

Full title: Paediatric tonsillectomy in England: a cohort study of clinical practice and outcomes usingHospital Episode Statistics data (2008-2019)Short title: Paediatric tonsillectomy in England: 2008-2019 using HES

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# **Ethical considerations**

Pseudonymised data from HES and the Civil Registration Mortality (formerly known as the Office of National Statistics Mortality) datasets were supplied under Data Access Request Service (DARS) agreement DARS-NIC-170211-Z1B4J. No patient identifiable information was used and ethical approval was not sought.

### Author contributions

All authors participated in the study conception and design. Young Persons Advisory Group North of England also contributed to the study design. KK extracted and analysed the data. All authors participated in the interpretation of the data, drafted the article or revisited it critically for important intellectual content. AJS had full access to all of the data in the study, and is the study guarantor.

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No specific funding was given for this study.

### Data availability statement

No additional data are available. Hospital Episodes Statistics data to reproduce results are available from the Health and Social Care Information Centre (HSCIC) via formal application process.

### Acknowledgements

HES data held by NHS Digital (formerly the UK NHS Health and Social Care Information Centre, HSCIC) have been used to help complete the analysis © 2020. Reused with the permission of NHS Digital/HSCIC. All rights reserved.

# **Competing interests**

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi\_disclosure.pdf and declare: no support from any organisation for the submitted work; Newcastle upon Tyne Hospitals NHS Foundation Trust, the employing institution of SP, KK, PC, HR, & AJS authors, is contracted as External Assessment Centre to the NICE Medical Technologies Evaluation Programme (MTEP); AJS reports grants from NIHR, Wellcome Trust and Academic Health Science Network North East and North Cumbria outside the submitted work; KK reports grants from NIHR outside the submitted work; no other financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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### Abstract

*Objectives:* To assess the safety of paediatric tonsillectomy procedures conducted in NHS hospitals in England between 2008 and 2019.

Design: Retrospective observational cohort study using Hospital Episode Statistics (HES) data.

Setting: Acute NHS trusts in England conducting paediatric tonsillectomy procedures

Participants: Children (≤16 years old) undergoing bilateral tonsillectomy

*Main outcome measures:* Number of tonsillectomies performed per year by procedural method. In-hospital complications including return to theatre for arrest of haemorrhage. Readmission within 28 days, including those for pain, haemorrhage and surgical arrest of haemorrhage. Long-term outcomes: all-cause mortality, revision tonsillectomy.

*Results:* A total of 318,453 paediatric tonsillectomies were performed from 2008 to 2019: 278,772 dissection (87.5%), 39,681 coblation (12.5%). The proportion of tonsillectomy performed using coblation increased from 7% in 2008/9 to 27% in 2018/9. Five patients died in hospital (including 4 due to respiratory complications). In-hospital complications occurred in 4,202 children (1.3%), with the most frequent being haemorrhage. Within 28 days of tonsillectomy, 28,170 patients (8.8%) were readmitted and 7 deaths occurred. Readmission rates for haemorrhage and pain have increased since

2008. The proportion of children undergoing revision tonsillectomy procedures within 5 years following coblation tonsillectomy (1.4%) was approximately double that of dissection (0.6%).

*Conclusions:* Clinical practice of paediatric tonsillectomy has changed in England over the past 11 years. The overall mortality rate associated with the procedure is 0.0037%. Differences in outcomes have been identified for different procedural methods. However, routine administrative data is limited in differentiating procedural detail (e.g. we are unable to differentiate intra or extra-capsular techniques from current clinical coding of tonsillectomy procedures). Therefore prospective national data collection or more granular clinical coding is essential to capture relative outcomes of the different tonsillectomy methods and techniques being used in the NHS.

Keywords: Health information systems; Treatment outcome; Patient safety; Tonsillectomy;

# Key points:

• The available technology and clinical practice in conducting tonsillectomy across have changed since the National Prospective Tonsillectomy Audit (data collected between 2003-4) and there is a lack of current evidence regarding safety and efficacy.

• This represents the largest study of paediatric tonsillectomy in England: including 318,453 procedures conducted over 11 years, with the median per-patient follow-up of over 6 years.

• 98.7% of children experienced no in-hospital complications. Rates of readmission for bleeding within 28 days are increasing; however, significant differences in safety outcomes (bleeding, pain and return to theatre) have been identified between coblation and dissection tonsillectomy methods across the study period.

• The need for further tonsil surgery at 5 years following coblation tonsillectomy is double that of dissection tonsillectomy, 1.4% and 0.6% respectively.

Mortality associated with the procedure (during procedure or within 28 days) is 0.0037%.
This up to date information using national data from all NHS hospitals across England should inform the consent process for future tonsillectomies.

Tonsillectomy is routinely used in children to treat recurrent acute tonsillitis and obstructive sleep apnoea. It is one of the most common surgical procedures performed in children, with 37,000 tonsillectomies conducted in the UK in 2016/17 at an estimated cost to the NHS of £42m.<sup>1</sup> In 2005, the UK National Prospective Tonsillectomy Audit of 33,683 patients (63% aged less than 16 years) reported that complication rates varied between surgical methods: which included cold steel dissection, electrocautery (mono/bi-polar diathermy) and radiofrequency controlled ablation (COBLATION<sup>™</sup> referred to as "coblation" for the remainder of this study).<sup>2</sup> The audit informed the UK National Institute for Health and Care Excellence (NICE) guidance on tonsillectomy in the UK.<sup>3</sup> However, the data collection for this audit concluded 16 years ago, the available technology and procedural techniques have continued to evolve, and national guidance on tonsillectomy has not been updated.

Despite the huge volume of tonsillectomy procedures conducted annually, there is uncertainty regarding the safety and efficacy of the different tonsillectomy methods currently being used in the NHS. In order to ensure patients receive both accurate information regarding procedural risks and the best possible care, more recent evidence relating to paediatric tonsillectomy is needed. Ideally, comparative trials and national audits would inform revised guidance, but these are expensive, lengthy and often do not represent real-world outcomes. However, the NHS in England routinely collects real-world information about every procedure, including tonsillectomy, in Hospital Episode Statistics (HES)<sup>4</sup> which can be used to inform prospective studies and national guidance.<sup>5</sup> Current procedure codes in HES give an indication of the *method* by which tonsils are removed (*e.g.* coblation, dissection, guillotine or laser) but not the exact instrumentation used (e.g. cold steel dissection or monopolar/bipolar electrocautery) or which *technique* was performed (intra-capsular or extra-capsular). Despite lacking granularity, a high volume of tonsillectomy data is clinically coded in the NHS and available to generate useful information on trends and outcomes.

The aim of this study is to use routinely collected administrative data from HES to determine changes in tonsillectomy clinical practice in the NHS in England and safety outcomes from 2008-2019.

### **Materials & Methods**

#### Patient and public involvement

The research team discussed the study with the Young Persons Advisory Group North of England (YPAG-Ne) at the concept stage, who concurred that observational data collection was the most appropriate way of determining evidence on current paediatric tonsillectomy in the NHS. YPAG-Ne also contributed ideas on ways of engaging young people in future research.

#### Data source

All paediatric bilateral tonsillectomy procedures recorded in NHS hospitals in England were identified from the HES Admitted Patient Care (APC) dataset (which includes day-case surgery). Data between 1<sup>st</sup> April 2008 and 31<sup>st</sup> March 2019 were interrogated for patients aged 16 years or less. Tonsillectomy was identified via search of Office of Population Censuses and Surveys (OPCS) codes appearing in any procedure field: Bilateral dissection tonsillectomy (F34.1), Bilateral guillotine tonsillectomy (F34.2), Bilateral laser tonsillectomy (F34.3), Bilateral excision of tonsil not elsewhere classified (F34.4), and Bilateral coblation tonsillectomy (F34.7). This was designed to capture all tonsillectomies, whether performed in isolation, or in combination with other procedures, including adenoidectomy. Cohort identification is described fully in Supplementary Material 1.

### Data cleaning

All episodes of care extracted from HES were aggregated into admissions (or spells). Those with missing or inconsistent patient identifiers were excluded from further analysis. Subsequent analysis was restricted to the earliest tonsillectomy procedure per patient within the study period (i.e. index procedure). Additional exclusions applied were: incomplete spells (with missing spell start and/or end flags), unknown discharge status, and unknown month and year of birth. Data cleaning is described fully in Supplementary Material 1.

### Longitudinal follow up

Each member of the cohort was followed for any records in the HES APC and the Civil Registration Mortality datasets, from the date of discharge from their tonsillectomy procedure until 31<sup>st</sup> March 2020 (provisional data) or the date of death if sooner.

#### **Outcome Measures**

Patient characteristics, reason for admission (using the primary diagnosis code), procedure type (identified from OPCS codes: Dissection (F34.1 & F34.4), Guillotine (F34.2), Laser (F34.3), coblation (F34.7)), in-hospital outcomes (from the index procedure) and length of stay were summarised using descriptive statistics. The proportion of procedures including concomitant adenoidectomy, in-hospital complication,<sup>6</sup> and return to theatre for bleeding prior to discharge (primary bleed) were identified using OPCS procedure codes, Supplementary Material 2.

Outcomes up to 28 days post-tonsillectomy discharge included all-cause readmission, admission due to infection, pain, haemorrhage, return to theatre (secondary bleed - see Supplementary Material 2) and all-cause mortality (main-cause and timing of death). All outcomes were further subdivided by procedural method of tonsillectomy.

Longitudinal outcomes included the need for revision tonsillectomy, identified from OPCS procedure codes, Supplementary Material 2, and all-cause mortality.

### Statistical analysis

All scripts for applying eligibility criteria, data cleaning, processing and statistical analysis were written in the statistical programming language R.<sup>7</sup> Kaplan-Meier analysis was applied from the time of tonsillectomy discharge until the date of event. Patients with no clinical event and known to be alive at the end of the study were considered censored. Differences in outcomes over the study period were tested using the proportion test. Differences in outcomes per year were also tested using the proportion test with Bonferroni correction applied to account for multiple testing across the 11 years of data.

#### Results

#### Cohort identification

A total of 324,700 episodes of care between 2008 and 2019 from 322,678 patients were identified by the initial search, Supplementary Material 3. After data cleaning, index tonsillectomy admissions were identified for 320,197 patients including the following tonsillectomy methods: 278,772 dissection (87.1%), 39,681 coblation (12.4%), 1509 guillotine (0.5%), 253 laser (0.1%). The frequency of the different tonsillectomy methods over time are shown in Figure 1.

Due to dissection and coblation accounting for 99.5% of all paediatric tonsillectomies all subsequent analysis was restricted to those techniques. For the remaining cohort of 318,453 patients, the median [Q1:Q3] age was 5 [4:9] years, with 49.5% male sex, Table 1.The reason for admission was recorded as acute/chronic tonsillitis in 58.2%, hypertrophy of tonsils/adenoids in 24.8%, and sleep apnoea in 10.5%. However, a change in procedural method across these main reasons for admission and increase in day-case procedures was identified between 2008 and 2019, Supplementary Material 4a and b. Concomitant adenoidectomy was reported in 172,339 patients (53.8%).

#### In-hospital outcomes

The median length of stay was 1 night, Table 2, which included 148,422 (46.6%) day cases, 156,646 (49.2%) patients staying in hospital 1 night only, and 13,385 patients (4.2%) staying in hospital for more than one night. Five in-hospital deaths (1:64,940) occurred: cause of death in 4 cases included complication of a procedure (one post-procedural respiratory disorder, one bronchopneumonia and respiratory failure, one post-procedural respiratory disorder and sepsis, and one lacking clinical detail), 1 case included respiratory failure. In-hospital complications were reported in 4202 patients (1.3%); the most frequent in-hospital complication was haemorrhage in 0.8% (n=2438), followed by nausea and vomiting in 0.1% (n=182), Supplementary Material 5. Primary bleeds from tonsillar bed and adenoid requiring a return to theatre occurred in 0.4% and 0.2% respectively. Trends in in-hospital events by procedure type over time are described in Supplementary Material 6.

### Follow-up

Within 28 days of discharge, a total of 28,170 patients (8.8%) were readmitted and a further 7 deaths (1:46,385) occurred: cause of death in two cases included complication of a procedure (one bronchopneumonia, one ARDS), one case included haemorrhage, and one case of haemorrhage and infection, one respiratory failure and bronchopneumonia, the remaining 2 cases appear unrelated to tonsillectomy. The overall death rate (including in-hospital and those occurring within 28 days) was 12 per 320,197 procedures, 0.0037% (95% CI 0.0020% to 0.0068%).

Patient outcomes at 28 days post-tonsillectomy, grouped by procedure type, are described in Table 2. Overall rates of readmission for bleeding 28-days post-tonsillectomy have increased over time, Figure 2. From 2017/18, assuming that two samples were drawn from the same population, dissection was found to have a significantly higher rate of readmissions for bleeding and pain when compared with coblation, Figure 3 (the proportion of patients readmitted due to infection and return to theatre due to secondary bleed are shown in Supplementary Material 7a and 7b respectively).

A total of 2,073,003 patient years of follow-up was recorded (median [Q1:Q3] follow-up of 2359 [1386:3373] days per patient, range 2 to 4388 days per patient). During follow-up, 2272 patients required revision tonsil surgery. At 5 years this was 0.6% (95% CI 0.6% to 0.6%) following dissection, and 1.4% (1.3% to 1.5%) following coblation, Figure 4. Follow-up for the cohort subgrouped by year of procedure are shown in Supplementary Material 8.

### Discussion

### Synopsis of key findings

This study constitutes the largest analysis of paediatric tonsillectomies performed in England to date. By utilising routinely collected data we have demonstrated a change in clinical practice of tonsillectomy in the NHS between 2008/9 and 2018/9, including an overall increase in the use of coblation tonsillectomy (from 7% to 27%), and increasing use of coblation specifically in the treatment of tonsil/adenoid hypertrophy (from 7.5% to 41.5%) and sleep apnoea (from 3.5% to 32.0%). Overall day case rates increased from 33.2% to 59.2%. This was driven by a significant rise in the proportion of procedures performed by coblation, but also an increase in the proportion of day case dissection tonsillectomy (Supplementary Material 4b). Day case procedures attract a higher tariff and result in lower bed occupancy and have been increasingly encouraged across the NHS in recent years. We also identified trends in patient outcomes across the study period; including a general increase in readmissions for bleeding (from 4.0% to 5.5%) and pain (from 0.2 to 0.7%), with significant differences in these outcomes between dissection and coblation surgical methods. Annual bleeding rates for dissection appear to be increasing which is surprising. This could be due to the population becoming more likely to bleed (e.g. increased obesity, increase in conservative management for less severe cases of tonsillitis), patient selection for dissection has changed over time (with patients less likely to bleed moving into the coblation group), or the rate has truly increased (which could be influenced by technique or perioperative management).

Annual bleeding rates for coblation in our study do appear to be falling. This may be due to a change in patient selection or consequence of widespread use of intracapsular coblation. This technique removes only part of the tonsil with the retained tonsillar capsule acting as a biological dressing and forming a physical barrier, avoiding injury to the underlying muscle and blood vessels. Large case series have demonstrated that the intracapsular technique results in less pain and bleeding (with rates as low as 0.4%), and fewer readmissions than the traditional extracapsular technique (which removes the whole tonsil).<sup>8,9</sup> Despite this, systematic reviews have been unable to draw conclusions regarding the safety and efficacy of intracapsular tonsillectomy due to low quality data.<sup>10-12</sup> Furthermore, intracapsular coblation was not included in the recent American Practice Guideline due to a lack of data on effectiveness.<sup>13,14</sup>

It is possible that an increased uptake of the intracapsular technique may have also led to a lower readmission rate from 2017/18. However, at 5 years the percentage of patients requiring revision tonsil surgery following coblation tonsillectomy was double that of dissection (1.4% versus 0.6%). This may be confounded by the learning curve associated with the newer method of coblation, or by difference in baseline patient characteristics (which could not be accounted for in our retrospective observational study), however it is plausible that increasing use of the intra-capsular technique which deliberately leaves tissue behind, may lead to higher tonsil regrowth rate. Unfortunately, it is not possible to determine the proportion of intracapsular coblation tonsillectomies performed in this study due to the limited granularity of procedure coding.

### Strengths and limitations

By using routine administrative data, our study has been able to monitor patient outcomes over an 11 year period with comprehensive follow-up. This timescale has allowed us to observe long-term trends and demonstrate significant changes in practice and outcomes since the publication of the National Tonsillectomy Audit in 2005.<sup>2</sup> This highlights that even common procedures like tonsillectomy require monitoring to ensure patient safety. The use of a very large national data set has also allowed us to identify rare negative outcomes, such as deaths and revision surgery, and to compare the prevalence of relatively uncommon outcomes (in-hospital complications and readmission) across different tonsillectomy techniques.

Our retrospective study design relies on accuracy and consistent usage of clinical coding, and is restricted by the clinical codes available. For example, our analysis using routine data does not allow us to discriminate between the impact of the procedural methods and techniques applied, as they cannot be distinguished by existing procedure codes (OPCS 4.8). Current procedure codes give some indication of the *method* by which tonsils are removed (*e.g.* coblation, dissection, guillotine or laser) however it is not detailed enough to make a distinction of the exact instrumentation used (e.g. cold steel dissection or monopolar/bipolar electrocautery). It is also not possible to derive information about which *technique* was performed (intra-capsular or extra-capsular). This lack of detail in national datasets was highlighted by Getting It Right First Time (GIRFT) within their recommendation to revise clinical coding to enable coders to more accurately capture the variety of tonsillectomy.<sup>15</sup> Our

observations confirm that further research is required in order to determine the relative risks of each specific tonsillectomy approach and how they balance a possible advantage in reducing haemorrhage and pain over other variants. The diagnosis codes available (ICD10) also have their limitations. Acute or chronic tonsillitis was the most common reason for admission in our cohort, followed by hypertrophy of the tonsils or adenoids. While describing that tonsils and adenoids may be enlarged, this by itself is not a clinical condition that would lead to tonsillectomy. It may be representative of enlarged tonsils or adenoids which in turn contribute to sleep apnoea, however this inference cannot be made using current coding.

### Comparisons with other studies

The 2005 National Tonsillectomy Audit reported a 1.3% primary complication rate (which included delayed discharge, return to theatre and blood transfusion in-hospital) and a 3.9% secondary complication rate (readmission, return to theatre and blood transfusion within 28 days).<sup>2</sup> Whilst our study reports different in-hospital outcomes we were able to determine that 1.3% had a reported in-hospital complication, and 0.4% required surgical arrest of post-operative bleeding from tonsillar bed during their index admission. In our cohort, 4.2% remained in hospital for more than 1 night but it was not possible to determine what proportion of the cohort were originally intended as day case and what proportion were intended as overnight stay. GIRFT has already reported;<sup>15</sup> our study confirmed that readmission rates are double that reported in the previous national audit (8.8% versus 3.9%). Although death is an extremely rare event following tonsillectomy, we identified 5 in-hospital deaths (4 due to respiratory complications) and a further 7 within 28 days; an overall death rate of 12 per 320,197 procedures, 0.0037%. Whilst we cannot determine whether these deaths were related to tonsillectomy from HES and ONS, the mortality rate identified in our study is in line with that reported by a large Swedish population study that included both adults and children (0.0024%).<sup>16</sup>

Systematic reviews have identified lower post-operative pain for coblation tonsillectomy.<sup>17,18</sup> Our observational study shows a small but steady increase in readmissions for pain within 28 days, however this was significantly lower for coblation procedures within 2018/19. The general increase in readmission for pain may be confounded by changes in anaesthesia technique and/or analgesia regimes which occurred during the study period (such as restriction on use of codeine in children with obstructive sleep apnoea following tonsillectomy)<sup>19</sup> which could not be accounted for in our study of HES data, as they are not recorded.

Clinical applicability of the study

Informed consent is underpinned by accurate outcome data, and the Montgomery decision has redefined the standards for informed consent and disclosure.<sup>20</sup> In current clinical practice, information provided during the consent process on the safety of tonsillectomy is based on a voluntary audit of practice more than 15 years ago. Our results, based on a comprehensive national dataset, provide an overall figure for mortality associated with the procedure. Whilst this study is unable to demonstrate causality, it does raise a large number of questions regarding the safety of a well-established procedure. The lack of procedural detail (regarding method and intra/extra capsular technique used), increasing bleed rates, and significant differences in event rates between procedural methods used, all warrant further prospective investigation. This will inform clinicians on the combination of technique and methods with the lowest morbidities, and will aid shared decision making with parents and their children. Indeed, it is essential that these figures are established to enable accurate informed consent. The study highlights the potential benefits of more granular clinical coding which would be able to distinguish surgical methods and intra- versus extra-capsular techniques to enable more detailed retrospective analyses of outcomes in the future. In the absence of more granular coding prospective observational data could provide accurate figures for all complications associated with individual procedures and techniques.

The Cumberlege report considered three routine healthcare interventions, which were found, belatedly, to cause avoidable harm.<sup>21</sup> Tonsillectomy, the most common procedure conducted in children, has not been systematically assessed for its safety or efficacy for over 15 years, during which time clinical practice has changed. Using routinely collected national administrative data, this study has indicated that the complication rate of paediatric tonsillectomy has been steadily increasing over the past decade. The procedure is done so frequently (around 30,000 per year in the UK, for example) that, in the light of the Cumberlege recommendations, there can be no excuse for failing to routinely monitor its safety. This study, together with its recommendations for improvement in clinical coding, lays the foundation for how such a monitoring system could be built.

### References

1. Sumilo D, Nichols L, Ryan R, Marshall T. Incidence of indications for tonsillectomy and frequency of evidence-based surgery: a 12-year retrospective cohort study of primary care electronic records. Br J Gen Pract. 2019;69(678):e33-e41.

2. Lowe D, van der Meulen J, Cromwell D, Lewsey J, Copley L, Browne J, et al. Key messages from the National Prospective Tonsillectomy Audit. The Laryngoscope. 2007;117(4):717-24.

3. The National Institute for Health and Care Excellence. Electrosurgery (diathermy and coblation for tonsillectomy. Interventional procedure guidance [IPG490]. 14th December 2005. Available from: https://www.nice.org.uk/guidance/ipg150 [Last accessed 06/11/2020].

4. Herbert A, Wijlaars L, Zylbersztejn A, Cromwell D, Hardelid P. Data Resource Profile: Hospital Episode Statistics Admitted Patient Care (HES APC). Int J Epidemiol. 2017;46(4):1093-1093i.

5. The National Institute for Health and Care Excellence. Broader types of data to be used in development of NICE guidance. Available from: https://www.nice.org.uk/news/article/broader-types-of-data-to-be-used-in-development-of-nice-guidance [Last accessed 06/11/2020]

6. Aylin P, Tanna S, Bottle A, Jarman B. Dr Foster's case notes: how often are adverse events reported in English hospital statistics? BMJ 2004; 329(7462).

7. R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. Available from http://www.R-project.org/ [Last accessed 06/11/2020].

8. Hoey AW, Foden NM, Hadjisymeou Andreou S, Noonan F, Chowdhury AK, Greig SR, et al. Coblation((R)) intracapsular tonsillectomy (tonsillotomy) in children: A prospective study of 500 consecutive cases with long-term follow-up. Clin Otolaryngol. 2017;42(6):1211-7.

9. Albright JT, Duncan NO, Smerica AM, Edmonds JL. Intracapsular complete tonsillectomy, a modification of surgical technique to eliminate delayed post operative bleeding. Int J Ped Otorhinolaryngol 2020 https://doi.org/10.1016/j.ijporl.2019.109703

10. Sathe N, Chinnadurai S, McPheeters M, Francis DO. Comparative Effectiveness of Partial versus Total Tonsillectomy in Children. Otolaryngology - Head & Neck Surgery. 2017;156(3):456-63.

11. Walton J, Ebner Y, Stewart MG, April MM. Systematic review of randomized controlled trials comparing intracapsular tonsillectomy with total tonsillectomy in a pediatric population. Arch Otolaryngol Head Neck Surg. 2012;138(3):243-9.

12. Zhang LY, Zhong L, David M, Cervin A. Tonsillectomy or tonsillotomy? A systematic review for paediatric sleep-disordered breathing. Int J Pediatr Otorhinolaryngol. 2017;103:41-50.

 Mitchell RB, Archer SM, Ishman SL, Rosenfeld RM, Coles S, Finestone SA, et al. Clinical Practice Guideline: Tonsillectomy in Children (Update)-Executive Summary. Otolaryngol Head Neck Surg. 2019;160(2):187-205.

14. Parikh SR, Archer S, Ishman SL, Mitchell RB. Why Is There No Statement Regarding Partial Intracapsular Tonsillectomy (Tonsillotomy) in the New Guidelines? Otolaryngol Head Neck Surg. 2019;160(2):213-4.

15. Ostvoll E, Sunnergren O, Ericsson E, Hemlin C, Hultcrantz E, Odhagen E, et al. Mortality after tonsil surgery, a population study, covering eight years and 82,527 operations in Sweden. European Archives of Oto-Rhino-Laryngology. 2015;272(3):737-43.

 Ahmad MU, Wardak AN, Hampton T, Siddiqui MRS, Street I. Coblation versus cold dissection in paediatric tonsillectomy: a systematic review and meta-analysis. Journal of Laryngology & Otology. 2020;134(3):197-204.

17. Getting It Right First Time. Ear, Nose and Throat Surgery. November 2019. Available from: https://gettingitrightfirsttime.co.uk/wp-content/uploads/2019/12/ENT-Report-Nov19-M.pdf [Last accessed 06/11/2020].

18. Pynnonen M, Brinkmeier JV, Thorne MC, Chong LY, Burton MJ. Coblation versus other surgical techniques for tonsillectomy. Cochrane Database of Systematic Reviews. 2017;8:CD004619.

19. GOV.UK. Codeine for analgesia: restricted use in children because of reports or morphine toxicity. Available from: https://www.gov.uk/drug-safety-update/codeine-for-analgesia-restricted-use-in-children-because-of-reports-of-morphine-toxicity [Last accessed 06/11/2020]

20. Chan SW, Tulloch E, Cooper ES, Smith A, Wojcik W, Norman JE. Montgomery and informed consent: where are we now? BMJ. 2017; 357; j2224

21. First Do No Harm The report of the Independent Medicines and Medical Devices Safety Review.July 2020. Available from: https://www.immdsreview.org.uk/downloads/IMMDSReview\_Web.pdf[Last accessed 06/11/2020]

# **Figure legends**

Figure 1: Tonsillectomy procedures used in the NHS (2008-2019) broken down by procedural method, and reason for admission.

Figure 2: The proportion of patients being readmitted (with error bars representing the 95% confidence intervals) within 28-days of tonsillectomy discharge due to bleeding, pain, infection and return to theatre (RTT) for surgical arrest of tonsillar bleed

Figure 3: Proportion of patients readmitted (with error bars representing the 95% confidence intervals) within 28-days of tonsillectomy discharge due to bleeding and pain separated by procedural method (with significant differences in event rates between methods marked with '\*').

Figure 4: Kaplan Meier analysis for time to further tonsil intervention from index tonsillectomy procedure for dissection (red, n=278,772 patients), and coblation (blue, n=39,681 patients).

Table 1: Demographics by tonsillectomy method.

	Tonsille	Dissecti	Coblatio
	ctomy	on	n
Total procedures	318,453	278,772	39,681
Male gender	157,520	137,032	20,488
	(49.5%)	(49.2%)	(51.6%)
Age, years	5 (4:9)	5 (4:9)	5 (3:8)
median (Q1:Q3) [min-max]	[0-16]	[0-16]	[0-16]
Reason for admission			
- Acute/chronic tonsillitis (J03,J350)	185,435	167,796	17,639
	(58.2%)	(60.2%)	(44.5%)
- Hypertrophy of tonsils/adenoids (J351-3)	79,024	64,348	14,676
	(24.8%)	(23.1%)	(37.0%)
- Sleep apnoea (G473)	33,377	28,425	4952
	(10.5%)	(10.2%)	(12.5%)
- Other	20,617	18,203	2414
	(6.5%)	(6.5%)	(6.1%)
Total with concomitant	172,339	146,752	25,587
adenoidectomy	(53.8%)	(52.6%)	(64.5%)

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Table 2: Patient outcomes by procedural method.

1

28-day

		Total	Dissection	Coblation
		tonsillectomy		
	Length of stay			
	- Day case	148,422 (46.6%)	125,710 (45.1%)	22,712
				(57.2%)
	- 1 night	156,646 (49.2%)	141,450 (50.7%)	15,196
5				(38.3%)
	- More than 1	13,385 (4.2%)	11,612 (4.2%)	1773 (4.5%)
	night			
nes	Total in-hospital	4202 (1.3%)	3634 (1.3%)	568 (1.4%)
TICOL	complications			
	Primary bleed			
ndsc	- Surgical arrest of	1236 (0.4%)	1030 (0.4%)	206 (0.5%)
	postoperative			
	bleeding from			
	tonsillar bed			
	- Surgical arrest of	294 (0.2%*)	266 (0.2%*)	28 (0.1%*)
	postoperative			
	bleeding of			
	adenoid			
	Death (all-cause)	5 (0.0016%)	2 (0.0007%)	3 (0.0076%)
	Readmitted	28,170 (8.8%)	24,266 (8.7%)	3904 (9.8%)
	- Bleed	16,120 (5.1%)	13,902 (5.0%)	2218 (5.6%)
	- Infection	2483 (0.8%)	2181 (0.8%)	302 (0.8%)
	- Pain	1243 (0.4%)	1072 (0.4%)	171 (0.4%)
	Secondary bleed			
es	- Surgical arrest of	2485 (0.8%)	2130 (0.8%)	355 (0.9%)
com	postoperative			
out	bleeding from			
	tonsillar bed			
	- Surgical arrest of	33 (0.019%*)	29 (0.020%*)	4 (0.016%*)
	postoperative			
	bleeding of			
	adenoid			

	Death (all-cause)	7 (0.0022%)	6 (0.0021%)	1 (0.0025%)
*1	Denominator combines tot	al adenoidectomy and suction di	athermy adenoidectomy	I
Y				
4				

Acce



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