The Actual Role of Cardiocirculatory Assistance in Heart-Failure Treatment as Destination Therapy and Bridge to Life

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KEYWORDS

• End-stage heart failure • Ventricular assist devices • Heart transplantation • Destination therapy • Bridge to transplantation • Bridge to recovery • Bridge to life

KEY POINTS

- Heart transplantation is the gold-standard treatment with a mismatched offer-demand ratio.
- The REMATCH study demonstrated that first-generation pulsatile implantable devices, though burdened with a high rate of complications (infectious and thromboembolic events), allowed an improvement of quality and duration of life when compared with medical therapy alone. The subsequent evolution of ventricular assist device technology has reduced device-related complications, thereby improving survival and quality of life of patients. According to some investigators, 2-year survival has now achieved results comparable with those of cardiac transplantation.
- One of the main advancements in long-term mechanical support has been the advent of continuous-flow rotary pumps; being smaller, more reliable, and totally implantable, they represent the best compromise for long-term assistance with adequate quality of life (destination therapy/bridge to life).
- Further studies are needed to confirm initial data and to lay the foundations of this new therapeutic frontier.

INTRODUCTION

End-stage heart failure may present as the terminal stage of a chronic heart disease or as an acute event. In the latter scenario, the indication for mechanical support depends on the assessment of the potential of recovery of the cardiac function and on the patient's eligibility to transplantation or definitive mechanical assistance. In such a setting, dedicated guidelines could help in performing a rapid assessment of the clinical status and in providing the best therapeutic options. End-stage chronic heart failure, on the other hand, requires an even more complex therapeutic procedure. These patients have poor prognosis and quality of life, with symptoms at rest, frequent hospitalizations, and complex, difficult-to-manage medical treatments. Mortality rate at 1 year is approximately 50%.[1,2] The key treatment is heart transplantation. Other therapeutic options, both medical and

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surgical, affect prognosis and quality of life only marginally.[3,4] The introduction of second-generation and third-generation left ventricular assist devices (LVADs) guarantees operational reliability for longer periods, small footprint, and an excellent quality of life, thus widening the treatment options.[5–7] Patients who have contraindications to transplantation can receive these new "artificial ventricles" to realize a "destination therapy" and a "bridge to life."

Patients awaiting a heart largely exceed the number of available organs worldwide. Even extending the pool of potential donors to older subjects does not appear sufficient to increase the actual availability of transplantable hearts.[3] In Tuscany, for example, for every million inhabitants, only 4.6 hearts are implanted of 32.6 available, mostly because of the high average age of the donors (63 years) and the high rate of death from cardiovascular causes (**Fig. 1**).[8] Moreover, transplanted hearts are not immune to complications, as is evident from the data register collected by the International Society of Heart and Lung Transplantation (ISLHT) (**Tables 1** and **2**).[9]

The possibility of replacing human organs with artificial ones has stimulated medical research since the beginning of the twentieth century. In the 1960s, with the advent of the heart-lung machine and the increased number of complex cardiac interventions, the development of systems for ventricular assistance experienced a boost In 1963, DeBakey implanted the first intrathoracic pump in a 42-year-old man who was in postcardiotomy cardiogenic shock following aortic valve replacement. For many years, few improvements and poor results restricted the implantation of these devices to a few selected centers. In the pioneering age, scarce biocompatibility appeared to be the major problem (**Box 1**). Technological advancements resolved most of the issues, so that new devices were designed and marketed for clinical use.

CARDIOVASCULAR SUPPORT DEVICES WITH PULSATILE-FLOW PUMPS

First-generation pumps were designed to provide a pulsatile flow, mimicking the physiology of the human heart. The blood volume was moved by means of a pneumatic system driven by a compressor; a reservoir chamber and unidirectional valves were needed.

Pulsatile pumps were initially used in extracorporeal systems, in which both the pump and the source of energy were placed outside of the patient's body. The artificial ventricles were connected by means of cannulas positioned in the peripheral or central vessels and were able to provide left, right, or biventricular support, depending on clinical needs. Assistance could last for a relatively short period (up to a few weeks). These devices were burdened by a high rate of complications and required the patient to stay in bed at all times.

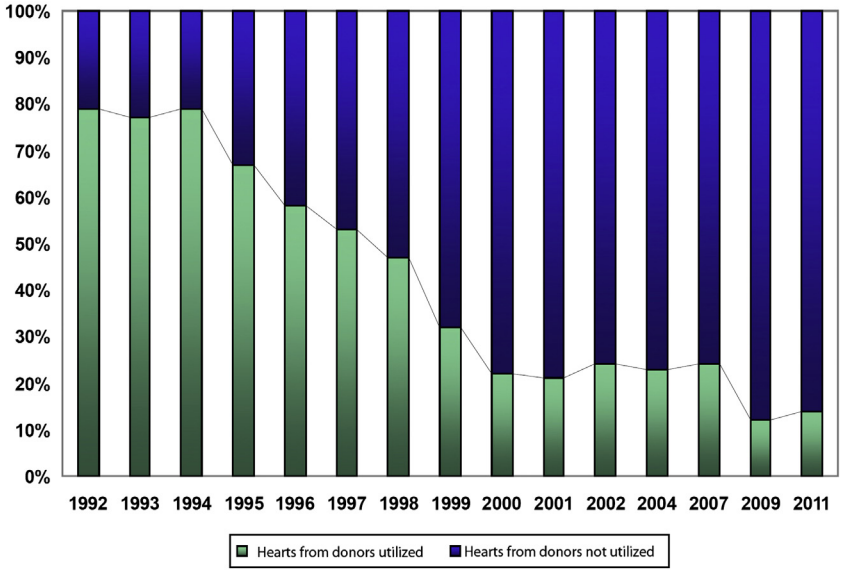

Fig. 1. "Useful heart donations," Tuscany, Italy, 1992 to 2011. As can be seen from the graph, heart donors shifted from almost 80% in 1992 to just over 10% in 2011, as a result of substantial changes in the characteristics of the donor population, in particular age-donor media, which increased from 48.7 years (1999) to 63 years (2011); vascular cause of death rose from 30% (1994) to 78% (2011). (*Data from* AIRT 2012 report data. Available at: www.AIRT.it.)