ORIGINAL ARTICLE

Intubation without muscle relaxation for suspension laryngoscopy: A randomized, controlled study

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Abstract

Objective and Aim: The objective of the following study is to examine the effectiveness and safety of suspension laryngoscopy under intubation with propofol and remifentanil alone for vocal fold nodule (VFN) excision.

Materials and Methods: A total of 40 patients were equally and randomly assigned to elective VFN excision using suspension laryngoscopy under intubation with propofol and remifentanil alone (Group A) or with supplementary cisatracurium (Group B).

Results: Intubation time was significantly longer in Group A than in Group B (300.0 ± 30.0 s vs. 265.2 ± 38.7 s, $P = 0.003$). The two groups showed similar Cormack-Lehane classifications, intubation conditions and ease of suspension laryngoscopy. Both groups showed favorable cardiopulmonary safety profiles. Post-anesthesia recovery was significantly more rapid in Group A than in Group B, in terms of times to spontaneous breathing return (7.2 ± 1.4 min vs. 10.9 ± 1.6 min, $P < 0.001$), consciousness return (7.4 ± 1.5 min vs. 12.3 ± 1.8 min, $P < 0.001$), removal of tracheal intubation (8.1 ± 1.5 min vs. 13.2 ± 1.7 min, $P < 0.001$) and operating room discharge (12.7 ± 1.4 min vs. 22.1 ± 1.3 min, $P < 0.001$).

Conclusion: Use of propofol and remifentanil alone provides favorable intubation and anesthesia conditions for suspension laryngoscopic VFN excision and accelerates post-anesthesia recovery.

Key words: Endotracheal intubation, muscle relaxant, propofol, randomized controlled study, remifentanil, suspension laryngoscopy, vocal fold nodule

Date of Acceptance: 12-Nov-2013

Introduction

Vocal fold nodule (VFN) is a common laryngological condition that mainly occurs secondary to chronic abusive voice practice and inflammation.[1] The most frequently reported chief complaint is hoarseness of speech, which rarely harms the patient's general well-being but impairs his/her activities of daily life, especially for professionals depending on voice and speech.[2] The basic treatment for VFN consists of vocal training, speech therapy and, more importantly, vocal rest. Medical intervention is required in some cases, but the therapeutic effect is believed to be limited. In contrast, VFN excision, a minor laryngological procedure, achieves a definitive treatment outcome.[3] Multiple laryngoscopic techniques, including direct, indirect, electronic and fiber-optic laryngoscopies, have been used for VFN excision in current practice.[3] The selection of a specific laryngoscopic technique depends mainly on the location and pathology of the disease.[3]

Suspension laryngoscopy is a laryngological technique that enables clear visualization of the laryngeal anatomy and precise excision of vocal fold lesions, especially refractory

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Access this article online

Quick Response Code:

Website: www.njcponline.com

DOI: 10.4103/1119-3077.134038

PMID: 24909469

or recurrent VFNs.[4] The incorporation of laser ablation in suspension laryngoscopy preserves the normal vocal fold mucosae and minimizes the risk of VFN recurrence.[5] A review of the current literature regarding the laryngoscopic treatment of VFNs showed that suspension laryngoscopy is more effective and has a better safety profile than other laryngoscopic techniques.[6]

Suspension laryngoscopy is inevitably subject to some technical problems, especially with respect to anesthesia management.[7] VFN excision using suspension laryngoscopy is highly irritative, but can be completed within a short period of time.[7] This short operative time requires rapid induction, maintenance and recovery of anesthesia, a challenge that anesthesiologists resolve by using superficial anesthesia or, more frequently, general anesthesia with rapid induction and intubation, which normally requires muscle relaxant supplementation.[8] However, the use of neuromuscular blockers (NMBs) is risky in patients undergoing suspension laryngoscopy due to the limited time period available for anesthesia management. Recovery from muscle relaxation also prolongs anesthesia and operating turnover times.

Intubation without muscle relaxation (IWMR) has been developed in current adult and pediatric practice.[9] The administration of a combined regimen of propofol, a short-acting intravenous hypnotic agent and remifentanil, a potent ultra-short-acting synthetic opioid analgesic, has been recommended for patients scheduled for brief operations under IWMR.[10] This combined anesthetic modality offers a favorable condition for intubation and laryngoscopic procedures.[10,11] Recent studies have also shown that the combined modality is associated with a better cardiopulmonary safety profile than the administration of propofol or remifentanil alone.[10,11] However, a knowledge gap exists in the current literature regarding the safety and effectiveness of IWMR for VFN excision using suspension laryngoscopy. We thus investigated the anesthetic effectiveness and safety of IWMR in patients with VFNs undergoing suspension laryngoscopic excision in a patient-blinded, randomized, controlled study.

Materials and Methods

Patient enrollment and assignment

This study protocol was approved by the institutional review board at the First Hospital of Jilin University and was performed in accordance with the Declaration of Helsinki. Patients with VFNs were prospectively and consecutively enrolled at the First Hospital of Jilin University between July 2010 and January 2011. All subjects provided voluntary written informed consent prior to enrollment. The inclusion criteria were: Age 18-65 years, body mass index (BMI) of 18.5-25 kg/m^2, Class I or II physical status according to the American Society of Anesthesiologists (ASA), Mallampati class (a measure predicting the ease of intubation) I or II,[12] and scheduling for elective suspension laryngoscopic excision under IWMR. The exclusion criteria were: A medical history of myopathy; a known history of allergy to propofol and/or remifentanil or drug abuse; and/or a previous history of upper respiratory tract infection within 3 weeks of enrollment, gastrointestinal reflux, intracranial pathology, suspected difficult airway, or serious cardiopulmonary or hepatorenal insufficiency.

A computer-generated random number table was used to randomly and equally assign subjects to IWMR with propofol/remifentanil alone (Group A) or tracheal intubation with propofol/remifentanil and additional cisatracurium (Group B). All operations were performed by an assigned team of head and neck surgeons assisted by resident surgeons, anesthesiologists, surgical nurses, clinical pathologists and research nurses. Patients were blinded to the treatment assignment throughout the study.

Anesthetic technique

All patients were premedicated with 0.5 mg intramuscular atropine sulfate (Harvest Pharmaceutical Co., Ltd, Shanghai, China) 30 min prior to the operation. Intravenous access was established and an automated non-invasive monitoring system (Philips Medical Systems, Herrsching, Germany) equipped with an electrocardiograph, automatic cuff inflation/deflation sphygmomanometer and pulse oximeter was used to continuously measure the patient's heart rate (HR), mean arterial pressure (MAP) and blood oxygen saturation (SpO_2). Midazolam (0.03 mg/kg; Nhwa Pharmaceutical Co., Ltd., Xuzhou, China) was administered for the induction of anesthesia, followed by a target-controlled infusion (TCI) of 3.0 μg/mL propofol (AstraZeneca UK Limited, London, UK) and 5.0 ng/mL remifentanil hydrochloride (Humanwell Pharmaceutical Co., Ltd., Yichang, China) using a TCI syringe pump system (SLGO Medical Technology Co., Ltd., Beijing, China). Patients in Group A were medicated with normal saline as placebo (Kelun Pharmaceutical Co., Ltd., Chengdu, China) and those in Group B with 0.1 mg/kg cisatracurium besilate (Hengrui Pharmaceutical Co., Ltd., Lianyungang, China), in accordance with the treatment assignment. Prior to intubation, patients received superficial anesthesia with 10 mg/mL tetracaine (Jiuxu Pharmaceutical Co., Ltd., Jinhua, China). An independent anesthetist performed tracheal intubation within 5 min of superficial anesthesia for patients in Group A or at the time of the first twitch response (T_1) maximum depression rate <5% for patients in Group B. An automatic neuromuscular conductivity monitor (Axon Systems Ltd., Inning, Germany) was used to determine the level of muscle relaxation. The TCI of propofol and remifentanil was adjusted according to HR and MAP monitoring during

suspension laryngoscopy, whereas intravenous remifentanil was uptitrated by 1 ng/mL, but no more than 2 ng/mL. Supplementary 1 × ED_{95} cisatracurium besilate was given if the T_1 maximum depression rate was>10%.

Post-anesthesia management

Following VFN excision, the intravenous medication was withdrawn immediately in patients in Group A. For patients in Group B, intravenous propofol and remifentanil were downtitrated to 2 μg/mL and 2 ng/mL, respectively; the intravenous medication was withdrawn and residual muscle relaxants were antagonized using intravenous neostigmine (Ange Pharmaceutical Co. Ltd, Huai'an, China) when the train-of-four (TOF) response manifested as one or two twitches. Tracheal intubation was removed when the patient exhibited normal swallowing and coughing reflexes, voluntary eye opening in response to vocal stimulation, tidal volume >5 mL/kg and a respiratory rate of 10-20 breaths/min. The patient was discharged from the operating room (OR) when he or she showed normal vital signs and respiration and coughing reflexes, remained alert and oriented and maintained an SpO_2 >94% while breathing air for 3 min consecutively. In addition, patients in Group B were required to have a TOF ratio >0.9, which was depressed following TOF peripheral nerve stimulation.

Outcome measures

The primary outcome measures were post-anesthesia recovery times, including the times from induction to spontaneous breathing return, consciousness return, removal of tracheal intubation and OR discharge. The secondary outcome measures included HR and MAP prior to (T_0) and following (T_1) induction, as well as at the times of intubation (T_2), laryngoscope insertion (T_3) and withdrawal (T_4), tracheal extubation (T_5) and OR discharge (T_6). Other secondary measures included intubation time from induction to the completion of intubation; operative time; Cormack-Lehane classification,[13] which describes the laryngeal view on laryngoscopy; and overall intubation condition assessment,[14] number of intubation attempts, ease of suspension laryngoscopy[15] and Observer's Assessment of Alertness/Sedation (OAA/S) Scale[16] scores at T_5 and T_6.

Statistical analysis

The SPSS 13.0 software package (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. All continuous data are expressed as means ± standard deviations and differences in means were analyzed using Student's *t*-test for two independent samples or one-way analysis of variance for multiple independent samples. All categorical data are expressed as *n* (%) and intergroup differences were examined using Fisher's exact probability test. For two-tailed tests, a *P* value was considered to be statistically significant if <0.05.

Results

A total of 40 patients with VFNs, consisting of 17 males and 23 females, were included in this study and equally assigned to the two treatment arms. The patients' demographic data are shown in Table 1. The two groups were comparable in terms of age, sex, height, weight, BMI and ASA classification ($P > 0.05$).

Intubation conditions are shown in Table 2. Laryngoscope introduction and endotracheal intubation were completed successfully completed in a single attempt in all patients. Visualization of the vocal cord was determined to be very satisfactory and satisfactory in 80% (32/40) and 20% (8/40) of patients, respectively. Intubation time was significantly longer in Group A than in Group B (300.0 ± 30.0 s vs. 265.2 ± 38.7 s, $P = 0.003$), whereas overall operative

Table 1: Demographic data of patients (*n*=40) scheduled for elective suspension laryngoscopic excision of vocal fold nodules

Characteristics	Group A (*n*=20)	Group B (*n*=20)	*P* value
Age, years	43.3±6.7	45.2±7.4	0.399
Sex, M/F	11/9	6/14	0.200
Height, cm	166.6±5.6	164.0±6.2	0.177
Weight, kg	64.6±7.9	63.8±9.5	0.759
Body mass index, kg/m^2	23.3±3.1	23.7±2.8	0.739
ASA classification, *n* (%)			
Class I	12 (60.0)	10 (50.0)	0.751
Class II	8 (40.0)	10 (50.0)	

Group A=Patients undergoing intubation with propofol/remifentanil but without muscle relaxants, Group B=Patients undergoing intubation with propofol/remifentanil and additional cisatracurium, ASA=American Society of Anesthesiologists

Table 2: Intubation conditions and ease of suspension laryngoscopy without and with muscle relaxants

Parameters	Group A (*n*=20)	Group B (*n*=20)	*P* value
Intubation time, s	300.0±30.0	265.2±38.7	0.003
Operative time, min	7.2±2.5	6.8±7.2	0.589
Cormack-Lehane classification, *n* (%)			
Class 1	15 (75.0)	16 (80.0)	0.705
Class 2	5 (25.0)	4 (20.0)	
Overall intubation condition, *n* (%)			
Excellent	17 (85.0)	20 (100.0)	0.072
Good	3 (15.0)	0 (0.0)	
Ease of suspension laryngoscopy, *n* (%)			
Very satisfactory	16 (80.0)	17 (85.0)	0.677
Satisfactory	4 (20.0)	3 (15.0)	

Group A=Patients undergoing intubation with propofol/remifentanil but without muscle relaxants, Group B=Patients undergoing intubation with propofol/remifentanil and additional cisatracurium

time (interval between laryngoscope introduction and completion of suspension laryngoscopy) was comparable between groups (7.2 ± 2.5 min vs. 6.8 ± 7.2 min, $P = 0.589$). Groups A and B also exhibited similar Cormack-Lehane classifications (Class 1, 75.0% vs. 80.0%; Class 2, 25.0% vs. 20.0%; $P = 0.705$). Intubation conditions were excellent in nearly all patients, except in 3 patients in Group A with good intubation conditions (excellent, 85.0% vs. 100.0%; good, 15.0% vs. 0.0%; $P = 0.072$). In addition, surgeon-assessed ease of suspension laryngoscopy was comparable between groups (very satisfactory, 80.0% vs. 85.0%; satisfactory, 20.0% vs. 15.0%; $P = 0.677$). No laryngeal spasm occurred in any patient.

Peri-anesthesia hemodynamic changes are plotted in Figure 1. No significant difference in HR was found between groups at any timepoint ($P > 0.05$). Moreover, the two groups showed comparable MAPs at all timepoints (all $P > 0.05$), except at the time of extubation (T_5), when MAP was significantly lower in Group A than in Group B (94.7 ± 3.8 mmHg vs. 99.6 ± 9.0 mmHg, $P = 0.031$). In Group A, HRs were stable compared with baseline (T_0) values at all timepoints, except for a significantly lower HR at T_1 (67.5 ± 6.4 bpm vs. 76.2 ± 5.8 bpm, $P < 0.001$); however, MAPs were significantly lower than baseline at most timepoints following induction (T_1–T_4, T_6; all $P < 0.05$), except at T_5 (94.7 ± 3.8 mmHg vs. 96.1 ± 8.3 mmHg, $P = 0.497$).

Table 3: Post-anesthesia recovery times and OAA/S scores (mean±SD) of patients (n=40) undergoing suspension laryngoscopic excision of vocal fold nodules

Parameters	Group A (n=20)	Group B (n=20)	P value
Time to (min)			
Spontaneous breathing return	7.2±1.4	10.9±1.6	<0.001
Consciousness return	7.4±1.5	12.3±1.8	<0.001
Extubation	8.1±1.5	13.2±1.7	<0.001
Operating room discharge	12.7±1.4	22.1±1.3	<0.001
OAA/S score at			
Extubation	4.4±0.8	4.5±0.8	0.836
Operating room discharge	4.8±0.4	4.8±0.4	0.714

OAA/S=Observer's assessment of alertness/sedation scale, SD=Standard deviation

Group B showed similar intragroup changes in HR and MAP: HRs were significantly lower at T_1 than at T_2 (69.8 ± 10.5 bpm vs. 77.9 ± 7.5 bpm, $P = 0.008$), MAPs were significantly lower than baseline at T_1–T_4 and T_6 (all $P < 0.05$) and HR and MAP remained relatively stable at all other timepoints (all $P > 0.05$). Changes in HR and MAP from baseline values were <20% in both groups and were determined to be clinically insignificant. No episode of muscle rigidity, bradycardia, or hypotension requiring specific medical intervention was reported during the study. SpO_2 values remained normal (95-100%) during anesthesia and suspension laryngoscopy in all patients, regardless of treatment assignment.

Post-anesthesia recovery times are shown in Table 3. Post-anesthesia recovery was significantly more rapid in Group A than in Group B in terms of times to spontaneous breathing return (7.2 ± 1.4 min vs. 10.9 ± 1.6 min, $P < 0.001$), consciousness return (7.4 ± 1.5 min vs. 12.3 ± 1.8 min, $P < 0.001$), removal of tracheal intubation (8.1 ± 1.5 min vs. 13.2 ± 1.7 min, $P < 0.001$) and OR discharge (12.7 ± 1.4 min vs. 22.1 ± 1.3 min, $P < 0.001$). However, OAA/S scores were comparable between groups at T_5 (4.4 ± 0.8 vs. 4.5 ± 0.8, $P = 0.836$) and T_6 (4.8 ± 0.4 vs. 4.8 ± 0.4, $P = 0.714$).

Discussion

Suspension laryngoscopy normally offers an excellent view of the laryngeal anatomy, but requires delicate peri-anesthesia management in current practice.[7] Non-depolarizing NMBs are used adjunctively in general anesthesia to facilitate endotracheal intubation and to maintain skeletal muscle relaxation in laryngeal intervention. The most serious safety concerns regarding the use of NMBs in endotracheal intubation and general anesthesia for suspension laryngoscopy are delayed breathing recovery and respiratory impairment following extubation due to residual NMBs.[17] The TOF response is commonly used for NMB monitoring, which requires the use of a delicate NMB monitoring system.[18] Recovery from NMBs prolongs the anesthesia time and increases medical cost, especially for a minor laryngeal operation such as suspension

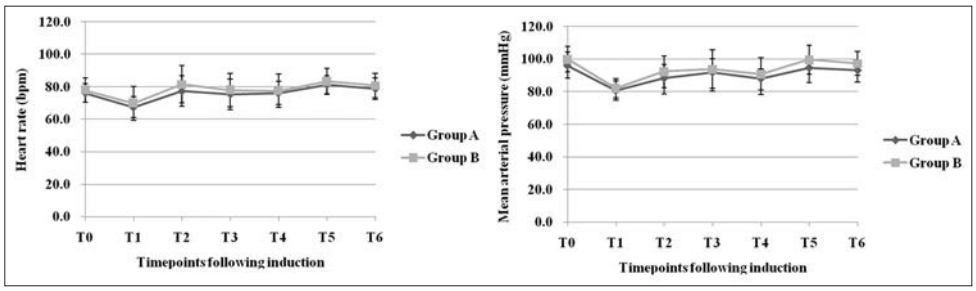

Figure 1: Changes in heart rate (a) and mean arterial pressure (b) in patients with vocal fold nodules undergoing suspension laryngoscopy without (Group A) and with (Group B) muscle relaxants. Timepoints are prior to (T_0) and following (T_1) anesthesia induction and at the times of intubation (T_2), laryngoscope insertion (T_3) and withdrawal (T_4), tracheal extubation (T_5) and operating room discharge (T_6)

laryngoscopy. Thus, the proper use of NMBs plays a critical role in the effectiveness and safety of VFN excision using suspension laryngoscopy. Multiple modified IWMR regimens have been proposed for laryngoscopic surgery.[10,11] Our primary study finding was that endotracheal intubation with propofol and remifentanil alone yielded favorable anesthesia and surgical outcomes, comparable with those achieved with NMB supplementation, in patients undergoing suspension laryngoscopic VFN excision. In addition, this anesthetic technique significantly shortened the post-anesthesia recovery time.

The use of NMBs is believed to reduce the time required for endotracheal intubation, but the difference is only 35 s and is not clinically significant. Moreover, the number and success rate of intubation attempts are similar between patients undergoing IWMR and those receiving NMBs. The absence of NMBs does not impair the endoscopic view of the laryngeal structures, clear visualization of which is essential for definitive and safe VFN excision using suspension laryngoscopy. Precise excision also minimizes the risks of iatrogenic injury and disease recurrence. The intubation condition is known to be closely associated with the depth of anesthesia at the time of intubation.[19] Although the intubation conditions are excellent in a smaller percentage of patients undergoing IWMR with propofol and remifentanil alone, this situation does not increase the difficulty of intubation in terms of the clinical outcome. From the point of view of otorhinolaryngologists, IWMR with propofol and remifentanil alone also facilitates the performance of suspension laryngoscopy. Patients remain well sedated and the vocal folds remain static, although suspension laryngoscopy without the use of NMBs can be stressful. Choking occurs frequently during IWMR,[20] but this adverse event can be prevented by administering superficial tetracaine prior to the procedure. Only four of our patients experienced mild choking during IWMR, probably due to an incomplete superficial blockade, whereas no limb or vocal fold movement was observed.

The primary safety concerns in the use of a combined regimen of propofol and remifentanil are sympathetic nervous system hypotonia, respiratory depression and muscle rigidity.[21] However, our hemodynamic data demonstrate that IWMR with propofol and remifentanil alone provided favorable hemodynamic stability, similar to that achieved with NMB supplementation. The risk of adverse effects depends primarily on the dose and infusion rate of propofol and remifentanil.[22] We used optimal doses of 3.0 μg/mL propofol and 5.0 ng/mL remifentanil by TCI in this study, as recommended by previous reports for adult patients.[23] This combined anesthetic modality maintained an adequate depth of anesthesia, with hemodynamic changes remaining within 20% of baseline values following intubation with and without NMBs. However, the absence of NMBs in patients undergoing IWMR can maximize the safety of the combined propofol and remifentanil modality because NMBs such as cisatracurium can multiply the adverse effects of the two drugs, such as hypotension, respiratory depression and histamine release, although these effects have been rarely reported.[22]

The most striking benefit of IWMR compared with intubation with NMBs for patients undergoing suspension laryngoscopic excision is the significant acceleration of post-anesthesia recovery, due primarily to rapid muscle tone recovery. This favorable effect further shortens the times required for consciousness return, tracheal extubation and OR discharge. No muscle relaxant antagonist administration is required in patients undergoing IWMR. This technique is expected to reduce patients' physical and psychological stress, as well as medical costs related to general anesthesia with intubation.

We acknowledge that this study had some limitations. Firstly, the sample size was relatively small; the study included only 40 patients with VFNs who were scheduled for suspension laryngoscopic excision. Secondly, the investigators were not blinded to the treatment assignment, as required by the institutional protocol due to safety concerns regarding NMB use; thus, the study data were likely confounded by the investigators' bias. Thirdly, we were unable to stratify our patients according to the complexity of VFN excision due to the small sample size. As the great majority of our patients did not have complex vocal fold disease, it remains unknown whether IWMR with propofol and remifentanil alone can be attempted in patients with VFNs requiring longer intubation due to complex laryngeal conditions. Fourthly, the eligibility criteria for intubation, extubation and OR discharge were mainly based on predefined TOF ratio cutoffs, whereas the TOF ratio is known to be highly variable among individuals and not always accurately predictive of NMB residual.

Conclusion

The combined regimen of propofol and remifentanil provides favorable intubation and anesthesia conditions for subsequent suspension laryngoscopic VFN excision, similar to the modality with NMB supplementation. The two anesthetic techniques exhibited good cardiopulmonary safety profiles, but IWMR with propofol and remifentanil alone significantly shortened post-anesthesia recovery times from induction to extubation and OR discharge. Large-scale, double-blind, randomized, controlled trials are required to further validate the benefits of IWMR with propofol and remifentanil alone in patients with VFNs undergoing suspension laryngoscopic excision.

Acknowledgement

We thank Medjaden Bioscience Limited for assisting in the preparation of this manuscript.

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How to cite this article: Pang L, Zhuang YY, Dong S, Ma HC, Ma HS, Wang YF. Intubation without muscle relaxation for suspension laryngoscopy: A randomized, controlled study. Niger J Clin Pract 2014;17:456-61.

Source of Support: This work was supported by Jilin Provincial Department of Science and Technology under the International Collaborative Initiative (#20110759), **Conflict of Interest:** None declared.