American Journal of Otolaryngology–Head and Neck Medicine and Surgery 43 (2022) 103187

Contents lists available at ScienceDirect

American Journal of Otolaryngology–Head and Neck Medicine and Surgery

journal homepage: www.elsevier.com/locate/amjoto

Evaluation of the impact of deep neuromuscular blockade on surgical conditions for laryngeal microsurgery with High Frequency Jet Ventilation. A comparison with no block during intravenous general anesthesia with topical lidocaine

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ARTICLE INFO

Keywords:
Laryngeal microsurgery
High Frequency Jet Ventilation
Surgical conditions
Deep neuromuscular block

ABSTRACT

Objective: Laryngeal transoral surgery classically requires a neuromuscular block (NMB) to facilitate tracheal intubation and to improve surgical conditions. However, the short duration of most procedures and the potential complications of residual NMB lead to consider a no block approach. The hypothesis that intravenous anesthesia (remifentanil and propofol infusions) without NMB but including glottis topical lidocaine anesthesia would allow clinically acceptable laryngeal exposure and good surgical conditions was tested in the specific context of procedures undergone with High Frequency Jet Ventilation (HFJV).

Study design: A prospective randomized clinical comparison.

Methods: 66 consenting patients were planned to receive 0.6 $mg \cdot kg^{-1}$ rocuronium or saline at random. The outcome measurements included the time and conditions to complete suspended laryngoscopy, and the surgical conditions rated by the surgeon. Any vocal cord movement or coughing was recorded. Data were compared using a Wilcoxon rank-sum test for numerical variables and chi-square test for categorical ones. Treatment failure was defined as an impossible laryngoscopy or a grade 4 surgical field occurring at any time during surgery and was compared to its null theoretical value by a general z-test. An interim analysis after completion of 50% patients was performed using Pocock boundaries at 0.0294 significance levels.

Results: A significant failure rate occurred in the non paralysed group (27%, $p < 0.001$). No coughing and no vocal cords movement occurred in the NMB group. Poorer surgical conditions were obtained without NMB ($p = 0.011$).

Conclusion: Inducing a deep NMB ensured improved conditions during direct laryngeal microsurgery with HFJV.

1. Introduction

Laryngeal transoral microscopic-assisted surgery through a rigid laryngoscope is most frequently a short procedure classically requiring a neuromuscular block (NMB) to facilitate tracheal intubation with a reduced diameter tube and to improve surgical conditions [1].

Unexpected movements precipitated by laryngeal stimulation (during suspension laryngoscopy and surgical manipulation including laser therapy) can be dangerous for the patient leading to respiratory complications (coughing, laryngospasm), dental, pharyngeal or laryngeal injuries, and hemodynamic changes [2,3]. The intense nociceptive stimuli of laryngoscopy and laryngeal surgery can result in hypertension, tachycardia, or conversely bradycardia caused by vagal stimulation, and much more adverse events [4]. Propofol and remifentanil are potent intravenous agents most commonly used in laryngeal microsurgery to limit respiratory and cardiovascular reactivity during general anesthesia. However, hemodynamic instability can be the result of high doses even in young patients, which has also demonstrated a negative impact on hyperalgesia, postoperative pain and patient outcome [5,6]. Consequently, a proper depth of anesthesia is recommended, using

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https://doi.org/10.1016/j.amjoto.2021.103187
Received 4 April 2021;
Available online 4 September 2021

specific monitoring (including BiSpectral Index) [7].

In this context, because laryngeal muscles are more resistant to neuromuscular blocking agents (NMBA) than most other muscles [8], the interest of deep rather than moderate NMB to improve the surgical conditions during laryngeal microsurgery has been demonstrated during intravenous anesthesia with propofol and remifentanil in intubated patients [9–11]. The risk of delayed discharge as a result of deep NMB can be avoided using sugammadex, a deep NMB until the end of the procedure being now compatible with a fast and predictable operating room discharge [12].

However, numerous clinicians still frequently choose to proceed with low dose NMBA or even without NMB with the aim to reduce the duration and cost of the procedure, and to avoid the side effects induced by NMBA. Some new arguments in favor of this no NMB approach have been recently put forward in the POPULAR study, as it confirmed that the use of NMBA is a risk factor for postoperative pulmonary complication [13]. Interestingly, the authors recommended avoiding NMBA when it is not really indicated. This could be especially interesting when dealing with very short procedures (less than 20 min), which it is frequently the case for laryngeal microsurgery.

In order to reduce the laryngeal reactivity, preoperative topical lidocaine can be applied under direct vision (laryngoscopy) to insure glottic and supra-glottic local anesthesia and superior laryngeal nerve inhibition (spray of lidocaine on the laryngeal surface of the epiglottis, the arytenoid cartilages and the vocal cords). It may be helpful in attenuating airway reflexes and cardiac complications during suspension laryngoscopy, and in reducing postoperative pain and agitation [2,14].

Furthermore, a less invasive option of intraoperative pulmonary ventilation is High Frequency Jet Ventilation (HFJV). Requiring intravenous general anesthesia, it allows proper lung ventilation while ensuring the best glottic exposition during suspension laryngoscopy [15–17]. HFJV is provided through a thin metallic catheter positioned in the supra or subglottic level, allowing an excellent surgical access to the larynx and the vocal folds, since these organs are not displaced or obstructed by an endotracheal tube. Moreover, the procedural time can be reduced [17]. Laser therapy and HFJV require the absence of any movement of the vocal cords or coughing in order to avoid inadvertent airway lesions or barotrauma. Although most frequently recommending a deep NMB, there is currently no study comparing the conditions of glottic exposure and endolaryngeal surgery under HFJV with or without NMB.

We tested the hypothesis that a balanced and properly monitored intravenous anesthesia without neuromuscular block but including glottic and supra-glottic topical anesthesia would allow clinically acceptable laryngeal exposure and good surgical conditions under HFJV. In this specific context, the primary outcome was the timing and conditions of laryngeal initial exposure. Unacceptable clinically conditions would be considered as a failure. Secondary outcomes were the surgical conditions during laryngeal microsurgery (including the quality of glottic exposure, the occurrence of coughing and vocal cords movements) as well as the timing of surgery and operating room discharge after surgery.

2. Methods

2.1. Patient selection

The protocol of this monocentric prospective randomized study was approved before patients' inclusion by the Institutional Ethical Committee (CHU UCL Namur, Yvoir, Belgium, OM 050 Prof. P. Evrard, under registration number B039201629150). It was performed in accordance with the ethical standards of the Declaration of Helsinki and was included in the Australian and New Zealand Clinical Trials Registry (ACTRN12619001700123).

After obtaining written informed consent from all participants, ASA I to II patients (aged 18 to 80 years) scheduled to undergo any laryngeal microsurgery (subepithelial cordectomy, benign lesions excision, Reinke's oedema, hyaluronic acid injection or laser-assisted biopsy) were included in the study. Criteria for exclusion were pregnant or breast-feeding women, patients with vocal cord paralysis (preoperative videoendoscopic screening), with renal or hepatic insufficiency, with neurological disorders, and any patient with a suspected allergy to the drugs used in the protocol or receiving medications that could interfere with neuromuscular transmission.

2.2. Sample size, study groups and randomisation

A sample size with a minimum of 66 patients was estimated to be required for an alpha error of 0.05 and a power of 0.80, assuming that the primary outcomes (laryngoscopic conditions) of Deep NMB and No NMB groups were 100% and 80% respectively using G*Power 3.1.9.2 program [18]. We used a group sequential approach and plan to perform one interim analysis after completion of 50% patients ($n = 33$) allowing to stop the trial if a significant difference was observed in the primary outcome at this interim analysis. The method used Pocock boundaries, that is a total of two analyses including the final one, at 0.0294 significance levels [19,20].

The patients were randomly assigned to one of two treatment groups by a minimisation procedure [21] with QMinim software, as follows:

Group No NMB: 10 ml Saline (NaCl 0.9%) is administered during the induction sequence. If an unacceptable condition (insufficient vocal folds exposure, sustained coughing, or vocal cords adduction) was obtained during laryngoscopy or surgery, a relief bolus dose of rocuronium 0.6 mg/kg was administered and the conditions further evaluated. The patient was consequently excluded from the No NMB group.

Group Deep NMB: rocuronium 0.6 $mg.kg^{-1}$ induced the deep NMB before laryngoscopy, followed by repeated 5 mg boluses as soon as a single muscular response reappeared to maintain the NMB in the deep level (train-of-four (TOF) count <1) [22,23]. Sugammadex 4 $mg.kg^{-1}$ was administered at the end of surgery (removal of the rigid laryngoscope) to reverse the deep NMB.

The randomisation criteria were as follows: gender (M/F), age (18–40, 41–60, 61–80 years), body mass index (BMI) (<20, 20–24, 25–29, 30–34, 35–39), and Mallampati score (1–4).

Both senior surgeons and all the clinical care nurses were blinded to the group assignment throughout the study. The senior anaesthesiologist in charge of the patients strictly observed the following protocol.

2.3. Patient management

All patient received alprazolam 0.5 mg 60 min before arriving in the operating theatre. They were conventionally monitored with a pulse oximeter, a 3-leads electrocardiogram and non-invasive blood pressure (NIBP), scheduled in automatic mode at three-minute intervals. A catheter was inserted into a forearm vein for crystalloid infusion. BiSpectral Index (BIS™ Brain monitoring system, Medtronic, Minneapolis, USA) was installed on the patient forehead. Neuromuscular monitoring was set up according to the criteria for good clinical practice in pharmacodynamics studies [22]. On the opposite side of NIBP, the skin was cleaned with diethylether and two ECG skin electrodes (E152, IMMED Benelux, Brussels, Belgium) were placed above the ulnar nerve. The Philips Intellivue NMT acceleromyographic transducer (Royal Philips Electronics, Amsterdam, The Netherlands) was taped on the thumb' pulp and the hand was inserted and stabilized into the SL TOF-Tube [24]. The arm was then positioned alongside the body on soft padding to protect nerve structures.

Anesthesia was induced with continuous intravenous infusions of remifentanil 0.3 μg/kg/min and propofol 1% (Diprifusor Cardinal

Health, Basingstoke, UK) and lidocaïne 1 mg/kg as an intravenous bolus. After loss of consciousness -confirmed by BIS under 60, manual ventilation with O2 100% was provided during NMTM calibration, and the hemodynamic baseline (ECG rate, systolic NIBP) was determined. From this moment, ulnar nerve Train-Of-Four (TOF) stimulations were repeated every 15 s during all the procedure. Then, saline or rocuronium 0.6 mg/kg was administered according to the group. Once the TOF count reached zero, or after 3 min in the No NMB group, glottic and supraglottic local anesthesia was performed with lidocaïne 2% 2 mg/kg under soft laryngoscopy (Macintosh blade 3). After one more minute under manual ventilation, the surgeon started the standardized procedure for suspension laryngoscopy using a Kramer laryngoscope (Richard Wolf GmbH) in all patients, and finally inserted the Metal JET Catheter (Acutronic Switzerland ltd, Bubikon, Switzerland) between the vocal cords apart of the surgical site [25]. Then, HFJV (Monsoon III, Acutronic Switzerland ltd) was initiated and adapted to every patient compliance: P 1.5–3 Bar, frequency 130–180 /minute, Peak pressure max 10 mBar, End expiratory pressure 5 mBar, inspiratory/total time ratio 0.3, FiO_2 was maintain at 100% except during laser therapy (40%). Anesthesia was maintained with continuous intravenous administration of remifentanil 0.15 μg/kg/min and propofol with a target theoretical plasma concentration of 2 to 6 μg.ml to maintain the BIS in the 40–60 range. Blankets prevented heat loss from the body.

The outcome measurements included the time (in seconds) to achieve a complete suspended laryngoscopy until initiation of HFJV, the conditions of laryngoscopy (evaluated by the surgeon from 1 to 4 as easy, fair, difficult, or impossible) [11,22] and the final glottic exposure (100, 75, 50, 25 or 0% of the vocal cords visualized).

Every 5 min, the laryngeal exposure was rated by the surgeon on a 4 grade scale (excellent, good, poor or unacceptable) [11,22]. For each patient, the worst surgical condition was taken into account to perform the comparison between both groups. Any movements of the vocal cords or any coughing event were also recorded as secondary outcomes measurements.

In case of difficult exposure and poor surgical conditions, or if hemodynamic parameters increased more than 20% of baseline, the remifentanil infusion was increased to 0.25 μg/kg/min.

In case of impossible exposure, or unacceptable surgical conditions (including insufficient exposure, sustained coughing, or vocal cords adduction), a relief rocuronium 0.6 mg/kg bolus was administered in the No NMB group and was considered as a failure. The patient was excluded from the No NMB group and the event considered for the analysis. Once the NMB was induced, the surgical conditions were reassessed before continuing the procedure.

At the end of the surgical procedure, the Metal JET Catheter was removed as well as the rigid laryngoscope, the remifentanil and propofol infusions were stopped, sugammadex 4 mg/kg was administered in the Deep NMB group to reach a TOF ratio >0.9, and the patient was manually ventilated to ensure maximal end-tital CO_2 45 mmHg until recovery of spontaneous ventilation and awakening. The operating room discharge was considered as the time between the end of surgery (laryngoscope removal) and when the patient was transferred in post-anesthesia care unit.

2.4. Statistics

The collected data in both groups (timing and conditions of laryngoscopy, glottis exposure, surgical conditions and duration, OR discharge) were compared using a Wilcoxon rank-sum test for numerical variables and chi-square test for categorical ones. Numerical variables are expressed as means ± standard deviations and also by medians for ordinal scores. Treatment failure and thus treatment change was defined as an impossible laryngoscopy or a grade 4 surgical field rating occurring at any time during surgery and was compared to its null theoretical value by a general z-test. All statistical tests were performed using MedCalc statistical software 19.2 (MedCalc Software Ltd., Ostend, Belgium). According to Pocock boundaries [19,20], p values <0.0294 were considered statistically significant.

3. Results

Eighteen consenting patients were included in the Deep NMB group, and 15 in the No NMB group. Table 1 presents the demographic data which were similar among both groups.

Four men were excluded from the No NMB group because of impossible laryngeal exposure ($n = 1$), or unacceptable surgical conditions ($n = 3$). They did not present particularly more severe criteria of difficult intubation than the others: BMI 24-24-27-40 respectively (the latter had a neck circumference > 43 cm), Mallampati scores 2–3 but neck extension, thyromentonal distance, and mouth opening were in favor of easy intubation for the 4 patients.

This failure rate of 27% (4/15) was statistically different from the theoretical value of 0 of the Deep NMB group in which rescue NMB was not necessary ($p < 0.001$). After the rescue bolus of rocuronium, all conditions improved: fair exposure with 50% vocal cords visualized, and good (2) to excellent (1) surgical conditions respectively.

Glottic exposure conditions and timing are compared in Table 2. The benefit of the NMB to improve the conditions of laryngoscopy reached borderline significance.

The surgical conditions and timings are compared in Table 3. No coughing and no vocal cords movement occurred in the Deep NMB group. Poorer surgical conditions were obtained without NMB ($p = 0.011$).

4. Discussion

With a significant failure rate in the non paralysed group (27%), the results cannot support the hypothesis that properly monitored intravenous anesthesia (propofol and remifentanil) associated with lidocaine topical glottis anesthesia would provide clinically acceptable glottis exposure and surgical conditions during suspended rigid laryngoscopy for transoral microsurgery with HFJV.

Several studies have demonstrated that clinically acceptable intubating conditions could be obtained without neuromuscular blockade after propofol and alfentanil or remifentanil administration [26,27]. This no NMB approach was also adopted in the particular context of laryngeal surgery [28]. In a way to reduce the postoperative pulmonary complications, the authors of the POPULAR study recently suggested the avoidance of neuromuscular blocking agents any time surgery does not require muscle paralysis [13].

In addition to potent hypnotic and opiate intravenous agents, some studies stated that 60–100 mg lidocaine topical glottis anesthesia could reduce hemodynamic instability during laryngoscopy [2,14]. Indeed, Arslan et al. suggested that higher dosage of lidocaine may reduce the incidence of laryngospasm and coughing [2].

Table 1
Demographic data.

Mean ± SD [median]	Deep NMB ($n = 18$)	No NMB ($n = 15$)
Age, years old	61.1 ± 9.5	60.3 ± 12.7
Gender M/F	12/6	10/5
BMI kg/m^2	26 ± 5	26 ± 6
Mallampati score (1–4)	2.1 ± 0.8 [2]	2.0 ± 0.8 [2]
Type of surgery:		
Benign lesion excision	6	3
Subepithelial cordectomy	4	4
Reinke's oedema	4	3
Hyaluronic acid injection	3	4
Laser-assisted biopsy	1	1

Patients were randomly assigned to Deep NMB or No NMB group according to gender, age, body mass index (BMI), and Mallampati score. Surgery included similar numbers of procedures.

Table 2
Glottic exposure timing and conditions.

Mean ± SD [median]	Deep NMB ($n = 18$)	No NMB (n = 15)	p
Timing (seconds)	74 ± 50	95 ± 88	NS (0.563)
Condition (1–4)	1.2 ± 0.5 [1]	1.7 ± 1.0 [1]	NS (0.051)
Glottic exposure (0–100%)	88 ± 13	78 ± 33	NS (0.856)

See the Methods section for details. Numerical variables are expressed as means ± standard deviations and also by medians for ordinal scores.

Table 3
Surgical conditions and timing.

N (%) or mean ± SD [median]	Deep NMB ($n = 18$)	No NMB ($n = 14$)	p
Coughing	0	1 (7%)	NS (0.257)
Vocal cords movements	0	3 (21%)	NS (0.042)
Worst surgical conditions	1.1 ± 0.3 [1]	2.0 ± 1.2 [1.5]	0.011
Surgery duration	18:14 ± 11:13	17:27 ± 6:18 ($n = 11$)	NS (0.787)
OR discharge	12:33 ± 2:53	12:17 ± 3:16 (n = 11)	NS (0.719)

See the Methods section for details. Numerical variables are expressed as means ± standard deviations and also by medians for ordinal scores. OR: operating room.

However, our results demonstrate that, even under potent intravenous anesthesia (propofol and remifentanil) and after 1 mg/kg intravenously and 2 mg/kg topical glottis anesthesia, clinically acceptable surgical conditions could not be guaranteed in all cases. The high failure rate might be detrimental to patient safety.

Recent studies have already demonstrated the need for deep rather than moderate NMB to ensure good laryngeal exposure and to improve surgical conditions in intubated patients [9–11]. While maintaining the NMB in the deep level (TOF ratio < 1), our study confirmed a non-significant trend toward faster and easier glottic exposure (Table 2). It also demonstrated that the deep NMB provided better surgical conditions and prevented any coughing or vocal cords movements during surgery (Table 3). This could be considered as a major improvement in the safety and quality of the surgical procedure.

HFJV is a unique lung ventilation approach. During laryngeal microsurgery under direct suspended laryngoscopy, it provides an excellent access to the surgical field, more space and flexibility for the surgeon while ensuring adequate lung ventilation at the same time. The glottis exposure is improved and enables easier and faster treatment on the vocal folds and arytenoids [15–17]. To fully benefit of its advantages, HFJV requires deep intravenous anesthesia and close collaboration between the surgeon and the anesthetist. The goal of this study was to evaluate the need for supplemental deep NMB in this specific setting. Currently, a complete paralysis of the diaphragm and vocal cords was recommended when using HFJV [11]. However, this recommendation was only based on a few case reports of laryngospasm during HFJV [3], experimental studies investigating the evolution of airway pressure during NMB recovery [29,30], and comparison of deep versus moderate level of NMB to improve surgical conditions in a majority of intubated patients [9–11]. The ability to perform laryngeal microsurgery with or strictly without NMB was not addressed. The results of our study dedicated to this outcome clearly emphasize the need of a deep NMB to ensure clinically acceptable conditions in all cases.

Our results came from an interim analysis of a limited sample ($n = 15$ in the No NMB group). But the strict method provided by the Pocock's boundaries during this interim analysis after inclusion of 50% of the planned patients allowed us to reject the hypothesis [19,20]. Convinced of the impact of these significant results on the procedure safety, we did not include more patients and completed the study. Actually, clinically acceptable conditions were encountered in the majority of cases without NMB, which could give some reason to try a no NMB protocol in daily clinical practice. However, we believe that the potential complications related to insufficient laryngeal exposure, sudden increased airway pressure, vocal cords or body's movement or sustained coughing during suspended rigid laryngoscopy are critical and potentially harmful to patient safety [2–4,29,30]. These adverse events can absolutely be prevented by inducing a deep NMB throughout all the procedure, even during the shortest ones.

This continuous deep NMB strategy requires a fast and predictable reversal strategy with sugammadex. As demonstrated in Table 3, operating room discharge was similar after deep NMB reversed by sugammadex compared to the no NMB group. Further studies are needed to evaluate the cost effectiveness of this strategy in preventing intra- and postoperative complications.

As suggested by Laosuwan and Almeida [11,31], surgeon's satisfaction score is a subjective and multifactorial measurement. It would be useful to determine an objective method to quantify the impact of anesthesia (including muscle relaxation) on the laryngeal transoral surgical conditions and patient outcome.

In conclusion, this study demonstrated the need for inducing a deep NMB to provide improved exposure and surgical conditions during direct laryngeal microsurgery under general anesthesia with HFJV.

CRediT authorship contribution statement

Laurie Putz: methodology, investigation, original draft writing, Linda Lovqvist: investigation, manuscript review, Vincent Bachy: methodology, investigation, manuscript review, Sébastien Van der Vorst: methodology, investigation, manuscript review, Jacques Jamart: methodology, data analysis, manuscript review, Philippe Dubois: conceptualization, methodology, original draft writing, supervision.

Funding

Departmental funds.

Declaration of competing interest

The authors have no conflict of interest.

Acknowledgement

None.

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