ORIGINAL ARTICLE

Incidence and risk factors of surgical site infection in general surgery department of a Tunisian tertiary teaching hospital: A prospective observational study

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ABSTRACT

Background: Effective surveillance systems and identification of risk factors have been described as a preventive measure for reducing Surgical Site Infections (SSI). The purpose of our study was to determine the incidence rate and risk factors of SSIs in the General Surgery Department of Sahloul University Hospital.

Methods: We carried out a prospective observational study from January 2015 to May 2015 in the General Surgery department at the University Hospital of Sahloul in Sousse, Tunisia. We actively followed up all patients who underwent general surgical procedures and matched the inclusion criteria at 30 days of surgical procedures.

Results: Overall, 349 patients were followed to 30 days after operation. We identified 30 SSIs. The incidence rate was 8.6%, 95% Confidential Interval= [5.7% - 11.5%]. The incidence density was 12.9 cases for 1000 days of hospitalization. The superficial infections were the most frequent (14 cases/30) followed by organ/space infections and deep infection. The most common isolate identified was Escherichia Coli. In multivariate analysis, an extended length of preoperative stay and risk index NNIS superior to 1 were found to be statistically significant risk factors for surgical site infection.

Conclusion: More efficient programs are needed to decrease the SSIs rate. Hence, among means of prevention, ongoing surveillance has proven to be an independent factor for long-term reduction of SSI rates.

KEY WORDS:

Surgical site infection, risk factors, incidence, general surgery

INTRODUCTION

SSI is a severe surgical complication and is among the most frequently reported types of healthcare associated infections (HAIs) [1]. They are the most prevalent nosocomial infections in surgical clinics [2].

They represent one of the main complications in patients undergoing surgery, with major implications in terms of morbidity, including additional surgical procedures or transfer to an intensive care unit (ICU), mortality, longer duration of hospital stay, and financial burden [3, 4].

An extensive surveillance program can reduce the rates of SSI by 30 to 40%, and for its effectiveness, the real incidence of these infections and associated risk factors must be known [5].

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Thus, SSI incidence has been recommended by the Council of the European Union who made the recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections and proposed as an indicator of healthcare quality in the context of clinical governance and performance monitoring, and is therefore a target of many healthcare systems [6, 7].

For instance, in France, the implementation of national surveillance program of SSI (INCISO program) by the Inter-regional centers for the coordination of the fight against the nosocomial infections (C-CLIN), has resulted in a decrease in the rates of SSI from 4.1% in 1998 to 2.7% in 2000. In 2010, the overall incidence of SSI was 1.2% [8, 9].

In fact, surveillance itself, even without any specific intervention, has been associated with a reduction in SSI incidence, another reason to recommend implementation of national surveillance systems [10-12].

In the framework of the program of control and prevention of HAI of the university hospital of Sahloul, our department conducts each year a survey on prevalence of HAI.

Given the importance of measures for the prevention and control of SSI because of its high rates found in the two last years in our hospital (17.6% in 2014 and 12% in 2015), this study aimed to determine the incidence of SSI and its risk factors in General surgery department of university hospital Sahloul.

METHODS

Study design

We carried a prospective cohort study between January 2015 and May 2015 in General Surgical department of university hospital Sahloul, Sousse, Tunisia.

Study patients

We included all patients who underwent general surgical procedures (appendicectomy, cholecystectomy, cure of inguinal or femoral hernia, surgery of the colon sigmoid, and rectum, intervention on the peritoneum, the mesentery and the omentum, surgery of the biliary tract, liver and pancreas, of the esophagus, stomach, and of the duodenum by abdominal track), who were hospitalized at the general surgical department or hospitalized in another department and then transferred to our department, and who were followed to 30 days after operation.

We excluded from our study patients who have undergone invasive procedures for diagnostic purposes or acts of interventional radiology, who underwent non-tumoral proctology surgery, and those who already suffered from cutaneous or soft tissue infections before the study.

Procedures involving implants of prosthetic material were not considered due to the different length of post-intervention follow-up that is required (one year).

Overall, out of 316 patients, we followed 349 at 30 days after the intervention.

Definitions of variables

The main outcome variable was the occurrence of a SSI within 30 days of the operation. SSIs were further classified depending on the depth of the infection as superficial, deep incisional, or organ/space, according to the definitions of SSI retained in the French protocol monitoring of SSI (RAINSIN-2015) and which are based on the definition criteria published in 1992 by the CDC (Centers for Disease Control) [13].

Wound classification of Altemeier [14], ASA score [15] , and duration of intervention [9] were used to calculate the SSI risk index NNIS [16]. The NNIS can therefore take values of 0 (no risk factor) to 3 (all risk factors are present).

Data collection

We collected patient data using a form built on the French national protocol for the SSI surveillance of ISO-RAISAN 2015 [17] and on data from the literature.

Data included sociodemographic characteristics (age, gender, date of admission, date and mode of discharge), and intrinsic risk factors (smoking, diabetes, high blood pressure, corticotherapy, cirrhosis, multiple scars, and immune deficit).

Data were collected from patients' charts, the plug of anaesthesia of the surveillance of patient during intervention, and the interview with the patient himself, as well as with the nurse and the doctor.

Charts were reviewed by the investigators and when needed with the doctor in charge of the patient.

Patients were reviewed in the outpatient clinic in the 30 days which followed the intervention whenever they assessed the hospital for post-discharge visits, or contacted by phone to have information about the state of the surgical scar.

The forms were filled by two investigators (an internal trainee and a resident of the service of prevention and safety of care of the Sahloul hospital of Sousse) during the stay of the patient as well as during his follow-up during the 30 days following the intervention.

The bacteriological analysis of the operating site had been conducted either by a nurse, or the operating surgeon. Bacterial identification was made by manual classic methods which are based on morphological and metabolic characteristics. In addition to these methods, a phenotypic automated system of identification VITEK 2 has been used for the identification of strictly anaerobic bacteria and some other bacteria not identified by conventional methods.

An oral consent was obtained from participants in order to use information from their records, and that was approved by the ethical committee of the Faculty of medicine of Sousse – Tunisia.

Statistical analysis

Statistical analysis was done by another resident performed in statistical analyses.

Continuous variables were described as means ± standard deviations, and compared using the *Student t-test*. Categorical variables were summarized with absolute and relative frequencies, and compared using the *Chi-squared test* (or *Fisher Exact tests* where appropriate). Univariate and then multivariate regression analysis were used to examine the associations of various risk factors and SSI between patients with and without SSI. *Binair logistic regression* was performed including only variables with $p \leq 0.20$ in univariate regression. All analyses were conducted using the SPSS software version 18 with significance set at the 5% level.

TABLE 1: Characteristics of patients with and without surgical site infection

Characteristics		Number (n) Or Mean	Frequency (%)
Age (years)		44.6±20.7	
Gender	Male	175	50.1
	Female	174	49.9
ASA score	1 and 2	335	96
	3 and 4	14	4
Tobacco use	Yes	64	18.3
	No	285	81.7
High blood pressure	Yes	70	20.1
	No	279	79.9
Diabetes	Yes	38	10.9
	No	311	89.1
Corticotherapy	Yes	10	2.9
	No	339	97.1
Multiple scars	Yes	4	1.1
	No	345	98.9
Immune deficit	Yes	8	2.3
	No	341	97.7
Cirrhosis	Yes	2	0.6
	No	347	99.4
Duration of pre-operatory stay (days)		1.7±2.4	
Pre-operatory infection	Yes	3	0.9
	No	346	99.1
Contamination class of Altemeier	Class I and II	283	81.1
	Class III and IV	66	18.9
Duration of the intervention	Over 75^{th} percentile	39	11.2
	Under 75^{th} percentile	309	88.88
NNIS risk index	0	251	71.9
	1	74	21.2
	2	23	6.6

RESULTS

Patient characteristics (Table 1)

Overall, 349 patients were followed at 30 days of the operation out of 365 patients included. The mean age was 44.60±20.78 years.

The population was made up of 50.1% of men and 49.9% of women.

High blood pressure was the most frequent pathology (20.1% of cases) followed by tobacco use (18.33% of cases).

The immune deficit was found in 2.3% of patients. This deficit was caused by a long course of immunosuppressive therapy in 8 cases, and in one case by an end-stage renal disease.

Pre-operatory hospital stay lasted for an average of 1.7±2.4 days.

A pre-operatory infection was present in three patients; it was a chronic peritonitis in one case, and a urinary tract infection in the other two cases.

For the skin preparation of the patient, nine patients (2.5%) had showers at home the day before the procedure, and mechanical shaving was the only depilation mode used.

The cholecystectomy and appendectomy were the most frequent surgical procedures carried out (27.2% and 26.4% respectively).

More than three-quarter of the surgeries were classified I or II

Table 2: Distribution of the SSI according to the type of intervention

Type of the intervention	SSI N (%)		Total
	Yes	No	
Surgery on the peritoneum, the mesentery and the omentum	3 (18.7)	13	16
Appendectomy	9 (9.78)	83	92
Surgery of the biliary tract, liver and pancreas	9 (13.6)	57	66
Cholecystectomy	1 (1.08)	91	92
Surgery of the colon, and rectum	5 (13.15)	33	38
Surgery by abdominal track of the esophagus, the stomach and the duodenum	2 (12.5)	14	16
Surgery of the hail	0 (0)	7	7
Herniaire surgery	1 (5)	19	20
Cure of belly feeding	0 (0)	2	2
Total	30	319	349

according to the wound classification of Altemeier which means how much does the intervention may cause infection. For the 66 cases of wound classification of III and IV, 63 have benefited from a curative antibiotic therapy on post-intervention. The associations of antibiotics such as (cefotaxime + metronidazole) and (cefotaxime + metronidazole + gentamycin) as well as the amoxicillin-clavulanic acid accounted for 84.1% of therapeutic measures used.

The average duration of intervention was 92±71 minutes, with extremes ranging from 15 to 485 minutes.

Interventions duration was greater than the 75th percentile in 39 cases (11.2%).

The risk index NNIS was equal to 0 in 71.9% of cases. No patient had an index equal to 3.

The cefazolin, cephalothin as well as the association amoxicillin-clavulanic acid were the main antibiotics used in prophylaxis with a rate of use that exceeded 90%

Surgical site infection and risk factors (Tables 2 and 3)

Overall, 30 SSIs were identified in 349 patients (every included patient had only one SSI). The incidence rate was 8.6% ($CI_{95\%}$= [11,5% – 5,7%]). The incidence density was 12.9 cases for 1000 days of hospitalization.

The superficial infections were the most frequent (14 cases/30) followed by organ/space infections (13 cases/30) and deep infections (3 cases/30) (Figure 1).

The colon and rectum surgery (13,1%), surgery on the peritoneum (18,7%) as well as the surgery of the liver and biliary tract (13,6%) generated the most SSIs (Table 2).

Of the 30 SSIs, 40% were developed during the first week and 90% before the end of the third week after the surgery, with a median time of onset of SSI after the intervention of nine days.

Among the 30 patients having a SSI, 15 had tissues analyzed. The 15 patients' cultures yielded 17 bacterial strains. In present study, *Staphylococcus aureus* accounted for only 11% of all isolated strains while the bacilli of Gram-negative bacteria represented by *Enterobacteriaceae* namely *Escherichia coli, Klebsiella pneumoniae, Morganella morganii* as well as the *anaerobic bacteria* were the germs the most frequent and represented 76% of isolated germs. The most common isolate identified was *Escherichia Coli* (5 strains/17) (Figure 2).

The study of the sensitivity revealed only one multi-resistant bacteria, it was of a strain of *Pseudomonas aeruginosa*.

Among the 14 superficial infections, four have benefited from an antibiotic therapy using amoxicillin-clavulanic acid and one case using the association of cefotaxime-metronidazole-gentamycin which has been adapted according to the results of the sensitivity. No complications were found after treatment in 29 patients. Only a single case of death has been reported which was not associated with the SSI.

Univariate analysis identified as risk factors of SSI ASA score ($p < 10^{-4}$), the length of pre-operatory stay (p=0.024), the contamination class of Altemeier (p=0.002), carcinologic surgery (p=0.03), laparoscopic intervention (p=0.009), abdominal drainage (p=0.003), duration of the intervention over the 75th percentile ($p<10^{-4}$), NNIS index = 2 ($p<10^{-4}$) and NNIS index = 1 ($p<10^{-4}$) (Table 3).

Whereas, SSI was independently associated with the length of pre-operatory stay, NNIS index = 1 and NNIS index = 2 (Table 4).

DISCUSSION

We demonstrated an average incidence of 8.6% SSIs among all patients of the General Surgical department. This number is beyond the average SSI rate of 2.61% presented by the NNIS review [18].

The digestive tract surgery is one of specialties which are the most providers of SSI in addition to the cardiovascular surgery and transplantation of organs [5, 19].

Based on the same procedures, our SSI rate was higher than the one reported in some developed countries [19-21]. It was

TABLE 3: Univariate analysis of risk factors of surgical site infection in general surgery department of Sahloul hospital of Sousse (Tunisia)

Factor		SSI (n=30) Mean or n (%)	No SSI (n=319) Mean or n (%)	RR [CI 95%]	P
Age		48.3 ± 20.27	44,26 ± 20.8	1.01 [0.95-1.03]	0.3
Gender	Male	13 (7.5)	161 (92.5)	1.33 [0.62-2.85]	0.45
	Female	17 (9.7)	158 (90.3)		
ASA score	1 and 2	24 (7.2)	311 (92.8)	9.71 [3.1-30.3]	$< 10^{-4}$
	3 to 6	6 (42.9)	8 (57.1)		
Tobacco use	Yes	9 (14.1)	55 (85.9)	2.05 [0.89-4.73]	0.08
	No	21 (7.4)	264 (92.6)		
High blood pressure	Yes	6 (8.6)	64 (91.4)	1.004 [0.39-2.55]	0.99
	No	24 (8.6)	255 (91.4)		
Diabetes	Yes	5 (13.2)	33 (86.8)	1.75 [0.62-5]	0.35
	No	25 (8)	286 (92)		
Corticotherapy	Yes	0 (0)	10 (100)	NA	1
	No	30 (8.8)	309 (91.2)		
Multiple scars	Yes	0 (0)	4 (100)	NA	1
	No	30 (8.7)	315 (91.3)		
Immune deficit	Yes	1 (12.5)	7 (87.5)	1.53 [0.18-12.92]	0.51
	No	29 (8.5)	312 (91.5)		
Cirrhosis	Yes	0 (0)	2 (100)	NA	1
	No	30 (8.6)	317 (91.4)		
Duration of pre-operatory stay (mean ± standard deviation)		3.4 ± 4.2	1.5 ± 2.1	1.22 [1.09-1.36]	0.024
Pre-operatory infection	Yes	1 (33.3)	2 (66.7)	5.5 [0.48-62.5]	0.23
	No	29 (8.4)	317 (91.6)		
Contamination class of Altemeier	Class I and II	18 (6.4%)	265 (93.6%)	3.27 [1.48-7.18]	0.002
	Class III and IV	12 (18.2%)	54 (81.8%)		
Emergency surgery	Yes	16 (10.3)	139 (89.7)	1.48 [0.69-3.22]	0.3
	No	14 (7.2)	180 (92.8)		
Laparoscopic intervention	Yes	29 (10.7)	242 (89.3)	9.22 [1.23-68.85]	0.009
	No	1 (1.3)	77 (98.7)		
Carcinologic surgery	Yes	9 (16.7)	45 (83.3)	2.61 [1.12-6.05]	0.03
	No	21 (7.1)	274 (92.9)		
Abdominal drainage	Yes	16 (15.5)	87 (84.5)	3.04 [1.42-6.50]	0.003
	No	14 (5.7)	232 (94.3)		
Duration of the intervention	Over 75^{th} percentile	16 (41)	23 (59)	14.65 [6.37-33.73]	$< 10^{-4}$
	Under 75^{th} percentile	14 (4.5)	295 (95.5)		
NNIS risk index	0	7 (2.8)	244 (97.2)	1	-
	1	10 (13.5)	64 (86.5)	34.48 [16.39-71.42]	$< 10^{-4}$
	2	13 (56.5)	10 (43.5)	6.41 [3.33-12.5]	$< 10^{-4}$

TABLE 4: Multivariate analysis of risk factors of surgical site infection in general surgery department of Sahloul hospital of Sousse (Tunisia)

Factor	Adjusted RR	95% CI	P
NNIS index 1	45.45	14.70 – 142.85	$< 10^{-4}$
NNIS index 2	10.10	3.28 – 31.25	$< 10^{-4}$
Preoperative length of stay	1.20	1.06 – 1.36	0.004

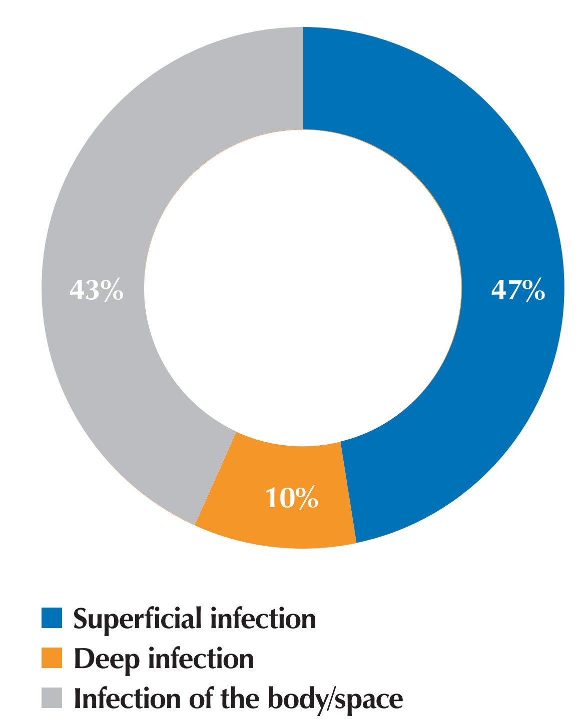
also higher than some less developed ones [22, 23], but was approaching the rates found in Spain (8.25%) and Pakistan (7.3%) [22, 24].

However, it was lower than the rates of some developing countries such as Brazil (24.5%), Peru (26.7%) [25, 26], Iran (17.4%), Nigeria (26%), and Algeria (9.8%) [27-29], and higher than that of Morocco (5.2% at the military hospital Mohamed V of Rabat) [30].

Because of the lack of epidemiological surveillance systems of SSI in Tunisia, only few studies of incidence have been carried out in some academic institutions in the east of the country, while, no investigation has been carried out in the interior of the country.

In Tunisia, our rate was higher compared to that found at the Charles Nicolle Hospital of Tunis in 2000 (5.6%) but much lower than that found at the Farhat Hached Hospital of Sousse which revealed a rate of incidence in digestive surgery of 21.8% in 2002 [31, 32].

FIGURE 1: Distribution of SSIs according to the depth of the infection



At the Sahloul Hospital of Sousse two surveys of incidence have been carried out in the general surgery department in 2003 and 2006. They have concluded at a rate of respectively 3.4% and 7.4%. Hence, there was a continued increase in the rate of SSIs in our facility, which must push to review, monitor and improve the prevention measures initiated in our hospital, which seemed to be insufficient [33, 34].

Regarding the depth of infections, our results lined with those reported by many other studies [4, 11, 35-37].

Our findings regarding bacteriological results are consistent with those of studies carried out in Morocco, Algeria, Tunisia, Japan, and United States [25, 29, 30, 36, 38].

An extended length of preoperative stay and risk index NNIS superior to one were the independent risk factors for SSI in our study.

The extended duration of surgical intervention, a class of contamination three and four, the presence of an anaemia, the presence of drain, a bad preparation of patients and an extended preoperative length of stay were identified as risk factors of SSI in one study [27].

Another study has identified the following factors: co-morbidity, the extreme age, a high NNIS index and the complexity of the intervention. In addition, the diabetes was considered as risk factors in a multivariate analysis as well as an extended duration of the intervention [39].

The extended length of preoperative stay is not negligible, due to the change in the microbial flora of the skin and digestive tract at three to four days of hospitalization, the increasing frequency of complications of supine, and the frequency of invasive explorations and treatments during this period [40].

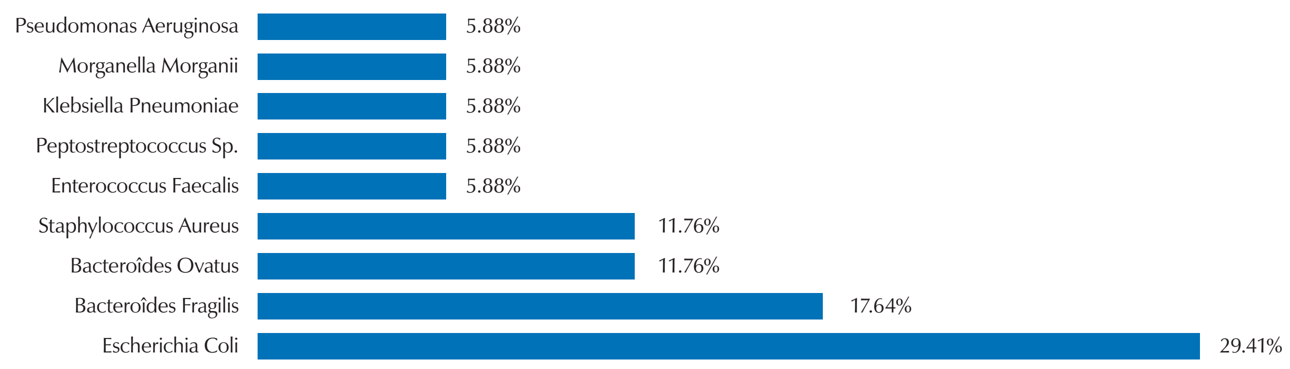
In Morocco, the risk factors of the SSI found were: the emergency surgery, the age, the ASA score, the class of contamination of Altemeier, the type of intervention and the its duration [30]. The NNIS index established by the developed countries must be adjusted in order to be applied in developing countries [41].

Present study has a number of limitations. We did not include enough infected patients and our study was single centre. Thus, the results should not be generalized to other settings.

CONCLUSION

In present study, SSI rate was found to be within the upper international limits. This confirms the need for more efficient programs to decrease the SSIs rate since this complication increases hospitalization costs and length of stay, and impairs patient's quality of life. Surveillance allows for identification of key factors that can be targeted as benchmarks for improvement. Hence, among means of prevention, aside from ongoing surveillance, identification and control of known risk factors, has proven to be an independent factor for long term reduction of SSI rates.

FIGURE 2: Distribution of SSI culture isolates



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