evaluate the videolaringoscopy (VL) effectiveness, through Trueview® device, for routine oro-tracheal intubation as compared with direct laringoscopy, on patients scheduled for surgery under general anaesthesia.

MATERIAL AND METHOD

With the approval of the Ethics Committee of the Clinical County Emergency Hospital of Tirgu- Mures and after obtaining the written and informed consent (patient or legal representative) 237 patients were enrolled in the study. Randomization was made by choosing daily and randomly the operating theatres where the videolaringoscopy intubation or the classic direct laringoscopy will be performed.

The study was carried out in the Clinical County Emergency Hospital, Tîrgu Mureş between October 2011 and March 2012. The study enrolled 237 patients aged between 4

weeks and 87 years who underwent elective surgery (abdominal and plastic surgery) and who necessitated oro-tracheal intubation. All the patients who were scheduled for elective surgery were included, if they were supposed to receive general anesthesia with tracheal intubation. Patients were divided in two groups:

The VL group (n=139) - patients which received oro-tracheal intubation by videolaringoscopy. The DL group (n=98) - patients which received oro-tracheal intubation by direct laringoscopy with the McIntosh laringoscope

At the pre-anesthetic assessment, age, height, weight, pathologic background, mouth opening degree, cervical spine mobility, Mallampati degree and thyro-mental distance were recorded. During surgery, patients were hemodynamic and respiratory monitored. Reactions during endotracheal intubation (coughing, movements, tachycardia) were also recorded.

Intra-operative monitoring comprised in registering the hemodynamic parameters (ECG - DII, heart rate, non-invasive blood pressure) monitoring of the inhaled and exhaled gases (capnography, inspiratory oxygen fraction, volatile minimum alveolar concentration) and pulseoxymetry. This monitoring was carried out by the monitors included in the anesthesia machines Drager Infinity Delta (Drägerwerk AG & Co, Lubeck, Deutchland).

Patients over 18 years received premedication with midazolam 2 mg and atropine 0.5 mg i.v. Children (< 18 ani) did not received any premedication. Patients were pre-oxygenated for 3 minutes, after that anesthesia was induced with fentanyl 2 μg/kg and Propofol® 2 mg/kg. After the installation of hypnosis the muscle-relaxant was administered (rocuroniu 0.4 – 0.5 mg/kg or atracurium 0.5 mg/kg) and patients received manually assisted ventilation.

In VL group the videolaringoscopy was performed with a Trueview® device (Truphatek Holdings Limited, Netanya, Israel). The videolaringoscopy kit comprises different sized blades (available sizes 0 to 5), two handles (long and short size), different

sized and shaped guide wires for the tracheal intubation tube and a display, where the image from the tip of the blade can be visualized. These blades are equipped with a system for oxygen connection, which assures continuous delivery of oxygen at the tip of the blade. Direct laringoscopy was performed using a Heine laringoscop with different sized curved blade (Heine, Herrsching, Deutchland).

Fig.: 1 Trueview videolaryngoscopy kit.

Fig. 2: Trueview videolaringoscope.

Potential difficulties in ventilation, patient oxygen saturation in every minute, Cormack Lehane degree and number of intubation attempts, blood pressure and patient's heart rate were recorded.

It has been noted the intubation time, defined as the time measured from the initiation of the intubation attempt until the moment of inflation of the tracheal tube balloon and its connection to the anesthesia machine. When multiple attempts were needed, each attempt was separately timed and all durations were summarized at the end. The variable periods of mask ventilation between attempts were not taken into consideration. The working protocol was the same for all the patients, including those with predicted difficult airway. The predictive criteria for a difficult airway are presented in Table 1.

Table 1. Predictive criteria for difficult airway

Predictive criteria for a difficult airway	
Mallampati degree	4
BMI	> 35
Thyro-mental	> 6,5 cm
Cervical spine mobility	decreased
Mouth opening	< 2 fingers

The patients considered difficult to intubate were the ones who needed more than 2 intubation attempts and those who had a drop in oxygen saturation under 87% during the intubation procedure.

In DL group protocol provided that after 2 unsuccessful intubation attempts, the intubation shall be taken over by a more experienced anesthetist, and after another 2 unsuccessful intubation attempts the videolaringoscopy will be used for intubation.

The recorded parameters were: intubation time and success rate by any of the two described methods.

Data were statistically processed with Microsoft Excell 2010 (Microsoft Corporation, Albuquerque, SUA) and GraphPad Prism 6.0 (GraphPad Software, Inc., La Jolla, SUA).

Results were expressed as average (SD standard deviation) and percentiles. Parametric data were compared with the „t student test" and for the nonparametric data, the Mann-Whitney test was used. A value of $p<0.05$ was considered to be statistically significant. For the patients with multiple attempts of intubation, the successful attempt was taken into consideration and processed statically.

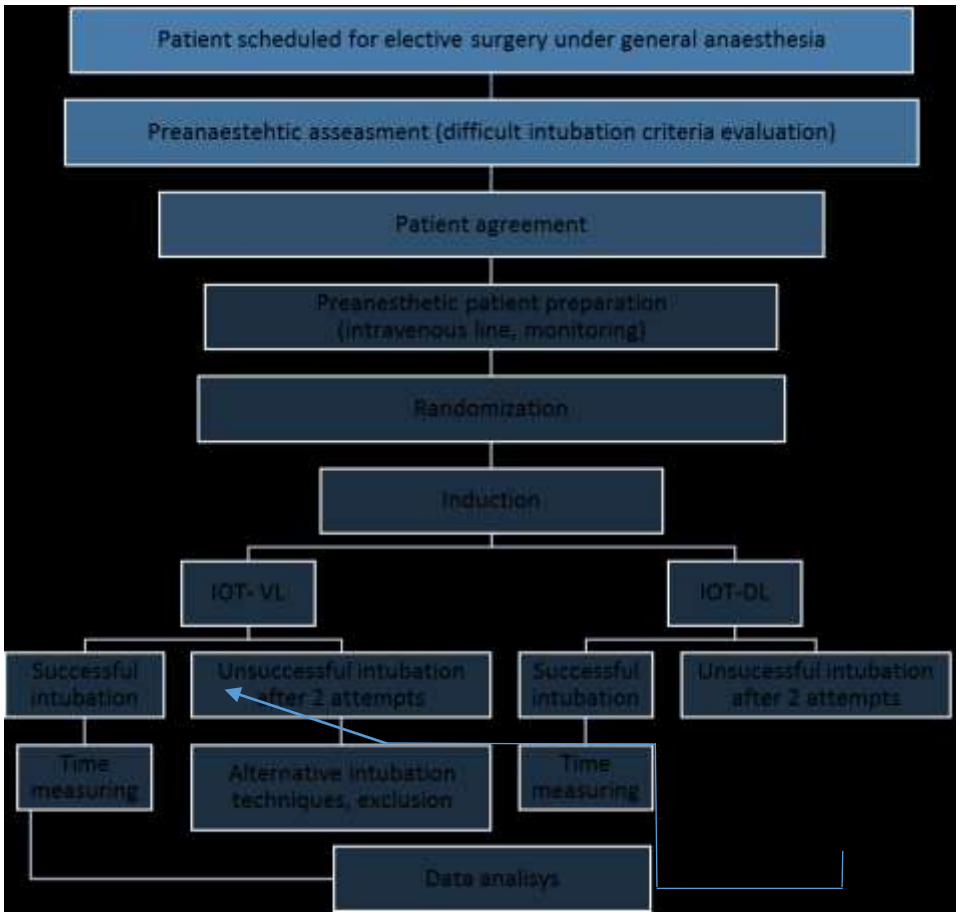

Fig. 3: Study flowchart.

RESULTS

The demographic data of the enrolled patients are shown in Table 2.

Table 2: Demographic data

Parameter		VL group (n=139)	DL group (n=98)	P
Age (years)*		51.45 (18.99)	54.94 (17.04)	0.1481
Sex B/F		61/78	36/62	0.2860
BMI (kg m^{-2})*		26.16 (5.49)	27.24 (4.43)	0.1066
Mallampatidegree	I	25	18	0.0166
	II	44	74	0.2358
	III	18	32	0.4223
	IV	11	15	0.9999
SpO2before-induction*		98.05 (1.63)	98.58 (3.76)	0.7124

- Data are expressed as average (SD), SD- standard deviation , BMI- body mass index, SpO_2 – hemoglobin saturation in oxygen,
- VL- Videolaringoscopy
- DL- Direct Laringoscopy

Table 3; Patient's predictive parameters for the difficult airway

Difficult intubation predictive factors	VL (n=139)	DL (n=98)	P
Mallampati degree 4	15	11	0.9999
BMI > 35	6	4	0.9999
Thyro-mental > 6,5 cm	33	32	0.0774
Reduced cervical spine mobility	5	3	0.2805
Mouth opening < 2 fingers	0	0	1

BMI- body mass index, VL- videolaringoscoy, DL- direct laringoscopy

Out of the 139 patients who were intubated by videolaringoscopy, 2 cases were intubated naso-traheal and one case of oro- tracheal intubation was performed in lateral position.

The success rate on first intubation attempt was high in VL group, 96.4% versus 86.7% in DL group, without a statistically significant difference (p=0.81). The overall intubation success rate was 100% for VL and 90, 81% for DL (p=0, 0003).

Regarding the average time of intubation in the two groups, they were 34, 4 (20,3) sec in VL group vs 35,3 (26,9) sec in DL group, (p=0.41 – Mann Whitney test). A positive correlation was revealed between the intubation time and Mallampati and Cormack degree (Figure 3). Also, a statistically significant correlation was obtained between the time of intubation and the thyro-mental distance ($p<0.05$).

The incidence of obesity (BMI>30) was 20% (47 cases). We did not find any relation between obesity and the intubation time (p = 0, 95 – Mann Whitney test), whoever we found a significant correlation between BMI and intubation time (p<0, 0001 – paired T test). No significant difference was found between the average time of intubation in the two groups, for the obese patients, (p=0, 34 – Mann Whitney test).

The incidents within the intubation procedure (desaturation, blood pressure increase) and also the superior airway irritation had a low incidence in both groups.

Two patients from the VL group presented a decrease in oxygen peripheral saturation < 87%. For these patients the manual ventilation was difficult and the intubation time was prolonged over 120 seconds. The average time for intubation, in both groups, is shown in figure 4.

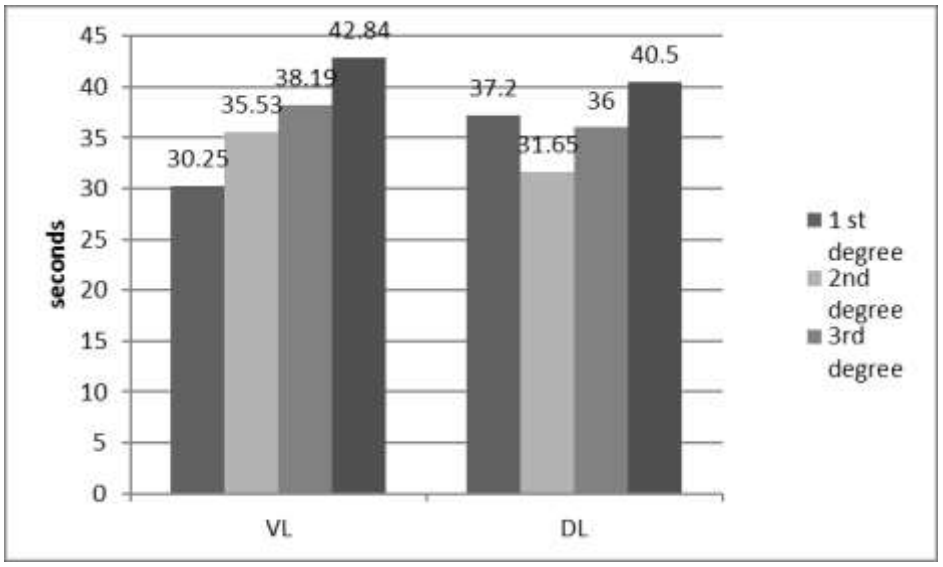

Figure 4. Graphic illustration of the average time of intubation for the two groups divided accordingly to Cromack-Lehane scale

Nine patients from the DL group, because of the impossibility to be intubated after more than 4 attempts, were intubated with the videolaringoscopy technique. The causes for the difficult intubation of these patients are described in Table 4.

Table 4: The causes for the difficult intubation of the 9 patients in DL group

situation	Cases
Micrognathism histicytoma	1
Palatoschisis with pharyngeal malformations	1
Micrognathism and palatoschisis	1
Ankylosing spondylitis	1
Morbid obesity	1
Mallampati and Cormack 4	4

VL- videolaringoscopy

DL- direct laringoscopy

We did not have patients who couldn't be intubated by videolaringoscopy on second attempt. Eight medical doctors, out of whom 2 senior doctors experienced in direct laringoscopy intubation, took part to this study.

DISCUSSION

The Truview PCD (Trupathek) device is a complex optical and video system designed for oro-nasotracheal intubation. Its blade has a special designed curve which allows the visualization of the vocal cords, without head tilting and it is provided with an oxygen adapter and a system for the delivery of oxygen towards the tip of the blade, which reduces the fogging on the video camera. This oxygen flux is thought to deliver a high concentration of oxygen into the airways, proximally, contributing to maintain the patient's saturation throughout the technique. .

The incidence of difficult airway prediction, represented by Mallampati and Cormack fourth degree in the total number of the enrolled patients - 237- was 7.17% (17cases), the results resembling the ones other authors have been described (6.4%) (2).

Our study showed a rate of success on first attempt with the videolaringoscope of 96.4%. We obtained lower results on direct laringoscopy (86.7%), although other authors do not describe differences (5). The overall intubation success is significantly different tough (p=0, 0003). Regarding the intubation of the patients with difficult airways (Cormack-Lehane =4), the rate of intubation success on first attempt by videolaringoscopy is high; in our study we succeeded the intubation on 11 cases of difficult intubation. Out of these cases 10 were on first attempt (90.9%) which is consistent with the results from other studies (79%) (6).

In a study performed on a mannequin, the authors are describing that in the case of a difficult intubation scenario, the visualization of the vocal cords is quicker with the help videolaringoscopy (7).

We estimated that the average time for intubation with the videolaringoscope, in patients with difficult airway, to be lower as compared with direct laringoscopy. Regarding the average time of intubation between the two groups no statistically significant difference was recorded (VL=37, 1±24, 3 seconds vs DL= 35, 6 ± 26, 8 seconds p=0, 24). These results are also consistent with the literature and other published studies (8, 9).

The visualization of the vocal cords was improved by videolaringoscopy on patients with higher Cormack-Lehane degrees, an aspect also pointed out by other authors (5, 10). The image obtained on the videolaringoscope display had a good quality, when the oxygen source was used continuously. The studies carried out by other authors, on videolaringoscopes without oxygen source, are describing the fogging of the lens, which increases the incidence of an incorrect intubation (11).

In our study we did not record any soft tissues lesions during intubation, although other studies find the videolaringoscopy less traumatic compared to direct laringoscopy (12).

Finally, we consider factors of bias that the intubations were performed by young anesthetists residents and specialists in anaesthesia and intensive care, which might have influenced the

time of intubation and the success rate and also the fact that we did not take blood samples for the measurement of the partial pressure of oxygen from the arterial a parameter considered to be more accurate for the evaluation of optimal oxygenation.

CONCLUSIONS

1. The videolaringoscope Truphatek TrueView PCD is a useful device for the management of the patients with difficult intubation, and proved a superior success rate compared with direct laringoscopy, despite the fact that we didn't found significant intubation time difference between the two techniques.
2. Due to the fact that 9 patients weren't intubated successfully by direct laringoscopy, we recommend that the video-assisted techniques should be included in the protocol of difficult airway management of every anesthesia and intensive care compartment.
3. The continuous source of oxygen from the videolaringoscope blade is useful in obtaining high quality images during intubation, preventing the lens fogging.

AUTHORS' NOTE

The authors of this article have no conflict of interest to declare.Parts of this article were presented in an oral presentation at the National Congr-Ses of Anesthesiology, held in Sinaia, Romania in 2012.

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