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Surgical Site Infections in Elective Abdominal Operations: Predisposing Factors. A Prospective Randomized Clinical Trial

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Abstract

Background: Surgical site infection (SSI) is the third most common hospital-acquired infection (HAI). Specific patient characteristics and comorbidities appear to be independent prognostic factors for SSIs. In addition, operation and hospitalization characteristics affect the incidence of SSIs.

Methods: This prospective clinical study was conducted in the 1st Department of Surgery of the Sismanoglion General Hospital of Athens over a period of 7 years. Patients undergoing elective abdominal surgery received antimicrobial treatment as chemoprophylaxis. Monitoring of the patients was carried by multiple daily visits during their hospitalization and continued after they were discharged via phone until postoperative day 30.

Results: During the study period, 31 of the 715 patients undergoing elective abdominal surgery were diagnosed with SSI, giving an infection rate of 4.3%. The age of the patients with SSIs was significantly higher. Patients with certain comorbidities, including diabetes mellitus (DM), respiratory deficiency and heart failure (HF), a severity score on the American Society of Anesthesiologists (ASA) physical status classification system of ASA>3, and those with concomitant infections had a significantly increased risk of SSIs. SSIs were more common following open surgery than laparoscopic surgery, and surgery of the lower than the upper gastrointestinal (GI) tract, and postoperative hemorrhage increased the risk.

Conclusion: There is a paucity of studies assessing the relative contribution of the various predisposing factors to the incidence of SSIs. In our study, patients with DM, HF, respiratory deficiency, postoperative hemorrhage and concomitant infections, and patients undergoing lower GI tract operation appeared more prone to SSIs, presenting this complication 2 to 8 times more frequently. The risk of SSI following laparoscopic surgery was one quarter of that of open elective abdominal surgery. On the other hand, patients in this series with obesity, renal failure, steroid intake, radiation therapy, thyroid disease, stomas, previous surgery, intraperitoneal adhesions and inflammatory bowel disease did not develop SSIs more frequently.

Key words: *Surgical site infections (SSIs); elective abdominal surgery; surgical chemoprophylaxis; predisposing factors*

Introduction

Every surgical wound is colonized by bacteria, but only a small percentage of wounds display symptoms of infection. The risk of infection increases when a wound is contaminated by more than 10^5 microorganisms per gram of tissue. Surgical site infection (SSI) is the third most common hospital-acquired infection (HAI), with a rate of 14-16% and it is the commonest infection in surgical patients. Around two thirds of SSIs are limited to the surgical incision area and only one third involve organs and anatomical spaces that were accessed during the surgical procedure.

The distribution of pathogens isolated from SSIs has not significantly changed over the last few decades [8]. *Staphylococcus aureus*, Coagulase (-) *Staphylococcus spp.*, *Enterococcus spp.* and *Escherichia coli* are the main strains recorded to cause SSIs. In addition, a continuously rising proportion of SSIs caused by resistant bacterial species, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and also *Candida albicans*, has been reported, which reflects the increase in immunosupressed and critically ill patients undergoing surgery, but also the misuse of antibiotics.

In the majority of SSIs the source of pathogens is the normal microbiota of the skin, mucosa and bowel. Prosthetic implants can also become sources of bacterial proliferation. Other external sources include the surgical staff, the operating room and every machine and instrument used during the surgical procedure [10].

SSIs can also be caused by unusual pathogens such

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as *Rhizopus orizae, Clostridium perfrigens, Rhodococcus bronchialis, Nocardia farcinica, Legionella pneumophilla, Legionella dumoffil* and *Pseudomonas multivorans*. Whenever an unusual strain causes an SSI, it is mandatory that an extended investigation is conducted to reveal the source of the pathogen.

Several studies have already revealed that specific patient characteristics, such as age, and comorbidities such as obesity, smoking [6], heart failure (HF) or respiratory deficiency, and pre-existing localized infections appear to be independent prognostic factors for SSIs. In addition, the duration of preoperative hospitalization, the type of the surgical incision, the complexity of the surgical operation, prolongation of operation time and the need for blood transfusion have all been documented as factors increasing the incidence of SSIs [7].

Method

Study Design

This prospective, randomized clinical study was conducted in the 1st Department of Surgery of the Sismanoglion General Hospital of Athens over a period of seven years. The study protocol was approved by the Scientific Council of the Sismanoglion Hospital and informed written consent was given by all the patients included in the study.

Patients undergoing elective surgery on the upper or lower digestive system were randomized to receive antimicrobial treatment as chemoprotection. The antibiotics were administered iv preoperatively within 60 minutes prior to the surgical incision. A repeat dose of antibiotics was administered intraoperatively when the procedure lasted more than 3 hours and/or if blood loss exceeded 300 ml.

The exclusion criteria were: preoperative hospitalization of longer than 15 days, emergency surgery for obstruction, bleeding or inflammation of the gastrointestinal (GI) tract, and active infection and current systemic antibiotic administration.

Antibiotic treatment

Cefuroxime (1.5 gr) was administered iv in 1 or 3 doses, depending on randomization, for upper GI interventions, while ticarcillin-clavulanate (5.2 gr) was selected for chemoprotection in lower GI surgery, due to its broad spectrum of activity against Gram (+) Gram (-) bacteria and anaerobes, all found in the intestinal microflora, and because of its rapid action (maximum blood concentration 30 minutes after iv administration). Patients undergoing scheduled colectomy underwent mechanical bowel cleansing without oral antibiotic intake.

In the case of known and certified hypersensitivity to beta-lactams, aztreonam (2gr) was administered alternatively, combined with metronidazole (1gr) for lower GI tract surgery, 1 or 3 doses on a randomization basis. In the case of previous antibiotic intake, patients were randomized according to their medication with penicillin, ampicillin, amoxicillin-clavulanate, aminoglycosides, cephalosporins, cefaclor, cefprozil, cotrimoxazol or quinolones.

For each patient a specially designed monitoring form was completed, recording epidemiological data, surgery related information, details of SSIs (deep and superficial) and postoperative morbidity, including urinary and respiratory infections.

The monitoring of patients was carried out by multiple daily visits during their hospitalization and continued after discharge via phone, up to postoperative day 30.

Statistical analysis

The numerical variables are described as mean ±1 standard deviation (SD) and the categorical variables as the rate (%). Normality of distribution was estimated with the Kolmogorov-Smirnov test and graphical methods. Comparisons between qualitative parameters were performed by χ^2 and Fisher's Exact testing. Comparisons between independent continuous variables were performed by the Student's unpaired t-test and the Mann-Whitney's U test, as appropriate. Logistic regression analysis was performed by model introduction to known basic parameters. Their selection was either hierarchical or by gradual retrograde insertion, based on maximum likelihood ratio. The chosen level of statistical significance was p=0.05.

Results

In a total of 715 patients undergoing abdominal surgery during the study period, 31 patients were diagnosed with SSIs, which translates to a percentage of 4.3%. Specifically, the percentage of SSIs in operations for the upper digestive system was 2.2% (11 of 500 patients) and for the lower digestive system 9.3% (20 of 215 patients). This proportion of SSIs for upper digestive system elective surgery is among the lowest documented in the literature.

In this study, 7 main pathogens were isolated from patients with SSIs: *Escherichia coli* (20.4%), *Klebsiella pneumoniae* (9.8%), *Enterobacter cloacae* (9.1%), *Pseudomonas aeruginosa* (10.5%), *Bacteroides fragilis* (13.4%), *Staphylococcus aureus* (17.3%) and *Enterococcus faecalis* (19.5%). All the SSIs were found to be multimicrobial.

Patients with SSIs were of statistically significantly greater age (p <0.001). Patients with greater severity of the underlying disease, rated according to the physical status classification system of the American Society of Anesthesiology (ASA) of ASA> 3, and those with concomitant diseases demonstrated a significantly increased risk of SSIs. Furthermore, patients developing SSIs more often had severe comorbidities (p <0.001).

Regarding comorbidities, patients with diabetes mellitus (DM) developed SSIs more frequently (p=0.014), with the relative risk in patients without DM being remarkably lower (Table1).

Table 1. *Diabetes mellitus and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
Diabetes Mellitus	No	Patients	562	20	582
		%	96.6%	3.4%	100%
	Yes	Patients	122	11	133
		%	91.7%	8.3%	100%

p=0.014

Patients with respiratory deficiency were predisposed to SSIs (p=0.01) and the relative risk in patients without respiratory failure was significantly lower (RR=0.38) (Table 2).

Table 2. *Respiratory deficiency and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
Respiratory Deficiency	No	Patients	596	22	618
		%	96.4%	3.6%	100%
	Yes	Patients	88	9	97
		%	90.7%	9.3%	100%

p=0.01

In addition, patients with HF developed SSIs more frequently (p=0.006), while the relative risk in patients without heart failure was low (RR=0.37) (Table 3).

Table 3. *Heart failure and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
Heart Failure	No	Patients	586	21	607
		%	96.5%	3.5%	100.0%
	Yes	Patients	98	10	108
		%	90.7%	9.3%	100.0%

(p=0.006)

No significant differences were found between various other subgroups of patients with comorbidities and the rest, specifically, patients receiving steroids (p = 1), or radiation therapy (p = 0.2), or patients with renal failure (p = 1), atrial fibrillation (p = 0.33), thyroid diseases (p = 0.63) or hypertension (p = 1). In addition, no significant difference was found between obese and non-obese subgroups (p = 0.16). Regarding concomitant postoperative infections, 29 of the patients in the study developed pneumonia, and those patients were significantly more prone to SSIs (p= 0.001) (Table 4).

Table 4. *Pneumonia and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
Pneumonia	No	Patients	660	26	686
		%	96.2%	3.8%	100%
	Yes	Patients	24	5	29
		% Quota	82.8%	17.2%	100%

p=0.001

Additionally, 19 patients presented a urinary tract infection (UTI), and those with UTI developed SSIs more often (p=0.007). The relative risk for patients without UTIs was 5 times lower (Table 5).

Table 5. *Urinary tract infection (UTI) and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
UTI	No	Patients	669	27	696
		%	96.1%	3.9%	100%
	Yes	Patients	15	4	19
		%	78.9%	21.1%	100%

P=0.007

Certain factors associated with the surgery itself were found to be associated with a higher rate of SSIs. Patients with postoperative hemorrhage were 8 times more likely to develop SSI (p=0.001) (Table 6).

Table 6. *Postoperative hemorrhage and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
Postoperative Hemorrhage	No	Patients	673	26	699
		%	96.3%	3.7%	100%
	Yes	Patients	11	5	16
		%	68.8%	31.3%	100%

p=0.001

Regarding the type of surgery, 401 of the patients in the study underwent laparoscopic surgery. The rate of SSIs in these patients was 1.7%, compared with 7.6% in patients undergoing open surgery (p=0.001), with the relative of open surgery being 4 times higher (Table 7).

Table 7. *Laparoscopic surgery and surgical site infections (SSIs) in patients undergoing elective abdominal surgery (n=715).*

		SSIs:	No	Yes	Total
Laparoscopic Surgery	No	Patients	290	24	314
		%	92.4%	7.6%	100%
	Yes	Patients	394	7	401
		%	98.3%	1.7%	100%

Of the 715 patients, 500 underwent surgery for the upper GI tract and 215 for the lower GI tract. The rate of SSIs was 2.2% and 9.3% respectively (p=0.001), with a relative risk 4 times higher for lower GI tract surgery (Table 8).

Table 8. *Elective upper and lower gastrointestinal (GI) tract operations and surgical site infections (SSIs) (n=715).*

		GI:	Upper	Lower	Total
SSIs	No	Patients	489	195	684
		%	97.8%	90.7%	95.7%
	Yes	Patients	11	20	31
		%	2.2%	9.3%	4.3%
Total			500	215	715

p=0.001

Discussion

Infection of the surgical site is the third most frequent hospital infection, accounting for 16% of all HAI and it prolongs the duration of hospital stay and increases the cost of hospitalization [9,11,12,14]. It is also the most frequent infection among surgical patients, with a rate of 38% of all infections. Most SSIs are limited to the surgical wound, but some are located in organs or anatomical sites which were accessed during the operation.

In patients with SSIs, 77% of the total death rate could be associated with this condition and 93% of these patients had severe infections of organs or anatomical sites accessed during operation [26].

The exact frequency of SSIs has not yet been determined [13,18]. As the duration of hospitalization is often short, the monitoring of postoperative patients outside the hospital is very important if accurate rates are to be achieved. Several methods are currently in use for post-operative monitoring by various hospitals, including direct examination of the surgical wound and monitoring of patients by mail or telephone communication.

The literature provides only a few prospective randomized studies to assess the relative contribution of the various risk factors to the development of SSIs [24,25]. Related data from statistical models is considered to be very important for general surgery.

The studies that have been published reveal that specific patient characteristics and comorbidities such as age (especially if the age exceeds 65 years, obesity, smoking [21,22], heart and respiratory failure and pre-existing localized infections appear to be independent prognostic factors for surgical site infections. In addition, the duration of preoperative hospitalization, the classification of the surgical wound, the surgical operation complexity, prolongation of surgical time, the need for blood transfusion and concomitant postoperative infections have all been reported to affect the incidence of SSIs.

All the patients participating in our study underwent scheduled operations of the upper or lower digestive system that are considered potentially contaminated. Our overall SSI incidence was 4.3% (31 from a total of 715 patients), which is among the lowest, based on the Greek and international literature (published results provide rates varying between 4 and 15%) [7,13]. Specifically, in this series, the incidence of SSIs for scheduled surgery of the upper GI tract was 2.2% (11 of 500 patients), when the rates in published results range between 2 and 8%. Regarding the lower GI tract, the overall SSI rate was 9.3% (20 of 215 patients), surprisingly low compared to national and international data, where the SSI incidence can reach up to 25%.

In our study a number of comorbidities and and events and concomitant diseases during hospitalization were investigated to determine whether they predispose to SSIs incidence. Respiratory deficiency, DM, steroid intake, radiation therapy, renal failure, HF, obesity, thyroid disease, stomas, previous surgery, intraperitoneal adhesions and inflammatory bowel disease (IBD), and postoperative pneumonia, UTI and hemorrhage were some of the conditions analyzed.

In our study, patients with DM developed SSIs more frequently (p=0.014). DM has been documented to be a significant contributor to SSIs, potentially beyond its role in causing hyperglycemia [1-5,20]. The pathophysiology behind this mechanism includes microcirculation disturbances, suspension of physiological complement function, increases in pro-inflammatory cytokines, freezing of chemiotaxis, a decrease in the competence of phagocytes and T and B cells and apoptosis of lymphocytes. Current literature points out the significance of DM as an independent factor for SSIs and studies, as ours, consistently reveal significant differences between non-diabetic and diabetic groups [1-4].

Comorbidities and high ASA scores are reported to affect the incidence of SSIs due to impaired tissue perfusion [6,23,25]. In our study, patients with respiratory deficiency appeared predisposed to SSIs (p=0.01) with the relative risk for the rest of the patients being less than half. In addition, patients with HF presented SSIs significantly more often (p=0.006) and patients without HF had a relative risk of less than half.

Concerning obesity, it has been proved that adipose tissue is a tissue with poor blood perfusion and low oxygen concentration [23]. As a result, obese people tend to have an increased occurrence of SSIs. Moreover, surgical operations in obese patients are often more complex and time consuming. While the risk of SSIs in obese patients has been studied in cardiac surgery, neurosurgery and gynecology, it has not yet been widely studied in general surgery [23,27,28]. In this series, no significant difference in SSI incidence was demonstrated between obese and non-obese patients (p = 0.16). This can possibly be explained by the fact that obese patients were more frequently treated for upper GI diseases (p=0.002) and in particular underwent laparoscopic cholecystectomy with short-term hospitalization. The laparoscopic procedure was associated with a much lower risk of SSI.

Among other comorbidities, patients in this study with renal failure, steroid intake, radiation therapy, obesity, thyroid disease, stomas, previous surgery, intraperitoneal adhesions and inflammatory bowel disease did not develop SSIs more frequently, but the numbers were small.

Patients with concomitant infections are also reported to be prone to SSIs. Pneumonia, UTI, *S. Aureus* nasal colonization and skin infections both close to or distanced from the surgical site have been associated with increased SSI incidence [15,17]. In this series of patients who developed postoperative pneumonia were prone to SSIs (p<0.001), as were patients with UTI (p=0.007).

The patients in this study who experienced postoperative hemorrhage had a higher incidence of SSIs (p<0.001). Blood transfusion has been associated with increases in both SSIs and other postoperative infections such as pneumonia and UTI. The incidence of infections is proportional to the amount and even to the storage time of the transfused blood [19]. Irrational use of other iv fluids appears to be another important factor for SSI development. According to literature, limited administration of fluids can decrease infections, and thus the older notion of massive fluid infusions has been abandoned [24].

In our study, laparoscopic surgery appeared to reduce the SSI frequency (p<0.001) with the relative risk for patients undergoing open surgery being 4 times higher. This difference between open and laparoscopic surgery is surprisingly large, since, according to literature reports, the risk for patients undergoing open surgery is between 1.5 and 2 times higher than for those undergoing laparoscopic surgery [29].

The patients undergoing upper GI tract operations presented significantly fewer SSIs compared with those undergoing lower GI tract operations (p<0.001). The lower GI tract interventions had a 4 times higher relative risk for SSIs, which is a remarkable deviation compared to the outcomes of other trials [7].

Conclusion

Many factors affect the incidence of SSIs, but there is still a scarcity of studies assessing the exact contribution of each factor to this postoperative complication. This study investigated a number of patient characteristics and comorbidities, along with the type of operation, concomitant infections and other events during hospitalization of patients undergoing elective abdominal surgery. Summarizing our findings, patients with DM, HF and respiratory deficiency developed SSIs twice as frequently, and patients with concomitant infections up to 5 times more often. Postoperative hemorrhage increased the incidence of SSI by up to 8 times. Patients undergoing lower GI tract operation were more prone to SSIs, presenting with this complication 4 times more often than those undergoing Upper GI tract surgery. The relative risk of SSI after laparoscopic surgery was one quarter that of open surgery.

The findings from this study will be used as a data base and will provide incentive for further, wider studies on the factors associated with SSIs, that will facilitate the work of surgeon and contribute to the optimal recovery of their patients.

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