SHORT REPORT
Incidence of surgical-site infections in orthopaedic surgery: a northern Italian experience

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SUMMARY
A prospective cohort study with a 1-year telephone follow-up was performed to estimate the incidence of surgical-site infections (SSIs) in hip and knee prostheses. Twenty-five public hospitals equipped with orthopaedic units in two Italian regions were involved. An 8-month surveillance period was set to obtain significant data at a regional level and data were collected by the infection control nurses of each centre. One-year follow-up was completed in 75% of cases. SSIs were recorded in 45 cases (incidence rate 1.9/100 person-years, 95% CI 1.4–2.5). Thirty-six percent of SSIs were diagnosed during hospitalization and 95.3% within 90 days post-operation. This incidence is similar to that reported by European and USA surveillance systems. The proposed investigative method proved to be reliable and feasible. A prolonged surveillance for at least 3 months post-operation yields a good estimate of SSI in joint replacements.

Key words: Epidemiology, hospital-acquired (nosocomial) infections, surveillance.

Surgical-site infections (SSIs) are a serious problem in terms of morbidity and mortality [1]. In the case of total joint replacement (TJR), contamination of the surgical site can lead to deep infections that necessitate additional diagnostic and therapeutic procedures such as multiple lavages, surgical revision and antibiotic treatment, as well as prolonging hospitalization and isolation. By definition, SSIs may occur up to 1 year after surgery [2]. Although many national surveillance systems use a standardized surveillance methodology for hospital in-patients for detecting SSIs, post-discharge (PD) surveillance modalities are still challenging [3, 4].

In Europe, several national surveillance studies have been performed on SSIs in orthopaedic operations, such as those conducted in Britain and France with regard to hip and knee replacement [5–7]. The HELICS project, which involves 14 countries, has established a network for the collection, analysis and diffusion of data on nosocomial infections; one of the surgical operations that it monitors is hip prostheses [8, 9]. In the USA, the National Nosocomial Infections Surveillance System (NNIS), which has been operating since 1970, included hip and knee replacements in the operations monitored [10].

Surveillance is generally carried out on total hip replacement (THR) (ICD-9-CM 81.51) and total knee...
replacement (TKR) (ICD-9-CM 81.54) as surgical performance indicators. In Italy, no national surveillance programmes have so far been implemented. Recently, however, the INF-OSS project, which is supported by the CCM (National Center for the Prevention and Control of Disease), has drawn up a national protocol for the surveillance of SSIs similar to that of the HELICS project.

This paper reports the data on active surveillance of SSIs in hip and knee replacements followed-up for 1 year. The objectives of the study were to assess the incidence of SSIs through the implementation of a standardized method of surveillance at the regional level and to establish the optimum duration of surveillance that would provide the most accurate estimate of the incidence of SSIs. The study involved two Italian regions, which together have a population of about 4,700,000 inhabitants, a total of 510,000 admissions and about 9,600 hip and knee prostheses per year.

The study was carried out from September 2004 to May 2005 in 25 of the 45 public hospitals equipped with orthopaedic units in the Piemonte and Valle d’Aosta regions of Northern Italy. Hospital participation in the study was voluntary. The study population was composed of patients aged >14 years who underwent surgery in an orthopedic surgery unit during the study period. Operations performed during hospitalization were considered; repeat operations at the same site due to complications (infective or otherwise) arising from a previous procedure were excluded from surveillance. Surgical procedures were grouped according to ICD-9-CM codes: 81.51 (total hip replacement), 81.52 (partial hip replacement), 81.53 (revision of hip replacement), 81.54 (total knee replacement) and 81.55 (revision of knee replacement).

On the basis of the incidences reported by the NNIS and the expected case series in the two regions, an 8-month surveillance period was set in order to obtain significant data at the regional level. The expected regional rate was 52 infections per 4821 procedures, assuming an incidence rate of 1.1% [95% confidence interval (CI) 0.8–1.4].

Data were collected by the infection control nurse in collaboration with healthcare workers on the ward (a surgeon and a nurse appointed by the head of the department). For each patient, a form containing the following information was completed: age, gender, date of admission, surgery and discharge, index risk [according to the American Society of Anesthesiologists (ASA) score risk category, duration and class of operation], whether the surgery was an elective or emergency procedure, date of SSI, classification of SSI (according to the definition of CDC), and microorganism isolated [2, 11]. The patient forms were completed with information obtained from: clinical records (risk factors, temperature, antibiotic prophylaxis, SSI); laboratory data (pathogens responsible for SSIs, antibiotic resistance); medical charts (antibiotic prophylaxis); temperature charts; operating room records (ASA score, duration and class of operation); consultation with ward staff to obtain any information missing from the clinical records; direct observation of the patient by the surgeon during the hospital stay and at the time of the PD medical examination; active surveillance was conducted during PD follow-up by means of telephone interviews at 30, 90 and 365 days using a standardized multiple-choice questionnaire that investigated for signs and symptoms attributable to infection (pain or tenderness, localized swelling, redness, heat, etc.), type of SSI, and diagnosis given by the attending physician or surgeon who had examined the patient, and the therapy prescribed [2].

Data were recorded and analysed using Epi Info 2000 software, version 3.3 (Centers for Disease Control and Prevention, USA). The infection rates, incidence rate per 100 person-years and 95% CIs were calculated. The $\chi^2$ test for categorical variables and Mann–Whitney test for continuous variables were performed to assess whether a significant difference could be evidenced between infected and non-infected groups. For all tests a $P$ value $<$ 5% was taken as significant. The incidence of SSI was stratified by the American NNIS risk index, composed of three SSI risk factors (ASA score of 3, 4, or 5; duration of surgery $>$ 75th percentile; contaminated or dirty wound class) [10, 12]. A specific analysis was performed on the data concerning THR as elective surgery, excluding patients undergoing hemiarthroplasty for trauma.

Surveillance was carried out on 2944 operations (2298 hip prostheses and 646 knee prostheses). Table 1 shows the demographic and clinical characteristics of all patients and of those who developed a SSI. Patients undergoing partial hip replacement (ICD-9-CM 81.52) were of an older mean age (82 years, s.d. = 8) than that of the overall sample, and more of these patients had an ASA score $\geq 3$ (58.5% vs. 31%) and a risk index $> 0$ (59% vs. 37.7%). They also had a significantly ($P < 0.001$) higher mean age than patients...
undergoing TJR (81.51), and more of them had an ASA score ≥3, even when the score was adjusted for age (>65 years).

Follow-up was carried out for 1 year in 75% of cases, for 3 months in 13.5%, and for 30 days in 7%, for an overall observation period of 2393 person-years. A total of 4.5% of patients were lost to follow-up. Thirty days after surgery, 39.4% of patients had been seen by a doctor, after 3 months 29.6%, and after 1 year 18.6%.

We identified 45 SSIs, with a SSI ratio of 1.5% (95% CI 1.1–2.0) and an incidence rate of 1.9/100 person-years (95% CI 1.4–2.5). However, different results were obtained if the incidence was calculated by taking into account only infections arising during hospitalization (SSI ratio 0.5%, 95% CI 0.3–0.9) or patients who completed the 1-year follow-up (SSI ratio 1.5%, 95% CI 1.1–2.0), or all patients regardless of duration of follow-up (SSI ratio 2.0%, 95% CI 1.5–2.7), or the incidence rate per 100 person-years (1.9/100 person-years, 95% CI 1.4–2.5). Figure 1 shows the cumulative percentage of diagnosed SSIs according to the time interval between the operation and the onset of infection.

As shown in Table 1, 64.4% of SSIs were superficial, 27% deep and 4.4% involved an organ/space; data were missing in two cases. Diagnosis was made after discharge in 20 of the 29 superficial infections.

### Table 1. Demographic and clinical characteristics of all patients and of the 45 patients with surgical-site infections (SSI), stratified by ICD-9-CM codes [data are absolute frequencies and (%) if not otherwise stated]

<table>
<thead>
<tr>
<th>ICD-9-CM code</th>
<th>Total (n = 2944)*</th>
<th>81.51 (n = 1567)</th>
<th>81.52 (n = 632)</th>
<th>81.53 (n = 93)</th>
<th>81.54 (n = 622)</th>
<th>81.55 (n = 23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>1129 (38.6)</td>
<td>619 (39.5)</td>
<td>120 (19.0)</td>
<td>44 (47.3)</td>
<td>193 (31.0)</td>
<td>12 (52.2)</td>
</tr>
<tr>
<td>Age, yr (mean ± S.D.)</td>
<td>68.6 ± 10.7</td>
<td>82.2 ± 8.5</td>
<td>71.7 ± 8.9</td>
<td>70.8 ± 7.0</td>
<td>69.0 ± 7.8</td>
<td>72.1 ± 10.9</td>
</tr>
<tr>
<td>Elective procedures</td>
<td>1472 (93.9)</td>
<td>565 (89.4)</td>
<td>89 (95.7)</td>
<td>592 (95.2)</td>
<td>23 (100.0)</td>
<td>2743 (93.2)</td>
</tr>
<tr>
<td>NNIS index risk ≥1</td>
<td>464 (29.6)</td>
<td>373 (59.0)</td>
<td>56 (60.2)</td>
<td>205 (32.9)</td>
<td>11 (47.8)</td>
<td>1111 (37.7)</td>
</tr>
<tr>
<td>Pre-operative stay &gt;2 days</td>
<td>393 (25.1)</td>
<td>433 (68.5)</td>
<td>36 (38.7)</td>
<td>114 (18.3)</td>
<td>2 (8.7)</td>
<td>982 (33.4)</td>
</tr>
</tbody>
</table>

Follow-up was carried out for 1 year in 75% of cases, for 3 months in 13.5%, and for 30 days in 7%, for an overall observation period of 2393 person-years. A total of 4.5% of patients were lost to follow-up. Thirty days after surgery, 39.4% of patients had been seen by a doctor, after 3 months 29.6%, and after 1 year 18.6%.

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eight of the 12 deep infections and one of the two organ/space infections.

In those cases in which infections developed, the duration of hospitalization proved to be significantly longer ($P=0.0002$) than that of patients who did not develop infections. Similarly, the mean post-operative hospital stay was significantly longer ($P=0.006$) in these patients than in patients without infections. There was no significant difference for age, NNIS risk $\geq 1$ or pre-operative stay $>2$ between the two groups.

Microbiological analysis was performed in 51% of infections (100% of organ/space infections, 66.7% of deep infections, and 38% of superficial infections). A total of 29 pathogens (seven double infections) were isolated; of these, nine were *Staphylococcus aureus*, five *Escherichia coli*, five *Pseudomonas aeruginosa*, three *Staphylococcus epidermidis*, two *Proteus mirabilis*, and five were other pathogens.

SSIs developed in 14 of the 1392 elective THR (81.51); the SSI ratio was therefore 1.0% (95% CI 0.6–1.7) and the incidence rate 1.2/100 person-years (95% CI 0.7–2.0). The incidence rates of SSI/100 person-years stratified by risk index were as follows – risk index 0 (771 patients): 0.8/100 person-years (95% CI 0.3–1.8); risk index 1 (357 patients): 1.2/100 person-years (95% CI 0.5–3.0); risk index 2 (22 patients): 5.6/100 person-years (95% CI 1.0–25.9).

The findings of our study underline the importance of PD surveillance. Surveillance performed only during hospitalization is unable to detect the expected number of SSIs in TJR, as only 36% of infections were diagnosed during that period. However, owing to the high percentage of cases in which 1-year follow-up was completed, no great differences emerged in our study between the SSI ratio calculated on all patients without considering the completion of follow-up and the incidence rate that takes the follow-up duration into account. As 76.7% of infections appeared within the first month of surveillance and 95.3% within the third month, it is important to contact the patient at a minimum of 90 days if the recommended 1-year follow-up is not feasible; this finding is in agreement with the data from the literature [3, 13].

The frequency of infections in our region is consistent with that reported for Europe and the USA; however, caution is warranted when comparing our data with those obtained from international surveillance systems. First, the modality of follow-up varies; it may be limited to the period of hospitalization, continue for 1 month after the operation, or for 1 year. Moreover, the category of procedure monitored may be different. Hip replacements are generally considered but knee replacements were more rarely included. Even the type of operation defined by the ICD-9-CM code does not always coincide; indeed, only the American surveillance system includes the code 81.55 (revision of knee replacement), while the code 81.53 (revision of hip replacement) rarely appears. In addition, hip hemiarthroplasty is generally excluded from studies because it is performed in patients with femoral neck fractures in whom, with few exceptions, numerous confounding factors are also present [14]. Furthermore, the presentation of the results of surveys is not always homogeneous. For instance, the NNIS report presents the SSI rate stratified by risk index but not by ICD-9-CM, while in the British and French reports the data are stratified by risk index and ICD-9-CM; in the HELICS report, in addition to
the SSI rate, the incidence rate is also calculated on the basis of the duration of hospitalization.

In the case of hip replacement, it is important to be able to analyse the data stratified by ICD-9-CM, as the risk of infection varies according to the type of operation performed. In accord with other studies, we found the incidence of infection to be higher in hemiarthroplasty (ICD-9-CM 81.52), although this difference did not reach statistical significance. Indeed, these procedures, which are generally associated with trauma, are more frequent in elderly patients and require longer hospitalization [6, 7, 15].

The current study is the first to document the incidence of SSIs in orthopaedic operations on a regional scale. In our regions, the frequency of infections was comparable to those reported for other countries. Our data provide a good estimate of the true situation only when the number of operations is high (risk index 0 and 1, ICD-9-CM 81.51, 81.52, 81.54); it would be difficult to make generalizations from them for smaller samples. The investigative method used proved to be both reliable and feasible, and could be usefully adopted in future investigations. The network of facilities charged with the prevention of infections proved capable of performing investigations of this kind and furnished optimal PD follow-up results, with 75% of the patients contacted within 1 year after the operation.

APPENDIX. Piemonte Nosocomial Infection Study Group
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DECLARATION OF INTEREST
None.

REFERENCES


