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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heart failure model, created by micro-embolization of the coronary artery, was used in their study, and they clearly demonstrated that the impaired cardiac function made workload control easier.

Pirbodaghi and colleagues¹ evaluated coronary flow in response to rotational speed change. However, previous studies⁴ have already reported that coronary flow is diminished as left ventricular assist device support is increased, and the increased rotational speed in the diastolic phase optimizes coronary flow. As Pirbodaghi and colleagues mentioned, the coronary arteries have an autoregulatory system that maintains optimal coronary flow according to oxygen demand. Therefore, the coronary flow with the pulsatile control system should be examined in ischemic heart models when considering practical clinical settings.

Pirbodaghi and colleagues¹ discuss that unloading of the left ventricle became a method to promote cardiac recovery. In their study, they were able to control cardiac workload by changing the rotational speed of a rotary blood pump via synchronization with the electrocardiogram. We believe that unloading is not the only method of cardiac functional recovery. In fact, excessive unloading of the left ventricle might lead to cardiac disuse atrophy.⁵ Instead, favorable work for the native heart in each phase of cardiac recovery is extremely important to obtain the best improvement of cardiac function.

In summary, we were greatly interested in Pirbodaghi and colleagues'¹ idea of rotational speed change with waveform modulation for controlling native cardiac load and hemodynamics, and look forward to these authors' further reports. However, we feel compelled to point out that the control system of the rotational speed change in synchronization with the native cardiac cycle described by Pirbodaghi and colleagues¹ is similar to previous studies²⁻⁴ and the authors are remiss in failing to mention these other articles. We also need to point out

that the impaired cardiac function model, which is very important for investigating the efficacy of this novel pump control method in actual clinical settings, may lead to different results, as shown by Umeki and colleagues.³

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Reply to the Editor:

We appreciate the comments and concerns expressed by Arakawa and colleagues regarding our article, titled "Pulsatile control of rotary blood pumps: Does the modulation waveform matter?"¹

Unfortunately, we have to disagree with Arakawa and colleagues. As is

obvious from the title of our article, it investigates the effect of different waveforms on the heart-device interaction. In contrast to the authors' claim, this is the first article in the literature that uses basic waveforms (sine, triangle, saw tooth, and rectangular) with different phase shifts to examine their impact on left ventricular unloading. The previous publications²⁻⁴ just varied the pump speed during systole and diastole, which was first reported by Bearnson and associates⁵ in 1996, and studied its effect on aortic pressure, coronary flow, and end-diastolic volume. We should mention that dp/dtmax is a load-sensitive parameter of contractility and not representative for the degree of unloading. Moreover, none of the aforementioned reports has studied mechanical unloading and in particular the stroke work of the left ventricle. Our method is unique because we do not just alternate between high and low speed but have accurate control of the waveform because of the direct drive system of Levitronix Technologies LLC (Waltham, Mass) and a custom-developed pump controller.

Without referring, Arakawa and associates state "several previous studies have already reported the coronary flow diminishes as the left ventricular assist device support increases." It should be noted that all the waveforms used in our study have 2000 rpm average value with 1000 rpm amplitude, which is not an excessive speed for the Centri-Mag rotary pump (Levitronix) to collapse the ventricle and diminish the coronary flow.

We agree with Arakawa and co-workers that there is a need for a heart failure model to come to more relevant results with respect to clinical expectations. However, we have explored many existing models, including species and breeds that have a native proneness to cardiomyopathy, but all of them differ from the genetic presentation in humans. We certainly do not believe that the use of microembolization, in which the coronary circulation is impaired by the injection of