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Patient injuries in pediatric otorhinolaryngology

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ABSTRACT

Objectives: Patient injuries in children can have lifelong effects on the patient and a marked impact on the whole family. The aim of this study was to identify the errors and incidents leading to patient injuries in pediatric otorhinolaryngology (ORL) by evaluating accepted patient injury claims.

Methods: The records of all accepted patient injury claims in ORL between 2001 and 2011 were searched from the nationwide Patient Insurance Centre registry. Pediatric injuries were reviewed and evaluated in detail, and factors contributing to injury were identified.

Results: In the 10-year study period, 17 (7.6%) of the 223 patient injuries occurred in children, and of these, 15 (88%) were considered operative care. The median age of the patients was 8 years (range 3–16 years). All operations were performed as daytime elective surgery and by a fully trained specialist in 93% of the cases. One-half of the cases were routine surgeries for common ORL diseases. The most common incidences were incomplete surgery, retained gauze or foreign body, injury to adjacent anatomic structure, and insufficient charts or instructions (each occurred in 3 cases). The most frequent consequence was burn ($n = 4$). One child died because of post-tonsillectomy hemorrhage.

Conclusions: Patient injuries in pediatric ORL are strongly related to surgery. Most injuries occurred after routine operations by a fully trained specialist. Clinicians should be aware of the most likely scenarios resulting in claims.

1. Introduction

Patient injuries in children can be devastating to the patient, having lifelong consequences. Research on patient injuries in children is limited and study settings vary. Most studies have reported errors and adverse events among hospitalized patients through retrospective chart review [1–4]. In a meta-analysis, the pooled incidence of adverse events in hospitalized pediatric patients was 2% [5].

The majority of reported errors in otorhinolaryngology (ORL) are related to surgical management [6]. In a study of claim records in otology in England, 65% of complications were surgery-related [7]. According to Finnish patient injury claims data, the complications in ORL were related to surgery overall in 84% and specifically to otologic surgery in 73% [8–10].

Children as patients differ from adults. Most children operated on in ORL do not have severe diseases or comorbidities, and high-volume outpatient surgeries are typical. Despite the large pediatric patient population in ORL, relatively few studies report adverse events. In a

study by Shah et al., 50 inpatient admissions of pediatric ORL patients were analyzed, and no major events or permanent morbidity were found [2]. Studies of injury claims data in pediatric ORL could not be found, and the proportion of surgical errors in pediatric ORL is unknown.

Prevention of patient injuries in children should be a high priority, and therefore, it is crucial to understand the patterns underlying patient injuries. The aim of this study was to identify the errors and incidents leading to patient injuries in pediatric ORL by examining accepted patient injury claims.

2. Materials and methods

The Finnish Patient Insurance Centre (PIC) insures all patients treated by public and private healthcare providers and practitioners in Finland. Finland's social welfare and healthcare system is characterized by the universal right to social welfare and healthcare services. It is founded on government-subsidized municipal social welfare and

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healthcare services. According to the Patient Injuries Act (Potilasvahinkolaki 585/1986), all healthcare providers shall have patient insurance that compensates bodily damages to patients on a non-fault basis. The insurance covers any personal injury caused to patients in the course of medical care. Compensation is, however, not paid for minor injuries. Insurance claims are addressed to the Finnish PIC, which processes claims and pays compensation accordingly. Seven compensation criteria are listed in the Act: treatment injury, infection injury, accident injury, equipment-related injury, injury arising from damage to premises or treatment equipment, injury due to incorrect delivery of pharmaceuticals and unreasonable injury. A treatment injury is the most typical compensable injury. A compensable treatment injury is a bodily injury caused by an examination, treatment or other similar action performed on the patient, or the failure to do so. A prerequisite for compensation is that an experienced medical professional could have performed a different procedure in the examination or treatment situation in question, thereby avoiding the injury. Consequently, a treatment injury may be, for example, a postoperative complication, such as a nerve injury or a delay in diagnosis, which could have been avoided by an experienced professional. The Finnish patient insurance system is not targeted to determine the guilty party, but to provide fair compensation to the patient and serve as a tool in the healthcare system to provide better patient care in the future [11].

In this study, the accepted patient injury claims in children under the age of 17 years within the specialty of ORL that had closed between 2001 and 2011 were searched from the PIC claim records. Studied claims concerned treatment given between 1998 and 2011. Medical records, expert's assessments, and indemnity decisions were reviewed. Age, gender, diagnosis, and major comorbidities as well as information about healthcare providers and institutions were recorded as background data. Treatment provided and the incident leading to injury were ascertained, and operation-related injuries were evaluated in detail.

2.1. Definition of key variables

Classification of the errors and incidents was based on the care flow of the patient. Structure of our classification was modified from the classification presented for ORL by Shah et al. [6]. The categories of 'manual and judgment errors in surgery' were added to the classification [12,13]. The classification used in this study was developed by the research group and has been used in three previous publications [8,10,14]. Incidents and errors contributing to the injury were identified and classified by two senior otolaryngologists (KB and PH). One or two noteworthy independent incidents were specified for each patient.

2.2. Ethical considerations

This was a retrospective claim records study. The study protocol and data search were approved by PIC. All information regarding the identities of patients and healthcare providers was excluded from the data.

3. Results

Between 2001 and 2011, a total of 223 claims in all age groups in ORL were accepted, 17 (7.6%) of which were associated with children less than 17 years of age. Two claims concerned outpatient care due to 'delay or error in diagnosis or treatment'; one was a misjudgment in the need for tonsillectomy and the other a delayed diagnosis of congenital hearing impairment.

During the study period a total of 188 claims associated with surgical care in ORL were accepted. Claims concerned treatment given between 1998 and 2011. Of these 188 patient injuries, 15 (8.0%) occurred in children less than 17 years of age. The median age of the children was 8 years (range 3–16 years), and there were 9 girls and 6

Table 1

Characteristics of 15 surgery-related patient injuries in pediatric ORL in Finland between 2001 and 2011.

	Children N (%*)
Outcome	
Burn	4 (27)
Re-surgery	3 (20)
Injury to adjacent anatomic structure	3 (20)
Permanent nerve lesion	2 (13)
Re-anesthesia	2 (13)
Death	1 (7)
Medical unit	
Tertiary academic hospital	2 (13)
Central hospital	7 (47)
Local hospital	2 (13)
Primary healthcare	3 (20)
Other	1 (7)
Education of physician	
Otolaryngologist	14 (93)
Resident in ORL	1 (7)
Urgent operation	0

N=Number, *Percentage of all surgery-related pediatric ORL patient injuries.

boys.

All of the operations leading to injury were performed as daytime elective surgery. Nearly all children (n = 14) were treated by fully trained specialists in ORL (Table 1). Most often the surgeries (n = 7) were performed in central hospitals, three in private hospitals, two in local hospitals, and two in university hospitals. One operation was performed at a community clinic where surgeries took place only occasionally. One-half of the patients (n = 7) had tonsillar surgery (adenotomy and/or tonsillectomy) due to common ORL disease (e.g. snoring). In four cases (27%), the operation could be considered demanding (e.g. revision attic-antro-mastoidectomy because of cholesteatoma).

The most common incidents leading to injury were incomplete surgery (n = 3), injury to an adjacent anatomical structure (n = 3), and insufficient charts or instructions (n = 3) (Table 2). In the three patients with retained foreign material-related problems, there was insufficient or missing charting of the materials left in situ. In one child, two noteworthy and independent incidents were detected: iatrogenic trauma to the facial nerve during ear surgery and postoperative infection due to retained packing. All operative case incidents are presented in Table 3.

Re-operation because of incomplete primary surgery was necessary for 3 patients (20%). The most frequent consequence of injury was burn, which occurred in 4 operations (27%). Nerve lesion occurred in 2 operations (13%) and injury to adjacent anatomic structure in 3 operations (20%). Nerve injuries resulted in permanent, but not severe, morbidity. The consequence of injury was severe in one case. The 16-year-old patient died of hemorrhage after tonsillectomy (Table 1).

4. Discussion

During the 10-year study period in Finland 7.6% of all patient injuries in ORL occurred in children and adolescents. The relative proportion of patient injuries associated with children among all patients treated in ORL was very small.

Compared with adults, patient injuries in children can be even more devastating for the patient and have a strong impact on the whole family. Permanent injury, such as facial nerve paresis or unintended scarring in the face, can have lifelong effects on the patient's well-being and determine the future of the child. Luckily, the natural healing process in children is usually good, and thus, recovery can be rapid. Although patient injuries in children are not common, prevention of

Table 2

Incidents and errors resulting in patient injuries in pediatric ORL, classified on a care flow basis.

	Incident	
	N ^a	%
Outpatient care		
Delay or error in diagnosis or treatment	2	12
Injury in outpatient procedures		
Other error in outpatient care		
Preoperative judgment and surgical planning		
Incorrect/unnecessary procedure or technique	2	12
Insufficient patient information		
Error in preoperative care		
Operative unit		
Lack of prophylactic antibiotic		
Problems in anesthesia procedures		
Wrong site surgery		
Nerve lesion	2	12
Other injury to adjacent anatomical structure	3	18
Incomplete surgery	3	18
Other errors in surgical technique	1	6
Retained gauze/instrument	2	12
Equipment-related errors	2	12
Insufficient charts or instructions	3	18
Other errors in operation room		
Postoperative period		
Postoperative ward care		
Wrong/insufficient medication		
Infection		
Hemorrhage	1	6
Insufficient postoperative treatment/follow-up		
Retained foreign body, e.g. nasal tampons	1	6
Unintended result	1	6

^a N = number and proportion (%) of 21 incidents detected in 17 patient injuries.

such injuries should be a high priority.

As in other studies in ORL with adults, in our study most injuries (88%) were associated with operative care [6,8,9]. In ORL, complex medications and prolonged inpatient care are rarely needed. Therefore, it is understandable that accepted injury claims, which are usually

severe adverse events, are mainly associated with surgery.

Burns were the most common consequences of surgical errors in this study. In two cases, the burn was by the tonsillectomy device and in one case diathermy inflamed inadequately dried disinfectant. These are examples of cases where the injury could have been prevented with more meticulous performance. In one case, monopolar diathermy caused a fire in the mouth, the leading causes presumably being dry gauze and oxygen leak from a loose intubation tube. This is a case where a cluster of small incidents leads to a serious consequence that could not have been anticipated.

During the study period one death occurred due to post-tonsillectomy hemorrhage in a 16-year-old patient. This is rare, but feared complication. Based on a large tonsillectomy register study, the rate of post-tonsillectomy hemorrhage could be decreased by selecting a cold steel dissection technique [15]. However, currently, there are no surgical methods that can prevent all post-tonsillectomy hemorrhages. Means of prevention should focus on fast and efficient management of severe bleeding by rigorous training of healthcare personnel [16].

Most of the errors in our study occurred in common procedures conducted by experienced ORL surgeons. This is in accordance with the findings of US surgical claims, including the field of ORL [12]. Some of the surgical errors are linked to lack of surgeon specialization and low hospital volume. In our material, only one error occurred in an operation with a resident surgeon and one operation was performed in a community clinic where surgeries are performed only occasionally. Centralization and creating larger pediatric surgery units with higher patient volumes, constructive supervision, and experienced pediatric anesthetists has been the trend in Finland in recent years.

In a large study reviewing a total of 7926 hospital admissions, the incidence of adverse events in children was 1.7%, one in five which were preventable [4]. In our study, nasopharyngeal gauze was left in place in two patients after adenotomy. This error is a potentially life-threatening event, which could have been prevented by the use of a surgical safety checklist. Today, surgical safety checklists are required by the PIC. Pediatric ORL outpatient surgery is typically fast, with similar operations occurring, one after another. The awareness of the possibility of an error and the use of safety checklists are even more important with routine operations. The use of checklists helps

Table 3

Details of operative patient injury cases in pediatric ORL in Finland between 2001 and 2011.

Patient no.	Consequence	Type of incident	Type of surgery	Reason for surgery	Age (years)
1	Death	Postoperative hemorrhagia	Tonsillectomy	Tonsillar hypertrophy, snoring	16
	Injury to or impairment of adjacent anatomical structure				
2	Nerve lesion	Accessory nerve paresis	Removal of thyroglossal duct cyst	Thyroglossal duct cyst	16
3	Nerve lesion, infection	Facial nerve paresis, retained packing in the ear for 2 months	Revision attico-antro-mastoidectomy	Cholesteatoma of middle ear	7
4	Diplopia	Injury to adjacent anatomic structure	Transantral exploration and biopsy	Langerhans cell histiocytosis	11
5	Tympanic membrane perforation	Tympanic membrane perforation	Meatoplasty	Exostosis of external ear canal	8
6	Hypernasal speech	Adenotomy in a patient with submucous palatal cleft	Adenotomy	Recurrent acute otitis media	4
	Burn				
7	Burn and scar to the lip	Burn and scar to the lip with an ultrasound knife	Tonsillectomy	Tonsillar hypertrophy	8
8	Burn to the lip	Diathermy caused burn to the lip	Tonsillectomy and adenotomy	Tonsillar hypertrophy	11
9	Burn to the mouth	Fire inside the mouth caused by monopolar diathermy and dry gauze	Tonsillectomy	Tonsillar hypertrophy, snoring	7
10	Burn to the skin	Diathermy inflamed inadequately dried disinfectant on the skin	Removal of the wart together with ORL surgery	Wart in palm	10
	Re-surgery				
11	Multiple re-surgeries	Inadequate removal of preauricular sinus	Excision of preauricular sinus	Preauricular sinus	15
12	Re-surgery	Otoplasty with inadequate result	Otoplasty	Otoplastosis	8
13	Re-surgery, scarring	Inadequate removal of tumor	Open biopsy	Parotid gland tumor	14
	Re-anesthesia				
14	Re-anesthesia, infection	Retained gauze in the nasopharynx	Adenotomy	Recurrent acute otitis media	3
15	Re-anesthesia	Retained gauze in the nasopharynx	Tonsillectomy and adenotomy	Tonsillar hypertrophy, snoring	7

personnel to quickly check for potential sources of error in a calm moment. In addition, it provides an opportunity to observe and react to other possible disturbing factors such as excessive noise in the operating room.

Only a small proportion of adverse events and errors lead to patient injury. In this study, we analyzed accepted injury claims, but comparison with other studies is difficult since most have reported errors and adverse events among hospitalized patients through a retrospective chart review [1–4]. Adverse events do not appear to be common among pediatric patients. Shah et al. retrospectively reviewed 50 randomly selected inpatient admissions of pediatric ORL patients to search for any errors or adverse events ranging from unreadable notes to major events. Among the study patients, no major events or permanent morbidity occurred, and only eight moderate adverse events (e.g. unnecessary hospitalization) were identified [2]. A meta-analysis including nine studies reported that the pooled incidence of adverse events in hospitalized pediatric patients was 2% [5]. Specific trigger tools have been developed to facilitate efficient quality review [1,3]. By using these tools in 22 Canadian hospitals, the incidence of adverse events in pediatric hospital care was found to be 9.2%, with one-third of events occurring in surgical care [1].

The main strength of our study is that it is based on nationwide data of accepted claims, not only the records of a single hospital. PIC insurance charts are nationwide and highly representative. In Finland, between 2004 and 2011, altogether 26.1% of claims in ORL were accepted [9]. Although all patients treated by the official healthcare providers are insured by PIC and by law doctors should guide patients to make a claim, it is likely that not all who sustained an injury submitted a claim. As these claims are patient-derived, these data most probably represent only a portion of the most serious incidents and errors in pediatric ORL. In addition, it might be that mistakes in diagnosis or the noteworthy complications with no immediately apparent symptoms or long-lasting sequels give no reason for claims and are not recorded or are even denied. As a limitation of a study with retrospectively collected data, we are always dependent on information recorded in charts.

A large proportion of patients in ORL are children. Treatment of children differs from that of adults, e.g. surgery in children can be demanding due to the small size of the patient. Errors in treatment can diminish a child's trust in healthcare providers, and severe patient injuries can have lifelong consequences. Thus, prevention of patient injuries in children should be a high priority, and research in identifying the causes of surgical adverse events is needed.

5. Conclusion

Patient injuries in pediatric ORL are strongly related to operative care. Most injuries occurred in routine daytime surgery performed by a fully trained specialist. Clinicians should be aware of the most likely scenarios resulting in claims.

Conflicts of interest

None to declare.

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