Temporary Right-Ventricular Assist Devices

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Contributor: Mahmoud Abdelshafy

Acute right-sided heart failure (RHF) is a complex clinical syndrome, with a wide range of clinical presentations, associated with increased mortality and morbidity, but about which there is a scarcity of evidence-based literature. A temporary right-ventricular assist device (t-RVAD) is a potential treatment option for selected patients with severe right-ventricular dysfunction as a bridge-to-recovery or as a permanent solution.

right-sided heart failure | temporary right ventricular assist device | safety | efficacy

1. Introduction

Increasing use of advanced heart failure (HF) treatments including temporary and durable mechanical circularity support (MCS) are mostly directed to left-sided HF. However, concomitant or primary right-sided heart failure (RHF) are not uncommon and increases significantly morbidity and mortality [1]. This is especially vitally important in the era of long-term, durable left-ventricular assist devices (LVAD) solutions. RHF prevalence and associated mortality vary according to the underlying cause. Common clinical phenotypes are acute-on-chronic right-ventricular dysfunction with or without left-ventricular cardiomyopathy, myocardial infarction or ischemia, post-cardiotomy (PCCS), post LVAD implantation, post myocarditis, post-heart transplantation (HTX), and pulmonary thromboembolic events [1][2][3]. Management of RHF is usually medical, but in patients with imminent or full-blown cardiogenic shock, mechanical circulatory support including a right-ventricular assist device (RVAD) is indispensable. RHF usually requires temporary support in contrast to left-ventricular failure as its main pathophysiologic mechanisms, adaptive remodeling and impaired contractility, could be reversible along with lacking of established long-term, durable RVAD solutions [4]. RVAD could be surgically or percutaneously implanted and according to the duration of support could be short-term (temporary) or (rarely) long-term [1]. Despite several clinical RVAD devices, the existing literature is limited with rarely small prospective randomized trials, heterogenous, and conflicting studies, and single center cohorts.

2. Efficacy and Safety of Temporary Right-Ventricular Assist Devices

2.1. Efficacy of t-RVAD

Survival rate following t-RVAD implantation varied across different studies. It is likely related to the primary cause of RHF, the severity of end-organ dysfunction, and much less dependent on adverse events and complications related to t-RVAD. In addition, the timing of t-RVAD implantation probably plays a major role in the survival post t-

RVAD. Planned t-RVAD implantation in patients at high risk of RHF likely remains the optimal strategy to improve survival. Similarly, even when t-RVAD implantation is unplanned, early t-RVAD implantation in patients with acute severe RHF are likely to improve the chance for survival than delayed implantation. Percutaneous novel developed t-RVAD represent a good option in those patients in the perioperative period [5].

Herein the largest data on t-RVAD was derived from the EUROMACS and the INTERMACS registries. Vierecke et al. [6] reported a 30-day survival of 73% in 342 patients with LVAD and t-RVAD in the EUROMACS registry. Kiernan et al. [7] reported a 30-day survival of 73.5% in 386 patients with LVAD and t-RVAD in the INTERMACS registry. A smaller study reported extreme rates of survival including Jaidka et al. [8] who reported 100% 30-day survival in 10 patients at high risk for RHF (severe baseline right ventricular dysfunction or systemic pulmonary artery pressures) underwent valve surgery and prophylactic CentriMag insertion. Likewise, the lowest 30-day survival of 45.5% was reported by Schaefer et al. [9] in 11 LVAD patients treated with t-RVAD via sternotomy in the comparative arm of the study while the 30-day survival was 80% in the main group of 10 LVAD patients treated with minimally invasive t-RVAD.

Data on the comparison of percutaneous and surgical t-RVAD is scarce. Coromilas et al. [5] reported 84.2% 30-day in 19 LVAD patients with t-RVAD percutaneously inserted mixed group of ProtekDuo (n = 15) and Impella RP (n = 4) versus 66.7% 30-day survival in 21 LVAD patients with CentriMag surgically inserted.

Likewise, data on the optimal timing of t-RVAD insertion is scarce. Khorsandi et al. [10] reported higher 30-Day survival (93.1% vs. 71.4%) in patients who received t-RVAD as concurrent (with LVAD surgery) vs. delayed (staged after LVAD) t-RVAD insertion. Moreover, Bhama et al. [11] reported 90-day survival was better (79% vs. 46%) for patients who received immediate (within 24 h of being indicated to RVAD) in comparison to delayed (after 24 h of being indicated to RVAD) t-RVAD support. Takeda et al. [12] reported numerically higher but statistically insignificant successful t-RVAD weaning (54% vs. 38% p = 0.3) for concurrent vs. delayed t-RVAD insertion. The timing of a temporary RVAD insertion is probably of utmost importance. The RVAD should be inserted as early as possible before the development of secondary organ/multi-organ failure. The best strategy depends on a good prediction of RHF, which is not established yet. One step further, the t-RVAD implantation should be probably planned prophylactic in intermediate to high-risk patients, including the selection of the best appropriate device and the best technique. In fact, the RVAD device and implantation technique selection, percutaneous versus surgical depend on the situation and the availability of the devices with consideration of the advantages offered by the percutaneous RVAD as they are less invasive, easy insertion and easy removal particularly if the RHF occurs in the ICU or perioperatively [13].

Another important aspect that might affect the t-RVAD outcome is RHF patient's phenotypes. Overall, post-LVAD RHF patients have higher 30-day survival than other phenotypes [14][11][15][16] and higher survival to weaning in one study [17]. However, this subgroup analysis is not adequately powered to detect meaningful difference. In contrast, one study [14] reported a higher (80% vs. 67%) 30-day survival in patients with non-ischemic cardiomyopathy. Likewise, one study [18] reported a higher (75% vs. 47%) one-year survival in the post-cardiotomy patients (n = 4) than patients requiring t-RVAD support following LVAD implantation (n = 17). Although some studies [6][19][11][20][9]

[21][22][18][23][12][24][25] included details about the underlying disease and/or etiology of heart failure in patients undergoing LVAD, no direct comparison related to the etiology of HF was (i.e., could be) performed, mainly due to wide variation of the survival rates and other outcome measures among patients with different RHF etiologies such as post-cardiotomy or myocarditis. This reflects the fact that the primary cause of RHF and/or indication for t-RVAD were important determinants of outcome following t-RVAD implantation. Although the subgroup analysis was reported in some papers, these studies are obviously not adequately powered to detect a meaningful difference between the different RHF phenotypes/indications for t-RVAD. Furthermore, due to the significant heterogeneity, and the use of different endpoints among included studies, subgroup analyses based on data pooling was not considered. Specific for the underlying disease, almost no outcome was mentioned based on it in any paper.

In brief, the most favorable outcome was found in post-LAVD patients with early planned insertion of pRVAD versus other patients' phenotypes or delayed insertion or insertion of sRVAD. However, this analysis also is not adequately powered to detect a meaningful difference between the different subgroups.

2.2. Duration of t-RVAD Support

Impella RP is approved for use as t-RVAD for up to 14 days only [26] also the ProtekDuo Cannulas have not been qualified through in vitro, in vivo, or clinical studies for long-term use (i.e., longer than 30 days) as mentioned by the manufacture [27]. The CentriMag is approved for use as t-RVAD up to 30 days [28]. In some studies [29][6][30], the duration of t-RVAD support exceeded the previous mentioned duration. Vierecke et al. [6] in the EUROMACS registry reported that six months after LVAD + t-RVAD implantation, more than 40% of patients who received t-RVAD remain dependent on the t-RVAD support. However, the authors did not provide details on management of RVADs during that time nor the outcome after that. Development of RHF predictive models to choose between temporary or long-term RVAD and global scientific consensus for the definition of RHF and management algorithms will contribute to solve this issue.

2.3. Safety of t-RVAD

Definitions of the reported complications following t-RVAD implantation were not clear and standardized between the studies. Acute kidney injury, bleeding, neurological events and device thrombosis were the main reported complications. Furthermore, as these complications related to percutaneously implanted t-RVAD two studies [31][15] reported the incidence of tricuspid and pulmonary valves affection and two studies [31][32] reported the incidence of superior vena cava syndrome.

3. Conclusions

Temporary RVAD is a lifesaving option for patients with severe RHF, but the evidence stems from small non-randomized heterogeneous studies utilizing a variety of devices. Both aetiology of RHF and time of intervention might play a major role in determining the temporary RVAD outcome. Standardized endpoints definitions, design

and methodology for temporary RVAD trials is needed. Furthermore, efforts should continue to improve the technology as well as improve the timely provision of a temporary RVAD.

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