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A silver-based antimicrobial dressing for the prevention of surgical site infection - a pilot study

Surgical site infection is a postoperative complication that affects many surgical patients worldwide. It has been estimated that up to 60% of SSIs are preventable and that their risk can be minimised by applying the best practice in the perioperative period. Proper wound management is one way of preventing the incidence of SSIs. This paper describes results of a descriptive case series focused on the usage of silver dressing on post-operative wounds.

Keywords:
surgical site infection, antimicrobial dressing, prevention of infection

ABSTRACT

Background

Surgical site infection (SSI) is a postoperative complication that affects many surgical patients worldwide. It has been estimated that up to 60% of SSIs are preventable and that their risk can be minimised by applying the best practice in the perioperative period. Proper wound management is one way of preventing the incidence of SSIs.

Aim

Our aim was to test the SSI-related serviceability of a novel silver-based dressing material for acute wound management on a group of 22 patients who underwent planned surgery.

Method

Our observational case series is a descriptive clinical study for quality assurance purposes. Participants were male and female patients over 18 years old who were scheduled to undergo "clean" surgical procedures. We monitored the total number of dressing changes until stitches were removed and the incision had healed, possible local and systemic clinical signs of infection, the current state of the wound and the patient's and surgeon's satisfaction with the dressing.

Results

No superficial or deep surgical site infection was observed during the treatment or follow-up periods (total: four weeks). All incisions (100%, 22) healed by primary intention with no wound dehiscence. The dressing was well tolerated by the patients (71.4% rated it "excellent", 23.8% rated it "very good") and the healthcare professionals' satisfaction rates were also positive (66.7% rated it "excellent", 33.3% rated it "very good").

Conclusion

The dressing has shown good clinical serviceability and was well tolerated by the patients. To obtain robust evidence for wider use, a randomised controlled trial is required.

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The company manufacturing the product tested in the study provided free samples of the dressing but had no influence on the clinical evaluation.

Key messages

- Paper describes results of a descriptive case series focused on the usage of silver dressing on post--operative wounds.
- The aim of the study was to test the SSI-related serviceability of a novel silver-based dressing for acute wound management.
- No superficial or deep surgical site infection was observed during the treatment or follow-up periods.

INTRODUCTION

Surgical site infection (SSI) is a postoperative complication that affects many surgical patients worldwide. It is the third most commonly reported health-associated infection[1] and results in significant patient postoperative morbidity and mortality and increased additional health-care related costs. Surgical site infections are defined[2] as infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the skin incision or deep tissue at the operation site. The risk of SSI is influenced by a number of intrinsic and extrinsic factors, particularly the number of microorganisms present at or introduced into the incision during the surgical procedure. The incidence of SSIs varies depending on multiple factors, including the type of operation, the patient's pre-existing health status, and the quality of perioperative management. In 2017, Berríos-Torres et al.[3] reported that almost 50% of SSIs become evident after discharge. This may be caused by efforts to shorten patient's stay (often seen in many hospitals), which leads to early discharge and can make diagnosis and surveillance of SSIs more difficult. It is questionable whether health-care systems across Europe are able to ensure appropriate conditions for good surveillance and smooth diagnosis of SSIs in outpatient settings. It has been estimated that up to 60% of SSIs are preventable[4] and that the risk of such infections can be minimised by applying best practice in the perioperative period. Precautions to prevent SSIs are particularly focused on the reduction of risk factors present at the time of surgery to reduce or forestall contamination of the operating site. The rates of SSIs associated with surgery[5] on sterile sites are, therefore, very low (< 2%) compared with the rates of SSIs associated with surgery on contaminated sites, which may be over 10%. An excellent surgical technique, preoperative preventive precautions and proper wound management are considered the foundations of an undisturbed healing process[2] and are among the ways to decrease the number of clinically manifesting SSIs.

Current clinical recommendations for SSI prevention can be found in several published guidelines: the 2018 World Health Organization (WHO) Global Guidelines for the Prevention of Surgical Site Infection); the National Institute for Health and Care Excellence (NICE) Surgical Site Infections: Prevention and Treatment, updated in 2017[7]; and the Centers for Disease Control and Prevention's (CDC) Guideline for the Prevention of Surgical Site Infection3, published in 2017. These guides highlight specific recommendations for the preoperative phase (staphylococcus aureus screening and decolonisation, smoking cessation, modification of treatment in the light of existing medical conditions, thoughtful hair removal, patient showering and reasonable surgical antibiotic prophylaxis), the intraoperative phase (preparing surgical hand and skin at the surgical site, wearing sterile gowns and sterile gloves, maintaining patient perioperative normothermia and optimal oxygenation and covering surgical incisions with an appropriate interactive dressing) and the postoperative phase (an aseptic technique for changing or removing surgical wound dressings, adequate nutritional interventions and proper wound care after discharge from hospital).

Antimicrobial dressings are an effective tool for local treatment of infected wounds. Although they are widely used in clinical practice, we have very little data or evidence to support their universal usage in wound management, especially in the prevention of wound infection.[8] Silver dressings provide extensive protection against bacteria, fungi and viruses, including nosocomial pathogens, methicillin-resistant Staphylococcus aureus (MRSA) and vancomycin-resistant Enterococci (VRE), making them a valuable adjunct in the prevention and treatment of infection. In 2017, Tisosky et al.[9] conducted a clinical trial showing that the use of silver dressings significantly reduced the incidence of superficial and deep prosthetic joint infection following total joint replacement. A literature review[10] published in 2014 reported that silver nylon dressings are associated with a reduced risk of SSI in small studies across several specialities, including colorectal surgery, neurosurgery, spinal surgery and some cardiac and orthopaedic procedures, although the authors recommend larger powered trials on these cohorts to determine the comparative effectiveness

of silver nylon dressings in the prevention of SSIs. The 2017 update to the NICE guidelines[7] concludes that no particular dressing type emerges as the most effective in reducing the risk of SSI, although silver nylon dressings may be more effective than gauze.

Positive outcomes of clinical trials investigating the effectiveness of silver dressings for SSI incidence reduction provide some justification for stating that antimicrobial dressings could decrease the negative impact of extrinsic SSI risk factors related to contamination of the patient's body surface. Nevertheless, the current evidence for the efficacy of antimicrobial dressings in reducing the risk of SSI is weak.

The aim of our observational pilot case series is to describe SSI-related effectiveness of a novel silver-based dressing material for acute wound management through a study of a group of 22 patients who underwent planned surgery.

METHODS

The observational pilot case series has been designed as a descriptive clinical study to evaluate the efficacy of a silver dressing for quality assurance purposes. The study was approved by a local ethics committee Český Těšín. The multicentric study was carried out on patients who visited the Salvatella Ltd surgical outpatient clinic in Trinec, Czech Republic or the surgical department of Hospital Podlesi, Trinec, Czech Republic, for planned surgery from September 2019 to November 2019. Salvatella Ltd is an outpatient health-care facility specialising in general surgery, vascular surgery and complex treatment of non-healing wounds. It is located in the North Moravian region. Hospital Podlesi is part of the Czech Cardiovascular Centre Network. Its surgical department provides specialised care to patients with surgical and vascular disorders, and its catchment area has more than 500,000 inhabitants.

Patients included in the sample were randomly selected. Male or female patients over 18 years old who were consecutively scheduled to undergo "clean" surgical procedures in an outpatient or inpatient setting at either of the aforementioned health-care facilities and who had provided written informed consent to participate in the study were included. Patients were treated by three experienced surgeons in the two institutions. The exclusion criteria were surgical procedures to treat infections, primary infected wounds, a known allergy to the tested dressing, an inability to follow the study protocol or recommendations specific to the primary diagnosis.

Patient characteristics, including age at the time of surgery, sex, smoking habits, body mass index, grave comorbidities and medication, were collected. All surgical incisions were treated by primary closure using skin sutures. The intervention consisted of the application of the sterile silver-based dressing onto the sutured incision at the time of surgery and during subsequent dressing changes. The dressing was placed on the incision before the patient left the operation hall and removed according to the clinical needs of the wound (leakage, spontaneous dressing release or requirement for a surgeon to examine the wound). At the end of the treatment period, the stitches were removed from the incision (upon the decision of the attending surgeon) and the wound was covered with the last sheet of dressing. Clinical data were collected by the attending surgeon and continuously recorded in the clinical report. The same investigator observed the patient at the hospital (in cases of inpatient intervention), at the outpatient clinic and during the follow-up period. We monitored the frequency and the total number of dressing changes until the stitches were removal and the incision had healed, the possible local and systemic clinical signs of infection and the current state of the wound. The postoperative protocol was consistent across all surgeons and at both institutions and was compliant with an institutional standardised protocol for all patients. No patient received perioperative antibiotics. The study patients were followed prospectively to check for the onset of superficial or deep infection. The treatment period was terminated two weeks after surgery by removal of the suture material, after which the follow-up period lasted a further two weeks. The final diagnosis for SSI was made by the attending surgeon at the end of the follow-up period (i.e. four weeks after surgery) based on the criteria defined by the WHO guidelines[11] for safe surgery and the NICE guide[7], published in 2017. Assessed clinical signs of infection included purulent drainage, wound pain or tenderness, localised swelling, redness, heat, cellulitis of soft tissue at the place of surgery or wound abscess. Tolerance of the dressing (assessed by the patient) and satisfaction with the local treatment and the dressing was evaluated by a healthcare professional (HCP) or patients themselves by labelling the appropriate answer from the offered options (see Table 5) during the final clinical appointment at the end of the second week of the observation.

Table 1. Population characteristics of the study group

Population Characteristics	
Age at surgery, yrs, mean ± SD; median	50.7±12.7 ; 46
Sex	
Female, % (n)	61.9 (13)
Male, % (n)	38.1 (8)
Tobacco use	23.8 (5)
Body mass index over 35, % (n)	14.3 (3)
Drug allergy %,(n)	9.5 (2)
Diabetes mellitus, % (n)	9.5 (2)
Length of incision, cm, mean ± SD; median	5.3±2.1 ; 6

DESCRIPTION OF THE TESTED DRESSING

The tested dressing was developed in 2018 by a Czech technological company, Grade Medical.* The dressing is produced using a patented nanotechnology called sol-gel, which works through a spray atomisation method. The inner surface of the dressing comprises an organic-anorganic hybrid oligomer with silver ions bound in a fluid containing silver nitrate[12] (see Figures 1 and 2). In a moist environment, the silver ions are released from the dressing pad and interfere with present microorganisms. This provides an antibacterial barrier that protects the surface of a wound from external contamination, potentially reducing the risk of wound infection. The dressing is available for clinical usage in two forms, both of which were available for dressing changes during the trial. The first form has an adhesive border and is used for low-exuding acute wounds, while the second one has no border and is suitable for non-healing infected wounds.

RESULTS

The study involved 22 surgeries (postoperative wounds) performed on 22 patients from September 1, 2019 to November 30, 2019. One patient was excluded from the observation due to a failure to follow the study protocol. Therefore, 21 patients were included for final evaluation. The demographic details of the study group are presented in Table 1. All patients underwent surgical interventions resulting in clean or clean-contaminated wounds2 with a generally low risk of SSIs. Table 2 presents a detailed list of the surgical interventions and the length of the procedures.

We did not observe any superficial or deep SSIs among the studied group of patients during either the treatment period or the follow-up period (lasting a total of four weeks). All incisions healed by primary intention with no wound dehiscence (see Table 3). The length of treatment was similar for surgeries in both inpatient and outpatient setting (see Table 4). In cases of inpatient treatment, patients were discharged from the hospital on the second day (2.6 ± 0.8 days; median 2 days) after surgery. In both groups, the stitches were removed from the wound margins on the 10th day after wound closure (hospital surgeries 10.4 ± 1.8 days; median 10 days, outpatient surgeries 11.5 ± 2.6 days; median 10 days). The dressing was changed four times per treatment period (see Table 4). In 81% (n = 17) of wounds, no wound exudation was observed, and the surface remained dry. We observed two adverse events with no association to the tested dressing: one patient suffered embolisation to the lung after varicose vein surgery, although the complication was resolved without consequences. Another patient noticed a seroma in the inguinal canal after inguinal hernia laparoscopic repair. Four patients (19%) noticed temporary itching under the adhesive border of the dressing, a symptom that completely subsided after treatment with the silver-based dressing was terminated. Tolerance of the dressing was evaluated as "excellent" by 74.1% of patients and "very good" by 23.8% of patients. Patient satisfaction with the dressing was rated as "excellent" by 61.9% of patients, as "very good" by 28.6% and as "good" by 9.5% of patients (see Table 3c). Satisfaction of HCPs with the dressing was "excellent" in 66.7% of cases and "very good" in 33.3% of cases (see Table 3c).

DISCUSSION

Surgical site infections are unpleasant complications

*StopBac, Grade Medical

Table 2a. Type of surgical intervention in the study group

Type of surgical intervention	
Varicose vein surgery, % (n)	38.1 (8)
Superficial soft-tissue benign tumour excision, % (n)	28.6 (6)
Strumectomy, % (n)	4.8 (1)
Laparoscopic hernia repair, % (n)	9.5 (2)
Laparoscopic cholecystectomy, % (n)	9.5 (2)
Direct endarterectomy, % (n)	4.8 (1)
Thoracoscopic sympathectomy, % (n)	4.8 (1)
Length of surgical procedure , min., mean ± SD; median	**39 ± 22; 40**

Table 2b. Anatomical location of surgery in the study group

Anatomical location of surgery	
Groin, % (n)	38.1 (8)
Back, % (n)	14.3 (3)
Abdomen, % (n)	19.0 (4)
Chest, % (n)	4.8 (1)
Neck, % (n)	9.5 (2)
Thumb, % (n)	9.5 (2)
Thigh, % (n)	4.8 (1)

that occur after surgical procedures, impairing the patient's quality of life and causing dissatisfaction and frustration among surgeons and other clinicians. They are connected with significant patient morbidity and mortality, longer hospital stays and considerable extra health-care costs.[13]

In common clinical practice, the preoperative elimination of all intrinsic and extrinsic risk factors for SSIs can be difficult. Although health-care facilities have to follow many preventive procedure-dependent and patient-related precautions to forestall the transmission of germs to the site of surgery in the perioperative period, SSIs remain a substantial threat. Efforts to prevent SSIs are based on early detection of high-risk patients, preoperative preparation of the patient, skilled medical staff and adequate equipment, a gentle and tactful operative technique, and postoperative wound management. In the early postoperative period, dressing the incision provides a barrier with an absorptive capacity to manage wound exudation and ensure a secure, stable and healing-friendly environment. As Woo reported in 2012[14], silver-based antimicrobial dressings can reduce the bacterial burden on the surface of a chronic wound, protect wound surfaces from microbial invasion and effectively suppress bacterial proliferation, For acute wounds, however, the evidence remains questionable. Routine use of antimicrobial dressings for the postoperative management of surgical wounds can increase treatment costs, affect patient by possible local action of the antimicrobials and have an impact on the antimicrobial resistance of present germs. In 2019, Stanirowski et al.[15] published the results of a randomised controlled on women (N = 543) who underwent caesarean section, which revealed that the use of bacterial-binding dressings following caesarean section could reduce the incidence of SSI and health-care costs. In 2017, Tisosky et al.[9] reported a positive impact of application of antimicrobial dressing on the postoperative wound on the reduction of SSI incidence. Their case-control study (N = 834) discovered that the use of a silver dressing significantly reduced the incidence of superficial and deep prosthetic joint

Table 3a. Overall treatment outcomes	
Total number of surgical site infections, % (n)	0 (0)
Total number of primary healed wounds, % (n)	100 (21)
Adverse events with no connection to the dressing, % (n)	9.5 (2)
Adverse event with possible connection to the dressing - itching, % (n)	19 (4)

Table 3b. Dressing tolerance evaluated by patient	
Dressing tolerance evaluated by patient (1-5) median	1
Dressing tolerance evaluated by patient: "excellent", % (n)	74.1 (15)
Dressing tolerance evaluated by patient: "very good", % (n)	23.8 (5)
Dressing tolerance evaluated by patient: "good", % (n)	4.8 (1)

Table 3c. Satisfaction with the dressing evaluated by patient/HCP	
Satisfaction with the dressing evaluated by patient (1-5) median	1
Satisfaction with the dressing evaluated by patient: "excellent", % (n)	61.9 (13)
Satisfaction with the dressing evaluated by patient: "very good", % (n)	28.6 (6)
Satisfaction with the dressing evaluated by patient: "good", % (n)	9.5 (2)
Satisfaction with the dressing evaluated by HCP (1-5) median	1
Satisfaction with the dressing evaluated by HCP: "excellent", % (n)	66.7 (14)
Satisfaction with the dressing evaluated by HCP: "very good", % (n)	33.3 (7)

infection following total joint replacement.

Our pilot study describes our experience with a novel silver-based dressing material appointed for acute wound management. It is based on the theoretical assumption that the antimicrobial action of the tested dressing would be effective in decreasing the incidence of SSIs. The available European Centre for Disease Prevention and Control (ECDC) data[16] shows that in 2015, the incidence of SSIs in colon surgery in the Czech Republic reached eight cases per 100 operations. Data on other surgical procedures performed in the Czech Republic are not currently available. If we apply the available data to our study group, the expected incidence rate would be 1.7 SSIs in total. Comparing the Czech countrywide incidence and our study group incidence of SSIs, we cannot exclude a potential positive effect of the tested antimicrobial dressing. However, critical analysis of this finding and the known limitations of this study (a low number of participants, no control group, no randomisation, a broad spectrum of surgical procedures and surgeries performed in outpatient and inpatient setting) prevents us from definitively proving a direct effect of the tested dressing on the zero incidence of SSIs observed in our study group. Nevertheless, patients and HCP involved in this study expressed positive subjective clinical experience based on an evaluation of the dressing tolerance ("excellent"; range 1-5) and overall satisfaction with local treatment of wounds and the tested dressing (patients and HCP: "excellent"; range 1-5). The adverse events associated with the tested dressing were few and were all related to the adhesive border of the dressing (erythema, itching and burning).

IMPLICATIONS FOR CLINICAL PRACTICE

The tested sterile antimicrobial dressing can be used in clinical practice for covering surgical wounds. We have confirmed its safety and good tolerance by patients in inpatient and outpatient settings. We see no

Table 4. Treatment Period Description	
Total number of dressing changes, mean ± SD; median	4.2 ± 0.7; 4
Total length of treatment (i.e. suture removal), mean ± SD; median	10.7 ± 2.1; 10
Length of hospitalization - inpatient setting, mean ± SD; median	2.6 ± 0.8; 2
Total length of treatment for inpatient surgeries, mean ± SD; median	10.4 ± 1.8; 10
Total length of treatment for outpatient surgeries, mean ± SD; median	11.5 ± 2.6; 10
Length of treatment - outpatient setting, mean ± SD; median	8.8 ± 2.6; 9
No wound exudation, % (n)	81 (17)
Surrounding skin reaction, % (n)	4.8 (1)

Table 5. Satisfaction scale for the trial (1-5)	
excellent	1
very good	2
good	3
poor	4
bad	5

reason to avoid usage of the dressing for the perioperative management of surgical wounds in high-risk patients and high-risk surgical procedures.

FURTHER RESEARCH

There is a need for well-designed randomised prospective studies confirming the effects of different types of antimicrobial dressings on the reduction of SSI incidence. Such studies should be conducted on larger populations of high-risk patients.

CONCLUSION

Regarding the aims of this study, we can confirm good serviceability of tested dressing in both outpatient and inpatient setting. We do not see any reason to avoid using antimicrobial silver-based dressings for the perioperative management of surgical wounds in high-risk patients undergoing high-risk surgical procedures. To obtain robust evidence for widespread use of the tested antimicrobial dressing on non-complicated incisions, it is necessary to design and carry out a larger randomised controlled trial.

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