Current Trends

With the introduction of continuous flow (CF) devices, mechanical circulatory support (MCS) volumes have been rapidly growing worldwide. There also has been a trend toward earlier patient referral for MCS, with a 65% reduction in INTERMACS profile 1 patients being implanted over the past 5 years. Device intention at implant has become increasingly hazy, with 40% of patients having an indeterminate strategy at implantation. Nevertheless, it has been destination therapy with CF devices which has driven most of the growth in implants. Outcomes continue to improve in the LVAD patients, with an overall 1-year survival between 80 and 90% with the CF pumps.1,2

Update on Devices in Trials

In the U.S., the HeartWare HVAD was approved by a vote of 9 to 2 as BTT by the FDA Circulatory Systems Device Advisory Committee. The FDA is still in the process of finalizing the review of the PMA. In addition, HeartWare has completed a 450-patient enrollment for ENDURANCE, its prospective, randomized DT trial.

Newer miniaturized products, such as the Circulite Synergy, are being developed which are implanted off-bypass and via less invasive operative approaches. The Synergy device is presently undergoing CE Mark Trials in Europe.

Emerging Surgical Issues

As long-term survival continues to improve, increasing focus has been placed on early and late complications that have important ramifications for intraoperative and postoperative management, such as aortic insufficiency (AI), RV dysfunction and TR, and driveline infection.

An area of continuing controversy is how to manage AI intraoperatively and postoperatively. In patients with significant AI recognized intraoperatively, most clinicians agree that the aortic valve should be addressed in some fashion. Goda et al. demonstrated that aortic valve procedures can be performed at the time of VAD implantation with acceptable results.3 However, which procedure should be performed is more controversial. Options range from central coaptation (Park’s stitch) to complete valve closure to aortic valve replacement with a tissue valve.

Late de novo AI after VAD implantation is a worrisome development. In a study by Toda et al, patients who develop late AI have a worse overall prognosis.4 Two postoperative factors were associated with the development of AI in this study: >2+ MR and no aortic valve opening at 1 month. Moreover, failure of the aortic valve to open at least intermittently while on MCS is considered a risk factor for the development of aortic root thrombus and
gastrointestinal arteriovenous malformations. Therefore, many centers have been striving to maintain intermittent aortic valve opening in their LVAD patients. For late AI, interesting emerging options include percutaneous closure or TAVI.

RV dysfunction remains a difficult predicament confronting the MCS field. According to INTERMACS, the need for an RVAD in DT patients yields a 50% mortality rate at three months. To minimize RV dysfunction, it is critical to both appropriately select patients and optimize RV function perioperatively. For those patients requiring permanent biventricular support, options include pulsatile paracorporeal PVAD BiVADS or the TAH. However, small series using an HVAD for RV support have now been reported. Krabatsch et al (2011) have reported using the HVAD either as an RVAD or in a BIVAD configuration. However, implantation of the HVAD on the right side may require modifications to the outflow graft diameter. Lastly, percutaneous RVADs are under development which will allow a less invasive means to support the right ventricle in the near future.

Related to the topic of RV dysfunction, correction of TR at the time of LVAD implantation is a continuing area on controversy. Piacentino et al found that patients with significant TR at LVAD implantation had a higher incidence of concomitant RVAD requirement, prolonged inotropic infusions, prolonged hospital stay, and worse survival. The same group, in a separate publication, showed that tricuspid valve procedures to address significant TR at the time of LVAD implantation improved overall survival. However, a study from Northwestern University could not demonstrate any clinical benefit from concomitant TVR. Furthermore, Maltais and colleagues demonstrated a more than four-fold increase in mortality in patients undergoing concomitant TVR during LVAD implantation. A group from Berlin showed similar survival in patients undergoing concomitant TVR at time of LVAD implantation as compared to primary BIVAD patients. Overall, it seems that the presence of severe TR is a marker for high risk, likely due to pulmonary hypertension and RV dysfunction, however which patients may benefit from such a procedure remains unclear.

Patients remain at risk for driveline infections throughout the duration of support, but with longer support times and patients implanted as destination therapy, there has been an increasing focus on mitigating this risk. Over the past year newer surgical approaches have been reported which try to address this challenge by changing the way the driveline exits the body. Instead of the having some of the velour exposed, several centers have adopted varied approaches that completely incorporate the velour portion of the driveline in the abdominal wall and ensure that the portion of the driveline that exits the skin is the silastic portion. Theoretically, the silastic portion allows an epithelialized track to form along the driveline. This would theoretically minimize the tissue disruption that occurs when velour-covered exit sites are exposed to torqueing or bending forces. Preliminary data from this change in driveline exit strategy appears to be promising in decreasing the incidence of infections but more long-term data is needed.

**Improving Cost Effectiveness**

As the world economies deal with increasing healthcare costs in a challenging economic environment, it behooves the MCS community to demonstrate the cost-effectiveness of VAD therapy. Several publications have examined this issue, the most recent of which was published this year by Rogers et al. Comparing the cost-effectiveness data derived from the REMATCH trial to that of the HeartMate II DT trial, Rogers and colleagues showed a substantial
improvement in cost-effectiveness. In present value dollars, the cost-effectiveness of DT has improved by 85%. Although the cost-effectiveness remains higher than the conventional threshold of $50-100K cost per QALY, the large improvement seen over a 7 year interval holds further promise for improving future cost-effectiveness.

What’s Next?

As outcomes continue to improve, emphasis will be placed on ameliorating the long-term morbidities of VAD therapy. Perhaps foremost among these will be efforts to create a totally implantable VAD with the help of transcutaneous energy transfer (TET) technology. It is clear that technological improvements will be necessary to allow the safe transmission of energy across the skin and to improve the capacitance of the charge so that less frequent charging episodes will be required. Two competing technologies—coil transfer and wireless electricity (witricity)—are under development by different companies.

Efforts at miniaturization of VAD technology will continue, with the hope that VADs will be a viable option in the pediatric population as well as in the earlier class III HF patients. The REVIVE-IT trial is expected to begin enrolling soon. This multicenter trial will randomize patients with heart failure who are less sick to destination therapy with an HVAD versus optimal medical management. The ROADMAP is a multicenter nonrandomized observational trial of outcomes with a HeartMate II as destination therapy in an approved, but still less sick population, INTEMACS profiles 4-6.

Disclosure Statement: The authors have no conflicts of interest to report.

References: