Partial Mechanical Cardiac Support

Part of the Solution or Part of the Problem?

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Intuitively it makes sense that providing a significant portion of the cardiac output while unloading the ventricle will improve the patient’s hemodynamic status, clinical condition, and quality of life. This is particularly true for patients with milder forms of heart failure. But for those with truly advanced end-stage disease and cardiogenic shock, total cardiac support is typically required. The pragmatic issue is: how does one provide partial cardiac support that is effective, safe, and ideally performed with a minimally invasive procedure?

In this issue of the Journal, Meyns et al. (1) report on the long-term partial support with the Synergy Pocket Micropump (CircuLite, Inc., Saddle Brook, New Jersey) and have taken an important step in that direction (1). The operation uses a minimally invasive incision below the right clavicle that allows for pump outflow to the axillary artery (a cannulation technique that is becoming increasingly familiar to cardiac surgeons as we deal with complex aortic pathology) and provides pump inflow through a more difficult access approach, across the chest and through Waterston’s groove into the left atrium. This seems to be a significant improvement compared with routine left ventricular assist device (LVAD) implants performed through a full sternotomy, including a large pocket below the heart in the upper abdomen for the pump itself. This new, small pump will sit roughly where a right-side pacemaker would be placed. Patients chosen for this implant were generally not as sick as most patients undergoing LVAD implants. Fifteen of the 17 patients were INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) class IV (recent hospital stays for heart failure). In contrast, INTERMACS class I or II (cardiogenic shock or progressive decline despite inotropes), as reported from the INTERMACS registry, account for 80% of recent LVAD implants (2). Partial support in this less-sick group of patients seems to accomplish the hemodynamic effectiveness goals. There was a significant improvement in cardiac index (2.0 ± 0.4 l/min/m² increased to 2.8 ± 0.6 l/min/m², \( p = 0.01 \)) with significant improvement in pulmonary artery diastolic pressure and pulmonary capillary wedge pressure documented in later follow-up. Hemolysis was only detected in 1 patient. Clinical outcomes were generally good, with 1 patient requiring conversion to a different biventricular assist device system, and 3 patient deaths. One death was due to sepsis from an unrecognized pre-existing renal abscess; 1 from sepsis of unknown origin; and 1 death occurred when a patient discontinued his anticoagulation, developed pump thrombosis, and subsequently had an embolization during an explant of the device. The subset of patients who had peak oxygen uptake measured showed a substantial improvement (increasing by mean of 4.5 ± 2.0 ml/kg/min), which would be clinically meaningful, and the B-type natriuretic peptide dropped precipitously and was reduced by 4,475 ± 1,389 pg/ml.

However, partial support might have only been a partial solution. The peak oxygen uptake, although significantly higher, was still very low (14.1 ± 1.6 ml/kg/min) and at a level where patients could still qualify as transplant candidates. This might, however, reflect overall deconditioning and perhaps would improve with more time. Also, although the B-type natriuretic peptide levels plummeted, they were still extremely elevated with a value of 2,381 ± 675 pg/ml. Historically, there have been 3 major problems with chronic mechanical circulatory support: strokes or other embolic events, mechanical device failure, and infection (3). Although the authors report pocket hematomas, it does not seem that infection around the device or drive line infection has been a serious issue in this small, early experience. They had to increase the target international normalized ratio level because of pump thrombosis, which would lead to potential embolic events.

Most concerning is that 8 of the first 12 patients required pump exchange because of pump thrombosis. Fortunately, it is a much simpler operation to replace this pump than changing many of the other LVADs. The authors describe the procedure as lasting only 30 to 60 min. Also, fortunately, they were able to identify design problems regarding the wash-out channel within the pump rotor. The pump was modified after stopping the clinical trial and performing bench testing, and then they re-released a new pump with enhanced washing within the rotor and a new target international normalized ratio. With the new design and anticoagulation strategy, they have not had further episodes of pump thrombosis with 9 implants with a duration of
support of almost 4 months. However, it is a relatively short duration of support, and their longest duration is only 7 months in this article. One concern regarding partial support has been that pumps might be more liable to develop pump thrombosis at low flow. Unfortunately, this experience has not done anything to allay that concern.

In summary, we are embarking on a new phase of mechanical circulatory support when using small, less-invasive pumps for partial support in patients who are not nearly as sick as those we have historically treated. There are many encouraging signs in this experience such as the improvement in hemodynamic status, and this is the “proof of concept” (1). There are some signs that this might be a partial solution and that patients improved but, at least from some objective early measurements, were still far from normal. There is some concern that we might be creating a problem with pump thrombosis is becoming a more frequent occurrence than we see otherwise with pumps flowing at 5 to 8 l/min. Despite these risks, the authors have achieved good clinical outcomes similar to what we frequently see with the bridge to transplantation (2). When designing a clinical trial for the Food and Drug Administration, all of these considerations will be extremely important. To justify use in earlier-stage heart failure patients, it will be very important to have a strong safety profile with hemodynamic improvement that translates into improved clinical condition. The authors should be congratulated on this innovative work, and we eagerly anticipate more news.

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