Regarding “InterGard silver bifurcated graft: Features and results of a multicenter study”

Ricco1 recently published an article containing a meta-analysis but did not describe the techniques of the analysis. The absence of methodology stimulates the following questions: What were the inclusion/exclusion criteria for selection of the comparator studies? As presented, it is impossible to reproduce the meta-analysis or, more importantly, discern the effect of various biases.2,3 How robust was the conclusion from the meta-analysis when possible confounding factors were considered? Various types of bias are inherent within any meta-analysis. It is a basic necessity of all meta-analyses to perform sensitivity analyses to demonstrate the robustness of results.4,5 Did the studies in the meta-analysis report graft infection in terms of odds ratios, or did the authors extrapolate these data from reported percentages and counts? Translation of percentage and count data directly into an odds ratio without accounting for differences in follow-up duration between individual studies would introduce statistical bias. Moreover, the authors fail to state whether individual study data were weighted to derive the combined odds ratio and did not describe the calculation method used: either fixed-effect or random-effect modeling.6 Do the wide confidence intervals for the odds ratio of the author’s study (0.21 with a 95% confidence interval of 0.01-4.4) really reflect a reproducible outcome? The dashed vertical line in their Forrest plot (fig 6)1 corresponds to no effect (odds ratio = 1.0). If the confidence interval of individual studies includes 1, then it is debatable whether any difference in the effect estimate of one treatment vs another is significant at conventional levels (P < .05). Finally, did the authors consider the homogeneity vs heterogeneity of individual studies used? The poolability of individual study data in the meta-analysis was not discussed, although the data in the Forrest plot (fig 6)1 suggest that individual study data were homogeneous. Consequently, we believe that the authors should have commented on the applicability of their conclusion toward patient populations with characteristics (eg, comorbidities and risk factors) that are different from the patient populations considered.5

This postmarketing study has a commendable data return, considering its study type and follow-up duration, with just 2.8% patients lost to follow-up over a mean of 55 months.1 Complete disposition of all patients from all centers through each study period would have been useful. Kaplan-Meier curves with a 3-year follow-up are presented despite a reported mean follow-up longer than 4.5 years. The low attrition rate and follow-up duration suggest that data are available to show outcomes well beyond the selected follow-up of 3 years. A rationale for limiting the survival data to 3 years would be appropriate.

There are remarkably few English-language publications on the use of silver-coated bifurcated vascular grafts.1,6 Answers to the above methodologic and reporting issues would allow readers to better judge the validity of the stated conclusions.

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REFERENCES

Reply

We appreciate the letter from O’Connor and Andrew concerning our article, but we want to clarify the following points concerning the methodology of the study and the meta-analysis presented in the article.

The purpose of our prospective multicenter study was to evaluate the safety, patency, and infection rate of a bifurcated aortic polyester graft coated with collagen and silver acetate. As pointed out by O’Connor and Andrew, our study had only 2.8% of patients lost to follow-up over a mean of 55 months. This result was achieved by adequate monitoring of all centers. In addition, uniformity and completeness in complication reporting was verified during on-site monitoring visits by comparing complications in charts with those in the case-report form. As usual, the Kaplan-Meier curves were used to report patient survival and primary and secondary patency up to 3 years. As pointed out by O’Connor and Andrew, follow-up was longer for some patients, and technically any survival plot can be extended right through to the longest follow-up time. However, this extension is not good statistical practice, because for any such plot the eye is drawn to the right (ie, where the plot finishes), where there is least information and greatest uncertainty. Much of the right-hand part of the plot can

![Funnel Plot of Standard Error by Log odds ratio](image_url)

Fig. Funnel plots with graft infection log odds ratios from individual studies on the horizontal axis and standard error reflecting the study size on the vertical axis. The name funnel plot is based on the fact that the precision in the estimation of graft infection will increase as the sample size of component studies increases. Effect estimates from small studies will therefore scatter more widely at the bottom of the graph, with the spread narrowing among larger studies. In the absence of bias, as shown here with data from our studies, the plot will resemble a symmetrical inverted funnel.