



ORIGINAL ARTICLE

A new silver dressing, StopBac, used in the prevention of surgical site infections

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Abstract

Ideal dressings of surgical wounds should provide moist, semi-permeable, and antiseptic environments for optimal wound healing. To maximise patient comfort, surgical dressings must be hypoallergenic, not restrict movement, and allow patients to manage their personal hygiene. From the aspect of health care personnel, dressings should enable visual monitoring of the wound without the need for removing them, thus reducing the number of dressing changes. The active antimicrobial effect of silver cations has been demonstrated by many studies. StopBac is a unique surgical dressing based on the sol-gel process. Silver cations are bound in a colloidal solution in an organic-inorganic hybrid organosilicate oligomer. This gel is deposited on a pad using spray atomisation. The result is a polymer nanolayer matrix with prolonged and controlled release of silver ions. This pad forms part of a waterproof hypoallergenic transparent adhesive bandage. The goal of this study was to prospectively evaluate the ability of StopBac to prevent surgical site infections (SSIs) in patients after abdominal surgery. The secondary goal was to compare costs and determine the properties of this new material. A total of 32 patients were included in the study. The patients were followed up until their surgical wounds healed completely. An SSI occurred only in one patient.

KEYWORDS

economic costs, silver cations, sol-gel, surgical dressing, surgical site infection

1 | INTRODUCTION

There is currently a wide range of dressings available for surgical wounds. At the Department of Surgery of University Hospital Kralovske Vinohrady, the standard dressing used after surgical procedures is a sterile gauze compress (Sterilkompres, Bastist Medical, CZE) with a non-transparent elastic film roll (Elastopore, Batist Medicial s.r.o. CZE).

The aim of this prospective observational study was to evaluate the effect of StopBac (Grade Medical, CZE), a new surgical dressing, in preventing surgical wound infections. StopBac consists of a matrix of organic-inorganic hybrid oligomers that ensure the controlled release of silver (Ag⁺) cations. The importance of silver ions in the treatment of chronic and especially infected wounds has been demonstrated in many studies.¹⁻⁵

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Under laboratory conditions, silver ions demonstrate high antimicrobial activity not only against bacteria but also against viruses and fungi.⁶ The antibacterial effect of the StopBac dressing, based on the controlled release of silver ions, is further enhanced locally by the high hydrophobicity of the hybrid polymer matrix layer, which creates an environment unsuitable for bacteria propagation.

The aim of our study was to demonstrate the effect of this material in the prevention of surgical site infections (SSIs). Secondary aims were to report the total number of dressing changes per patient and the cost of the dressing.

2 | MATERIALS AND METHODS

From January to March 2020 at the Department of Surgery of University Hospital Kralovske Vinohrady, we used the StopBac dressing in 34 patients. Two patients were excluded from the study as they were transferred to other departments for part of their perioperative care. One had a massive pulmonary embolism, and the other developed coronavirus disease 2019. Both these patients were transferred to different departments where StopBac was not used. Thus, in total, 32 patients were included. These patients underwent hepatopancreatobiliary, colorectal, and hernia repair surgery, and they were prospectively followed for the duration of the study.

Patient medical histories were reviewed for the presence of any disease, which may impair wound healing, such as diabetes, ischaemic cardiac disease, hypertension, chronic lower limb ischaemia, chronic venous insufficiency, lipid metabolism disorders, and alcohol abuse (see Table 1). Furthermore, we noted whether patients were on anticoagulation therapy, had received neoadjuvant therapy, or had been taking antibiotics prior to the surgery. Another factor that can significantly influence wound healing is the nutritional status of the patient. All patients undergoing hepatopancreatobiliary surgery in our department undergo complex preoperative examination at the department of clinical physiology, as part of this examination, the nutritional status is assessed and when indicated preoperative nutritional support is given. The preoperative levels of total protein and albumin of the patient cohort are also reported in Table 1.

The patient cohort consisted of 19 females and 13 males. The average age was 66 years (median 67 years, range 50-84). Indications for surgery were pancreatic malignancy ($n = 17$), chronic pancreatitis ($n = 1$), hepatic cancer or liver metastases ($n = 8$), bile duct cancer ($n = 1$), kidney tumour ($n = 1$), and inguinal hernia ($n = 3$). Eleven patients underwent hemipancreatoduodenectomy (HPD), in one case this was combined with an extended right hepatectomy for bile duct cancer. One patient underwent total

Key Messages

- The effect of a new wound dressing using silver ions, StopBac, in preventing surgical site infections (SSIs) was investigated in this prospective observational study
- A total of 32 patients were included in the study from which one developed an SSI
- StopBac was associated with fewer dressing changes and lower costs when compared with the standard dressing used in our institution

pancreatectomy, and one underwent an exploratory laparotomy. All these patients had undergone preoperative endoscopic retrograde cholangio pancreatography (ERCP) with drainage of the bile ducts. Two patients underwent distal pancreatectomy with splenectomy. Four patients with pancreatic cancer and inoperable findings underwent palliative gastroenteroanastomosis. Nine patients underwent liver resection (one combined with a HPD as mentioned above). One patient had a nephrectomy, and three patients underwent inguinal hernia repair.

3 | RESULTS

The average number of necessary wound dressing changes per patient was 1.8 (median 2; range 1-3). The first dressing change was performed on average 3.75 days after surgery (median 4, range 1-6). A second dressing change was performed on average 7 days after surgery (median 7, range 4-11). A third dressing change was required in only four patients, on average 9 days after surgery (median 8, range 7-13).

In accordance with the antibiotic guidelines in our hospital, all patients received ampicillin-sulbactam (1 g ampicillin, 0.5 g sulbactam) prophylactically 30 minutes before the start of surgery. In the case of longer procedures, a second dose was administered after 4 hours.

Antibiotics were administered postoperatively in nine patients: in four patients for macroscopic signs of bile infection during surgery, in two patients for urinary tract infections, and in three patients for empyema of the gallbladder. The average duration of postoperative antibiotic therapy was 4.44 days (median 2, range 1-9).

Four patients had serum albumin levels below the normal range (Table 1), three of which also had low total protein. Two additional patients had isolated low total protein. All of these patients received nutritional preoperative support as

part of their preoperative preparation. No complications occurred in these patients. After hepatopancreatobiliary procedures, patients received complete parental nutrition; after HPD, this was combined with gradually increasing enteral nutrition given via a nasojejun tube.

An SSI developed in only one patient. This patient underwent HPD for pancreatic cancer. A postoperative pancreatic fistula was detected on the third postoperative day, which drained into the surgical wound. The patient was treated with meropenem (Meropenem; Pfizer s.r.o,

TABLE 1 Patient characteristics

No	Age	Sex	Albumin (g/L)	Total protein (g/L)	Comorbidities	Diagnosis	Procedure	SSI
1	70	F	65.2	42.2	HY	C250	GEA	No
2	66	F	72.9	44.7	DMII-T, MLG	C250	HPD	SSI
3	80	F	65.6	43.3	HY, CVD, MLG, AA	C250	GEA	No
4	60	F	70.9	41.0	HY, CVD, LMD, MLG	C250	GEA	Hematoma
5	67	F	80.5	39.8	MLG, S, AA, NAC	C250	GEA	No
6	68	F	69.4	47.0	HY, DMII-D, Y	C250	HPD	No
7	72	M	62.4	40.9	DMII-T, IHD, LMD, MLG, AA	C250	HPD	No
8	59	M	67.5	33.8	DMII-D, MLG, S, AA	C250	TPE	No
9	64	M	69.2	46.2	DMII-T, MLG, S, AA	C250	HPD	No
10	84	F	68.2	43.2	HY, DMII-T, PT, LMD, MLG	C250	HPD	No
11	56	F	76.2	43.2	CVD, PT, MLG, AA	C250	HPD	No
12	71	M	66.7	43.6	DMII-T, MLG, AA, NAC	C251	DPE	Hematoma
13	58	F	72.4	43.0	LMD, MLG, S, AC	C251	HPD	No
14	62	F	68.6	40.8	HY, MLG, S, AA, NAC	C251	DPE	No
15	69	F	58.3	31.8	CVD, MLG, S, AA, NAC	C787	LR	No
16	68	F	62.3	38.3	HY, MLG, AA	C787	LR	No
17	55	F	70.2	46.8	HY, MLG, AA, NAC	C787	LR	No
18	75	F	67.5	43.7	MLG, AA, NAC	C787	LR	No
19	73	M	69.8	40.0	LMD, MLG, NAC	C787	LR	No
20	70	M	65.1	38.2	HY, IHD, CVD, LMD, MLG, AA	C220	LR	No
21	59	F	71.1	42.8	HY, MLG	C220	LR	No
22	69	M	56.9	35.6	IHD, PT, MLG, S, AA, Y	C221	LR	Hematoma
23	58	F	72.7	47.5	MLG, AA	C240	HPD	No
24	50	M	68.3	46.5	HY, DMII-T, LMD, MLG, AA, AC	C241	HPD	No
25	76	F	71.8	43.4	MLG, S, AA	C240	HPD + LR	No
26	72	F	74.4	50.1	HY, MLG, AA	C241	HPD	No
27	53	M	46.2	31.9	MLG, AA	C210	Miles	Seroma
28	57	M	65.2	45.1	HY, MLG, S, AA	C64	NE	No
29	60	M	45.1	30.5	S, AA	K861	EL	No
30	76	F	61.5	40.9	CVD, AA	K451	HP	No
31	61	M	NA	NA	HY, CVD, LMD, AA	K409	HP	No
32	64	M	NA	NA	HY, DMII-T, IHD, CVD, LMD, AA, AC	K432	HP	No

Note: Normal range for whole protein level: 65 to 85 g/L; albumin level: 35 to 53 g/L. Abnormal values are highlighted in grey.

Abbreviations: AA, alcohol abuse; AC, anticoagulation therapy; CVD, chronic venous disease; DM II-D, diabetes mellitus treated with diet; DM II-T, diabetes mellitus type II treated with insulin; DM-I, diabetes mellitus type I; DPE, distal pancreatectomy with splenectomy; EL, explorative laparotomy; GEA, palliative gastroenteroanastomosis; HP, hernioplasty; HPD, hemipancreatoduodenectomy; HY, hypertension; ICD, International Classification of Diseases; IHD, ischaemic heart disease; LMD, lipid metabolism disorders; LR, liver resection; Miles, abdominoperineal amputation; MLG, malignant disease in previous medical history; NAC, neoadjuvant chemotherapy; NE, nephrectomy; PT, phlebothrombosis; S, smoking; SSI, surgical site infection; TP, total pancreatectomy.



FIGURE 1 StopBac left on a wound until planned wound dressing. A serosanguineous exudate is seen seeping through the dressing

CZE) at a dose of 4 g per 24 hours four from the third to tenth postoperative day. A fluid collection was drained under computed tomography guidance on the seventh postoperative day. Microbial cultures revealed the presence of *Escherichia coli* and *Enterococcus faecium*. On the 30th postoperative day, the drain was removed and the fistula was considered healed. The patient underwent daily wound irrigation using Prontosan Wound Irrigation Solution (B. Braun Medical AG, CH) and daily changes of sterile dressings until the twelfth postoperative day. The surgical wound healed completely on the 16th postoperative day.

Three patients developed subcutaneous haematomas in the surgical wound. One of these patients was taking nadroparin (Fraxiparine 9500 IU/1 mL; Aspen Pharma Trading Limited, IRL) in the perioperative period at a dose of 0.6 mL every 12 hours due to atrial fibrillation. Another had received neoadjuvant chemoradiotherapy consisting of three doses of gemcitabine, 36 greys of radiation therapy in 15 fractions followed by five series of FOLFIRINOX. One patient developed a seroma in the perineal wound after rectal amputation, which was drained during an outpatient visit. No other wound complications occurred in the remaining 22 patients.

In most patients following major surgery (pancreas, liver, or colorectal resections) with a surgical wound length of 30 ± 5 cm (bilateral subcostal incision or extended midline incision), an average of 1.8 dressings were applied (median 2; range 1-3) using StopBac STERILE (10 × 30 cm and 10 × 10 cm over each other). The

first dressing change took place at an average of 3.8 days after surgery (median 4; range 1-6) and the second on the seventh postoperative day (median 7; range 4-11). The wound was inspected during each dressing change, and if it was clean and dry without signs of inflammation or retention, it was dressed using only OpSite spray (Smith & Nephew Consumer, GB). Four patients required three dressing changes using StopBac STERILE on the ninth postoperative day on average (median 8; range 7-13) because of mild serous and in one case sanguineous discharge. As mentioned previously, in one patient who developed a pancreatic leak and subsequently an SSI, the wound was treated by regular irrigation and covered with sterile gauze from the second dressing change (third postoperative day) onwards.

Standard procedure at our department calls for wound dressings to be changed on the first or second postoperative day, depending on their appearance and subsequently on the third to fifth and seventh postoperative days. After this, if there are no complications and the wound is healing by primary intention, the wound is covered by only the OpSite spray until the sutures are removed. In our department, the standard material used on the first to third wound dressings are the sterile compress Sterilkompres (Batist Medical, CZE) and the adhesive tape Elastopore (Batist Medical, CZE). If the wound does not show any signs of SSI and is healing by primary intention on the second or third dressing change, it is covered using only the Elastopore adhesive pad (Batist Medical, CZE).

Overall, the cost of dressing a surgical wound in the hepatopancreatobiliary area per patient using StopBac STERILE if one to two dressing changes are needed ranges from CZK 110 to 164 (EUR 4.04-6.03 or USD 4.80-7.15). The cost using the classical form of wound dressings (two to three dressing changes using two packages of sterile compresses and one dressing change using Elastopore adhesive tape per dressing change) ranges from CZK 142 to 213 (EUR 5.23-7.83 or USD 6.19-9.29)—based on the exchange rate on October 25, 2020, of EUR/CZK 27.21 and USD/CZK 22.94. Moreover, these costs do not include a calculation of the work performed by the nursing staff, the disinfectant swabs and instruments used, or the decreased need for analgesics during dressing changes.

4 | DISCUSSION

The composite material of the StopBac pad ensures efficient drainage of exudate into the absorbent layer, which is separated from the wound by a specifically perforated film, thus preventing the exudate from leaking back into

the wound. The surface of the pad's outer layer is covered by a nanolayer consisting of an organic-inorganic hybrid oligomer matrix with a high degree of conversion that ensures the controlled release of silver ions (antibacterial effect). At the same time, given its hydrophobic properties, it minimises the risk of the dressing adhering to the wound.

The StopBac material creates an environment suitable for healing, where undesired microbial contamination is at the same time controlled thanks to the prolonged release of silver ions. If used correctly, dressings that use silver as an antimicrobial agent are suitable for dressing wounds with bacterial infection.⁷ Silver ions have been demonstrated to have an inhibitory effect against both gram-positive and gram-negative bacterial strains.⁸ The antibacterial effect of silver ions is also due to their high potential for interrupting the transport and release of potassium ions (K⁺) from bacterial cells and blocking the synthesis of adenosine triphosphate.⁹ Moreover, the ions of silver easily bind to a whole range of biomolecules such as DNA, RNA, and peptides, forming insoluble compounds and thus preventing bacterial cell division and reproduction.¹⁰ Hybrid nanolayers prepared using the sol-gel method based on 3-trimethoxy-silyl propyl-methacrylate containing ion-bound silver cations introduced in the form of a solution of silver nitrate,

demonstrate high antibacterial effects, and are suitable for medical applications.⁷

Our prospective observational study focused primarily on postoperative surgical wounds that were aseptic (hernia surgery) and potentially contaminated (hepatopancreatobiliary and colorectal surgery and nephrectomy). It is a well-known fact that ERCP with stent implantation prior to surgery significantly increases the risk of intra-abdominal infection and wound contamination.^{11,12} However, in our study, neither ERCP nor any other known risk factors affected the development of SSI. Twenty-eight patients underwent surgery for a malignancy, seven of which had neoadjuvant chemotherapy.

It is a well-documented fact that preoperative nutritional status significantly influences healing after gastrointestinal surgery, and for this reason, patients undergoing major abdominal procedures in our institution undergo nutritional screening as part of the preoperative preparation.¹³ In our cohort, the one patient who developed an SSI had serum values of total protein and albumin within the normal range for our laboratory (72.9 and 44.7 g/L, respectively).

In contrast to other studies that used silver in their dressings, we did not focus on its effect on wound healing but rather on its role in the prevention of SSI development. In this study, if the dressing did not show signs of loss of integrity or seepage outside its margins. It was



FIGURE 2 Wound appearance after StopBac dressing saturated with wound secretion is removed (the text on a dressing marks the day of planned removal)

kept on the wound until the planned dressing change on the third or fourth postoperative day. The dressing was not removed even if it was bloody or saturated with secretions (see Figures 1 and 2). This was fundamentally different from our routine practice, where the gauze dressing is changed at any time if blood or secretions are seen.

With regard to the focus of our department being hepatopancreatobiliary surgery, the majority of the patients included in this study (18 patients) underwent pancreatic procedures, 11 of which were hemipancreatoduodenectomies, in one case combined with an extended hepatectomy. It is necessary to bear in mind that the complications of these, the most common being pancreatic leak, can significantly complicate healing of the surgical wound. A pancreatic fistula occurred in one patient in our cohort. The fistula drained through the surgical wound, as a consequence this led to a wound infection and healing via secondary intention. Our team plan to follow this study with a larger multicentre study where the pancreatic procedures will be analysed as a unique cohort.

In total, only one SSI occurred in our cohort of 32 patients (3.12%). In the year 2019, a total of 1935 operations were performed in our department. SSIs occurred in 86 (4.4%) of these patients. Hepatopancreatobiliary procedures constituted 168 of these operations, from them 19 patients (11.3%) developed SSIs. Published data from large hepatobiliary surgery centres report SSIs in HPB surgery to range from 18% to 29%.^{14,15}

The lower prevalence of SSIs in our cohort may be explained by the preoperative preparation of these patients, which includes nutritative interventions and prehabilitation. Nonetheless, an accurate comparison is not possible with a small patient cohort and observational study design.

From the patient's perspective smaller, elastic and thin dressings facilitate mobilisation and are more comfortable. StopBac is water repellent on its superficial surface, which dressing enables patients to more easily manage their personal hygiene earlier after surgery. We did not record any allergic reactions, reddening or skin irritation. Another benefit of using the StopBac dressing was the overall reduction in the number of dressing changes. This increases patient comfort and decreases the risk of surgical wound contamination. Even dressings that appeared saturated with secretions did not require immediate changing.

A comparison of the costs between classical wound dressing methods used in our department with StopBac, which required less frequent changing, slightly favours StopBac. For an accurate cost analysis, we would have to take into account all parameters associated with treating the wound. This would include nursing care, prolonged

hospital stay, and antibiotics among others. At this time, we can say that as the total average number of dressing changes was less for StopBac, the cost of the materials is lower than it would have been for the traditional dressings.

Although not yet reported, there has been some concern regarding the possibility of bacteria developing resistance to dressings containing silver and some authors have advocated restricting the use of silver dressing to primarily aseptic surgical wounds such as those in orthopaedic procedures.¹⁶ On the other hand, however, minimising the risk of SSIs should always be considered a priority as should be the patient's interest.

Our observational study confirmed the suitability of the StopBac dressing for surgical wounds in patients after major abdominal surgery and with potentially infected surgical wounds. Given the small number of patients in our non-homogenous sample, these results will have to be verified by a robust randomised study. Nonetheless, it appears that using StopBac in this indication may be suitable, safe, and economically advantageous. Furthermore, it increases patient comfort by decreasing the number of dressing changes needed and ensuring early patient mobilisation and proper personal hygiene.

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CONFLICT OF INTEREST

This study used material provided free of charge by GRADE MEDICAL Ltd, Ing. Petr Brařka works for GRADE MEDICAL Ltd, CZ.

DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions

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