BMJ Open

Study of postoperative laryngopharyngeal discomfort: protocol for a single-centre cohort study

Li Fang Wang ,[1] Meng-Tao Zheng,[1] Nan Liang,[2] Hao Ning Ma,[2] Wei Xia Li[2]

To cite: Wang LF, Zheng M-T, Liang N, *et al*. Study of postoperative laryngopharyngeal discomfort: protocol for a single-centre cohort study. *BMJ Open* 2024;**14**:e079841. doi:10.1136/bmjopen-2023-079841

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2023-079841).

Received 13 September 2023
Accepted 05 December 2023

[1]Department of Anesthesiology, China-Japan Friendship Hospital, Beijing, China
[2]China-Japan Friendship Hospital, Beijing, China

Correspondence to
Dr Wei Xia Li;
liweixia12@126.com

ABSTRACT

Introduction Postoperative laryngopharyngeal discomfort after extubation can lead to severe throat pain, dysphagia, or postoperative tongue oedema. Possible mechanisms include increased oral pressure, obstruction of venous and lymphatic return in the neck, and increased capillary hydrostatic pressure, which leads to oedema of the tongue and upper airway. However, real-time monitoring indicators of anaesthesia are lacking. Therefore, we designed this study to accurately measure the contact force of the tracheal tube on the tongue in different surgical positions during general anaesthesia.

Methods and analysis This prospective single-centre observational study will enrol 54 patients undergoing elective surgery under general anaesthesia for>2 hours with endotracheal tube application from 1 July 2023 to 30 June 2024. Patients will be divided into the supine (*Supine group*) and high-risk (*Flexion group*) groups. Dynamic changes in the contact force between the tracheal tube and tongue will be measured using T-Scan technology. All patients will be followed up for 7 days postoperatively. The primary endpoint is postoperative laryngopharyngeal discomfort. Secondary outcomes include the time to the first successful recovery of oral intake of fluids and solid food, and airway-related events.

Ethics and dissemination Ethical approval was obtained from the Ethics Committee of Clinical Research of China-Japan Friendship Hospital (2023-KY-219, approved on 14 September 2023). Informed consent will be obtained during anaesthesia evaluation. This study aims to explore the characteristics of the contact force on the tongue caused by endotracheal intubation in different surgical positions and to provide a better understanding of the risk factors and prevention of postoperative laryngopharyngeal discomfort. The findings of this study will be presented at our hospital, reported on ClinicalTrials.gov, and published in peer-reviewed journals.

Trial registration number NCT05987293.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The observations used to investigate postoperative laryngopharyngeal discomfort will include common clinical risk factors, such as surgical positions, airway condition and duration of mechanical ventilation.
⇒ This study will employ T-scan pressure distribution measurement technology—which records the contact force between the tracheal tube and tongue in real time—to allow for quantitative analysis.
⇒ The focus of the research is typical of routine perioperative procedure; however, it may lead to potential bias.
⇒ The pressure distribution measurement does not interfere with anaesthesia airway management or surgical strategies; thus, the results can be extended to common elective surgery under general anaesthesia.

INTRODUCTION

Postoperative laryngopharyngeal discomfort is a common clinical complication of extubation during routine elective surgery. General symptoms include throat pain, dysphagia and tongue oedema, which may delay water and food intake and affect postoperative daily activities. On average, one in three patients may experience the above symptoms after extubation.[1 2] The most severe manifestations may be postextubation stridor, macroglossia, and airway obstruction, resulting in prolonged mechanical ventilation, unplanned tracheotomy, postoperative pneumonia and increased postoperative mortality.[3–5] The incidence of pharyngeal complications after extubation under general anaesthesia has been demonstrated; even after a short elective surgery (median time of tracheal intubation: 132 min), the incidence of dysphagia and sore throat and cough after extubation was 43% and 32%, respectively.[6] Possible preventive and therapeutic methods include avoiding prolonged exposure to dangerous positions, using glucocorticoids to reduce airway oedema, and dehydration treatment.[1 7] However, quantitative metrics that can provide objective guidance to anaesthesiologists and surgeons are lacking.

There is a lack of clear risk factors, effective clinical indicators and diagnostic methods for postoperative laryngopharyngeal discomfort. According to previous studies, the three pathophysiological mechanisms are as follows: (1) gravity, intrathoracic pressure or intra-abdominal pressure increase the hydrostatic pressure and cause fluid redistribution; (2) surgical or aesthetic procedures lead to soft-tissue damage to the airways and

oropharynx; and (3) systemic stress and inflammation contribute to tissue oedema.

From a clinical perspective, there are different contributions to the above mechanisms in specific perioperative aetiologies, which can be divided into three categories: surgical, aesthetic and patient factors. (1) Surgical factors: (a) surgical position that causes gravity to be distributed to the mouth and face; (b) head and neck flexion position, such as the prone position or posterior fossa surgery in the beach chair position, which leads to blockage of venous and lymphatic return[8]; (c) surgical trauma that changes the permeability of vascular endothelial cells in the inflammatory state of the body and causes water retention; and (d) some surgical procedures that involve potential compression of the airway wall (cervical spine, thyroid, etc). (2) Aesthetic factors: (a) repeated or unskilled intubation[9]; (b) compression of the tracheal tube on the intraoral tissue and airway during the operation[10 11]; (c) method of endotracheal intubation, catheter type, tube size and material[6 12]; (d) additional mechanical compression such as those caused by teeth, intraoral instruments, ultrasound probes, oropharyngeal airways, or throat packs[12]; and (e) fluid overload.[13] (3) Patient factors: (a) duration in high-risk positions and (b) difficult airway (narrow oropharyngeal cavity or conditions that cause difficulty in intubation).[13]

The three clinical factor categories described above were considered in this trial. Based on current clinical procedures, the contact force of the tracheal tube on the tongue may be a measurable index.[14 15] The T-scan pressure distribution system is a non-invasive technology that is used to measure the tracheal tube–tongue contact force in real time during surgery. This study attempted to analyse the catheter–tongue pressure distribution, resultant force position, contact area and pressure values at different surgical positions.[14–16] Combined with patient anatomical measurements, airway management, fluid therapy, intraoperative medication, and other factors, this study comprehensively analysed clinical monitoring indicators to identify the risk factors for postoperative laryngopharyngeal discomfort in routine elective surgery under general anaesthesia.

Objectives

This study aims to determine the incidence of postoperative laryngopharyngeal discomfort in different surgical positions during general anaesthesia with tracheal tube intubation. We aim to explore the distribution and duration of the tracheal tube–tongue contact force during routine surgeries. We summarise the risk factors in patients with postoperative laryngopharyngeal discomfort undergoing routine elective surgery under general anaesthesia.

METHODS AND ANALYSIS

Study design

This study was designed in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement.[17] This is a single-centre, prospective, parallel-group, observational study protocol to be conducted from 1 July 2023 to 30 June 2024 (trial registration: NCT05987293). This study was approved by the Ethics Committee of Clinical Research of China-Japan Friendship Hospital (application number: 2023-KY-219, approved on 14 September 2023).

Settings and participants

This study will be performed at the Department of Anesthesiology of China-Japan Friendship Hospital, Beijing, China. This single-centre study will be conducted in a tertiary general hospital, with 1400 beds, 50 operating rooms and 90 anaesthesiologists, which annually conducts more than 15 000 operations under general anaesthesia. The research group collaborates with the Departments of Otolaryngology, Spine Surgery, General Surgery, Neurosurgery and Medical Engineering.

Fifty-four patients undergoing elective surgery under general anaesthesia for more than 2 hours with an endotracheal tube at the China-Japan Friendship Hospital will be enrolled (see ‘Sample size’). Patients will be divided into two groups according to the surgery: supine position (*Supine group*) and high-risk position (*Flexion group*), which includes the prone, cervical traction and beach chair positions. Patients with existing oral or airway problems, or other factors influencing postoperative dietary recovery, will be excluded.

Hypothesis

We assume that the incidence of postoperative laryngopharyngeal discomfort in the *Supine group* is different from that in the *Flexion group* and that tongue compression and pressure distribution differ between the two groups.

Patient enrolment

The inclusion and exclusion criteria are shown in box 1. Patients with difficulties in endotracheal intubation, limitations in routine surgical position and delayed oral water intake after surgery will be excluded. After enrolment, demographic data, medical history related to surgery and airway assessment results will be collected. During surgery, the tracheal tube–tongue pressure distribution and dynamic changes from different positions before extubation will be monitored. Patients with unplanned changes in surgical position, unplanned changes in strategy for establishing an artificial airway, unexpected difficult airway, intraoperative airway injury, delayed extubation due to non-airway factors and aggressive fluid therapy administration will be withdrawn from the study. Participants will be followed up for 1 week after the operation. The incidence of postoperative laryngopharyngeal discomfort will be compared between the two groups. Airway measurements, operation duration, mechanical ventilation time, recovery of water and solid food intake, and other airway-related events will be recorded. Figure 1 shows the timeline of this study protocol.

Box 1 Study eligibility

Inclusion criteria

⇒ ASA class I–III
⇒ Aged 18–85 years
⇒ Scheduled for elective surgery with tracheal intubation under general anaesthesia, with operation duration ≥2 hours
⇒ The intended surgical position is supine, prone, cervical traction, or beach chair position
⇒ Informed consent is obtained

Exclusion criteria

⇒ Informed consent is not obtained
⇒ Maxillofacial surgeries or other surgeries involving the oral cavity and upper airway
⇒ History of head and neck radiotherapy
⇒ Deformity, trauma, infection and active bleeding exist in the mouth and tongue
⇒ Airway hyperresponsiveness, active asthma, acute exacerbation of chronic obstructive pulmonary disease or laryngeal osteomalacia
⇒ Respiratory insufficiency, moderate-to-severe ventilation or diffusion dysfunction
⇒ Existing chronic sore throat, recurrent laryngeal nerve injury, dysarthria, dysphagia, severe gastroesophageal reflux, upper oesophageal sphincter dysfunction, cardiac stenosis and other basic diseases
⇒ Postoperative total parenteral nutrition therapy is planned

Data collection

Tracheal tube–tongue pressure is measured using a computerised occlusal analysis system based on the T-scan technique, suitable for multipoint real-time monitoring of intraoral pressure.[18] A flexible film sensor with a thickness of 0.11 mm is placed between the tongue and tracheal tube to measure the pressure distribution, contact force and dynamic changes in pressure at different sites of the tongue. A sensor placed between the tongue and tracheal tube is extensively used to measure the contact force of the tracheal tube on the tongue. The marker line on the tracheal tube used to locate the glottis during intubation is used as the standard position of our T-scan sensor to ensure that it covers the base, middle and tip of the tongue. Through preliminary experiments, we will verify that the pressure measurement range and sensitivity of this technology are suitable for measuring the force of the tracheal tube on the tongue.

Five channels of pressure values will be recorded separately: Channel (Ch) 1, tip of the tongue; Ch2, middle of the tongue; Ch3, base of the tongue; Ch4, right side at the base of the tongue; and Ch5, left side at the base of the tongue. The pressure values will be recorded at the following points during the operation: t_1, after intubation; t_2, highest pressure during patient positioning; t_3, after position fixation; t_4, at the end of surgery; and t_5, before extubation.

Preoperative information

Demographic characteristics, such as age, sex, height, body weight, body mass index (BMI), and airway measurements, including neck circumference, Mallampati classification, mouth opening, nail–chin distance and mandibular angle, will be recorded. Having a suspicious difficult airway is determined based on baseline data and airway measurements: BMI≥30 kg/m^2, neck circumference>40 cm, Mallampati grade≥3, mouth opening<3 transverse fingers, nail–chin distance<3 transverse fingers, mandibular angle length<6 cm, and one or more of them will be identified as having a suspicious difficult airway.

Intraoperative information

After entering the operating room, vital sign monitoring, anaesthetic administration, tracheal intubation and mechanical ventilation will be routinely established. Laryngoscope/video laryngoscope/rigid bronchoscope-assisted tracheal intubation will be performed. The tracheal tube cuff will be inflated after confirming its position. A manometric sensor will be placed intraorally between the tracheal tube and tongue. Mechanical ventilation will be set with conventional parameters (tidal volume, 6–8 mL/kg; respiratory rate, 10–14 beats/min; positive end expiratory pressure, 2–10 cm H_2O), and respiratory parameters will be adjusted according to the intraoperative ventilatory status.

Body position and maintenance time (t_{op}), duration of mechanical ventilation with an endotracheal tube (t_{tube}), type of endotracheal tube (inner diameter, pressure-resistant tube/normal tube/nasal tube), intraoperative intake and output volume (I/O), glucocorticoid use, visible intraoral injury on video laryngoscopy before extubation, and tracheal tube-related events, including tube kinking, abnormal airway pressure and ventilatory dysfunction, will be recorded.

Postoperative information

Patients will be followed up until postoperative day 7. Patients will be asked if they experience a 'burning throat', 'dry throat', 'tingling tongue', 'tightness in the throat', or any head, neck and throat discomfort. The first successful postoperative intake of water and solid food will be recorded. Obvious oedema of the head and face, glucocorticoid use and self-rated scores of patient satisfaction (1–10/10) will be recorded. Airway-related events including bronchospasm, aspiration, unplanned reintubation, pulmonary infection, ventilation insufficiency and prolonged oxygen therapy will be recorded. Table 1 shows the collected data and follow-up data.

Outcome measurement

Primary outcome: the primary composite endpoint is assessed as the incidence of postoperative laryngopharyngeal discomfort, which is either the state of severe sore throat (Visual Analog Scale score≥4), dysphagia after extubation, or any of the symptoms of tongue oedema. Secondary outcomes include the time of first smooth water intake (t_{liquid}), time of first smooth solid food intake (t_{food}) and airway-related events (bronchospasm,

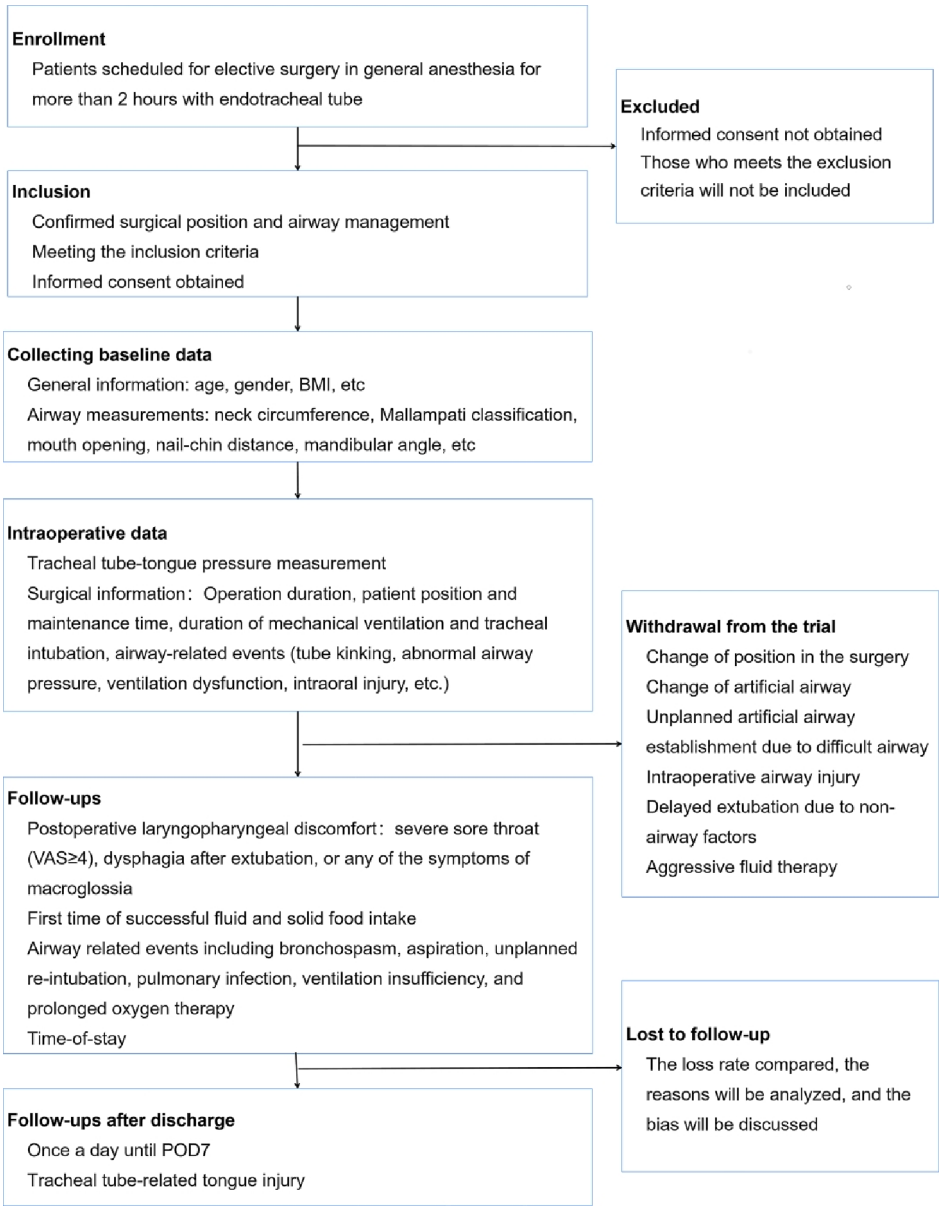

Figure 1 Strengthening the Reporting of Observational Studies in Epidemiology flow chart of the trial. BMI, body mass index; POD, postoperative day; VAS, Visual Analog Scale.

aspiration, secondary intubation, respiratory tract infection, respiratory insufficiency and prolonged oxygen therapy).

Sample size

According to the literature, the incidence of postoperative laryngopharyngeal discomfort in the high-risk positions is approximately 78%,[19] and the incidence in the supine position is approximately 33%.[20]

The sample size was estimated using PASS 2021 software (NCSS Statistical Software, USA). We assumed a two-sided hypothesis, power=0.8, α=0.05, G (group)=2, allocation ratio 1:1, using the formulae for t-tests for proportion ratios for two samples. Considering an allowable dropout rate no higher than 20%, the total sample size will be 54 (n=27 in each group).

Missing data

Attrition bias may influence our results. The participants' characteristics between the completed and dropout cases will be compared and analysed. The reason for the data default will be published in detail. We will evaluate whether the characteristics of the population with missing data differ from those of other patients and whether they have an impact on the research results. The reasons for withdrawal, loss to follow-up, or missing data, as well as the validity of the study, will be fully discussed.

External validity

The results of this study can be applied to non-critically ill patients undergoing conventional general anaesthesia and routine elective surgery. Our study does not change the intraoral pressure, nor does it influence the surgical

Table 1 Data collection and follow-up

	Pre-op	Intra-op	Post-op 1 hour	Post-op 3 hours	Post-op 12 hours	POD 1	Follow-up once a day until POD 7
Informed consent	×						
Demographic data	×						
Airway assessment*	×						
Artificial airway management†		×					
Intraoperative airway-related data‡		×					
Tracheal tube–tongue pressure		×					
Intraoperative intake and output volume		×					
Visible intraoral injury before extubation		×					
Oedema of the head and face		×	×	×	×	×	×
Postoperative laryngopharyngeal discomfort			×	×	×	×	×
Perioperative glucocorticoid use		×	×	×	×	×	×
Water intake			×	×	×	×	×
Solid food intake			×	×	×	×	×
Airway-related events§			×	×	×	×	×
Patient satisfaction (1–10/10)			×	×	×	×	×

*Preoperative airway assessment includes neck circumference, Mallampati classification, mouth opening, nail–chin distance and mandibular angle.
†Artificial airway management includes tracheal tube type, intubation device, and ventilation parameters.
‡Intraoperative airway-related data include patient position and maintenance time, duration of mechanical ventilation and endotracheal tube intubation, and special events, such as tube kinking, abnormal airway pressure and abnormal ventilation.
§Airway-related events include bronchospasm, aspiration, secondary intubation, respiratory tract infection, respiratory insufficiency and prolonged oxygen therapy.
POD, postoperative day.

or aesthetic protocols. We will analyse the demographic characteristics of the participants and perioperative indicators to further statistically analyse the external validity.

Statistical analysis

Based on the primary and secondary outcomes, the prognostic factors for postoperative laryngopharyngeal discomfort will be compared between the two groups. The distribution characteristics and dynamic changes will be described and compared between the two groups, and the aetiological factors will be analysed. A single-factor analysis will be used to screen the risk factors for postoperative laryngopharyngeal discomfort using the primary outcome as the dependent variable, whereas airway-related and surgery-related factors will be used as the independent variables. Logistic multivariate analysis will be performed to determine independent and significant risk factors. Statistical significance will be set at $p<0.05$.

Patient and public involvement

The patients and public will not be involved in this study

ETHICS AND DISSEMINATION

Ethical approval for this study has been obtained from the Ethics Committee of the China-Japan Hospital (2023-KY-219). A form that explains all the details, benefits and risks of the study will be provided to the patients to read and sign (in both Chinese and English). The researcher will explain the study details to the patients. The medical devices used in this study will be licensed[21] and verified for safety prior to the trial.

The results of this study will be published in a peer-reviewed journal. The conclusion of this trial will also be disseminated locally through hospital publicity and it will be comprehensively presented at academic conferences.

Data management

The original data of this trial will include a case record form and electronically captured data. Informed consent forms with patient signatures will be stored in a private database for clinical trials at the Department of Anesthesiology. Electronic information will be stored on an authorised computer while maintaining clinical trial confidentiality. Patient records will be available from the GOODWILL Electronic Medical Record System (version 6.0) with medical access only. Test data related to this trial will be uploaded to http://www.medresman.org.cn/ within 2 weeks after collection and will be available to the public.

Acknowledgements We thank Dr Jiang-Shan Huang for providing detailed information during clinical observations and follow-ups prior to our trial. We thank the residents for their careful follow-up and communication with patients, surgeons,

and nursing teams, and for considering the needs of the patients. We thank Dr Ding-Yi Wang for critical advice on the trial design. We thank the experimental assistant of the Scientific Research Department for providing suggestions regarding the research methods.

Contributors Study design, data interpretation and article writing: LFW. Measurement of clinical indicators and follow-up: M-TZ. Quality control and safety control: HNM. Data collection and analysis: NL. Protocol management: WXL. All authors have approved the final manuscript.

Funding This work is supported by the National High Level Hospital Clinical Research Funding grant number 2023-NHLHCRF-PY-09.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Li Fang Wang http://orcid.org/0000-0002-0494-9841

REFERENCES

1 Lin C-W, Chiang T-Y, Chen W-C, *et al*. Is postextubation dysphagia underestimated in the era of COVID-19? A systematic review and meta-analysis. *Otolaryngol Head Neck Surg* 2023;168:935–43.
2 Gao ZF, Yang ZZ, Ma KC. The stimulative effect of injection epimedium on the growth of chick embryo femur in vitro. *J Tradit Chin Med* 1988;8:305–6.
3 Perren A, Zürcher P, Schefold JC. Clinical approaches to assess post-extubation dysphagia (PED) in the critically ill. *Dysphagia* 2019;34:475–86.
4 Brodsky MB, Pandian V, Needham DM. Post-extubation dysphagia: a problem needing multidisciplinary efforts. *Intensive Care Med* 2020;46:93–6.
5 Zuercher P, Moser M, Waskowski J, *et al*. Dysphagia post-extubation affects long-term mortality in mixed adult ICU patients-data from a large prospective observational study with systematic dysphagia screening. *Crit Care Explor* 2022;4:e0714.
6 Brodsky MB, Akst LM, Jedlanek E, *et al*. Laryngeal injury and upper airway symptoms after endotracheal intubation during surgery: a systematic review and meta-analysis. *Anesth Analg* 2021;132:1023–32.
7 Markovitz BP, Randolph AG, Khemani RG. Corticosteroids for the prevention and treatment of post-extubation stridor in neonates, children and adults. *Cochrane Database Syst Rev* 2008:CD001000.
8 Paul S, Pande RK. Post-extubation dysphagia-early detection by serial tongue pressure measurements: is it practical? *Indian J Crit Care Med* 2022;26:1233–4.
9 Hasegawa K, Shigemitsu K, Hagiwara Y, *et al*. Association between repeated intubation attempts and adverse events in emergency departments: an analysis of a multicenter prospective observational study. *Ann Emerg Med* 2012;60:749–54.
10 Ono Y, Shinohara K, Shimada J, *et al*. Lower maximum forces on oral structures when using gum-elastic bougie than when using endotracheal tube and stylet during both direct and indirect laryngoscopy by novices: a crossover study using a high-fidelity simulator. *BMC Emerg Med* 2020;20:34:34.:.
11 Goto T, Koyama Y, Kondo T, *et al*. A comparison of the force applied on oral structures during intubation attempts between the pentax-AWS airwayscope and the macintosh laryngoscope: a high-fidelity simulator-based study. *BMJ Open* 2014;4:e006416.
12 Ababneh O, Alghanem S, Al-Shudifat A, *et al*. Acute macroglossia post craniotomy in sitting position: a case report and proposed management guideline. *Int Med Case Rep J* 2020;13:391–7.
13 Rewari V, Ramachandran R. Prolonged steep trendelenburg position: risk of postoperative upper airway obstruction. *J Robot Surg* 2013;7:405–6.
14 Shinohara M, Iwashita M, Abe T, *et al*. Risk factors associated with symptoms of post-extubation upper airway obstruction in the emergency setting. *J Int Med Res* 2020;48.
15 Dube SK, Rath GP, Gupta N, *et al*. Tracheal tube Kinking during craniotomy in supine position after application of fish hook retractors. *Neurol India* 2011;59:647–8.
16 Singh N, Chauhan R, Sarna R, *et al*. Tracheal tube kinking amidst prone position during neurosurgical procedures: an attempt to elucidate the mechanism. *J Pediatr Neurosci* 2021;16:332–4.
17 von Elm E, Altman DG, Egger M, *et al*. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann Intern Med* 2007;147:573–7.
18 Solaberrieta E, Etxaniz O, Otegi JR, *et al*. Customized procedure to display T-scan occlusal contacts. *J Prosthet Dent* 2017;117:18–21.
19 Teo EYL, Kelley BS, Black IH. Observational study of mallampati changes after prone spinal surgery. *J Clin Anesth* 2014;26:606–10.
20 Orandi A, Orandi A, Najafi A, *et al*. Post-intubation sore throat and menstruation cycles. *Anesth Pain Med* 2013;3:243–9.
21 Hara M, Ishida R, Ohkubo M, *et al*. Effects of varying fixed lingual apex positions on tongue pressure during straw drinking. *J Oral Rehabil* 2014;41:374–80.