

References

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Choosing Inclusion Criteria and Publishing Mortality Data: A Critique

To the Editor:

We would like to make some remarks about the article by Dr. Görlinger and his colleagues.¹ Their study demonstrates vividly the primary end point: Hemostatic therapy based on point-of-care testing reduced the number of packed erythrocytes after cardiac surgery.

The study has a very straightforward and precise design. We appreciate the structure of the algorithm even though the progression of the therapeutic options, analyzed step by step, is quite different from the one chosen by our group.

However we disagree with one of the two inclusion criteria outlined. We consider the second criterion reported—“intraoperative or postoperative blood loss exceeding 250 ml/h or 50 ml/10 min”—is very precise because it leads to a reproducible choice of the sample from the population. On the contrary, the first criterion is absolutely dependent on the personal assessment by the singular physician looking after the patient: “diffuse bleeding from capillary beds at wound surfaces requiring haemostatic therapy.” Moreover, it seems to be in conflict with the following algorithm of management that aims to investigate if the patients need treatment for bleeding issues and to assess which therapeutic option to choose.

Our second point of criticism is on the description of the results regarding numerous different secondary outcomes. We agree that many of them may be considered very interesting and probably close to statistically significant results, such as the decreased number of fresh frozen plasma and platelet concentrate units transfused in the point-of-care group. We always have to consider that the sample size analysis and the interim analysis reveal the sample size required to statistically demonstrate the primary outcome, and not other outcomes.

Regarding this, we think that publishing the Kaplan-Meier curve is misleading. In this article, this curve

demonstrates a survival rate completely different from the one reported in a lot of other articles on the mortality in cardiac surgical patients.^{2,3}

According to this Kaplan-Meier curve, the mortality rate after six months in complex cardiac surgery reaches the value of 20%.¹ On the other hand, we noticed that the authors have chosen another important study as a main reference published in 2007 in *Circulation*.² In this article, the Kaplan-Meier curve shows a mortality rate around 6%.²

We think that proving a statistically significant reduction in exposure to allogenic blood products in patients treated with hemostatic therapy based on point-of-care testing is interesting, as some previous studies demonstrate an increased mortality in patients transfused in the same surgical context.

Nevertheless, we think that publishing a misleading graph may not help the reader or give value to the notion demonstrated.

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In Reply:

We appreciate Dr. Ziemann-Gimmel’s commendation of our randomized clinical trial (RCT) on efficacy of point-of-care (POC) testing in coagulopathic cardiac surgery patients and are happy to comment on his two important considerations.¹

We agree that increased intraoperative blood loss and subsequent retransfusion of salvaged washed erythrocytes can result in dilutional coagulopathy and, therefore, may further increase transfusion requirements. In addition, transfusion of fresh frozen plasma in order to treat or avoid dilutional coagulopathy results in dilution of erythrocytes and platelets and may increase transfusion requirements for erythrocytes and platelets, too. The only way to avoid this vicious circle is to stop bleeding as quickly as