

Brief report: Tracheal intubation using the Bonfils intubation fibroscope or direct laryngoscopy for patients with a simulated difficult airway

[Compte-rendu court : L'intubation trachéale à l'aide du fibroscope d'intubation Bonfils ou la laryngoscopie directe pour le traitement de patients présentant des voies aériennes difficiles simulées]

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Background: The Bonfils intubation fibroscope (BIF), a rigid, straight and reusable fibreoptic device, is being used increasingly to facilitate endotracheal intubation after direct laryngoscopy has failed. We tested the hypothesis that, with the BIF compared to direct laryngoscopy, the rate of failed endotracheal intubation could be reduced in patients with a difficult airway, simulated by means of a rigid cervical immobilization collar.

Methods: Seventy-six adults undergoing elective gynecological surgery under general anesthesia were randomly assigned to have endotracheal intubation, facilitated with either a standard size 3 Macintosh laryngoscope blade, or the BIF. A rigid cervical immobilization collar was used to simulate a difficult airway, by reducing mouth opening and limiting neck extension. If endotracheal intubation could not be achieved within two attempts, the cervical collar was removed, and direct laryngoscopy was performed thereafter, using a Macintosh blade in all subjects. The success rate of endotracheal tube placement was the primary outcome variable.

Results: Patient characteristics were similar in the two groups. After neck immobilization, the inter-incisor distance was reduced to 2.6 ± 0.7 cm (Macintosh) and 2.6 ± 0.8 cm (BIF). Tube placement was successful in 15/38 (39.5%) patients with a Macintosh blade, and in 31/38 patients with the BIF (81.6%; $P = 0.0003$). Time required for tube placement was 53 ± 22 sec (Macintosh) and 64 ± 24 sec (BIF; $P = 0.15$).

Conclusion: The Bonfils intubation fibroscope is a more effective intubating device for patients with immobilized cervical spine and significantly limited inter-incisor distance, when compared to direct laryngoscopy.

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Contexte : Le fibroscope d'intubation Bonfils (BIF) est un appareil fibroscopique rigide, droit et réutilisable qui est de plus en plus utilisé pour faciliter l'intubation endotrachéale lors de l'échec d'une laryngoscopie directe. Nous avons testé l'hypothèse que lorsque le BIF est comparé à la laryngoscopie directe, le taux d'échec de l'intubation endotrachéale pouvait être réduit chez des patients présentant des voies aériennes difficiles, lesquelles ont été simulées grâce à un collier d'immobilisation cervicale rigide.

Méthode : Soixante-seize adultes devant subir une chirurgie gynécologique programmée sous anesthésie générale ont été randomisées à recevoir une intubation endotrachéale, facilitée soit par une lame de laryngoscope Macintosh de taille standard 3 ou par le BIF. Un collier d'immobilisation cervicale rigide a été placé pour simuler des voies aériennes difficiles en réduisant l'ouverture de la bouche et en limitant l'extension du cou. Si l'intubation trachéale ne réussissait pas après deux essais, le collier cervical était retiré et une laryngoscopie directe réalisée ensuite à l'aide d'une lame Macintosh chez toutes les patientes. Le critère d'efficacité principal était le taux de positionnement correct de la sonde endotrachéale.

Résultats : Les caractéristiques des patientes étaient similaires dans les deux groupes. Après immobilisation du cou, l'espace entre les incisives a été réduit à $2,6 \pm 0,7$ cm (Macintosh) et $2,6 \pm 0,8$ cm (BIF). La sonde a été placée correctement chez 15/38 (39,5 %) patientes avec une lame Macintosh et chez 31/38 patientes avec le BIF (81,6 %; $P = 0,0003$). Le temps requis pour le positionnement

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de la sonde était de 53 ± 22 sec (Macintosh) et 64 ± 24 sec (BIF; $P = 0,15$).

Conclusion : Comparé à la laryngoscopie directe, le fibroscope d'intubation Bonfils est un appareil d'intubation plus efficace pour les patients ayant la colonne cervicale immobilisée et un espace entre les incisives considérablement limité.

PATIENTS with an unanticipated difficult airway requiring endotracheal intubation, remain an ongoing challenge for anesthesiologists and emergency physicians. If direct laryngoscopy fails, various supraglottic devices can be used to establish an artificial airway, according to the American Society of Anesthesiologists' difficult airway algorithm.¹ For some patients, however, endotracheal intubation is crucial to securing the airway, protecting the lungs from aspiration of gastric contents, and for managing patients in the prone position. In addition to flexible fibreoptic bronchoscopy, and the less commonly used Bullard® (Circon ACMI, Stamford, CT, USA) and Wu® (Achi Co., San Jose, CA, USA) scopes, other devices are used with increasing frequency for endotracheal tube placement in patients with potentially challenging intubating conditions. For example, due to cervical spine immobilization, the intubating laryngeal mask (ILMA)® (LMA Deutschland GmbH, Bonn, Germany) allows blind insertion of an endotracheal tube,² while the Trachlight® stylet (Laerdal Medical Co., Wappingers Falls, NY, USA) facilitates intubation based upon the principle of transillumination of the soft tissues of the neck.^{3,4} Devices which apply the principle of indirect visualization of the laryngeal structures include the GlideScope® (Verathon Inc., Bothell, WA, USA), a video laryngoscope with a digital camera located at the blade tip, and a small, separate LCD-monitor connected to the laryngoscope handle with a short cable.^{3,4} The rigid Bonfils® intubation fibroscope (Karl Storz GmbH and Co. KG, Tuttlingen, Germany),⁵ which has been shown to be effective for difficult airway management,⁶ allows visualization of the glottic aperture and the trachea, and thus endotracheal tube placement under vision. Although the efficacy of the Bonfils intubation fibroscope has been demonstrated in patients with *anticipated* difficult airway based on predictors,⁷ its use has not been prospectively evaluated in patients with *documented* difficult airways. We tested the hypothesis that the rate of failed endotracheal intubation with direct laryngoscopy could be reduced with the Bonfils intubation fibroscope in patients with a difficult airway, simulated by means of a rigid cervical immobilization collar.

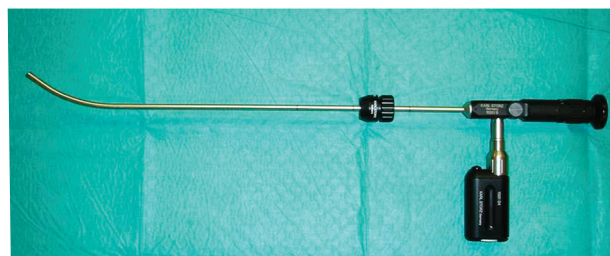


FIGURE 1 Bonfils intubation fibroscope with battery-powered light source attached. The fibroscope is a reusable, rigid, straight device with a 40° curved tip, and a movable eyepiece mounted on the handle. The length is approximately 40 cm, with an external diameter of 5 mm. It Bonfils fibroscope is suitable for endotracheal tubes with an internal diameter ≥ 6.0 mm and a length ≤ 39 cm.

Methods

After approval of the study protocol by the institutional Review Board, 76 adult patients undergoing elective gynecological surgery under general anesthesia were included in the study after informed, written consent was obtained. All patients underwent preoperative evaluation and thorough airway examination on the day before surgery. Those patients presenting with two or more predictors for difficult mask ventilation,⁸ difficult endotracheal intubation, or both, were excluded from the study. In addition, any patient with a history of difficult endotracheal intubation was excluded. A combination of at least two of the following factors was considered predictive for a potentially difficult airway: intraoral, pharyngeal, laryngeal or cervical masses, history of surgery in these regions, Mallampati class 3 or 4, thyromental distance < 6.5 cm, neck extension $< 30^\circ$, inter-incisor distance < 3.5 cm, patients who were edentulous, patients with a beard, and patients with a history of snoring or obstructive sleep apnea.

Patients were randomly allocated to one of two groups, to receive endotracheal intubation, facilitated either by direct laryngoscopy with a size 3 Macintosh blade, or with the Bonfils intubation fibroscope. Allocation concealment was achieved with the use of coded, sealed, opaque envelopes, and randomization was established by simple shuffling of the envelopes. In the operating room, routine monitors were applied, and anesthesia was induced intravenously in all patients. Following verification of adequate bag-mask ventilation, neuromuscular blockade was achieved with cisatracurium $0.1 \text{ mg}\cdot\text{kg}^{-1} \text{ iv}$. A difficult airway was created with a cervical immobiliza-

tion collar (Stifneck Select, Leardal Medical GmbH, Puchheim, Germany), the appropriate size being selected according to the manufacturer's instructions with the finger-sizing method. This device effectively downsizes mouth opening, and limits neck extension.

The Bonfils intubation fibroscope is a reusable, rigid, straight device with a 40° curved tip, and a movable eyepiece mounted on the handle of the scope (Figure 1). The length is approximately 40 cm, with an external diameter of 5 mm. It is suitable for tracheal tubes with an internal diameter ≥ 6.0 mm and a length ≤ 39 cm; thus, all standard single-lumen endotracheal tubes can be used without cutting them. The fibroscope carries a connector that fits onto the 15-mm tracheal tube adapter, thereby allowing oxygen insufflation. A cold light source or a small battery handle, powered by two 1.5 V alkaline batteries, can be attached to the stylet handle. In contrast to a flexible fibroscope, the Bonfils intubation fibroscope does not have a working or suctioning channel. The scope is inserted from the right, alongside the patient's molars. A conventional size 3 Macintosh blade was simultaneously inserted with the operators' left hand to create sufficient retropharyngeal space (Figure 2). Guided by the operator's right hand, the Bonfils intubation fibroscope was advanced underneath the epiglottis, then carefully guided through the glottic aperture, until tracheal rings could be identified. The endotracheal tube was then inserted into the trachea under direct vision. A 7.0-mm internal diameter endotracheal tube, with an outer diameter of 9.6 mm, was used in every instance (Lo-Contour™ Tracheal Tube, Nellcor, Pleasanton, CA, USA). All tracheal intubations were performed by a single operator, who had a experience with over 50 tracheal intubations using the Bonfils intubation fibroscope.

Before endotracheal intubation, all patients received bag-ventilation for three minutes with 100% oxygen. A maximum of two direct laryngoscopy attempts was carried out in patients assigned to undergo endotracheal intubation with a Macintosh blade. The same applied to the Bonfils group. Regardless of group allocation, intubation attempts were stopped either after 120 sec, or when oxygen saturation measured by pulse oximetry decreased below 92%. In these cases, the cervical immobilization collar was removed and, after intermittent mask ventilation with 100% of oxygen, conventional direct laryngoscopy was performed with a standard size 3 Macintosh laryngoscope blade.

The primary outcome variable was success in correct endotracheal tube placement. Due to the nature of this study, the physician who performed the tracheal intubation was not blinded to the airway device being

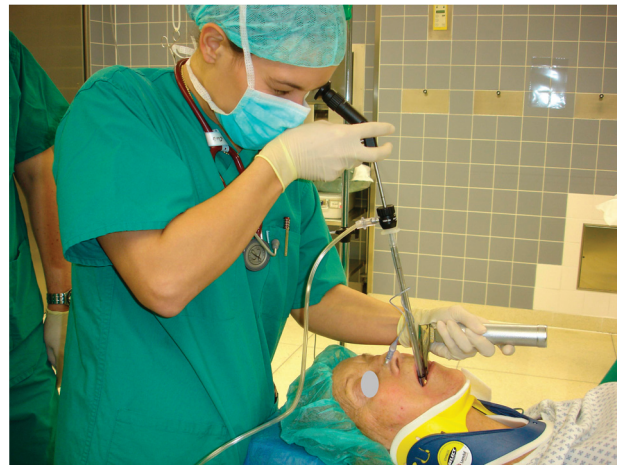


FIGURE 2 While sufficient retropharyngeal space is created with a size 3 Macintosh laryngoscope blade, the Bonfils intubation fibroscope loaded with an endotracheal tube is inserted from the right side of the patient's mouth, alongside the molars.

used. Secondary variables comprised the time required for endotracheal tube placement, defined as the interval between cessation of mask ventilation, until sufficient ventilation via the endotracheal tube was established (endtidal $\text{CO}_2 \geq 20$ mmHg, endtidal volume ≥ 400 mL). Furthermore, the best view obtained with direct laryngoscopy was rated according to the Cormack and Lehane scoring system⁹ as modified by Yentis and Lee:¹⁰ 1 = full view of the glottis; 2a = partial view of the glottis; 2b = arytenoids, or posterior portion of cords only visible; 3 = only the epiglottis visible; 4 = neither epiglottis nor glottis visible.

Statistical considerations

Sample size estimates suggested that 38 subjects per group would be needed to achieve 80% power to detect an absolute 35% reduction in the frequency of failed endotracheal intubation ($\alpha = 5\%$). After Gaussian distribution of the raw data was confirmed, all data were summarized as mean \pm standard deviation, or numbers and per cent. Statistical analysis was carried out using a software package (GraphPad InStat Version 3.06; GraphPad Software Inc., San Diego, CA, USA). Student's *t* test was applied to the primary outcome, and Fisher's exact test was used where appropriate. Statistical significance was assumed with a probability of type I error less than 5% ($P < 0.05$).

Results

No patient had any predictors for a difficult airway, or a history of difficult intubation. No intubation attempt had to be aborted because of oxygen desaturation, and all 76 patients completed the study. A post-hoc analysis of the study data calculated 96.8% power ($\beta = 0.032$).

The groups were similar with respect to mean age, height, weight, and inter-incisor distance (Table). Endotracheal tube placement was successful in 15 (39.5%) of 38 patients in the Macintosh group, and in 31 (81.6%) of 38 patients in the Bonfils fibrescope group ($P = 0.0003$). However, two attempts were required in one patient of the Macintosh group, and in four patients of the Bonfils group. All patients in whom tracheal intubation failed with the immobilization collar *in situ* ($n = 30$ in total) had successful tracheal intubation with a standard size 3 Macintosh blade, after removal of the collar.

The distribution of patients, according to the best glottic view obtained during direct laryngoscopy, was as follows: grade 1 ($n = 2$); grade 2a ($n = 3$); grade 2b ($n = 14$); grade 3 ($n = 18$); and grade 4 ($n = 1$). For all 31 patients in the Bonfils group whose tracheas were intubated successfully with the Bonfils device, a full view of the glottis (corresponding to Cormack and Lehane grade 1) could be obtained. Of remaining patients in the Bonfils group, lifting the epiglottis, and maneuvering the Bonfils device into the vallecula, failed in five subjects. In another subject, severe fogging of the lens obscured the view completely. For the one remaining patient in this group, a very tight fit of the cervical immobilization collar prevented any degree of mouth opening, and thus insertion of the Bonfils intubation fibrescope was impossible. The time required for successful endotracheal tube placement was 53 ± 22 sec with the Macintosh blade, compared to 64 ± 24 sec with the Bonfils intubation fibrescope ($P = 0.1508$). No procedure-related complication, such as dental, lip, or airway injury, was observed in either group.

Discussion

In this study, the Bonfils intubation fibrescope was associated with a higher success rate of endotracheal tube placement compared to a standard size 3 Macintosh laryngoscope blade, in patients with simulated difficult airway. With the Bonfils intubation fibrescope, a trend towards a longer duration of endotracheal intubation was observed.

Bein *et al.*⁷ showed previously, that endotracheal tube placement is faster with the Bonfils fibrescope when compared to the intubating laryngeal mask

TABLE Demographic data and inter-incisor distances

Group	Macintosh blade ($n = 38$)	Bonfils intubation fibrescope ($n = 38$)
Age (yr)	44.2 \pm 19.3	46.4 \pm 20.3
Height (cm)	168.2 \pm 7.0	167.4 \pm 5.7
Weight (kg)	71.2 \pm 9.9	69.3 \pm 8.3
BMI (kg·m ⁻²)	25.2 \pm 3.4	24.7 \pm 2.7
Inter-incisor distance (cm)	2.6 \pm 0.7	2.6 \pm 0.8

Data are expressed as mean \pm standard deviation. BMI = body mass index.

airway (ILMA), in patients with predicted difficult airway. The predictors of difficult airway included one or more of the following: Mallampati score ≥ 3 , thyromental distance < 6 cm, inter-incisor distance < 3.5 cm, or mobility at the atlanto-occipital joint $< 15^\circ$ according to Bellhouse and Dore.¹¹ The median time to first ventilation was significantly shorter with the ILMA (20 sec) in comparison with the Bonfils intubation fibrescope (40 sec).⁷ In contrast, the patients in our study had two strong predictors for difficult intubation after placing the rigid collar: inter-incisor distance < 3.5 cm, and immobility at the atlanto-occipital joint. Despite this challenging airway presentation, adequate ventilation via the endotracheal tube was achieved in a mean times of 64 ± 24 sec and 53 ± 22 sec, with the Bonfils intubation fibrescope and direct laryngoscopy, respectively. However, in contrast to Bein *et al.*,⁷ who reported a 100% success rate in endotracheal intubation using the Bonfils intubation fibrescope,⁷ success was achieved in 82% of patients in our study. In another investigation, Bein *et al.*⁶ observed that endotracheal intubation was successful in 96% of patients, when the Bonfils intubation fibrescope is used in patients with an unanticipated difficult airway, after direct laryngoscopy had failed.⁶

The main reason for intubation failure with the Bonfils intubation fibrescope in our study was most likely due to an inability to direct the rigid device underneath the epiglottis, despite the application of external laryngeal pressure. Since the patients' heads were fixed in a neutral position, it remains speculative as to whether or not endotracheal intubation would have been successful with a certain degree of atlanto-occipital joint mobility. It seemed likely, however, that this problem could have been overcome with greater curvature of the tip of the Bonfils device, e.g., 60° , instead of 40° . Unfortunately, the curvature of this device is fixed.

Lens fogging resulted in failed intubation in one patient of the Bonfils group. It is conceivable that

storing the Bonfils intubation fibrescope in a warm location could reduce the incidence of lens fogging. Regardless of the fact that the tip of the Bonfils intubation fibrescope is placed inside the endotracheal tube, thus protecting the lens from soiling to a greater extent than with a flexible fibrescope, the use of the Bonfils fibrescope also requires a relatively “dry” airway. Its usefulness is therefore limited, in patients with blood and/or extensive airway secretions.

Difficult laryngoscopy (Cormack and Lehane grades 3 and 4), was reported in 64% of patients when the cervical spine was immobilized in a rigid collar, with sandbags placed on either side of the neck, and tape placed across the forehead.¹² Using manual in-line stabilization of the cervical spine, difficult laryngoscopy with a Macintosh blade occurred in only 16–33% of patients.^{13,14} This improvement in intubating conditions can be attributed to almost unrestricted mouth opening during manual in-line stabilization, compared to a substantively diminished inter-incisor distance when a rigid cervical collar is used. Therefore, manual in-line stabilization of the cervical spine simulates a difficult airway to a lesser extent than a rigid immobilization collar.

With the introduction of the ILMA in 1997, an alternative to direct laryngoscopy became available for patients with an unanticipated difficult airway.² Several studies investigated the success of tracheal intubation with the ILMA in patients with cervical spine immobilization collars, however, their results were inconsistent. While tracheal intubation failed in 70% of patients in a study by Wakeling and Nightingale,¹⁵ Komatsu *et al.*¹⁶ reported a success rate of 96%. In the latter study, inter-incisor distance was smaller in the study group (4.1 ± 0.8 cm) than in the control group of subjects who had normal cervical spine clearance (4.6 ± 0.7 cm). The clinical impact of this small but statistically significant difference is uncertain. In our study, inter-incisor distance was only 2.6 ± 0.7 cm in the Macintosh group, and 2.6 ± 0.8 cm in the Bonfils group. These degrees of mouth opening were notably smaller than those reported in other randomized controlled trials. An inter-incisor distance which minimally exceeds the outer diameter of the corresponding endotracheal tube, when using the Bonfils fibrescope, is generally adequate when using this device. Supplementary insertion of a standard size 3 Macintosh blade to create sufficient retropharyngeal space for improved handling of the Bonfils intubation fibrescope, can be of additional benefit in patients with more restricted mouth opening. However, manipulating the Macintosh blade to obtain an improved laryngoscopic view that facilitates endotracheal tube

placement, requires more oropharyngeal space.

One methodological weakness of this study is that the operating physician performing tracheal intubation, could not be blinded, according to the airway device being evaluated. While potential bias therefore exists with respect to both the primary and secondary outcomes of interest, the fact that the outcome measures were objective, minimizes the potential negative impact of lack of blinding procedures.

In conclusion, the Bonfils intubation fibrescope is an effective and safe intubating device for patients with an immobilized cervical spine associated with limited inter-incisor distance. Even though the success rate of endotracheal intubation was significantly higher compared to direct laryngoscopy, a failure rate of 18% was observed with the Bonfils intubation fibrescope. Nevertheless, after gaining familiarity with the Bonfils intubation fibrescope in patients with normal airways during elective procedures, physicians should consider this device in patients with anticipated difficult airways due to limited neck extension and mouth opening.

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