3. In a neonatal case with a common chamber located inferiorly, a sufficiently large flap cannot be created to completely cover the atrial communication.
4. Insufficient anastomosis between the intima of common chamber and the endocardium in the LA may cause a coronary artery steal.
5. Late postoperative atrial arrhythmia is unknown.

We believe that this new procedure is applicable even in neonatal cases with TAPVC drainage into the CS. However, a long observation period will be required for those patients who undergo this new procedure.

Mitsugi Nagashima, MD
Fumiaki Shikata, MD
Kanji Kawachi, MD

Department of Surgery
Division of Cardiothoracic Surgery
and Regenerative Surgery
Stroke and Cardiovascular Center
Ehime University School of Medicine
Shitsukawa, Toon City, Japan

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Reply to the Editor:

I thank Dr Nagashima and colleagues for their insightful comments on our new surgical technique for cardiac-type total anomalous pulmonary venous drainage (TAPVD).¹ Pulmonary venous obstruction (PVO) is an inevitable, serious complication after the repair of cardiac-type TAPVR by conventional surgical techniques.^{2,3} Turbulent blood flow at the warped pulmonary venous pathway through

the coronary sinus² or a narrow communication between the pulmonary venous channel and the left atrium³ may cause intimal proliferation followed by PVO. Although the coronary sinus is usually dilated in cardiac-type TAPVD, it is by no means wide enough to serve as the permanent pulmonary venous pathway. In contrast, the posterior wall transference technique¹ can create laminar pulmonary venous blood flow through a wide and straight communication into the left atrium.

With the posterior wall transference technique, the common wall between the left atrium and the pulmonary venous chamber is cut out as a tongue-like flap. It is also important not to cut the pulmonary venous orifice to avoid postoperative PVO. Ordinarily, it should be possible to incise the posterior left atrial wall while preserving the pulmonary venous orifices, because the pulmonary venous orifices are clearly visible during the procedure.

The roof of the coronary sinus and posterior wall of the left atrium is applied to a new atrial septum with the posterior wall transference technique. To avoid damage to the atrioventricular node, the roof of the coronary sinus should not be cut longitudinally along its caudal edge but along little to the middle. The right atrial portion of the roof of the coronary sinus can then be safely anastomosed to the floor of the coronary sinus far away from the atrioventricular node.

The neonatal posterior left atrial wall is certainly a rather small area. Indeed, a small posterior left atrial wall flap would be insufficient to completely fill the atrial septal defect. A supplementary autologous pericardial patch is necessary in such cases. The pericardial patch will not cause PVO, because the patch is used to fill the residual atrial septal defect rather than to construct the pulmonary venous pathway. Furthermore, stenosis at the junction of the common pulmonary chamber with the coronary sinus or within the coronary sinus is rare.⁴

PVO is not usually exacerbated during the neonatal period in cardiac-type TAPVD. The posterior wall transference technique¹ is easily performed in infancy. Therefore, risky emergency surgical intervention is unnecessary for neonates without signs of PVO.

Nagashima and colleagues also pointed out postoperative abnormal coronary artery flow toward the atrium. This excursive complication does not arise from a deficiency of the posterior wall transference technique. Mural coronary artery steal is certainly avoidable by adequate firm anastomosis of the atrial wall.

Three infants with cardiac type TAPVD underwent repair by the posterior wall transference technique at our institution. Ages at the time of operation were 2, 4, and 6 months. Body weights ranged from 3.9 to 5.5 kg. The follow-up period ranged from 22 to 70 months. No arrhythmias were seen on postoperative electrocardiography. Postoperative echocardiograms demonstrated a wide pulmonary venous pathway without stenosis. The posterior wall transference technique for cardiac-type TAPVD is a useful surgical option without the complications of late PVO and arrhythmias.

Masaaki Yamagishi, MD, PhD

Department of Pediatric
Cardiovascular Surgery
Children's Research Hospital
Kyoto Prefectural University of Medicine
Kyoto, Japan

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THE FUNDAMENTAL IMPORTANCE OF BASELINE COMPARISONS IN A CLINICAL TRIAL

To the Editor:

We read with interest the study by Hecht-Dolnik and associates in the September 2009 issue of the *Journal*, "Hetastarch Increases the Risk of Bleeding Complications in Patients After Off-Pump Coronary Bypass Surgery: A Randomized Clinical Trial." In this article, they conclude that the intraoperative administration of 1 L of hetastarch was associated with an increase in postoperative chest tube drainage and transfusion of blood products, which resulted in early termination of the study.

Although we acknowledge the importance of the clinical question the authors have addressed, we have major concerns regarding the equality of the intervention and the control groups at baseline and the method in which this is reported. Although the authors claim that there were no statistically significant differences in baseline characteristics between groups, Table 1 indicates the baseline international normalized ratio (INR) in the hetastarch group was 1.47 (2.12) whereas in the albumin group baseline INR was 1.07 (0.10), values presented as mean (standard deviation). Although the mean value between these 2 groups may not be statistically different, it is misleading to claim baseline equivalence between the groups. The upper limit of INR is typically quoted at 1.3, indicating the mean INR in the hetastarch group is abnormal and in the albumin group mean INR is normal. Furthermore, the large standard deviation in baseline INR in the hetastarch group can only be explained by the presence of one or more outliers with markedly abnormal baseline value. In contrast, the standard deviation for INR of the

albumin group is small (0.10), indicating a typically normal distribution. We would suggest that this method of reporting baseline INR is potentially misleading. Presenting the proportion of patients in each group with abnormal INR at baseline would be substantially more informative to judge baseline equivalence of the 2 groups.

This difference in baseline INR and, by inference, bleeding risk is difficult to explain in a trial whose group assignment was by random allocation. However, in a study whose primary outcome was transfusion of blood products, understanding a difference of this nature is vitally important to interpretation of the results, particularly where transfusion practice was neither blinded nor protocol guided, as in this study.

We believe this highlights the importance of using the appropriate method of data presentation to describe baseline characteristics in a clinical trial as well as the potential pitfall of relying on *P* values greater than .05 to indicate baseline equivalence of groups rather than clinical interpretation for the potential influence of an observed difference on the outcome of interest.

David McIlroy, MD, MClinEpi, FANZCA
Ervant Nishanian, MD, PhD
Department of Anesthesiology
Columbia University College of
Physicians and Surgeons
New York, NY

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Reply to the Editor:

We extend our thanks to Drs McIlroy and Nishanian for their careful reading of our article. Their concerns would be well placed if the average baseline international normalized ratio (INR) in the hetastarch group were 1.47. Their comment led us to review the project source data. That review revealed several transcription errors in which the decimal place in the INR was misplaced. The average baseline INR after correction of those transcription errors

is 1.06 (standard deviation = 0.11). This correction thus reverses the direction of the difference between the hetastarch and albumin groups in the average INR from that presented in the initial article. The statistical significance of the difference in average INR between the albumin and hetastarch groups becomes even weaker, remaining not statistically significant (Student *t* = 0.77; *P* = .44, not significant).

We then investigated how many cases in each group had a baseline INR above the 1.30 threshold, as Drs McIlroy and Nishanian suggested. That threshold is crossed by 2 members (2.6%) of the albumin group and 3 members (3.8%) of the hetastarch group. The difference in the proportion in each group with an INR above the 1.3 threshold is not statistically significant (Fisher exact test = 1.0, not significant).

This corrected finding supports treating the intervention and control groups in this study as equivalent. We apologize for any misunderstandings caused by this inaccuracy in the initial reported statistics summarizing and comparing baseline characteristics.

Marketa Hecht-Dolnik, MD^a
Howard Barkan, DrPH^b
Ananse Taharka, MD^a
John Loftus, MD^a

^aKaiser Permanente Medical Center
Oakland, Calif
^bUniversity of California
Berkeley, Calif

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TECHNICAL OPTIONS FOR THE TREATMENT OF ANOMALOUS ORIGINS OF RIGHT OR LEFT CORONARY ARTERIES ASSOCIATED WITH AORTOPULMONARY WINDOWS

To the Editor:

Aortopulmonary window (APW) and anomalous right coronary artery (RCA) originating from the pulmonary