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A Randomized Prospective Study To Compare Truflex Articulating Stylet Vurses Conventional Rigid Malleable Stylet As An Intubating Guide With The Macintosh Laryngoscopy During Elective Tracheal Intubation

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Abstract:
Background*: Tracheal intubation is the most common and routinely performed procedure in any surgeries requiring general anaesthesia. The current study compares the Truflex articulating stylet with the conventional rigid malleable stylet during elective tracheal intubation with respect to intubation time, number of attempts and any complications during the procedure.*
Materials And Methods*: It was single blinded, prospective, randomized, interventional study. After institutional ethics committee approval 160 patients were randomly allocated into 2 groups. One group with 80 subjects were intubated using Truflex articulating stylet and other group with 80 subjects were intubated using conventional rigid malleable stylet.Successful or failed intubation during first attempt was the primary objective. Total intubation time, glotticoscopy time, endotracheal tube negotiation time and any complications during procedure were the secondary objective.*
Statistical Analysis*: Data were statistically described in terms of mean (±SD), frequencies (number of cases) and percentages where appropriate. Student t test, Fisher's exact test, Mann–Whitney U test and Chi square test were used where appropriate. A p value of less than 0.05 was considered statistically significant.*
Results*:In conventional stylet group, 96.3%, 2.5% and 1.3% of patients were intubated in 1, 2 and 3 attempts respectively whereas 100% subjects were intubated in first attempt by Truflex stylet. There was no significant difference in the proportion of patients between the two groups with respect to number of failed attempts at intubation (p=0.2453). Meanglotticoscopy time while using conventional stylet and Truflex stylet was 7.85 ± 0.96 seconds and 7.89 ± 0.92 seconds respectively with a p value of 0.8293. There was no significant difference between the two groups with respect toglotticoscopy time. Mean endotracheal tube negotiation time using conventional stylet and Truflex stylet was 8.83 ± 1.84 seconds and 8.33 ± 0.92 seconds respectively. The endotracheal tube intubation time was significantly less in patients in whom Truflex stylet was used as compared to patients in whom conventional rigid stylet was used (p=0.0328). Average total intubation time using conventional stylet and Truflex stylet was 16.68 ± 2.74 seconds and 16.22 ± 1.82 seconds respectively. There was no significant difference between the two groups with respect to total intubation time (p=0.2095). There were no complications observed during the procedure with either of the stylets.*
Conclusions*:The results suggest that the patients intubated using Truflex articulating stylet and or conventional stylet has no difference in terms of successful or failed intubation. The patients intubated using Truflex articulating stylet has significantly lesser endotracheal tube negotiation time compared to the patients intubated with conventional rigid malleable stylet and without much significant difference in number of attempts, total intubation time, glotticoscopy time and any complications in any stylets.*
Keywords*: Tracheal intubation, Truflex articulating stylet, laryngoscope*

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I. Introduction

Difficult airway management is a major responsibility for anaesthesia providers and also major cause of morbidity and mortality. Intubation may be extremely formidable, when confronted with a patient who has a predicted difficult airway like difficulty in opening of the mouth, lack of mobility of the atlanto-occipital joint, inability to assume the sniffing position. In cases such as these, it may be more advantageous to secure the

airway while the patient is still awake. An airway device that allows for intubation without the need of a straight line of sight while lifting and navigating through airway structures would be beneficial.[1]Identifying situations and patients at frequent risk for airway management problems is a key to optimal care and has been the focus of numerous publications.[1,2] At the time of induction of anaesthesia, most anaesthesia mishaps can occur.[3]

Tracheal intubation is a resuscitative procedure and is regarded as the optimal means of securing the airway. For patients, it provides effective ventilation and also protects them from regurgitation.[4,5]Tracheal intubation is most commonly performed, and is considered as a gold standard in securing the airway and is considered mandatory in a variety of patient populations and operations.[6] For intubation, a variety of methods are available, direct laryngoscopy, intubating LMA, fibreoptic endoscopic intubation, retrograde intubation and awake intubation.[7] Tracheal intubation is not a simple procedure and thus may give rise to complications known as difficult intubation even when performed by an experienced anaesthesiologist. Difficult intubation can also be encountered under pre-hospital conditions e.g. serious damage to the craniofacial region, or in the presence of swelling, heavy bleeding or foreign bodies.[4] The Direct Laryngoscopy (DL) technique is universally used for tracheal intubation in emergency. However in cases of difficult intubation DL technique may yield poor laryngeal view and require multiple attempts and may be associated with an increased risk of hypertension, hypoxia, airway and dental injuries, intensive care unit admission, neurologic impairment, aspiration, cardiac arrest and death.[8]Now a days video-laryngoscopes and different stylets play an important role as an alternative to conventional rigid laryngoscopy. It is useful for the better visualization of larynx.[8,9,10] The Macintosh laryngoscope has been the most widely used device for intubation. The Macintosh laryngoscope is used to visualize laryngeal structures and thereby the endotracheal tube is inserted and advanced into the trachea. .

Despite the visualization of the laryngeal structures by Macintosh laryngoscope, the insertion and advancement of the endotracheal tube may be prolonged and occasionally fail depending on the Cormack and Lehanne's classification of vocal cords.[11] To overcome this handicap, it is recommended to use a pre-shaped, styleted tracheal tube during intubation. Unfortunately, these malleable rigid stylets permit only a fixed shape to the advancing endotracheal tube. This may necessitate withdrawal of endotracheal tube-stylet assembly for reshaping, before undertaking a new attempt. This may increase total intubation time and may cause soft tissue injury and hemodynamic disturbance.[9,12]

Truflex articulating stylet has an articulating tip which can be manually controlled. Therefore a preloaded endotracheal tube with the Truflex articulating stylet will not only shorten the intubation time but also attenuate the possibility of soft tissue trauma in patients whose anatomy makes access more difficult; compared to endotracheal tube preloaded with conventional rigid malleable stylet.

II. Aims And Objectives:

Aim

To compare the Conventional rigid malleable stylet with the Truflex articulating stylet as an intubation guide during laryngoscopy in elective tracheal intubation.

Objectives

Primary Objective:

To compare successful or failed intubation during first attempt.

Secondary Objectives:

1. To compare the total intubation time which included-
   - Glotticoscopy time (From introduction of the Macintosh laryngoscope blade between the teeth to the best laryngeal view)
   - Endotracheal Tube (ETT) negotiation time (From receiving the styleted ETT in anaesthesiologist's hand to passage of black line just beyond the vocal cord.[This will include the comparison of ETT negotiation time since the glotticoscopy time in groups intubated with Truflex articulating stylet or conventional rigid malleable stylet was same]
2. To compare the Intubation attempts - maximum three attempts, after which the technique was considered as failure. An attempt was counted if the laryngoscope needs to be removed for reoxygenation (drop in oxygen saturation by 5%) or the ETT needs to be removed for reshaping.
3. To document any direct complications related to the above procedure.

III. Materials And Methods

It was a single blind, prospective, randomized interventional phase IV controlled study conducted in patients undergoing elective tracheal intubation. After obtaining institutional ethics committee approval (LETTER NO: IEC(I)/OUT/28/15) of Seth G S Medical College and KEM Hospital, Mumbai and written informed consent from the patients involved in the study, 160 patients (80 in each group) were recruited by closed envelope method .

IV. Statastical Analysis

Data were described in terms of mean (±SD), frequencies and percentages where appropriate. Comparison of quantitative variables was done using Student t test if samples were normally distributed (e.g. age, height, weight, pulse rate, systolic, diastolic and mean arterial blood pressures, mouth opening, thyromental distance, sternomental distance, Total intubation time, glottiscospic time, endotracheal tube negotiation time). For categorical data, Chi square test was performed (e.g. Gender, ASA grade, Malampatti score). Mann–Whitney U test was used for non-normally distributed quantitative and ordinal data (e.g.Cormack and Lehane's Grading). Fisher Exact test was used for analysis ofnumber of attempts at intubation. A p value of less than 0.05 was considered statistically significant. All statistical calculations were done using computer programs Microsoft Excel 2007 and SPSS, version 17.

Sample Size Estimation:

Sample size of the study was calculated using nMaster1.0 software. With alpha error at 5%and 90% power(1-*B)* using 2sided test, 80 patients were allotted to both the groups per group. Hence a total of 160 patients for both the groups were needed i.e. 80 for group A and 80 for group B.

$$n = \{Z1 - \frac{\alpha}{2}\sqrt{2P(1-P)} + Z1 - B\sqrt{P1(1-P) + P2(1-P2)}$$
$$(P1 - P2)2$$

The patients were divided into two groups as follows-

Group A: In first group intubation had done using conventional rigid malleable stylet

Group B: In second group intubation had done using Truflex articulating stylet.

Randomization of patients- Randomization of the patients was Computer based i.e. by randomization.com software.

Inclusion criteria:

- Patient had been informed about the investigational nature of this study and the patients had given written informed consent in accordance with Ethical Committee guidelines
- ASA I–II patients were included in this study
- Subjects included in the study were between 18 to 60 years.
- Patients requiring elective surgical procedure under general anesthesia needing tracheal intubation.

Exclusion criteria:

- Pregnant female were not included in this study.
- Known bleeding/coagulation disorder and patients on anticoagulants who might bleed during endotracheal intubation were excluded.
- Patients with cervical spine injury were not part this study.
- Suspected difficult intubations due to any intra oral mass was not included.
- ASA III – ASA VI patients were excluded.

Methodology

- After approval from research Ethics Committee and written informed consent, either from the subject, 160 ASA I–II patients who present for elective surgeries under general anaesthesia needing tracheal intubation, was enrolled for this study. After the patient arrives in the operating theatre, routine monitoring (heart rate, non-invasive arterial pressure, ECG and pulse oximetry) and i.v. access was established before they were positioned for tracheal intubation after giving general anaesthesia. The above procedure before induction was same for both groups.
- Patients in both groups were to undergo a same induction technique with propofol 2.0 to 2.5 mg/kg and adequate relaxation with vecuronium 0.1mg/kg and after 4 minutes of oxygenation intubation done. With the induction of anesthesia, patients were administered 3ug/kg Buprenorphine and Midazolam 0.03ug/kg.
- For patients in group A, a well-lubricated Conventional rigid intubating stylet was used to shape the ETT. This pre-shaped ETT was guided into the trachea after visualising the glottis of an anesthetized and fully relaxed patient using Macintosh laryngoscope.
- For patients in group B, a well-lubricated Truflex articulating stylet was used in place of the conventional rigid malleable stylet to change the curvature of the ETT as per need to negotiate into the glottis, using the same Macintosh laryngoscope.

V. Results

The Mean age, gender distribution, mean height, mean weight, ASA status, Malampatti score, Mouth Opening, Thyromental distance, Sternomental distance and Cormack & Lehane's grading in both study groups have a p value >0.05 and hence the two groups were comparable and follows normal distribution and are representatives of the population. This allowed us to apply statistical tests to other parameters/ values and compare them (Table 1). Both the groups received same premedication and induction agents. The hemodynamic parameters of the patients of both the groups i.e. pulse, systolic blood pressure and diastolic blood pressure were recorded preoperatively and; 1 minute and 5 minutes after intubation and they have p value >0.05 and hence two groups were comparable (Table 2).

Table 1: Demographic Data:

CATEGORY	CONVENTIONAL STYLET GROUP (MEAN ± SD or %)	TRUFLEX STYLET (MEAN ± SD or %)	p value
AGE(YEARS)	40.64 ± 12.17	39.85 ± 12.58	0.6879
SEX(M/F)	M:47.5% F:52.5%	M:53.75% F:46.25%	0.5271
HEIGHT(cm)	161.25 ± 6.23	162.5 ± 5.30	0.1738
WEIGHT(kg)	64.09 ± 8.55	64.65 ± 7.53	0.6596
ASA I	70%	73.8%	0.7251
ASA II	30%	26.3%	
MPC I	65%	57%	0.5433
MPC II	23%	17%	
MPC III	5%	6%	
MOUTH OPENING	4.89 ± 0.45	5.00 ± 0.61	0.1886
THYROMENTAL DISTANCE	6.54 ± 0.22	6.54 ± 0.25	0.9999
STERNOMENTAL DISTANCE	12.64 ± 0.31	12.61 ± 0.28	0.5556
CORMACK LEHANE GRADE	1 TO 3 (MEDIAN)	1 TO 3 (MEDIAN)	0.8682

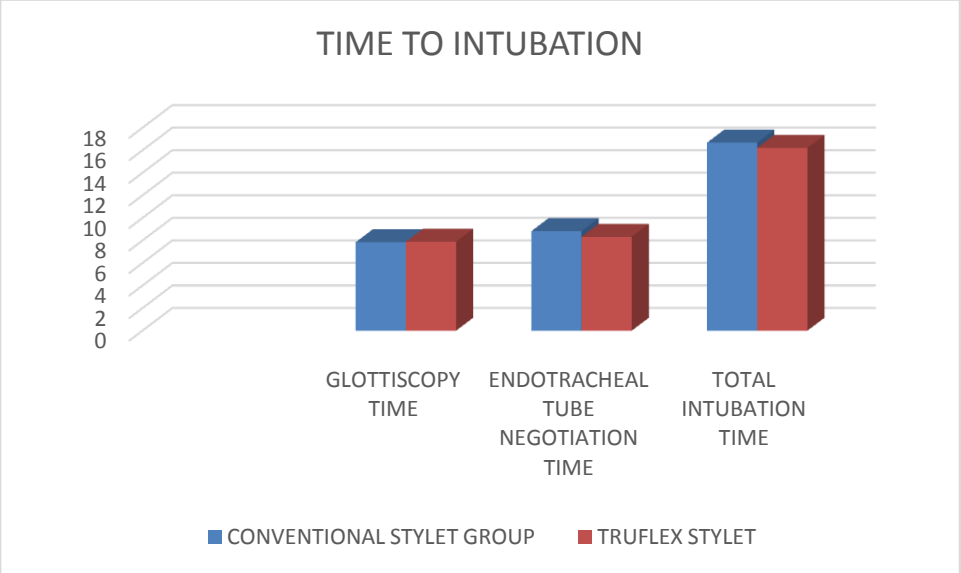
Table 2: Hemodynamic Variables

CATEGORY	CONVENTIONAL STYLET GROUP (MEAN ± SD or %)	TRUFLEX STYLET (MEAN ± SD or %)	p value
PREOPERATIVE PULSE	80.07 ± 6.04	78.66 ± 5.67	0.1295
PULSE at 1 min	91.21 ± 5.56	90.30 ± 5.78	0.3162
PULSE at 5 min	78.85 ± 4.49	78.52 ± 5.06	0.6682
PREOPERATIVE SBP	128.15 ± 11.23	127.72 ± 9.43	0.7958
SBP at 1 min	138.5 ± 9.64	137.71 ± 8.50	0.5843
SBP at 5 min	122.9 ± 9.3	124.38 ± 7.99	0.2836
PREOPERATIVE DBP	78.92 ± 6.21	78.82 ± 5.64	0.9153
DBP at 1 min	83.15 ± 5.23	83.45 ± 5.40	0.7215
DBP at 5 min	76.80 ± 5.10	77.70 ± 5.19	0.2704

Meanglotticoscopy time while using conventional stylet and Truflex stylet was 7.85 ± 0.96 seconds and 7.89 ± 0.92 seconds respectively with a p value of 0.8293. There was no significant difference between the two groups with respect toglotticoscopy time. Mean endotracheal tube negotiation time using conventional stylet and Truflex stylet was 8.83 ± 1.84 seconds and 8.33 ± 0.92 seconds respectively. The endotracheal tube intubation time was significantly less in patients in whom Truflex stylet was used as compared to patients in whom conventional rigid stylet was used (p=0.0328). Average total intubation time using conventional stylet and Truflex stylet was 16.68 ± 2.74 seconds and 16.22 ± 1.82 seconds respectively. There was no significant difference between the two groups with respect to total intubation time (p=0.2095).

VI. Time To Intubation

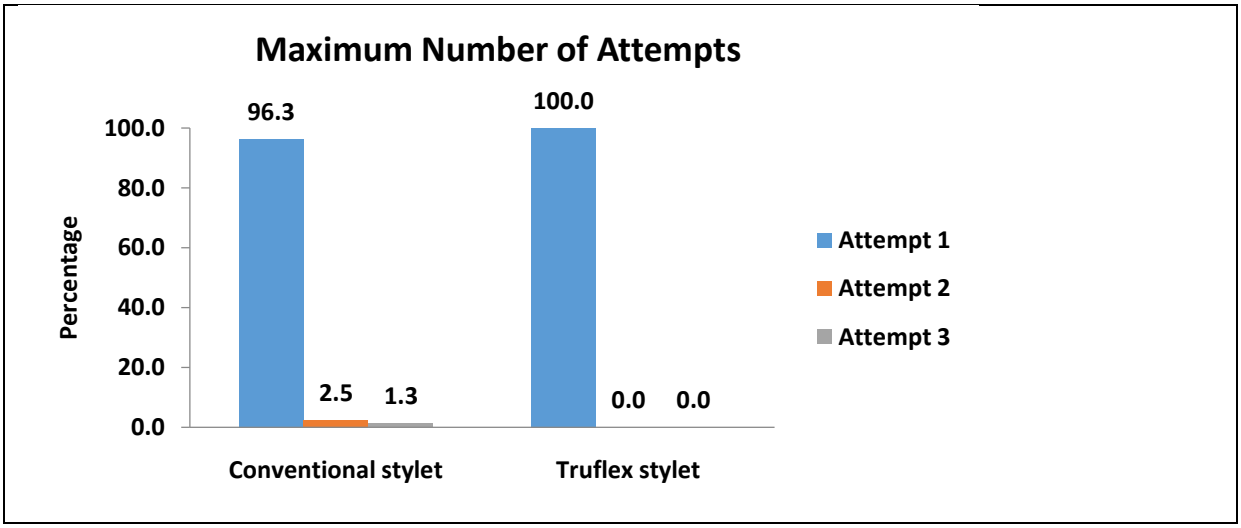
CATEGORY	CONVENTIONAL STYLET GROUP (MEAN ± SD)	TRUFLEX STYLET (MEAN ± SD)	p value
GLOTTISCOPY TIME	**7.85 ± 0.96**	**7.89 ± 0.92**	**0.8293**
ENDOTRACHEAL TUBE NEGOTIATION TIME	**8.83 ± 1.84**	**8.33 ± 0.92**	**0.0328**
TOTAL INTUBATION TIME	**16.68 ± 2.74**	**16.22 ± 1.82**	**0.2095**



Number Of Attempts At Intubation / Successful Or Failed Intubation

In conventional stylet group, 96.3%, 2.5% and 1.3% of patients were intubated in 1, 2 and 3 attempts respectively whereas 100% subjects were intubated in first attempt by Truflex stylet. There was no significant difference in the proportion of patients between the two groups with respect to number of failed attempts at intubation. (p=0.2453)

Maximum number of Attempts	Conventional stylet		Truflex stylet	
	Number of patients (N)	Percentage	Number of patients (N)	Percentage
1	77	96.3	80	100.0
2	2	2.5	0	0.0
3	1	1.3	0	0.0
Total	80	100.0	80	100.0
p=0.2453, using Fisher's exact test				



VII. Discussion

Securing airway is one of the most important skills that we anaesthesiologist acquire. Securing of airway is an art and can be secured by use of multiple devices ranging from simple Macintosh laryngoscope, video laryngoscopes, light wands, stylets, bonfils and fibre optic laryngoscopy. Truflex articulating stylet is a rapid, simple, safe, and non-surgical method which gives Endotracheal tube the desired angulated shape matching that of the laryngoscope blade which allows easy negotiation of endotracheal tube through the glottis.

The demographic data of the patients in our study were comparable with respect to age, sex, weight and height as well as the baseline patient characteristics were comparable with respect to ASA status, Mallampati grade, mouth opening, Thyromental distance, Sternomental distance and Cormack Lehane's grading and there were no statistically significant variations in the patient population. The hemodynamic variables pulse rate, systolic blood pressure and diastolic blood pressure were recorded preoperatively and then 1 minute and 5 minutes after intubation. There was no statistical variation among the patient population in hemodynamic variables.

In our study the primary outcome was to compare successful or failed intubation. The maximum time allowed for intubation was 60 seconds, after which it was considered as unsuccessful attempt and three unsuccessful attempts were regarded as failed intubation. In our study with conventional stylet group, 96.3%, 2.5% and 1.3% of patients were intubated in 1, 2 and 3 attempts respectively whereas 100% subjects were intubated in first attempt by Truflex stylet (p=0.2453, using Fisher's exact test). Thus in our study there is no statistical difference between Truflex and conventional stylet with respect to successful or failed intubation.

We estimated mean glottiscopy time of conventional stylet group and Truflex stylet group, which were are 7.85 ± 0.96 seconds and 7.89 ± 0.92 seconds respectively (p=0.8293, using unpaired t-test).Thus in our study there is no statistical difference between Truflex and conventional stylet and is not comparable to previously conducted studies.

In our study, mean endotracheal tube negotiation time of conventional stylet group and Truflex stylet group was 8.83 ± 1.84 seconds and 8.33 ± 0.92 seconds respectively (p=0.0328, using unpaired t-test). The endotracheal tube intubation time was significantly less in patients in whom Truflex stylet was used as compared to patients in whom conventional rigid stylet was used. (p=0.0328). Thus in our study it shows that there is statistical difference between Truflex and conventional stylet ; and therefore prove that Truflex stylet is associated with decreased endotracheal negotiation time.

In this study, average total intubation time of conventional stylet group and Truflex stylet group was 16.68 ± 2.74 seconds and 16.22 ± 1.82 seconds respectively (p=0.2095, using unpaired t-test). Thus in our study there is no statistical difference between Truflex and conventional stylet and is not comparable to previously conducted studies.

In our study no complications were found in either groups.

VIII. Conclusion

In this study we compared Conventional rigid malleable stylet with Truflex articulating stylet and this study demonstrated that there is a significant difference in endotracheal negotiation time which was shorter while using Truflex articulating stylet ; while there were no statistically significant difference in glottiscopy time, total intubation time, number of attempts, hemodynamic variables and associated complications.

In our study we have observed that success rate of Truflex stylet is better for endotracheal negotiation as compared to Conventional stylet for Cormack- Lehane's grade 2 and grade 3 patients. Although this is incidental finding, this could be further explored by separate study having only Cormack- Lehane classification as the stratification criterion. This could give a clear picture for the said difference.

IX. Strength And Limitations Of The Study

The strength of the present study lies in its prospective design as there are very few prospective studies to assess the efficacy of Truflex articulating stylet for tracheal intubation. Our study included patients in different age groups and randomization minimized further confounders making the results more scientifically robust.

In our study all the intubations were performed by experienced anaesthesiologist; therefore the results obtained may differ when the intubations are performed by less experienced anaesthesiologists. In our study only elective surgical patients with normal airways were included, so the utility of Truflex stylet during difficult intubation is not known.Since Truflex stylet is a new device, a learning curve is associated with the use of device.The cost of Truflex stylet also limits its use.

References

1. Boedeker BH, Barak-Bernhagen MA, Miller DJ, Nicholas TA 4th, Linnaus A, Murray WB. Improving rigid fiberoptic intubation: a comparison of the Bonfils Intubating Fiberscope with a novel modification. BMC Emerg Med. 2010 May 27;10:11
2. Juvin P, Lavaut E, Dupont H, Lefevre P, Demetriou M, Dumoulin JL, DesmontsJM.Difficult tracheal intubation is more common in obese than in lean patients. Anesth Analg. 2003 Aug;97(2):595-600
3. Cheney FW, Posner KL, Caplan RA. Adverse respiratory events infrequently leading to malpractice suits. A closed claims analysis. Anesthesiology 1991;75:932- 9.
4. Marcin Cierniak, Marcin Nowakowski, DariuszTimler, Tomasz Gaszyński. A comparison of the effectiveness of intubation using a McGrath Series 5 videolaryngoscope with either a Truflex articulating stylet or a standard intubation stylet in a group of medical students. Signa Vitae 2015; 10(1): 127-135.
5. EftekharianJahromi HR. Guide Wire J-Tip Technique for Easy Exchange of In Situ Endotracheal Tubes. Iran J Med Sci 2012;37:141-3.
6. Cattano D, Schober P, Krage R, van Rijn C, van Groeningen D, Loer SA, Schwarte LA. Cormack-Lehane classification revisited. Br J Anaesth. 2010 Nov;105(5):698-9
7. Kulkarni AP, Tirmanwar AS. Comparison of glotticvisualisation and ease of intubation with different laryngoscope blades. Indian J Anaesth 2013;57:170-4.
8. Noppens RR, Mobus S, Heid F, Schmidtmann I, Werner C, Piepho T: Evaluation of the McGrath Series 5 videolaryngoscope after failed direct laryngoscopy. Anaesthesia 2010, 65:716–20.
9. Al-Qasmi A, Al-Alawi W, Malik AM, Khan RM, Kaul N. Trials. Assessment of Truflex articulating stylet versus conventional rigid Portex stylet as an intubation guide with the D-blade of C-Mac videolaryngoscope during elective tracheal intubation: study protocol for a randomized controlled trial. BioMed Central.2013;14:298.
10. Kenneth Rothfield. The Video Laryngoscopy Market past present, and Future. August, 2014;40:8.
11. Cormack RS, Lehane J. Difficult tracheal intubation in obstetrics. Anaesthesia 1984; 39: 1105–11.
12. Tomasz Gaszynski. King Vision video laryngoscope with TruFlex articulating stylet for awake intubation. August 28,2014.

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