# Scoring system to guide decision making for the use of gentamicin-impregnated collagen sponges to prevent deep sternal wound infection

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**Objectives:** The effectiveness of the routine retrosternal placement of a gentamicin-impregnated collagen sponge (GICS) implant before sternotomy closure is currently a matter of some controversy. We aimed to develop a scoring system to guide decision making for the use of GICS to prevent deep sternal wound infection.

**Methods:** Fast backward elimination on predictors, including GICS, was performed using the Lawless and Singhal method. The scoring system was reported as a partial nomogram that can be used to manually obtain predicted individual risk of deep sternal wound infection from the regression model. Bootstrapping validation of the regression models was performed.

**Results:** The final populations consisted of 8750 adult patients undergoing cardiac surgery through full sternotomy during the study period. A total of 329 patients (3.8%) received GICS implant. The overall incidence of deep sternal wound infection was lower among patients who received GICS implant (0.6%) than patients who did not (2.01%) ($P = .02$). A nomogram to predict the individual risk for deep sternal wound infection was developed that included the use of GICS. Bootstrapping validation confirmed a good discriminative power of the models.

**Conclusions:** The scoring system provides an impartial assessment of the decision-making process for clinicians to establish if GICS implant is effective in reducing the risk for deep sternal wound infection in individual patients undergoing cardiac surgery through full sternotomy. (J Thorac Cardiovasc Surg 2014;■:1-7)

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Median sternotomy is the method of first choice in most cardiac surgical interventions. Postoperative sternal wound infections are reported to occur with an incidence of approximately 0.5% to 8% following median sternotomy.[1] Deep sternal wound infections (DSWIs) are particularly devastating because they are associated with high mortality rates of 14% to 47%.[2]

Gentamicin-impregnated collagen sponge (GICS) implants were developed to provide high local antibiotic concentrations in wounds thus limiting postoperative bacterial growth and preventing systemic adverse events (mainly nephrotoxicity).[3] GICS implants have been advocated to reduce the risk of DSWI after cardiac surgical procedures through sternotomy.[4,5] However, the effectiveness of the routine retrosternal placement of a GICS implant before sternotomy closure is currently a matter of some controversy[6] and the upfront cost of the routine implant constitutes a barrier to their widespread implementation.[4] On the other hand, GICS implants as a strategy to minimize the risk of DSWI should not be denied to patients at higher risk of DSWI because DWSI exacts a high cost in terms of high morbidity, mortality, and relative resource consumption.[7]

Therefore we aimed to develop a scoring system for an impartial assessment to guide decision making for the use of GICS to prevent DSWI.

## METHODS

### Study Population

The study was conducted in accordance with the principles of the Declaration of Helsinki. The local ethical committee approved the study, and the requirement for individual patient consent was waived. We retrospectively analyzed prospectively collected data from the PATS institutional surgical database (Dendrite Clinical Systems, Ltd, Oxford, United Kingdom) from April 2001 to January 2014. The PATS database captures detailed information on a wide range of preoperative, intraoperative, and hospital postoperative variables (including complications and mortality) for all patients undergoing cardiac surgery in our institution. The data is collected and reported in accordance with the Society for Cardiothoracic Surgery in Great Britain & Ireland database criteria. The database is maintained by a team of

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**Abbreviations and Acronyms**

- BMI = body mass index
- CABG = coronary artery bypass grafting
- DWSI = deep sternal wound infection
- GICS = gentamicin-impregnated sponge
- RCT = randomized controlled trial

full-time clinical information analysts who are responsible for continuous prospective data collection as part of a continuous audit process. Data collection is validated regularly.

Our analysis included adult patients undergoing cardiac surgery through full sternotomy.

### Pretreatment Variables and Study End Points

The effect of GICS implant on the incidence of DSWI was adjusted for the following pretreatment variables: age, female gender, diabetes mellitus, previous sternotomy, chronic obstructive pulmonary disease (defined as long-term use of bronchodilators or steroids for lung disease or spirometry showing airflow limitation; that is, a forced expiratory volume in 1 second to forced vital capacity ratio <0.70 or less than the lower limit of normal plus a forced expiratory volume in 1 second <80% of predicted), previous stroke, peripheral vascular disease, left ventricular function, renal impairment (defined as baseline serum creatinine >150 mmol/L), body mass index (BMI), nonelective indication and type of operation (isolated or combined coronary artery bypass grafting [CABG], CABG vs other than CABG procedure), including the use of bilateral internal mammary arteries, and the harvesting technique used (skeletonized or pedicled).

The primary end points were the incidence of DSWI. As defined by the Centers for Disease Control and Prevention, DSWI requires the presence of 1 of the following criteria: an organism isolated from culture of mediastinal tissue or fluid; evidence of mediastinitis seen during operation; or presence of either chest pain, sternal instability, or fever (>38°C), and either purulent drainage from the mediastinum, isolation of an organism present in a blood culture, or culture of the mediastinal area.[8] Superficial sternal wound infection, defined as an infection involving only skin or subcutaneous tissue at the incision site, was excluded from this study.

### GICS Implant Technique

Starting from 2007, GICS implant (Collatamp, EUSA Pharma [Europe], Oxford, United Kingdom) was used in patients deemed to be at high risk for sternal wound complications according to the surgeon's preference. Before closure of the sternum and after placement of the sternal wires, a single Collatamp sponge (20 × 5 × 0.5 cm; 1 $cm^2$ containing 2.8 mg native collagen fibrils of equine origin and also containing 2 mg gentamicin sulphate, equivalent to 1.10-1.43 mg gentamicin) was implanted without premoistening. The sponge was placed transsternally between bone edges. Sternal wires were then tightened. Collatamp is an approved Food and Drug Administration prescription product.

### Statistical Analysis

Multiple imputation using full Bayesian multiple imputation procedure using the bootstrap was used to address missing data. Partial $\chi^2$ Wald statistic from saturated main effects model was used to test the association of each predictor with responses. Proportional odds ordinal logistic regression models using ordinary unpenalized maximum likelihood estimation was implemented to estimate individual linear predictors ($n_i$) of DSWI. The predicted probability was derived as $1/(1 + \exp(n_i))$. Fast backward elimination on predictors was performed using Lawless and Singhal method, which uses the fitted complete model and computes approximate Wald statistics by computing conditional (restricted) maximum likelihood estimates assuming multivariate normality of estimates. Bootstrapping validation of the regression models was performed using 200 samples of the original data, with replacement, and the models were fitted using training set. A testing set was finally used for validation. Somers' *Dxy* rank correlation coefficient was used as measure of discrimination. *Dxy* corresponds to $2*(C - 0.5)$ where *C* is the generalized receiver operating characteristic area (concordance probability). Calibration curves were then estimated using resampling. Density of linear predictor was assessed as cause of model overfitting. The individual predicted risk for DSWI was then derived and patients at higher risk for DSWI were defined as those with a predicted DSWI higher than the 75th percentile of predicted DSWI risk distribution. Predicted risk for DSWI was then plotted against predictors for patients who received GICS implant and who did not to identify subgroups that are likely to benefit from GICS implant.

The effect of independent predictors was reported as a score in a nomogram that can be used to manually obtain predicted individual risk of DSWI. The nomogram has a reference line for reading scoring points (default range 0-100). Once the reader manually totals the points, the predicted values can be read at the bottom.

R version 2.15.2 (R Foundation for Statistical Computing, Vienna, Austria) and the rms package (R Foundation for Statistical Computing) were used for analysis.

## RESULTS

The final populations consisted of 8750 adult patients undergoing cardiac surgery through full sternotomy during the study period. A total of 5275 patients underwent isolated CABG and 973 patients (18.4%) received bilateral internal mammary arteries grafting. Skeletonized harvesting technique was used in 421 patients.

A total of 329 patients (3.8%) received GICS implant. Data regarding the incidence of DSWI was not available for 106 patients and none of them received GICS implant. Table 1 summarizes the distribution of baseline characteristics, the number of missing values, and the proportion of patients who presented DSWI postoperatively. The overall incidence of DSWI was 180 (2.0%). The relative effect size of predictors on the incidence of DSWI is reported as partial $\chi^2$ Wald *P* value. Patients presenting with DSWI were more likely to be women, obese, and diabetic taking insulin. Isolated or combined CABG was more likely to be associated with DSWI as well as the need for reexploration. The overall incidence of DSWI was lower among patients who received a GICS implant (0.6%) than patients who did not (2.01%) ($P = .02$). Fast backward elimination on predictors selected the following variables as independent risk factors for DSWI: female gender ($\chi^2$ Wald, 5.7; $P < .0001$), BMI ($\chi^2$ Wald, 5.5; $P < .0001$), diabetic taking insulin ($\chi^2$ Wald, 3.1.8; $P = .001$), need for reexploration ($\chi^2$ Wald, 10.1; $P < .0001$), and isolated or combined CABG ($\chi^2$ Wald, 3.1; $P < .0001$). Bilateral internal mammary arteries grafting significantly increased the risk of DSWI ($P = .0001$) but the internal mammary artery harvesting technique did not show a significant effect on the incidence of DSWI ($P = .3$). GICG implant was retained into the model as a protective factor ($\chi^2$ Wald, −2.2; $P = .02$). The model showed a good discrimination power





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**TABLE 1. Patient characteristics and relative incidence of deep sternal wound infection (DSWI)***

| Characteristic | Category | N | DSWI | $\chi^2$ statistic *P* value† |
|---|---|---|---|---|
| Age (y) | 16-60 | 2310 | 0.014 | .42 |
| | 60-69 | 2305 | 0.026 | |
| | 69-75 | 1889 | 0.018 | |
| | 75-93 | 2140 | 0.023 | |
| Female gender | No | 6504 | 0.015 | <.0001 |
| | Yes | 2139 | 0.035 | |
| | Missing | 1 | 0.000 | |
| Body mass index | 14.5-24.5 | 2143 | 0.011 | <.0001 |
| | 24.5-27.2 | 2135 | 0.016 | |
| | 27.2-30.4 | 2139 | 0.018 | |
| | 30.4-54.1 | 2138 | 0.036 | |
| | Missing | 89 | 0.011 | |
| Renal impairment | No | 8304 | 0.020 | .45 |
| | Yes | 335 | 0.020 | |
| | Missing | 5 | 0.000 | |
| Chronic obstructive pulmonary disease | No | 7686 | 0.020 | .57 |
| | Yes | 957 | 0.021 | |
| | Missing | 1 | 0.000 | |
| Previous stroke | No | 8511 | 0.020 | .10 |
| | Yes | 117 | 0.042 | |
| | Missing | 16 | 0.000 | |
| Diabetes mellitus | No | 6874 | 0.018 | Ref |
| | Oral therapy | 1210 | 0.023 | .61 |
| | Taking insulin | 557 | 0.048 | .0013 |
| | Missing | 3 | 0.000 | |
| Peripheral vascular disease | No | 7881 | 0.020 | .94 |
| | Yes | 760 | 0.025 | |
| | Missing | 3 | 0.000 | |
| Left ventricular ejection fraction | Good (≥50%) | 6700 | 0.020 | Ref |
| | Moderate (>30% to <49%) | 1458 | 0.021 | .73 |
| | Poor (≤30%) | 475 | 0.021 | .75 |
| | Missing | 11 | 0.000 | |
| Redo sternotomy | No | 8321 | 0.021 | .66 |
| | Yes | 322 | 0.015 | |
| | Missing | 1 | 0.000 | |
| Nonelective surgery | No | 6009 | 0.018 | .17 |
| | Yes | 2625 | 0.025 | |
| | Missing | 10 | 0.000 | |
| Surgery, including coronary artery bypass grafting | No | 2270 | 0.014 | .003 |
| | Yes | 6373 | 0.023 | |
| | Missing | 1 | 0.000 | |
| Gentamicin-impregnated collagen sponge | No | 8315 | 0.021 | .02 |
| | Yes | 329 | 0.006 | |
| Need for reexploration | No | 8027 | 0.016 | <.0001 |
| | Yes | 615 | 0.079 | |
| | Missing | 2 | 0.500 | |
| Overall | | 8750 | | |
| | No missing for DSWI | 8644 | .0208 | |
| | Missing | 106 | | |

*Ref*, Reference category; *DWSI*, deep sternal wound infection. *Missing data are reported. †The *P* values were averaged over the 5 imputed model fits.

(*C* statistic = 0.75). Bootstrapping validation confirmed a good discriminative power of the model (*Dxy* training dataset *Dxy* = 0.49, testing dataset *Dxy* = 0.49). Calibration curve analysis showed a good predictive power of the model for value of predicted probability <0.10 (Figure 1). Beyond this value, the model was overfit with an overestimation of the actual risk and this was due to the small number of patients (n = 175; 2%) presenting a predicted risk >0.1.



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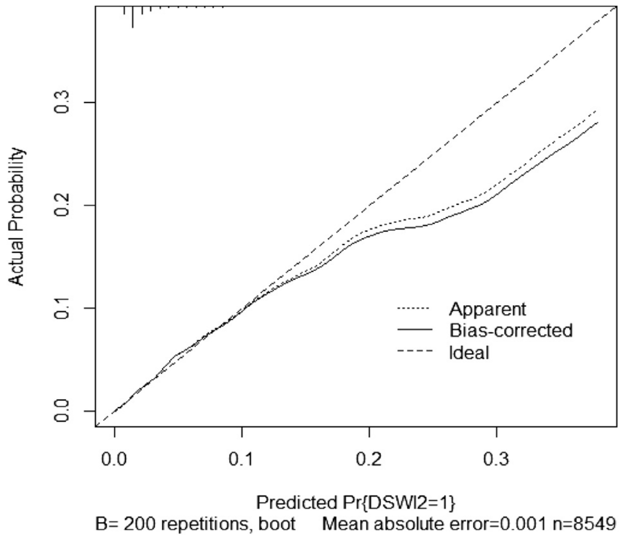


**FIGURE 1.** Bootstrap overfitting-corrected Loess nonparametric calibration curve for casewise deletion model for deep sternal wound infection (*DSWI*).

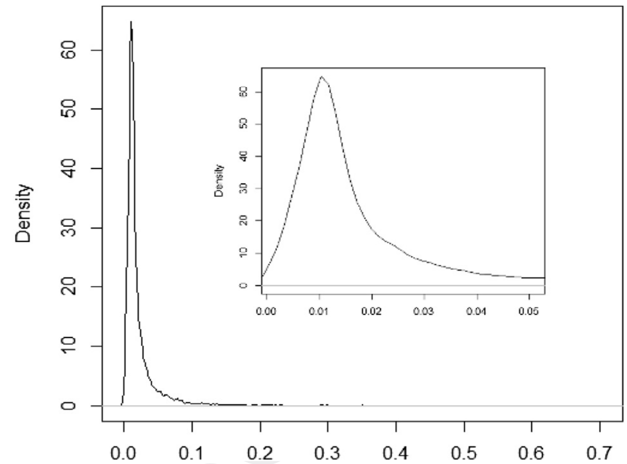


**FIGURE 2.** Distribution of predicted risk for deep sternal wound infection.

Figure 2 shows the distribution of predicted risk for DSWI. The median DSWI predicted risk was 1% and the 75th percentile corresponded to 2%. This cut-off was chosen to define patients at higher risk for DSWI. The graphic representation of the effect on GICS implant of the predicted risk for DSWI according to BMI, gender, and need for reexploration is reported in Figure 3. In patients who did not require reexploration (Figure 3) the use of GICS implant allowed to reclassify the following high-risk subgroups as low risk: male with diabetes and BMI > 30, female without diabetes and BMI > 35, female with diabetes taking oral therapy and BMI > 30, and female with diabetes taking insulin and BMI > 25. In patients who did require reexploration (Figure 3) the use of GICS implant allowed us to reclassify the following high-risk subgroups as low risk: male without diabetes or diabetes taking oral therapy and BMI > 20, male with diabetes taking insulin regardless of BMI, and female regardless of diabetes status and BMI.

Finally a nomogram was derived with scores assigned for the presence and magnitude of each predictor including the use of GICS implant (Figure 4). The baseline score was calculated using female gender (26 points), BMI (33, 44, or 56 points for BMI of 25, 30, and 35, respectively), diabetes receiving insulin therapy (20 points), isolated or combined CABG (19 points with and extra 15 points if BIMA grafting was used), and need for reexploration (51 points). A score ≥136 represented the cut-off score to identify patients at higher risk for DSWI (>2% predicted probability). The use of GICS implant reduced the total score by 63 points (Figure 4 and Table E1). Therefore, in patients with a baseline score ranging between 136 and 199 points, the use of GICS alone was able to reclassify patients with a high risk profile into the lower risk category. Above this cut-off level, GICS implant is expected to reduce the patient profile risk, although these patients should be still considered to have a higher risk for DSWI.

No negative ototoxic or nephrotoxic aminoglycoside side effects were recorded in patients who received GICS implant.

## DISCUSSION

The main finding of our study was that a personalized individual assessment of DSWI risk was achievable for patients undergoing adult cardiac surgery through full sternotomy. This scoring system is expected to guide the decision making process for the use of GICS implants in patients at high risk for sternal would infection.

Surgical-site infection remains a major public health problem despite the routine use of prophylactic systemic antibiotics. In particular, DSWI after cardiac surgery substantially increases illness severity, hospital stay length, mortality, and costs. It occurs in 0.5% to 4.4% of patients after cardiac surgery overall and in up to 12% to 20% of high-risk patients.[2] Preventive measures include skin preparation, prophylactic antibiotic therapy, control of the operating room environment, and improvements in surgical techniques. Antibiotic prophylaxis has been a cornerstone in surgical site infection prevention, and there is growing interest in the local delivery of antibiotics.[3] Local delivery can potentially lead to a higher concentration of antibiotics within the target site while minimizing the risk of systemic toxicity.

Gentamicin has a broad spectrum of bactericidal activity that includes staphylococci and gram-negative bacteria. Local gentamicin administration is used to avoid diffusion in tissues with disruption of the commensal flora and



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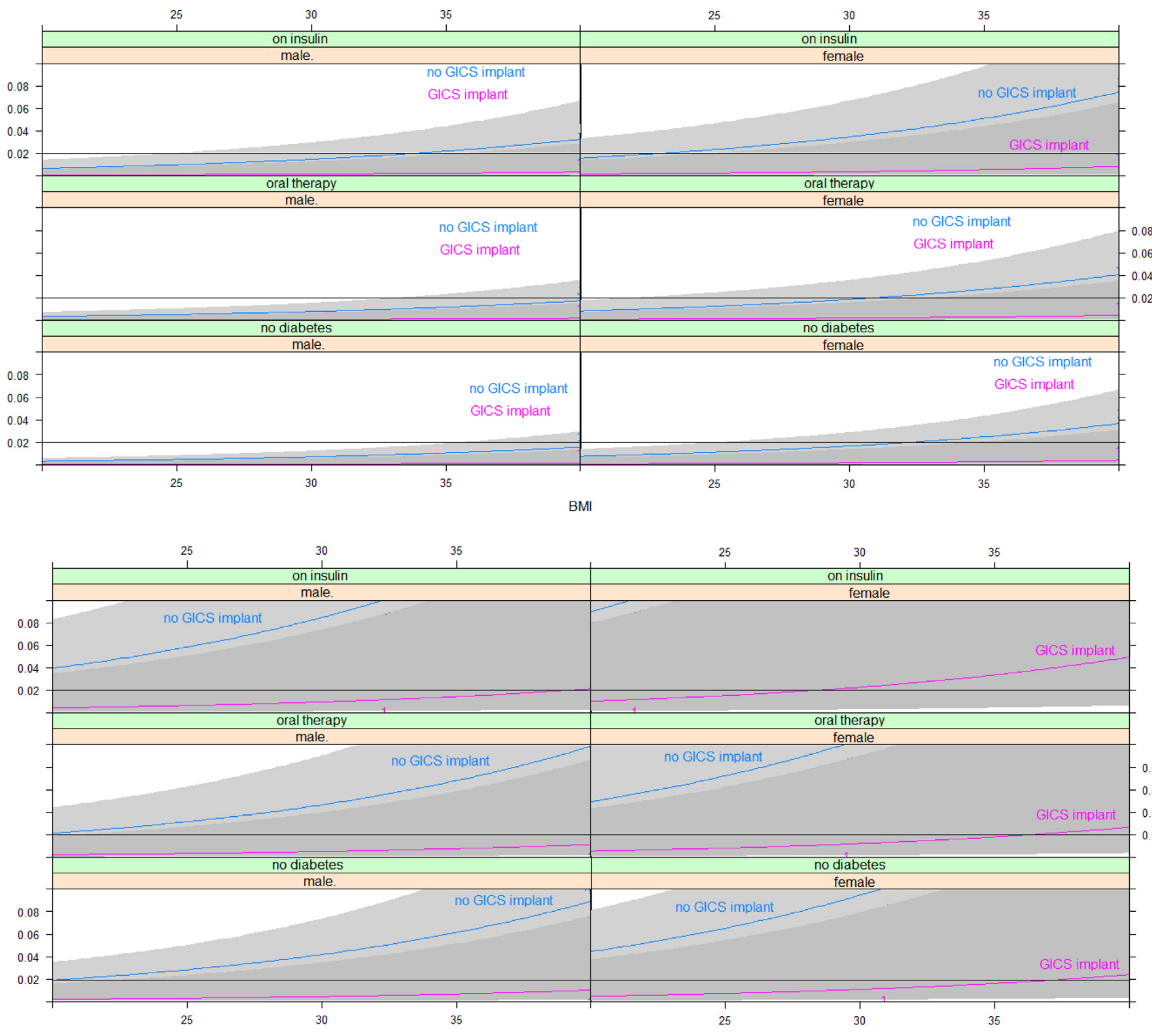




**FIGURE 3.** Graphic representation of the effect of gentamicin-impregnated collagen sponge (*GICS*) implant on the predicted risk for deep sternal wound infection according to body mass index, gender, and need for reexploration. *BMI*, Body mass index.

emergence of bacterial resistance.[7] GICS implants have been proposed as 1 method of employing local delivery of antibiotics.[7] They are inexpensive, easy to use, and have an established safety profile.[9] The majority of the studies published to date have demonstrated that prophylactic use of GCCI can significantly reduce the wound infection rate following cardiac surgery (via sternotomy) compared with standard treatment alone.[3] Previous meta-analyses on available randomized controlled trials (RCTs) suggested that the application of GICS implants perioperatively may be beneficial in preventing postoperative DSWI in patients undergoing cardiac surgery.[4,5] By pooling data from the 4 trials[10-13] (4672 patients), GICS use seemed to significantly reduce DSWI rate (relative risk [RR], 0.62; 95% confidence interval [CI], 0.39-0.97; $P = .04$).[5] Schimmer and colleagues[10] conducted a double-blind RCT on 800 consecutive patients undergoing cardiac surgery with median sternotomy closure. Patients were randomized into 2 groups; closure with GICS (maximum 143 mg gentamicin) or with simple collagen sponge retrosternally. The gentamicin group (2 of 354; 0.56% DSWI)/(7 of 354; 1.9% superficial sternal wound infection) versus the placebo group (13 of 369; 3.5% DSWI)/(11 of 369; 2.9% superficial sternal wound infection) showed a RR reduction of 83.9%/33.7%, respectively ($P = .013$). Friberg and colleagues[11] in 2005 conducted a double-blind RCT at 2 centers where 1950 consecutive patients undergoing cardiac surgery were evaluated; sternotomy closure with GICS was compared with standard closure. Incidence of SWI was noted during the postoperative stay and up to 2





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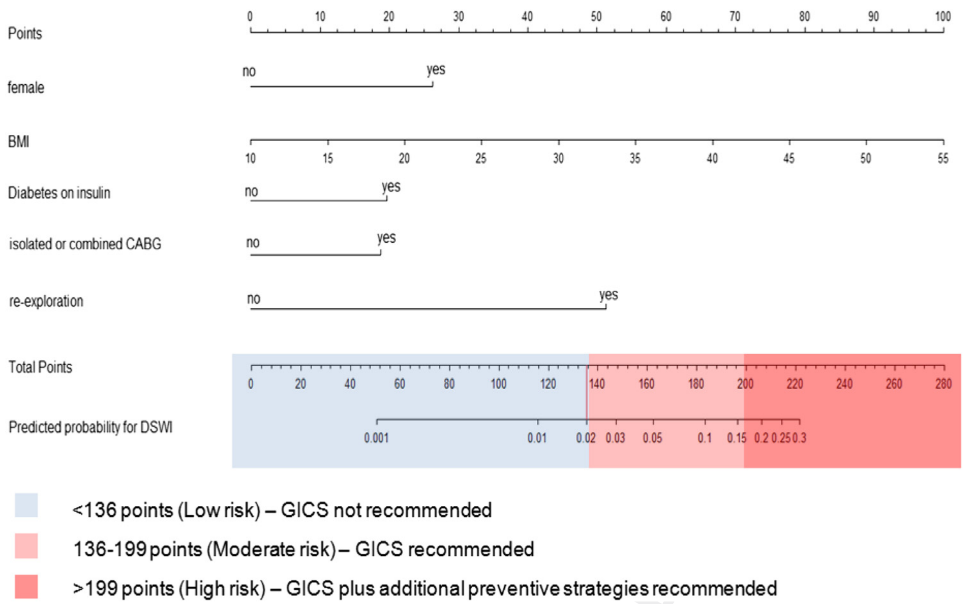


**FIGURE 4.** Nomogram for deep sternal wound infection (*DSWI*) risk prediction. (If bilateral internal mammary artery grafting is used, add 15 extra points). *CABG*, Coronary artery bypass grafting; *GICS*, gentamicin-impregnated collagen sponge; *BMI*, body mass index.





months after the procedure. Incidence of sternal wound infection was 4.3% (42 of 983) in the GICS group, which was lower than in the control group (9%; 87 of 967) (RR, 0.47; 95% CI, 0.33-0.68; $P < .001$). Two out of 4 RCTs[11,12] failed to show a benefit from routine use of GICS implant. Bennett-Guerrero and colleagues,[12] in a multicenter study, did not demonstrate any benefit of use of GCCI over standard treatment. The authors suggested a combination of factors to explain the lack of benefit seen in the GCCI group, including differences in design and ethnic differences between their study and the other positive study. One important difference that the authors do not highlight is the fact that the protocol for the Bennett-Guerrero and colleagues study[12] required that the implants be wetted in saline before implantation. The effect of wetting implants has been researched by Lovering and colleagues[14] and they have shown that presoaking may influence the gentamicin release profile of the GICS to cause premature depletion of the active compound in addition to that lost during the presoaking period. The manufacturer's recommendation is that GICS should be used dry before implantation. Friberg and colleagues[15] point out that in contrast to the other published studies a large proportion of the sternal wound infections in the Bennett-Guerrero and colleagues study[12] were caused by gram-negative rods that are not normally found on the skin of the chest (and should not be present in the air in operating rooms) and this might suggest that contamination may have occurred later in the postoperative phase. Finally Shimmer and colleagues[10] point out that a multicenter study is meant to be unsuitable for addressing the question being investigated. The aim was to evaluate the efficacy of a single procedure (ie, the use of a gentamicin-collage sponge) with respect to a complication with a low incidence and multifactorial genesis. This requires keeping all potential influencing factors as constant as possible. Otherwise, the positive effect of a procedure could be swamped by the overall influence of a wide range of factors. Furthermore, it is difficult to assess the effect of the sponge in isolation because there was apparently little standardization of practice in relation to stabilization of the sternum in individual studies, let alone across studies. It is well established that failure to achieve stabilization of the sternum is associated with an increased incidence of postoperative infection. Eklund and colleagues[13] also showed no additional benefit of GCCI in reducing wound infection rate following cardiac surgery. The authors themselves concluded that the study population might have been too small to draw conclusions.

Despite the fact that GICS implant has been shown to reduce the incidence of DSWI, the effectiveness of the routine retrosternal placement of a GICS implant before suture closure is currently a matter of some controversy.[6] Despite the routine use of GICS to reduce the incidence of DSWI, surgeons are reluctant to implant it in all patients because nearly 98% of patients are not expected to develop sternal infection regardless of its use. As a consequence, the indiscriminate application of GICS implant might not be cost-effective. It has been suggested that the use of GICS implant should be used only in high-risk patients.[7] Of note, 2 out of 4 RCTs we reviewed included participants defined a priori as high risk: Bennett-Guerrerro and colleagues[12] only included high-risk patients (defined as having diabetes and/or a BMI higher than 30), whereas Friberg and colleagues[11] included a high-risk subgroup defined as having diabetes and/or a BMI higher than 25. The 2 studies with participants who were considered high risk also reported the incidence of DSWI. Creanor and colleagues[4] demonstrated a statistically significant difference between the intervention and control groups in the incidence of DSWI pooling data from high-risk patients (OR, 0.62; 95% CI, 0.39-0.98).

Our scoring system provides an impartial assessment for decision making to establish if the use of GICS implant is effective in reducing the risk of DSWI in individual patients. As previously reported[2,16,17] we found female gender, increased BMI, having diabetes and taking insulin, reexploration for bleeding, and history of CABG as an isolated or combined procedure as independent risk factors for DSWI. The use of GICS implants showed a protective effect on the incidence of DSWI. According to our scoring system, we suggest that the use of GCSI implants should be recommended in patients with a predicted risk >2% (75th percentile) corresponding to an overall score of 136 or higher. In patients with a baseline score ranging between 136 and 199 points, the use of GICS alone is expected to reclassify patients with a high risk profile into the lower risk category. Above this cut-off level, GICS implant is expected to reduce a patient's risk profile, although these patients should be still considered at higher risk for DSWI and additional strategies should be considered, such as prolonged antibiotic prophylaxis.

Our results must be interpreted taking into account several limitations. Like any investigation of data on file, our study's findings are dependent on the quality of the database, which is open to a variety of measurement biases. Despite the fact that this database is validated regularly, it is not possible to guarantee that no information was left out of the patient charts and thus, our databases. Furthermore, we cannot exclude that because this was a single site study at a tertiary medical center with internal validation, there is a question of applicability to the general population. This could be addressed by external validation in a nationwide patient population. In addition, it is important to emphasize that the score, by definition, can only explain a fraction of variables that affect the risk of DSWI. Intraoperative management as well as elements of postoperative care can affect the incidence of DSWI.

## CONCLUSIONS

Decision making for the use of GICS implant after sternotomy has traditionally been an area free from a compelling evidence base. Our score provides a valuable tool in the decision-making process for clinicians to establish if GICS is expected to reduce the risk of DSWI. To the best of our knowledge, this is the first study that developed a nomogram to assess individual risk of DSWI in patients undergoing cardiac surgery. Such an instrument might help to more clearly and objectively define the often uncertain line that separates patients at high risk for DSWI and who might benefit from additional prophylactic strategies such as the use of GICS implants. Further validation studies are needed to confirm these findings.

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TABLE E1. Scoring system and predicted risk of deep sternal wound infection (DSWI) according to total points

| Predictor | Points | Total points | Predicted risk |
|---|---|---|---|
| Female gender | 26 | | |
| Body mass index | | 51 | 0.10% |
| 15 | 11 | 116 | 1.00% |
| 20 | 22 | 136 | 2.00% |
| 25 | 33 | 147 | 3.00% |
| 30 | 44 | 156 | 4.00% |
| 35 | 56 | 162 | 5.00% |
| 40 | 67 | 168 | 6.00% |
| 45 | 78 | 172 | 7.00% |
| 50 | 89 | 177 | 8.00% |
| 55 | 100 | 180 | 9.00% |
| Diabetes mellitus taking insulin | 20 | 183 | 10.00% |
| Isolated or combined coronary artery bypass grafting | 19 | 196 | 15.00% |
| Reexploration | 51 | 206 | 20.00% |
| Gentamicin-impregnated collagen sponge implant | −63 | 214 | 25.00% |







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**000 Scoring system to guide decision making for the use of gentamicin-impregnated collagen sponges to prevent deep sternal wound infection**

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The effectiveness of the routine retrosternal placement of a gentamicin-impregnated collagen sponge implant before sternotomy closure is currently a matter of some controversy. We developed a scoring system to guide decision making for the use of gentamicin-impregnated collagen sponges to prevent deep sternal wound infection.







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