A Comparison of McGrath® MAC versus C-MAC® Videolaryngoscopes in Morbidly Obese Patients Undergoing Bariatric Surgery: A Randomized, Controlled Clinical Trial

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Conflict of Interest:

The authors declare that they have no conflict of interest.

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None

Study Protocol

Protocol: This study was approved by the Local Ethics Committee. We conducted a prospective, randomized, controlled clinical study with 80 morbidly obese adult patients undergoing bariatric surgery from 8 September to 20 October 2018 at a university hospital. This study was prepared in accordance with the Consolidated Standards of Reporting Trials [9].

Study Participants: Our study participants (n = 80) were morbidly obese patients with American Society of Anesthesiology (ASA) scores of III who were aged 18–65 years old, had a BMI ≥ 40 kg/m2, and were presenting for bariatric surgery at our hospital. All surgery patients meeting these criteria during the study period were interviewed before surgery to obtain written informed consent to participate in the study. Patients who were aged under 18 - over 65 years old, pregnant or who had a BMI ≤ 40 kg/m2, an allergy to anesthetic drugs, uncontrolled cerebrovascular disease, or drug and alcohol addiction were excluded, as were all patients who refused written informed consent.

Preoperative Procedures: Preanesthetic evaluations were performed on all patients one day before surgery. Age, gender, height, weight, BMI, ideal body weight (IBW), ASA physical status, and type of surgery were recorded. On the day of surgery, patients were taken to the operating room without premedication. Standard monitoring procedures were used, including heart rate (HR), noninvasive blood pressure (NIBP), electrocardiogram (ECG), peripheral oxygen saturation (SpO2), mean arterial pressure (MAP), and body temperature monitoring by esophageal probe.

General Anesthesia Protocol: A standardized general anesthesia protocol was administered to all patients. After preoxygenation (100% 4 L/min O2 for 3 min), patients were induced with propofol (1–2 mg/kg), rocuronium (0.8 mg/kg), and fentanyl (0.1 μg/kg) via intravenous (IV) route at doses calculated according to IBWs. Mask ventilation and tracheal intubation using

either the McGrath MAC (blade size: 4) or C-MAC videolaryngoscopes (blade size: 4) were performed by an experienced anesthesiologist who had previously used both videolaryngoscopes successfully at least two years (more than 200 times). Also, tracheal intubations were performed by both videolaryngoscopes with the blade size 4 and using stylet in endotracheal tubes. End-tidal carbon dioxide (EtCO2) was continuously monitored after intubation. Tidal volume and ventilation rate were adjusted to maintain the EtCO2 partial pressure of arterial blood at 35–45 mmHg. Additional rocuronium was intermittently injected according to need based on Train of Four (TOF; Dräger AG, Lübeck, Germany) values. TOF responses were assessed by ulnar nerve stimulation and adductor muscle response. Additional fentanyl (0.1–0.2 μg/kg) was titrated for analgesia, as needed, if HR and/or MAP increased by 20% above baseline during surgery. Anesthesia was maintained in both groups by desflurane inhalation in a 0.5 O2 oxygen-air mixture. Desflurane was discontinued with the beginning of skin sutures and fresh gas flow was changed to 4 L/min of oxygen. In patients who did not experience complications during surgery, sugammadex (IV, 2–4 mg/kg; Bridion®, MSD, Greenville, USA) was then administrated to reverse residual muscle relaxation at the end of surgery.

Randomization: This study was planned as a randomized prospective study. Randomization was performed using MedCalc v. 16 statistical software for Windows (medcalc.com.tr). Eighty patients were randomly allocated to two groups: McGrath (n = 40) and C-MAC (n = 40) (**Figure 1.** Flow diagram). All patients received standard surgical procedures determined by the same team of surgeons with experience in gastroenterology surgery. Patient pneumoperitoneum pressure ranged from 10–12 mmHg and pneumoperitoneum levels ranged from 30–45 degrees. Surgical management of sleeve gastrectomy and gastric bypass surgeries was not changed in any way.

Postoperative Management: All patients were transferred to the post-anesthesia care unit (PACU) after surgery. Patients were then transferred to the general surgery intensive care unit when they achieved a score of 9 or higher on the Modified Aldrete score (range 0–12; scores of 9 and above indicate that the patient can be discharged from the PACU) [10]. In all patients, postoperative analgesia was achieved using appropriate IV doses of tramadol (0.5–1 mg/kg) and paracetamol (1 gr) at the time of beginning skin sutures [11].

Outcome Measures: Primary outcome measures were time to intubation and incidence for successful intubations. Time to intubation was defined as the time from when the anesthesiologist picked up the videolaryngoscope to when the anesthesiologist successfully placed the endotracheal tube through the vocal cords, which was assessed by the detection of meaningful EtCO2 levels using capnography. Also, time to intubation was recorded by another anesthesiologist, who accompanied to the study. The characteristics of each tracheal intubation were recorded perioperatively for both groups as secondary outcome measures, including the position requirements for successful intubations (the position at which successful intubation was achieved, neutral vs. sniffing position, i.e., head extension and neck flexion), Cormack Lehane grades (laryngeal view during endotracheal intubation with the videolaryngoscope on a grade of 1=full view of the glottis, 2=partial view of the glottis, 3=only epiglottis visible, 4=neither glottis nor epiglottis visible), glottic view (measured as percentage of glottic opening [POGO] scores), ease of intubation, patient hemodynamic responses and adverse events during intubation. POGO scores were measured on a scale of 1–4 (1 = 75–100% glottic opening; 2 = 50–75%; 3 = 25–50%; 4 = 0–25%). Ease of intubation was defined on a grade of 1–3 (1 = no external manipulation of larynx was required; 2 = external manipulation of larynx was required; 3 = failed intubation on first two attempts). Incidence, attempts and position for successful intubation, Cormack Lehane grades, POGO scores, and ease of intubation were recorded by the anesthesiologist who performed the tracheal intubation.

Also demographic characteristics, comorbidities, and preoperative airway assessment, including each patient's Mallampati score (1–4), thyromental distance (cm), and mouth opening (cm), were recorded one day before surgery. HR, MAP, respiratory rate, and SpO2 were recorded at baseline before anesthesia (T_0), before intubation (T_1), 1 min after intubation (T_2), 2 min after intubation (T_3), 3 min after intubation (T_4), and 5 min after intubation (T_5). In addition, adverse events of tracheal intubation, including dental trauma, blood on blade, cuff burst, laryngospasm, bradycardia (HR < 65 beats/min), and hypoxemia (SpO2 < 90%), were recorded during the 15 min perioperative period. Hoarseness and sore throat were also recorded during the first 24 hours after surgery.

Sample Size: Statistical power analysis was performed based on a pilot study on 14 morbidly obese patients in our institution showing mean time to intubation of 45 ± 18.0 s [standard deviation (SD)] with the McGrath MAC. For power calculations (OpenEpi, Version 3), equal standard deviation for both groups was assumed. To show a difference of 12 s between the two groups and with an alpha of 0.05 and two tailed and a power of 80%, we calculated that a minimum of 36 patients per group should be included in this study. We ultimately included a total of 80 patients to allow for patient drop-out.

Statistical Analysis:

Data were analyzed using the Statistical Package for the Social Sciences program (SPSS 22.0, IBM). The Kolmogorov-Smirnov normality test was used to test whether quantitative variables showed a normal distribution. As some patient preoperative and anesthetic characteristics were distributed abnormally, nonparametric statistics was used. Quantitative data are presented as mean or standard deviation and categorical data are shown as numbers or percentages. Continuous variables were compared between the groups using a Mann-Whitney U test. Categorical variables were summarized using frequencies and percentages, and were compared between the groups using a Chi-Square test or Fisher's exact test. A repeated measures ANOVA was used to compare hemodynamic data within each group, while an unpaired t-test was used for comparisons between the two groups. Results were evaluated at a 95% confidence interval at a significance level of $p < 0.05$.