

A Clinical Trial to Investigate the Effect of Silver Nylon Dressings on Mediastinitis Rates in Postoperative Cardiac Sternotomy



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Abstract: Mediastinitis is a rare but serious postoperative complication of cardiac surgery that increases mortality rates, hospital length of stay, and medical costs. A clinical trial was conducted to investigate whether the type of postoperative surgical dressing (silver nylon or standard gauze) affects the rate of mediastinal infections. The sample consisted of 1,600 surgical cardiac patients. Infection rates in the standard gauze group (control, n = 1,235) were collected retrospectively from 24 months of infection control records. In the prospective treatment arm of the study, the wounds of all consecutive surgical patients (n = 365) were covered with a silver nylon dressing and patients were assessed during the 3-week postoperative visit. Thirteen (13) patients in the control group (1%) and none of the patients in the treatment group developed mediastinitis ($\chi^2 [1, N = 1,600] = 3.88, P < 0.05$). Study findings support the need for a large, prospective, controlled clinical study to confirm the effects of these dressings on mediastinitis, resultant morbidity, and costs of care.

KEYWORDS: silver nylon fabric, mediastinitis, mediastinum infections

Although uncommon, mediastinitis is a serious postoperative complication associated with many negative outcomes. Methicillin-susceptible *Staphylococcus aureus*, Gram-negative bacilli, and methicillin-resistant *S. aureus* are three strains of bacteria most commonly associated with mediastinitis.^{1,2} The occurrence of mediastinal infections varies but has been reported to be between .04% and 5.0%.^{1,3} Heart transplant patients have the greatest risk for developing mediastinitis when compared to other cardiac procedures, with rates ranging between 2.5% and 6.0%.⁴ Mortality rates, hospital stays, and medical costs increase considerably for patients who develop this infection.⁵⁻⁷ Mortality rates for patients who develop mediastinitis after undergoing any cardiac procedure increase by an average of 10% to 20%⁸ and can be as high as 47%.⁹ Milano et al,¹⁰ after conducting a study involving 6,459 patients undergoing coronary bypass grafting (CABG), report that early debridement and delayed closure can decrease mortality rates to less than 20%. Medical costs and hospital stays have been found to increase with the development of mediastinitis, on average, by \$20,000¹¹ and 12.2 days,¹² respectively.

Many studies have identified preoperative risk factors that increase the risk of developing mediastinitis. These factors include smoking, obesity, vascular disease, longer stays in the intensive care unit, infections at other sites, diabetes, and hypertension.¹³⁻¹⁶ Additional studies^{17,18} have shown the benefits of using different postoperative care techniques to reduce mediastinitis, including incision closure with rigid fixation and the application of topical bacitracin ointment. Song et al¹⁸ showed a

significant reduction in the incidence of mediastinitis when rigid plate fixation rather than wire-circilage was utilized for sternotomy closure. None of the patients in the prospective rigid plate fixation study group (n = 45) developed mediastinitis compared to 28 cases reported in the retrospective, wire-closed control group. In 2006, MacIver et al¹⁷ investigated the impact of topical bacitracin ointment on mediastinitis development in patients who underwent sternotomy incisions for valvar and ischemic heart disease. They compared patients who underwent surgery before 1999 (n = 1,036) who did not receive topical bacitracin to patients treated after 1999 (n = 1419) who had bacitracin ointment applied to their incisions. The results showed 12 patients in the untreated group and three patients in the treated group developed mediastinitis. These findings suggest topical antimicrobial agents may be an effective method to lower the incidence of mediastinitis.

Silver's antimicrobial properties have been well documented throughout history. Silver was used by the Roman Empire, American settlers, and the National Aeronautics and Space Administration (NASA) as a method to preserve water purity.^{19,20} Medical practitioners have utilized silver in advanced wound care for more than 40 years.²¹ Clinical and laboratory research¹⁹⁻²⁵ has shown silver to be an effective antimicrobial agent against bacteria, viruses, yeast, and fungi. In the 1970s, *in vitro* studies^{26,27} demonstrated that silver ions had a broad-spectrum bacteriocidal profile with favorable outcomes compared to synthetic antibiotics. Wound histology is also different in silver-treated wounds compared to controls. Reporting on the results of porcine wound study, Warriner and Burrell²¹ noted that wounds treated with silver had active fibroblasts, thicker granulation beds, limited inflammation, and no signs of contracture as compared to control wounds that showed raised edges, edema, and full contracture, which are signs of inflammation. They also found wounds treated with silver healed an average of 10 days faster than control wounds. Wright et al,²⁸ after conducting a porcine study, had similar histology findings, reporting silver-treated wounds displayed more apoptosis and higher levels of fibroblasts, monocytes, and neutrophils compared to controls.

In the early 1980s, silver was plated on nylon fabrics and shown *in vitro* studies to contain antimicrobial properties.²⁹ Since the initial studies, the antimicrobial benefits of silver-plated nylon dressings have been well recognized in both *in vitro* and *in vivo* studies²⁷⁻³² that demonstrate that silver nylon fabric inhibits common wound pathogens including *Pseudomonas aeruginosa* and *S. aureus*.³²⁻³⁴ A major advantage of silver nylon fabric is its reported ability to continuously release silver ions, providing constant antimicrobial protection.³¹

Silver-containing fabrics are now available for use in the care of partial- and full-thickness burns and acute and chronic wounds. Postsurgical dressings constructed with the same silver nylon fabric are available but data to support outcomes that would justify the associated costs are limited.

The purpose of this study was to compare the incidence of mediastinitis in cardiac surgery patients whose wounds dressed with standard gauze dressings (SGD) (historical control) to the incidence of infection in wounds covered with silver nylon dressings (SND).

Methods

Participants and variables.

Silver nylon dressing (study) group. All consecutive patients receiving CABG or valve replacement procedures (VR) at a southern Missouri tertiary care hospital were considered for enrollment in the study group. Exclusion criteria included patients younger than 18 years of age and patients who were pregnant, incarcerated, and/or enrolled in another clinical study within the past 30 days.

Variables collected included demographics, history of procedure and study compliance, and infection rates. All were recorded with anonymous identifiers, ensuring anonymity and confidentiality.

Standard gauze dressing (control) group. Patients who underwent a CABG or VR procedure in previous years and received a SGD were included in the control group. The only variables collected from the 24-month period retrospective review were the number of patients undergoing surgery and whether mediastinitis developed as recorded by the treating physician based on infection control records.

Materials and design. The hospital's Institutional Review Board approved both the retrospective and prospective components of this study. Because all CABG and VR procedures were conducted at the same hospital, each patient received similar pre-operative care. Sternotomy incisions were performed in a similar method and closed with staples and/or vicryl suture. The incisions then were covered with a SND or a SGD. All data for both retrospective and prospective arms of this study were maintained under control of study coordinator in a secure office.

Dressing application and management in the SND group. The SND used in this study was Silverlon® Island Dressing (Argentum Medical, LLC, Willowbrook, Ill). This dressing is comprised of fabric with a polymeric substrate surface, silver-plated via a proprietary autocatalytic electroless chemical (reduction-oxidation) plating technique. The dressing releases silver in the ionic (Ag^{+1}) form and has electrical conductivity of 0.10 ohms/cm^2 . According to the manufacturer, during the first 24 hours, 42.615 ppm or 10% of the total amount of silver is released into the wound.³⁵ The remaining silver continues to be released until the dressing is removed.

All dressings in this group were left in place for 7 days after surgery unless they became loose or saturated with drainage. Patients discharged before the seventh postoperative day received a new SND and were instructed to leave the new dressing on for 5 days after discharge. After removal, the patients were instructed to use standard postoperative wound care. The incisions were examined by the study coordinator and treating surgeon for signs of infection at the patients' 3-week follow-up visits.

Dressing application and management for the SGD group. Standard procedures in the control group consisted of the application of gauze and abdominal dressing secured with tape. Dressings remained in place for the initial 24 hours after the surgery unless they became saturated. After 24 hours, dressings were changed daily or more frequently as needed depending on drainage.

Identification of mediastinal infection. To confirm the diagnosis of a mediastinal infections, all incisions with signs or symptoms of an infection were cultured and evaluated by a surgeon following standard procedure — ie, cultures were collected using standard wound culture protocols and sent to the hospital's microbiology laboratory for evaluation. A surgeon made the final diagnosis based on culture results and wound appearance in both the retrospective and prospective arms of the study.

Statistical analysis. All variables were entered in a computer database and analyzed using SPSS version 15 (SPSS Inc, Chicago, Ill) and frequency distributions of demographic variables in the experimental group were obtained. A χ^2 test for independence using a 2×2 contingency table analysis was used to investigate the mediastinal infection frequencies. Although there were small expected frequencies, this remained an appropriate mode of analysis due to the large sample size.³⁶

Results

Data from patients who did not receive dressing placement per-protocol, who died of unrelated causes without signs of mediastinitis, or failed to return for their 3-week postoperative appointment also were collected but not included in the analysis. A total of 435 patients were enrolled in the SND

experimental group. Of those, 70 were excluded from the infection rate data analysis. Sixteen (16) died from unrelated complications without signs of mediastinitis and 46 failed completion of study protocol due to premature dressing removal (no signs of mediastinitis were present as noted by study coordinator and treating physician). Out of the 46 patients who did not follow study protocol, two (4.35%) developed mediastinitis and one (2.8%) developed a superficial wound infection, six did not return for the follow-up visit, and two returned to the operating room for bleeding complications. Of the remaining 365 patients, 257 (70.4%) were men and 108 (29.6%) were women, average age 65.6 (range 33 to 87) years. The SGD control group consisted of 1,235 patients, of whom 13 (1%) developed mediastinitis. In the SND group (n = 365), the infection rate was 0.

A chi-square test for independence was conducted by using a 2 x 2 contingency table analysis. A contingency table representing the distributions of the two nominal variables is presented in Table 1. The type of dressing applied to the wound and the development of mediastinitis were found to be significantly related, Pearson χ^2 (1, N = 1600) = 3.88, P < 0.05, phi = 0.049. The mediastinal infection rate was 0.0% in the SND and 1.1% in the SGD group.

Discussion

The cumulative evidence from *in vitro* and *in vivo* research strongly supports an empirical association between silver dressings and antimicrobial benefits.²⁹⁻³⁴ The current study investigated the association of SND and mediastinal infection rates. Although causal inference cannot be made, the actual infection rate was significantly lower than the expected infection rate in the SND treatment arm of this study and a significant relationship between surgical dressing type and the rate of mediastinitis was observed. The rate of mediastinitis in the retrospective control group was within the range of 0.04% to 5.0% reported in the literature^{1,3} but underreporting in this arm of the study may have occurred. Although many postsurgical dressings are commercially available (some with silver antimicrobial properties), gauze dressings were the standard of care at this institution and continue to be widely used. While no institutional infection control changes were implemented during the study period, the possibility of outside confounds affecting the final results always remains. These study findings support the need for a large, prospective, controlled clinical study to confirm the effects of dressing types on mediastinitis and resultant morbidity.

Limitations

The study design, including the absence of demographic patient information and the potential of underreporting in the retrospective control group, limits the ability to draw conclusions about the relationship between dressing type and infection rates. A prospective, randomized, multicenter study would more accurately be able to identify a causal relationship between dressing type and the rate of mediastinitis, mortality, morbidity and costs of care.

Conclusion

This clinical trial examined whether silver nylon or standard gauze dressings affected the rate of mediastinal infections in cardiac surgery patients. Silver nylon dressings were statistically related to lower mediastinitis rates. Conclusions should be drawn with caution because these results support the need for a multicenter, prospective, randomized clinical trial to completely delineate the effects of silver nylon dressings on mediastinal infections.

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