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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: 23 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 12nd 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 then patients without device thrombus ($p<0.05$ at 6th and 12nd 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 12nd 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 of complications [3]. A combination of antiplatelet and anticoagulant treatments is advised against pump thrombosis, [4, 5]. however, pump thrombosis can still occur under seemingly effective anticoagulation. 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. Patients aged >18 years who were regularly followed up in our center for at least 1 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 the 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 xxxxxxx Research and Education Hospital approved the study protocol. The study conformed with the principles of 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 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 (Thoratec Corp., Pleasanton, CA,USA) device, between the inflow cannula and device body, termed the "device angle" (Fig. 2).

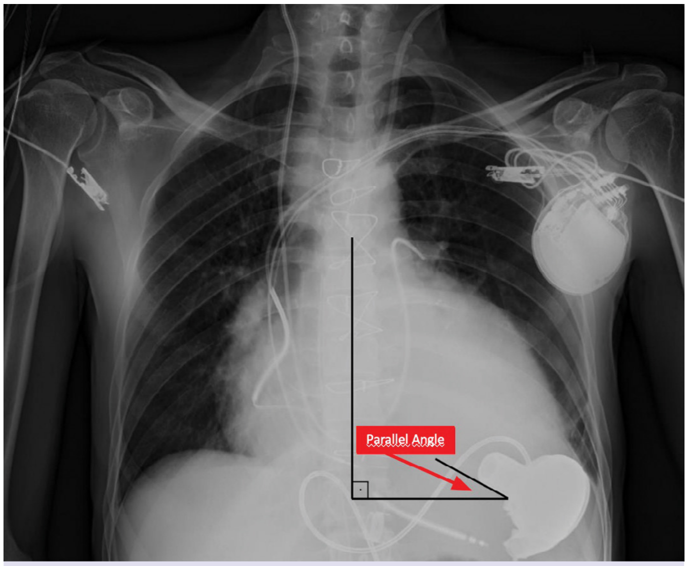

Figure 1. Parallel angle of HeartWare.

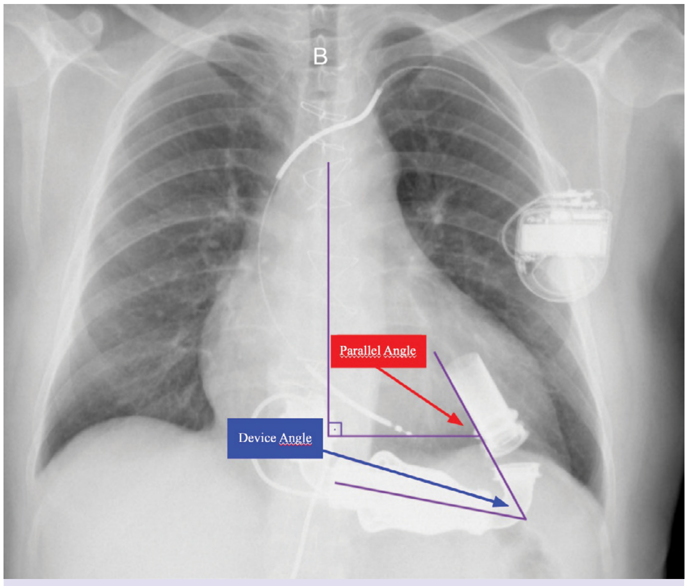

Figure 2. Parallel angle and device angle of HeartMate II.

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 deviation, median, frequency, minimum, maximum),

Table 1. Baseline characteristics

Characteristics	n	%
Age (year)		
Mean±SD	51.04±6.21	
Median (Min.-Max.)	51 (42–61)	
Gender		
Male	21	91.3
Female	2	8.7
BMI (kg/m²)		
Mean±SD	26±2.81	
Median (Min.–Max.)	26 (21–32.4)	
Etiology		
Dilated	8	34.8
Ischemic	15	65.2
Intermacs		
2	2	8.7
3	9	39.1
4	12	52.1

n: Patients number; SD: Standard deviation; Min.: Minimum; Max.: Maximum; BMI: Body mass index.

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 was accepted for significance.

RESULTS

38 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 5 patients with a HeartWare (Medtronic, Minneapolis, MN,USA) LVAD. 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 the study the rate was 26%. Only 1 of these patients required device exchange. Of 6 patients with pump thrombosis, the implanted device was HeartMate II. None of the 5 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 the 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).

Levels of LDH values were compared against changes in change parallel angle, as shown in Table 3. Patients with higher changes in parallel angle of the inflow cannula had higher LDH values at all measurement points. This difference was significant in the 3rd, 6th, and 12nd months. (p<0.05 at 3 and 12 months, p<0.01 at 6 months). The same significance (p<0.05) was obtained at 3 and 6

Table 2. Comparison of parallel angle changes according to device

Time (month)		Device: HeartWare (n=5)	Device: HeartMate II (n=18)	p
1	Mean±SD	4.00±2.55	4.50±4.85	0.735
	Median	4.0	3.0	
3	Mean±SD	4.80±3.63	6.22±5.45	0.765
	Median	3.0	4.5	
6	Mean±SD	6.20±5.67	8.00±6.25	0.575
	Median	4.0	6.5	
12	Mean±SD	4.40±2.07	8.22±5.62	0.191
	Median	5.0	9.0	

SD: Standard deviation.

Table 3. Comparison of parallel angle changes and LDH level

Time (month)		LDH: Normal (n=9)	LDH: Elevated (n=14)	p
1	Mean±SD	3.0±2.35	5.29±5.22	0.374
	Median (range)	3 (0–8)	4 (0–18)	
3	Mean±SD	3.22±3.38	7.64±5.31	*0.031*
	Median (range)	3 (0–11)	7.5 (1–21)	
6	Mean±SD	4.11±4.65	9.86±5.89	*0.005*
	Median (range)	3 (1–16)	8.5 (2–24)	
12	Mean±SD	4.44±2.92	9.29±5.65	0.040
	Median (range)	5 (0–8)	10.5 (1–19)	

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

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

Time (month)		LDH level Normal (n=5)	Elevated* (n=13)	p
1	Mean±SD	2.20±1.64	5.38±5.42	0.320
	Median (range)	3 (0–4)	4 (0–18)	
3	Mean±SD	1.60±1.82	8.00±5.35	*0.010*
	Median (range)	1 (0–4)	8 (1–21)	
6	Mean±SD	2.40±1.67	10.15±6.03	*0.005*
	Median (range)	2 (1–5)	9 (2–24)	
12	Mean±SD	4.60±3.58	9.62±5.74	0.067
	Median (range)	5 (0–8)	11 (1–19)	

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

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

Time	LDH level Normal (n=5)	Elevated* (n=13)	p
1st day			
Mean±SD	35.20±4.71	38.85±14.61	0.921
Median	37	32	
1st month			
Mean±SD	37.40±6.80	41.77±13.48	0.693
Median	41	37	
3rd month			
Mean±SD	39.60±7.99	39.62±1296	0.621
Median	41	35	
6st month			
Mean±SD	40.60±7.99	41.31±15.11	0.656
Median	42	35	
12nd month			
Mean±SD	41.80±7.79	41.08±14.37	0.554
Median	43	38	

*Elevated: Level above 2,5 times normal at least for once. n: Patients number; SD: Standard deviation; LDH: Serum lactate dehydrogenase.

months when only HeartMate II patients were analyzed at 3 and 6 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 parallel angle are given in Table 6. Patients with device thrombosis had higher changes in parallel angle compared to patients without device thrombosis at all measurement times. This difference was significant at 6 and 12 months ($p<0.05$). When the devices were compared for changes in parallel angle, HeartWare patients had lower parallel angle measurements than HeartMate II patients. Changes in 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 [9]. Device complications are an important cause of morbidity and mortality in LVAD patients. Pump thrombosis among the most significant of 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 require 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 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 to 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 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 others 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 to most 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 the study. Further studies with greater 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 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 greater change in the telecardiographically measured angle.

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 elevation in serum LDH. The telecardiogram as a simple and inexpensive method can be used to assess LVAD migration.

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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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