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The Evolving Role of Ventricular Assist Device Support in Adolescents with End-Stage Dilated Cardiomyopathy

Over the past two decades, there have been incredible advances in the application of ventricular assist device (VAD) support for children with end stage heart failure. Many of us have witnessed this evolution firsthand, and I will briefly share some illustrative experiences.

Fifteen years ago, recently graduated from fellowship and immersed in an on-the-job apprenticeship in pediatric heart transplantation under Drs. Jim Kirklin and Bennett Pearce, I admitted a 9-year old girl with a new diagnosis of severe dilated cardiomyopathy. Incredibly enough, having just wheeled into the unit, this little girl suffered a devastating left MCA occlusive stroke right before my eyes. Remarkably, she was in the best possible place to have a stroke — a full-service pediatric heart center embedded in a tertiary adult hospital. Within two hours, she had complete neuro-interventional recanalization and was left with mild, almost imperceptible, right arm deficits. Despite her neurologic recovery, she remained too unstable on inotropic therapy, and our team worried how she would wait for an organ match. At that time, the use of VADs in pediatric patients was still a burgeoning field. Most of the experience had been extrapolated from adult patients and older adolescents, with only scattered case reports and small series available from a handful of institutions. The Berlin Heart Excor pediatric trial had been completed, but we remained concerned about the risk of intracranial hemorrhage associated with that device in that era. After careful consideration, we elected to implant a HeartWare VAD as a bridge to transplant.[1]

A decade later, now an experienced heart transplant attending, I evaluated two additional candidates for transplantation. Both had new diagnoses of severe dilated cardiomyopathy. One was a 16 year old girl with multisystem organ failure, BMI > 40 kg/m^2 and a tumultuous home environment and social support structure. The other was a 15 year old boy with an intensely managed salt-wasting renal disorder. The care team weighed the pros and cons of transplant and VAD support. Both patients ultimately underwent placement of HeartMate 3 (HM3) left VAD.

These three cases illustrate a fundamental shift in how we think about mechanical circulatory support – from VADs as reluctant short-term bridges to their emerging role as a deliberate, longer-term therapeutic strategy. In just over a decade, the medical literature documenting the use of these devices has evolved from single case reports and small case series to more recent multi-institutional registry reports. These studies remain small compared with the adult experience, where larger trials have provided much of the evidence informing longer-term expectations.

Thinking about the two more recent teenage patients on HM3 support, I was often asked in the ensuing months when they would be waitlisted. Having seen adolescents and young adults struggle with medication compliance and suffer rejection and death, I wondered if we were justified in maintaining long-term VAD support. In these two particular patients with their unique circumstances, would extending VAD support provide a survival benefit over proceeding with transplantation? All other things being equal, wouldn't transplanting someone at 23 instead of 16 lead to a longer life – especially if they could better care for their transplant medical condition as an adult? I could not find helpful pediatric data at the time, though adult data was promising. On the transplant side, I questioned whether pediatric registry studies accurately capture long term outcomes as some single center studies focused on transition reveal worrying mortality rates.[2,3]

With these uncertainties in mind, I embarked on a combined PHTS and PediMACs analysis with Dr. David Morales. We were ultimately joined by an excellent group of co-authors from the two registries. The results of this analysis Comparing Outcomes of HeartMate 3 and Heart Transplantation in Older Children with Dilated Cardiomyopathy – Can Transplantation Be Delayed or Avoided? are published in the latest issue of Pediatric Transplantation.[4] Briefly, we found excellent 3 year survival in both groups and a very low incidence of bleeding, stroke, and device malfunction in the HM3 group. Unfortunately, our analysis was quite limited by the high rate of HM3 patients undergoing transplantation by one year after device placement, and this rate of transplantation did not decrease over the study era (2018 to 2022). Future registry or multicenter analyses with more complete follow-up and more recent data would be very informative and represent an excellent opportunity for investigators in this space.

I believe that the decision to place a VAD or offer transplantation to an adolescent patient with dilated cardiomyopathy should be individualized based on expected patient survival with either of these strategies. Late adolescence into early adulthood is a well-established period of increased risk for heart transplant recipients, driven by biological susceptibility to rejection, medication nonadherence, and vulnerability during the pediatric-to-adult care transition. While many patients will have a more favorable expected outlook with transplantation, there will certainly be some patients whose medical and social support factors raise the question of how successful they will be managing their new transplanted organ. In these patients, clinicians should certainly consider the role of VAD support, weighing the potential cumulative risks long term. Current iteration of devices offer good long term outcomes but still have important complications and patient desirability factors including an externalized drive line. However, just as devices have evolved greatly over the past generation, so too do they have the potential to continue evolving and improving. In my view, the ultimate goal of mechanical support would be a VAD that has real-world long term survival outcomes greater than transplantation without jeopardizing transplant candidacy (i.e. sensitization) and with patient desirability at least as good as or better than transplantation. The patient desirability would come from improvements in internalization of the power source and continued low risk of bleeding and stroke with a simpler anticoagulation regimen. (For further reading on the future prospects of LVAD evolution, the reader is pointed to a review article by Kanwar et al in the latest issue of the *Journal of Heart and Lung Transplantation*.[5] Once we arrive at that point in our field, then clinicians and patients may willingly prefer device support over transplantation, leaving the latter to some future time where device support can no longer be continued. As my co-author Dr. Morales has proposed, sequential use of device therapy and then transplantation has the potential to improve overall net survival for patients compared to transplantation alone as an initial step. This sequential strategy would also come with the side benefit of increasing the supply of donor hearts for patients who are not optimal LVAD candidates.

Further research to evaluate the role of longer-term VAD support in adolescents with cardiomyopathy should be a priority for our field. Survival represents only one component of treatment success; however, pediatric HM3 research to date has not addressed other important factors. Patient-reported outcomes, psychosocial development, functional status, and quality of life are well studied in adults, where significant challenges have been documented; the absence of comparable data in adolescents is a notable gap. The impact of long-term VAD support on subsequent transplant outcomes requires further study. Likewise, healthcare resource utilization and cost-effectiveness will become increasingly relevant as our community adopts longer-term VAD support. Importantly, all of these questions are discussed in the context of biventricular hearts and can not necessarily be extrapolated to our single ventricle patients who will have their own unique medical factors. Our analysis was not designed to address these additional considerations.

Finally, future changes in pediatric heart allocation policy could inadvertently accelerate this evolution. Excellent outcomes with improving VADs raise the question of whether these patients merit status 1A listing priority. Lower waitlist priority for stable VAD patients would lead to longer support times, providing the very evidence needed to establish durable VAD therapy as a viable longer-term strategy.

We are fortunate to have been involved in remarkable progress in pediatric VAD support and great improvement in outcomes of patients with end-stage heart failure. Revisiting the three patients I mentioned above is worthwhile. Fifteen years after overcoming two potentially fatal new diagnoses on the same day, that 9-year old girl, originally bridged to transplant with a HeartWare VAD, got married – with Dr. Kirklin in attendance. She is wonderful example of how a VAD can safely bridge a child to transplantation, allowing time for recovery, rehabilitation, and optimization before transplant. The teenagers who required HM3 support are doing well. The young lady is now 4 years on her device, achieving weight loss success and working towards transplant candidacy. The young man is now 3 years on his device and doing quite well with no stated interest in transplantation. Both patients have transitioned to the adult VAD program. These children illustrate the evolving role of VAD support in the individualized decision-making surrounding end-stage heart failure. I look forward to the next fifteen years of innovation in VAD technology and the new opportunities these advances will create to individualize therapy, improving and prolonging the lives of children with end-stage heart failure.

References

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