Turkish Journal of Thoracic and Cardiovascular Surgery 2023;31(1):37-44

ORIGINAL ARTICLE / ÖZGÜN MAKALE

Off-pump implantation of left ventricular assist device via minimally invasive left thoracotomy: Our single-center experience

Sol ventrikül destek cihazının minimal invaziv sol torakotomi ile off-pump implantasyonu: Tek merkez deneyimimiz

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ABSTRACT

Background: The aim of this study was to compare our experience of left ventricular assist device implantation via minimally invasive left thoracotomy with off-pump versus on-pump technique.

Methods: Between June 2013 and April 2020, nine patients (8 males, 1 female; mean age: 47±11.9 years; range, 30 to 61 years) who underwent off-pump left ventricular assist device implantation and nine patients (8 males, 1 female; mean age: 47±11.4 years; range, 29 to 60 years) who underwent on-pump minimally invasive left thoracotomy were retrospectively analyzed. Postoperative outcomes and mid-term results of both groups were evaluated.

Results: Outflow graft was anastomosed to the ascending aorta with J-sternotomy in all patients. The median duration of intubation and intensive care unit stay were one (IQR: 1.5) day and eight (IQR: 6.5) days in the off-pump group, respectively and one (IQR: 0) day and seven (IQR: 7) days in the on-pump group, respectively. Intra-aortic balloon pump was needed during the weaning of cardiopulmonary bypass in one (11%) of the patients in both groups. Postoperative right ventricular failure was observed in two (22%) patients in the off-pump group who were treated medically and recovered. There was no need for revision due to bleeding or postoperative extracorporeal membrane oxygenator implantation in either group. In the off-pump group, three patients underwent heart transplantation after median 854 (IQR: 960) days. Three patients died one month, two and four years after implantation. Three patients were still alive with left ventricular assist device and were being uneventfully followed for 365, 400, and 700 days after implantation.

Conclusion: Off-pump technique is safe and feasible option for implantation of left ventricular assist device via minimally invasive left thoracotomy.

Keywords: Left ventricular assist device, minimally invasive, off-pump, thoracotomy.

ÖZ

Amaç: Bu çalışmada, minimal invaziv sol torakotomi yoluyla sol ventrikül destek cihazı off-pump ve on-pump implantasyonu deneyimimiz karşılaştırıldı.

Çalışma planı: Haziran 2013 - Nisan 2020 tarihleri arasında, off-pump sol ventrikül destek cihazı implantasyonu yapılan dokuz hasta (8 erkek, 1 kadın; ort. yaş: 47±11.9 yıl; dağılım, 30-61 yıl) ve on-pump minimal invaziv sol torakotomi yapılan dokuz hasta (8 erkek, 1 kadın; ort. yaş: 47±11.4 yıl; dağılım, 29-60 yıl) retrospektif olarak incelendi. Her iki grubun ameliyat sonrası sonuçları ve orta dönem sonuçları değerlendirildi.

Bulgular: Çıkım grefti tüm hastalarda J-sternotomi ile çıkan aorta anastomoz edildi. Medyan entübasyon ve yoğun bakımda kalış süreleri off-pump grubunda sırasıyla 1 (IQR: 1.5) gün ve sekiz (IQR: 6.5) gün ve on-pump grubunda sırasıyla bir (IQR: 0) gün ve yedi (IQR: 7) gün idi. Her iki gruptaki hastaların birinde (%11) kardiyopulmoner baypas çıkışında intraaortik balon pompası ihtiyacı oldu. Off-pump grubundaki iki (%22) hastada medikal olarak tedavi edilen ve düzelen ameliyat sonrası sağ ventrikül yetmezliği görüldü. Her iki grupta da kanamaya bağlı revizyon veya ameliyat sonrası ekstrakorporeal memran oksijenatörü implantasyonu gereksinimi olmadı. Off-pump grubunda üç hastaya medyan 854 (IQR: 960) gün sonra kalp nakli yapıldı. Üç hasta implantasyondan bir ay, iki ve dört yıl sonra kaybedildi. Üç hasta sol ventrikül destek cihazı ile hala hayattaydı ve implantasyondan sonra 365, 400 ve 700 gün boyunca sorunsuz takip edildi.

Sonuç: Off-pump teknik, minimal invaziv sol torakotomi yoluyla sol ventrikül destek cihazı implantasyonu için güvenli ve uygulanabilir bir seçenektir.

Anahtar sözcükler: Sol ventrikül destek cihazı, minimal invaziv, off-pump, torakotomi.

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Doi: 10.5606/tgkdc.dergisi.2023.23370

Received: January 27, 2022
Accepted: August 23, 2022
Published online: January 30, 2023

Cite this article as: Karahan M, Kervan Ü, Kocabeyoğlu SS, Sert DE, Akdi M, Yılmaz A, et al. Off-pump implantation of left ventricular assist device via minimally invasive left thoracotomy: Our single-center experience. Turk Gogus Kalp Dama 2023;31(1):37-44. doi: 10.5606/tgkdc.dergisi.2023.23370.

Continuous-flow left ventricular assist device (LVAD) implantation is an effective treatment option for advanced heart failure unresponsive to medical therapy, and over 25,000 implants have been performed to date.[1] In recent years, in parallel with advanced technology and understanding the mechanism of continuous flow physiology, survival after LVAD implantation has increased.[2]

In LVAD surgery and other cardiac interventions, there is an orientation toward minimally invasive techniques by its nature. The main factors that cause this orientation in heart failure surgery are the devices miniaturized and operations that can be performed via minimal incisions.[3-5] Moreover, minimally invasive LVAD surgery via left thoracotomy (MILT) is an increasingly important option owing to less trauma, blood loss, arrhythmogenic complications, and less intensive care hospitalizations.[6,7]

The tendency to off-pump surgery has become inevitable to reduce possible postoperative complications such as blood product use.[8] On-pump surgery has detrimental effects on coagulation system by activation of systemic inflammatory response.[9] Moreover, reducing the need for blood products also reduces the likelihood of patients encountering possible blood antigens, thereby reducing the risk of sensitization of transplant candidates.[10]

In the present study, we aimed to compare our off-pump LVAD implantation via MILT experience with on-pump surgery and to evaluate the impact on postoperative outcomes and follow-up.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Ankara City Hospital, Department of Cardiovascular Surgery between June 2013 and April 2020. The hospital records of a total of 186 patients aged 18 years or older who underwent isolated LVAD implantation were screened. Implantation was performed in 41 of the patients using MILT. Of these, nine patients (8 males, 1 female; mean age: 47±11.9 years; range, 30 to 61 years) who underwent off-pump LVAD implantation and nine patients (8 males, 1 female; mean age: 47±11.4 years; range, 29 to 60 years) who underwent on-pump MILT with similar demographic characteristics were included. Patients with aortic valve regurgitation more than Grade 1, any concomitant heart surgery, thrombus formation in left ventricle (LV) or left atrium were excluded.

Device

Continuous-flow, centrifugal pumps were used for surgery. The HeartWare® (HVAD; Medtronic Inc., Framingham, MA, USA) and HeartMate 3® (HM3; Abbott Inc., Chicago, IL, USA) systems and their implantation have been previously described for minimally invasive surgery and ascending/descending aorta anastomosis.[4,5,11,12]

Surgical technique of minimally invasive implantation of LVAD

After general anesthesia and single-lumen endotracheal intubation, transesophageal echocardiography probe was placed, and implantable cardioverter defibrillator was switched off before surgery. First, the LV apex was reached through the left fourth or fifth intercostal space. Then, the appropriate location for the inflow cannula of the LV apex with transesophageal echocardiography (TEE) was marked and four felt sutures were placed, one for each quadrant and the sewing ring was sutured to the LV apex with 3/0 polypropylene or polyester stitches individually. Insufflation of carbon dioxide (CO_2) in the surgical field with a flow set at 2 to 4 bar was initiated. The ascending aorta was exposed via mini-J-sternotomy for outflow anastomosis. After administration of unfractionated heparin to achieve an activated clotting time of at least 300 sec, the aorta was partially clamped and outflow anastomosis was performed with a continuous polypropylene 5-0 suture in end-to-side fashion. The clamp was, then, removed, allowing the blood to de-air the graft and the graft was clamped again. The graft was directed intrapericardially to the apex of LV. The driveline was tunneled from the thoracotomy to the right upper quadrant of abdomen. Outflow graft and device were combined as suggested and de-airing of the pump was repeated. With rapid ventricular pacing, blood pressure was lowered briefly, and coring was performed through the sewing ring. Inflow cannula was passed through the sewing ring by performing de-airing maneuver and the device was secured. The speed of LVAD was gradually increased according to the septum position. We attempted to close the pericardium over the LVAD, whenever possible. In patients with previous surgery, a polytetrafluoroethylene membrane to avoid the adhesion to the surrounding lung tissue was needed. Full reversal of heparin by protamine infusion was administered.

Statistical analysis

Statistical analysis was performed using the SPSS version 15.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed in mean ± standard deviation (SD) or median

(interquartile range [IQR]), while categorical variables were expressed in number and frequency. The Shapiro-Wilk test was used, if a continuous variable followed a normal distribution. The Levene test and independent samples t-test were used to test for significance between two independent groups with normal distribution. The Mann-Whitney U test was used for continuous variables and chi-square test or Fisher exact test for categorical variables. A p value of <0.05 was considered statistically significant.

RESULTS

Demographic and preoperative data of the patients are shown in Table 1. Underlying disease

Table 1. Demographic and preoperative clinical characteristics of patients undergoing off-pump or on-pump implantation of left ventricular assist device

	Off-pump (n=9)			On-pump (n=9)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			47±11.9			47±11.4	0.953
Sex (%)							
Male	8	89		8	89		1.000
Height (cm)			170±6.9			172±7.3	0.539
Weight (kg)			69±12.3			65±9.7	0.445
Body surface area (m^2)			1.79±0.17			1.76±0.13	0.671
Body mass index (kg/m^2)			23.76±3.5			21.96±3.6	0.299
Etiology							
Dilated cardiomyopathy	6	66		5	55		1.000
Ischemic cardiomyopathy	3	34		4	45		
History of cerebrovascular event	1	11		1	11		1.000
INTERMACS level							
INTERMACS 1	1	11		1	11		1.000
INTERMACS 2	2	22		2	22		
INTERMACS 3	4	45		4	45		
INTERMACS 4	2	22		2	22		
Central venous pressure (mmHg)			12±4.3			11±4.2	0.489
Systolic PAP (mmHg)			48±16.3			42±10.3	0.348
Mean PAP (mmHg)			30±8.8			25±7.7	0.242
Pulmonary vascular resistance (wood units)			2.31±1.71			3.61±1.31	0.090
Transpulmonary gradient (mmHg)			6±5.5			8±4.1	0.604
Cardiac output (CO) (L/min)			3.72±1.1			2.84±0.5	0.061
Cardiac index (CO/m^2)			2±0.4			1.5±0.3	0.050
Pulmonary capillary wedge pressure (mmHg)			24±5.6			17±5.2	0.050
Systolic blood pressure (mmHg)			93±8.3			87±10.3	0.188
Heart rate (bpm)			86±14			90±14	0.578
Total bilirubin (mg/dL)			1.4±1.3			1.3±0.7	0.875
Urea (mg/dL)			61.4±27.8			59.7±28.3	0.901
Creatinine (mg/dL)			0.96±0.38			1.11±0.6	0.543
Hematocrit (%)			35±7.1			38±7.8	0.478
Left ventricular ejection fraction (%)			15±5.2			19±7.7	0.218
Right ventricular fractional area change (RV-FAC) (%)			25±7.4			28±5.2	0.273
Tricuspid annular plane systolic excursion (TAPSE) (mm)			13.5±2.8			14.6±3	0.431
Preoperative IABP (%)	2	22		2	22		1.000
Preoperative ECMO (%)	0	0		0	0		1.000

SD: Standard deviation; INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support; PAP: Pulmonary artery pressure; RV: Right ventricular; FAC: Fractional area change; TAPSE: Tricuspid annular plane systolic excursion; IABP: Intra-aortic balloon counterpulsation; ECMO: Extracorporeal membrane oxygenation; Mann-Whitney U test for continuous variables and chi-square test or Fisher exact test for categorical variables.

Table 2. Operative and postoperative characteristics of patients undergoing off-pump or on-pump implantation of left ventricular assist device

	Off-pump (n=9)					On-pump (n=9)					
Characteristics	n	%	Mean±SD	Median	IQR	n	%	Mean±SD	Median	IQR	*p*
Device type											
HeartMate 3	1	11				4	44				
HeartWare	8	89				5	56				
Duration of cardiopulmonary bypass (min)	-							63±22			
Intraoperative red blood cell use (patients)	3	33				5	55				0.637
Duration of intubation (days)				1	1.5				1	0	0.477
Duration of intensive care unit stay (days)				8	6.5				7	7	0.316
PO 1st day drainage (mL)				400	162.5				500	200	0.109
PO 1st day red blood cell use (patients)	2	22				4	44				0.620
PO IABP	1	11				1	11				1.000
PO right ventricular failure	2	22				0	0				0.471
PO ECMO	0	0				0	0				1.000
PO ischemic cerebrovascular event	2	22				3	33				1.000
PO gastrointestinal bleeding	0	0				2	22				0.471
Heart transplantation	3	33				2	22				1.000
Death	3	33				4	44				1.000
Alive with VAD	3	34				3	34				1.000

SD: Standard deviation; IQR: Interquartile range; PO: Postoperative; IABP: Intra-aortic balloon counterpulsation; ECMO: Extracorporeal membrane oxygenation; VAD: Ventricular assist device; Mann-Whitney U test for continuous variables and chi-square test or Fisher exact test for categorical variables.

was dilated cardiomyopathy (DCMP) in six (66%) patients and ischemic cardiomyopathy (ICMP) in three (34%) patients in the off-pump group and five (55%) patients were DCMP and four (45%) patients were ICMP in the on-pump group. At the time of implantation, according to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), one (11%) of the patient were in Profile 1, two (22%) in Profile 2, and four (44%) in Profile 4 in both groups. No significant differences were observed in the body mass index and body surface areas between the groups.

Preoperative pulmonary artery catheterization, hemodynamics, laboratory, and echocardiographic parameters are summarized in Table 1. The mean LV ejection fraction was 15±5.2% and 19±7.7% in the off-pump and on-pump groups, respectively ($p>0.05$). The mean values of right ventricular (RV) - fractional area change (FAC) and tricuspid annular plane systolic excursion (TAPSE) were 25±7.4% and 13.5±2.8 mm, respectively and 28±5.2% and 14.6±3 mm, respectively in the off-pump and on-pump groups ($p>0.05$). All other preoperative pulmonary artery catheterization, hemodynamics, laboratory, and echocardiographic parameters were similar in both groups ($p>0.05$). The HeartMate 3® in one (11%) patient and HeartWare® in eight (89%) patients in the off-pump group and the HeartMate 3® in four (44%) patients and HeartWare® in five (56%) patients in the on-pump group were implanted (Table 2).

Postoperative outcomes and follow-up

The mean duration of cardiopulmonary bypass (CPB) time in the on-pump group was 63±22 min. Three (33%) patients in the off-pump group and five (55%) patients in the on-pump group needed intraoperative red blood cell (RBC) replacement. The median duration of intubation and intensive care unit stay (ICU) were one (IQR: 1.5) days and eight (IQR: 6.5) days in the off-pump group and one (IQR: 0) days and seven (IQR: 7) days in the on-pump group, respectively. Intra-aortic balloon pump (IABP) was needed during the weaning of CPB in one (11%) of the patients in both groups. Postoperative RV failure (RVF) was observed in two (22%) patients in the off-pump group who were treated medically and recovered. There was no need for revision due to bleeding or postoperative extracorporeal membrane oxygenator (ECMO) support in either group. In the off-pump group, three patients underwent heart transplantation after median 854 (IQR: 960) days. Three patients died one month, two and four years after implantation. Three patients were still alive with LVAD and were being uneventfully followed for 365, 400, and 700 days after implantation. In the on-pump group, two patients underwent heart transplantation 510 and 850 days after implantation, respectively. Four patients died in one, four, five and six years after implantation, respectively. Three patients were still alive with LVAD and were being uneventfully followed for five, five, and six years after implantation, respectively (Table 2).

DISCUSSION

In the current study, we compared patients who underwent LVAD implantation via MILT with the age- and sex- matched on-pump patients. Based on the study results, off-pump surgery has similar results to on-pump surgery.

Left ventricular assist device implantation is a complex surgical procedure in patients with end-stage heart failure. When these patients are compared with standard cardiac surgery patients, they have a higher surgical risk. Previous studies have shown that minimally invasive LVAD implantation is associated with less trauma, blood loss and infection, and shorter ICU stay.[7,13,14] Moreover, minimally invasive surgery is thought to prevent RVF, since the geometry of the pericardium does not deteriorate, the RV construction remains more stable.[15] Cardiopulmonary bypass has, itself, certain disadvantages such as activation of systemic inflammatory response and deleterious effects on the coagulation system.[9] The idea of off-pump surgery is plausible, as these effects may disrupt hemodynamics and cause undesirable outcomes during or after surgery in patients with end-stage heart failure.

Off-pump LVAD implantation has no long-term outcomes in large series. In studies conducted with a small number of patients so far, the survival rate of off-pump LVAD implantation was 92% at one month and 85% at one year.[16,17] These results are consistent with those of standard LVAD implantation.[18] However, whether off-pump surgery is truly safe is still uncertain and needs to be investigated in randomized trials. Since off-pump surgery is performed in patients at high risk for CPB, these high-risk patients need long-term comparative results with those undergoing on-pump surgery.

One of the most detrimental complications of mechanical circulatory support, early cerebrovascular events that have not been documented after off-pump LVAD surgery in the studies, yet. During follow-up, number of emerging new cerebrovascular events are similar with on-pump surgery.[8] Despite the advantages

of off-pump LVAD implantation, embolization of an atheroma is still a possible threatening issue during manipulations of ascending or descending aorta during outflow anastomosis.

One disadvantage of off-pump LVAD surgery is the LV cavity that cannot be examined thoroughly and may cause apical thrombi or trabeculae obstruct the inflow of the device. Thus, it is crucial to perform a precise intraoperative TEE and it is extremely important to investigate the heart cavities, if there is an obstacle that can clog the device. Moreover, without a circulatory assist of CPB, maintaining a stable hemodynamic status is challenging while sewing the ring, coring the apex, and securing the device. It is particularly important that the perfusion team, and the CPB circuit must be ready in the operation room, as hemodynamics of the patient with heart failure can be impaired at any time.

Conventional LVAD implantation under CPB via median sternotomy increases the need for blood transfusion.[19] Sensitization of the patients with LVAD implantation and concomitant transfusion have been reported to have a negative effect on survival and graft failure after heart transplantation.[20] In the study by Gaffey et al.,[21] it has been shown that increased transfusion rates may cause an increase in infection rates, which is associated with undesired events in heart transplantation. In Gregoric et al.'s[13] study, requirement of blood transfusion during surgery and within the early postoperative period in off-pump LVAD implantation was lower than the on-pump surgery. They also reported shorter duration of postoperative mechanical ventilatory support for patients in off-pump group. In the present study, although ICU stay seemed to be higher (mean 6 days), it was found to be lower compared to studies with sternotomy (13.1 days).[22]

Cardiopulmonary bypass has negative effects on platelet dysfunction, fibrinolysis, and degradation of coagulation factors.[23-25] This response is a pathway similar to the occurrence of an acute phase reaction seen in sepsis.[26] The activation of systemic inflammatory response is the cause of these adverse events.[9] Additionally, activation of these systems by LVAD may be exacerbated or aggravated the effects of CPB.[27] The off-pump surgery approach in patients with heart failure, which may be more affected by the negative effects of CPB than the normal patient population, may change the results positively.

Off-pump implantation of LVAD is a surgery that is thought to be associated with many risks, such as piercing and wearing the heart in common parlance, and that is a challenge for surgeons. However, while a patient with advanced heart failure has already risk for surgery, adding the adverse events of CPB on it can create negative effects for the mortality and morbidity. Off-pump approach is plausible in selected patient groups, and off-pump surgery is not an approach that should come to mind first by the teams at the beginning of the learning period. Surgeons must have been experienced in conventional technique of LVAD implantation, then perform MILT and off-pump surgery. Therefore, technique-related undesirable events may not be observed in the learning curve of off-pump surgery. In this approach, not only surgeons should not pay attention; but also, anesthesiologists and perfusionists should also be familiar with this technique and be prepared for its complications.

Nonetheless, this study has some limitations. First, the sample size is small. Second, although the data were collected prospectively, our study is limited by its retrospective design. Third, this is a single-center experience; therefore, outcome interpretation is limited by institutional bias.

In conclusion, off-pump left ventricular assist device implantation via minimally invasive left thoracotomy is safe and a feasible option. Our study results show that off-pump implantation of left ventricular assist device have similar outcomes with the on-pump group. Off-pump technique may be applied to prevent additional complications related to cardiopulmonary bypass. Avoiding cardiopulmonary bypass may not only prevent adverse events, but may also provide potentially better results at the time of heart transplant.

Ethics Committee Approval: The study protocol was approved by the Ankara City Hospital Ethics Committee (date: 03.03.2021, no: E1-1572-2021). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Idea/concept: M.K., U.K., S.K.; Design: M.K., U.K., S.K., D.S.; Data collection: M.A., A.Y. C.K.; Analysis: D.S.; Writing article: M.K., U.K., S.K., D.S., M.A., Z.C.; Critical review: U.K., S.K., Z.C.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding: The authors received no financial support for the research and/or authorship of this article.

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