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Evaluation of the effect of triclosan coated sutures in the prevention of surgical site infections in a Spanish hospital setting: A prospective, observational study

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SUMMARY

Background: Surgical site infections (SSIs) are one of the most frequently reported types of hospital-acquired infection and are associated with substantial clinical and economic burden.

Aim: To assess the incidence of SSIs and analyze contributing risk factors in a real-world Spanish hospital setting before and after the implementation of triclosan-coated sutures (TCS).

Methods: A prospective, observational study was conducted at Hospital Clínico Universitario de Santiago de Compostela, Spain. Enrolled patients underwent surgery in the following specialties: general surgery, urology, neurosurgery, gynaecology, and traumatology. The primary outcome of the study was SSI incidence, assessed at a 30-day follow-up. Secondary outcomes were length of hospital stay, and readmission, reintervention, and mortality rates, also at 30 days.

Findings: 5,081 patients were included in the study, of which 2,591 were treated using non-coated sutures (NCS) and 2,490 using TCS. After adjusting for potential confounders, TCS significantly reduced SSI rate by 36%, compared with NCS (odds ratio [OR]: 0.64; 95% confidence interval [CI]: 0.48—0.85; $P<0.003$). When stratified by wound classification, a statistically significant reduction in SSI incidence, in favour of TCS use, was observed for Class IV (dirty) wounds (35.6% versus 22.7% for NCS and TCS, respectively; OR: 0.53; 95% CI: 0.31—0.90).

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Conclusion: The use of TCS reduced SSI risk when compared with NCS. This reduction was significant for Class IV wounds, providing evidence that supports the use of TCS for this type of wound.

Introduction

Surgical site infections (SSIs) are one of the most frequently reported types of hospital-acquired infection (HAI), accounting for an estimated 20% of all HAIs globally, [1] and approximately 26.3% of all HAIs in Spain. [2] In the most recent Annual Epidemiological Report on Communicable Diseases in Europe, 10,149 SSIs were reported from 648,512 surgical procedures, with incidences ranging from 0.5—10.1%, depending on the type of procedure. [3] Consistent with this data, the incidence of SSIs in Spain is estimated to be 4.4%, across all surgical specialties. [2] SSIs result in prolonged hospital admission, higher rates of readmission and reintervention, increased morbidity and mortality, and a reduction in measures of quality of life (QoL). [4—6] As a consequence, SSIs result in increased healthcare costs and are associated with substantial economic burden. [4,6—8].

Sutures used for wound closure are a recognized source of SSIs, whereby the surface promotes microorganism adhesion and biofilm formation. [9—11] To avoid this, sutures can be coated with antibacterial substances such as triclosan, a broad-spectrum antimicrobial agent with activity against Gram-positive and Gram-negative bacteria, conventional surgical pathogens. [12] *In vitro* and *in vivo* studies have demonstrated the effectiveness of triclosan-coated sutures (TCS), including VICRYL® PLUS, MONOCRYL® PLUS, and PDS® PLUS, in addressing the known risk factors for SSI by inhibiting bacterial colonization of suture material. [12—15] Specifically, TCS exhibited significant and sustained efficacy against a range of bacteria, including meticillin-resistant strains. [12,14].

A recent systematic review and meta-analysis including 11,957 patients across 25 randomized controlled trials (RCTs), from multiple surgical specialties, concluded that TCS significantly reduce the risk of SSIs compared with non-coated sutures (NCS). [16] These results are consistent with a further 12 meta-analyses that have all shown TCS to reduce the incidence of SSIs by 24—39% compared with NCS. [17—28] TCS are now recommended for the purpose of reducing the risk of SSI by the Centers for Disease Control and Prevention (CDC), [29] the World Health Organization (WHO), [30] the American College of Surgeons and Surgical Infection Society (ACS/SIS), [31] and the National Institute for Health and Care Excellence (NICE). [32]

Despite this broad evidence base and strong recommendations, there is a lack of data which demonstrate the association between the use of TCS and SSI prevention under real-world settings in Spain. The aim of this study was to assess the incidence of SSIs in a real-world Spanish hospital setting before and after the implementation of TCS, analyze risk factors contributing to the risk of SSI and evaluate the effect of suture type on length of hospital stay (LOS), readmission, reintervention, and mortality.

Methods

Study design and patients

This prospective, observational study was conducted at the Complejo Hospitalario Universitario de Santiago, Santiago de Compostela, Spain; a level 3 hospital (higher level of complexity) with 1,395 beds, 35 operating rooms, and ∼40,000 surgical procedures performed per year.

All patients undergoing surgery between 1st May 2017 and 30th June 2018 — in the following surgical specialties: general surgery, urology, neurosurgery, gynaecology and traumatology — were enrolled in the study. Transplant patients were excluded. Conventional sutures, VICRYL® (polyglactin 910; polyglycolic acid), MONOCRYL® (poliglecaprone 25), and PDS® (polydioxanone; Ethicon GmbH, Norderstedt, Germany) were used for three months, from 1st May 2017 to 31st July 2017. After a washout period, antimicrobial TCS, VICRYL® PLUS (polyglactin 910; polyglycolic acid), MONOCRYL® PLUS (poliglecaprone 25), and PDS® PLUS (polydioxanone; Ethicon GmbH, Norderstedt, Germany) were used for three months from 1st April 2018 to 30th June 2018.

Surgical procedures

The surgical procedures included within each surgical specialty are listed in Supplementary Table I. The level of contamination for each surgical procedure was determined according to CDC criteria. [33]

Antibiotic prophylaxis

Antibiotic prophylaxis was administered as indicated in Supplementary Table I, between five and 60 minutes before anaesthetic induction depending on whether the surgery was urgent, and the antibiotic used. The latter was dependent on the procedure. In general, a single antibiotic dose was administered, except in cases which involved the placement of implants. In patients with normal kidney function, and in the event of prolonged surgery or if blood loss was considerable (>1—1.5 litres), an additional dose was administered 3—4 hours following the initial dose. In the case of renal failure, the dose or antibiotic was modified. If the patient had recently been administered immunosuppressants or antibiotic treatments, antibiotics that covered the possible presence of β-lactam resistant bacteria were utilized.

Wound closure

As this study comprised several specialties, it is difficult to specify the wound closure technique for all procedures. However, the same techniques were used in both the NCS and TCS groups, since the same surgeons performed the operations. In

general, median laparotomies were closed in a single layer using a looped PDS® suture, most often in one section though this depended on the length of the wound. Transverse incisions were, in general, closed in two layers, using a continuous looped PDS® suture. For subcutaneous tissue, either a continuous or an interrupted polyglycolic acid suture was used, depending on the length of the wound. PROLENE polypropylene suture was used for mesh fixation, and staples and PROLENE polypropylene suture were used for skin closure. Polyglactin was most often used for other closures. In some instances, poliglecaprone was used for intestinal anastomosis, due to personal preference. For neurosurgical procedures, TCS were used only at the muscle fascia and subcutaneous level and did not come into contact with neural structures.

Follow-up

An in-person, 30-day follow-up was performed for all patients by a healthcare professional from the relevant surgical specialty (e.g., general surgery, traumatology, urology, gynaecology or neurosurgery specialist) at an appropriate outpatient facility, to determine if an SSI had occurred; CDC criteria was followed to confirm the presence of an SSI. [33] Following readmission or reintervention, an additional in-person, 30-day follow-up was performed. Future incidences of SSI were additionally reviewed by patients' primary care physician. All data were recorded in patients' electronic medical records.

Outcomes

The primary outcome of the study was SSI incidence. Secondary outcomes included incidence of SSI stratified by surgical specialty and CDC wound classification; identification of risk factors associated with SSIs; LOS, readmission rate, reintervention rate, and mortality rate, stratified by suture type and SSI versus no SSI.

Statistical analysis

All statistical analyses were performed by Dynamic Science S.L, Madrid, Spain, using SPSS Statistics 22.0 (IBM, Armonk, NY).

Sample size was calculated using an estimation of the national SSI prevalence in Spain (~5.5%) when the study was initiated in 2016, [34] and an estimation of the reduction in SSI when using TCS, based on eight published meta-analyses (~33.3%). [17–21,24,27,28] Using an assumed α error of 0.05 and β error of 0.20, it was calculated using a two-sided test that a minimum of 1,844 patients in each arm would be needed to detect an absolute difference greater than 1.8%.

Kolmogorov tests were used to probe data distributions. T-tests were used for all continuous variables with normal distributions (parametric), Mann Whitney rank-sum tests (for unpaired data) for non-parametric data, and Chi-square tests to analyze all categorical variables. To assess the comparability of the two treatment arms, and address risk factors involved in SSI development other than suture type, a bivariate analysis was first conducted on all independent variables. Any variable with a statistically significant response (correlation with incidence of SSI), or very close to it ($P<0.20$), was considered a potential confounding factor. A multivariate logistic regression model, which considered the impact of all possible confounding factors identified in the bivariate analysis, was used to measure the adjusted effect of suture type on the development of SSI. The model was constructed using an automatic stepwise selection method, [35] and was performed for all bilateral cases. The hypothesis test used was two-tailed and a *P* value of less than 0.05 indicated statistical significance.

Table I
Clinical patient characteristics.

	Treatment group		
	Non-coated (n=2,591)	Triclosan-coated (n=2,490)	*P* value
Age, mean (SD)[a]	59.8 (18.4)	60.4 (16.9)	0.972
Males, % (n)[b]	44.4 (1,151)	41.2 (1,027)	**0.022**
Comorbidities, % (n)[b]			
Arterial hypertension	35.1 (910)	34.3 (854)	0.537
Diabetes mellitus	12.4 (320)	11.7 (292)	0.495
Smoker	10.4 (269)	8.7 (217)	**0.043**
Immunosuppressant treatment	5.2 (135)	5.2 (129)	0.962
Morbid obesity	5.6 (146)	3.3 (83)	**<0.001**
Chronic renal insufficiency	2.8 (73)	1.5 (38)	**0.002**
Bladder catheter	0.5 (12)	0.2 (6)	0.183

Bold in the P value column indicates an association.
[a] Mann-Whitney test.
[b] Chi-squared test. SD: standard deviation.

Ethics

Patient information was stored in a password-protected electronic database. All information stored in the registry was dissociated from the patient's identity. The protocol of the study was approved by the Research Ethics Committee of the SERGAS (Galician Health Service; approval number 2017/312).

Results

Clinical and intraoperative patient characteristics

A total of 5,081 patients were included in the study; 2,591 were treated using NCS and 2,490 were treated using TCS. Patients had a mean age (standard deviation) of 59.8 (18.4) and 60.4 (16.9) years, respectively. Baseline clinical and intraoperative patient characteristics are summarized in Table I and Table II, respectively. Statistically significant differences were seen for sex ($P=0.022$); smoking status ($P=0.043$); morbid obesity ($P<0.001$); chronic renal insufficiency ($P=0.002$); Class III wounds ($P=0.005$); and adequate antibiotic prophylaxis ($P<0.001$).

Risk of SSI

A statistically significant reduction in the risk of SSI was observed when using TCS, compared with NCS (odds ratio [OR]: 0.68 (95% confidence interval [CI]: 0.54–0.87). However, bivariate analysis of all independent variables found morbid obesity, CDC wound classification, American Society of Anesthesiologists (ASA) score, adequate antibiotic prophylaxis,

Table II
Surgical procedure characteristics.

	Treatment group		
	Non-coated (n=2,591)	Triclosan-coated (n=2,490)	*P* value
Type of surgery, % (n)[a]			
Inpatient	82.4 (2,134)	80.3 (1,999)	0.088
Outpatient major surgery	12.2 (317)	13.0 (324)	
Outpatient minor surgery	5.4 (140)	6.7 (167)	
ASA score, % (n)[a]			0.068
ASA 1	16.9 (397)	15.8 (345)	
ASA 2	48.7 (1,142)	51.6 (1,129)	
ASA 3	30.4 (712)	29.8 (652)	
ASA 4	4.0 (94)	2.9 (63)	
CDC wound classification, % (n)[a]			
Class I (clean)	60.1 (1,558)	61.6 (1,535)	0.281
Class II (clean-contaminated)	27.6 (716)	28.3 (705)	0.612
Class III (contaminated)	6.6 (171)	4.7 (118)	**0.005**
Class IV (dirty)	5.6 (146)	5.3 (132)	0.645
Class I vs others	60.1 (1,558)	61.6 (1,535)	0.269
Surgery Characteristics			
Mean surgery length, minutes (SD)[b]	101.3 (76.9)	104.9 (87.2)	0.644
Adequate antibiotic prophylaxis, % (n)[a]	75.4 (1,954)	70.3 (1,751)	**<0.001**
Elective surgery, % (n)[a]	86.8 (2,248)	87.3 (2,174)	0.562
Urgent surgery, % (n)[a]	13.2 (343)	12.7 (316)	0.562
Laparoscopic, % (n)[a]	14.4 (372)	13.7 (340)	0.471

Bold in the P value column indicates an association. Level of contamination classified using CDC criteria.
[a] Chi-squared test.
[b] Mann-Whitney test. ASA score: American Society of Anesthesiologists; CDC: Centers for Disease Control and Prevention; SD: standard deviation.

duration of surgery and open surgery to be possible confounding factors (Table III). Adjusting for these potential confounders, using a multivariate logistic regression model, resulted in an adjusted OR for SSI of 0.64 (95% CI: 0.48–0.85) in favour of TCS (Table IV).

Incidence of SSI

In the total study population, a statistically significant 36% reduction in the incidence of SSI was observed when using TCS, compared with NCS (7.2% versus 5.1%; *P*=0.001) (Figure 1A). Of the SSIs in the TCS group, 57.9%, 17.5% and 24.6% were superficial, deep and organ-space, respectively. Of the SSIs in the NCS group, 47.6%, 26.2% and 26.2% were superficial, deep and organ-space, respectively. When grouped by surgical specialty, SSI incidence was lower following closure with TCS than with NCS in all specialties except urology, and was statistically significantly lower in general surgery (*P*=0.004; Supplementary Figure 1A). When grouped by the CDC wound classification, the use of TCS was associated with a reduction in the incidence of SSIs: 25% for Class I (clean), 18% for Class II (clean-contaminated), 48% for Class III (contaminated), and – statistically significantly – 47% for Class IV (dirty) wounds (*P*=0.019) (Figure 1B). When grouped by elective versus urgent surgery, SSI incidence was lower in the TCS group than in the NCS group, and the difference reached statistical significance in the former (*P*=0.001; Supplementary Figure 1B).

OR estimates were similar to the adjusted overall OR of 0.64 and reached statistical significance for general surgery, Class IV wounds and elective surgery, though the study was not powered to identify significant differences between NCS and TCS within subgroups (Figure 2).

Table III
Bivariate analysis of independent variables to identify confounding factors.

Factor	*P* value	OR (95% CI)
Surgery length (minutes)	<0.001	1.002 (1.001–1.004)
Smoker (yes vs no)	**0.833**	1.042 (0.710–1.529)
ASA score	<0.001	
ASA: A2 (1)	0.078	1.488 (0.957–2.314)
ASA: A3 (2)	<0.001	2.367 (1.515–3.698)
ASA: A4 (3)	<0.001	4.674 (2.561–8.531)
Surgery (open vs laparoscopic)	0.013	1.637 (1.108–2.420)
CDC wound classification	<0.001	
Class II (clean-contaminated)	<0.001	1.689 (1.269–2.248)
Class III (contaminated)	<0.001	2.888 (1.885–4.425)
Class IV (dirty)	<0.001	10.834 (7.883–14.890)
Class I vs others	<0.001	2.864 (2.260–3.631)
Antibiotic prophylaxis (yes vs no)	0.028	1.362 (1.033–1.795)
Bladder catheter	**0.078**	3.066 (0.883–10.649)
Morbid obesity (yes vs no)	<0.001	2.537 (1.706–3.775)
Chronic renal failure (yes vs no)	**0.390**	1.354 (0.678–2.704)

Bold in the *P* value column indicates no association. ASA: American Society of Anesthesiologists; CDC: Centers for Disease Control and Prevention; CI: confidence interval; OR: odds ratio.

Table IV
Multivariate logistic regression analysis.

Factor	*P* value	OR (95% CI)
Suture type (TCS vs NCS)	0.003	0.641 (0.476–0.854)
Morbid obesity	0.126	1.612 (0.875–2.969)
Surgery (open vs laparoscopic)	0.015	1.984 (1.142–3.448)
Antibiotic prophylaxis (yes vs no)	0.108	0.722 (0.485–1.075)
CDC wound classification	<0.001	2.316 (1.657–3.236)
ASA score	<0.001	1.790 (1.323–2.422)
Surgery length (minutes)	0.002	1.651 (1.196–2.281)

ASA: American Society of Anesthesiologists; CDC: Centers for Disease Control and Prevention; CI: confidence interval; NCS: non-coated suture; OR: odds ratio; TCS: triclosan-coated suture.

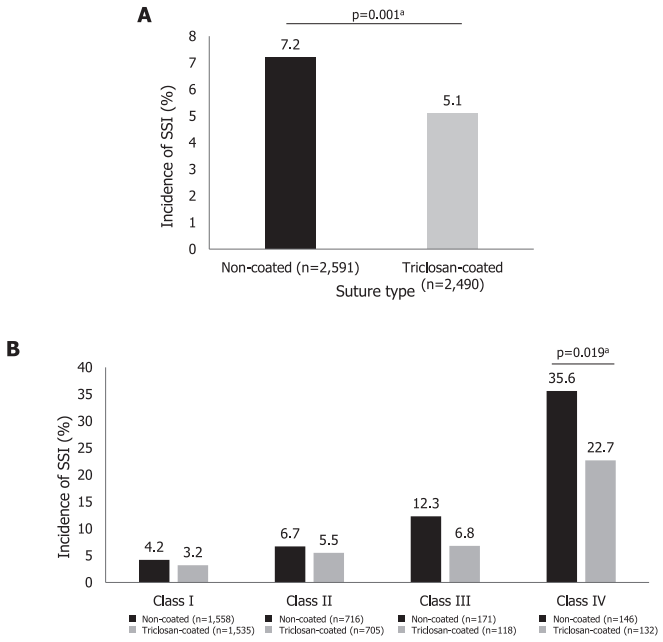

Figure 1. Incidence of surgical site infections (A) in the total population and (B) stratified by CDC wound classification. Level of contamination classified using CDC criteria.
[a]Chi-squared test. CDC: Centers for Disease Control and Prevention; SSI: surgical site infection.

SSI risk factors

Multivariate logistic regression analysis of SSI risk factors is summarized in Supplementary Table II. The use of NCS, compared with TCS, was found to increase the risk of SSI by 1.4 times (95% CI: 1.05—1.93). Every additional minute in surgery duration increases SSI risk by 1.002 times (95% CI: 1.000—1.003). Compared with patients with an ASA score of 1, patients with an ASA score of 3 have a 2.4 times higher risk of SSI (95% CI: 1.40—4.26) and patients with an ASA score of 4 have a 2.3 times higher risk of SSI (95% CI: 1.01—5.03). Open surgery increments 2.1 times SSI risk compared with laparoscopic surgeries (95% CI: 1.16—3.66). Class IV surgeries increase SSI risk by 19 times (95% CI: 11.49—31.76), compared with Class I surgeries, and Class III surgeries increase SSI risk by 2.2 times (95% CI: 1.15—4.42).

Secondary endpoints

No differences were observed between NCS and TCS for LOS (P=0.606), readmission rate (P=0.565), reintervention rate (P=0.418) and mortality rate (P=0.364). However, statistically significant differences were observed when comparing patients with and without an SSI. Median LOS was significantly longer for patients with an SSI versus those without (11.0 days [interquartile range (IQR): 5.0—27.8]). Compared with patients without an SSI, patients with SSI had significantly higher rates of readmission (1.6% vs 24.3%, respectively, P<0.001), reintervention (1.8% vs 25.9%, respectively, P<0.001), and mortality (1.2% vs 5.1%, respectively, P<0.001).

Discussion

SSIs account for an estimated 20% of all HAIs globally and are associated with substantial clinical, social and economic burden. [1,4—8] It is therefore important to adopt any available measure, including medical devices, to reduce the incidence of SSIs.

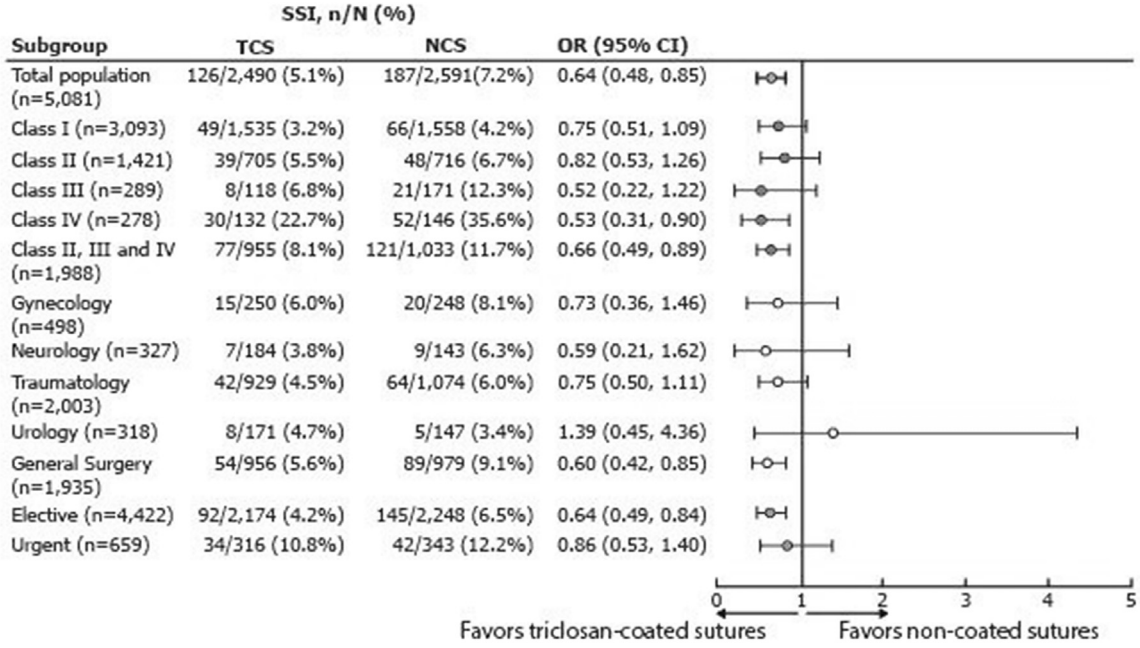

Figure 2. Subgroup analysis comparing triclosan coated sutures versus standard sutures on the risk of developing surgical site infections. Level of contamination classified using Center for Disease Control and Prevention criteria. CI: confidence interval; NCS: non-coated sutures; OR: odds ratio; SSI: surgical site infection; TCS: triclosan-coated sutures.

TCS have been demonstrated to exhibit efficacy against a range of bacteria and have been recommended for the purpose of reducing the risk of SSI by the CDC, WHO, ACS/SIS, and NICE. [29–32] Additionally, 13 pan-specialty meta-analyses have demonstrated an overall impact of using TCS, estimating a reduction in the risk of SSI of between 24% and 39% in favour of TCS use. [16–28].

In contrast to the evidence supporting the use of TCS, several studies have failed to demonstrate TCS-associated reductions in SSIs. A multi-centre RCT involving 485 patients undergoing colorectal surgery found no significant difference in SSI incidence between NCS and TCS (12.2% versus 12.2%, respectively), [36] while a more recent multi-centre RCT involving 281 patients undergoing colorectal surgery reported no change in the incidence of SSI with TCS use (10.6% for NCS versus 12.9% for TCS; P=0.564). [37] In addition to these RCTs, three meta-analyses have found no significant difference in SSI incidence between NCS and TCS. [38–40] These discrepancies may be a result of differences in study population, type of procedure, or the layers where the sutures were applied.

In our study, TCS reduced the SSI rate when compared with NCS; adjusting for potential confounding factors did not result in an OR change >10%, indicating that observed differences between treatment groups did not bias results, and confirming the efficacy of TCS in reducing the risk of SSI. [41] When patients were stratified by CDC wound classification, the use of TCS resulted in reductions in SSI risk ranging from 18–48%, compared with NCS. Although, this study was not powered to detect differences between subgroups, a statistically significant decrease in SSI incidence with TCS was observed for Class IV wounds, from 35.6% to 22.7% (OR: 0.53; 95% CI: 0.31–0.90; P=0.019). Moreover, statistically significant differences were observed when comparing Class I wounds with Class II, Class III and Class IV wounds combined; the use of TCS resulted in a reduction in SSI incidence from 11.7% to 8.1% (OR: 0.66; 95% CI: 0.49–0.89). For Class IV wounds, the results observed in this study are consistent with a number of other studies. A retrospective, randomized study reported a statistically significant reduction in SSI risk for abdominal fascial closure in patients with faecal peritonitis, in favour of TCS (risk ratio [RR]: 9.0; 95% CI: 3.1–26.4; P=0.003). [42] Similarly, in a randomized study of patients undergoing primary closure for pilonidal disease, a reduction in SSI incidence was observed upon implementation of TCS (20.8% for NCS versus 10.5% for TCS; P=0.044). [43] The results of an RCT involving 410 patients undergoing colorectal surgery also showed a statistically significant reduction in SSI incidence, in favour of TCS (9.3% for NCS versus 4.3% for TCS; P=0.047). [44] The use of TCS was also associated with reductions in SSI incidence for Class I, Class II and Class III wounds, though these were not statistically significant. When patients were stratified by surgical specialty, statistically significant differences were observed for general surgery; SSI incidence decreased from 9.1% to 5.6% (OR: 0.60; 95% CI: 0.42–0.85; P=0.004). Although statistical differences were not observed in other surgery specialties, clinically relevant trends favouring TCS were observed in all groups except urology. However, it should be noted that the sample size for urology was small (n=318), and of these patients only 13 were diagnosed with an SSI; additionally, a greater proportion of patients with an SSI had two or more comorbidities in the TCS group, compared with the NCS group (4/8 [50%] and 1/5 [20%], respectively). Therefore, these results should be interpreted with caution. Although statistically significant reductions in SSI incidence were observed for general surgery, Class IV wounds and elective surgery, this study was not powered to detect differences in subgroup analyses.

Several risk factors for SSI have been previously reported, including suture material used, ASA score, CDC wound classification, and surgery length, all of which were found to increase the risk of SSI in our study. [45,46] In an analysis of 6,919 patients undergoing elective surgery, smoking was demonstrated to have an OR of 1.51 (95% CI: 1.20–1.90); [47] while multiple studies have shown patients with chronic renal failure to be at an increased risk of SSI. [47–50] Though smoking and chronic renal failure have previously been shown to increase the risk of SSI, our bivariate analysis of all independent variables did not show a statistical difference for these two factors. To investigate why no statistically significant association was observed between these variables was beyond the scope of the present study. However, we suggest that this discrepancy may have been observed as a result of the study being run in a single centre, which may limit its generalizability.

A reduction in the risk of SSI with TCS, compared with NCS, was observed for urgent procedures, however, the effect was not as large as might be expected (Figure 2; OR: 0.86; 95% CI: 0.53–1.40) given that most Class IV wounds fall under this category. However, many procedures involving Class II wounds performed as part of this study were also classified as urgent. Therefore, the statistically significant reduction in SSI risk with TCS observed for Class IV wounds may have been offset by the relatively smaller reduction for Class II wounds (OR: 0.82; 95% CI: 0.53–1.26).

The present study has notable strengths. Foremost, as a real-world study, it permitted the analysis of a broader and more diverse distribution of patients, reflective of clinical practice, than would be practical in an RCT setting. [51,52] Further, as it was unicentric, potential variables such as surgeon experience, SSI prevention measures, and differences across operating rooms were the same in all time periods. In addition, patients were recruited from different surgical specialties, and with different characteristics, facilitating the study of a more representative population.

This study is associated with limitations. The study design was observational and so potentially carries the risk of intrinsic biases; nevertheless, several measures were taken to minimize these, such as outsourcing the statistical analyses to an external vendor. The percentage of patients administered adequate antibiotic prophylaxis was statistically significantly different between the two study groups, possibly biasing results in favour of non-coated sutures, though, antibiotic prophylaxis was used when necessary, as per international SSI prevention guidelines. [29] There was also a statistically significant difference in the percentage of Class III wounds between NCS and TCS groups, however, the same criteria were used to classify level of contamination for both groups. These differences reflect the real-world nature of the present study, with the resulting potential bias an inherent caveat of real-world studies. The potential time difference between the two study groups was not adjusted, however, both time periods were in the same season and included a similar number of procedures, conducted by the same surgical teams.

Conclusions

In this prospective study of five surgical specialties, the use of TCS was associated with a statistically significant reduction in the incidence of SSI when compared with NCS under real-world conditions. This reduction was significant for general surgery and Class IV wounds; therefore, TCS use is recommended in particular for these types of procedures.

Authors' contributions

all authors made substantial contributions to study conception and design, analysis and interpretation of the data, drafting the article or revising it critically for important intellectual content, final approval of the version of the article to be published.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Ethics

The study was approved by the Research Ethics Committee of the Santiago-Lugo.

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Conflict of interest statement

AGI, AFN, AF, ACP, CFB, LMGG, LPC and RDG declare conflict with other funding; MBM and MC declare conflict with expert testimony.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.infpip.2021.100154.

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