BMJ Open

Multicentre clinical study of haemorrhage after coblation tonsillectomy in children: a prospective study protocol

Hongming Xu,[1] Shuyao Qiu,[2] Shilei Pu,[1] Bin Hu,[1] Dabo Liu,[2] Xiaoyan Li [1]

To cite: Xu H, Qiu S, Pu S, *et al*. Multicentre clinical study of haemorrhage after coblation tonsillectomy in children: a prospective study protocol. *BMJ Open* 2023;**13**:e063401. doi:10.1136/bmjopen-2022-063401

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-063401).

DL and XL contributed equally.

HX and SQ are joint first authors.

Received 21 April 2022
Accepted 21 December 2022

[1]Shanghai Children's Hospital, School of Medicine, Shanghai Jiao Tong University, Shanghai, China
[2]Department of Pediatric Otolaryngology, Shenzhen Hospital, Southern Medical University, Shenzhen, China

Correspondence to
Dr Xiaoyan Li;
lixiaoyanent@sina.com

ABSTRACT

Introduction Post-tonsillectomy haemorrhage (PTH) is the most common and significant life-threatening complication following tonsillectomy, especially in children. Coblation tonsillectomy (CTE) at low temperature is extensively used in China and has gradually replaced conventional tonsil dissection. However, risk of late PTH has been shown to increase with the use of hot instruments. The aim of this study is to detect post-CTE haemorrhage (PCTH) rates and analyse risk factors of PCTH in China, through a nationwide multicentre prospective study.

Methods and analysis This investigator-initiated, prospective, multicentre clinical trial will involve children with tonsil disease who will undergo CTE from 22 research centres in different cities in China. All operations will be performed using the same technique of extracapsular tonsillectomy. Data will be collected for all patients enrolled in this study through a preoperative visit, intraoperative data and a postoperative visit. The measurement data conforming to a normal distribution will be expressed by means±SDs, and a Student's t-test will be used for comparison. The comparison among groups of counting data will be expressed by percentage or rate, and a χ^2 test will be used for comparison. Non-conditional logistic regression analysis will be used to analyse the preoperative, intraoperative and postoperative risk factors for haemorrhage rate after CTE. P<0.05 will be considered statistically significant.

Ethics and dissemination This study protocol was approved by the Ethics Committee of Shanghai Children's Hospital/Shanghai Jiao Tong University (reference number 2021R096-E01). All patients will provide written informed consent. Results of this study are to be published in respected, peer-reviewed journals and findings presented at scientific conferences in the field of paediatric otorhinolaryngology.

Trial registration number NCT05206799.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a prospective and observational, multicentre clinical study of haemorrhage after coblation tonsillectomy in children initiated by the investigator.
⇒ This is a nationwide multicentre prospective study to detect post-coblation tonsillectomy haemorrhage (PCTH) rates and analyse risk factors of PCTH in China.
⇒ Preoperative, intraoperative and postoperative data related to PCTH will be collected for all patients enrolled in this study.
⇒ Differences in cultural, economic and social factors that affect patients' willingness to participate in the study will limit the inclusivity of the study population.
⇒ Due to tight scheduling and insufficient funding, surgical methods other than coblation tonsillectomy cannot be assessed at this time.

INTRODUCTION

Tonsillectomies are one of the most frequently performed surgical procedures in otolaryngology to resolve upper airway obstruction and recurrent or chronic throat infections, and to manage recurrent childhood ear disease. Despite numerous efforts, haemorrhage is the most common and significant complication following tonsillectomy.[1 2] Post-tonsillectomy haemorrhage (PTH) is not rare, ranging from 1.5% to 20%, and is a potentially life-threatening complication, especially in children.[3]

There are many proven methods of tonsillectomy, including cold knife dissection, laser, guillotine, bipolar and unipolar electrocautery, and most recently described, coblation. Coblation tonsillectomy (CTE) at low temperature has gradually replaced conventional tonsil dissection, and is extensively used in China.[4] The main advantages of the coblation technique are shorter operation times and low perioperative blood loss.[5] However, the risk of late PTH has been shown to increase with the use of hot instruments.[6]

The aim of this study is to detect post-CTE haemorrhage (PCTH) rates and analyse risk factors of PCTH in China, through a nationwide multicentre prospective study.

METHODS AND ANALYSIS

Patient and public involvement

Patients and the public will be involved in the design, conduction, reporting and dissemination of this research.

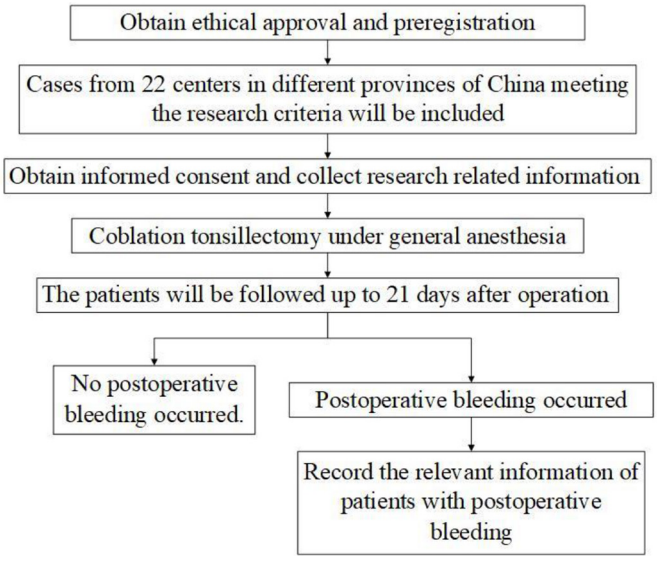

Figure 1 Study flow chart.

Trial design

This study is an investigator-initiated, multicentre prospective observational cohort study of the haemorrhage rate and risk factors after CTE in children (figure 1—study flow chart). The study started on 15 January 2022 and is scheduled to end on 14 January 2024. The study will be conducted in accordance with ethical principles of the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of Shanghai Children's Hospital, Shanghai Jiao Tong University, which is the study initiator. Each clinical centre will obtain their own ethics approval by their respective committees. Before the study starts, written informed consent forms will be obtained from patients willing to participate in the study and will be approved by the institutional review board/independent ethics committee of Shanghai Children's Hospital, Shanghai Jiao Tong University (2021R096-E01). The protocol of the trial has been registered at http://clinicaltrials.gov (NCT05206799).

Study objectives

The primary objective of this study is to obtain haemorrhage rates after CTE in children of the Chinese population. The major secondary objective is to research haemorrhage risk factors after CTE in Chinese children.

Study population

Children with tonsil disease who will undergo CTE from 22 research centres in different cities will be screened, during the study period. The participants will have to agree on the following requirements: (1) the indication of tonsillectomy, according to clinical practice guidelines for standardised low-temperature plasma radiofrequency ablation tonsillectomy and adenoidectomy in children[7]; (2) complete history collection and preoperative examination; (3) age over 0 years but less than or equal to 18 years. Exclusion criteria are: (a) children with a history of adenoid or tonsillectomy; (b) association with refractory bleeding diseases; (c) cleft palate; (d) Down syndrome, Prader-Willi syndrome or other chromosomal abnormalities; (e) neuromuscular diseases (including cerebral palsy); (f) other medical conditions making the patient medically unstable for surgery[8]; (g) contraindications of surgery and anaesthesia; (h) inability to obtain informed consent.

Data collection

Data will be collected at individual centres with online case record forms based on an Electronic Data Capture (EDC) system for every patient recruited. All subcentres have access to the EDC system for data entry through the internet. Access to the data entry system will be protected by a username and password delivered during the registration process. All participants' names will be displayed in the EDC system using initials. Data managers of each centre can find basic information of participants to follow up; however, this information will not be disclosed to all centres.

The main risk factors that may affect haemorrhage rates after CTE will be collected in this study.[9–20] Risk factors due to the patient's own condition include, gender, age, body mass index, education status of the primary guardian, date of symptoms onset, parameters of polysomnography, concomitant symptoms other than sleep disorders, history of other systemic diseases, tonsil size, adenoid size, etc. Risk factors due to surgical intervention include surgery date, surgery time, intraoperative blood loss, use of suture haemostasis technique, use of medicine during anaesthesia, brand and model of plasma radiofrequency used in the operation, etc. Risk factors due to postoperative intervention measures include diet conditions after surgery, Use of medicine after surgery (painkillers, antibiotics, non-steroidal antipyretic analgesics, etc), symptoms of cough after surgery, fever after surgery, complete blood count parameters (if postoperative bleeding occurs), etc. Hence, risk factor variables for statistical analysis are estimated to be 25–30.

Each centre will maintain a secure trial file including a protocol, local investigator delegation log, ethics approval documentation, participant list, etc.

A final summary printout of included patients with major variables will be produced for each centre together with the final data submission to double check for completeness and accuracy.

Preoperative patient visit and screening questionnaire

Patients who meet the inclusion criteria will be visited 1 day before surgery. Screening questionnaire (online supplemental file 1) information, including basic patient information, medical history, physical examination and laboratory results, will be collected and filled out by residents. A paper or electronic medical record of all the subjects will be checked by the visiting physician for complications history questions in the screening questionnaire. If medical history records are not available,

data will be recorded faithfully and be considered during statistical analysis.

Operative details and outcome measures

Bilateral CTE will be performed on an inpatient basis with general anaesthesia and endotracheal intubation. Surgeons will perform CTE using their preferred or available brand of coblation equipment. All operations will be performed using the same technique of extracapsular tonsillectomy.

Non-steroidal non-aspirin anti-inflammatory analgesics will be used postoperatively if needed, during the hospital stay. In the case of constant postoperative fever (temperature of 38.0°C or higher, lasting for more than 4 hours) with bacterial infection, antibiotics will be given, always a β-lactam, either oral or intravenous administration, if not contraindicated. When started, the treatment will continue for 7 postoperative days.

Data will be collected for all patients enrolled in this study through a preoperative visit, intraoperative data and a postoperative visit. Preoperative visits will be made 24–48 hours before surgery. The inclusion and exclusion criteria will be reviewed, and informed consent will be signed on the day of the preoperative visit. Medical history, physical examination data, laboratory examination data and polysomnography data will be obtained on the day of preoperative visit. Medical history includes the presence and severity of snoring, open mouth breathing, nasal congestion, runny nose, sleepwalking, enuresis, somniloquy, rhinocnesmus, occlusive nasal sound, attention disorder, and the presence and severity of recurrent tonsillitis. Physical examination information includes grading of adenoid hypertrophy (4-grade method)[21] and tonsil hypertrophy (Brodsdy's method),[22] and an assessment of adenoid facial appearance. Laboratory examination includes allergen serology and coagulation test results. Polysomnography data include OAHI (Obstructive apnea hypopnea index) , $LSaO_2$ (%) (Lowest oxygen saturation) and SaO_2(Oxygen saturation) <90% duration (min).

Intraoperative data will be collected on the day of surgery and recorded in the EDC system of this clinical study within 24 hours after the surgery. These data include surgery date, start and end time of operation, the doctor's name and practising period (number of tonsillectomy cases that have been performed), intraoperative blood loss, adenoidectomy status, suture haemostatic status, glucocorticoids status during anaesthesia, haemostatic status during anaesthesia, and the brand and model of coblation equipment used.

If the subject did not experience postoperative bleeding, a postoperative visit was performed on day 21 (±1 day). Observations included whether or not the patient was eating semifluid (includes porridge, flour, noodles), whether or not the patient was participating in strenuous exercise (competitive sports, such as running, playing ball, swimming, etc, excluding normal walking and daily activities), symptoms of cough, haemostasis, intravenous hormone use, intravenous antibiotic use, painkiller use and number of postoperative fevers. The type, frequency and dose of postoperative medication will also be recorded. Postoperative visits (occurrence of postoperative bleeding) also include emergency observation, readmission, frequency of admission, use of compression for haemostasis, blood routine and coagulation function test results, and bleeding grading (Windfuhr five-level method).[23]

Grade 1 was any postoperative haemorrhage with a spontaneous cessation, where ice packing was administered and sufficient.

Grade 2 bleeding needed further treatment under local anaesthesia. This was either by infiltration of 1:250.000 epinephrine containing 1% lidocaine, or additional bipolar coagulation.

Grade 3 bleeding needed suture ligation under general anaesthesia was necessary. In cases with diffuse bleeding, the tonsillar pillars were sutured.

Grade 4 bleeding patients who had been returned to the operating room for persistent or excessive bleeding, in whom local measures to control bleeding had failed, or shock was imminent from continued blood loss, or ligature of the external carotid artery was mandatory.

Grade 5 bleeding was any postoperative haemorrhage with lethal outcome regardless of what treatments had been carried out.

Postoperative haemorrhages were classified either as primary (within 24 hours of the operation) or secondary (24 hours postoperatively).

Sample size

The sample size will depend on the number of centres recruited and their respective caseloads. Each centre will also complete a screening of all eligible patients during the study.

With 25–30 variables potentially associated with bleeding rates after tonsillectomy in children,[9–20] mentioned in the Data collection section, the minimum sample size required is approximately 250–300 bleeding patients to avoid violating the principle of approximately 10 outcome events (ie, bleeding) per variable in the regression.[24] According to reports in the literature on the incidence of PTH,[3] a lower incidence of 1.5% was chosen as the estimated incidence of PTH to ensure adequate enrolment of patients with postoperative bleeding. Therefore, the total number of participants required is 20 000. Given the rate of loss to follow-up, 25 000 participants will be recruited. The sample size has been determined with the guidance of professional statisticians from the Clinic Research Unit of Shanghai Children's Hospital. The case collection system was established in January 2022, and the database will be locked once the sample size is reached.

Statistical analysis

All institutional-level data will be anonymised prior to publication. Categorical variables will be described as counts and proportions, which will be compared using X^2

tests. Continuous variables will be described as means and SDs if normally distributed, or medians and IQRs if not normally distributed. Comparisons of continuous variables between groups will be performed using t-tests, one-way analysis of variance or an equivalent non-parametric test as appropriate. Univariate analysis will be performed to test factors associated with PCTH.

Single-level and hierarchical multilevel logistic regression models will be constructed to identify factors independently associated with these outcomes and to adjust for differences in confounding factors. Factors will be entered into models.

Current status

The study has been approved by the Ethics Committee of Shanghai Children's Hospital, Shanghai Jiao Tong University. A project kick-off meeting has been held for 22 clinical research centres. Subjects have been recruited since 15 January 2022. Three research centres are now recruiting subjects.

DISCUSSION

Tonsillar surgery was recorded in the first century AD, with complications and bleeding that have been greatly reduced in the 20th century. The earliest adenoid surgery was performed in the 1860s by Hans Wilhelm Meyer, a Danish doctor. The 1990s ushered in a new era of adenoid surgery under direct vision. In the 21st century, tonsillar and adenoid resection methods such as laser, microdebrider, bipolar cautery and ultrasonic coblation based on the stripping principle have been popularised. Coblation has been widely used for tonsillectomy for more than 10 years in China because it provides a bloodless surgical field for operators and reduces intraoperative bleeding without frequent replacement of surgical instruments. However, there is still a certain probability of postoperative bleeding, infection and other complications reported in the literature.[25]

There are several reports which provide evidence for an increased secondary haemorrhage with CTE. Windfuhr *et al*[26] report a high rate of return (9.5%) to surgery for controlling haemorrhage following CTE. Divi and Benninger[27] reported a secondary haemorrhage rate of 5.4% in their retrospective study for CTE. Javed *et al*[28] reported a high incidence of secondary haemorrhage following CTE; they compared coblation with the cold steel method and reported that 9.1% of patients needed surgical intervention to control secondary haemorrhage. However, Belloso *et al*[29] showed that coblation for tonsil dissection offers significant advantages in the postoperative period compared with dissection tonsillectomy with bipolar diathermy haemostasis. CTE is associated with a lesser incidence of delayed haemorrhage that is more significant in children. A study in which surgery was performed by a single surgeon showed the PTH rate was 5.0% for cold steel and 5.8% for CTE—like previous results.[30] Several other studies, including a meta-analysis, did not show the superiority of cold steel surgery over coblation surgery in terms of PTH, either.[31 32] A comparison between diathermy tonsillectomies and CTEs also revealed inconsistent results. The National Prospective Tonsillectomy Audit showed that coblation was better than monopolar diathermy and comparable with bipolar diathermy in PTH.[33] In a study of over 17 000 procedures, coblation alone was not associated with a higher PTH rate as compared with other techniques. The patient's personal condition may also be related to postoperative bleeding.[34] It is necessary to obtain postoperative haemorrhage data of CTE via a nationwide clinical study, with wide application of CTE in China. Little literature that reports about how the use of different coblation equipment affects postoperative tonsillectomy haemorrhage rates exists. Therefore, surgeons will be allowed to use their preferred or available brand of coblation equipment. Differences between different equipment groups will also be compared.

Inuzuka *et al*[35] analysed 325 adult patients and found smoking status and sex to be significant risk factors of PTH in adults. Kshirsagar *et al*[36] reviewed 138 998 procedures performed on adolescents from 2005 to 2011. Haemorrhage occurred in 156 cases (0.1%) and was associated with age and obesity. Multivariate analysis revealed that haemorrhage was about 2.3 times more likely to occur in obese children. There was no association between haemorrhage and gender. However, Ordemann *et al*[9] analysed 1418 patients under the age of 15 years who underwent tonsillectomy with or without adenoidectomy and found no correlation between weight-for-age percentile and occurrence of PTH. Mudd *et al* reviewed 6710 children who underwent tonsillectomy.[10] A total of 222 children required surgical control of PTH.

Some studies believe that postoperative bleeding is related to the experience of the operator. Carney *et al*[11] found that there was a significant learning curve with respect to both primary and secondary haemorrhage rates. Previous studies have reached similar conclusions.[12] However, Manimaran *et al*[13] analysed 1284 patients who underwent tonsillectomy with or without adenoidectomy and found reactionary haemorrhage after tonsillectomy was similar in procedures performed by trainees and consultants. Praveen *et al*[14] found a high incidence of secondary haemorrhage in CTE performed by experienced consultant surgeons compared with middle-grade surgeons.

Perioperative medication may also be associated with postoperative bleeding. Diercks *et al*[15] analysed 741 children; the rate of bleeding requiring operative intervention was 1.2% in the acetaminophen group and 2.9% in the ibuprofen group. A review from the Cochrane Collaboration that included 1100 children in 15 studies found that non-steroidal anti-inflammatory drugs did not significantly increase the risk of bleeding as compared with placebo or other analgesics, did not significantly alter the number of perioperative bleeding events requiring non-surgical intervention and resulted in less vomiting.[16]

Frelich *et al*[17] report that dexamethasone (0.15 mg/kg) significantly reduced the incidence of postoperative nausea and vomiting without increasing the risk of postoperative haemorrhage. Junaid *et al* reported that regular use of antibiotics in post-tonsillectomy patients does not prevent or reduce postoperative complications.[18]

Environmental factors may also be associated with postoperative bleeding. Račić *et al*[19] found a significant correlation between increased primary PTH rates and cyclonic air mass conditions. Another study including 4438 patients showed a higher risk of bleeding during the warmer seasons, comparing the winter with spring, summer and fall. A statistically significant positive association was also found with the average temperature on the day of surgery. Bleeding more than 3 days after surgery was less likely in summer.[20]

Though many studies have been carried out on post-tonsillectomies, research results are inconsistent. Coblation is a new, minimally invasive technology that has been widely used in China only in recent years. So far, there are no large-scale studies in China about haemorrhage after CTE in children. The primary objective of the study is to obtain haemorrhage rates after CTE in children of Chinese population. The major secondary objective is to research haemorrhage risk factors after CTE in Chinese children.

Ethics and dissemination

This research will not increase the risk or economic burden of patients and the patients' rights will be fully protected. The study will be conducted in accordance with the ethical principles of the Shanghai Children's Hospital. The study protocol was approved by the Ethics Committee of Shanghai Children's Hospital/Shanghai Jiao Tong University (reference number 2021R096-E01). All patients will provide written informed consent. Results of this study are to be published in respected, peer-reviewed journals and findings presented at scientific conferences in the field of paediatric otorhinolaryngology.

Acknowledgements We thank our colleagues in all the clinical centres participating in this study.

Contributors XL and DL participated in study design, statistical hypotheses and sample size calculation. HX and SP participated in manuscript preparation, sample size calculation, writing the protocol of preoperative patient visit and screening period questionnaire. SQ and BH were involved in manuscript preparation, writing the protocol of operative details and outcome measures.

Funding This work was supported by the National Natural Science Foundation of China (grant number 82171121).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Xiaoyan Li http://orcid.org/0000-0003-3080-9321

REFERENCES

1 Amoils M, Chang KW, Saynina O, *et al*. Postoperative complications in pediatric tonsillectomy and adenoidectomy in ambulatory vs inpatient settings. *JAMA Otolaryngol Head Neck Surg* 2016;142:344–50.
2 Mitchell RB, Archer SM, Ishman SL, *et al*. Clinical practice guideline: tonsillectomy in children (update). *Otolaryngol Head Neck Surg* 2019;160:S1–42.
3 Gonçalves AI, Rato C, de Vilhena D, *et al*. Evaluation of post-tonsillectomy hemorrhage and assessment of risk factors. *Eur Arch Otorhinolaryngol* 2020;277:3095–102.
4 Liu Q, Zhang Y, Lyu Y. Postoperative hemorrhage following coblation tonsillectomy with and without suture: a randomized study in Chinese adults. *Am J Otolaryngol* 2021;42:102760.
5 Metcalfe C, Muzaffar J, Daultrey C, *et al*. Coblation tonsillectomy: a systematic review and descriptive analysis. *Eur Arch Otorhinolaryngol* 2017;274:2637–47.
6 Söderman A-CH, Odhagen E, Ericsson E, *et al*. Post-tonsillectomy haemorrhage rates are related to technique for dissection and for haemostasis. An analysis of 15734 patients in the National tonsil surgery register in Sweden. *Clin Otolaryngol* 2015;40:248–54.
7 Chinese M. [Clinical practice guidelines for standardized low-temperature plasma radiofrequency ablation tonsillectomy and adenoidectomy in children]. *Lin Chung Er Bi Yan Hou Tou Jing Wai Ke Za Zhi* 2021;35:193–9.
8 Marcus CL, Brooks LJ, Draper KA, *et al*. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics* 2012;130:e714–55.
9 Ordemann AG, Hartzog AJ, Seals SR, *et al*. Is weight a predictive risk factor of postoperative tonsillectomy bleed? *Laryngoscope Investig Otolaryngol* 2018;3:238–43.
10 Mudd PA, Thottathil P, Giordano T, *et al*. Association between ibuprofen use and severity of surgically managed posttonsillectomy hemorrhage. *JAMA Otolaryngol Head Neck Surg* 2017;143:712–7.
11 Carney AS, Harris PK, MacFarlane PL, *et al*. The coblation tonsillectomy learning curve. *Otolaryngol Head Neck Surg* 2008;138:149–52.
12 Liu D-bo, Tan Z-yu, Zhong J-wen, *et al*. [A preliminary study of the secondary postoperative haemorrhage in pediatric coblation adenotonsillectomy]. *Zhonghua Er Bi Yan Hou Tou Jing Wai Ke Za Zhi* 2010;45:373–6.
13 Manimaran V, Mohanty S, Jayagandhi SK, *et al*. A retrospective analysis of peroperative risk factors associated with posttonsillectomy reactionary hemorrhage in a teaching hospital. *Int Arch Otorhinolaryngol* 2019;23:e403–7.
14 Praveen CV, Parthiban S, Terry RM. High incidence of post-tonsillectomy secondary haemorrhage following coblation tonsillectomy. *Indian J Otolaryngol Head Neck Surg* 2013;65:24–8.
15 Diercks GR, Comins J, Bennett K, *et al*. Comparison of ibuprofen vs acetaminophen and severe bleeding risk after pediatric tonsillectomy: a noninferiority randomized clinical trial. *JAMA Otolaryngol Head Neck Surg* 2019;145:494–500.
16 Lewis SR, Nicholson A, Cardwell ME, *et al*. Nonsteroidal anti-inflammatory drugs and perioperative bleeding in paediatric tonsillectomy. *Cochrane Database Syst Rev* 2013;2013:D3591.
17 Frelich M, Divák J, Vodička V, *et al*. Dexamethasone reduces the incidence of postoperative nausea and vomiting in children undergoing endoscopic adenoidectomy under general anesthesia without increasing the risk of postoperative hemorrhage. *Med Sci Monit* 2018;24:8430–8.
18 Junaid M, Malik NW, Abdelsalam Soliman Galbt Y, *et al*. To give or not to give? Prescribing antibiotics to the tonsillectomy patients in a tertiary care setting. *Cureus* 2021;13:e16405.

19 Racic G, Kurtovic D, Colovic Z, *et al*. Influence of meteorological conditions on post-tonsillectomy haemorrhage. *J Laryngol Otol* 2008;122:1330–4.
20 Mendel R, Yitshak-Sade M, Nash M, *et al*. Assessment of the association between post-tonsillectomy hemorrhage and weather conditions. *Isr Med Assoc J* 2018;20:349–53.
21 Franco RA, Rosenfeld RM, Rao M. First place--resident clinical science award 1999. Quality of life for children with obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2000;123:9–16.
22 Brodsky L. Modern assessment of tonsils and adenoids. *Pediatr Clin North Am* 1989;36:1551–69.
23 Windfuhr J, Seehafer M. Classification of haemorrhage following tonsillectomy. *J Laryngol Otol* 2001;115:457–61.
24 Peduzzi P, Concato J, Kemper E, *et al*. A simulation study of the number of events per variable in logistic regression analysis. *J Clin Epidemiol* 1996;49:1373–9.
25 Sarny S, Ossimitz G, Habermann W, *et al*. Hemorrhage following tonsil surgery: a multicenter prospective study. *Laryngoscope* 2011;121:2553–60.
26 Windfuhr JP, Deck JC, Remmert S. Hemorrhage following coblation tonsillectomy. *Ann Otol Rhinol Laryngol* 2005;114:749–56.
27 Divi V, Benninger M. Postoperative tonsillectomy bleed: coblation versus noncoblation. *Laryngoscope* 2005;115:31–3.
28 Javed F, Sadri M, Uddin J, *et al*. A completed audit cycle on post-tonsillectomy haemorrhage rate: coblation versus standard tonsillectomy. *Acta Otolaryngol* 2007;127:300–4.
29 Belloso A, Chidambaram A, Morar P, *et al*. Coblation tonsillectomy versus dissection tonsillectomy: postoperative hemorrhage. *Laryngoscope* 2003;113:2010–3.
30 Khan I, Abelardo E, Scott NW, *et al*. Coblation tonsillectomy: is it inherently bloody? *Eur Arch Otorhinolaryngol* 2012;269:579–83.
31 Amir I, Belloso A, Broomfield SJ, *et al*. Return to theatre in secondary post-tonsillectomy haemorrhage: a comparison of coblation and dissection techniques. *Eur Arch Otorhinolaryngol* 2012;269:667–71.
32 Alexiou VG, Salazar-Salvia MS, Jervis PN, *et al*. Modern technology-assisted vs conventional tonsillectomy: a meta-analysis of randomized controlled trials. *Arch Otolaryngol Head Neck Surg* 2011;137:558–70.
33 Lowe D, van der Meulen J, National Prospective Tonsillectomy Audit. Tonsillectomy technique as a risk factor for postoperative haemorrhage. *Lancet* 2004;364:697–702.
34 Tomkinson A, Harrison W, Owens D, *et al*. Risk factors for postoperative hemorrhage following tonsillectomy. *Laryngoscope* 2011;121:279–88.
35 Inuzuka Y, Mizutari K, Kamide D, *et al*. Risk factors of post-tonsillectomy hemorrhage in adults. *Laryngoscope Investig Otolaryngol* 2020;5:1056–62.
36 Kshirsagar R, Mahboubi H, Moriyama D, *et al*. Increased immediate postoperative hemorrhage in older and obese children after outpatient tonsillectomy. *Int J Pediatr Otorhinolaryngol* 2016;84:119–23.