Randomized Controlled Trial

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A Randomized Trial of Ionic Silver Dressing to Reduce Surgical Site Infection After Gastrointestinal Surgery

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Objective: To determine whether Aquacel Ag Hydrofiber dressings containing ionic silver are superior to film dressings for preventing superficial surgical site infections (SSI) in patients undergoing elective gastrointestinal surgery.

Background: Multiple clinical trials have assessed the effectiveness of silver-containing wound dressings; however, systematic reviews failed to find any advantages of these dressings and concluded that there was insufficient evidence to indicate that they prevented wound infections. This study aimed to evaluate the efficacy of Aquacel Ag Hydrofiber dressings for preventing superficial SSIs in patients undergoing gastrointestinal surgery.

Methods: Patients undergoing elective gastrointestinal surgery were randomly assigned to receive either Aquacel Ag Hydrofiber (study group) or film dressings (control group). The primary end point was superficial SSI within 30 days after surgery (UMIN Clinical Trials Registry ID: 000043081).

Results: A total of 865 patients (427 study group, 438 control group) were qualified for primary end-point analysis. The overall rate of superficial SSIs was significantly lower in the study group than in the control group (6.8% vs 11.4%, $P = 0.019$). There was no significant difference in superficial SSI rates between the groups in patients undergoing upper gastrointestinal surgery; however, the rate was significantly lower in the study group in patients undergoing lower gastrointestinal surgery ($P = 0.042$). Multivariate analysis identified Aquacel Ag Hydrofiber dressings as an independent factor for reducing superficial SSIs (odds ratio, 0.602; 95% confidence interval, 0.367–0.986; $P = 0.044$).

Conclusions: Aquacel Ag Hydrofiber dressings can reduce superficial SSIs compared to film dressings in patients undergoing elective gastrointestinal surgery, especially lower gastrointestinal surgery.

Keywords: Aquacel Ag Hydrofiber, gastrointestinal surgery, surgical site infection

INTRODUCTION

Surgical site infections (SSIs) are the most common health care-associated infections in surgical patients and are a major cause of postoperative morbidity.[1–3] Wound infections are particularly common superficial SSIs in patients undergoing gastrointestinal surgery. Several publications have addressed ways to reduce the risk of wound complications associated with surgery,[4–8] including the intraoperative administration of antimicrobial prophylaxis,[5,6] skin preparation, barrier retraction wound protection,[9] use of absorbable sutures during intraoperative procedures,[10,11] pulsatile lavage irrigation of wounds before closure,[12,13] intraoperative peritoneal lavage,[14] and triclosan-coated abdominal wall sutures.[15] However, one trial using antibacterial materials, including triclosan-coated sutures, produced negative results.[16] Currently, there is no consensus on how to apply the findings of these studies to digestive surgery, and an optimal method of skin dressing for patients undergoing digestive surgery remains to be established.

Ionic silver (Ag^+), the oxidized active state of silver, has received renewed interest for use as a prophylactic antimicrobial agent in wound dressings because of its broad-spectrum antibacterial range, including aerobic, anaerobic, Gram-negative, and Gram-positive bacteria, as well as yeast and fungi.[17–19] Aquacel Ag Hydrofiber dressing (ConvaTec, Princeton, NJ, USA) is a moisture-retentive dressing consisting of soft nonwoven sodium carboxymethylcellulose fibers combined with 1.2% ionic silver distributed throughout the dressing material. This dressing retains the physical properties of the hydrofiber with the additional benefits of ionic silver, which is slowly released into the wound to create a moist antimicrobial environment.

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Disclosure: The authors declare that they have nothing to disclose.

The study protocol and informed consent forms were approved by the Ethics Committee of Teikyo University, Tokyo, Japan (reference number: 13-093). All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or research committee and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from individual participants included in the study. Patients provided written informed consent regarding publication of their data.

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Multiple clinical trials have assessed the effectiveness of Aquacel Ag Hydrofiber dressings for the treatment of various wounds in both acute and chronic settings. However, a Cochrane systematic review of 26 randomized controlled trials (RCTs) that compared silver-containing wound dressings and topical agents with silver-containing and nonsilver-containing comparators in patients with uninfected wounds failed to find any advantages of silver-containing wound dressings.[20] This review concluded that there is insufficient evidence to determine whether silver-containing dressings or topical agents promote wound healing or prevent wound infections.

Biffi et al[21] conducted a randomized trial to examine the effect of silver-containing wound dressings on the incidence of SSIs in patients undergoing elective surgery for colorectal cancer. They failed to confirm any significant superiority of the Aquacel Ag Hydrofiber dressing in terms of reducing SSIs; however, the sample size was relatively small (n = 112).

The aim of the current study was to evaluate the efficacy of Aquacel Ag Hydrofiber dressings for preventing superficial SSIs in patients undergoing gastrointestinal surgery. We hypothesized that Aquacel Ag Hydrofiber dressings would reduce the incidence of superficial SSIs by 50% compared to standard film dressings. We conducted a prospective, single-center, large-scale, RCT directly comparing Aquacel Ag Hydrofiber dressings with traditional film dressings in patients undergoing gastrointestinal surgery (UMIN Clinical Trials Registry ID: 000043081).

PATIENTS AND METHODS

Study Design and Participants

This prospective, single-hospital, phase 3 RCT was conducted at the Teikyo University Chiba Medical Center from August 2013 to March 2017. The eligibility criteria included patients undergoing elective gastrointestinal surgery with an anticipated abdominal incision ≥4 cm, age ≥15 years, adequate organ function, and adequate nutrition. Patients who had undergone laparoscopic surgery with extraction-site incision ≥4 cm were also included. We excluded patients who had an incision <4 cm, required emergency surgery for active infection such as peritonitis due to gastrointestinal tract perforation, appendicitis with abscess cavity, signs of abdominal wall infection, or conditions that prevented full skin closure during the primary operation.

Perioperative Protocol

All participants underwent a standardized perioperative preparation. Patients with upper gastrointestinal diseases continued to eat until the evening of the day before surgery and took laxatives (dihydro-dirheinanthrone glucoside) after their evening meal. Patients with lower gastrointestinal diseases received mechanical bowel preparations, without chemical preparations or enemas, and fasted the day before surgery.

All patients received routine antibiotic prophylaxis for 2 to 3 days based on the Centers for Disease Control and Prevention (CDC) guidelines,[2] regardless of group assignment. Patients undergoing upper gastrointestinal surgery received cefazolin sodium hydrate (Astellas, Tokyo, Japan) for 2 days and patients undergoing lower gastrointestinal surgery received flomoxef sodium (Shionogi, Osaka, Japan) for 3 days. Antibiotics were administered as follows: 1 g administered intravenously 30 minutes before surgery on the day of the operation, 1 g every 3 hours during surgery based on the antibiotic half-life, and 1 g 3 hours after completion of the surgery, followed by 2 g/d (1 g/12 h) following the day of the operation. Prophylactic administration was terminated on postoperative day 2. The antibiotics were restarted after the initial 24 to 48 hours when there was a fever over 38 °C, leukocytosis, or clear evidence of infection.

For patients who had laparoscopic surgery, a wound protector (Alexis O-ring device, Applied Medical, Rancho Santa Margarita, CA, USA) was used in all cases during specimen extraction. After removal of the resected organs and/or anastomosis of the gastrointestinal tract and confirmation of hemostasis, both groups underwent irrigation with sterile saline (3000 mL for open surgery, 1000 mL for laparoscopic surgery) at approximately 37 °C, directed at the dissected area. The peritoneum and fascia were then closed using absorbable sutures (1-VICRYL; Johnson & Johnson, Somerville, NJ, USA). Wound washout was performed using warm sterile saline after fascia closure but before skin closure in both groups. Skin closure was performed using 3-0 Nylon, a skin stapler, or subcuticular sutures using 3-0 VICRYL (Johnson & Johnson).

This study was approved by the Ethics Committee of Teikyo University, and informed consent was obtained from all patients.

Study Intervention and Randomization

Patients were recruited by the investigators and an eligibility report form was sent to the registration center at the Department of Surgery, Teikyo University Chiba Medical Center (Ichihara, Chiba, Japan). Patients were randomly assigned in a 1:1 ratio to receive either Aquacel Ag Hydrofiber with film dressing (study group) or film dressing (control group) and balanced according to sex and type of surgery (upper or lower gastrointestinal surgery). Randomization was performed preoperatively by the registration center using the nQuery software. Allocation was performed on the day of surgery, and the surgeons were blinded to the treatment allocation during surgery until dressing was applied. The patients were not blinded to their group assignment.

The dressing was applied by the surgical team in the operating room while the patient was under general anesthesia. After skin closure, patients in the study group received an Aquacel Ag Hydrofiber dressing, 1.5 cm in width, placed over the incision and covered with a film dressing (Tegaderm Film, Transparent Film Dressing Frame Style, 3M Health Care, St. Paul, MN, USA), while patients in the control group received a standard film wound dressing (Tegaderm Film) directly to cover the closed incision. No patients received gauze dressings and no subcutaneous drains were used. Patients with class III or higher operations before concluding surgery, according to the CDC guidelines,[2] were excluded from the analysis.

The surgical staff removed the dressing at least 48 hours after surgery in both groups, because the 1999 CDC guidelines[2] recommends the use of a sterile dressing to protect closed incisions for 24 to 48 hours postoperatively. The operating surgeon and other surgical staff then observed the wound for signs of any superficial SSI, according to the CDC criteria, including redness, swelling, pain at the wound site, and fever. The surgical site and patients' vital signs were assessed at least twice a day during hospitalization, on discharge, and at the time of follow-up until 30 days after surgery. If a superficial SSI was suspected, clinically relevant microbiological samples were cultured by the surgical staff. The determination of whether a superficial SSI occurred was made by at least 3 unblinded surgical staff members who were not the operating and/or attending surgeon. The primary end point of the study was the incidence of superficial SSIs within 30 days after surgery.

Statistical Analysis

The primary end point of this randomized study was the development of superficial SSI after gastrointestinal surgery. Lower gastrointestinal surgery was more common than upper gastrointestinal surgery at our institution; therefore, the baseline infection rate was calculated based on the incidence in previous studies in patients undergoing colorectal surgery.[22–24] The sample size was calculated based on the expected SSI rates of 15%

in the control group and 7.5% in the Aquacel Ag Hydrofiber group. The calculated sample size was 398 patients per group with a confidence level of 5% and statistical power of 90%.

Binary variables were compared using a 2-sided Fisher exact test with a 2-sided significance level of 0.05, and continuous variables were compared using the Mann–Whitney *U* test. Efficacy outcomes were compared between the groups using multivariate odds ratios (ORs) and 95% confidence intervals (CIs) in logistic regression analysis.

All statistical analyses were performed using the SPSS version 28 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $P < 0.05$.

RESULTS

A CONSORT diagram is shown in Figure 1. A total of 921 patients were enrolled and randomly assigned, including 454 to the Aquacel Ag Hydrofiber group (study group) and 467 to the control group. The registration period was from August 15, 2010 to March 31, 2017, and the follow-up period was 30 days from enrollment of the last subject. Twenty-four patients in the study group and 27 in the control group in whom the surgical method was changed from gastrointestinal resection and/or bypass to exploratory laparotomy intraoperatively were excluded from intention-to-treat analysis. Three patients in the Aquacel group and 2 patients in the control group with colon diseases who required reoperation within 30 days because of anastomotic leakage were also excluded from the intention-to-treat analysis.

Baseline Characteristics

The median age of all patients was 69 years [interquartile range (IQR), 62–76 years], and the median body mass index of all patients was 22.1 kg/m^2 (IQR, 20.07–24.46). The patients in both groups included in the intention-to-treat analysis were similar with respect to age, sex, body mass index, and risk factors for infection (smoking status, diabetes, chronic kidney disease, arterial hypertension and/or antihypertensive medication, preoperative antibiotics, preoperative steroid medication, American Society of Anesthesiologists physical status, and preoperative serum albumin) (Table 1).

Table 2 shows the intraoperative details of the 2 groups. A total of 100 patients who underwent upper gastrointestinal surgery (esophagus, n = 12; stomach, n = 88) were allocated to the Aquacel Ag Hydrofiber group and 104 patients (esophagus, n = 10; stomach, n = 94) were allocated to the control group, while 330 patients who underwent lower gastrointestinal surgery (small bowel, n = 64; colon, n = 141; rectum, n = 125) were allocated to the Aquacel Ag Hydrofiber group and 336 patients (small bowel, n = 63; colon, n = 152; rectum, n = 121) were allocated to the control group.

The median operative time among all patients was 160 minutes (IQR, 108–249 minutes), and the median blood loss was 50 mL (IQR, 20–223 mL). The distribution of intraoperative details was balanced between the groups (surgery, surgeon grade, skin-closure method, operative time, blood loss, rate of laparoscopic/open surgery, and duration of hospital stay after surgery).

Primary Outcome and Adverse Events

The patients with and without superficial SSIs are compared in Supplemental Table 1, see http://links.lww.com/AOSO/A306 and Table 3. The overall rate of superficial SSIs was 9.1% (n = 79), deep incisional SSI was 0.9% (n = 8), and organ space infection was 5.2% (n = 45). Regarding the baseline

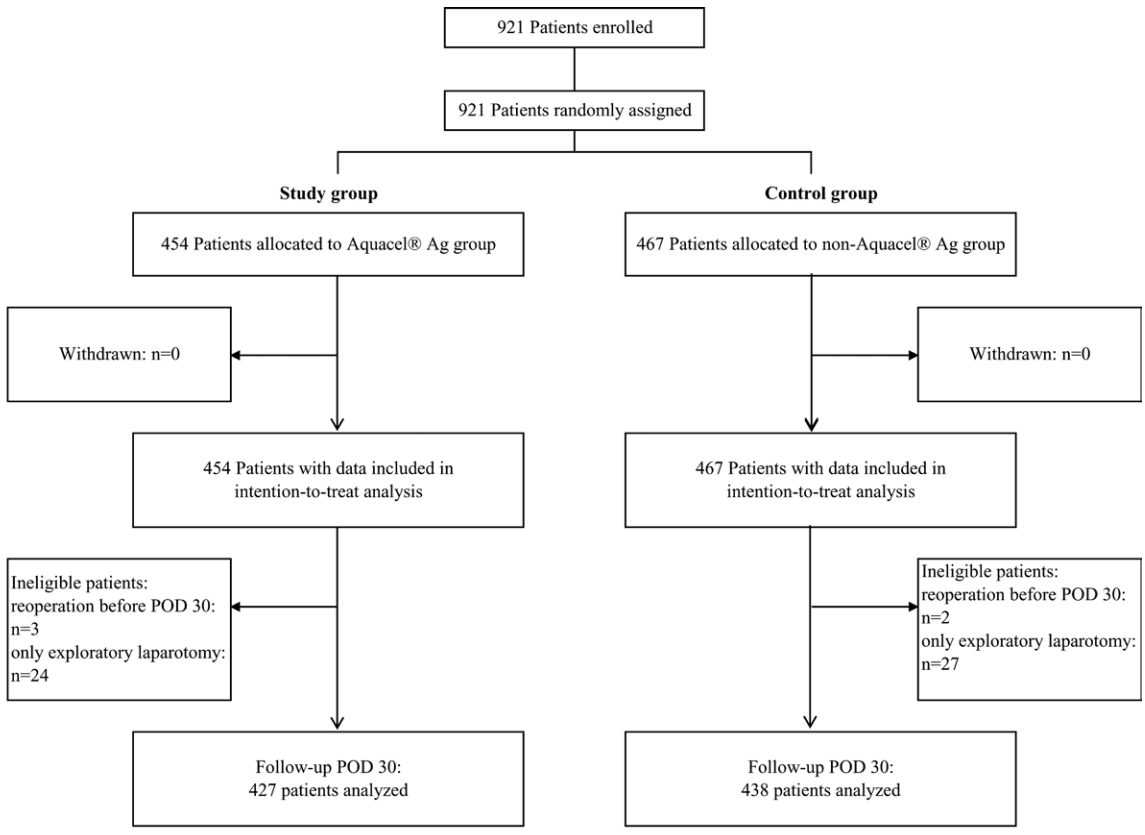

FIGURE 1. CONSORT diagram.

TABLE 1.

Baseline Characteristics of Patients Included in Intention-to-Treat Analysis

	Aquacel Ag Group (n = 454)	Control Group (n = 467)	*P* Value
Age (years)*	69 (29–90)	69 (20–89)	0.085
Sex (male:female)	306:148	324:143	0.565
Risk factors and comorbidities			
BMI (kg/m^2)†	22.5 ± 3.5	22.4 ± 3.6	0.500
Smoking	143 (31.5%)	155 (33.2%)	0.632
Diabetes	115 (25.3%)	98 (21.0%)	0.137
Chronic kidney disease (eGFR <30 mL/min/1.73 m^2)	17 (3.7%)	16 (3.4%)	0.934
Arterial hypertension and/or antihypertensive medication	209 (46.0%)	200 (44.5%)	0.361
Preoperative antibiotics –30 d	0 (0%)	0 (0%)	0.548
Preoperative steroid medication	8 (1.8%)	16 (3.4%)	0.168
ASA-PS (1–2:3–4)	364:90	393:74	0.136
Preoperative serum albumin (g/dL)†	4.0 ± 0.4	3.9 ± 0.5	0.069

*Median (range).

†Mean ± standard deviation.

ASA-PS indicates American Society of Anesthesiologists physical status; BMI, body mass index; eGFR, estimated glomerular filtration rate.

TABLE 2.

Intraoperative Details of Patients Included in Intention-to-Treat Analysis

	Aquacel Ag Group (n = 454)	Control Group (n = 467)	*P* Value
Surgery			
Upper gastrointestinal	100 (22.0%)	104 (22.2%)	0.992
ESOP	12 (2.6%)	10 (2.1%)	0.777
GAST	88 (19.4%)	94 (20.1%)	0.840
Lower gastrointestinal	330 (72.7%)	336 (71.9%)	0.859
SB	64 (14.1%)	63 (13.5%)	0.864
COLN	141 (31.1%)	152 (32.5%)	0.678
REC	125 (27.5%)	121 (25.9%)	0.630
Exploratory laparotomy	24 (5.3%)	27 (5.8%)	0.857
Surgeon grade			
Consultant	315 (69.4%)	314 (67.2%)	0.529
Senior training registrar	108 (23.8%)	128 (27.4%)	0.237
Junior training registrar	31 (6.8%)	25 (5.4%)	0.424
Skin-closure method			
Skin clips	343 (75.6%)	378 (80.9%)	0.057
Interrupted suture	89 (19.6%)	71 (15.2%)	0.094
Subcuticular suture	22 (4.8%)	18 (3.9%)	0.564
Operative time (min)*	198.0 ± 144.2	196.2 ± 143.2	0.424
Blood loss (mL)*	195.6 ± 458.2	244.4 ± 510.5	0.070
Laparoscopic surgery:open abdominal surgery	240:214	225:242	0.220
Duration of hospital stay after surgery (d)†	12 (3–162)	12 (3–128)	0.263

*Mean ± standard deviation.

†Median (range).

COLN indicates colon surgery; ESOP, esophageal surgery; GAST, gastric surgery; REC, rectal surgery; SB, small bowel surgery.

characteristics, age, sex, body mass index, smoking, diabetes, chronic kidney disease, arterial hypertension, and American Society of Anesthesiologists physical status were not associated with higher rates of superficial SSIs; however, preoperative serum albumin was significantly lower in patients with superficial SSI than in those without SSI (OR, 0.500; 95% CI, 0.310–0.807; P = 0.004). Regarding surgical factors, patients with superficial SSIs tended to have a longer surgical time (OR, 0.698; 95% CI, 0.436–1.118; P = 0.156) and greater blood loss (OR, 0.639; 95% CI, 0.396–1.031; P = 0.076) than those without SSIs. Superficial SSIs occurred in significantly fewer patients (29/427, 6.8%) in the Aquacel Ag Hydrofiber group than in the control group (50/438, 11.4%) (OR, 0.565; 95% CI, 0.350–0.912; P = 0.019). There was no significant difference in superficial SSI rates between the 2 groups following upper gastrointestinal surgery (OR, 0.600; 95% CI, 0.210–1.718; P = 0.484); however, the rate was significantly lower in the Aquacel group compared with that in the control group following lower gastrointestinal surgery (OR, 0.556; 95% CI, 0.325–0.952; P = 0.042). Additionally, there was no significant difference in deep incisional SSI rates between the Aquacel group (n = 6) and control group (n = 2) (OR, 1.010; 95% CI, 0.997–1.023; P = 0.271), and there was also no significant difference in organ space SSI rates between the Aquacel group (n = 20) and control group (n = 25) (OR, 1.011; 95% CI, 0.980–1.043; P = 0.599).

Multivariate analysis identified Aquacel Ag Hydrofiber dressings as an independent factor for reducing superficial SSIs (OR, 0.602; 95% CI, 0.367–0.986; P = 0.044) (Table 4).

There were no adverse events, such as allergic reactions or wound pain, which could be attributed to the Aquacel Ag Hydrofiber. All patients with superficial SSI were treated with open wounds, drainage, and irrigation, and no antibiotics were readministered. No patients were identified to have surgical site infection-related readmissions.

Microbiology and Adverse Events

Wound cultures from 79 patients with superficial SSIs revealed bacteria in all patients. A total of 148 bacteria were isolated

from patients with superficial SSIs, of which *Enterococcus faecalis* (32 patients, 40.5%) and *Pseudomonas aeruginosa* (29 patients, 36.7%) were the most common. *Staphylococcus aureus* or *Staphylococcus epidermidis* was isolated from 15 patients (19.0%). Methicillin-resistant *S. aureus* accounts for 69.2% of *S. aureus* infections. *Enterobacteriaceae*, including *Escherichia coli* and *Citrobacter freundii*, were each isolated in 6 patients (7.6%), *Klebsiella pneumoniae* in 2 patients (2.5%), and *Enterobacter cloacae* in 4 patients (5.1%). *Bacteroides fragilis* was not isolated. There were no significant differences in the frequencies of isolated bacterial species between the Aquacel and control groups.

DISCUSSION

This study demonstrated the feasibility of conducting a large-scale, single-center RCT to investigate the effectiveness of Aquacel Ag Hydrofiber postoperative dressings for the prevention of superficial SSIs. To the best of our knowledge, this is the first RCT to address the efficacy of these dressings in reducing the incidence of superficial SSIs in patients undergoing gastrointestinal surgery. Aquacel Ag Hydrofiber dressings reduced the incidence of superficial SSIs by approximately 40% compared with standard film dressings. The incidence rate of superficial SSIs in the control dressing group is 11.4%, which is similar to previous reports.[22–24]

In 2007, Yates et al[25] reported that Aquacel Ag Hydrofiber dressings lowered wound-bacterial loads compared with untreated infected wounds in an infected mouse wound model. Several studies in patients with burns have also shown that Aquacel Ag Hydrofiber dressings reduce pain during dressing changes, promote wound healing, need fewer dressing changes, and are more cost-effective compared with standard treatment or silver sulfadiazine.[26–30] Several reports have investigated the effect of Aquacel Ag Hydrofiber dressings on postoperative SSIs. In the field of orthopedics, Aquacel Ag Hydrofiber dressings suppressed periprosthetic joint infections compared with standard gauze dressings in patients undergoing total joint arthropathy surgery.[31] In patients with breast cancer, however, there was no significant difference in the frequency of SSIs in patients treated with Aquacel Ag Hydrofiber and standard gauze dressings.[32] Although several studies have examined the preventive effect of Aquacel Ag Hydrofiber dressings against SSIs caused by resident skin bacteria, their preventive effect against superficial SSIs caused by bacteria originating from the gastrointestinal tract remains unclear.

The SSI complication rate following upper gastrointestinal surgery was as high as 12.7% in this study, which was higher than that following lower gastrointestinal surgery (9.5%). A nationwide survey by the Japanese surveillance committee reported that 7 main organisms were collected from SSIs at 27 medical centers in 2010,[33] including *S. aureus* (24.7%), *E. faecalis* (16.5%), *Enterobacteriaceae* (25.6%), *P. aeruginosa* (19.2%), and *B. fragilis* group (13.7%) of cases. The main isolate from upper gastrointestinal surgery was *S. aureus* and the main isolate from lower gastrointestinal surgery was *B. fragilis*. In the present study, there were no significant differences in the frequencies of isolated bacterial species from patients with SSIs between the Aquacel Ag Hydrofiber and control groups. Although the isolation rates of *S. aureus* and methicillin-resistant *S. aureus* were similar to those reported by Takesue et al,[33] the isolation rates of *B. fragilis* and *Enterobacteriaceae* were low. The results suggest

TABLE 3.

Univariate Risk Estimates of Acquiring a Postoperative Superficial Surgical Site Infection

	Superficial SSI, n (%)	No Superficial SSI, n (%)	Odds Ratio (95% CI)	*P* Value
All patients				
Aquacel Ag Hydrofiber dressing group	29 (6.8%)	398 (93.2%)	0.565 (0.350–0.912)	0.019
Control group	50 (11.4%)	388 (88.6%)		
Upper gastrointestinal surgery				
Aquacel Ag Hydrofiber dressing group	6 (6.0%)	94 (94.0%)	0.600 (0.210–1.718)	0.484
Control group	10 (9.6%)	94 (90.4%)		
Lower gastrointestinal surgery				
Aquacel Ag Hydrofiber dressing group	23 (7.0%)	304 (93.0%)	0.556 (0.325–0.952)	0.042
Control group	40 (12.0%)	294 (88.0%)		

TABLE 4.

Binomial Logistic Regression Analysis of Identified Variables Associated With Increased Incidence of Superficial Surgical Site Infections

			95% CI		
Variable	Wald	OR	Lower	Upper	*P* Value
Age	0.211	0.994	0.970	1.019	0.646
Sex (male)	0.191	0.883	0.506	1.542	0.662
BMI	0.527	1.025	0.959	1.096	0.468
Smoking	0.266	0.870	0.511	1.479	0.606
Diabetes	0.003	1.016	0.574	1.798	0.956
Chronic kidney disease	0.511	1.532	0.476	4.937	0.475
Arterial hypertension and/or antihypertensive medication	0.965	1.306	0.767	2.223	0.326
Preoperative steroid medication	0.353	1.504	0.391	5.789	0.553
ASA-PS (grade 1–2)	0.002	0.983	0.496	1.949	0.962
Preoperative serum albumin	3.770	0.584	0.339	1.005	0.052
Operation time	2.949	1.001	1.000	1.003	0.086
Blood loss	2.061	1.000	1.000	1.001	0.151
Laparoscopic surgery	1.971	0.683	0.402	1.163	0.160
Aquacel Ag Hydrofiber dressing	4.060	0.602	0.367	0.986	0.044

ASA-PS indicates American Society of Anesthesiologists physical status; BMI, body mass index.

that Aquacel Ag Hydrofiber may have limited effects against *P. aeruginosa*, *S. aureus*, and methicillin-resistant *S. aureus*, but it may help to prevent superficial SSIs caused by *B. fragilis* and *Enterobacteriaceae*, and may reduce superficial SSIs following lower gastrointestinal surgery.

This study has several limitations. First, this was a single-center rather than multicenter RCT and was not double blinded. The open-label design led to the possibility of bias in the primary outcome; however, we considered that any potential bias could be reduced by using at least 3 surgical staff members, other than the operating and/or attending surgeon, to evaluate the patient's wound. The single-center nature of the study may also have led to bias; therefore, further multicenter studies are required. Second, the study protocol assumed that the incidence of superficial SSIs would be lower in patients undergoing upper gastrointestinal surgery than in patients with in those undergoing lower gastrointestinal surgery; however, Aquacel Ag Hydrofiber dressings suppressed the incidence of SSIs following lower gastrointestinal surgery but failed to suppress superficial SSIs in patients undergoing upper gastrointestinal surgery. These results warrant a phase 3 trial to examine the effect of Aquacel Ag Hydrofiber dressings in patients undergoing lower gastrointestinal surgery. Finally, we did not target hepatobiliary or pancreatic surgeries in the present study. Although these surgeries are known to have a high incidence of postoperative SSIs, we did not include them in the present study because they involve a variety of procedures and are expected to have longer operation times and greater blood loss. Although Aquacel Ag Hydrofiber dressings had no significant effect on patients undergoing upper gastrointestinal surgery in the present study, further studies are needed to consider hepatobiliary and pancreatic surgery limited to pancreaticoduodenectomy and/or biliary tract reconstruction.

CONCLUSIONS

Aquacel Ag Hydrofiber dressings may significantly reduce the rate of superficial SSIs compared to film dressings in patients undergoing elective gastrointestinal surgery, especially lower gastrointestinal surgery, with no adverse events. Further multicenter phase 3 trials are needed to assess the effect of these dressings specifically in patients undergoing lower gastrointestinal surgery.

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All the authors contributed to the conception and design of the study. C.K., K.K., and H.S.: wrote the protocol, collected and interpreted the data, analyzed the data, and wrote the manuscript. M.Y., K.S., and M.M.: performed the statistical analysis and wrote the paper. A.U., H.N., S.E., H.Y., H.A., T.T., T.S., M.H., and H.K.: data collection and paper writing.

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