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Influence of Rescrubbing Before Laparotomy Closure on Abdominal Wound Infection After Colorectal Cancer Surgery

Results of a Multicenter Randomized Clinical Trial

Hector Ortiz, MD, PhD; Pedro Armendariz, MD, PhD; Esther Kreisler, MD, PhD; Eduardo Garcia-Granero, MD, PhD; Eloy Espin-Basany, MD, PhD; Jose V. Roig, MD; Adán Martín, MD; Alberto Parajo, MD; Graciela Valero, MD, PhD; Marta Martínez, MD; Sebastiano Biondo, MD, PhD

Objective: To test the hypothesis that strict asepsis in closing wounds following laparotomy reduces the risk for surgical wound infection in elective colorectal cancer surgery.

Design: Multicenter randomized clinical trial conducted from June 1, 2009, through June 1, 2010.

Settings: Colorectal surgery units of 9 Spanish hospitals.

Patients: A total of 969 patients who underwent elective colorectal cancer surgery were eligible for randomization. In closing the laparotomy wound, the patients were randomized to 2 groups: conventional (n=516) and new operation (n=453). In the conventional group, a new set of instruments was used, surgical staff changed their gloves, and the surgical drapes surrounding the laparotomy were covered by a new set of drapes. The new operation group involved removing all drapes, the surgical staff scrubbed again, and a new set of drapes and instruments was used.

Main Outcome Measures: Incisional (superficial and deep) surgical site infection 30 days after the operation and risk factors for postoperative wound infections.

Results: A total of 146 incisional surgical site infections (15.1%) were diagnosed. Of these, 96 (9.9%) were superficial and 50 (5.1%) were deep infections. On an intent-to-treat basis, significant differences were found between both groups (66 [12.8%] in the conventional group vs 80 [17.7%] in the new operation group [*P*=.04]).

Conclusion: This study does not support the use of rescrubbing to reduce the incidence of incisional surgical site infection.

Trial Registration: isrctn.org Identifier: ISRCTN19463413

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Author Affiliations are listed at the end of this article.

INCISIONAL SURGICAL SITE INFECTION (SSI) is the most frequent cause of postoperative morbidity after colorectal operations. It increases medical costs and prolongs hospital stay.[1,2] The incidence of this complication varies in the medical literature from 3% to 49%.[3-5]

There is level I evidence that thoughtful use of antibiotics,[6] hair removal with a clipper,[7] perioperative normothermia,[8] and mechanical bowel preparation in rectal surgery[9,10] reduce the rate of SSI. However, management policies of the laparotomy wound are not clearly established. The usefulness of several measures such as protection of the wound edges with sponges soaked with povidone iodine, plastic wound protectors, change of gloves, or the use of new instruments to close the wound is not well defined. On the other hand, there is a tendency to believe that operative factors such as strict asepsis would have a strong impact on SSI.[11]

The Spanish Society of Surgeons[12] performed a survey on the rates of SSI in a sample of 60 tertiary hospitals throughout Spain. US Centers for Disease Control and Prevention [13] criteria for defining SSI were used. In elective colorectal surgery, incisional SSI wound infection occurred in 19% of the patients (range, 16-23%). In our study, the procedures used to close the abdominal wound varied widely. However, some measures were used alone or in combination by some of the centers: a new set of instruments was used, surgeons and nurses changed their gloves, and the surgical drapes surrounding the laparotomy were covered by a new

set of drapes even though some centers considered the closure of the laparotomy wound as a new operation and the surgical staff thus scrubbed again.

Guidelines that provide comprehensive recommendations for detecting and preventing health care associated infections have been published.[14] Moreover, various imprecise recommendations have been suggested for the time of glove changing, ranging from 30 minutes to 180 minutes,[15] and there is no direct evidence that additional glove protection worn by the surgical team reduces SSIs in patients.[16]

To our knowledge, no comparative studies on 2 different policies just before the abdominal wound closure have been published.

Based on this variability, a task force was developed in the setting of the Spanish Rectal Cancer Project, launched by the Spanish Society of Surgeons in 2006[17] to standardize a policy of intraoperative wound management. It was hypothesized that a decreased fecal load in the surgical wound during the closure of the laparotomy would diminish the incidence of SSI. To prove this, a prospective, multicenter randomized trial was carried out to compare 2 policies of closure of the surgical wound in a sample of patients undergoing elective surgery for colon and rectal cancers.

The aim of our study was to determine the actual incidence of abdominal wound infection (superficial and deep) and SSI 30 days after the operation with these 2 policies. The secondary endpoint was identification of risk factors for developing incisional SSI.

METHODS

This was a multicenter randomized study. The trial was designed to identify the superiority of a policy of closure of the laparotomy wound in patients operated on electively for colon and rectal cancers, with a view to reducing the incidence of incisional SSI. This policy consisted of considering closure of the laparotomy wound as a new operation.

Eligibility criteria included all adults aged 18 years or older, colon and rectal cancers suitable for elective surgical treatment, and the obtainment of informed consent. Exclusion criteria were patients with nonresectable or recurrent tumors and patients in whom 1 of the following procedures was planned: multivisceral resection, placement of a mesh simultaneously for incisional hernia, and laparoscopic abdominoperineal resection.

The study took place in the colorectal units of 9 Spanish hospitals, 7 academic centers and 2 nonacademic hospitals, from June 1, 2009, through June 1, 2010. A population of 2 685 827 patients is attended in these 9 hospitals, and an estimated 1200 colon and rectal cancer operations are performed every year. All the participating surgeons were trained colorectal surgeons.

GENERAL PEROPERATIVE MEASURES

Mechanical bowel preparation with polyethylene glycol administered on the day before surgery was used exclusively in patients diagnosed with rectal cancer.[10] On the day of the operation, all patients had a shower with water and soap,[18] and hair removal with an electric clipper was performed where necessary.[7] The preoperating room policy, followed by all the surgeons involved in the study, included the following: skin was prepared with chlorhexidine scrub or betadine paint[19]; the edges of the laparotomy wound were covered with povidone iodine–soaked gauzes and plastic wound ring drapes; and perioperative normothermia was maintained. Also, antibiotic prophylaxis was administered as a single dose at the time of anesthetic induction and discontinued within 24 hours. The antibiotics used were based on the internal recommendations of each institution. Amoxicillin/clavulanic acid was used in 4 institutions, and cefotaxime sodium and metronidazole in 5 institutions. Gentamicin and metronidazole were used in patients with allergies to penicillin or cephalosporin in all centers. Redosing was applicable after 3 hours to keep adequate circulating levels particularly if there had been significant blood loss. Abdominal incisions were closed primarily in all cases using polydioxanone monofilament absorbable sutures for the fascia and staplers for the skin. The decision to use closed drainages in colon surgery was made by the operating surgeon. Closed drainages were recommended in rectal surgical procedures. When a loop ileostomy or an end colostomy was performed, the stoma was opened after the laparotomy was closed and covered with sterile dressing.

SPECIFIC MEASURES

In the conventional group, a new set of instruments was used to close the laparotomy, surgeons and nurses changed their gloves, and the surgical drapes surrounding the laparotomy were covered by a new set of drapes. In the new operation group, the drapes were removed, the laparotomy wound was covered with povidone iodine–soaked drapes, the nurses and surgeons scrubbed again, and a new set of drapes and instruments was used. All the participating surgeons were instructed to obtain uniformity in the 2 policies of management of the laparotomy wound.

DEPENDENT VARIABLES

The primary end point of the study was the incidence of incisional (superficial and deep) SSI occurring within 30 days of surgery as defined by the Centers for Disease Control and Prevention.[13] The criteria for superficial SSI were an infection that occurred at the incision site within 30 days after surgery involving only the skin and subcutaneous tissue and at least 1 of the following: purulent drainage from the incision; an organism isolated from a culture of fluid from the incision; incisional pain, tenderness, localized swelling, redness, or heat; and opening of the wound. The criteria for deep incisional SSI were an infection that occurred within 30 days after surgery involving the muscle and fascial layers and at least 1 of the following: purulent drainage from the deep incision, an incision that spontaneously dehisced, or an incision that was deliberately opened by the surgeon in the presence of the signs and symptoms of infection described previously. Infections involving both superficial and deep incision sites were classified as deep incisional. Moreover, organ/space SSI draining through the incision was reported as deep incisional SSI. The secondary end point was identification of the risk factors for developing incisional SSI.

SAMPLE SIZE

A previous study by the Quality Control Section of the Spanish Society of Surgeons estimated that 19% of all patients may experience incisional SSI after elective colorectal surgery. It was assumed that this percentage could be reduced by 50% if more strict antiseptic measures are applied. To detect a reduction in SSI with a 2-sided 5% significance level and a power of 80%,

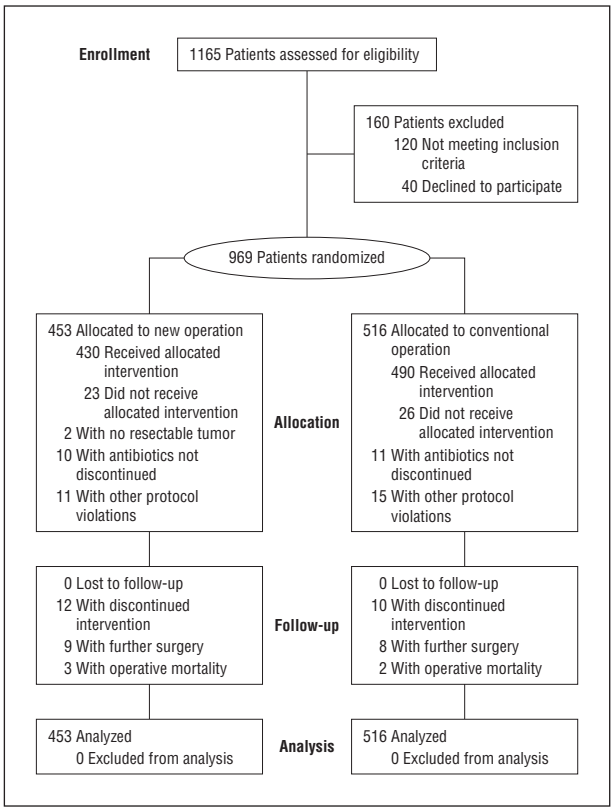

Figure. Trial flow diagram.

a sample size of 315 patients per group would be needed, given an anticipated dropout rate of 30%. To recruit this number of patients, a 12-month inclusion period was anticipated. Interim analyses were not planned.

RANDOMIZATION

Participants were randomly assigned following simple randomization procedures (computerized random numbers, one built up for each hospital) to the conventional or new operation treatment groups. The assignment was done centrally in an academic center, Virgen del Camino Hospital in Pamplona, Spain. To prevent subversion of the allocation sequence, the participating centers sent an e-mail to the central registry indicating the number of the hospital record of each patient.

Patients were blinded to the type of intervention. Wound surveillance was performed while the patient was in the hospital by a colorectal surgeon, who was blinded to the type of intervention and different from the operating surgeon, and the nurses of the epidemiology department of each institution. Postdischarge surveillance of SSI was carried out in the outpatient clinic by a dedicated, trained colorectal surgery nurse, and all patients were followed up for at least 30 days postoperatively.[20] When an infection was diagnosed, clinical decisions were left at the discretion of the operating surgeon.

Data were centrally registered using a database designed for this purpose. A data manager monitored the included data under the guidance of a steering committee. The participating centers sent the files online when patients had been followed up for 30 days. The observation of data confidentiality was assured.

INDEPENDENT VARIABLES

Patient age, body mass index (calculated as weight in kilograms divided by height in meters squared), and duration of the operation were evaluated as continuous variables. Dichotomized variables included sex, history of diabetes mellitus, preoperative corticosteroid use, location of the tumor (colon/rectum), preoperative irradiation, perioperative transfusion of cellular or plasma products, ostomy placement, and the use of drainages. The American Society of Anesthesiologists grade (I-IV) as determined by the anesthesiologist was considered a categorical variable.

The study was conducted in accordance with the principles of the Declaration of Helsinki (1975) and the Good Clinical Practice guidelines. The protocol was approved by the local ethics committees of Virgen del Camino Hospital and the participating centers. The trial was registered in the International Standard Randomised Controlled Trial Number Register (ISRCTN19463413). Prior to randomization, informed consent was obtained from all patients.

The article was drafted according to the Consolidated Standards of Reporting Trials statement 2010.[21]

STATISTICAL ANALYSIS

The continuous variables are presented as mean (standard deviation) or median (quartile 1/quartile 3). Categorical variables are presented as absolute numbers and percentages. Comparative analysis of proportions was performed by means of the χ^2 test. The *t* test, Mann-Whitney *U* test, or Kruskal-Wallis test was used to analyze continuous variables among categories. Differences and their 95% confidence intervals are presented.

The relationship between wound infection rate and treatment group with potential confounding variables was analyzed. Confounding variables with a marginal association ($P < .15$) were included in a logistic regression model and removed whether they failed to significantly change the likelihood of the model as well as the estimates of the remaining variables in the model. The linearity of the risk of continuous confounding variables was tested by nonparametric regression analysis (penalized smoothed spline regression).

P values were 2-tailed for all analyses, and $P < .05$ was considered statistically significant. Data were analyzed using the R statistical package version 2.11 (R Foundation for Statistical Computing).

RESULTS

Between June 1, 2009, and June 1, 2010, a total of 1165 patients were assessed for the study. Of these, 969 patients were randomized after confirming compliance with the inclusion/exclusion criteria. The flow diagram is presented in the **Figure**. A total of 516 patients were randomized to the conventional group and 453 to the new operation group.

The patient and tumor characteristics at baseline are reported in **Table 1**. Surgical characteristics and adverse surgical events are detailed in **Table 2**. There were no differences between the 2 groups except for a more frequent use of drains in the conventional operation group ($P = .04$).

Forty-nine patients (5.0%) did not undergo the allocation procedure. Two patients had nonresectable tumors; and in 21 operations, antibiotics were not discontinued because the surgeons considered that fecal spillage during the operation changed the wound classification from class II (clean contaminated) to class III (contaminated). Other protocol violations in the allocation phase

Table 1. Patient and Tumor Characteristics

	No. (%)			
	Total Patients (N = 969)	Conventional (n = 516)	New Operation (n = 453)	*P* Value
Age, mean (SD), y[a]	69.2 (11.5)	69.0 (11.5)	69.5 (11.5)	.51
Sex				
Female	414 (40.4)	212 (38.3)	202 (40.9)	.31
Male	555 (59.6)	342 (61.7)	291 (59.1)	
BMI, mean (SD)[a]	27.1 (4.2)	26.9 (4.16)	27.3 (4.3)	.19
ASA score				
1	79 (8.2)	51 (9.9)	28 (6.1)	.13
2	483 (49.8)	255 (49.5)	227 (50.2)	
3	375 (38.7)	193 (37.3)	183 (40.4)	
4	32 (3.3)	17 (3.3)	15 (3.3)	
ASA, grades III-IV	407 (42.0)	210 (40.7)	198 (43.7)	.35
Diabetes mellitus				
Positive	194 (20.0)	112 (21.8)	81 (17.9)	.16
Negative	775 (80.0)	404 (78.2)	372 (82.2)	
Corticosteroids				
Positive	65 (6.7)	40 (7.7)	25 (5.7)	.26
Negative	904 (93.3)	476 (92.3)	428 (94.3)	
Neoadjuvant treatment				
Positive	104 (10.7)	58 (11.2)	45 (10.0)	.57
Negative	865 (89.3)	458 (88.8)	408 (90.0)	
Location of the tumor				
Colon	593 (61.2)	302 (58.5)	290 (64.1)	.08
Rectum	376 (38.8)	214 (41.5)	163 (35.9)	
Tumor stage[b]	2.00 (2.00/3.00)	2.00 (1.00/3.00)	2.00 (2.00/3.00)	.34

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).
[a] Calculated using the Mann-Whitney *U* test.
[b] Median (quartile 1/quartile 3).

Table 2. Surgical Characteristics and Adverse Effects Related to Surgical Site Infections

	No. (%)			
	Total Patients (N = 969)	Conventional (n = 516)	New Operation (n = 453)	*P* Value
Type of operation				
Laparotomy	536 (55.3)	316 (57.0)	264 (53.5)	.43
Laparoscopy	383 (39.5)	213 (38.4)	200 (40.5)	
Converted laparoscopy	50 (5.2)	25 (4.6)	29 (5.9)	
Duration of operation, min[a]	180 (130/210)	180 (130/210)	180 (120/210)	.96
Blood transfusion				
Positive	139 (14.3)	76 (13.8)	74 (15.0)	.66
Negative	830 (85.7)	478 (86.2)	419 (85.0)	
Ostomy formation				
Positive	295 (30.5)	172 (31.1)	146 (29.7)	.70
Negative	674 (69.5)	382 (68.9)	347 (70.3)	
Drainage				
Positive	530 (54.7)	320 (57.8)	252 (51.2)	.04
Negative	439 (45.3)	234 (42.2)	241 (48.9)	
Anastomotic leakage				
Positive	30 (3.1)	17 (3.1)	15 (3.1)	.86
Negative	939 (96.9)	537 (96.9)	478 (96.9)	
Organ/space infection				
Positive	65 (6.7)	31 (5.6)	39 (7.9)	.19
Negative	904 (93.3)	523 (94.4)	454 (92.1)	

[a] Median (quartile 1/quartile 3).

were detected in 26 patients. At follow-up, further surgery was required in 17 patients, and 5 patients died in the postoperative period.

On an intent-to-treat basis, all 969 patients were included in the analysis. A total of 146 incisional SSIs (15.1%) were identified (**Table 3**). Of these, superfi-

Table 3. Incisional SSI in Both Patient Groups

	No. (%)				
	Total Patients (N = 969)	Conventional (n = 516)	New Operation (n = 453)	*P* Value	Conventional–New Operation, Difference (95% CI)
Overall infection					
No infection	823 (84.9)	450 (87.2)	373 (82.3)	.07	
Superficial	96 (9.9)	46 (8.9)	50 (11.1)	.30	–2.16 (–5.69 to 1.63)
Deep SSI	22 (2.3)	11 (2.1)	11 (2.4)	.87	–0.31 (–2.19 to 1.58)
Organ/space SSI draining through the incision	28 (2.9)	9 (1.7)	19 (4.2)	.03	–2.46 (–4.63 to –0.30)
Overall deep SSI	50 (5.2)	20 (3.9)	30 (6.64)	.91	–2.77 (–5.60 to 0.06)
Overall incisional SSI	146 (15.1)	66 (12.8)	80 (17.7)	.04	–4.93 (–9.48 to –0.39)

Abbreviation: SSI, surgical site infection.

Table 4. Univariate Analysis of Patient and Surgical Characteristics and Incisional SSI

	No. (%)			
	No Infection	Overall SSIs	*P* Value	OR (95% CI)
New operation group	373 (45.2)	80 (54.8)	.04	1.47 (1.03-2.09)
Age	68.9 (11.5)	72.1 (9.9)	.001	1.03 (1.01-1.04)
Sex			.24	
Female	361 (41.8)	53 (36.3)		0.79 (0.55-1.14)
BMI	27.0 (4.1)	27.8 (4.5)	.07	1.04 (1.00-1.09)
ASA score[a]				
1	69 (8.4)	9 (6.2)		1 [Reference]
2	424 (51.7)	55 (37.9)	<.001	0.99 (0.47-2.10)
3	301 (36.7)	75 (51.7)		1.91 (0.91-4.00)
4	26 (3.2)	6 (4.1)		1.77 (0.57-5.46)
ASA grades III-IV	327 (39.9)	81 (55.9)	<.001	1.91 (1.34-2.72)
Diabetes mellitus	150 (18.9)	38 (27.3)	.03	1.61 (1.07-2.44)
Corticosteroids	49 (6.2)	14 (10.0)	.13	1.69 (0.91-3.15)
Neoadjuvant treatment	103 (12.5)	12 (8.2)	.18	0.63 (0.33-1.17)
Tumor located in the colon	498 (60.7)	94 (64.4)	.45	1.17 (0.81-1.69)
Tumor stage[b]	2.00 (1.00/3.00)	2.00 (2.00/3.00)	.03	1.21 (1.02-1.44)
Type of operation				
Laparotomy	439 (53.8)	92 (63.4)		1 [Reference]
Laparoscopy	336 (41.2)	44 (30.3)	.04	0.62 (0.42-0.92)
Converted laparoscopy	41 (5.0)	9 (6.2)		1.05 (0.49-2.23)
Duration of operation[b]	180 (125/210)	180 (130/240)	.49	1.00 (1.00-1.00)
Blood transfusion	101 (12.3)	38 (26.0)	<.001	2.50 (1.64-3.83)
Ostomy formation	247 (30.4)	44 (30.1)	.97	0.99 (0.67-1.45)
Drainage	443 (54.6)	82 (56.6)	.73	1.08 (0.76-1.54)
Anastomotic leakage	17 (2.1)	13 (9.0)	<.001	4.65 (2.21-9.79)
Organ/space infection	24 (2.9)	40 (27.6)	<.001	12.60 (7.30-21.70)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); OR, odds ratio; SSI, surgical site infection.
[a] Calculated by Kruskal-Wallis test.
[b] Median (quartile 1/quartile 3).

cial SSI was diagnosed in 96 patients (9.91%) and deep SSI in 50 patients (5.16%). Of the 50 patients diagnosed with deep SSI, an organ/space SSI draining through the incision was confirmed in 28 cases (2.9%).

There were no differences for superficial or deep incisional SSI, excluding organ/space infections draining through the wound. However, significant differences were found in overall SSI (66 patients [12.8%] in the conventional group vs 80 [17.7%] in the new operation group; $P = .04$) and in organ/space SSI draining through the incision (9 patients [1.74%] in the conventional group vs 19 [4.20%] in the new operation group; $P = .03$).

UNIVARIATE ANALYSIS

The patient characteristics of age, American Society of Anesthesiologists risk score, and presence of diabetes mellitus were statistically associated with the development of incisional SSI (**Table 4**). Moreover, in the new operation group, perioperative blood transfusion and anastomotic leakage were associated with an increased risk for developing incisional SSI as their *P* values were less than .05. Patients operated on by laparoscopy appear to be protected from SSI ($P = .04$).

MULTIVARIATE ANALYSIS

Table 5 summarizes the results of the multivariate analysis. The new operation group, American Society of Anesthesiologists grade, and perioperative blood transfusion were found to be independent predictive risk factors for developing incisional SSI.

Table 5. Multivariate Analysis for Surgical Site Infection

	OR (95% CI)	*P* Value
New operation group	1.43 (1.00-2.05)	.05
ASA score, 3-4 vs 1-2	1.74 (1.21-2.50)	.003
Blood transfusion	2.25 (1.46-3.47)	>.001

Abbreviations: ASA, American Society of Anesthesiologists; OR, odds ratio.

COMMENT

Our study shows that considering the closure of the laparotomy wound as a new operation in which the nurses and surgeons—all following the same preoperative management of wound protection—scrub again and with all the material being changed, does not decrease the incidence of incisional SSI 30 days after the operation in clean contaminated wounds compared with the more conventional policy in which the nurses and surgeons only change their gloves and use a new set of instruments.

In reference to the use of a drain, it was recommended in all the patients undergoing rectal surgery. In colon resections, the decision for the use of a drain was left to the surgeon's choice and by chance a greater number of patients in the conventional group was drained.

Although the analysis of the results was done on an intent-to-treat basis, a limitation to the interpretation of the results of our study lies in the 49 patients (5.0%) who did not undergo the allocation procedure. Moreover, further surgery was required in 17 patients, and the inclusion of 2 operations in the same patient could lead to misinterpretation in the analysis of the results. Lastly, 5 patients died in the postoperative period.

On the other hand, all patients were followed up in the outpatient clinic. A direct method of SSI surveillance in outpatients essentially identifies 100% of all SSIs. Even though it is considered impractical for widespread implementation, it was considered that the strictest possible method for the surveillance of infection had to be used in the frame of a prospective clinical trial.[20]

According to the literature, the American Society of Anesthesiologists grade plays an important role in SSI.[13] Moreover, perioperative blood transfusion was found to be an important risk factor for incisional SSI.[3,22,23] It is known that allogenic blood transfusion exerts an immunosuppressive effect and predisposes to infective complications after surgery.[24,25]

The incidence of SSI in this study is within the ranges reported in the medical literature (from 3% to 49%).[3-5]

In reference to the higher incidence of SSI in the new operation group, the reason could be related to the organ/space infection rate. In fact, organ/space SSI draining through the incision was observed in a significantly greater number of patients in the new operation group than in the conventional group. Organ/space infection is not likely affected by wound-management policies.

Although the incidence of SSI in the conventional group of our study (13%) proved statistically different from the results of a previous survey performed by the Spanish Society of Surgeons (19%), it must be taken into account that these data were in the setting of a prospective trial and generalization of these results could be doubtful. In this sense, some national projects have launched health initiatives aimed at preventing SSIs. In the United States, the National Surgical Infection Prevention program was established in 2004, and some institutions have developed multidisciplinary task forces to reduce the rate of SSIs after colorectal operations.[26-28] Although such initiatives increased compliance with the measures proposed by the national initiative consistent with evidence-based practice to reduce SSI in different periods, their results did not yield a significant decrease in SSI rates as was observed in a recent randomized trial that failed to prove that an evidence-based intervention bundle for preventing SSIs actually reduced them.[28]

In conclusion, our study shows that considering closure of the laparotomy wound as a new operation, in which the nurses and surgeons scrub again, does not reduce the rates of SSI in elective colon and rectal surgical procedures.

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Author Affiliations: Department of Surgery, Colorectal Unit, Virgen del Camino University Hospital, Pamplona (Drs Ortiz and Armendariz); Department of Surgery, Colorectal Unit, Bellvitge University Hospital (Drs Kreisler and Biondo) and Department of Surgery, Colorectal Unit, University Hospital Vall d'Hebron (Dr Espin-Basany), Barcelona; Department of Surgery, Colorectal Unit, University Hospital la Fe (Dr Garcia-Granero); Department of Surgery, Colorectal Unit, General Hospital (Dr Roig), Valencia; Department of Surgery, Colorectal Unit, Hospital Universitario Josep Trueta, Girona (Dr Martín); Department of Surgery, Colorectal Unit, Orense Hospital, Orense (Dr Parajo); Department of Surgery, Colorectal Unit, University Hospital Virgen de la Arrixaca, Murcia (Dr Valero); and Department of Surgery, Colorectal Unit, Hospital Meixoeiro, Vigo (Dr Martínez), Spain.
Correspondence: Sebastiano Biondo, MD, Bellvitge University Hospital, Department of General and Digestive Surgery, C/Feixa Llarga s/n, L'Hospitalet de Llobregat, 08907 Barcelona, Spain (sbn.biondo@gmail.com).
Authors Contributions: *Study concept and design:* Ortiz and Valero. *Acquisition of data:* Kreisler, Garcia-Granero, Espin-Basany, Roig, Martín, Parajo, Valero, Martínez, and Biondo. *Analysis and interpretation of data:* Ortiz, Armendariz, Kreisler, Garcia-Granero, Roig, Martín, Parajo, Martínez, and Biondo. *Drafting of the manuscript:* Ortiz, Armendariz, and Kreisler. *Critical revision of the manuscript for important intellectual content:* Kreisler, Garcia-Granero, Espin-Basany, Roig, Martín, Parajo, Valero, Martínez, and Biondo. *Obtained funding:*

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