

Systematic analysis of ear-nose-throat malpractice complaints may be beneficial for patient safety

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ABSTRACT

INTRODUCTION: The analysis of malpractice complaints can provide valuable information on patient safety. This study offers a detailed examination of the backgrounds concerning reasons and outcomes of ear, nose and throat (ENT) malpractice complaints handled by the National Board of Patients' Complaints (NBPC), 1998-2008.

MATERIAL AND METHODS: All NBPC decisions related to the ENT specialty from 1998-2008 in Denmark were analysed.

RESULTS: Deficient medical recording was criticized even though the complainant did not mention this in the complaint. The juridical theme of medical error was the most complained about, but the least criticized compared with six other juridical themes. In contrast, retained packaging, wrong-site surgery, laser burns and peeling injuries were medical errors with high rates of criticism. Complaints concerning accidental surgical complications did not lead to criticism. Tonsillectomy was the most frequently alleged ENT operation in our study data.

CONCLUSION: Thorough preoperative information about potential surgical complications undersigned by the patient and the newly introduced safe surgery procedures are likely to reduce both faults and complaints. Malpractice complaints have not hitherto been used as a learning instrument. We propose a systematic registration of these incidents to enable more learning in the future. The new act on the handling of malpractice complaints may make it easier to avoid malpractice and to learn from malpractice complaints and may thus improve patient safety in Denmark.

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Otorhinolaryngology is a combined medical-surgical specialty with a broad patient clientele. It is therefore a specialty with a high litigation risk. Complications following surgery can occur in even the best of situations; poor outcomes may occur in the face of delivery of outstanding medical care. The analysis of malpractice complaints can provide valuable information on prevention of adverse events and patient safety. The complaint pattern of diagnoses and treatments in Denmark and the actions taken are largely unexplored and have not been reported before. In Denmark, the National Board of Patients' Complaints (NBPC) was founded in 1988. The Danish NBPC is not engaged in settling financial

compensation for patient injuries. Its decision-making is based on the Public Administration Act [1]. In cases of suspected severe negligence, the case is furthermore forwarded to the police authority (**Figure 1**). A settled file mostly consists of the patient complaint, information from the Medical Officer of Health, relevant medical records, statements from involved health-care personnel, expert reviews and the decision reached by the NBPC [2]. Please note that per 1.1.2011 the work of NBPC was transferred to the National Agency for Patients' Rights and Complaints.

Malpractice complaints are classified into the following seven juridical theme categories by the NBPC: medical error, lack of adequate informed consent, deficient information provided by the health-care personnel, deficient medical recording, lack of access to patient's own medical journal, breach of physician's confidentiality and deficient medical certificates provided by the physician. The same juridical classification is used in the decision-making when the health-care personnel is found guilty of medical malpractice. This study examined the detailed background for the reasons and outcomes of ear, nose and throat (ENT) malpractice complaints handled by the NBPC in the 1998-2008-period.

The following research questions were addressed:

1. Is there a recurrent pattern of malpractice complaints;
2. Are ENT malpractice complaints mostly due to technical shortcomings; and
3. Are a limited number of ENT procedures overrepresented with regard to malpractice complaints?

ORIGINAL ARTICLE

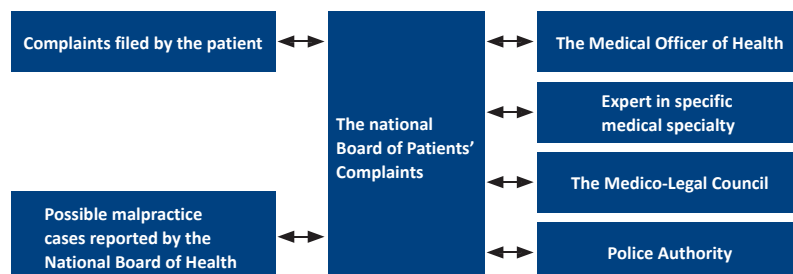
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FIGURE 1

Overview of the case procedure of the National Board of Patients' Complaints in Copenhagen, Denmark (valid until 31.12.2010).



MATERIAL AND METHODS

Design

This was an observational and retrospective register study.

Ethics

The study was approved by the Regional Research Ethics Committee, the Danish Data Protection Agency and by the NBPC.

Subjects

All ENT specialty-related decisions made by the NBPC in the 1998-2008-period were analysed. Detailed information on diagnosis, treatment provided by the ENT physician, reason for the complaint and decision reached by the NBPC were recorded in a standardized register created for the study. Both the complaints and the NBPC criticisms were classified according to the seven juridical categories used by the NBPC during the processing of malpractice complaints.

Information relating to the demographic data of the complainant, the health-care professionals and services and the decision reached by the NBPC are analysed in another publication [3].

The disease diagnoses of the complaints were classified according to anatomical site.

We identified and performed a detailed analysis of the two numerically most frequent kinds of ENT surgery leading to complaints and also malpractice complaints with lethal outcomes and serious complications.

Complaints assigned to the category of "medical error" were further reviewed for their causes and subcategorized. More than one subcategory could be assigned to a single malpractice complaint.

Statistics

The study was complete and descriptive. Test for differ-

ences between frequencies was performed using the χ^2 test with Yates correction and p values ≤ 0.05 were considered significant.

Trial registration: not relevant.

RESULTS

A total of 480 NBPC decisions were found to involve newly filed malpractice complaints filed against ENT specialty professionals in the 1998-2008 period. In 18% (87/480) of the decisions, one or more ENT health-care professionals were criticized. In 1.4% (7/480) of the decisions, the ENT physician was not only criticized but also enjoined. None of the 480 decisions resulted in police reports due to severe negligence. In the 480 ENT decisions, 88 involved complaints on two or more juridical themes, the rest concerned only a single theme (**Table 1**). The subcategorization of the theme "medical error" is noted in **Table 2**. **Table 3** presents the distribution of the anatomical sites of the disease diagnoses.

Serious complications

Seven ENT malpractice complaints were filed in cases in which meningitis had occurred as a complication to the following: trauma of the head, chronic maxillary sinusitis, acute tonsillitis, two cases of acute otitis media, polyp removal from the nasal cavity and endoscopic nasal surgery.

Lethal outcomes

Seventeen (3.5%) ENT malpractice complaints were filed due to a lethal outcome of a treatment at either ENT departments or clinics. One of the cases concerned an accidental morphine overdose in a patient with oral cancer. In eight other cases, death resulted as a complication to the following diseases: peritonsillar abscess, mononucleosis with insufficient respiration, parapharyngeal abscess, tooth abscess, acute otitis media with meningitis, head trauma with liquorrhoea and meningitis, chronic maxillary sinusitis with meningitis and abscess in the frontal sinus. A surgical procedure prior to death was found in seven cases: bronchial tumour resection with a lethal bleeding complication, tonsillectomy with a late bleeding complication, two cases of tracheotomy with respiratory complications, tumour removal of oral cavity cancer prior to heart attack, middle ear operation for cholesteatoma removal with bleeding complications, nasal polyp removal with intracerebral complications and oesophagoscopy removal of foreign body with perforation of the oesophagus.

The most frequent ENT surgeries leading to complaints

The following ENT operations were numerically the most frequent in the project data: tonsillectomy and adeno-

 **TABLE 1**

Distribution of complaints according to juridical themes of all otorhinolaryngology complaints and criticism filed in the National Board of Patients' Complaints (NBPC) in Denmark in the 1998-2008-period. Malpractice cases in which criticism was given by the NBPC without the juridical theme being mentioned in the complaint (criticism without allegation) are also presented. The values are n (%).

Juridical theme	Complaint	Complaints resulting in criticism	Criticism without allegation
Medical error	461	57 (12) ^a	4
Lack of adequate informed consent	60	11 (18) ^a	2
Deficient information	31	6 (19) ^a	0
Deficient medical recording	10	0	21
Lack of access to medical records	4	2 (50) ^a	0
Physicians confidentiality	2	0	0
Deficient certificates & statements	1	0	0

df = degrees of freedom.

a) $\chi^2 = 2.2$; df = 3; p = 0.5 between the four marked frequencies of juridical themes resulting in criticism.



TABLE 2

Subcategory	Complaints (n = 480)	Criticisms
Unsatisfactory treatment or examination	81 (17)	14 (17)
<i>Delay of diagnosis</i>		
Cancer	45	6 (13)
Cholesteatoma	8	1 (13)
Hearing loss	7	1 (14)
Miscellaneous	10	2 (20)
Total	70 (15)	10 (14)
Delay in treatment	5 (1)	1 (20)
Misdiagnosis/diagnostic error	32 (7)	4 (13)
Medication related errors	11 (2)	3 (27)
Rough handling, inattention to discomfort	26 (5)	1 (4)
Unnecessary surgical intervention	12 (3)	1 (8)
Wrong site surgery	3 (0.5)	2 (67)
<i>Surgical accidents</i>		
Tooth injury	4	0
Left retained packing	5	4 (80)
Removed material not sent to pathologist	2	1 (50)
Laser burn/peeling injuries	5	3 (60)
Miscellaneous	2	0
Total	18 (4)	8 (44)
<i>Procedure related accidental perforation of organ</i>		
Nasal septum	5	1 (20)
Eardrum	2	0
Oesophagus	9	0
Palatal arch	6	1 (17)
Total	22 (6)	2 (9)
<i>Unsatisfactory surgical results</i>		
Cosmetic	8	0
No effect on the voice quality	6	0
No hearing improvement	11	0
No effect on nasal flow, septoplasty	10	0
Residual tissue after tonsillectomy/adenoidectomy	6	0
Ventilation tube insertion	2	0
Miscellaneous	29	1 (3)
Total	72 (15)	1 (1)
<i>Postoperative complications</i>		
Infection	20	0
Velopharyngeal insufficiency	16	2 (13)
Haemorrhage, haematoma	22	0
Pain, pain management	17	0
Vertigo and tinnitus	6	0
Tinnitus	7	1 (14)
Total	88 (18)	3 (3)
<i>Nerve dysfunction</i>		
Recurrent laryngeal nerve	11	0
Spinal accessory nerve	4	0
Facial nerve	5	1 (20)
Numbness	6	0
Miscellaneous nerve dysfunction	5	0
Miscellaneous postoperative complications	3	0
Total	34 (7)	1 (3)
Negligent postoperative care	13 (3)	1 (8)
Unsatisfactory further reference	26 (5)	2 (8)
Unsatisfactory follow-up of treatment	28 (6)	7 (25)
Unsatisfactory i.v. access	2 (0.5)	0
Delayed appointment	2 (0.5)	0

The medical error category subdivision of filed otorhinolaryngology complaints and criticism in the National Board of Patients' Complaints in Denmark in the 1998-2008 period. The subdivision is based on the diagnostic category the complaint adhered to. The values are n (%).

tonsillectomy (50.1%), septum-, rhino- or septum rhinoplasty (25.5%), direct laryngoscopy (16.3%), tumour removal (16.3%), broncho-, mediastino- or broncho-mediastinoscopy (15.3%), tympanoplasty (15.3%), oesophagoscopy (11.2%) and adenotomy alone (11.2%).

Tonsillectomy and adenotonsillectomy

Annually, approx. 6,000 persons undergo tonsillectomy or adenotonsillectomy in Denmark. The 50 malpractice complaints regarding tonsillectomy were reviewed for further details, especially regarding the causes of the complaints. The vast majority of the tonsillectomies in this study were performed at hospitals (45.9%), while ENT clinics were responsible only for 10%.

Therapeutic tonsillectomy was performed in 40 complaints, diagnostic tonsillectomies in three and adenotonsillectomy in seven. Complaints were filed for the following reasons: postoperative velopharyngeal insufficiency (n = 13), postoperative pain and pain management (n = 11), postoperative bleeding (n = 10), residual or reoccurred tonsillar tissue (n = 6), perforation of the palatal arch (n = 6), postoperative food taste changes (n = 3), postoperative hoarseness (n = 3) and left retained packing in the nasopharynx after adenotomy (n = 2). Ten (20%) of the 50 complaints resulted in criticism for either medical error (n = 4), deficient medical recording (n = 5), deficient information (n = 1) or lack of adequate informed consent (n = 1).

Septo-rhinoplasty

Annually, approx. 2,000 patients undergo septoplasty or septorhinoplasty in Denmark. In this study, septoplasty (n = 16), rhinoplasty (n = 3) and septorhinoplasty (n = 6)

form the group of ENT procedures that was numerically the second most complained about; and 92% (n = 23) of these procedures were carried out at hospitals, while 8% (n = 2) derived from private ENT clinics. Complaints were filed for the following reasons: no effect of the operation on the nasal flow (n = 10), unsatisfactory cosmetic result (n = 9), postoperative septum perforation (n = 3), postoperative nasal pain (n = 3), rough handling and inattention to patient discomfort (n = 2), postoperative infection (n = 2) and postoperative bleeding (n = 1). Three (12% of 25) complaints resulted in criticism for deficient medical recording (n = 2) and for lack of adequate informed consent (n = 1).

DISCUSSION

During the malpractice complaint treatment, the NBPC not only considers the specific questions and allegations stated by the complainant, but also the entire course of the medical treatment recorded in the timetable of the malpractice complaint. It is assessed whether the health-care professionals mentioned in the complaint acted in accordance with the generally accepted professional standard in their diagnostic work-out or medical treatment and whether these were performed thoroughly and conscientiously. Thus, the NBPC decision can lead to criticism of malpractice of one or more health-care staff by one or more juridical themes related to aspects of medical treatment not necessarily stated in the complaint.

The NBPC criticized deficient medical recording in 21 complaints where the complainant had not alleged that medical recording was deficient (Table 1). This emphasizes the importance of correct and sufficient medical recording, even though deficient medical recording is very seldomly mentioned by complaints.

Medical error, deficient information and lack of adequate informed consent were the most frequently alleged juridical themes (Table 1). However, the least criticized juridical theme was the medical error category (12% criticized) compared with lack of access to medical records (50%), deficient information (19%) and lack of adequate informed consent (18%). This difference was, however, not statistically significant (Table 1). A patient-signed document stating which information was received may lower the frequency of these juridical themes.

Analysis of the medical error category showed that unsatisfactory treatment or examination, delay of diagnosis, unsatisfactory surgical results and postoperative complications are the main reasons for the complaints. Those medical errors that lead to high frequencies of criticism were left retained packaging (80%), wrong-site surgery (67%), laser burns and peeling injuries (60%) and removed material not sent for pathology (50%). A lower frequency of criticism was found for medical errors such



TABLE 3

Distribution of the anatomical site of the disease diagnosis mentioned in the 480 malpractice complaints filed at the National Board of Patients' Complaints in Denmark in the 1998-2008-period.

Anatomical site	n (%)
Ear: internal, middle, external ear canal	142 (30)
Nasal cavity and sinuses	92 (19)
Pharynx	78 (16)
Neck including thyroid gland	38 (8)
Larynx	28 (6)
Oral cavity	25 (5)
Face including facial fractures and facial nerve palsy	20 (4)
Oesophagus	17 (3)
Lungs and airways	17 (3)
Salivary glands	10 (2)
Cerebrum	7 (2)
Mediastinum	3 (1)
Other sites	4 (1)
Total	480

as medication-related errors (27%), unsatisfactory follow-up of treatment (25%), facial nerve dysfunction (20%), procedure-related nasal septum perforation (20%), delay of treatment (20%) and miscellaneous delay of diagnosis (20%). All of the above-mentioned criticisms arose because the ENT treatment was not sufficiently thorough and conscientious.

An interesting finding was that complaints for surgical procedure-related nerve damage, tissue perforation, infection, bleeding and velopharyngeal insufficiency were frequently the cause of complaints, but were very seldomly criticized as these were considered accidental complications not depending on the quality of the provided medical service. There were a few exceptions to the latter, such as accidental removal of a facial nerve branch instead of the temporal superficial artery, nasal septum perforation as a result of burning bleeding arteries on both sides of the septum, palatal arch rupture not detected at postoperative rounds and adenoidectomy despite either submucous or complete cleft palate. These accidents were considered preventable if treated thoroughly and conscientiously.

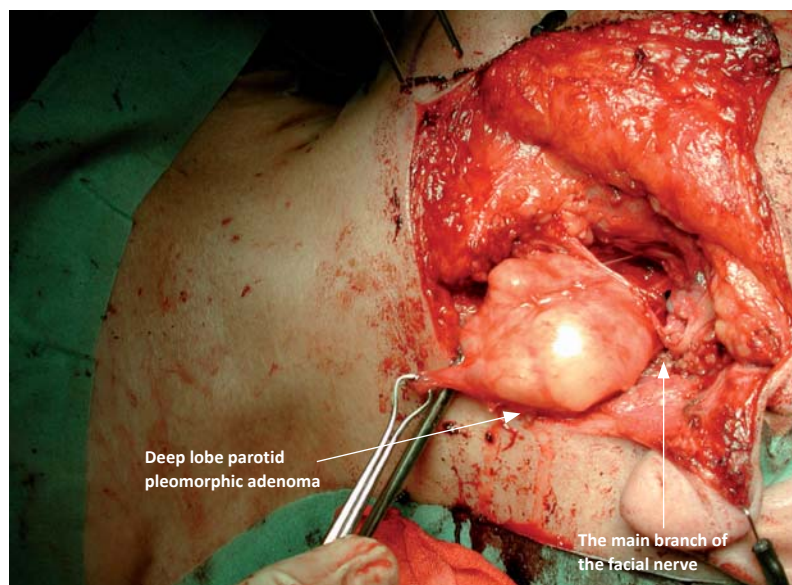
The distribution of the anatomical site of the disease diagnosis shows an overrepresentation of ear and hearing-related diseases (30%). In total, 3.5% of the cases were due to lethal outcome of ENT treatment which probably reflects that this outcome is rare.

The most frequently alleged ENT operation in our data was tonsillectomy with a criticism rate of 20%. The annual sum of patients receiving tonsillectomy is approx. 6,000, which makes it the second most frequent type of ENT surgery in Denmark, the most frequent is ventilation tube insertion [4]. Hospitals were responsible for 90% of tonsillectomies in this study. The reason that tonsillectomy led to complaints in so many cases was mostly postoperative velopharyngeal insufficiency, pain and bleeding. While the two latter are always part of preoperative information, velopharyngeal insufficiency is not. We therefore suggest that this complication should be part of common preoperative information, particularly for tonsillectomy.

Based on the presented findings, it is evident that it is possible to learn from malpractice complaints. Efforts to ensure such learning should be implemented more systematically. The new act on the handling of malpractice complaints may prove to be an improved instrument for learning and gaining an improved understanding of malpractice complaints in Denmark [5]. This may, in turn, benefit patients and health care providers and professionals alike.

CONCLUSION

Criticism concerning deficient medical recording was issued even though the complainant did not state this in



Postoperative complications such as nerve dysfunction, haemorrhage and infection are common causes of malpractice complaints. Many important nerves are at risk in ear, nose and throat surgery, e.g. the facial nerve in parotidectomy.

the complaint. This emphasizes the importance of sufficient and meticulous medical recordings. Thorough preoperative information about potential surgical complications undersigned by the patient in combination with the newly introduced safe surgery procedures are likely to reduce both faults and complaints at hospitals as well as in private practices. The juridical theme of medical error was the theme most complained about, but the least criticized theme compared with six other juridical themes. In contrast, retained packaging, wrong-site surgery, laser burns and peeling injuries were medical errors carrying a high risk of criticism. Complaints on accidental surgical complications did not lead to criticism as they were not considered preventable. The most frequently alleged ENT surgery in this study was tonsillectomy. Malpractice complaints have not hitherto been systematically used as a learning instrument. We propose a systematic registration of these incidents to enable more learning from complaints in the future.

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CONFLICTS OF INTEREST: none

LITERATURE

1. Lovbekendtgørelse 1365 af 07/12/2007. Bekendtgørelse af forvaltningsloven.
2. Læge-Karnov. Copenhagen: Karnovs Forlag, 1996:37.
3. Nikoghosyan-Bossen G, Hauberg A, Homøe P. Increased number of ear-nose-throat malpractice complaints in Denmark. Dan Med J 2012;59(5): A4321.
4. Sundhedsstyrelsens Landspatientregister. www.sst.dk/Indberetning%20og%20statistik/Landspatientregisteret.aspx (1 July 2011).
5. Lov nr. 706 af 25/06/2010. Lov om ændring af lov om klage- og erstatningsadgang inden for sundhedsvæsenet, lov om autorisation af sundhedspersoner og om sundhedsfaglig virksomhed, sundhedsloven og forskellige andre love.