## Letters to the Editor

### Catheter-Based Device Closure of Fontan Fenestrations

#### TO THE EDITOR:

I read with interest the article by Cowley et al. [1] on transcatheter closure of Fontan fenestrations with the Amplatzer. In the introduction section, they state that there are a variety of transcatheter methods to close the fenestrations and mention clamshell device, Rashkind ductal umbrella, coil, and Amplatzer septal occluder. I would like to draw the attention of the readers to our reported experience [2] in transcatheter inverted buttoned device occlusion of atrial defects producing right-to-left shunt associated with previously operated complex congenital cardiac anomalies. Four of the 12 patients in that report were Fontan fenestrations. Increase in arterial oxygen saturation, pulmonary-to-systemic flow ratio, and system venous saturation occurred without a significant change in heart rate, cardiac index, and systemic oxygen transport. At follow-up  $12 \pm 5$  months after the procedure, the arterial oxygen saturation remained improved for the group as a whole. In the four patients in whom we closed the Fontan fenestrations, the oxygen saturations remained high and no residual shunt was detected by Doppler studies. A larger experience with 22 patients, reported in an abstract form [3], confirms the previous observations [2].

I might take this opportunity to comment on other issues pertaining to device closure. The single-strand component of the inverted buttoned device goes onto the left atrial side of the baffle and is unlikely to interfere with the function of the atrioventricular valve such as that reported by Cowley et al. [1] with Amplatzer device.

With the advent and wide use of staged Fontan concept, i.e., bidirectional Glenn initially, followed by diversion of the inferior vena caval blood into the pulmonary artery either by an intra-atrial tunnel or an extracardiac conduit (total cavopulmonary connection), we find it extremely unusual to require a fenestrated Fontan. Consequently, the need for closure of these fenestrations became less.

Finally, the seminal observation that implantation of Amplatzer septal occluder is feasible, safe, and effective in occluding Fontan fenestration has already been made by Tofeig et al. [4], and the current report by Cowley et al. [1] adds little to our existing knowledge. However, the number of patient in the series by Cowley et al. [1] (n = 12) is slightly larger than those of Tofeig et al. [4] (n = 5). The complication rate is also higher in Cowley et al. [1].

In summary, inverted buttoned device, ignored by Cowley et al. [1], is a useful device in closing Fontan fenestrations, perhaps even with less probability of interference with atrioventricular valve function than Amplatzer. The need for performing fenestrated Fontans and consequently the necessity to transcatheter-occlude them is becoming less since the wide use of staged total cavopulmonary connection.

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# REPLY TO THE LETTER TO THE EDITOR BY RAO

tration closure by the Amplatzer septal occluder in five patients. This study was appropriately cited in our article. However, Rao's claim that our article [2] adds "little to our existing knowledge" is at best disingenuous. In addition to the more detailed and statistically evaluated data

We appreciate Rao's drawing attention to the report by Tofeig et al. [1], an excellent brief description of feneson hemodynamics and residual shunting and improved radiation exposure times reported in our study, unique aspects of this study included transhepatic placement of five Amplatzer devices and radiographic evidence of progressive compaction of the device during follow-up. Most importantly, we reported a previously unrecognized complication of the device, i.e., tricuspid valve injury, pointing out the importance of not placing the fenestration site too close to the atrioventricular valve orifice.

We are familiar with the inverted buttoned device, having attempted fenestration closure with this device in two patients in whom snare closure could not be accomplished [3]. Unlike the four patients reported by Rao et al. [4], both our patients had lateral tunnel Fontans, and the "single-strand component" referred to by Rao (a 25 mm length of stainless steel wire wrapped in polyurethane foam) proved to be problematic. In one patient, with an anterior snare location, this component was coaxed into a position parallel to the axis of the baffle and the fenestration was closed. Unlike the patient reported in the present study, this fenestration was sufficiently superior that the device could lie in the sulcus between the baffle and the atrial wall without interfering with the tricuspid valve. The second patient had a posterior fenestration, and difficulties with finding a position for the left atrial component of the device contributed to the decision to retrieve the device and abandon the procedure. This fenestration position is near the right inferior pulmonary vein orifice, and the inferior extent of the baffle sulcus was insufficient for the occluder to lie parallel to the baffle. To the extent that the straight occluder lies transversely to the cylindrical baffle, its arms will be directed into the atrial wall (or pulmonary vein) and the cavity of the pulmonary venous atrium, increasing the risks of thrombosis and arrhythmia. Although we are less impressed than Rao with the inverted buttoned device for Fontan fenestration closure, the report of Rao et al. [4] remains important because the procedure-related death of one patient is reported.

Finally, Rao's assertions regarding the utility of Fontan fenestration deserve comment. Staging of the Fontan through bidirectional Glenn or hemi-Fontan procedures has been routine at our institution for over a decade, yet we continue to find Fontan fenestration useful. An explanation for this difference in philosophy may perhaps be found in the nature of the Fontan population at our respective centers. All the Fontan patients in the report by Rao et al. [4] have left ventricles, with what we would consider relatively straightforward defects. In contrast, our Fontan patients tend to have much higher risk anatomy: 70% of our fenestrated Fontan patients have single right ventricles, most of whom have hypoplastic left heart syndrome [5]. It is understandable that a center that undertakes fewer operations in high-risk patients would be slower to adopt the staged approach and see less benefit from fenestration. Certainly a more significant deterrent to the wider use of any experimental device for Fontan fenestration occlusion is the recent Humanitarian Device Exemption approval of the CardioSEAL device for this indication by the U.S. Food and Drug Administration. While we have not yet had occasion to implant a CardioSEAL device from the transhepatic approach, we have found it very effective from the femoral approach in occluding those fenestrations that would otherwise be favorable for closure with the Amplatzer septal occluder.

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