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ORIGINAL ARTICLE

Impact of raising the upper extremity siding cardiac implantable electrical devices on postoperative safety

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Abstract

Background: The upper extremity siding cardiac implantable electrical device tends to have a limited range of motion during the perioperative period; however, the underlying reason lacks scientific evidence. This study aimed to investigate the safety of the two methods (stepwise or early) of postoperative early upper extremity rehabilitation.

Methods: We retrospectively investigated 650 consecutive patients with a new implantable pacemaker (PM), implantable cardioverter-defibrillator (ICD), cardiac resynchronization therapy (CRT), or generator exchange between March 2017 and December 2020.

The limitation program was conducted from March 2017 to March 2018. The intervention program started as a stepwise protocol in April 2018 and was switched to an early protocol in December 2019.

Results: This study analyzed 591 patients, excluding 59 who met the exclusion criteria. The mean age was 76.0 (69.0–82.0) years; 412 (69.7%) patients had a PM, 79 (13.4%) had an ICD, and 100 (16.9%) utilized CRT. There were 155 patients in the limitation protocol, 251 in the stepwise protocol, and 185 patients in the early protocol groups. Postoperative complications occurred in 53 (9.0%) patients. There was no significant difference in the incidence of all complications between the three groups (16 patients [10.3%] vs. 26 patients [10.4%] vs. 11 patients [5.9%]). Shoulder exercise-related complications were defined as hematoma ($p = .94$), lead dislodgement ($p = .16$), and increased pacing threshold ($p = .23$). General complications included wound infection ($p = .51$), pneumothorax ($p = .27$), tamponade ($p = .07$), and deep venous thrombosis ($p = .26$).

Conclusion: Raising of the upper extremity siding cardiac implantable electrical devices above the head did not compromise postoperative safety.

KEYWORDS
cardiac resynchronization therapy, implantable cardioverter defibrillators, pacemaker artificial, postoperative complications, rehabilitation

1 | INTRODUCTION

Pacemakers (PM), implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy (CRT) reduce the incidence of sudden cardiac death,[1,2] improving survival and quality of life (QOL).[3] Furthermore, cardiac implantable electrical devices (CIED)[4–6] are safe, reliable, and the number of procedures has increased.[7–10] Within the last few years, rehabilitation of the upper extremity on the side of the CIED will become an important component area in the field of CIED, attributable to the restrictive use of the upper extremity on the side of the CIED.[11,12] However, many hypotheses regarding the limitations of the upper extremity on the side of CIED use are not well-grounded, and restriction of movement of the upper extremity using a rib belt has been performed unfoundedly in many institutions. In recent years, several problems of the upper extremity on the side of the CIED have been reported,[13] for example, pain, limited range of motion, and subjective loss of upper extremity function. Furthermore, these problems of the upper extremity on the side of the CIED affect not only physical activity but also mental health and quality of life.[2] Thus, the use of the upper extremity on the side of the CIED in daily life situations is important to improve the physical health, mental health, and quality of life of postoperative CIED patients.

Rehabilitation interventions have been proposed to improve upper-extremity function on the side of the CIED. It has been reported that early postoperative pendulum exercise of the upper extremity on the CIED side improved the range of motion of shoulder joint.[14] Furthermore, a study[15] reported that exercise therapy using an elastic band improved shoulder function on the side of the CIED. These two reports suggest that the upper extremity function adjacent to the CIED can be improved by rehabilitation after CIED surgery. Although these rehabilitation programs are innovative, they propose limitations that the upper extremity on the side of the CIED should not be raised above shoulder height. This is to avoid the risk of exacerbation of wound hematoma, lead dislodgement, and wound dehiscence. In contrast,[11] opposite findings have reported that early raising of the upper extremity on the CIED side above the head does not cause lead dislodgement or impedance fluctuation. However, the main weakness of this study was the small sample size (10 patients). Thus, whether the upper extremity on the side of the CIED can be safely raised above the head after CIED surgery has not yet been established.

Hence, the aim of this novel study was to investigate the safety of raising the upper extremity above the head on the side of the CIED postoperatively.

We hypothesized that there would be no difference in the incidence of complications between patients who raised the upper extremity on the side of the CIED above the head and those who did not raise the upper extremity on the side of the CIED above the head.

2 | METHODS

2.1 | Participants and data collection

This was a single-center case–control retrospective study. We enrolled patients with newly implanted CIED (PM, ICD, CRT) and patients who underwent generator exchange at the hospital from March 4, 2017 to December 15, 2020. The exclusion criteria were patients who had undergone subcutaneous cardioverter defibrillator implantation and patients who visited another hospital 1 month after surgery. All atrial and ventricular leads used intraoperatively in this study period were active fixation leads. For all patients, we collected data on age, sex, diagnosis, co-morbidities, medical history, echocardiographic findings, laboratory data, date of surgery, operative records, routine medical procedures, the range of motion of shoulder joint on the patient's side of the CIED, and rehabilitation program from the electronic medical record system. We defined hematoma, swelling, wound dehiscence, lead dislodge, pacing threshold or lead impedance values requiring re-treatment, wound infection, pneumothorax, tamponade, and venous obstruction as complications based on a previous study.[16]

The patients in the first group underwent surgery and were followed by physicians, and they did not receive any rehabilitation after surgery (limitation group) from March 4, 2017 to March 15, 2018 (Figure 1). The patients in this group used a rib belt postoperatively for prevention of lead dislodgement due to conscious or unconscious movement of their shoulder and prevention of wound hematoma and were allowed to remove it at discharge. Patients were given two instructions: the range of motion of the shoulder joint adjacent to the CIED should not be more than 90 degrees in flexion and abduction, and to restrict upper extremity usage on the side of the CIED immediately after the implantation till discharge.

Patients in the second group increased the range of motion of the shoulder joint on the side of the CIED stepwise (stepwise protocol group) supervised by occupational therapists from March 20, 2018 to November 28, 2019 (Figure 2). The patients in this group used a rib belt postoperatively. On the first postoperative day, the occupational therapist increased the range of motion of the shoulder joint on the side of CIED flexion and abduction to 45 degrees. On the second postoperative day, the patients were allowed to move the shoulder joint of the upper extremity on the side of CIED flexion and abduction within 90 degrees. They were allowed to remove the rib belt when the shoulder of the upper extremity on the side of CIED reached flexion and abduction angle of 90 degrees. On the third day, they were allowed to move the shoulder joint of the upper extremity on the side of the CIED flexion and abduction of 120 degrees and this was increased to 180 degrees by postoperative day four. On the fifth postoperative day, the patients were told by occupational therapists that a protocol of no restrictions on using the upper extremity on the adjacent side of CIED in daily life. However, there are restrictions such as not vigorously rotating the arm and not moving that shoulder joint into excessive horizontal abduction positions. In

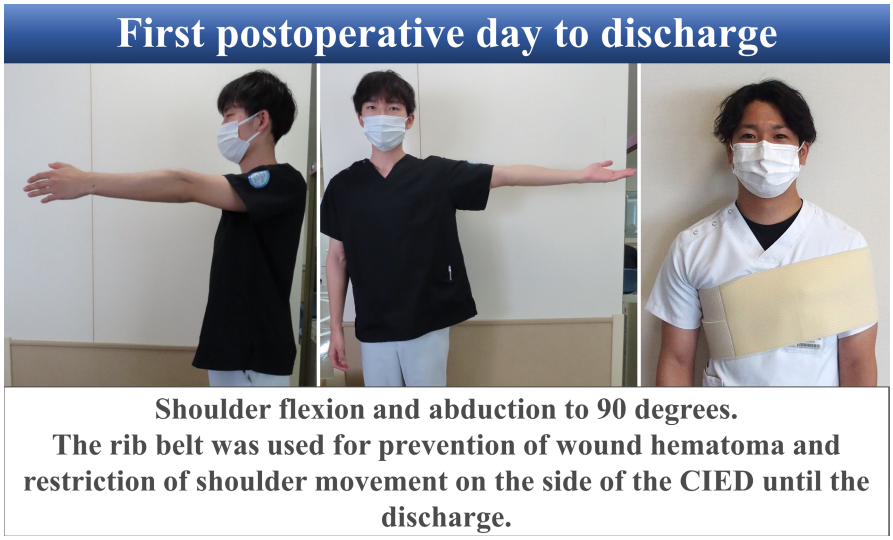


FIGURE 1 The limitation protocol.

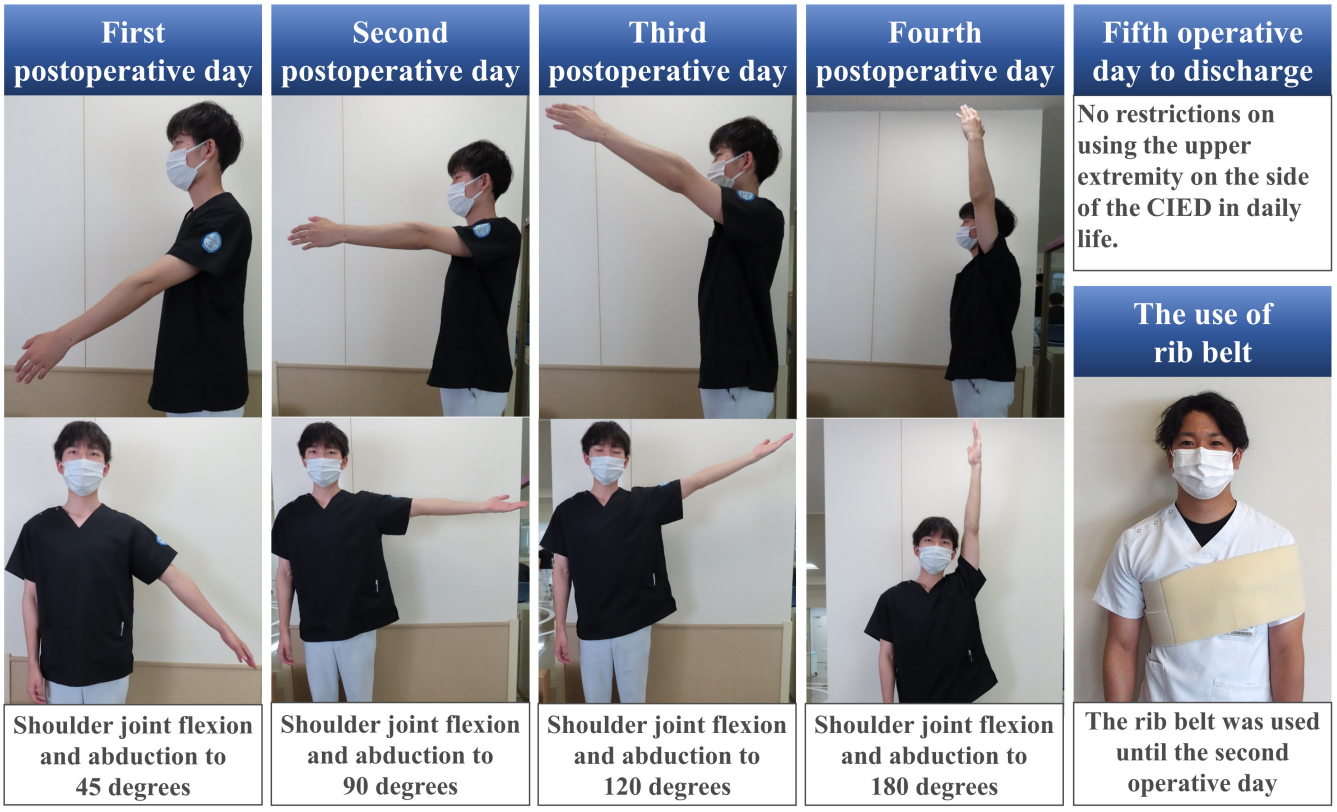


FIGURE 2 The stepwise protocol.

case of pain, hematoma, swelling, or wound dehiscence at the surgical wound site, the range of motion of shoulder joint exercises during hospitalization was limited to 90 degrees of flexion and abduction.

From December 7, 2019 to December 15, 2020, the patients were allowed to move intentionally the range of motion of the shoulder joint on the side of the CIED flexion and abduction to 180 degrees from the day after surgery if there was no pain (early protocol group) supervised by occupational therapists (Figure 3). Patients in this group were not allowed to use a rib belt postoperatively. The occupational therapist performed the range of motion of shoulder joint exercises, daily living exercises, and upper extremity functional exercises on the side of the CIED according to pain from the day after surgery. Similar to the stepwise rehabilitation group, if there was pain, hematoma, swelling, or wound dehiscence at the surgical wound site, the range of motion of the shoulder joint of the upper extremity on the side of the CIED exercises during hospitalization was limited to 90 degrees of flexion and abduction.

FIGURE 3 The early protocol.

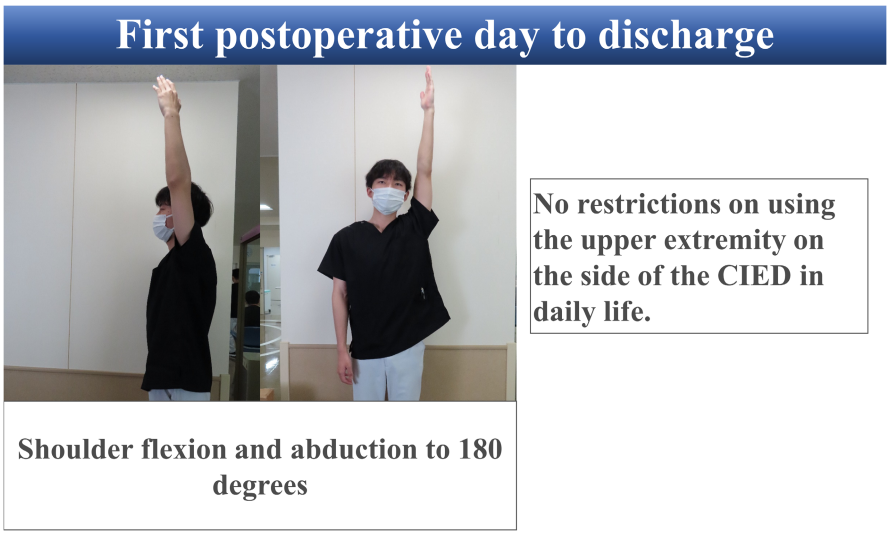
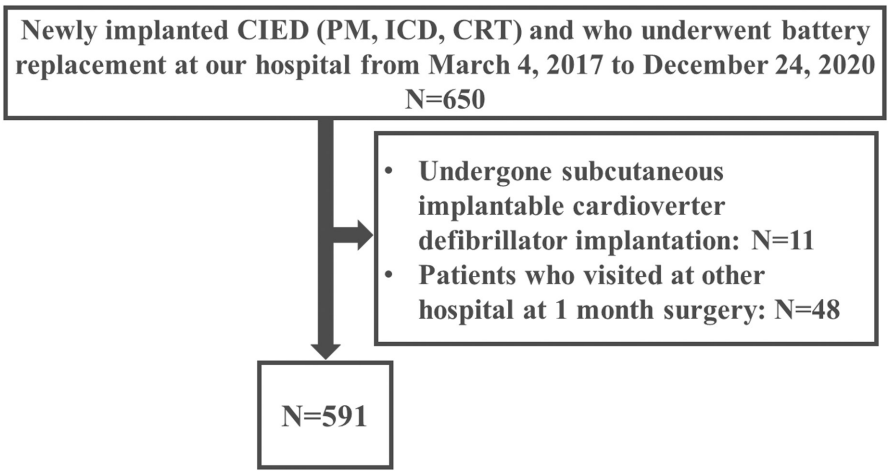


FIGURE 4 Flowchart showing the selection of the study population.



2.2 | Statistical analysis

To verify the safety of each protocol, we compared the frequency of complications and evaluated them using Fisher's exact probability test in three groups. Previous studies have reported the influence of anticoagulation and antiplatelet therapies on hematoma, swelling, and wound dehiscence.[17,18] To evaluate the complication rates of hematoma, swelling, and wound dehiscence, the use of anticoagulation therapy and antiplatelet therapy in three groups was analyzed. Statistical analysis was performed using EZR version 1.52 (Saitama Medical Center, Jichi Medical University), which is a graphical user interface for R version 4.02 (The R Foundation for Statistical Computing), with the level of significance set at 5%.

2.3 | Ethical considerations

This study was approved by the Ethics Committee of our hospital (No. 2021–208). The requirement of informed consent from patients was waived, and we adopted an opt-out method, which allows patients to express their desire not to participate. It was approved by the ethics committees. The information regarding the use of medical record data for the study and the opt-out method is presented on our hospital's website.

3 | RESULTS

A total of 650 patients were included in the study. Eleven patients who were postoperative with a subcutaneous implantable cardioverter-defibrillator, and 48 patients who were seen at another hospital in the first month after surgery or who did not visit the outpatient clinic were excluded, resulting in a final analysis of 591 patients (Figure 4). The participant characteristics are described in Table 1. The mean age was 76.0 (69.0–82.0) years, 253 patients (42.8%) were women, 412 patients (69.7%) used PM, 79 patients (13.4%) utilized ICD, and 100 patients (16.9%) had CRT. There were 155 patients, 251 patients, and 185 patients in the limitation, stepwise, and early protocol groups, respectively. The rib belt wearing rate was 100% in the limitation group and the stepwise group and the average usage days were 10.6 ± 9.9 days and 2.3 ± 1.7 days, respectively. However, no patient in the early protocol group used the

TABLE 1 Participant characteristics.

	Overall	Limitation	Stepwise protocol	Early protocol	
	N = 591	*N* = 155	*N* = 251	*N* = 185	*p*-value
Sex					
Female	253 (42.8)	69 (44.5)	99 (39.4)	85 (45.9)	0.35
Male	338 (57.2)	86 (55.5)	152 (60.6)	100 (54.1)	
Height (cm)	159.0 [151.0, 165.0]	158.0 [151.0, 165.0]	160.0 [151.0, 165.2]	158.5 [151.0, 165.0]	0.52
Body weight (kg)	56.9 [48.62, 65.5]	56.0 [49.0, 63.4]	57.8 [49.4, 66.4]	56.7 [47.6, 65.4]	0.32
Age (years)	76.0 [69.0, 82.0]	76.0 [70.0, 83.0]	76.0 [68.0, 81.0]	76.0 [70.0, 82.0]	0.21
Rib belt wearing rate	406 (68.7)	155 (100.0)	251 (100.0)	0 (0.0)	<0.01
Number of days with rib belt (days)	3.8 ± 6.7	10.6 ± 9.9	2.3 ± 1.7	0.0 ± 0.0	<0.01
Laboratory data					
BNP (mg/dL)	133.5 [50.1, 303.9]	128.3 [54.0, 285.1]	136.3 [49.8, 307.0]	132.2 [47.6, 308.6]	0.98
Cr (mg/dL)	0.9 [0.7, 1.2]	0.9 [0.7, 1.2]	0.9 [0.8, 1.1]	0.9 [0.7, 1.2]	0.89
eGFR (mL/min/1.73 m^2)	57.5 [41.8, 72.7]	59.0 [41.9, 74.3]	57.6 [43.7, 72.6]	56.6 [39.1, 71.2]	0.64
Hb (g/dL)	12.7 [11.4, 14.0]	12.8 [11.6, 13.9]	12.9 [11.6, 14.3]	12.4 [11.1, 13.7]	0.06
LVEF (%)	59.0 [42.0, 72.0]	61.0 [47.5, 73.0]	58.5 [38.0, 72.0]	56.0 [45.3, 69.0]	0.35
Na (mEq/L)	141.0 [139.0, 142.0]	141.0 [139.0, 142.0]	140.0 [139.0, 142.0]	141.0 [138.0, 142.0]	0.99
PT-INR	1.1 [1.0, 1.3]	1.1 [1.0, 1.5]	1.1 [1.0, 1.4]	1.1 [1.0, 1.2]	0.07
Etiology					
CAVB	203 (34.4)	55 (35.5)	75 (30.0)	73 (39.5)	0.12
SSS	144 (24.4)	41 (26.5)	64 (25.6)	39 (21.1)	
Advanced AVB	54 (9.2)	16 (10.3)	21 (8.4)	17 (9.2)	
DCM	32 (5.4)	5 (3.2)	20 (8.0)	7 (3.8)	
HCM	22 (3.7)	6 (3.9)	8 (3.2)	8 (4.3)	
VT/VF	57 (9.7)	22 (14.2)	23 (9.2)	12 (6.5)	
HF	46 (7.8)	4 (2.6)	26 (10.4)	16 (8.6)	
Atrial fibrillation with bradycardia	6 (1.0)	2 (1.3)	1 (0.4)	3 (1.6)	
MI	14 (2.4)	3 (1.9)	5 (2.0)	6 (3.2)	
Paroxysmal AVB	10 (1.7)	1 (0.6)	5 (2.0)	4 (2.2)	
Tachycardia bradycardia syndrome	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	
Pacing-induced cardiomyopathy	1 (0.2)	0 (0.0)	1 (0.4)	0 (0.0)	
Treatment in previous surgery					
ACE.ARB	214 (36.2)	46 (29.7)	102 (40.6)	66 (35.7)	0.08
β-blocker	186 (31.5)	39 (25.2)	86 (34.3)	61 (33.0)	0.13
MRA	116 (19.6)	30 (19.4)	53 (21.1)	33 (17.8)	0.71
Amiodarone	88 (14.9)	15 (9.7)	47 (18.7)	26 (14.1)	0.04
Antiplatelet therapy	116 (19.6)	31 (20.0)	56 (22.3)	29 (15.7)	0.23
Anticoagulation therapy	164 (27.7)	25 (16.1)	85 (33.9)	54 (29.2)	<0.001
Diuretic	206 (34.9)	49 (31.6)	95 (37.8)	62 (33.5)	0.40
Type of CIED					
PM	412 (69.7)	112 (72.3)	170 (67.7)	130 (70.3)	0.68
ICD	79 (13.4)	32 (20.6)	31 (12.4)	16 (8.6)	0.01
CRT	100 (16.9)	11 (7.1)	50 (19.9)	39 (21.1)	<0.001

Note: The continuous variables are means ± standard deviations. The nominal scales are *N* (%), median [inter-quartile range].

Abbreviations: ACE, angiotensin-converting enzyme; AVB, advanced atrioventricular block; ARB, angiotensin II receptor blocker; BNP, brain natriuretic hormone; CAVB, complete atrioventricular block; CIED, cardiac implantable electrical device; Cr, creatinine; CRT, cardiac resynchronization therapy; DCM, dilated cardiomyopathy; LVEF, left ventricular ejection fraction; eGFR, estimated glomerular filtration rate; HCM, hypertrophic cardiomyopathy; HF, heart failure; HGB, hemoglobin; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonist; Na, sodium; PM, pacemaker; SSS, sick sinus syndrome; VT, ventricular tachycardia; VF, ventricular fibrillation.

rib belt. Complication rates are listed in Table 2. Postoperative complications occurred in 53 (9.0%) patients. Hematoma, swelling, and wound dehiscence occurred in 14 patients (2.4%), lead dislodgement in 15 patients (2.5%), unstable pacing threshold or lead impedance values requiring repositioning in 16 patients (2.7%), wound infection in two patients (0.3%), pneumothorax in three patients (0.5%), tamponade in two patients (0.3%), and venous obstruction in one patient (0.2%). There was no significant difference in the incidence of any complications among the three groups, regardless of the type of device or type of implant (16 patients [10.3%] vs. 26 patients [10.4%] vs. 11 patients [5.9%]). There were no significant differences in the rates of shoulder exercise-related complications (hematoma, lead dislodgement, and rising pacing threshold) and general complications (wound infection, pneumothorax, tamponade, and deep venous thrombosis) between the three groups (Table 2).

The characteristics of patients with lead dislodgement are listed in Table 3. Four patients had dislodgement with a range of motion of the shoulder joint at 90 degrees of flexion and abduction. Ten patients had lead dislodgement during the range of motion of the shoulder joint at 45 degrees flexion and abduction. Eight patients experienced lead dislodgement before beginning rehabilitation. Eight patients consisted of three in the limitation group, three in the stepwise group, and two in the early protocol group.

We compared the incidence of hematoma, swelling, and wound dehiscence in the limitation, stepwise protocol, and early protocol groups with and without anticoagulation therapy, antiplatelet therapy, and combined anticoagulation and antiplatelet therapy. No significant differences were observed among the three groups (Table 4).

In addition, data on the range of motion of the shoulder joint pre and post-rehabilitation were presented in Table S1. Only the data who were surveyable were provided and patients in limitation group have not been investigated.

There are 364 patients including the stepwise protocol group ($n=229$) and the early protocol group ($n=135$). There was a significant difference in the range of motion of the shoulder joint flexion and abduction at the initial assessment between the stepwise protocol and the early protocol. However, no significant difference was observed in the final assessment.

4 | DISCUSSION

4.1 | Major findings

This study aimed to determine the safety of the upper extremity on the side of the CIED raised above the head. There was no significant difference in complication rates among the three groups. Results of this study indicate that raising the upper extremity on the side of the CIED was safe and the use of rib belt may not have enough clinical advantage. Thus, this critical report will have

TABLE 2 Results of the complication rates.

	Overall	Limitation	Stepwise protocol	Early protocol	
	N = 591	*N* = 155	*N* = 251	*N* = 185	*p*-value
Any complication	53 (9.0)	16 (10.3)	26 (10.4)	11 (5.9)	0.22
Type of device					
PM	37 (6.3)	12 (7.7)	15 (5.9)	10 (5.4)	0.70
ICD, CRT	16 (2.7)	4 (2.5)	11 (4.3)	1 (0.5)	0.0501
Type of implant					
New CIED implant	48 (8.1)	15 (9.7)	23 (9.2)	10 (5.4)	0.29
Generator exchange	5 (0.8)	1 (0.6)	3 (1.2)	1 (0.5)	0.59
Shoulder exercise-related complication					
Hematoma	14 (2.4)	3 (1.9)	6 (2.4)	5 (2.7)	0.94
Lead dislodgement	15 (2.5)	3 (1.9)	10 (4.0)	2 (1.1)	0.16
Right ventricular lead	10 (1.7)	3 (1.9)	7 (2.8)	0 (0.0)	0.06
Right atrial lead	5 (0.8)	0 (0.0)	3 (1.2)	2 (1.1)	
ICD shock lead	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
Increased pacing threshold	16 (2.7)	5 (3.2)	9 (3.6)	2 (1.1)	0.23
General complication					
Wound infection	2 (0.3)	0 (0.0)	2 (0.8)	0 (0.0)	0.51
Pneumothorax	3 (0.5)	1 (0.6)	0 (0.0)	2 (1.1)	0.27
Tamponade	2 (0.3)	2 (1.3)	0 (0.0)	0 (0.0)	0.07
Deep venous thrombosis	1 (0.2)	1 (0.6)	0 (0.0)	0 (0.0)	0.26

Note: The nominal scales are *N* (%).
Abbreviations are same as Table 1.

TABLE 3 The characteristics of patients with lead dislodgement.

Pt Nr	Sex	Age (years)	BMI	LVEF (%)	Etiology	Type of CIED	Type of implant	Type of dislodge lead	Date of complication from surgery (days)	Type of lead	Type of lead used in reoperation	Protocol	Shoulder range of motion during lead dislodgement (degrees)
1	f	80	19.4	65	SSS	PM	New	RV	1	Screw	Screw	Limitation	0
2	f	74	26.7	73	Advanced AVB	PM	New	RV	3	Screw	Screw	Limitation	0
3	f	63	19.8	75	SSS	PM	New	RV	3	Screw	Screw	Limitation	0
4	f	77	32.6	72	SSS	PM	New	RV	1	Screw	Screw	Stepwise	0
5	m	76	24.5	58	CAVB	PM	New	RA	5	Screw	Tined	Stepwise	120
6	f	62	22.2	36	DCM	CRT	New	RV	1	Screw	Screw	Stepwise	0
7	f	78	32.0	30	HF	CRT	New	RV	1	Screw	Screw	Stepwise	45
8	f	77	26.7	69	SSS	PM	New	RV	7	Screw	Screw	Stepwise	180
9	m	54	22.9	82	CAVB	PM	New	RV	5	Screw	Screw	Stepwise	90
10	m	56	30.8	30	MI	CRT	New	RA	2	Screw	Screw	Stepwise	45
11	m	64	21.0	21	DCM	CRT	New	RV	14	Screw	Screw	Stepwise	180
12	f	71	24.3	18	DCM	CRT	New	RV	1	Screw	Screw	Stepwise	45
13	m	72	29.2	35	VT/VF	ICD	New	RA	0	Screw	Screw	Stepwise	0
14	f	89	23.6	55	AF with bradycardia	PM	New	RA	0	Screw	Screw	Early	0
15	f	83	27.5	90	CAVB	PM	New	RA	2	Screw	Screw	Early	0

Abbreviations: AF, atrial fibrillation; CRT-D, cardiac resynchronization therapy with defibrillator; f, female; m, male; Other abbreviations are same as Table 1.

TABLE 4 Results of complications differences with and without anticoagulation and antiplatelet therapy.

	Limitation	Stepwise protocol	Early protocol	
	N = 155	*N* = 251	*N* = 185	*p*-value
Anticoagulation therapy	*N* = 26	*N* = 85	*N* = 55	
	0 (0.0)	4 (4.7)	1 (1.8)	0.39
Without anticoagulation therapy	*N* = 129	*N* = 166	*N* = 130	
	3 (2.3)	2 (1.2)	4 (3.1)	0.53
Antiplatelet therapy	*N* = 31	*N* = 56	*N* = 29	
	1 (3.2)	2 (3.6)	2 (6.9)	0.73
Without antiplatelet therapy	*N* = 124	*N* = 195	*N* = 156	
	2 (1.6)	4 (2.1)	3 (1.9)	0.96
Combined anticoagulation and antiplatelet therapy	*N* = 5	*N* = 20	*N* = 7	
	0 (0.0)	1 (5.0)	1 (14.3)	0.56
Without anticoagulation and antiplatelet therapy	*N* = 150	*N* = 231	*N* = 178	
	3 (2.0)	5 (2.2)	4 (2.2)	0.99

Note: The nominal scales are *N* (%).

a significant impact on changing the paradigm of postoperative CIED management.

4.2 | Comparison with prior studies

This study considered the complication rates to be within the normal range of common complications. The overall complication rates in this study were 7.1%: hematoma, swelling, wound dehiscence in 2.4%, lead dislodgement in 2.5%, increased pacing threshold in 2.7%, wound infection in 0.3%, pneumothorax in 0.5%, tamponade in 0.3%, and venous occlusion in 0.2%. The European Society of Cardiology guideline 2021[16] states that the overall complications are 5.0–15.0%, hematoma is 2.1–5.3%, lead dislodgement is 1.0–5.9%, increased pacing threshold is 0.1–1.5%, wound infection is 0.7–1.2%, venous occlusion is 0.1–2.6%, pneumothorax is 0.5–2.2%, and tamponade was 0.3–0.7%. Therefore, we believe that the results of this study did not significantly deviate from previously reported complication rates. In this study, raising the upper extremity above the head on the side of the CIED was not a factor in the development of postoperative complications.

Two studies investigated the relationship between rehabilitation of the upper extremity and complications. The first study[14] reported that postoperative complications occurred in two patients in the pendulum exercise group and one in the no-exercise group after CIED surgery. However, the complication rates were not analyzed. Furthermore, the second study[11] reported no lead dislodgement in patients who performed exercises involving elevation of the upper extremity on the side of the CIED in the early period after CIED surgery. Unfortunately, the sample size in their study[11] was small (10 patients). Therefore, our study analyzed a bigger sample size of 591 patients to compare the complications after CIED surgery.

The results of this study have further strengthened our conviction that raising the upper extremity on the side of the CIED above the head is not associated with lead dislodgement. To prevent lead from being dislodged when standing or breathing, the lead is generally deflected and retained in the pocket after it is fixed in the endocardium.[19] It would seem that although the generator and lead itself may move upward during the raising movements of the upper extremity adjacent to the CIED, the distance of movement is small and the possibility of traction to the extent of lead dislodgement is minimal. Furthermore, the present study found no statistically significant differences among the three groups in terms of pacing threshold or lead impedance values that necessitated re-treatment based on the presence or absence of upper extremity motion.

4.3 | Effect of anticoagulation therapy for complication

Risk factors for hematoma, swelling, and wound dehiscence were reported to be influenced by concomitant use of antiplatelet drugs[17] and warfarin,[18] suggesting that usage of drugs had a more significant effect than rehabilitation of the upper extremity on the side of the CIED. However, no significant difference was found between the antiplatelet and anticoagulation therapies in the present study. Because wound infection, pneumothorax, tamponade, and venous obstruction have been usually considered as perioperative complications,[18–22] those complications seem not to be related to the shoulder rehabilitation. Our results supported those speculations.

4.4 | Assessment of the range of motion of the shoulder joint and the use of rib belt after CIED surgery

Our study showed that the early protocol could detect limitation in the range of motion of the shoulder joint after the surgery. It has been reported that the range of motion of shoulder joint flexion and

abduction must have at least 130 degrees to allow patients to perform upper extremity tasks and self-care at a position higher than the head.[23] However, even in the early protocol group, shoulder motion was no more than 130 degrees by an initial assessment. In addition, we believe that the use of rib belt may not have any clinical advantages after the implantation of CIED because there were no significant differences in the rate of complications including lead dislodgement among three groups of patients, that is, patients of the limitation group using a rib belt, patients of the stepwise group using a temporary rib belt, and the patients of the early group who did not use a rib belt.

4.5 | Clinical implication

This study provides additional support that the raising of upper extremities on the side of the CIED above the head is safe. Relief from a limited range of motion on the side of the CIED, which adversely affects patient activity and mental health, is important for the quality of life of CIED patients. Thus, our research has highlighted the importance of exercise of the shoulder joint after the implantation of CIED.

4.6 | Study limitation

This study has some limitations. First, long-term safety and efficacy are unknown because the postoperative follow-up period was only 1 month. In addition, the *p*-value was .0501 for the comparison of the three groups with high-power devices such as ICD and CRT. Therefore, the results of this group of patients with high-power devices may vary depending on sample size and number of events. Therefore, it is necessary to validate the efficacy of this study in terms of delayed complications and upper-extremity function through follow-up. Second, all the data were collected from a single center. Ellenbogen et al. and Kirkfeld group reported[19,24] that the complication rates differed depending on the number of CIED surgeries performed at a hospital. Further multicenter study needs to be done to establish the safety of the upper extremity on the side of the CIED rehabilitation. Third, the degree of improvement in the range of motion of the shoulder joint on the side of the CIED is unclear. Future studies on the current topic are therefore required for preoperative and postoperative measurements of the range of motion of the shoulder joint on the side of the CIED. Fourth, the number of days that the limitation group wore the rib belt after discharge from the hospital is unclear. There is no evidence for the use and usage period of rib belts after CIED implantation, thus prospective studies may be needed to corroborate our results.

5 | CONCLUSION

The exercise in the upper extremity on the side of the CIED with shoulder joint elevation and abduction from the day after the CIED did not compromise postoperative safety.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

All relevant data are within the paper.

ETHICS APPROVAL STATEMENT

This study was approved by the Ethics Committee of our hospital (No. 2021–208).

PATIENT CONSENT STATEMENT

The requirement of informed consent from patients was waived, and we adopted an opt-out method, which allows patients to express their desire to not participate. The study was approved by the ethics committee of our hospital. The information regarding the use of medical record data for the study and the opt-out method is presented on our hospital's website.

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REFERENCES

1. Srinivasan NT, Schilling RJ. Sudden cardiac death and arrhythmias. Arrhythm Electrophysiol Rev. 2018;7:111–7.
2. Sezgin Özcan D, Gülcihan Balcı K, Polat CS, Özcan ÖU, Köseoğlu BF, Balcı MM. Shoulder problems and related conditions in patients with implantable cardioverter-defibrillators. Annals of Medical Research. 2019;26(9):1861–7.
3. Beck H, Boden WE, Patibandla S, Kireyev D, Gutpa V, Campagna F, et al. 50th anniversary of the first successful permanent pacemaker implantation in the United States: historical review and future directions. Am J Cardiol. 2010;106:810–8.
4. Burke MC, Gold MR, Knight BP, Barr CS, Theuns DAMJ, Boersma LVA, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE study and the EFFORTLESS registry. J Am Coll Cardiol. 2015;65:1605–15.
5. Kondo Y, Ueda M, Kobayashi Y, Schwab JO. New horizons for infection prevention technology and implantable devices. J Arrhythm. 2016;32:297–302.
6. Acha M, Soifer E, Hasin T. Cardiac implantable electronic miniaturized and micro devices. Micromachines. 2020;11(10):902.
7. Uslan DZ, Tleyjeh IM, Baddour LM, Friedman PA, Jenkins SM, St Sauver JL, et al. Temporal trends in permanent pacemaker implantation: a population-based study. Am Heart J. 2008;155:896–903.
8. Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT, et al. Trends in permanent pacemaker implantation in the United States from 1993 to 2009: increasing complexity of patients and procedures. J Am Coll Cardiol. 2012;60:1540–5.

9. Bradshaw PJ, Stobie P, Knuiman MW, Briffa TG, Hobbs MST. Trends in the incidence and prevalence of cardiac pacemaker insertions in the aging population. Open Heart. 2014;1:e000177.
10. Lee JH, Lee SR, Choi EK, Jeong J, Park HD, You SJ, et al. Temporal trends in cardiac implantable electronic device implantations: a nationwide population-based study. Korean Circ J. 2019;49:841–52.
11. Naffe A, Iype M, Easo M, McLeroy SD, Pinaga K, Vish N, et al. Appropriateness of sling immobilization to prevent lead displacement after pacemaker/implantable cardioverter-defibrillator implantation. Proc (Bayl Univ Med Cent). 2009;22:3–6.
12. Collins G, Hamill S, Laventure C, Newell S, et al. A survey of post-cardiac rhythm device implantation: movement and mobilization advice in the UK. Br J Cardiol. 2019;26:14–8.
13. Surendran PJ, Jacob P, Selvamani D, Papasavvas T, Swaminathan N, Mathew G, et al. Upper extremity dysfunction in patients with cardiac implantable electronic devices: a systematic review. Int J Ther Rehabil. 2021;28:1–18.
14. Wongcharoen W, Petvipusit W, Prasertwitayakij N, Gunaparn S, Meemajam S, Pisespongsa C, et al. The effect of early pendulum exercise on shoulder function after cardiac rhythm management device implantation. J Interv Card Electrophysiol. 2019;55:343–7.
15. Daniels JD, Sun S, Zafereo J, Minhajuddin A, Nguyen C, Obel O, et al. Preventing shoulder pain after cardiac rhythm management device implantation: a randomized controlled study. Pacing Clin Electrophysiol. 2011;34:672–8.
16. Glikson M, Nielsen JC, Kronborg MB, et al. ESC guidelines on cardiac pacing and cardiac resynchronization therapy: developed by the task force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) with the special contribution of the European heart rhythm association (EHRA). EP Europace. 2021;24:71–164.
17. Tompkins C, Cheng A, Dalal D, Brinker JA, Leng CT, Marine JE, et al. Dual antiplatelet therapy and heparin "bridging" significantly increase the risk of bleeding complications after pacemaker or implantable cardioverter-defibrillator device implantation. J Am Coll Cardiol. 2010;55:2376–82.
18. Nichols CI, Vose JG. Incidence of bleeding-related complications during primary implantation and replacement of cardiac implantable electronic devices. J Am Heart Assoc. 2017;6:e004263.
19. Ellenbogen KA, Kaszala K. Cardiac pacing and ICDs. 6th ed. Hoboken: Wiley Blackwell; 2014. p. 150–210.
20. Tarakji KG, Mittal S, Kennergren C, Corey R, Poole JE, Schloss E, et al. Antibacterial envelope to prevent cardiac implantable device infection. N Engl J Med. 2019;380:1895–905.
21. Palmisano P, Accogli M, Zaccaria M, Luzzi G, Nacci F, Anaclerio M, et al. Rate, causes, and impact on patient outcome of implantable device complications requiring surgical revision: large population survey from two centres in Italy. Europace. 2013;15:531–40.
22. Poole JE, Gleva MJ, Mela T, Chung MK, Uslan DZ, Borge R, et al. Complication rates associated with pacemaker or implantable cardioverter-defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. Circulation. 2010;122:1553–61.
23. Oosterwijk AM, Nieuwenhuis MK, van der Schans CP, Mouton LJ. Shoulder and elbow range of motion for the performance of activities of daily living: a systematic review. Physiother Theory Pract. 2018;34:505–28.
24. Kirkfeldt RE, Johansen JB, Nohr EA, Jørgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J. 2014;35:1186–94.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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