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ORIGINAL ARTICLE

Local GENTA-COLL Resorb Reduces Sternal Wound Infections after Cabg Surgery: A Randomized Controlled Trial

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ABSTRACT

Background: In cardiac procedures, particularly CABG, post-sternotomy deep sternal wound infection (DSWI), also known as mediastinitis, can be problematic. DSWIs are extremely dangerous postoperative complications that raise hospital stays, postoperative morbidity, death, and overall medical expenses. In order to further reduce wound infections following a sternotomy, we set out to assess the effectiveness of implanted gentamicin-collagen implants (GENTA-COLL resorb).

Methods: Our study was performed from May 2023 to December 2023. It included 36 high risk CABG patients for sternotomy wound infections (SWI) divided into two equal groups: GENTA-COLL and control groups. The GENTA-COLL group had local gentamycin-collagen implants inserted between sternal halves immediately before sternal closure. The control group had reinforced closure technique without gentamycin -collagen implants application. All cases were followed up for symptoms and signs of SWI.

Results: Results shows increased prevalence of post sternotomy superficial wound infection among patients of control group. Purulent discharge was detected in 1 case of control group versus no cases in GENTA-COLL group, serous discharge (2 cases in control group (6.7%) versus no cases in GENTA-COLL group. As regards DSWI no cases in GENTA-COLL group versus 1 case in control group (3.3%), CT healing was much better in GENTA-COLL group rather than control group with significant statistically increase in CT healing score (p-value=0.005).

Conclusion: Application of GENTA-COLL resorb possibly reduces post sternotomy superficial wound infection, prevents DSWI and improves sternal healing.

Keywords: Post-sternotomy; Infection; mediastinitis; GENTA-COLL; Local.

INTRODUCTION

Despite the growing popularity of minimally invasive techniques, median sternotomy remains the conventional procedure for CABG. Despite its ease, safety, and speed, it has a number of drawbacks, including infection, nonunion, and malunion [1]. One of the most dangerous postoperative complications following heart surgery is still SWI. While DSWI following heart surgery is a major complication that significantly increases both morbidity and mortality, superficial sternal wound infection (SSWI) increases morbidity. There have been attempts to reduce the prevalence of SWI. But in spite of everything, SWI is a daily struggle for cardiothoracic surgeons[2].

One potentially fatal side effect following heart surgery is mediastinitis. Postoperative mediastinitis is reported to occur 1–5% of the time. individuals who have mediastinitis after heart surgery have a mortality rate that is more than 30% greater than that of individuals who do not have a deep sternal wound infection[3].

It has been repeatedly demonstrated that routine intravenous antibiotic prophylaxis, contemporary hygiene standards, and

advancements in cardiac surgery, cardiac anesthesia, and critical care medicine started prior to cardiac surgery lower the postoperative rates of infections and, consequently, related morbidity and mortality[4]. The Centers for Disease Control distinguish between superficial and deep surgical site infections (SSIs). While deep sternal SSI affects the sternum, muscle, fascia, and organs/spaces, only the skin and subcutaneous tissue are affected by superficial sternal SSI [5].

In order to reduce sternal wound infections during heart surgery, several novel approaches were studied. To reduce perioperative and postoperative wound infection, local antibiotic eluting devices, like the resorbable gentamicin-collagen sponge (Genta-Coll resorb), provide a high local concentration of gentamicin. Since Genta-coll resorbs were placed in the mediastinum shortly before sternal closure, they locally release large amounts of gentamicin into the wound, reducing the risk of acquired bacterial resistance to antibiotics while also avoiding the systemic side effects of such high antibiotic dosages [6].

Aim of the work:

This clinical study sought to identify independent risk factors for an elevated SSI rate as well as the impact of Genta-Coll resorb treatment on the sternum's SSI rate and sternal healing in patients having CABG.

METHODS

Our study comprised 36 high-risk CABG patients who underwent surgery at the cardiothoracic surgery department of Zagazig University Hospital between May 2023 and December 2023. Every patient provided written informed permission, and Zagazig University (IRB #11121-20-9-2023) approved the study. The World Medical Association's (Declaration of Helsinki) rule of ethics for human subjects' research was followed in the conduct of the study.

They all had one or more high-risk criteria for SWI, such as female gender, diabetes mellitus, obesity, advanced age (>65 years), COPD, sternum osteoporosis, LIMA harvesting, lengthy CPB, IABP use, re-examination for high drain, long intensive care unit stay, and prolonged hospitalization. Eighteen patients who received topical Genta-Coll resorb shortly before strengthened sternal closure were included in the first group, known as the Genta-Coll group. Only reinforced sternal closure in the second group (control group).

Preoperative preparations

The study was authorized by our ethics committee, and each patient signed an informed consent form a complete history was recorded, a clinical examination was conducted, and all laboratory and radiological tests, including echocardiogram, CT chest, chest x-rays, and coronary angiography, were completed. All precautions against SSI were taken, and blood sugar was appropriately controlled in accordance with standards. All patients received a prophylactic antibiotic in the form of cefotaxime 1 gm by IV infusion one hour prior to skin incision, and a second dose at the onset of CPB.

Surgical technique

Classic median sternotomy, LIMA harvesting, great saphenous vein harvesting, and on-pump method were performed on all patients.

Sternal closure Genta-Coll resorbs were implanted under the sternal halves just prior to sternal closure in the Genta-Coll group, whereas nothing was inserted in the other group. This was done utilizing reinforced sternal stainless steel wires in size 7 and simple sternal wires with a modified Robiscek technique. Following surgery, Every patient was sent to the intensive care unit (ICU) for cardiac care where they received prophylactic antibiotics, proper glycemic management, and drain amount monitoring. Every patient's information was documented.

Two grams of cefotaxime intravenously every day was used as a post-operative

prophylactic antibiotic, and satisfactory glycemic control was maintained.

For six months following surgery, all patients were monitored in our PT clinic for any indications of sternal dehiscence or sternotomy wound infection. After surgery, routine CT scans were conducted six months later.

According to our institution's standard operating procedure, the treatment of superficial and deep sternal SSI included routine wound checks, sternum stability tests, fever, leucocyte, and CRP checks, swab taking, antibiotic treatment, and, if necessary, surgical sternal wound revision with negative suction until secondary closure of the chest. A chest CT scan was done in every instance when superficial sternal SSI treatment failed and there were indications of a deep sternal wound infection.

In few situations, surgical debridement and rewiring were required (table 1).

Statistical analysis:

Laboratory tests, outcome assessments, basic clinical examinations, and data collected over time are all coded, entered, and analyzed using Microsoft Excel software. The Statistical Package for the Social Sciences (SPSS) software (version 26.0) was then used to analyze the data.

RESULTS

Pre-operative data

Table 2 showed that there was no statistically significant difference ($p>0.05$) between the Genta-Coll and non-Genta-Coll groups in terms of demographic statistics.

Table 3 indicates that the comorbidities such as diabetes, obesity, and COPD did not show statistically significant differences between the gentamicin-collagen group and the non-gentamicin-collagen group ($p>0.05$).

Intra-operative data

This table 4 showed that the number of grafts in the genta-coll and non-genta-coll groups did not differ statistically significantly ($p>0.05$).

Post-operative data

This table 5 indicates that the gentamicin-collagen and non-gentamicin-coll groups did not experience any statistically significant differences in complications ($p>0.05$). However, problems were more common in the non-gentamicin-coll group.

This table 6 showed that, in comparison to the non-genta-coll group, the CT healing score of the genta-coll group increased statistically substantially ($p \leq 0.05$). The genta-coll and non-genta-coll groups did not differ statistically significantly in terms of CT at the start of infection symptoms ($p>0.05$).

Table 1: Parameters of 6-Point Scale to Evaluate Sternal Bone Healing

Score	Definition	Description
0	**No signs of healing (non-union)**	No contact between sternal halves, absence of gab mineralization, and sclerotic osteotomy margins similar to that of cortical bone
1	**indeterminate**	No contact or mineralization between the sternal halves, but osteotomy margins were non sclerotic, concave or irregular
2	**Signs suggesting minimal or early healing**	Faint mineralization between non-contacting sternal halves, a thin (1 mm) bridge of bone connecting the sternal halves anteriorly or posteriorly, or near bone-on-bone contact between the sternal halves, with sclerotic osteotomy margins
3	**Mild synthesis**	Bridging bone (i.e., no perceptible gap) along with less than 50% of the anteroposterior dimension of the sternal halves, with the sternal halves either offset in the anteroposterior dimension or aligned in the anteroposterior dimension

4	**Moderate synthesis**	Bridging bone (i.e., no perceptible gap) along 50% or more of the anteroposterior dimension of the sternal halves, with the sternal halves either offset in the anteroposterior dimension or aligned in the anteroposterior dimension, with visible remnants of the previous osteotomy
5	**Complete synthesis**	Sternal halves were well-aligned, and the appearance was that of essentially normal bone, without a gap or visible osteotomy margin

Notes: Adapted from: Stacy GS, Ahmed O, Richardson A, Hatcher BM, MacMahon H, Raman J. Evaluation of sternal bone healing with computed tomography and a quantitative scoring algorithm. Open Med Imaging J 2014;8;29–35. doi:10.2174/1874347101408010029.10 © Stacy et al; Licensee Bentham Open. Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/bync/3.0/)

Table 2: Some demographic data among the studied groups

Variable	**Genta-coll group (N=30)**		**Non-genta-coll group (N=30)**		**t-test**	**P-value**
Age (years): • ***Mean ± SD*** • ***Range***	63.1 ±4.7 53-71		64 ±5.2 50-77		-0.734	0.466
Variable	**N**	**%**	**N**	**%**	**χ 2**	**P-value**
Sex: • ***Male*** • ***Female***	17 13	56.7 43.3	17 13	56.7 43.3	-----	1

Table 3: Co-morbidities among the studied groups

Variable	**Genta-coll group (N=30)**		**Non-genta-coll group (N=30)**		**χ 2**	**P-value**
	N	**%**	**N**	**%**		
Obesity: • ***No*** • ***Yes***	13 17	43.3 56.7	13 17	43.3 56.7	-----	1
COPD: • ***No*** • ***Yes***	24 6	80 20	24 6	80 20	-----	1
Diabetes: • ***No*** • ***Yes***	9 21	30 70	10 20	33.3 66.7	0.077	1

Table 4: Number of grafts among the studied groups

Variable	**Genta-coll group (N=30)**	**Non-genta-coll group (N=30)**	**t-test**	**P-value**
Number of grafts: • ***Mean ± SD*** • ***Range***	2.7 ±0.8 1-4	2.8±0.7 1-4	-0.321	0.749

Table 5: Complications among the studied groups

Variable	Genta-coll group (N=30)		Non-genta-coll group (N=30)		χ 2	P-value
	N	%	N	%		
Re-exploration for bleeding: • ***No*** • ***Yes***	27 3	90 10	26 4	86.7 13.3	Fisher	1
Deep mediastinitis: • ***No*** • ***Yes***	30 0	100 0	29 1	96.7 3.3	Fisher	1
Superficial Sternotomy infection: • ***No*** • ***Purulent discharge*** • ***Serous discharge***	30 0 0	100 0 0	27 1 2	90 3.3 6.7	3.2	0.206

Table 6: CT among the studied groups

Variable	Genta-coll group (N=30)		Non-genta-coll group (N=30)		t-test	P-value
CT healing score: • ***Mean ± SD*** • ***Range***	3.5 ±0.82 2-5		2.9 ±0.77 1-5		2.9	0.005 (S)
Variable	**N**	**%**	**N**	**%**	**χ 2**	**P-value**
CT at time of appearance of signs of infection: • ***Non*** • ***No retrosternal extension*** • **Retrosternal extension**	30 0 0	100 0 0	27 2 1	90 6.7 3.3	3.2	0.206

DISCUSSION

Following heart surgery, mediastinitis is an uncommon but potentially fatal consequence. High morbidity, a worse long-term survival rate, an extended hospital stay, and higher medical expenses are all linked to it. After heart surgery, individuals with mediastinitis have a mortality risk that is more than three times higher than those who do not have a severe sternal wound infection [7].

Current hygienic practices, the use of prophylactic antibiotics both during and after surgery, and developments in heart surgery and anesthesia, and critical care medicine are the reasons for the comparatively low reported incidence of mediastinitis, which ranges from 1 to 5% [3].

We attempted to assess the effectiveness of local genta-coll in avoiding sternal wound infection following CABG in our study.

In terms of demographic data and co-morbidities (e.g., age, gender, obesity, COPD, and diabetes), our study's results showed no statistically significant difference between the genta-coll and non-genta-coll groups (p>0.05). While many authors concluded that there was no correlation between age, gender, and obesity and SWI after CABG, others found that there was, as Raja et al. [8] found that

female gender and obesity are predictors of post-sternotomy wound infection in CABG patients, and others found that the only modifiable preoperative risk factors for mediastinitis are obesity. Bennett-Guerrerro et al. conducted a multicenter randomized control research (RCT) with 1052 patients undergoing elective CABG and/or valve surgery who were at high risk of sternal wound infections (SWIs) because they had diabetes, were obese (body mass index, BMI, >30), or both [9].

Numerous authors have noted the connection between a high number of grafts and a lengthy CPB duration and SWI following CABG, but our study found no statistically significant difference between the genta-coll and non-genta-coll groups in terms of graft count.

Although Lu et al. [10] showed that re-exploration for bleeding has been linked to sternal wound infections, our investigation found no correlation between re-exploration for bleeding and SWI following CABG.

The frequency of SWI was higher in the non-genta-coll group, but our study found no statistically significant difference between local use of Genta-Coll and SWI after CABG. Raja et al. [8] found that using the Genta-Coll® sponge significantly decreased the sternal SSI rate in a single center propensity score analysis. Kowalewski, et al [6] the risk of sternal SSI was dramatically reduced by implantable gentamicin-collagen sponges, according to a 2015 meta-analysis of 14 studies involving 22,135 patients. Otherwise, in a large-scale randomized examination of 1502 cardiac surgery patients at 48 US facilities, Bennett-Guerrero et al. [9] were unable to confirm these findings. Schimmer et al. conducted a double-blind RCT with 800 consecutive patients who underwent heart surgery with closure of a median sternotomy [11].

Patients were randomly assigned to one of two groups: closure with gentamicin–collagen sponge (Verum, maximum 143 mg gentamicin) or simple collagen sponge retrosternally. The occurrences of deep SWI (DWSI) and superficial SWI (SSWI) in the two groups were compared 30 days post-operatively. In an RCT with 542 CABG patients, Eklund et al. [12] contrasted the intervention group (272) that had retrosternal wound closure using a gentamicin–collagen implant (Genta-coll) with a group of 270 patients who underwent standard closure. The gentamicin group had a 4% (11 of 272) incidence of SWI, while the control group had a 5.9% (16 of 270) incidence (P = 0.20). Mediastinitis did not differ between the two groups (1.1 vs. 1.9%, P = 0.47). Gram-positive infections predominated. However, according to the authors, the study lacked sufficient power. 2.1/2.5% was the total incidence of DSWI/SSWI. A relative risk (RR) reduction of 83.9%/33.7%, P = 0.013, was seen between the gentamicin group (2 of 354; 0.56% DSWI)/(7 of 354; 1.9% SSWI) and the placebo group (13 of 369; 3.5% DSWI)/(11 of 369; 2.9% SSWI).

Our investigation shown that the sternum healing of the genta-coll group was considerably superior than that of the non-genta-coll group using the CT healing score. On the other hand, vancomycin paste applied to the sternal edges of patients undergoing heart surgery did not appear to be associated with a decreased incidence of deep sternal wound infection, according to Lander et al. [13].

Conclusion

Application of GENTA-COLL resorb possibly reduces post sternotomy superficial wound infection, prevents DSWI and improves sternal healing.

Conflict of interest: The authors declare no conflict of interest.

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