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Commentary: Direct cardiac compression device for biventricular support: If we put lipstick on a pig, is it still a pig?

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The limitations of the currently available options for patients with end-stage heart failure are well documented. There are not enough organ donors to meet the need for patients awaiting transplant, and the complications associated with ventricular assist devices (VADs) have limited their widespread adoption. With this in mind, alternative devices that can augment cardiac output but potentially avoid these well-documented and persistent complications, such as external direct compression devices, can and should be pursued.

The concept of direct cardiac compression devices to augment the systolic function of the heart has been around for more than 50 years, and the first iterations were not even devices. In 1959, Kantrowitz and McKinnon attempted to increase cardiac output with a pedicled muscle flap from the diaphragm, which spurned interest in dynamic cardiomyoplasty with latissimus dorsi muscle flaps. The Anstadt device, first described in the 1960s for cardiopulmonary resuscitation, was an elliptically shaped cup that would fit over the right and left ventricle. A pulsatile pneumatic driver would deliver pulsed pressure via the inflatable inner diaphragm. The limited technology at the time did not allow synchronous compressions to be delivered and instead the device would work asynchronously with the cardiac cycle at a fixed rate. This particular device never became clinically relevant, and the limitations of cardiomyoplasty have been well documented.

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CENTRAL MESSAGE

It is too early to know if direct compression cardiac devices can be applied in the clinical setting.

A newer, more advanced device, called the CardioSupport System (Cardio Technologies, Inc) was another “cuff-like” structure designed to be placed on the epicardial surface of the heart at the level of the atrioventricular groove. The device was fixated to the apex of the heart by application of negative pressure. The inner surface of the vacuum seal was fitted with 2 meshed electrode bands to detect the electrocardiogram and provide synchronous compression with the cardiac cycle primarily with the compressions primarily applied at the base of the ventricles to provide biventricular support. As far as we know, this company is no longer in existence.

Another similar concept, The Heart Booster (Abiomed, Inc) incorporated several parallel individual compression tubes added serially to cover both ventricles around the base of the ventricles. The device was to be secured to the epicardium with “surgical adhesives.” The design involved serial compression to be delivered by a hydraulic pump delivering fluid to drive the cuffs. The whereabouts of this device are probably lost somewhere in the archives of the United States Patent and Trademark office, not unlike so many other similar devices based on these concepts.

In this issue of the *Journal*, Schueler and colleagues¹ report another embodiment of a direct cardiac compression device. So why is such a concept so attractive? The appeal of the concept of external compression is well delineated in the manuscript and is the primary reason why interest in this type of technology is still present. Despite the success of the current iterations of VADs, several imitations remain. While the term “hemocompatibility” is used to describe the newer generation of pumps, stroke, pump thrombosis, and gastrointestinal bleeding remain common

complications associated with left VAD technology. Avoidance of blood contact would presumably reduce these complications. Furthermore, the true impact of lack of pulsatility with continuous-flow pump has yet to be defined. Quite possibly gastrointestinal bleeding and hemorrhagic stroke may be related to microcirculatory dysregulation from lack of pulsatile flow. An external compression device with no blood-contacting surface that allows for a pulse may mitigate the risk of these complications. Finally, the significant lingering problem of early or delayed right ventricular dysfunction, which limits the full potential benefit of current left VADs, provides significant challenges for the treatment and management of a substantial portion of patients with end-stage heart failure. A properly designed direct cardiac compression device may be an option for patients with biventricular failure, and it may prevent the development of right ventricular failure in those who have primarily left-sided failure to begin with. Experimental data have clearly demonstrated that timed systolic compression of the heart augments the net ventricular pumping capacity by adding to the contraction generated by myocardial work. Under these circumstances, the pressure inside the ventricular cavity becomes the sum of the pressure generated by the myocardium (transmural pressure) plus the pressure generated by the direct compression of the epicardium. Despite systolic augmentation, the impact of these devices on diastolic filling is negligible and, certainly, if the timing is off relative to ventricular diastole, the device will interfere with proper diastolic filling.

Despite these theoretical advantages, to date there have been no clinically applicable devices for use as direct cardiac compression. The reason for that has always been

that the theoretical advantages have not aligned with the physiological pumping of the heart. The reBEAT device described here represents significant technological advancements over what has been previously available. For one, the device shape is individualized and molded to the shape of each heart using a 3-dimensional reconstructed image from computed tomography scans. This certainly is advantageous, as it removes the constraint of one-size-fits-all and may obviate some of the problems with previous generations of devices which interfered with diastolic filling. Second, it is designed with a sophisticated electrocardiogram sensing system and algorithm that can time the cycle of the compression/decompression to that of the heart better than any previous device. The ability to deploy and secure this device via a minimally invasive technique is also intriguing. The acute experimental data provided are convincing that direct compression works but there is no novelty to that as all previous devices have been successful in that setting. They have also provided 30-day data on two pigs that is limited but with good results. Extending these early experimental results from a normal-sized heart in a pig model to the human with heart failure and all the associated anatomical and physiological concerns, such as pulmonary hypertension, is very different from reality. Whether this novel device will be beneficial to patients with advanced end-stage heart failure in the real clinical setting remains to be seen. Is this device really a significant advance, or just a pig with lipstick on?

Reference

1. Schueler S, Bowles CT, Hinkel R, et al. A novel intra-pericardial pulsatile device, reBEAT, for individualized, biventricular circulatory support without direct blood contact. *J Thorac Cardiovasc Surg.* XXX, 2021 [Epub ahead of print].