

Tonsil surgery

STUDIES ON SURGICAL METHODS
AND POSTOPERATIVE HAEMORRHAGE

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UNIVERSITY OF GOTHENBURG

Cover illustration: Cold steel tonsillectomy instruments. Photo: Jonas Berg

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To Emma, Alice, John and Hjalmar

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Abstract

Tonsil surgery is one of the most common surgical procedures in the world, with about 13,500 operations performed annually in Sweden. Sleep-disordered breathing in children and infection-related problems are the two most common indications. Tonsil surgery is an effective treatment, but is often associated with pain and discomfort, as well as risk of complications, the most serious of which is postoperative haemorrhage. There are two types of tonsil surgery: complete removal of the tonsils (tonsillectomy) or partial removal (tonsillotomy). Given the large number of procedures carried out annually, it becomes extremely important to minimise the risks of this procedure insofar as possible. The overarching purpose of the thesis is to identify risk factors for preventable complications of tonsil surgery. The purpose was also to assess and compare postoperative complications and the risk of reoperation following TT and TE in children.

METHODS/RESULTS: *Paper I*, a retrospective cohort study based on the National Tonsil Surgery Register in Sweden (NTSRS), describes the occurrence of post-tonsillectomy haemorrhage (PTH), as well as how the risk of haemorrhage is related to surgical technique. The study, which included 15,734 patients, shows that all hot techniques used for dissection and haemostasis increase the risk of late PTH, compared with cold dissection and cold haemostasis. The study also shows that the occurrence of early PTH (during hospital stay) increases the risk of late PTH after discharge. *Paper II* aims to describe and assess a quality improvement project (QIP) with the goal of reducing postoperative haemorrhage following tonsillectomy. Six ENT surgical centres, all with PTH rates above the Swedish average, participated in a seven-month QIP. A case study design is used in which

changes implemented by the surgical centres are described and the outcome monitored in the NTSRS. The six surgical units reduced the rate of PTH from 12.7% the year before the project to 7.1% the year after. **Paper III**, a retrospective register-based cohort study, compares the risk of reoperation after TE and TT in children with upper airway obstruction. A total of 27,535 patients, aged 1-12 years, who had tonsil surgery between 2007 and 2012 in Sweden, were identified using the National Patient Register (NPR). The risk of additional tonsil surgery was 7 times higher after TT compared with TE, with the greatest differences between groups found among the youngest children. **Paper IV**, a register-based cohort study, describes postoperative morbidity following TE and TT in children with tonsil-related upper airway obstruction. A total of 35,060 patients, aged 1-12 years, who had tonsil surgery between 2007 and 2015 in Sweden were identified through the NPR. TT entails less risk for postoperative complications than TE. This was observed for all outcome variables: readmission due to postoperative haemorrhage, return to theatre due to postoperative haemorrhage, readmission for any reason, and postoperative contact with health services for any reason.

CONCLUSIONS: Hot surgical techniques increase the risk of late PTH compared with cold dissection and cold haemostasis. The rate of PTH can be reduced by a QIP based on data from a national quality register. The risk of reoperation is seven times higher following TT compared with TE in children with tonsil-related upper airway obstruction. TT is associated with significantly less risk of postoperative complications compared with TE among children treated surgically for upper airway obstruction.

KEYWORDS: Post-tonsillectomy haemorrhage, Quality improvement project, Tonsillectomy, Tonsillotomy, Reoperation, Postoperative morbidity

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Sammanfattning på svenska

Tonsilloperation är ett av de vanligaste kirurgiska ingreppen i världen, där det i Sverige utförs ca 13500 operationer årligen. Sömnrelaterad andningsstörning hos barn och infektionsrelaterade besvär är de två vanligaste indikationerna. Tonsilloperation är en effektiv behandling men medför ofta smärta och obehag, samt risk för komplikationer där blödning är den mest allvarliga. Det finns två typer av tonsilloperation; borttagande av hela halsmandlarna (tonsillektomi) eller del av dem (tonsillotomi). Vid sömnrelaterad andningsstörning hos barn har tonsillotomi, i mindre kontrollerade studier, visat sig vara lika effektivt som tonsillektomi samt ha en mindre risk för postoperativa komplikationer. Nackdelen med tonsillotomi är risk för återväxt och ett eventuellt behov av en reoperation vilket belyses i delarbete 3. Givet det stora antalet operationer som utförs årligen är det av stor vikt att i möjligaste mån minimera riskerna med operationen. Avhandlingens övergripande syfte var att identifiera riskfaktorer för komplikationer som är möjliga att förebygga vid tonsilloperation. Syftet var också att utvärdera och jämföra postoperativa komplikationer och risk för reoperation efter tonsillotomi och tonsillektomi hos barn.

Delarbete 1, en retrospektiv kohortstudie baserad på det svenska kvalitetsregistret för tonsilloperation, beskrev förekomst av blödning efter tonsillektomi samt hur risken för blödning påverkades av operationstekniken. Studien som inkluderade 15734 patienter visade att samtliga varma tekniker vid dissektion och hemostas ökade risken för sena blödningar efter tonsillektomi, jämfört med kall dissektion och kall hemostas. Studien visade även att förekomst av tidig blödning (under sjukhusvistelsen) ökade risken för blödning under läkningsfasen efter utskrivning.

Delarbete 2 syftade till att beskriva och utvärdera ett kvalitetsförbättringsprojekt med mål att minska postoperativa blödningar efter tonsillektomi. Sex ÖNH-kliniker, alla med blödningsfrekvens över det svenska genomsnittet, deltog i ett sju månaders kvalitetsförbättringsprojekt. Studien lades upp som en fallstudie där klinikernas förändringar beskrevs och utfallet följdes i det svenska kvalitetsregistret för tonsilloperation. De sex klinikerna minskade frekvensen av postoperativa blödningar från 12.7% året före projektet till 7.1% året efter. Man såg också en ökad användning av kalla operationstekniker bland dessa kliniker.

Delarbete 3, en retrospektiv registerbaserad kohortstudie, jämförde risken för reoperation efter tonsillektomi och tonsillotomi hos barn med övre

luftvägsobstruktion. Genom Patientregistret identifierades 27535 patienter, 1–12 år som tonsillopererats 2007–2012 i Sverige. Risken för ytterligare tonsillkirurgi var 7 gånger högre efter tonsillotomi jämfört med tonsillektomi, med den största skillnaden mellan grupperna bland de yngsta barnen.

Delarbete 4 utgjordes av en registerbaserad kohortstudie som beskrev postoperativ morbiditet efter tonsillektomi och tonsillotomi hos barn med tonsillrelaterad övre luftvägsobstruktion. I Socialstyrelsens Patientregister identifierades 35060 barn 1–12 år som tonsillopererats 2007–2015 i Sverige. Tonsillotomi innebar mindre risk för postoperativa komplikationer än tonsillektomi. Detta sågs för samtliga utfallsvariabler nämligen; återinläggning pga. postoperativ blödning, reoperation pga. postoperativ blödning, återinläggning av någon anledning samt kontakt med sjukvården.

List of papers

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Söderman AC, Odhagen E, Ericsson E, Hemlin C, Hultcrantz E, Sunnergren O, Stalfors J.

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.

Clinical Otolaryngology. 2015 Jun;40(3):248-54

II. Odhagen E, Sunnergren O, Söderman AH, Thor J, Stalfors J.

Reducing post-tonsillectomy haemorrhage rates through a quality improvement project using a Swedish National quality register: a case study.

European Archives of Otorhinolaryngology. 2018 Jun;275(6):1631-1639

III. Odhagen E, Sunnergren O, Hemlin C, Hessén Söderman AC, Ericsson E, Stalfors J.

Risk of reoperation after tonsillotomy versus tonsillectomy: a population-based cohort study.

European Archives of Otorhinolaryngology. 2016 Oct;273(10):3263-8

IV. Odhagen E, Stalfors J, Sunnergren O.

Morbidity after pediatric tonsillotomy versus tonsillectomy: a population-based cohort study.

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Abbreviations

A	Adenoidectomy
AHI	Apnoea-Hypopnoea Index
ATE	Adenotonsillectomy
ATT	Adenotonsillotomy
CI	Confidence interval
ENT	Ear, nose, and throat
GABHS	Group A beta-haemolytic Streptococcus
HR	Hazard ratio
ICD	International Statistical Classification of Diseases
NOMESCO	Nordic Medico-Statistical Committee Classification of Surgical Procedures
NPR	Swedish National Patient Register
NTSRS	National Tonsil Surgery Register in Sweden
OR	Odds ratio
OSA	Obstructive sleep apnoea
PONV	Postoperative nausea and vomiting
PROM	Patient-reported outcome measure
PSG	Polysomnography
PTH	Post-tonsillectomy haemorrhage
QIP	Quality improvement project
QoL	Quality of life
RCT	Randomised controlled trial
ROC	Receiver operating characteristics
RR	Relative risk
RTT	Return to theatre
SD	Standard deviation
SDB	Sleep disordered breathing
TE	Tonsillectomy
TT	Tonsillotomy

1.



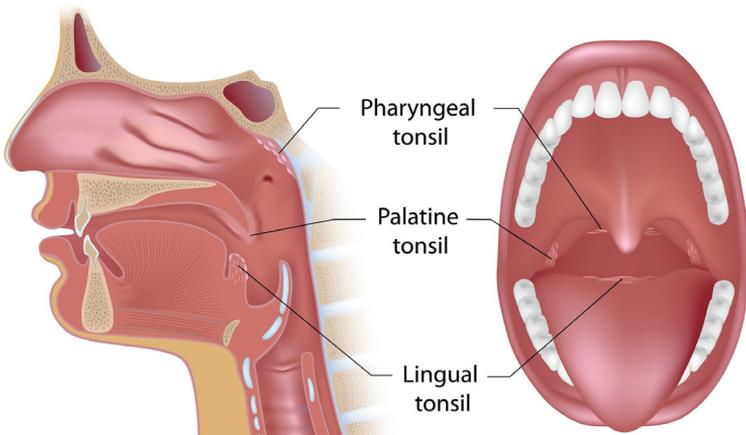
Introduction

“This operation is not only too severe and cruel, but also too difficult in the performance to come much into the practice of the moderns, because of the obscure situation of the tonsils.”

This is how Heister Lorenz (1683-1758), German professor of anatomy and surgery, describes tonsil surgery in his work *Chirurgie* from 1719.¹ Much has changed both in regard to surgical technique and indications since the eighteenth century and today tonsil surgery is considered to be a simple and common procedure, one of the first operations taught to younger ENT doctors. Tonsil surgery has proven to be an effective treatment, but is often associated with pain and discomfort, as well as risk of complications, the most serious of which is postoperative haemorrhage.² Given the large number of procedures carried out annually, it becomes extremely important to minimise the risks of this procedure insofar as possible. This thesis is based on studies that focus on the various aspects of complications associated with tonsil surgery, how they are affected by different surgical techniques and methods, as well as what changes can be made to minimise complications.

1.1 THE TONSILS

The pharynx possesses a circular lymphatic barrier that surrounds the entry opening into the airways and oesophagus called Waldeyer’s ring.^{3,4} This ring consists of structured lymphatic tissue in which the anterior portion comprises the lingual tonsils, which are located at the posterior base of the tongue. The palatine tonsils (referred to in this thesis as the tonsils) and lymphoid tissue adjacent to the meatus of the auditory tube (tubal tonsils) comprise the lateral portions of the ring. The pharyngeal tonsils or adenoids, which are located in



the nasopharynx, comprise the posterior and superior portions of the ring. Sparse lymphoid tissue can be found scattered between these formations.^{3,5} The two palatine tonsils are located in their respective tonsillar fossa. The tonsillar fossa is bordered anteriorly by the palatoglossus muscle, which comprises the anterior tonsillar pillar, and posteriorly by the palatopharyngeal muscle, which comprises the posterior tonsillar pillar. The pharyngeal constrictor comprises the bottom of the fossa and covers the glossopharyngeal nerve. The nerve supply to the palatine tonsils originates from the glossopharyngeal nerve and the maxillary nerve. The primary blood supply comes from the tonsillar branch of the facial artery, which originates from the external carotid artery. The tonsillar bed is also supplied with blood from small branches of the ascending palatine, lingual, descending palatine and ascending pharyngeal arteries.⁵

The lymphatic tissue in Waldeyer's ring is strategically located to react to airborne and foodborne antigens and thereby plays an important defensive role as part of the mucosal immune system.⁶ The tonsils consist of various immune cells where the presence of antibody-producing B-cells in lymphoid follicles is a salient feature.^{3,7} The question of whether tonsil surgery may have a negative impact on the immune system has remained controversial over the years and is still subject to debate. A recently published review article concludes that there is no evidence that tonsil surgery has a negative impact on the immune system.⁸

1.2 TONSIL SURGERY – A BRIEF HISTORY

Tonsil surgery has a long history and was first mentioned in the literature almost 3,000 years ago.⁹ Roman author Aulus Cornelius Celsus provided the first detailed description of tonsil surgery in 30 AD. He described a technique of using a finger to remove the tonsils and if unsuccessful, recommended using a scalpel. Afterwards, the fossae should be washed out with vinegar and painted with a medication to reduce bleeding.¹⁰ Surgical techniques made rapid progress during the nineteenth century and a variety of instruments from this era were developed to excise the tonsils including special knives, wires and automated instruments such as the tonsil guillotine or tonsillotomes.¹¹ Inadequate anaesthesia made it imperative that the procedure be carried out swiftly. The various techniques described prior to the twentieth century entailed removing only a portion of the tonsil, which meant that the procedure was actually a “tonsillotomy” or “subtotal tonsillectomy”. Note was taken in the late nineteenth century that although the tonsillotomy procedure was swift, the outcomes were hardly satisfactory.¹¹ Recurrent infections in the tonsillar remnants (infection was the dominant indication during this period) and regrowth were problematic, motivating further development of the procedure in order to remove the

entire tonsil, known as total tonsillectomy. One of the earliest publications to describe total tonsillectomy was written by the American otorhinolaryngologist Griffin in 1907.¹² At about the same time, in 1909, the British surgeon Waugh published a detailed description in the *Lancet* of a dissection technique to remove the tonsils in their entirety.¹³

During the first half of the twentieth century, tonsillotomy and tonsillectomy were both commonly carried out, but around the 1950s, as advances were made in anaesthesiologic methods, tonsillectomy came to be the predominant procedure, while tonsillotomy was abandoned.⁹ The transition to tonsillectomy, however, increased the need for inpatient care since this method was considered to be associated with more pain and an increased risk of serious postoperative bleeding.⁹ During the latter half of the twentieth century electrosurgical devices were developed with the aim of reducing both operation time and intraoperative bleeding. However, not until the 1980s did electrosurgical devices come into popular use for tonsillectomy.¹⁴

Meanwhile, the indications for tonsillectomy also changed. Recurrent infections have long been the predominant indication, but as oral penicillin became readily available in the 1960s, the number of tonsil surgeries dramatically declined.⁹ During the following decades, 1970-2000, the number of patients operated for sleep-disordered breathing due to upper airway obstruction increased and today this is the main indication, at least in children.^{15,16} Despite the technological advances, tonsillectomy continues to be associated with postoperative pain and risk of both intraoperative and postoperative bleeding. Consequently, there is an ongoing search for alternative surgical methods and since the 1990s, the previously abandoned tonsillotomy has once again become popular in many countries, including Sweden, for the surgical treatment of SDB.^{9,14}

1.3 CURRENT STATE OF TONSIL SURGERY

Tonsil surgery is still one of the most common surgical procedures in the world, and in the US about 700,000 tonsillectomies are performed annually.¹⁷ In Sweden, a country with a population of almost 10 million, about 13,500 tonsil surgeries are carried out annually.¹⁸ Most of the procedures in Sweden, about 70%,¹⁵ are done on an outpatient basis, which is generally considered to be safe for tonsil surgery.^{19,20} There are large variations in the reported number of tonsil surgeries carried out both within and between countries, worldwide.^{21,22} The argument has been made that such variations are usually due to differences in clinical practices and education, rather than any differences in the actual need for care.²³ In Sweden today, both tonsillectomy (TE), complete removal of the

tonsils, and tonsillectomy (TT) partial removal are carried out.¹⁵ The two main indications for tonsil surgery are: 1) upper airway obstruction in children and 2) infection-related problems such as recurrent tonsillitis, chronic tonsillitis and peritonsillar abscess. Tonsil surgery is often carried out in combination with adenoidectomy (surgical removal of adenoid tissue from the nasopharynx), especially for the indication upper airway obstruction. Patients operated for upper airway obstruction are usually younger (disease incidence peaks at ages 3-5 years) and predominantly male, while patients operated for infection-related problems are somewhat older (disease incidence peaks at 16-18 years) and predominantly female.^{24,25} Less common surgical indications include dysphagia, speech abnormalities, orthodontic aberrations and malignancy or suspicion of malignancy, none of which will be further discussed in this thesis.

1.4 INDICATIONS

1.4.1 Upper airway obstruction

Upper airway obstruction in children is the most common indication for tonsil surgery, with or without simultaneous adenoidectomy.^{15,16} The main symptom of upper airway obstruction caused by hypertrophy of the tonsils and/or adenoids is sleep-disordered breathing (SDB). SDB encompasses a broad spectrum of symptoms of varying clinical severity, ranging from primary snoring to pronounced obstructive sleep apnoea (OSA) with disturbed breathing during sleep characterised by prolonged periods of incomplete and/or intermittent complete upper airway obstruction.²⁶

Polysomnography (PSG) is considered to be the gold standard for diagnosing SDB.²⁷ The Apnoea-Hypopnoea Index (AHI) which describes the number of episodes apnoea and hypopnoea per hour of sleep is the PSG parameter most often used to determine the severity of SDB.²⁸ An AHI of >5 has been used as a cut-off value for tonsil surgery, but lower limits have also been used.²⁹ The major disadvantage of PSG is its limited availability in many countries, including Sweden. In the UK and the US fewer than 10% of patients who have tonsil surgery for the indication SDB undergo PSG prior to surgery.^{30,31} The majority of cases of paediatric SDB are therefore diagnosed through history and clinical examination,³¹ despite the demonstrated low predictive value of these methods.²⁷

Tonsillectomy with or without adenoidectomy (TE ± A) has been the traditional first-line treatment for children with SDB.³² However, no well-designed studies have been carried out comparing the outcome of isolated adenoidectomy, tonsillectomy, or adenotonsillectomy in children with SDB.²⁹ Several studies have shown that TE is an effective treatment for SDB in otherwise healthy children

with enlarged tonsils,^{33,34} but the procedure is also associated with postoperative morbidity including pain, bleeding and infection.³⁵ Consequently, in recent decades TT has become increasingly common for the surgical treatment of SDB.²⁵ Since 2011 Sweden recommends TT as first-line surgical treatment for SDB that is assessed to be due to tonsillar hypertrophy.³⁶

1.4.2 Infection-related indications

From an historical perspective, infection-related problems have been the main indication for tonsil surgery and currently account for about 35% of the total number of tonsil surgeries in Sweden.¹⁵ Acute tonsillitis or pharyngotonsillitis is a common condition that may be caused by either bacteria or viruses, where the latter is the most common.³⁷ Regarding bacterial tonsillitis, the overwhelmingly predominant agent is *Streptococcus Pyogenes*, also known as group A beta-haemolytic *Streptococcus* (GABHS).³⁸ Since GABHS tonsillitis is treatable with antibiotics and untreated puts patients at increased risk of suppurative complications (e.g. peritonsillar abscess, cervical lymphadenitis, mastoiditis, sinusitis and otitis media) and rheumatic fever, it becomes important to determine the aetiology of the diagnosis, especially in patients with recurrent tonsillitis.^{38,39} The evidence in support of tonsil surgery to treat recurrent tonsillitis is limited and most studies were conducted on a paediatric population.⁴⁰ In 1984 Paradise et al. published their well-known study highlighting the benefits of tonsillectomy for treatment of recurrent tonsillitis in children. Table 1 summarises the commonly used Paradise criteria for TE.⁴¹

TABLE 1
Paradise criteria for tonsillectomy.

Criterion	Definition
Minimum frequency of sore throat episodes	≥ 7 episodes in the preceding year OR ≥ 5 episodes in each of the preceding 2 years OR ≥ 3 episodes in each of the preceding 3 years
Clinical features (sore throat plus the presence of one or more qualifies as a counting episode)	Temperature > 38.3°C OR Tonsillar exudate OR Positive lymphadenopathy (tender lymph nodes or > 2 cm) OR Positive culture for GABHS

In recent years, several national guidelines have been published pertaining to tonsil surgery for recurrent tonsillitis. In summary, all guidelines recommend conservative treatment and watchful waiting before tonsil surgery.^{40,42-44} Most guidelines, including those from the UK and the US, are based on the Paradise criteria.^{40,43} In 2009 the Swedish Association for Otorhinolaryngology, Head and Neck surgery published the Swedish national guidelines for tonsil surgery.

These guidelines have somewhat broader indications for tonsil surgery than the Paradise criteria since they took into account studies that demonstrated the benefits of tonsil surgery even among children with somewhat fewer episodes of tonsillitis.⁴⁵ Moreover, the Swedish guidelines make no distinction between whether the cause of the tonsillitis is viral or bacterial. The Swedish treatment guidelines for tonsil surgery in recurrent tonsillitis are summarised below.⁴⁶

TABLE 2
Swedish guidelines for tonsil surgery in recurrent tonsillitis (translated from Swedish).

Base criteria	Additional criteria
1. Sore throat due to tonsillitis	<ul style="list-style-type: none"> • At least 3-4 episodes of tonsillitis • Recurrent fever in children with no other focus of infection • Systemic disease worsened by tonsillitis
2. Sore throat symptoms affect patient's ability to participate common activities	
3. Epidemiological situation with determination of source of infection (if any) with adherence to treatment ladder recommendations concerning antibiotics	

Indications for tonsil surgery

All base criteria should be met along with at least one additional criterion. The duration of the problems is limited by the base criteria. The shortest period is limited to one year due to base criterion 3 and the longest to two years due to base criterion 2.

The term “chronic tonsillitis” is poorly defined in the literature, but has been described as a sore throat with inflammation of the tonsils for a duration of at least 3 months.⁴⁷ Tonsillectomy has been proposed as treatment in cases where improvement does not occur despite appropriate treatment with antibiotics.^{47,48} No clinical guidelines have been established for when tonsil surgery is appropriate for treatment of chronic tonsillitis as defined above.

Peritonsillar abscess entails an accumulation of pus between the tonsil and surrounding muscles. Typical symptoms include pain on swallowing, trismus, muffled voice, fever and impaired general health. The clinical presentation entails asymmetry of the oropharynx with swelling of the soft palate and displacement of the uvula to the contralateral side.⁴⁹ Acute surgical treatment of peritonsillar abscess includes needle aspiration, incisional drainage and abscess tonsillectomy (tonsillectomy á chaud).⁵⁰ The literature contains contradictory information concerning the benefits of abscess TE versus elective prophylactic TE.^{49,51} An evidence-based review by Powell et al. recommends abscess TE when needle aspiration or incisional drainage are not tolerated under local anaesthesia, which is often the case among children.⁵⁰ According to the Swedish national guidelines, there is an indication for elective TE when two episodes of

peritonsillar abscess occur in the adult population or a single episode in children, without taking prior infections into account.⁴⁶

1.5 SURGICAL METHODS

1.5.1 Tonsillectomy

Tonsillectomy (TE) involves the removal of the entire tonsil, including the surrounding capsule, through dissection of the peritonsillar space between the tonsil and the muscle wall in the tonsillar fossa. The traditional technique of cold steel dissection and cold haemostasis, using packs and ligatures, is considered to be the gold standard for TE.⁵² Since the introduction of electrosurgical devices 30 years ago many new TE techniques have been introduced, aimed at reducing operation time, intraoperative bleeding and postoperative complications.⁵³ Common to all these techniques is the transfer of heat in some form, for which reason they are often known as hot techniques.⁵² In many countries, including Sweden, hot techniques have become common and the exclusively cold technique is used less often.⁵⁴ The most common hot surgical techniques for TE are presented below.

Diathermy

Diathermy is a technique that uses electrical current to generate heat (about 400-600°C) for the surgical instrument which burns away tissue while simultaneously achieving haemostasis. The diathermy instrument can be used both for dissection of the tonsil and for haemostasis. There are basically two types of diathermy: monopolar and bipolar. In monopolar diathermy, a single electrode, known as a grounding pad, is placed somewhere on the patient's body, often the thigh. The surgical instrument contains the other electrode, where the heat is generated. In bipolar diathermy, both electrodes are placed in the surgical instrument, usually a forceps or scissors used for dissection of the tonsils.⁵⁵

Coblation®

Coblation TE was introduced in the late 1990s. The coblation instrument uses radiofrequency energy to dissect the tissues, but at substantially lower tissue temperatures than diathermy (40-70°C compared with 400-600°C). Radiofrequency energy is sent through a conductive medium, a saline solution, which creates a plasma field that divides tissue and coagulates blood vessels.⁵⁶

Vessel-sealing systems

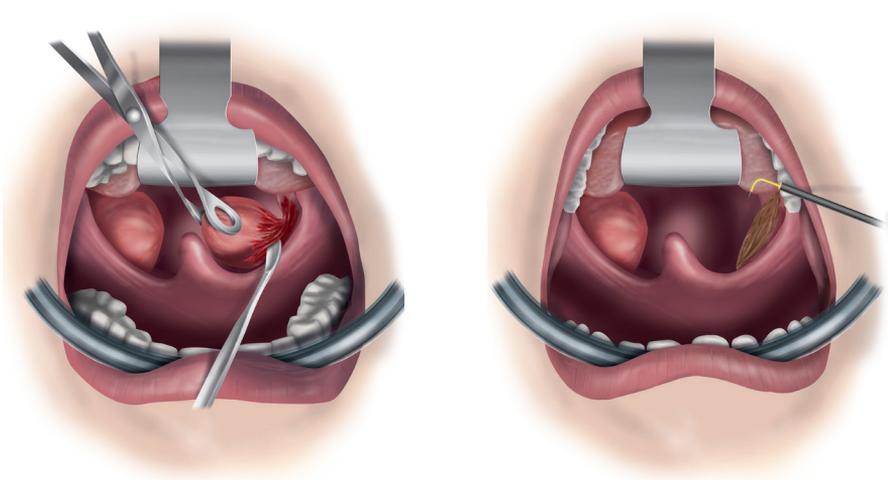
Common to vessel-sealing systems (e.g. LigaSure®, Thermal Welding®) is the use of handheld surgical instruments that measure tissue impedance for the purpose of adjusting and minimising the delivery of electrical current, which

results in less tissue damage. The advantage claimed for these systems is the ability to divide larger vessels (up to 5 mm).⁵⁷

Ultrasound/Harmonic scalpel

The harmonic scalpel is an ultrasonic dissection coagulator. This instrument converts electrical energy to high frequency vibrations (55 KHz per second) which dissects tissues and achieves coagulation at lower temperatures (50-100° C) compared with diathermy.⁵⁷

In summary, a large number of studies have been published in recent years comparing various electrosurgical techniques for tonsillectomy. It can be concluded that the principal advantages of using hot techniques are reduced intra-operative bleeding and operation time.⁵⁸ Hot techniques, however, have been shown to increase the risk of late post-tonsillectomy haemorrhage (PTH),⁵³ which is further investigated and discussed in paper I.



Cold steel tonsillectomy

Radiofrequency tonsillotomy

1.5.2 Tonsillotomy

Tonsillotomy (TT) entails partial excision of the tonsils where some tonsillar tissue and the lateral capsule are left intact to protect underlying nerves and blood vessels. The procedure is also referred to as subtotal, intracapsular or partial TE. It has been suggested that this procedure be classified as either tonsillotomy (Class 1) or subtotal/intracapsular/partial tonsillectomy (Class 2).⁵⁹ In Class 1 procedures the anterior and posterior palatine arches are used as anatomical landmarks to determine the quantity of tonsillar tissue to be removed.

In Class 2 procedures the goal is to remove most of the tonsillar tissue, leaving only a rim of tissue in the tonsillar fossa.⁵⁹ Different methods can be used for TT, including radiofrequency instruments, coblation and microdebrider. Common for radiofrequency instruments is that the instrument delivers radiofrequency energy (>4.0 MHz) that excite electrolytes in the tissue to cut and coagulate at lower temperatures than diathermy.⁶⁰ The microdebrider is a mechanical surgical instrument which uses a cutting blade that rotates at high speed to dissect and remove tonsillar tissue. Since no heat is applied, postoperative complications appear to be minor, but an increase in operation time and a somewhat higher rate of intraoperative bleeding have been described.⁵⁹ In Sweden TT is well accepted as surgical treatment for SDB. Almost all paediatric TTs in Sweden are carried out using radiofrequency instruments.⁶⁰

1.6 EFFECTIVENESS OF TONSIL SURGERY

1.6.1 Infection-related indications

The evidence supporting the benefits of tonsil surgery to treat recurrent tonsillitis is limited and most studies were conducted on a paediatric population.⁴⁰ A recently published Cochrane review compared TE with non-surgical treatment for recurrent acute tonsillitis, focusing on reducing the severity and number of episodes.⁶¹ The authors concluded that TE in children results in a reduction of the number of episodes and days spent with sore throat during the first postoperative year compared with non-surgical treatment. In addition to the two articles published by Paradise et al.^{41,45} mentioned above, only three additional studies on TE in children were included. Moreover, the scientific basis was too limited for the authors to express their opinions on the benefits of tonsil surgery for recurrent tonsillitis in adults since only two randomised controlled trials (RCT) were included in the overview.⁶¹ In a small (n=70) RCT, Alho et al. showed benefit from TE in adults with confirmed recurrent streptococcal pharyngitis. TE reduced the incidence of GABHS during the 90-day follow-up period with number needed to treat = 5.⁶²

However, several studies focused on patient-reported outcome measures (PROMs) and quality of life have shown benefit from tonsil surgery for recurrent tonsillitis in both children and adults. In 2012 Stalfors et al. published an article based on data from 1997-2008 obtained from the National Tonsil Surgery Register in Sweden (NTSRS) and found that 97% of patients who had surgery for recurrent tonsillitis stated that “My symptoms are gone” or “My symptoms are almost gone” six months after surgery.²⁴ In a systematic review from 2013 the authors conclude that “the identified literature provides consistent evidence that TE is likely to produce long-lasting and continuous improvement of general

QoL in adult patients”.⁶³ In a 2008 study regarding quality of life (QoL) after TE in children with recurrent tonsillitis, Goldstein et al. concluded that patients showed significant improvements in disease-specific and global QoL after surgery.⁶⁴

1.6.2 Upper airway obstruction

Several studies show that TE, with or with or without adenoidectomy, is an effective treatment for SDB in otherwise healthy children with enlarged tonsils, resulting in improved symptoms, PSG outcomes, behavioural outcomes and quality of life.^{33,34,65,66} Although TE is considered to be an effective treatment, it is not curative in all patients. A meta-analysis from 2016 drawing on 51 studies with a total of 3414 patients showed an average reduction of AHI of 12.4 events/hour after TE with a success rate of 51% for AHI <1 postoperatively and 81% for AHI < 5. Residual disease was more common among patients with severe OSA and obesity.⁶⁷

1.7 COMPLICATIONS OF TONSIL SURGERY

Even though tonsil surgery is generally considered to be a safe treatment, the procedure is associated with a risk of complications and postoperative morbidity. Potential complications can be divided into intraoperative, early postoperative (within 30 days) and late postoperative. Table 3 presents an overview of complications described in the literature.^{2,35,68,69}

TABLE 3

Complications of tonsil surgery.

Intraoperative complications	Anaesthetic complications Excessive intraoperative haemorrhage
Early postoperative complications (within 30 days after surgery)	Nausea, vomiting (PONV) Pain Dehydration Haemorrhage Infection Grisel’s syndrome
Late postoperative complications	Taste disorders Eagle syndrome Velopharyngeal insufficiency

This thesis focuses on the most common category in Table 3, that of early postoperative complications (within 30 days), which often result in repeat visits that increase the load on the healthcare system. Shay et al. reported a 7.6% revisit rate following paediatric TE, with acute pain given as the most common cause.⁷⁰ Similar figures were reported by Bhattacharyya et al. following TE in adults,

with a revisit rate of 11.6%, where postoperative bleeding was the most common cause followed by acute pain and fever/dehydration.⁷¹

Post-tonsillectomy haemorrhage (PTH) is the most dreaded complication following tonsil surgery. PTH is a potentially life-threatening event that often results in acute hospitalisation and sometimes a return to the operating theatre. Reported incidence of PTH varies in the literature, and large recently published studies suggest a rate ranging between 6% and 15%.⁷²⁻⁷⁵ It is likely that the variations can largely be explained by different definitions of PTH, different study designs and different populations. In the literature, PTH has often been classified as either early (within 24 hours) or late bleeding (> 24 hours) depending on when the problem occurs.⁷² The time when PTH occurs appears to follow a certain pattern, with a higher rate of PTH on the day of surgery, as well as during days 5-8 postoperatively.⁷⁶ The literature frequently addresses risk factors for PTH and other than the indication of infection-related conditions, which appear to put patients at higher risk of PTH,^{77,78} a number of additional factors have been studied, including age,⁷⁸⁻⁸⁰ gender,⁸¹ the surgeon's experience,⁸² medication use,⁸² other concurrent surgery⁸² and the use of disposable instruments.⁸¹ Surgical technique has also been discussed as a risk factor for PTH and serves as the basis for study I in this thesis.^{53,81} Studies of risk factors for PTH often compare a specific subgroup with the entire population of patients who had tonsil surgery. This approach may overlook how risk factors that affect PTH interact. Just a handful of authors have used multivariable logistic regression to test multiple risk factors simultaneously in a model.^{81,83,84}

Fatal outcome following PTH is rare but should not be overlooked. A large Swedish cohort study reported a mortality rate of 1/40,000 following tonsil surgery (including both TE and TT).⁸⁵ In Austria, 5 children under the age of 6 died of severe post-tonsillectomy haemorrhage in 2006-2007.⁸⁶

It is well known that tonsil surgery is associated with significant postoperative pain.⁸⁷ The pain is described as moderate to severe and often persists for one to two weeks in children.^{88,89} Among adults, pain reportedly lasts for an average of twelve days after TE.⁹⁰ The pain typically follows a pattern with less pain the first few days, followed by an increase on days 4-5 and finally a decrease from day 6 onward.⁹¹ Most tonsil surgery is conducted on an outpatient basis, which means that patients themselves or their parents/guardians are responsible for pain management.⁹² Inadequate pain control may lead to poor nutritional intake, dehydration and an increased need for inpatient care.^{43,69} Both paracetamol and Cox-inhibitors are effective pharmacological treatment for such pain, which has been well-documented in a number of studies.^{93,94} Children reportedly often experience inadequate pain control at home following

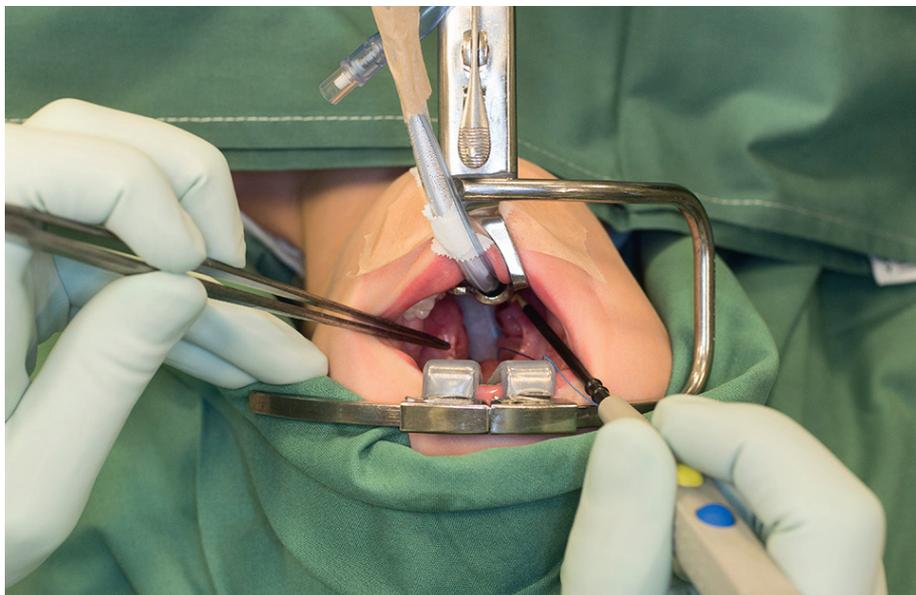
tonsil surgery.⁸⁹ This was the basis for formulating the 2013 Swedish national guidelines for pharmacological treatment of pain associated with tonsil surgery in children. These guidelines recommend paracetamol combined with COX-inhibitors for postoperative pain management, and if necessary, the addition of oral clonidine as first-line add-on treatment, followed by opioids.⁹⁵

A Cochrane review showed that there is no evidence that local anaesthesia in conjunction with tonsil surgery decreases postoperative pain.⁹⁶ Postoperative infection has been proposed as a contributing factor to pain following tonsil surgery. Routine treatment with antibiotics following tonsil surgery, however, has been shown to have very little or no effect on postoperative pain and a return to normal diet.^{97,98}

Postoperative nausea and vomiting (PONV) is a common problem following tonsil surgery and reportedly occurs in 50%-80% of children who did not receive prophylactic antiemetics.^{99,100} Corticosteroids and antiemetics administered preoperatively have been shown to significantly decrease the risk of PONV.^{101,102}

1.8 TONSILLECTOMY VS TONSILLOTOMY

At the end of the 1990s the first studies were published comparing TT with TE in children with upper airway obstruction and SDB.¹⁰³ Some of the first randomised studies were conducted in Sweden by Hultcrantz and Ericsson, who initially used CO2 laser methodology for TT, to be followed in later publications by use of the radiofrequency technique.¹⁰³⁻¹⁰⁵ The results showed a shorter recovery period and less postoperative morbidity following TT compared with TE. Subsequently, a number of studies have been published showing that TT is associated with less postoperative morbidity than TE for the indication upper airway obstruction/SDB in children. In 2012 Walton et al. published a systematic overview of RCTs comparing TE and TT in children with SDB. The authors looked at 16 RCTs and concluded that TT was equivalent or superior to TE in regard to recovery-related outcomes, including postoperative pain, secondary bleeding and return to normal diet.¹⁰⁶ In addition, TT has proven to be as effective as TE regarding improvement in self-reported symptom relief, quality of life and airway obstruction during sleep, as measured by PSG.¹⁰⁷⁻¹⁰⁹ The major objection to TT has been the potential risk of regrowth of the tonsils with recurrent upper airway obstruction and/or future infections in the tonsillar remnants, which may require repeat tonsil surgery. Several published studies investigated this question and reported reoperation rates of 0% – 11.9%.¹¹⁰ Unfortunately, many of these studies were quite small or had short follow-up times, for which reason the results should be interpreted with caution. The lack of studies with



Radiofrequency tonsillectomy, Södra Älvsborg Hospital. Photo: Pernilla Lundgren.

larger groups of patients and longer follow-up times has been noted by multiple authors,^{106,110,111} which set the background for study III in this thesis.

In Sweden, TT has gradually replaced TE as the most common surgical treatment for children with SDB.²⁵ In 2013 TT accounted for 77% of tonsil surgeries conducted on children with SDB in Sweden.¹⁸ Despite the wide use of TT, there is still a lack of population-based studies comparing postoperative morbidity in paediatric TT vs TE. Most published reports are hospital-based single-centre series on small numbers of patients.¹¹⁰ Compared with small single-centre studies, larger population-based studies allow for investigation of the clinical consequences of a new surgical method in a less controlled environment. Moreover, population-based cohort studies are suitable for the study of more unusual outcomes and the investigation of prognostic factors associated with postoperative morbidity.^{56,112} And this comprises the background for study IV in this thesis.

1.9 REGISTRY-BASED RESEARCH

The introduction of any new surgical method, such as the use of TT as treatment for paediatric SDB, should be followed by a structured assessment of safety, efficacy and effectiveness. Ideally, the introduction of a new surgical method should follow the same steps as the development of a new drug.¹¹³ Historically, however, this has not often been the case, which has sometimes resulted in undesirable consequences such as the general adoption of new surgical techniques and instruments that subsequently prove to be less effective or even downright dangerous.¹¹² In 2009 the IDEAL Framework and Recommendations were formulated with the aim of standardising implementation of new surgical innovations. This framework describes the optimal assessment of a surgical method in the following five stages: idea (1), development (2a), exploration (2b), assessment (3), and long-term study (4). Each stage is defined by a research-based key question in accordance with Table 4.¹¹⁴

TABLE 4
Key research questions, IDEAL framework.

Stage	Key research question
Idea	What is the new treatment concept and why is it needed?
Development	Has the new intervention reached a state of stability sufficient to allow replication by others?
Exploration	Have the questions that might compromise the chance of conducting a successful RCT been addressed?
Assessment	How does the new intervention compare with current practice?
Long-term study	Are there any long-term or rare adverse effects or changes in indications or delivered quality over time?

An appropriate study design that can answer the research questions associated with the different stages should be chosen. For example, randomised controlled studies are considered to be the gold standard for assessment of efficacy and safety in regard to new surgical techniques regarding stage 3. In contrast, register-based cohort studies are promoted for assessment of long-term effects. A 2018 update of the IDEAL concept explicitly notes the importance of high-quality data collection through registers pertaining to all stages within the framework. The strength of well-designed register-based research lies in discovering late and/or unusual outcomes and in identifying changes in how treatments are used. Registers also make it possible to assess real world outcomes in a less controlled environment.^{56,112} Studies I, III and IV of this thesis pertain to stage 4 in the IDEAL framework.

1.10 QUALITY IMPROVEMENT IN HEALTH CARE

Quality in healthcare is a broad concept that encompasses many different definitions and interpretations. The Institute of Medicine defines quality in health care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”.¹¹⁵ Meanwhile, many studies show that patients are not receiving the health care they should according to evidence-based medicine and best practices.¹¹⁶ A frequently cited study from the US shows that only about half of adult patients receive care in accordance with well-established evidence or recommended treatment.¹¹⁷ The integration of new research and guidelines into daily medical practice has proven difficult.¹¹⁶ Thus there is a gap between best possible care and what is actually delivered in daily medical practice and the purpose of quality improvement is to bridge and eradicate this gap. One way to increase quality of care is to undertake various types of quality improvement projects (QIP). Unfortunately the effectiveness of QIPs appears to be uncertain and varied.^{118,119} A 2010 Swedish study showed that 58% of investigated QIPs were successful.¹²⁰ A crucial question with respect to quality improvement is whether or not the implemented changes actually result in improvement. To answer this question one must be able to measure the improvements.¹²¹ The Swedish national quality registers are considered to be a large underutilised resource for measuring the results of systematic quality improvement.¹²² For many years, the National Tonsil Surgery Register in Sweden (NTSRS), one of Sweden’s about 100 quality registers, has demonstrated large variations in PTH rates between various surgical centres in Sweden,¹²³ suggesting a potential gap between local practice and best practice. A top priority for the NTSRS steering committee is to reduce PTH rates in Sweden. Examples from other clinical fields have shown that structured QIPs that use quality registers can improve clinical outcomes.¹²⁴⁻¹²⁶ This serves as the foundation for study II in this thesis.

2.



Aims

The overall aim of this thesis is to identify preventable factors that increase the risk of postoperative haemorrhage after tonsil surgery. Additional aims are to evaluate and compare postoperative morbidity and risk of reoperation after tonsillectomy and tonsillectomy in children.

The specific aims of the four papers are as follows:

PAPER I

To determine post-tonsillectomy haemorrhage rates in Sweden and to evaluate the risk of post-tonsillectomy haemorrhage related to surgical technique and technique for haemostasis.

PAPER II

To describe and evaluate a multicentre quality improvement project that was initiated to reduce post-tonsillectomy haemorrhage rates.

PAPER III

To compare the risk of reoperation of the tonsils following tonsillectomy and tonsillectomy in children with tonsil-related upper airway obstruction and to determine the estimated risk of reoperation within 5 years of the first surgery.

PAPER IV

To evaluate and compare postoperative morbidity in a comprehensive national database following paediatric tonsillectomy and tonsillectomy performed because of tonsil-related upper airway obstruction. To evaluate the risk factors for postoperative morbidity and to compare morbidity after primary tonsil surgery with morbidity after reoperation of the tonsils.

3.

Patients and methods

3.1 THE NATIONAL TONSIL SURGERY REGISTER IN SWEDEN

In 1997, the Swedish Association for Otorhinolaryngology Head and Neck Surgery initiated the National Tonsil Surgery Register in Sweden (NTSRS), a national quality and research register.¹²⁷ The aim of the NTSRS is to monitor patient-related outcomes, complications and clinical practice patterns in order to identify trends, initiate and perform research projects and stimulate local clinical improvement programmes. In 2009, the register was revised to include new items that focused on surgical techniques as well as the patient experience of the postoperative period and complications. As of August 2018, the NTSRS contained detailed information on nearly 100,000 tonsil surgeries since its 2009 revision. Since 2013 the inclusion rate has been over 80% of all tonsil surgeries performed in Sweden. The NTSRS has evolved over the years to adapt to trends in society and clinical practice. For example, changes have been made to include newly introduced surgical techniques and to facilitate collection of patient-related outcome measures (PROMs) by e-mail. However, all changes have been undertaken with great caution to ensure that longitudinal analyses and comparisons of older and newer data are possible.

Data are prospectively collected through three questionnaires: one questionnaire to be completed by the ENT surgeon at the time of surgery and two questionnaires by the patient or the legal guardian. The first questionnaire records patient data, surgical indication, surgical method (TE or TT) and the surgical instruments used for dissection and haemostasis. This questionnaire also records episodes of early postoperative haemorrhage requiring intervention from a physician during hospital stay. The two patient questionnaires collect patient-related outcome measures (PROMs), 30 and 180 days after surgery. The first of these asks questions about postoperative pain, infection and haemorrhage, while the second focuses on symptom relief. All three questionnaires are supplemented in the appendix and a detailed description of the data collection is published elsewhere.¹⁵

Since the start of the register, all participating ENT centres have had complete access to their own data, enabling in-depth analyses that include comparisons of processes and outcomes with average Swedish rates. A public annual report has been published since 2012 containing analyses and comparative data from all participating ENT centres.^{18,123}

3.2 THE SWEDISH NATIONAL PATIENT REGISTER

The Swedish National Patient Register (NPR) is a national register, managed and administered by the National Board of Health and Welfare, a government agency under the Ministry of Health and Social Affairs, with the aim of collecting data on all healthcare procedures performed in Sweden.¹²⁸ The NPR was initiated in 1964 and contains patient-based information on both inpatient and outpatient care. The NPR has had complete national coverage for inpatient care since 1987. Outpatient surgical procedures were added in 1997 and outpatient physician visits were added in 2001. The NPR does not yet cover primary care, but all other public and private healthcare providers in Sweden are legally required to register their data in the NPR, including medical data (diagnoses and surgical procedures), patient data (age, gender and personal identity number), administrative data (e.g. dates of admission and discharge, inpatient/outpatient care) and information regarding healthcare providers. The personal identity number can be used to follow each individual over time in the register. Surgical procedures are coded in the NPR according to The Nordic Medico-Statistical Committee Classification of Surgical Procedures (NOMESCO), while diagnoses are coded according to the International Statistical Classification of Diseases (ICD). An analysis of completeness of the NPR regarding tonsil surgery has shown that only 3% of these procedures were missing from the NPR in 2014.¹²³

3.3 STUDY DESIGN AND SUBJECTS

Paper I

This retrospective cohort study is based on data from the NTSRS. All patients who had tonsillectomy (TE) without adenoidectomy from 1 March 2009 to 26 April 2013 and who were registered in the NTSRS were included in the study. All relevant data were collected from the NTSRS including: age, gender, indication for surgery, surgical instrument used for dissection and haemostasis, readmission to hospital due to post-tonsillectomy haemorrhage (PTH) and return to theatre (RTT) due to postoperative haemorrhage. Patients with insufficient data on surgical technique and patients with technique defined as “other” or “laser” were excluded. The techniques used for dissection and haemostasis were classified into groups, “cold” and “hot”, based on whether or not the chosen surgical instruments added heat to the surgical field. Early PTH was defined as bleeding that occurred during hospital stay and late PTH as bleeding that occurred after discharge and within 30 days.

The primary outcome was the risk of PTH following cold surgical techniques

compared with hot techniques. Secondary outcomes were rates of early and late PTH and RTT.

Paper II

This case study describes and evaluates the quality improvement project (QIP) that was initiated to reduce PTH rates. Data were obtained from the NTSRS and supplemented with data from both the National Patient Register (NPR) and the quality improvement plans of the participating centres. Six ENT centres, all with PTH rates above the Swedish average, were invited and agreed to participate in the QIP. The project started in October 2013 and ended in April 2014. The QIP began with a two-day workshop at which the local project managers were updated on best practices and evidence-based medicine regarding tonsil surgery, as well as quality improvement tools. Each participant created an individual action plan based on the discrepancy between best practices and local practices, including remedial measures to reduce PTH. A control group consisting of 15 surgical centres with similar PTH rates 12 months prior to the QIP was identified. The process indicators retrieved from the NTSRS included the techniques used for dissection and haemostasis. These techniques were classified into groups, “cold” and “hot”.

The primary outcome for the QIP was the difference in PTH at baseline (12 months prior to the QIP) and at follow-up (12 months after the QIP) for both groups. Secondary outcome was the difference in use of cold surgical techniques at baseline and follow-up.

Paper III

This retrospective population-based cohort study is based on data from the NPR. The NPR searches were based on surgical codes for tonsillectomy and tonsillotomy (with or without adenoidectomy) and the initial data set included all patients from January 1964 to December 2012. Data from the NPR included individual information on the type of surgery performed, indication for surgery, gender, age at first surgery and date of surgery. The main indication for surgery (based on ICD codes) was classified into one of three groups: “Upper airway obstruction”, “Infection-related indications” or “Other”. All children in the NPR aged 1-12 years who underwent tonsillotomy or tonsillectomy, with or without simultaneous adenoidectomy between 1 January 2007 and 31 December 2012 for the indication “Upper airway obstruction” were included in the study. Exclusion criteria were: previous tonsil surgery, history of emigration, contradictory surgical procedure codes and follow-up less than 30 days. The unique personal identity numbers were used to follow patients over time and identify additional tonsil surgery.

The primary outcome was the risk of reoperation after tonsillectomy versus tonsillectomy. Secondary outcomes were to identify potential predisposing factors for reoperation and to determine the estimated risk of reoperation within 5 years of the first surgery.

Paper IV

This retrospective population-based cohort study is based on data from the NPR. The study population derived from a national cohort consisting of all children aged 1-12 years who underwent tonsil surgery due to “obstruction/SDB” between 1 January 2007 and 31 December 2015. The search was based on surgical procedure codes covering TE and TT with or without adenoidectomy. To minimise the influence of confounding factors, patients with other simultaneous surgery and patients with diagnoses at surgery other than “obstruction/SDB” were excluded. Other exclusion criteria were previous (before 2007) tonsil and/or adenoid surgery, history of emigration and follow-up less than 30 days. Data from the NPR included information on gender, age at surgery, indication for surgery, type of surgery, level of care, date of surgery and all in- and outpatient care (except primary care) received within 30 days after surgery.

The primary outcome was readmission due to postoperative haemorrhage after TT and TE within 30 days after surgery. The secondary outcomes were return to theatre (RTT) due to postoperative haemorrhage, readmission due to any reason after surgery and contact with health care (including outpatient visits) for any reason after surgery, all within 30 days after surgery.

3.4 STATISTICS

Statistical analyses were performed by a professional statistician in close collaboration with the authors, using SAS Software Version 9 (SAS Institute, Cary, NC, USA). Table 5 presents an overview of statistical methods used in Paper I-IV.

TABLE 5

Overview of statistical methods in paper I-IV.

	Paper I	Paper II	Paper III	Paper IV
Descriptive statistics				
Continuous variables: Mean (SD) / Median (Min; Max)	X	X	X	X
Categorical variables: n (%)	X	X	X	X
For comparison between two groups				
Dichotomous variables: Fisher´s exact test	X	X	X	X
Continuous variables: Mann-Whitney <i>U</i> test		X	X	X
Ordered categorical variables: Mantel-Haenszel chi-square test		X	X	X
Unordered categorical variables: Chi-square test		X	X	
Adjustment for confounders of dichotomous outcome: Multivariable logistic regression	X			X
Generalized Estimating Equations (GEE) in order to adjust for the dependence within patients				X
Calculation of relative risk (RR) with 95% CI	X	X		
Generalized Estimating Equations (GEE) with binomial distribution for the dependent variable, and log-link function.		X		
Survival analyses, unadjusted and adjusted with Poisson regression			X	
Identifying independent predictors for dichotomous outcome				X

All significance tests were two-sided and conducted at the 5% significance level.

3.4.1 Paper I

Relative risk (RR) and odds ratio (OR) for tonsillectomy techniques were calculated for the haemorrhage rates and are given with 95% confidence intervals and p-values. The cold steel group with cold techniques for both dissection and haemostasis was used as reference. Multivariable logistic regression was used for adjustment of confounders in analyses of group comparisons of dichotomous outcome variables. To be a confounder, a baseline variable should differ between the groups and correlate with the outcome variable. The results from the logistic regression analyses are given as odds ratios (OR) with 95% confidence intervals and p-values. For comparison between two groups regarding dichotomous variables Fisher's exact test was used.

3.4.2 Paper II

Generalized Estimating Equations (GEE) were used in analyses of change in PTH rate before and after the QIP, with binomial distribution for the dependent variable, and log-link function. Time point variable before and after the QIP,

grouping variable of the intervention group and the control group and the interaction between the two variables were specified as fixed effects. The significant interaction term indicates the significant effect of the QIP. Relative Risks (RR) with 95% CI and p-values between time points for each site group were shown from these analyses.

3.4.3 Paper III

Person-years at risk for reoperation were calculated from the date of first surgery to the date of reoperation, death, emigration or December 31 2012, whatever came first. For the survival analysis of time to reoperation a continuous hazard function for reoperation was estimated by a Poisson regression model for time-varying data in which the risk was computed using midpoint approximation by dividing the observation period of each individual into small consecutive intervals. The hazard function at time t describes the momentary risk of a reoperation after time t given no reoperation up to time t . The probability of reoperation, within one, three and 5 years in relation to age at first surgery was calculated by integration over the hazard functions and graphically presented. The hazard ratio (HR) with 95% confidence interval (CI) for TT compared to TE was calculated unadjusted and adjusted for all baseline variables that differed significantly between the two groups.

3.4.4 Paper IV

Multivariable logistic regression was used for adjustment of confounders in analyses of group comparison of dichotomous outcome variables. To be a confounder, a baseline variable should differ between the groups and correlate with the outcome variable.

Univariable logistic regression was used to identify tentative predictors of “readmission due to postoperative haemorrhage” and “return to theatre due to postoperative haemorrhage”. The variables tested in the univariable logistic regression were age, gender, surgical method (TT/TE), year of surgery, level of care (inpatient/outpatient) and simultaneous adenoidectomy. Significant predictors were entered into a forward stepwise multivariable logistic regression analysis to identify independent predictors.

The results from the logistic regression analyses are given as odds ratios (OR) with 95% confidence intervals and p-values.

The analysis of primary TT compared to secondary TT (Table 14) was performed using generalized estimating equations (GEE) in order to adjust for the dependence within patients.

3.5 ETHICAL CONSIDERATIONS

The studies were conducted in accordance with the Declaration of Helsinki and data management was handled according to Swedish law and regulations. The studies were approved by The Regional Ethical Review Board in Gothenburg, Sweden, Reg. No: 885-12 (Paper I & III), 257-14 (Paper II) and 437-16 (Paper IV). For these types of studies, formal consent is not required.

4.



Results

4.1 PAPER I

A total of 15,734 patients with complete data concerning technique for dissection and for haemostasis were identified in the NTSRS from 1 March 2009 to 26 April 2013 and included in the study. Techniques used were: cold steel dissection with unipolar or bipolar diathermy haemostasis (65.3%), diathermy scissors (15.7%), coblation (9.1%), cold steel dissection with cold haemostasis (7.4%) and ultracision (2.5%). Table 6 presents demographics, indication and postoperative haemorrhage related to technique for dissection and haemostasis.

TABLE 6
Demography, indication and postoperative haemorrhage related to technique for dissection and haemostasis

Variables	Total	Cold steel with cold haemostasis	Cold steel with hot haemostasis	Bipolar scissors	Ultracision	Coblation
Number	n=15734	n=1169 (7.4%)	n=10278 (65.3%)	n=2472 (15.7%)	n=391 (2.5%)	n=1424 (9.1%)
Demography						
Age	21.6 (12.0) 19.0 (1.0; 91.0)	20.8 (11.9) 19.0 (1.0; 75.0)	21.7 (12.0) 19.0 (1.0; 91.0)	22.1 (11.6) 20.0 (1.0; 83.0)	21.7 (12.0) 18.0 (2.0; 77.0)	20.7 (11.5) 19.0 (1.0; 77.0)
Sex						
M	6489 (41.2%)	496 (42.4%)	4226 (41.1%)	1023 (41.4%)	160 (40.9%)	584 (41.0%)
F	9245 (58.8%)	673 (57.6%)	6051 (58.9%)	1449 (58.6%)	231 (59.1%)	840 (59.0%)
Indication						
Obstruction	3743 (23.8%)	297 (25.4%)	2581 (25.1%)	398 (16.1%)	126 (32.2%)	341 (23.9%)
Recurrent tonsillitis	6179 (39.3%)	393 (33.6%)	3810 (37.1%)	1263 (51.1%)	132 (33.8%)	581 (40.8%)
Peritonsillar abscess	1765 (11.2%)	87 (7.4%)	1208 (11.8%)	299 (12.1%)	54 (13.8%)	117 (8.2%)
Chronic tonsillitis	3490 (22.2%)	348 (29.8%)	2291 (22.3%)	439 (17.8%)	66 (16.9%)	346 (24.3%)
Complication to systemic disease	32 (0.2%)	2 (0.2%)	20 (0.2%)	4 (0.2%)	1 (0.3%)	5 (0.4%)
Other indication	525 (3.3%)	42 (3.6%)	368 (3.6%)	69 (2.8%)	12 (3.1%)	34 (2.4%)
Postoperative Bleeding						
Early bleeding	506 (3.2%)	35 (3.0%)	354 (3.4%)	58 (2.3%)	4 (1.0%)	55 (3.9%)
Response rate						
Number responding 30-day questionnaire	9603 (61.0%)	636 (54.4%)	6406 (62.3%)	1314 (53.1%)	259 (66.2%)	902 (63.3%)
Late bleeding	894 (9.4%)	21 (3.3%)	566 (8.8%)	176 (13.4%)	42 (16.2%)	89 (9.9%)
Return to theatre	252 (2.7%)	7 (1.1%)	171 (2.7%)	42 (3.3%)	10 (3.8%)	22 (2.4%)

For continuous variables Mean (SD) /Median (Min; Max) is presented

For categorical variables n (%) is presented.

Early haemorrhage: haemorrhage that occurs during hospital stay

Late haemorrhage: Haemorrhage that occurs after discharge but within 30 days postoperatively

The response rate of the 30-day questionnaire was 61%, including some questionnaires in which patients did not answer all questions. Early bleeding was reported in 506 of 15,734 (3.2%) and late bleeding in 894 of 9,517 (9.4%) cases. Return to theatre (RTT) was necessary in 252 of 9,394 cases (2.7%). The highest rate of early PTH was after coblation (3.9%) and of late PTH after ultracision (16.2%).

TABLE 7

Rates of early PTH, late PTH and RTT by surgical technique.

Early PTH (N=15734)					
Technique	Number of operations	Number of events	Rate (%)	Relative risk with 95% CI	p-value*
Cold steel + cold haemostasis	1 169	35	2.99	1	-
Cold steel + hot haemostasis	10 278	354	3.44	1.15 (0.82-1.62)	0.42
Bipolar scissors	2 472	58	2.35	0.78 (0.52-1.19)	0.25
Coblation	1 424	55	3.86	1.29 (0.85-1.96)	0.23
Ultracision	391	4	1.02	0.34 (0.12-0.96)	0.031
Late PTH (N=9517)					
Technique	Number of operations	Number of events	Rate (%)	Relative risk with 95% CI	p-value*
Cold steel + cold haemostasis	636	21	3.30	1	-
Cold steel + hot haemostasis	6 406	566	8.84	2.68 (1.74-4.10)	<.0001
Bipolar scissors	1 314	176	13.39	4.06 (2.61-6.31)	<.0001
Coblation	902	89	9.87	2.99 (1.88-4.76)	<.0001
Ultracision	259	42	16.22	4.91 (2.97-8.13)	<.0001
RTT (N=9394)					
Technique	Number of operations	Number of events	Rate (%)	Relative risk with 95% CI	p-value*
Cold steel + cold haemostasis	621	7	1.13	1	-
Cold steel + hot haemostasis	6 326	171	2.70	2.40 (1.13-5.08)	0.018
Bipolar scissors	1 285	42	3.27	2.90 (1.31-8.83)	0.0056
Coblation	901	22	2.44	2.17 (0.93-5.04)	0.065
Ultracision	261	10	3.83	3.40 (1.31-8.83)	0.0077

* p-value calculated using Cochran-Mantel-Haenszel test

PTH rates and RTT for the different techniques are shown in table 7. Regarding early PTH, the use of ultracision resulted in lower haemorrhage rate compared

with the cold/cold group. The other techniques did not differ significantly from the cold/cold group with respect to early PTH. However, any use of hot techniques for dissection or haemostasis resulted in higher risk for late PTH. The risk of RTT was higher for all hot techniques except coblation (table 7).

The results for late PTH and RTT were adjusted for age, gender and indication for surgery in a multivariable analysis since these variables differed between groups and correlated to the outcome. However, no effect for indication was detected in regard to early PTH, for which reason this was not included in the model.

Table 8 presents adjusted outcomes of early and late PTH and RTT in cold steel and cold haemostasis compared with other techniques.

TABLE 8

Early and late post tonsillectomy haemorrhage (PTH) and return to theatre (RTT) due to postoperative bleeding in cold steel and cold haemostasis compared to other techniques used for tonsil-surgery outcomes from adjusted logistic regression analysis.

Techniques	Early PTH* (N=15734)		Late PTH** (N=9517)		RTT** (N=9394)	
	Odds ratio (CI)	p-value	Odds ratio (CI)	p-value	Odds ratio (CI)	p-value
Cold steel + cold haemostasis	1		1		1	
Cold steel + hot haemostasis	1.13 (0.79:1.61)	0.4998	2.80 (1.80:4.36)	<.0001	2.43 (1.13:5.20)	0.0223
Bipolar scissors	0.74 (0.48:1.14)	0.1717	4.28 (2.69:6.82)	<.0001	2.89 (1.29:6.49)	0.0099
Coblation	1.29 (0.84:1.99)	0.2417	3.20 (1.97:5.22)	<.0001	2.20 (0.93:5.19)	0.0712
Ultracision	0.33 (0.12:0.92)	0.0351	5.63 (3.25:9.73)	<.0001	3.50 (1.32:9.32)	0.0121

*) The analysis is adjusted for sex and age.

**) The analysis is adjusted for sex, age and indication. CI= 95% confidence interval

Early PTH: haemorrhage that occurs during hospital stay

Late PTH: haemorrhage that occurs after discharge but within 30 days postoperatively

The adjusted odds ratio demonstrated that compared with the cold/cold group, all other techniques were associated with a higher risk of late PTH. The risk of RTT was higher for all hot techniques except coblation, while ultracision resulted in a lower risk of early PTH. The adjusted odds ratios were comparable (also regarding statistical significance) with the relative risks presented in table 7.

Furthermore, an early haemorrhage was associated with an increased risk of late PTH (table 9).

TABLE 9

The risk for late PTH related to the occurrence of early PTH.

Variables	Total (n=9517)	Early PTH (n=276)	No early PTH (n=9241)	p-value
Late PTH	894 (9.4%)	85 (30.8%)	809 (8.8%)	
No late PTH	8623 (90.6%)	191 (69.2%)	8432 (91.2%)	<.0001

For categorical variables n (%) is presented.

For comparison between groups Fisher´s Exact test (lowest 1-sided p-value multiplied by 2) was used for dichotomous variables.

4.2 PAPER II

Six surgical centres (“Intervention group”) participated in the QIP. Each surgical centre in the intervention group created a unique improvement plan aimed at reducing PTH. Five main themes for change emerged (table 10)

TABLE 10

Themes of improvement activities and their use by the surgical centres.

Themes of improvement activities	Borås	Falun	Karlstad	Norrbotten	Skövde	Västerås
Change in surgical technique						
Increase the use of cold dissection and haemostasis	X		X	X	X	X
Decrease the use of coblation and/or bipolar diathermy and/or bipolar scissors	X	X	X	X	X	X
Reduce the power settings for bipolar diathermy	X	X		X	X	X
Revise the strategy for pharmacological pain treatment						
Improve adherence to the national guidelines for pain treatment in paediatric patients		X	X	*	X	X
Revise the use of NSAIDs preoperatively		X		X		X
Information for patients and caregivers						
Improve postoperative information to patients		X	X	X	X	X
Introduce telephone follow-up			X	*	X	*
Elevate the status of tonsillectomy						
Improve training in the surgical technique of tonsillectomy among junior doctors	X	X	X	X		X
Discuss the quality improvement project in staff meetings	X	X	X	X	X	X

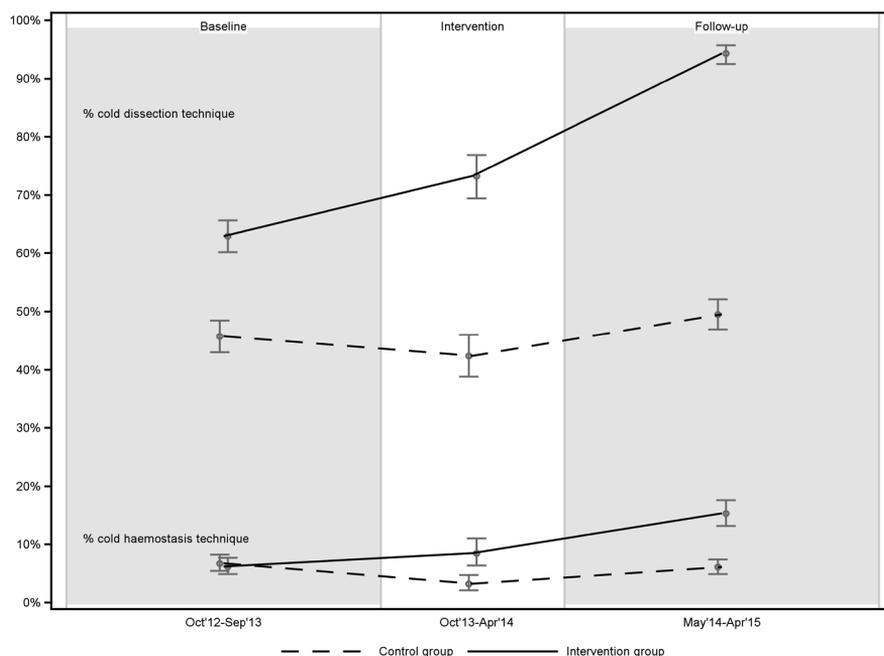
* Implemented before the quality improvement project

At baseline (12 months prior to the QIP), the number of TEs performed at the six surgical centres in the intervention group varied between 155 and 233, with a total of 1,220 surgeries. In the control group, between 17 and 372 surgeries were performed at each centre, with a total of 1,318 TEs performed during the same period. There were no gender or age differences between the patients operated in the control and intervention groups. There was a small but statistically significant difference in the indication for surgery, with slightly more patients treated for infection-related problems in the control group at baseline. Outpatient TE was more common in the control group than in the intervention group both at baseline and at follow-up.

In the intervention group, there was a significant ($p < 0.0001$) increase in the use of cold dissection techniques between baseline (63.0%) and the follow-up period (94.1%). There was also an increase in the use of cold haemostasis techniques in the intervention group, from 6.2% at baseline to 15.6% at follow-up ($p < 0.0001$). The control group showed no significant changes in techniques for dissection ($p = 0.053$) or haemostasis ($p = 0.42$) between baseline and follow-up (figure 1). In the Intervention group, there was a significant greater change from baseline to follow-up in the use of cold dissection ($p < 0.0001$) and cold haemostasis ($p < 0.0001$) compared to the control group.

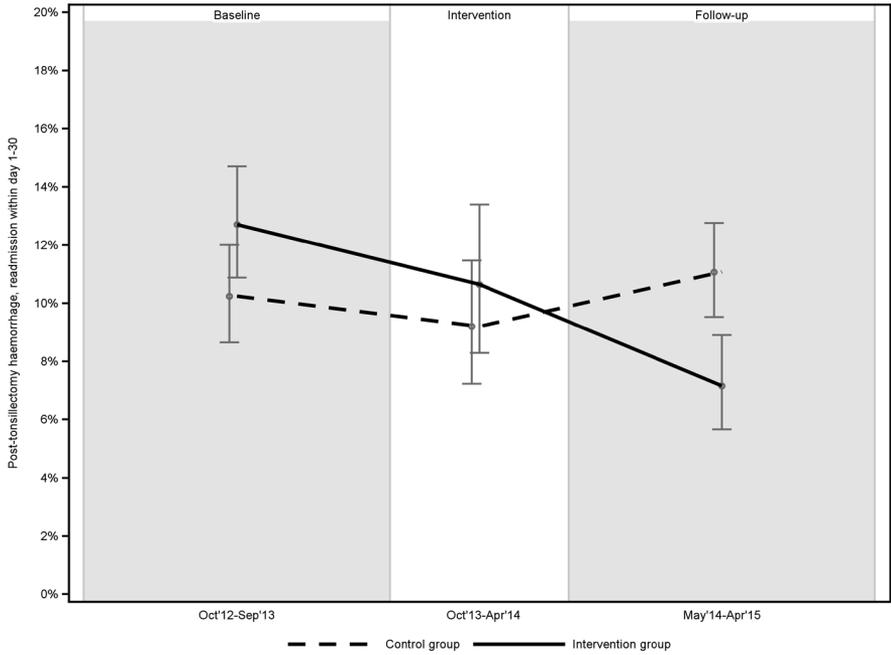
FIGURE 1

Techniques for dissection and haemostasis at baseline, intervention period and follow-up, displayed with 95% confidence interval.



There was no statistically significant difference at baseline between the two groups regarding the outcome variable, PTH rate. A comparison between baseline and follow-up in the intervention group demonstrated a significant reduction of PTH rate, from 12.7% to 7.1% (RR 0.56, 95% CI 0.43-0.74, $p < 0.0001$). The control group showed no significant change in PTH rate between baseline and follow-up (RR 1.06, 95% CI 0.85-1.32, $p = 0.59$). There was a statistically significant ($p = 0.0025$) difference in PTH rate between the intervention group (7.1%) and the control group (10.9%) at follow-up, (figure 2). In the Intervention group, there was a significant greater reduction of PTH rate from baseline to follow-up compared to the control group ($p = 0.0003$).

FIGURE 2
 PTH rates at baseline, intervention period and follow-up, displayed with 95% confidence interval.



4.3 PAPER III

A total of 27,535 patients were included in the study, amounting to 76,054 person-years of follow-up. Of these, 11,741 patients (42.6%) underwent primary TE±A and 15,794 (57.4%) underwent primary TT±A. Table 11 presents demographics and baseline characteristics.

TABLE 11
Demographics and baseline characteristics.

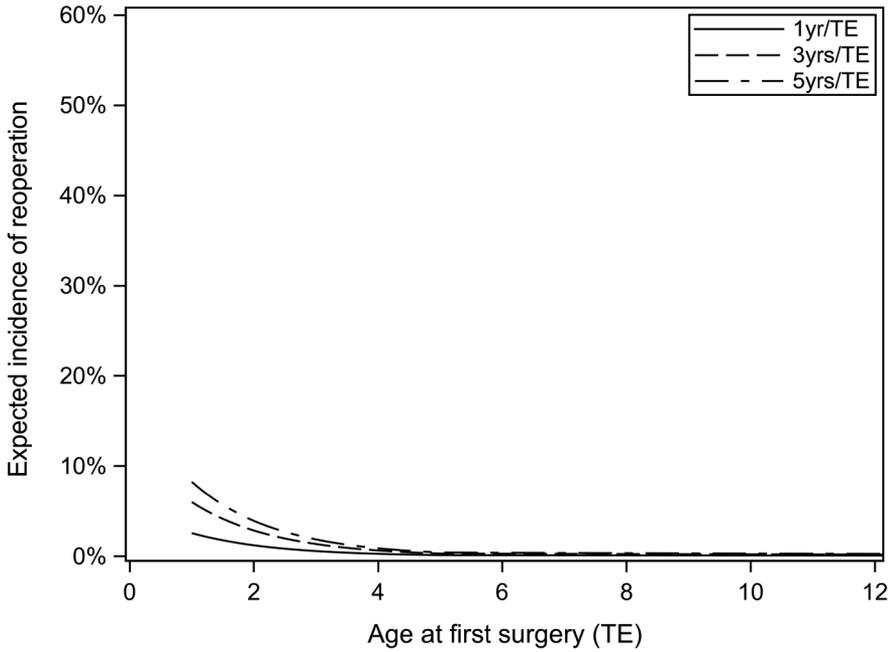
	Tonsillectomy (n=11741)	Tonsillotomy (n=15794)	p value
Gender			
Male	6648 (56.6%)	9132 (57.8%)	
Female	5093 (43.4%)	6662 (42.2%)	0.048
Age at first surgery	5.64 (2.62) 5.00 (1.03; 12.99)	5.10 (2.33) 4.57 (1.00; 12.99)	<.0001
Year of first surgery			
2007	2570 (21.9%)	1204 (7.6%)	
2008	2204 (18.8%)	1834 (11.6%)	
2009	2023 (17.2%)	2646 (16.8%)	
2010	1795 (15.3%)	2886 (18.3%)	
2011	1566 (13.3%)	3253 (20.6%)	
2012	1583 (13.5%)	3971 (25.1%)	<.0001
Follow-up time (years)	3.30 (1.73) 3.41 (0.08; 6.00)	2.36 (1.58) 2.12 (0.08; 5.99)	<.0001

For categorical variables n (%) is presented, and for continuous variables Mean (SD) / Median (Min; Max) is presented.

A total of 684 patients (2.5%) underwent reoperation of the tonsils during the follow-up period. The rate of reoperation was 1.94 per 1,000 person-years in the TE group and 16.34 per 1,000 person-years in the TT group. The most common indication for reoperation was recurrence of upper airway obstruction in both groups. The risk for reoperation was significantly ($p < 0.0001$) higher following TT than TE, with an unadjusted Hazard Ratio (HR) of 8.54 (95 % CI 6.72-10.85). The adjusted HR (gender, age and year of first surgery) was 7.16 (95 % CI 5.52-9.13, $p < 0.0001$). Figures 3 and 4 present the expected rates of reoperation within 1, 3 and 5 years in relation to age at first surgery.

FIGURE 3

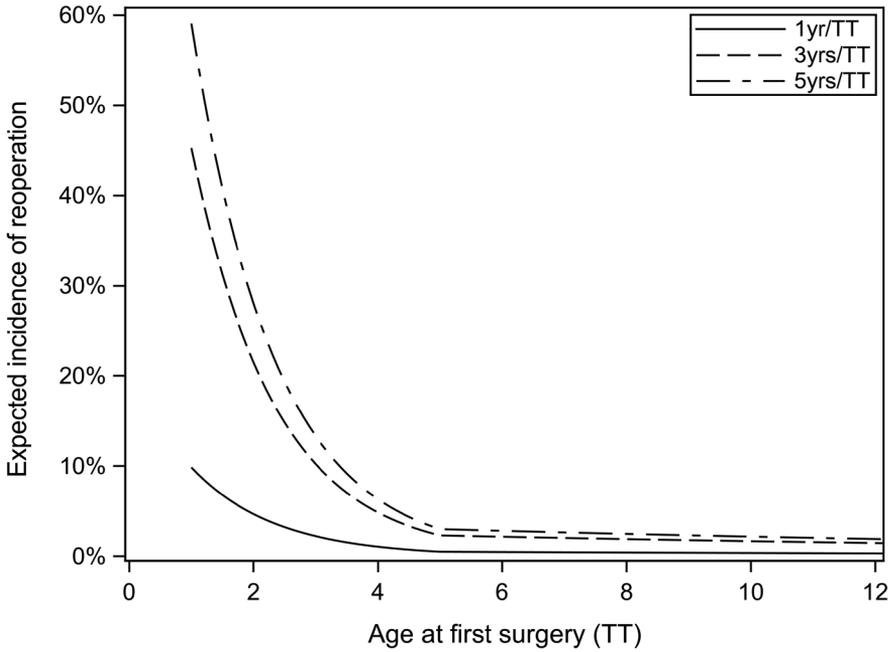
Expected incidence of reoperation after TE within 1, 3 and 5 years from first surgery by age at first surgery



As shown in the figures, younger age at first surgery was strongly and significantly ($p < 0.0001$) associated with reoperation following both TE and TT and the difference in risk between groups gradually decreased with increased age at first surgery.

FIGURE 4

Expected incidence of reoperation after TT within 1, 3 and 5 years from first surgery by age at first surgery



4.4 PAPER IV

The search in the NPR identified 58,587 patients between 1 and 12 years of age who underwent tonsil surgery with or without simultaneous adenoidectomy during the study period (2007-2015). After exclusion, mainly because of simultaneous surgeries other than adenoidectomy (n=10,446) or a diagnosis other than obstruction/SDB (n=10,436), a total of 35,060 patients were included in the study. Of these, 23,447 underwent TT±A, and 11,613 underwent TE±A. In total, 772 patients who had previously undergone primary TT underwent reoperation of the tonsils due to recurrence of “obstruction/SDB”. Of these, 230 underwent secondary TT and 552 underwent secondary TE. Table 12 presents the demographics.

TABLE 12
Demographics

		Primary TT vs TE			Primary vs secondary TT		Primary vs secondary TE	
Total (n=35060)		TT (n=23447)	TE (n=11613)	TT vs TE p-value	TT after primary TT (n=230)	p-value	TE after primary TT (n=552)	p-value
Gender								
boys	19721 (56.2%)	13224 (56.4%)	6497 (55.9%)		121 (52.6%)		326 (59.1%)	
girls	15339 (43.8%)	10223 (43.6%)	5116 (44.1%)	0.43	109 (47.4%)	0.28	226 (40.9%)	0.16
Age at surgery	5.39 (2.45) 4.79 (1.01); 13.00 n=35060	5.19 (2.32) 4.64 (1.01); 13.00 n=23447	5.79 (2.66) 5.12 (1.02); 13.00 n=11613	<.0001	5.54 (2.10) 5.04 (1.85); 12.20 n=230	0.0008	5.36 (1.90) 5.08 (1.74); 12.83 n=552	0.13
Year of surgery								
2007	2510 (7.2%)	849 (3.6%)	1661 (14.3%)		1 (0.4%)		1 (0.2%)	
2008	2877 (8.2%)	1297 (5.5%)	1580 (13.6%)		2 (0.9%)		7 (1.3%)	
2009	3456 (9.9%)	1974 (8.4%)	1482 (12.8%)		6 (2.6%)		30 (5.4%)	
2010	3548 (10.1%)	2233 (9.5%)	1315 (11.3%)		11 (4.8%)		38 (6.9%)	
2011	3732 (10.6%)	2609 (11.1%)	1123 (9.7%)		26 (11.3%)		55 (10.0%)	
2012	4595 (13.1%)	3378 (14.4%)	1217 (10.5%)		27 (11.7%)		70 (12.7%)	
2013	4646 (13.3%)	3575 (15.2%)	1071 (9.2%)		43 (18.7%)		112 (20.3%)	
2014	4890 (13.9%)	3790 (16.2%)	1100 (9.5%)		51 (22.2%)		99 (17.9%)	
2015	4806 (13.7%)	3742 (16.0%)	1064 (9.2%)	<.0001	63 (27.4%)	<.0001	140 (25.4%)	<.0001
Adenoidectomy								
no adenoidectomy	5751 (16.4%)	3417 (14.6%)	2334 (20.1%)		47 (20.4%)		188 (34.1%)	
adenoidectomy	29309 (83.6%)	20030 (85.4%)	9279 (79.9%)	<.0001	183 (79.6%)	0.020	364 (65.9%)	<.0001
Level of care								
inpatient	11785 (33.6%)	6072 (25.9%)	5713 (49.2%)		45 (19.6%)		230 (41.7%)	
outpatient	23275 (66.4%)	17375 (74.1%)	5900 (50.8%)	<.0001	185 (80.4%)	0.031	322 (58.3%)	0.0006

For categorical variables, n (%) is presented.

For continuous variables, mean (SD)/median (min; max)/n= is presented.

The primary outcome, readmission due to postoperative haemorrhage was significantly ($p < 0.0001$) more common after TE (2.5%) than after TT (0.6%) (OR 3.91, 95% CI 3.20 – 4.77). Age, adenoidectomy and year of surgery were considered to be confounders since these variables differed between groups and correlated with the outcome (table 12, figure 5). After adjustment for these confounders, the OR was 3.90 (95% CI 3.17 – 4.80, $p < 0.0001$).

The stepwise multivariable logistic regression analysis revealed that TE (OR 3.74, 95% CI 3.06-4.578, $p < 0.0001$) and older age at surgery (OR 1.05, 95% CI 1.01-1.08, $p = 0.016$) both increased the risk for readmission due to postoperative

haemorrhage, while simultaneous adenoidectomy instead decreased the risk (OR 0.77, 95% CI 0.61-0.96, $p = 0.023$). Table 13 presents unadjusted and adjusted outcomes, while Figure 5 shows predictors for readmission due to postoperative haemorrhage (Area under ROC-curve for multivariable model; 0.68, 95% CI 0.65-0.71).

TABLE 13

Unadjusted and adjusted analyses of outcomes, primary TT vs TE.

	Total (n=35060)	TT (n=23447)	TE (n=11613)	Unadjusted OR (95% CI)	p-value*	Adjusted OR (95% CI)	p-value**
Readmission, postoperative haemorrhage	435 (1.2%)	150 (0.6%)	285 (2.5%)	3.91 (3.20-4.77)	<.0001	3.90 (3.17-4.80)	<.0001
RTT postoperative haemorrhage	90 (0.3%)	27 (0.1%)	63 (0.5%)	4.73 (3.01-7.43)	<.0001	4.90 (3.07-7.81)	<.0001
Readmission, any reason	976 (2.8%)	427 (1.8%)	549 (4.7%)	2.68 (2.35-3.04)	<.0001	2.74 (2.40-3.13)	<.0001
Contact with healthcare, any reason	6051 (17.3%)	3684 (15.7%)	2367 (20.4%)	1.37 (1.30-1.45)	<.0001	1.46 (1.38-1.55)	<.0001

For categorical variables, n (%) is presented.

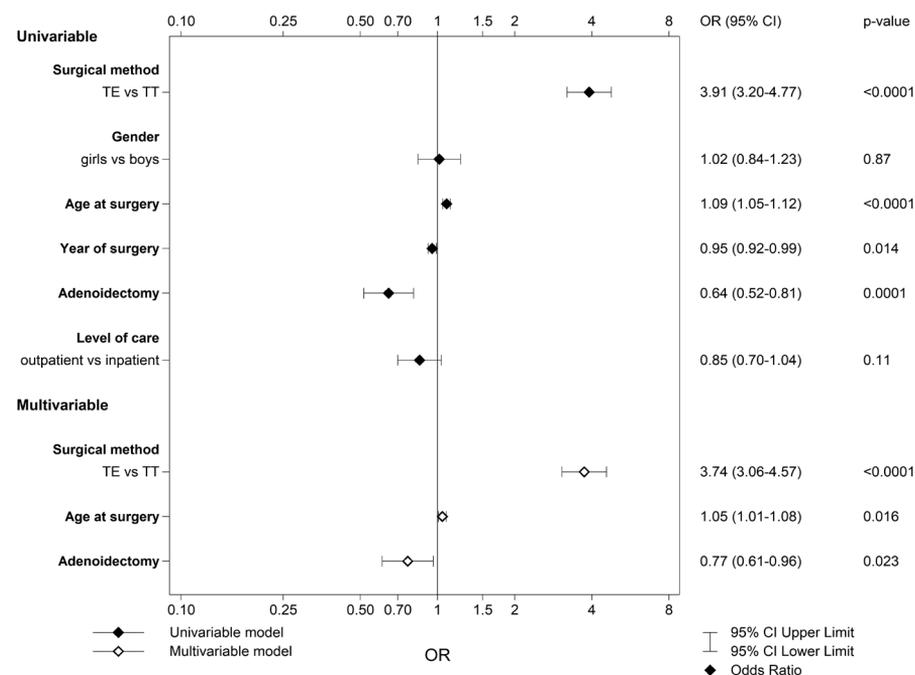
RTT = Return to theatre

*) All tests are performed with univariable logistic regression.

**) Adjusting for age at surgery, adenoidectomy and year of surgery using logistic regression.

FIGURE 5

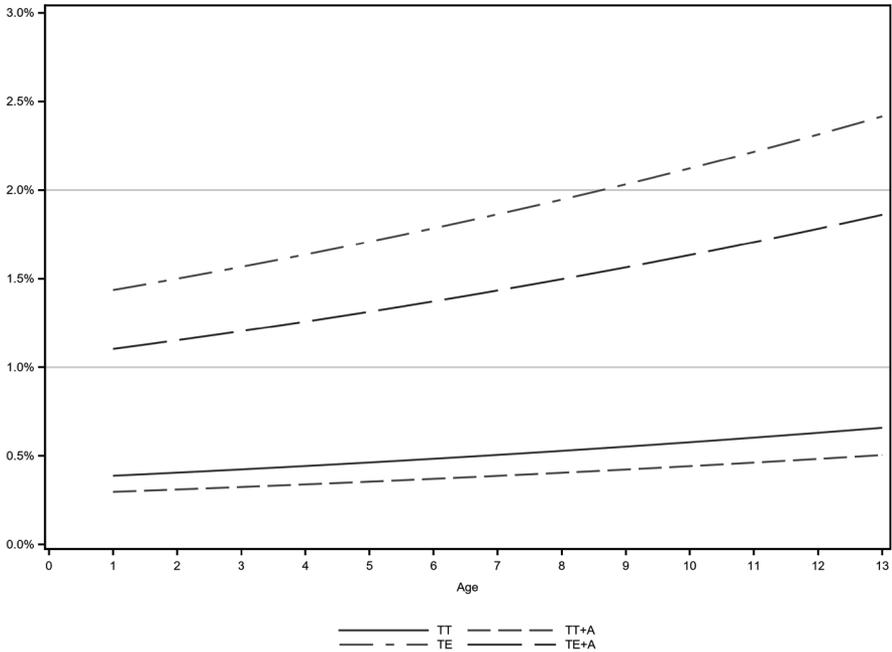
Univariable and multivariable predictors of readmission due to postoperative haemorrhage.



As Table 13 shows, the secondary outcomes return to theatre (RTT) due to postoperative haemorrhage, readmission due to any reason and contact with healthcare (including outpatient visits) for any reason after surgery, were all less common after TT than after TE.

Figure 6 shows estimated risk of readmission due to postoperative haemorrhage by surgical method (TT, TT+A, TE, TE+A) and age at surgery.

FIGURE 6
 Estimated risk of readmission due to postoperative haemorrhage by surgical method and age at surgery.



When comparing morbidity following primary TT vs secondary TT (reoperation), there were no significant differences in the abovementioned outcome measures (table 14).

TABLE 14

Outcomes, primary TT vs secondary TT.

	Primary TT (n=23 447)	TT after primary TT (n=230)	Unadjusted OR (95% CI)	p-value*
Readmission, postoperative haemorrhage	150 (0.6%)	2 (0.9%)	1.36 (0.34-5.53)	0.66
RTT postoperative haemorrhage	27 (0.1%)	0	n.e.**	-
Readmission, any reason	427 (1.8%)	5 (2.2%)	1.24 (0.52-2.94)	0.63
Contact with healthcare, any reason	3 684 (15.7%)	41 (17.8%)	1.11 (0.78-1.57)	0.54

For categorical variables n (%) is presented.

*) Due to the dependence within patients, all tests are performed using generalized estimating equations (GEE) with binomial distribution for outcome variable and logit function

**) Non-estimable

Secondary TE after primary TT resulted in a higher frequency of postoperative haemorrhage than primary TE (OR 1.65, 95% CI 1.06-2.57, $p = 0.027$). The outcome measures “readmission to hospital due to any reason” and “contact with the healthcare for any reason” also revealed more frequent complications following secondary TE than after primary TE. After adjustment for age, adenoidectomy and year of surgery, significant differences between groups only remained for “readmission to hospital due to any reason” (OR 1.96, 95% CI 1.43-2.68) (Table 15).

TABLE 15

Outcomes, primary TE vs secondary TE.

	Primary TE (n=11613)	TE after primary TT (n=552)	Unadjusted OR (95% CI)	p-value*	Adjusted OR (95% CI)	p-value**
Readmission, postoperative haemorrhage	285 (2.5%)	22 (4.0%)	1.65 (1.06-2.57)	0.027	1.55 (0.98-2.44)	0.061
RTT postoperative haemorrhage	63 (0.5%)	5 (0.9%)	1.68 (0.67-4.18)	0.27	1.32 (0.52-3.39)	0.56
Readmission, any reason	549 (4.7%)	50 (9.1%)	2.01 (1.48-2.72)	<.0001	1.96 (1.43-2.68)	<.0001
Contact with healthcare, any reason	2367 (20.4%)	136 (24.6%)	1.28 (1.05-1.56)	0.016	1.18 (0.96-1.44)	0.12

For categorical variables, n (%) is presented.

RTT = Return to theatre

*) All tests are performed with univariable logistic regression.

**) Adjusted for age at surgery, year of surgery and adenoidectomy using logistic regression.

5.

Discussion

5.1 GENERAL ASPECTS

Tonsil surgery has a long history and remains a very common surgical procedure with well-documented beneficial effects for a number of medical conditions. However, as in all surgical interventions, tonsil surgery is associated with a risk of complications. The most dreaded postoperative complication, bleeding, not only puts patients at risk of fatal outcome, but is often an unpleasant and traumatic experience. The interests of both patients and the healthcare system are well served by keeping postoperative complications such as bleeding to a minimum. This thesis focuses on how different surgical techniques and methods affect the risk of postoperative haemorrhage. It also explores the risk of reoperation following different surgical methods (tonsillotomy and tonsillectomy).

5.2 SURGICAL TECHNIQUE AND POST-TONSILLECTOMY HAEMORRHAGE

Paper I describes the occurrence of post-tonsillectomy haemorrhage (PTH) as well as how this risk is related to surgical technique. The main finding of the study is that all hot techniques used for dissection and haemostasis increase the risk of late PTH, compared with cold dissection and cold haemostasis. The literature frequently discusses whether cold tonsillectomy should be viewed as the gold standard.⁵⁷ Our results clearly show that this should be the case. These findings are in line with a large study from the UK (the British National Prospective Tonsillectomy Audit), in which Lowe et al. showed that hot techniques increased the risk of PTH.⁵³ Sarny et al. reported in a large Austrian multicentre cohort study from 2011 that the use of bipolar diathermy was a risk factor for PTH, which is also in line with our results.⁷² Based on the findings in the British audit, national guidelines were issued in the UK advocating caution with the use of diathermy, along with the need for training in traditional cold surgical technique.⁸³ Another important finding of paper I is that early PTH (during hospitalisation) is associated with increased risk of late PTH. Other studies have shown the same thing, which underscores the importance of viewing early PTH as a risk factor for late PTH.^{72,129}

This study showed a high rate of late PTH (9.4%) compared with other studies.⁵⁷ The rate of RTT (2.7%), however, was lower than had been reported, for example, in the previously mentioned Austrian study.⁷² It has been proposed that PTH may be under-reported in studies based on patient chart reviews compared with questionnaire-based studies in which patients themselves report complications.⁷² The case mix of studied populations as well as various definitions of PTH

may also help account for differences in PTH rates. The most common surgical technique reflected by the current study was cold steel dissection combined with hot haemostasis (65.3%). Cold technique alone for both dissection and haemostasis was used in only 7.4% of cases. However, the relatively widespread use of hot techniques for TE has also been observed in other countries. In the UK and Northern Ireland (the British Audit) cold steel dissection combined with hot haemostasis (monopolar and bipolar diathermy) was the most common method (40%), followed by dissection and haemostasis with bipolar diathermy (30%). Cold technique alone was used in 13% of cases.¹³⁰ A 2011 study from the US showed that monopolar cautery was the most commonly used method for TE, while a study from Australia showed that some type of hot technique was used in 64% of TEs.^{131,132}

A recently published study describing tonsil surgery in Sweden between 2013 and 2015 noted that hot techniques were still commonly used for tonsillectomy in Sweden,¹⁵ even though for several years the NTSRS steering committee has been recommending cold technique for dissection and haemostasis in tonsillectomy.¹²³

5.3 IS IT POSSIBLE TO REDUCE PTH RATES?

Many publications have reported on the incidence of post-tonsillectomy haemorrhage, frequently with large variations, which suggests that many of these incidents could have been prevented. The National Tonsil Surgery Register in Sweden (NTSRS) has also shown large variations in PTH between various Swedish surgical centres, which is the motivation for the quality improvement project (QIP) presented in paper II. The main finding in paper II was that it is possible to reduce PTH rates through a QIP based on data from a national quality register. The QIP centres reduced the PTH rate from 12.7% to 7.1%, which is an average reduction of 5.6 episodes of PTH per 100 TEs. As far as we are aware, this is the first published assessment of a QIP aimed at reducing PTH. In order to describe and assess QIP, we used a case study design well suited to elucidate multifaceted changes over time in relation to various situations.¹³³ This project advocated the use of cold surgical technique for TE based on the previous findings in paper I. The quality improvement project resulted in beneficial changes in the process indicators: techniques used for dissection and haemostasis. The QIP centres planned for changes in surgical technique and subsequently an increased use of cold dissection and cold haemostasis techniques could be measured in the quality register. These changes were not observed in the control group. Since we could find no other explanation for the reduction of PTH rates in the QIP centres, we therefore concluded that the QIP led to the PTH rate reduction.

There are likely multiple reasons for the reduced rates of PTH seen in the study. The reasons may also differ among the participating centres. Due to the study design and limitations in the data available from the NTSRS, it is unfortunately impossible to study each individual contributing factor for this outcome. However, our results strongly suggest that the main reason for the reduction in rates of PTH was the increased use of cold techniques for TE. Other factors, too, may have contributed in varying degrees to these results, such as increased awareness of PTH, an upgrade in the status of the tonsillectomy procedure and improved surgical training. Other contributing factors included the involvement of the local project manager, support from the surgical centre administration and the tailoring of improvement plans to each centre's local context, a key consideration in health care improvement.^{134,135}

5.4 REOPERATION AFTER TONSILLOTOMY AND TONSILLECTOMY

The main finding in paper III was that the risk of reoperation is seven times higher (HR 7.16) following tonsillectomy (TT) compared with tonsillectomy (TE). As far as we are aware, this is the first large population-based study that compares the risk of reoperation after TT and TE as surgical treatment for upper airway obstruction in children. In our study, the risk of reoperation was strongly related to age at time of first surgery for both TT and TE and the difference in risk between TT and TE gradually decreases with increased age at time of surgery. The most common reason for reoperation was recurrence of upper airway obstruction after both TT and TE. Recently published review articles by Windfuhr et al.¹¹⁰ and Acevado et al.¹¹¹ reported reoperation rates following TT ranging from 0% to 11.9%, 6 months to 14 years after surgery. The articles included in these reviews differ in the number of included patients (20–1731), study design, surgical technique, number of patients lost to follow-up and age of included patients, which makes them difficult to compare.

The largest difference in risk of reoperation when comparing TT with TE was found in the youngest age groups. Young age has previously been proposed to be a risk factor for reoperation following TT,^{111,136} which the data in our study also confirm since younger age was associated with a significantly higher rate of reoperation for both TT and TE. The study presents the risk of reoperation in relation to age at the time of first surgery. These findings, which are described as “expected incidence of reoperation” indicate a significantly higher risk of reoperation than previously reported. Young age has also previously been shown to be a risk factor for reoperation following adenoidectomy.^{137,138} The reason for

this finding is unknown, but the speculation has been that it may be explained by the immunological function of the lymphatic tissue in Waldeyer's ring.¹³⁸

A quick glance at our results could lead to the conclusion that TE should be carried out on the youngest children to avoid the increased risk of reoperation associated with TT. However, one should not forget that the reason that TT has been reintroduced is the decrease in postoperative morbidity compared with TE. In Austria, 5 children, all under the age of 6 years, died from serious haemorrhage following TE between 2006 and 2007, which led to the recommendation that TT should now be considered first line therapy in paediatric tonsil surgery in Austria.¹³⁹ Our current study contributes important information to guide doctors and parents/guardians in decisions related to choice of tonsil surgery. This applies especially to the youngest group of children, where the advantages of TT regarding fewer postoperative complications and reduced morbidity should be compared with the disadvantages related to higher risk of reoperation due to recurrence of symptoms.

5.5 MORBIDITY AFTER TONSILLOTOMY AND TONSILLECTOMY

The most important finding in paper IV is that TT, compared with TE, proved to be associated with significantly lower risk for postoperative morbidity especially regarding postoperative haemorrhage in children with tonsil-related upper airway obstruction. The primary outcome, readmission due to postoperative haemorrhage, was more common after TE (2.5%) than after TT (0.6%) (Adjusted OR 3.90, 95% CI 3.17-4.80, $p < 0.0001$). As far as we are aware, this is the largest study to date comparing postoperative morbidity following TT and TE, respectively. The strength of a well-designed register-based cohort study is the opportunity to study unusual outcomes such as return to theatre (RTT) due to postoperative haemorrhage, as well as prognostic factors for postoperative morbidity. Registries also make it possible to assess real world outcomes in a less controlled environment.

Two different outcomes of postoperative haemorrhage were studied: readmission due to postoperative haemorrhage and RTT due to postoperative haemorrhage. Both these outcomes were more favourable following TT compared with TE. Our results are in line with a recently published cohort study in which Chang et al. reported a 0.2% rate of postoperative haemorrhage following TT and 2.9% following TE. In this study, RTT occurred in 1.6% of cases following TE and 0% of cases following TT. Unfortunately, the authors did not include what definition

of postoperative haemorrhage was used in the study.¹⁴⁰ A systematic review by Zhang et al. (32 studies, 19 randomised and 13 non-randomised) showed that the odds of secondary haemorrhage (after 24 h) were 79% lower following TT compared with TE (OR 0.21, 95% CI 0.17-0.27, $p < 0.01$). Among the studies in the review that reported haemorrhage resulting in hospitalisation, TT was associated with a much lower rate than TE (0.2% versus 1.4%).¹⁴¹

TE and higher age at surgery proved to be independent risk factors for readmission due to postoperative haemorrhage, while simultaneous adenoidectomy was associated with lower risk. The finding that simultaneous adenoidectomy was an independent factor for lower risk of readmission due to postoperative haemorrhage was unexpected and has no simple explanation. Intuitively, the addition of a concurrent surgical procedure should increase the risk of postoperative morbidity. To reduce the influence of confounders, we excluded patients who had other concurrent surgeries (except adenoidectomy), as well as patients with diagnoses other than “obstruction/SDB” at the time of surgery. Perhaps, despite these efforts, patients who undergo tonsil surgery with simultaneous adenoidectomy differ in some respect from the group of patients who undergo tonsil surgery without adenoidectomy in such a way that it is not possible to detect using the data available in the NPR.

The major disadvantage of TT is the risk of regrowth, which may require reoperation of the tonsils. A recently published Swedish RCT comparing adenotonsillectomy (ATE) with adenotonsillotomomy (ATT) in children with obstructive sleep apnoea, found that 13% of children in the ATT group required reoperation with tonsillectomy (TE) compared with none in the ATE group.¹⁰⁹ In paper III we showed that the risk of reoperation due to recurrent symptoms was seven times higher after TT compared with TE and that the risk was strongly associated with age at surgery. This begs the question of whether there is a difference in morbidity following primary tonsil surgery compared with reoperation due to recurrent symptoms. This question has not previously been investigated. On the one hand, when comparing morbidity following primary TT with that following secondary TT (reoperation) we found no significant differences. On the other hand, compared with primary TE, secondary TE following primary TT resulted in an increased risk of postoperative complications. However, after adjustment for age, year of surgery and simultaneous adenoidectomy, only differences in rate of “readmission due to any reason” remained significant.

5.6 LIMITATIONS

The four studies in this thesis are based on data from two registries: The National Tonsil Surgery Register in Sweden (NTSRS) and the Swedish National Patient Register (NPR). The use of registries for observational cohort studies makes it possible to obtain data for many patients at a limited cost. The quality of the obtained data, however, will always be dependent on how meticulously they were entered into the register. By using medical registers, we are also relegated to using parameters and outcome measures that are predetermined by the structure of the register. Moreover, patients in the included studies were not randomised, which always entails a risk of influence from confounding factors.

Paper I

About 75% of tonsillectomies carried out in Sweden during the study period were included in the NTSRS. The outcome measures late PTH and RTT were obtained through 30-day questionnaires, which had a 61% response rate. There is a risk that the non-response rate may have depended on patient outcome, since those who experienced PTH may have been more inclined to answer the questionnaire, which would skew the results. However, this does not appear to be the case, since a comparison of cases entered in the NPR and the NTSRS regarding postoperative haemorrhage after all tonsil surgeries in 2012 (tonsillectomies entailing less risk of haemorrhage were also included here) showed a similar rate of haemorrhage (4.4 in the NPR and 4.9% in the NTSRS). In addition, a separate analysis of patients included in the study, but who did not respond to the 30-day questionnaire, showed no relevant clinical differences regarding demographics, indication or surgical technique compared with those who responded.

There is also a risk of selection bias since the choice between cold and hot surgical technique could have depended on whether or not the tonsillectomy was expected to be complicated, which may have resulted in a preference for cold technique alone in easier cases, such as children with obstruction-related problems. However, this does not appear to be the case since adjusting for age and indication did not change the results.

Paper II

The six surgical centres that participated in the QIP were invited and participated voluntarily, while the control group included surgical centres with similar PTH rates, but that had not been invited to participate in the QIP. Voluntary registration is comparable to self-selection and may be associated with greater willingness to embrace change, which could have affected the results. However, baseline measurements show only minor or no differences regarding PTH rates

and process indicators (dissection and haemostasis techniques), which means that even if the intervention group had been more willing to embrace change, there would have been no positive impact on their PTH rates prior to the start of the QIP.

Although the groups had similar PTH rates prior to the QIP, there were minor differences in other variables at baseline. A small but significant difference for the indication of TE was seen; the control group contained more patients with infection-related indications at baseline. However, no differences in indication were seen within the groups between baseline and follow-up, suggesting that the indication for TE had no effect on the lower PTH rate seen in the intervention group. Moreover, some centres in the control group carried out relatively fewer TEs per year. Data from the NTSRS, however, have not shown any association between surgical procedure volume at centres and their PTH rates.¹²³

Preferably the follow-up period should also have been longer than one year in order to assess whether the lower PTH rates seen after the QIP could be maintained. Unfortunately, data from the NPR did not provide longer follow-up times and we only wanted to present full years in order to avoid the risk of seasonal effects.

Papers III and IV

Both papers III and IV are at potential risk for selection bias in the choice between TE and TT for the first surgery. Nevertheless, longitudinal data from the NTSRS suggest that the most important factor determining choice of surgical procedure is traditions and accepted clinical practice at the local ENT department. Data from the NTSRS show that TT has gradually, ENT department by ENT department, replaced TE as first-line surgical treatment for children with obstruction/SDB.¹⁸ This process can be viewed as a type of pseudo-randomisation, which should minimise the influence of selection bias.

In both studies, patients in the TT group were somewhat younger than those in the TE group. However, the outcomes were adjusted for age in both studies and remain significant even after such adjustment.

An important limitation of study III pertains to the age-related pattern seen in the rate of tonsil surgery among children and adolescents. Patients operated for obstruction/SDB are generally younger than patients operated for infection-related problems (surgical rates peak at ages 3 to 5 years and 16 to 18 years, respectively).^{24,25} Despite a relatively long follow-up period (up to 6 years), it is not long enough to cover the second peak in rates of tonsil surgery attributable to infection-related problems. Consequently, the need for a second tonsil

surgery following TT could be underestimated in our study.

To reduce the influence of confounding factors in paper IV, we excluded patients who had other concurrent surgeries (except adenoidectomy), as well as patients with diagnoses other than “obstruction/SDB”.

One limitation of paper IV is that the surgical techniques used for TT and TE are not specified in the NPR. In a recently published study surgical technique was found to be the most important factor affecting postoperative morbidity after paediatric TE.⁸⁴ The lack of this information in our study may impact generalisability.

6.

Conclusions

All hot techniques, including cold dissection combined with hot haemostasis, result in significantly higher risk for late PTH compared with cold steel and cold haemostasis. An early PTH is associated with a higher risk for late PTH

A quality improvement program is able to reduce PTH rates. A national quality register can be used not only to identify areas for improvement, but also to evaluate the impact of subsequent improvement efforts and thereby guide professional development and enhance patient outcomes.

The risk of reoperation is seven times higher after TT compared with TE when performed in children for the indication tonsil-related upper airway obstruction. Younger age is associated with increased risk of reoperation in relation to both TT and TE and the difference in risk between TT and TE is greatest in the youngest age groups.

TT is associated with significantly lower risk of postoperative complications than TE when performed to relieve tonsil-related upper airway obstruction in children. The only difference found between secondary TE after primary TT or primary TE was in the outcome variable “readmission for any reason”, with higher risk seen following secondary TE.

7.



Future perspectives

Despite the lengthy history of tonsil surgery, there are still aspects that need to be elucidated by future research. Developmental advances in surgical techniques for tonsil surgery continue and it is important to integrate new techniques in an orderly manner as described in the introduction to this thesis. In this context register-based research serves as an important complement to other research. The NTSRS and other Swedish quality registries can play an important role, for which reason continued development of the register is worthwhile. Increased “completeness” and increased response rate regarding data pertaining to Patient Reported Outcome Measures (PROM) are crucial for the continued relevance of the NTSRS. Recently a collaboration has been initiated with the other Nordic countries which will further increase the generalisability of data from the NTSRS.¹⁴² Integrating a specific register such as the NTSRS into the medical record system is important for reducing duplicate entries. Furthermore, it is possible that register-based RCTs will serve as the foundation for increased standardisation of future implementation of new surgical techniques, since such studies would not be saddled with the same problems regarding external validity as traditional RCTs.

As was previously noted in this thesis, there is a gap between the best possible care according to current research and the care that is actually provided in daily medical practice. In paper II we show that a QIP helped to reduce the rate of PTH. The NTSRS played an important role in monitoring the effects of the quality improvement project at each surgical centre. It would be interesting to see whether these improvements can be maintained for a time period longer than one year. Moreover, it would be interesting to see whether similar QIPs can be implemented at other surgical centres in order to further reduce the complications following tonsil surgery. In such case it would be important to analyse which changes contribute most to positive outcomes.

In papers III and IV we contribute important perspectives to the discussion concerning what should be the preferred surgical procedure for children with obstruction/SDB. Regrowth of the tonsils with recurrent symptoms of obstruction/SDB and the need for reoperation comprise the major disadvantage of TT. The reasons why some children tend to experience tonsil regrowth while others do not is an important area for continued research. Identifying risk factors for regrowth of tonsil tissue is extremely interesting since such knowledge might enable customised surgical treatment for the individual child. The role played by removal of the adenoids (adenoidectomy) in conjunction with tonsil surgery has yet to be elucidated by research. Large well-designed prospective studies that compare different combinations of tonsil procedures and adenoidectomy would be of considerable value.

8.

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Appendix

Tonsilloperation peroperativ enkät.

Reviderad version 161110

* obligatoriskt

Personnummer: _____

Namn: _____

e-post: _____

Datum när enkäten fylls i: _____

Operationsdatum*: _____

Huvudindikation* (endast ett alternativ)

- Luftvägsobstruktion/snarkning /hypertrofa tonsiller
- Upprepade tonsilliter
- Peritonsillit
- Kronisk tonsillit
- Systemkomplikation till tonsillit
- Om annat, specificera:
-

Operationsteknik

- Kallt stål
- Radiofrekvens
- Diatermisax
- Ultracision
- Dissektion med bipolär diatermi
- Annan, nämligen:
-

Blödningskomplikationer

Postoperativ blödning som krävt åtgärd?

Ja Nej

Om ja, vilken åtgärd?

- Cyklokapron/Octostim
- Transfusion
- Stillande av blödning i narkos
- Annat

Läkarens namn:



Tonsilloperationsregistret

Tonsilloperationsregistret,
ÖNH-registret, Registercentrum Västra Götaland,
413 45 Göteborg,
ordförande Joacim Stalfors
Joacim@stalfors.se

PATIENTENKÄT

Fylls i 30 dagar efter tonsilloperation

Reviderad version (180301)

Du/ditt barn har blivit opererad för halsmandlarna för ca 30 dagar sedan. För att kunna förbättra vården är det viktigt att få veta om komplikationer har uppstått efter operationen. Vi är angelägna om dina/ditt barns svar även om allt har varit besvärsfritt. Om du är vårdnadshavare eller annan anhörig vill vi att du besvarar frågorna som du tror att barnet upplever sin situation.
Tack på förhand för Din medverkan!

Namn: Patientens personnummer:

Epostadress:
(6 månader efter genomförd operation kommer du återigen tillfrågas att besvara en enkät. Om du önskar att den skickas via epost, ange här aktuell epostadress.)

Datum för ifyllandet av enkäten:

Du som fyller i enkäten är den som opererats anhörig/annan

Har du kontaktat sjukvården på grund av blödning från halsen? Ja Nej
Om Ja, hur många dagar efter operationen började det blöda?

Har du blivit inlagd på sjukhus på grund av blödning från halsen? Ja Nej
Om Ja, på vilket sjukhus blev du inlagd?

Utfördes ytterligare operation p g a blödning? Ja Nej

Uppstod någon infektion under vårdtiden eller inom 30 dagar efter operationen? Ja Nej
Om Ja, vilken sorts infektion?

Har du kontaktat sjukvården på grund av infektionen? Ja Nej

Har du fått antibiotikabehandling på grund av infektionen? Ja Nej

Har du kontaktat sjukvården på grund av smärta efter operationen? Ja Nej

Hur många dagar efter operation tog du smärtstillande läkemedel?

Hur många dagar efter operation började du äta vanlig mat?

Har informationen som du fått, stämt med hur du upplevde operationen och tiden efter? Ja Nej
Om Nej, vad stämde inte?

Har du tagit del av patientinformationen på www.tonsilloperation.se? Ja Nej



Tonsilloperationsregistret,
ÖNH-registret, Registercentrum Västra Götaland,
413 45 Göteborg.
ordförande Joacim Staffors
Joacim@staffors.se

PATIENTENKÄT

Fylls i 6 månader efter tonsilloperation

Reviderad version (161110)

Du/ditt barn har blivit opererad för halsmandlarna för ca 6 månader sedan. För att kunna förbättra vården är det viktigt att få veta hur dina/ditt barns besvär har förändrats efter operationen. Om du är vårdnadshavare eller annan anhörig vill vi att du besvarar frågorna om hur du tror att barnet upplever sin situation. Tack på förhand för Din medverkan!

Namn:

Patientens personnummer:

Datum för ifyllandet av enkäten:.....

Du som fyller i enkäten är den som opererats anhörig/annan

Sätt kryss i den ruta som bäst stämmer in på Din/Ditt barns situation:

- Besvären är borta
- Jag har blivit ganska bra från mina besvär
- Jag har kvar mina besvär
- Mina besvär har förvärrats

Har Du/Ditt barn fått andra besvär? Ja Nej

Om Ja, vilka?

.....

Eventuella kommentarer:.....

.....



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