

Bonfils Fiberscope: Intubating Conditions and Hemodynamic Changes without Neuromuscular Blockade

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Abstract- To compare intubating conditions and hemodynamic changes between Bonfils Intubation Fiberscope and Macintosh laryngoscopy without administering neuromuscular blocking drugs (NMBDs). **METHODS:** In this randomized controlled trial, 80 male and female patients, scheduled for elective surgery, aged 15 to 60 years, ASA class II or I, non-obese, non smokers, without anticipated difficult intubation; were randomly allocated into two groups of 40: Bonfils and Macintosh. Following adequate hydration and preoxygenation, midazolam 0.03 mg.kg⁻¹ was administered, followed by intravenous alfentanil 20 µg.kg⁻¹, lidocaine 1.0 mg.kg⁻¹, and propofol 2 mg.kg⁻¹ sequentially. Trachea was then intubated using Bonfils Intubation Fiberscope in the Bonfils group and conventional Macintosh laryngoscopy in the Macintosh group. Intubating condition, mean arterial blood pressure, heart rate, pulse oximetry, and success rate were measured. **RESULTS:** Clinically acceptable intubating condition scores did not differ significantly between the groups ($P=0.465$). Compared to the baseline values, heart rate rose significantly after intubation only in the Macintosh group ($P<0.001$). Although mean arterial blood pressure increased immediately after intubation in the Macintosh group ($P=0.022$), its post-intubation values were significantly less than baseline in both groups ($P<0.001$). Intubation time took much longer in the Bonfils group (40 s) than the Macintosh group (11 s), $P<0.001$. In the absence of NMBDs, Bonfils Intubation Fiberscope compares well with Macintosh laryngoscopy in terms of success rate and intubating conditions, but with less mechanical stress and hemodynamic compromise and longer intubation time.

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Introduction

Neuromuscular blocking drugs (NMBDs) are the drugs most frequently incriminated in the occurrence of severe perioperative bronchospasm (1) because of the release of endogenous histamine and/or their involvement in an 'immunoglobulin E'-mediated immune response (2, 3). It has been suggested to accomplish endotracheal intubation without the use of NMBDs (4) in patients with known allergic reactions or with myopathies. Moreover, avoiding NMBDs when they are not required for the planned procedure may also reduce the likelihood of awareness during general anesthesia (5).

Avoidance of NMBDs, however, may compromise excellent intubating conditions during Macintosh laryngoscopy⁴; and consequently triggers inadvertent injuries and prolonged intubation time with resulting

deleterious sympathetic responses (6, 7). In such settings, therefore, it is sound to seek alternative anesthetic regimens for induction of anesthesia and improved techniques for laryngoscopy.

Administration of propofol and a short-acting opioid such as alfentanil without utilizing NMBDs has proved to provide adequate intubating conditions and to inhibit harmful sympathetic responses after conventional Macintosh laryngoscopy (4, 5, 8-10). However, this requires higher doses of propofol (11) and opioids, which results in dose related hypotension, bradycardia, and delayed recovery (4, 5). The Bonfils Intubation Fiberscope (BIF, Figure 1) is suitable for tracheal intubation, causes less injury to the pharyngeal and laryngeal regions, and also helps avert excessive pressure and sympathetic responses seen during conventional Macintosh laryngoscopy in a well-

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paralyzed patient (12-15). The BIF has recently been evaluated against different intubation devices as well as the standard direct laryngoscopy (16-21). However, NMBD sparing techniques has not been an issue in these studies. If the BIF can retain its benefits in the absence of NMBDs, it may ultimately help reduce the optimal dosage of propofol and opioids and consequently minimize their adverse effects. We designed this study to address this issue.

Patients and Methods

Selection and description of participants

We obtained approval from the institutional review board, and patients' signed informed consent beforehand. We studied 80 patients in this randomized controlled trial at Sina hospital in Tehran. They were ASA I-II, aged 15-60 yr of both sexes, and presenting for elective surgery requiring endotracheal intubation. They were not smokers, alcohol or drug users, pregnant, or expected to present difficult intubation. They had not body mass index (BMI) >30, any systemic or airway disease, history of esophageal reflux, inability to assume the 'sniffing' position, or known allergy to the protocol medications. Predictions of a difficult intubation were based on 1) a history of failed tracheal intubation, 2) Upper Lip Bite Test (ULBT) class III (22), or 3) Mallampati score 3 or 4 (as modified by Samsoun & Young) (23, 24) combined with thyromental distance < 6.5 cm (25).

To allocate the patients into the two study groups of 40 patients, the Bonfils group and the Macintosh group, we used Random Allocation Software (26) version 1.0 to generate the allocation sequence in 4 permuted blocks of 20. Opaque sealed envelopes with printed serial numbers from one to 80 contained the name of either of the two study groups according to the randomization list. Envelopes were opened sequentially, by a nurse blinded to the patients, to assign the eligible patients to one of the two study groups before admitting each patient to the operating room.

Technical information

Fasting patients were placed supine on the operating table with occiput resting in the neutral position. Hydration with 7 ml.kg⁻¹ Ringer's solution was instituted over 20 minutes. Meanwhile, monitoring of electrocardiogram (Dynascope 3300, Fukuda Denshi Ltd. Co., Tokyo, Japan) and finger pulse oximetry (CO2SMO-Capnograph/Pulse Oximeter, Novamatrix, Wallingford, USA) was installed. After local infiltration of 1 ml lidocaine 1% through a 27 G needle, the radial artery of the non-dominant hand was cannulated with a 20 G over-the-needle catheter for invasive blood pressure monitoring.

When adequately hydrated, patients were preoxygenated with 5 L.min⁻¹ of 100% oxygen using the carbon dioxide absorption circuit (Sula 808, Dräger, Germany) for 5 minutes prior to induction of anesthesia. Two minutes before the induction, midazolam 0.03 mg.kg⁻¹ was injected intravenously. At time zero, alfentanil (Rapifen®, Janssen Pharmaceutical) 20 µg.kg⁻¹ was administered intravenously over 20 seconds. At minute one, 1.0 mg.kg⁻¹ (up to 100 mg) of lidocaine 2% was rapidly injected intravenously, to be followed immediately by 2.0 mg.kg⁻¹ propofol 1% (Fresenius Kabi, Hamburg, Germany) administered intravenously at a rate of 10 mg.s⁻¹. Bag-mask ventilation with 100% oxygen was initiated whenever the patient had lost consciousness and ceased spontaneous respiration, and continued toward initiation of laryngoscopy. Forty-five seconds following the conclusion of propofol administration, the anesthesiologist started introducing the previously prepared device (Bonfils fiberscope or Macintosh laryngoscope) into the patient's mouth.

In the Bonfils group, the laryngoscopy was performed using the Bonfils intubation fiberscope (Bonfils™ 10331 B, Karl Storz Endoscopy Ltd GmbH, Tuttlingen, Germany) by a retromolar approach (12-14). The Bonfils intubation fiberscope is a rigid endoscope with 5 mm OD and 40 cm working length which serves as a guiding rail for the endotracheal tube to enable intubation under endoscopic vision. The distal end of the fiberscope is bent in order to pass with the tip under the epiglottis and into the larynx (Figure 1).

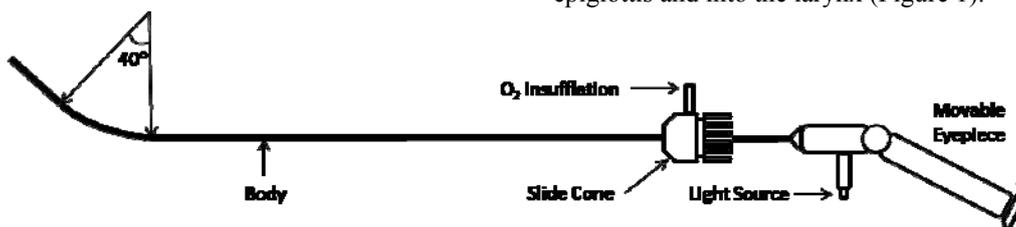


Figure 1. Schematic diagram of the Bonfils intubation fiberscope 10331 B

Sliding the endotracheal tube over the fiberscope and holding it with the right hand, the patient's mandible was pulled forward by the left hand to open the mouth and the fiberscope was inserted horizontally into the right corner of the mouth, along the molars, pointing to the left. After reaching the posterior wall of the pharynx, the fiberscope was rotated clockwise until the epiglottis appeared at the top of the screen. By further rotating on the longitudinal axis and tilting out to the right (utilizing the flexibility of the cheek tissue), the user precisely advanced the instrument under endoscopic vision beneath the epiglottis and into the larynx until the vocal cords were visible bilaterally. Then holding the fiberscope in the right hand, the tube was advanced carefully by the left hand into the trachea and the fiberscope removed.

Since no suctioning channel is built into the Bonfils intubation fiberscope (at least into the employed model in our study), the oral secretions were suctioned through an accompanying suction catheter inserted simultaneously into the mouth. In contrast to other studies utilizing the Bonfils intubation fiberscope, we did not use jaw thrust, insertion of an accompanying Macintosh blade, or administering anticholinergic drugs in the Bonfils groups in order to improve endoscopic view, since they would all confound the hemodynamic comparisons in our study. In the Macintosh Group, direct laryngoscopy was performed using a Macintosh blade size 3. In both groups, a backward, upward, and rightward pressure was applied externally by an assistant on the cricoid cartilage when necessary.

Orotracheal intubation was accomplished using a cuffed silicone Magill endotracheal tube, size 7.0 and 8.0 mm ID for females and males respectively. To reduce interobserver bias, a single anesthesiologist, experienced with both the intubation techniques, performed and scored laryngoscopy or fiberscopy and tracheal intubation. Following tracheal intubation in all patients, the tracheal cuff was gently inflated, and maintenance of anesthesia was left at the discretion of the attending anesthesiologist. Intubation time in either group was recorded beginning from the insertion of the laryngoscope into the oral cavity and ending at verification of proper placement of endotracheal tube by end-tidal capnography.

Tracheal intubation would be considered as 'failed' in either group if pulse oximetry (SpO₂) fell below 90%, or it were not possible to visualize any portion of the vocal cords after multiple attempts. Thereafter, succinylcholine 1.0 mg.kg⁻¹ was administered intravenously and the patient was intubated by

conventional Macintosh laryngoscopy as the rescue approach. In the face of failed intubation even after these modifications, the anesthesia would be abandoned and the surgery postponed.

Intubating conditions, as defined by Cooper and colleagues (27), comprise assessment of three components: jaw relaxation, vocal cord position, and response to intubation; and then scoring each of them from 0 (worst) to 3 (best). The intubating condition in either group was graded based on the sum of these three scores as excellent (8-9), good (6-7), poor (3-5), and bad (0-2). We regarded excellent and good intubating conditions as 'clinically acceptable' while poor and bad intubating conditions as 'clinically unacceptable' intubating condition scores. For each of the three components, we also considered scores 3 and 2 as 'clinically acceptable', while scores 1 and 0 as 'clinically unacceptable'. Three consecutive readings of mean arterial blood pressure (MABP), heart rate (HR), and SpO₂ were recorded: 1) on arrival to the operating room (baseline), 2) during laryngoscopy just before intubation, and 3) just after intubation. Coincident events including mucous secretion, aspiration, regurgitation, laryngospasm, airway obstruction, soft tissue or dental trauma, chest wall rigidity, and excitatory movements were recorded during intubation.

A single resident of anesthesiology recorded patient and procedural data on a data-collection sheet. Neither the resident nor the intubating anesthesiologist was blinded to the device being used owing to the inherent characteristics of the study.

Statistical Analysis

The analysis was performed with the SPSS 13.0 program by a statistician blinded to the groups. The mean values for continuous variables of age, weight, height, and intubation time were compared using independent samples t-test (or Mann-Whitney Test when appropriate), as well as intergroup comparisons of HR and MABP. Repeated measures and paired samples t-test were used for changes in HR and MABP. Comparisons of dichotomous variables between groups were analyzed by χ^2 -test (Fisher's exact test when appropriate). The 95% confidence interval (CI) was calculated for every outcome measure with significant difference. We considered clinically acceptable intubating conditions as our primary outcome measure. Based on our pilot study, with a type I error of 0.05 and a type II error of 0.20, a minimum of 40 patients in each group would be required to detect a 25% improvement in the clinically acceptable intubating conditions.

Bonfils fiberscope w/o neuromuscular block

Table 1. Characteristics of the 80 patients intubated using either Bonfils intubating fiberscope or conventional Macintosh laryngoscopy who received propofol and alfentanil and lidocaine without neuromuscular blocking drugs.

	Bonfils	Macintosh	p-value
Total Patients, n	40	40	
Male/Female, n (%)	32/8 (80/20)	28/12 (70/30)	0.439*
Age (y), mean (SD)	43.8 (17.4)	45.8 (15.9)	0.584**
BMI (Kg.m ⁻²), mean (SD)	26.2 (3.9)	25.6 (4.0)	0.507**
ASA Class I/II, n (%)	32/8 (80/20)	30/10 (75/25)	0.790*
ULBT Class I/II, n (%)	36/4 (90/10)	34/6 (85/15)	0.737*
Mallampati Score 1/2/3/4, n	4/28/8/0	10/24/6/0	0.205***
TMD (cm), mean (SD)	6.3 (0.7)	6.6 (0.9)	0.100**

* Using Fisher's exact test

** Using Independent Samples Test

*** Using Pearson Chi-Square Test

ULBT = Upper Lip Bite Test; TMD = Thyromental Distance

Results

The study was carried out between May and September 2006. The patient characteristics were not different between two groups (Table 1). We did not face any difficult or failed intubation in either group. Despite applying suction in the Bonfils group, mucous secretions in the mouth and pharynx were noted in 32 patients (80%) in this group. In 16 patients (40%), gross oral secretions prevented a good endoscopic view of the glottic aperture, but the overall success rate was 100%.

Clinically acceptable intubating conditions did not differ significantly between the Bonfils group and the Macintosh group (Table 2). The rate of clinically acceptable vocal cord position and response to intubation were neither different between the two groups. Clinically acceptable jaw relaxation, on the other hand, was significantly more common in the Bonfils group.

Baseline values ('the first reading') of HR and MABP did not differ significantly between the Bonfils group and the Macintosh group (Table 3). Heart rate and MABP both dropped after induction by a degree not different between the two groups, and pointed at significantly lower values at the second reading 'during laryngoscopy just before intubation' (Figure 2).

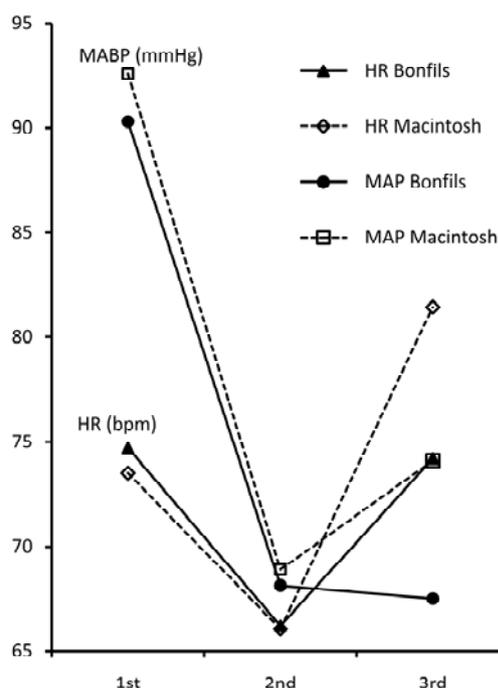


Figure 2. The trends of heart rate (HR) and mean arterial blood pressure (MABP) in the Bonfils group and the Macintosh group at the baseline (1st reading), during laryngoscopy just before intubation (2nd reading), and just after intubation (3rd reading). bpm, beat per minute

Table 2. Intubating conditions in the 80 patients intubated using either Bonfils intubating fiberscope or conventional Macintosh laryngoscopy who received propofol and alfentanil and lidocaine without neuromuscular blocking drugs.

	Bonfils	Macintosh	P-value*
Total Patients, n	40	40	
Acceptable Intubating Condition, n (%)	30 (75)	26 (65)	0.465
Acceptable Jaw Relaxation, n (%)	40 (100)	34 (85)	0.026
Acceptable Vocal Cord Position, n (%)	30 (75)	30 (75)	1.000
Acceptable Response to Intubation, n (%)	32 (80)	30 (75)	0.790

* Using Fisher's exact test

Table 3 Comparisons of the cardiovascular values at the baseline (1st reading), during laryngoscopy just before intubation (2nd reading), just after intubation (3rd reading) and the degree of change between these readings between the 80 patients intubated using either Bonfils intubating fiberscope (40 patients) or conventional Macintosh laryngoscopy (40 patients) who received propofol and alfentanil and lidocaine without neuromuscular blocking drugs.

	Heart Rate (beats.min ⁻¹)			Mean Arterial Blood Pressure (mmHg)		<i>P</i> -value Error! Bookmark not defined.
	Bonfils	Macintosh	<i>P</i> -value*	Bonfils	Macintosh	
1 st reading**	75 (9)	74 (9)	0.553	90 (16)	93 (14)	0.486
1 st to 2 nd change***	-9 (-6 - -11) <i>P</i> <0.001	-8 (-7 - -8) <i>P</i> <0.001	0.461	-22 (-17 - -23) <i>P</i> <0.001	-24 (-21 - -27) <i>P</i> <0.001	0.602
2 nd reading**	66 (11)	66 (9)	0.948	68 (12)	69 (9)	0.752
2 nd to 3 rd change***	8 (6 - 10) <i>P</i> <0.001	15 (12 - 19) <i>P</i> <0.001	0.001****	-1 (-2 - 3) <i>P</i> =0.605	5 (1 - 10) <i>P</i> =0.022	0.023 ⁺
3 rd reading**	74 (16)	82 (13)	0.026 ⁺⁺	68 (15)	74 (14)	0.044 ⁺⁺⁺
1 st to 3 rd change***	-1 (-3 - 4) <i>P</i> =0.771	8 (4 - 12) <i>P</i> <0.001	0.002 ⁺⁺⁺⁺	-23 (-17 - -29) <i>P</i> <0.001	-19 (-14 - -23) <i>P</i> <0.001	0.256

* Using Independent Samples Test

** Mean (SD)

*** Mean difference (CI 95%); paired samples test is used for two-tailed *P*-values

**** Mean difference 7.40, CI 95% 3.00 - 11.80

+ Mean difference 5.83, CI 95% 0.86 - 10.81

++ Mean difference 7.25, CI 95% 0.90 - 13.60

+++ Mean difference 6.60, CI 95% 0.17 - 13.03

++++ Mean difference 8.45, CI 95% 3.31 - 13.59

Heart rate rose from the second reading toward the last reading after intubation in both groups, but the amount of increase was significantly more in the Macintosh group than the Bonfils group.

While the last readings for MABP showed an increase in the Macintosh group compared to the second reading, MABP continued to decrease in the Bonfils group but without a significant difference with the second reading.

Comparing the last readings to the baseline values, HR almost did not change in the Bonfils group but it increased significantly in the Macintosh group. The amount of change was also significantly different between two groups. Mean arterial blood pressure declined significantly from the baseline values toward the last readings in both groups, but the amount of change was not significantly different between two groups. The median time of intubation was 40 seconds (IQR 15 - 93) in the Bonfils group versus 11 seconds (IQR 7 - 21) in the Macintosh group. This 30-second difference was significant between the groups (using Mann-Whitney Test, *P*<0.001). Pulse oximetry values did not decrease below 92% in either group. There was no instance of adverse outcome during intubation.

Discussion

Various regimens of alfentanil-lidocaine-propofol, in the absence of NMBDs, have attained good intubating conditions and speed (4, 5 8-10). The choice of propofol in this study was based on its ability to relax laryngeal muscles and to obtund or dampen the reactivity of the upper airway reflexes (11). The administration of propofol in a dose of 2-2.5 mg.kg⁻¹ is expected to reduce MABP by 25-40% (28). The dose of propofol needs to be increased when relaxants are omitted¹¹, and this, of course, raises the risk of dose related side effects (4). In the Macintosh group, we detected a 10% rise in HR and a 20% decline in MABP after intubation as compared to baseline. The Bonfils intubation fiberscope, on the other hand, exerts negligible mechanical forces during laryngoscopy and lessens subsequent sympathetic responses. That is why in the Bonfils group, however, we observed no change in HR, but about 25% decrement in MABP after intubation, despite its longer intubation time. This may represent the excess doses of propofol and/or alfentanil administered for the Bonfils group in this study, as previously supported by Andel and colleagues (29). The employed dosage in our study was reproduced from studies conducted with Macintosh laryngoscopy where larger doses were needed owing to the mechanical stress imposed by the instrument.

Nevertheless, we expected such hemodynamic responses to be obvious during laryngoscopy and before intubation (at the second reading), rather than after intubation (at the third reading). The relatively short intubation time in the Macintosh group may not provide enough time for the clinical reflection of the sympathetic stimulation; and it may instead be implicated during the third readings. The confounding step here is the intubation itself with its consequent sympathetic release, which we ignored, as it was imposed on both groups equally. Despite the longer period of laryngoscopy in the Bonfils group, we achieved lower values for HR and MABP as against the Macintosh group. This corroborates the better hemodynamic profile of the Bonfils intubation fiberscope over conventional Macintosh laryngoscopy for tracheal intubation in situations where NMBDs are avoided for obvious reasons.

The median intubation time with this device has been reported variably between 25 seconds (30) to even 80 seconds (15). Simultaneous jaw thrust or using a Macintosh blade to insert the instrument by an assistant may actually help faster intubations with the Bonfils intubation fiberscope. Although anticholinergic drugs have no role in successful intubations with the Bonfils intubation fiberscope (30) but their antisialogogue properties may actually improve intubation time with the instrument. However, as mentioned earlier, we had to avoid all these interventions for their confounding autonomic effects. This may explain our somewhat long intubation times with the Bonfils intubation fiberscope.

It is important to emphasize that the major focus in the present study has been the intubating conditions and cardiovascular impacts of the two mentioned intubating techniques during the described regimen for induction of anesthesia. The longer intubation times with the Bonfils fiberscope may obviously appear to be a drawback. However, in situations where sudden hemodynamic changes, as noticed with Macintosh laryngoscopy, could be detrimental for the patient, the relative longer intubation times as experienced with the Bonfils intubation fiberscope under enough preoxygenation, close surveillance and SpO₂ monitoring, may not discredit the obvious advantages of a harmless laryngoscopy and could well be regarded as a boon to the patient, especially not-paralyzed patients with poor cardiovascular reserve.

Better jaw relaxations in the Bonfils group in our study is not surprising because moving or rotating the device inside the patients' oral cavity, pharyngeal or laryngeal structures does not impart manual force and

thus little or no jaw resistance is felt during its maneuvering.

We suggest further similar studies incorporating larger sample sizes with different anesthesiologists, blinded to the purpose of study, using the Bonfils intubation fiberscope with lower doses of propofol and/or alfentanil, and more relaxed inclusion criteria to extend the generalizability of these results. In conclusion, when anesthesia is induced by propofol-lidocaine-alfentanil while NMBDs are avoided, tracheal intubation using the Bonfils intubation fiberscope offers comparable success rate, intubating conditions, better jaw relaxation, less mechanical stress and hemodynamic compromise, but longer intubation time compared with conventional Macintosh laryngoscopy.

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