Rotary Blood Pumps as Long-Term Mechanical Circulatory Support: A Review of a 15-Year Berlin Experience

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This article reports our 15-year single-center experience with rotary blood pumps (RBPs) as long-term mechanical circulatory support (MCS) with emphasis on outcomes. For more than 15-year period, we have used various RBPs as bridge to transplantation or to myocardial recovery. Our group performed the first human implantation worldwide of RBCs, the MicroMed DeBakey ventricular assist device in November 1998 in a patient with end-stage heart failure who was supported for 47 days until his death. Based on this initial experience, we recognized the feasibility of providing long-term support and since then it has been our primary armamentarium in treating patients with heart failure. Between 1987 and September 2013, we have implanted 2208 ventricular assist devices ranging from pulsatile to continuous-flow systems, as short-term, long-term, or permanent support in patients with end-stage heart failure. In total, 1009 RBPs were implanted on 908 patients, and their outcomes are reported here. We have shared some milestones in MCS including the first implantation of Jarvik 2000 on the oldest patient (81-year old) in 2008 and the first worldwide implantation of a biventricular HeartWare. Over time, implantation techniques, anticoagulation, and postoperative care have been modified and individualized. A relevant aspect of our experience has been the incidence of pump thrombosis. This is particularly frustrating because the problem has occurred in the setting of full anticoagulation and antiplatelet therapy, guided by strict anticoagulation monitoring. It has become clear to us that the devices are still not perfect. Technical pump failures such as cable breaks also occur, prompting urgent pump exchange, and infection. A 15-year cumulative mortality rate is 46.9%. This report emphasizes that MCS with RBPs has evolved into a routine treatment in heart failure and is a highly feasible option for permanent therapy particularly for elderly patients.

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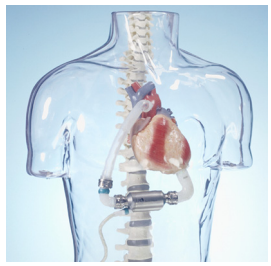

A rotary blood pump for long-term or permanent mechanical circulatory support.

Central Message

Rotary blood pumps have been introduced as bridge-to-transplant and as permanent circulatory support. They have become an important progress in cardiac care medicine.

Perspective Statement

Rotary blood pumps have evolved into a routine treatment in heart failure and are a feasible option for permanent therapy in elderly patients. These findings should stimulate the development of smaller pumps with more durable components, simple to implant or exchange, thrombus minimization by optimal interior pump design, continuous flow-pulse modulation, demand-based pump activity, safe automatic system monitoring, non–skin-breaking energy supply to minimize infection, and simple handling for patients.

See Editorial Commentary pages 24–25.

INTRODUCTION

Mechanical circulatory support (MCS) as a bridge to transplantation was successfully introduced in Berlin in 1987.[1,2] The ensuing routine use of assist devices to keep patients alive until transplantation facilitated the way for their clinical use as a valid treatment for end-stage heart failure. In view of the ever-increasing shortage of donor organs, these devices evolved as an essential treatment option, with many patients receiving permanent assist devices and fewer receiving heart transplants. A revolution in the development of ventricular assist devices (VAD) began in 1988, when the first rotary pump, known as the Hemopump, designed and developed by Wampler, was

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used as a circulatory support in patients experiencing cardiogenic shock.[3] This is a catheter-mounted VAD for short-term support. In contrast to electromechanical and pneumatic VADs, which pumped blood using positive-displacement methods providing a pulse-mimicking action of the native heart, the Hemopump pumped blood continuously. Eventually, these devices were termed rotary or continuous-flow VADs. Use of the Hemopump did not cause hemolysis or damage to other formed blood elements despite the high number of revolutions per minute at which it was operated. This finding led the MCS researchers to focus on the development of continuous-flow VADs in the late 1980s. The advantages of rotary blood pumps (RBPs) over implantable pulsatile and extracorporeal devices are that they are silent, small, and implanted with less trauma, allowing patients to lead a fairly uncompromised life. The first human implantation worldwide of a long-term RBP, the Micromed DeBakey I, was performed in Berlin on November 11, 1998,[4] in a patient with end-stage heart failure, and he was supported for 47 days until his death. Based on this initial experience, we recognized long-term support as feasible, and since then it has been our primary armamentarium in treating patients with heart failure. For more than 15-year period, we have used various RBPs as bridge to transplantation or to myocardial recovery. Our initial primary concern was the side effects of continuous-flow systems on organ functions in humans (ie, cerebral function, memory, and circulatory regulation). However, we discovered that there were no discernible adverse effects of continuous flow early after implantation; hence, we were prompted to continue. Over the years, technical problems appeared, such as pump stop, thrombotic problems related to inflow cannulae, the latter mostly because the area surrounding the apical cannula inside the ventricle is thrombogenic, and disappeared when improvements had been made. Likewise, we have learned that bleeding is not only due to anticoagulation but also due to a physiological consequence of continuous flow.

This article reviews a 15-year Berlin experience on RBPs as long-term or permanent MCS with emphasis on outcomes.

PATIENTS, DEVICE SELECTION, AND IMPLANTATION TECHNIQUES

Patients

At the Deutsches Herzzentrum Berlin, 2208 VADs ranging from pulsatile to continuous-flow systems, as short-term, long-term, or permanent support in patients with end-stage heart failure, were implanted between 1987 and 2013. There were 1009 RBPs implanted in 908 patients. Etiologies of heart failure for which VADs were implanted were acute myocardial infarction, ischemic cardiomyopathy, dilated cardiomyopathy, postcardiotomy cardiac failure, graft failure, VAD failure, end-stage congenital heart disease (CHD), and intractable arrhythmia (Table 1).

Mean age of patients in this series was 54.5 ± 12.9 (median = 57, range: 5-82) years. Age-stratified distribution is described in Table 1.

Our policy has not changed over time. We do not select patients for VAD implantation—whether elderly, in cardiogenic shock, or in profound heart failure. We believe it is ethically questionable to exclude patients from life-saving assist implantation.

On RBP implantation, most patients were on Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) level 2 ($n = 367$, 40.4%) and INTERMACS level 3 ($n = 314$, 34.6%), and 163 (17.9%) patients were on INTERMACS level 1 (Table 1).

The RBPs were implanted as left, right, and bi-VAD in 884, 4, and 20 patients, respectively, either as bridge to transplantation, as bridge to myocardial recovery, or as permanent circulatory support.

Duration of support was a median of 183 (range: 1-2537) days, that is, 7.9 years, at the longest.

Device Selection

Selection of devices is in part a preference of the implanting surgeon. HeartMate II was selected for patients having a higher bleeding risk because the device was claimed to require less anticoagulation. On the contrary, the HeartMate II is somewhat bulkier than the HeartWare pumps; hence, it is more often used in patients with larger chests. Likewise, it often needs an extra tissue pocket for the pump.

Since 2002 until 2005, our preference was Berlin Heart INCOR, which then eventually competed with HeartMate II and HeartWare.

The main criterion in device selection is the patient's ease of pump handling, followed by thromboembolic complications, anticoagulation issues, and technical defects necessitating pump exchange.

In this respect, the 3 mostly used pumps, Berlin Heart INCOR, HeartMate II, and HeartWare qualified as follows.

Berlin Heart INCOR, the first magnet-levitating pump, is technologically advanced in its rational design without morbid technical defects, even in long-term use. Initially, the thromboembolic rate was low. This was followed by a period of increased thrombogenicity, which eventually turned out to be detrimental to the pump's acceptance.