and colleagues, a split could be not be achieved in most cases because of severe commissural fusion. Tearing of the anterior leaflet (16/25) was the commonest cause of MR necessitating surgery in their study and in most other large series.^{1,3} These data further support our findings that severity of commissural disease may be the most important determinant of production of MR after PTMC.

Failure to assess adequately the commissural disease might be the reason why many scoring systems for assessment of valves for PTMC have poor predictive value regarding the outcome and complications.⁴ However, echocardiographic assessment of commissural morphology has excellent correlation with outcome.^{4,5} These researchers⁴ observed that there was more frequent need for oversizing the balloon in patients with single or no commissural splitting. Furthermore, in patients in whom commissural splitting could not be achieved (n = 4), there was a tear of the anterior mitral leaflet. This corroborates our findings that, in the presence of severe fusion, more pressure is required to split the commissures and then areas that offer lesser resistance can "give way." Hence, in the presence of severe commissural fibrosis detected by echocardiography, especially in the presence of calcified leaflets and thin anterior leaflets, and given the fact that valvular disease tends to be underestimated by echocardiography, PTMC carries an increased risk of leaflet tear.

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FloWatch and pseudoaneurysm: Complication versus coincidence To the Editor:

Michel-Behnke and colleagues¹ reported the development of pseudoaneurysm of the main pulmonary artery after implantation of an adjustable FloWatch-PAB for pulmonary artery banding.

The observed complication has been reported as subsequent to the device implantation, but no data were available to consider it as consequent to the use of the device itself. The authors carefully specified that "the mechanism of rupture of the pulmonary artery with pseudoaneurysm formation is unclear but might have been due to a lesion set during preparation."¹ Their conclusion was that "careful preparation of the pulmonary trunk and smooth placement of the device around it seem essential to prevent aneurysm formation."¹

Pseudoaneurysm formation is a well-known complication of conventional pulmonary artery banding.² Although we appreciate the suggestions proposed by Michel-Behnke and colleagues,¹ and we could not agree more on the importance of a very careful dissection of the pulmonary artery to avoid a "via falsa" for the placement of the band, we respectfully disagree with the observation that the FloWatch-PAB could be implicated with the mechanism of pseudoaneurysm formation.

Looking carefully at the available intraoperative images, the main pulmonary artery appears with a visible mark like a previous conventional banding. If this was the case, the surgical dissection of the adhesions from the previous operation could have contributed to the observed complication, independently from the use of FloWatch-PAB. Also, the time frame of the formation of the pseudoaneurysm (7 days) is quite unusual for such a complication.

Furthermore, among the several advantages of the FloWatch-PAB,^{3,4} 3 in particular are useful to reduce the incidence of pseudoaneurysm formation in comparison with the conventional banding. First is the capability of performing a progressive narrowing of the pulmonary artery with a gradual increase of the pressure gradient through the banding, avoiding the traumatism of the sudden constriction of a dilated, hypertensive, fragile pulmonary artery.^{3,4} Second is the shape of the device (banana-like), allowing a reduction of the cross-sectional area of the pulmonary artery without modification of the length of the circumference of the pulmonary artery itself. This is a major advantage on conventional banding, in which reduction of the cross-sectional area was obtained with significant circumferential reduction of the length of the pulmonary arterial wall.⁵ Because of the shape of the device, there is not need for additional sutures to fix the device to the wall of the pulmonary artery to prevent migration, as for the conventional banding. Finally, because of the 2 above advantages, we were able to show in our animal experiments normal macroscopic and histologic aspects of the pulmonary artery in correspondence of the placement of the device up to 14 months with the device in situ.³

The experimental data have been confirmed in the clinical experience, extended to 26 patients in the combined series of Lausanne and Liverpool, and extended to a total number of 67 devices implanted to our knowledge, with the only pseudoaneurysm in the case reported by Michel-Behnke and colleagues.¹

Furthermore, the absence of lesions of the wall of the pulmonary artery has been substantiated by the observation that, as previously observed in all animals at the moment of FloWatch-PAB removal³ and in all 12 in the combined series of Lausanne and Liverpool who underwent FloWatch-PAB removal at the time of intracardiac repair, there was no need for pulmonary artery reconstruction because the pulmonary artery expanded to the normal size with the simple FloWatch-PAB removal.⁵

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doi:10.1016/j.jtcvs.2005.11.026

Reply to the Editor:

We appreciate the thoughtful comments of Corno and associates¹ about our recent study. The exciting results pointing out the advantages of the FloWatch-PAB^{2,3} forced us to use this device in the case presented. Because of the localization of the ventricular septal defect in the muscular septum, increased pulmonary artery pressure and the patient's young age made us optimistic that the adjustable FloWatch banding device would be the ideal solution for this patient. For this reason, we avoided a conventional banding as suspected by the authors, and even looking thoroughly at all available intraoperative images, we are not able to visualize surgical damaging of the pulmonary artery trunk before placement of the device. After removal, the device was carefully studied for any sharp edges that might have occurred during the manufacturing process and could have been responsible for the observed pseudoaneurysm formation, which could be ruled out.

However, the early detection of pericardial effusion and the loss of the banding effect suggest some damage to the integrity of the vessel wall while the aneurysm was detected on radiography only 7 weeks later. Therefore we are confident that the patient had a real complication rather than a coincidence. We agree that the physical prop-

erties of the FloWatch-PAB, especially the maintenance of the circumferential length of the pulmonary artery, should be helpful to prevent the complications of conventional banding procedures. Our personal experience in 2 other patients with multiple ventricular septal defects, in whom we removed the device 16 and 27 months after placement, respectively, support the usefulness of this new medical implant. Nevertheless, facing even rare complications, as we described, should contribute to increase patient safety.

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doi:10.1016/j.jtcvs.2005.12.007

Evaluation of a modified ThermoWrap™ for the Allon™ warming system in patients undergoing elective off-pump coronary artery bypass grafting

To the Editor:

We have previously shown in this journal¹ that the Allon™ patient-warming system (Allon™ 2001 system; MTRE Advanced Technologies Ltd, Or-Akiva Industrial Park, Israel) is efficient in maintaining normothermia during off-pump coronary artery bypass grafting (OPCABG), resulting in reduced perioperative blood loss and transfusion requirements. However, the ThermoWrap™ used with this system is expensive, complications (ie, burns) have been described,² and handling

can be time consuming. Meanwhile, we evaluated the new version of a ThermoWrap™ for the Allon™ system in terms of handling and efficacy. In contrast to the old version of the ThermoWrap™, the design of the new wrap has been modified to improve patient care and to reduce potential skin damage, as well as costs. With institutional approval and informed consent, 40 consecutive patients (mean age $\pm$ standard deviation [SD], 68 ± 10 years; mean body mass index $\pm$ SD, $28 \pm 5 \text{ kg} \cdot \text{m}^{-2}$; mean Euroscore $\pm$ SD, 6 ± 3) undergoing elective OPCABG were randomly assigned to either the original (group A, $n = 20$) or the modified (group B, $n = 20$) ThermoWrap™. According to our previous temperature measurement study,¹ active warming was started after induction of anesthesia, with the Allon™ system set to 36.9°C body core temperature (BCT). BCT was recorded every 30 minutes during surgical intervention, and maximal intraoperative BCT decrease, as well as increase, was calculated. Skin alterations (reddening) were assessed by using a visual analog scale (score, 1-10) at the end of the procedure. During the clinical evaluation, 15 involved staff members completed a questionnaire on handling of the Allon™ system. The answers were recorded by using a Likert scale (score, 1-4). The Student *t* test was used for statistical analyses. Durations of OPCABG procedures were comparable (group A, 257 ± 59 minutes; group B, 269 ± 53 minutes; $P = .89$). There was no significant difference of BCT at the beginning and end of the intervention (Figure 1). Intraoperative BCT changes were significantly different for group A compared with group B (BCT decrease/increase: group A, $-0.7^\circ\text{C} \pm 0.4^\circ\text{C}/+1.2^\circ\text{C} \pm 0.3^\circ\text{C}$; group B, $-0.4^\circ\text{C} \pm 0.3^\circ\text{C}/+1.0^\circ\text{C} \pm 0.3^\circ\text{C}$; $P < .05$). Skin alterations were comparable for both groups (visual analog scale: group A, 6 ± 1 ; group B, 6 ± 1 ; $P = .78$). According to 80% of the interviewed staff members, positioning of the modified wrap B was superior and less time consuming compared with wrap A. On the basis of these results, patient management can be further improved by using the Allon™ system with the new modified ThermoWrap™.

This study was performed without any financial support from manufacturers or the pharmaceutical industries. The Allon™