ISSN 0001-6002/2010/52/3/159-166
Acta Médica Costarricense, ©2010
Colegio de Médicos y Cirujanos

Factors Associated with Surgical Wound Infection in Patients for Elective Clean Surgery at the "*Rafael Ángel Calderón Guardia*" Hospital, Costa Rica

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Abstract

Aim: Hospital surgical wound infection (SWI) is one of the three most frequent causes of nosocomial infection worldwide, leading to high social and medical costs. This study aims to identify and quantify risk factors for SWI in a Costa Rican hospital.

Methods: A cohort study of 488 elective patients operated between April and June 2006. The patients were divided in 2 groups: those in which operating room traffic was restricted, group A, and those in which it was not, group B. The statistical analysis was performed in 2 major phases: descriptive and analytical. In the first one, frequency measures (absolute and relative) were calculated; and the second one was carried out in 2 stages; both of them through unconditional logistic regression, univariate and multivariate analysis.

Results: An overall incidence of 35.2 % (172/488) of SWI was found. The cumulative incidence in the unexposed was 31.8% (76/239), while in those exposed, it was 38.6% (96/249) (p=0.12). Only organ and bone/joint surgery presented a higher risk of SWI (OR 2.42; 95% CI:1.5-3.8), surgeries in unrestricted traffic rooms and diabetes had no association with the infection.

Conclusion: Diabetes and depth of surgery should be taken into account in the profile of patients with increased risk of suffering SWI; furthermore, even though there was no epidemiological association between restricted operating room traffic and not restricted, and SWI, although the difference in incidence of SWI, was not statistically significant, it is advisable to restrict the transit of persons in operating rooms, according to international standards.

Key words: hospital infection, surgical wound infection, cohort study, risk factors.

Received: *August 31, 2009* ***Accepted:*** *April 13, 2010*

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Abbreviations: SWI, Surgical Wound Infection; HCG, *Dr. Rafael A. Calderón Guardia* Hospital; OR, odds ratio; RR, relative risk

Support: *Caja Costarricense del Securo Social* [Social Security Institution]; *Universidad Nacional* [National University]

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A hospital infection is defined as one that develops in a patient 72 hours after admission to a hospital or other health care service, which the infected person was not suffering or incubating at the time of hospitalization; or the residual effect of a previous hospitalization that appears after the patient was discharged from the hospital, and those registered among the hospital's staff and visitors.[1] It has been determined that hospital infection appears worldwide and affects in average 5% of patients who leave hospitals,[2] causing added morbidity, longer hospital stays, an impediment to admission of other patients and an increase in lethality of nearly 3% of those infected.[3] Thus, it has a high direct and indirect economic cost for institutions, in particular in items such as bed cost per day, drug use, diagnostic and therapeutic procedures, isolation needs and increased demand of human resource for patient care, among others.[4] Also, they produce important effects to users of medical services, since it can worsen their functional capacity and cause emotional and social stress due to the lost effort, besides, they reduce the quality of life, among other family-life, social and economic impacts.[5]

There are many intrinsic and extrinsic risk factors that favor the development of these infections. The former are related to the patient's inherent characteristics such as age, sex and associated diseases such as *diabetes mellitus*, obesity, immunosuppression and malnutrition, among others.[6] Extrinsic factors are linked to environmental factors, and to asepsis and antisepsis characteristics, number of medical procedures, invasive techniques, number of days of hospital stay and the hospital's environmental microbiological pollution.

It is reported that in hospitals worldwide, surgical wound infections are found, with 24% of cases, just behind urinary tract infections (40%), while respiratory tract and other infections represent 20% and 16%, respectively. However, the order in which infections appear varies according to each hospital's characteristics; but in general, these systems prevail.[7]

For 2005, the *Comité de Prevención y Control de Infecciones Hospitalarias* [Committee for Prevention and Control of Hospital Infections] of the *Dr. Rafael Angel Calderon Guardia* Hospital (HCG), registered an 11.5% overall rate of hospital infections, of which 34% were surgical wound infections and 28% respiratory tract infections.[8] Thus, SWI are of great importance and concern to the hospital because they are the most common, even though approximately half of them are highly preventable. Moreover, some operating rooms allow unrestricted traffic of persons unrelated to the surgical procedures, which entails an increased risk of surgical contamination, a situation to which physicians attribute a high proportion of SWI.

This research aims to identify and quantify risk factors for nosocomial infections at the surgery site in HCG patients with elective clean surgery.

Methods

Study's population

A cohort study was carried out in 488 clean elective surgery patients, who underwent surgery between April and June 2006, in the HCG, a third level care hospital with 350 total beds and 150 surgery beds. These patients were randomly selected from a total of 1800 surgeries of the type under consideration. The study included 249 in the exposed individuals' cohort and 239 in the unexposed individuals' cohort.

The patients admitted had to show a stable health condition prior to surgery, no remote septic foci, a normal white blood cell count and a previous blood glucose test. Patients with any transoperative complication, which meant a change in the risk of acquiring a hospital infection, were excluded. The patients were admitted to the hospital one day before the procedure.

The study was conducted with the consent of the Hospital's Direction, confidentiality in the administration, handling of data and use of the resulting information was guaranteed.

Collection, edition and data analysis

A questionnaire with the variables to be studied was constructed and previously validated to detect and correct inconsistencies or collection problems in the interpretation of responses. Answers were registered in an Excel 2007 ® (Microsoft Corporation ®) database.[9]

The statistical analysis was conducted in two major phases: the first one descriptive and the other analytical. In the first phase, frequency measures were calculated (absolute and relative) to describe the occurrence of the event. The second phase, in turn, was conducted in two stages: univariate and multivariate analysis. In the first, using 2 x K tables, the relative risk (RR) and odds ratio (OR) with their corresponding confidence intervals to 95% and the p value based on Fisher's exact test, were calculated for each independent variable. The variables with $p < 0.25$ values moved to the second phase, in which a backward stepwise modeling strategy was employed, according to the *p* value of the likelihood ratio test.[10] The presence of confounding variables was evaluated by comparing the estimated coefficients in the new model with the estimates and the likelihood ratio test of the previous model, after exclusion of every variable in the multivariate model. Confounding variables were considered to be present when the coefficient of any of the exposure variables changed by more than 10% (if the coefficient had values between -0.4 and 0.4), or if the coefficients change by more than 25% (if the coefficient had values less than -0.4 or greater than 0.4). All the logistic and 2xK tables' processes were performed using the program EGRET (Cytel Corp.)

Study's variables

The dependent variable was SWI, which was identified as presence of pain, flushing, erythema, swelling, heat, secretions or wound dehiscence, alone or accompanied, 72 or more hours after surgery.

The main exposure variable was the restriction on the traffic of persons in operating rooms, as there are rooms with traffic restricted to the surgical staff (unexposed) and unlimited traffic (exposed).

The collection of information began immediately after surgery was performed. During the time of hospitalization the patient was visited daily to record progress and to detect the presence or absence of infection. When the patient was discharged, he or she received an appointment eight days later for suture removal and to observe the surgical wound to complete the required information.

Results

In the studied population, 153 men (31.4%) and 355 women (68.7%) were identified. The age range was 13 to 92 years, for an overall average of 46 years, without differences by sex.

The distribution of surgeries, according to age groups ranged between 12.1% and 22.1%, values that belong to the 57-67 and 36 to 45 years age group, respectively. Of the comorbidities studied, both *diabetes mellitus* and obesity were found in a similar percentage distribution, with a 7.0%; only 7 cases shared both conditions (Table 1).

Regarding the conditions related to surgeries, according to the type, the most frequent ones were organ surgeries, with 46.5%, followed by those of bone and joints (25.0%) and the skin and mucous membranes (16.0%); those of cavities were less frequent; only 12.5%. 76.4% of the surgeries were completed between 1 and 3 hours; followed by those completed in less than an hour (17.8%). 85.6% of procedures were carried out between 7:30 am and 1:29 pm; besides, the use of prophylactic antibiotics in almost half of the patients studied (44.3%) was recorded and only 18.2% of surgeries required surgical drainage (Table 1).

Surgery wound infection

An overall incidence of 35.2% (172/488) of infectious processes of the surgical wound was recorded. Infection rates, according to the patients' characteristics showed significant differences only when there was presence of *diabetes mellitus*, but not with other studied comorbidities, neither with sex or age.

Regarding the conditions of surgery, only the type of surgery showed significant differences, however two groups were observed according to frequency of occurrence, thus, those of organ and bone/joint showed the highest, while those of cavities and skin and mucous membranes, the lowest, with valued around 40% and 23.7%, respectively (Table 1).

Risk factors

Of the patients studied, 49% (239/488) were operated in a restricted traffic area, and the remaining percentage in an area of unrestricted traffic. The cumulative incidence in the unexposed group was 31.8% (76/239), whereas in the exposed was 38.6% (96/249), however this difference is not statistically significant (p = 0.12). Consistent with this result, according to the univariate analysis, the main exposure variable of the study, unrestricted traffic in operating rooms, did not present a risk of SWI, with a RR of 1.2 (CI 95%: 0.9 - 1.6) and the OR of 1.4 (CI95%: 0.9 - 1.9) (Table 2).

Of the remaining variables studied in the univariate analysis and using the RR as a measure of association, only *diabetes mellitus* and the type of surgery showed some degree of risk to SWI. Patients with diabetes were nearly twice as likely as non-carriers; those who received organ or bone/joint surgery, about 1.7 times. Surgeries with an extent between 1 and 3 hours showed no increased risk, according to the RR, but did have an OR of 3.1, thus some kind of risk is possible (Table 2). Although the main exposure variable showed no statistically significant association, this variable, along with age and sex as potential confounders were added to those of diabetes and type and duration of surgery in the multivariate analysis.

The best-fit multivariate model revealed that only organ and bone/joint surgery showed a higher SWI risk; which was almost 2.5 times higher compared to the skin and mucous membranes surgeries (OR 2.42, CI 95% 1.5 to 3.8). Surgeries performed in unrestricted traffic operating rooms showed no association with SWI, as well as the fact that the patient had diabetes, but there was a significant trend toward risk on both conditions (Table 3). The other variables were not relevant and were excluded from the model.

Discussion

Several recent clinical and epidemiological studies have shown that the complexity and variety of additional risk factors may affect without distinction the incidence of wound infection. Thus, the multi-factor hypothesis, composed of extrinsic and intrinsic factors, as elements of the risk of infection is stronger every day. From this data, it follows that knowledge of risk factors prior to surgical intervention may allow the medical and health team to adopt specific preventive measures.

During the study, a 35.2% overall incidence of SWI was registered, which is higher than that reported in other studies in North America[12] and Colombia[13], that indicate that 3.7% of patients undergoing surgery in the United States suffer a serious adverse event, of which 14.0% are surgery site infections; these studies also indicate that 58% of these events are preventable if the place and aseptic conditions in which these processes are carried out are taken into consideration.

Concerning the unrestricted traffic area, 6% more SWI were found compared to the restricted area. However, there was no epidemiological association, therefore, at least for purposes of this research, the original null hypothesis that there was no risk of SWI according to free access to an operating room area with respect to the restricted area, could not be rejected. Notwithstanding, since 16 000 surgeries are performed annually in the hospital in which the study was carried, a 6% difference in SWI in the exposed group is a significant figure in absolute terms due to the cost entailed for the CCSS and for patients themselves.

Little has been registered on this aspect and at least in one study, the direct effect of the distribution of operating rooms and access of unauthorized persons to them on the incidence of SWI was not demonstrated.[14] Despite this, it is not unknown that the probability of infection increases as the presence of individuals in operating rooms increases; also, the limitation and separation of activities decreases the chance of bacterial transfer from one place to another, either by direct or indirect contact.[15] Nonetheless, common sense and the basic principles of antisepsis indicate that it is necessary to continue with the recommended practices in order to uphold the principles of aseptic surgery techniques.

With regard to sex, which in this research showed no differences in incidence, this study is consistent with other authors[16], that conclude that there is no apparent difference in susceptibility between the two sexes. Yet, it was interesting to note that there was no age group with the most SWI risk, contrary to other studies, that highlight age as an important systemic factor that increases vulnerability to infections. In this regard, it is argued that individuals experience a gradual reduction in immunocompetence as their age increases; in particular, the extreme ages of life are at increased risk of acquiring a hospital infection.[7, 17]

With respect to the site of surgery, we found that bone surgeries, as well as those of joint and organ, double the percentage of infection risk with respect to cavities and skin and mucous membranes' surgeries, which suggests that risk has a proportional relationship with the depth of surgery. This behavior has been described before.[18] These authors attribute this effect to the different resistance degrees of tissues to infection according to depth, location, exposure and handling time, as these surgeries usually consume a lot of time. They also mention that risk is influenced by the complexity characteristics of the surgery, as well as by the surgeon and health team's skills.

There are suggestions that vulnerability to infection acquired at the operating room, is concentrated among the events held in the morning, and increases with time and the number of surgeries, were up to 38% are registered among those carried out between 10:30 am and 1:29 p.m. This is explained by the number of people in the room; ventilation; the concentration of microbiological pollution; hygiene measures; cleaning and disinfection between one surgery and another; the strict application of aseptic practice; as well as the physical and mental fatigue of the surgical team. In fact, in the afternoon shift, in which much less procedures are performed, the incidence of infections dropped to 3%.

With regard to the pathological conditions of patients as possible risk factors for surgical site infection, *diabetes mellitus* is the predominant disease. The contribution of *diabetes mellitus* to SWI is controversial, however, preliminary findings by a recent study show a significant relationship between glycolated hemoglobin levels and SWI frequency.[7] Also, elevated glucose levels greater than 200 mg/dl in the immediate postoperative period (<48 hours) are associated with increased risk. Among the CDC recommendations for preventing category 1B surgery site infections,[19, 20] is the adequate control of blood glucose concentration in all diabetic patients who undergo surgery and, in particular, avoid perioperative hyperglycemia.

Although the time of surgery, and specifically the exposure of tissues has been described as a risk factor for acquiring the infection, the variable duration of surgery and status of the infection does not suggest significant differences between surgery duration ranges, although it is possible to expect infection frequency to increase as duration of the surgery increases, due to its relationship to handling of tissues.

In the study, antibiotic prophylaxis did not reveal any practical effect in preventing infections, however, Ludwig et al (1993)[21] state that when this practice is adequately used, is has proved to be an effective measure to prevent surgical infection, as its mechanism of action is not intended to sterilize tissues, but to act as a contributor at the critical moment, thus achieving a reduction in the microbial load, that occurred during the intraoperative contamination, to a level not exceeding the host's immune defenses, this, if provided just before (30-60 minutes) starting the surgery. No benefit was found; but it is not possible to conclude negatively in this regard, because the study did not consider whether the scheme provided to patients came from a well-established protocol or from individual decisions by surgeons at the time of the procedure.

Finally, the use of surgical drainage was not related to SWI, nevertheless, Nichols et al[17] describe the benefit of closed suction surgical drains, due to their ability to effectively evacuate postoperative hematomas, which could eventually precede the surgical wound infection. However, they insist on early scheduled withdrawal of drainage, since these originally sterile tracts can become colonizing medium, since they are classified as materials that react as strange bodies, thereby promoting inflammation and consequently, raising the risk of surgical site infection. For these reasons, they recommend that surgical drains are placed in a separate and distant incision from the surgical site. Furthermore, that its placement has well-established clinical criteria and, when required, be closed suction ones.

While performing surgery on an unrestricted traffic area was not associated with risk of SWI, it is neither ethical, or medically appropriate, to conclude that this anomaly should go unnoticed, especially due to the imminent threat that surgery alone represents coupled with the increasing incidence of surgical site infection in this hospital. The presence of comorbidities in surgery patients, in particular *diabetes mellitus*, should be taken into account in the profile of the subject with SWI risk, especially if related to deep surgeries or bone / joint surgeries.

The high percentage of SWI indicates that effective interventions should be implemented in order to decrease these events and thereby improve patient's prognosis, reduce costs and optimize the quality of life of patients and their families.

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Translate by: Natalia Porras

Table 1. Frequency of nosocomial infections in the surgery site, according to patient's characteristics and surgeries' conditions. "Dr. Rafael Ángel Calderón Guardia" Hospital, April to June 2006

Variable	Age group	N° infected	%	CI 95%	Total
Age (years)	< 25	27	39,1	33,5 - 44,8	69
	25- 35	28	32,6	27,9 - 37,2	86
	36- 45	37	34,3	30,0 - 38,5	108
	46- 56	29	35,4	30,4 - 40,3	82
	57- 67	21	35,6	29,7 - 41,4	59
	> 68	30	35,7	30,8 - 40,6	84
Sex	Female	118	35,2	32,8 - 37,7	335
	Male	54	35,3	31,7 - 38,9	153
Diabetes mellitus	Yes	17	50,0	33,1 - 66,8	34
	No	155	34,1	29,8 - 38,5	454
Obesity	Yes	11	32,4	16,5 - 48,0	34
	No	161	35,5	31,0 - 39,8	454
Immunosuppression	Yes	2	33,3	0,0 - 71,0	6
	No	170	35,3	31,0 - 39,0	482
Type	Skin and mucous membranes	15	23,8	19,3 - 28,3	63
	Cavity	18	23,7	19,6 - 27,7	76
	Organ	90	39,6	36,5 - 42,8	227
	Bone/joint	49	40,2	35,9 - 44,4	122
Duration (hrs)	< 1	31	36,0	27,9 - 44,2	86
	1 - < 3	131	35,1	31,2 - 39,0	373
	3 - < 6	10	35,7	21,5 - 50,0	28
	≥ 6	0	0,0	0,0 - 0,0	1
Drainage	Yes	35	39,3	31,4 - 47,2	89
	No	137	34,3	30,6 - 38,1	399
Antibiotic prophylaxis	Yes	80	37,2	32,1 - 42,3	215
	No	92	33,7	29,1 - 38,3	273
Start time	7:30 am - 10:29 am	80	34,8	31,8 - 37,7	230
	10:30 am - 1:29 pm	71	37,8	34,4 - 41,1	188
	1:30 pm - 4:30 pm	21	3,0	25,1 - 34,9	70

Table 2. Factors associated with nosocomial infections in the surgery site, according to the univariate analysis. "Dr. Rafael Ángel Calderón Guardia" Hospital, April to June 2006

Variable	Age group	OR	CI95%	RR	CI95%
Traffic through operating rooms	Restricted	-	-	-	-
	Unrestricted	1,35	0,9-2,0	1,2	0,9-1,5
Age (years)	< 25	-	-	-	-
	25- 35	0,75	0,4 - 1,4	0,83	0,5 - 1,3
	36- 45	0,81	0,4 - 1,5	0,88	0,6 - 1,3
	46- 56	0,85	0,4 - 1,6	0,90	0,6 - 1,4
	57- 67	0,86	0,4 - 1,7	0,91	0,6 - 1,4
	> 68	0,86	0,4 - 1,7	0,91	0,6 - 1,4
Sex	Female	-	-	-	
	Male	1,00	0,7 - 1,5	1,00	0,8 - 1,2
Diabetes mellitus	No	-	-	-	-
	Yes	1,93	1,0 - 3,8	1,46	1,0 - 2,1
Obesity	No	-	-	-	-
	Yes	0,87	0,4 - 1,8	0,91	0,6 - 1,5
Immunosuppression	No	-	-	-	-
	Sí	0,9	0,2 - 5,0	0,95	0,3 - 2,9
Type	Skin and mucous membranes	-	-	-	-
	Cavity	0,87	0,4 - 1,9	0,99	0,6 - 1,8
	Organ	3,55	1,8 - 6,9	1,67	1,1 - 2,6
	Bone/joint	2,59	1,3 - 5,2	1,69	1,1 - 2,7
Duration (hrs)	< 1	-	-	-	-
	1 - < 3	3,06	1,7 - 5,3	0,97	0,8 - 1,3
	3 - < 6	0,19	0,1 - 0,4	0,99	0,4 - 2,7
	≥ 6	ne	ne	ne	ne
Drainage	No	-	-	-	-
	Yes	1,24	0,8 - 2,0	1,15	0,9 - 1,5
Antibiotic prophylaxis	No	-	-	-	-
	Yes	0,86	0,6 - 1,3	0,91	0,7 - 1,2
Start time	7:30 am - 10:29 am	-	-	-	-
	10:30 am - 1:29 pm	1,14	0,8 - 1,7	1,09	0,9 - 1,3
	1:30 pm - 4:30 pm	0,80	0,5 - 1,4	0,86	0,6 - 1,3

Table 3. Best-fit model (multivariate) for factors associated with nosocomial infections at the surgery site. "Dr. Rafael Ángel Calderón Guardia" Hospital, April to June 2006					
Variable	**Coefficient**	**EE**	**p**	**OR**	**CI 95%**
% GM	-1.471	.235	< 0.001	0.23	0.15 - 0.37
Area	0.299	.194	0.124	1.35	0.92 - 1.97
Type of surgery	0.884	.235	< 0.001	2.42	1.53 - 3.84
Diabetes	0.630	.365	0.084	1.88	0.92 - 3.84