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Bariatrik Cerrahi Geçiren Obez Hastalarda CookRe-Entübasyon Seti Katateri ve Telinin Aşamalı Ekstübasyonda Kullanımının Karşılaştırılması,Randomize Kontrollü Klinik Çalışma

Comparison of CookRe-intubation Catheter and Guidewire in Staged Extubation in Obese Patients Undergoing Bariatric Surgery: A Randomized Controlled Clinical Trial

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ÖZ

Giriş: Aşamalı ekstübasyon setleri zor hava yolu vakalarında güncel bir ekstübasyon stratejisi olarak kullanılmaktadır. Hava yolu güvenliği açısından yararlı olmasına rağmen, hastaların intolerans bulguları olduğunda kullanılamazlar. Bu çalışmada laparoskopik cerrahi geçiren morbid obez hastaların ekstübasyonunda Cook aşamalı ekstübasyon seti, entübasyon kateteri ve ekstübasyon telinin ayrı ayrı kullanımının etkinliğini ve hasta uyumunu karşılaştırmayı amaçladık.

Yöntem: Bu çalışma elektif laparoskopik bariatrik cerrahi planlanan 30 hasta üzerinde gerçekleştirilmiştir. Hastalar iki gruba ayrılmış ve ilk grupta (Grup C) yeniden entübasyon kateteri, ikinci grupta (Grup W) ise ekstübasyon teli kullanılmıştır. Kalp hızı (KH), ortalama arter basıncı (OAB), SpO2, end-tidal CO2 (ETCO2), pH, pO2, PaCO2 ve öksürme ve ıkınma gibi hastaların intoleransını gösteren semptomlar kaydedilmiştir.

Bulgular: 0 ve 15. dakikalardaki SpO2, kalp hızı ve öksürük, 0 ve 15. dakikalardaki pH ve PaCO2 değerleri benzer bulunmuştur, Grupların 0. dakikadaki ıkınma varlığı benzer olmasına rağmen, 15. dakikadaki ıkınma varlığı kateter grubunda anlamlı olarak daha düşük bulunmuştur. 0. ve 15. dakikadaki PaO2 değerleri kateter grubunda anlamlı olarak daha yüksek bulunmuştur (sırasıyla p: 0.011, p: 0.03).

Sonuç: Morbid obezite cerrahisi geçiren hastaların ekstübasyonunda Cook aşamalı ekstübasyon setinin re-entübasyon kateteri, ekstübasyon teline kıyasla hasta uyumu ve hemodinamik yanıt açısından daha avantajlı bulunmuştur.

Anahtar Kelimeler: extubasyon, obezite, havayolu değişim kateteri

ABSTRACT

Objective: Staged extubation sets are used as a current extubation strategy in difficult airway cases. Although useful for airway safety, it cannot be used when patients have symptoms of intolerance. We aimed to compare the efficiency and patient compliance of using the Cook staged extubation set, intubation catheter, and extubation wire separately in the extubation of the morbid obese patients having laparoscopic surgery.

Method: This study was performed on 30 patients who were planned for elective laparoscopic bariatric surgery. Patients were divided into two groups, where re-intubation catheter was used for the first (Group C) and extubation wire for the second (Group W). The heart rate (HR), mean arterial pressure (MAP), SpO2, end-tidal CO2 (ETCO2), pH, pO2, Parsiyel Arteriyel Oksijen Basıncı(PaCO2), and symptoms indicating patients' intolerance, such as coughing and straining, were recorded.

Results: The 0 and 15th minute SpO2, heart rate, and rate of coughing, the pH and PaCO2 values at the 0 and 15th minutes were found to be comparable, Although the 0 minute strain rate of the groups was similar, the 15th minute strain rate was found to be significantly lower in the catheter group. The 0 and 15th minute PaO2 values were found to be significantly higher in the catheter group (p: 0.011, p: 0.03, respectively).

Conclusion: In the extubation of patients undergoing morbid obesity surgery, the re-intubation catheter of the Cook staged extubation set was found to be more advantageous in terms of patient compliance and hemodynamic response compared to the extubation wire.

Keywords: extubation, obesity, airway exchange catheter

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INTRODUCTION

The ASA task force on the management of difficult airways defines a "difficult airway" as a clinical situation in which a conventionally trained anesthesiologist experiences problems with facemask ventilation of upper airway or tracheal intubation or both [1]. In cases where ventilation or intubation is thought to be difficult from careful history and physical examination, preparation should be made before induction of anesthesia. Awake intubation can be considered in the airway management of these patients, or help can be obtained from new-generation supraglottic airway devices.

Airway management ensures proper breathing and oxygenation, notably during surgeries or in critical care. In a controlled environment like the operating room, professionals closely monitor the patient's airway, while extubation marks the shift to an uncontrolled setting, such as the recovery area, where spontaneous breathing resumes, potentially requiring vigilant monitoring. 1/3 of major anesthesia-related airway complications occur during or shortly after extubation [2, 3]. Complications related to extubation can cause morbidity and mortality. The Difficult Airway Society (DAS) extubation guide recommends extubation of difficult airway cases while the patient is awake or using advanced techniques, such as Bailey's maneuver, Remifentanil technique, and airway extubation catheter (AEC) [4]. Staged extubation set is manufactured by cook Medical for the safe extubation of difficult airway patients. The set contains a wire and reintubation catheter with a central lumen for the wire and oxygenation, if required. Reintubation is performed using a two-staged Seldinger-like technique. For safe extubation, the guidewire is advanced through the endotracheal tube (ETT) and left in place after the ETT is removed. If reintubation is required, the 14-Fr reintubation catheter is advanced over the wire, and then the ETT is advanced over the catheter [5-7].

Obese patients have changes not only in their external airway anatomy, but also in their oropharynx and larynx. Visceral and abdominal fat distribution directly parallels the increasing size of the parapharyngeal fat pads, irrespective of the total body fat content. Occipital deposition of fat can lead to restriction of neck extension and make laryngoscopy difficult [8]. A higher body mass index (BMI), thick neck, obstructive sleep apnea syndrome (OSAS), or history of snoring is associated with a difficult airway [9]. For all these reasons, alternative techniques like tube exchange catheters or staged extubation sets have been developed for the safe extubation of obese patients.

Staged extubation sets, extubation catheters, and extubation wires are all utilized in difficult airway cases, but their effectiveness and patient compliance may vary. We hypothesize that comparing these methods individually in the extubation process of laparoscopic morbid obesity surgery patients will reveal differences in efficiency and patient tolerance.

MATERIALS AND METHODS

Study Design

Ethical approval for this study was provided by the Ethical Committee of Kocaeli University. (Adress : Kocaeli University Medical School, Kocaeli, Türkiye, Chairperson Prof. N. Ersoy, Protocol number : KİA 2018/19) on 4 January 2018. Our study was conducted on morbidly obese patients who underwent laparoscopic bariatric surgery between 2019-2021. In the extubation of these patients, the results of the separate application of the re-intubation catheter and extubation wire of the cook staged extubation set were compared.

The inclusion criteria were elective laparoscopic bariatric surgery, American Society of Anesthesiologists (ASA) Class 2 or 3, body mass index (BMI) > 35 kg/m2, and age >18. The exclusion criteria were previous laryngeal-tracheal surgery, lung surgery and lidocaine allergy.

Interventions, Blinding, and Randomization

A total of 30 patients whose informed verbal and written consents have been obtained were included in the study. The patients were randomly divided into two groups using the closed envelope method. The patients in which the re-intubation catheter of the cook staged extubation set was used for extubation were classified as Group 1 (n = 15), and the patients in which the extubation wire was used were classified as Group 2 (n = 15).

No preoperative premedication was applied to the patients. Electrocardiography (ECG), invasive arterial pressure, and peripheral oxygen saturation monitoring were applied to the patients who were taken to the operating room. Before the induction of anesthesia, preoxygenation was performed with 5 lt/min oxygen support so that the SpO2 was > 90%. The standard anesthesia method was applied to all patients included in the study. Lidocaine 0.5-1 mg/kg, propofol 2-3 mg/kg, rocuronium 0.6-1 mg/kg and fentanyl 1-1.5 mcg/kg were used intravenously in anesthesia induction. In the maintenance of anesthesia, remifentanyl 0.25 mcg/kg/min and sevoflurane 2-3% were used, targeting 1 MAC anesthesia depth.

After the surgical procedure ended, the re-intubation catheter of the cook staged extubation set was advanced to the patients in Group 1, whose MAC value decreased to 0.3 and below, through the endotracheal tube at 25 cm on the level of incisor. For the patients in Group 2, the extubation wire of the cook staged extubation set was advanced through the endotracheal tube at the same level.

Sugammadex (3 mg/kg) was administered to all patients as a muscle relaxant antagonist.

Afterwards, the endotracheal tube was removed, and a reintubation catheter or extubation wire was fixed to the lip. The outer part of the guidewire was inserted into its sheath and taped to the edge. In the postoperative recovery unit, the patients' heart rate (HR), SpO2, mean arterial pressure (MAP), end-tidal CO2 (ETCO2), and blood gas values were followed and recorded. Also, the patients' re-intubation-related intolerance symptoms like cough, straining or hypoxemia (SpO2 at 94%) were followed up and recorded. In addition, arterial blood gas analysis was performed and recorded for each patient immediately after extubation and 15 min after extubation. A re-intubation catheter or extubation wire was removed from the patients who were followed for 20 minutes and whose respiratory parameters were stable.

Statistical Analysis

We performed statistical analysis using the SPSS Version 24 for Mac (IBM Corporation, USA). Mean, standard deviation, median lowest, highest, frequency, and ratio values were used in the descriptive statistics

of the data. The distribution of continuous variables was measured using the Kolmogorov–Smirnov test. Independent sample t-tests and Mann–Whitney U-tests were used in the analysis of quantitative independent data. A paired-sample t-test was used in the analysis of the dependent quantitative data. The McNemar's test was used in the analysis of the dependent qualitative data. The chi-square test was used in the analysis of qualitative independent data, and the Fisher's exact test was used when the chi-square test conditions were not met.

To test the statistical significance of a difference of at least 10% in terms of change in Horowitz level from baseline between the two groups at 90% power and a 5% error level at any follow-up time, it was planned to include at least 15 cases for each group. A 10% difference in information was obtained from both the pilot study and clinical experience.

A p value <0.05 was considered statistically significant. Bonferroni correction was performed to control for Type I errors in all possible multiple comparisons.

RESULTS

A consort flow chart of patient inclusion and exclusion is shown in Figure 1. A total of 43 consecutive patients who underwent elective bariatric surgery with laparoscopy between January 2019 and November 2021 were assessed for eligibility for this study. Eleven patients were excluded from the study as follows: seven patients were ASA 4, and four patients declined to participate. A total of 30 patients underwent randomization, 15 of whom were in the re-entubation catheter group (Group C) and 15 in the extubation wire group (Group W).

Age, gender, BMI, ASA risk scores, Diabetes Mellitus, presence of Asthma/ Chronic obstructive pulmonary disease (COPD) and operation durations of the groups were found to be statistically similar. Basic demographic data and comorbidities are displayed in Table 1.

When the arterial blood gas parameters of the groups at the 0 and 15th minutes after extubation were compared, the pH and pCO2 values were found to be statistically similar. On the other hand, the pO2 value at the 0 and 15th minutes in Group 1 was statistically significantly higher than in Group 2 (Table 2).

When the vital signs of the groups at the 0 minute and 15th minute after extubation were compared, the HR, MAP, SpO2, and EtCO2 values were found to be comparable (Table 3).

When the 0 minute and 15th minute intolerance findings of the groups were compared, the rates of hypoxia and cough were found to be comparable. In addition, the 0 minute strain rate was found to be comparable between the groups. On the other hand, the rate of straining at the 15th minute was found to significantly higher in Group 2 (Table 4).

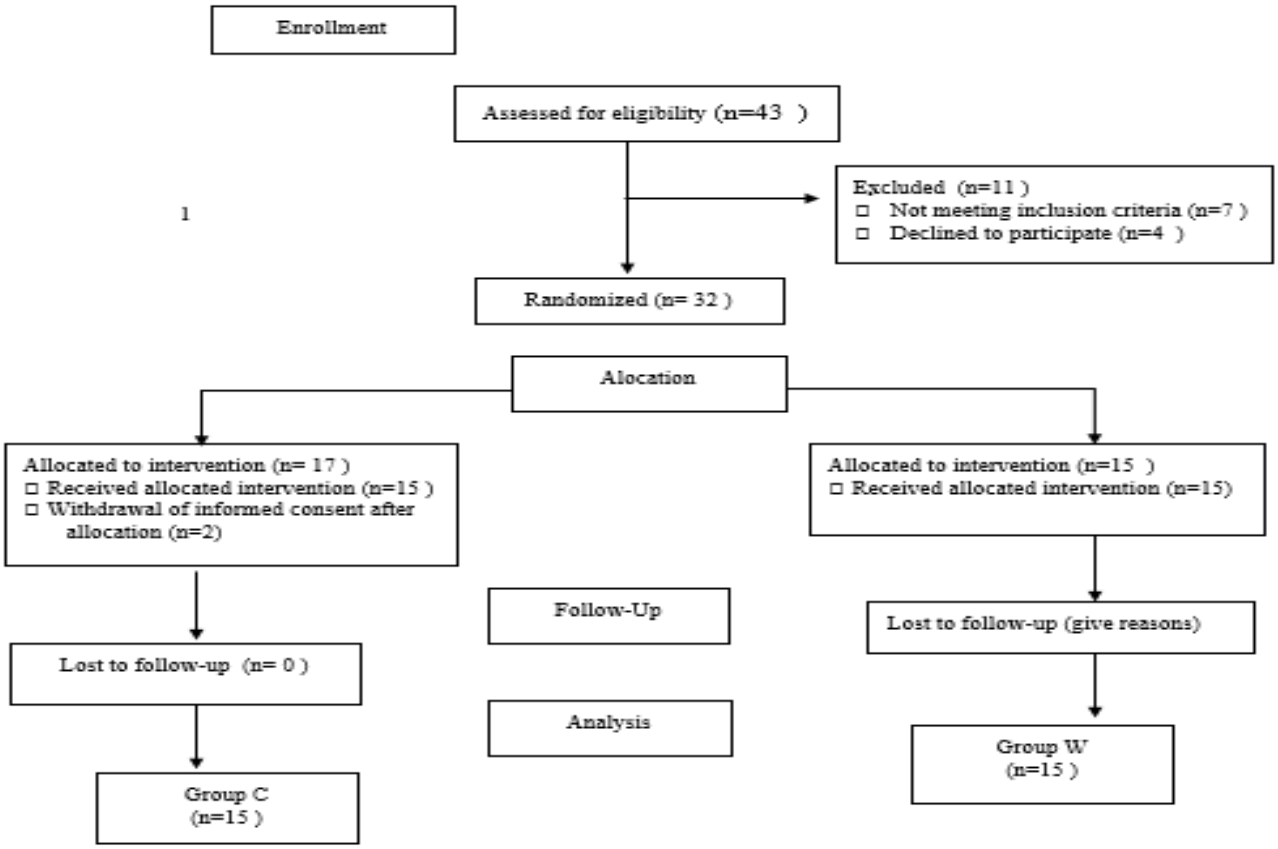

Figure 1. Flow Chart

Table 1. Demographic Data of the Patients

		Group C (n:15)	Group W (n:15)	p
Age (year)		37,5 ± 10,4	41,7 ± 10,7	0,277 [t]
Sex	**Female**	14 (93,3%)	10 (66,7%)	0,068 [X²]
	Male	1 6(,7%)	5 (33,3%)	0,068 [X²]
BMI (kg/m²)		42,0 ± 3,4	42,7 ± 1,8	0,078 [t]
ASA	**2**	11 (73,3%)	10 (66,7%)	0,690 [X²]
	3	4 (26,7%)	5 (33,3%)	0,690 [X²]
DM		10 (66,7%)	11 (73,3%)	0,256 [X²]
Astma/COPD		10 (66,7%)	12 (80%)	0,624 [X²]
Duration of Surgery (min)		120,9 ± 49,3	111,5 ± 38,1	0,564 [m]

Note: Categorical Data are Presented as Number (%). Continuous Data are Presented as Mean ± SD. [t] t Test / [m] Mann-Whitney u Test / [X²] Chi-square Test / BMI : Body Mass Index /ASA : American Society of Anesthesiologists / DM : Diabetes Mellitus / COPD : Chronic Obstructive Pulmonary Disease

Table 2. Blood Gas Analyses and Vital Signs Data of the Patients

		Group C	Group W	p
pH	0	7,40 ± 0,04	7,42 ± 0,04	0,158 [t]
	15. min	7,36 ± 0,04	7,38 ± 0,04	0,144 [t]
pO_2 (mmHg)	0	174,4 ± 34,3	141,6± 32,0	**0,011** [t]
	15. min	212,8 ± 75,8	161,5± 42,3	**0,030** [t]
pCO_2 (mmHg)	0	36,2 ± 3,5	37,3 ± 6,2	0,575 [t]
	15. min	38,6 ± 4,8	39,3 ± 5,0	0,689 [t]
Heart Rate	0	94,1 ± 15,2	89,5 ± 10,8	0,347 [t]
	15. min	92,8 ± 12,3	89,7 ± 9,9	0,128 [t]
MAP	0	102,1 ± 11,8	95,4 ± 15,0	0,183 [t]
	15. min	103,5 ± 6,0	98,4 ± 10,2	0,109 [t]
SpO_2	0	98,7 ± 0,8	98,1 ± 1,9	0,263 [t]
	15. min	98,8 ± 0,6	98,6 ± 0,7	0,311 [t]
$EtCO_2$	0	35,7 ± 4,0	34,2 ± 3,4	0,271 [t]
	15. min	42,9 ± 3,0	42,7 ± 2,6	0,847 [t]

[t] t test/ MAP : Mean Arterial Pressure, spo2 : peripheral oxygen saturation , EtCO2: end-tidal carbon dioxide

Table 3. Patients' Intolerance Symptoms

		Grup C	Grup W	p
Coughing	0	15 (100%)	15(100%)	1,000 [x2]
	15. min	3 (20%)	2(13,3%)	0,624 [x2]
Straining	0	14(93,3%)	15(100%)	1,000 [x2]
	15. min	2(13,3%)	8(53,3%)	**0,020** [x2]

[X²] Chi-square Test

Table 4. Patients' Intolerance Symptoms

			Grup 1	Grup 2	p
Coughing	0.min	NO	0	0	1,000 [x2]
		YES	15 (%100)	15(%100)	
	15.min	NO	12	13	0,624 [x2]
		YES	3 (%20)	2(%13,3)	
Straining	0. min	NO	1	0	1,000 [x2]
		YES	14(%93,3)	15(%100)	
	15.min	NO	13	7	0,020 [x2]
		YES	2(13,3)	8(53,3)	

[X²] Chi-square test

DISCUSSION

In this study, we compared the usability of a re-intubation catheter and guidewire in a staged extubation set separately during re-intubation. The blood gas parameters and coughing rates of the groups were found to be comparable.

On the other hand, the strain rate in Group 2 using guide wire was higher compared to the group using a re-intubation catheter. We used airway-changing catheters during recovery from anesthesia, and there were no unsuccessful attempts during these processes.

We did not observe complications, such as perforation or pneumothorax, in the patients.

Due to the short apnea time and potential risk of difficult airways in obese patients, it is recommended to evaluate the airway in detail before the operation, to perform preoxygenation, to put the patient in a ramp-up position and to continue apneic oxygenation during laryngoscopy [3, 10]. While the frequency of difficult airways is between 1.5 and 13.5% in the general population, this rate is between 10.5% and 20.5% in obese patients [11].

Patients with difficult airways should be prepared for possible reintubation after extubation. Tachypnea, hypoxia, and dyspnea observed after extubation should warn clinicians that extubation may fail. Alternative extubation strategies can be used for the safe extubation of patients with difficult airways. These strategies are airway exchange kits, which include laryngeal mask-assisted extubation and intravenous administration of short-acting opioid remifentanil. The Difficult Airway Society (DAS) Guidelines recommend using tube exchange catheters to extubate difficult-to-intubate patients if reintubation is needed [4].

There are limited publications on the use of AEC during extubation of patients and the use of guidewires in the cook staged extubation set. In these publications, it is mentioned that the use of AEC provides ease of operation during re-intubation.

In the study of Döşemeci et al., 11% of patients who underwent maxillofacial or major neck surgery and were extubated by placing an airway exchange catheter needed emergency reintubation. All of these patients were successfully reintubated with an airway exchange catheter. [5]The use of an airway exchange catheter can be life-saving in the reintubation of patients with a difficult airway.

On the other hand, complications, such as trachea and stomach perforation, can be seen due to the use of AEC, especially in emergency conditions. Although AEC is frequently used for ETT replacement, perforations of the bronchial tree and stomach have been documented during reintubation using AEC [9] [12]. Considering these complications, it may be more appropriate to use staged extubation sets for possible reintubation of patients with difficult airways.

McManus et al. conducted a study on patients extubated with the guidewire of the cook staged extubation set. It was observed that 77% of the patients extubated with the guidewire of the cook staged extubation set could tolerate the guidewire fixed to the corner of the mouth for four hours. The majority of patients in this study were able to tolerate the guidewire for four hours. In addition, the most common finding of intolerance in this study was a mild cough [13]. In our study, all patients tolerated both the re-intubation catheter and the guidewire in the postoperative recovery room. Although the straining reflex was similar at the 0 minute, it was found to be significantly higher in the wire group at the 15th minute.

Considering the blood gas values at 0 and 15th minutes postoperatively between the two groups; the PO2 value was found to be higher in the catheter group at both 0 and 15 minutes. But no patient in either group had clinical hypoxia or require supplemental oxygen. It has been observed that the use of the catheter alone is more comfortable for the patient, and the blood gas parameters are better than the use of the wire alone.

Furyk et al. in their study, in which they examined the safety and ease of use of the CookProgressive extubation set, used the set on 24 patients and successfully reintubated 22 patients. In one of the two patients who could not be intubated, a catheter was placed over the guidewire, and the guidewire came out of the trachea during laryngoscopy in one of them. In the study, it was stated that, due to the length of the guidewire, it was difficult to ensure the continuity of stabilization in both the insertion phase and the trachea. Each patient was intubated by a different anesthesiologist to avoid learning effects. Both positive and negative comments of users regarding the catheter and wire were recorded. While 13 users had negative comments about the use of wires, 4 users gave negative comments about the use of the catheter, 2 of which were due to the problems that occurred during the threading of the catheter. It is important to become familiar with the set and be prepared for intubation failure before use [14].

To the best our knowledge, there is no study in the literature that uses the guidewire and re-intubation catheter in the cook staged extubation set alone. None of the patients in our study needed reintubation. Therefore, we could not evaluate and compare the intubation procedure with the guidewire and re-intubation catheter. On the other hand, tolerances to re-intubation catheter or wire and respiratory parameters were compared between the groups.

In our study, although the arterial blood gas values and cough incidence rates of the patients in both groups were similar, the straining rate in the guidewire group was statistically higher. We believe that the guidewire, which is thinner and lighter than the re-intubation catheter, can move more in the trachea due to airflow during inspiration and expiration and that this movement may stimulate the upper airway reflexes more and may have an effect on this result.

This study has several limitations. In our study, difficult airway prediction was estimated using BMI. This may not always be accurate. The results need to be confirmed in studies with larger groups including patients with known difficult airways. We did not have any patients who needed reintubation. Therefore, we could not evaluate the difference between catheter or wire use regarding reintubation efficiency.

CONCLUSION

The re-intubation catheter in the cook staged extubation set provides better patient tolerance while showing similar oxygenation values compared to guidewire use. With this feature, we think that the re-intubation catheter in the cook staged extubation set can be used safely in the extubation of patients with difficult airways. We also think that the re-intubation catheter included in the cook staged extubation set can be used alone without a guidewire.

Ethics Committee Approval: Ethical approval for this study was provided by the Ethical Committee of Kocaeli University. (Adress : Kocaeli University Medical School, Kocaeli, Türkiye, Chairperson Prof. N. Ersoy, Protocol number : KİA 2018/19) on 4 January 2018.

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