The StyletScope™ is a better intubation tool than a conventional stylet during simulated cervical spine immobilization

[Le StyletScope™ est un meilleur outil d'intubation que le stylet traditionnel pendant l'immobilisation simulée de la colonne cervicale]

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Purpose: We compare the StyletScope™ fibreoptic stylet (FOS) and the Satin Slip™ conventional metal stylet (CMS), during simulated difficult airway management with manual-in-line stabilization in terms of ease of intubation and esophageal intubation.

Methods: 193 patients (ASA I–II, 18–80 yr) were studied in a non-crossover, randomized fashion. Manual-in-line stabilization was applied and the best laryngoscopic view obtained. For the CMS, the primed tracheal tube was advanced under direct vision if Cormack-Lehane grade 1/2, placed behind the epiglottis and advanced blindly if grade 3, and intubation was not attempted if grade 4. For the FOS, the primed tracheal tube was advanced under the direct vision if grade 1/2 and under fibreoptic vision if grade 3/4.

Results: Intubation was successful more frequently ($P = 0.02$) and required fewer attempts ($P = 0.003$) with the FOS than the CMS. Intubation with the FOS was successful more frequently ($P = 0.02$) and required fewer attempts ($P = 0.007$) than the CMS if grade 3/4. For both stylets, intubation required fewer attempts ($P < 0.007$) and was quicker ($P \leq 0.0001$) for grade 1/2 than 3/4. Esophageal intubation occurred more frequently with the CMS (14 *vs* 0, $P = 0.0001$).

Conclusion: Tracheal intubation is more successful, requires fewer attempts and esophageal intubation is less frequent with the FOS than the CMS during cervical spine immobilization using manual-in-line axial stabilization. The FOS is a more effective intubation instrument compared to the CMS in patients with simulated cervical spine immobilization.

Objectif : *Comparer le stylet fibroscopique (SFS) StyletScope™ et le stylet de métal traditionnel (SMT) Satin Slip™, pour la simulation d'un contrôle difficile des voies aériennes avec stabilisation manuelle en ligne quant à la facilité d'intubation et à l'intubation œsophagienne.*

Méthode : *L'étude randomisée, non croisée, a porté sur 193 patients (ASA I–II, 18–80 ans). On a appliqué la stabilisation en ligne et obtenu la meilleure vue laryngoscopique. Pour le SFS, le tube endotrachéal amorcé a été avancé sous vision directe avec un grade de Cormack-Lehane de 1/2, placé derrière l'épiglotte et avancé à l'aveugle avec un grade 3 et l'intubation n'a pas été tentée avec un grade 4. Pour le SMT, le tube a été avancé sous vision directe avec un grade 1/2 et sous vision fibroscopique avec un grade 3/4.*

Résultats : *L'intubation a été réussie plus souvent ($P = 0,02$) et a demandé moins d'essais ($P = 0,003$) avec le SFS qu'avec le SMT. Avec un grade 3/4, l'intubation avec le SFS a été réussie plus souvent ($P = 0,02$) et avec moins d'essais ($P = 0,007$) qu'avec le SMT. Pour les deux stylets, l'intubation a nécessité peu d'essais ($P < 0,007$) et a été plus rapide ($P \leq 0,0001$) pour un grade 1/2 qu'un grade 3/4. L'intubation œsophagienne est survenue plus souvent avec le SMT (14 vs 0, $P = 0,0001$).*

Conclusion : *L'intubation trachéale réussit mieux et en moins d'essais, et l'intubation œsophagienne est moins fréquente, avec le SFS qu'avec le SMT lors de l'immobilisation de la colonne cervicale réalisée avec la stabilisation axiale manuelle en ligne. Le SFS, comparé au SMT, est plus efficace pour l'intubation en cas d'immobilisation simulée de la colonne cervicale.*

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THE StyletScope™ fibreoptic stylet (FOS; Nihon Koden Corporation, Tokyo, Japan) is a new intubating device that is similar to a metal intubation stylet, but provides a fibreoptic view and has a maneuverable tip that can be flexed by depressing a lever (Figure 1). Kitamura *et al.*,[1] the inventors of the FOS, reported a 100% intubation success rate in 32 patients with simulated Cormack-Lehane grade 3, and Kitamura and Yamada[2] reported a 100% intubation success rate in 11 patients without laryngoscopy. In the following randomized study, we compare the performance of the FOS with a Satin Slip™ conventional metal stylet (CMS; Mallincrodt Medical, Glens Falls, NY, USA) during simulated difficult airway management with manual-in-line stabilization in terms of ease of intubation, hemodynamic changes, and frequency of hypoxia, esophageal intubation, tissue trauma and postoperative pharyngolaryngeal complaints.

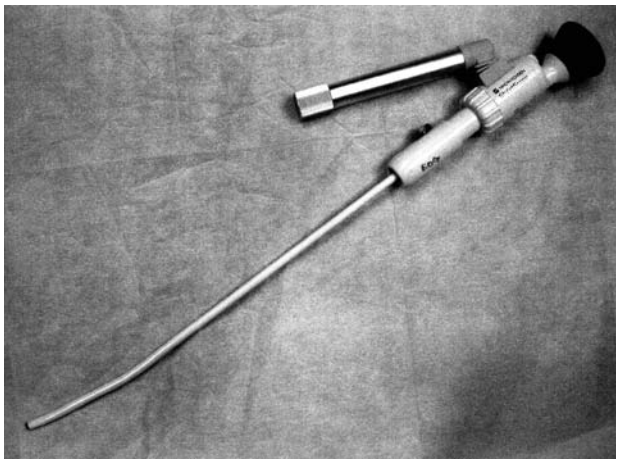

FIGURE 1 The StyletScope™.

Methods

We studied 193 patients (ASA physical status I–II, 18–80 yr) scheduled for elective surgery under general anesthesia requiring tracheal intubation. Ethical Committee approval and written informed consent were obtained. Exclusion criteria from the trial were a known or predicted difficult airway, cervical spine and airway pathology, cardiorespiratory and cerebrovascular disease, mouth opening < 2.5 cm, a body mass index > 35 $kg \cdot m^2$, or a risk of aspiration. Patients were randomly assigned to laryngoscope-guided tracheal intubation using a FOS or CMS by opening a sealed opaque envelope.

All patients were fasted for at least eight hours and premedicated with diazepam 5 mg and roxatidine 75 mg 100 min pre-induction. Modified Mallampati score,[3] thyromental, sternomental[4] and inter-incisor distances (with head extension)[4] were measured at the preanesthetic visit. Monitoring included an electrocardiograph, pulse oximeter, gas analyzer, non-invasive blood pressure (BP) monitor (BP508, Nippon Colin Co., Ltd., Tokyo, Japan) and peripheral nerve stimulator. The patient was in the supine position with the head on a standard pillow 7 cm in height. Oxygen was administered via a face mask for five minutes. Lidocaine 0.5 $mg \cdot kg^{-1}$ was given *iv* with a venous tourniquet inflated to prevent pain on injection of propofol. Thirty seconds later, the tourniquet was released and anesthesia was induced with propofol 2 $mg \cdot kg^{-1}$ and fentanyl 2 $\mu g \cdot kg^{-1}$, and maintained with sevoflurane 2% in oxygen 33% and nitrous oxide. Muscle relaxation was obtained with vecuronium 0.1 $mg \cdot kg^{-1}$. Patients were ventilated via a face mask for five minutes until the train-of-four count was zero. Face mask ventilation was graded as easy (Guedel airway not required), moderately easy (Guedel airway required), difficult (Guedel airway plus jaw thrust required) and failed (failure to ventilate, alternative technique required).

Immediately pre-intubation, the pillow was removed, the head and neck placed in the neutral position, and manual-in-line stabilization applied by a trained assistant by holding the patient's temple and applying counter traction against the intubator to maintain the neutral head-neck position. A curved PVC tracheal tube (7.0-mm internal diameter) was primed with the randomized stylet. A single experienced anesthesiologist (> 3,000 conventional laryngoscope-guided tracheal intubations, including > 100 with each stylet) obtained the best possible view of the glottis without laryngeal pressure using a #3 Macintosh laryngoscope. In the CMS group, if the glottic view[5] was Cormack-Lehane grade 1 or 2, the tracheal tube was advanced into the trachea under direct vision. If the glottic view was Cormack-Lehane grade 3, the tracheal tube was placed behind the epiglottis and advanced towards the glottis; however, if tactile resistance was encountered, the primed tracheal tube was removed and the angle of the stylet adjusted into a 'hockey stick' shape, as judged by the anesthesiologist. If the glottic view was Cormack-Lehane grade 4, tracheal intubation was not attempted and considered failed. In the FOS group, if the glottic view was Cormack-Lehane grade 1 or 2, the primed tracheal tube was advanced into the trachea

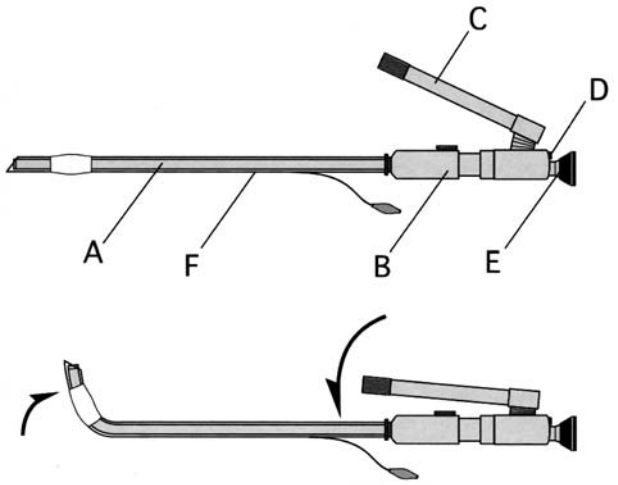

FIGURE 2 Schematic of the StyletScope™: A) Stylet with maneuverable tip and plastic fibrescope; B) Handle with 1.5 mm tracheal tube adapter and stylet length adjuster; C) Lever incorporating two 1.5-V alkaline batteries; D) Light source; E) Eyepiece; F) Tracheal tube. By depressing the lever on the handle, the distal tip of the stylet, together with the tracheal tube, can be flexed 75°. The StyletScope™ can be used by a single operator. There is no camera attachment.

TABLE I Demographic and airway assessment characteristics

	FOS	*CMS*
Number of patients	97	96
Gender (m/f)	57/40	45/51
Age (yr)	50.1 ± 16.1	49.3 ± 16.4
Height (cm)	160.8 ± 9.8	159.9 ± 9.5
Weight (kg)	61.1 ± 10.2	59.5 ± 11.5
ASA PS (1/2)	84/13	77/19
Mallampati score (1/2/3)	69/27/1	68/27/1
Thyromental distance (cm)	7.8 ± 0.9	7.9 ± 0.9
Sternomental distance (cm)	12.4 ± 1.6	12.3 ± 1.6
Inter-incisor distance (mm)	44.1 ± 6.1	44.3 ± 7.1
Dentition (own/partial/edentulous)	76/13/8	78/11/7

Data are mean ± SD or number of patients. No significant difference between groups. FOS = fibreoptic stylet; CMS = conventional metal stylet; ASA PS = American Society of Anesthesiologists physical status.

TABLE II Intubation data

	FOS	*CMS*
Cormack-Lehane grade (1/2/3/4)	6/26/64/1	3/30/61/2†
Laryngoscope used (yes/no)	32/65	33/61
Intubation success rate (%)	99*	92
Number of intubation attempts (1/2/3/fail)	84/10/2/1*	61/21/4/8
Duration of intubation (sec)	36 ± 19	36 ± 20
$EtCO_2$ immediately pre-intubation (mmHg)	32 ± 4	33 ± 5
EtSevo immediately pre-intubation (%)	1.3 ± 0.2	1.4 ± 0.2

Data are mean ± SD or number of patients. *$P < 0.05$. FOS *vs* CMS. †Intubation not attempted in two patients with Cormack-Lehane grade 4. FOS = fibreoptic stylet; CMS = conventional metal stylet.

under direct vision with the angle of the tip being adjusted by manipulation of the lever, as necessary. If the glottic view was Cormack-Lehane grade 3 or 4, intubation was attempted under fibreoptic vision as follows: 1) the primed tracheal tube was advanced behind the epiglottis under direct vision (Cormack-Lehane grade 3) or fibreoptically (Cormack-Lehane grade 4); 2) the glottis was identified under fibreoptic vision by manipulation of the tip; and 3) the primed tracheal tube was advanced into the trachea. A maximum of three attempts was permitted. A failed attempt was defined as removal of the primed tracheal tube from the mouth. Laryngoscopy was maintained throughout the intubation attempts. If intubation failed after three attempts or was Cormack-Lehane grade 4 in the CMS group, manual-in-line stabilization was released and intubation was attempted without manual-in-line stabilization.

The following data were collected by an unblinded observer: ease of face mask ventilation; number of intubation attempts; reason for failure (CMS; Cormack-Lehane grade 4, tactile resistance; esophageal intubation; FOS; failure to locate glottis; view obstructed by secretions or fogging; esophageal intubation); intubation time (from insertion of the laryngoscope to confirmation of tracheal intubation by capnography); mucosal trauma (blood seen on the laryngoscope); lip or dental injury; and hypoxia (SaO_2 < 95%). Non-invasive BP and heart rate were recorded immediately pre-induction, immediately pre-intubation, and one minute after successful intubation. End-tidal sevoflurane and CO_2 concentrations were recorded immediately pre-intubation.

Pharyngolaryngeal morbidity was assessed 18 to 24 hr postoperatively by an investigator blinded to the method of intubation. Sore throat and hoarseness were graded on an established four-point scale.[6] Sore throat was graded as: 0 = no sore throat; 1 = less severe than with a cold; 2 = similar to that noted with a cold; 3 = more severe than with a cold. Hoarseness was graded as: 0 = no hoarseness; 1 = noted by a patient; 2 = obvious to observer; 3 = aphonia.

TABLE III Intubation characteristics for direct and indirect techniques

	FOS		*CMS*	
Cormack-Lehane grade	1,2	3,4	1,2	3
Intubation technique	Direct	Fibreoptic	Direct	Blind
Number of patients	32	65	33	61
Intubation success rate (%)	100	98.5*	100	87†
Number of intubation attempts (1/2/3/fail)	32/0/0/0	52/10/2/1*†	31/0/2/0	30/21/2/8†
Duration of intubation (sec)	25 ± 5	41 ± 21†	27 ± 13	41 ± 21†

Data are mean ± SD or number of patients. *$P < 0.05$. FOS *vs* CMS. †$P < 0.05$. Direct *vs* blind or fibreoptic. FOS = fibreoptic stylet; CMS = conventional metal stylet.

Sample size was selected to detect a projected difference of 20% between groups for a type I error of 0.05 and a power of 0.8 with respect to intubation success rate in Cormack-Lehane grade 3/4 patients (based on a 60% incidence of grade 3/4 with manual-in-line stabilization).[7] Descriptive data were tested using a two-tailed independent t test. Categorical data were tested by Chi-square test. The Mann Whitney U test was used for scored data. Unless otherwise noted, data are presented as mean ± SD. Significance was taken as $P < 0.05$.

Results

There were no differences in demographic and airway assessment characteristics between groups (Table I). Face mask ventilation was graded as easy in all patients. Intubation was successful more frequently ($P = 0.02$) and required fewer attempts ($P = 0.003$) with the FOS than the CMS, but duration of intubation was similar (Table II). Intubation was always successful at the first attempt with the FOS if grade 1/2; two patients required three attempts with the CMS (Table III). Intubation with the FOS was successful more frequently ($P = 0.02$) and required fewer attempts ($P = 0.007$) than the CMS if grade 3/4 (Table III). Intubation was successful more frequently in patients who were grade 1/2 than 3/4 for the CMS ($P = 0.004$), but not for the FOS (Table III). For both stylets, intubation required fewer attempts ($P < 0.007$) and was quicker ($P \leq 0.0001$) for grade 1/2 than 3/4 (Table III). The reasons for failure (at the first, second or third attempt) with the CMS were Cormack-Lehane grade 4 ($n = 2$), esophageal intubation ($n = 14$) and tactile resistance ($n = 39$). The reasons for failure (at the first, second or third attempt) with the FOS were failure to locate glottis ($n = 13$) and view obstructed by persistent secretions ($n = 3$) or fogging ($n = 1$). Esophageal intubation occurred more frequently with the CMS (14 *vs* 0, $P = 0.0001$). Hemodynamic variables (Table IV) and the frequency of hypoxia, bleeding, lip and dental trauma, and postoperative pharyngolaryngeal complaints were similar between groups (Table V) and were unaffected by Cormack-Lehane grading within groups.

TABLE IV Hemodynamic variables

	FOS	*CMS*
Systolic blood pressure (mmHg)		
Pre-induction	136 ± 21	134 ± 22
Pre-intubation	85.9 ± 15	87 ± 13
Postintubation	126 ± 27	122 ± 29
Diastolic blood pressure (mmHg)		
Pre-induction	76 ± 12	75 ± 13
Pre-intubation	46 ± 9	47 ± 9
Postintubation	74 ± 20	70 ± 19
Heart rate (beats·min^{-1})		
Pre-induction	75 ± 15	72 ± 14
Pre-intubation	63 ± 11	63 ± 12
Postintubation	80 ± 15	78 ± 15

Data are mean ± SD. Interdevice comparison. No significant difference between groups. FOS = fibreoptic stylet; CMS = conventional metal stylet.

TABLE V Airway complications

	FOS	*CMS*
Desaturation (y/n)	0/97	0/96
Mucosal injury (y/n)	9/88	13/83
Dental damage (y/n)	0/97	1/95
Lip injury (y/n)	8/89	7/89
Sore throat (0/1/2/3)*	67/19/10/1	71/11/10/4
Hoarseness (0/1/2/3)†	71/12/13/1	71/7/17/1

Data are number of patients. *Sore throat: 0 = no sore throat; 1 = less severe than with a cold; 2 = similar to that noted with a cold; 3 = more severe than with a cold. †Hoarseness: 0 = no hoarseness; 1 = noted by a patient; 2 = obvious to observer; 3 = aphonia. No significant difference between groups. FOS = fibreoptic stylet; CMS = conventional metal stylet.

Discussion

The FOS has a higher intubation success rate with fewer attempts and a lower frequency of esophageal intubation than the CMS during simulated difficult airway management with manual-in-line stabilization. All the improvement in performance was in patients who were Cormack-Lehane 3/4. This is not surprising since the fibreoptic component allows the vocal cords to be seen and the maneuverable tip allows it to be redirected. These findings suggest that the FOS may be useful in the difficult airway scenario and in patients requiring manual-in-line stabilization. Our first attempt success rate for Cormack-Lehane 3/4 was slightly lower than that of Kitamura *et al.*[1] (80% *vs* 94%). This may be related to our use of manual-in-line stabilization rather than intentional insufficient laryngoscopy. Our success rate with the CMS was higher than previously reported for a metal stylet (66%), but our success rate with the FOS was similar to the gum elastic bougie (96%).[8] An advantage of the FOS over some other difficult airway devices is that it can be used with or without a laryngoscope.[2] Three of the four failures with the FOS were due to persistent secretions (could not be removed by suction) and the other due to fogging. Perhaps the secretions could have been reduced by an antisialagogue and the fogging by warming the FOS or applying an anti-fogging solution.

Three techniques have been used to simulate the difficult airway: 1) intentional insufficient laryngoscopy,[9] 2) manual-in-line stabilization plus laryngeal pressure,[10–13] and 3) use of a rigid neck collar.[13] Intentional insufficient laryngoscopy runs the risk of inter-observer bias because the grade of laryngeal exposure is primarily decided by the effort of the intubator. The rigid neck collar method solves this problem, but puts the patient at risk of hypoxia since face mask ventilation may be difficult due to poor fit against the face. The frequency of Cormack-Lehane grade 3/4 using manual-in-line stabilization plus laryngeal pressure is 22 to 39%[10–13] and using a rigid collar is 64 to 65%.[13–15] We found that the frequency of Cormack-Lehane grade 3/4 using manual-in-line stabilization without laryngeal pressure was 66% and that there were no episodes of hypoxia. This technique should allow smaller sample sizes than manual-in-line stabilization with laryngeal pressure and hypoxia may be less likely than with a rigid collar.

We found no difference in hemodynamic responses, or the frequency of trauma and postoperative pharyngolaryngeal complaints between stylets. This suggests that the additional attempts with the CMS were relatively unstimulating and atraumatic. It is possible that more trauma would have occurred with the CMS if the two Cormack-Lehane grade 4 patients were included. We did not attempt intubation in these patients because we felt the risk of trauma was too high. The study findings would not have been influenced by the inclusion of these patients. The hemodynamic responses, frequency of trauma and postoperative pharyngolaryngeal complaints were similar to conventional laryngoscopy and tracheal intubation.[16]

Our study has two limitations. Firstly, an experienced user conducted all intubations and our results may not be applicable to inexperienced personnel. Secondly, the intraoperative data were collected by an unblinded observer, a potential source of bias.

We conclude that tracheal intubation is more successful, requires fewer attempts and esophageal intubation is less frequent with the FOS than the CMS during cervical spine immobilization using manual-in-line axial stabilization. The FOS is a more effective intubation instrument compared to the CMS in patients with simulated cervical spine immobilization.

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