Original article

Incidência e fatores de risco de infecção do sítio cirúrgico: uma coorte de 960 pacientes em um centro pediátrico terciário brasileiro

Incidence and risk factors of surgical site infection: a cohort of 960 patients in a brazilian pediatric tertiary Center

Incidencia y factores de riesgo de infección del sitio quirúrgico: una cohorte de 960 pacientes en un Centro pediátrico terciario brasileño

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ABSTRACT

Background and objectives: To assess the incidence of surgical site infection (SSI), establish its risk factors and the importance of post discharge active surveillance in determining its real incidence. **Methods:** All children operated from April/2013 to April/2015, at the Department of Pediatric Surgery of the Instituto Fernandes Figueira, in Rio de Janeiro, Brazil and followed prospectively for 30 days were included. CDC criteria were used for definition of SSI, wound classification and level of infection. Student's t-test or chi-square test was applied for numeric variables or categorical variables, respectively. The adjusted odds ratios of SSI were estimated from the logistic model. **Results:** In 960 patients who underwent 1003 operations, of whom 179 neonates with 189 surgeries, the overall SSI rate was 5.5%. A significant association for the occurrence of SSI was observed with age, wound class (clean, clean-contaminated, contaminated, dirty/infected), and patient status (inpatient or outpatient). Multivariate analisys identified an association of SSI with inpatient status (OR=5.581;95% CI 1.677 – 18.574) and neonate (OR=2.631; 95% CI 1.430 – 4.389). Active search covered 91% of patients and identified 9% of SSI by phone interview. **Conclusion:** Patient status, neonate and wound class were associated to a statistically significant higher risk of developing SSI. Active surveillance until the 30th postoperative day was important for accuracy of SSI rates.

KEYWORDS: Pediatric quality indicators. Surgical site infection. Risk factors. Surveillance. Postoperative infection.

RESUMO

Justificativa e objetivos: Avaliar a incidência de infecção de sítio cirúrgico (ISC), estabelecer seus fatores de risco e a importância da vigilância ativa pós-alta na determinação de sua real incidência. **Métodos**: Todas as crianças operadas de abril / 2013 a abril / 2015, no Departamento de Cirurgia Pediátrica do Instituto Fernandes Figueira, no Rio de Janeiro, Brasil, acompanhadas prospectivamente por 30 dias foram incluídas. Os critérios do CDC foram utilizados para definição de ISC, classificação de feridas e nível de infecção. O teste t de Student ou qui-quadrado foi aplicado para

variáveis numéricas ou variáveis categóricas, respectivamente. Os *Odds Ratios* ajustados de ISC foram estimados a partir do modelo logístico. **Resultados:** Em 960 pacientes submetidos a 1003 operações, dos quais 179 neonatos com 189 cirurgias, a taxa geral de ISC foi de 5,5%. Uma associação significativa para a ocorrência de ISC foi observada com a idade, classe da ferida (limpa, contaminada, contaminada, suja / infectada), e status do paciente (internação ou ambulatorial). A análise multivariada identificou associação do ISC com o status de internação (OR = 5,581; IC95% 1,677 - 18,574) e neonatal (OR = 2,631; IC95% 1,430 - 4,389). Pesquisa ativa cobriu 91% dos pacientes e identificou 9% de SSI por entrevista telefônica. **Conclusão:** O estado do paciente, o recém-nascido e a classe de ferida foram associados a um risco estatisticamente significativo de desenvolver ISC. A vigilância ativa até o 30º dia de pós-operatório foi importante para a precisão das taxas de ISC.
DESCRITORES: Indicadores de qualidade pediátrica. Infecção do sítio cirúrgico. Fatores de risco. Vigilância. Infecção pós-operatória.

RESUMEN

Justificación y objetivos: Evaluar la incidencia de infección del sitio quirúrgico (ISQ), establecer sus factores de riesgo y la importancia de la vigilancia activa posterior al alta para determinar su incidencia real. **Métodos:** Todos los niños operados desde abril / 2013 hasta abril / 2015, en el Departamento de Cirugía Pediátrica del Instituto Fernandes Figueira, en Río de Janeiro, Brasil y seguidos prospectivamente durante 30 días fueron incluidos. Los criterios de los CDC se usaron para la definición de SSI, clasificación de las heridas y nivel de infección. La prueba t de Student o la prueba de chi-cuadrado se aplicó para variables numéricas o variables categóricas, respectivamente. Las Odds Ratios ajustadas de ISQ se estimaron a partir del modelo logístico. **Resultados:** En 960 pacientes que se sometieron a 1003 operaciones, de las cuales 179 recién nacidos con 189 cirugías, la tasa total de ISQ fue del 5,5%. Se observó una asociación significativa para la aparición de ISQ con la edad, clase de herida (limpia, limpia contaminada, contaminada, sucio / infectado) y el estado del paciente (paciente hospitalizado o ambulatorio). Los análisis multivariados identificaron una asociación de SSI con el estado hospitalario (OR = 5,581; IC del 95%: 1,677 a 18,574) y neonato (OR = 2,631; IC del 95%: 1,430 a 4,389). La búsqueda activa cubrió al 91% de los pacientes e identificó el 9% de ISQ por entrevista telefónica. **Conclusión:** El estado del paciente, el recién nacido y la clase de herida se asociaron con un mayor riesgo estadísticamente significativo de desarrollar SSI. La vigilancia activa hasta el día 30 postoperatorio fue importante para la precisión de las tasas de SSI.
PALABRAS CLAVE: Indicadores de calidad pediátrica. Infección del sitio quirúrgico. Factores de riesgo. Vigilancia. Infección posoperatoria.

INTRODUCTION

Surgical site infection (SSI) is the most common postoperative complication, being responsible for increasing morbidity, mortality and hospitalization costs. The risk factors and rates of SSI are important indicators for implementation by Hospital Infection Control Committees (HICC) of routines for antibiotic prophylaxis, policies for reduction of postoperative infections and to evaluate their effectiveness over time.[1-3]

Incidence of SSI vary by age, patient status, surgical wound classification, duration of operation, emergency procedure, perioperative prophylaxis. In addition, patients who develop SSI after hospital discharge may not return to the same hospital where surgery was performed. Thus active surveillance after discharge is necessary to calculate the real incidence of SSI.[4]

This study aimed to assess the incidence, risk factors of SSI and the importance of postoperative active search in a cohort of 960 children operated at the Department of Pediatric Surgery of the Instituto Nacional de Saude da Mulher, da Criança e do Adolescente Fernandes Figueira (IFF), Fundação Oswaldo Cruz, Rio de Janeiro, Brazil.

METHODS

This study was approved by the Ethics Committee (CEP-IFF), under number 1.0.6.296 of 3/26/2015. All patients (from zero to 17 years old), operated at the Department of Pediatric Surgery of Instituto Nacional de Saúde da Mulher, da Criança e do Adolescente Fernandes Figueira (IFF) from April/2013 to April 2015 were included. Circumcision, placement of central venous catheter, percutaneous endoscopic gastrostomy, pleural drainage and excision of small cutaneous lesions were excluded. All surgeries were performed in the operating room, under general or epidural anesthesia. Complete 30 days surveillance was observed in 97% of surgical procedures.

IFF is a Brazilian public health tertiary maternal and children care center in Rio de Janeiro. The Department of Pediatric Surgery has 3 units: Neonatal Intensive Care Unit (NICU), Inpatient Unit(IPU), for more than 24h stay and Outpatient Unit(OPU), for less than 24h stay. Most surgeries requiring IPU were: fundoplication, urological, esophageal replacement, pull-through bowel procedures and thoracic surgery for bronchopulmonary malformations or pleural empyema.

Open and video-surgeries (videolaparoscopy and videothoracoscopy) were included.

The following variables were evaluated for the risk of SSI: sex, age (neonate ≤ 28d or non-neonate > 28d), wound class (clean, clean-contaminated, contaminated, dirty/infected), patient status (inpatient status (IP): postoperative stay ≥ 24h and outpatient status (OP): postoperative stay < 24h).

Centers for Disease Control and Prevention (CDC) criteria were used for SSI definition, wound classification and level of SSI (superficial incisional, deep incisional and organ/space).[5-7]

Patients were prospectively followed for 30 days. Surgical wound inspection and complementary exams, if necessary, were performed during hospital stay or outpatient visit, to confirm the diagnosis of SSI. For those not seen on 30^{th} day, a phone interview was conducted with their parents. They were specifically asked for signs of infection and purulent discharge. The diagnosis of SSI was established only if purulent discharge was informed.

Statistical Analysis

Univariate analysis was performed to describe the variables by mean, standard deviation and frequency of occurrence. The Odds Ratio (OR) was used to evaluate the association of the occurrence or not of SSI with exposition variables. Statistical significant differences were verified by Chi-square test. A multivariate logistic model was used to estimate the adjusted odds ratio of SSI. All analyzes were performed considering a confidence interval (CI) of 95% and a p-value of 5%. The data base was built EpiInfo 7 and statistical analyses was performed in SPSS version 20.

RESULTS

During the study period, 960 children underwent 1047 surgeries. Forty four were excluded from analysis: 13 patients died before 30^{th} post operative day (without SSI) and 31 were unfollowed. The total number of valid procedures was therefore 1003, on which the SSI rate was calculated and the possible risk factors analysed.

SSI occurred in 55 cases, overall SSI rate being (5.5%). Of those 35 (63.6%) SSI were diagnosed during hospital stay and 20 (36.4%) after discharge. SSI were more common in IP (92.7%) than in OP.

Among 604 operations performed in IP, 51 SSI (8.4%) occurred and 4 SSI in 399 OP (1.0%). Even excluding IP neonates, SSI rate is 6.5%, showing that patient status (IP/OP) alone is a risk factor.

Wound classification was a predictor of SSI. There were 13 SSI (2.5%) in clean wounds, 40 SSI (8.5%) in clean-contaminated, no infection in contaminated wounds and 2 SSI (12.5%) in dirty/infected wounds. SSI was not observed in contaminated wounds probably due to the small sample size.

Out of 55 SSI cases, 44 (78.6%) were Superficial Incisional Infection(SII), 1 (1.8%) Deep Incisional Infection (DII) and 10 (17.9%) Organ/Space Infection (OSI).

Majority of OSI were urinary tract infections(UTI) 8/10, the remaining were 1 mediastinitis with pneumonia and 1 pleural empyema.

In 680 male patients 37 SSI (5.4%) occurred and in 323 females, 18 SSI (5.6%).

Of 1003 operations, 189 (18.8%) were in newborns, with 25 SSI (13.2%). Infection rate in neonates was significantly higher than that of older patients (p-value < 0.001). In this group, of 93 gastroschisis closure, 17(18.2%) developed SSI. Even excluding gastroschisis, SSI occurred in 8/96 neonates (8.3%), nonetheless higher than in non neonates (3.7%).

Significant association for the occurrence of SSI was observed with age, wound class and patient status (In or Outpatient). There was no statistically significant difference for gender. (Table 1)

Table 1 - Analysis of patient factors related to surgical site infections using the chi-square test

Variables	Categories	SSI Yes (%) n=55	SSI No (%) n=948	p-value	OR (95%CI)
Gender	Male (680)	37 (5.4)	643 (94.6)	0.932	0.975 (0.546-1.1741)
	Female (323)	18 (5.6)	305 (94.4)		
Age	Neonate (189)	25 (13.2)	164 (86.8)	**0.000[a]**	**3.984 (2.283-6.952)**
	Non-neonate (814)	30 (3.7)	784 (96.3)		
Wound classification	Clean (505)	13 (2.6)	492 (97.4)	**0.000[a]**	-
	Clean-contaminated (470)	40 (8.5)	430 (91.5)		**3.516 (1.886-6.891)**
	Contaminated (12)	0 (0)	12 (100)		-
	Infected (16)	2 (12.5)	14 (87.5)		**5.407 (1.113-26.260)**
Level of SSI	Superficial incisional (44)	44 (80.0)			N/A
	Deep incisional (1)	1 (1.8)			
	Organ/space (10)	10 (18.2)			
Pacient status	OP (399)	4 (1.0)	395 (99.0)	**0.000[a]**	**0.110 (0.039-0.306)**
	IP (604)	51 (8.4)	553 (91.6)		

Pacient status (no-neonate)	OP(397)	3 (0.8)	394 (99.2)	**0.000[a]**	**0.110 (0.033-0.366)**
	IP(417)	27 (6.5)	390 (93.5)		

[a] Statistically significant ($p < 0.05$)

The multivariate logistic model for the occurrence of SSI identified a statistically significant association ($p<0.05$) for the patient status(IP/OP) and age of the patient (neonate or non-neonate).For these variables, the data indicates that IP and neonates have a higher probability of infection(OR of 5.58; 95%CI 1.68-18.57 and OR of 2.63; 95% CI 1.43-4.84, respectively (Table 2).

Table 2 - Analysis of risk factors for surgical site infection using a final multivariate logistic regression Model.

Variables	OR	95%CI	p-value
Gender			
Male	1.406	0.771 – 2.563	0.250
Female	-	-	-
Age			
Neonate	**2.631**	**1.430 – 4.839**	**0.002[a]**
Non-neonate	**-**	**-**	**-**
FO Classification			
Clean-contaminated	1.327	0.603 – 2.919	0.482
Infected	2.631	0.506 – 13.698	0.250
Clean	-	-	-
Access route			
Video	2.082	0.781 – 5.548	0.143
Open	-	-	-
Pacient status			
IP	**5.581**	**1.677 – 18.574**	**0.005[a]**
OP	**-**	**-**	**-**

[a] statistically significant ($p < 0.05$)

Postoperative surveillance has been conducted by nurses and physicians by means of active search, for 30 days after operation. A total of 55 SSI were diagnosed, 50 (91%) by wound inspection, 35 (63.6%) during hospital stay and 15 (27.3%) after discharge, during outpatient visit. Phone interview with parents detected 5 (9.0%) more cases of SSI. They were contacted by nurse or physician and informed purulent discharge from the wound in 4 cases and admission of their child to another hospital with UTI, after an urological surgery. Nine per cent of SSI would have been missed if we limited ourselves to spontaneous arrival of patients to the hospital (Table 3).

Table 3 - Analysis of SSI identification by clinical evaluation and active case search .

Information	SSI	
	Yes (%)	No (%)

Physician and nurse assessment	50 (91)	407 (43)
Phone interview	5 (9)	541 (57)
Total	55 (100)	948 (100)

DISCUSSION

We conducted a prospective study to establish the SSI rate in a cohort of 960 children subjected to 1047 surgical procedures, from Apr/2013 to Apr/2015. After exclusion of patients who died before the 30th postoperative day or were lost to follow up, 1003 valid surgeries remained, on which SSI rate was calculated and risk factors analyzed.

Active search on SSI was conducted prospectively until the 30th postoperative day by wound examination during hospital stay or outpatient visit, and phone call to parents. We could get information from 97% of patients.

The incidence of SSI in this study was 5.5%. Other studies reported SSI rates varying from 1.2% to 18.7%.[8,9] Brazilian studies have reported rates of 6.7% and 11.9%.[2,10] Comparison among different studies is difficult due to several factors: age of patients, case-mix, specialties included (cardio-vascular, urology, orthopedics, neurosurgery) and surveillance methods. There is divergence among surgeons on how operations are classified based on contamination.[7,11] Vu et al. reported a lack of consensus among Pediatric Surgeons in the classification of common neonatal surgeries, such as: omphalocele and gastroschisis closure, esophageal atresia repair and colostomy, were in varying proportions each, labeled as clean, clean-contaminated, contaminated.[7] Fundoplication without gastrostomy classified as clean-contaminated does not fulfill the requirement of CDC, because the gastro-intestinal tract is not opened.[12]

In our study, fundoplication was considered a clean procedure, except when gastrostomy was added (clean-contaminated). Gastroschisis and omphalocele were classified as clean-contaminated, regardless of the time elapsed between diagnosis and closure. Opening of the urinary tract, in presence of sterile urine, is classified as clean-contaminated, same classification of colon opening, despite the difference in contaminant potential. Therefore, until consensus is established among Pediatric Surgeons in assigning surgical wound classification, discrepancy on of wound class contamination will occur.

Our Infection rates increased according to wound class, except for contaminated wounds. Clean sites had a SSI rate of (2.6%), clean –contaminated (8.5%), contaminated (0%) and dirty/infected (12.5%). Probably the low incidence of SSI in contaminated wounds is explained by the small sample (n=12) in this class. An example how case mix may influence results: if 17 SSI in 93 gastroschisis were excluded, our SSI rate for clean-contaminated wounds, would drop from 8.5% to 3.4%. Other 2 studies revealed the incidence of SSI in all wound classes: Clean-0.5% and 2.8%, clean-contaminated-1.0% and 7.4%, contaminated-5.3 and 12.5% and dirty/infected-13.3% and 30.0%.[8,9] Proportion of newborns and of emergency procedures, antibiotic policies and surveillance method may explain these differences in SSI rates. In our study bivariate analysis showed statistical significance of SSI with wound class.

Most SSI were Incisional Superficial (80%), 1 deep incisional infection (DII) and 10 (18.2%) Organ/Space Infection (OSI). UTI were the most common OSI (8/10). Urological surgeries performed in dilated urinary tract, with urinary stasis and use of nephrostomies and stents may explain this high incidence of postoperative UTIs.

The overall infection rate of 5.4% in males and 5.6% in females were not statistically different in our cohort. Gender difference has not been reported as a risk factor for SSI.[13]

Neonates were more susceptible to SSI in our evaluation of risk factors. This is in agreement with Bucher et al. but not with Horwitz, who did not find a higher SSI rate in neonates.[4,12] Neonates contributed with 25 SSI (13.2%), in 189 surgical procedures, a lower rate than that of Davenport (16.6%).[13] This high rate is influenced by the 17 SSI that occurred in 93 gastroschisis of our series, corresponding to 68% of SSI in this age group. In agreement with Baird et al.[14] progressive abdominal wall hyperemia was considered a diagnostic criterion for SSI in this study, although not fulfilling the CDC criteria for SSI. In 2 other studies, gastroschisis displayed SSI rates of 12.6% and 32.3%.[14,15] So gastroschisis is a risk factor for SSI and this must be considered when evaluating this age group. The others SSI occurred in duodenal atresia (2), diaphragmatic hernia (2), anorectal anomaly (2), esophageal atresia (1) and inguinal hernia (1).

Our data showed that SSI rate (8.4%) in IP is higher than the SSI rate (1.0%) in OP. Most likely IP is a surrogate for complexity of surgical disease, duration of operation and comorbidities. The multivariate logistic model for the occurrence of SSI identified neonates and IP as risk factors for SSI.

This study has some limitations. Duration of operation and antibiotics administration, for instance, were not included as risk factors. Although some consider duration of operation a risk factor for SSI (9), in the study of Varik et al duration of operation did not prove significant in multivariate analysis.[16] Opinion about antibiotics use are also discordant. Porras Hernandez et al showed that antibiotic prophylaxis is a protective factor against SSI.[8] Horwitz et al, otherwise, demonstrated the absence of association between preoperative antibiotic administration and SSI.[4]

During the study period, 97% of patients were followed. Thirteen patients died before 30th postoperative day (without SSI) and 31 were unfollowed.

The specialized literature recommends 30 days of the follow-up with a rate above 80% for adequate surveillance of SSI.[17] The phone interview by nurses and physicians improved the identification of SSI cases. Five cases were identified by telephone information from parents. Therefore, 9% of SSI would be missed if there was no telephone contact until the 30th postoperative day. In 4 cases, purulent discharge was reported by parents, allowing the diagnosis of SSI. In these cases, there was spontaneous cure without intervention. In the 5th case, the parents reported that the child was hospitalized at another hospital with a urinary tract infection. Although diagnosis of SSI based on parents information is considered not so reliable as direct examination of the surgical wound, it has been used as an acceptable source for diagnosis.[4] These data demonstrate the importance of surveillance until the 30th postoperative day and the active search for obtaining reliable SSI rates. Nine per cent of SSI would have been missed if we limited ourselves to the spontaneous arrival of patients to the hospital.

The overall SSI rate was 5.5%. Neonates, wound class and inpatients were risk factors for SSI. Thirty days follow-up and active search are essential to guarantee reliable data for SSI rates. The knowledge of SSI rate and risk factors are tools for implementation of policies for antibiotics prophylaxis and lowering postoperative infections.

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