Attachment 1

Study Protocol

（Version number： V4.0 Version Date： 2022/04/28）

Project Name： A novel SaCoVLM™ video laryngeal mask airway in airway management for morbidly obese patients in bariatric surgery: a single-arm prospective study

Project source： Researchers initiated

Department responsible: Anesthesia and Postoperative Medicine Department

Principal Investigator: Yongtao Sun

A novel SaCoVLM™ video laryngeal mask airway in airway management for morbidly obese patients in bariatric surgery: a single-arm prospective study

Abstract

Objective: The SaCoVLM™ video laryngeal mask is a novel video-assisted device that integrates the functions of both a dual-channel laryngeal mask airway (LMA) and an intubating laryngeal mask airway (ILMA). Theoretically, it can provide reliable awake airway management for obese patients undergoing laparoscopic sleeve gastrectomy (LSG). **Methods:** This single-arm prospective study evaluated the efficacy and safety of the SaCoVLM™ video laryngeal mask airway in 57 morbidly obese patients (BMI ≥35 kg/m²) undergoing LSG.

Keywords: Video laryngeal mask airway; Morbidly obese patients; Airway management; Laparoscopic sleeve gastrectomy; First-attempt success rate.

Background

With rapid social and economic development, the dietary environment and lifestyles of residents have undergone tremendous changes, resulting in a steady increase in the prevalence of overweight and obesity [1]. However, in morbidly obese patients, the long-term results of lifestyle management and medication regimens with poor adherence are unsatisfactory [2]. Twelve previous randomized clinical trials have found surgery to be significantly more effective than medication for weight control in morbidly obese patients [3]. Laparoscopic sleeve gastrectomy (LSG) has become one of the mainstream bariatric surgeries globally due to its simple operation and minimal impact on the physiological structure of the digestive tract [4]. Unfortunately, airway management in morbidly obese patients remains a critical challenge in clinical practice due to anatomical and physiological alterations, such as increased neck circumference, reduced pharyngeal space, and decreased functional residual capacity [5]. These factors contribute to a higher incidence of difficult mask ventilation,

difficult intubation, and perioperative respiratory complications, posing significant risks to patient safety [6-8].

Conventional supraglottic airway devices, while widely used, may exhibit limitations in achieving optimal airway sealing pressure or providing reliable visualization during placement, particularly in patients with a high body mass index (BMI) [9, 10]. Recent advancements in airway technology, such as video laryngeal mask airways (VLMs), offer potential solutions by combining the benefits of supraglottic ventilation with real-time visual guidance, potentially enhancing first-attempt success rates and minimizing airway manipulation. The SaCoVLM™, a novel video LMA, integrates a high-resolution camera into its design, enabling direct visualization of the glottis during insertion and positioning [11]. Since 2022, several studies have reported that SaCoVLM™ allows partial or complete visualization of the laryngeal inlet and has the advantages of high success rate, high sealing pressure and smooth gastroesophageal drainage [11-14]. SaCoVLM™ is currently being used in many types of patients, including adult patients with normal BMI [12], children with microtia [13], patients with lateral decubitus surgery [14] and others. However, despite growing interest in video-assisted airway devices, evidence regarding their efficacy and safety in morbidly obese populations remains sparse. This single-arm prospective study aims to evaluate the feasibility, performance, and clinical outcomes of the SaCoVLM™ in airway management for morbidly obese patients undergoing LSG. By systematically video LMA analyzing first-attempt success rates and adverse events such as aspiration or airway trauma et al., this investigation directly addresses the relationship between obesity-related features and SaCoVLM™ advantages. Furthermore, the study will correlate intraoperative airway metrics with postoperative respiratory complications, a critical yet understudied linkage in bariatric surgery

outcomes. In summary, this study will contribute critical data to guide device selection and optimize perioperative care in this high-risk cohort.

Materials and methods

Trial design

This single-arm prospective study was conducted at the University-affiliated hospital to evaluate the efficacy of a novel SaCoVLM™ in airway management for morbidly obese patients. The details of the video laryngeal mask are as previously described by us (Figure 1) [14]. The study protocol received committee of the First Affiliated Hospital of Shandong First Medical University & Shandong Provincial Qianfoshan Hospital (Approval number: YXLL-KY-2022 035). Prior to any screening or study procedures, written informed consent was obtained from all participating patients. The research was conducted in strict accordance with Good Clinical Practice guidelines, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use standards, ethical principles outlined in the Declaration of Helsinki, and all relevant regulatory requirements.

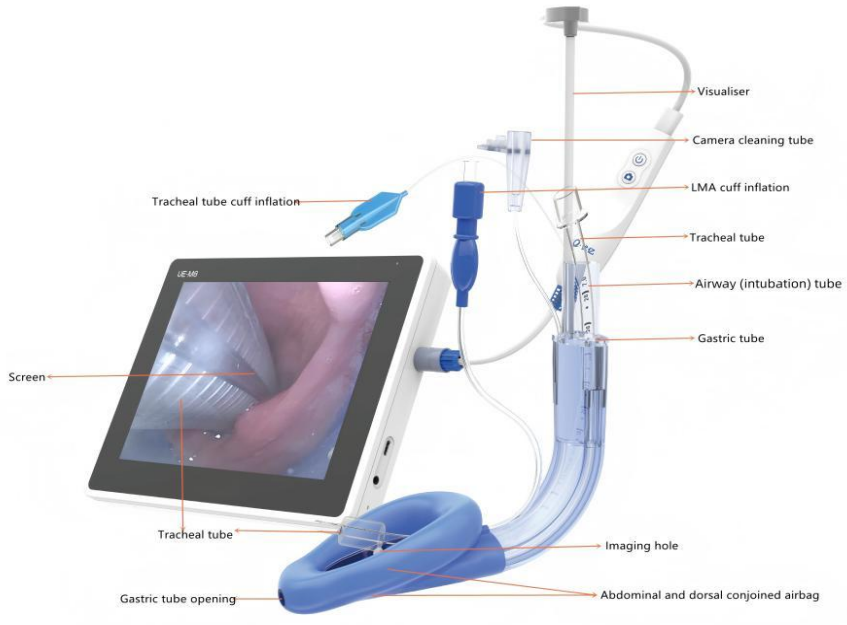

Figure 1. SaCoVLM™ video intubating laryngeal mask airway. Photo courtesy of Zhejiang UE Medical Corp (Hangzhou, China).

2.1 Participants

The study population comprised adult patients aged over 18 years diagnosed with morbid obesity, which was clinically defined as either a body mass index (BMI) ≥ 40 kg/m² or a BMI ≥ 35 kg/m² accompanied by at least one significant obesity-related comorbidity [15]. Eligible participants were required to have no known or suspected difficult airway, demonstrate tolerance for laparoscopic surgery and anesthesia, and be scheduled exclusively for LSG without concurrent additional procedures.

Anesthesia procedures

All anesthesiologists in this study underwent centralized training prior to trial initiation, with documented certification in protocol-specific procedures. No preoperative medications were administered to any patients. Upon entering the operating room, patients were positioned in a semi-fowler position, with intravenous access established. Standard monitoring protocols were implemented, including electrocardiography (ECG), heart rate (HR), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), end-tidal carbon dioxide ($EtCO_2$), and bispectral index (BIS), alongside radial artery catheterization for invasive blood pressure monitoring. All patients underwent awake insertion of the SaCoVLM™, with surgery completed under general anesthesia combining the video laryngeal mask and endotracheal intubation.

Immediately upon arrival in the operating room, patients were instructed to hold 10 mL of dyclonine mucilage orally for approximately 10 minutes to achieve topical anesthesia. Premedication included midazolam 2 mg and atropine 0.4 mg, followed by bilateral ultrasound-guided superior laryngeal nerve block using 0.375% ropivacaine. A properly sized laryngeal mask was selected, and under awake conditions, patients

were instructed to open their mouths to facilitate SaCoVLM™. Optimal positioning was confirmed by visualization of complete glottic structures on the monitor screen. The glottic exposure grade was as we previously described (Figure 2) [11, 14, 16, 17]. The cuff was inflated using a handheld manometer, and the mask was connected to the anesthesia machine. Clear glottic visualization on the monitor and the presence of a regular $EtCO_2$ waveform confirmed proper mask alignment, after which rapid anesthesia induction was initiated.

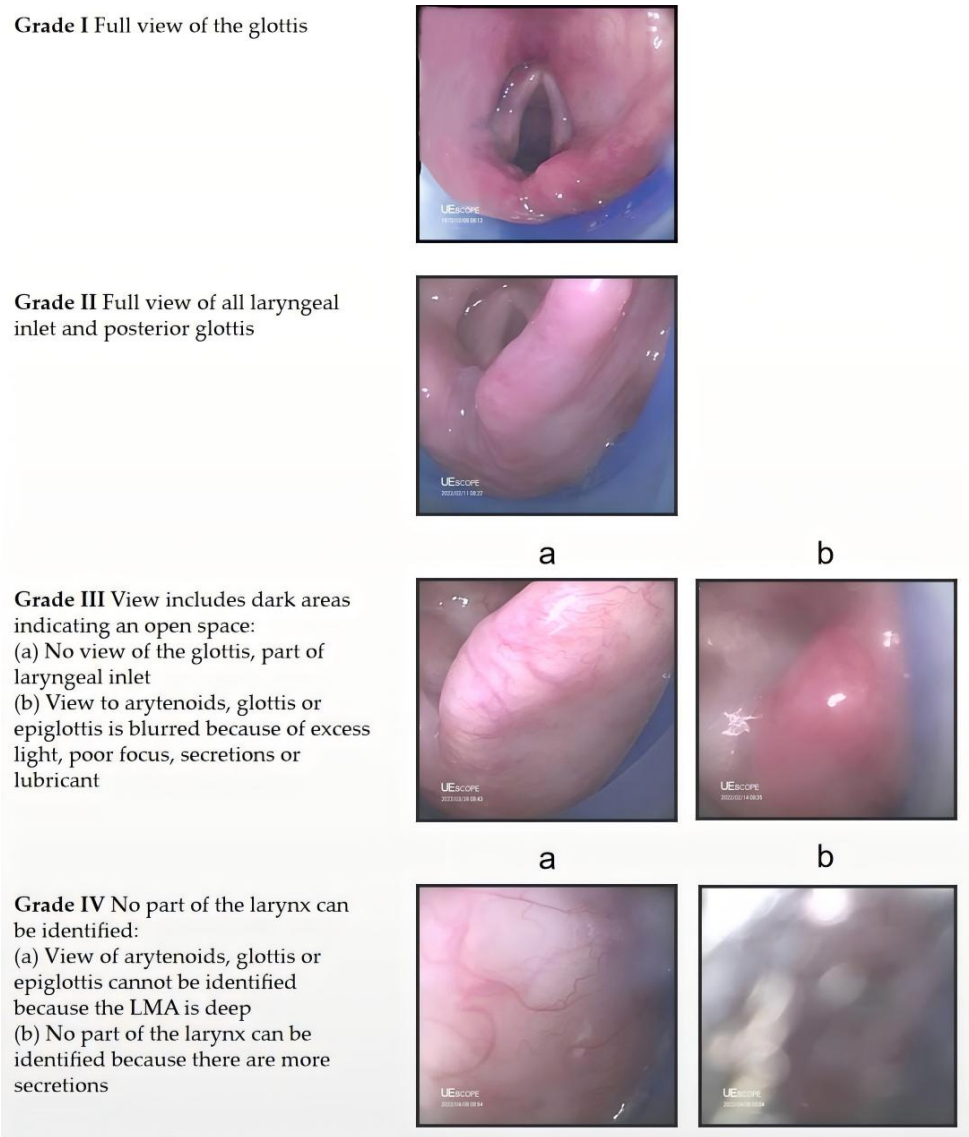

Figure 2. Glottic exposure grades. (Based on the suggestions of Timmermann A et. al.)

If suboptimal positioning occurred, the up-down maneuver, cricoid pressure, cuff pressure adjustment, fiberoptic bronchoscopy-guided intubation were applied for

minor adjustments. Under direct video guidance, the endotracheal tube was gently advanced along the natural curvature of the airway. Successful intubation was defined by unimpeded tube passage, direct visualization of tracheal entry, and sustained $EtCO_2$ waveform. Following intubation, the breathing circuit was immediately connected, and bilateral lung auscultation confirmed symmetrical breath sounds before securing both the mask and endotracheal tube. Intraoperative fluid administration and vasoactive medications were adjusted based on vital signs, urine output, and physiological requirements.

Postoperatively, the endotracheal tube was removed under deep anesthesia, and the video laryngeal mask was retained for transfer to the post-anesthesia care unit (PACU). The laryngeal mask was removed only after patients regained adequate spontaneous respiration, demonstrated responsiveness to verbal commands, and met established extubation criteria.

Outcomes and measures

The primary endpoints of this study were the first-time success rate of intubation after insertion of SaCoVLM™ and the duration of intubation. Secondary endpoints included the time to SaCoVLM™ insertion, the number of attempted insertions, the Endoscopic View Grading System of Laryngoscopic View (EVGS) classification, airway seal pressure, the airway optimization protocol used, postoperative sore throat (POST), postoperative hoarseness, and adverse events consistently detected throughout the study to assess safety.

Statistical analysis

The primary endpoint of this study was the first success rate of intubation after LMA insertion. As previously reported, the assumed first success rate for intubation after standard laryngeal mask insertion is 0.75 [18]. If we assume that the expected success

rate with the SaCoVLM™ is increased to 0.9, with a set level of significance (α=0.05, one-sided test), and statistical efficacy (1-β=0.8), the minimum number of participants required to reject the original hypothesis is at least 42. The final inclusion of 58 participants in this study meets the sample size requirement.

First-attempt intubation success rate was analyzed using an exact binomial test, with the null hypothesis defined as a success rate ≤75% and the alternative hypothesis as a success rate ≥90%, under a one-tailed significance threshold of α=0.05. For secondary outcomes, continuous variables (e.g., intubation time, SaCoVLM™ insertion time) are presented as mean ± standard deviation (SD) and median (range), while categorical variables (e.g., EVGS classification, POST) are reported as counts and proportions. Spearman and Pearson correlation coefficients were used to assess the correlation of variables such as BMI, neck circumference, and OSA severity with the number of intubations attempts and intubation time. Statistical significance was defined as $p < 0.05$. All statistical analyses were performed using IBM SPSS Statistics version 26.0 (IBM Corporation, Armonk, NY, USA), and graphical visualizations were generated with GraphPad Prism version 9.0 (GraphPad Software, San Diego, CA, USA).

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Institutional Review Board Statement

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Review Committee of the First Affiliated Hospital of Shandong First Medical University & Shandong Provincial Qianfoshan Hospital (Approval number: YXLL-KY-2022 035). Written informed consent was

obtained from all individual participants involved in the study prior to any study procedures.

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Author Contribution

Yong-Tao Sun: Conceptualization, Methodology, Data Curation, Writing - Review & Editing, Project administration, Funding acquisition.

Yan-Yan Feng: Validation, Formal analysis, Project administration,Writing - Original Draft.

Si-Yi Song: Methodology, Software, Validation, Formal analysis, Writing - Original Draft.

Jian-Bo Wu: Validation, Formal analysis, Data Curation, Funding acquisition.

Yong-Le Guo: Investigation, Resources, Data Curation.

Min Zhang: Software, Resources, Data Curation.

Meng-Jie Liu: Software, Investigation, Project administration.

Li-Na Chen: Software, Investigation, Visualization.

Shou-Zhan Sun: Investigation, Resources, Data Curation.

Informed Consent Statement

Written informed consent for publication of their clinical details was obtained from all participants involved in this study.

Data Availability Statement

The protocol for this study is available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare no conflict of interest.

References

1. Wang Y, Zhao L, Gao L, Pan A, Xue H: **Health policy and public health implications of obesity in China**. *Lancet Diabetes Endocrinol* 2021, **9**(7):446-461.
2. Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, Rossing P, Tsapas A, Wexler DJ, Buse JB: **Management of Hyperglycemia in Type 2 Diabetes, 2018. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)**. *Diabetes Care* 2018, **41**(12):2669-2701.
3. Arterburn DE, Telem DA, Kushner RF, Courcoulas AP: **Benefits and Risks of Bariatric Surgery in Adults: A Review**. *Jama* 2020, **324**(9):879-887.
4. Alsina M, Arrazubi V, Diez M, Tabernero J: **Current developments in gastric cancer: from molecular profiling to treatment strategy**. *Nat Rev Gastroenterol Hepatol* 2023, **20**(3):155-170.
5. Aceto P, Perilli V, Modesti C, Ciocchetti P, Vitale F, Sollazzi L: **Airway management in obese patients**. *Surg Obes Relat Dis* 2013, **9**(5):809-815.
6. Leoni A, Arlati S, Ghisi D, Verwej M, Lugani D, Ghisi P, Cappelleri G, Cedrati V, El Tantawi Ali Alsheraei A, Pocar M *et al*: **Difficult mask ventilation in obese patients: analysis of predictive factors**. *Minerva Anestesiol* 2014, **80**(2):149-157.
7. Bazurro S, Ball L, Pelosi P: **Perioperative management of obese patient**. *Curr Opin Crit Care* 2018, **24**(6):560-567.
8. Lagier D, Zeng C, Fernandez-Bustamante A, Vidal Melo MF: **Perioperative Pulmonary Atelectasis: Part II. Clinical Implications**. *Anesthesiology* 2022, **136**(1):206-236.
9. Nicholson A, Cook TM, Smith AF, Lewis SR, Reed SS: **Supraglottic airway devices versus tracheal intubation for airway management during general anaesthesia in obese patients**. *Cochrane Database Syst Rev* 2013, **2013**(9):Cd010105.
10. Murphy C, Wong DT: **Airway management and oxygenation in obese patients**. *Can J Anaesth* 2013, **60**(9):929-945.
11. Yan CL, Chen Y, Sun P, Qv ZY, Zuo MZ: **Preliminary evaluation of SaCoVLM™ video laryngeal mask airway in airway management for general anesthesia**. *BMC Anesthesiol* 2022, **22**(1):3.
12. Yan CL, Zhang YQ, Chen Y, Qv ZY, Zuo MZ: **Comparison of SaCoVLM™ video laryngeal mask-guided intubation and i-gel combined with flexible bronchoscopy-guided intubation in airway management during general anesthesia: a non-inferiority study**. *BMC Anesthesiol* 2022, **22**(1):302.
13. Zhi J, Deng XM, Zhang YM, Wei LX, Wang QY, Yang D: **Preliminary evaluation of SaCoVLM video laryngeal mask-guided intubation in airway management for anesthetized children**. *BMC Anesthesiol* 2023, **23**(1):49.
14. Sun Y, Zhang M, Gao X, Gao Z, Zou T, Guo Y, Liu M, Chen L, Zhang X, Liu Y *et al*: **Effect of the new video laryngeal mask airway SaCoVLM on airway management in lateral laparoscopic urological surgery: A single center randomized controlled trial**. *Sci Rep* 2024, **14**(1):2132.
15. Robert M, Espalieu P, Pelascini E, Caiazzo R, Sterkers A, Khamphommala L, Poghosyan T, Chevallier JM, Malherbe V, Chouillard E *et al*: **Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity (YOMEGA): a**

multicentre, randomised, open-label, non-inferiority trial. *Lancet* 2019, **393**(10178):1299-1309.

16. Timmermann A, Russo S, Graf BM: **Evaluation of the CTrach--an intubating LMA with integrated fibreoptic system**. *Br J Anaesth* 2006, **96**(4):516-521.
17. Dhonneur G, Ndoko SK, Yavchitz A, Foucrier A, Fessenmeyer C, Pollian C, Combes X, Tual L: **Tracheal intubation of morbidly obese patients: LMA CTrach vs direct laryngoscopy**. *Br J Anaesth* 2006, **97**(5):742-745.
18. Arslan ZI, Özdamar D, Yildiz TS, Solak ZM, Toker K: **Tracheal intubation in morbidly obese patients: a comparison of the Intubating Laryngeal Mask Airway™ and Laryngeal Mask Airway CTrach™**. *Anaesthesia* 2012, **67**(3):261-265.
19. Skues MA: **Perioperative management of the obese ambulatory patient**. *Curr Opin Anaesthesiol* 2018, **31**(6):693-699.
20. Hardt K, Wappler F: **Anesthesia for Morbidly Obese Patients**. *Dtsch Arztebl Int* 2023, **120**(46):779-785.
21. Peterli R, Wölnerhanssen BK, Peters T, Vetter D, Kröll D, Borbély Y, Schultes B, Beglinger C, Drewe J, Schiesser M *et al*: **Effect of Laparoscopic Sleeve Gastrectomy vs Laparoscopic Roux-en-Y Gastric Bypass on Weight Loss in Patients With Morbid Obesity: The SM-BOSS Randomized Clinical Trial**. *Jama* 2018, **319**(3):255-265.
22. Gómez-Ríos M, López T, Sastre JA, Gaszyński T, Van Zundert AAJ: **Video laryngeal masks in airway management**. *Expert Rev Med Devices* 2022, **19**(11):847-858.
23. Zhi J, Yan FX, Wei LX, Yang D, Deng XM: **Intubation using video laryngeal mask airway SaCoVLM and laryngeal mask airway Ambu® Aura-i in anesthetized children with microtia: a randomized controlled study**. *J Clin Monit Comput* 2023, **37**(3):857-865.
24. Van Zundert AAJ, Gatt SP, Van Zundert T, Kumar CM, Pandit JJ: **Features of new vision-incorporated third-generation video laryngeal mask airways**. *J Clin Monit Comput* 2022, **36**(4):921-928.
25. Natalini G, Franceschetti ME, Pantelidi MT, Rosano A, Lanza G, Bernardini A: **Comparison of the standard laryngeal mask airway and the ProSeal laryngeal mask airway in obese patients**. *Br J Anaesth* 2003, **90**(3):323-326.
26. Harjai M, Alam S, Rastogi S, Kumar S: **Effectiveness and Validity of Preoperative Ultrasonographic Airway Assessment and Clinical Screening Tests to Predict Difficult Laryngoscopy: A Prospective, Observational Study**. *Cureus* 2023, **15**(7):e41933.
27. Riad W, Vaez MN, Raveendran R, Tam AD, Quereshy FA, Chung F, Wong DT: **Neck circumference as a predictor of difficult intubation and difficult mask ventilation in morbidly obese patients: A prospective observational study**. *Eur J Anaesthesiol* 2016, **33**(4):244-249.
28. Parameswari A, Govind M, Vakamudi M: **Correlation between preoperative ultrasonographic airway assessment and laryngoscopic view in adult patients: A prospective study**. *J Anaesthesiol Clin Pharmacol* 2017, **33**(3):353-358.
29. Cao P, Li J, Wang G, Sun X, Luo Z, Zhu S, Zhu L: **Effects of sleeve gastrectomy on populations with obesity and obstructive sleep apnea: a meta-analysis**. *Surg Obes Relat Dis* 2025, **21**(3):288-300.
30. El-Boghdadly K, Desai N, Jones JB, Elghazali S, Ahmad I, Sneyd JR: **Sedation for awake**

tracheal intubation: A systematic review and network meta-analysis. *Anaesthesia* 2025, **80**(1):74-84.

31. Rao PN, Soffin EM, Beckman JD: **Comparative review of airway anesthesia and sedation methods for awake intubation**. *Curr Opin Anaesthesiol* 2023, **36**(5):547-559.
32. El-Boghdadly K, Bailey CR, Wiles MD: **Postoperative sore throat: a systematic review**. *Anaesthesia* 2016, **71**(6):706-717.
33. Moulder ZJ, Mann J, Bramley P, Heinz J, Wiles MD: **Postoperative sore throat: a systematic review**. *Anaesthesia* 2025.
34. Jaensson M, Gupta A, Nilsson U: **Gender differences in sore throat and hoarseness following endotracheal tube or laryngeal mask airway: a prospective study**. *BMC Anesthesiol* 2014, **14**:56.
35. Miller DM, Light D: **Laboratory and clinical comparisons of the Streamlined Liner of the Pharynx Airway (SLIPA) with the laryngeal mask airway**. *Anaesthesia* 2003, **58**(2):136-142.
36. Qin H, Wang Y, Chen X, Steenbergen N, Penzel T, Zhang X, Li R: **The efficacy of bariatric surgery on pulmonary function and sleep architecture of patients with obstructive sleep apnea and co-morbid obesity: a systematic review and meta-analysis**. *Surg Obes Relat Dis* 2023, **19**(12):1444-1457.
37. Nicholson A, Smith AF, Lewis SR, Cook TM: **Tracheal intubation with a flexible intubation scope versus other intubation techniques for obese patients requiring general anaesthesia**. *Cochrane Database Syst Rev* 2014, **2014**(1):Cd010320.
38. Hansel J, Rogers AM, Lewis SR, Cook TM, Smith AF: **Videolaryngoscopy versus direct laryngoscopy for adults undergoing tracheal intubation**. *Cochrane Database Syst Rev* 2022, **4**(4):Cd011136.
39. Stroumpoulis K, Isaia C, Bassiakou E, Pantazopoulos I, Troupis G, Mazarakis A, Demestiha T, Xanthos T: **A comparison of the i-gel and classic LMA insertion in manikins by experienced and novice physicians**. *Eur J Emerg Med* 2012, **19**(1):24-27.
40. Hanna SF, Mikat-Stevens M, Loo J, Uppal R, Jellish WS, Adams M: **Awake tracheal intubation in anticipated difficult airways: LMA Fastrach vs flexible bronchoscope: A pilot study**. *J Clin Anesth* 2017, **37**:31-37.
41. Liu EH, Goy RW, Lim Y, Chen FG: **Success of tracheal intubation with intubating laryngeal mask airways: a randomized trial of the LMA Fastrach and LMA CTrach**. *Anesthesiology* 2008, **108**(4):621-626.

Figure legends

Figure 1. SaCoVLM video intubation laryngeal mask airway. Photo courtesy of Zhejiang UE Medical Corp. (Hangzhou, China).

Figure 2. Trial flow chart.

Figure 3. Glottic exposure grades. (Based on the suggestions of Timmermann A et. al.)

Figure 4. Association of intubation time with study outcomes: (A) BMI, (B) thyromental distance, (C) mouth opening, (D) neck circumferenc, (E) Mallampati classification, (F) OSA classification.