

Telecardiographic measurements for device migration: A useful tool for follow-up

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ABSTRACT

OBJECTIVE: Pump thrombosis in left ventricular assist device (LVAD) patients is an important cause of mortality and morbidity. Inflow cannula migration is a predisposing factor for pump thrombosis. Telecardiographic measurements can be used to follow up apical cannula deviation. In this study, we aimed to evaluate the migration of the inflow cannulas in patients with LVADs using angle measurements on telecardiograms

METHODS: Twenty-three patients who were implanted left ventricular assist devices in our clinic between February 2013 and April 2016 were included in our study. During the first year of follow-up, changes in angle measurements on postoperative 1st, 3rd, 6th, and 12th month telecardiograms were compared against the incidence of device thrombus and serum Lactate Dehydrogenase (LDH) levels.

RESULTS: Patients who were diagnosed with device thrombosis had more change in inflow cannula angles than patients without device thrombus ($p < 0.05$ at 6th and 12th months). Patients with higher LDH values had more parallel angular changes at all intervals, and the change in angle was statistically significant at 3rd, 6th and 12th months ($p < 0.05$).

CONCLUSION: This study shows that it is possible to track the migration of inflow cannulas in patients with left ventricular heart failure using telecardiograms. The correlation between angle change and LDH levels and embolic events may suggest that telecardiographic follow up of angles may be a useful tool for ventricular assist devices teams for early detection of thrombus.

Keywords: Heart failure; thrombosis; ventricular assist device.

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Left ventricular assist devices (LVAD) allow bridging of end-stage heart failure patients to definitive treatments or sustain survival as destination therapy [1, 2]. Despite a reasonable period of survival with an increased quality of life, device-related complications are not rare. Pump thrombosis is among the most severe complications [3]. A combination of antiplatelet and anticoagulant treatments is advised against pump thrombosis [4, 5]. However, pump thrombosis may still occur under seemingly effective anticoagulation. The

migration of the assist device within the mediastinum is shown to be a predisposing factor for pump thrombosis. It has been postulated that the change in the angle of inflow cannula as a result of device migration causes changes in flow metrics that lead to thrombus formation within the device [6–8].

In this study, we aimed to evaluate the ability of the telecardiogram in assessing device migration and its utility in aiding the detection of pump thrombosis.



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MATERIALS AND METHODS

Patient Selection

Heart failure patients who received an LVAD between February 2013 and April 2016 (38 months) were retrospectively analyzed in this study. Patients aged >18 years who were regularly followed up in our center for at least one year after device implantation, with telecardiographies at 1, 3, 6, and 12 months and INR values consistently between 2.5–3.5 were identified and included in this study.

Data Collection

Demographic variables, preoperative and postoperative echocardiographic data were retrospectively collected. Angle measurements were made on anteroposterior telecardiographic images on postoperative day 1, and at 1, 3, 6, 12 months. Serum Lactate Dehydrogenase (LDH) levels on the same dates as the teleradiography images were recorded. LDH levels 2.5 times above the upper normal limit were accepted as high. The Institutional Committee of Haydarpasa Numune Training and Research Hospital approved the study protocol. This study conformed with the principles of the Declaration of Helsinki.

Technique for Angle Measurements

Correct inflow cannula position during LVAD implantation is routinely confirmed with transesophageal echocardiography (TEE) to assure a cannula position parallel to the interventricular septum. During the follow up, transthoracic echocardiography (TTE) and, when needed, TEE are utilized to evaluate LVAD patients. Certain objective measurement criteria were defined to utilize telecardiogram in the evaluation of the inflow cannula positions. Therefore, to prevent mistaken measurements and to assure a standard in the evaluation, images in which sternal wires were in line with the vertebral borders were chosen for angle measurements. A line parallel to the sternal wires, and therefore the vertebral borders, was extended and a second line perpendicular to the first was drawn. This second transverse line and a line through the inflow cannula were connected to acquire the angle in between, termed the “parallel angle” (Fig. 1).

A second angle was measured for patients implanted with a HeartMate II device (Thoratec Corp., Pleasanton, CA, USA) between the inflow cannula and device body, termed the “device angle” (Fig. 2).

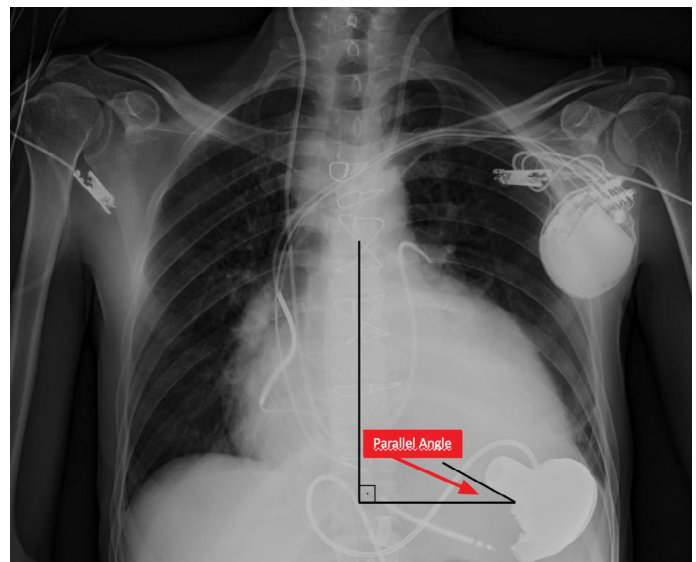


FIGURE 1. Parallel angle of the HearWare.

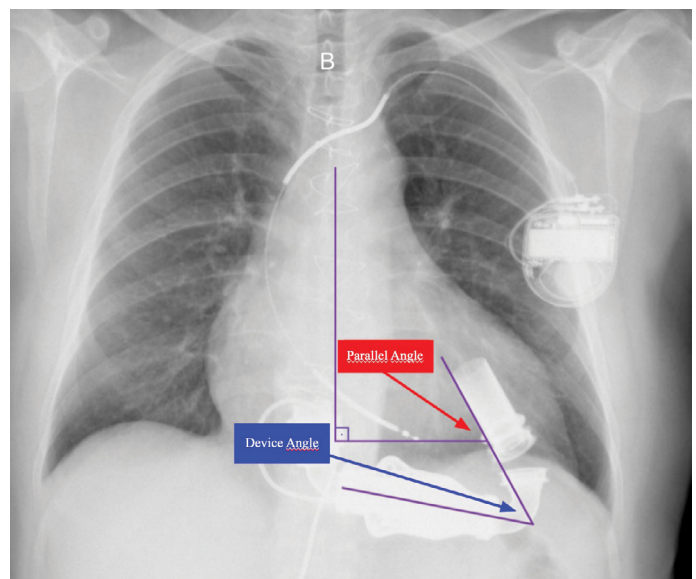


FIGURE 2. Parallel angle and device angle of the HeartMate II.

Device Thrombosis

Patients with ischemic cerebrovascular events, LDH levels 2.5 times above the upper normal limit, high device power usage, and device thrombosis determined by echocardiography were included in the device thrombosis group.

Statistical Analysis

NCSS (Number Cruncher Statistical System) 2007 (Kaysville, Utah, USA) was used to perform statistical analysis. Besides descriptive statistics (mean, standard

TABLE 1. Baseline characteristics

Characteristics	
Age (year); Mean±SD	51.04±6.21
Gender; %	
Male	91.3
Female	8.7
BMI (kg/m ²); Mean±SD	26±2.81
Etiology; %	
Dilated	34.8
Ischemic	65.2
Intermacs; %	
2	8.7
3	39.1
4	52.1

SD: Standard deviation; BMI: Body mass index.

deviation, median, frequency, minimum, maximum), the Mann-Whitney U test was applied to compare quantitative data without normal distribution. Fisher's Exact test was applied to compare quantitative data. P values <0.05 were accepted for significance.

RESULTS

Thirty-eight patients had received an LVAD between February 2013 and April 2016 in our institution. 23 patients met the inclusion criteria and were included in this study. 18 patients were implanted with HeartMate II and five patients with a HeartWare (Medtronic, Minneapolis, MN, USA) LVAD. The baseline characteristics of the patients are given in Table 1.

Among all LVAD patients in our clinic, the rate of clinically evident thrombosis was 16%, while among the 23 patients included in this study the rate was 26%. Only one of these patients required device exchange. Of the six patients with pump thrombosis, the implanted device was HeartMate II. None of the five patients in the study with HeartWare developed pump thrombosis. No pump thrombosis was observed in any of the patients that could not be included in this study.

Change in the parallel angle for HeartWare inflow cannula was lower than HeartMate II in all measurements. A higher degree of migration was detected in patients with HeartMate II devices; however, this difference was not statistically significant ($p>0.05$) (Table 2).

TABLE 2. Comparison of parallel angle changes according to device

Time (month)	Device		p
	HeartWare (n=5) Mean±SD	HeartMate II (n=18) Mean±SD	
1	4.00±2.55	4.50±4.85	0.735
3	4.80±3.63	6.22±5.45	0.765
6	6.20±5.67	8.00±6.25	0.575
12	4.40±2.07	8.22±5.62	0.191

SD: Standard deviation.

TABLE 3. Comparison of parallel angle changes and LDH level

Time (month)	LDH		p
	Normal (n=9) Mean±SD	Elevated (n=14) Mean±SD	
1	3.0±2.35	5.29±5.22	0.374
3	3.22±3.38	7.64±5.31	0.031
6	4.11±4.65	9.86±5.89	0.005
12	4.44±2.92	9.29±5.65	0.040

*Elevated: Level above 2.5 times normal at least for once. SD: Standard deviation; LDH: Serum lactate dehydrogenase.

Levels of LDH values were compared against changes in the change parallel angle, as shown in Table 3. Patients with higher changes in the parallel angle of the inflow cannula had higher LDH values at all measurement points. This difference was significant in the 3rd, 6th, and 12th months ($p<0.05$ at three and 12 months, $p<0.01$ at six months). The same significance ($p<0.05$) was obtained at three and six months when only HeartMate II patients were analyzed at three and six months (Table 4). HeartWare patients were not analyzed due to the low number of patients with this device. However, the increase in LDH values with the changes in device angle for HeartMate II patients was not found to be significant (Table 5).

Comparison of patients with and without pump thrombosis for changes in the parallel angle is given in Table 6. Patients with device thrombosis had higher

TABLE 4. Comparison of parallel angle changes and LDH level for HeartMate II

Time (month)	LDH level		p
	Normal (n=5)	Elevated* (n=13)	
	Mean±SD	Mean±SD	
1	2.20±1.64	5.38±5.42	0.320
3	1.60±1.82	8.00±5.35	0.010
6	2.40±1.67	10.15±6.03	0.005
12	4.60±3.58	9.62±5.74	0.067

*Elevated: Level above 2.5 times normal at least for once. SD: Standard deviation; LDH: Serum lactate dehydrogenase.

TABLE 5. Comparison of HeartMate II device angle measurements and LDH level

Time	LDH level		p
	Normal (n=5)	Elevated* (n=13)	
	Mean±SD	Mean±SD	
1 st day	35.20±4.71	38.85±14.61	0.921
1 st month	37.40±6.80	41.77±13.48	0.693
3 rd month	39.60±7.99	39.62±1296	0.621
6 th month	40.60±7.99	41.31±15.11	0.656
12 th month	41.80±7.79	41.08±14.37	0.554

*Elevated: Level above 2.5 times normal at least for once. SD: Standard deviation; LDH: Serum lactate dehydrogenase.

changes in parallel angle compared to patients without device thrombosis at all measurement times. This difference was significant at six and 12 months ($p < 0.05$). When the devices were compared for changes in the parallel angle, HeartWare patients had lower parallel angle measurements than HeartMate II patients. Changes in the parallel angle were higher at all times in HeartMate II patients at all measurement points, but this difference was not statistically significant ($p > 0.05$).

DISCUSSION

LVADs are a feasible treatment option for improving the quality of life and survival in late-stage heart failure patients bridged to transplant or implanted as destination therapy

TABLE 6. Comparison of parallel angle change and thromboembolic events

Time (month)	Thrombus		p
	- (n=17)	+ (n=6)	
	Mean±SD	Mean±SD	
1	3.82±3.21	6.00±6.96	0.888
3	5.18±5.34	8.00±3.85	0.106
6	6.35±6.15	11,17±4.40	0.032
12	6.12±4.73	11.00±5.44	0.049

-: Thrombus not detected; +: Thrombus detected; SD: Standard deviation.

[9]. Device complications are an important cause of morbidity and mortality in LVAD patients. Pump thrombosis among the most significant complications [10]. Several factors play a role in pump thrombosis, and migration of device body and inflow cannula are considered to increase the risk for its occurrence [6, 8]. In clinical practice, echocardiographic evaluation provides information on suspected device migration. We investigated whether a simpler imaging method, the telecardiogram, could be useful for the same purpose. Echocardiography for LVAD patients requires specific expertise and is optimally performed by the same clinician during follow up. These conditions may not be available at all times in centers that are not experienced in following up heart failure patients. We investigated whether under such conditions, a simpler and easily accessible telecardiogram could be utilized.

A limited number of studies exist on the detection of device migration using telecardiographic measurements. Taghavi et al. studied the angle between the inflow cannula and device body at the time of implantation and found an increased risk for pump thrombosis when the angle was smaller than 55 degrees [7]. They noted that device migration detected by the change in the angle of inflow cannula did not significantly correlate with pump thrombosis. They also reported that the depth of the device pocket where the LVAD body is placed decreased with time.

In a later study, Adamson et al. studied angles on telecardiographies of LVAD patients [6]. The amount of change in the angle of the device body was found to be greater in patients with device thrombosis. This study looked at the angle between the inflow cannula and a line vertical to the vertebra, somewhat different from the parallel angle we studied. The change in this angle over time after

implantation in all their LVAD patients was also found to be significant, with a 1-degree change detected at the end of the 2-year follow up. Our study using the parallel angle detected a 2-degree change, which was not statistically significant. A different study by Han et al. used the same angle measurements as Taghavi et al. to arrive at different results [11]. Mean change in the angle of inflow cannula was not significantly correlated with device thrombosis.

Sorensen et al. used computer tomography measurements to analyze the relationship between change in inflow cannula angle and device thrombosis and they found a significant correlation [8]. This study was different from the other studies in that the absolute value of the angle change was used to compare patients with device thrombosis against those without. The degree of the inflow cannula may be increased or decreased, which may cancel each other during the calculation of mean change despite the existence of migration. Thus, different from most of the other studies, we used the absolute value of the changes in inflow angles to compare patients, similar to Sorensen et al.

HeartWare patients were found to have lower parallel angle measurements than HeartMate II patients. A possible explanation for this difference could be the low number of HeartMate II patients included in this study. Further studies with a considerable number of patients with different devices need to be designed to compare the devices for changes in angles.

LDH increase is evident in case of pump thrombosis [12, 13]. Akin et al. have shown that a threefold increase in LDH has an 88% specificity and 97% sensitivity as a marker of hemolysis [13]. When LDH levels were compared with changes in parallel angle at the same time points, patients with a higher change in the angle also had higher LDH levels. This correlation supports our view that pump thrombosis and hemolysis are more frequent in patients with a considerable change in the telecardiographically measured angle.

The prevalence of pump thrombosis varies in studies [14, 15]. Taghavi et al. found a 22.4% prevalence of pump thrombosis [7], while Simon Maltais et al. with their surgical precautions detected a 4.8% rate of pump thrombosis after the 6-month follow-up [16]. Device thrombosis was seen in 16% of the LVAD patients in our clinic, while the rate was 26% among patients that met the inclusion criteria with available telecardiogram and echocardiography data. Pump thrombosis remains a vital issue for LVAD patients, and the telecardiogram

could prove useful in its detection when other imaging methods are not readily available.

Conclusion

Device migration is an important risk factor for pump thrombosis in LVAD patients. Our study showed that telecardiograms are a useful tool in detecting changes in cannula angles. The change in parallel angle, corresponding to the severity of device migration, is correlated with an elevation in serum LDH. The telecardiogram, as a simple and inexpensive method, can be used to assess LVAD migration.

Ethics Committee Approval: The Haydarpasa Numune Training and Research Hospital Clinical Research Ethics Committee granted approval for this study (date: 24.01.2017, number: 2017/44).

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Authorship Contributions: Concept – FAB, MS; Design – FAB, MS, SAA; Supervision – SAA, GO; Materials – MB, MS, MTM; Data collection and/or processing – MB, OY, MTM; Analysis and/or interpretation – SAA, GO, OY; Writing – FAB, MTM, MB; Critical review – OY, MTM, SBE.

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