

## Clinical research

# The role of topical Genta Fleece HD and gentamicin spray in prevention of sternum wound infections after open heart surgery: a comparative study

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Mazlum Sahin

Haseki Education and Research Hospital Cardiovascular Surgery, Istanbul, Turkey

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**Corresponding author:**

Mazlum Sahin

Haseki Education and

Research Hospital

Cardiovascular Surgery

34250 Istanbul, Turkey

Phone: +90 5346194374

E-mail: [mzlmshn@gmail.com](mailto:mzlmshn@gmail.com)

## Abstract

**Introduction:** The aim was to clarify and compare the efficacy of local Genta Fleece HD (GF) and topical gentamicin spray (GS) in prevention of wound infections by comparing their results with a control group.

**Material and methods:** In this retrospective study, charts of patients who underwent coronary artery bypass grafting in a tertiary academic center between January 2015 and January 2017 were analyzed. Patients were divided into three groups: patients in whom GF was applied, patients in whom GS was applied, and a control group in which no additional material was applied. All patients received intravenous antibiotic prophylaxis. Deep and superficial sternal wound infections (SWIs) during the postoperative period were analyzed.

**Results:** The overall infection rate was 13.8% ( $n = 51$ ). Patients in whom GF was applied had significantly fewer SWIs when compared to the GS group and control group ( $p = 0.002$ ). A significantly smaller number of deep SWIs occurred in the GS group (7/177; 3.9%) than in the control group (14/125; 11.2%). The superficial SWI rate was significantly lower (2/79; 2.5%) in the GF group than in the other two groups. Duration of hospital stay was significantly shorter in the GF group, followed by the GS and control groups. High EuroSCORE results ( $\geq 4$ ), obesity (BMI  $> 30$  kg/m<sup>2</sup>), performing the operations under emergency situations and presence of chronic obstructive pulmonary disease were identified as significant risk factors in the development of SWI.

**Conclusions:** Local GS reduced deep SWIs, whereas GF implantation reduced the overall and superficial SWIs. Also, GF application was superior in terms of reducing the duration of hospital stay.

**Key words:** mediastinitis, complication, gentamicin, sternal wound infection, local antibiotic.

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## Introduction

Sternal wound infections (SWIs) are serious postoperative complications that increase the morbidity and mortality of heart surgery. Routine intravenous antibiotic prophylaxis has been shown to reduce the rates of postoperative infections and their associated complications [1]. Local application of gentamicin on the incision area before wound closure was shown to provide a higher concentration of the antibiotic at the surgical site without reaching systemic toxic levels [2].

The literature provides controversial evidence regarding the use of topical antibiotics. Application of gentamicin collagen sponge was shown

to reduce the rates of SWIs in three meta-analyses [3–5], whereas another meta-analysis failed to demonstrate benefits of gentamicin collagen sponge usage [6]. Some authors sprayed a mixture of cefazolin and gentamicin antibiotics on the wound and they stated that this technique reduces deep sternal wound infections (DSWIs) [7, 8].

The objective of this study is to clarify and compare the efficacy of local Genta Fleece HD application (GF) and topical gentamicin spray (GS) at the surgical wound by comparing their results with a control group.

## Material and methods

In this retrospective study, charts of patients who underwent coronary artery bypass grafting (CABG) in a tertiary academic center between January 2015 and January 2017 were analyzed. All patients underwent isolated CABG with a median sternotomy incision. Patients were divided into three groups according to the type of local antibiotic application at the end of the operation. Patients were divided into three groups: patients in whom GF was applied, patients in whom GS was applied and a control group in which no additional material was applied. All patients were given a routine prophylactic antibiotic regimen with cefazolin sodium, which was approved by the institutional department of infectious diseases. Standard surgical wound care was applied to all patients. Patients' demographic data, medical history and risk factors for wound infection were

collected. Also, operative and postoperative parameters were recorded.

Surgical wounds were inspected daily for signs of infection during the postoperative period. The patients were routinely followed at the outpatient clinic at the first week, first month and 2 months after discharge from the hospital. All patients were followed up to a period of 2 months after surgery. The patients were instructed to re-visit the clinic if they noticed any sign of infection.

Classification of deep or superficial surgical site infection was done according to the criteria suggested by the Centers of Disease Control [9]. Superficial infections were considered as infections involving the cutis and/or the subcutaneous tissues but not reaching the sternal fixation wires. Deep surgical infections were considered as infections reaching posterior to the fascia, involving the sternal wires, unstable sternal fixation with signs of osteomyelitis or positive bacterial cultures from the mediastinum or the presence of a mediastinal abscess.

## Surgical technique

According to our pre-operative protocol, the skin at surgical sites was scrubbed with chlorhexidine 4% solution before the operation. After induction of general anesthesia, the skin was shaved and scrubbed with alcoholic iodine solution. Antibiotic prophylaxis was initiated 30 min before the first incision. One gram of cefazolin was given every 6<sup>th</sup> h and it was continued for at least 24 h.

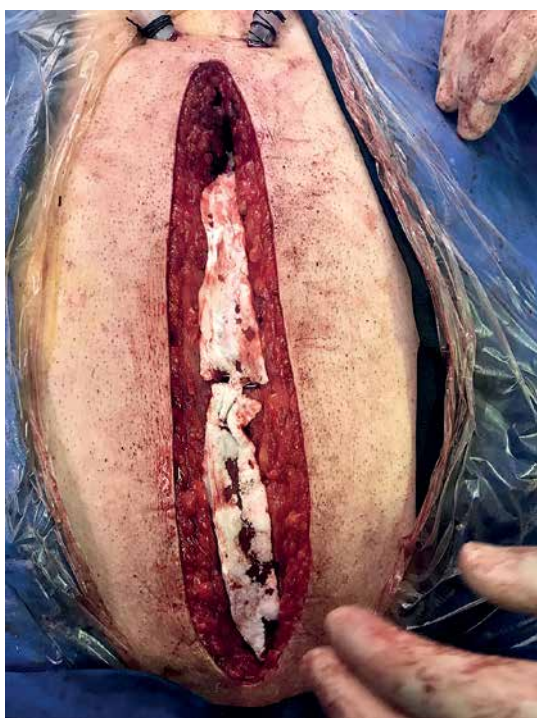
Surgery was performed in a strict sterile surgical environment. At the end of surgery, the sternum was fixed using 6 to 8 wires. The modified Robicsek technique or sternal plaques were used in certain cases. The fascia, subcutaneous tissues and skin were sutured using running absorbable sutures. No staples were used. Post-operatively, all patients were transported to the cardiac surgical intensive care unit where they were extubated following our institutional protocol.

## Application of the Fleece Genta HD

Strips of Parasorb Fleece Genta HD (AMS Group, Winsford, Cheshire, U.K.) were allowed to absorb a solution containing 25 mg of gentamicin sulfate. These strips were placed above the sternal wires after fixation of the sternum as shown in Figure 1. The subcutaneous tissues and skin were closed as describe above.

## Application of gentamicin spray

A 10 ml solution containing 80 mg of gentamicin was prepared and it was sprayed on the wound after the sternal wires were placed. The



**Figure 1.** Application of the Genta Fleece HD

subcutaneous tissues and the skin were closed as described above.

### Statistical analysis

Descriptive statistics were used to report patients' demographic data. Data were expressed as mean  $\pm$  standard deviation for continuous variables and percentages for categorical variables. The Mann-Whitney *U* test was used to compare the continuous variables between the three study groups. The  $\chi^2$  test was used to evaluate categorical variables. *P*-values  $< 0.05$  were considered statistically significant. Sub-group analysis was performed using the Bonferroni correction whenever the above-mentioned tests showed significant results. A *p*-value  $< 0.017$  was considered significant in sub-group analysis. All patients who died or who were re-operated on for post-operative bleeding were included in the analysis. Patients who were transferred to the inten-

sive care unit with an open sternum for persisting bleeding were not included in the study. Risk factors for sternal wound infections were identified using univariable and multivariable logistic regression analysis. The associations of independent predictors with SWI were expressed as odds ratios (OR) with 95% confidence intervals (CIs). All statistical analyses were performed using SPSS version 22.0 (IBM-SPSS Inc, Armonk, NY).

### Results

From January 2015 to January 2017, 381 patients who underwent CABG in a tertiary academic center were enrolled in the study. Obesity, diabetes mellitus and chronic obstructive pulmonary disease were significantly more common among patients who have had post-operative infection (*p* = 0.011, *p*  $< 0.001$  and *p* = 0.016, respectively). Also, EuroSCORE was higher in patients in whom

**Table I.** Comparison of patients according to the presence of postoperative wound infection

| Parameter                             | Infection (n = 51) | No infection (n = 333) | P-value   |
|---------------------------------------|--------------------|------------------------|-----------|
| Closure method:                       |                    |                        | 0.001     |
| Group 1                               | 26 (51.0%)         | 99 (29.7%)             |           |
| Group 2                               | 21 (41.2%)         | 159 (47.8%)            |           |
| Group 3                               | 4 (7.8%)           | 75 (22.5%)             |           |
| Gender (male/female)                  | 36/15              | 250/83                 | 0.428     |
| Age [year]*                           | 64.9 $\pm$ 8.9     | 65.5 $\pm$ 8.5         | 0.608     |
| Body mass index [kg/m <sup>2</sup> ]* | 31.2 $\pm$ 3.2     | 29.9 $\pm$ 3.5         | 0.011     |
| Comorbidity:                          |                    |                        |           |
| Diabetes mellitus                     | 39 (76.5%)         | 120 (36.0%)            | $< 0.001$ |
| Hypertension                          | 17 (33.3%)         | 158 (47.4%)            | 0.060     |
| Chronic renal failure                 | 6 (11.8%)          | 23 (6.9%)              | 0.223     |
| Chronic obstructive pulmonary disease | 16 (31.4%)         | 57 (17.1%)             | 0.016     |
| Cancer                                | 6 (11.8%)          | 18 (5.4%)              | 0.081     |
| Smoking history                       | 19 (37.3%)         | 147 (44.1%)            | 0.356     |
| EuroSCORE*                            | 4.1 $\pm$ 1.3      | 2.9 $\pm$ 1.5          | $< 0.001$ |
| Cardiac ejection fraction*            | 47.1 $\pm$ 10.8    | 48.8 $\pm$ 9.9         | 0.235     |
| Operation under emergency conditions  | 8 (15.7%)          | 7 (2.1%)               | $< 0.001$ |
| CABG                                  | 3.3 $\pm$ 0.9      | 3.0 $\pm$ 0.8          | 0.023     |
| Blood transfusion                     | 2.4 $\pm$ 1.1      | 1.3 $\pm$ 0.7          | $< 0.001$ |
| Revision due to hemorrhage            | 10 (19.6%)         | 14 (4.2%)              | $< 0.001$ |
| Intensive care unit time [day]*       | 5.3 $\pm$ 5.5      | 2.2 $\pm$ 0.4          | $< 0.001$ |
| Hospitalization time [day]*           | 13.3 $\pm$ 5.7     | 5.2 $\pm$ 0.6          | $< 0.001$ |
| Mortality                             | 5 (9.8%)           | 9 (2.7%)               | 0.012     |

\*Mean  $\pm$  standard deviation. CABG – coronary artery bypass grafting.

**Table II.** Comparison of infection rates and bacterial culture results among groups

| Parameter                        | Control group | Gentamicin spray group | Topical Genta Fleece HD | P-value |
|----------------------------------|---------------|------------------------|-------------------------|---------|
| All infections (%):              | 26 (20.8)     | 21 (11.6)              | 4 (5.0)                 | 0.004   |
| Superficial SWI                  | 12 (9.5)      | 14 (7.7)               | 2 (2.5)                 | 0.009   |
| Deep SWI                         | 14 (11.1)     | 7 (3.9)                | 2 (2.5)                 | 0.011   |
| Positive bacterial cultures (%): | 19 (73.1)     | 13 (61.9)              | 3 (75.0)                | 0.325   |
| MRSA                             | 4 (15.4)      | 8 (38.1)               | 2 (50.0)                |         |
| MSSA                             | 9 (34.6)      | 3 (14.3)               | 0 (0.0)                 |         |
| <i>Escherichia coli</i> (%)      | 3 (11.5)      | 1 (4.8)                | 1 (25.0)                |         |
| <i>Enterobacter</i> (%)          | 2 (7.7)       | 1 (4.8)                | 0 (0.0)                 |         |
| <i>Pseudomonas</i> (%)           | 1 (3.8)       | 0 (0.0)                | 0 (0.0)                 |         |

SWI – sternal wound infections, MRSA – methicillin-resistant *Staphylococcus aureus*, MSSA – methicillin-sensitive *Staphylococcus aureus*.

infectious complications had occurred ( $p < 0.001$ ) (Table I).

Among the 381 patients included in the study, 51 (13.8%) cases of SWI occurred post-operatively. In total, a significantly smaller proportion of SWIs occurred in the GF group (4/79; 5.1%,  $p = 0.002$ ) compared to the control and GS groups. Additionally, 21/177 (11.9%) of the patients in the GS group had SWI compared to 26/125 (20.8%) in the control group, but this difference was not statistically significant. Evaluation of superficial (SSWIs) vs. deep SWIs (DSWIs) revealed a significantly lower number of SSWIs (2/79; 2.5%) in the GF group than in the other two groups. A significantly smaller number of DSWIs occurred in the GS group (7/177; 3.9%) than in the control group (14/125; 11.2%) (Table II).

Evaluation of duration of hospital stay showed a significantly shorter stay in the GF group ( $5.3 \pm 1.6$  days,  $p < 0.01$ ). Application of GS was also associated with a significantly shorter hospital stay ( $6.2 \pm 3.6$  days,  $p < 0.001$ ) compared to the control group ( $7.1 \pm 4.0$  days;  $p < 0.001$ ). Hospital stay was found to be shorter in the GF group than in the GS group ( $p = 0.002$ ).

**Table III.** Multivariate analysis of infectious complications in terms of associated parameters

| Parameter                            | Odds ratio*      | P-value |
|--------------------------------------|------------------|---------|
| Obesity**                            | 3.18 (1.64–6.17) | 0.001   |
| Diabetes mellitus                    | 0.85 (0.43–1.66) | 0.635   |
| Hypertension                         | 0.52 (0.20–0.95) | 0.232   |
| COPD                                 | 1.44 (1.06–3.04) | 0.037   |
| EuroSCORE***                         | 3.22 (1.11–7.44) | < 0.001 |
| Operations under emergent conditions | 2.16 (1.04–5.53) | 0.003   |

COPD – chronic obstructive pulmonary disease, \*95% confidence interval, \*\*BMI < 30 kg/m<sup>2</sup> vs.  $\geq 30$  kg/m<sup>2</sup>, \*\*\*EuroSCORE < 4 vs.  $\geq 4$ .

On multivariate analysis, high EuroSCORE results ( $\geq 4$ ), obesity (BMI > 30 kg/m<sup>2</sup>), performing the operations under emergency situations and presence of chronic obstructive pulmonary disease were identified as significant risk factors in the development of SWI, with a respective odds ratio of 3.22, 3.18, 2.16 and 1.44, respectively. Diabetes mellitus and hypertension were not found to significantly increase the odds ratio of SWI (Table III).

## Discussion

This prospective randomized study demonstrated a significant decrease in SWIs and SSWIs after GF application at the surgical site. On the other hand, GS was associated with a statistically significantly lower number of DSWIs. On multivariate analysis, high EuroSCORE results ( $\geq 4$ ), obesity (BMI > 30 kg/m<sup>2</sup>), performing the operations under emergency situations and presence of chronic obstructive pulmonary disease were identified as significant risk factors in the development of SWIs.

Due to prolonged lifespan, patients referred for cardiac surgery are older and have more comorbidities than they were a few years ago. This may lead to an increase in post-operative complications [10]. In high-risk patients, the incidence of SWIs has been estimated between 12% and 20% [11]. The SWI is associated with a significantly longer hospital stay, increased medical care costs and higher mortality rate.

Although prophylactic intravenous antibiotic protocols were shown to reduce the incidence of SWIs, further attempts aim to reduce the rates of this complication [1]. Vander Salm *et al.* first reported the use of topical vancomycin [12]. Despite the promising results, vancomycin application was abandoned due to wound healing problems and development of vancomycin resistance [7].

Starting in 1987, assuming that the greatest risk of surgical wound infection was the open surgical field, Yoshii *et al.* attempted a procedure of spraying local antibiotics (cefazolin and gentamicin) at the surgical field. Deep surgical site infections occurred in 0.5% of 2613 cases which were included in their study [8]. In 2005, after demonstrating that topically applied gentamicin can provide high local concentrations without causing systemic side effects [2], Friberg *et al.* demonstrated that placement of a gentamicin collagen sponge at the sternal wound reduced the incidence of all SWIs by 53% [13]. They also noted a greater decrease in the rates of SSWI than in deep infections. In 2015, Balkanay *et al.* described another method of delivering local gentamicin locally at the surgical wound site [14]. In their study, they treated surgical sponges by placing them in a normal saline solution in which gentamicin was dissolved. These sponges were placed between the sternal retractors and the sternum underneath it. Their study included 100 patients. No SWIs occurred in the treatment group compared to 6 (12%) cases of SWI in the control group.

One large controlled study including 6960 patients from five institutions confirmed the findings that antibiotic spray (gentamicin and cefazolin) reduced the DSWI when compared to a control group (0.46% vs. 1.7%, respectively;  $p < 0.0001$ ) [7]. In our study, we demonstrated a similar decrease in DSWIs compared to the control group (3.9% vs. 11.1%, respectively;  $p = 0.013$ ). Neither of two studies which evaluated the effects of antibiotic spray reported its effects on superficial SWIs. In our study, a statistically significantly lower rate of superficial SWI in the GF group was found when compared to the control group (7.7% vs. 9.5%, respectively;  $p = 0.035$ ). In total, we found that spraying gentamicin was associated with a statistically significant decrease in the number of DSWIs (11.6% vs. 20.6%,  $p = 0.031$ ).

Gentamicin collagen sponge has been widely evaluated by several studies over the last decade. However, controversial results were reported. Application of gentamicin collagen sponge was shown to reduce the rates of SWIs in three meta-analyses [3–5], whereas another meta-analysis failed to find such evidence [6]. In our study, we demonstrated a statistically significant decrease in SSWIs in the GF group, compared to the control group (2.5% vs. 9.5%,  $p = 0.008$ ), whereas a non-significant reduction of DSWIs was found compared to the control group (2.5% vs. 11.1%,  $p = 0.024$ ). In total, we found that application of GF significantly reduced the number of all SWIs (5.0% vs. 20.6%,  $p = 0.002$ ).

There are some limitations to our study. First of all, our study sample was relatively small. Addi-

tionally, the costs of procedures and material applications were not evaluated. Moreover, patients' quality of life was not evaluated in the postoperative period. Lastly, this study focused on the short-term results of gentamicin, and long-term outcomes should be further evaluated.

In conclusion, our study demonstrated that GF application reduced the rates of overall SWI and SSWI, whereas local GS application reduced DSWIs. To clarify this issue, further prospective randomized trials with larger patient volumes are needed.

### Conflict of interest

The author declares no conflict of interest.

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