Reviewer’s report

Title: Superficial and deep sternal wound infection after more than 9000 coronary artery bypass graft (CABG): incidence, risk factors and mortality

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Reviewer: Örjan Friberg

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General

This manuscript contains a report of sternal wound infections (SWI) after cardiac surgery at Tehran Heart Center, Iran. The patient material consists of 9201 consecutive coronary artery bypass graft (CABG) operations during an approx. four-year period (Jan 2002 – Feb 2006). The objective of the study was to assess the incidence of, risk factors for and mortality in postoperative SWI.

The authors report a total incidence of SWI of 0.5%, (which is remarkably low) and in a multivariable analysis (logistic regression analysis) they identify hypertension, female gender and re-exploration for bleeding as the only independent risk factors for SWI.

In addition the authors analysed the potential impact of three different prophylactic antibiotic protocols.

The objective and methods presented here are not new and there have been just too many similar single institution retrospective studies published during the last 30 years. However, reports from North America and western Europe are overrepresented in the literature. Since it is not unlikely that this clinical problem does show geographical discrepancies, a report such as this, from a large Iranian centre, should be encouraged.

Unfortunately this study has severe flaws. Before the manuscript could be considered at all for publication, the authors need to clarify some particularly important issues and the manuscript requires major revisions. Importantly, the authors need to recognise and discuss the obvious limitations of the study in the discussion section. The paper is also in need of professional language editing.

Major Compulsory Revisions

· Background (p3). This section must be revised. The second and third paragraph contains essentially the same information repeated over again: A description of the CDC classification according to depth, and a short discussion of the incidence. There could be one paragraph about the reported/expected incidence followed by one paragraph about classification/deeps of SWI.

· Methods section
The method is not clear. It is stated (p4) “Data prospectively were collected from our hospital surgery database”. Normally these kinds of studies are conducted by analysing an already existing clinical database, which contains data on the operations performed during a certain period. That would be, and should be described as, a retrospective study. Or maybe “a retrospective analysis of prospectively collected data”, if this is true. My guess is that this is what the authors did in this case?

· Several prospective studies from different European centres that contain a detailed description of the follow-up process consistently report incidences of SWI of 5-10%, depending on the definition [1-5]. In this perspective the reported incidence of 0.5 % in the present paper is remarkable. However, the following points need clarification Unless these subjects are described in detail comparisons between the reported incidence of SWI with those of other reports are of no value.

o A constant problem with all clinical/hospital/quality-databases is the quality of the data. Complication rates retrieved from such registries are consistently lower compared with the figures in prospective randomised trials. How did the authors assure that data were valid? Could some cases of SWI be missing in the database? Who entered the data? Was there any systematic validation of the quality of data?

If no validation was performed this should me mentioned as an important limitation regarding the reported
There is no description of how the cases of SWI were identified. The majority of SWIs present after discharge. Were all patients followed, and contacted after discharge? If so, for how long were the patients followed? If not, how, when and by whom was the diagnosis of SWI made and then entered in the database? Were all less serious cases of SWI treated postoperatively as outpatients captured and entered in the database?

The CDC classification of superficial/deep infection can be described here or in the background section but not in both sections!!

I miss a brief description of the classification according to el Oakley

In-hospital mortality OR 30 day mortality? (or do the authors mean only in-hospital mortality < 30 days?)

Antibiotic prophylaxis was obviously started preoperatively. When? Immediately before surgery? Repeated at which intervals? Were the aminoglycosides (gentamicin and amikacin) also repeated at the same intervals?

The doses in gram of each of the antibiotics should be given.

Choice of antibiotic regimen was obviously according to the surgeon’s preference. This should be mentioned here.

Statistical methods: The logistic regression analysis deserves to be described in more detail. Since the result of this multivariable analysis is so unexpected (female gender and hypertension were highly significant independent variables, but NOT diabetes and high BMI – the two most constant risk factors from the literature) the interested reader certainly would like to have some more information. A problem that the authors have is that there are only 44 cases of SWI, which means that all possible risk factors cannot be entered in the multivariable model at the same time; therefore a forward stepwise analysis was performed. However, four factors should be ok to enter together. For example: it would be interesting to see the ORs and P-values if diabetes or BMI were to be entered together with the three factors that were found to be significant in the forward stepwise analysis.

Exactly which factors were entered in the multivariable analysis? All with a p-value less than .05? Was intubation time entered (or was it considered a consequence of SWI rather than risk factor for SWI)? (I suppose mortality was not entered?).

Were possible statistical interactions between factors tested? Was any alternative statistical analysis used (if e.g. a backward stepwise analysis would give the same final model, it would indicate a robust model)?

Results (p6)

The text in results section should be substantially shortened. Most figures are already given in the tables.

P7: Eight of the SWIs belonged to El Oakley type IVb. That type is defined as mediastinitis presenting after more than one failed therapeutic trial[6]. So, by definition, when a postoperative SWI presents for the first time, it cannot be type IVb. How did the authors handle this? Are e.g. microbiological data from the primary or the “secondary” (IVb) SWI. I guess each patient only contributed with only one wound infection (?).

Tables 1-3 could be put together into one table (summarizing potential pre- intra- and postoperative riskfactors). Mortality can be reported in the text, as it is not a risk-factor for SWI.

Table 1 BMI; I might be wrong, but to me the reported P-value of BMI seems incorrect. A simple t-test indicates that there might be a significant difference between the groups?? As this is a well-known risk factor, a difference is to be expected...

Table 4 should be omitted. There are no significant differences, and this was expected (!) since there are only 21 and 23 cases in each group, respectively.

Table 5 should be omitted! The rates in percent in each group can be briefly mentioned in the text. This is the “result” of a non-randomised comparison (actually the rates of three different groups of surgeons?). But most importantly: what reduction in rate with the addition of aminoglycosides would have been possible to detect given the “base-rate” of 0.5% in the first group?????

Table 6 should be omitted!! See above.

All tables. The same number of decimals should be given in all tables. Generally it is enough to give the figures with one (perhaps two) decimal accuracy.

Discussion

The finding of preoperative hypertension as an independent, highly significant risk factor for SWI was somewhat surprising. Do the authors think this reflects a true causal relationship and if so, what might be the mechanism? This would deserve some more comment.

The obvious limitations and weaknesses of the study should be acknowledged and discussed!!
Minor Essential Revisions

- The complete names of microorganisms are normally given the first time mentioned (e.g. staphylococcus aureus) and abbreviated the second time (S. aureus, not “staph aureus”).

- The last sentence of the background belongs to Methods.

Discretionary Revisions (which the author can choose to ignore)

References


What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests