

Sternotaneous Fistulas After Cardiac Surgery: Incidence and Late Outcome During a Ten-Year Follow-Up

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Background. Sternotaneous fistulas (SCFs) after cardiac surgery represent a complex surgical problem involving multiple hospital admissions, prolonged antibiotic treatment, and repeated debridements. Our objective was to identify the incidence of and risk factors for SCF, and to evaluate long-term survival.

Methods. A total of 12,297 patients underwent sternotomy for cardiac surgery between January 1999 and December 2008, and 32 patients were diagnosed as having SCF during follow-up. Risk factors were identified with multivariate analysis and survival was compared using the log-rank test.

Results. The cumulative incidence of SCF at one year was 0.23%. There was no significant difference in mean time from sternal closure after cardiac surgery to intervention for SCF with ($n = 9$) or without ($n = 23$) preceding sternal wound infection (SWI); 6.1 ± 4.2 versus 6.9 ± 4.6 months, ($p = \text{ns}$). Risk factors for developing

SCF were previous SWI (odds ratio [OR] = 15.7), renal failure (OR = 12.5), smoking (OR = 4.7), and use of bone wax during cardiac surgery (OR = 4.2). Negative-pressure wound therapy was applied in 20 cases of extensive SCFs. Five-year survival of SCF patients was $58\% \pm 1\%$ as compared with $85\% \pm 4\%$ in the control group ($p = 0.003$).

Conclusions. Sternotaneous fistula is a devastating diagnosis with significant morbidity and mortality. Previous SWI, renal failure, smoking, and use of bone wax are major risk factors. However, in a majority of patients SCF is not preceded by SWI and our results indicate that SCF may be a foreign body infection that develops in susceptible patients with risk factors for poor wound healing. Negative-pressure wound therapy may be a valuable adjunct in the treatment of extensive SCF.

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Patients undergoing cardiac surgery through a midline sternotomy can develop a chronic, low-virulence infection in the sternum, presenting with draining sinus tracts some weeks, months, or even years later [1–6]. These sternotaneous fistulas (SCFs), which sometimes develop into chronic osteomyelitis or osteochondritis, represent a complex surgical problem that results in multiple hospital admissions, prolonged antibiotic therapy, and repeated wound debridements [1–8]. Sternotaneous fistulas are often seen in outpatients by specialists other than cardiothoracic surgeons, which may lead to delay in correct diagnosis and proper treatment. Without proper surgical management, SCF may turn into a chronic and debilitating infection for some patients with an intractable clinical course.

The rate of fistulas after deep sternal wound infection (DSWI) is most often reported to be 3% to 10% [3, 9–11]; however, there have been very few studies on the incidence of primary SCF without preceding DSWI [12].

Furthermore, there have been few reports regarding risk factors for development of SCF after cardiac surgery, even though redo sternotomy and advanced age have been suggested as risk factors in some publications [10, 13]. The time from primary cardiac surgery to clinical onset of SCF can vary from weeks to many years [1–6], but no differences in time span between SCF presenting after DSWI and SCF presenting without any prior DSWI have yet been documented.

Even though the etiology of SCF may be multifactorial and is not yet fully understood, a common site for these infections is the steel wires used to close the sternum after open-heart surgery. Coagulase-negative staphylococci and *Candida albicans* are known to cause opportunistic infections originating from foreign bodies [14, 15], and studies involving small series have previously associated these pathogens with SCF [4, 12]. In some cases SCFs can be treated adequately with antibiotics alone

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Fig 1. Cumulative incidence (95% confidence interval) of sternocutaneous fistulas (SCFs) after midline sternotomy in 12,297 cardiac surgery patients. (— = cumulative incidence; --- = 95% confidence interval.)

[3, 4]; however, for the majority of patients surgical treatment is necessary to eradicate the infection [1-3, 5-9]. Conservative surgical treatment consists of the removal of infected wires and primary closure. Traditionally, in long-standing SCF a radical excision of parts of the sternum may be needed to eradicate the infection, followed by soft tissue flap surgery to fill up the sternal defect. However, SCF can become a recurrent problem despite adequate antibiotic therapy in combination with conventional surgical treatment [2, 5, 6, 8, 9, 11]. One recent innovation in wound-healing therapy is negative-pressure wound therapy (NPWT), which has been used successfully in DSWI [11]. At our center, the practice is to treat SCF with a combination of antibiotic therapy and local surgical revision with removal of wires, and in cases of extensive SCF the NPWT is applied in order to assist wound healing.

The aim of the present study was to calculate the incidence of SCF and define risk factors for its development. In addition, we wanted to evaluate the clinical results of SCF therapy over a ten-year period and to compare the long-term survival to that of a control group.

Material and Methods

Study Design

This was a retrospective case-control study using prospectively collected data from a computerized database at the Department of Cardiothoracic Surgery, Lund University Hospital. This database contained information on a total of 12,297 patients who underwent open-heart surgery through a midline sternotomy between January 1999 and December 2008. The study protocol was approved and the need for individual consent was waived

by The Ethics Committee for Clinical Research at Lund University, Sweden.

Study Population

All patients who were diagnosed with SCF and required surgical intervention at our department between January 1, 1999 and December 31, 2008 were included. Our department is the only cardiothoracic surgery unit in the region, and patients diagnosed with sternal wound infections are readmitted to our center. Two patients in the study population underwent emergent cardiac surgery at centers in other parts of Sweden, but were electively referred to our department and treated for late SCFs. Sternocutaneous fistulas was defined as a purulent draining sinus tract involving the sternum or the steel wires, the patients presenting after discharge for cardiac surgery with a closed sternal wound. The day of diagnosis of SCF was defined as the day of first surgical intervention for SCF and calculated from the day when the last sternal closure was performed during the hospi-

Table 1. Univariate Analysis of Preoperative and Perioperative Characteristics

Variable ^a	Fistula Group (n = 30)	Control Group (n = 120)	p Value
Age (years)	68 ± 10	66 ± 11	0.31
Female gender	7 (23)	39 (33)	0.45
Obesity ^b	9 (30)	26 (22)	0.47
Hypertension	15 (50)	62 (52)	0.97
Hypercholesterolemia	4 (13)	35 (29)	0.10
Diabetes mellitus ^c	8 (27)	14 (12)	0.07
History of smoking	10 (33)	13 (11)	0.006
COPD	5 (17)	7 (6)	0.06
Ischemic heart disease	24 (80)	92 (77)	0.88
Peripheral arterial disease	1 (3)	8 (6)	0.69
Preoperative CVI	6 (20)	14 (12)	0.38
Preoperative renal failure ^d	5 (17)	4 (3)	0.02
Immunocompromised ^e	2 (7)	6 (5)	0.66
EuroSCORE	6.2 ± 4.2	5.6 ± 3.9	0.49
LVEF < 30%	4 (13)	12 (10)	0.53
Procedure			
Isolated CABG	19 (63)	76 (63)	0.83
Other operation	11 (37)	44 (37)	0.83
Redo surgery	0 (0)	6 (5)	0.60
Emergency surgery	4 (13)	14 (12)	0.76
Cross-clamp time (min)	68 ± 33	68 ± 36	0.96
CPB time (min)	110 ± 47	106 ± 52	0.69
Total length (min)	233 ± 61	221 ± 67	0.37
Use of bone wax	23 (77)	62 (52)	0.02

^a Continuous variables are presented as mean ± standard deviation and categorical variables as number (%); ^b body mass index > 30 kg/m²; ^c oral medicated or insulin treated; ^d creatinine value > 200 μmol/L (2.27 mg/dL) or diagnosed chronic renal failure prior to procedure; ^e use of corticosteroids, methotrexate, or cytostatic therapy.

CABG = coronary artery by-pass grafting; COPD = chronic obstructive pulmonary disease; CPB = cardiopulmonary bypass; CVI = cerebrovascular incidence; LVEF = left ventricle ejection fraction.

tal stay for primary cardiac surgery. Antibiotic treatment was used according to the sensitivity of the strain of pathogen, which most frequently required vancomycin or clindamycin. Patients presenting with localized SCF were admitted and the wound debrided in the operating theater. If necessary, NPWT was applied to the wound (V.A.C. Therapy, KCI Inc, San Antonio, TX). Application of NPWT was performed under general anesthesia in the operating theater or, if the wound was very small, in the ward in local anesthesia, using a continuous negative pressure of -125 mm Hg. In a few cases of extensive SCF, a soft tissue flap was used to close the wound performed by the plastic and thoracic surgeon together. The soft tissue flaps used in the present study were pectoral muscle flaps in wounds pretreated with NPWT.

Control Group

Four patients were identified as controls for each case of SCF, based on the date of the primary heart operation; 2 patients immediately before and two patients immediately after the SCF patient. Controls were only included if they had had primary cardiac surgery through a midline sternotomy and had survived the first postoperative month.

Follow-Up

Follow-up was performed on December 31, 2008 and no patients were lost to follow-up. The total number of patient years was 593, mean follow-up being 4.0 ± 2.5 years, ranging from 0.3 to 9.6 years.

Statistical Methods

Cumulative rate of SCF was calculated using the Kaplan-Meier method. Continuous variables were compared using the Student *t* test; categorical variables were compared using a χ^2 test if the frequency was five or more in both groups and using the Fisher exact test if the frequency was less than five in either group. Multivariate

Table 2. Univariate Analysis of Postoperative Characteristics

Variable ^a	Fistula Group (n = 30)	Control Group (n = 120)	<i>p</i> Value
Reopen during hospital stay	6 (20)	6 (5)	0.02
Due to bleeding in the first 48 hours	3 (10)	3 (3)	0.09
Sternal dehiscence	2 (7)	2 (2)	0.18
Tamponade	1 (3)	1 (1)	0.36
Blood transfusion in the first week	16 (53)	54 (45)	0.54
ICU stay >48 hours	5 (17)	15 (13)	0.55
Renal failure during hospital stay ^b	5 (17)	3 (3)	0.008
Sternal wound infection	9 (30)	2 (2)	<0.001
Superficial	3 (10)	1 (1)	0.03
Deep	6 (20)	1 (1)	<0.001

^a Variables are presented as number (%). ^b creatinine value > 200 μ mol/L (2.27 mg/dL) or diagnosed chronic renal failure after operation without diagnosis of renal failure preoperatively.

ICU = intensive care unit.

Table 3. Independent Risk Factors for Development of Sternocutaneous Fistulas

Variable	OR (95% CI)	<i>p</i> Value
Sternal wound infection ^a	15.7 (3.3-116.4)	0.002
Renal failure ^b	12.5 (3.5-50.4)	<0.001
History of smoking	4.7 (1.4-15.8)	0.01
Use of bone wax in surgery	4.2 (1.4-15.4)	0.02

^a Superficial or deep sternal wound infection that required treatment; ^b Renal failure diagnosed before and (or) after primary cardiac surgery.

CI = confidence interval; OR = odds ratio.

analysis was conducted after univariate analysis. A *p* value of 0.05 was required to enter a variable into the model and a *p* value of 0.1 to be retained. Long-term survival was evaluated using Kaplan-Meier curves and compared using a log-rank test. The two patients who were referred from other hospitals were excluded from risk factor analysis, but they were included in the analysis of treatment and survival. Statistical analysis was performed and graphs plotted using the R statistical package version 2.7.0 (R Development Core Team, R Foundation for Statistical Computing, Vienna, Austria). All *p* values less than 0.05 were considered significant.

Results

Incidence

In total, 32 cases of SCF were identified during the 10-year study period. Thirty SCF patients were operated for primary cardiac surgery in our department and two SCF patients were referred from other cardiothoracic departments in Sweden, giving a cumulative incidence of 0.23% (95% confidence interval [CI] = 0.14 - 0.31) after one year (Fig 1).

Risk Factor Analysis

Preoperative, perioperative, and postoperative variables of the fistula patients and controls are presented in Tables 1 and 2. There was no significant difference regarding age, sex, type of operation, and European System for Cardiac Operative Risk Evaluation between SCF patients and controls. Univariate analysis showed that SCF patients were more often diagnosed as having preoperative (*p* = 0.02) or postoperative (*p* = 0.008) renal failure, more often had a history of smoking (*p* = 0.006), had more frequent use of bone wax during surgery (*p* = 0.02), were more often reexplored during their hospital stay (*p* = 0.02), and were treated more frequently for SWI within 30 days of cardiac surgery (*p* \leq 0.001). Independent risk factors for development of SCF were identified with multivariate analysis and are presented in Table 3.

Treatment Outcome and Long-Term Survival

Time to first surgical intervention, C-reactive protein level, and white blood cell count of SCF patients with and

Table 4. Clinical Presentation of Sternocutaneous Fistulas (SCFs) With or Without Preceding Sternal Wound Infection (SWI)

Variable ^a	SCF With Preceding SWI (n = 9)	SCF Without Preceding SWI (n = 23)	p Value
Time to surgical intervention (months)	6.1 ± 4.2 (4.5; 1.9-15.1)	6.9 ± 4.6 (5.1; 1.6-18.5)	0.69
Peak C-reactive protein (mg/L)	25 ± 19 (21; 8-62)	43 ± 72 (20; 2-324)	0.51
Peak WBC count (cells × 10 ⁹ /L)	7.6 ± 2.0 (6.7; 5.7-11.0)	9.7 ± 5.0 (8.7; 5.3-30.0)	0.30

^a Variables presented as mean ± standard deviation (median; range).

WBC = white blood cells.

without preceding SWI are presented in Table 4. Culture-verified pathogens identified at first intervention are presented in Table 5. The majority of pathogens were identified with tissue-based culture (n = 17); in 12 patients the pathogen was identified from positive swabs only, but with concomitant negative tissue-based cultures. In three cases, no pathogen was identified during treatment.

The mean number of treatment days in our hospital was 29 ± 34 (median 16; range, 0 to 162). The majority of SCF patients (n = 22) required one admission with surgical wound revision, 6 patients required two admissions, 3 had three admissions, and 1 patient had a total of 6 admissions. The first treatment with NPWT had a mean duration of 17 ± 13 days (median 12; range, 3 to 44). The second treatment with NPWT had a mean duration of 18 ± 12 days (median 15; 4 to 34). The different treatment regimes are presented in Figure 2.

Two patients died in our ICU from aggravated renal failure related to vancomycin therapy during SCF treatment. During follow-up there were seven late deaths in the SCF group: four died from cardiac-related causes, two died from carcinoma, and one patient died from warfarin-related gastrointestinal hemorrhage. Overall survival at one year was 93% ± 4% in the fistula group, as compared with 100% ± 0% in the control group. The corresponding survival figures at five years were 58% ± 1% and 85% ± 4%, respectively (Fig 3).

Comment

In the present study we determined the incidence of SCF at our department, identified risk factors, and compared

long-term survival with that of a control group. The majority of patients (72%) presented with late SCF without any previous history of SWI, while 28% presented after such infection (Fig 2).

Even though there have been few published studies regarding primary SCF, the cumulative incidence of SCF in this study at one year was 0.23%, which is similar to that in a previous report from 1978 by Stoney and colleagues [12]. The lack of reports on the incidence of SCF may reflect the fact that SCF is a neglected diagnosis, even though it can be a severe, life-long concern for some patients. Another problem related to SCF is the heterogeneous terminology used to describe SCF and its origins. Terms such as draining sinus, chronic sinus, chronic sternal osteomyelitis, delayed septic costochondritis, and recurrent sternal infection have been used in previous publications to describe infections in the sternum presenting as purulent draining sinus tracts after discharge of the patient with a closed sternal wound [2-4, 7, 9, 12].

In our multivariate analysis, renal failure and previous SWI were identified as independent risk factors for the development of late SCF. One might speculate if previous SWI is a causative variable directly related to the development of SCF, or rather indirectly related, as a composite risk factor. Furthermore, the use of bone wax during surgery and a history of smoking were also found to be independent risk factors in the present study. Jones and colleagues [13] have previously indicated that redo surgery may be associated with recurrent infections after deep SWI, but we did not identify redo surgery as a risk factor for development of SCF. In a previous study, Peivandi and colleagues [10] demonstrated that advanced age was associated with fistulas, but our present data are not in line with that finding. Furthermore, we did not identify previously reported risk factors for DSFI such as diabetes mellitus, sex, the use of internal mammary artery, or chronic obstructive pulmonary disease as independent risk factors for development of late SCF [16]. It should be kept in mind, however, that the number of SCF patients in the present report was limited and this may have influenced the multivariate analysis.

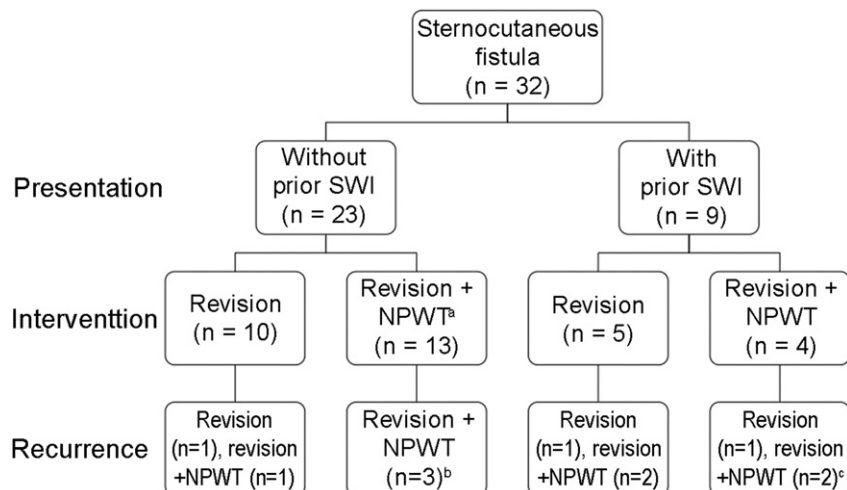
An interesting finding in the present study was that no significant difference in time to surgical intervention for SCF was noted between patients with or without preceding SWI. This could indicate that SCF arises de novo as a foreign body infection in patients who are prone to infections, by analogy with known foreign body infections such as prosthetic valve endocarditis and artificial

Table 5. Culture-Verified Pathogens Identified at First Intervention for Sternocutaneous Fistulas

Pathogen	Number (%) (n = 32)
CoNS	18 (56)
<i>Staphylococcus aureus</i>	4 (13)
CoNS + <i>S. aureus</i>	2 (6)
CoNS + <i>Candida albicans</i>	2 (6)
CoNS + <i>C. albicans</i> + <i>Enterococcus faecalis</i>	1 (3)
<i>S. aureus</i> + <i>C. albicans</i>	1 (3)
<i>Propionibacterium acnes</i>	1 (3)
None identified	3 (9)

CoNS = coagulase-negative staphylococci.

Fig 2. Flow chart for surgical treatment of sternocutaneous fistulas between January 1999 and December 2008. (a)One patient died from vancomycin-related renal failure in the ICU and one was closed with a pectoralis major muscle flap. (b)One patient was closed with a pectoralis major muscle flap, one had recurrent sternocutaneous fistula that was treated with NPWT and finally closed with a pectoralis major muscle flap, and one patient healed secondarily with the use of NPWT. (c)One patient died from vancomycin-related renal failure in the intensive care unit, and one patient healed secondarily with the use of NPWT. (NPWT = negative pressure wound therapy; SWI = sternal wound infection.)



joint infections. Previous reports have suggested that SCF arises from inadequate debridement after sternal wound infection [3, 9]. However, it is possible that in most cases SCFs are not related to previous sternal wound infections per se, but rather that patients who develop SCFs have similar risk factor profiles.

In this study, we identified coagulase-negative staphylococci as being the most common pathogen cultured from the SCF. This strengthens our hypothesis that SCF is a foreign body implant infection originating in connection to the steel wires. Several publications have established that coagulase-negative staphylococci adhere to foreign material while creating a biofilm, leading to a low-virulence infection with a slow onset [14, 15]. Usually, the host-immune mechanisms can eradicate such infections but in some patients, especially immunocompromised and renal failure patients, this may result in a persistent infection [14]. Bone wax could be regarded as a

foreign body in this respect, representing a possible site for low-virulence pathogens. This might explain our finding that the use of bone wax during cardiac surgery is associated with SCF, and in combination with other well-known risk factors for increased rate of infection (eg, smoking) may predispose patients to development of SCF.

We have demonstrated that the long-term survival of patients suffering from SCF was significantly worse than in a control group (Fig 3). This finding is analogous to previous studies showing a poor prognosis after treatment of DSWI, even after adjusting for several risk factors [16]. Furthermore, in the present study, 2 of the 32 SCF patients (6%) died of renal failure during treatment of their SCF unrelated to surgical mortality for the initial cardiac surgery procedure. Both of these patients had renal failure diagnosed prior to surgical intervention for SCF, but their condition was aggravated after treatment with vancomycin. This illustrates a clinical dilemma in SCF patients because coagulase-negative staphylococci are common pathogens and are often only sensitive to vancomycin. This may call for improved monitoring during treatment in this subgroup of patients and an active approach with earlier surgical intervention.

Several surgical regimes have been suggested for the treatment of SCF [1-3, 6, 7]. In the present study, several patients required multiple surgical revisions and all of them needed a prolonged antibiotic treatment. During the 10-year study period several SCF patients in the present cohort were treated with NPWT as an adjunct to conventional surgical debridement and soft tissue flaps (Fig 2). However, the optimal treatment for SCF has not yet been established. A common practice is to initially treat SCF that develops after cardiac surgery with antibiotics only. This may be one of the main reasons for the delay between presentation of SCF and surgical intervention in some of our patients. On the other hand, it is not well documented how many patients heal without surgical intervention, or how these patients are best identified.

In conclusion, we believe that SCF is a neglected diagnosis and represents a serious problem with multiple

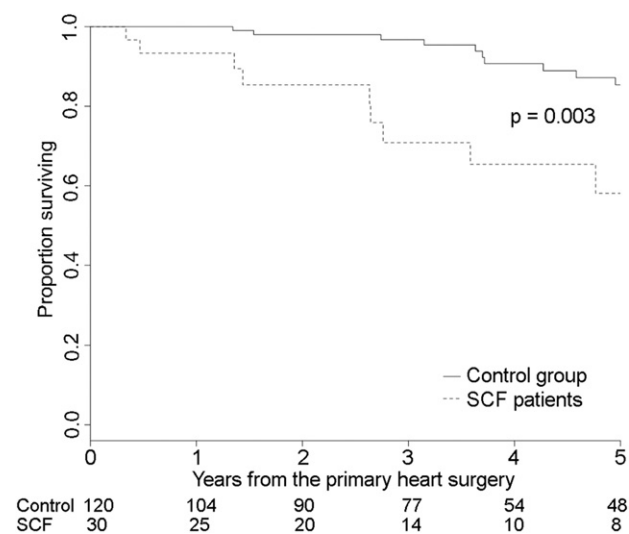


Fig 3. Overall survival of patients who developed sternocutaneous fistulas (n = 30) compared with that of controls (n = 120). (— = control group; --- = sternocutaneous fistula patients.)

hospital admissions, repeated surgical procedures, increased cost of management, and increased long-term mortality independent of surgical mortality. Based on our findings, we suggest that in the majority of cases SCF is a foreign body infection that arises de novo, similar to prosthetic valve endocarditis in susceptible patients, and therefore minimized use of bone wax after sternotomy may be beneficial. Finally, our data on surgical outcome suggest that negative-pressure wound therapy may be a valuable adjunct to conventional surgical debridement in order to improve the outcome in SCF treatment.

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