Reprinted from Diseases of the Colon and Rectum
Vol. 54 No. 6 August 2011
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Published by Lippincott, Williams & Wilkins Printed in U.S.A.

ORIGINAL CONTRIBUTION

The Use of Silver Nylon in Preventing Surgical Site Infections Following Colon and Rectal Surgery

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BACKGROUND: Patients who undergo colorectal surgery have up to a 30% chance of developing a surgical site infection postoperatively. Silverlon is a silver nylon dressing designed to prevent surgical site infections, but only anecdotal evidence has previously supported its efficacy.

OBJECTIVE: The aim of this study was to evaluate the effect of silver nylon dressings in patients undergoing colorectal surgery.

DESIGN: We performed a prospective, randomized, controlled trial comparing a silver nylon dressing with gauze dressings in patients undergoing elective colorectal surgery.

SETTING: The study was performed at a university-based, tertiary referral center.

PATIENTS: We studied patients undergoing elective colorectal surgery with an abdominal skin incision of at least 3 cm.

INTERVENTION: Patients were randomly assigned to receive either a silver nylon or a gauze dressing.

MAIN OUTCOME MEASURES: The primary end point was surgical site infection occurring within 30 days of surgery.

RESULTS: One hundred ten patients were enrolled in the study and were randomly assigned to 1 of 2 treatment groups. After a 30-day follow-up period, the incidence of surgical site infection was lower in the silver nylon group compared with the control group (13% vs 33%, $P = .011$). Twenty-five patients in the study developed superficial surgical site infections, 5 in the silver nylon group and 14 in the control group ($P = .021$). Two patients in the study group developed deep wound infections compared with 4 in the control group ($P = .438$). Multivariate analysis revealed that patients in the control group had a 3-fold increase in risk of infection compared with patients in the silver nylon group ($P = .013$).

LIMITATIONS: A limitation of this study is that the members of the surgical team were not blinded to the treatment groups.

CONCLUSION: Silver nylon is safe and effective in preventing surgical site infection following colorectal surgery.

KEY WORDS: Colon and rectal surgery; Silver; Surgical site infection.

Funding/Support: This work was supported by grants from Cura Surgical, Geneva, IL, and Argentum Medical, Chicago, IL.

Disclosures: This study was an investigator-initiated trial with Cura Surgical and Argentum Medical providing financial support to the University of South Florida in the form of a study grant. Study design, data accrual, and data analysis were accomplished independent of the sponsors. None of the investigators of this study are consultants for or receive any honoraria from the sponsors.

Clinical trials registration: http://www.clinicaltrials.gov. Number NCT01143883.

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Dis Colon Rectum 2011; 54: 1014–1019
DOI: 10.1097/DCR.0b013e31821c495d
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Surgical site infections (SSIs) are the third most common cause of hospital-acquired infection and are the leading cause of hospital-acquired infection in surgical patients.[1,2] A SSI is defined as an infection that occurs within 30 days of a surgical procedure and affects the incision or deep tissue at the operative site.[1] These infections increase the average length of hospitalization from 6 to 11 days and cost an estimated $11,000 to $35,000 per infection to treat.[3]

Colorectal surgery, because of its contaminated nature, is associated with rates of infection as high as 30%.[4,5]

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The colon is colonized by over 500 different species of bacteria in concentrations of 10^{11} to 10^{12} cells per g.[6] These bacteria are normal colonic flora, but when they are seeded into other tissues, they can result in infection.

Silver has long been known to have antimicrobial properties. In the 1800s silver nitrate was used in the treatment of venereal infections, acne, and leg ulcers.[7,8] Silver has broad antimicrobial activities against gram-positive and gram-negative bacteria including methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant enterococci and has antifungal activity against mold and yeast. Silver, as a metal, is relatively inert and poorly absorbed by cells. When it is exposed to a wound or other body fluids, it ionizes and becomes highly reactive to proteins and cell membranes.[9] It has been shown to interact with structural proteins and DNA, inhibiting bacterial replication and causing fatal structural changes within bacterial cell walls.[10–12] In addition, unlike antibiotics, microbial resistance to silver has rarely been reported.[13]

The application of silver in surgery dates back to when William Halsted used silver foil on his surgical wounds to reduce the incidence of postoperative infections.[14] Technology has since evolved, and there are now a variety of commercially available silver surgical dressings. Silverlon (Cura Surgical, Geneva, IL) is a silver-coated, nylon dressing designed to prevent postoperative SSIs. Its efficacy has been documented in case review studies, but definitive data on its true antimicrobial properties is lacking.[15,16] The aim of this study was to evaluate the efficacy of this dressing in preventing SSI. We conducted a prospective, randomized, controlled trial directly comparing silver nylon with standard gauze dressings in patients undergoing elective colorectal operations.

METHODS

This clinical study was designed as a prospective, randomized, controlled trial at a university-based, tertiary referral center. Institutional review board approval from the University of South Florida was obtained before starting the study. All procedures were performed by a board-certified colorectal surgeon. Patients undergoing elective surgery from July 2009 to April 2010 with an anticipated abdominal incision of at least 3 cm were considered for enrollment. Patients were excluded if they had incisions less than 3 cm, a known allergy to silver, signs of abdominal wall infection, conditions that would prevent full closure of the skin at the primary operation, or prior abdominal mesh that was not planned to be fully removed at the time of operation. Women who were pregnant or lactating and patients who had received antibiotics within 1 week of surgery were also excluded. Enrollment was not limited by any other preexisting medical condition or pathology (Fig. 1).

Perioperative Protocol

Participating patients underwent a standardized perioperative protocol. All patients were instructed to restrict their diet to clear liquids 24 hours before surgery. As is our practice, mechanical bowel preparations were not used, with the exception of patients undergoing left colon or rectal surgery who were given an enema the morning of their operation. All patients received preoperative antibiotics 30 to 60 minutes before surgery. Standard perioperative coverage for bowel surgery at our institution is ertapenem; patients with penicillin allergies are given alternative prophylaxis with ciprofloxacin and flagyl or gentamicin and clindamycin. All perioperative antibiotics were discontinued within 24 hours in accordance with the Surgical Care Improvement Project guidelines.[17]

Study Treatment and Randomization

Patients were randomly assigned in a 1:1 fashion to receive either a silver nylon dressing in the treatment group or a gauze dressing in the control group. Randomization was completed with nQuery software by a blinded statistician using sealed envelopes. The surgical team was blinded to the surgical dressing until the time of skin closure at the end of the operation.

The initial dressing was placed by the surgical team in the operating room. Patients randomly assigned to the treatment group had their silver nylon dressing hydrated in sterile water before application. The control group had their incisions dressed only with sterile gauze and paper tape.

The particular silver dressing used in this study is designed to last for 7 days. Product instructions specify hydrating the dressing daily and then replacing it with a new dressing after 7 days. On discharge, patients have a new dressing applied that remains for an additional 7 days.

First examination of the surgical wounds was performed at 48 hours. If the silver dressing dried out or the gauze dressing became saturated sooner than this time period, then hydration of the silver dressing or changing of the gauze dressings was done earlier. All dressing changes were performed by a member of the surgical team. On discharge from the hospital, patients with gauze dressings were instructed to change their dressings as needed, whereas the patients with silver nylon dressings were instructed to leave their dressings intact until their follow-up appointment. Although it is not routine practice to continue postoperative dressings after 48 hours, the efficacy of the silver product is based on a longer duration of use and we continued the gauze dressings to keep with a standardized protocol.

Follow-up appointments were scheduled for 7 to 10 days from hospital discharge. At this time, the dressings were discontinued, and the wounds were assessed and treated as needed. If dressing changes were still needed because of drainage or infection, standard dressings were applied per standard medical practice (including dry

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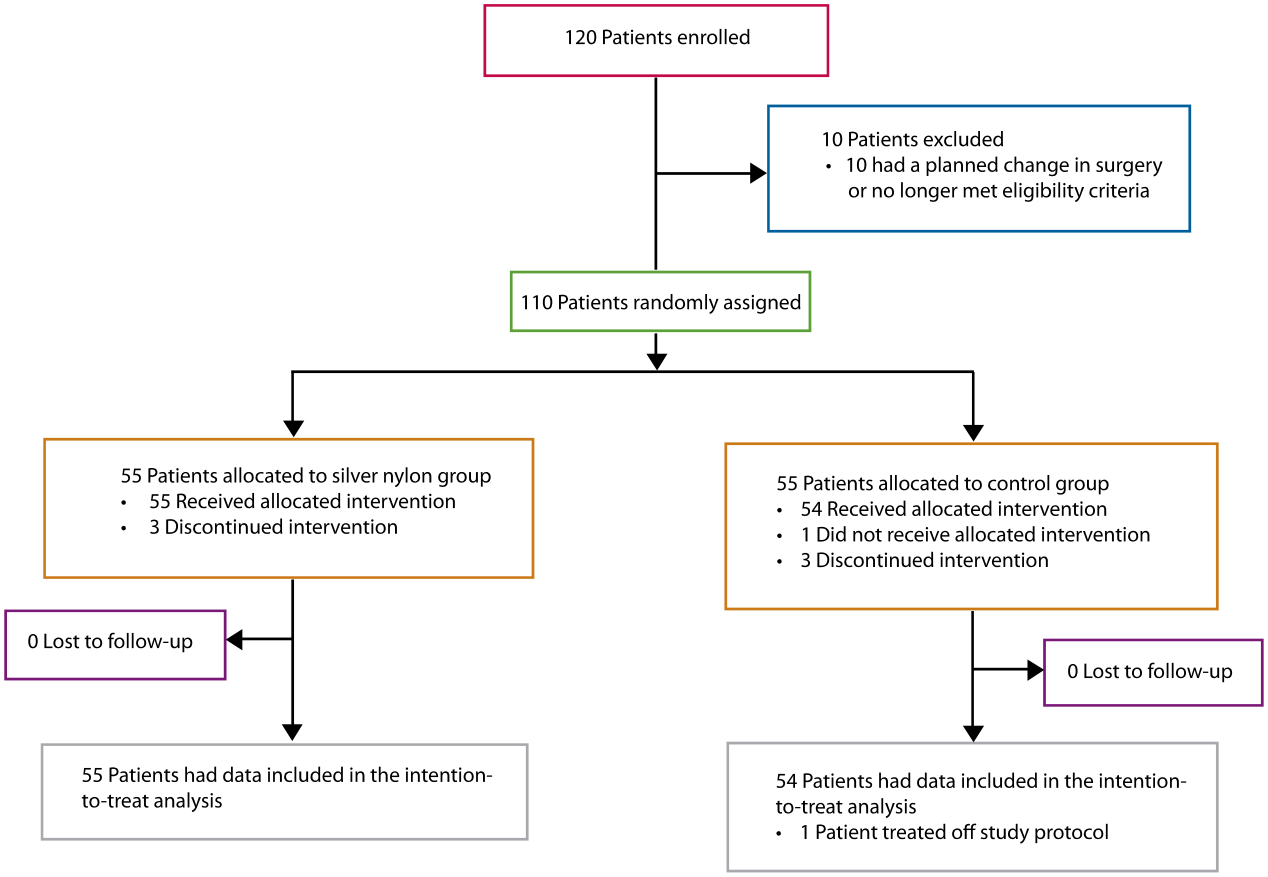

FIGURE 1. Enrollment, randomization, and follow-up of the patients.

gauze, wet to dry dressings, etc). Patients had additional follow-up by telephone at 30 days at which time they completed a standardized survey. Additional appointments were dictated by the patient's condition and any medical needs.

Determination of whether a wound was infected was made by an unblinded physician member of the surgical team. SSIs were classified by the Centers for Disease Control and Prevention (CDC) guidelines (Table 1).[1] Superficial incisional SSI included infection of the skin or subcutaneous tissue of the incision and either purulent drainage, isolated organisms from culture, wound opened because of signs of infection, or diagnosis of SSI by the surgeon. We modified this definition to include all patients who were placed on antibiotics specifically for these signs or symptoms. The CDC definition of deep incisional SSI and organ space SSI were used to further classify more significant infections.

Statistical Analysis

The primary end point of this study was the development of a SSI. Other prospectively collected data included sex, past medical history, indication for operation, type of operation, length of hospital stay, and complications.

Previous studies have demonstrated a SSI rate of 6% to 30% in patients undergoing colorectal surgery.[5,6] Because the incidence at our institution is approximately 25%, we chose this as our baseline infection rate. Based on the published Silverlon literature, we estimated that this dressing would reduce the incidence of SSI to 5% in our population. It was calculated that a sample size of 110 patients would be required to have 80% power to detect the difference between a group 1 proportion, p_1, of 0.25 and a group 2 proportion, p_2, of 0.05 using Fisher exact probability test with a 0.05 2-sided significance level. Descriptive statistics are reported as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables.

A multivariable logistic regression model using forward likelihood ratio methods was used to evaluate the independent contribution of various factors to infection status.

RESULTS

From July 2009 to April 2010, 110 patients were enrolled in the study. Fifty-five patients were randomly assigned to each of the 2 study groups. One patient assigned to the

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TABLE 1. Definition of surgical site infections

Superficial SSI
Infection occurs within 30 days of the operation *and* infection involves only skin or subcutaneous tissue *and* at least one of the following:
Purulent drainage, with or without laboratory confirmation
Organism isolated from an aseptically obtained culture of fluid or tissue
At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat *and* incision is deliberately opened by surgeon, *unless* incision is culture negative
Diagnosis of superficial incisional SSI by the surgeon
Deep SSI
Infection occurs within 30 days of the operation *and* infection involves deep soft tissue *and* at least one of the following:
Purulent drainage from the deep incision, but not from the organ space
A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever >38°C, localized pain, or tenderness, unless site is culture negative
An abscess or other evidence of infection involving the deep incision found on direct examination, reoperation, or histopathologic or radiologic examination
Diagnosis of deep incisional SSI by the surgeon
Organ/space SSI
Infection occurs within 30 days of the operation *and* infection involves any part of the anatomy, other than the incision, which was opened or manipulated during an operation *and* at least one of the following:
Purulent drainage from a drain that is placed through a stab wound into the organ space
Organism isolated from an aseptically obtained culture of fluid or tissue in the organ space
An abscess or other evidence of infection involving the organ space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
Diagnosis of an organ/space SSI by the surgeon

SSI = surgical site infection.

control group was treated off study protocol and was therefore not included in the final statistical analysis. The median age in the silver nylon group was 62 (range, 24–85), and in the control group, it was 58 (range, 26–76). There was a similar distribution of patient demographics between the 2 treatment groups (Table 2).

There was an equal division between patients undergoing open and laparoscopic surgery. Preoperative enemas were performed in 37 patients in the silver nylon group and 35 in the control group. Seven patients in the study group required intraoperative blood transfusions; no patients in the control group received transfusions.

The total incidence of SSI in the silver nylon group was 13%, which was significantly lower than the 33% in the control group ($P = .01$). Most SSIs in our cohort were superficial. However, 4 (7.4%) patients in the control group and 2 (3.6%) patients in the treatment group developed a deep SSI (Table 3).

Patients in the silver nylon group had an in-hospital SSI rate of 11% (n = 6), whereas patients in the control group had a rate of 22% (n = 12, $P = .11$). All patients who developed a SSI were treated with antibiotics. Two patients in the control group required additional treatment with surgical debridement or negative pressure therapy. During their hospitalization, 2 patients in the silver nylon group and 8 patients in the control group received antibiotics for conditions not related to their wound. Reasons for antibiotic use included urinary tract infection, sinus infection, and anastomotic leak. Length of hospitalization was similar between the 2 groups (6 days vs 6.5 days, $P = .21$).

In the immediate 7- to 10-day postoperative follow-up period, one additional patient in the silver nylon group developed a SSI compared with 6 in the standard of care group. Only one patient (silver nylon group) required readmission for a SSI. No new SSIs were diagnosed at the 30-day follow-up or in the interim.

Multivariate logistic regression revealed that use of the silver nylon dressing was the only independent predictor for infection status. Patients in the control group had an approximately 3-fold increase in risk of infection compared with the silver nylon group ($P = .013$) (Table 4).

One patient had an adverse reaction to the silver nylon dressing; the patient developed a rash at the site of the dressing that quickly resolved after the dressing was discontinued.

DISCUSSION

In this prospective, randomized, controlled trial, there was a significant reduction in the incidence of SSI in patients treated with the silver nylon dressing following elective colorectal surgery. Patients treated with the gauze dressings were 3 times more likely to develop a SSI than those treated with the silver nylon. The overall incidence of postoperative SSIs in our standard of care group was 33% which is similar to our previously reported rate.[18] Although this rate may appear high in comparison with other published reports of similar operations, and although there is likely a degree of underreporting of this complication, we believe our rate of infection is due to our adherence to the CDC's definition of infection.[2] In addition, in an attempt to capture even very early SSIs, our alteration of the CDC criteria may have also increased our

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TABLE 2. Study group demographics

	Silver nylon (n = 55)	*Control (n = 54)*	*P*
Patient age, y			**.049**[a]
Median	62	58	
Sex, n (%)			.773[b]
Male	28 (51)	26 (48)	
Female	27 (49)	28 (52)	
BMI	27.5	27.3	.868[a]
Tobacco, n (%)	8 (15)	14 (26)	.139[b]
Immunosupression, n (%)	4 (7)	6 (11)	.527[c]
Diabetes, n (%)	5 (9)	4 (7)	1.00[c]
pRBC transfusion, n (%)	7 (13)	0	**.013**[c]
Type of operation, n (%)			.778[b]
Laparoscopic-assisted	30 (55)	28 (52)	
Open	25 (45)	26 (48)	
Operation, n (%)			
Small-bowel resection	1 (2)	1 (2)	
Ileocecectomy	2 (4)	3 (6)	
Right colectomy	9 (16)	9 (17)	
Left colectomy	3 (5)	0	
Sigmoid resection	9 (16)	11 (20)	
Hartmann procedure	1 (2)	0	
Subtotal colectomy	3 (5)	7 (13)	
Proctocolectomy	3 (5)	3 (6)	
Proctectomy	1 (2)	3 (6)	
LAR	15 (27)	9 (17)	
APR	2 (4)	5 (9)	
Enterostomy creation	3 (5)	1 (2)	
Enterostomy reversal	2 (4)	2 (4)	
Colovesicle fistula repair	1 (2)	0	
Surgical indication, n (%)			.353[b]
Neoplastic	36 (65)	34 (63)	
IBD	5 (9)	10 (19)	
Other	14 (25)	11 (19)	
Hospitalization, days			.210[d]
Median	6	6.5	
Range	3–21	2–17	

pRBC = packed red blood cells; LAR = low anterior resection; APR = abdominoperineal resection.
[a]Student *t* test.
[b]χ^2 test.
[c]Fisher exact probability test.
[d]Mann-Whitney *U* test.

TABLE 3. Surgical site infections

	Silver nylon (n = 55)	*Control (n = 54)*	*P*
Type of SSI, n (%)			
Total	7 (13)	18 (33)	**.011**[a]
Superficial	5 (9)	14 (26)	**.021**[a]
Deep	2 (4)	4 (7)	.438[b]
Debridement	0	2 (4)	.243[b]
Timing of SSI, n (%)			
Before discharge	6 (11)	12 (22)	.112[a]
After discharge	1 (2)	6 (11)	.06[b]

SSI = surgical site infection.
[a]χ^2 test.
[b]Fisher exact probability test.

overall incidence. By CDC guidelines, the presence of erythema alone does not meet the definition of a SSI, but, for the purposes of our study, redness or evidence of cellulitis surrounding the incision was reason enough to start antibiotic therapy.

This is the first prospective, randomized, controlled trial analyzing the silver nylon dressing. Prior studies have been limited by their retrospective design and their evaluation in operations associated with low rates of infection. Huckfeldt et al[16] compared it with standard gauze dressings in 1600 patients who underwent median sternotomy. Patients in the silver nylon group (n = 365) were treated prospectively, whereas the control arm (n = 1235) consisted of retrospectively collected data from the prior 24 months. None of the patients treated with the silver dressing developed evidence of mediastinitis compared with 13 patients (1%) in the control group. Epstein performed a similar study in patients undergoing lumbar laminectomy; no patients treated with the silver nylon developed a SSI compared with 11% of patients treated with standard dressings.[15]

Several limitations to our study design are worthy of mention. As with any unblinded study, the possibility of bias must always be acknowledged. This is no less so in our trial, because the diagnosis of a SSI was determined by unblinded members of the surgical team. However, we attempted to standardize the definition by use of previously established CDC criteria. In addition, we included for analysis any questionable SSI that was being treated with antibiotics. This aggressive treatment of possibly early SSIs may also explain the low incidence of deep incisional infections. And whereas a minimum incision length was an inclusion criterion, we did not routinely measure the exact length in every patient in the study. Incision length could definitely factor into the development of a SSI, and these data are missing from our study.

Many prior studies have identified various risk factors associated with the risk of development of SSIs. Some of these risk factors include diabetes, smoking, systemic steroid use, extremes of age, malnutrition, obesity, coincident remote site infections, and perioperative blood transfusions.[4,5] Although a substantial portion of our study population had one or more of these risk factors, on multivariate analysis these factors fell out and the only independent predictor for risk of infection was the surgical dressing.

TABLE 4. Multivariate analysis

Variable	*P*
Age	.805
Immunosuppression	.775
Tobacco	.696
Diabetes	.078
pRBC transfusion	.895

pRBC = packed red blood cells.

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SSIs are a considerable health care problem in the United States that costs up to 1.8 billion dollars a year to treat.[19] Although a formal cost analysis of SSI prevention and treatment was not performed, it appears that there was a considerable monetary savings with the silver nylon group. The cost of the dressing is based on its size but ranges from $12 to 46. Because only 2 dressings are used on average per patient, the typical maximum cost for this treatment is less than $100. This compares favorably to the additional cost of antibiotics, surgical debridement, and negative pressure therapy that was needed to treat the infections in the control group.

CONCLUSION

SSIs are a source of significant morbidity following any surgical procedure, and they directly contribute to the increasing cost of health care in the United States. We have demonstrated a significant reduction of SSI with the use of a silver nylon dressing in patients undergoing elective colorectal surgery. Future efforts should be directed toward evaluating specific patient populations that would most benefit from its use.

ACKNOWLEDGMENTS

The authors thank Katheryne Downes for her help in the statistical analysis of this paper.

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