



Is older still good, or even better? Evaluation of possibility of using Miller laryngoscope for intubation in adults and comparison with the most widely used Macintosh laryngoscope. Protocol of a crossover randomized control trial

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ABSTRACT

Background: Macintosh laryngoscope is the most widely used laryngoscope for intubation. In some patients, e.g. with flaccid, drooping, aplastic epiglottis, usage of this laryngoscope, or even videolaryngoscopes, may not provide visualization of a glottis. Elevation of the laryngopharynx, like in intubation with Miller laryngoscope, may significantly improve intubating conditions.

Methods: An anaesthesiologist with over 20 years of experience will perform direct laryngoscopy with randomly chosen Miller or Macintosh blade, evaluating the visibility of rima glottidis with Cormack-Lehane classification and POGO score with and without external laryngeal pressure. Then the second evaluation of glottis with other blade type will be obtained and the patient will be intubated. Comparison of the rima glottidis visibility when using both blades will be the primary endpoint of the study. The secondary endpoints consist of: demonstrating whether there is a group of adult patients in whom the use of the Miller blade associated with better vocal cord visibility may be predicted based on an anesthesiological examination, and whether external laryngeal pressure improves vocal cord visualization more when using the Miller blade compared with the Macintosh blade.

Sample size: We performed minimal sample size calculations based on the data derived from the first 60 patients. We assessed the minimal sample size to obtain the alpha of 5 % and power of 90 %. We decide to enroll at least 286 patients.

Discussion: this will be the first trial assessing Miller and Macintosh blades in the same population of adult patients. It will determine group of patients in whom Miller laryngoscope will provide better visualization of rima glottidis than Macintosh blade and associated technique, diminishing rate of prolonging intubations and reducing possible aftermaths of hypoxia.

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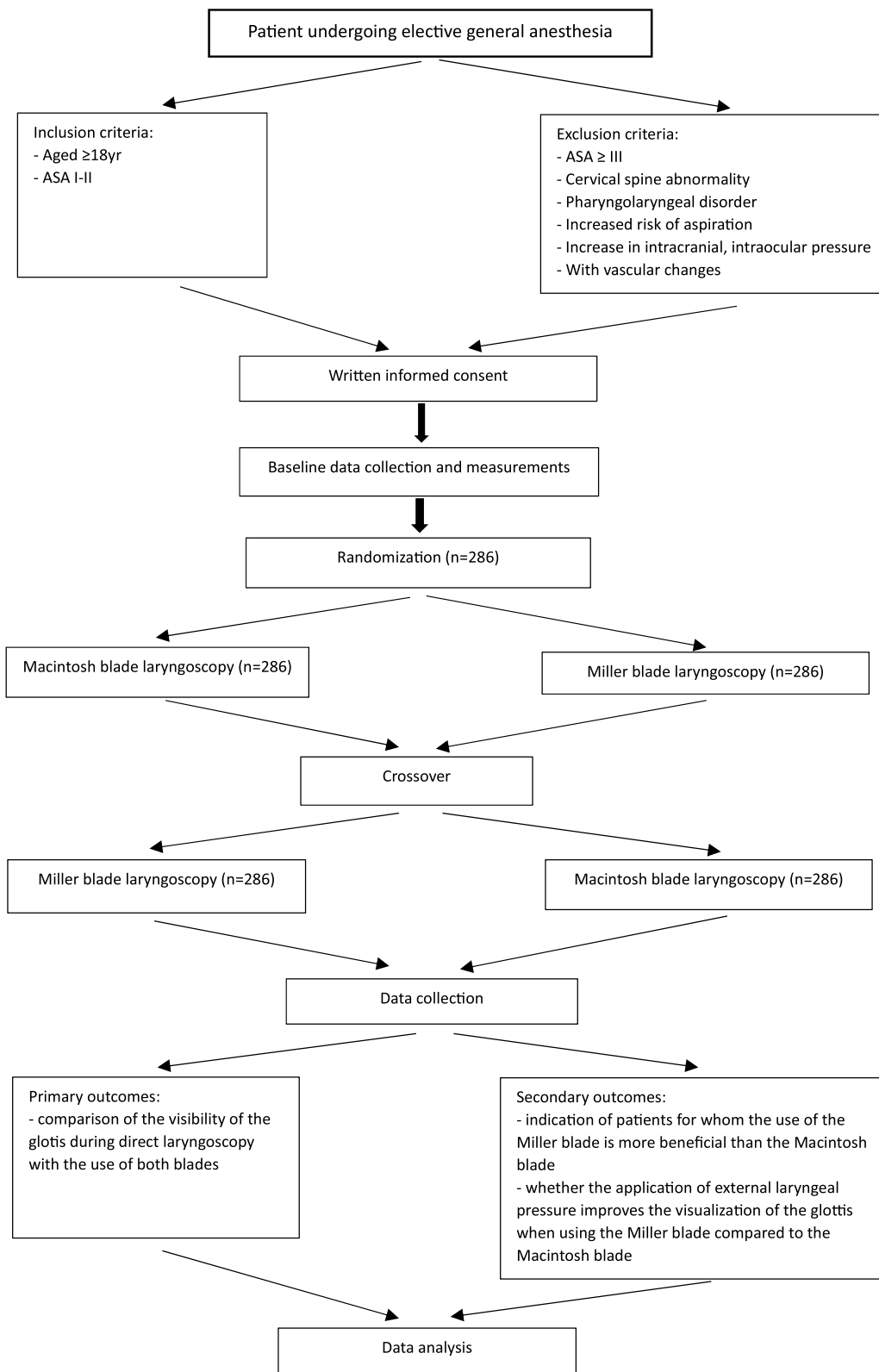


Fig. 1. Flow chart of the present study.

1. Introduction

Endotracheal intubation is the gold standard of restoring airway patency in patients with respiratory failure and undergoing general anaesthesia [1]. It enables implementation of adequate ventilation, concurrently protecting lungs from gastric content aspiration [2]. Proper intubation of a patient requires from the operator not only theoretical knowledge, but also sizeable manual skill [3]. To carry it out properly one has to unceasingly polish it in everyday work. Despite fulfilling those requirements there might happen some patients with “difficult airways”, in whom prolonged intubation may lead to CNS hypoxia and even cardiac arrest [4–6].

Since introduction of Macintosh and Miller laryngoscopes in 40s of 20th century the direct laryngoscope is the mostly used laryngoscope type enabling intubation of trachea [7]. Skillful usage of it is a valuable skill of all contractors working in both hospital and out-of-hospital care. However due to the necessity of obtaining straight line linking operator’s eyes with patient’s oral cavity and true glottis, intubation by means of direct laryngoscopes is a complex and technically fairly difficult procedure [1]. The visualization of the larynx can be improved by: head and neck positions (sniffing position), external manipulation of the larynx, proper selection of intubation technique and equipment. According to literature, Macintosh laryngoscope intubation success rate is only 50 % in case of use by an operator without clinical experience. It increases to the level of about 90 % after execution of at least 50 intubations [2]. Similar data is not available for Miller laryngoscope. According to some authors, the Miller blade provides better visibility of the glottis, but worse intubation efficiency [8]. According to others authors, the Miller blade laryngoscope is an effective and safe device with a low incidence of difficult visualization of the glottis and difficult tracheal intubation [9]. Over the years many variants of direct laryngoscopes with following blades were developed: Miller (1941), Macintosh (1943), Soper (1947), Jackson-Wisconsin (1952), Bizzari-Guffrid (1958), Bainton (1987) and recently VieScope laryngoscope, but until now primarily used remained the oldest two: Macintosh and Miller, with vast majority of Macintosh blade [9,10]. Nowadays Miller laryngoscope is not a very widely used device, but paediatric patients undergoing general anaesthesia with endotracheal intubation are the group of patients in whom the advantage of this blade over Macintosh laryngoscope was demonstrated [9,10].

In this research we proposed the hypothesis that Miller blade may be equally good for intubation in adults as the Macintosh blade, and there might even exist some group of patients in whom the use of Miller laryngoscope gives more benefits than the use of Macintosh blade.

2. Methods

2.1. Study settings

This research was endorsed by the Bioethics Committee of Medical University of Lodz (Number RNN/103/22/KE of May 10, 2022) and registered in Trial Registration (Number NCT05494463). It will be performed in the Central Operating Block of Norbert Barlicki University Teaching Hospital No. 1 in Lodz. Direct laryngoscopy with evaluation of size of rima glottidis will be performed by anaesthesiologists with over 20 years of experience in intubating of the patients. Miller and Macintosh blade sizes 3 or 4 will be used for the study (depending on indications). The conducted study is a randomized, controlled, blinded crossover trial with parallel control group. Sequence of use of different laryngoscope blades will be chosen randomly with the help of sealed non-transparent envelopes. Strategy of locked randomization will be generated by Randomizer Program (randomizer.org). The Flow chart of the study is presented on Fig. 1.

The research will involve adult patients (over 18 year old) of ASA I and ASA II, qualified to elected surgeries in general anaesthesia with endotracheal intubation, who gave the informed, voluntary consent for taking part in the trial. Patients of ASA III and more, with cervical spine trauma or qualified for cervical spine surgery, with elevated intraocular pressure, elevated intracranial pressure, vascular changes in CNS or other body parts, with stated pathology of airways, after surgeries of oral cavity, pharynx or larynx, pregnant women, with indications for urgent surgical intervention, not giving consent for partaking in the research, will be excluded from the trial. Patients meeting the inclusive criteria, without exclusions, regardless of their BMI, will be included in the study.

After transportation of the patient to the operating theater opening of the envelope and qualification for the first laryngoscopy with drawn by lot blade (Miller or Macintosh) will ensue. The patient’s head and neck will be in the sniffing position. During the induction the patients will have the standard monitoring attached: HR, NIBP, SpO₂. Patients qualified for the trial will undergo a unified technique of induction of anaesthesia: preoxygenation with 100 % oxygen for 3 min, FNT 1,5 µg/kg i.v., propofol 2,5 mg/kg i.v. and rocuronium bromide 0,6 mg/kg i.v. after confirmation of a proper bag mask ventilation. The bag mask ventilation with 100 % oxygen and 2 % sevoflurane will be continued for 3 min. After obtainment of a full neuromuscular blockade, confirmed by the lost of entire Train Of Four response with the use of a peripheral nerve stimulator (Innervator Constant Current Peripheral Nerve Stimulator, Fisher & Paykel Health Care System, New Zealand) the operator will start execution of the first direct laryngoscopy with the first drawn by lot Miller (Scope Medical Devices Pvt. Ltd.) or Macintosh (HEINE Optotechnik GmbH & Co. KG, Gilch-ing, Germany) blade and will evaluate the visibility of a true glottis based on Cormack-Lehane classification and POGO score without and with the external laryngeal pressure. Then the next direct laryngoscopy with use of other blade will be performed and one more evaluation of rima glottidis visibility based on both classifications without and with external pressure in the same patient will take place and the patient will be intubated and attached to the anaesthesia machine. Obtained data will be registered. Evaluation of a glottis visibility based on Cormack-Lehane Classification and POGO score without and with external pressure during direct laryngoscopy with Miller and Macintosh blade is the primary endpoint of the study. The secondary endpoint consists of determining whether there exists a target group of patients in whom usage of Miller blade is associated with better visibility of true glottis in comparison with Macintosh blade and determining whether external laryngeal pressure improves visualization of rima glottidis when Miller blade is used compared with

Macintosh blade.

2.2. Safety conditions

Besides experienced personnel we have at our disposal all accessible devices for intubation in patients with normal and so called difficult airways. Moreover, in order to prevent desaturation during direct laryngoscopy we will use the nasal CPAP. This method is applied to prolong the so called safe apnea time while attempting endotracheal intubation. We possess equipment and experience in its usage proved by publication on use of nasal CPAP in obese patients in aim of prolonging safe apnea. If any difficulties occur, the patient will be immediately intubated and attached to the anaesthesia machine. Also, the set containing supraglottic airways, videolaryngoscopes and intubating stylets for the so called difficult airways will be prepared.

2.3. Statistical considerations

In the current study, we would like to evaluate factors impacting the simplicity of intubation with Miller's laryngoscope in comparison to Macintosh's laryngoscope. We will evaluate the following parameters used in common anesthesiological practice, namely: sex, age, height, weight, BMI, neck circumference, thyro-mental distance, sternum-mental distance, mouth opening, assessment in Mallampati score. As there is not one standard definition of intubation's simplicity, we will use the following endpoints: better visualization in the Cormack-Lehane scale (assessed with and without external pressure of the larynx) as well as the POGO scale (assessed with and without the external pressure of the larynx).

Nominal data will be presented as n (% of total) and assessed with a test chosen based on the size of the smallest subgroup: $n < 5$ - Fisher exact test, $5 \leq n < 15$ - Yates's chi-squared test, and $15 < n$ - chi-squared test. Continuous data will be tested with the Shapiro-Wilk test and Brown-Forsythe test. Data with normal distribution will be present as mean \pm standard deviation and tested with parametric tests (Student's t-test, Pearson correlation). In another case, they will be presented as median with interquartile range (IQR). The dependencies between them will be assessed with Mann-Whitney *U* test and Spearman's rank correlation).

We will use Receiver operating characteristic (ROC) analysis with Younden's J statistics to find an optimal cut-off point for qualification to intubation with Miller's laryngoscope. Finally, we will perform a logistic regression analysis (a forward stepwise model) to predict the chance of obtaining each endpoint based on the aforementioned characteristics of the patient.

We performed minimal sample size calculations based on the data derived from the first 60 patients. We assessed the minimal sample size to obtain the alpha of 5 % and power of 90 % to compare differences in BMI between patients, who developed endpoints when compared to others (see Table 1). We decide to enroll at least 286 patients. The statistical analysis was performed using Statistica 13.1 PL (StatSoft, Poland, Krakow).

3. Discussion

Miller laryngoscope is a widely applied tool for children intubation [10]. Nowadays its role in airways visualization in adult patients is largely limited in behalf of Macintosh and MacCoy laryngoscopes and videolaryngoscopes [7]. Due to the mass development of videolaryngoscopes the Miller laryngoscope is also not a common matter of concern of researchers evaluating usefulness of different devices for restoring airways patency. One of the last big research papers concerning Miller blade is the work by William B. Landry 3rd et al. from 2016, who sought for attributes of possible difficult airways when using Miller laryngoscope in 978 patients of ASA I-III. The authors came to a conclusion that one characteristic deciding about possible intubating difficulties when using Miller blade cannot be specified, but only overlap of multiple risk factors, applied on evaluation of presumptive intubating difficulties, may speak in favor of worse rima glottidis visualization. They reached the general conclusion that laryngoscope with Miller blade is a highly rated, effective device and safe for patients undergoing general anaesthesia with intubation for elective surgeries with low rate of difficult visualization of rima glottidis and difficult orotracheal intubation [9]. However, those researchers did not compare Miller blade with Macintosh blade in the same patients, they also did not demonstrate which blade would be better in particular patient. Many authors believe that the Miller blade provides better visibility of the glottis than the Macintosh blade [11,12]. According to Arino, the Miller blade allows for 96 % of the best visibility of the glottis, while in the case Macintosh blade this percentage drops to 72 % [8]. Achen was of similar opinion, who showed that 25 % visibility of the glottis was obtained in 95 % of laryngoscopy cases using the Miller laryngoscope, and in the case using the Macintosh laryngoscope, 25 % visibility was obtained during 80 % of laryngoscopy [13]. The

Table 1

The minimal sample size calculation for the comparison of differences in BMI between patients, who has better visualization in Miller's laryngoscope than in Macintosh's laryngoscope when compared to others.

The used scale of visualization	External pressure of the larynx	Average BMI [kg/m ²]		Sample size	
		The same or worse visualization in Miller's laryngoscope	Better visualization in Miller's laryngoscope	In each group	Total
Cormack-Lehane	No	33.358	39.490	30	60
	Yes	35.512	38.371	131	263
POGO	No	34.078	38.886	48	96
	Yes	35.456	38.189	143	286

improved visibility obtained with the Miller laryngoscope is associated with less movement of the cervical vertebrae and less tissue volume present in the oropharynx to be displaced. Using the Macintosh blade, the tongue must be moved further into the submandibular space to achieve the same view of the glottis as with the straight blade. This is important in morbidly obese patients, in whom the accumulation of tissue in the oral cavity is greater than in patients with normal body weight [14]. Recently, Chaoin Chen et al. drew attention to the possible return to more frequent use of old Miller blade and associated intubation technique of external pressure of laryngeal part of epiglottis in adult patients [15]. Namely, he demonstrated that there exists a certain group of patients with flaccid, drooping or aplastic glottis in whom its elevation with a classic Macintosh laryngoscope, or its different variants, does not give significant results. The use of videolaryngoscopes, frequently used as an emergency equipment in difficult intubation, in this group of patients might also be unsatisfactory, regardless of how much the anaesthesiologists may modify the angle of the device. In the research described by the authors over 90 % of interviewed anaesthesiologists reported similar experiences, and their decisions aimed for solution to this problem were basically identical. At first, they used a delicate external laryngeal pressure and consecutive blind intubation, but this action may cause oedema of glottis. After a few attempts the next step consisted of using intubation stylets with illumination of its distal end or using the optical fibre bronchoscope. The researchers recognized that few anaesthesiologists knew that after coming into contact with flaccid epiglottis in adults, which was difficult to elevate with a classic laryngoscope or a videolaryngoscope, drawing on a conventional method used for Macintosh blades, it is possible for emergency purposes to place the end of a videolaryngoscope under the laryngeal surface of epiglottis, similarly to the technique used with Miller blade, or use the Miller blade itself [16]. Such a behavior provides the possibility to visualize rima glottidis and reduces proportion of blind intubations or using intubation stylets, as it was described by Ueda and Arai [16]. Presence of flaccid, drooping and aplastic glottis in patients cannot be predicted without specialistic laryngological examination [17]. We were interested whether there exist any other prognostic attributes accessible on a routine anaesthesiological examination bespeaking of the fact that Miller blade might be more useful than mostly used Macintosh blade in intubating the adults. To achieve this, in the same patients we will evaluate visibility of a true glottis with Cormack-Lehane classification and POGO score, using both Miller and Macintosh blade in a random order. The characteristics being studied will be: height, body mass, BMI, neck circumference, thyro-mental distance, sterno-mental distance, mouth opening width, Mallampati score. In our opinion the answer to this question will improve safety of patients undergoing procedures in general anaesthesia with endotracheal intubation, because the routine use of laryngoscopes with Macintosh blade, and in situations with potential difficulties the use of videolaryngoscopes, which are not always available, does not solve all the problems that may arise during the intubation. Application of the older intubation technique with Miller blade may reduce number of attempts undertaken in patients on unexpected intubation difficulties and restrict proportion of local and general complications that might occur in patients. Many authors also deem that for the patients' safety the education process of young anaesthesiologists should encompass as much equipment and intubation techniques as possible, including quite forgotten Miller blade and associated with it disparate technique of airways entrance visualization [13]. Our experimental design has some limitations. First, when performing a laryngoscope with the other blade and then immediately with the other blade, we cannot assess the complications caused by the use of a given blade, which may be cumulative. Second, performing the first laryngoscopy may make it difficult to assess the glottis during second laryngoscopy due to the potential for tissue injuries. In conclusion, in this clinical trial we will assess the effectiveness of the Miller blade in adult patients (excluding difficult airways, cervical abnormalities, ASA III-IV, emergency situations) and indicate in which use of the Miller blade is more effective than the Macintosh blade.

Trial status

The first participants were included on 05 September 2022. There were 60 patients recruited at the time this paper was submitted.

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Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Bioethics Committee of Medical University of Lodz (no. RNN/103/22/KE of 10,05,2022) and registered in Trial Registration (no. NCT05494463).

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Data availability statement

The data associated with the study has not been deposited into a publicly available repository. Data will be made available on request.

CRediT authorship contribution statement

Paweł Ratajczyk: Conceptualization, Methodology, Writing – original draft. **Krzysztof Wasiak:** Writing – review & editing. **Przemysław Kluj:** Writing – review & editing. **Bartosz Szmyd:** Formal analysis, Methodology. **Caridad G. Castillo-Monzón:** Writing – review & editing. **Tomasz Gaszyński:** Conceptualization, Methodology, Project administration, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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