SURGICAL INFECTION IN PATIENTS UNDERGOING ORTHOPEDIC SURGERY WITH IMPLANT*

Infecção cirúrgica em pacientes submetidos a cirurgia ortopédica com implante

Infección quirúrgica en pacientes sometidos a cirugía ortopédica con la implante

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ABSTRACT: Objective: To analyze the epidemiological aspects of the surgical infections in the patients undergoing orthopedic surgery with implantation. **Methods:** Concurrent cohort study of 222 patients undergoing orthopedic surgery with implantation was carried out between May and September 2011 with post-discharge follow-up for one year by telephone. In the statistical analysis we used the simple frequency central tendency and survival analysis using Kaplan Meier method and Cox regression. **Results:** The study population had an average of more than three comorbidities, Body Mass Index 26 kg/m^2 and 62 years. The surgical site infection rate was 12.6% and Staphylococcus aureus was the most isolated microorganism. They were risk factors for this infection: male patients, previous surgery at the surgical site, no bathe before surgery, blood transfusion, patients with renal disease, and no adherence to surgical protocol of hand hygiene by professionals. **Conclusion:** This population was characterized as high risk for surgical infection.

Keywords: Surgical wound infection. Epidemiological surveillance. Risk factors. Prostheses and implants. Nursing.

RESUMO: Objetivo: Analisar os aspectos epidemiológicos das infecções cirúrgicas nos pacientes submetidos à cirurgia ortopédica com implante. **Método:** Estudo de coorte concorrente de 222 pacientes submetidos a cirurgia ortopédica com implante, realizado entre maio a setembro de 2011, com acompanhamento pós-alta durante um ano por contato telefônico. Na análise estatística, utilizou-se a frequência simples, medidas de tendência central e análise de sobrevivência usando Kaplan Meier e regressão de Cox. **Resultados:** A população do estudo tinha em média mais de três comorbidades, índice de massa corporal 26 kg/m^2 e 62 anos. A taxa de infecção de sítio cirúrgico foi 12,6% e o *Staphylococcus aureus* o microrganismo mais isolado. Foram fatores de risco para essa infecção: sexo masculino, cirurgia prévia no local operado, não tomar banho pré-operatório, hemotransfusão, doença renal, e não adesão ao protocolo cirúrgico de higienização das mãos pelos profissionais. **Conclusão:** Essa população foi caracterizada de alto risco para infecção cirúrgica.

Palavras-chave: Infecção da ferida operatória. Vigilância epidemiológica. Fatores de risco. Próteses e implantes. Enfermagem.

RESUMEN: Objetivo: Analizar los aspectos epidemiológicos de las infecciones quirúrgicas en pacientes sometidos a cirugía ortopédica con implantación. **Método:** Estudio de cohorte concurrente de 222 pacientes sometidos a cirugía ortopédica con implantación que se llevó a cabo entre mayo y septiembre de 2011, con postoperatorio de seguimiento durante un año, por teléfono. El análisis estadístico utilizó la frecuencia simple, tendencia central y análisis de supervivencia mediante Kaplan Meier y regresión de Cox. **Resultados:** La población del estudio tenía un promedio de más de tres comorbilidades, índice de masa corporal 26 kg/m^2 y 62 años. La tasa de infección del sitio quirúrgico fue 12,6% y *Staphylococcus aureus* el microorganismo más aislado. Los factores de riesgo para la infección fueron: sexo masculino, cirugía previa en el sitio quirúrgico, no bañarse antes de la cirugía, transfusión de sangre, enfermedad renal y la falta de adherencia al protocolo quirúrgico para la higiene de las manos de los profesionales. **Conclusiones:** Esta población se caracterizó en alto riesgo de infección quirúrgica

Palabras clave: Infección de herida operatória. Vigilancia epidemiológica. Factores de riesgo. Prótesis e implantes. Enfermería.

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INTRODUCTION

Among the Health care-associated infections (HAIs), the surgical site infection (SSI) is one of the most common complications in institutions for acute health care[1]. In the United States, the SSI is the second most common cause of infection in hospitalized patients and the most costly one, occurring in between 2 and 5% of patients[1]. It is estimated that approximately 160,000 to 300,000 SSI occur each year in the United Stated and that 60% of them are predictable, with measures based on evidences[1]. In Brazil the SSI is the third cause of infection, occurring in between 14 and 16% of hospitalized patients[2].

In specific surgeries, such as orthopedic ones with the use of implants, the SSI is presented as a great problem for hospital institutions, since it significantly increases the rates of mortality and morbidity, elevates hospital costs for the treatment of the infection and restricts the quality of life of the patients[3].

The SSI rates resulting from orthopedic procedures vary significantly. The SSI rates being registered may vary from 1.4 to 22.7%[4,5]. These differences may occur depending on the type of orthopedic procedure, clinical conditions of the patients, complexity of the hospital and the kind of post-operative surveillance adopted[6].

National studies showed that using the intra-hospital search it was found a SSI orthopedic rate of 1.4%, and using the post medical discharge surveillance, the rates increased to 11.1%[4,7].

In 2010, according to the database of the Infection Control Committee (*Comissão de Controle de Infecção* – CCIH), of the hospital involved in this study, the SSI rate was 1.93%. However, in this period, the surveillance method used was just intra-hospital. It is noteworthy that, since the post medical discharge surveillance of the infections was not performed, the data generated by the Monitoring and Control Service of Hospital Infections may have been subnotified[8].

The orthopedic SSI prolong the patient's permanence in the hospital, on average, for two weeks, Double the readmission rates, increase hospital costs by more than 300% and physically limits the patient. Therefore, reliable information obtained from the SSI surveillance are extremely important, once they may be used in order to determine the effectiveness of the measures of prevention and control of infections[3].

Thus, from the important repercussion of an orthopedic SSI for the patient and for the health institution, by the scarcity of Brazilian studies involving these infection and for the divergences in the incidence rates presented in different studies, we consider important to know the epidemiological aspects of the SSI in orthopedic surgeries.

OBJECTIVE

To analyze the epidemiological aspects of the SSI in patients submitted to orthopedic surgeries with implants in a public, teaching, tertiary care hospital in the state of Minas Gerais.

METHOD

During the period from May to September 2011 was carried out in a concurrent cohort of 222 patients submitted to orthopedic surgeries with implants and with post medical discharge during an year, by telephone, in a public, teaching, tertiary care hospital in Minas Gerais.

In order to interpret the results of the statistical analysis and to ensure the test was powerful enough to detect real difference, it was calculated the statistical power of the sample for this study, finding a probability of 90% of detecting differences between the groups (with and without SSI), once that the difference is real.

The SSI was analyzed as for the presence or absence of infection. The independent variables studied were the ones related to the sociodemographic conditions, comorbidities, life habits, hospitalization, surgery, health professionals' behavior and use of antibiotics.

To ensure the comparability of the SSI, this study used the methodology of the National Healthcare Safety Network – Center of Disease Control and Prevention (NHSN-CDC).

The inclusion criteria of the patients in the study were: being aged over 16 years old; having a ground line telephone or a cellphone for future contact; being able to answer the information about the clinical signs of infections requested by the researchers during the telephone contacts (this information was also obtained through the legal guardian of the patient, in case they were not able to do it themselves); orthopedic surgical procedures classified by the NHSN in elective or emergency surgery, with permanent installation of any exogenous device, non-human,

during the surgical procedure; and absence of infectious focus in the place to be operated.

The data were collected during the perioperative period using an instrument developed by the researcher and validated by specialists in the infection control area. The instrument has information obtained in operating room sheet, in the patient's chart, about laboratory tests' results, in the active search performed by the researcher for the detection of cases of infection in operated patients. In the search after the hospital discharge, the patients were contacted for times by the telephone (in the first, second, sixth and tenth month post operation). Thus, the follow-up of patients was maintained for a year after surgery.

The data collected were analyzed using the Statistical Package for the Social Sciences software (SPSS) 15,0 for Windows Evaluation Version. The results were presented through simple frequency, central trend measures and variability measures in order to characterize and describe the population of patients submitted to orthopedical surgical procedures with implants.

The continuous variables were tested by the Kolmogorov-Smirnov test in order to evaluate the normality of the data. In the parametric variables, the Student's t-test was used and the Mann-Whitney tests were used for the non-parametric variables.

Univariate and multivariate analysis were conducted using the survival analysis in order to investigate the association of possible risk factors involved with the event of interest (SSI).

The curve of Kaplan Meier estimated the survival function and the empirical flaws rate for each risk factor. For the comparison of the survival curves between two groups of individuals, the log-rank test was adopted, which calculates the χ^2 between the expected and the observed flaws.

The initial model of the multivariate analysis was performed from the selected variables in the univariate analysis, whose p-value was ≤ 0.20. The variables were selected for the inclusion in the final model, performing the step-by-step process (stepwise) and the entrance of one by one of the variables was tested (forward). For the adjust of the model, it was considered the $p<0.05$ and the test for likelihood ratio.

The project of the research was approved by the Research Ethics Committee of the UFMG (Process No. ETIC 0071.0.203.000-11). The Informed Consent was presented to patients and doctors for the permission to carry out this study.

RESULTS

222 patients took part in the study. There was a loss of 13 (5.8%) patients due to death, changes in telephone contact and new intervention on other hospitals, during the follow-up period.

Of the 222 patients 131 (59%) were female, 140 (63.1%), were on average 62 years old (SD=17.1). The mean of the Body Mass Index (BMI) was 26 kg/m^2 (SD=4.9). The mean permanence time of the patient in the hospital was 6 days (SD=7.0). The mean duration time of the surgical procedure was 1 h and 37 minutes. The most often surgical procedure performed was the open fracture reduction (135, 60.8%), followed by knee arthroplasty (45, 20.3%) and hip arthroplasty (39, 17.6%). 98 (44.1%) plates and screws and 82 (36.9%) articular implants were used in the procedures. The blood transfusion was performed in 49 (22.1%) of the patients.

In relation to the clinical conditions of the patients before surgery, 704 previous diseases were diagnosed. On average, each patient had three comorbidities, being hypertension, hypercholesterolemia and osteoarthritis, the most common ones.

Evaluating the frequency of the pre-operative bath, 138 (62.2%) patients had a pre-operative bath. The surgical preparation of the hands in the team was performed according to the recommendations by the Hospital Infection Control Committee of the hospital involved in the study, regarding the use of antiseptic solutions (Degerming Polyvinylpyrrolidone iodine (PVPI) 10% or chlorhexidine gluconate 4%, followed by the same antiseptic solution containing alcohol), in 98 (44.1%) of the opportunities for hand sanitization. The prepare of the skin, in the surgery room, was performed according to the CCIH protocol, in all the patients, using the degerming PVPI solution, followed by the alcoholic solution of PVPI.

The surgical wounds were classified as clean in 211 (95.0%) of the 222 procedures performed. According to the classification of the clinical condition of the patent, as determined by the score of the American Society of Anesthesiologists (ASA), 146 (65.8%) patients were classified in the ASA II. In relation to the Surgical Infection Risk Index, 154 (69.4%) of the patients were classified in category 0. During the surgical act, on average, 8.1 health professionals went by the surgery room, considering that 3.6 professionals remained in the operation room.

Regarding surgical prophylaxis, the cefalozin was administered in 208 (93.7%) of the 220 patients, with rebound dose in the range of approximately 2 hours. The antibiotic was maintained after surgery in 200 (90.1%) of the patients, during approximately two days.

After one year of follow-up of these patients, 44 (36.0%) hospital readmissions occurred, 32 (72.7%) of them due to events related to the SSI and 12 (27.2%) of them by infection of the surgical site. The functional disability for the performing of daily life activities has been present in 28 (23.5%) patients after one year from the surgery.

During the period of the study, 28SSI were notified. The global incidence of infection was 12.6% (95%CI 8.5–17.7). The intra-hospital SSI incidence was 2.7% (n=6) and the post-medical discharge was 9.9% (n=22).

Of the 28 notified SSI 26 (92.8%) of them were diagnosed within 90 days after surgery. The mean time for patients to present the SSI was 39.7 (SD=60.3) days. The most common topography was the surface one, with 15 (53.6%) infections.

The incidence of the surface SSI was 6.7 (95%CI 33.8–72.5), deep infections of 4.5 (95%CI 18.6–55.9) and osteomyelitis of 1.3 (95%CI 2.3–28.2). Regarding the incidence of SSI by procedure, the open fracture reduction contributed with 14.1% (95%CI 8.7–21.1); hip replacement, 12.8% (95%CI 4.2–27.4); and knee arthroplasty, 6.7% (95%CI 1.4–18.2). The predominant pathogen in the SSI was the *Staphylococcus aureus* (3 to 30%).

After the univariate analysis, the variables collected in the study were eligible for the multivariate analysis, considering the p-value ≤0.20 and the importance of the variable as a risk factors recognized by the national and international literature.

For the multivariate analysis, the Cox regression was used in as an adjusting method of the co-variables, resulting in a final model consisting of five co-variables, as seen in Table 1.

DISCUSSION

In this study, the patients were elderly, mostly females, with BMI in the "overweight" category and had more than three comorbidities. Studies involving patients of orthopedic surgeries also present a population with similar characteristics in relation to age[6-10], predominantly females[9-10] and BMI[11] above 25 kg/m^2.

The orthopedic surgical intervention in elderly patients has become increasingly common, due to the significant growth of the elderly population in the last decades[6]. The increase of these interventions in this age range occurs, mainly, due to the great number of falls associated to the prevalence of osteoporosis[12].

The female prevalence in the population aged over 60 years old in orthopedic surgeries may be due to intense exposure to domestic activities, to chronic diseases and to the fact of having less lean muscle mass when compared to men[13].

The BMI higher than 25 kg/m^2 seems to be a common characteristics in most orthopedic surgical patients[10,11,14]. For each increase of 1 kg/m^2 in the BMI, there is an association of 10% in the increased risk of SSI in hip replacements, which is complicated due to the increasing dead space after surgery that promotes microbial growth[9].

The clinical condition of the patient has a cumulative effect on the risk of developing an infection in the periprosthetic articulation. Thus, it is important that the doctor informs the patient about the risks of a surgery, in order to improve the clinical state before the procedure[15].

The mean of three comorbidities per patient found in this study may be related to the age range above 60 years old, as already presented. The existence of chronic diseases in elderly patients at the moment of the fracture is

Table 1. Final adjustment of the Cox model with the covariables depending on time for the occurrence of orthopedic surgery infection. Belo Horizonte, May 2011 to September 2012.

Covariable	HR	95%CI	Valor p
Male gender	4.78	2.11-10.82	<0.0001
Previous surgery in the operation site	3.58	1.52- 8.46	0.004
Not bathing before surgery	3.30	1.30- 8.48	0.013
Blood transfusion during surgery	3.08	1.31- 7.26	0.010
Kidney disease	16.2	4.76-55.50	<0.0001
Not sanitizing the hands according to the CCIH protocol	2.35	0.99- 5.59	0.054

an important prognostic factor and the pulmonary, kidney, and cardiac diseases and diabetes and stroke are the ones of greater influence in post-operative complications[12]. In articulation surgeries, the SSI risk increases 0.35% for each comorbidity presented by the patient[15].

In relation to the mean hospitalization time, six days, in the literature, there were found higher timer to this value, varying between 7.5 to 9.3 days[6,9]. Probably, the increased hospitalization time is related to the comorbidities present in orthopedic patients at the moment of the surgery and the need to improve their clinical conditions, resulting in the postponement of the surgery.

The time of duration of surgery found in this study was corroborated by another concurrent study with 121 patients submitted to orthopedic surgery with implant, in which 77.2% of the patients had surgical time shorter than two hours[16]. In hip replacements, the interventions with duration time above two hours have increased risk for the SSI when compared to the ones with duration between 60 and 89 minutes[14].

The surgical wounds classified as clean were the most prevalent ones. Another study with orthopedic patients also found that 91% of surgeries were classified as clean. It was also observed that as the contamination potential of the wound increases, the SSI incidence may increase significantly[5].

The most common surgical procedure was the open fracture reduction followed by the knee arthroplasty and hip replacement. Within the last decades, it was observed an increase in the prevalence of surgeries for articulation replacement[17], which may be related to the increase of life expectation of the population.

The ASA score is an anesthetic risk index which classifies the patient according to their clinical status. Regarding the anesthetic risk index, in this study, 65.8% of the patients were classified in the ASA II, therefore they suffered from mild systemic disease[5]. However, the reliability of this classification has been questioned by the researchers when considered as a risk factor, once that its records is performed by the anesthesiologist, without a thorough evaluation of the patient[18].

The Surgical Risk Index stratifies the risk of SSI in surgical patients and it is classified from 0 to III. In this study, 69.4% of patients were classified in score zero and, therefore, with low SSI rates. Despite the health institutions, worldwide, using the Surgical Risk Index of the National Nosocomial Infection System (NNIS) in order to categorize the patient as for the risk of developing SSI, their applicability has also been questioned in relation to several surgical procedures. Thus, studies carried out in Brazil did not consider this index as a good infection predictor for the whole population of surgical patients[19].

The traffic in the operation room during surgery is considered a risk factors for infection of the surgical site. A number higher than sic professionals in the operating room may increase the SSI rates from 1.5 to 3.8[5]. In our study, during surgery, there were an average of 8.1 professionals transiting the operation room, showing a greater risk of infection for the patient.

Currently, it is well defined that the surgical prophylaxis performed within an hour before the patient's skin incision is a prevention measure for SSI[20]. In this study, the mean time in the performing of a surgical prophylaxis with cefazolin was 0:27:43h (SD±0:14:25h) before the surgery and the minimum range of 0:00:00h and maximum range of 1:25:00h. A study carried out by the Center for Medicare & Medicaid Services (CMS) in records of medical charts has shown that this recommendation was made in, only, 55.7% of surgical prophylaxis[20].

In relation to hospital readmissions, a study involving 947 patients submitted to arthroplasty between 2004 to 2008, in Denmark, identified a percentage of readmissions of 13% (225), being 87.5% (197) by complications not related to the SSI and 12.5% (28) by SSI[21]. However, even knowing about the damages caused by complications not related to the SSI, this area has been little explored by researchers, unlike infectious complications of the surgical site which are considered to be more relevant events[22].

It was identified a high overall incidence of SSI (12.6%), this demonstrated the considerable difference of SSI rates when performing intra-hospital and post medical discharge surveillance methods. Studies carried out in Poland, compared to SSI rates of hip replacement, using intra-hospital and post medical discharge surveillance, detected an increase of almost six times the rates when performed with patients after medical discharge[23].

The surface SSI was the most frequent one (53.6%) which may be explained by the surveillance methodology used, which is capable of detecting the SSI even if the hospitalization time of the patient was reduced. In post medical discharge surveillance there is greater possibility of detecting the SSI, since the patient will hardly readmit

themselves to treat a superficial infection[8]. A study with post medical discharge follow-up, carried out in Northern Italy, found that 64.4% of SSI in orthopedic patients were superficial[6].

Among the procedures performed, the highest incidence of SSI occurred in open fracture reductions (14.1%). Monitoring the patient only during their hospital stay, we have records of SSI rates of 1.1% for these procedures[4].

As for the time for the development of the SSI, it was identified, in this study, that most (92.8%) infections were notified within 90 days. Other studies corroborate with these data and found out that 54.5% of the SSI are diagnosed in patient's monitoring within 30 days[27], and that, 72.9% of them expressed themselves in less than 90 days[24]. Thus, in 2013, the NHSN changes the time of follow-up of surgical patients, setting a period of 90 days for the monitoring of surgeries with implants[25].

In this study, there was a low percentage of microbiological tests for the SSI, which is explained because the superficial infections are considered minor and easily solved[8], eliminating the need for microbiological tests. In agreement with the literature, in this study there was a predominance of isolation of *Staphylococcus aureus* in SSI. The prevalence of *Staphylococcus aureus* in orthopedic surgeries has been described in other studies and it is the most investigated pathogen in musculoskeletal infections[11,23].

In relation to the analysis of the independent variables which remained in the study from the Cox regression, it was observed that males, when compared to females, have five times more chance of having SSI. Despite the literature not explaining the relation between the male gender and the presence of SSI, a non-concurrent study performed with electronic medical records also found that the male gender is a risk factor for orthopedic SSI[17].

Male patients have high risk of reoperation by infection after knee arthroplasty, primary or by review, when compared to females. This difference disregards age. However, this association needs further studies[26].

Patients who have been submitted to previous surgery in the operation site had four times higher risk of developing infections. Multiple surgeries in the same place increase the risk of SSI and may be indicative of the complexity of the trauma[18].

Review surgeries of aorthroplasties, when performed within less than two years after the first procedure, increases twice the risk of infection when compared to periods longer than two years[26].

It is noteworthy, also, the importance of bathing the patient in the post-operative period as a risk factor for infection. Not bathing contributed for a three times higher risk when compared to patients who bathed before surgery. Interventions which will reduce the number of microorganisms on the skin may lead to the minimization of the risk of infection[6,9]. Despite the controversies in relation to the best solution to be used in pre-operative bath[27], the importance of these procedures before surgery is well defined, regardless the solution used[28]. However, what is observed in relation to this protocol is that there is still little adherence by health professionals, especially when the surgical patient in admitted under a hospital-day regimen[28].

Even with no statistical significance, the variable of not sanitizing hands of the surgical team, according to the CCIH protocol, was kept in the final model for stability. Besides, the guidelines for SSI prevention of the Society for Healthcare Epidemiology of America recommends that the performing of this procedure increases the risk of developing infection, as well as recommends the use of an appropriate antiseptic for brushing hands and arms during 2 to 5 minutes[1].

In the present studies, patients who had blood transfusion had risk of developing SSI three times higher when compared to those who did not have blood transfusion. Corroborating these findings, a study in a retrospective cohort showed that the blood transfusion is a risk factor to develop SSI, with twice a higher risk in periprosthetic articular surgery[29] due to decreased macrophage fucntion[1].

Patients with kidney diseases were independent predictors for the SSI, with a risk 17 times higher of developing SSI when compared to those who did not have the disease. Despite the results found in this research, a control case study conducted with patients undergone hip and knee replacement surgery did not find statistical significance between the SSI and patients with kidney disease[9].

CONCLUSION

The population of this study was characterized as under high risk of infection and the overall incidence if SSI

in orthopedic surgery with implants is above the rates described by the NHSN. Predisposing risk factors for SSI in orthopedic surgeries with implants were: male gender, previous surgery in the operated place, not bathing before surgery, having blood transfusion, kidney disease and not sanitizing the hands of the surgical team, according to the CCIH protocol.

The type of study conducted has a good level of evidence, considering the possibility of measuring the risk factors from the monitoring of the patient and that will hardly exclude important factors associated to the SSI.

From the knowledge of the risk factors for orthopedic surgical procedures and the reliable SSI rates, it is expected that the results found may be used as a measure of the reality of the service and implementing effective measures for the preventions and control of these infections.

Many conducts used in the control of SSI in orthopedics need better evidence in order to support the clinical practices. It stands out, then, the need for other multicenter, controlled and randomized studies in order to define the risk factors in orthopedic SSI.

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