

**The Effect of Placement of A Support Under Shoulders on Laryngeal Visualization With C- Mac Miller Video Laryngoscope in The Children Younger Than Two Years Of Age**

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Conflicts of Interest: **None**

## **Study Protocol**

### **Patient Selection**

This study was approved by the University's Institutional Review Board (IRB #2016/203) and written informed consent will be obtained from the parents of the children participating in the trial. This study will be conducted in compliance with the Good Clinical Practice guidelines and adheres to the applicable Consolidated Standards of Reporting Trials (CONSORT) guidelines.

96 children younger than two years of age who were classified as ASA I or II and will be scheduled for the elective surgery necessitating endotracheal intubation under general anesthesia in hospital of Inonu University Faculty of Medicine will be included in the study.

Children who had an upper respiratory tract infection in the last 4 weeks and who expected to have difficult airway in the preoperative evaluation or who will not be stable during intubation (due to underlying respiratory or cardiovascular problems), will be excluded from the study.

### **Randomization**

The present study will be planned as a prospective and randomized clinical trial. Randomization will be performed using the MedCalc package program ([www.medcalc.org](http://www.medcalc.org)). A total of 96 cases will be randomly divided into two groups. The cases will be intubated by placing a folded towel under the shoulder named as Group 1 (n=48), and the cases will be intubated without placement of folded towel named as Group 2 (n=48).

### **Intubation Protocol**

Age, gender, height, weight, ASA values and preoperative airway evaluation will be noted before the children will be taken to the operating room. No premedication was applied to the children. Intraoperative monitoring was provided with ECG, non-invasive blood pressure, capnography and pulse oximetry. The induction of general anesthesia will be achieved with sevoflurane (5% -8%) or thiopental (5-8 mg.kg-1 IV) and fentanyl (1 µg.kg-1 IV) in all children. After confirming mask ventilation, rocuronium (0.6 mg / kg-1 IV) will be administered in order to facilitate endotracheal intubation. During mask ventilation, shoulders of the children in Group 1 will slightly be raised with a folded towel, in the children of Group 2, folded towel will not be placed under shoulder.

Tracheal intubation will be performed using C-MAC Miller VL, after muscle relaxation will be confirmed using a neuromuscular monitoring (Organon, Dublin, Ireland). Uncuffed spiral Endotracheal tube (ETT) with stylet and appropriate size for age of children, will be used in all patients. All tracheal intubations will be performed by a single anesthesiologist who performed more than 50 tracheal intubations with C-MAC Miller VL in children.

### **Study Outcomes**

In our study, the primary outcome will be the POGO score. The percentage of glottis opening (POGO) score corresponds to the percentage of visualization of the glottis. A POGO score of 100% refers to the visualization of entire glottis opening from the anterior commissure of the vocal cords to the interarytenoid notch. If no part of the glottis opening is visible, the POGO

score is 0%. For the subsequent evaluation of a researcher who was blind to the position of the cases, screenshots of glottis will be taken during laryngoscopy with C-MAC Miller VL.

The secondary outcomes in the study will be the ease of use of the C-MAC VL device, the Cormack-Lehane Scores, the time to intubation, the number of intubation attempts, the optimization procedures during the endotracheal intubation and the complications.

The ease of use of the device in this position will be evaluated with a VAS score ranging from 0 (the most difficult and disturbing use) to 10 (easiest and most comfortable use) by anesthetist who used the C-MAC Miller VL device.

The time to intubation will be recorded as from the time C-MAC Miller VL entered the oral cavity until the time the end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>) trace was seen in the capnography. If intubation failed, the time of each attempt will be collected and more than three attempts will not be allowed.

The optimization procedures required for successful endotracheal intubation will be recorded as external laryngeal compression (displacement of the larynx by backward, upward and rightward pressure on the thyroid cartilage, or BURP) and position change (the rotation or vertical lifting of C-MAC Miller VL).

Complications including desaturation (peripheral oxygen saturation <90%), esophageal intubation, dental and mucosal damage will be noted.

### **Statistical Analysis**

The primary outcome of our study is the POGO score. Based on the study of Kim et al. (8); when the estimated POGO score difference between two groups was 20, standard deviation was 34, type 1 error (alpha) 0.05 was and type 2 error (beta) was 0.20 (power = 0.80), the required sample size consisting of at least 94 patients (at least 47 in each group) was calculated by power analysis.