Outcome of Temporary Circulatory Support As a Bridge-to-Left Ventricular Assist Device Strategy in Cardiogenic Shock Patients

OBJECTIVES: Temporary circulatory support (TCS) as a bridge-to-left ventricular assist device (BTL) in cardiogenic shock patients has been increasing, but limited data exists on this BTL strategy. We aimed at analyzing the outcome of BTL patients in a population of cardiogenic shock patients compared with those without TCS at the time of the left ventricular assist device (LVAD) surgery and identify predictors of postoperative mortality in this specific population.

DESIGN: A multicenter retrospective observational study conducted in 19 centers from 2006 to 2016.

SETTING: Nineteen French centers.

PATIENTS: A total of 329 cardiogenic shock patients at the time of LVAD implantation were analyzed. Patients were divided in three groups: those under TCS at the time of LVAD implantation ($n = 173$), those with TCS removal before LVAD surgery ($n = 24$), and those who did not undergo a bridging strategy ($n = 152$). Primary endpoint was 30-day mortality.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: Among the BTL group, 68 (39.3%), 18 (10.4%), and 15 (8.7%) patients were under venoarterial extracorporeal membrane oxygenation, Impella, and IABP support alone, and 72 patients (20.6%) were under multiple TCS support. BTL patients presented similar 30 days survival compared with the TCS removal and non-BTL groups. However, BTL group had a significantly longer ICU duration stay, with two-fold duration of mechanical ventilation time, but the three groups experienced similar postoperative complications. Multivariate analysis identified three independent predictors of mortality in the BTL group: combined surgery with LVAD, body mass index (BMI), and heart failure (HF) duration. BTL strategy was not an independent predictor of mortality in cardiogenic shock patients who underwent LVAD.

CONCLUSIONS: BTL strategy is not associated with a lower survival among cardiogenic shock patients with LVAD implantation. Predictors of mortality are combined surgery with LVAD, higher BMI, and HF duration.

KEY WORDS: bridge to strategy; cardiogenic shock; left ventricular assist device; temporary mechanical support

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Left ventricular assist device (LVAD) implantation has become an effective therapeutic option for patients with end-stage heart failure (HF) (1–3). Outcomes and long-term survival rate have continuously increased over the years (4–6) due to improved surgical techniques and medical management with the emergence of multidisciplinary heart teams (2). However, patients in cardiogenic shock before LVAD may be difficult to manage and the decision for LVAD implantation remains clinically challenging.

One specific population of interest is patients with critical cardiogenic shock undergoing temporary circulatory support (TCS) (i.e., intra-aortic balloon

pump [IABP], extracorporeal membrane oxygenation (ECMO), and Impella devices) before LVAD, as a "Bridge-to-LVAD" (BTL) strategy. These patients present advanced hemodynamic collapse and BTL strategy allows improvement of hemodynamic parameters and end-organ function before LVAD implantation (7, 8). However, TCS is associated with more adverse events after LVAD implantation (9–11). Herein, identifying predictors of mortality and risk stratification is essential for an optimal therapeutic strategy.

In this study, we aimed at describing the characteristics and outcomes of BTL patients receiving LVAD compared with those without TCS at the time of surgery and identify predictors of postoperative mortality among advanced cardiogenic shock patients with a BTL strategy.

MATERIALS AND METHODS

Study Design

This study is based on the ASSIST-ICD cohort, a retrospective, multicenter, observational study (NCT02873169) of LVAD implanted in 19 tertiary French centers. The methods of this study have been previously described (12). Patients greater than 18 years old implanted with a continuous-flow LVAD, including axial HeartMate II (Abbott, Chicago, IL), Jarvik 2000 (Jarvik Heart, New York, NY), or centrifugal Heartware pumps (Medtronic, Columbia Heights, MN) between February 2006 and December 2016 were included. The type of pump implanted depended on the local heart team's decision in each center. Exclusion criteria were patients who underwent total artificial heart placement or pulsatile flow LVAD; history of heart transplant; death or heart transplantation before discharge from hospital after LVAD implantation; and VentrAssist (Ventracor, Chatswood, NSW, Australia) recipients. This study was approved by the regional ethic committees, the French advisory committee on the Treatment of Research Information in the Field of Health, and the French National Commission of Informatics and Civil Liberties (authorization number 915649). A nonopposition letter was sent to the patients, as requested by French authorities.

Cardiogenic Shock and Bridge-to-LVAD Strategy

Among the patients included in this cohort, only those in cardiogenic shock at the time of LVAD implantation were enrolled. We defined patients in cardiogenic shock as LVAD candidates in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) 1–3 (6). This subset of patient was then divided in three groups: those under TCS at the time of LVAD implantation (BTL group), those with TCS removal before LVAD implantation (temporary BTL group), and those who did not undergo a bridging strategy (non-BTL group).

Implantation of TCS was performed for patients in refractory cardiogenic shock with the indication discussed by the local Heart Team and the choice of TCS guided by local expertise and preference. Types of TCS implanted were Impella 2.5/CP/5.0 (Abiomed, Danvers, MA), peripheral/central venoarterial ECMO, IABP, or a combination of the previous three TCS. We included in the BTL group patients who required TCS until LVAD implantation only.

Baseline Assessment and Follow-Up

Baseline data, including demographic characteristics, cardiac disease and HF history, echocardiography, and blood chemistry values, were collected from hospital files for all enrolled patients. The echocardiographic and blood sample data used for the analysis were the last performed before LVAD implantation.

For patients in cardiogenic shock, additional data were collected from ICU records in the preoperative and postoperative period. Preoperative data included type and number of vasoactive drugs, type of TCS and duration of support, mechanical ventilation, dialysis support, and preoperative complications.

Postoperative data were collected including ICU parameters (mechanical ventilation duration, vasoactive support duration, dialysis support, length of stay), postoperative complications (including major bleedings, infection, stroke, right ventricular dysfunction, pump thrombosis, need for revised surgery), and death. Right HF was defined as the need for vasoactive agents with record of any right ventricular dysfunction in medical reports, including operative reports, or temporary right mechanical circulatory support by extracorporeal life support (ECLS) during/after LVAD implantation.

Study Endpoint

The primary endpoint of the study was postoperative mortality (i.e., 30 d after the LVAD implantation). Deaths were classified as cardiovascular death

(cardiac/vascular cause) or noncardiac death. The secondary endpoint was the occurrence of postoperative complications.

Statistical Analysis

Qualitative variables are expressed as number (percentage) and continuous data as mean ± SD or median (interquartile range) depending on their distribution, which was assessed using the Kolmogorov-Smirnov test. Survival rates were summarized using Kaplan-Meier estimates, and log-rank tests were used to compare groups. Predictors of post LVAD mortality were analyzed using univariate and multivariable proportional hazard models (cumulative outcomes). The proportional hazards assumption was tested and verified for each covariate. All univariate analyses were performed on complete cases. Variables with p values of less than 0.10 in univariate analysis were included in the multivariable analysis. Kaplan-Meier estimates were used to construct the survival curves based on all available follow-up for the time-to-event analysis and were plotted by risk levels. All tests were two-sided at the 0.05 significance level. Statistical analysis was conducted using the SPSS Version 22 (IBM, Armonk, NY).

RESULTS

Study Population

From 2006 to 2016, among the 659 LVAD recipients included in the ASSIST-ICD study, 349 patients (52.9%) were in cardiogenic shock prior to LVAD implantation and included in the analysis. A total of 173 (49.6%), 24 (6.9%), and 152 (43.5%) patients were categorized as a BTL, temporary BTL, and non-BTL strategy, respectively. Overall, 94 of the study patients (26.9%) were initially listed for heart transplantation but failed to receive a heart transplant after 96 hours on national priority high emergency list and underwent LVAD implantation. Notably, among 24 patients with TCS removal before LVAD implantation, mean duration of mechanical support was 5.4 ± 3.4 days and was removed 22.0 days (14.0–60.5 d) before LVAD implantation.

Baseline characteristics of the three groups are presented in **Supplementary Table 1** (http://links.lww.com/CCM/G958). Patients with a BTL strategy were significantly younger, with a shorter HF duration before LVAD implantation, and lower left ventricular ejection fraction. Additionally, those with a BTL until LVAD surgery received significantly more vasoactive drugs, underwent more dialysis therapy and were more likely under mechanical ventilation with a longer duration of intubation prior to LVAD implantation. Notably, BTL and temporary BTL patients presented more infections prior to LVAD but only BTL group experienced more bleeding events. Last, the type of LVAD also differed between the groups since BTL patients were more often implanted with HeartMate II. Last, BTL and temporary BTL groups were more implanted as bridge-to-transplantation strategy (69.9% and 66.7% vs 52.6% in the non-BTL group, respectively).

Among the 173 BTL patients, 101 patients had a single TCS implanted, including 18 (10.4%) with an Impella, 15 (8.7%) with an IABP, and 68 (39.3%) with a venoarterial ECMO. A total of 72 patients were under multiple TCS support including: seven patients (4%) under Impella/IABP, 20 (11.5%) under Impella/ECMO, 34 (19.6%) under IABP/ECMO, and 11 (6.3%) under ECMO/Impella/IABP (**Fig. 1**). Total BTL time was significantly longer in patients with two or three TCS, respectively, 14.0 days (9.0–21.0 d) and 15.0 days (10.2–27.5 d) versus 9.0 days (6.0–15.7 d) in patients with a single TCS ($p = 0.002$) (**Supplementary Table 2**, http://links.lww.com/CCM/G959).

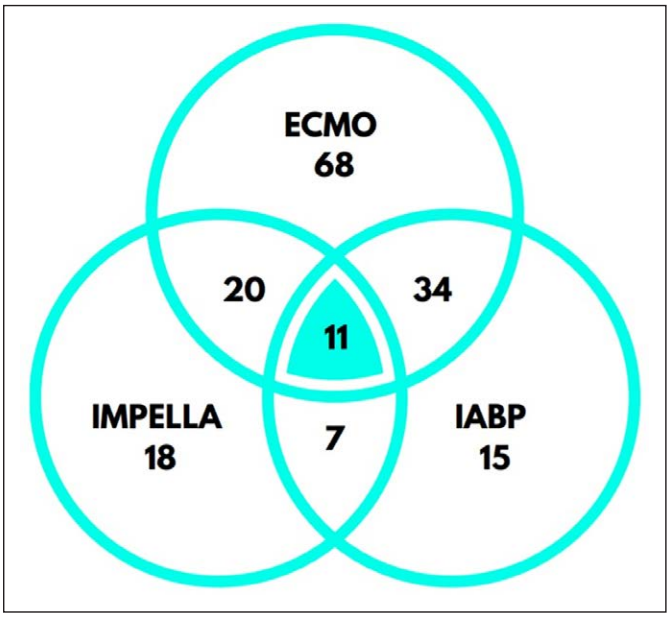

Figure 1. Distribution of patients in temporary circulatory support groups. ECMO = extracorporeal membrane oxygenation, IABP = intra-aortic balloon pump.

Postoperative Outcomes

After LVAD implantation, BTL group had a significantly longer ICU duration stay and a two-fold duration of mechanical ventilation time (**Supplementary Table 3**, http://links.lww.com/CCM/G960). However, these patients did not require longer vasoactive drugs support, right ECLS implantation, or cardiac surgery revision following LVAD implantation. Interestingly, they did not experience more LVAD-related complications during the postoperative period (i.e., stroke/infection/bleeding/thrombosis) but required more dialysis postoperative support compared with the two others patients groups.

There was no significant difference in postoperative outcomes based on type of TCS or number of TCS, except for total ICU time that was significantly longer in patients under ECMO at 32.0 days (22.5–57.0 d) (p = 0.012) (**Supplementary Table 4**, http://links.lww.com/CCM/G961). There was a trend toward more postoperative dialysis, infections, right ventricular dysfunction, and right ECLS after LVAD in the ECMO group, and a trend toward more postoperative infection, bleeding, and dialysis in patients with three TCS.

Mortality and Predictors of Postoperative Mortality

There was a significantly higher death rate at 30 days in the BTL group (37 [21.4%] patients), compared with 4 (16.6%) and 17 (11.8%) in the temporary BTL and non-BTL group, respectively (p = 0.048) (**Supplementary Table 5**, http://links.lww.com/CCM/G962).

Characteristics between BTL patients who died during the postoperative period and those who did not are presented in Supplementary Table 5 (http://links.lww.com/CCM/G962). Patients who died were older with a higher body mass index (BMI), more history of previous sternotomy, and longer HF duration. Additionally, they had a worse renal function prior to LVAD and were more likely implanted as destination therapy with higher rate of combined cardiac surgery. The number of TCS did not differ between both groups but there were more patients under Impella who died compared with patients with ECMO or IABP.

Figure 2 shows that patients under TCS at LVAD implantation experienced postoperative similar survival compared with the others groups (81%, 83%, and 91%, respectively). Additionally, no survival difference was observed in the BTL group based on the type of TCS in patients with one TCS or number of TCS (**Fig. 3**, ***A*** and ***B***).

Multivariate analysis (**Table 1**) identified three independent predictors of 30-day mortality in BTL patients: combined surgery with LVAD, BMI, and HF duration. Bridge-to-transplantation indication was the only independent predictor of survival.

Despite worse postoperative survival, BTL strategy was not an independent predictor of mortality in cardiogenic shock LVAD candidates (**Supplementary Table 6**, http://links.lww.com/CCM/G963).

DISCUSSION

In this study, we found that 1) a BTL strategy occurs in half of cardiogenic shock patients prior to LVAD; 2) postoperative complications do not differ significantly between the BTL and non-BTL groups except for skin infections; 3) cardiogenic shock patients with TCS prior to LVAD present similar postoperative survival rate and BTL strategy is not a predictor of postoperative mortality in this population of cardiogenic shock patients; and 4) predictors of mortality in the BTL group are higher BMI, longer acute HF duration, and combined surgery with LVAD.

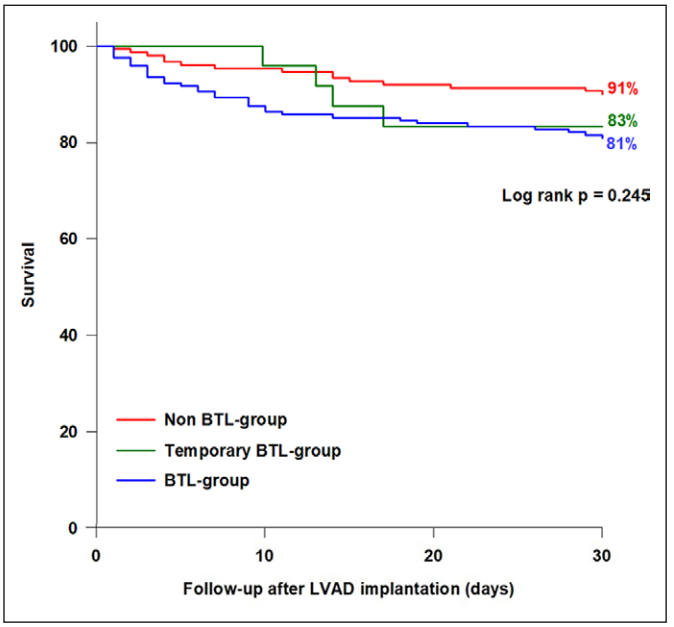

Figure 2. Kaplan-Meier survival curve at 30 d in the bridge-to-left ventricular assist device (BTL) group and non-BTL group. LVAD = left ventricular assist device.

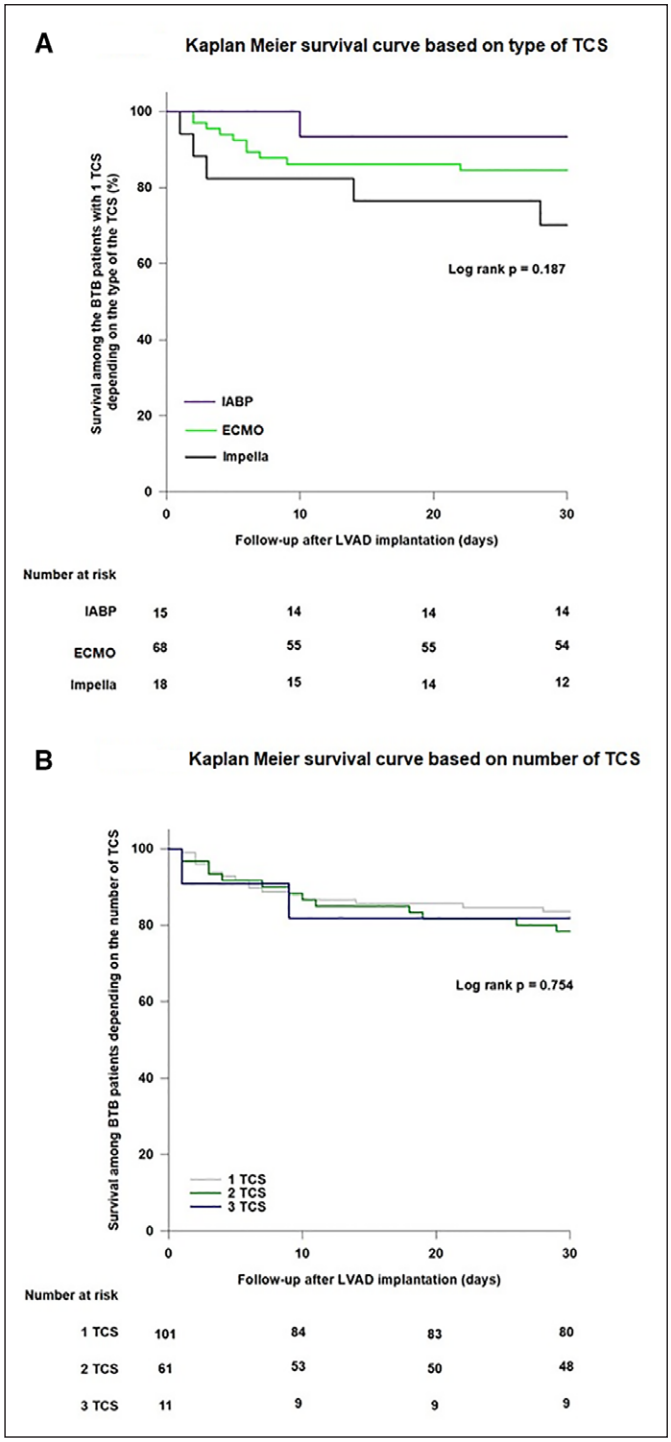

Figure 3. Kaplan-Meier survival curve based on type (**A**) and number (**B**) of temporary circulatory support (TCS). BTB = bridge-to-bridge, ECMO = extracorporeal membrane oxygenation, IABP = intra-aortic balloon pump.

Bridge-to-LVAD Strategy

Recent reports describe a BTL strategy in approximately 40% of cardiogenic shock patients prior to LVAD implantation (9, 11, 13), which is in line with our study results, with half of cardiogenic shock patients population.

TABLE 1.
Multivariate Analysis for Predictors of 30-Day Mortality in Bridge-to-Left Ventricular Assist Device Patients

Variable	Hazard Ratio (CI 95%)	*p*
Age, yr	0.99 (0.95–1.04)	0.740
Body mass index, kg/m^2	1.14 (1.03–1.26)	0.013
Hypertension	2.16 (0.80–5.81)	0.129
Heart failure duration, mo	1.01 (1.00–1.01)	0.037
Creatinine prior to LVAD, µmol/L	1.01 (0.99–1.01)	0.094
Previous sternotomy prior to LVAD	1.39 (0.40–4.81)	0.602
Bridge to transplantation	0.23 (0.08–0.73)	0.013
Combined surgery with LVAD	3.46 (1.16–10.34)	0.026

LVAD = left ventricular assist device.

Mean duration of support in the literature varies between 1.6 and 25 days for cardiogenic shock patients (11, 14, 15). One large meta-analysis on cardiogenic shock patients supported by TCS demonstrated that IABP bridging time greater than or equal to 6 days was associated with a worse outcome (16). Studies have shown that longer duration of ECMO support in a cardiogenic shock population, beyond 5 to 7 days, was associated with a worse prognosis, with more ECMO-related complications (17–19). TCS support was longer in our study (13.0 ± 6.3 d) with no significant difference between survivors and nonsurvivors. This relative long duration can be in part explained by heart transplantation access in France during the study period, with the possibility to ask for national priority on a high emergency list for patient under TCS. This may explain the relative longer time under TCS as most teams tried to transplant their candidate before considering LVAD implantation.

There is little data comparing postoperative complications of BTL and non-BTL patients. Higher rates of bleeding and infections have been reported in BTL patients (11), especially in ECMO patients who presented significantly more bleeding events, cerebrovascular events, and worse survival compared with non-BTL patients (9, 20). Conversely, in a retrospective study enrolling 133 INTERMACS-1 LVAD candidates (i.e., 26 ECMO patients and 107 non-ECMO patients), authors reported found no difference in 30

days postimplantation mortality (21). Interestingly, in our study, despite a longer postoperative intubation period and a longer ICU hospital stay, the occurrence of postoperative complications did not differ.

Short-term mortality rates for cardiogenic shock patients implanted with a LVAD range from 10% to 24% (9, 14, 22), which is coherent with our results, with a 16.6% total mortality in the cardiogenic shock group at 30 days. Additionally, despite nonsignificant, 30 days mortality rate was numerically higher in the BTL group compared with the non-BTL group (21.4% vs 11.9%). Similar results have also been reported in international registries (9, 23) and can be explained by a greater baseline severity of TCS patients, especially ECMO recipients, who are in critical cardiogenic shock with more severe end-organ dysfunction (24). BTL patients in our study were sicker at baseline with a significantly higher use of mechanical ventilation and inotropes. Furthermore, the higher mortality of BTL recipients can be correlated to the higher mortality of INTERMACS 1 and 2 patients compared with INTERMACS 3 patients (5). In our study, BTL recipients were INTERMACS 1 or 2, and non-BTL recipients were mostly INTERMACS 2–3. Nonetheless, the BTL group experienced good postoperative survival with more than 80% of patients alive at 30 days follow-up.

We included in our study 3 types of TCS: IABP, Impella, and venoarterial ECMO, which are most commonly used in France. There is little data about prognosis based on type of TCS. One large-scale study showed that ECMO recipients presented a worse prognosis compared with patients with other types of TCS (9), while other authors did not observe such pejorative prognosis of ECMO implantation prior to LVAD (25).

Predictors of Postoperative Mortality in Patients in Bridge-to LVAD Strategy

In our study, we identified three independent predictors of postoperative mortality.

Combined surgery with LVAD is associated with a three-fold increased risk of postoperative death. Indeed, the procedure is longer, with more myocardial ischemia due to longer cardiopulmonary bypass and aortic cross-clamped time. Similar results have also been reported, with a two-fold risk of death in patients requiring any combined surgery with LVAD implantation (12), especially concomitant coronary artery bypass graft (26).

Regarding HF duration, we may hypothesize that these patients presented a worse outcome due to delayed LVAD implantation for various reasons (Heart Team hesitation, national high priority heart transplantation failure, intercurrent complications that postponed LVAD implantation), leading to a worsening of the patient's hemodynamics, end-organ function, cachexia, and sarcopenia, which are known risk factors of worse prognosis after LVAD (27, 28). These patients might have benefited from earlier LVAD implantation, which should be considered early on in the therapeutic course, instead of waiting for the situation to deteriorate critically.

Last, a higher BMI was associated with a worse prognosis among the BTL candidates. Obesity has been linked to a higher rate of infections, but not mortality, after LVAD implantation (29–31). One can hypothesize that the higher mortality in overweight patients could be due to a deleterious effect of TCS or TCS combined with LVAD rather than LVAD implantation alone.

Clinical Implications

The decision to implant a LVAD in advanced cardiogenic shock patients under TCS is therefore challenging in clinical practice. BTL candidates present more postoperative death rate, but we show that BTL strategy is not a predictor of mortality and that these patients experienced an 81% postoperative survival at 30 days representing an interesting therapeutic option. However, identifying the optimal bridging strategy, and the right LVAD candidates, is a major issue to improve the outcome of BTL patients. Devices that do not provide full circulatory support (i.e., IABP, Impella 2.5/CP) may not be the best option in refractory cardiogenic shock patients. Choosing between Impella 5.0 and ECMO is a difficult question, and is left to the center's discretion, based on local expertise and devices availability. As ECMO offers a full biventricular circulatory support, it seems better indicated for cardiogenic shock, life-threatening arrhythmias, cardiac arrest, and biventricular failure. In the other hand, left ventricle (LV) overloading is a likely complication of the retrograde blood circulation imposed by an ECMO and involves increased LV pressures that may threatens pulmonary and myocardial recovery, especially in ischemic patients. Bridging patients with an Impella would in another hand prevent that and allow an evaluation of the right ventricle in an almost LVAD configuration.

BTL candidates should also be carefully selected in order to optimize medical management. Patients with higher BMI, longer acute HF situation, or requiring combined cardiac surgery with LVAD are more prone to worst postoperative outcomes. This population may require dedicated management strategies, such as earlier implantation of LVAD before reaching critical cardiogenic shock, and in some cases palliative care.

Study Limitation

One main limitation of our study is its retrospective nature, which might have influenced the results. There was no randomization between BTL or non-BTL group. We therefore could not compare BTL strategy results in patients of similar levels of cardiogenic shock severity based on the INTERMACS classification. Patients were not identical in both groups, as BTL recipients were more severe, but this also reflects real-life clinical practice, where TCS implantation is based on the heart team's judgment. We also did not evaluate how TCS improved biology parameters, with no data on postoperative biology. Last, our cohort did not collect all patients implanted with TCS, which does not represent a whole picture of this population of patients in critical cardiogenic shock under mechanical support.

CONCLUSIONS

Among cardiogenic shock patients, LVAD implantation under TCS is not associated with a lower survival compared with those with TCS removal or without TCS at the time of pump surgery. These data may suggest that INTERMACS 1 under TCS patients are also potentially good candidates for LVAD. However, for an optimal management, it is crucial to identify those at risk of a worse outcome. Futures studies are warranted to optimize bridging strategy and improve results in cardiogenic shock population.

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