



Prophylaxis of sternal wound infections with gentamicin-collagen implant: randomized controlled study in cardiac surgery

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KEYWORDS

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Summary Postoperative infections may lead to prolonged hospital stay and increased morbidity, mortality and hospital costs, especially in heart surgery. Finding new means to prevent infections would benefit both the patient and society. The aim of this study was to assess if locally administered gentamicin prevents sternal wound infections in coronary artery bypass (CABG) surgery. We randomized 542 consecutive CABG patients to two groups: those who received gentamicin-collagen implant under their sternum before closure ($N=272$) and controls ($N=270$). The subjects received routine intravenous antimicrobial prophylaxis (85% cefuroxime, 14% cefuroxime and vancomycin), and were followed-up for three months. The sternal wound infection rate was 4.0% (11/272) in the gentamicin group and 5.9% (16/270) in the control group. The mediastinitis rates were 1.1 and 1.9%, respectively. This treatment was safe and easy to administer, and no side-effects occurred. No statistically significant difference was demonstrated between infection rates in the two groups. This is the first study on the use of gentamicin-collagen sponge as prophylaxis in cardiac surgery. Our data show that infection was reduced slightly in the gentamicin-collagen group compared with the control group, but the study population was too small to draw conclusions. Further evaluation is needed, and the results may warrant another larger, better-powered study.

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Introduction

Despite the development of surgical techniques and antimicrobial therapies, no reduction has occurred in infection rates during the late 20th century. Since wound infections after cardiac surgery can be very serious, leading to increased morbidity and mortality, it seems justified to investigate new ways to prevent them. Local antibiotics have been widely used in bone and soft tissue infections.¹ In colorectal surgery, the use of gentamicin sponge significantly reduced the postoperative wound infection rate and hospital stay.² In cardiac surgery, local antibiotics have not been widely used.^{3,4} For patients with mediastinitis, the gentamicin-collagen sponge has been reported to be effective,³ but there are no published studies on prophylaxis with local gentamicin. This is the first study on the use of gentamicin-collagen sponge as prophylaxis in cardiac surgery. The aim of this study was to show the possible effects of local gentamicin in the prevention of sternal wound infections in coronary artery bypass grafting (CABG) surgery.

Materials and methods

Patients and procedures

The study population comprised 557 patients who underwent elective CABG surgery at Helsinki University Central Hospital between July 1998 and September 1999. In all patients, the operative approach was through a median sternotomy, with cardiopulmonary bypass. The patients were randomized to the gentamicin group or the control group using sealed envelopes. In the study group, the subjects gave their informed consent. The controls were not asked for informed consent because no additional appointments or investigations were necessary. The patients in the gentamicin group received a 10 cm × 10 cm gentamicin-collagen implant (Gentacoll, Schering-

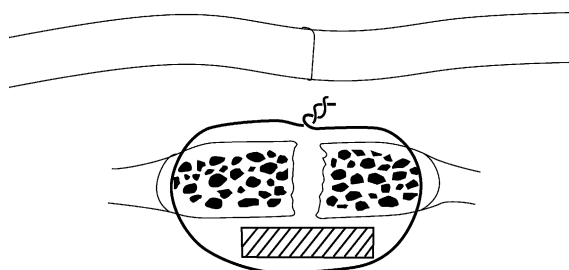


Figure 1 Cross-sectional view with gentamicin-collagen implant underneath sternum (gentamicin-collagen implant shown as hatched area).

Plough, PO 3, 02201 Espoo, Finland), which contains 130 mg gentamicin and 280 mg collagen, underneath their sternum before wound closure (Figure 1). The implant was cut into two or three strips before placement. The controls' sternums were closed in a routine manner with steel wires, without a gentamicin implant. All patients received antibiotic prophylaxis with two doses of intravenous (IV) cefuroxime 1.5 g in 6 h. The patients that were hospitalized at least three days pre-operatively also received IV vancomycin 500 mg on two occasions. In this hospital, patients staying over 72 h (three days) receive vancomycin as prophylaxis before cardiac surgery in case of acquisition of hospital pathogens. Subjects were excluded from the study if they were allergic to gentamicin or to multiple drugs, had severe renal insufficiency (uraemia or need for dialysis), had a previous kidney transplant or a redo procedure, or if they were foreigners. The Ethics Committee of our hospital approved the study design.

The following patient characteristics were recorded: age, sex, body mass index (BMI), underlying disease, New York Heart Association pre-operative functional class (NYHA classification), chronic obstructive pulmonary disease (COPD), presence of pre-operative serum creatinine, left ventricular ejection fraction and pre-operative hospitalization (Table I). The operative characteristics included antibiotic prophylactics, duration of surgery, types of bypass grafts used, number of bypasses, length of cardiopulmonary bypass, aortic cross-clamp time, mediastinal drain discharge, re-operation, duration of mechanical ventilation, blood transfusions, low

Table I Patient pre-operative characteristics [values are numbers (N) or mean (SD)]

Characteristics	Gentamicin group (N=272)	Control group (N=270)
Age	64.4 (9.3)	64.7 (9.3)
Male (N)	206 (76%)	192 (71%)
Body mass index (kg/m ²)	27.2 (3.7)	27.1 (4.1)
Diabetes (N)	61 (22%)	61 (23%)
COPD (N)	25 (9%)	26 (10%)
Serum creatinine (μmol/L)	98 (24)	100 (24)
LVEF ≤ 30% (N)	16 (6%)	8 (3%)
NYHA classification		
Class I	10 (4%)	7 (3%)
Class II	72 (26%)	76 (28%)
Class III	165 (61%)	153 (57%)
Class IV	24 (9%)	32 (12%)

COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association class.

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