Insufficient reporting of infections after ear, nose and throat surgery

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ABSTRACT

INTRODUCTION: In Denmark, it is compulsory to report post-operative infections (PI) to the Danish Health and Medicines Authority. The aims of the present study were to determine, firstly, the incidence of PI following elective ear, nose and throat (ENT) surgery as well as the number of cases reported to the Danish health authorities; secondly, the PI distribution in various surgical subgroups; and, thirdly, the extent to which the guidelines on prophylactic antibiotics had been followed.

MATERIAL AND METHODS: The study was carried out prospectively at the ENT Department, Aarhus University Hospital, Denmark, from 1 February to 30 April 2011. A total of 362 elective surgical procedures were evaluated in order to identify signs of PI. In case of PI, the following were registered: diagnosis, type of operative procedure and whether the patient had received prophylactic antibiotics according to instructions given at the Department. The ENT doctors were to hand in completed PI reporting schedules to one of the authors.

RESULTS: PI occurred in 40 patients, i.e. 11%. Seven (18%) of the 40 cases were reported to the Danish Health and Medicines Authority. The lowest rate of PI was observed after otosurgical procedures (6%) and the highest rate (13%) after head and neck (HN) procedures. Guidelines on prophylactic antibiotics were most frequently ignored in the HN group (30%).

CONCLUSION: To improve the reporting of PI, it is recommended to implement simple, less time-consuming and electronically available procedures. Furthermore, the present results indicate that it is necessary to more meticulously use prophylactic antibiotics and strict aseptic procedures.

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Post-operative infection (PI) increases morbidity and costs in health care. Thus, in 2004 Leaper et al estimated that PIs contribute to the economic costs of surgical procedures by "1.47-19.1 billion Euro dollars" a year in the European countries according to Leaper et al [1]. Despite the significance and impact of PI, the literature on the subject is rather sparse, and the incidence of PI within the ear, nose and throat (ENT) field is not well described. Some studies have focused on PI after head and neck (HN) surgery and have reported estimates of PI incidence in the 9-20% range [2, 3]. Certain HN procedures are associated with an increased risk of PI. Thus, clean procedures through skin incisions, e.g. surgery on the thyroid gland, were related to a PI risk of 0-2%, whereas PI was found in as many as 50-70% of cases after contaminated procedures through mucosal incisions [4].

Using prophylactic antibiotics, Coskun et al demonstrated a 3-7% risk of wound infection in clean procedures and a risk of up to 30% in clean-contaminated procedures, noting that the risk of wound infection increased to 80% without use of prophylactic antibiotics [5]. These data emphasize the importance of observing the guidelines on pre- or per-operative antibiotic treatment.

In Denmark, it has become compulsory to report PI to the Danish Health and Medicines Authority. PI incidences are not just reported, but also published with a view to 1) providing citizens/patients with information allowing them to make an informed choice between hospitals, and 2) providing a tool for political prioritizing within health care. In 2005, a survey from the Danish Health and Medicines Authority showed that reporting in this field was deficient [6]. Despite much information and encouragement from the Head of the ENT Department, Aarhus University Hospital, no instance of PI was reported by the Department in the 2006-2011 period [7]. Thus, a certain level of under-reporting in the Department is suspected.

The aims of the present study are to determine: 1. the incidence of PI following elective ENT surgery at the ENT Department at Aarhus University Hospital as well as the incidence of reported cases, 2. the distribution of PI in various surgical subgroups, and 3. the significance of following the guidelines on prophylactic antibiotics.

MATERIAL AND METHODS

The study was carried out prospectively at the ENT Department, Aarhus University Hospital, from 1 February to 30 April 2011. Since 2006, an application form for PI reporting had been available at the Department as well as updated guidelines for the use of prophylactic antibiotics. No incidents of PI were reported by the Department until February 2011. Before the initiation of the study, the doctors were re-introduced to the PI-report-

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ing schedule and encouraged both orally and by posters in all examination rooms to be aware of their obligation to report PI.

A total of 853 surgical procedures were performed during the study period. The following were excluded: acute procedures, diagnostic endoscopies, tube insertions (ear, sinus) and so-called assisted procedures (acute procedures performed for/at other departments). Thus, 362 operations were further investigated to identify signs of PI. In accordance with the obligation to notify infections established by the Danish Health and Medicines Authority, patients were considered to have a PI when signs of infection were observed within 30 days after the performed procedure. The signs were swelling, redness, and/or purulent secretion in the surgical field. Furthermore, findings resulting in prescription of antibiotics were accepted as cases where PI was present. In case of a PI, the following information was recorded: type of PI, type of operative procedure, diagnosis, previous treatment involving the affected area (radiotherapy, surgery), use of prophylactic antibiotics according to departmental instructions, microbiological tests and treatment of the PI. The ENT doctors were to hand in completed PI reporting schedules to one of the authors. At the end of the study period, the total number of PI identified through revision of the records was calculated and compared with the number of reported cases.

The surgical procedures were divided into three categories: otological procedures, rhinological procedures, and HN procedures (including the pharynx and larynx). Oto-surgical procedures counted explorations of the middle ear, tympanoplasties and mastoidectomies, including obliterations and reconstructions. Rhinological procedures included septumplasties, conchotomies, external opening of the sinuses, and computer-assisted functional endoscopic sinus surgery. Head and neck procedures comprised intraoral surgery, tonsillectomies, excision of pharyngeal/laryngeal tumours including laryngectomies, closure of tracheostomies, subglottic plastic surgery, surgery of the thyroid gland and the salivary glands, excision of tumours and lymph nodes, and flap/reconstructive procedures.

TABLE 1

Overview of the distribution of post-operative infections (PI) in the different subgroups and percentage of the PI cases in which guidelines on antibiotic prophylactics were not followed.

Procedure group	Procedures, n	Procedures, %	PI, n	Cases involving PI, %	PI cases in which the guidelines on prophylactic antibiotics were not followed, %
Ear	79	22	5	6	0
Nose	98	27	11	11	18
Head/neck	185	51	24	13	30

Statistics

The study was descriptive. Thus, all data are presented as total number and percentages.

Trial registration: not relevant.

RESULTS

The median age of the included 362 patients was 45 years (range 0-94 years), 41% were women. PI occurred in 40 patients, i.e. 11% (**Table 1**). The median age of patients with PI was 48 years (range 1-86 years) and 35% were women. Seven of the 40 PI cases (18%) were reported, all by the same four out of the 28 doctors at the Department (**Figure 1**).

The majority of procedures were HN surgery (185/362, 51%), whereas otosurgical and rhinosurgical procedures accounted for 22% and 27%, respectively (**Figure 2**). The highest PI rate (13%) was found in the HN group. The corresponding PI rates in the otosurgical and the rhinosurgical groups were 6% and 11%, respectively (Figure 2).

Division of the HN group into a non-malignant (109/185) and a malignant group (76/185) according to the diagnosis showed that PI developed in eight patients with malignancies and in 14 patients in the non-malignant group.

In all, 22 of the 185 patients in the HN group had previously been treated with radiotherapy against the surgical field. Two of these patients developed PI, whereas PI developed in 21 of 163 patients in the non-radiation group. Only one patient with malignant disease had previous surgery in the same field and developed PI.

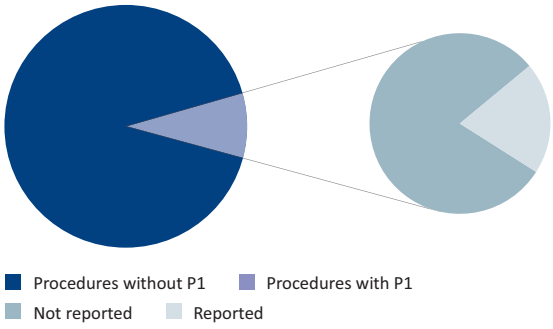
The use of prophylactic antibiotics is presented in Table 1. Overall, the given guidelines had been ignored in nine of the 40 PI cases (23%). In all cases of PI after otosurgery, the guidelines were followed. In the nose/sinus subgroup, two of the 11 cases did not adhere to the guidelines. In the HN subgroup, the guidelines were not followed in seven out of the 24 cases (30%).

Unfortunately, it has not been possible to obtain an overview of the bacteria causing the PI. The bacteria responsible for the PI were identified only in three out of the 40 cases; one case of *Escherichia coli* and two cases of various strains of *Staphylococcus aureus.*

DISCUSSION

The present study demonstrated that 11% of patients undergoing elective ENT surgery developed PI with the highest incidence of 13% being observed within HN procedures. Only 18% of PI cases were reported to The Danish Health and Medicines Authority. Overall, the guidelines on prophylactic antibiotics were ignored in 23% of PI, especially in HN patients (30%).

FIGURE 1



Incidence of post-operative infections (PI) at the Ear, Nose and Throat Department, Aarhus University Hospital, during a three-month period. A total of 362 elective surgical procedures were included (large circle). Among these, 40 (11%) developed a PI (smaller segment of the large circle). Of these PI (smaller circle) seven (18%) were reported (segment of the smaller circle) by the doctors at the department and 33 were discovered by the authors through revision of the patient files visualizing the under-reporting.

Only few studies have previously addressed the problem of PI after ENT surgery. Most of these studies have focused on the PI incidence after HN surgery alone and often in cancer patients. Furthermore, no reports from Denmark could be identified. Accordingly, more national surveys are needed.

In a comparable study from Texas, a total of 20% of HN surgery cases were complicated by PI, and incidences of 3-7% were found for clean HN surgery, whereas 30% had PI after HN surgery in clean-contaminated sites in Turkey [2, 5]. Thus, the observed incidences of PI in the present study are lower than those reported in previous studies. On the other hand, we may have underestimated the incidences, as some patients may have consulted their general practitioner and not the Department.

Consistent with the distribution of surgical procedures (oto-, rhino- surgery and HN), more than half of the PI cases occurred after HN surgery. This could be due to longer operation time, flap-surgery where the blood flow could be compromised, the size of the surgical field, and surgery through contaminated mucosal incisions. The age and gender of the patients with PI were similar to those of the entire study population.

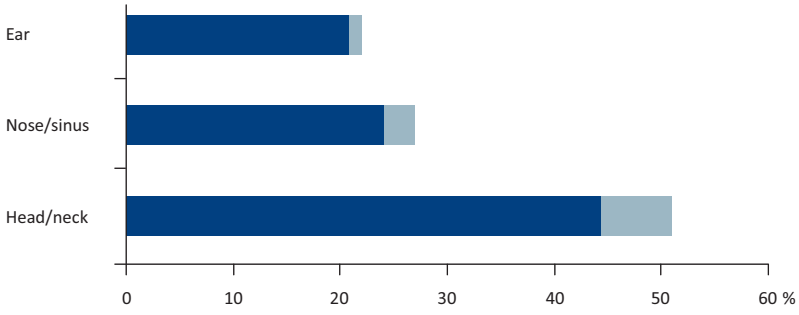
In future studies, it could be interesting to identify risk factors for developing PI, e.g. malignant diagnosis and previous radiation to the surgical field among patients undergoing HN surgery. This study was not designed to do so, nor did it have a sufficiently large population to investigate these issues. Hence, PI within these subgroups in the HN area is only mentioned as absolute numbers in the results.

All surgical specialties are challenged by PI. Watanabe et al estimated a PI rate of 15.5% in relation to upper and lower gastrointestinal surgery and suggested a strict aseptic policy at the surgical departments as one of the approaches to reducing the incidence of PI [8]. Although this is already a reality at Danish surgical departments, their advice should always be kept in mind. In orthopedic surgery, small numbers of organisms can cause implant infections and give rise to a considerable degree of morbidity and mortality. The infection rate from blood-borne infection has been estimated to be no more than 0-5% [9]. Whyte et al estimated that 98% of bacteria found in patient wounds come directly or indirectly from the air [10]. A solution to this problem may be ventilated operating theatres to improve air quality and special clothing preventing shed bacteria from getting into the air [11].

In Denmark, it has been compulsory to report PI to the health authorities since 2006. Based on the socio-economic burden associated with PI, a reporting system seems reasonable, especially with interventions and improvements in view. The reporting scheme consisted of one page which had to be filled in manually by the doctor identifying the PI. Before the study period, more doctors had claimed that they were unaware of their obligation to report PI and that they did know where to find the reporting scheme. Despite an intensive information campaign including posters in all examination

FIGURE 2

Distribution of the 362 patients according to the anatomical site of the surgical procedure. Part of patients in each category who developed a post-operative infection is depicted as the light blue area.



Post-operative wound infection after removal of the left submandibular salivary gland.

rooms at the Department during the study period, only eight of the 40 PI cases were reported. Of the 28 doctors in the Department, only four had reported PI. The explanation for this was lack of time as patients presenting PI were often acute and patients visiting the outpatient clinic. A solution to this under-reporting could be to implement the scheme as a part of the electronic patient journal or as a folder at E-dok (website used by Danish doctors). The schedule should be automatically activated in case of prescription of antibiotics within 30 days after surgery or in case of registering an International Classification of Diseases (ICD)-10 code indicative of infection. Alternatively, all patients with PI should be given the same ICD-10 code, and after a certain period these codes should be collected and reported to the Danish Health and Medicines Authority at the same time.

Another area which demands attention is the use of prophylactic antibiotics. It has been demonstrated that the incidence of PI is reduced by prophylactic antibiotics, also within the ENT field [4, 5]. Guidelines have been available at the Department since 2003, and they were updated prior to the present study. The instructions were accessible electronically as well as manually, and the update was presented at an information meeting in the Department. In every fourth case of PI, the guidelines had not been followed, especially not after HN surgery. However, it is clear that prophylactic antibiotics cannot prevent all PI cases which was also demonstrated by the fact that the correct prophylaxis had been given to the five incidents of PI after otosurgery in the present study.

CONCLUSION

PI occurred in 11% of elective ENT surgery at a university clinic. Only 18% of these were reported to the Danish Health and Medicines Authority. Notification has been compulsory since 2006. The study confirms a suspicion of substantial under-reporting. Furthermore, guidelines for prophylactic antibiotics had been ignored in every fourth case of PI. We recommend that the reporting system is simplified and that doctors are repeatedly informed of their obligations including the various treatment instructions, as it has been shown in previous studies that correct use of prophylactic antibiotics is effective in preventing PI. We encourage each ENT department to follow their guidelines within the area recommending the guidelines at the ENT Department at Aarhus University Hospital found at E-dok.

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