Fiberoptic Intubation and Laryngeal Morbidity

A Randomized Controlled Trial

Thomas Heidegger, M.D., * *Lukas Starzyk, M.D.,*† *Cornelia R. Villiger, M.D.,*‡ *Stefan Schumacher, M.D.,*§
Rolf Studer, M.D.,§ *Barbara Peter, M.D.,*§ *Matthias Nuebling, Ph.D.,*‖ *Hans J. Gerig, M.D.,*# *Thomas W. Schnider, M.D.**

Background: Tracheal intubation with neuromuscular blocking agents is associated with a low incidence of minor vocal cord sequelae (8%). The aim of this noninferiority trial was to demonstrate that the frequency of vocal cord sequelae after fiberoptic intubation with a flexible silicone tube without neuromuscular blocking agents was less than 25% (maximum tolerable inferiority).

Methods: Two-hundred seventy patients were prospectively randomized to two groups. All intubations were performed by anesthesiologists with extensive experience in fiberoptic and conventional techniques. Fiberoptic nasotracheal intubation consisted of a bolus dose of 2 µg/kg fentanyl; 0.25 ml cocaine instillation, 10%, into nasal canals; cricothyroid injection of 2 ml lidocaine, 1%; bronchoscopy; administration of 0.3 mg/kg etomidate; and advancing a flexible silicone tube after loss of consciousness. Orotracheal intubation was performed with a polyvinyl chloride tube after induction with 2 µg/kg fentanyl, 2 mg/kg propofol, and 0.6 mg/kg rocuronium. Patients were examined by laryngoscopy before surgery, 24 h after surgery, and daily until complete restitution. Postoperative hoarseness was assessed by a standardized interview.

Results: The incidence of vocal cord sequelae was 11 out of 130 (8.5%) in the fiberoptic group *versus* 12 out of 129 (9.3%) in the control group (chi-square = 0.057, *df* = 1, *P* = 0.81; upper limit of the one-sided 95% confidence interval for the difference: +5.1%). There were no persistent injuries. The incidence of postoperative hoarseness was 4% in both groups.

Conclusions: Because fiberoptic intubation without neuromuscular blocking agents is safe regarding vocal cord sequelae, routine use is justified for anesthesiologists experienced in this technique.

FIBEROPTIC intubation without using neuromuscular blocking agents (NMBAs) is the preferred method for management of the anticipated difficult airway and is recommended by many anesthesia societies.[1,2] However, severe laryngeal trauma during fiberoptic intubation has been described.[3]

Anesthesiologists must perform fiberoptic intubation frequently to gain and maintain proficiency.[4,5] If this method forms part of an institutional policy for management of the suspected difficult airway, it becomes routine practice.[6] However, there are important prerequisites if it is performed in situations other than emergencies. First, it must be integrated into the "normal" process of anesthesia induction, *i.e.*, the whole process must be safe and time-efficient. Second, the intubation maneuver must be well accepted by patients. Third, the whole procedure should have acceptably low minor laryngeal morbidity compared with conventional tracheal intubation using NMBAs. A recent study by Mencke *et al.*[7] showed that using NMBAs for tracheal intubation significantly decreased vocal cord sequelae (VCS). Because equivalence could not be expected, the aim of this study was to confirm the hypothesis that VCS after fiberoptic intubation without NMBAs are below a maximum tolerable inferiority compared with conventional intubation using NMBAs (see Material and Methods, Statistical Analysis).

Materials and Methods

Patients

With approval from the Cantonal Ethics Committee (Cantonal Hospital, St. Gallen, Switzerland) and written informed consent from all participants, we prospectively studied 270 men and women older than 16 yr, between February 2004 and June 2006. All patients underwent nasotracheal or orotracheal intubation for elective eye, ear, or salivary gland surgery. We excluded patients with a Mallampati score of 3 or 4, a mouth opening of less than 3.5 cm, a body mass index of more than 35 kg/m^2, a history of reflux, pathologic laryngeal findings (examined the day before surgery by an experienced ear, nose, throat, and neck [ENT] surgeon); and difficult laryngoscopy (control group = conventional orotracheal intubation), *i.e.*, a Cormack and Lehane score of at least 3. All patients gave a smoking history and were premedicated with 10–20 mg dipotassium clorazepate the evening before surgery. Monitoring included electrocardiography, noninvasive arterial pressure, pulse oximetry, and capnography.

Induction of Anesthesia

Patients were randomly assigned *via* a random number table[8] into two groups of 135 patients, to either nasotracheal fiberoptic intubation (study group) or orotracheal conventional intubation (control group). All intubations were performed by anesthesiologists

* Associate Professor and Head, Department of Anaesthesia, Spitalregion Rheintal Werdenberg Sarganserland, Walenstadt, Switzerland.   † Resident, ‡ Staff, # Deputy Head, ** Professor and Head, Department of Anaesthesiology, § Staff, Department of Ear, Nose, Throat, and Neck Surgery, Cantonal Hospital St. Gallen.   ‖ Empirical Consulting, Denzlingen, Germany.

Address correspondence to Dr. Heidegger: Department of Anaesthesia, Spitalregion Rheintal Werdenberg Sarganserland, Spitalstrasse 5, 8880 Walenstadt, Switzerland. thomas.heidegger@srrws.ch. Information on purchasing reprints may be found at www.anesthesiology.org or on the masthead page at the beginning of this issue. ANESTHESIOLOGY's articles are made freely accessible to all readers, for personal use only, 6 months from the cover date of the issue.

with extensive experience in this technique (>200 fiberoptic intubations).

Nasotracheal intubation consisted of the following steps: injection of 2 μg/kg intravenous fentanyl; instillation of 0.25 ml cocaine nasal drops, 10%, into each nostril; transcricoid injection of 2 ml lidocaine, 1%, for local anesthesia of the larynx and the proximal trachea (injection was regarded as successful when air could be aspirated without resistance); introduction of the bronchoscope (3.7 mm; Karl Storz GmbH & Co. KG, Tuttlingen, Germany) *via* the lower nasal canal into the trachea; and administration of 0.3 mg/kg etomidate.[9] If necessary, additional doses of 2 mg etomidate were titrated until patients did not open their eyes. After loss of consciousness, the previously threaded, armored tracheal silicone tube (6.0 mm ID; Rüschelit® endotracheal tube; Kernen, Germany) was advanced and connected to the anesthesia circuit. Rocuronium, 0.4 mg/kg, was administered after a capnography signal occurred. The target intracuff pressure was less than 20 mmHg.

We assessed the advancement of the tube through the glottis (easy, slow resistance, heavy resistance, or failure) and whether the patient coughed during the advancement of the tube (no cough, cough, sustained coughing >10 s), and measured the number of attempts and the time from beginning of bronchoscopy to verification of the tube's position in the trachea *via* capnography.

The control group received 2 μg/kg intravenous fentanyl. Anesthesia was induced with 2 mg/kg propofol (1 mg/kg for patients older than 60 yr).[10] If necessary, additional doses of 20 mg propofol were injected until patients did not open their eyes. Afterward, 0.6 mg/kg rocuronium was administered. Laryngoscopy was performed 2 min later, and the patient's trachea was intubated with a tube size of 8.0 mm ID for men or 7.0 mm ID for women (Mallinckrodt®; Hazelwood, MO; intracuff pressure <20 mmHg; common practice in our department). In the control group, we assessed the laryngoscopy grade according to Cormack and Lehane (grade 1 = complete visualization of the glottis; grade 2 = visualization of the inferior part of the glottis; grade 3 = only epiglottis visible; grade 4 = epiglottis not visible) and the intubation conditions according to the consensus conference on good clinical research practice in pharmacodynamic studies of NMBAs (excellent intubating conditions = all qualities [laryngoscopy, vocal cord position, vocal cord movement, reaction to insertion of endotracheal tube and/or cuff inflation, movement of the limbs, coughing] are excellent; good = all qualities are either excellent or good; poor = the presence of a single quality listed under poor).[11] We measured the number of intubation attempts and the time from beginning of laryngoscopy to verification of the tube's position in the trachea *via* capnography.

In both groups, anesthesia was maintained with either sevoflurane in oxygen–air and bolus doses of fentanyl (0.05–0.1 mg) as needed, or as intravenous anesthesia with propofol–remifentanil. Heart rate and mean arterial pressure were recorded after arrival of the patients in the operating room, 2 min after propofol administration but before tracheal intubation (only control group), and 2 min after tracheal intubation. Extubation of all patients was standardized (recovery of spontaneous breathing and eye opening), and the duration of surgery was measured.

Assessment of Postoperative Vocal Cord Sequelae and Postoperative Hoarseness

To enable comparison of the results in our control group with those of Mencke *et al.*,[7] we assessed the postoperative changes in a similar way. On the first postoperative day, an experienced ENT physician unaware of the patients' group assignment assessed VCS by oral laryngoscopy. In uncertain cases, a second ENT physician not involved in the study was consulted. In the case of pathologic findings, examinations were repeated every 24 h until complete resolution. VCS was assessed as follows: unilateral or bilateral location; type of sequelae: erythema, thickening or edema of the vocal cords, hematoma of the vocal cords or the aryepiglottic region, and granuloma of the vocal cords.

The same physician also asked the patients whether they had any hoarseness. The grade of hoarseness was recorded as follows: 0 = no hoarseness; 1 = noticed by patient; 2 = obvious to observer; 3 = aphonia.

Statistical Analysis

The calculation of the required number of patients was based on the following considerations. The results from the study of Mencke *et al.*[7] showed that the use of NMBAs for tracheal intubation significantly decreased minor vocal cord sequelae from 42% to 8%. Because fiberoptic intubation is performed without NMBAs, equivalence could not be expected. However, we were convinced that our technique of fiberoptic intubation—especially using a flexible tube and adequate diameters of the bronchoscope and the tube to reduce the gap between them—would decrease the incidence of minor vocal cord sequelae. We therefore assumed that our results would lie somewhere between 42% and 8%. The acceptable inferiority level is always a compromise between a tolerable drawback (in this case, minor laryngeal morbidity) and an advantage (learning and retaining competence of a very important and potentially lifesaving technique), and is finally based expert opinion. To enable us to continue performing this technique frequently, we decided to accept minor laryngeal morbidity, which had to be lower than 25% (= maximum tolerable inferiority of 24%).

Table 1. Fiberoptic Intubation: Intubation Time, Coughing, Grading of Hoarseness, Vocal Cord Sequelae, and Time to Recovery

	Time from Start to CO_2 Signal, s	Coughing during Tube Placement	Grading of Hoarseness*	Findings at Laryngeal Inspection	Complete Recovery on Day after Surgery
1	97	No	0	Hematoma of left arytenoid cartilage without swelling	6
2	124	No	0	Small hematoma at the pedicle	4
3	87	No	1 + 2	Erythema and hematoma of the right vocal cord	8
4	100	Yes	0	Erythema of arytenoid cartilage and left vestibular ligament	2
5	105	No	0	Hematoma of left vocal cord	2
6	55	No	1	Erythema of left processus vocalis	2
7	95	Yes	0	Erythema and hematoma of right vocal cord and of right arytenoid cartilage	2
8	110	No	1 + 2	Bilateral erythema of arytenoid cartilage	2
9	95	Yes	0	Erythema of right vestibular ligament	2
10	105	No	1 + 2	Bilateral erythema and edema of vestibular ligament and of arytenoid cartilage, erythema of both vocal cords	2
11	30	No	0	Slight bilateral erythema of arytenoid cartilage	2

* Grading of hoarseness: 0 = no hoarseness; 1 = hoarseness observed by patient; 2 = significant hoarseness (observed by examiner); 3 = complete aphonia.
CO_2 = carbon dioxide.

These assumptions required 128 patients per group ($\alpha = 0.05$, power = 0.8, one-tailed). To compensate for possible dropouts (*e.g.*, Cormack and Lehane grades 3 and 4), we enrolled 270 patients (135 in each group).

Statistical analysis was performed using SPSS version 12 (SPSS Inc., Chicago, IL).

Data are expressed as mean ($\pm$SD) and number (percent). For the comparison of proportions (percentages of adverse events) and the calculation of the confidence interval for this difference, the method recommended by Newcombe[12] based on the Wilson score method for the single proportion and performing better than simple asymptotic methods was applied (called method number 10 without continuity correction in the article).

The effect size of the difference in proportions of adverse events between the standard treatment and the study group was assessed with the Cohen d coefficient (d* for 2 × 2 tables) as described by Hasselblad *et al.*,[13] to provide a coefficient numerically comparable to d given for the comparison of means.

For the comparison of sociodemographic and hemodynamic characteristics, the Pearson chi-square test (asymptotic two-sided, nominal data) and analysis of variance (metrical data) were performed; $P < 0.05$ (two-tailed) was considered significant.

Results

Two-hundred seventy patients were enrolled into the study (135 in each group). Four patients in the study group were excluded from analysis because of pathologic ENT findings on the day before surgery, and 1 patient refused postoperative ENT follow-up. Six patients in the control group had to be excluded because of a Cormack and Lehane score of 3 or 4. Therefore, VCS and hoarseness were investigated in 259 patients (130 in the study group and 129 in the control group). The two groups did not differ significantly with respect to patient characteristics, history of smoking, duration of surgery, and postintubation hemodynamics. Mean arterial pressure significantly decreased after induction in the control group.

In the study group, all transcricoid injections except one were successful, and all patients were successfully intubated.

The number of patients with VCS in the fiberoptic group was 11 of 130 (8.5%) *versus* 12 of 129 (9.3%) in the control group (chi-square = 0.057, $df = 1$, $P = 0.81$). The difference in VCS between the two treatments was less than 1%. The value of d* was −0.057, indicating a low effect size (usually values <0.20 are considered low).[14] The upper bound of the 95% one-sided confidence interval for the difference of −0.84% was +5.1%.

Erythema was the most frequent laryngeal injury in the study group (8 of 11 patients), followed by hematoma (5 patients). In the control group, erythema occurred in 12 patients, and 1 of them had hematoma. One patient in the study group had erythema and a hematoma for 8 days. There were no persistent injuries in either group.

There was no difference in postoperative hoarseness: 4% (5 patients) in both groups.

Detailed results for all cases with VCS are shown in tables 1 and 2.

Discussion

This prospective randomized study showed that the hypothesis of inferiority of VCS after fiberoptic intubation without NMBAs is unlikely compared with conventional intubation with NMBAs. On the contrary, our findings suggest that the two techniques are comparable regarding the rate of VCS.

Table 2. Conventional Intubation: Intubation Time, Glottic Exposure/Intubation Conditions, Grading of Hoarseness, Vocal Cord Sequelae, and Time to Recovery

	Time from Start to CO_2 Signal, s	Glottic Exposure/ Intubation Conditions*	Grading of Hoarseness†	Findings at Laryngeal Inspection	Complete Recovery on Day after Surgery
1	24	1/Excellent	0	Erythema and hematoma of left vocal cord	2
2	25	1/Excellent	1 + 2	Bilateral erythema of arytenoid cartilage and posterior vocal cord	2
3	45	2/Good	0	Slight bilateral erythema of arytenoid cartilage and vocal cord	2
4	38	1/Excellent	1 + 2	Small bilateral erythema of dorsal vocal cords	3
5	28	1/Excellent	1 + 2	Small erythema of left arytenoid cartilage	2
6	33	2/Good	0	Slight erythema of the right anterior part of vestibular ligament	2
7	32	1/Good	0	Slight erythema of left arytenoid cartilage	Patient declined further examination
8	15	1/Excellent	1	Bilateral erythema of arytenoid cartilage and vocal cords	2
9	35	2/Excellent	0	Slight erythema of right vocal cord	2
10	35	1/Excellent	1	Bilateral erythema of arytenoid cartilage	2
11	30	1/Excellent	0	Slight bilateral erythema of arytenoid cartilage and vocal cords	2
12	43	1/Good	0	Erythema of right vestibular ligament	2

* Glottic exposure according to Cormack and Lehane; intubation conditions according to Viby-Mogensen *et al.*[11] † Grading of hoarseness: 0 = no hoarseness; 1 = hoarseness observed by patient; 2 = significant hoarseness (observed by examiner); 3 = complete aphonia.

CO_2 = carbon dioxide.

Our results contrast with those of a prospective, non-randomized study in 29 patients by Maktabi *et al.*,[15] which was recently published as an abstract. This study showed that "awake" fiberoptic intubation after sedation resulted in a higher acute laryngeal injury score than conventional intubation by direct laryngoscopy.

There are several possible reasons for the low incidence of minor laryngeal morbidity with the fiberoptic technique used in the current study.

First, the type of endotracheal tube chosen is crucial. Brull *et al.*[16] reported that the incidence of difficulty in advancing a tube over a fiberscope is very high (up to 35%) when a conventional polyvinyl chloride tube is used. Consequently, the number of attempts and the possibility of causing laryngeal trauma increases. A flexible tube, however, follows the curve of the bronchoscope more easily.[16] In the current study, where we used only flexible armored silicone tubes in the study group, 91% of the fiberoptic intubations were successful at the first attempt. An analysis of more than 1,600 fiberoptic intubations performed by 18 anesthesiologists with different levels of experience in this technique using only flexible silicone tubes showed that 85% were successful on the first attempt, and 96% were successful on the second attempt (no difference between nasotracheal and oral approach).[9] It is also likely that impingement of the laryngeal structures occurs more frequently when a tube with an acute bevel at the tip is used rather than an endotracheal tube with a soft tapered end with no bevel.[16-18]

Second, reducing the gap between the endotracheal tube and the fiberscope should lower the incidence of difficulty in advancing the tube over the fiberscope.[19]

This is of prime importance when the tube is advanced toward the glottis, because a large gap results in more frequent contact between the tip of the tube and the posterior arytenoid region; hence the "railroading" effect will be weakened. In our study, we used a 3.7-mm fiberscope and an endotracheal tube with an ID of 6.0 mm. This choice of equipment had been successfully used in the previous study.[9]

Third, intubation conditions are one of the potential factors that might influence laryngeal morbidity after tracheal intubation. Mencke *et al.*[7] demonstrated that excellent intubating conditions as defined by Viby-Mogensen *et al.*[11] were less frequently associated with laryngeal morbidity and postoperative hoarseness. Interestingly, the same group reported that they were unable to confirm their results in recently published articles.[20,21] According to the definition of good clinical research practice,[11] sustained coughing is defined as a poor intubating condition, among other factors. In our study, we observed only slight and no sustained coughing in the study group. This might have been due to the application of a local anesthetic through the cricoid membrane, railroading the tube only after loss of consciousness, and advancing the tube not just above the carina (there is no local anesthetic effect just above the carina *via* transcricoid injection). However, the extent of influence of intubating conditions on laryngeal morbidity is still unclear.[20,21]

There was no difference between the incidence of postoperative VCS in the NMBA group in the study by Mencke *et al.*[7] (8%) and in our control group (9%). Similar figures had already been shown in a study in 1,000 patients almost 30 yr ago and were confirmed

some years later (incidence of direct lesions of 6.3% and 6.2%, respectively).[22,23]

The range of the reported incidence of postoperative hoarseness after short-term tracheal intubation is very large (3–50%).[24-26] The low incidence in our study (4% in both groups) may be explained by the same possible reasons as mentioned above (study group), and by the excellent intubating conditions in most cases in the control group.[7]

The best way to maintain practical skills such as fiberoptic intubation is still controversial.[27,28] Besides basic training on mannikins, daily practice is still recommended and warranted.[4-6] Real-life situations, including manipulation of human tissue, and complications, such as bleeding and edema, are not replicated in the mannikin model.[29] However, to justify the frequent use of a technique, the method itself should be well accepted by patients (Thomas Heidegger, M.D., Matthias Nuebling, Ph.D., Hans J. Gerig, M.D., Patient satisfaction with awake fiberoptic intubation compared to conventional intubation: A retrospective analysis. St. Gallen, Switzerland, 2006; unpublished data) and should have acceptably minor laryngeal morbidity compared with the gold standard. This was confirmed in our study. By setting a broad indication for fiberoptic intubation and thereby defining a greater range of airway situations as suspected to be difficult, it is likely that fewer unexpected difficult situations will arise.

Our study had some limitations. One might argue that we should have used armored tracheal silicone tubes, the same approach, and the same medication in both groups. Because the goal of this study was to compare the minor laryngeal morbidity of two well-established techniques, some differences in the method (tube, drugs, *etc.*) were part of the study design. The doses we used were clinically reasonable, and, as we have recently shown, they are approximately equieffective with regard to an electroencephalographic parameter (Bispectral Index).[30] In addition, we wanted to compare our study with the results from Mencke *et al.*[7]

Some patients were excluded from the analysis who might have introduced a selection bias. However, because this affected both groups to an equal extent, this seems unlikely.

A very large number of patients would be required to demonstrate that armored flexible tracheal tubes in patients receiving NMBAs might cause fewer VCS than the accepted standard. Although this was not the goal of our study, it would certainly be worthy of investigation.

Because all intubations were performed only by anesthesiologists with extensive experience in fiberoptic intubation, we cannot rule out that we would have achieved the same results had the intubations been carried out by less experienced anesthesiologists. This, however, would also apply to conventional intubation.

In conclusion, because fiberoptic intubation without NMBAs is safe regarding VCS, routine use for the suspected difficult airway is justified for anesthesiologists experienced in this technique.

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