

Risk of surgical site infections following hip and knee arthroplasty: results of the ISChIA-GISIO study

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Parole chiave: Infezioni del Sito Chirurgico, Sorveglianza, Indice di Rischio di Infezione, Durata dell'intervento

Abstract

Background. Surgical Site Infection (SSI) is one of the major complications following insertion of hip or knee prosthesis. The aim of the present study was to describe rates of SSIs and associated risk factors during hip and knee prosthesis procedures in Italian hospitals.

Methods. Italian hospitals were invited to join the ISChIA (Surgical Site Infections in Arthroplasty Surgery) project and participated in the study on a voluntary basis. SSI surveillance was performed according to the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) -SSI protocol. The study population consisted of all patients who had a prosthetic knee or hip joint replacement between March 2010 and February 2011. Only elective operations were included.

Results. A total of 14 hospitals and 1285 surgical procedures were included. SSI cumulative incidence was 1.3 per 100 hip and 2.4 per 100 knee surgical procedures; a significant positive trend of SSI incidences was observed with increasing SSI risk index. In multivariate analysis, considering hip procedures, the single independent risk factor associated to SSI was operation length (RR: 4.54; 95%CI: 1.06-19.48). For knee procedures, no significant risk factor was identified.

Conclusions. In the present study, SSI cumulative incidence was in the range of European data. However, a larger number of operations is needed to better estimate SSI rates. A second edition of the ISChIA project has been already conducted and results of the two surveys will provide new insight to further our knowledge for infection control.

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Introduction

Surgical Site Infection (SSI) is one of the major complications following insertion of hip or knee prostheses. Known risk factors for SSI are related to the environment, the surgeon, and the patient. Some of these factors are amenable to intervention, other factors are intrinsic patient features and some of them cannot be modified (1-3). The number of hip and knee replacements has increased rapidly over the past ten years in most European countries, including Italy, and is expected to rise in the coming years (4). As such the risk of SSI represents a growing concern and prevention continues to be the focus of considerable public and academic debate.

In the framework of the multicenter project ISChIA (Surgical Site Infections in Arthroplasty Surgery), of the GISIO-SItI (Italian Study Group of Hospital Hygiene of the Italian Society of Hygiene, Preventive Medicine and Public Health), surveillance of SSIs in hip and knee prosthesis procedures in Italian hospitals has been conducted together with the evaluation of the level of compliance with the national guidelines of current practices of Perioperative Antibiotic Prophylaxis (PAP) (5) and the air microbial contamination in operating theatres (6, 7). The aim of the present study was to describe rates of SSIs and associated risk factors during hip and knee prosthesis procedures in the Italian hospitals participating in the ISChIA project.

Methods

SSI surveillance methodology

A patient-based prospective SSI active surveillance was performed, according to the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) - SSI protocol (8), in Operative Units (OUs) from Italian hospitals, that were invited to

join the ISChIA project. The OUs were not selected but participated in the study on a voluntary basis.

The study population consisted of all patients who had a prosthetic knee or hip joint replacement between March 2010 and February 2011. Only elective operations were included. All included patients were followed-up for 1 year after surgery. SSIs occurring within 1 year of surgery were defined according to standard criteria (8) and classified in superficial incisional, deep incisional, and organ-space SSIs.

In each OU, trained investigators were responsible for prospective data collection: they checked data quality (accuracy and precision) and completeness, and entered the data in three different electronic data forms that were designed, for web-based data collection, using SPSS Data Entry Enterprise Server (SPSS Inc.) at the LAPOSS (Laboratory for Planning, Experimentation and Analysis of Public Policies and Service for People), University of Catania, by means of a previously validated methodology of data collection (9). To comply with confidentiality, codes for hospitals, OUs, operating theatres, and patient identifiers were anonymous at the level of the central Committee.

OUs were classified, based on the surgical annual volume, using the median value of the distribution of the number of surgical procedures performed by OUs, as cut-off, in low-medium volume and high volume.

SSI Risk Index (RI), proposed by the National Healthcare Safety Network (NHSN) (10), based on American Society of Anesthesiology (ASA) score and duration of operation was used to assign surgical patients into categories. Wound contamination class was not included because all procedures were clean.

Indicators were computed, separately, for hip prosthesis and knee prosthesis procedures, as SSI rate (cumulative incidence), the number of SSIs per 100 procedures and as incidence

density, the number of SSIs per 1000 postoperative patient-days of follow-up.

Statistical analyses

Statistical analyses were performed using the SPSS 14.0 statistical package (SPSS Inc., Chicago, IL, USA). Descriptive analyses for categorical variables were based on percentages and frequencies, and for continuous variables on mean and standard deviation (SD), median and range. The main characteristics of patients underwent hip surgical procedures and of those underwent knee surgical procedures were compared using the χ^2 -test (categorical variables), and by Student's t-test (continuous variables). A $p < 0.05$ was considered significant.

In order to assess SSI-associated risk factors, patients with SSI were compared with patients without SSI. The factors included were: gender, age (above the 75th percentile of age distribution), length of hospital stay (above the 75th percentile of distribution), SSI RI (>0), use of cemented prosthesis, non-compliance to national guidelines for PAP, as previously reported (5, 6), and surgical OU annual volume. In a second analysis, SSI RI components were considered, i.e. the ASA score >2 and the duration of operation $> 75^{\text{th}}$ percentile of the NHSN distribution. To measure the association level, the Relative Risk (RR) and the corresponding 95% confidence interval (95%CI) were calculated. Furthermore, risk factors associated to SSI were evaluated using multiple logistic regression analysis with a backward stepwise process to control for potentially confounding variables and to obtain the adjusted RR with the respective 95%CI.

Results

Patient characteristics and surgical procedures

A total of 14 hospitals and 19 OUs participated in the surveillance: 9 teaching

hospitals, 2 general hospitals, 2 specialist hospitals and 1 Research Hospitals (IRCCS). The size of hospitals ranged from 100 to ≥ 900 beds (the majority of hospital had between 400 to 499 beds: 28.6%) and of OUs from 9 to 40 beds. The surgical OU annual volume varied from 31 to 699 (median 112) hip surgical procedures and from 9 to 474 (median 50.5) knee surgical procedures. Considering all procedures performed, the surgical OU annual volume varied from 74 to 1173 (median 158) surgical procedures.

A total of 1285 surgical procedures were included. The main characteristics of patients and of surgical procedures and comparison are listed in Table 1.

Surgical site infections

A total of 22 SSIs were identified (10 infections in hip surgical procedures and 12 in knee surgical procedures): 11 of the SSIs reported were superficial incisional, followed by 9 deep incisional and 2 organ-space SSIs.

SSI cumulative incidence was 1.3 per 100 hip (10/785) and 2.4 per 100 knee (12/500) surgical procedures ($p > 0.05$). SSI incidence density was 0.04 per 1000 of postoperative patient-days for hip procedures (10/283) and 0.07 per 1000 of postoperative patient-days for knee (12/179) surgical procedures ($p > 0.05$). In 36.4% of SSIs, no microbiological examination was performed; in 13.6% of SSIs microbiological examinations were negative (e.g. negative culture). Among the isolated microorganisms (13 microorganisms), coagulase-negative staphylococci were the most frequently reported (4), followed by *Staphylococcus aureus* and *Pseudomonas aeruginosa* (2, each).

Cumulative SSI incidences by surgical procedures and SSI RI are reported in Table 2. For hip procedures, a significant positive trend of cumulative SSI incidences was observed with increasing SSI RI.

SSI cumulative incidences were computed by operating theatres: the mean was 1.3

Table 1 - Main characteristics of patients and of surgical procedures

Characteristics	All surgical procedures	Hip prosthesis procedures	Knee prosthesis procedures	p-value*
Number of operations (%)	1285	785 (61.1)	500 (38.9)	
Type of operation (ICD-9-CM)				
- Total hip replacement (81.51)	605 (47.1%)			
- Total knee replacement (81.54)	480 (37.4%)			
- Partial hip replacement (81.52)	101 (7.9%)			
- Revision of hip replacement (81.53; 00.70 – 00.73)	79 (6.1%)			
- Revision of knee replacement (81.55; 00.80 – 00.84)	20 (1.6%)			
Mean age \pm SD (years) (<i>range</i>) [median value]	69.9 \pm 11.1 (21-98) [72]	69.2 \pm 12.7 (21- 98) [71.5]	71.0 \pm 7.8 (36- 85) [72]	0.001
Female (%)	66.1%	63.4%	70.5%	0.010
Total length of hospital stay (days)	14644	9675	4969	
Mean length of hospital stay \pm SD (days) (<i>range</i>)	12.2 \pm 7.6 (3-70)	13.1 \pm 8.1 (3-70)	10.9 \pm 6.2 (3-65)	<0.001
Total length of post-operative hospital stay (days)	11431	7376	4055	
Mean length of post-operative hospital stay \pm SD (days) (<i>range</i>)	9.5 \pm 6.1 (1-66)	9.9 \pm 6.4 (1-66)	8.9 \pm 5.5 (2-64)	0.003
Total length of post-operative follow-up (days)	463596	283971	179625	
Mean length of post-operative follow-up \pm SD (days) (<i>range</i>)	360.8 \pm 40.8 (7-366)	361.7 \pm 37.7 (7-366)	359.3 \pm 45.3 (14-366)	0.305
Mean operation length \pm SD (minutes) (<i>range</i>)	83.3 \pm 42.7 (13-500)	85.5 \pm 46.7 (500)	79.7 \pm 35.3 (13-240)	0.013
Type of prosthetic implant				<0.001
- metal- polyethylene	37.9%	32.3%	46.8%	
- metal-metal	32.7%	20.8%	51.6%	
- ceramic-ceramic	14.4%	23.4%	0.2%	
- ceramic- polyethylene	11.8%	18.6%	1.0%	
- other	3.2%	5.0%	0.4%	
Cemented prosthesis	46.4%	19.3%	89.7%	<0.001
ASA score				0.001
1	5.9%	7.1%	4.0%	
2	52.1%	46.3%	61.3%	
3	38.2%	41.2%	33.5%	
4	3.7%	5.3%	1.3%	
5	0.1%	0.1%	0	
≥ 3	42.0%	46.6%	34.7%	<0.001
Surgical Site Infection Risk Index				<0.001
0				
1	52.1%	57.6%	59.4%	
2	42.4%	45.4%	37.6%	
3	5.4%	7.0%	5.4%	
	0.0%	0.0%	0.0%	
Patient status at hospital discharge (alive)	99.3%	98.9%	100%	0.029

* Comparison between hip and knee prosthesis procedures; statistically significant p-values ($p < 0.05$) are indicated in bold font

Table 2 - Cumulative SSI incidences by surgical procedures and SSI Risk Index

Risk Index	Cumulative incidence (<i>per</i> 100 surgical procedures)		
	All (SSI/procedures)	Surgical procedure	
		Hip* (SSI/procedures)	Knee (SSI/procedures)
0	0.8 (5/632)	0.6 (2/354)	1.1 (3/278)
1	2.1 (11/514)	1.5 (5/338)	3.4 (6/176)
2	4.5 (3/66)	5.8 (3/52)	0 (0/14)

SSI: Surgical Site Infection

* $p=0.009$

(median 0; range 0-10.5) for 100 hip surgical procedures and 2.3 (median 0; range 0-17.7) for 100 knee surgical procedures.

Risk factors analysis

For risk factors analysis, data were separately considered for knee and hip surgical procedures and subsequently as combined data. The results are shown in Table 3. In univariate analysis, for hip procedures, only operation length (>75th percentile) was identified as a significant risk factor. For knee procedures no significant risk factor was identified. When considering all surgical procedures performed, only the SSI RI >0 and ASA score >2 were significantly associated with SSI risk.

The single independent risk factor associated with SSI in a multivariate analysis (model A, see Table 3), considering hip procedures, was the SSI RI >0 (RR: 5.05; 1.01-25.25). Furthermore, when SSI RI components were considered, i.e. the ASA score >2 and the duration of operation > 75th percentile of the NHSN distribution (wound contamination class was not included because all procedures were clean) the single independent risk factor associated with SSI was the operation length (RR: 4.54; 1.06-19.48) (model B, see Table 3). For knee procedures, no significant risk factor was identified in multivariate analysis. Considering all surgical procedures performed, the independent risk factor associated with SSI was the SSI RI >0 (RR: 3.55; 95%CI: 1.21-10.40) and

among its components the ASA score >2 (RR: 3.29; 95%CI: 1.18-9.18).

Discussion

In the present study, SSI cumulative incidence was in the range of European data (11). However, comparisons across countries are complicated due to incompleteness of case reporting, differences in definitions and in post-discharge surveillance (11, 12). The SSI cumulative incidences varied considerably among operating theatres. SSI rates should be used to target activities for which there is evidence that infection control procedures could be improved. Particular attention should be directed toward those hospitals with high SSI rates but also toward hospitals that report low SSI rates that may indicate either an excellent performance or, conversely, an inadequate surveillance method and a low sensitivity of case finding (12).

PAP contributes to the reduction of the associated SSI risk and an overall inadequate compliance with PAP recommendations has been reported (5, 13), underlining the need to develop and to implement successful strategies to improve adherence to guidelines. In our study, compliance with national guidelines for PAP did not lead to lower SSI, as it has been recently reported elsewhere (14). Thus, other factors are associated with the development of SSI and although PAP is a foundational strategy to prevent infections,

Table 3 - Univariate and Multivariate Analyses of SSI Risk Factors

Risk factors	Number of SSI per 100 procedures		Univariate analysis	Multivariate analysis	
	With risk factor	Without risk factor	<i>p</i> -value*	RR (95%CI)*	
				Model A ^o	Model B [§]
Hip Surgical Procedures					
Gender, male	1.4	1.2	0.823	1.26 (0.34-4.71)	1.31 (0.35-4.95)
Age > 75th percentile (>78 years)	1.1	1.3	0.781	0.54 (0.10-3.00)	0.71 (0.12-4.14)
Length of hospital stay above the 75th percentile (>15 days)	1.1	1.4	0.720	0.49 (0.09-2.56)	0.47 (0.09-2.51)
SSI RI (>0)	2.1	0.6	0.079	5.05 (1.01-25.25)	-
ASA score (>2)	2.0	0.7	0.135	-	3.16 (0.74-13.47)
Operation length (>75 th percentile)	4.2	0.9	0.008	-	4.54 (1.06-19.48)
Non-compliance to national guidelines	1.4	1.2	0.855	1.53 (0.41-5.78)	1.88 (0.47-7.50)
Use of cemented prosthesis	1.4	1.3	0.955	1.07 (0.19-6.11)	0.87 (0.15-5.12)
Annual volume of surgical procedures (low-medium)	1.5	1.2	0.729	1.69 (0.46-6.23)	1.33 (0.33-5.33)
Knee Surgical Procedures					
Gender, male	2.8	2.4	0.769	1.60 (0.36-7.05)	1.72 (0.37-7.89)
Age > 75th percentile (>77 years)	1.2	2.7	0.429	0.63 (0.07-5.45)	0.43 (0.05-4.05)
Length of hospital stay above the 75th percentile (>12 days)	2.7	2.4	0.861	2.18 (0.37-12.97)	3.43 (0.59-19.97)
SSI RI (>0)	3.2	1.1	0.108	2.68 (0.59-12.08)	-
ASA score (>2)	3.6	1.3	0.090	-	0.00 (0.00)
Operation length (>75 th percentile)	0	2.5	0.308	-	3.74 (0.83-16.80)
Non-compliance to national guidelines	2.3	2.7	0.793	1.16 (0.27-5.00)	0.97 (0.23-4.16)
Use of cemented prosthesis	2.4	4.2	0.466	0.68 (0.08-6.23)	0.37 (0.04-3.54)
Annual volume of surgical procedures (low-medium)	1.1	2.8	0.341	0.00 (0.00)	0.00 (0.00)
All procedures					
Gender, male	1.9	1.7	0.805	1.29 (0.48-3.44)	1.32 (0.49-3.51)
Age > 75th percentile (>78 years)	1.1	1.9	0.391	0.53 (0.15-1.90)	0.52 (0.14-1.94)
Length of hospital stay above the 75 th percentile (>15 days)	1.6	1.8	0.775	0.78 (0.24-2.55)	0.79 (0.24-2.63)
SSI RI (>0)	2.4	0.8	0.023	3.55 (1.21-10.40)	-
ASA score (>2)	2.5	1.0	0.036	-	3.29 (1.18-9.18)
Operation length (>75 th percentile)	2.9	1.5	0.225	-	1.95 (0.60-6.37)
Non-compliance to national guidelines	1.8	1.7	0.858	1.28 (0.48-3.43)	1.36 (0.50-3.68)
Use of cemented prosthesis	2.1	1.5	0.439	1.14 (0.43-3.00)	1.12 (0.43-2.97)
Annual volume of surgical procedures (low-medium)	2.0	1.7	0.809	0.87 (0.24-3.21)	0.91 (0.25-3.36)

SSI: Surgical Site Infection

Statistically significant *p*-values (*p*<0.05) and RR (95%CI) are indicated in bold font.^oModel A: adjusted for all variables including the SSI RI[§]Model B: adjusted for all variables including ASA score >2 and operation length > 75th percentile of the NHSN distribution

other preventive strategies must be evaluated and implemented.

The SSI RI proposed by the NHSN is a combined surgery-related assessment tool developed to identify high-risk patients, and to evaluate the risk of SSI (15). SSI RI appears to be optimal for identification of patients who are at risk of infection after arthroplasty. In fact, for hip procedures, a significant positive trend of cumulative SSI incidences was observed with increasing SSI RI and, after multivariate analysis, considering all surgical procedures performed, the single independent risk factor associated with SSI was the SSI RI > 0 that treble the risk of infection controlling for potentially confounding variables. Interestingly, when ASA score and operation length were included in the multivariate analysis, the single independent risk factor associated with SSI, considering all procedures was the ASA > 2, that is the only marker of intrinsic risk in the index, which accounts for variation in the patients' underlying severity of illness. Notably, for hip procedures, the single independent risk factor associated with SSI was the operation length. Within the conceptual framework of the SSI RI proposed by the NHSN, an operation lasting longer than a certain threshold is regarded as an indicator of a complicated surgical situation for a specific patient, although it has been suggested that the duration of an operation could also relate to the coordination and efficiency of the support staff in the operating theatre (16, 17), the management, the experience and skills of the surgeons, as well as a number of other factors. Recently, it has been reported that the operation length was better predicted by hospital-based factors than by patient-based factors (17).

Our study has some limitations and particularly, other SSI risk factors, not included in the protocol, should be considered in the analysis and although diabetes mellitus, malignancy, and corticosteroid use are included in the ASA score, separate reporting of these

known risk factors might have rendered risk assessment more precise. Furthermore, other risk factors that are not included in the ASA classification and shown to be relevant in other studies, e.g. obesity, should be also considered. In addition, one of the main limits is the number of surgical procedures available for analysis that is relatively small and vary considerably among hospitals that were heterogeneous in terms of "size", i. e. annual surgical procedure volume. One solution is to accumulate data over time until the number of operations is sufficient to provide a reasonably precise estimate of the SSI rate and of the role of risk factors (12). A second edition of the ISChIA project has been already conducted in the period 2013-2015 and results of the two surveys will provide new insight to further our knowledge for infection control. Finally, it will be worthwhile to investigate microbiological findings in order to define specific patterns in this particular healthcare setting, also highlighting the role of multidrug resistant organisms and emerging pathogens using molecular epidemiology methods as it has been shown for different patient groups (18-24).

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Riassunto

Rischio di Infezioni del Sito Chirurgico in interventi di artroprotesi di anca e ginocchio: risultati dello studio ISChIA-GISIO

Introduzione. Le Infezioni del Sito Chirurgico (ISC) costituiscono una delle principali complicanze in interventi ortopedici con impianto di protesi d'anca e di ginocchio. L'obiettivo dello studio è stato quello di descrivere la frequenza di ISC e i fattori di rischio associati, in interventi di protesi d'anca e di ginocchio eseguiti in ospedali italiani.

Metodi. Gli ospedali sono stati invitati a partecipare al progetto (Infezioni del Sito Chirurgico in Interventi di Artroprotesi). La sorveglianza delle ISC è stata eseguita utilizzando il protocollo dell'*Hospitals in Europe Link for Infection Control through Surveillance* (HELICS) - SSI. La popolazione in studio è consistita in tutti i pazienti sottoposti ad interventi di protesi d'anca e di ginocchio durante il periodo compreso tra marzo 2010 e febbraio 2011. Solo gli interventi in elezione sono stati inclusi.

Risultati. Sono stati inclusi 14 ospedali e 1285 interventi chirurgici. L'incidenza cumulativa di ISC è risultata pari a 1,3 per 100 interventi su anca e 2,4 per 100 interventi su ginocchio; è stato rilevato un significativo trend positivo tra l'incidenza di ISC e l'indice di rischio di infezione. All'analisi multivariata, considerando gli interventi su anca, la durata dell'intervento è risultata significativamente associata al rischio di ISC (RR: 4,54; 95%CI: 1,06-19,48). Per gli interventi su ginocchio non sono stati rilevati fattori di rischio significativi.

Conclusioni. Nel presente studio l'incidenza cumulativa di ISC è nel range dei dati europei. Tuttavia, è necessario un più ampio numero di interventi chirurgici per stimare meglio la frequenza di ISC. La seconda edizione del progetto ISChIA si è già conclusa ed i risultati delle due indagini forniranno una visione approfondita per il controllo delle infezioni.

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