PREVENTION OF INCISIONAL HERNIA AFTER MIDLINE LAPAROTOMY FOR ABDOMINAL AORTIC ANEUVRYSM REPAIR

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Dear Editors of “Updates in Surgery”,

We have read with great interest the publication by Honig et al. reporting the long-awaited results of the “Abdominal incision defect following abdominal aneurysm study” (AIDA) trial in a recent issue of the Journal (1). Prevention of incisional hernias (IH) by prophylactic mesh augmentation during closure of midline laparotomy for treatment of aortic abdominal aneurysm (AAA) has long been a topic of interest for the members of the Section for Abdominal Wall Surgery of the Royal Belgian Society for Surgery. In fact, we published a randomized controlled trial (RCT) using a retromuscular mesh placement after open AAA repair and found this intervention to be effective and safe in the prevention of IH (2). This RCT has been confirmed by further well-designed and completed RCTs, and we consider that there is now enough evidence to recommend the use of prophylactic mesh when an AAA is repaired through a midline laparotomy incision (3-5). We agree with Honig et al. that an onlay mesh augmentation is probably easier for surgeons who do not frequently perform retromuscular hernia repairs (1). We were therefore delighted when the PRIMA trial showed that an onlay repair could be as effective and safe as a retromuscular repair for prevention of IH (4).

Honig et al. claimed that their study shows that “the rate of incisional hernias at 24 months is not reduced by onlay mesh augmentation compared to primary suture” and that “the existing evidence on prophylactic mesh augmentation in patients undergoing AAA repair through a midline incision needs critical review” (1). We challenge the validity of these claims. The AIDA study, and its publication, has severe flaws in design, execution and reporting that need to be brought to attention.

First, the choice of using a RCT with three arms is questionable. We do not see a clear rationale for it, and this design probably has played an important role in the failure to achieve the required sample size. Moreover, contrary to expectations described by the authors, an innovative Monomax® (Aesculap AG, Tuttlingen, Germany) suture performed inferiorly to Monoplus® (Aesculap AG, Tuttlingen, Germany) and to onlay mesh augmentation. This difference was the only result of the primary outcome in the entire study with a *P* value < 0.05 (0.018), notwithstanding the low sample size achieved. This is not mentioned in the abstract or the discussion of the study, which is a publication bias that might be related to the study sponsor. In addition, we wonder why this study was published 6 years after termination for assessing the primary endpoint (24-months follow-up).

Second, only 37% of the calculated sample size was reached in the AIDA trial (104 patients included versus 282 patients needed) (1). Needless to say, we understand the problem of inclusions in this patient group where an ever-increasing number of procedures are performed endovascularly. Indeed, we faced a similar problem in our RCT where we had to extend our inclusion period from 2 to 4 years. We have no issue with a prospective study not achieving the required sample size, that can happen. However, we do have a major problem with the fact that this study report does not mention this failure to achieve the study size in its abstract. Moreover, any statistical analysis of a highly underpowered study should not be published without clearly highlighting this limitation. The current data of the underpowered study showed the primary endpoint, incisional hernia rate at 24 months to be lower following onlay mesh augmentation than for primary suture (6.25% (2/32) versus 20.9% (14/67), respectively). This seems to be in line with the AIDA study hypothesis that mesh augmentation reduces the IH rate at 24 months from 30% to 10%. Consequently, if the study had been completed as planned, it might have shown prophylactic mesh to be effective, but

because the sample size was not reached, no conclusion can be drawn in either direction. Therefore, a claim that the mesh intervention was not effective due to the AIDA study results is not justified, and scientifically unacceptable.

Third, Honig et al. suggest that the results of their study should challenge the current recommendation that prophylactic mesh should be used when performing an open AAA repair through a midline laparotomy (1). We can only hope future guideline developers will critically assess the limitations of the AIDA study and balance it appropriately with the quality evidence that has already been published.

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The 3 authors worked together on this manuscript. They exchanged ideas concerning the publication of the AIDA study results. The first draft of the manuscript was written by the first author and was sent to the 2 others who proposed modifications and improvements. The second draft was again shared, and few new modifications were decided. All authors confirmed their agreement with the final version of the manuscript.

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