Ventricular assist devices for all?

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In the past 5 years, the numbers of ventricular assist device (VAD) systems implanted worldwide have increased exponentially. Thus, since the introduction of the HeartMate II LVAD by Thoratec (Thoratec Inc., Pleasanton, CA, USA) over 10,000 of these pumps have been implanted. The HVAD manufactured by HeartWare (HeartWare Inc., Framingham, MA, USA) has also found widespread application in Europe, and particularly in Germany, before it has even been approved for the US market.

The driving force behind the spread of this form of treatment for terminal heart failure was, in the first place, not only the increasingly good results found in studies, but also the results achieved in broad clinical routine with the application of these systems, which have been further developed since VAD use began. The 6-month survival in bridge-to-transplant patients, for example, rose to 93% [1], whereas in 2008 a rate of 82% was reported [2].

Several factors have contributed to this improvement in the results. The systems are easier to implant than their predecessors and are relatively easy to exchange in an emergency and, in the case of HeartMate II, the postoperative anticoagulation can be less intensive and less specific. In addition, many institutions have gained sound experience with the application of VADs, so that their expertise has increased.

Nevertheless, heart transplantation (HTx) is still regarded as the gold standard in the surgical treatment of terminal heart failure. Whether this is still justified in the year 2012 in Europe, and especially in Germany, needs to be seriously questioned.

HTx carries, in addition to the need for immunosuppression, two fundamental and significant disadvantages: on the one hand, far too few donor hearts become available to offer transplantation to even the patients with the most urgent indication, and, on the other hand, far more patients die on the waiting list for a HTx than is generally assumed. The pre-eminent role of HTx in the treatment of terminal heart failure is often based on results that are deemed excellent. But how good are these results really? It is true that the long-term results after HTx, with a survival rate of almost 50% after 15 years and >20% after 20 years, are unbeatable [3]. However, when assessing these figures, it is generally overlooked that during the waiting time for a donor organ, which in Germany is on average over 1 year [4], ~20–30% of the patients die [5, 6]. In addition, increasingly liberal donor criteria have led to a mortality rate in the first year after HTx in Europe of over 22% [7].

Ultimately, the pronounced scarcity of donor organs poses a serious ethical dilemma for us doctors: each year almost 800 patients in Germany are added to the waiting list for HTx but fewer than half of them have any hope of receiving an organ.

Therefore, it seems to be time to give thought to alternatives to our current practice.

Should we perhaps declare LVAD implantation to be the primary therapy for terminal heart failure? This treatment is always available and is suitable for ~90% of the patients so far considered candidates for transplantation (around 10% of the patients, in our experience, need bi-VAD implantation for a variety of reasons).

If one adds the reported 1-year mortality rate for HTx of 22% to the mortality on the HTx waiting list of ~20–30% in the first year and compares these figures with the current survival rates after LVAD implantation, there is scarcely a difference, at least for the first 3–5 years. Changing the treatment strategy as described above would, however, tend to improve the results after VAD implantation in comparison with today’s situation, since currently patients are all selected for VAD implantation when their condition is such that they would not survive the time on the HTx waiting list. In some cases, advanced organ damage due to manifest heart failure existing for many years then leads to an elevated risk of mortality after LVAD implantation.

Such a change in treatment strategy would probably lead to twice as many VAD implantations being performed in Germany every year.

Subsequently, the patients could live for as long as possible with the LVAD. Failures of the VAD pumps or (rare) pump thromboses could be treated in the long-term course by surgical pump exchanges. If, after years of VAD treatment, complications such as recurrent cable or even systemic infection or secondary right-sided heart failure occur, HTx could be regarded as a ‘bail-out’ solution. This would, however, probably apply to only a small percentage of patients.

Now, no one can seriously expect that a switch from the current practice to the ‘new’ strategy will take place simply in view of these considerations. However, we believe that the time has come to compare the two approaches in a prospective, randomized study. This will not be methodologically straightforward, since most centres that offer both forms of therapy are linked with each other via the common allocation system (Eurotransplant). If some centres were suddenly to perform primarily LVAD implantations instead of placing patients on the
waiting list for HTx, the remaining transplantation centres would probably transplant the ‘surplus’ organs, so that there might be too few organs available for HTx in patients with life-threatening complications on a VAD.

Our aim is, however, to kick off the discussion on how such studies could be performed. Possibly they could be supported by our national or European specialist societies.

REFERENCES


