

Triclosan-coated sutures do not reduce leg wound infections after coronary artery bypass grafting

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Abstract

OBJECTIVES: Leg wound infection is a common complication after coronary artery bypass grafting (CABG). Suture contamination has been suggested as a mechanism of surgical site infections. Vicryl Plus[®] is a polyglactin suture coated with the antiseptic chemical substance Triclosan, which has been shown to inhibit the growth of *Staphylococcus aureus in vitro*. The first aim of the present study was to compare Vicryl Plus with conventional Vicryl[®] sutures with regard to leg wound infections following CABG. The second aim was to examine patient- and operative characteristics, which are assumed to predict leg wound infections.

METHODS: After statistical calculations *a priori*, 328 CABG patients were prospectively randomized to leg wound closure with Vicryl Plus (164 patients) or conventional Vicryl sutures (164 patients). Incidences of leg wound infection and predictors of infection related to patient- and operative characteristics were examined.

RESULTS: The incidence of leg wound infections was 10.4% (17/163) in the Vicryl group, and 10.0% (16/160) in the Vicryl Plus group ($P = 1.00$). Patients with leg wound infections had increased body mass index and prolonged extracorporeal circulation and aortic clamping time compared with patients without infections.

CONCLUSIONS: In the present study, we report for the first time that Vicryl Plus did not reduce the incidence of leg wound infections in patients undergoing CABG. Obesity and prolonged time of extracorporeal circulation were both associated with the increased risk of infections. Currently, the clinical role and indication for the use of Vicryl Plus have yet to be defined.

Keywords: Surgery (complications) • Coronary artery bypass grafting • Infection (leg wound)

INTRODUCTION

Annually, about 2700 coronary artery bypass grafting (CABG) operations are performed in Norway [1]. Despite the widespread use of the left internal mammary artery, the larger saphenous vein is still the most commonly used conduit for CABG. The reasons for this surgical practice are related to the availability, the length of the saphenous vein and the documented patency rates of vein grafts [2]. However, surgical site infections following vein harvesting still represent a significant postoperative problem with substantial economical costs [3]. Leg wound infections following saphenous vein harvesting have been reported in 2–20% of patients after CABG [4].

Several studies have analysed the risk factors for the development of surgical site infections [5–7]. Advanced age, female gender, body mass index (BMI), diabetes mellitus, renal failure, smoking, peripheral vascular disease (PVD) and chronic obstructive pulmonary disorder are among the most common risk factors reported. Also, operative characteristics such as the duration of surgery and cardiopulmonary bypass (CPB), as well as different vein-harvesting techniques have been shown to affect

the incidence of surgical site infections [4, 8–10]. Different mechanisms have been suggested to be involved in the pathogenesis of wound infections, such as a reduced amount of oxygen and its affinity to haemoglobin, low oxygen tension and reduced oxygen delivery at the capillary level, compromised drainage of wound haematoma and duration of wound exposition during vein harvesting [4, 7]. Another mechanism suggested is bacterial colonization of the suture material [11]. Antibacterial-coated sutures have been reported to reduce the incidence of surgical site infections both in the experimental and clinical studies [12–15]. Vicryl Plus[®] (Ethicon Inc., Somerville, NJ, USA) is a polyglactin suture, coated with the antiseptic chemical substance triclosan [5-chloro-2 (2,4-dichlorophenoxy)phenol]. Triclosan acts bacteriostatic by inhibiting enzymes involved in the bacteria's fatty acid synthesis [16]. Experimentally, Triclosan has been shown to inhibit the growth of selected Gram-positive and Gram-negative bacteria [12, 13]. Favourable effects of Vicryl Plus have been found with regard to sternal wound infections following cardiac surgery [15]. Reduced surgery site infection rates of Vicryl Plus have also been reported following other types of major surgery [17, 18]. In contrast, other studies have

not demonstrated positive effects of Vicryl Plus [19, 20]. However, as far as we are aware, no other studies have examined the effect of Vicryl Plus on leg wound infections after saphenous vein harvesting, the leg being the site with the highest wound infection rate in CABG surgery.

The aim of this study was to evaluate the effects of Vicryl Plus (with Triclosan coating) on Vicryl® standard sutures (without Triclosan coating) with regard to surgical leg wound infections following saphenous vein harvesting in a prospective randomized study. Secondly, we wanted to examine patient- and operative characteristics, which are assumed to predict leg wound infections.

MATERIALS AND METHODS

Patients

From September 2009 to September 2011, a total of 328 patients who underwent elective CABG at the Department of Cardiothoracic Surgery at Oslo University Hospital (OUH), Ullevaal, were included in this study. The randomization sequence was performed by the main surgeon by opening sealed envelopes on the day of surgery. Following this randomization procedure, the patients were allocated to either wound closure with conventional Vicryl, or wound closure with Triclosan-coated suture Vicryl Plus. Four patients in the Vicryl Plus group and one patient in the Vicryl group were lost to follow-up. The Regional Ethics Board approved the study. Informed consent was obtained from each patient in advance before the operation. The surgeons were not blinded to the suture material used. Patients with leg wounds, bilateral vein harvesting, harvesting of the short saphenous vein, varicose veins and those undergoing emergency CABG were excluded.

Blood samples were obtained pre- and postoperatively and analysed for haemoglobin, C-reactive protein, white blood cells, glucose and creatinine. We also registered wound length, vein quality and the attending surgeon's evaluation of the harvesting procedure.

Hair removing was performed with an electric razor the afternoon the day before surgery. In the evening before the operation, all patients took a shower including washing with soap and Hibiscrub® (chlorohexidinegluconate 40 mg/ml). This procedure was repeated on the day of surgery.

Surgical technique

All patients were operated on with the standard technique for CABG in our department, using CPB, moderate hypothermia (32°C), cold crystalloid or cold blood cardioplegia and aortic cross clamping. At the operating theatre, the skin was disinfected with chlorohexidine solution, 5 mg/ml with 70% ethanol. The greater saphenous vein was harvested from the medial malleolus by a continuous skin incision, ending either below or over the knee. Side branches were ligated or clipped. For practical reasons, the left leg was predominantly preferred. The prophylactic antibiotic regimen consisted of Cefalotine administered as a single dose of 2 g intravenously before skin incision, and continued with 3-h intervals to a total of 8 g in both groups. The leg wound was closed with Vicryl or Vicryl Plus sutures and covered with drape, compresses and elastic bandages. The first day after

the operation, the compresses and the elastic bandages were removed. The drape was removed the third postoperative day, and the leg examined for wound integrity, any wound exudates and signs of infection. In case of a suspected wound, swabs for culture were taken, and a surgeon evaluated the wound for eventual surgical revision. The patients were given customized stockings for continuous use for 3 days, and beyond that only during daytime for approximately 3 weeks.

Outcomes

After discharge, all patients with uncomplicated wound healing returned a registration form 4 weeks after the operation. Patients with questionable wound integrity or any wound exudates and signs of infection observed during this 4-week period were told to be examined by their general practitioner. The diagnosis of SSI was secured on the basis of positive bacterial culture and clinical judgement.

Statistical analysis

The SigmaPlot® software version 11.0 (Systat Software Inc., San Jose, CA, USA) was used for data analysis. Statistical power analysis was performed *a priori*. In order to detect an estimated infection rate reduction of 50% in the Vicryl Plus group and a statistical power level of 0.8, this study required a sample size of a minimum of 302 patients. A *P*-value < 0.05 was considered significant. The values are reported as means ± SEM. Comparisons between the two normally distributed groups were analysed using the Student's *t*-test. If the data were not normally distributed, we used the corresponding non-parametric test (Mann-Whitney rank sum test). For proportion analysis, the Fisher's

Table 1: Demographic patient characteristics in the Vicryl and the Vicryl Plus groups

	Vicryl, n = 163	Vicryl Plus, n = 160	<i>P</i> -value
Age (years)	63.1 ± 0.8	63.5 ± 0.7	0.67
Female, n (%)	19 (11.7%)	17 (10.6%)	0.86
BMI (kg/m ²)	27.5 ± 0.3	27.7 ± 0.3	0.88
Diabetes mellitus, n (%)	40 (24.5%)	31 (19.4%)	0.28
IDDM	17 (10.4%)	9 (5.6%)	0.15
NIDDM	23 (14.1%)	22 (13.8%)	0.88
Hb (g/100 ml)	14.1 ± 0.1	14.1 ± 0.1	0.50
CRP (mg/l)	5.9 ± 0.9	6.6 ± 1.1	0.47
WBC (10 ⁹ /l)	7.1 ± 0.1	7.2 ± 0.1	0.33
Glucose (mmol/l)	8.5 ± 0.8 ^a	6.6 ± 0.3	0.05
Creatinine (µmol/l)	81.0 ± 1.7	85.0 ± 2.7	0.35
Smoking, n (%)	40 (24.5%)	42 (26.3%)	0.80
PVD, n (%)	21 (12.9%)	16 (10.0%)	0.49
EuroSCORE	2.9 ± 0.2	2.8 ± 0.2	0.77

Data represent mean ± SEM or %.

BMI: body mass index; IDDM: insulin dependent diabetes mellitus; NIDDM: non-insulin dependent diabetes mellitus; CRP: C-reactive protein; EuroSCORE: European System for Cardiac Operative Risk Evaluation; Hb: haemoglobin; PVD: peripheral vascular disease; WBC: white blood cells.

^a*P* < 0.05; patients with Vicryl vs patients with Vicryl Plus.

Table 2: General perioperative data of the Vicryl and Vicryl Plus groups

	Vicryl, n = 163	Vicryl Plus, n = 160	P-value
Number of vein grafts	2.1 ± 0.1	2.1 ± 0.1	0.73
Operation time (min)	167.2 ± 3.0	170.5 ± 3.0	0.50
CPB (min)	76.2 ± 1.8	80.5 ± 1.9	0.16
Aortic cross-clamping (min)	41.2 ± 1.1	45.4 ± 3.2	0.62
Vein harvesting time (min)	55.5 ± 1.5	53.2 ± 1.6	0.17

Values are presented as mean ± SEM.
CPB: cardiopulmonary bypass.

Table 3: Patient characteristics in the infection and non-infection groups

	Infection, n = 33	Non-infection, n = 290	P-value
Age (years)	62.8 ± 1.6	63.3 ± 0.6	0.74
Female, n (%)	5 (15.2%)	31 (10.7%)	0.39
BMI (kg/m ²)	29.5 ± 0.8 ^a	27.5 ± 0.2	0.02
Diabetes mellitus, n (%)	9 (27.3%)	62 (21.4%)	0.51
IDDM	5 (15.2%)	21 (7.2%)	0.17
NIDDM	4 (12.1%)	41 (14.1%)	1.00
Hb (g/100 ml)	13.9 ± 0.2	14.1 ± 0.1	0.29
CRP (mg/l)	6.6 ± 2.1	6.2 ± 0.8	0.78
WBC (10 ⁹ /l)	6.9 ± 0.3	7.2 ± 0.1	0.44
Glucose (mmol/l)	7.3 ± 0.5	7.5 ± 0.5	0.88
Creatinine (µmol/l)	78.0 ± 2.4	76.0 ± 1.8	0.42
Smoking, n (%)	10 (30.3%)	72 (24.8%)	0.53
PVD, n (%)	5 (15.2%)	32 (11.0%)	0.56
EuroSCORE	3.1 ± 0.3	2.8 ± 0.1	0.61

Data represents mean ± SEM.

BMI: body mass index; IDDM: insulin dependent diabetes mellitus; NIDDM: non-insulin dependent diabetes mellitus; CRP: C-reactive protein; EuroSCORE: European System for Cardiac Operative Risk Evaluation; Hb: haemoglobin; PVD: peripheral vascular disease; WBC: white blood cells.

^aP < 0.05; patients with infection vs patients without infection.

exact test was performed. All data were recorded prospectively and stored in a database.

RESULTS

Wound closure with Vicryl vs Vicryl Plus

Patient characteristics. Patient characteristics of the Vicryl and Vicryl Plus study groups are comparable and are given in Table 1. There were no significant differences between the two study groups with respect to age, BMI, gender, smoking habits, EuroSCORE, diabetes mellitus or PVD. Also, levels of haemoglobin, C-reactive protein, white blood cells or creatinine were not significantly different. Glucose levels were significantly higher in the Vicryl group (P = 0.05).

General perioperative data. The general perioperative data of the two groups are presented in Table 2. There were no significant differences between the groups concerning number of grafts, operation time, CPB time, aortic clamping time or harvesting time.

Infection incidence. During the study period, the overall infection rate was 10.2% (33/323). Furthermore, the infection rates were equal in both study groups. The infection rates were found to be 10.4% (17/163) in the Vicryl group, and 10.0% (16/160) in the Vicryl Plus group, respectively.

Patients with infection vs non-infection patients

Patient characteristics. The characteristics of patients with and without infections are presented in Table 3. Patients with infections had significantly higher BMIs compared with patients without infections (P = 0.02). There were no significant differences between the two groups when comparing age, sex and occurrence of diabetes mellitus or atherosclerosis, smoking habits and EuroSCORE. There were also no significant differences between the groups with regard to haemoglobin, C-reactive protein, white blood cells, glucose or creatinine levels.

General perioperative data. The general operative data in patients with or without infections in both study groups are shown in Table 4. Increased time of CPB (P = 0.03) and aortic cross-clamping (P = 0.05) were both associated with a significant increase in the surgical site infection rate. However, there were no

Table 4: Perioperative variables in the infection and non-infection groups

	Infection n = 33	(Vicryl/Vicryl Plus) n = 17/n = 16	Non-infection n = 290	(Vicryl/Vicryl Plus) n = 146/n = 144	P-value
Number of vein grafts	2.2 ± 0.1	(2.1 ± 0.2/2.3 ± 0.2)	2.1 ± 0.0	(2.0 ± 0.1/2.1 ± 0.1)	0.37
Operation time (min)	173.2 ± 7.3	(167.8 ± 12.3/178.9 ± 7.5)	168.1 ± 2.2	(167.0 ± 3.0/169.1 ± 3.2)	0.60
CPB (min)	86.4 ± 5.5 ^a	(81.3 ± 9.1/92.2 ± 6.0)	77.2 ± 1.2 ^a	(75.7 ± 1.7/79.2 ± 1.9)	0.03
Aortic cross-clamping (min)	48.3 ± 4.1 ^a	(44.4 ± 5.8/53.7 ± 5.8)	41.4 ± 1.1 ^a	(40.1 ± 1.1/43.5 ± 3.5)	0.05
Vein harvesting time (min)	57.4 ± 3.8	(51.9 ± 3.5/62.5 ± 6.4)	54.0 ± 1.1	(55.9 ± 1.6/52.1 ± 1.6)	0.58

Data represents mean ± SEM.

CPB: cardiopulmonary bypass.

^aP < 0.05 patients with infection vs patients without infection.

differences regarding infections when comparing the two studied groups with respect to number of vein grafts, total operation time, vein harvesting time and different surgeons (data not shown).

DISCUSSION

Surgical site infection following vein-harvesting on the leg is one of the most common complications in patients who undergo CABG, and represents one of the main reasons for postoperative morbidity and contributes to increased economic costs [3]. In the present study, we failed to demonstrate the beneficial effects of the Triclosan-coated Vicryl Plus suture with regard to preventing surgical site infections when compared with a conventional Vicryl suture. We found that increased BMI, prolonged extracorporeal perfusion time and prolonged aortic clamping time were associated with a higher rate of infections.

In the present study, the overall surgical site infection rate of the legs was 10.2%, irrespective of whether the suture was Triclosan coated or not. This result is in accordance with previous studies, showing infection rates in the range of 2–20% [4]. Also, Stadler and Fleck [19] showed that Triclosan-coated sutures did not reduce the rate of sternal infections in patients who underwent cardiac surgery. Likewise, other publications report no reduction in infections, when studying Triclosan-coated sutures by other surgical procedures [20]. However, to show the effect of an antibacterial-coated suture, the incidence of infections must not be too low as might be the case with sternal infections. Since Vicryl Plus has been shown to reduce the incidence of infections in other types of surgery such as abdominal surgery by Justinger *et al.* [17] and Rozelle *et al.* [18] in a study of cerebrospinal fluid shunt surgery, we wanted to test the hypothesis that Vicryl Plus might reduce the relatively high incidence of postoperative leg wound infections after CABG. We were, however, not able to confirm our hypothesis. Given our power of 0.8, the likelihood of a type II statistical error should be below 20%.

The mechanisms of surgical site infections are not fully understood, but it has been shown that bacterial colonization and different suture material may play a role regarding wound infections [11]. Therefore, creating an antibacterial environment within the wound is supposed to reduce the risk of site infections. For this purpose, Triclosan-coated sutures have been under consideration for many years and the actuality of these sutures has been supported by numerous *in vitro* studies, showing that Triclosan-coated sutures may, experimentally, inhibit the growth of known wound infection bacteria, both Gram-positive (*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Corynebacterium*, *Enterococcus*) and Gram-negative (*Pseudomonas aeruginosa* and *E. coli*) [12, 13]. One reason why the Triclosan-coated sutures failed to demonstrate reduced wound infection rates in our study may be due to the 'cleanness' of the wound environment in this patient population. According to this, the leg wounds following saphenous vein harvesting are characterized by lack of primary contamination. Furthermore, our prophylactic perioperative antibiotics regimen might also be an explanation contributing to the lack of effect of Vicryl Plus in the present study. Supporting this idea, Justinger *et al.* [17] demonstrated the beneficial effects of Triclosan-coated sutures in more contaminated wounds in abdominal surgery. Another explanation might be the developed antimicrobial resistance to Triclosan activity. The widespread use of Triclosan for many years in topic products may lead to diminished Triclosan activity [21]. In agreement with this, Suller and Russel [22] suggest that the intensive

use of Triclosan will increase the amount of Triclosan-resistant *Staphylococcus aureus*. Previously, blunted Triclosan activity due to resistance has been demonstrated in selected microbial populations *in vitro*. Bamber and Neal [23] also demonstrated low-level Triclosan resistance among *Staphylococcus aureus*, thus suggesting that both antimicrobial resistance to Triclosan and insufficient amount of Triclosan-coating may facilitate bacterial adherence and suture contamination. Although suture contamination may be a potential mechanism of surgical site infections, convincing data are still missing to demonstrate the clinical significance of different suture materials, including Triclosan coating, in the pathogenesis of surgical site infections in patients undergoing cardiac surgery. On the other hand, and more seriously, Deliart *et al.* [24] report that Triclosan coating may have adverse effects on wound healing. Therefore, further clinical evidence is necessary to define the final role of Triclosan-coated sutures.

Other researchers have analysed and reported predictors of infections in patients undergoing CABG. Identified risk factors include ageing, female sex, BMI, diabetes mellitus, PVD, operation time and preoperative levels of haemoglobin. In this study, we confirmed that BMI, extra corporeal circulation time and aortic clamping time were the main patient and operative predisposing factors associated with an increased risk of leg wound infections. In our department, we did not demonstrate an association between different surgeons and rates of surgical site infections. During the last years, in an attempt to reduce the frequency of leg wound complication, less-invasive conduit harvesting techniques have been introduced. Endoscopic vein harvesting has been reported to be associated with less surgical site infections and a better cosmetic outcome [8–10].

On the other hand, the use of arterial conduits for coronary revascularization has increasingly been widely adopted and shows both favourable outcomes and patency [25]. Consequently, alternative and individual surgical techniques of conduit harvesting should be considered in all CABG patients. Although less-invasive conduit-harvesting techniques may be attractive in selected patients, conventional open harvest of the great saphenous vein still represents a well-documented conduit-harvesting technique, associated with good quality and long-term patency.

CONCLUSION

In this study, we report for the first time that the Triclosan-coated suture, Vicryl Plus, did not reduce the incidence of surgical site infections on the legs in CABG patients. Obesity, prolonged extracorporeal circulation time and aortic clamping time were all associated with an increased risk of infections.

Conflict of interest: none declared.

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