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BIVENTRICULAR MECHANICAL CIRCULATORY SUPPORT. HISTORY AND CURRENT STATE OF THE PROBLEM

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Medical management of end-stage chronic heart failure (HF) has evolved significantly over the past few decades. With a better understanding of the pathophysiology of HF, new pharmacological agents have been synthesized. However, survival in this cohort of patients with medical treatment remains extremely low. This has stimulated the development of surgical methods of treatment. Recent technological advances in the development of mechanical circulatory assist devices have made possible a single-stage implantation of two centrifugal pumps as an alternative to a total artificial heart. Today ventricular assist devices can be implanted to provide both univentricular and biventricular support depending on the severity of hemodynamic disorders, target organ damage, likelihood of recovery and heart transplantation.

Keywords: heart transplantation, mechanical circulatory assist device, heart failure, circulatory support.

Despite all the efforts by doctors and scientists, nearly 300,000 patients worldwide die of HF as a primary or contributory cause each year [1]. Heart transplantation (HTx) remains the gold standard therapy for end-stage HF. However, this operation is severely limited by the number of available donor organs. That is why implantation of the left ventricular assist device (LVAD) has become the only and most effective alternative option to help this cohort of patients. Since the first LVAD was approved by the U.S. Food and Drugs Administration (FDA), the number of implanted devices has grown every year and now exceeds the number of heart transplants performed [2].

For many years, the development of surgical methods of treating HF was focused on restoring and maintaining the pumping function primarily of the left ventricle. As a result, much less attention has been paid to the study of pathogenesis and ways of maintaining right heart function. However, in the majority of cases, end-stage HF represents a biventricular heart dysfunction. In such cases, LVAD implantation is not only ineffective, but also associated with a high risk of right ventricular (RV) dysfunction. Thus, according to studies, right ventricular (RV) dysfunction is estimated to occur in 10% to 30% of patients post-LVAD implantation [3–5]. Data from the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) show that even with the current level of development of LVAD systems, 1-year survival for those with biventricular failure remains unchanged in different periods (2006–2012/2013–2016) at 56% versus 55%, respectively [6]. According to J.K. Kirklin et al., 368 biventricular assist devices (BiVADs) were implanted in 2011, with survival rates decreasing as the duration of biventricular mechanical support increased: 70% at 3 months, 62% at 6 months, 55% at 12 months, and 53% at 24 months of intervention [7].

Despite the discovery of a number of predictors of RV dysfunction (published literature identifies at least 25 different potential predictors of severe RV failure in LVAD recipients) post-LVAD implantation, most of them have low specificity and sensitivity and therefore are of low effectiveness in clinical practice [5, 8–12]. The absence of precise predictors of RV dysfunction has forced clinicians to use intraoperative decision-making tools based on the results of hemodynamic parameter studies after LVAD implantation or within hours/days after implantation. Lack of exact data and algorithms lead to longer decision-making in choosing a right heart mechanical support method, and also the optimum model of the device. Because of this, clinical results of this strategy were suboptimal, which explained the significant morbidity and mortality [13].

The bulkiness of the early LVAD models ruled out the possibility of concurrent implantation of two pumps in order to realize biventricular cardiac support [14–16]. For this reason, the only way to restore hemodynamics of pulmonary circulation was to use temporary extracorporeal mechanical circulatory support techniques [17]. Unfortunately, extracorporeal devices had a number of drawbacks – poor blood compatibility, high infection rate, high frequency of cerebrovascular complications and the need for a long hospital stay. This reduced the quality of life of patients significantly and triggered scientific interest in the development of implantable devices [18, 19].

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Over the past decades, LVAD models have undergone significant technological improvement. However, the desire of surgeons to replicate the success of LVADs and implant the developed models of long-term mechanical circulatory support devices in the right side came with a number of challenges [6, 20]. The first models of devices implanted as BiVAD were pulsatile models. One of the most recognizable biventricular support devices was the Thoratec VAD system (Abbott Laboratories, Chicago, Illinois). Post-implant actuarial survival was 69.1 ± 5.0%, 48.7 ± 5.5%, 41.9 ± 5.5%, and 38.4 ± 5.6% at 1 month, 1 year, 3 years, and 5 years, respectively. Because of the ease of implantation, the device was widely used in patients with cardiogenic shock [21, 22].

Another pulsatile pump model currently used as a BiVAD is the EXCOR VAD (Berlin Heart AG, Berlin, Germany). This device has been widely used in the pediatric group. Despite the extracorporeal connection scheme and significant limitations in the postoperative period, EXCOR VAD is the only method of saving children with HF, it allows waiting for a donor organ. According to S.E. Bartfay et al., the overall 5-year survival rate after EXCOR Berlin Heart implantation was 90% for children and 75% for adults (P = 0.3), with a 1-year survival rate of almost 80% [23].

Subsequently, pulsatile models replaced axial and centrifugal pumps that generate continuous flow, such as the Jarvik-2000 VAD model (Jarvik Heart, NewYork, NY) [24–27]. According to the last report from INTERMACS, 618 continuous-flow BiVADs have been implanted [6]. The HeartMate II LVAD (Thoratec, Pleasanton, CA) has long been one of the best LVAD models because of the low risk of device thrombosis. However, limited experience of using this device for biventricular support has been published in the literature, since, due to significant dimensions of the device, single-stage implantation of two pumps required complete ventricular removal [28–30].

For this reason, miniaturization of engineered device models remains an important challenge for engineers. One widely known miniaturized device model is the Impella RP device (Abiomed Inc., Danvers, Massachusetts), approved in 2015 by the FDA as a percutaneous temporary support device. Later, a number of studies proved the high efficacy of this device as a right ventricular assist device (RVAD) in the short term. In the RECOVER RIGHT study, the survival rate was 78%, significantly higher than for open RVAD implantation options [31–33]. In 2019, a clinical case study of minimally invasive BiVAD was published; the Impella 5.0 and Impella RP (Abiomed, Inc, Danvers, Massachusetts) were first successfully used as devices. This was the first successful case of using a single-stage implantation of this device model as a bridge to transplantation in BiVAD configuration [34].

The small profile and possibility of intrapericardial concurrent insertion of two HeartWare HVAD devices (Medtronic Corp, Minneapolis, Minnesota) have generated great interest in application of this device as a BiVAD [35–40]. According to A. Loforte et al., the 1-year survival in a series of 13 implantations of HeartWare HVAD as BiVAD was 62% [36]. According to T. Krabatsch et al., HeartWare HVAD model was implanted as a BiVAD in 17 patients. The postload for the right device was artificially increased by local reduction of the outflow tract diameter, and the effective length of the inlet cannula was reduced by adding two 5-mm silicone rings. The 30-day survival rate was 82%, with 59% of patients being discharged home. In this patient series, postoperative bleeding was the most frequent complication (6 patients) [41]. A small series of S. Shehab et al. reported 100% survival in 3 patients and 54% survival in 13 patients [42]. In F.A. Arabía et al., 1-, 6- and 12-month survival rates post-BiVAD implantation (HeartWare HVAD model) were 89%, 68% and 62%, respectively. Moreover, there was no statistical difference in survival in comparison with the patients who received LVAD/temporary RVAD [43].

Recently, there have been a number of publications describing experience with the HeartMate III (Thoratec Inc., USA). J. Lavee et al. evaluated the safety and clinical efficacy of the HeartMate III in a BiVAD configuration in 14 patients at 6 medical centers worldwide. Nine of these patients (64%) were alive as of January 1, 2018. Eight of the 9 had continued on BiVAD support for 95 to 636 (mean 266) days: 7 at home, and 1 successfully transplanted after 98 days of BiVAD support. Five patients died after 10, 60, 83, 99, and 155 days of support, respectively. The causes of death were sepsis in three patients, as well as hemorrhagic stroke and right pump thrombosis [44]. According to D. McGiffin et al. in a series including 12 patients, actuarial survival at 18 months was 91.7%. At 18 months after the procedure, 5 patients (41.7%) had undergone cardiac transplantation, 5 patients (41.7%) were alive and on biventricular support, 1 patient had died (8.3%), and 1 patient had device explantation for myocardial recovery (8.3%) [45].

Despite the existing world experience in the use of BiVAD, the surgical technique for device implantation is still under discussion. Insertion of an LVAD inflow cannula through the left ventricular (LV) apex or diaphragmatic wall is considered convenient and safe in most cases. Placement of the RVAD inflow cannula into the RV cavity or right atrium remains less clear. However, RVAD thrombosis is one of the major problems of BiVAD with an event rate of 30% to 37% in early reports [42, 46–48]. The multicenter and recent single-center HeartMate III study as a BiVAD showed a lower rate of thrombosis (7–20%), but the inflow spigot and outflow tract locations remain an open question [44, 45].

The study in these series showed a trend towards a better result in the case of right atrial (RA) cannulation. However, it is unclear what factors contribute to more frequent right pump thrombosis. Potential advantages of RA cannulation may be the convenient positioning of the pump in the right pleural cavity compared with intrapericardial RVAD placement over the diaphragm, and the absence of RV and interventricular septum compression by the pump body. Whereas right ventricular cannulation can lead to 'swallowing' of the tricuspid valve leaflets or subclavian structures. This complication was often observed in the case of implantation of pulsatile RVAD models, where one of the solutions was tricuspid valve dissection. It should be kept in mind that although removal of tricuspid valve leaflets helps to solve the problem of 'swallowing' by the pump and partially thrombosis of the device, still in case of mechanical device failure, the patient will need immediate restoration of quasi-normal RV function. Another reason for higher frequency of RVAD thrombosis is the need to reduce rotor speed to the maximum allowable values in order to optimize pulmonary circulation hemodynamics. However, in the case of devices implementing hydrodynamic suspension of the rotor, such modes threaten to unbalance the rotor position in the pump cavity and to increase the risk of thrombosis. For this reason, the latest HeartMate III fully magnetic suspension centrifugal pump compares favorably with its predecessors. In a number of studies, the low rate of thrombosis reported when using the HeartMate III as an LVAD has also been noted in the RVAD configuration [33, 35].

The inflow cannula of mechanical circulatory support devices was designed based on LV geometry and is unsuitable for RA and RV cannulation. Therefore, in the case of RA cannulation, in order to reduce the intraluminal length of the RVAD inflow cannula, the pump profile was increased using felt plates glued together using Bioglue (CryoLife, Guildford, UK) (Fig.).

In reviewing the outcomes of inflow cannula placement for RVAD in a study by E.J. Maynes et al., pump thrombosis occurred at a similar rate between RA cannulation and RV cannulation groups: 3/10 (30.0%) versus 6/20 (30.0%), respectively. However, Kaplan–Meier analysis when censored for transplant showed higher survival with RA HVAD compared to RV HVAD (P = .036), with an estimated survival at 1 year of 91.7% (95% CI 77.3–100.0) in RA HVAD versus 66.2% (95% CI 48.9–89.6) for RV HVAD [51].

The series by S. Shehab et al. showed a higher incidence of pump thrombosis with inflow cannula implantation in the right ventricle compared with placement in the right atrium (50% versus 14%) [42]. The authors

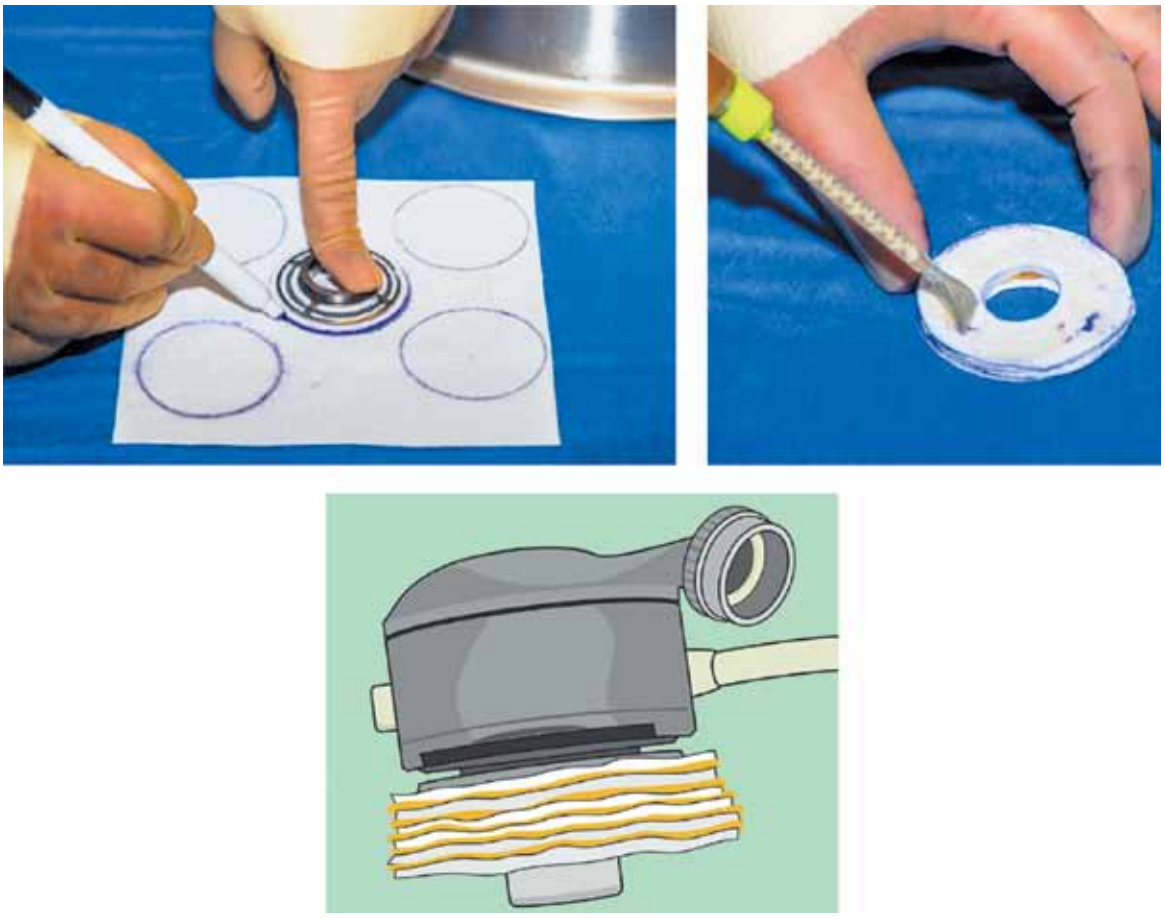

Fig. Preparation of the RVAD inlet cannula [49, 50]

concluded that this complication may have been associated with post-implant RV remodeling, which led to reduced chamber size [36, 39, 42].

Another object of controversy has been the RVAD outflow tract, since a number of surgeons have suggested the possible effectiveness of narrowing and lengthening the RVAD outflow line in order to optimally switch the two devices [48, 49]. On the contrary, in the BiVAD group by C. Lo et al., 9 out of 14 cases did not use RVAD outflow tract reduction [52]. A similar point of view is shared by E. Potapov et al., who point out that there is no need to narrow the outflow tract, and also recommend reducing the length of the prosthesis and anastomose the latter with the pulmonary trunk at an angle of 90° [48].

The timing of the decision to use BiVAD plays a key role in treatment outcomes. For example, according to T. Kuroda et al., 40% of BiVAD patients (HeartMate III model) received RVAD within 0–2 days post-LVAD implantation, and 23% of RVAD implantations were performed within 3–14 days [53]. Severe late RV failure among LVAD patients requiring mechanical support 3–12 months post-LVAD implantation is very rare [54]. Therefore, if BiVAD placement after LVAD implantation occurred earlier, the duration of BiVAD support is expected to be short (up to 17 days) [55–57].

J. Vierecke et al. investigated 37 long-term BiVADs, 342 LVAD + short-term RVAD implants and 34 total artificial heart (TAHs). Berlin Heart Excor (n = 5), HeartWare HVAD (n = 22), Thoratec pVAD (n = 10) were used as models for RVAD. The 1-year survival rate was 55% for patients with a continuous flow BiVAD; 52% for patients with an LVAD + short-term RVAD; 37% for patients with pulsatile BiVADs; and 36% for patients with a TAH. The adverse events profile remained high, with no significant difference among pump types. After 3 months of LVAD + short-term RVAD support, 46.7% still required ongoing support, and only 18.5% were weaned from RVAD support; 33.1% died. Device freedom from dysfunction and thrombosis was similar across all groups at 18 months (P = 0.63): 83% in patients with TAH, 82% in the pulsatile BiVAD model group, 95% in continuous-flow BiVAD patients, and 86% for patients with LVAD + short-term RVAD. Freedom from neurological deficit at 1 year was 84% for the TAH group, 73% for the pulsatile BiVAD flow, 76% for the continuous-flow BiVAD, and 94% for the LVAD + short-term RVAD group with no statistical difference between the investigated groups (P = 0.091). According to the authors, the LVAD + short-term RVAD group had the most favorable outcomes in terms of survival and freedom from complications. The possibility of easy weaning from extracorporeal RVAD models was an additional advantage [58].

The J.C. Cleveland Jr et al. study comparing LVAD and BiVAD implantation outcomes (Heartmate IP, VE, VXE, and Heartmate II LVAD models (Thoratec, Pleasanton, CA); the MicroMed Debakey Child left VAD (MicroMed, Houston, TX); Thoratec IVAD and PVAD pumps (Thoratec)) reported 6-month survival rates of 86% for LVADs and 56% for BiVADs (p < .0001). Adverse event rates, expressed as episodes / 100 patient-months for the BiVAD group compared with LVAD, were significantly higher for infection (33.2 *vs* 14.3), bleeding (71.6 *vs* 15.5), neurologic events (7.9 *vs* 2.6), and for device failure (4.9 *vs* 2.0) [59].

The question of choosing an optimal pump model for BiVAD is still open. For example, a group of authors led by A.C.W. Baldwin et al. report successful performance of BiVAD cardiac support with two different device models. In this case, after implanting a HeartMate II model as an LVAD and performing temporary RV support with CentriMag (Abbott Laboratories; Abbott Park, Ill) for long-term RVAD support, the patient was implanted with a HeartWare HVAD model [60]. A similar experience is also described in the works of J.J. Eulert-Grehn et al. and S. Saito et al. [47, 61].

In a recent study by D.M. Mancini et al., it was shown that 26% of patients after LVAD implantation, after several months of mechanical circulatory support, restored LV pumping function, so that the devices were ultimately explanted [62]. A similar strategy can be successfully implemented in the case of BiVAD support. According to E. Potapov et al., in a series of 10 patients treated with BiVAD, 3 cases showed a recovery of normal RV function to the extent that the RVAD device was stopped without explantation. Two patients were left with successfully functioning LVADs, one patient died of sepsis [63].

Thus, the strategy of concurrent implantation of two non-pulsatile mechanical circulatory support devices in a BiVAD configuration can be considered an effective alternative treatment option for patients with biventricular heart failure. Moreover, the latest HeartMate III centrifugal pump, fully magnetically levitated, can be used as a TAH in clinics that are unable to use the original TAH models. However, the issue of predictors of device-related complications requires further research.

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