

FULL PAPERS

Surgical site infection after caesarean section: space for post-discharge surveillance improvements and reliable comparisons

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SUMMARY

Surgical site infections (SSI) after caesarean section (CS) represent a substantial health system concern. Surveying SSI has been associated with a reduction in SSI incidence. We report the findings of three (2008, 2011 and 2013) regional active SSI surveillances after CS in community hospital of the Latium region determining the incidence of SSI. Each CS was surveyed for SSI occurrence by trained staff up to 30 post-operative days, and association of SSI with relevant characteristics was assessed using binomial logistic regression.

A total of 3,685 CS were included in the study. A complete 30 day post-operation follow-up was achieved in over 94% of procedures. Overall 145 SSI were observed (3.9% cumulative incidence) of which 131 (90.3%) were superficial and 14 (9.7%) complex (deep or organ/space) SSI; overall 129 SSI (of which 89.9% superficial) were diagnosed post-discharge. Only higher NNIS score was significantly associated with SSI occurrence in the regression analysis.

Our work provides the first regional data on CS-associated SSI incidence, highlighting the need for a post-discharge surveillance which should assure 30 days post-operation to not miss data on complex SSI, as well as being less labour intensive.

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INTRODUCTION

Cesarean section (CS) is one of the most frequent surgical procedures worldwide carried out in an estimated proportion of deliveries greater than 20% ranging to almost 40% in Italy (Souza *et al.*, 2013; Gibbons *et al.*, 2012; Mackeen *et al.*, 2014). Surgical site infection (SSI), the most common healthcare-associated infection (HAI) among surgical patients, is an important complication of CS. A multicenter study conducted in the UK reported that 9.6% of women undergoing CS developed a SSI (Wloch *et al.*, 2012).

Therefore, SSI after CS may be a non-negligible burden on the Italian health system, Italy being among the European countries with the highest overall CS rate, accounting for 38% of all deliveries (Euro Peristat, 2010).

Programs surveying SSI have been associated with a reduction in SSI incidence in a range of interventions (Marchi *et al.*, 2014; Rioux *et al.*, 2007; Gastmeier *et al.*, 2009). However, there is still no international agreement on the preferred method of surveillance. Due to the short length of post-operative hospital stay following most CS, SSI oc-

curing mainly post-discharge could remain undetected by surveillance systems which fail to attain the usually recommended 30 day post-intervention follow-up with a consistent loss of observation (Moro *et al.*, 2008; Marchi *et al.*, 2010-2011; Grilli *et al.*, 2012-2013; Ward *et al.*, 2008; Koek *et al.*, 2015).

We report the findings of three surveillances including post-discharge follow-up, conducted in the Latium Region, to determine the incidence of CS-associated SSI.

MATERIALS AND METHODS

In 2008 (April to June), 2011 (April to June), and 2013 (March to May), as Regional Center for Healthcare Associated Infections, we coordinated three surveillances on SSI incidence after CS in community hospitals of the Latium Region, Central Italy. The surveillances were conducted in accordance with a protocol based on the Hospitals in Europe Link for Infection Control through Surveillance (HELICS) project (ECDC, 2012a), and following the Centers for Diseases Control and Prevention/National Nosocomial Infections Surveillance (NNIS) methodology (Horan *et al.*, 2008; CDC, 2015).

Participation was voluntary, and 21 centers were enrolled in at least one of the three surveillances. The staff conducting the survey in each participating center attended a training course before the start of each surveillance.

All consecutive CS, both performed in emergency or elec-

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tive surgery during the study period, were included. A set of demographic and clinical data, as well as the characteristics of surgical procedures and data on peri-operative antibiotic use, was collected. Each CS was surveyed to assess the SSI occurrence up to 30 post-operative days. Diagnosis of SSI was defined, according to CDC/NNIS, as superficial incisional, deep incisional or organ/space SSI. Deep incisional and organ/space were further classified as complex SSI. Moreover, SSI were divided as during admission (i.e. during the hospital stay) or post-discharge SSI. During admission surveillance was performed by direct examination of patients' wounds during daily visits or daily chart review before discharge after the surgical procedure; post-discharge surveillance was performed by direct examination of patients' wounds during the planned ambulatory surgical visits, chart review of ambulatory visit or, for consenting patients, through telephone interview conducted by trained staff using a standardized questionnaire. Data were collected using a modified version of the HELICS-Win software (Wilson *et al.*, 2007) provided to each center.

Statistical analysis

The statistical analysis was performed using SPSS version 22 (SPSS Inc., Chicago, IL, USA) and STATA version 13 (Stata Corp LP, College Station, TX, USA).

χ^2 test (or Fisher's exact test when applicable) or Mann Whitney non-parametric test were used to compare groups

for categorical or continuous variables respectively. The cumulative incidence (i.e. the crude percentage of surgical procedures resulting in a SSI) with its 95% confidence intervals, (CI) was used to express the risk of SSI.

Association of SSI with relevant characteristics was assessed using binomial logistic regression and expressed with relative risk (RR) and their respective 95% CI. Variables included in the analysis were year of surveillance, age, National Nosocomial Infections Surveillance (NNIS) risk-index score (CDC, 2015), pre-surgery stay, type of intervention, and peri-operative antibiotic use.

RESULTS

A total of 3,685 CS were included in the study (1,185 in 2008, 535 in 2011 and 1,965 in 2013) (Table 1).

Overall post-operative follow-up added up to a total of 105,794 person-days, of which in-hospital stay accounted for 15,399, with a median of 3.5 days (IQR: 3.5-4.5). A complete 30 day follow-up was achieved in over 94% of procedures, with a mean length of observation of 28.7 days.

Peri-operative antibiotic administration was performed in 3,462 surgical operations (93.9%). Of 2,292 procedures performed in 2011 and 2013, 53.1% of antibiotics were administered at umbilical cord clamping, while 35% within 1 hour before skin incision (data not available for 2008 surveillance study).

Table 1 - Characteristics of 3,685 caesarean sections surveyed.

		N.	%
Total			3,685
Median Patient Age (IQR)			34 (30-37)
Year of surveillance	2008	1,185	32.2
	2011	535	14.5
	2013	1,965	53.3
Type of intervention	Election	1,903	51.7
	Emergency	1,772	48.1
	NA	10	0.3
Wound class	Clean/clean contaminated	3,557	96.6
	Contaminated/Dirty	99	2.7
	NA	29	0.8
ASA score	1-2	3,062	83.1
	3-5	155	4.1
	NA	468	12.7
Duration of the procedure >75th percentile	No	3,183	86.4
	Yes	498	13.5
	NA	4	0.1
NNIS risk-index score	0	2,564	70.0
	1	606	16.5
	2	28	0.8
	NA	468	12.7
Pre-surgery stay (days)	0-1	3,113	84.3
	2+	572	15.5

ASA: American Society Anesthesiologists; NA: Not available; NNIS: National Nosocomial Infections Surveillance; IQR: Interquartile Range.

Table 2 - Distribution of surgical site infection cases among 3,685 caesarean sections surveyed.

Year	N.	SSI (%)	In-Hospital/ Post-discharge*	Superficial/Complex#
2008	1,185	29 (2.4)	1/28	19/10
2011	535	22 (4.1)	1/21	21/1
2013	1,965	94 (4.8)	14/80	91/3
Total	3,685	145 (3.9)	16/129	131/14

*SSI occurred during original hospital admission (In-Hospital) or post-discharge. #Complex SSI include deep and organ-space infections.

Table 3 - Analysis of risk factors associated with SSI after caesarean section.

		Tot (N=3,685)	SSI (N=145)	RR* (95% CI)
Year of surveillance	2008	1,185	29	0.66 (0.38-1.16)
	2011	535	22	Ref.
	2013	1,965	94	1.28 (0.79-2.06)
Age (yrs)	By 5 years increase			1.06 (0.93-1.22)
NNIS risk-index score	0	2,564	86	Ref.
	1-2	634	43	2.06 (1.43-2.97)
	NA	487	16	0.96 (0.56-1.63)
Pre-surgery stay (days)	0-1	3,113	116	Ref.
	2+	572	29	1.33 (0.90-1.99)
Type of intervention	Election	1,903	74	Ref.
	Emergency	1,772	70	1.01 (0.73-1.39)
	NA	10	1	2.18 (0.35-13.57)
Antibiotic use	No	199	12	Ref.
	Yes	3,462	132	0.75 (0.42-1.33)
	NA	24	1	0.77 (0.10-5.83)

RR: Relative Risk; CI: Confidence Intervals; NNIS: National Nosocomial Infections Surveillance; NA: Not available. *Model adjusted for all variables included in the table.

A total of 145 SSI were observed, with a cumulative incidence of 3.9% (95% CI: 3.3-4.6); 131 (90.3%) were superficial incisional, while 14 were complex (6 deep and 8 organ/space) (Table 2). Overall, diagnosis of SSI was ascertained at a median time of 9.5 days after CS (IQR: 6.5-11.5).

A trend of increasing SSI risk was observed through surveillance periods with a cumulative incidence ranging from 2.4% in 2008, to 4.1% in 2011 and 4.8% in 2013. However, when considering the complex SSI, the cumulative incidence decreased over time from 0.8% in 2008 to 0.2% in 2011 and 2013, while the cumulative incidence for superficial SSI increased from 1.6% in 2008 up to 3.9% and 4.6% in 2011 and 2013 respectively.

Sixteen SSI (11.0%) were detected during admission (0.4% cumulative incidence): all but one were superficial SSI, while only one was an organ/space SSI. Of the 129 post-discharge SSI, 116 (89.9%) were superficial, and 13 complex (6 deep and 7 organ/space) (Table 2).

No difference in post-operative hospital length of stay was reported for patients who developed SSI during admission vs post-discharge (p=0.664).

In the binomial logistic regression analysis the only variable resulting significantly (p<0.05) associated with SSI occurrence was increasing NNIS score 1-2 (vs 0 score,

RR=2.06, 95% CI: 1.43-2.96). Peri-operative antibiotic use was associated, al Puro though not significantly, with a diminished SSI risk (Table 3). Timing of antibiotic use, at clamping or at skin incision, was not associated with SSI risk (data not shown).

DISCUSSION

Even if limited by voluntary participation and performed in relatively brief periods, our work provides the first regional data on CS-associated SSI incidence, monitoring approximately 10% of overall CS procedures performed in the study period in the Latium Region (ASP-Lazio, 2011). This is a first step in the challenge of harmonization of regional SSI surveillance and control activities, through the data reporting for aggregation into a single regional database, according to a common protocol.

Our data show a SSI incidence higher than those from the national surveillance, collected in the same years (2.45% vs 1.90% in 2008, 4.11% vs 2.58% in 2011 and 4.78% vs 1.75% in 2013) (Moro *et al.*, 2008; Marchi *et al.*, 2010-2011; Grilli *et al.*, 2012-2013). Similar findings can be observed when comparing our results with the European surveillance performed in 2008 and 2011 (3.58% and 2.98%, re-

spectively) (ECDC 2012b; ECDC 2013). Nevertheless when considering only SSI diagnosed during admission, our regional incidence was lower than national estimates in the first two surveillances (0.08% vs 0.34% in 2008 and 0.19% vs 0.28% in 2011) while higher in 2013 study (0.71% vs 0.34%) (Moro *et al.*, 2008; Marchi *et al.*, 2010-2011; Grilli *et al.*, 2012-2013). Conversely, post-discharge SSI cumulative incidence was constantly higher than national estimates, almost tripling in the last surveillance (2.36% vs 1.54% in 2008; 3.93% vs 2.28% in 2011 and 4.07% vs 1.33% in 2013).

The national surveillance, as well as other similar studies, reports average and median length of surveillance extremely variable from 20 to 14 days, making it hard to have a clear and meaningful intercomparison (Moro *et al.*, 2008; Marchi *et al.*, 2010-2011; Grilli *et al.*, 2012-2013; Ward *et al.*, 2008). Although SSI incidence is reported at comparable rates, the observed differences may be partially still affected by the different follow-up performed, SSI incidence not being a linear function of time after intervention (Koek *et al.*, 2015). To allow comparison, a fixed duration of follow-up should thus be appropriate.

In our study, two results are noteworthy: the increasing trend of SSI cumulative incidence, and the proportion of post-discharge complex SSI. The inability to evaluate the presence of comorbidities, not considered in the shared protocol, associated with a higher risk of SSI precludes a proper risk factor assessment, but confirms the known association of increased NNIS score with SSI risk (Friedman *et al.*, 2007).

The increasing trend of SSI cumulative incidence has to be ascribed to superficial SSI, that accounted for almost all (96%) SSI observed in the last two surveillances, while, when considering only complex SSI, the incidence actually dropped from 0.84% in 2008 to 0.19% in 2011 and 0.15% in 2013. Although we cannot exclude in our Region a real worsening in the occurrence of superficial infections following CS, we believe that these findings are more likely due a better post-discharge detection capacity acquired through experience (11/21 centers participated at least two regional surveillances). Indeed, the post-discharge SSI were primarily superficial. Recently, it has even been proposed to exclude superficial SSI and/or SSI diagnosed out of healthcare setting from the surveillance, as the subjective, inconsistent and prone to error diagnosis of them, especially if patient self-assessed, leading to a wide variability of data reporting, and to their unreliability as a proxy of health system quality (Kao *et al.*, 2011; Ming *et al.*, 2012).

In our experience, the recommended 30 day post-discharge surveillance was also labour intensive (Koek *et al.*, 2015). However, since we were able to perform a recommended 30-day surveillance in the majority of cases, we were able to detect almost all complex SSI (13/14) in post-discharge. Due to the usually short hospitalization after caesarean delivery, shorter follow-up limited to the hospital admission would have missed these infections.

Complex SSI are likely to require medical care in the healthcare setting, in which adherence to standardized surveillance methods is more easily attained. Thus, surveillance of complex SSI is more likely to be unaffected by underreporting if a complete 30 day follow-up is raised (Koek *et al.*, 2015) even when a "passive" approach is applied. Løwer *et al.* reported that at least after hip arthroplasty, an active surveillance within 30 days followed by a

passive surveillance relying on data on hospital readmission up to 90 days post-intervention can replace full-active 90 days surveillance without reducing sensitivity (Løwer *et al.*, 2015).

We therefore highlight the need for approaches alternative to traditional surveillance methods which should assure 30 days post-operation discharge so as not to miss data on complex SSI, as well as being less labour intensive. Moreover, these approaches should keep data comparable.

Clinical data on complex SSI and antibiotic use should be readily available in electronic records implemented in healthcare systems (Ming *et al.*, 2012). Linking in an automated electronic surveillance system hospital admission ICD (International Classification of Diseases) codes with antibiotic administration (in-hospital and in out-patient settings) in the 30 days period after surgical procedures could be a useful proxy of SSI occurrence, warranting further evaluation.

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