Commentary: Lack of benefit of tricuspid valve intervention with left ventricular assist device implantation? It’s all in the details

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In this issue of the Journal, Mendiola and colleagues have presented the results of a prospective, randomized, controlled, open-label, single-center clinical trial investigating the benefit of concurrent tricuspid valve (TV) repair or replacement for moderate or severe TV regurgitation in the setting of durable left ventricular assist device (LVAD) implantation. At 6 months after LVAD implantation, subjects undergoing TV intervention had mild or no TV regurgitation more frequently on follow-up echocardiogram compared with subjects not receiving TV intervention. However, at 6 months, the incidence of moderate and severe right heart failure was similar in each group. Additionally, there was no significant difference in postoperative mortality or requirement for right ventricular assist device between groups, as well as no significant differences in the secondary end points of functional status and adverse events. On the basis of these findings, the investigators concluded that the presence of significant TV regurgitation before LVAD implantation is associated with a high incidence of right heart failure within the first 6 months after surgery and that TV intervention, although effective in reducing postimplant TV regurgitation compared with no TV intervention, did not reduce the incidence of right heart failure at 6 months.

The benefit of concurrent TV surgery at the time of durable LVAD implantation has been a long and frequently contested issue in the field. Arguments for and against TV intervention at the time of durable LVAD implantation have been based largely on observations from large registry data or single-center observational experiences. The study by Mendiola and colleagues highlights a number of important insights into the clinical problem, yet raises a number of important questions in an attempt to try and understand the lack of benefit of concurrent TV intervention. Of note, LVAD implantation alone had a significant impact on reducing the frequency of severe TV regurgitation and increasing the frequency of patients with no or only mild TV regurgitation at 3 to 6 months after LVAD implant in the control arm. Thus, it is likely that the addition of a TV intervention would not have improved the reduction in TV regurgitation achieved with LVAD implant alone in approximately one-third of patients with moderate to severe TV regurgitation at implant. The resolution of TV regurgitation alone with LVAD implant may identify patients who retain the capacity for early favorable right ventricular remodeling or have early resolution of elevated pulmonary vascular resistance. Thus, one could hypothesize that TV intervention would not provide an additional benefit in this group. For patients with persistent important TV regurgitation at 3 to 6 months after LVAD implant, there may be significant underlying persistent right ventricular dysfunction and dilation or elevated pulmonary vascular resistance that contributes to ongoing valvular regurgitation.
TV intervention would be of greater benefit in this potentially higher-risk subgroup of patients is not readily answerable. One could hypothesize that TV intervention in this subgroup would be of no benefit in the setting where there is limited reversibility of right ventricular dysfunction (ie, ventricular problem) after LVAD implantation. It would be important to understand whether the incidence of postoperative right heart failure in the subgroup of patients who resolved TV regurgitation with LVAD implant alone differs from the incidence of right heart failure in the subgroup of patients who experienced persistent moderate to severe TV regurgitation at 3 to 6 months. If there were differences in rates of postoperative right heart failure between these subgroups, it would be important to understand differences in baseline patient characteristics. Substantial differences in incidences of early right heart failure between these subgroups would have important implications in interpretation of the study conclusions.

Additionally, although TV intervention failed to reduce right heart failure after LVAD implantation, the observations on mortality and incidence of early, acute right heart failure (ie, those patients requiring a right ventricular assist device) between groups appears clinically important, although not statistically significant. Unfortunately, a trial design examining these end points would require significantly more subjects to explore and likely not feasible.

Regardless of the scientific findings of this study, Mendiola and colleagues1 should be congratulated in conducting a rigorous, prospective, randomized clinical study of a cardiac surgical intervention. To a large extent, cardiac surgery has been guided by observational studies because randomized clinical trials are difficult to successfully accomplish. Conducting a randomized clinical trial of a surgical intervention is arduous. The investigators deserve significant praise in bringing rigorous randomized clinical data to the topic even if the trial has not completely resolved all the issues of concurrent TV intervention at the time of durable LVAD intervention.

Reference