



Concomitant cardiac surgery procedures during left ventricular assist device implantation: single-centre experience

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Background: Additional cardiac pathologies including tricuspid or mitral valve regurgitation are common in left ventricular assist device (LVAD) recipients and whether to address them remains controversial. We present our institutional outcomes of concomitant cardiac procedures, other than temporary right ventricular (RV) support, at the time of LVAD implantation.

Methods: From 03/2006 to 06/2020, 352 adult patients {median age 60 [interquartile range (IQR): 52–66] years; INTERMACS level 1 29%; INTERMACS level 2 17%; INTERMACS level 3 23%, INTERMACS level 4–6 31%; male 86%} underwent continuous-flow LVAD [Medtronic HVAD[®] (HVAD) 50%; Abbott HeartMate II[™] (HMII) 17%; Abbott HeartMate 3[™] (HM3) 33%] implantation. Concomitant valvular procedures were performed in 86 patients (24%) and the majority of patients received the LVAD as bridge to candidacy (BTC) for transplant (74%). Primary study endpoints were short- and mid-term mortality, as well as need for temporary RV support.

Results: Tricuspid valve annuloplasty was the most frequent concomitant procedure (77%), followed by aortic valve replacements (AVRs) or Park's stitch (33%). Temporary RV support was common in the study cohort (35%) using either extracorporeal life support (ECLS, 37%) or a temporary RV assist device (RVAD, 63%). A less invasive (LIS) implantation technique was pursued in 12%. Thirty-day mortality was comparable between those with and without concomitant surgery (4% vs. 6%, P=0.426). In-hospital mortality was significantly higher for additional interventions (22% vs. 14%, P=0.05), whereas one-year survival was similar (71% vs. 79%, P=0.106).

Conclusions: Concomitant cardiac procedures, especially tricuspid and aortic valve surgery, are frequent but are associated with a higher perioperative morbidity and mortality.

Keywords: MCS; left ventricular assist device (LVAD); concomitant cardiac surgery; outcomes



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Introduction

Left ventricular assist device (LVAD) implantation as bridge to transplantation, recovery or destination therapy (DT) is a standard treatment for patients with end-stage heart failure (1). Additional cardiac pathologies, especially valvular ones, are common in advanced heart failure with a reported prevalence of 30% to 50% for tricuspid valves, 40% to

70% for mitral valves and 20% for the aortic valve (2-5). It remains controversial whether issues other than more than mild aortic valve regurgitation or intracardiac shunts [both Class I indications for concomitant surgery according to the International Society of Heart and Lung Transplantation (ISHLT) guidelines (6)] should be addressed at the time of LVAD implantation. Multiple studies have shown contrary

results with both adverse effects and improvement of outcomes in terms of right ventricular (RV) function, length of intensive care unit and hospital stay, catecholamine dependency, mortality and more, after LVAD and concomitant cardiac surgery (7-12).

With this study, we sought to examine our institutional outcomes of adult continuous-flow LVAD recipients with and without additional cardiac procedures over the past fourteen years.

Methods

Study population

Overall 357 consecutive adult patients underwent continuous-flow LVAD implantation between March 2006 to July 2020 at our department. Out of these, a total of 91 patients had a concomitant cardiac procedure at the time of LVAD implantation. Patients undergoing non-valvular procedures additional to LVAD implantation (n=5) were excluded from further analysis. Data was obtained from our department's Mechanically Circulatory Support database. The study was approved by the local Ethics Committee.

Ventricular assist device systems and implantation techniques

LVAD systems used in the study population were the Medtronic HVAD[®] (HVAD), the Abbott HeartMate II[™] LVAD (HMII) and the HeartMate 3[™] LVAD (HM3). Implantations were performed either via standard full sternotomy (FS) or in a less invasive (LIS) fashion. Briefly, the LIS techniques are conducted as follows: For isolated LVAD implantation, bilateral mini-thoracotomy in the fourth or fifth left intercostal space and the second right intercostal space is performed, granting access to the left ventricular apex as well as to the ascending aorta. For combined procedures, a left-sided mini-thoracotomy and an upper hemi-sternotomy in the third intercostal space are performed (13-15).

We perform mitral valve repair (MVR) in high grade secondary insufficiency, primary mitral regurgitation is always addressed. A similar policy is pursued in the management of tricuspid valve regurgitation. The preferred technique is a prosthetic ring annuloplasty. In selected cases, implantation of a biological prosthesis might be necessary. Aortic valve procedures and closure of intracardiac shunts are performed as indicated by the ISHLT guidelines (6).

Outcome measures

Study endpoints were short-term survival (thirty-day mortality and in-hospital mortality), one-year outcomes and the need for temporary RV support.

Statistical analysis

Categorical variables were presented as numbers and percentages. Mean values with standard deviations (SDs) or median values with interquartile ranges (IQRs) were determined for continuous variables. Comparison of means was performed using the paired *t*-test or Wilcoxon test, when appropriate. Comparison of categorical variables was performed with the Pearson's χ^2 test or Fisher's exact test, when indicated. A P value <0.05 was considered statistically significant.

Results

Overall cohort

Patient characteristics

Median age was 60 (IQR: 52–66) years, the majority of patients were male (86%) and suffered from ischemic cardiomyopathy (ICMP; 58%). Most patients (n=107) were in INTERMACS level 4 at the time of LVAD implantation (32%), 76 patients were in INTERMACS level 3 (23%), 58 were in INTERMACS level 2 (17%) and 97 were in INTERMACS level 1 (29%). Fifty-eight patients (17%) were on preoperative extracorporeal life support (ECLS). A bridge to candidacy (BTC) strategy was pursued in 260 patients (74%).

Operative procedure

Overall 177 patients received a Medtronic HVAD system (50%), 115 patients a HM3 (33%) and 60 patients a HMII (17%). Isolated LVAD implantation with or without temporary RV support was performed in 266 patients (76%). Twenty-four percent had a concomitant cardiac procedure (other than temporary RV support systems). A LIS implantation technique was carried out in 128 patients (36%).

Postoperative outcomes

Median duration of LVAD support was 503 (IQR: 214–967) days. Thirty-day and in-hospital mortality were 6% and 16%, respectively, one-year survival was 77%. After

Table 1 Patient characteristics

Characteristics	Overall cohort (n=352)	Concomitant procedure (n=86)	Isolated LVAD (n=266)	P value
Age	60 [52–66]	60 [52–67]	60 [52–66]	0.555
Male gender	303 [86]	69 [80]	234 [88]	0.072
ICMP	184 [58]	35 [44]	149 [63]	0.004*
DCMP	126 [40]	42 [53]	84 [35]	0.005*
Other	6 [2]	2 [2]	4 [2]	0.642
INTERMACS				
I	97 [29]	13 [16]	84 [33]	0.003*
II	58 [17]	15 [18]	43 [17]	0.755
III	76 [23]	23 [28]	53 [21]	0.166
IV–VII	107 [31]	31 [38]	76 [29]	0.154
Preop. ECLS	58 [17]	4 [5]	54 [20]	0.001*
BTC	260 [74]	62 [72]	198 [74]	0.667
DT	88 [25]	23 [27]	65 [24]	0.628
BTR	4 [1]	1 [1]	3 [1]	1.000

Unless stated otherwise, data is presented as median [IQR] for continuous and numbers [percentage] for categorical variables. *, $P < 0.05$. LVAD, left ventricular assist device; ICMP, ischemic cardiomyopathy; DCMP, dilatative cardiomyopathy; ECLS, extracorporeal life support; BTC, bridge to candidacy; DT, destination therapy; BTR, bridge to recovery; IQR, interquartile range.

a median follow-up time of 30 (IQR: 9–67) months, 42% (n=149) of the patients were deceased, 32% (n=111) were transplanted, 24% were alive on the device (n=86) and 6 patients (2%) were successfully weaned.

Patients with concomitant cardiac procedures

Patient characteristics and procedural data

The median age of this sub-cohort's patients was 60 (IQR: 52–67) years, the vast majority were male (80%). Patients with concomitant cardiac procedures suffered from dilatative cardiomyopathy (DCMP) more often than patients undergoing isolated LVAD implantation (53% *vs.* 36%, $P=0.005$). There was also a significant difference in the distribution of INTERMACS level: patients receiving additional interventions were more frequently in INTERMACS level 4 (38% *vs.* 30%, $P=0.154$), whereas the majority of the isolated LVAD group were in level 1 (32% *vs.* 16%, $P=0.003$). Significantly less patients were on preoperative ECLS compared to isolated LVAD procedures (5% *vs.* 20%, $P=0.001$).

A BTC concept was pursued in 62 patients (72%),

similar to the isolated LVAD group (74%). For more details see *Table 1*.

The most common concomitant cardiac procedure was tricuspid valve annuloplasty in 66 patients (77%), followed by aortic valve procedures in 28 patients (33%; bio-prosthesis in 86%, and modified Park's stitch in 14%). Other procedures included mitral valve annuloplasty (9%) and mitral valve replacement (1%). Overall 18 patients (21%) had two or more cardiac procedures in addition to LVAD implantation.

LIS techniques were carried out in 10 patients (12%) with concomitant cardiac procedures and in 118 patients (44%) without concomitant cardiac procedures ($P=0.000$).

Mean cardiopulmonary bypass (CPB) times were 163 ± 50 min. Aortic cross-clamping was required in 42% of the cases.

Temporary RV support was necessary in 30 patients (35%), using either ECLS (37%) or a temporary RV assist device (RVAD) to the pulmonary artery (63%). Though not statistically significant, there is still a trend towards a higher need for RV support compared to what was observed in isolated LVADs (25%, $P=0.06$) (*Table 2*).

Table 2 Procedural data				
Procedural data	Overall cohort (n=352)	Concomitant procedure (n=86)	Isolated LVAD (n=266)	P value
LIS	128 [36]	10 [12]	118 [44]	0.000*
Device				
HVAD	177 [50]	40 [46]	137 [51]	0.421
HMI	60 [17]	23 [27]	37 [14]	0.006*
HM3	115 [33]	23 [27]	92 [35]	0.178
TVR	NA	66 [77]	NA	NA
AVR	NA	24 [28]	NA	NA
Park stitch	NA	4 [5]	NA	NA
MVR	NA	8 [9]	NA	NA
X-clamp	NA	36 [42]	NA	NA
Temporary RV support	96 [27]	33 [36]	66 [25]	0.068

Unless stated otherwise, data is presented as median [IQR] for continuous and numbers [percentage] for categorial variables. *, P<0.05. LVAD, left ventricular assist device; LIS, less invasive; TVR, tricuspid valve repair; AVR, aortic valve replacement; MVR, mitral valve repair; X-clamp, cross-clamp; RV, right ventricular; IQR, interquartile range.

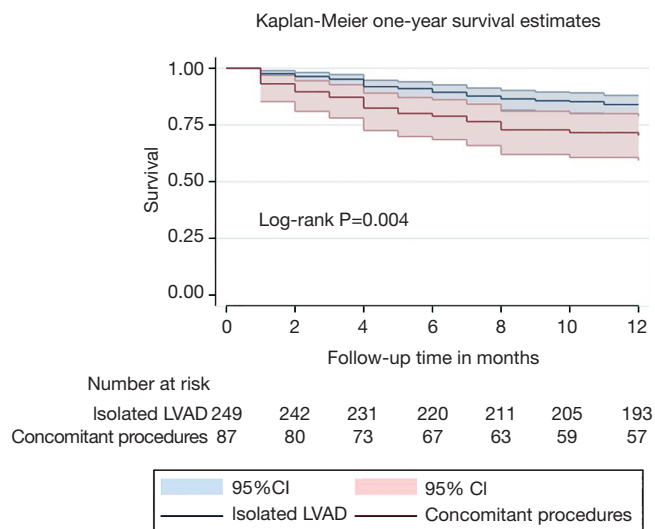


Figure 1 Postoperative outcomes. LVAD, left ventricular assist device.

Upon detailed analysis of the two most frequent concomitant procedures, isolated tricuspid valve repair (TVR) (56%) and isolated aortic valve procedures (18%), we observed similar durations of CPB (163 ± 71 min for aortic procedures *vs.* 153 ± 39 min for tricuspid repair, $P=0.975$). Not surprisingly, aortic cross-clamping was necessary in

only one case of tricuspid repair and all aortic procedures (2% *vs.* 100%, $P=0.000$).

Postoperative outcomes

Median duration of LVAD support was 403 (IQR: 125–1,004) days, compared to 544 (IQR: 254–965) days in the isolated LVAD group ($P=0.187$). Their status at 1-year is 57% alive on the device, 30% deceased and 13% have been successfully transplanted.

Thirty-day mortality is comparable between those with and without concomitant surgery (4% *vs.* 6%, $P=0.426$). The in-hospital mortality is significantly higher in the group with additional cardiac procedures (22% *vs.* 14%, $P=0.05$) but the one-year survival is similar (71% *vs.* 79%, $P=0.106$). See also *Figure 1*.

When comparing aortic and tricuspid valve procedures, the two most common procedures, we found a greater amount of DT patients (44% *vs.* 16%; $P=0.035$) with a significantly higher age [median age 65 [57–71] *vs.* 57 [50–65] years, $P=0.019$] in the aortic valve group. All other baseline characteristics were similar. Furthermore, no significant differences in terms of survival [30-day mortality aortic valve replacement (AVR) 12% *vs.* 2% TVR, $P=0.137$; in-hospital mortality 25% AVR *vs.* 22% TVR, $P=0.743$; one-year survival 56% AVR *vs.* 77% TVR, $P=0.202$] or

need for RV-support (13% AVR *vs.* 37% TVR, $P=0.063$) were detected.

Discussion

Valvular pathologies are a common finding in terminal heart failure and concomitant cardiac surgery at the time of LVAD implantation, especially tricuspid, aortic or mitral valve procedures, is frequent, providing reasonable short- and mid-term results.

We analysed our LVAD recipients undergoing additional cardiac surgery and compared them to isolated LVAD implantations. As a main finding of the study, we observed a significantly higher in-hospital mortality and a tendency towards a lower 1-year survival for patients having combined procedures. Furthermore, there was a significantly higher need for temporary RV support.

The study cohort is rather heterogenous in terms of some baseline characteristics, including reason for and duration of heart failure or INTERMACS level. Nevertheless, our results add to what has been published by other groups and registers.

Guidelines are clear regarding the necessity to address more than mild aortic regurgitation or intracardiac shunts (Class I indication according to current ISHLT guidelines) in atrioventricular valve procedures, but this controversial in the literature. A recent INTERMACS database analysis revealed that in tricuspid regurgitation, the repair had no survival benefit. On the contrary, they found a higher risk of bleeding, arrhythmia and stroke, and no improvement in quality of life. The main finding was that tricuspid valve procedure in patients for whom, tricuspid repair may be considered per current ISHLT recommendation, was associated with increased mortality (10). Veen and colleagues presented data from the EUROMACS registry, showing comparable survival rates for patients with or without concomitant tricuspid valve procedure at thirty days (13% *vs.* 10%), in-hospital (20% *vs.* 17%), and one year, but diverging survival curves after two years of follow up (76% in isolated LVADs *vs.* 63% in patients with concomitant procedures) (7). The effect of tricuspid repair seemed to be unsustainable, resulting in comparable risks for a recurrence of moderate to severe regurgitation after one-year.

Repair of mitral valve regurgitation has been shown to improve hemodynamic parameters (pulmonary hypertension, pulmonary vascular resistance) and hospital readmission rates after LVAD implantation. However, no survival benefit could be found (4,8,9). One-year survival

here was comparable, with 72% *vs.* 60% ($P=0.81$), but still worse than what we achieved in our patients.

These results and those of several other studies imply beneficial effects of concomitant valve surgery in the acute phase, however long-term effects remain the subject of controversial discussion.

It was suggested that patients in need of valve repair are their own entity of LVAD recipients. Such patients are less acute with a longer history of heart failure and fewer ischemic etiologies (7). Valvular insufficiencies, especially of the tricuspid valve, are probably—in the absence of structural defects—more an expression of secondary long-term effects of dilatation and pulmonary hypertension on the RV function in chronic heart failure rather than a symptom to treat per se.

In our study we can confirm these findings. Isolated LVAD recipients presented with a significantly higher proportion of ischemic disease, were more often in INTERMACS level one, and in higher need for preoperative ECLS.

The second finding, the tendency of an increased need for temporary RV support, can at least partially be explained by the higher proportion of chronic heart failure patients. Unfortunately, the exact details of preoperative RV status cannot be drawn from the retrospective data set, but this observation is in line with what is reported by the aforementioned studies. Mullan *et al.* found a significantly higher need for temporary RV support in patients undergoing concomitant tricuspid valve procedures (4.4% *vs.* 3.3%, $P=0.001$), and Sugiura *et al.* also reported an early RV failure rate of 28% in LVAD recipients with concomitant valve procedures (10,12). Even though the difference was statistically not significant, it is still interesting that in our cohort, patients undergoing aortic valve procedures at the time of LVAD implantation had the highest percentage of short-term mortality (12% thirty-day mortality), whereas those undergoing tricuspid annuloplasty as concomitant procedure to LVAD implantation showed the highest need for temporary RV support (37%). This finding might be associated with the need for aortic cross-clamping in aortic valve surgery or slightly longer CPB times, leading to an increased inflammatory response which then negatively influences perioperative morbidity and mortality (16). Another factor explaining this finding might be the older age and greater portion of DT patients that was observed for these patients.

Overall, we can state that concomitant cardiac procedures in LVAD recipients remain controversial. It

is debatable whether beneficial effects can be expected in the long run, since study results are highly diverse and often present opposing results, possibly caused by the heterogenous patient groups. There is evidence for improved hemodynamics after repair of mitral valve regurgitation, probably enhancing transplantability and improving late RV function. However, recent guidelines only suggest to address aortic valve regurgitation when more than mild and to close intracardiac shunts (Class I indication). In the absence of prospective randomized data resulting in reliable guidelines, performance of a concomitant cardiac surgery at the time of LVAD implantation remains mostly an individual choice.

Limitations

The present study is limited by its retrospective and non-randomized design. This has to be considered when evaluating the differences between patients with and without concomitant cardiac procedures.

Conclusions

Concomitant cardiac procedures in LVAD recipients are common but associated with an increased perioperative morbidity and mortality. The longer-term benefits of atrio-ventricular valve procedures remain unclear.

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Footnote

Conflicts of Interest: DZ, DW and TS: Research Grants, Travel Grants, Advisors and Proctors for Abbott and Medtronic, all institutional Grants from Abbott, Medtronic, Edwards, Berlin Heart. The other authors have no conflicts of interest to declare.

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