

# Outcomes of Tele-follow-up and Conventional Follow-up to Detect Postoperative Complications after Cardiac Implantable Electronic Device Implantation

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**Background:** Cardiac implantable electronic device (CIED) recipients require follow-up at hospitals to identify complications that may occur after implantation.

**Objective:** The present study aimed to assess the outcomes of telephone and conventional follow-up for detecting complications among CIED recipients.

**Materials and Methods:** The present study was a pragmatic, randomized trial comparing tele-follow-up and conventional follow-up. The tele-follow-up group sent the investigator a photo of the incision wound and answered questions about the complications on postoperative day 7 via their smartphones. The conventional follow-up group visited the CIED clinic for routine follow-up. The complications associated with CIED implantation were compared between the two groups.

**Results:** A total of 80 patients were included in the present study: 40 in the tele-follow-up group and 40 in the conventional follow-up group. Complications related to implantation occurred in six patients (15.0%) in the tele-follow-up group and six patients (15.0%) in the conventional follow-up group (hazard ratio [HR] 0.87, 95% confidence interval [CI] 0.16 to 4.68,  $p=0.44$ ) 7 days after surgery. Furthermore, 17 (42.5%) patients in the tele-follow-up group and 12 (30.0%) patients in the conventional follow-up group (HR 1.56, 95% CI 0.65 to 3.74,  $p=0.16$ ) developed complications 30 days after surgery. The satisfaction scores were  $22.49 \pm 1.67$  and  $21.10 \pm 2.26$  in the tele-follow-up and conventional follow-up groups, respectively ( $p=0.003$ ).

**Conclusion:** In patients with CIED implantation, the procedure-related complications were not significantly different between the tele-follow-up and conventional follow-up groups. However, the tele-follow-up group had higher satisfaction scores than the conventional follow-up group.

**Keywords:** Cardiac implantable electronic devices; Postoperative complication; Tele-follow-up

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Patients who underwent cardiac implantable electronic device (CIED) implantation need to visit hospitals for follow-up. After the postimplantation period, patients are scheduled for follow-up visits quite frequently. Patients often complain of many problems that they encounter during hospital follow-up visits, including crowded outpatient departments, provider shortages, expenses, and traffic jams,

especially in the case of tertiary care. Therefore, the use of communication technology, such as smartphones, to follow-up patients with CIED implantation has been introduced to address this issue<sup>(1)</sup>.

Patients with CIEDs (both those with new CIED implantation and those changing the pulse generators) are at risk of complications, such as bleeding, hematoma, wound infection, thrombotic complications, and even shoulder pain<sup>(2)</sup>. Therefore, close monitoring of patients with CIEDs is necessary to detect complications.

Previous studies have shown that 1.2% of patients experience major complications that require reoperation or hospitalization after 90 days of implantable cardioverter-defibrillator implantation<sup>(3)</sup>. Additionally, minor complications that do not require reoperation or hospitalization have been observed. Minor bleeding has been reported to occur in approximately 7.2% of all patients receiving anticoagulant therapy and 1.6% of those receiving dual antiplatelet therapy<sup>(4)</sup>. The prevalence of

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thromboembolic events is <5%<sup>(5)</sup>. The estimated incidence of wound infection is 1.6% at 6-month follow-up among patients with CIED implantation<sup>(6)</sup>. There also are studies showed that the prevalence of shoulder pain or frozen shoulder was about 60% at 3-month follow-up<sup>(7,8)</sup>.

CIED implantation and pulse generator replacement were performed for approximately 100 patients at Vajira Hospital in 2018. These patients were periodically monitored in the hospital. They face many problems during hospital visits. Therefore, a tele-follow-up system was developed to resolve patient complaints, which involves using a smartphone to send pictures of the surgical wound and answer questions about the complications 7 days after surgery. Approximately 30 days after surgery, the patient needed to visit the hospital for CIED interrogation.

The authors hypothesized that the rates of major and minor complications would not differ by >20% (the noninferiority margin) between the tele-follow-up and conventional follow-up groups. Therefore, this study aimed to compare the CIED procedure-related complications and patient satisfaction scores between the tele-follow-up and conventional follow-up groups.

## Materials and Methods

### Study design

This was a noninferiority randomized controlled trial. The present study was approved by the Ethics Committee of the Faculty of Medicine, Vajira Hospital, Navamindradhiraj University (COA 018/2562). Informed consent was obtained from all patients. Patients were informed about the advantages and disadvantages of participating in this research.

### Implantation protocol

CIED implantation was performed by experienced implanters performing >40 implantations per year who were randomly assigned and were blinded to the study groups. All patients received ceftriaxone before surgery. If the patients were allergic to penicillin or cephalosporin, clindamycin was administered instead. Axillary vein puncture or cephalic vein cutdown was the preferred access approach. No pocket irrigation was routinely performed. Skin closure was performed using absorbable Vicryl sutures and Steri-Strip. Postprocedure oral antibiotics are optional and up to the implanter's decision.

### Study patients

The present study included patients who underwent CIED implantation at the Faculty of Medicine, Vajira Hospital, Navamindradhiraj University, between February 1, 2019, and December 25, 2019. The inclusion criteria were patients aged >18 years, those who underwent CIED

implantation or pulse generator replacement, those who had a smartphone, tablet, or personal computer to enable communication with the investigator, and those who were able to participate in the present study. Patients who were not comfortable with specific follow-up were excluded from this study.

### Data collection

Patients who met the inclusion criteria were randomly assigned to the tele-follow-up and conventional follow-up groups. On postoperative day 1, the wound was opened at the hospital, and photographs of patients in both groups were taken. On postoperative day 7, patients in the tele-follow-up group were asked to send a photograph of the incision wound to the investigator and answer questions about the complications, whereas those in the other group were asked to visit the CIED clinic to open the wound. During the follow-up period, if patients had any problems, those in the tele-follow-up group could send questions or problems to the investigator using a smartphone, whereas those in the conventional follow-up group could not send their questions. Approximately 30 days after surgery, patients in both groups were followed-up at the hospital on the appointment for physical examination, underwent 12-lead electrocardiography to detect complications, and answered a questionnaire about their satisfaction. Data were recorded in case record forms.

Demographic data, underlying medical conditions, current medications, baseline laboratory parameters, clinical presentation, and indications for CIEDs were collected from electronic medical records and patient interviews.

### Definitions

CIED procedure-related complications were defined as complications that occurred during or after CIED implantation. Minor bleeding was defined as bleeding or hematoma that did not require any treatment, intervention, or prolonged hospitalization (Figure 1). Major bleeding was defined as bleeding or hematoma that required any treatment, intervention, or prolonged hospitalization, such as resuture and reoperation (Figure 2).

### Statistical analysis

This non-inferiority randomized controlled trial was conducted to compare cardiovascular implantable electronic device complications between conventional follow-up and telehealth follow-up in device follow-up clinics. The authors hypothesized that the rate of major and minor complications in the telehealth follow-up (intervention) group would not differ by more than 20% (the non-inferiority margin) compared to the conventional follow-up group. All data analyses were performed using SPSS software



**Figure 1.** Small hematoma and blood oozing without needing further intervention.



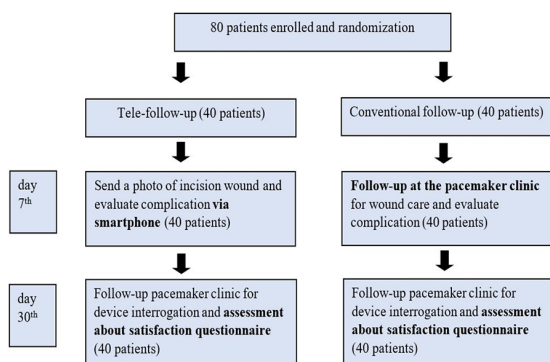
**Figure 2.** Large hematoma and ecchymosis need to prolonged interrupt oral anticoagulant.

(version 21.0) and Excel version 2019. Continuous variables were presented as mean and standard deviation, whereas categorical data were presented as frequencies and percentages. Comparisons between the tele-follow-up and conventional follow-up groups were performed using the independent t-test to compares means and continuous variables between two groups Mann–Whitney U test to compare the data which is not normally distributed, or ordinal variables, Chi-square test and Fisher's exact test to examine the relationship between two categorical variables. A p-value less than 0.05 indicated statistical significance.

## Results

A total of 80 patients with CIEDs were included in this study. The CONSORT diagram, shown in Figure 3, illustrates the flow of the present study and the randomization process. The mean ages of the patients were  $72.95 \pm 16.15$  years in the tele-follow-up group and  $69.03 \pm 14.01$  years in the conventional follow-up group. The proportion of male patients was not different between the two groups (52.5% in the tele-follow-up group vs. 47.5% in the conventional follow-up group). Body mass index, urban residency, family income, and education level were the same between groups. The prevalence of underlying diseases was not significantly different between the tele-follow-up and conventional follow-up groups. The use of antiplatelets, anticoagulants, and antibiotics was not different between the two groups. No significant differences in baseline laboratory values and left ventricular ejection fraction were observed between the two groups (Table 1). Venous access via the axillary vein was the main access in the present study (62.5% in the tele-follow-up group vs. 67.5% in the conventional follow-up group). The proportion of first implantation was also similar between the two groups (62.5% in the tele-follow-up group vs. 67.5% in the conventional follow-up group). The procedure duration and length of hospital stay were not different between the two groups. Table 1 shows the important baseline characteristics.

CIED procedure-related complications occurred in 6 (15.0%) patients in the tele-follow-up group and 6 (15.0%) in the conventional follow-up group (hazard ratio [HR] 0.87, 95% confidence interval [CI] 0.16 to 4.68,  $p=0.44$ ) at 7 days after surgery and in 17 (42.5%) patients in the tele-follow-up group and 12 (30.0%) in the conventional follow-up group (HR 1.56, 95% CI 0.65 to 3.74,  $p=0.178$ ) at 30 days after surgery. The complications reported in the tele-follow-up and conventional follow-up groups included minor bleeding (10% vs. 2.5%,  $p=0.169$  at 7 days after surgery; 12.5% vs. 2.5%,  $p=0.267$  at 30 days after surgery), major bleeding,



**Figure 3.** CONSORT diagram shows the flow of study and randomization.

**Table 1.** Baseline characteristics

Characteristics	Tele follow-up, n=40 (%)	Conventional, n=40 (%)	p-value*
Male	21 (52.5)	19 (47.5)	0.66
Age (year)	73.0±16.2	69.0±14.0	0.25
Body mass index (kg/m <sup>2</sup> )	23.7±3.7	24.6±4.2	0.30
Urban Residency	27(67.5)	33(82.5)	0.12
Family income (baht)	25,000 (10,000 to 40,000)	20,000 (10,000 to 30,000)	0.63
Education			0.31
No education	4 (10.0)	3 (7.5)	
Primary school	20 (50.0)	16 (40.0)	
Secondary school and above	14 (35.0)	20 (50.0)	
Underlying disease			
Diabetes mellitus	13 (32.5)	17 (42.5)	0.36
Hypertension	23 (57.5)	22 (55.0)	0.82
Dyslipidemia	15 (37.5)	11 (27.5)	0.34
Coronary artery disease	9 (22.5)	7 (17.5)	0.58
Heart failure	4 (10.0)	1 (2.5)	0.36
Atrial fibrillation	7 (17.5)	14 (35.0)	0.08
Cirrhosis	1 (2.5)	1 (2.5)	1.00
Chronic kidney disease	6 (15.0)	5 (12.5)	0.75
Medications			
Aspirin	11 (27.5)	16 (40.0)	0.67
Clopidogrel	6 (15.0)	3 (7.5)	0.23
Warfarin	5 (12.5)	3 (7.5)	0.16
NOACs	0 (0.0)	0 (0.0)	1.00
Laboratories value			
Hematocrit	35.6 (32.0 to 40.6)	37 (31.1 to 40.5)	0.95
White blood cell	6,600 (5,580 to 8,220)	7,365 (5,817.5 to 8,700)	0.38
Platelet	203,000 (157,000 to 267,000)	187,500 (151,250 to 236,500)	0.27
Estimated glomerular filtration rate	49 (31.75 to 87)	55.5 (47 to 76.75)	0.76
aPTT	26.7 (24.6 to 30.2)	26.765 (24.925 to 30.475)	0.84
INR	1.12 (1.04 to 1.335)	1.18 (1.06 to 1.41)	0.38
Albumin	3.3 (2.7 to 3.695)	3.4 (2.9 to 3.6)	0.92
HbA1C	5.8 (5.15 to 6.75)	7.2 (6.525 to 9.5)	0.02
LVEF (%)	48.67±20.81	51.45±23.97	0.69
Antibiotic	40 (100)	40 (100)	1.00
Ceftriaxone	37 (92.5)	37 (92.5)	1.00
Clindamycin	1 (2.5)	1 (2.5)	1.00
Cloxacillin	2 (5.0)	2 (5.0)	1.00
Azithromycin	1 (2.5)	0 (0.0)	1.00
Gentamycin	1 (2.5)	1 (2.5)	1.00
Venous access			0.64
Axillary vein	25 (62.5)	27 (67.5)	
Other venous access	15 (37.5)	13 (32.5)	
Duration of procedure (min)			
Median (IQR1 to IQR3)	55 (37.5 to 75)	60 (40 to 82.5)	0.50
Length of stay (day)			
Median (IQR1 to IQR3)	2 (2 to 2)	2 (2 to 4)	0.50

NOACs=non-vitamin k antagonist oral anticoagulants; aPTT=activated partial thromboplastin time; INR=international normalized ratio; HbA1C=hemoglobin A1C; LVEF=left ventricular ejection fraction; IQR=interquartile range; AICD=automatic implantable cardioverter defibrillator; CRT-D=cardiac resynchronization therapy-defibrillator; CRT-P=cardiac resynchronization therapy-pacemaker

Table 1. Cont.

Characteristics	Tele follow-up, n=40 (%)	Conventional, n=40 (%)	p-value*
Type of CIEDs			0.87
Single chamber pacemaker	8 (20.0)	6 (15.0)	
Dual Chamber Pacemaker	18 (40.0)	21 (52.5)	
Single Chamber AICD	9 (22.5)	6 (15.0)	
Dual Chamber AICD	3 (7.5)	2 (5.0)	
CRT-D	2 (5.0)	4 (10.0)	
CRT-P	0 (0.0)	1 (2.5)	
First implantation	25 (62.5)	27 (67.5)	0.64

NOACs=non-vitamin k antagonist oral anticoagulants; aPTT=activated partial thromboplastin time; INR=international normalized ratio; HbA1C=hemoglobin A1C; LVEF=left ventricular ejection fraction; IQR=interquartile range; AICD=automatic implantable cardioverter defibrillator; CRT-D=cardiac resynchronization therapy-defibrillator; CRT-P=cardiac resynchronization therapy-pacemaker

which required wound dressing (2% vs. 0%,  $p=N/A$  at 30 days after surgery), wound infection (2.5% vs. 0%,  $p=N/A$  at 30 days after surgery), and shoulder pain (5% vs. 7.5%,  $p=0.78$  at 7 days after surgery; 22.5% vs. 12.5%,  $p=0.186$  at 30 days after surgery). Other complications (not shown in the table), such as abrasion wound (5% vs. 5%), wound pain (5% vs. 5%), and subcutaneous emphysema without pneumothorax (0% vs. 2.5%), were not significantly different between the two groups. Table 2 shows the CIED procedure-related complications.

An analysis of the factors that affected the occurrence of complications after CIED implantation was performed. Multivariate analysis using Cox’s proportional hazards model revealed that most of following factors didn’t affected the occurrence of complicationsexcept use of anticoagulants which associate with more complications in both 7 days and 30 days after operation. (HRadj 10.02, 95% CI 1.10 to 91.05,  $p=0.02$  at 7 days after surgery; HRadj 6.61, 95% CI 1.51 to 28.95,  $p<0.01$  at 30 days after surgery) (Table 3.1 and 3.2). The satisfaction scores in the tele-follow-up and conventional follow-up groups were  $22.49\pm1.67$  and  $21.10\pm2.26$ , respectively ( $p<0.01$ ). Table 4 shows the results of each satisfaction questionnaire in detail.

Discussion

Crowded-out patient departments, provider shortages, expenses, and traffic jams are the main problems that patients complain of. The present study aimed to resolve these problems. This randomized controlled trial compared CIED procedure-related complications between the tele-follow-up and conventional follow-up groups. The results showed no significant difference in the incidence of CIED procedure-related complications between the two groups at 7 days after surgery (6 in the tele-follow-up group vs. 6 in the conventional follow-up group [HR 0.87, 95% CI 0.16 to 4.68,  $p=0.44$ ]). One month after surgery, the incidence of CIED procedure-related complications was higher in the tele-follow-up group than in the conventional

follow-up group (17 in the tele-follow-up group vs. 12 in the conventional follow-up group [HR 1.56, 95% CI 0.65 to 3.74,  $p=0.16$ ]) because patients in the tele-follow-up group could directly contact the investigator when they experienced complications, whereas those in the conventional follow-up group could not do this. The incidence of CIED procedure-related complications was similar to that reported in previous studies at 1-month follow-up. However, the present study reported a higher incidence of wound complications, such as bleeding from the wound and abrasion.

In the present study, the prevalence of CIED procedure-related complications was approximately 15% in both groups on postoperative day 7, whereas the prevalence was 42.5% in the tele-follow-up group and 30% in the conventional follow-up group on postoperative day 30. Within 30 days post surgery, minor complications could be easily reported in the tele-follow-up group via smartphones compared to conventional group that patient need to visit hospital to report minor complication

Subgroup analysis revealed that only anticoagulant use was significantly associated with complications on postoperative days 7 and 30.

The follow-up survey revealed that the tele-follow-up group had higher satisfaction scores than the conventional follow-up group ( $22.49\pm1.67$  vs.  $21.10\pm2.26$ ,  $p<0.01$ ). The tele-follow-up group showed higher satisfaction with follow-up convenience, accessibility to caregivers, and transportation obstacles. However, satisfaction scores regarding confidence in treatment, concern for treatment, barriers to communicating with physicians, and knowledge about CIED care were not significantly different between the two groups.

These results showed no significant differences in CIED procedure-related complications assessed using tele-follow-up and conventional follow-up. However, satisfaction was significantly higher in the tele-follow-up group.

Our results provide new information that we can



**Table 2.** Post implanted CIEDs related complication

Complication	Tele follow-up, n=40 (%)	Conventional, n=40 (%)	p-value for non-inferiority
CIEDs related complication	17 (42.5)	12 (30.0)	0.178
Minimal bleeding			
0 to 7 days	4 (10.0)	1 (2.5)	0.169
7 to 30 days	1 (2.5)	0 (0.0)	NA
Major bleeding			
0 to 7 days	0 (0.0)	0 (0.0)	NA
7 to 30 days	2 (5.0)	0 (0.0)	NA
Shoulder pain			
0 to 7 days	2 (5.0)	3 (7.5)	0.780
7 to 30 days	9 (22.5)	5 (12.5)	0.186
Infection			
0 to 7 days	0 (0.0)	0 (0.0)	NA
7 to 30 days	1 (2.5)	0 (0.0)	NA
Venous thromboembolism			
0 to 7 days	0 (0.0)	0 (0.0)	NA
7 to 30 days	0 (0.0)	0 (0.0)	NA
CIEDs malfunction			
0 to 7 days	0 (0.0)	0 (0.0)	NA
7 to 30 days	0 (0.0)	0 (0.0)	NA
Cardiac perforation			
0 to 7 days	0 (0.0)	0 (0.0)	NA
7 to 30 days	0 (0.0)	0 (0.0)	NA
Death			
0 to 7 days	0 (0.0)	0 (0.0)	NA
7 to 30 days	0 (0.0)	1 (2.5)	NA
Other complication			
0 to 7 days	7 (17.5)	5 (12.5)	0.168
7 to 30 days	3 (7.5)	5 (12.5)	0.069

Descriptive data are presented as frequency and (column percentage).

\* Significant level at  $p < 0.05$ , univariable poisson regression was used to investigated the effectiveness of telemedicine-based care compared to conventional care on clinical endpoints.

CIEDs=cardiac implantable electronic devices

use telemedicine to follow-up these patients safely. Our results are consistent with previous studies<sup>(9-11)</sup> that used telemedicine to follow-up after many post-operative settings. That trials and our trial showed the effectiveness and increased patients' satisfaction without any harm to them with tele-follow-up.

### Limitations

The present study has some limitations. Firstly, this was only a single-center randomized controlled trial, further multicenter trials are needed. Secondly, it was easy to report minor complications in the tele-follow-up group because the patients could easily contact the investigator. On the other hand, there might be underreported of minor complications in conventional group because they didn't want to come to hospital for little complaints such as mild of pain at

shoulder from immobilization. Finally, it wasn't easy to assess satisfaction scores among older adults, therefore, the visual analog scale was used in some elderly patients.

### Conclusion

The present study showed no significant difference in CIED procedure-related complications between the tele-follow-up and conventional follow-up groups. However, the tele-follow-up group had significantly higher satisfaction scores than the conventional follow-up group due to the higher levels of satisfaction with follow-up convenience, accessibility to caregivers, and transportation obstacles.

### What is already known on this topic?

Cardiac implantable electronic device (CIED) recipients require follow-up at the hospital to identify any

**Table 3.1.** Factors associated with CIEDs-related complications within 7 days post-implantation

Factors	Univariate analysis			Multivariate analysis		
	HR	95% CI	p-value	HRadj	95% CI	p-value
Intervention						
Conventional	1.00	Reference		1.00	Reference	
Tele follow-up	0.98	(0.20 to 4.87)	0.49	0.87	(0.16 to 4.68)	0.44
Sex						
Male	1.00	Reference		1.00	Reference	
Female	0.98	(0.20 to 4.87)	0.49	0.98	(0.16 to 5.83)	0.49
Age (year)						
<70	1.00	Reference		1.00	Reference	
≥70	0.79	(0.16 to 3.91)	0.39	0.83	(0.13 to 5.06)	0.42
Income (baht)						
≥30,000	1.00	Reference		1.00	Reference	
<30,000	1.59	(0.29 to 8.67)	0.30	3.14	(0.39 to 25.24)	0.14
Antiplatelet						
No	1.00	Reference		1.00	Reference	
Yes	3.55	(0.65 to 19.41)	0.07	4.86	(0.71 to 33.46)	0.05
Anticoagulant						
No	1.00	Reference		1.00	Reference	
Yes	4.95	(0.9 to 27.08)	0.03	10.02	(1.10 to 91.05)	0.02

**Table 3.2.** Factors associated with CIEDs-related complications within 30 days post-implantation

Factors	Univariate analysis			Multivariate analysis		
	HR	95% CI	p-value	HRadj	95% CI	p-value
Intervention						
Tele follow-up	1.56	(0.65 to 3.74)	0.16	1.73	(0.60 to 4.99)	0.15
Conventional	1.00	Reference		1.00	Reference	
Gender						
Male	1.00	Reference		1.00	Reference	
Female	0.60	(0.25 to 1.45)	0.13	0.72	(0.23 to 2.31)	0.29
Age (year)						
<70	1.00	Reference		1.00	Reference	
≥70	0.78	(0.30 to 2.02)	0.30	0.84	(0.26 to 2.64)	0.38
Income (baht)						
≥30,000	1.00	Reference		1.00	Reference	
<30,000	0.73	(0.28 to 1.90)	0.26	1.28	(0.37 to 4.48)	0.35
LVEF						
> 40	1.00	Reference		1.00	Reference	
≤40	1.08	(0.23 to 5.01)	0.46	0.56	(0.08 to 3.82)	0.28
Antiplatelets						
No	1.00	Reference		1.00	Reference	
Yes	1.90	(0.79 to 4.57)	0.08	1.97	(0.58 to 6.63)	0.14
Anticoagulants						
No	1.00	Reference		1.00	Reference	
Yes	4.94	(1.51 to 16.12)	<0.01	6.61	(1.51 to 28.95)	<0.01

complications that may occur after the procedure.

**What this study adds?**

In patients with CIEDs, the procedure-related

complications were not significantly different between patients who were followed up via telephone and those who were followed up at the hospital. However, the tele-follow-up group had higher satisfaction scores than the conventional

**Table 4.** Satisfactory questionnaires

Satisfaction	Tele follow-up, n=39 (%)	Conventional, n=40 (%)	p-value*
Confidence in treatment			1.00
Very poor	0 (0.0)	0 (0.0)	
Poor	0 (0.0)	0 (0.0)	
Average	2 (5.1)	1 (2.5)	
Good	12 (30.8)	13 (32.5)	
Very good	25 (64.1)	26 (65.0)	
Convenience in follow-up			<0.01
Very poor	0 (0.0)	1 (2.5)	
Poor	2 (5.1)	7 (17.5)	
Average	8 (20.5)	19 (47.5)	
Good	13 (33.3)	12 (30.0)	
Very good	16 (41.0)	1 (2.5)	
Concern in complication			1.00
Not at all concern	11 (28.2)	11 (27.5)	
Slightly concern	16 (41.0)	17 (42.5)	
Moderately concern	10 (25.6)	11 (27.5)	
Very concern	2 (5.1)	1 (2.5)	
Extremely concern	0 (0.0)	0 (0.0)	
The convenience of relatives for looking after the patient			<0.01
Very poor	1 (2.6)	3 (7.5)	
Poor	6 (15.4)	12 (30.0)	
Average	6 (15.4)	21 (52.5)	
Good	8 (20.5)	4 (10.0)	
Very good	18 (46.2)	0 (0.0)	
Obstacles of transportation			<0.01
Never	13 (33.3)	4 (10.0)	
Rarely	17 (43.6)	13 (32.5)	
Sometimes	8 (20.5)	12 (30.0)	
Often	1 (2.6)	10 (25.0)	
Always	0 (0.0)	1 (2.5)	
Obstacles of communication with medical personnel			0.12
Never	13 (33.3)	10 (25.0)	
Rarely	19 (48.7)	14 (35.0)	
Sometimes	7 (17.9)	13 (32.5)	
Often	0 (0.0)	3 (7.5)	
Always	0 (0.0)	0 (0.0)	
Knowledge for looking care of themselves after device implantation			0.27
Very poor	0 (0.0)	0 (0.0)	
Poor	1 (2.6)	3 (7.5)	
Average	8 (20.5)	14 (35.0)	
Good	19 (48.7)	17 (42.5)	
Very good	11 (28.2)	6 (15.0)	
Overall satisfaction scores	22.49±1.67	21.10±2.26	<0.01

follow-up group.

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