Spine

SPINE Volume 47, Number 8, pp 615–623

EPIDEMIOLOGY

Effect of the Implementation of a Surgical Care Bundle in the Incidence of Surgical Site Infection in Spine Surgery

A Quasi-Experimental Study

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Study Design. Quasi-experimental intervention study.

Objective. To assess the effect of a clinical safety and quality improvement plan for patients undergoing spinal fusion surgery on the incidence of surgical site infection (SSI).

Summary of Background Data. In recent years, infection surveillance and control programs based on care bundles have been included in surgical protocols. These have proven to be essential tools for the prevention and control of SSI, providing indicators for improvement and allowing the characterization of related risk factors.

Methods. A quasi-experimental study was carried out with analysis before and after the introduction of a preventive care bundle (clinical safety and quality improvement plan). Patients who underwent spinal fusion surgery were included. The incidence of SSI up to 90 days after surgery (maximum incubation period) was assessed. The effect of the intervention was evaluated with the adjusted odds ratio (oR) using a logistic regression model.

Results. A total of 1554 patients were included, 690 in the period 2007 to 2011 (before) and 864 during 2012 to 2018 (after). SSI incidence decreased from 4.2% to 1.9% after the plan (OR: 0.43; 95% confidence interval: 0.23–0.80; $P = 0.006$). There was also an improvement in the adequacy of antibiotic prophylaxis, preoperative preparation, and hair removal procedure after the introduction of the care bundle.

Conclusion. After implementation of the care bundle, the incidence of SSI in spine fusion surgery decreased significantly. Multivariate analysis showed that the care bundle was an independent protective factor. The implementation of these measures should be reinforced on the routine medical practice to reduce the SSI incidence.

Key words: antibiotic prophylaxis, centers for disease control and prevention, humans, incidence, infection control, non-randomized controlled trials, patient care bundles, preoperative care, spinal fusion, surgical wound infection.

Level of Evidence: 3

Spine 2022;47:615-623

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Acknowledgment date: March 27, 2020. First revision date: May 4, 2021. Acceptance date: July 29, 2021.

The manuscript submitted does not contain information about medical device(s)/drug(s).

The Mutua Madrileña Foundation (research project AP174532020) funds were received in support of this work.

No relevant financial activities outside the submitted work.

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DOI: 10.1097/BRS.0000000000004212

Healthcare-associated infections (HAIs) are an important public health problem and the most frequent adverse effect from a patient safety standpoint worldwide.[1] HAIs affect up to one-third of hospitalized patients, and surgical site infection (SSI)[2] is one of the most frequent of these, with an incidence ranging from 0.5% to 15%[3] of all surgically intervened patients.[1] SSI incidence in orthopedic and trauma-related interventions involving spinal fusion surgery is estimated at 1% to 10%. This complication entails an increase in patient morbidity and mortality, which in turn translates as an increase in mean stay, healthcare costs occasioned by readmissions and reinterventions, and is accompanied by a major reduction in quality of life.[4,5]

SSI incidence is a quality indicator of surgical practice, and it is estimated that 38% through 60% of SSIs could be prevented by implementation of preventive and control strategies which are associated with epidemiologic surveillance programs[6–8] and can be targeted at related risk factors.[3,4,9,10]

Infection surveillance and control programs have shown themselves to be both efficacious and cost-effective,[7,11] making it possible to measure the incidence of SSI and assess the effect of preventive measures, whether isolated or grouped into preventive care bundles. One of the main characteristics of care bundles is that multiple strategies yield significantly better results when implemented jointly than when applied independently.[12] Bearing in mind the impact of such SSI prevention measures, a care bundle was implemented in spinal fusion surgery (Clinical Quality & Safety Improvement Plan) at university teaching hospital in 2011. The aim of this study was thus to assess its effect on the incidence of SSIs.

MATERIAL AND METHODS

We conducted a quasi-experimental intervention study with before-and-after analysis, covering patients who underwent spinal fusion at the Department of Orthopaedics and Trauma of our institution. The surgical procedures evaluated are shown in Table 1. The surgical indications contemplated the diagnostic categories of lumbar disc disorder with/without myelopathy, spinal stenosis with/without neurogenic claudication, spondylolysis/spondylolisthesis, lumbar disc degeneration, cervical disc disorder, etc. according to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM). Patients were selected consecutively across the periods 2007 to 2011 (non-intervention or pre-intervention period) and 2012 to 2018 (intervention or post-intervention period). Any patient with suspicion or presence of infection at the time of surgery or undergoing antibiotic treatment was excluded.

The intervention was performed in 2011, during which, based on the evidence, the care bundle based in five components was implemented: (1) antibiotic administration adequacy; (2) 2% alcoholic chlorhexidine skin preparation; (3) hair removal replacement; (4) staff training on care bundle; and (5) screensavers with reminders of measures adopted, outlined in Table 2. Indeed, 2011 was included in the non-intervention period, since implementation was gradual and was not completed until the end of the year.

Sample size was calculated by reference to a 95% confidence level, a statistical power of 95%, an envisaged cumulative SSI incidence of 5% in the non-intervention group and 1.5% in the intervention group, and 5% of losses to follow-up. This led to a total of 1520 patients being considered necessary. The study was approved by the Hospital Research Ethics Committee (no. 16/91).

Patients were clinically followed up from date of admission prior to surgery until the end of the maximum incubation period of 90 days, in view of the fact that implant surgery was involved. The follow-up was conducted by reviewing the clinical course of patients' respective surgical wounds during their time of admission and their microbiological cultures. Following discharge, an active follow-up was conducted at scheduled medical visits to trauma clinics, emergency care rooms, and medical visits to primary care centers, in order to reduce risk of losses. For diagnosis of SSIs, we used the criteria applied by the Centers for Disease Control and Prevention (CDC).[13]

Data were collected on the following variables: sex; age; comorbidity (malnutrition, renal failure, coma, diabetes mellitus, neoplasm, chronic obstructive pulmonary disease [COPD], immunosuppression, cirrhosis, obesity, injection drug use, and neutropenia); mean hospital stay; preoperative preparation (2% chlorhexidine soapy antiseptic shower, antiseptic collutory with 0.12% chlorhexidine gluconate, and appropriateness of the hair removal of the surgical area); antibiotic prophylaxis (choice of antibiotic, dose, route, time of initiation, and duration) in accordance with the prevailing antibiotic guideline established by our hospital infections committee (cefazolin 2 gr IV, 30 minutes before induction of anesthesia); operative time; blood

TABLE 1. Surgical Procedures Included

Procedure Code	Description
03.09	Other exploration and decompression of spinal canal
81.00	Spinal fusion, not otherwise specified
81.01	Atlas-axis spinal fusion
81.02	Other cervical fusion of the anterior column, anterior technique
81.03	Other cervical fusion of the posterior column, posterior technique
81.04	Dorsal/dorsolumbar fusion, anterior technique
81.05	Dorsal/dorsolumbar fusion, posterior technique
81.06	Lumbar and lumbosacral fusion of the anterior column, anterior technique
81.07	Lumbar and lumbosacral fusion of the posterior column, posterior technique
81.08	Lumbar and lumbosacral fusion of the anterior column, posterior technique

ICD-9-CM indicates International Classification of Diseases, Ninth Revision, Clinical Modification.

TABLE 2. Measures of the Care Bundle Implemented

"Clinical Quality and Safety Improvement Plan".
1. Antibiotic prophylaxis adequacy and continuous follow-up: compliance with antibiotic prophylaxis was reinforced according to the guidelines established by the center's infectious disease committee (cefazolin 2 g IV, 30 minutes before induction of anesthesia).
2. Surgical field antisepsis with 2% alcoholic chlorhexidine: standard povidone iodine scrub and skin preparation was replaced by regular scrub with 2% alcoholic chlorhexidine.
3. Hair removal replacement: surgical field hair removal was implemented only when necessary. Razor blade use was replaced by electrical hair clipper use.
4. Staff training on care bundle: a training campaign was conducted through weekly 1-hour sessions for all surgical staff explaining the care package, which included reinforcement of compliance with World Health Organization hand hygiene recommendations.
5. Screensavers with reminders: screen savers reminding of the measures taken were automatically and periodically projected on all computers in the surgical departments.

transfusion; postsurgical drainage; anesthetic risk as per the American Society of Anesthesiologists (ASA) score (0-IV); degree of surgical contamination (I = clean wound, II = clean-contaminated, III = contaminated, or IV = dirty); laparoscopic intervention; presence of surgical wound infection (Yes/No); causative microorganism; and site of infection.

We designed an *ad hoc* data-collection sheet and a relational database standardized with the Microsoft Access program. A descriptive study of the sample was performed: the qualitative variables were described with their frequency distribution and compared with the Pearson χ^2 test, or with Fisher exact test where they did not meet the criteria of application; and the quantitative variables were described with mean and standard deviation (SD), or with the median and interquartile range (IQR) in the event of non-normal distributions. They were compared with the Student *t* test or the Mann–Whitney *U* test. Quantitative variables having more than two categories were compared using analysis of variance (ANOVA), or the Kruskal-Wallis nonparametric test in the event of non-normal distributions.

Cumulative SSI incidence was calculated, both overall and during the two periods, that is, pre- and post-intervention. Risk of surgical infection was stratified with the aid of the National Nosocomial Infections Surveillance System/National Healthcare Safety Network (NNIS/NHSN) index, comprising degree of surgical contamination, operative time greater than the 75th percentile, and ASA anesthetic risk score. The effect of the intervention on incidence of SSI was evaluated using the odds ratio (OR) and its confidence interval (CI), adjusted for the different covariates with a backward stepwise logistic regression model. All analyses were performed using the SPSS v.22 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp) and Epidat v.4.2. (Epidat: software for epidemiological data analysis, Version 4.2. Released 2016. Conselleria de Sanidade, Xunta de Galicia, Spain; Pan American Health Organization (PAHO-WHO); CES university, Colombia) software programs. Differences were considered statistically significant at $P < 0.05$, and all estimates were described with their 95% CI.

RESULTS

A total of 1554 patients were studied: 690 across the period 2007 to 2011 (pre-plan), and 864 across the period 2012 to 2018 (post-plan). The median age was 58.3 years (IQR: 24.0). Patient characteristics and the main study variables are shown in Table 3.

There were 45 infections, amounting to an overall SSI incidence of 2.9% (95% CI: 2.1–3.7%), with 48.9% being superficial and 51.1% deep infections. The most frequently implicated microorganisms were *Staphylococcus epidermidis* (24.4%) and methicillin-sensitive *Staphylococcus aureus* (20.0%). After implementation of the Plan, incidence of SSI decreased from 4.2% (n = 29) to 1.9% (n = 16) (OR: 0.43; 95% CI: 0.23–0.80; $P = 0.006$) (Figure 1). Incidence of SSI decreased steady during the study period ($P < 0.05$) (Figure 2). The number needed to treat in order to prevent an infection was 43 (95% CI: 24–165).

With respect to implementation of the various measures, there was a reduction from 17% to 9.1% in the percentage of patients requiring removal of hair after introduction of the improvement bundle ($P = 0.0001$). When it came to preoperative preparation, this was appropriately performed pre- and post-plan in 88.1% *versus* 96.6% of cases, respectively ($P = 0.0001$). In terms of antibiotic prophylaxis, an improvement was observed in pre- and post-plan adequacy of 71.8% *versus* 86.1% of cases, respectively ($P = 0.0001$). Inadequate timing of prophylaxis was the most frequent cause of inappropriateness of antibiotic prophylaxis in both periods.

The univariate analysis indicated the association between SSI and the preventive care bundle, age, presence of diabetes mellitus, COPD, degree of contamination of the surgery >II (contaminated or dirty surgery), operative time greater than the 75th percentile, and presenting with an NNIS risk index score of 1 or 2 (Table 4).

The multivariate analysis showed the following to be statistically significant: care bundle (OR: 0.50; 95% CI 0.26–0.94); age (OR: 1.03; 95% CI 1.01–1.05); presence of COPD (OR: 2.66; 95% CI 1.14–6.19); and presenting with an NNIS risk index score of 1 (OR: 2.11; 95% CI 1.10–4.02) or 2 (OR: 2.92; 95% CI 1.02–8.33) (Table 5).

TABLE 3. Patient's Characteristics Before and After Bundle in Spine Surgery

Risk Factors	Before N (%)	After N (%)	*P*-Value
Sex			
Male	313 (45.4)	403 (46.6)	0.615
Female	377 (54.6)	461 (53.4)	0.615
Mean age, yrs (SD)*	58.26 (24.0)	58.43 (24.1)	0.071
Comorbidity			
Renal failure	25 (3.6)	2 (0.2)	0.0001
Diabetes mellitus	83 (12.0)	85 (9.8)	0.167
Neoplasm	70 (10.1)	31 (3.6)	0.0001
COPD†	60 (8,7)	17 (2.0)	0.0001
Immunosuppression	4 (0.6)	3 (0.3)	0.707
Cirrhosis	4 (0.6)	20 (2.3)	0.006
PWID‡	2 (0.3)	0 (0.0)	0.197
Obesity	115 (16.7)	44 (5.1)	0.0001
Neutropenia	10 (1.4)	1 (0.1)	0.003
ASA§			
I	114 (16.5)	130 (15.0)	0.880
II	475 (68.8)	624 (72.2)	0.880
III	96 (13.9)	106 (12.3)	0.880
IV	5 (0.7)	4 (0.5)	0.880
V	0 (0)	0 (0)	–
VI	0 (0)	0 (0)	–
Surgical type			
Urgent	35 (5.1)	15 (1.7)	0.0001
Non-urgent	655 (94.9)	849 (98.3)	0.0001
Mean duration of surgery, min (SD)	125 (60.0)	115 (60.0)	0.0001
Degree of contamination			
I. Clean	677 (98.1)	859 (99.4)	0.017
II. Clean-contaminated	0 (0)	0 (0)	–
III. Contaminated	0 (0)	0 (0)	–
IV. Dirty	13 (1.9)	3 (0.3)	0.017
NNIS index¶			
0	422 (61.2)	617 (71.4)	0.0001
1	232 (33.6)	215 (24.9)	0.0001
2	36 (5.2)	32 (3.7)	0.0001
3	0 (0)	0 (0)	–

SD, standard deviation.
†*COPD, chronic obstructive pulmonary disease.*
‡*PWID, people who injected drugs.*
§*ASA, American Society of Anesthesiologists.*
¶*NNIS, National Nosocomial Infection Surveillance.*

DISCUSSION

Spinal fusion is a surgical procedure with a high risk of SSI,[14] which registers a higher infection rate than other orthopedic surgeries, such as total arthroplasty of hip or knee.[15] In our study, incidence of SSI after spinal fusion, across 12 years of follow-up, was 2.9%. These findings are in line with a recent meta-analysis in which incidence of SSI in spinal surgery was estimated at 3.1% (95% CI: 2.3–4.3%).[16] SSIs entail an increase in mean stay and healthcare costs, often being associated with a significant degree of morbidity and a reduction in the quality of life.[3,4,7,17,18] Hence, SSI incidence is a good indicator of improvement in healthcare quality and safety,[19] and accounts for the fact that actions grouped into preventive care bundles and targeted at preventing SSI, have not only achieved a significant decrease in incidence, but have also proved to be cost-effective.[11,20–25]

In Spain, previous experiences have provided evidence, both of 10.9% to 1.9% ($P < 0.05$) decrease in risk of SSI after application of a preventive care bundle in pediatric patients for heart surgery,[26] andofa27.5% to16.9% ($P = 0.03$) drop in SSI recorded by a similar study on colorectal surgery.[27] Furthermore, other international reviews have reported favorable results similar to those described.[28–32] Our study observed a reduction in SSI from

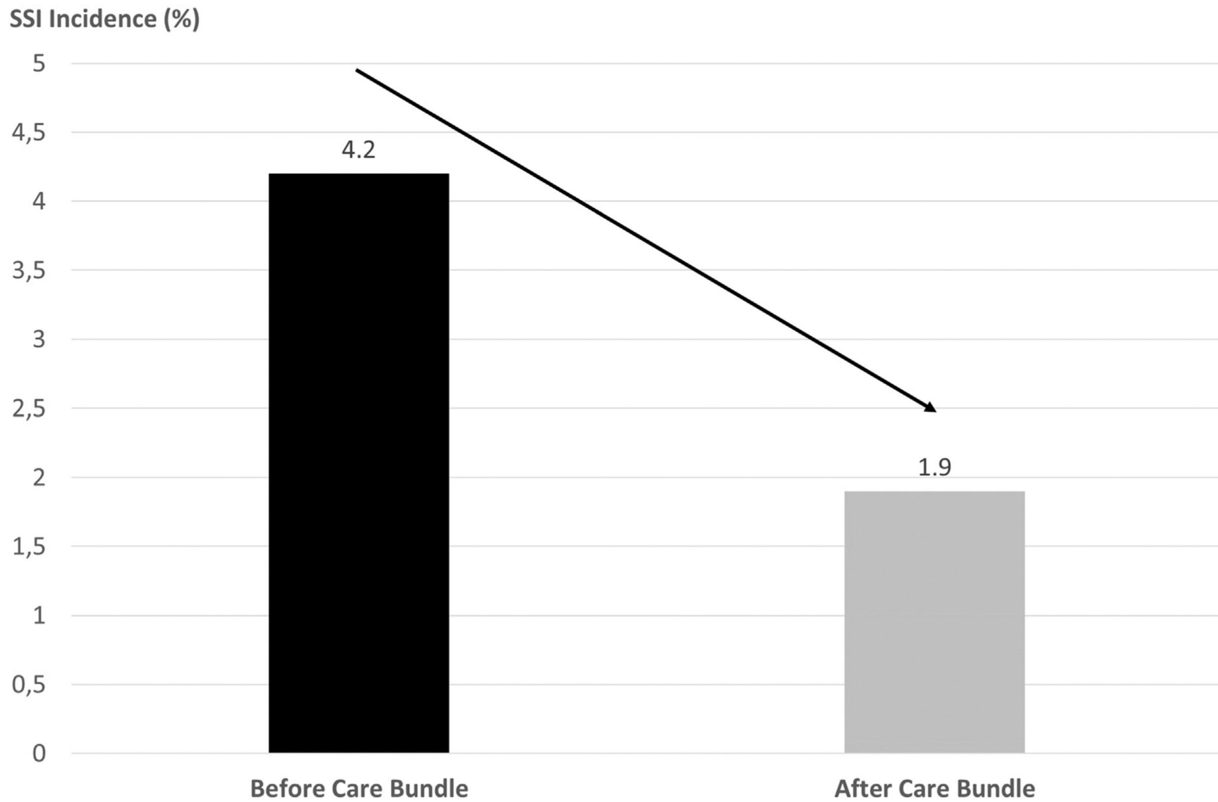

Figure 1. SSI incidence before and after implementation of the care bundle. SSI indicates surgical site infection.

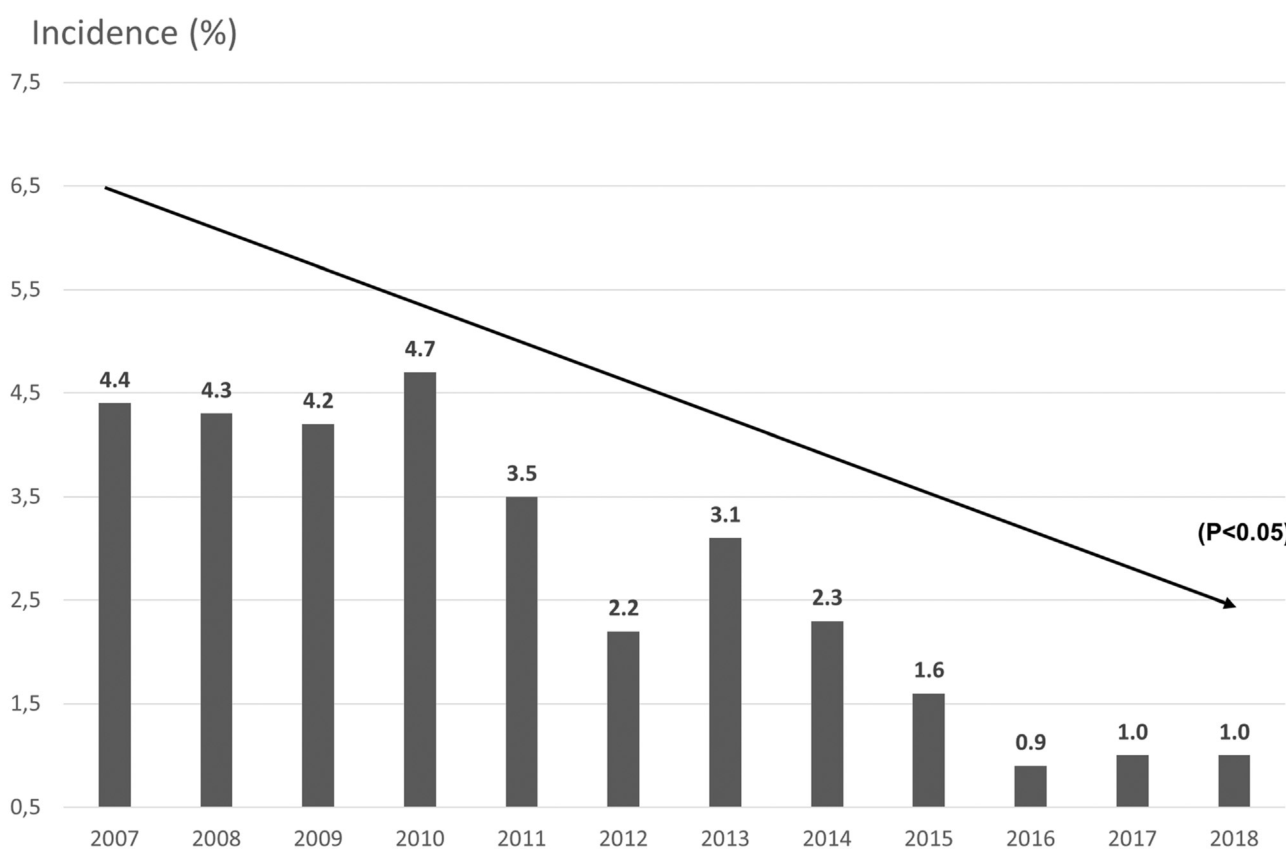

Figure 2. Evolution of SSI during the study period. SSI indicates surgical site infection.

TABLE 4. Univariate Analysis for SSI Risk Factors

Risk Factors	OR*	95% CI†	*P*-Value
Care bundle	0.43	0.23–0.80	0.006
Sex (female)	1.18	0.65–2.14	0.599
Renal failure	1.30	0.17–9.77	0.551
Diabetes mellitus	2.44	1.19–5.03	0.024
Neoplasm	2.29	0.95–5.54	0.067
COPD‡	4.51	2.03–10.06	0.001
Obesity	1.95	0.89–4.25	0.126
Hair removal	1.29	0.57–2.92	0.546
Inappropriate preoperative preparation	1.28	0.45–3.63	0.558
Inadequate antibiotic prophylaxis	0.96	0.44–2.09	0.909
Urgent surgery	2.22	0.67–7.43	0.174
Drains	1.35	0.32–5.66	0.999
Transfusion	0.88	0.12–6.55	0.999
ASA§ >2	1.62	0.77–3.40	0.202
Surgical contamination >II	11.23	3.51–35.91	0.0001
Duration of surgery >75th percentile	2.32	1.26–4.26	0.005
NNIS¶ 1	2.57	1.37–4.83	0.0001
NNIS¶ 2	4.02	1.46–11.10	0.0001

**OR, odds ratio.*
†CI, confidence interval.
‡COPD, chronic obstructive pulmonary disease.
§ASA, American Society of Anesthesiologists.
¶NNIS, National Nosocomial Infection Surveillance.

4.2% pre-plan to 1.9% post-plan, amounting to a reductionin risk of55% (95% CI: 19.5–75.8).

In this respect, reductions of around 50% to 90% in risk of SSI in spinal surgery have been described after implementation of different preventive care bundles, findings similar to those reported by our study.[25,33–36] The components of our Improvement Plan included measures to optimize antibiotic prophylaxis, appropriateness of patients' preoperative preparation, reinforcement of hand hygiene promotion, and the participation of members of the multidisciplinary group, so as to ensure prolonged maintenance over time of the measures implemented. A significant post-plan improvement ($P = 0.0001$) was seen in the variables affected by the care bundles implemented, similar to that reported by other studies.[5] Appropriateness of antibiotic prophylaxis went from 71.8% to 86.1%, with timing of administration being the most frequent cause of inappropriateness, a finding in line with those of other SSI studies conducted in Spain.[5,37] While there was a 17% to 9.1% reduction in hair removal, indicating heightened awareness of the need to remove hair only where this is essential,[8] appropriateness of preoperative preparation rose from 88.1% to 96.6%. The recent study by

TABLE 5. Multivariate Analysis for SSI Risk Factors

	OR*	95% CI†	*P*-Value
Care bundle	0.50	0.26–0.94	0.032
Age, yrs	1.03	1.01–1.05	0.021
COPD‡	2.66	1.14–6.19	0.023
NNIS§ 1	2.11	1.10–4.02	0.024
NNIS§ 2	2.92	1.02–8.33	0.045

**OR, odds ratio.*
†CI, confidence interval.
‡COPD, chronic obstructive pulmonary disease.
§NNIS, National Nosocomial Infection Surveillance.

Bagga *et al*,[33] showed how implementation of a similar care bundle, including preoperative bathing with chlorhexidine, hair removal with electric clippers, monitoring of antibiotic use, optimization of hand hygiene compliance, and intraoperative glycemic control, achieved reductions of 3.42% through 1.22% in SSI. For their part, Featherall *et al*,[25] supplemented preoperative bathing measures and compliance with antibiotic prophylaxis with a further six interventions which, among other things, included detection of *S. aureus* nasal colonization and nasal decolonization with mupirocin, along with use of vancomycin in the case of instrumented surgeries, achieving reductions in SSI of 4.12% to 2.0%.

Detection of methicillin-resistant *S. aureus* (MRSA) nasal colonization and decolonization, in tandem with other MRSA-infection prevention measures, made up the care bundle described by Yamada *et al*,[34] with which they managed to achieve a 3.8% to 0.7% reduction in SSI in instrumented surgeries. In our context, the most frequent microorganisms in SSIs were S. *epidermidis* (24.4%) and methicillin-sensitive *S. aureus* (20.0%), a finding similar to that described in the literature.[4,15,38] Presence of MRSA was found in only 2.2% of SSIs, in contrast with other studies on orthopedic surgery in which the former is present in up to 30% of SSIs.[6,16,34] It is possible that the low incidence of MRSA might be due to the characteristics of our patients, in that they did not present with advanced age, repeated hospitalizations, chronic wounds or an important morbidity and mortality burden, characteristics which are found in other studies,[6] and which favor previous MRSA colonization along with the development of SSIs associated with this microorganism.[9,10] In our case, the need to establish concrete MRSA control measures would not be relevant, thus highlighting the fact that the strategies to be incorporated into care bundles should be individualized according to the patients in whom and the context in which these are to be implemented.[12]

Additionally, our study evaluated other possible risk factors, both intrinsic and extrinsic to the patient. In the univariate analysis the following proved significant: the preventive care bundle; age; diabetes mellitus; COPD; degree of contamination of surgery more than II (contaminated or dirty surgery); operative time more than p75; and presenting with an NNIS risk index score more than or equal to 1. All these have already been described as protective factors, in the case of care bundles,[26–32] and as risk factors in all other respects.[5,10,38] It was decided that neither degree of contamination nor operative time would be included in the multivariate analysis because this would have amounted to a duplication of information, on their already being included in the NNIS index, with all factors proving significant except for presence of diabetes mellitus. Rather than diabetes *per se,* this may be more closely connected to the fact that, what really predisposes patients to suffer infections is poor glycemic control of the disease; but on not having access to the blood glucose levels of these patients, we have no way of confirming their baseline status for the purpose of establishing such an association. For its part, the NNIS lists a number of risk factors, highlighting the existence of other measures to be taken into account in order to achieve better results, even though these may not be included in the combined bundle.[12]

It is noteworthy that neither hair removal, preoperative preparation nor antibiotic prophylaxis proved to be significant individually, which goes to reinforce the idea that application of combined preventive care bundles is more effective than implementation of individual preventive measures.[7,11,12] It has even been mooted that, in itself, implementation of the various measures would not improve care, but that their joint adoption would lead to teamwork being redesigned, thereby improving communication and the effectiveness of efforts to achieve these goals.[12] Hence, the continuing education of health professionals may well be fundamental, ensuring both training and input with respect to any findings, and fostering their collaboration in the maintenance of preventive measures. In our case, a series of briefing sessions were held to inform the physicians responsible of the results, with the aim of enhancing compliance with these recommendations. One of the strengths of our study, as compared with previous studies,[25,33,34] is precisely its long follow-up period, with incorporation of data covering the 5 years before and 7 years after implementation, thus reinforcing the evidence of the long-term success of the measures adopted.

Despite the favorable results, the study's potential limitations must be borne in mind. Although its design ensures a high degree of scientific evidence in comparison with other observational studies, the non-randomization of patients hinders the establishment of a causal relationship between the care bundle's introduction and a reduction in SSI; even so, its implementation in the context of routine clinical practice makes it possible to provide a pragmatic view of the improvements achieved in patient care. Another possible limitation resides in not having been able to capture some of the SSIs in the postoperative period, which occurred in a non-hospital setting and might not have been recorded in the clinical history. This is extremely uncommon, however, and measures were established to minimize losses, including follow-up in primary care after hospital discharge, all of which leads us to think that the results were not affected in this respect. Other biases, such as those of selection and information, were addressed in the design through consecutive inclusion of all patients who underwent spinal fusion at the hospital, and the use of electronic clinical records to facilitate control. Insofar as the intervention is concerned, both the preoperative preparation performed by the nursing staff and/or nursing assistants in the different departments, as well as the antibiotic prophylaxis administered by operating theatre nursing staff, were conducted in accordance with the hospital's clinical quality & safety improvement plan and supervised by anesthesiologists, in a such way that none of them knew who would be evaluated, thereby ensuring that the Hawthorne effect was controlled for.

CONCLUSION

In our study, implementation of preventive care bundles significantly reduced incidence of SSI, while bringing about a parallel improvement in both the appropriateness of preoperative preparation and the adequacy of antibiotic prophylaxis.

Among the factors implicated in development of SSI in patients undergoing spinal fusion, the preventive care bundle was objectively identified as the sole protective factor, a finding that reinforces the importance of incorporating these types of measures in routine medical practice.

➢ Key Points

- ❑ The association of a surveillance system together with a preventive care bundle in our hospital proved to be a key element in the surveillance and control of surgical site infection.
- ❑ Factors found to be significantly related to the development of surgical site infection in patients undergoing spinal fusion surgery after multivariate analysis included the preventive care bundle, as a protective factor, and the presence of chronic obstructive pulmonary disease, older age, or a National Nosocomial Infection Surveillance surgical risk of 1 or 2, as risk factors.
- ❑ It is necessary to reinforce the knowledge of healthcare professionals on preventive measures in order to achieve adequate multidisciplinary action and implement strategies that consolidate the constant improvement of healthcare quality and patient safety.

Acknowledgments

The authors thank the Mutua Madrilena Foundation supporting the research project which enabled the completion of this study.

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