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#### Major article

## May the drain be a way in for microbes in surgical infections?



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Key Words: Surgical site infection Risk factor Wound classification **Background:** Surgical site infection (SSI) is among the most frequent hospital-acquired infections occurring in surgical patients and leads to increased morbidity, mortality, and costs. We aimed to identify risk factors for SSI in patients undergoing surgical procedures, with a particular attention to the use of drains.

**Methods:** This study includes all patients undergoing abdominal surgical procedures in 2 surgical wards in a teaching hospital in central Italy. Collected data included patient's demographic and clinical characteristics, procedure characteristics, administration of perioperative antibiotic prophylaxis, and microorganism isolated. The outcome of interest was SSI.

**Findings:** A total of 872 abdominal surgery procedures were surveyed during the study period. Drains were placed in 37.0% of cases. SSI rate was 6.4% globally and 13.6% among the patients with drains, versus 2.4% in those without a drain (P < .001). In 72.1% of cases antibiotic prophylaxis was administered. The logistic regression analysis (P < .001) shown insertion of a drain (odds ratio [OR], 5.14; 95% confidence interval [CI], 2.63-10.08), prolonged surgery (OR, 1.98; 95% CI, 1.09-3.59), and American Society of Anesthesiologists score equal to 3 (OR, 6.13; 95% CI, 2.33-16.11) as independent risk factors for SSI, whereas antibiotic prophylaxis was protective (OR, 0.53; 95% CI, 0.29-0.99).

**Conclusion:** This study revealed surgical drains as a risk factor for SSI, pointing out the need of a clearer understanding of drain role in the dynamics of SSI occurrence, with the purpose of decreasing infection risk through targeted preventive interventions.

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#### **BACKGROUND**

Significant progress has been made in the prevention of surgical site infection (SSI); nonetheless, it still represents 1 of the most frequent hospital-acquired infections occurring in surgical patients and leads to increased morbidity, mortality, and use of hospital resources. Some risk factors for surgical infections are well known; however, remarkable controversy exists about the actual necessi-

In memory of Dr Gino Tosolini.

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ty of drain use after surgery, because studies evaluating the risk of SSI associated with routine postoperative drains have yielded conflicting results across most surgical disciplines.<sup>2-4</sup>

Evidence shows that for some kinds of surgery the application of drains may even be obsolete<sup>5,6</sup>; on the other hand, some authors have demonstrated that the use of drains remains useful for some procedures.<sup>7</sup> Standardization of perioperative management is needed to clarify risk factors for SSI and to improve patient outcomes.

The primary goal of our surveillance study was to identify the risk factors for SSI in patients undergoing abdominal surgical procedures, with a particular attention to the use of drains.

#### **METHODS**

This study was based on a surveillance system for SSI that recruited all patients undergoing abdominal surgical procedures in 2 general surgery wards of the tertiary care center Azienda

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Ospedaliera Universitaria "Ospedali Riuniti di Ancona" in central Italy. Data were collected during a period of 8 months during 2010-2011.

In our setting, global SSI rate has been reported to be 2.7%, the sample size for this study was set at 674 to allow the detection among the drain group of an SSI rate double (5%) or higher than that of the control group, with 90% power and 5% significance. To remedy any possible missing data or error, the sample size was increased by 20%. In this way we determined an optimum number of 809.

The outcome of interest was SSI, defined according to the Centers for Disease Control and Prevention diagnostic criteria (ie, superficial incisional, deep incisional, or organ/space).<sup>9</sup>

Surveillance was performed by 4 physicians of the Hospital Hygiene Service, who reported on a questionnaire the data about the drainage observed at patient's bed and all of other data collected from medical records. To avoid potential bias in data collection, the physicians were properly trained to perform standardized medical surveillance until interobserver agreement reached 0.70 (Cohen *K*).

SSI surveillance was based on clinical and microbiologic criteria for inpatients, whereas after discharge, SSI development was monitored only by laboratory surveillance and readmission to hospital up to 30 days after the surgical procedure. <sup>10</sup> It should be noted that the lack of postdischarge surveillance could represent a potential confounder in our study.

For each patient, collected data included sex, age (grouped in 4 categories, each containing an equal number of individuals), type of operation (ICD-9 code), category of the procedure according to the National Healthcare Safety Network, duration of operation (originally measured as a continuous variable, was dichotomized according to the National Nosocomial Infections Surveillance system: T time is the 75th percentile of the distribution of procedures duration, rounded to the nearest hour, and is specific for each category of surgical procedure<sup>11</sup>), wound contamination class (clean, cleancontaminated, contaminated, or dirty based on the classification system introduced in 1964<sup>12</sup> and also described in Centers for Disease Control and Prevention Guidelines for SSI prevention<sup>9</sup>), urgency of surgery (defined as an operation performed within 24 hours after an unscheduled admission to the hospital), patient's preoperative American Society of Anesthesiology (ASA) score (1 = healthy; 2 = mild systemic disease; 3 = severe systemic disease; 4 = severe systemic disease that is a constant threat to life; and 5 = not expected to survive > 24 hours without surgery), use of surgical drains (yes/ no), hospital length of stay and length of stay with drain in place (originally measured as a continuous variable, grouped in 3 categories), administration of perioperative antibiotic prophylaxis, and microorganism isolated from wound or drain specimen culture (performed if appropriate).

Perioperative antibiotic prophylaxis was administered according to standardized hospital-based protocols<sup>8</sup> established for each surgical procedure on the basis of national and international guidelines and local epidemiology of microbial circulation.

All hospital and patient variables were tested using bivariate analysis for their association with SSI (no SSI = 0; SSI = 1) and those with P value results < .40 were selected to be included in the final logistic regression analysis. Stepwise log method was used to build the final model. Moreover, 3 further logistic regression analyses were performed setting as the dependent variable each category of SSI; that is, superficial incisional, deep incisional, or organ/space.

All statistical analyses were repeated after stratifying the patients into 2 groups by wound classification: clean and clean-contaminated in 1 group and contaminated and dirty in the other group. Therefore, SSI rates and patients' demographic characteristics, perioperative risk factors, and comorbidities were analyzed among the 2 wound class groups, using  $\chi^2$  tests and multivariate logistic regression.

The level of significance was set at P < .05. Data collection was accurate and a few missing data were detected during the analysis. Data were collected using SOR.R.I.S.O. software (Department of Biomedical Sciences and Public Health, Unit of Hygiene, Preventive Medicine and Public Health, Università Politecnica delle Marche, Ancona, Italy),  $^{13}$  and analyzed using Stata Software (version 11, 2009, Stata Corp, College Station, TX).

#### **RESULTS**

A total of 872 procedures involving 854 patients were surveyed during the study period (Table 1), reaching and slightly exceeding the optimum sample size, which was set at 809. The majority (57.1%; n = 498) of procedures were performed in men (gender data were missing in 7 cases [0.9%]). The mean age of the patients was  $59.5 \pm 17.9$  years (95% confidence interval [CI], 58.3–60.7). The mean hospital length of stay was  $7.4 \pm 8.0$  days (range, 1-80 days). Drains were placed in 37.0% of cases (n = 323), with a mean duration of stay with the drain in situ of  $7.8 \pm 6.6$  days (range, 1-63 days); in 28.8% of cases (n = 93) the drain was kept in place for fewer than 5 days, in 35.0% (n = 113) for 5-7 days and in the 36.2% of them (n = 117) the drains were in place for longer than 7 days.

The distribution of surgical wound contamination classes varied as follows: clean sites, 5.0% (n = 44); clean-contaminated sites, 70.5% (n = 615); contaminated sites, 18.4% (n = 160); and dirty or infected sites, 6.1% (n = 53).

Among the total study population, 53.3% (n = 465) of patients had an ASA score of 2; 25.5% (n = 222) of the procedures were performed using a laparoscopic approach, and 22.2% (n = 194) showed a duration longer than the T time for that specific category of surgical procedure. In 72.1% of cases (n = 629), antibiotic prophylaxis was administered.

The study included abdominal surgery procedures involving the gallbladder in 12.7% of cases (n = 111); the colon in 18.1% (n = 158); the rectum in 9.6% (n = 84); the stomach in 3.7% (n = 32); the appendix in 6.7% (n = 58); the small bowel in 4.4% (n = 38); the spleen in 1.3% (n = 11); and the bile ducts, liver, and pancreas in 1.9% (n = 17). Herniorrhaphies made up 9.7% (n = 85) of the operations and 1.8% (n = 16) were exploratory laparotomies.

The global SSI rate was 6.4% (56 procedures), with 3.9% (n = 34) superficial incisional events, 1.2% (n = 10) deep incisional SSIs, and 1.4% (n = 12) organ/space involvements. SSI rate was 13.3% (n = 43) among the patients with drains in place, versus 2.4% (n = 13) in those without drain (P < .001). The SSI rate was 18.8% (n = 22) in the group of patients who had the drainage in place for more than 7 days, versus 8.6% (n = 8) in those having a drain in place for fewer than 5 days and 11.5% (n = 13) in those having it placed for 5-7 days (P = .08) (Table 1). Higher incidence rates were observed in colonic surgery (13.9%); gastric surgery (12.5%); bile duct, liver, and pancreatic surgery (11.8%); and in exploratory laparotomy (25%).

When stratifying the procedures into 2 groups by wound classification, 659 had a clean or clean-contaminated wound, whereas 213 were included in the contaminated or dirty category; the distribution of patients' baseline demographic characteristics, perioperative risk factors, and SSI rates in clean and clean-contaminated versus contaminated or dirty wounds is shown in Table 2 and Table 3.

According to the results of the logistic regression analysis (P<.001; area under receiver operating characteristic curve = 0.80; Hosmer-Lemeshow test, P>.05), prolonged surgery (odds ratio [OR], 1.98; 95% CI, 1.09-3.59), ASA score equal to 3 (OR, 6.13; 95% CI, 2.33-16.11), and insertion of a drain (OR, 5.14; 95% CI, 2.63-10.08) were independent risk factors for SSI in the total study population, whereas the administration of antibiotic prophylaxis (OR, 0.53; 95% CI, 0.29-0.99) was a protective factor. Moreover, adjusting for the different

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