Surgical site infection in elderly patients with hip fractures, silver-coated versus regular dressings: a randomised prospective trial

• **Objective:** Surgical site infection (SSI) after hip fracture surgery is a well-known complication with serious consequences for both the patient and the medical system. Silver ion treatment is considered an effective antibacterial agent, however, the use of silver dressing (SD) in the primary prevention of SSIs is controversial. The aims of this study were to compare SD with regular dressing (RD) in the prevention of SSI in elderly patients undergoing surgery for hip fractures, and to compare costs.

• **Method:** A matched group of 55 patients with hip fractures undergoing surgery with dynamic hip screw, cephalomedullary nail or hemiarthroplasty were randomised to either SD or RD groups. The dressings were applied in the operating theatre, and the patients were followed for one week for clinical signs of infection (discharge, erythema and fever). The RDs were replaced daily. The SDs were not removed for 5–7 days and kept moist. Skin swabs were taken from the wound surface on postoperative day 5–7 for bacterial skin colonisation.

• **Results:** The SD (n=31) and RD (n=24) groups were similar in age, sex and comorbidities. Infection signs were seen in two (2/31, 6.4%) of the SD patients compared with 2 (2/24, 8.3%) RD patients (p=1.0). Skin colonisation by bacteria at postoperative day 5–7 was tested in 27 patients: it was higher in the SD group (positive skin swab, 12/19, 63.2%) compared to the RD group (4/8, 50%, p=0.67). The use of SD added ~US$5 (UK ~£3.19) per patient.

• **Conclusion:** The use of SD was associated with higher costs than RD, but not superior in preventing SSIs in elderly patients undergoing hemiarthroplasty or fixation of hip fractures. SD was also not effective in reducing bacterial skin colonisation following hip fracture and surgery.

• **Declaration of interest:** The authors have no conflict of interest to declare.

silver dressing; infection; hip fracture; skin colonisation; cost analysis

Surgical site infection (SSI) is a complication of hip fracture surgery in the elderly, with rates of SSI among elderly patients as high as 4.97% for a primary hemiarthroplasty procedure,[1] and between 1–2% for an internal fixation procedure.[2] Silver is known to have antibacterial properties, and its efficacy recognised well before the discovery of bacteria.[3,4] Silver-coated dressings (SD) containing silver ions have been used to treat infected wounds caused by bacteria, yeast, and viruses. However, there is contradictory evidence of the use of silver in the primary prevention of surgical wound infections.[5] The use of SD after lumbar laminectomies was shown to limit the rate of both deep and superficial SSIs,[6] and a recent study showed a reduction in the rate of pin-site infection among patients who underwent external fixation and were treated with SD.[7] In contrast, Masse et al. stopped a randomised control trail (RCT) comparing silver-coated pins to regular pins after the former proved ineffective in preventing SSI.[8] The aim of this RCT was to compare the effectiveness of SD in the prevention of SSI with RD in elderly patients who underwent hemiarthroplasty or fixation surgery for hip fractures, and to assess the additional costs associated with its use compared to RD.

Patients and methods

Study design and randomisation

This non-blinded RCT (level of evidence II) was conducted in a level I trauma centre (1100 beds). Institutional ethics and scientific committee approvals were obtained for this study (TLV-12-0111), and informed consent was obtained from all the participants. The patients were recruited and followed-up between January–September 2013. They were randomised into two groups using the last digit of their identification number: those ending with odd numbers received an RD and those ending with even numbers received an SD.

Patient population

Patients with either an intracapsular or extracapsular hip fracture who underwent hip joint hemiarthroplasty or internal fixation (dynamic hip screw

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Table 1. Patient and injury characteristics

	Entire cohort (n=55)	Silver dressing (n=31)	Regular dressing (n=24)	p value
General patients demographics				
Male/female	18/37	11/20	7/17	0.77*
Age (SD)	79.6 (12.37)	80.2 (12.54)	78.83 (12.36)	0.66†
Type of surgery (ORIF/hemiarthroplasty)	38/17	23/8	15/9	0.39*
Baseline laboratory values				
Hemoglobin, mg/dl (SD)	14.41 (15)	16.16 (19.5)	11.98 (1.57)	0.3†
Creatinine, mg/dl (SD)	1.23 (0.5)	1.17 (0.43)	1.31 (0.57)	0.32†
Comorbidities				
Hypertension (%)	29 (53%)	15 (48%)	14 (58%)	0.58*
Diabetes (%)	9 (16%)	7 (23%)	2 (8%)	0.27*
Heart disease (%)	23 (42%)	9 (29%)	14 (58%)	0.052*
CVA (%)	8 (15%)	2 (6%)	6 (25%)	0.06*
COPD (%)	6 (11%)	4 (13%)	2 (8%)	0.68*
Tracers of postoperative infection				
Positive skin culture 5–7 days postoperative (%)	16/27 (59%)	12 (63%)	4 (50%)	0.67*
Signs of infection (%)	4/55 (7%)	2 (6%)	2 (8%)	1*

*Fisher's exact test
†Student's unpaired t-test
ORIF – open reduction and internal fixation (dynamic hip screw and cephalomedullary nail); CVA – cerebrovascular accident; COPD – chronic obstructive pulmonary disease; postop – postoperative; SD – standard deviation

or cephalomedullary nail) were enrolled. Inclusion criteria were adult patients who were scheduled for surgery following hip fractures, able to understand and willing to accept the trial procedures, and agreeing to sign an informed consent form in accordance with national legislation. Excluded were patients with active systemic infection, those who were immunocompromised (excluding diabetes mellitus), and those who could not or refused to sign the informed consent form or take part in the full follow-up study.

Interventions

The SD was the SilvalGuard dressing (Pollak International Ltd, Israel). The pad is an absorbent wound dressing consisting of an active layer of silver covered with porous adhesive tapes. The RD was a transparent moisture vapour permeable adhesive film (OPSITE, Smith & Nephew). The patients were randomised into either the SD or RD groups. General demographic details were collected for each patient, including age, gender, comorbidities, and type of fracture, surgery and implant. Baseline laboratory values, including creatinine and haemoglobin levels, were also recorded. The anaesthetist administered prophylactic intravenous antibiotics (2g cefazolin or 1g vancomycin if allergic to cephalosporins) to all the patients 20 minutes before skin incision. After the surgical procedure had been completed, the surgical sites of the patients of both groups were swabbed (superficial incision on the skin surface) in the operating theatre as a baseline for bacterial skin colonisation. The surgical wound was then dressed with either dressing. A second swab was taken for culture from the same sites on postoperative day 5–7, and the extent of bacterial colonisation in the two groups was compared.

Clinical evaluation for SSI was performed on postoperative day 5-7. Signs of infection were recorded, including fever, wound erythema, swelling or discharge. The sterile SD was applied to the wound after surgery, and it was moistened periodically in order to activate silver ion release. It was replaced every 5–7 days, according to the manufacturer's instructions. The RD was applied by means of a sterile technique following surgery. It was replaced with conventional gauze dressing on postoperative day 2 and daily thereafter according to departmental policy.

Statistical analysis

Data were analysed with the SPSS for Windows Version 17.0 (SPSS Inc, Chicago, IL). Means and standard deviations (SD) were used to describe continuous variables, and categorical variables are presented as numbers (percentages). Univariate analyses were performed with the Fisher's exact test for categorical data, and Student's unpaired t-test for continuous variables. A p value less than 0.05 was considered statistically significant.

Results

A total of 55 elderly patients (mean age ± SD 79.6 ± 12.37 years) were recruited. The 31 patients in the SD group were similar to the 24 patients in

the RD group in age, gender, comorbidities, baseline laboratory values and type of surgery (Table 1). There were also no significant differences related to the surgical technique in the internal fixation group: 7 SD patients had a dynamic hip screw procedure compared to 4 RD patients, and 14 SD patients received a cephalomedullary nail compared to 10 RD patients (p=1.0).

All 55 patients completed the clinical follow-up on postoperative days 5–7. There were four patients with clinical signs of SSI, two in each group identified on the follow-up days. In the SD group one of the two SD patients with signs of SSI had a serous discharge and erythema and the other had surgical site cellulitis. Both RD patients with clinical signs of SSI had a serous discharge and erythema.

There were no significant differences between groups with regard to skin colonisation (Table 2). All 34 cultures (62% of the cohort) taken at baseline in the operating theatre were negative. Of the 27 (49% of the cohort) the skin swabs taken between days 5–7 postoperatively 16 were positive. In the SD group 12 SD patients (63%) had a positive culture, of which 7 (58%) grew more than one bacterium. In the RD group four patients (50%) had a positive culture of which 1 (25%) grew more than one bacterium (Table 2).

Cost analysis

A basic cost analysis of the dressings was performed according to the prices provided by the hospital acquisitions unit. The price of one SD pad was US$7.25, the price of the OPSITE pad was US$0.725 and a regular long gauze cost US$0.35. The cumulative cost of the regular pads and the strips of gauze up to the postoperative day 5 or 7 was US$1.775 and US$2.475 respectively. The additional costs of an SD compared to an RD was 408% (US$5.475; UK £3.497) or 292% (US$4.775 UK £3.050) at postoperative days 5 or 7 respectively.

Table 2. Bacteria colonising the skin cultured from skin swabs at postoperative day 5–7

Silver dressing (n=12)	Regular dressing (n=4)
Proteus mirabilis	*Coagulase negative Staphylococcus*
Escherichia coli	*Staphylococcus haemolyticus*
Klebsiella pneumonia	*Morganella morganii*
Stenotrophomonas maltophilia	*Klebsiella pneumonia*
Methicillin-resistant *Staphylococcus aureus*	*Streptococcus mitis*
Bacillus species	
Staphylococcus aureus	
Enterococcus faecalis	
Staphylococcus epidermidis	
Citrobacter	
Staphylococcus haemolyticus	
Enterobacter cloacae	
Pseudomonas aeruginosa	

Discussion

To our knowledge this is the first randomised trial to test the effectiveness of an SD dressing compared to an RD in elderly patients with either an intracapsular or extracapsular hip fracture who underwent hip joint hemiarthroplasty or internal fixation. The results suggest that SDs did not reduce the incidence of infection and bacterial skin colonisation in the short term compared to RDs. Moreover, the use of SDs was associated with the additional cost of approximately US$5 per patient.

Silver has been used for centuries as an antibacterial, antiviral and anti-parasitical substance.[3,4,9] Clinical and experimental studies claimed that the silver released from silver-containing dressing promoted wound healing by activating processes associated with haemostasis, neovascularisation, re epithelialisation and the control of inflammation.[10] Silver has a dose-related bacteriostatic or bacteriocidic ability attributed to its ability to overturn the transmembranous energy metabolism of bacteria.[11] Studies have shown that SD is effective in burn victims and chronic wounds, reducing nosocomial infections, wound adhesion and promoting wound healing.[6]

Several studies have shown the effectiveness of SD in reducing SSIs. Epstein[6] reported a positive trend toward postoperative reduction of deep and superficial wound infections using SD in patients undergoing lumbar laminectomy. Furthermore, an RCT in patients undergoing colorectal surgery, comparing SD (n=81 patients) and RD (n=79 patients), found a significant reduction in bacterial skin colonisation in the SD group, as well as a trend towards reduction in SSIs.[12] However, the positive effect of the SD was exploited only when the surgical sites were infested with bacteria immediately postoperatively. Moreover, the conclusions of that study were relevant only to contaminated surgical wounds following colorectal surgery, and could not be generalised to clean surgical wounds, as in the case of orthopaedic surgeries.

The main use of silver-containing products in the orthopaedic field is in the prevention of pin-site infection in external fixators. Pin-site wounds have a higher infection rates and are different in nature from hip surgery wounds. According to a Cochrane review,[13] evidence supporting the use of silver ion in the contaminated setting of a pin-site is still lacking. Several studies have investigated this issue in recent years and reached opposite conclusions. For example, Amanti et al.[7] reported a reduction in pin-site infections in a small group of patients with external fixators. In contrast, an RCT comparing silver-coated pins to regular pins was stopped after the former proved ineffective in preventing SSIs and elevated serum silver ion levels.[8]

Infection after surgery for hip fracture although uncommon is a potentially devastating complication.[14] Rates of 1.2% of deep wound infection and

1.1% superficial infection were reported in a series of 3000 patients.[2] Postoperative mortality significantly increased to 50% at one year in cases of deep infection, and hospital costs also increased significantly: specifically, infections doubled operative costs, tripled investigation costs, and quadrupled ward costs. The use of preoperative antibiotics proved to be effective in reducing the rates of these infections.[2]

From a microbiological aspect, it is difficult to understand why a material with a proven anti-bacterial activity, such as silver, was ineffective in eliminating skin colonisation in our study. We hypothesise that the lack of product standardisation and sub-therapeutic levels of silver delivered to the wound could account for the lack of effectiveness. There is growing criticism over the abundance of new silver ion-containing products that claim to be effective antibacterial substances. In reality, there is no standardisation of the amount of silver released from these products, and that lack might lead to sub-therapeutic levels and the development of bacterial resistance.[15] A study by Cavanagh et al.[5] compared the effectiveness of six commercially available SDs. Their main finding was that only one dressing was actually bacteriocidic and reduced the bacterial load. Hence, we cannot generalise our findings of SD ineffectiveness in hip fractures to other types of silver dressings.

Limitations

One limitation of this study is that it was not blinded. However, it would be difficult to blind patients and physicians to group allocation due to the obvious difference in their appearance and method of application (RDs are changed daily and SDs are changed weekly). Second, there was a relatively small number of patients. According to power analysis, proving small differences in an uncommon complication of wound infections requires a very large sample size, which would be impossible in our setting. Third, the follow-up time was short, although most wound infections would have developed within the 7-day timeframe.[16] Fourth, all the patients completed the clinical follow-up at 7 days, the main endpoint, but the bacteriological analysis of the skin swab had not been completed in 51% of cases by postoperative day 5–7. That said, the Center for Disease Control criteria for SSI is clinically and not culture based,[17] and a correlation between positive cultures and the development of superficial SSIs was never proven. Moreover, the abundance of organisms cultured from the 49% of patients whose bacteriological analyses were completed demonstrated that bacteriocidal activity has not occurred and that additional skin swabs would be futile. Finally, the findings of SD ineffectiveness in hip fractures can not be generalised to other types of SDs in other surgical settings.

Conclusions

SD dressings neither reduced the incidence of SSIs nor the extent of bacterial skin colonisation in elderly patients with either an intracapsular or extracapsular hip fracture who underwent hip joint hemiarthroplasty or internal fixation. Those findings, taken together with the additional cost of SDs, cast doubt on the justification of its routine use in this era of cost containment. ■

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