Effectiveness of silver dressing in preventing surgical site infections in contaminated wounds

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SUMMARY

Introduction: Silver gauzes are designed to treat infected wounds, but there is controversial evidence about their effectiveness in preventing surgical site infections in contaminated wounds.

Objective: To evaluate the effect of silver gauzes in patients undergoing surgery with contaminated wounds at a university-based tertiary referral center.

Methods: This was a prospective, controlled trial comparing a silver gauze dressing with saline gauze dressings in patients undergoing abdominal surgeries with contaminated wounds. Patients were randomly assigned to receive either silver gauze (SG) dressing or saline gauze dressings (SD). The primary end point was surgical site infection occurring within 30 days of surgery.

Results: 65 patients were enrolled in the review. The incidence of surgical site infection was 14% (9/65). No differences were observed among groups (15.2% vs. 12.5%, p = 0.75). Multivariate analysis revealed no relationship between the type of dressing and surgical site infection.

Conclusion: Silver gauzes are safe and effective in preventing surgical site infections in surgeries with contaminated wounds. Further trials are required to find out if they have advantages over standard dressings.

KEY WORDS

Silver; Surgical Wound Infection

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RESUMEN

Efectividad de los apósitos de plata en la prevención de la infección del sitio operatorio en heridas contaminadas

Introducción: existe controversia sobre la eficacia de los apósitos impregnados de plata en la prevención de la infección del sitio operatorio en heridas contaminadas.

Objetivo: evaluar el efecto de los apósitos con plata en pacientes posquirúrgicos con heridas contaminadas en un hospital de III nivel.

Métodos: estudio prospectivo, controlado, que comparó los apósitos con plata con las gasas en solución salina en pacientes posquirúrgicos con heridas contaminadas. Las heridas recibieron uno de dos tipos de tratamiento tópico: gasas en solución salina (GS) o apósitos con plata (GP). El efecto final para medir fue la aparición de infección del sitio operatorio (ISO) en los 30 días siguientes a la intervención quirúrgica.

Resultados: se analizaron 65 pacientes. La incidencia de ISO fue del 14% (9/65) sin diferencias estadísticamente significativas entre ambos grupos (15,2% frente a 12,5%, p = 0,75). El análisis de regresión multivariado no mostró relación entre el tipo de apósito y la aparición de infección.

Conclusión: los apósitos impregnados de plata son seguros y efectivos para la disminución de la ISO. Se requieren estudios adicionales para saber si su efecto es superior al de los apósitos tradicionales.

PALABRAS CLAVE

Infección de Herida Operatoria; Plata

INTRODUCTION

Surgical Site Infection (SSI) is the third most common cause of nosocomial infection and the most frequent cause of infection in operating rooms. The SSI rate could be up to 5% in clean surgeries and approximately 30% in clean-contaminated surgeries (1). In addition, it has been estimated that superficial incisional SSI amounts to 44.9%, deep incisional SSI to 35.4% and organ/space SSI to 18.3% (2). Its occurrence is related to an extension of hospitalization, readmissions, admission to intensive care units (ICU), complications associated with healing and death, and at a cost that almost doubles that of a patient without an infection (3). A superficial SSI can result in expenses of up to US$ 400 per case, compared to almost US$ 30,000 for a patient with organ SSI (4). It is estimated that between 40% and 60% of the SSIs can be prevented (5).

Additionally, the recognition of the humid microenvironment as part of the topic therapy in handling wounds (6) led to a revolution that resulted in the creation of biologic dressings that preserve humidity, increase the rate of epithelization and encourage recovery. In the list of the so-called biological dressings are hydrocolloid compounds, alginate, hydrogel, hydrofiber, foams and paraffin, etc.

Recently, new products have appeared with the theoretical advantage of promoting angiogenesis and decreasing the infection. Hyaluronic acid and activated charcoal silver dressings stand out in this group.

Regarding the latter, despite that the antimicrobial properties of silver have been recognized for more than 100 years (silver nitrate and sulfadiazine, among other preparations), its effectiveness and safety for handling wounds have become an area of renewed interest.

For handling contaminated wounds, the silver crystals have anti-inflammatory and antimicrobial properties that act on the superficial areas of the skin, with minimum dermis penetration and subcutaneous cell tissue in *in vitro* models (7). However, the lack of a worldwide consensus to promote the use of silver dressings over other dressings for handling infected wounds or prevention (8, 9) is the result of the continuous discrepancy between the *in vitro* results and those from studies with patients (10).

The clinical studies in chronic or infected wounds show different results in terms of the real benefit of using silver dressings on chronic wounds (11), venous ulcers (12), burns (13), central and ventricular catheter coating (14), open abdomen (15), colorectal surgery (16), open fractures (17), grafts (18), obstetric wounds (19), etc. In addition, the use of silver dressings in specific groups of patients has been proved to decrease hospital expenses (20, 21).

In acute wounds, the use of silver could prevent surgical site infection (SSI). In theory, the benefit from its use in wounds with high risk of infection is based on a decrease of the microbial bioburden, control of the local

infection and prevention of systemic dissemination. Consequently, this study assesses the effectiveness of silver-coated dressings in preventing SSIs in patients with contaminated wounds.

METHODOLOGY

This is a randomized, controlled trial carried out in a level III hospital. The study population was a sample of surgical patients older than 15 years whose wound was left open during the post-operative period as part of the protocol for handling contaminated surgical wounds. These are elective or emergency procedures, such as peritonitis secondary to perforated appendicitis, perforated peptic ulcer, perforated diverticulitis, colon trauma and pyocholecyst over the period between March 2010 and March 2012. All the procedures were conducted by general surgeons.

The patients with known allergies to silver and signs of abdominal wall infection upon surgery were excluded, as well as those whose conditions prevented the primary fascial closure or required surgical mesh, together with pregnant women.

Perioperative protocol and randomization

The study was approved by the Ethics Committee of Universidad Tecnológica de Pereira and the Research Ethics Committee of Hospital Universitario San Jorge. All the patients signed their individual informed consents in compliance with the parameter of Article 11 or Resolution 8430 of 1993 of the Ministry of Health for minimal risk research.

The study population was randomized by using an EPIDAT subroutine that executed the randomization in blocks for each group, the silver dressing group (SG) or saline gauze solution group (SD). The surgical team did not know the type of dressing to be applied until the very moment of handling the contaminated wound.

Based on previous studies, a decrease of 10% in the incidence of SSI in the SG was calculated, equivalent to a decrease expected for the SSI frequency of 44% for the experiment group (SG) and 33% for the control group (SD). The value of the sample obtained was 33 patients for each arm, with a level of reliability of 90%.

An antimicrobial dressing was applied to the SDG with a silver-coated polyamide mesh impregnated with an ointment composed by fatty acids of diglycerides and triglycerides. The dressing was removed within 48 hours to avoid desiccation and the wound was closed unless some early signs of infection appeared.

Gauzes humidified with saline solutions were applied to the SD and covered with a sterile gauze dressing that was removed within 72-96 hours after the surgery, according to the institution's guidelines (22). The wound was closed unless signs of infection appeared.

After discharge, weekly check-ups were scheduled for the following 30 days. Additional follow-ups by telephone were carried out for the subgroup of patients with difficulties to go to the hospital. All the check-ups were conducted by the research team.

Statistical analysis

The final effect to be assessed was the incidence of SSI, which diagnosis was based on guidelines for CDC diagnosis and classification (23). The descriptive statistics were reported as medians and ranges for continuous variables and as frequencies and percentages for categorical variables. The continuous variables were assessed with Mann-Whitney nonparametric tests and the categorical variables were compared using the Fisher test. Finally, a multivariate logistic regression model was created to assess the effect adjusted per confounding factors.

RESULTS

Between March 2010 and March 2012, seventy-two patients were randomized to one of two groups: saline solution gauzes (SD) or silver dressings (SG). During the post-surgery period, four patients in the SG and three in the SD were excluded because at least 50% of the scheduled post-surgery check-ups could not be guaranteed. The final study population was 65 patients. The average age was 35 years for the SD (range 14-85) and 38 years for the SG (14-78 range) ($p = 0.97$). The distribution of the demographical variables was similar in both groups (table 1).

The SSI overall incidence was 13.8% (9/65). The SSI frequency in the SD increased (15.2% compared to 12.5%); however, this was not statistically significant ($p = 0.75$). Only superficial SSI occurred. Follow-up until day 30

was achieved in 96.9% of the patients (256 check-ups). No SSI was diagnosed after Day 12. The SSI took longer to appear in the SG (6 days compared to 3.2 days), which was statistically significant (p=0.0001).

Table 1. Demographic profile of the study population

Variable		Saline group (n = 33)	Silver group (n = 32)	p value
Age (median)		35	38	0.97
Sex	Male	19	22	0.35
	Female	14	10	
SENIC[a]	1	2	2	0.61
	2	30	30	
	3	1	0	
NNIS[b]	1	17	13	0.37
	2	16	19	
Prophylaxis Ab	Yes	25	31	0.01
	No	8	1	
Type of surgery	Elective	2	8	0.03
	Emergency	31	24	
Surgery	Appendectomy + washing	23	18	0.5
	Laparotomy + drainage (peritonitis)	6	4	
	Colostomy closure	2	6	
	Cholecystectomy due to pyocholecyst	2	3	
	Colostomy	0	1	
	Superficial SSI	5 (15.2)	4 (12.5)	0.75
Average day of occurrence		3.2	6	0.0001
Stay (median)		5	5	0.49
Days of stay		193	204	

[a] SENIC : Study on the effectiveness of nosocomial infection control

[b] NNIS: National Nosocomial Infections Surveillance

One patient in the SG suffered an adverse reaction to the dressing, characterized by an outbreak at the site where the gauze was applied. This was quickly resolved once the gauze was removed.

The average stay at the hospital was similar in both groups (p = 0.49). However, we observed that the stay of the SD was 11 days longer compared to the SG (204 days vs. 193 days).

After setting the variables for type of dressing, hospitalization, usage and type of antibiotics, type of surgery and infection indicators, the logistic regression analysis did not find any statistic relationship between the type of dressing used and the occurrence of SSI.

DISCUSSION

The antibacterial mechanism of the silver compounds is not clearly defined. It has been proposed that silver induces morphological and structural changes into the cell wall and the cytoplasm, which interrupt the respiratory chain and cause cell mortality. The

compromise of replication and division, mediated by the union of silver ions and bacterial DNA, has also been proposed (24).

It has been impossible to accurately replicate these *in vitro* effects in the *in vivo* model. Two recent studies showed the *in vitro* antimicrobial effectiveness of an iodine dressing compared to the application of silver dressings that, in the clinical context, contradicted the evidence shown in the controlled environment (25, 26).

Moore et al., in their *in vitro* comparative study of three dressings with different presentations and silver contents, failed to show benefits when compared to a hydrogel dressing with oak extract (27). Manizate et al. also failed to report advantages with the use of two specific types of dressings impregnated with silver crystals in the bioburden of chronic wounds in lower limbs (28).

On the other hand, other clinical studies concluded that silver-impregnated dressings are associated with an improvement in the quality of life, expressed in a higher rate of healing, decrease in the ooze, less pain and longer interval between surgical cleanings, etc. (11, 29, 30).

This controlled, randomized, prospective study could not show a significant advantage in the incidence of SSI in contaminated wounds with the use of silver-coated dressings (SG) compared to the traditional handling. Notwithstanding this, the low overall incidence of SSI (14%) is within the lowest value expected for this complication (15% to 40%) and allows to conclude that both methods are effective in reducing the incidence of SSI in contaminated and unclean wounds.

The delay in the occurrence of SSI for the SG found in this study may be explained by a bioburden drop. In fact, Guthrie et al. reported significant bioburden drops in full thickness wounds in mice when treated with silver nanoparticles (31).

This is the first study in Colombia to evaluate the effect of silver in contaminated wounds. Trial et al., in their study with 44 patients, showed results similar to those reported herein (32).

Likewise, Connery et al. also failed to find a beneficial effect of silver dressings compared to traditional dressings in a group of women that underwent C-section (19).

For their part, Brown-Etris reported a decrease in the healing time of previously colonized wounds when treated with silver-impregnated dressings (33). Similarly, Stinner et al., in their study of contaminated orthopedic wounds supported the use of silver-impregnated dressings, especially in wounds contaminated by *Staphylococcus aureus* (17).

Part of the discrepancy in the results is due to the difficulty in comparing the different dressings containing silver, since silver varies in presentation, proportion and combination. It can be found as elemental silver (nanocrystals), as an inorganic compound (silver oxide, silver chloride) or as an organic compound (silver alginate). Sometimes, it is combined with a biological compound (hydrogel, hydrofiber) as coating or inside the dressing structure itself. The aforementioned makes it harder to evaluate its efficacy or antimicrobial effect (34).

No patient suffered from deep or organ SSI. This can be explained because the entire study population received antibiotic therapy during their hospitalization.

Regarding adverse reactions, only one patient was reported with an outbreak at the injury site, which disappeared after removing the product. Cutting et al. refer to these types of reactions as innocuous and easily reversible. The grayish perilesional coloration has also been reported as a relatively common phenomenon, mainly in patients with burns (35). Its occurrence is directly related with the exposure time and the component and type of silver contained in the dressing (36).

Regarding costs, the SSI is considered as an important issue for public health. In the United States, it can generate additional costs for up to 1.8 million dollars a year (37). The use of a dressing that reduces its incidence or favorably affects any of the variables associated with the cost increase due to its treatment is an attractive proposal. In some cases, the high initial costs for using products for the care of wounds are justified by shorter healing times. Therefore, the cost differences for application and application frequency are variables to be taken into account when considering the final costs. In this specific study, a shortening of hospitalization from 24-48 hours by using a dressing impregnated with silver may result in significant institutional saving. The international

consensus on the proper use of silver dressings and reports from other investigators credit the aforementioned (38, 39).

This study had some noteworthy limitations. Despite the good level of reliability, the size of the sample was not sufficient to reach a proper power (16%), notwithstanding its likely use in further systematic revisions.

The length of the incision was not measured. This factor can encourage the development of SSIs because more tissue is exposed. Patient-inherent variables considered as risky for the development of SSIs (smoking, diabetes, obesity, etc.) were not taken into account either, because the priority of the design was given to the local status of the wound (contaminated wound) and its relationship with the subsequent occurrence of SSIs.

Finally, the impossibility of designing a double-blind study (the physical characteristics of both dressings are hard to hide) could have been an additional limitation.

CONCLUSION

SSIs are an important problem for public health. Due to the costs for attending it and the functional disability they generate, it is necessary to channel all the resources to decrease its occurrence. This study presents evidence in favor of the use of silver-impregnated dressings in patients with contaminated wounds with and an effectiveness similar to saline gauzes, but with a clear delay in the occurrence of the SSI. This could be used as a therapeutic advantage, as it enables its ambulatory treatment by the comprehensive wound treating group, with the consequent decrease in hospitalization costs.

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