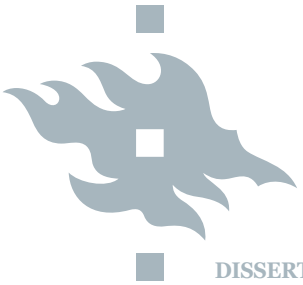

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JOHANNA RUOHOALHO

Complications and Their Registration in Otorhinolaryngology – Head and Neck Surgery

Special Emphasis in Tonsil Surgery Quality Registration

DEPARTMENT OF OTORHINOLARYNGOLOGY — HEAD AND NECK SURGERY
HELSINKI UNIVERSITY HOSPITAL
FACULTY OF MEDICINE
DOCTORAL PROGRAMME IN CLINICAL RESEARCH
UNIVERSITY OF HELSINKI

Department of Otorhinolaryngology – Head and Neck Surgery
Helsinki University Hospital

Doctoral Programme in Clinical Research
Faculty of Medicine
University of Helsinki

COMPLICATIONS AND THEIR REGISTRATION IN OTORHINOLARYNGOLOGY – HEAD AND NECK SURGERY

Special emphasis in tonsil surgery quality registration

Johanna Ruohoalho

ACADEMIC DISSERTATION

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Supervised by

Docent Leif Bäck
Department of Otorhinolaryngology – Head and Neck Surgery
University of Helsinki and Helsinki University Hospital
Helsinki, Finland

Professor Antti Mäkitie
Department of Otorhinolaryngology – Head and Neck Surgery
University of Helsinki and Helsinki University Hospital
Helsinki, Finland

Reviewed by

Professor Heikki Löppönen
Department of Otorhinolaryngology – Head and Neck Surgery
University of Eastern Finland and Kuopio University Hospital
Kuopio, Finland

Docent Heikki Teppo
Deparment of Otorhinolaryngology
Kanta-Häme Central Hospital
Hämeenlinna, Finland

Opponent

Professor Jaakko Pulkkinen
Department of Otorhinolaryngology – Head and Neck Surgery
University of Turku and Turku University Hospital
Turku, Finland

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To My Family

Life is best filled with learning as much as you can
about as much as you can.

- Tim Minchin

CONTENTS

LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications:

I Ruohoalho J, Mäkitie AA, Atula T, Takala A, Keski-Säntti H, Aro K, Haapaniemi A, Markkanen-Leppänen M, Bäck LJ. Developing a Registry for Complications in Otorhinolaryngologic Surgery: Tonsil Surgery as a Pilot Cohort. Otolaryngol Head Neck Surg. 2015 Jul;153(1):34-40.

II Ruohoalho J, Mäkitie AA, Aro K, Atula T, Haapaniemi A, Keski-Säntti H, Takala A, Bäck LJ. Complications after surgery for benign parotid gland neoplasms: A prospective cohort study. Head Neck. 2017 Jan;39(1):170-176.

III Ruohoalho J, Aro K, Mäkitie AA, Atula T, Haapaniemi A, Keski-Säntti H, Kylänpää L, Takala A, Bäck LJ. Prospective experience of percutaneous endoscopic gastrostomy tubes placed by otorhinolaryngologist – head and neck surgeons: safe and efficacious. Eur Arch Otorhinolaryngol. 2017 Nov;274(11):3971-3976.

IV Ruohoalho J, Østvoll E, Bratt M, Bugten V, Bäck L, Mäkitie A, Ovesen T, Stalfors J. Systematic review of tonsil surgery quality registers and introduction of the Nordic Tonsil Surgery Register Collaboration. Eur Arch Otorhinolaryngol. 2018 Mar 27. doi: 10.1007/s00405-018-4945-0. [Epub ahead of print]

The publications are referred to in the text by their roman numerals.

ABBREVIATIONS

CISP	Clinical Instrument Surveillance Program
ECD	Extracapsular dissection
EP	Extended parotidectomy
HNC	Head and neck cancer
HUH	Helsinki University Hospital
MDR	Medical data register
M&M	Morbidity and mortality
NSQIP	National Surgical Quality Improvement Program
NSQIP-P	Pediatric National Surgical Quality Improvement Program
NTSRC	Nordic Tonsil Surgery Register Collaboration
ORL-HN	Otorhinolaryngology – Head and Neck
ORL-HNS	Otorhinolaryngology – Head and Neck Surgery
PEG	Percutaneous endoscopic gastrostomy
POD	Postoperative day
PSP	Partial superficial parotidectomy
SP	Superficial parotidectomy

ABSTRACT

The incidence of complications is one of the most commonly used outcome measures in surgery. Nevertheless, systematic and continuous registers of surgical complications in Otorhinolaryngology – Head and Neck Surgery (ORL-HNS) are scarce. A systematic registration of complications creates possibilities to monitor and improve quality of care, allows for the comparison of treating units, and provides tools for treatment decisions and patient education.

Estimates of complication incidence for certain operation types of ORL-HNS have been presented in the literature, but corresponding analyses of complication rates at the Helsinki University Hospital (HUH) Department of ORL-HNS or nationwide in Finland have not been performed. This study aimed to evaluate the complication prevalence of three common procedures at our center, to discover corresponding predisposing factors for complications, and to develop a feasible prospective registration system for surgical complications in ORL-HNS. Additionally, this pursuit of register development has resulted in cooperation with Sweden, Norway, and Denmark, leading to the HUH Department of ORL-HNS's participation in the Nordic Tonsil Surgery Register Collaboration (NTSRC).

In the first study, 573 patients undergoing tonsillectomy or tonsillotomy at the Department of ORL-HNS, HUH, were prospectively recorded and evaluated for patient- and operation-related characteristics and postoperative complications. In addition, the comprehensiveness of prospective complication data recording was assessed, aiming to determine the pitfalls of the prospective registration process. The overall complication rate was 13.8%, with secondary hemorrhage being the most common complication at a rate of 9.6%. Altogether, 69.6% of patients with a complication were identified prospectively, and the rest were found when reviewing patient records. The most commonly occurring complications were recorded most comprehensively in prospective data retrieval.

In the second study, procedure-specific incidences of complications after benign parotid surgery were evaluated in a prospective cohort of 132 patients at the Department of ORL-HNS, HUH. Additionally, the study aimed to identify predictive factors for the development of postoperative facial nerve dysfunction. On the first postoperative day, 40.2% of patients had facial palsy. Palsy rates in the subgroups of extracapsular dissection, partial superficial

parotidectomy, superficial parotidectomy, and extended parotidectomy were 6.3%, 41.5%, 43.8%, and 53.8%, respectively. Results suggested age, duration of surgery, and use of an ultrasound knife as independent risk factors for transient facial palsy.

At HUH, otorhinolaryngology – head and neck (ORL-HN) surgeons have performed percutaneous endoscopic gastrostomy (PEG) tube placements for patients with head and neck cancer (HNC) since 2008. The aim of the third study was to evaluate this practice and the outcomes of PEG tube insertions in a prospective setting (n = 127). Furthermore, the study assessed delays in PEG tube insertions compared with the earlier practice of referring HNC patients needing a PEG to the Department of Gastrointestinal Surgery. Four patients (3.2%) suffered from a major complication. Peristomal granulomatous tissue was the most common minor complication (18.5%). Independence from gastrointestinal surgeons' services reduced the median time delay from 13 to 10 days and enhanced the availability of urgent PEG placements.

The fourth study of this thesis was a systematic literature review of tonsil surgery quality registers, and an introduction of the formed NTSRC. The systematic review revealed five registries, databases, quality improvement programs or comprehensive audit programs with an inclusion principle of tonsil surgery, and two of them had ongoing activity. The history of tonsil surgery quality registration in Sweden dates back to 1997, and the objective of our collaboration is to establish similar registration systems to other Scandinavian countries.

The three prospective studies acted as pilot projects for surgical complication registration at the Department of ORL-HNS, HUH, and a long-term objective is to develop a systematic surgical quality register to our unit. One part of it is the Finnish Tonsil Surgery Register, which will be implemented as part of the Helsinki and Uusimaa health care district's new patient record system, Apotti. The register variables are designed to be compatible with NTSRC, and after piloting the register in Helsinki, the future aim is nationwide coverage. NTSRC is the first reported international register collaboration project within the specialty of ORL-HNS, and in the future, it will allow for an extensive data pool for quality assurance and research purposes in tonsil surgery. NTSRC has the obvious potential to improve the current clinical practices of tonsil surgery, and to promote the establishment of definite guidelines.

TIIVISTELMÄ

Leikkauskomplikaatioiden ilmaantuvuus on yksi käytetyimmistä kirurgian tulosmittareista. Komplikaatioiden systemaattinen rekisteröinti mahdollistaa hoidon laadun seurannan, toiminnan kehittämisen ja yksiköiden välisen vertailun, sekä antaa eväitä hoitopäätösten tekoon ja potilasohjaukseen. Silti kattavia kirurgisten komplikaatioiden seurantajärjestelmiä on Suomessa hyvin vähän ja kansainvälisestikin korva-, nenä- ja kurkkutautien (KNK) erikoisalalla niukasti. Pään ja kaulan alueen kirurgian komplikaatioiden kirjo on alueen monimuotoisen anatomian ja fysiologian vuoksi varsin erityinen, joten yleiskirurgiset komplikaatiorekisterit soveltuvat huonosti KNK-alan leikkauskomplikaatioiden seurantaan.

Tutkimuksen tavoitteena oli kartoittaa kolmeen yksikössämme tavalliseen toimenpiteeseen liittyvien komplikaatioiden yleisyyttä ja riskitekijöitä, sekä samalla kehittää käytännön työhön soveltuvaa komplikaatioiden seurantajärjestelmää KNK-alan leikkausten erityispiirteet huomioiden. Rekisterin kehitystyö on poikinut yhteistyötä Ruotsin, Norjan ja Tanskan kanssa, ja johtanut HYKS KNK-klinikan osallistumiseen yhteispohjoismaiseen nielurisakirurgiarekisteriin.

Väitöskirjan ensimmäisessä osatyössä kartoitettiin prospektiivisessa asetelmassa nielurisakirurgian komplikaatioita ja niihin liittyviä riskitekijöitä. Lisäksi prospektiivisen keräyksen kattavuutta tutkittiin tavoitteena arvioida rekisteröintiprosessia ja siihen liittyviä ongelmakohtia. Aineisto sisälsi 537 potilasta, joille tehtiin tonsillektomia tai tonsillotomia. Komplikaatioita esiintyi 13.8%:lla. Myöhäisvaiheen jälkiverenvuoto oli tavallisin komplikaatio: sen ilmaantuvuus oli 9.6%. Kaikkiaan 69.6% komplikaatiopotilaista saatiin kiinni prospektiivisessa tiedonkeräyksessä, ja loput todennettiin retrospektiivisessä tietojen tarkistuksessa. Kattavimmin prospektiiviseen rekisteriin oli kirjattu yleisimmin ilmenevät komplikaatiot.

Toisessa osatyössä tutkittiin 132 potilaan prospektiivisessa aineistossa korvasylkirauhaskirurgian komplikaatioita, ja pyrittiin tunnistamaan ennustetekijöitä postoperatiivisen kasvohermohalvauksen ilmaantumiselle. Ensimmäisenä leikkauksenjälkeisenä päivänä 40.2%:lla potilaista oli kasvohermon toiminnan häiriö. Leikkauslaajuus vaikutti ilmaantuvuuteen: kapselin ulkopuolisen kasvaimen poiston jälkeen toimintahäiriö havaittiin 6.3%:lla, osittaisen pintalohkon poiston jälkeen 41.5%:lla, koko pintalohkon poistossa 43.8%:lla ja tätä laajemmissa poistoissa 53.8%:lla.

Riskitekijäanalyysin perusteella ikä, leikkauksen pidempi kesto ja ultraääniveitsen käyttö muodostuivat ohimenevän kasvohermohalvauksen itsenäisiksi riskitekijöiksi.

HYKS:ssa KNK-lääkärit ovat asentaneet perkutaanisia endoskooppisia gastrostoomaletkuja (PEG) pään ja kaulan alueen syöpäpotilaille vuodesta 2008. Kolmannen osatyön tavoitteena oli arvioida tätä käytäntöä ja tuloksia 127 potilaan prospektiivisessa tutkimuksessa. Lisäksi osatyössä arvioitiin PEG-letkun asennuksen viiveaikoja verrattuna aiempaan toimintatapaan lähettää PEG-letkua tarvitsevat syöpäpotilaat vatsaelinkirurgian endoskopiayksikköön. Neljällä (3.2%) potilaalla ilmeni vakava postoperatiivinen komplikaatio. Lievistä komplikaatioista tavallisin oli stooma-aukon granulaatio (18.5%). Riippumattomuus vatsaelinkirurgien palveluista lyhensi PEG-asennuksen viivettä ja paransi kiireellisten asennusten saatavuutta.

Kirjallisuudessa ei ole aiemmin kuvattu KNK-alan kansainvälistä laaturekisteriyhteistyötä. Neljännessä osatyössä arvioitiin systemaattisen kirjallisuuskatsauksen avulla nielurisakirurgian laaturekisterejä, ja kuvattiin pohjoismainen yhteisrekisteri kattaen alkuvaiheet, rekisteröitävät muuttujat, kansalliset rekisterit ja tähänastinen kokemuksemme. Yhteistyön tavoitteena on Ruotsissa vuodesta 1997 toimineen nielurisakirurgian laaturekisterin mallia noudattaen luoda vastaavat rekisterit muihin pohjoismaihin. Systemaattinen kirjallisuuskatsaus tunnisti viisi rekisteriä, laadunparannusohjelmaa tai kattavaa auditointiohjelmaa nielurisakirurgian alalta. Näistä kaksi on aktiivisesti toiminnassa.

Kolme prospektiivista tutkimusta toimivat kirurgisen komplikaatiorekisterin pilottihankkeina, ja pitkän aikavälin tavoitteena on kehittää systemaattinen kirurginen laaturekisteri klinikkaamme. Sen yksi osa tulee olemaan Suomen nielurisakirurgiarekisteri, joka toteutetaan osana Helsingin ja Uudenmaan sairaanhoitopiirin uutta potilastietojärjestelmää Apottia. Kun rekisteriä on pilotoitu Helsingissä, on toimintaa tulevaisuudessa tarkoitus laajentaa kansalliseksi. Suomen rekisterin muuttujat on suunniteltu yhteensopiviksi pohjoismaisen nielurisakirurgiarekisterin kanssa. Jatkossa yhteisrekisteri tarjoaa laajan potilasaineiston laadunvalvontatarkoituksiin ja tutkimusprojekteihin. Pohjoismaisella nielurisakirurgiarekisterillä on ilmeinen potentiaali nielurisakirurgian turvallisuuden parantamisessa ja standardoitujen hoitokäytäntöjen luomisessa.

1 INTRODUCTION

Surgical complication may be a sequela of medical error, patient-specific feature or comorbidity, or underlying disease process. Accordingly, some of the complications are inevitable, but part of the events could be prevented by improving treatment processes. Systematic measurement of surgery- and patient-related factors and outcomes of surgical procedures is a prerequisite for quality improvement, and therefore, surgical complication registration is a crucial element of safety enhancement in surgery.

In Finland, tonsil operations are the second most common procedure in otorhinolaryngology – head and neck surgery (ORL-HNS), only exceeded in number by tympanostomies [1]. Despite the regular nature of tonsil procedures, rather high proportion of the patients suffer from postoperative complications, most commonly bleeding [2,3]. Several studies have demonstrated that postoperative hemorrhage rates can be reduced by paying attention to surgical techniques and instrumentation [4-6]. Nonetheless, a large variation in clinical practices regarding tonsil surgery exists, and no international or national guidelines of best clinical practices have been established.

Parotid gland procedures represent relatively common but more complex ORL-HNS operations. The vast majority of parotid gland neoplasms are benign, but surgery is the treatment of choice. The facial nerve passes through the parotid gland, dividing it into superficial and deep lobes, and the nerve is exposed in most surgical modalities. Thus, benign parotid surgery is associated with relatively high postoperative morbidity in the form of facial nerve dysfunction. Only a few studies have assessed the complications after surgery on benign parotid gland neoplasms with a prospective study setting [7-11], and those evaluating procedure-specific complication rates and conducting the assessment of facial dynamics in a strict and standardized manner are lacking. Additionally, the discrepancy of risk factors of postoperative facial nerve palsy remains.

Percutaneous endoscopic gastrostomy (PEG) tubes are sometimes warranted in head and neck cancer (HNC) patients as an alternative route for nutrition, if the tumor obstruction, pain, or HNC treatments or their side effects prevent oral feeding. Although gastrointestinal surgeons have traditionally performed PEG tube placements, the responsibility of HNC management usually falls to the head and neck surgeons. Therefore, performing PEG tube insertions in ORL-HNS centers may be advantageous

in terms of cost effectiveness, logistics, and minimizing delay and the burden of the patient. In several countries, otorhinolaryngologist – head and neck (ORL-HN) surgeons are performing PEG tube placements [12]. However, prospective studies on otorhinolaryngologists' performance in PEG tube insertions have not been published. Furthermore, the time gains of such practice have not been analyzed.

Since 2008, the Department of ORL-HNS, Helsinki University Hospital (HUH), has carried out all PEG tube placements of HNC patients. There have been around 80 operations annually.

This doctoral thesis assessed patient characteristics, surgery-related factors, and complication rates of three commonly performed procedures (tonsil surgery, parotid surgery, and PEG tube placements) with prospective study settings. Regarding tonsil surgery, the comprehensiveness of prospective complications registration was evaluated, and the reasons for incomplete recording were contemplated. The parotid surgery study assessed the postoperative facial function with standardized evaluation methods and analyzed the risk factors of postoperative temporary facial palsy. Furthermore, for PEG tube placements, the study compared the time delay before and after the PEG insertion service of HNC patients was transferred from gastrointestinal surgeons to ORL-HN surgeons at HUH.

These three projects act as pilot projects for surgical complication registration at our unit. Tonsil surgery was chosen because it is a frequent procedure performed by both residents and consultant surgeons, and has a relatively short complication-prone recovery period. Parotidectomies represented more challenging operations with longer timelines in complication occurrence and the slowly reversible nature of the most common complication, postoperative facial palsy. PEG tube insertion is a rather novel surgical procedure in the ORL-HN surgeon's tool kit, and it was selected due to a recent change in practice at our hospital. The long-term objective of this project is to establish a surgical complication register database to improve the safety of surgery and quality of care at the Department of ORL-HNS, HUH.

Surgical quality registers in the field of ORL-HNS are sparse. To improve the knowledge of the existing quality registers within the tonsil surgery area, the fourth study of this thesis included a systematic review of the literature encompassing tonsil surgery quality registers.

As part of this doctoral dissertation project, the Department of ORL-HNS, HUH, has participated in the Nordic Tonsil Surgery Register Collaboration (NTSRC). Sweden has already had a tonsil surgery quality register for 20

years [13]. The NTSRC's objective is to launch national quality registers for tonsil surgery also in Denmark, Finland, and Norway. With uniform variables and consistent definitions, the NTSRC aims to achieve an extensive dataset to compare national practices, to assess uncommon events, to develop the best clinical practice protocols, and to enhance the safety of tonsil surgery.

2 REVIEW OF THE LITERATURE

2.1 DEFINITIONS AND CLASSIFICATIONS

2.1.1 DEFINING NORMAL POSTOPERATIVE RECOVERY

Recovery after surgery is a complex process including physical, psychologic, social, and economic aspects [14]. Sixty years ago, 20th century pioneer surgeon Francis D. Moore defined the recovery period as having been completed when "the individual has returned to normal physical well-being, social and economic usefulness, and psychological habitus" [15]. The more recent definition of postoperative recovery by Allvin et al. includes the same dimensions, but emphasizes the patient's individual preoperative level as a comparative standard for the normality of functions, independency, and well-being [16].

Lee et al. divide the recovery after surgery into three stages: The early phase is spent in the post-anesthesia care unit, usually lasting hours after surgery. The intermediate phase begins when the patient is transferred to the surgical ward. The final phase, late recovery, begins at hospital discharge and lasts until the patient returns to normal function and activity.[14]

Due to huge diversity in patient-, disease-, and surgery-specific characteristics, and to the multidimensional and complex nature of the recovery process, it seems impossible to define "normal" postoperative recovery. Instruments and measurements to assess some of the multiple dimensions of recovery have been developed [17,18], but a holistic definition or measure for normal recovery cannot be found. However, when the convalescence is hindered by surgical complication, recovery cannot be considered normal.

2.1.2 DEFINING A SURGICAL COMPLICATION

The term *complication* can encompass a broad spectrum of events resulting from the disease process or from surgical or other health care intervention. However, confusion and discrepancy about the definition of surgical complication remains [19].

In Gough's view, "the surgical complication is an undesirable or adverse outcome of an operation" [20]. The definition is simple and clear, but not very

precise, and some other authors have brought the semantic derivation of the definition further. The Association of Surgeons in the Netherlands has defined a surgical complication as "any state or event unfavorable to the patient's health, which arose during admission or within 30 days after discharge that either causes unintentional injury or requires additional treatment" [21]. This definition covers not only postsurgical complications, but also those occurring within surgical patients who have not undergone operation. Sokol and Wilson[19] emphasize the direct causal connection to surgery in their proposal: "A surgical complication is any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped." However, a direct causality between the surgery and complications is sometimes impossible to assess, and *failure to cure* or *sequelae* are different from a complication. Therefore, Dindo and Clavien suggest defining a surgical complication as "any deviation from the ideal postoperative course that is not inherent in the procedure and does not comprise a failure to cure" [22].

The further the definition is specified, the more restrictive it gets, and in view of complications registration in quality improvement purposes, the more exclusive it will be. To allow a wide variety of complications to be included and prevent the risk of underreporting, broad definitions may serve better in complications registration covering surgical and technical as well as other aspects of care.

Surgical complications can further be classified according to timing in relation to surgery. An intraoperative complication is any complication that occurs during the surgical operation, and a postoperative complication occurs after the end of the procedure. Some authors divide complications into early and late categories, and depending on the type of the operation, the time limit separating those two can be markedly variable [23-25].

Some other terms related to complications but with slightly different denotations should also be clarified. *Adverse events* represent a complication subgroup that is associated with health care intervention with a suboptimal outcome [26]. *Medical error* is defined by Grober and Bohnen as "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result" [27]. *Operative morbidity* is a temporary or permanent disability during or after the procedure, and even the most successful operation is associated with some degree of temporary morbidity, with or without a complication involved [26].

Other terms to designate inappropriate care and adverse outcomes in health care include (but are not restricted to) maloccurrences, medical injuries, therapeutic misadventures, substandard care, unexpected outcomes, preventable deaths, iatrogenic injuries, mishaps, negligence, and malpractice.

2.1.3 DEFINING A MEDICAL DATA REGISTER

The word *register* derives from the Medieval Latin *registrum*, which means a list of a book in which things are recorded. Solomon et al. [28] define the medical data registry (MDR) as "a database of identifiable persons containing a clearly defined set of health and demographic data collected for a specific public health purpose". A more detailed definition of MDR has been created by Drolet and Johnson [29], who propose five characteristics to be met: 1) mergeable data, 2) a standardized dataset, 3) rules for data collection, 4) observations associated over time, and 5) knowledge about patient outcomes. Furthermore, an inclusion principle, a characteristic that is common to all patients in a register, is required.

Other terms referring to MDR include patient registers, clinical registers, clinical data registers, disease registers, and outcome registers, among numerous others.

MDRs can be exploited to clinical, scientific, and health policy purposes. One register can serve several purposes, but these purposes should be defined before data collection. Namely, the data collection is purpose-driven rather than the purpose being data-driven. MDR can be used to observe the course of disease, to understand differences of distinct treatments and their outcomes, to assess factors influencing the outcome and prognosis, to monitor safety, and to measure quality of care. [30]

2.1.4 CLASSIFICATION OF COMPLICATIONS

Complications are important outcome measures of surgical procedures. Besides evaluating the type of complication, the severity of complications also warrants consistent reporting. Classifying complications increases the uniformity of reporting and enables more precise comparisons.

The general classification of surgical complications is the division of minor and major, major being the ones warranting revision surgery, hospital admission, blood transfusion or other significant treatment procedures, or leading to a patient's death. Minor complications are either self-limiting or

require only minimal intervention.[31] As this classification is rather vague, several more detailed classification systems have been proposed.

Clavien Dindo Classification of Surgical Complications

In 1992, Clavien et al. published a four-grade classification of surgical complications based on a therapy used to treat them [32]. In 2004, the classification was modified regarding the grading of life-threatening complications and long-term disability due to complication, and the duration of the hospital stay was no longer used as a criterion to grade complications [33]. This improved classification has five grades containing seven levels of severity (Table 1). Ever since, it has been widely used in the surgical literature, with more than 10,000 citations to date.

Table 1. *Clavien-Dindo Classification of Surgical Complications*[33]

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic or radiological interventions. Allowed therapeutic regimens are antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. Grade I includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drug other than such allowed for Grade I complications. Blood transfusions and total parenteral nutrition included in Grade II.
Grade III	Requiring surgical, endoscopic, or radiological intervention.
Grade IIIa	Intervention not under general anesthesia.
Grade IIIb	Intervention under general anesthesia.
Grade IV	Life-threatening complication (including CNS complications*) requiring IC/ICU management.
Grade IVa	Single organ dysfunction (including dialysis).
Grade IVb	Multiorgan dysfunction.
Grade V	Death of a patient.
Suffix "d"	*If the patient suffers from a complication at the time of discharge, the suffix "d" (disability) is added to the respective grade of complication, indicating the need for a follow-up to fully evaluate the complication.*

Abbreviations: CNS, central nervous system; IC, intermediate care; ICU, intensive care unit
**brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks.*

Accordion Severity Classification of Surgical Complications

Accordion classification has been modified from other previously proposed classifications to fit the needs of surgical authors. The creators' ambition was to make severity grading of complications more flexible, more understandable, and more accessible. The creators analyzed the studies' use of the Clavidien-Dindo Classification and other two classification systems and noticed that 59% of authors had to contract the classifications to meet their studies' needs. As a result, they proposed an expandable classification: a contracted version with four severity levels and an expanded version with six levels, to correspond to the needs of simple and more complex studies (Table 2). Instead of numerical grading, they introduced the descriptive terms for severity classes to clarify the internally evident meaning. Third, they introduced a standard reporting table system and created a web site where anyone can enter their study data and download a standard table of complications ready for publication. [34]

Table 2. *Accordion Severity Classification of Postoperative Complications: Contracted and expanded classifications*.[34]

Accordion Severity Classification of Postoperative Complications	
1. Mild Requires only minor invasive procedures that can be done at the bedside (i.e., intravenous lines, urinary catheters, nasogastric tubes, drainage of wound infections). Physiotherapy and the following drugs are allowed: antiemetics, antipyretics, analgesics, diuretics, and electrolytes.	
2. Moderate Requires pharmacologic treatment with drugs other than those allowed for minor complications (e.g., antibiotics). Blood transfusions and total parenteral nutrition included.	
CONTRACTED	**EXPANDED**
3. Severe All complications requiring endoscopic or interventional radiologic procedures or re-operation as well as complications resulting in the failure of one or more organ systems	**3. Severe** Invasive procedure without general anesthesia **4. Severe** Invasive procedure under general anesthesia **5. Severe** Organ system failure
4. Death Postoperative death	**6. Death** Postoperative death

2.2 GENERAL ASPECTS OF REGISTERING SURGICAL COMPLICATIONS

Up to half the complications in surgical patients are due to provider error and could be preventable [35], contrary to disease-related unavoidable events. In 2001, the Institute of Medicine Committee on Quality of Health Care in America stated six values to define health care quality: safety, effectivity, patient-centricity, timeliness, efficiency, and equitability [36].

To produce and improve the quality, measuring it first to identify the requisites for quality improvement actions is warranted. Along with the effectiveness of the treatment, complications are the most evident outcome measure in surgery, and their systematic registration is fundamental to evaluate the safety and success of different approaches to a procedure in order to monitor the safety of devices and compare the performance of different units.

2.2.1 MORBIDITY AND MORTALITY CONFERENCES

Morbidity and mortality (M&M) rounds have been used for quality assurance and educational purposes in surgical departments for over a century [37]. The Accreditation Council of Graduate Medical Education requires departments offering surgical education, including ORL-HNS, to incorporate M&M conferences in their education programs [38]. M&M rounds represent a primary quality assurance method by which surgical units are monitoring and responding to complications and adverse events [39]. A traditional surgical M&M conference is a weekly session in which residents and attendees present all identified complications and deaths, which are then discussed and reported [40].

M&M conferences are usually based on voluntary reporting, so their role in the registration of surgical complications is not encompassing, but they can be considered as a component of a quality assurance program [41]. The educational value of M&M conferences is acknowledged [39], but compared to surgical quality registers, their value in quality assurance is considered insufficient [41,42]. M&M conferences seem to underreport both in-hospital and post-discharge complications and deaths. Hutter et al. demonstrated that approximately half of the deaths and 75% of complications remained underreported compared to systematic quality improvement program. [40]

2.2.2 SURGICAL QUALITY REGISTERS

Surgical quality registers provide an organized and standardized method to systematically collect data on a specific group of patients. Data can be used as a source of information regarding health care patterns, decision-making, and delivery, and can help in analyzing the association of these factors with outcomes. Registers have the advantage of uniform and often comprehensive data collection methods. Additionally, the management of patients is determined by the caregiver, not by the register protocol, so the reported outcomes can be representative and well generalized to the real-world practice. [30]

Surgical quality registers can serve several potential functions. They can be used as a tool to study disease processes, to analyze the factors influencing the clinical course or prognosis, to assess the efficacy and safety of treatment protocols or surgical devices, to study regional differences and disparities in the delivery of care, and to measure quality or cost-effectiveness [30,43]. Clinicians, patients, health care organizations, payers, or device manufacturers can all exploit register data differently to respond to their own purposes [30].

Larsson and Lawyer have demonstrated that quality registers have a great potential to both improve outcomes and decrease the costs of health care [44]. Although the expenses of surgical quality registration with large-scale data collection, auditing, validation, and active follow-up have been criticized, cost analyses have demonstrated that the gained reduction in complication occurrence covers the expenses of the surgical quality register multiple times [45,46]. Only a 1.8% reduction of complication rates can cover the annual expenses of surgical quality register actions [47].

2.3 QUALITY REGISTRATION IN ORL-HNS

2.3.1 GENERAL SURGICAL QUALITY REGISTERS COVERING ORL-HNS PROCEDURES

The National Surgical Quality Improvement Program (NSQIP) administered by the American College of Surgeons (ACS) collects data in a standardized manner on preoperative risk factors, intraoperative variables, and 30-day-postoperative outcomes for patients undergoing surgical procedures [48]. Today, almost 700 hospitals (mainly in the United States, but also in Canada, Australia, and the Middle East) are

participating [49]. The number and types of variables collected differ from hospital to hospital depending on the hospital's size, the patient population, and the quality improvement focus. A variety of ORL-HNS procedures is registered and includes, but is not restricted to, surgery on the salivary glands, oral cavity, thyroid, neck, middle ear, mastoid, inner ear, and larynx. [50-52] Adult tonsillectomies are included, but in pediatric NSQIP (NSQIP-P), some low-risk, high-volume procedures such as adenotonsillectomy and tympanostomy are not collected, so that the capture rate of rarer procedures with potentially higher complication risks could be increased [53].

Several studies have demonstrated that hospitals using NSQIP have achieved measurable savings and improvement in quality of care by reducing complications and mortality related to operations [54-56]. Compared to NSQIP, the traditional M&M conferences seem to underreport both in-hospital and post-discharge complications and deaths, and therefore, NSQIP may provide a better foundation for quality improvement [40,42]. However, the NSQIP has certain limitations and is not actually a complication registry. It only collects a small sample of the operations performed, making subgroup analyses, such as procedure-specific outcomes or individual surgeon performances, impossible or unreliable. The follow-up window is only 30 days, so complications occurring after that are not registered. It also excludes some operations, e.g., additional operations on the same patient within 30 days of the index procedure and some specific operations with low mortality and morbidity rates. [40,42]

The Association of Surgeons in the Netherlands has developed a uniform nationwide reporting system of surgical adverse events [57-59], including head and neck procedures. The Dutch register is doctor-driven and integrated into routine clinical care. The register is managed with special software, and information can be retrieved directly from other hospital information systems. Also, a web-based submission of data is possible. [57] In addition to the three-dimensional complication data including type, location, and appropriate contextual information of the complication [60], the recently updated version also records the complication severity according to the Clavien Dindo Classification [57]. The interactive online reporting tool provides feedback and comparative data to a single surgeon and to the attending health care units, and gives insight into potential quality improvement targets [57].

2.3.2 WHY ARE ORL-HNS QUALITY REGISTERS NEEDED?

Due to the anatomical aspects and complex physiological functions of the head and neck area, surgical complications in ORL-HNS differ remarkably from those in other surgical fields. General surgical quality registries do not always take site-specific factors into account.

Several examples can be found in studies using NSQIP data. The weakness of NSQIP regarding ORL-HNS outcome assessment is that the complication information collected is not sufficiently adjusted to site-specific complications. Awad et al. evaluated NSQIP's ability to identify postoperative complications in oral cavity squamous cell carcinoma and found the rate of identified complications to be only 33% [61]. Another analysis of NSQIP data revealed that infectious complications (urinary tract infection, pneumonia, and superficial site infection) are the most common postoperative adverse events after tonsillectomy [62]. The third publication using NSQIP data affirmed a reoperation rate of 3.6% after adult tonsillectomy [63], which most certainly mirrors the hemorrhagic complications, but as most post-tonsillectomy hemorrhages can be treated at an outpatient clinic, it obviously does not reflect the true incidence. In view of these NSQIP studies, it is apparent that this general surgical quality register's ability to detect site-specific complications is inappropriate.

2.3.3 ORL-HNS QUALITY REGISTERS

Specialty-focused reporting programs have the advantage of being able to tailor to the practical needs of their respective specialties. In ORL-HNS, a few specialty-specific quality registration programs have been described.

The American Academy of Otolaryngology – Head and Neck Surgery is developing a Reg-ent[SM] ENT Clinical Data Registry in partnership with FIGmd Inc., a company that specializes in integrating electronic patient records with registries. Reg-ent focuses on patient outcomes and quality improvement from the ORL-HNS specialty-specific perspective. Relevant data are extracted automatically from patient records to the register, and a web entry tool for reporting is available for the practices without an electronic patient record system. Reg-ent is still under development, and it now offers participating practitioners the possibility to run queries to evaluate their performance and compare it to larger aggregated data to uncover potential areas for quality improvement. It also helps members complete reporting for federal programs, as a Merit-based Incentive Payment System. In the future,

more benefits will be launched. [64] No publications of Reg-ent data could be found in Pubmed as of the time of this writing.

In Sweden, the establishment of health care quality registers is highly developed. Currently, more than 100 medical quality registers exist, nine of which focus on ORL-HNS and operate under the supervision of the Swedish Association for ORL-HNS. They broadly represent the care of ear, nose, and throat diseases, covering both surgical procedures and hearing rehabilitation. [65]

One of the registers is the National Tonsil Surgery Register in Sweden, which was launched in 1997 and has since been under constant development to improve the safety of tonsil surgery [5,66-69]. The primary register operated until 2008 and recorded only complications occurring during the hospital stay. In 2009, the register was updated, and web-based questionnaires have since been distributed in order to collect more detailed information on patients' experiences and complications during the postoperative period. Today, the register covers approximately 80% of all tonsil surgery procedures performed in Sweden and includes data on over 120 000 patients. [70]

2.4 BRIEF INTRODUCTION TO THE PROCEDURES UNDER SCRUTINY

2.4.1 TONSIL SURGERY

Tonsillectomies and tonsillotomies are among the most frequently performed surgical operations in ORL-HNS in Finland [71]. Tonsillectomies have been conducted for over two thousand years, and tonsillotomies (partial removal of the tonsils) date back even further [72].

Until the 1930s, tonsillotomy was the most popular operation performed on the tonsils, but since the 1940s, tonsillectomy has replaced it in popularity. In recent years, tonsillotomy has once again become more accepted as an alternative to the tonsillectomy, especially when treating children with obstructive disorders. [73]

Indications

The Finnish Ministry of Social Affairs and Health has defined the general criteria for elective tonsil surgery. Indications for tonsillectomy include

recurrent acute tonsillitis, chronic tonsillitis, periodic fever in children, and pharyngeal obstruction caused by enlarged tonsils. [74] Additionally, unilateral tonsil hypertrophy presumed to be neoplastic is an indication for a more urgent tonsillectomy [75]. Practice regarding tonsillectomy in peritonsillar abscess is variable. Commonly, pediatric peritonsillar abscesses are treated with acute tonsillectomy [76]. In adult patients, tonsillectomy is considered in the case of recurrent peritonsillar abscess, or if the abscess cannot be drained and the antibiotic treatment is insufficient [75,77].

In Finland, indication for tonsillotomy is restricted in practice to obstructive symptoms in children: obstructive sleep apnea syndrome, problems in swallowing, or oral breathing causing dental malocclusion due to enlarged tonsils. However, the literature describes several patient series in which tonsillotomies have been performed for adult patients with indication of recurrent or chronic tonsillitis [78-80].

Surgical techniques

Tonsillectomy (also termed extracapsular, total, or subcapsular tonsillectomy) is the total removal of tonsils in the plane between the tonsillar capsule and the pharyngeal muscles. Tonsillotomy (subtotal, intracapsular, or partial tonsillectomy) involves removing the protruding tonsillar tissue while carefully avoiding damage to the capsule.

Tonsillectomy and tonsillotomy techniques can be categorized as "hot" and "cold". Hot techniques use electrosurgical instruments, either for the dissection of tonsil tissue or for hemostasis. Instruments may include different types of monopolar, bipolar, laser, ultrasonic, or radiofrequency devices. The cold technique uses only cold steel instrumentation, i.e., scalpel or scissors, and a snare may be used to amputate the inferior pole of the tonsil. Tonsillotomy may also be performed using a microdebrieder. [81] The surgical technique has been demonstrated to affect the incidence of postoperative hemorrhage and the severity of postoperative pharyngeal pain [4,82,83].

Complications

Although tonsillectomy is common and is usually an elective procedure, the risk of postoperative complications, most commonly postoperative hemorrhage, is relatively high. The reported incidences of post-tonsillectomy complications are widely variable: primary hemorrhage 0–1.5% [2,13,83,84],

secondary hemorrhage 0.8–40% [2,3,85-89], pain management problems 5.4–24.4% [87,90,91], dehydration 2.0–4.1% [85-87], postoperative infections 12.8% [90], and long-term taste disorders 0–1% [92,93]. Also, tonsillectomy- and tonsillotomy-related mortality has been reported [94-96]. Evidence of tonsillotomy patients having lower risk of postoperative hemorrhage, less pain, less readmissions due to dehydration, and a shorter recovery period is abundant [66,97,98]. Nevertheless, the risk of tonsil regrowth and re-operation is significantly higher after tonsillotomy. Recent meta-analysis reported an average regrowth rate of 3.2% and a secondary surgery rate of 1.6% in tonsillotomy patients [98].

2.4.2 BENIGN PAROTID SURGERY

Approximately 75% of parotid gland neoplasms are benign [99]. Surgical resection is the treatment of choice for most benign parotid neoplasms. For optimal surgical outcome, the benign parotid tumors must be completely excised, whereas the facial nerve should stay intact.

Indications

Benign parotid disease includes a wide spectrum of different pathologies, the most common being pleomorphic adenomas, Warthin's tumors, non-neoplastic cysts, and infectious or inflammatory processes [100,101]. Less common benign tumors of the parotid gland include basal cell adenomas, canalicular adenomas, oncocytic papillary cystadenomas, oncocytomas, myoepitheliomas, and papilliferous sialadenomas [102]. It is generally agreed that surgical treatment is indicated for all patients with parotid gland mass, as the surgical excision enables a definitive diagnosis [103]. A follow-up can be an option for surgery in a selected group of patients with cytological evidence of a Warthin's tumor without suspicious elements on the imaging [104].

Occasionally, inflammatory processes of the parotid gland may also be treated with surgical excision [105].

Surgical techniques

Parotid surgery for benign indication is a compromise between adequate tumor excision and preservation of facial function. Thus, surgery aims to complete removal of the neoplasm with an adequate cuff of surrounding

normal tissue, while the branches of the facial nerve are carefully dissected and preserved. The extent of the operation depends on the histology, size and location of the tumor [106].

Most benign neoplasms are in the superficial lobe of the parotid gland, and superficial parotidectomy (SP) is considered to be a traditional approach in treating benign parotid tumors. SP involves the identification of the main trunk of the facial nerve and the removal of the entire superficial lobe of the parotid gland, i.e., all the gland that is superficial to the facial nerve. Partial superficial parotidectomy (PSP) is a more conservative approach; it still identifies the main trunk of the facial nerve, but solely excises the part of the superficial lobe that contains the tumor. [106] The most conservative surgical modality is extracapsular dissection (ECD), in which only the tumor is resected with an adequate margin, but the facial nerve trunk is not exposed [107]. Subtotal or total parotidectomy is required in deep lobe tumors. Upton et al. [108] proposed the term "extended parotidectomy" (EP) to describe a parotid surgery in which any portion of the deep lobe is removed. The most extensive form of parotid surgery is a radical parotidectomy, which refers to the complete removal of the parotid gland and some parapharyngeal tissue, as well as the sacrifice of all branches of the facial nerve [109], but it is not indicated in benign parotid surgery.

Complications

The most frequent complications after benign parotid surgery include facial palsy, hemorrhage, infection, seroma/sialocele, salivary fistula, and gustatory sweating (Frey's syndrome).

Facial palsy may result from a direct incisive trauma, nerve stretching and manipulation, or a thermal effect on the nerve during surgery. It can also ensue postoperatively from swelling or hematoma of surrounding tissues. Reported rates of temporary facial palsy after parotid surgery with benign indication vary between 15% and 66%[7,9,100,110-112] and strongly depend on the extent of surgery and methodological factors such as the assessment methods of facial function and the timing of evaluation. The incidence of permanent facial palsy in benign parotid surgery varies between 1% and 6% [110-115].

Sialoceles are collections of saliva at the surgical site, and seromas contain serum. However, distinguishing these two is often irrelevant, and without measuring the amylase level of the fluid, it is impossible. Furthermore, one can speculate that at the parotidectomy site, at least a portion of the fluid is saliva in all cases, so even the amylase testing is not definitive. [116] The reported

postoperative sialocele/seroma incidence in benign parotid surgery is 1.9–19.6% [9,117-119]. Salivary fistula formation has been recognized after 1–10% of benign parotidectomies [110,112,114,117]. Pathogenesis of both sialocele and fistula is related to gland parenchyma damage, resulting in the leakage of saliva into the tissue. Postoperative infection incidences after parotid surgery for benign indication are between 1.6% and 9.2% [9,110,114,117].

Parasympathetic nerve fibers stimulating parotid secretion are damaged during parotid procedures. Cross-innervation of those fibers to the sympathetic nerve branches of cutaneous sweat glands may promote gustatory sweating and flushing, also known as Frey's syndrome [102]. The occurrence of Frey's syndrome in studies is widely variable. The time of evaluation and the performed diagnostic examinations strongly influence the detection of sweating. Generally, 5–10% of patients need treatment, approximately 20%–30% will admit their symptoms when questioned, and over 90% will have some degree of gustatory sweating during mastication with the starch iodine test [110,120,121].

2.4.3 PEG TUBE INSERTION

Dysphagia is a common sequela of HNC and its treatments. The inability to swallow and maintain a nutritional status with oral intake indicates an alternative route for feeding, and PEG is often the treatment of choice. PEG tubes are traditionally placed by gastrointestinal surgeons, but the execution of the procedure has increasingly been carried out by ORL-HN or maxillofacial surgeons [12]. Complication rates between gastrointestinal surgeons and ORL-HN surgeons have been considered comparable in previous studies [122].

Indications

Generally, percutaneous gastrostomy is recommended for parenteral nutrition if the expected time for tube feeding exceeds 30 days [123].

Enteral feeding with PEG is often necessary in patients with HNC or esophageal cancer; their oral intake may be impaired and their nutritional status compromised, either by the disease itself or because of treatment or its side-effects, such as xerostomia, fibrosis, mucositis, or neuropathies. The optimal time for PEG placement in HNC treatment –induced swallowing difficulties is controversial. A prophylactic PEG may be beneficial in terms of a better quality of life and less aspiration, strictures, hospitalizations, or

interruptions in oncologic treatments [124-128], but concern about the prophylactic PEG tube's impact on the swallowing function has been raised [129,130].

Other conditions in which a PEG tube may be indicated include a variety of neurological disorders caused by cerebrovascular stroke, cerebral trauma, brain tumor, or progressive neurological disease. In patients with psychomotoric retardation, progressive degenerative conditions, congenital anomalies, short bowel syndrome, prolonged coma, or polytrauma, PEG can be useful. Furthermore, PEG can be employed for supplemented nutritional support in catabolic conditions such as cystic fibrosis, burns, and AIDS wasting syndrome, or for gastric decompression, for instance in unresolved gastrointestinal stenosis, ileus, or gastroparesis. [131,132]

Surgical technique

Several techniques for PEG introduction have been described. The "pull-out", "push-over-wire", and "introducer" are currently the most used methods in clinical practice [132]. Cephalosporin- or penicillin-based intravenous antibiotic prophylaxis is recommended to reduce the risk of postoperative surgical site infection [133].

In all techniques, the proper site for the PEG is determined by transilluminating the abdominal wall with an endoscope light, applying finger pressure at the maximal transillumination point, and verifying that point in the anterior gastric wall endoscopically.

In the "pull-out" method, first described by Ponsky and Gauderer [134], a needle-catheter is passed through a horizontal 5- to 10-mm skin incision at the selected site. A guidewire, passed through this catheter into the stomach, is then pulled out through the mouth along with the endoscope. The PEG tube is secured to the guidewire and pulled through the mouth, esophagus, stomach, and out of the incision site, so that the internal bumper settles against the gastric mucosa.

The Sachs-Vine [135] "push-over-wire" technique's first steps are similar to the "pull-out" method. After pulling the guidewire out of the patient's mouth, a special long, firm gastrostomy tube with a tapered end is loaded onto the wire. The wire is then held taut as the long gastrostomy tube is "pushed" over the wire and down the esophagus, into the stomach, and out the abdominal wall.

The "introducer" method described by Russell et al. [136], is initiated similarly to the other techniques. After inserting a short guidewire

transabdominally into the stomach, the PEG tube is pushed over the guidewire directly through the anterior abdominal wall to the stomach, under visual control through a gastroscope. Several modifications to the original introducer technique have been described [137,138].

In all techniques, adequate placement of the tube is confirmed endoscopically in the end, and the external bumper is positioned to hold the stomach in apposition to the abdominal wall. The tube can be rinsed with a small amount of saline after the procedure, and the enteral feeding can usually be initiated on the second postoperative day. The external bumper is loosened approximately three to five days post-insertion to avoid pressure necrosis.

Complications

PEG insertion for HNC patients is considered to be a relatively safe procedure [31,122]. Tumor-related stenosis or trismus may sometimes complicate the procedure, but in most HNC series, the success rate for PEG placement is over 94% [139-141]. Operation-related mortality rates of 0.3–0.8% have been reported in recently published HNC populations. [122,139,142]

Complications in PEG tube insertions are often divided into minor and major. Table 1 lists the complications, adapting the classifications presented by Shapiro and Edmundowicz [143] and Grant [31].

Most of the complications are self-explanatory. Buried bumper syndrome is a condition resulting from the submucosal embedding of the internal bumper of the PEG tube. The bumper disc can end up anywhere between the stomach mucosa and the surface of the skin and can lead to gastrointestinal hemorrhage, perforation, peritonitis, abdominal wall or intra-abdominal abscesses, or phlegmon. [144]

Abdominal wall metastasis following PEG tube placement is a rare but unfortunate complication specific to HNC patients. Its reported occurrence is about 0.5–1% [145-147]. Several theories about the pathogenesis include direct traumatic seeding at the time of tube placement, tumor desquamation along the gastrointestinal track, and hematogenous spreading of circulating tumor cells to the PEG site [148,149].

Table 3. *Complications associated with PEG insertion*[31,143]

Major complications	Minor complications
Peritonitis requiring surgery	Granulation of stoma site
Sepsis	Local infection
Intra-abdominal abscess	Late extrusion of PEG tube
Gastric hemorrhage	Paralytic ileus
Intestinal fistula	Tube blockage
Obstruction of gastric outlet	Peristomal leakage
Early extrusion of PEG tube	Minor wound bleeding or hematoma
Buried bumper syndrome	Symptomatic pneumoperitoneum
Visceral perforation	
PEG site metastasis	
Necrotizing fascitis	
Aspiration pneumonia	
Abscess/necrosis of the abdominal wall	
Procedure-related mortality	

Abbreviations: PEG, percutaneous endoscopic gastrostomy

3 AIMS OF THE STUDY

The general aim of this thesis was to obtain accurate information about the complication prevalence in common surgical procedures at our center and to chart feasible prospective complication registration modalities to comprehensively register surgical complications in ORL-HNS, with special emphasis in tonsil surgery.

The specific objectives were:

1. To evaluate the complication rates in tonsillectomy and tonsillotomy at our center and to analyze the risk factors of post-tonsillectomy hemorrhage. (Study I)
2. To assess the comprehensiveness and pitfalls of prospective complication registration in tonsil surgery. (Study I)
3. To analyze the complication rates in benign parotid surgery at our center as well as the predisposing factors of transient postoperative facial nerve dysfunction. (Study II)
4. To evaluate the outcome of PEG tube insertions performed by ORL-HN surgeons and to assess the benefits obtained with transferring the HNC patients' PEG tube placement service from gastrointestinal surgeons to ORL-HN surgeons. (Study III)
5. To improve understanding of quality registries addressing tonsil surgery and to evaluate and design possibilities for a Northern European collaborative effort in this issue. (Study IV)

4 MATERIALS AND METHODS

4.1 PATIENT MATERIALS

All patients in studies I, II, and III underwent their operations and treatment at the Department of ORL-HNS, HUH, Helsinki, Finland.

4.1.1 TONSIL SURGERY (STUDY I)

All patients undergoing elective tonsillectomy or tonsillotomy (with or without adenoidectomy) between September 2011 and February 2012 were prospectively recruited. Re-operations and procedures performed due to malignancy or as part of a multilevel surgery for obstructive sleep apnea were excluded. Participants (n = 573) gave written informed consent. A wide range of demographic and clinical data were recorded into a complication database at the time of the operation.

All complications resulting in a visit to the outpatient department or warranting a hospital readmission were recorded by emergency department personnel (doctors or nurses) on hard copy forms, and the study group transferred detailed information on complications into a complication database. All adverse events occurring within nine months after the operation were recorded.

Nine months after the end of the study period, all medical records were reviewed retrospectively to assess the accuracy of the data in the complication register. The comprehensiveness of prospective data recording was assessed and postoperative complication rates were analyzed.

4.1.2 BENIGN PAROTID SURGERY (STUDY II)

Adult patients undergoing parotid surgery for benign indication between September 2011 and November 2012 were prospectively recruited. Patients were excluded for suspected malignancy or facial schwannoma, tumor extension into the parapharyngeal space, and previous parotid surgery. Altogether, 132 patients were included. Demographic, clinical, and operation related data were collected at the time of surgery, and the incidents of postoperative complications within 12 months of the procedure were prospectively recorded. Facial function was evaluated on the first

postoperative day (POD) by two physicians separately, with a clinical examination of all facial nerve branches. If any facial palsy was detected, the patient was assessed again after two weeks, and if necessary, after 6 months and 12 months.

Before data analysis, all the prospectively collected data were verified by reviewing the patient records. To analyze the complications, the patients were divided according to the type of operation (ECD, PSP, SP, EP). Risk factors for transient facial palsy were evaluated.

4.1.3 PEG TUBE INSERTION (STUDY III)

At HUH, all gastrostomy insertions were originally performed at the Department of Gastrointestinal Surgery, but since 2008, ORL-HN surgeons have carried out the PEG placements of HNC patients.

A prospective cohort of HNC patients having PEG tubes inserted by ORL-HN surgeons between October 2011 and May 2013 comprised 127 patients. Demographic data, tumor characteristics, indication for PEG insertion, time interval between the decision and the operation, and details of the procedure were gathered. All PEG placements were carried out using the "pull-out" technique described earlier (see page 29). All adverse events and data on PEG tube removal or patient death occurring within 12 months of the procedure were recorded.

To assess how much this new practice changed the delay from decision to procedure, a separate group of 110 HNC patients referred from our department to the Department of Gastrointestinal Surgery for PEG tube placement between September 2005 and September 2008 was reviewed. The complications of this patient cohort were previously analyzed and published [122]. Therefore, no comparison of the complication rates between the groups was included in this thesis.

After a 12-month follow-up period, the medical charts were reviewed to double-check the prospective data and complete any missing relevant data. Patient characteristics and complication rates were analyzed, and the time delay from decision to procedure was compared between the study group and the reference group.

4.2 STATISTICAL ANALYSIS

All the statistical analyses were conducted with SPSS software (Study I and II: version 19.0; Study III: version 21.0. IBM®, Armonk, NY). In Study I, the normality distribution of continuous variables was evaluated using the Kolmogorov-Smirnov Test. In Studies II and III, the normality of data distribution was determined with a visual inspection of histograms and with Skewness and Kurtosis measures.

In Study I, comparisons between the tonsillectomy and tonsillotomy groups were evaluated using the Mann-Whitney U Test for continuous variables and the Kruskal-Wallis Test for categorical data. Risk factor analysis of postoperative hemorrhage was conducted with binary logistic regression.

In Study II, the Kruskal-Wallis Test and a one-way analysis of variance were used to compare the surgical groups. Risk factors of transient facial palsy were assessed with univariate logistic regression analysis and the multivariable logistic regression model, and were reported by using odds ratios (ORs) with 95% confidence intervals (CIs).

In Study III, time delay comparisons between the groups were performed using the Mann-Whitney U Test and the Pearson χ^2 Test.

In all three studies, two-sided *P* values of < 0.05 were considered significant.

4.3 METHODOLOGY OF THE SYSTEMATIC REVIEW (STUDY IV)

The objective of the systematic review was to analyze the existing quality registers, databases, quality improvement programs and comprehensive audit programs addressing tonsil surgery. A search strategy was planned in co-operation with an information specialist at the Helsinki University Library of Health Sciences.

Systematic searches were conducted in two biomedical electronic databases, MEDLINE and EMBASE, using key words and Medical Subject Headings (MeSH) based on the terms Registries/Quality Assurance (Health care)/Quality Improvement/Population Surveillance/Databases (Factual)/Database management Systems/Outcome and Process Assessment (Health care)/ Audit.mp. combined with Tonsillectomy/Tonsil*.mp. A MEDLINE search was performed using the Ovid search engine, and supplemental EMBASE reference search with the Scopus database. Searches

were restricted to studies with an available abstract. Articles published in Danish, English, Finnish, German, Norwegian, or Swedish between January 1990 and December 2016 were included. The date of the last search was March 29, 2017. The MEDLINE search strategy using the Ovid search engine is described in detail in Table 4.

The initial title and abstract review to find potentially relevant publications was performed. Full texts of appropriate articles were then obtained for detailed evaluation. Registries, databases, quality assurance programs and comprehensive audit programs fulfilling the MDR definition of Drolet and Johnson[29] (see page 17), pursuing prospective data recording, and having a patient inclusion principle of tonsil surgery were accepted. The ones meeting criteria were analyzed to obtain data on the administration and history of the register, recorded variables, follow-up time, current activity, and clinical outcomes. To find additional studies and thorough information on the registries identified with a systematic search, the reference lists of the relevant publications were scrutinized, and additional internet searches (i.e., for database websites and other material concerning register content) were performed.

To design possibilities for Nordic collaboration, national statistics from Denmark, Finland, Norway, and Sweden were obtained, and literature regarding the differences in clinical practices between the collaborating countries was charted.

4.4 ETHICAL CONSIDERATIONS

Studies I, II, and III were approved by the Research Ethics Committee of HUH (DNRO 89/13/03/02/2011). All were observational cohort studies. The study subjects were prospectively monitored and the findings documented, and the study design did not actively affect the management of the participants. However, due to the prospective setting, all participants gave written informed consent. For study IV, no ethical approval was required, as the methodology was composed of a systematic literature review and the introduction of NTSRC, and no study subjects were included.

Table 4. *Strategy of Ovid MEDLINE systematic search for tonsil surgery quality registers*

	Searches	Result
1	exp Quality Assurance, Health Care/ or exp Quality Improvement	335675
2	exp Registries	86016
3	exp Population Surveillance	66359
4	exp Databases, Factual/ or exp Database Management Systems	126066
5	"Outcome and Process Assessment (Health Care)"	26991
6	audit.mp.	45788
7	exp Tonsillectomy/ or Tonsil*.mp.	36606
8	1 or 2 or 3 or 4 or 5 or 6	633834
9	7 and 8	625
10	limit 9 to (abstract and yr="1990–2016" and [Danish or English or Finnish or German or Norwegian or Swedish])	441

5 RESULTS

5.1 COMPLICATIONS IN TONSIL SURGERY (I)

Altogether, 794 patients underwent tonsillectomy or tonsillotomy during the study period. However, 143 chose not to participate, and 78 others did not fulfill the inclusion criteria. The final study group comprised 573 patients with the median age of 19 (range, 2–17). Tonsillectomy was performed for 454 (79.2%) patients, and 119 (20.8%) underwent tonsillotomy. The tonsillectomy and tonsillotomy groups' clinical features are described in Table 5.

Altogether, 85 complications were recorded in 79 patients. The overall complication rate following tonsillectomy was higher than that following tonsillotomy (17.0% vs. 1.7%, $P < 0.001$). Seventeen patients had a major complication that required hospital admission, 16 of them in the tonsillectomy group (3.5% vs. 0.8%, $P = 0.125$).

The complications encountered in each patient group are listed in Table 6. No primary postoperative hemorrhages (< 24 h) occurred. Secondary postoperative hemorrhage warranted an outpatient visit or hospitalization in 55 patients, and 13 of them had two separate episodes of bleeding. Only one patient (0.8%) in the tonsillotomy group vs. 54 (11.9 %) patients in the tonsillectomy group experienced minor bleeding ($P < 0.001$). The median manifestation time for the first secondary hemorrhage was on the seventh POD (range, 2–13).

In the tonsillectomy group, higher age was the only identified risk factor for secondary hemorrhage (Table 7): the hemorrhage rate was 6.0% in patients aged ≤ 16 compared to 14.2% in the > 16 age group ($P < 0.05$). The use of hot dissection techniques led to a higher post-tonsillectomy hemorrhage incidence compared to the cold techiques (13.6% vs. 7.6%), but the result did not reach statistical significance ($P = 0.07$).

When comparing tonsillectomy and tonsillotomy complication rates in children (aged ≤ 16), the total number of manifested complications and the secondary hemorrhage rate were significantly higher in the tonsillectomy group (10.7% vs. 1.7%, $P < 0.01$ and 6.1% vs 0.8%, $P < 0.05$).

Table 5. *Patient characteristics and surgical features in groups of tonsillectomy and tonsillotomy patients (n=573)*

	Tonsillectomy	Tonsillotomy	*P*
Total number of patients	454	119	
Age (median, range)	21 (2–70)	5 (2–14)	**< 0.001**
≤ 16	131 (28.9%)	119 (100%)	
Median, range	8 (3–16)	5 (2–14)	**< 0.001**
> 16	323 (71.1%)	0	
Sex			**< 0.05**
Male	187 (41.2%)	71 (59.7%)	
Female	267 (58.8%)	48 (40.3%)	
BMI (median, range)	22.4 (12.1–41.6)	16.7 (12.9–25.0)	**< 0.001**
Indication for surgery			**< 0.001**
Chronic tonsillitis	216 (47.6%)	0	
Recurrent acute tonsillitis	79 (17.4%)	0	
History of peritonsillar abscess	48 (10.6%)	0	
Upper airway obstruction	99 (21.8%)	117 (98.3%)	
Periodic fever	5 (1.1%)	0	
Other	7 (1.5%)	2 (1.7%)	
Operation technique			**< 0.001**
Bipolar dissection	320 (70.5%)	3 (2.5%)	
Cold steel dissection	134 (29.5%)	13 (10.9%)	
RFA		103 (86.6%)	
Use of local anesthetics	53 (11.7%)	104 (87.4%)	**< 0.001**
Surgeon			0.585
Consultant	317 (69.8%)	80 (67.2%)	
Resident	137 (30.2%)	39 (32.8%)	
Duration of operation (median, range)	0:20 (0:06–1:03)	0:22 (0:07–0:59)	0.092
Postoperative follow-up			0.380
Day case surgery	441 (97.1%)	117 (98.3%)	
Short stay surgery	13 (2.9%)	2 (1.7%)	

Abbreviations: BMI, body mass index; RFA, radio frequency ablation

Table 6. *Complication rates in tonsillectomies and tonsillotomies*

	Tonsillectomy (n = 454)	Tonsillotomy (n = 119)	*P*
Secondary bleeding	54 (11.9%)	1 (0.8%)	**< 0.001**
Minor	47 (10.4%)	1 (0.8%)	**< 0.01**
Major	7 (1.5%)	0	0.174
Infection minor	6 (1.3%)	0	0.208
Infection major	1 (0.2%)	0	0.609
Dehydration	3 (0.7%)	1 (0.8%)	0.843
Pain major	4 (0.9%)	0	0.305
Taste disturbance	5 (1.1%)	0	0.803
Other complication	10 (2.2%)	0	**< 0.05**
Any complication	77 (17.0%)	2 (1.7%)	**< 0.001**

Table 7. *Univariate analysis of factors associated with secondary postoperative hemorrhage in tonsillectomy patients (n=454)*

	Hemorrhage rate	P-value	OR	CI
Age				
≤ 16 y	6.0%	Ref.	1	
> 16 y	14.2%	**0.02**	2.6	1.19–5.66
Sex				
Female	11.2%	Ref.	1	
Male	12.8%	0.61	1.16	0.66–2.06
BMI				
< 20	8.5%	Ref.	1	
20–24.9	15.7%	0.08	2.00	0.93–4.29
≥ 25	10.6%	0.61	1.27	0.51–3.11
Operation technique				
Cold dissection	7.6%	Ref.	1	
Hot dissection	13.6%	0.07	1.92	0.94–3.95
Duration of surgery				
≤ 15 min	14.2%	Ref.	1	
16–24 min	11.1%	0.40	0.76	0.40–1.45
≥ 25 min	10.3%	0.34	0.69	0.32–1.48
Surgeon				
Resident	9.5%	Ref.	1	
Specialist	12.9%	0.31	1.41	0.73–2.72
Use of local anesthetic				
Yes	5.9%	Ref.	1	
No	12.4%	0.18	2.27	0.68–7.58

Abbreviations: BMI, body mass index

5.2 COMPREHENSIVENESS OF PROSPECTIVE COMPLICATION REGISTRATION IN TONSIL SURGERY (I)

Altogether, 55 of 84 complications were registered to the prospective complication database, and the remaining 29 were found when reviewing clinical charts. Generally, the common complications were prospectively identified better than the rare ones: 81.8% of postoperative hemorrhages were caught prospectively (Figure 1).

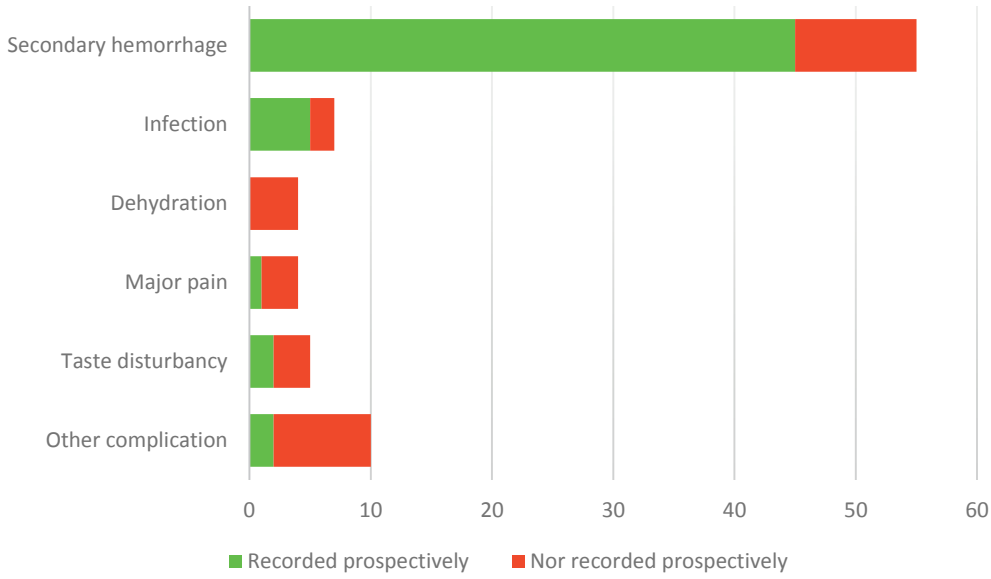

Figure 1. Proportions of prospectively registered complications according to complication type

5.3 COMPLICATIONS IN BENIGN PAROTID SURGERY (II)

A total of 132 prospectively recruited patients met the inclusion criteria. In five of them, the postoperative facial palsy assessment did not follow the study protocol, so they were excluded from the facial nerve dysfunction analysis. The distribution of operation types and histological diagnoses is presented in Figure 2.

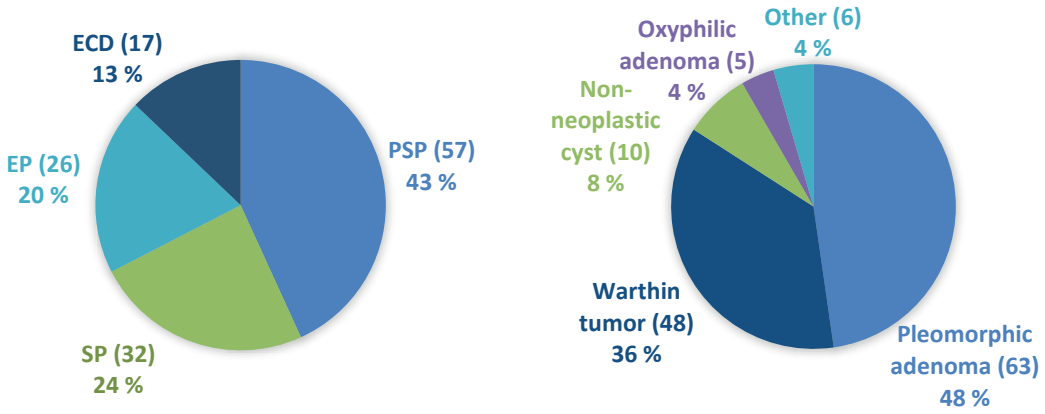

Figure 2. Extent of operation and distribution of histological diagnoses in the study group (n = 132). Abbreviations: ECD, extracapsular dissection; PSP, partial superficial parotidectomy; SP, superficial parotidectomy; EP, extended parotidectomy

The median operative time was 2:02 (two hours, two minutes; range 0:32–7:17). Subgroup-specific median durations of operations were 1:55 for PSP (1:05–3:00), 2:17 for SP (1:25–7:17), 2:29 for EP (1:19–4:23) and 1:05 for ECD (0:32–2:25). The most common operative instrumentation (always combined with cold steel instruments) was a bipolar device only (52.2%), followed by a combination of bipolar and monopolar devices (28.8%) and an ultrasound device (18.9%).

Figure 3 illustrates the occurrence of facial palsy at different time points after surgery, categorized according to operation type. The overall transient palsy rate was 40.2% on the first POD. Permanent facial palsy remaining at 12 months occurred in two patients (1.6%).

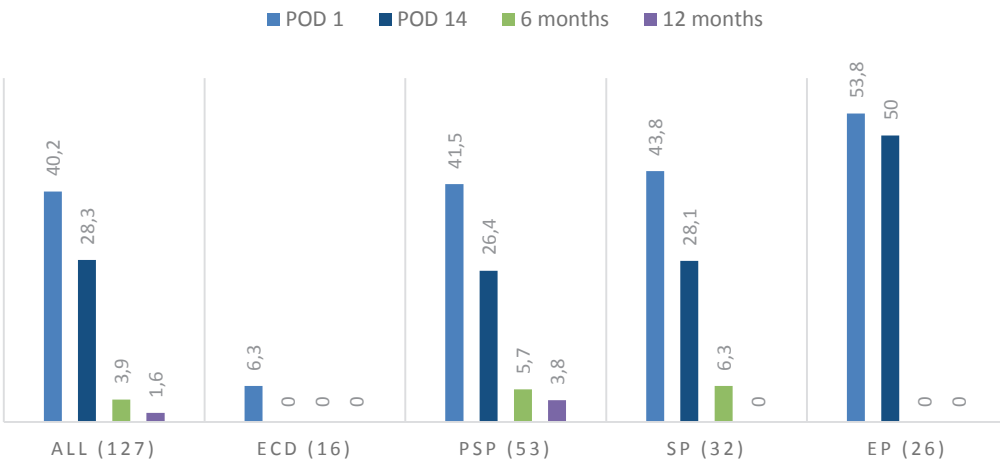

Figure 3. Incidence of facial nerve dysfunction according to operation type and timing in relation to surgery. Abbreviations: ECD, extracapsular dissection; PSP, partial superficial parotidectomy; SP, superficial parotidectomy; EP, extended parotidectomy; POD, postoperative day.

Postoperative infections affected 17 (12.9%) patients. The incidence of salivary fistula was 9.8% (n = 13), sialocele/seroma 6.1% (n = 8), and Frey's syndrome 3.0% (n = 4). The primary hemorrhage (< 24h) rate was 5.3% (n = 7), and the rate of secondary hemorrhage (>24h) was 1.5% (n = 2).

Factors affecting facial palsy development on POD1 and POD14 were assessed. In univariate logistic regression analysis, advanced age (> 60 years) (OR 2.25, CI 1.08–4.68), impaired functional status (2.90, 1.22–6.92), higher comorbidity (2.38, 1.07–5.29), prolonged operation time (5.90, 2.22–15.73), and use of an ultrasound knife (10.88, 3.24–36.50) had a statistically significant association with transient facial palsy. On the first POD, the risk of facial nerve dysfunction was significantly lower in the ECD group compared to other operation types (0.09, 0.01–0.77). At two weeks, EP patients had more palsies than others (2.79, 1.04–7.44).

In the multivariable logistic regression model, advanced age, longer duration of surgery, and ultrasound use remained independent risk factors for transient facial palsy. The extent of operation was insignificant in POD1 analysis and was excluded from POD14 analysis due to a palsy rate of 0% in the ECD group at that time. Impaired functional status and comorbidities were also excluded from multivariable analyses due to a strong collinearity with age.

5.4 COMPLICATIONS OF PEG TUBE INSERTION BY ORL-HN SURGEONS (III)

During the study period, 127 HNC patients were referred for PEG placement. Insertion failed in three patients, leading to a success rate of 97.6%. The final study group included 124 patients. Distributions of primary tumor sites and treatment modalities appear in Figure 4. PEG insertion was prophylactic in 95 (76.6%) patients. Simultaneous other procedures were performed for 21 (17.9%) patients.

Complications occurring within 12 months of operation are encountered in Table 7. Major complications were present in four (3.2%) patients. The most common minor complication was peristomal granulation, which affected 23 (18.5%) patients. No procedure-related mortality occurred. The 30-day mortality rate was 0.8% and the one-year mortality was 21%.

After the PEG placement service was transferred from gastrointestinal surgeons to ORL-HN surgeons, the median time delay in HNC patients' PEG insertions fell from 13 to 10 days ($P < 0.005$). The proportion of early interventions within 0–3 days had increased from 3.6% to 14.6% ($P < 0.005$).

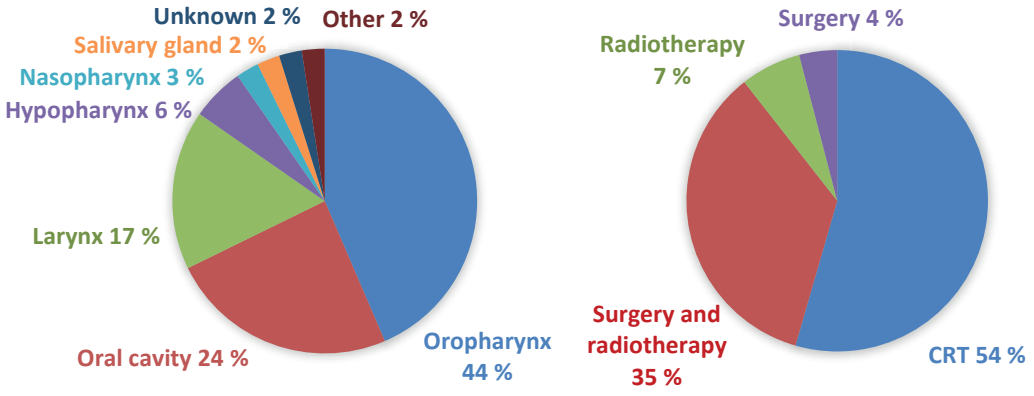

Figure 4. Tumor sites and treatment modalities in study population undergoing PEG placement (n = 124). Abbreviations: CRT, chemoradiotherapy.

Table 7. *Complications of PEG tube insertions (n = 124)*

MINOR COMPLICATIONS	
Granulation of stoma site	18.5% (23)
Local infection	8.1% (10)
Peristomal leakage	4.8% (6)
Tube occlusion	3.2% (4)
Local hemorrhage	2.4% (3)
Late extrusion of PEG tube	0.8% (1)
MAJOR COMPLICATIONS	
Buried bumper syndrome	1.6% (2)
Major hemorrhage and intra-abdominal abscess	0.8% (1)
PEG site metastasis	0.8% (1)

Abbreviations: PEG, percutaneous endoscopic gastrostomy.

Nomenclature differs from that in original publication, and has been updated to correspond to the classification presented in Table 3 (page 31).

5.5 TONSIL SURGERY QUALITY REGISTERS IDENTIFIED IN SYSTEMATIC REVIEW (IV)

The systematic search of MEDLINE and EMBASE databases generated 532 results. After title and abstract scrutiny, a total of 32 full-text articles were assessed, and 15 of them were included. Additional internet searches generated six more articles for inclusion. Figure 5 presents a flow-diagram demonstrating the screening, eligibility assessment, and inclusion of the search results.

Altogether, one quality register (The National Tonsil Surgery Register in Sweden), one quality improvement program (The Clinical Instrument Surveillance Program [CISP] in Wales), and three comprehensive audit programs (National Prospective Tonsillectomy Audit of England and Northern Ireland; Scottish Prospective Audit of Tonsil and Adenoid Surgery with Disposable Surgical Instruments; Austrian Tonsil Study) were identified.

The Swedish register and CISP have current activity, while the audit programs in Austria, England and Northern Ireland, and Scotland were all of limited duration and were finished in 2010, 2004, and 2005, respectively.

All registers recorded tonsillectomies and adenotonsillectomies, but tonsillotomies were registered only in Sweden and Austria. Coverage, number of operations included, length of inclusion period, and length of follow-up was markedly variable, but collected variables were rather similar in all registers. The main indicators included patient demographics, indications for surgery, surgical techniques, the surgeon's educational level, and postoperative complications. The Austrian audit program was the only one to classify postoperative hemorrhages by severity. In all but the Swedish register, post-discharge complication data were reported by health professionals. In Sweden, complications within 30 days of operation and symptom relief at 6 months are reported by patients via web-based questionnaires.

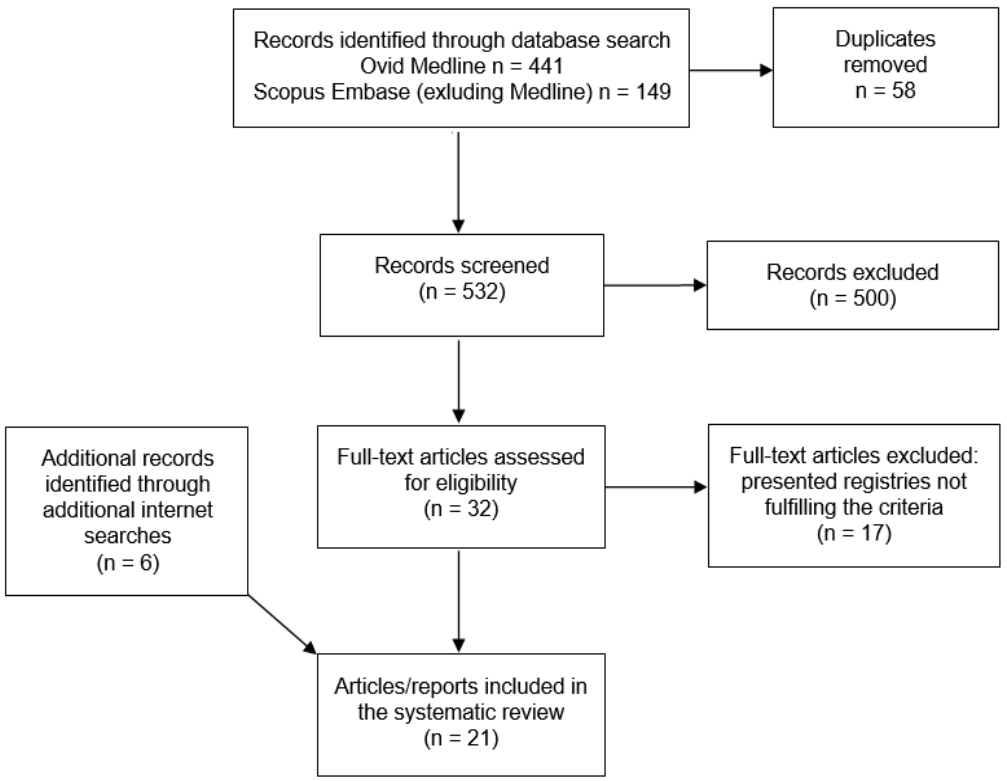

Figure 5. Flow chart of screening, eligibility assessment, and inclusion of the systematic review results.

To assess the possibilities and design future research projects for NTSRC, national statistics and information on current national practices in tonsil surgery were acquired. Differences in applied surgical modalities and population-related procedure rates were discovered (Table 8). All countries except Norway have national guidelines for tonsil surgery indications [74,150,151]. Only Sweden has national guidelines for postoperative pain management [152]. The literature also revealed marked differences in the management of quinsy tonsillectomy in the Nordic countries; in Finland and Sweden, most of the quinsy tonsillectomies were conducted after a recovery period, whereas in Denmark 90% of the operated patients had undergone surgery within 24 hours. The approach in Norway fell between these two aforementioned practices. [76]

Table 8. *Tonsil surgery statistics from NTSRC countries (2014).*

	Denmark	Finland	Norway	Sweden
Population in 2014 (million)[153]	5.64	5.46	5.14	9.70
Number of procedures in 2014[1,154-156]				
Tonsillectomies	6063	7319	10004[b]	7516[c]
Tonsillotomies	< 80[a]	825	282[b]	6011[c]
Tonsil procedures / 1000 inhabitants in 2014	1.09	1.50	2.00	1.40
Proportion of day case tonsillectomies in 2014 (%)[157]	46.1	84.0	59.7	59.0

[a]*Exact number of tonsillotomies is unavailable.*
[b]*Private practice tonsillotomies are included in the total number of tonsillectomies in Norway due to coding practices in private institutions.*
[c]*Proportions of tonsillectomies and tonsillotomies are calculated from The Swedish Patient Register statistics using the distributional data of the Swedish National Tonsil Surgery Register.*

6 DISCUSSION

6.1 COMPLICATIONS IN TONSIL SURGERY

In the present study, the risk of secondary hemorrhage after tonsillectomy was moderately high (11.9%), although only the hemorrhages needing outpatient contact or hospital admission were registered and all age groups were included. No primary hemorrhages occurred in the study population.

Electrosurgical techniques have been reported to reduce primary hemorrhages in tonsillectomies, but they have also been linked to an increase in secondary hemorrhage [4,83]. Bipolar dissection was the most common technique in tonsillectomies (70.5%), which may partly explain the missing primary and the relatively high rate of secondary hemorrhage in this study population, although the technique did not reach significance in risk factor analysis. Increased hemorrhage incidence in the older age groups has been consistently described [83,89,158,159], and also in this study, secondary post-tonsillectomy hemorrhage was significantly more common among adults than among children (14.2% vs. 6.0%). All other complications were relatively rare.

Walton et al. published a systematic review of randomized controlled trials comparing tonsillotomy and tonsillectomy in the pediatric population and reported superior outcomes for tonsillotomy for secondary hemorrhage rate and number of days until the patient was pain free [160]. In another systematic review not restricted to the pediatric population, tonsillotomy had a lower postoperative bleeding and dehydration rate and better postoperative pain outcomes compared with tonsillectomy [161]. In the present series, the hemorrhage rate for tonsillotomy was very low: only one patient (0.8%) experienced bleeding postoperatively, which reinforces previous findings.

6.2 COMPREHENSIVENESS OF PROSPECTIVE REGISTRATION OF TONSIL SURGERY COMPLICATIONS

In the present prospective study of tonsil surgery complications, one-third of the events were missing and were observed only when reviewing the patient charts. Fine et al. assessed the completeness of the cardiac surgery outcome database and found 25% of essential data elements to be missing [162].

Gunnarson et al. evaluated the complication outcome accuracy in three colorectal cancer surgery databases, and the proportion of missed events varied between 7% and 69%, the registration of serious complications being more valid than that of wound infections [163]. The accuracy of prospective registered events in the Dutch surgical complication register has been evaluated, and the rate of missed complications was 27% [21]. Dindo's study assessing a prospective surgical quality database administered by residents revealed an underreporting rate of 80%, and despite active training, the reliability did not markedly improve [164]. The number of successfully reported complications in this study is far from satisfactory, but is comparable to these other studies.

Underreporting in surgical complication databases has been speculated to be multifactorial: time consumption of registration and additional work load; lack of incentives (rewards of registration or the sanction of unreliable data); and surgeons' ambition to focus on work in the operating theater rather than on administrative duties [164]. In addition, one factor that may have influenced underreporting in this study was an imprecise assignment of recording responsibility. In the emergency department where the complication recording took place, registration was tasked collectively for nurses and doctors, not to a specific staff member, leading to a significant underreporting. Therefore, registration of the adverse event should be clearly assigned to the physician commencing the treatment of the complication.

Patients were particularly instructed to contact the Department of ORL-HNS, HUH, if any postoperative adverse event were to occur. The department is the only ORL-HNS center in the Helsinki area. Nevertheless, it cannot be ruled out that some complications may have remained unregistered due to a patient's being treated somewhere else. This should be considered as one limitation of the study.

6.3 COMPLICATIONS IN BENIGN PAROTID SURGERY

The present analysis showed that temporary facial palsy incidences in the ECD, PSP, SP, and EP subgroups were 6.3%, 41.5%, 43.8%, and 53.8% on POD1. Previous prospective studies assessing postoperative facial palsy separately in all extents of parotidectomies could not be found. In a meta-analysis of benign parotid surgery, the average temporary facial dysfunction rate was 11% for ECD, 18% for PSP, 26% for SP, and 60% for total

parotidectomy [165]. Somewhat higher rates in the present material can be partly explained with a prospective and standardized evaluation, strict criteria for facial palsy, and early assessment of facial dynamics. In many studies, the timing of the first evaluation or the assessment methods are not declared or standardized, or the evaluation is carried out at one week postoperatively. This study's palsy rates on POD14 were 0% (ECD), 26.4% (PSP), 28.1% (SP), and 50% (EP), rather equable to previous findings.

Like facial palsy, Frey's syndrome incidence also strongly depends on methodological details and performed diagnostics. In this study, the diagnostics were based on patients' spontaneous complaints, and the rate of 3.0% is congruent with other studies using a similar methodology [108,166]. Incidences of sialocele/seroma, salivary fistula, postoperative infection, and hemorrhage were also comparable to the previous findings [9,114,119].

Previously reported risk factors of postoperative facial palsy in parotid surgery include malignancy [108,167,168], more extensive surgery [100,108,110,112,169], higher age [166,170,171], larger tumor size [166,167], inflammatory histology [114], revision surgery [110,115], duration of operation [166], deep lobe tumor [115], and diabetes [100]. The results of the present study establish the role of advanced age, extent of surgery, and the longer duration of surgery as risk factors of postoperative facial palsy in benign parotid surgery. Additionally, the use of an ultrasound knife seemed to increase the risk of transient facial palsy, but considering that only one surgeon used the ultrasound technique in the study cohort, and instrumentation is only one factor in a complex operation, confounding factors regarding this finding cannot be excluded. The role of surgical instrumentation is widely unknown and further research is warranted.

6.4 COMPLICATIONS OF PEG TUBE INSERTION BY ORL-HN SURGEONS

In previously reported HNC populations, the occurrence of minor complications associated with PEG tube insertion has been between 10% and 40%, and that of major complications 0–8% [31,122,139-141,172,173]. A wide variation can partly result from differences in follow-up time, operative techniques, and sample sizes.

In the present prospective cohort of 124 HNC patients, the rate of minor complications was 34.7% and that of major complications was 3.2%. A fairly high incidence of minor complications partly results from the inclusion of

granulation at the stoma site (18.5%) to the recorded events. In all studies, granulation is not considered a complication, but rather a discomfort related to the PEG tube.

The outcome for PEG insertion in HNC populations has been previously considered comparable between gastroenterologists, general surgeons, and ORL-HN surgeons [12]. After PEG tube insertions in HNC patients were transferred from gastrointestinal surgeons to ORL-HN surgeons at HUH, the new process was validated with a retrospective audit. No differences were noted in success or complication rates when comparing the ORL-HN surgeons' performance to that of gastrointestinal surgeons [122].

ORL-HN surgeons usually carry the main responsibility of managing the HNC patients. Implementing PEG placement into the armamentarium of ORL-HN oncologic surgeons seems beneficial in terms of logistic advantages, minimizing delays and costs, and simplifying the treatment process. As demonstrated in this study, independence from gastrointestinal surgeons' services enhanced the obtainability of urgent PEG insertions and reduced the median time delay from 13 to 10 days at our unit.

One advantage of adding PEG placements to the ORL-HN surgeons' tool kit is the possibility of performing other operations (endoscopies, biopsies, tracheotomy, dental procedures, definitive surgery, comprehensive physical status examination, or any other procedures an HNC patient might need) within the same session as the PEG tube insertion. In the present study, simultaneous other procedures were performed for 17.9% of the patients. There is room for improvement, and in the future, special attention will be paid to exploiting this advantage.

6.5 TONSIL SURGERY QUALITY REGISTERS – INCENTIVES AND CONSEQUENCES

In the systematic review, five prospective registers, comprehensive audit programs, or quality assurance programs with the inclusion principle of tonsil surgery were identified: The National Tonsil Surgery Register in Sweden, CISP in Wales, and national audit programs in Austria, England and Northern Ireland, and Scotland.

Safety monitoring and improvement have served as a stimulus for all these national projects. In 2001, the prion contamination of re-usable surgical instruments was identified as a theoretical transmission route for a Creutzfeldt-Jacob disease variant (vCJD) [174]. As a response, the United Kingdom introduced single-use surgical instruments for tonsil surgery, and

audits in Scotland, England and Northern Ireland, and CISP in Wales were initiated to monitor their safety. Secondly, the suspicion of diathermy techniques' connection to increasing postsurgery hemorrhage rates in tonsil surgery served as an incentive for audit programs in the United Kingdom [175].

Results reinforced the role of electrosurgical techniques in increasing the postsurgical hemorrhage incidence [175], and the National Institute for Health and Clinical Excellence issued guidance to use bipolar diathermy as little as possible and omit monopolar diathermy in tonsillectomies in England. Subsequently, this guidance was influential in clinical practices and produced a moderate improvement in patient outcomes. [176,177]

Recently, the regulations considering the transmission risk of vCJD in tonsil surgery have been changed, and the use of disposable instruments is no longer required [178]. During the transition to reusable instruments, CISP has been tasked with continuing the tonsil surgery audits to guarantee a safe changeover [179].

Between 2006 and 2007, five children died from post-tonsillectomy hemorrhage in Austria. Tragic events raised the discussion of potential life-threatening risks of tonsil surgery, and the Austrian Society of ORL-HNS and the Austrian Society of Pediatrics launched the Austrian audit program to evaluate the validity of tonsil surgery indications and surgical techniques, and they released a consensus paper recommending tonsillotomy over tonsillectomy in children under the age of six. [180]

Austrian results reinforce the finding that hot techniques carry a greater risk of postoperative hemorrhage. They also observed that the occurrence of a minor postoperative hemorrhage increased the risk of subsequent severe bleeding, resulting in the recommendation of an overnight hospitalization for all patients experiencing postoperative bleeding after tonsil surgery. [181]

The National Tonsil Surgery Register in Sweden has also demonstrated its feasibility in the form of several quality improvement actions. They have launched postoperative pain management guidelines for children [152], which are now widely used around Sweden. The Swedish register has also confirmed the results of the United Kingdom and Austria: Compared to the totally cold technique, the risk of re-admission because of hemorrhage is 2.8–5.6 times higher with electrosurgical techniques, depending on the instrumentation [5]. This finding has generated improvement projects in hospitals with a particularly high post-tonsillectomy hemorrhage rate [154].

6.6 NORDIC TONSIL SURGERY REGISTER COLLABORATION

An international register collaboration allows large datasets to survey rare endpoints and enables the critical evaluation of national clinical practices in comparison to other countries. To our knowledge, no international register collaboration in the field of ORL-HNS has been previously described.

Denmark, Finland, Norway, and Sweden have long and successful experience with health care quality registers financed and administered by governmental authorities [65,182-184]. Considering the homogenous populations, similar health care systems, and unique personal identity codes for all citizens, prerequisites for quality register collaboration among the Nordic countries are favorable.

Although the Scandinavian countries are rather similar regarding the aforementioned features, the national statistics on tonsil surgery revealed substantial differences considering the annual prevalence of tonsil procedures, the proportion of day case surgery, and clinical practices.

NTSRC was established in 2016 with collaborators from Denmark, Finland, Norway and Sweden. NTSRC aims to build national registries with common indicators in order to launch a benchmarking tool to improve the quality and safety of tonsil surgery. The ambition of NTSRC is three-pronged:

1. To provide accurate information for patients and health care personnel about the process and outcome of benign tonsil surgery
2. To acquire evidence-based data for implementing best clinical practice standards for tonsil surgery
3. To promote the quality improvement actions of tonsil surgery

The National Tonsil Surgery Register in Sweden has been operating for over 20 years, but other countries' registry activities are still in the early stages. In Norway, the national tonsil register's nationwide launch started in March 2017, and by the end of January 2018, all 20 hospitals and 9 out of 19 private institutions performing tonsil surgery had begun submitting data. Denmark's Tonsil Surgery Register is being piloted in Central Region Denmark, where registration started in September 2017. Nationwide coverage is intended by the end of 2018. Both Norway and Denmark have adopted the Swedish register platform and have translated it into their domestic languages.

In Finland, the tonsil surgery register launch will take place in 2019 at the Helsinki University Hospital, Department of ORL-HNS. Subsequently, the pursuit is to expand the register system nationwide.

NTSRC data collection is performed in three phases. Demographic data and surgery-related information are provided at the time of operation by the surgeon. Patients are requested to fill out questionnaires at 30 days and six months postoperatively: The first questionnaire assesses postoperative recovery and complications, and the second asks about symptom relief at six months. Patients receive web links to the questionnaires by e-mail, SMS, or digital postbox (Norway).

One aspect of the Nordic cooperation is a translation of Swedish patient education webpages into other Nordic languages. Webpages (www.tonsilloperation.se) offer information for patients and their families about tonsil operations, postoperative care, possible complications, and pain relief. The Finnish web address (www.nielurisaleikkaus.fi) will be linked to the pages in the near future.

6.7 UTILITY AND VALIDITY OF QUALITY REGISTERS

The register data quality and utility are highly dependent on the consistency of definitions [185]. Therefore, using standardized, valid, and reliable definitions is essential to the accurate registration of surgical complications. The Nordic collaboration has had the strength of consistent definitions from the beginning, as all the other countries have adopted the Swedish National Tonsil Surgery Register variables and the data collection methods are congruent. Aggregation and analysis of data should therefore generate high-quality statistics.

Assessing the internal and external validity of the register data is crucial to ensuring the register quality. Comparing MDR data with national administrative registries is a feasible way to perform external validation. Internal validation is usually performed by auditing a random sample of registered patients retrospectively from the hospital database and comparing the data conformity.

Studies on the internal validation of the Finnish Vascular Register indicate that the procedural variables (i.e., indication, operation code, anatomy) show good correspondence, but preoperative risk factors have a higher proportion of missing data [186,187]. Some evidence suggests that in surgical quality registers, the missing patients have worse outcomes compared to the registered ones, and register data thus reflects too optimistic an outcome [188].

Emergency operations, especially during the night, most likely remain unregistered [186].

As detected in the tonsil surgery study (Study I), the rare complications were not as comprehensively registered to the prospective database as the common and obvious ones. Thus, in outcome recording, paying special attention to the registration of unexpected events is warranted.

In the Swedish National Tonsil Surgery Register, the readmission data has shown a correspondence to the national patient register. The hemorrhage rates of patients included in the Swedish register have also demonstrated a congruence with those not registered, and no significant difference has been discovered in hemorrhage rates between patients responding and those not responding to the questionnaires. [5,154] As populations and health care systems in the Nordic countries are rather similar, it can be assumed that the Swedish validity analysis applies accordingly to NTSRC data.

Even the best register data can be rather useless if the data analysis plan and its users' capability to construe the results is inappropriate [30]. In NTSRC, the information service platforms of The National Tonsil Surgery Register in Sweden will also be used for the management of aggregated Nordic data, which enables the comprehensive exploitation of collected data. Swedish and Norwegian registers have webpages for both professionals and patients to report results and make comparative data available for everybody. Pursue is to also present Finnish data and NTSRC international results openly in an easy access web format.

6.8 MOTIVATORS AND PITFALLS OF SURGICAL QUALITY REGISTRATION

In addition to the safety issues and cost-effectiveness discussed previously, some other aspects of the motives behind surgical quality registration should be considered. The most obvious motivator for the development of quality assessment is competition, but in health care, the lack of true competition among providers has led to a slow adoption of quality assessment programs and quality registering. In Finland, the health care system is undergoing a major change, as the financing and organization of public health care will be reformed in the near future. As a result, both the private and public sectors will provide tax-financed health care services, and patients will have the discretion to choose their providers. This new setup will undoubtedly increase the competition and interest in quality improvement,

and the availability of comparative data on different hospitals and even on a single surgeon's performance form a powerful market force.

The purpose of surgical quality registering is primarily to assess and improve systems and processes, but registers can also serve as a single surgeon's self-assessment tool. If the register reveals that a surgeon's performance is below average, their reaction of seeking solutions and retaining professional pride may trigger fast and effective changes [46]. Surgical quality registration can also enhance the results through the surgical Hawthorne effect: Outcomes tend to improve when surgeons know they are under scrutiny [189].

Collecting and publishing clinical performance data of individual surgeons is most organized in England, where governmental authorities maintain publicly available websites presenting nationwide surgeon-specific outcomes in several surgical specialty areas, including ORL-HNS [190]. The websites aim to provide patients with objective information on the performance of their clinicians and hospitals, and to enhance the transparency of surgical quality metrics. Only certain procedures are included, so the sites do not serve as a definite standard for all operating clinicians.

Publishing a single surgeon's mortality rates in the open arena is somewhat controversial and has its pitfalls. The risk of mortality in surgical procedures is highly dependent on patient-related factors and hospital processes and characteristics [191-193], and the surgeon's performance is only one piece of a complex puzzle. Surgeon-specific death rates do not account for all the multi-disciplinary care before, during, and after surgery [194], and even with the risk adjustment of the data, patient populations are not completely comparable [195]. Usually, most experienced surgeons operate in the most challenging cases, thereby distorting their mortality statistics. For patients, these statistics represent mainly a surgeon's skills and competence. Therefore, "gaming" occurs: Surgeons may refuse to operate on high-risk patients or may pass the difficult cases to colleagues to keep their own statistics clean [196,197]. Furthermore, concern about the potentially harmful impact on surgical training has been raised [198].

During the tonsil surgery complication project (Study I), many colleagues were interested in their personal complication rates, reflecting the desire to self-evaluate and improve their performance. There was considerable variation in the incidence of complications between individual surgeons, but the sample size was not large enough for a statistically valid surgeon comparison. If complication registers are used for a single surgeon's

performance analyses, emphasizing the delicate approach without blame and desecration, as well as the consideration of patient-specific differences, is crucial when interpretating the register data.

6.9 CURRENT STATUS AND FUTURE PERSPECTIVES OF TONSIL SURGERY QUALITY REGISTRATION AT HUH

The Tonsil Surgery Quality Register at the HUH Department of ORL-HNS will be implemented along with the new patient record system Apotti (Epic Solutions Ltd., Cork, Ireland). From a quality registration perspective, Apotti offers the advantage of structured patient records, which enable automatic data retrieval from other hospital databases. As the register data input is incorporated into the structured patient records, the registration effort and human error associated with it is minimized, costs of registration are low, and high coverage is assured. Internet-based patient questionnaires will be incorporated into the system. Structured patient record variables are designed to be consistent with NTSRC.

BCB Medical, a Finnish software company specializing in health care quality registering, has implemented over 60 disease-specific quality registers for different specialities within all the health care districts in Finland [199]. BCB Medical has created compatible integration interfaces with several patient record systems and hospital databases so that the same disease-specific quality registers are integratable into different health care units' systems. Also, the HUH Department of ORL-HNS is developing a quality registration system for specialty-specific needs in co-operation with BCB medical. Rhinological procedures and head and neck surgery are piloting the BCB disease-specific quality registers at our unit. Head and Neck Surgery Register will be implemented in May 2018. The test version of the Rhinological Register has been launched, and the register will be introduced to clinical use in the near future.

The Apotti-based tonsil surgery register will cover only the Helsinki and Uusimaa health care districts. As the aim is to expand the Finnish tonsil surgery register nationwide in the future, the long-term strategy is to also implement the BCB quality register for tonsil surgery. The current plan is to promote this tonsil surgery register as the next BCB quality register project at the HUH department of ORL-HNS as soon as resources from other BCB quality register projects are liberated and financing is available.

7 CONCLUSIONS

1. The overall complication rate after tonsillectomy was 17.0% and after tonsillotomy 1.7%. Respective rates of postoperative secondary hemorrhage were 11.9% and 0.8%, reinforcing the advantages of tonsillotomy over tonsillectomy for obstructive indications in children. Other complications were rare. No primary hemorrhages occurred, confirming the suitability of tonsil procedures for day case surgery. Higher age was the only significant risk factor for post-tonsillectomy hemorrhage.
2. The comprehensiveness of prospective outcome data is a challenge, and the recording of serious and rare complications requires special attention. To optimize the coverage, the responsibility of recording should be precisely assigned, the registry database easily available, the number of registered parameters carefully considered, and the essential procedure-specific data included.
3. Depending on the type of operation, up to half of the patients undergoing parotid surgery for benign indication experience facial dysfunction, but it is seldom permanent. Age, duration of the procedure, and operative technique may affect the risk, but the role of surgical technique and instrumentation warrants further investigation.
4. ORL-HN surgeons can successfully and safely insert PEG tubes. The PEG tube placement at ORL-HNS units can reduce the delay in PEG insertion and simplify the treatment process of HNC patients. Including PEG tube insertion in the training of ORL-HN oncological surgeons is recommended.
5. In the systematic literature review, two active registers and three completed comprehensive audit programs focusing on tonsil surgery quality registration were identified. A large variety of clinical practices in tonsil surgery exists, and considering the fact that tonsil surgery is one of the most commonly performed surgical procedures worldwide, the demand for evidence-based guidelines is apparent. NTSRC has great potential to create those guidelines and improve the quality and safety of tonsil surgery.

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