FLOWATCH DEVICE FOR ADJUSTABLE PULMONARY ARTERY BANDING

To the Editor:

In a recent article, Di Bardino and colleagues¹ once again are stressing the importance of having an adjustable device for pulmonary artery banding available in the surgical armamentarium, particularly for the management of complex patients, such as those who require left ventricular retraining.^{2,3}

The advantages of an adjustable device for pulmonary artery banding have been proved in other categories of congenital heart defects, such as functionally univentricular hearts,³ multiple ventricular septal defects,³ and complete atrioventricular septal defects.⁴

In all the above categories, including congenital heart defects requiring left ventricular retraining, the favorable results obtained by the implantation of the adjustable FloWatch device (Leman Medical Technologies SA, Lausanne, Switzerland) have been reported.²⁻⁴

Di Bardino and colleagues,¹ recognizing that “the FloWatch device is conceptually sound,” report that the device “is not available in the United States and is not applicable to all size patients and all anatomic subtypes.”

Although it is true that the device has not received Food and Drug Administration approval, it is possible to obtain limited authorization for implantation in patients in the United States following the regulation for

Humanitarian Device Exemption, as already done for endless other medical devices with the CE mark (European equivalent to Food and Drug Administration approval).

With regard to the statement that the FloWatch device “is not applicable to all size patients and all anatomic subtypes,” a clarification is required. The implantation of a FloWatch device is generally possible even in neonates with a body weight of 2.5 kg or greater, for all types of congenital heart defects.²⁻⁵

In patients with an anterior aorta, such as those who require left ventricular retraining,^{1,2} there is the risk of potential coronary artery compression by the box of the device, by necessity positioned posteriorly to the ascending aorta to avoid device compression at the moment of sternal closure. Nevertheless, personal and reported experience proved the feasibility of this technique even in small neonates.^{2,3}

The same is true for patients with late referral for left ventricular retraining, when presenting with a large sized pulmonary artery. The FloWatch device has been successfully implanted in a patient aged 3 years with a main pulmonary artery diameter of 3.2 cm.

Finally, for patients with late referral, potentially requiring a longer period with the device in situ, the pulmonary artery can grow and remain pliable up to 14 months after the device implantation.⁵

These clarifications should be useful to expand the use of the FloWatch device, with several clinical advantages already proved by reports from different hospitals across Europe.

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PULSATILE CONTROL OF ROTARY BLOOD PUMP AND CARDIAC WORKLOAD

To the Editor:

We were greatly interested in the recent article by Pirbodaghi and colleagues,¹ in which they looked into the influence of rotary blood pump speed change in synchronization with electrocardiogram. We are pleased to know that the rotational speed change with waveform modulation and phase change is an additional method to control cardiac workload. However, several reports demonstrating similar results have been already published, although the authors did not refer to them. For example, Ando and colleagues² showed the efficacy of the pulsatile mode with increased rotational speed in the systolic phase in relation to the change in arterial pulse pressure, maximum derivative of pressure over time, and energy equivalent pulse pressure. In addition, Umeki and colleagues³ demonstrated an ability of the newly developed rotational speed control algorithm called the “native heart load control system” to control left ventricular end-diastolic volume, which was increased in the co-pulse mode and decreased in the counter-pulse mode. Furthermore, an acute

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