Toward zero: Deep sternal wound infection after 1001 consecutive coronary artery bypass procedures using arterial grafts: Implications for diabetic patients

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Objective: Coronary artery bypass graft (CABG) surgery with arterial conduits is considered optimal. A deterrent to bilateral internal thoracic artery (BITA) grafting is the risk of deep sternal wound infection (DSWI). We introduced infection prevention measures sequentially, attempting to reduce DSWIs. The aim was to determine (1) if the absence of DSWIs in the last 469 of 1001 consecutive operations was significant; (2) which measures explained the change; and (3) the impact of diabetes.

Methods: The measures included internal thoracic artery (ITA) skeletonization, no bone wax, wound irrigation, 1 observer per case, harmonic scalpel harvest of ITAs, vancomycin paste on sternal marrow, iodine-impregnated skin drapes, chlorhexidine-alcohol skin preparation, no BITA grafts in obese, diabetic women, more off-pump procedures, aseptic wound care, and marrow irrigation before sternal approximation.

Results: Mean age was 65 ± 10.4 years, 78% were male, 34% had diabetes, and 34% were obese. The first 532 patients had 16 DSWIs (3%) and the subsequent 469 had none ($P < .001$). Analysis of the data suggested that the first 11 measures likely contributed to the absence of DSWI and less likely, the twelfth. Key measures were likely chlorhexidine-alcohol use and avoidance of BITAs in obese diabetic women who had a 10-fold higher DSWI rate than the other patients (21.4% vs 2.0%). Other diabetics, including obese men, had no increased risk of DSWI.

Conclusions: The measures applied caused a substantial reduction in DSWIs. Key measures included the use of chlorhexidine-alcohol and avoidance of BITA grafting in obese diabetic females. These measures reduced DSWIs after BITA grafting in most diabetics. (J Thorac Cardiovasc Surg 2014;148:1887-95)

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See related commentary on pages 1896-8.

For more than 25 years, the standard of care for coronary artery bypass graft (CABG) conduits has been the use of 1 internal thoracic artery (ITA) and saphenous veins. However, the shorter life span of venous grafts limits the long-term benefits of the procedure. Use of bilateral ITAs (BITA), although known to improve results in all patient groups, is not common (4% in North America, 12% in Europe, and 30% in Japan).[1] Reasons for limited use of BITAs include longer operating times, technical challenges, perceived conduit−coronary perfusion mismatch, and risk of deep sternal wound infection (DSWI). The latter is considered a major deterrent to using BITA grafts.[2,3] If this risk could be reduced to that associated with single ITA grafts, BITA grafting might be considered more often.[4] Although mediastinitis is infrequent after CABG surgery (0.4%-4%), the associated mortality ranges from 10% to 47%.[5]

After sequential implementation of numerous changes designed to reduce infection rates associated with CABG, we analyzed our data to (1) verify that the perception of a reduced DSWI rate was indeed significant, (2) determine which prevention measures were responsible for the reduced rate, (3) assess the relative risk in diabetics, and (4) compare DSWI rates with those of our other surgeons who did not systematically use the same measures.

MATERIALS AND METHODS

From July 2003 to October 2012, total arterial grafting was performed where possible in all patients operated on by 1 surgeon, regardless of age, level of urgency, and comorbidities. There was continuous effort to mitigate infections by implementing sequential preventative measures. This retrospective analysis of prospectively collected data from consecutive patients was undertaken when it was noted that there were no DSWIs over 4 years, 7 months. For the first 532 patients, the DSWI rate was 3%. This study was approved by our institutional Research Ethics Board.

Surgical Details

All operations were performed with standard cardiopulmonary bypass or off-pump using high spinal and light general anesthesia. Intermittent

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Disclosures: Teresa M. Kieser reports consulting fees and lecture from Medistim USA and Medistim ASA, and consulting fees from Ethicon Endosurgery. Thomas Louie reports consulting and lecture fees from Optima Pharma and grant support from Cubist and Actelion. All other authors have nothing to disclose with regard to commercial support.

Received for publication Oct 8, 2013; revisions received Jan 21, 2014; accepted for publication Feb 3, 2014; available ahead of print March 7, 2014.

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0022-5223/$36.00

http://dx.doi.org/10.1016/j.jtcvs.2014.02.022

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Abbreviations and Acronyms

BITA	= bilateral internal thoracic artery
BMI	= body mass index
CABG	= coronary artery bypass graft
CI	= confidence interval
COPD	= chronic obstructive pulmonary disease
DSWI	= deep sternal wound infection
IEI	= interevent intervals
ITA	= internal thoracic artery

antegrade blood cardioplegia and systemic hypothermia (32°C) were used for on-pump procedures; off-pump CABG was performed with the Octopus stabilizing device (Medtronic, Inc, Minneapolis, Minn). ITA conduits were harvested and skeletonized, most with an ultrasonic scalpel (Harmonic Scalpel; Ethicon Endo-Surgery, CVD, Cincinnati, Ohio). ITAs were used mostly as in situ grafts and wrapped in papaverine-soaked gauze. Negative air pressure was used in operating rooms. Antibiotic coverage (cephazolin 2 g 30 minutes before knife to skin, every 4 hours intraoperatively, and every 8 hours for 3 doses) was routine as was intraoperative glycemic control (4-9 mmol/L) by insulin infusion. Seven single horizontal sternal wires were used for a single ITA and 8 for BITA or when body surface area was greater than 2.0 m^2.

Deep Sternal Wound Infection

DSWI was defined as infection involving the sternum, pericardium, and/or mediastinum requiring 6 weeks of antibiotics with or without surgical debridement, rewiring, or muscle flap reconstruction.[6] In the infectious disease literature for all types of surgery, 3 categories of surgical site infection are defined: type 1, superficial incisional; type 2, deep incisional (muscle and fascia); type 3, deep organ space, bone, and/or mediastinum.[6] The DSWI definition used in this study is the same as type 3. Patients were followed for a minimum of 2 months at their postoperative clinic assessment; all DSWIs appeared before 4 weeks.

Infection Prevention Measures

Before 2003, 4 measures were in place: bone wax was not used on sternal edges and subcutaneous tissues were irrigated with a solution of bacitracin/saline before skin closure. From 1994, we limited observers to 1. Skeletonization of the ITAs began in 2000. From July 2003 onwards, 8 measures were added sequentially and continued subsequently. (1) Starting in November 2003, an ultrasonic scalpel was used to skeletonize ITAs (Harmonic Scalpel; Ethicon Endo-Surgery). Because a bloodless surgical field is required, less clot or charred tissue in the mammary bed reduces substrate for infection. (2) Starting in July 2005, vancomycin paste (2 g of vancomycin powder in 2 to 3 mL of saline) was applied to the sternal marrow before approximation.[7] (3) Beginning in January 2006, iodine-impregnated surgical adhesive drapes (Ioban 3M, St Paul, Minn) were applied on the chest area before incision and removed at skin closure. (4) DSWIs occurred in 15 of the first 500 patients in this study; 5 were in obese (body mass index [BMI] $\geq$30 kg/m^2) diabetic women. Thereafter (November 2007), only 1 ITA and radial arteries were used in this group with diabetes, either the left ITA as a Y with itself, or the radial divided into two-thirds/one-third with the one-third used as a Y graft with the left ITA and the two-thirds used as a separate graft. (5) Beginning in November 2007, operative skin preparation was changed to 2% chlorhexidine gluconate/70% isopropyl alcohol (Soluprep 2% to 70% tinted; Laval, Quebec) (instead of 10% povidone-iodine) which was applied for at least 30 seconds over potential incision sites. Also, the night before, patients underwent skin preparation with a 6-wipe package of chlorhexidine (Sage Products LLC, Cary, Ill). (6) Beginning in April 2008, off-pump CABG was performed in 75% of cases versus 6% before then. (7) In June 2008, wound care was changed to an aseptic technique (Figure 1). (8) Irrigating and manual cleansing of the sternal marrow before applying vancomycin paste began in September 2009, which was part of a protocol for a trial of Kryptonite bone cement[8] for approximation of the sternum (15 patients). Marrow cleansing was necessary before applying the cement; this was done in all subsequent patients.

Data Collection

Systematically collected data from consecutive patients were entered prospectively into a surgical database. DSWIs were recorded prospectively by the Infectious Disease Department of the hospital. For comparison with rates from other surgeons at the same hospital, data were retrieved from our APPROACH database[9] (prospectively collected data from patients enrolled at the time of cardiac catheterization and followed to assess outcomes).

Statistical Analysis

Objective 1. To determine whether there was a significant change in DSWI rate and, if so, when the change occurred. Because the surgeries were unevenly distributed over time, we used groups of 20 consecutive surgeries to model the infection rate, ensuring sufficient numbers in the denominator for adequate precision. To avoid the use of zero (for statistical reasons), the rate of successful surgeries (ie, those without a DSWI) was modeled instead of infection rates. In this case, time was considered as the sequential number representing each consecutive group of 20 surgeries. To determine our objective, a nonlinear 4-parameter logistic model was fitted to the successful surgery rate. One equation for this model is[10]

$$\text{rate} = \beta_0+\beta_1/\{1+\exp[-\beta_2\times(\text{time}-\beta_3)]\}$$

This describes a sigmoidal function that allows for an initial infection rate β_0 and a final infection rate β_1 and a gradual change over a period of time (midpoint β_3).

Objective 2. To determine which measure was key in reducing DSWIs, we considered that a change in the rate was most likely due to the measure implemented just before when the infection rate attains the right-hand asymptote (the new infection rate). This key intervention was considered necessary (but not necessarily sufficient) to reduce the rate, provided that the probability of observing a DSWI (after the last observed infection if the rate remained the same) was nonzero. Any of the measures implemented before this key intervention may also have contributed, but we were unable to determine this in this study. Similarly, it is possible that any measure implemented after this key intervention also contributed to a decreased rate, if the probability of a DSWI at this point after the last change point was nonzero.

To estimate the probability of a DSWI after the last observed infection as a function of the number of surgeries completed, we assumed that the DSWIs formed a stationary Poisson point process with mean λ. This required examination of the number of surgeries between each infection. To be considered a stationary point process, there should be no autocorrelation between the interevent intervals (IEI) and the cumulative distribution function should be exponential with rate $1/\lambda$ where λ is the mean of the IEI. After this assumption was checked, we calculated the probability of a DSWI for a given number of surgeries after the last infection using an exponential distribution with rate $1/\lambda$. To examine the assumptions, we calculated the autocorrelation function of the IEIs and used a survival-type analysis to determine the distribution function of the IEI.

Objective 3. We examined whether the proportion of patients in the subgroup of obese diabetic women significantly decreased after the change point and then examined the difference in DSWI rates between this subgroup and the remainder of the patients before the change point. In both cases, we used the Fisher exact test to compare the proportions.