

Effects of early shoulder exercise on functional recovery after cardiac implantable electronic device implantation: A 3-year randomized cohort follow-up

Muharrem Said Cosgun¹, Cansu Cosgun²

Background. Shoulder dysfunction after cardiac implantable electronic device (CIED) implantation may impair upper-extremity function and quality of life (QoL). Although a prior randomized trial demonstrated short-term benefits of early postoperative exercises, long-term outcomes remain unclear.

Aim. To evaluate the 3-year efficacy and safety of an early postoperative shoulder exercise protocol after CIED implantation.

Methods. Of 92 patients randomized in the original trial, 82 completed the 3-year follow-up. Participants had completed a 6-week intervention consisting of pendulum exercises (PE), stretching & strengthening exercises (SSE) or standard care, without further structured exercise. Outcomes included Visual Analog Scale (VAS) pain scores, grip strength, shoulder flexion and abduction range of motion (ROM), Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH), and the Physical and Mental Component Summary scores (PCS and MCS) of the 36-Item Short-Form Survey (SF-36). Lead-related complications were also assessed.

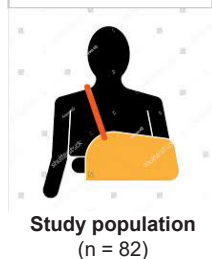
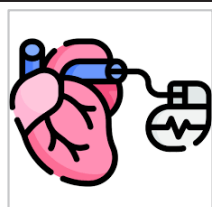
Results. VAS and SF-36 MCS scores were comparable across groups. However, compared with standard care, both exercise groups maintained superior outcomes at 3 years for grip strength (PE: +9.0 kgf; SSE: +9.0 kgf), shoulder flexion ROM (PE: +10.0°; SSE: +11.0°), shoulder abduction ROM (PE: +7.0°; SSE: +7.0°), QuickDASH (PE: -5.0 points; SSE: -6.0 points), and SF-36 PCS (PE: +9.0 points; SSE: +10.0 points) (all $P < 0.05$). No lead-related complications occurred during follow-up.

Conclusion. Early postoperative shoulder exercise after CIED implantation provides sustained improvements in shoulder function and physical QoL without compromising lead safety.

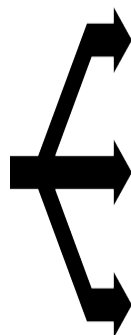
Trial registration. ClinicalTrials.gov, NCT07496554. <https://clinicaltrials.gov/study/NCT07496554>

EARLY SHOULDER EXERCISE AFTER CIED

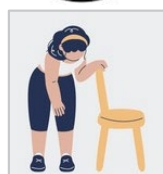
CIED + movement restriction



Study population
(n = 82)



Control
(n = 27)



Pendulum
(n = 29)



Stretching &
Strengthening
(n = 26)



Long-term outcomes (3-year follow-up)

- 👊 **Strength** ↑
(Grip: +9.0 kgf)
- 📏 **ROM** ↑
(Flexion: +10/11°, Abduction: +7°)
- 👤 **Function** ↑
(QuickDASH: -5/6 points)
- ❤️ **QoL** ↑
(SF-36 PCS: +9/10 points)
- ✓ **Safe**
(No lead complications)

Early shoulder exercise preserves long-term function without compromising lead safety.

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Graphical Abstract

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Key words: cardiac implantable electronic device, shoulder dysfunction, exercise therapy, rehabilitation, quality of life, lead safety

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¹Department of Cardiology, Mengucek Gazi Education and Research Hospital, Faculty of Medicine, Erzincan Binali Yildirim University, Erzincan, Turkey

²Department of Physical Therapy and Rehabilitation, Mengucek Gazi Education and Research Hospital, Faculty of Medicine, Erzincan Binali Yildirim University, Erzincan, Turkey

Corresponding author: Muharrem Said Cosgun, e-mail: drsaidcosgun2009@hotmail.com

INTRODUCTION

Cardiac implantable electronic devices (CIEDs) are central to the treatment of cardiac rhythm disorders and have markedly improved survival and symptom control in appropriately selected patients¹⁻³. With expanding device indications and increasing life expectancy, more individuals are living long term with CIEDs (ref.^{4,6}). Consequently, attention has shifted from procedural success to the preservation of functional status and quality of life (QoL) after device implantation^{7,8}.

Although CIED implantation is generally considered minimally invasive, ipsilateral shoulder dysfunction has emerged as a relevant postoperative concern^{9,10}. Patients often report reduced shoulder mobility, decreased strength, and discomfort in the implant-side upper extremity^{9,11}. These limitations can interfere with daily activities and contribute to diminished physical QoL (ref.^{7,12,13}). While surgical factors such as pocket creation and tissue trauma may play a role in the early postoperative period, behavioral adaptations – particularly, reduced shoulder movement due to fear of lead displacement – appear to substantially contribute to persistent dysfunction¹⁴.

Post-implantation recommendations regarding upper-limb activity vary widely^{15,16}. In many centers, patients are advised to restrict shoulder movement – typically avoiding lifting the affected arm above shoulder level for the first 2 to 4 weeks – to minimize the theoretical risk of lead dislodgement^{17,18}. However, prolonged immobilization may promote muscle deconditioning, capsular stiffness, and altered shoulder mechanics, potentially leading to longer-term functional impairment^{14,19,20}. Increasing evidence indicates that excessive restriction may be unnecessary and, in some cases, counterproductive^{21,22}.

Previous studies of structured shoulder exercise programs after CIED implantation have demonstrated improvements in strength, mobility, pain, and upper-limb function during early follow-up^{11,22,23}, indicating that controlled mobilization can be safely implemented in the immediate postoperative phase^{18,24}. However, most available data focus on short-term outcomes. The long-term trajectory of shoulder function after CIED implantation remains insufficiently characterized^{9,25}, including whether early benefits of exercise persist.

In 2022, a prospective randomized trial evaluated the impact of early initiation of pendulum exercises (PEs) and stretching & strengthening exercises (SSEs) on functional recovery following CIED implantation²⁶. The results showed improved shoulder function and QoL during short-term follow-up, without increasing lead-related complications. To address the lack of long-term evidence, the present study was designed as a 3-year longitudinal follow-up of this cohort. We aimed to determine whether the functional advantages of early postoperative shoulder

exercise are sustained, with particular attention to muscle strength, mobility, pain, functional disability, QoL, and device-related safety outcomes.

MATERIALS AND METHODS

Study design, patient groups, and exercise protocols

This study represents the long-term longitudinal follow-up of a published prospective, single-blind, randomized trial conducted in patients undergoing transvenous subcutaneous prepectoral CIED implantation. The original study design, randomization procedures, eligibility criteria, and baseline assessments have been reported in detail in our publication and were consistently applied during the 3-year long-term follow-up.

Briefly, 92 patients were randomized in the original study and allocated to the control (n = 30), PE (n = 31), or SSE (n = 31) groups. In the SSE group, three patients were excluded due to non-compliance, leaving 28 participants for the original trial analysis.

All participants received standard post-implantation care instructions at discharge, including temporary restriction (for the first two weeks) of implant-side upper limb movements above shoulder level and avoidance of heavy lifting during the early postprocedural period.

Patients in the control group did not receive any additional exercise recommendations beyond standard care. At the 2-week post-implantation visit, patients in the PE group were instructed to perform PEs involving gentle, gravity-assisted circular movements of the implant-side arm, performed twice daily for six weeks. Patients in the SSE group were instructed to perform a structured program of SSEs targeting the shoulder girdle muscles, performed every other day for six weeks. No additional exercise programs were prescribed for either exercise group beyond the initial protocol.

During the 3-year follow-up period, patients were re-evaluated using the same predefined exclusion criteria applied in the initial study. Accordingly, patients who developed neurological, orthopedic, or vascular conditions involving the upper limb, psychiatric disorders, uncontrolled endocrinological disorders, a history of mastectomy, or who required redo (replacement or revision) surgeries were excluded from the long-term analysis. In the original randomized study, one patient in the control group who developed a lead fracture and subsequently underwent revision surgery had already been excluded before the initiation of long-term follow-up, consistent with these criteria.

Of the 89 participants who completed the original trial, a small number could not be reached for long-term evaluation for non-study-related reasons, including death or loss of contact (control, n = 3; PE, n = 2; SSE, n = 2).

Consequently, long-term follow-up data were available for 27 patients in the control group, 29 in the PE group, and 26 in the SSE group. The 3-year denominator of $n = 26$ in the SSE group refers to the 28 participants who completed the original trial, after excluding 3 non-compliant patients from the original 31 randomized. No intention-to-treat sensitivity analysis was performed, as losses to follow-up were small and unrelated to the study intervention or outcomes (Fig. 1).

Long-term shoulder and device assessment

All patients included in the 3-year follow-up underwent the same clinical, functional, and device-related assessments as in the original randomized protocol, allowing direct comparison of early and long-term outcomes. Shoulder and upper limb evaluations were performed by a single experienced physiotherapist blinded to group allocation and included grip strength, shoulder flexion and abduction range of motion (ROM), pain intensity assessed by the Visual Analog Scale (VAS), functional

disability assessed by the Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH) questionnaire, and QoL assessed using the Physical and Mental Component Summary (PCS & MCS) scores of the 36-Item Short-Form Survey (SF-36).

Device evaluations were performed by the same experienced cardiologist at all visits using standard device interrogation and plain chest radiography. All measurements were recorded systematically.

Ethics

This study represents a 3-year longitudinal follow-up of a previously published trial. The original trial was conducted prior to mandatory clinical trial registration requirements and was therefore not registered in a public trial registry. The present follow-up study was prospectively registered prior to data collection. It was conducted in accordance with the latest Declaration of Helsinki and approved by the Erzincan Binali Yıldırım University Non-Interventional Clinical Research Ethics Committee

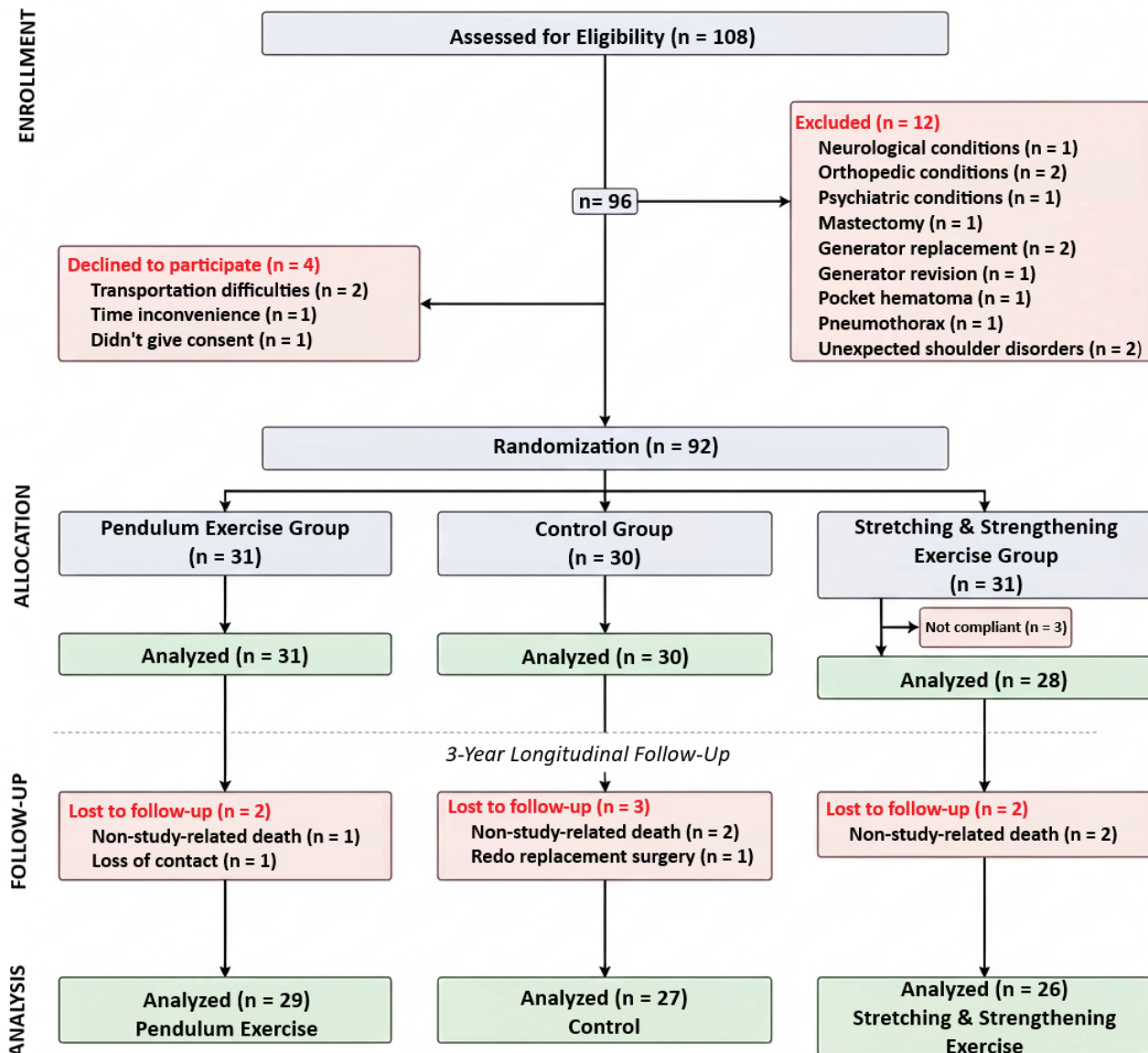


Fig. 1. CONSORT Flow Diagram.

(approval date: November 12, 2025; decision number: 2025-22/01). Written informed consent was obtained from all participants.

Statistical analysis

Continuous variables are presented as means $\pm$ standard deviation. Normality of continuous variables was assessed using the Shapiro-Wilk test. Between-group comparisons were performed using one-way ANOVA with Bonferroni correction, with the adjusted significance level defined as α/k ($\alpha = 0.05$), where k represents the number of comparisons; for the three-group comparisons in this study (control, PE, and SSE), the Bonferroni-adjusted threshold was $P < 0.017$. Repeated-measures ANOVA was used for longitudinal analyses across all continuous outcome measures, including grip strength, shoulder flexion and abduction ROM, VAS, QuickDASH, and SF-36 PCS and MCS scores. Sphericity was assessed using Mauchly's test; where the assumption of sphericity was violated, the Greenhouse-Geisser correction was applied. Post hoc pairwise comparisons between specific time points were adjusted using Bonferroni correction. Within-subject correlation was accounted for by the repeated-measures ANOVA model structure, which partitions within-subject variance across time points. The 3-year analysis was performed on a complete-case basis; participants lost to follow-up were excluded, and no imputation was performed for missing data. No formal power calculation was performed for the 3-year follow-up, as this study was designed as a longitudinal extension of the original trial. A P -value < 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics version 28 (IBM Corp., Armonk, NY, USA) for Windows. Figures were generated using the Matplotlib library (v3.8) in the Python (v3.11) environment (Python Software Foundation).

RESULTS

Demographic and clinical characteristics

During the 3-year follow-up period, a small number of patients (two to three per group) could not be reached for non-study-related reasons, as detailed in the Methods section. Long-term data from a total of 82 participants were analyzed.

No statistically significant differences were observed among the control, PE, and SSE groups in age, sex distribution, smoking status, hand dominance, body mass index, or educational status. The prevalence of comorbid conditions, including diabetes mellitus and hypothyroidism – recognized risk factors for adhesive capsulitis – was comparable across groups. Functional status assessed by New York Heart Association class and left ventricular ejection fraction did not differ significantly. Demographic and clinical characteristics are summarized in Table 1.

Procedural and device-related characteristics were also well balanced. No significant between-group differences were observed in device type, number of implanted leads,

incision length, venous access route, procedural duration, early postprocedural complications, or generator position at 3 years. Procedural characteristics are summarized in Table 2.

Grip strength

Grip strength was similar among groups at baseline and at the 2-week post-implantation assessment. At 2 months, grip strength was significantly higher in both exercise groups compared with the control group, with mean differences of +9.0 kgf (95% CI: 4.7–13.3) for PE and +10.0 kgf (95% CI: 5.3–14.7) for SSE versus controls, with no difference between the PE and SSE groups.

At 3 years, this between-group pattern was maintained. Grip strength remained higher in the PE and SSE groups than in the control group, with mean differences of +9.0 kgf (95% CI: 5.5–12.5) for PE and +9.0 kgf (95% CI: 5.1–12.9) for SSE versus controls, while no significant difference was observed between exercise groups. Within-group analysis demonstrated stable grip strength from 2 months to 3 years in the exercise groups, whereas no comparable long-term improvement was observed in the control group (Fig. 2A).

Shoulder range of motion

Shoulder flexion and abduction ROM were comparable among groups at baseline and decreased significantly at the 2-week assessment in all groups. At 2 months, both flexion and abduction ROM had returned to baseline levels in the PE and SSE groups but remained reduced in the control group. At this timepoint, shoulder flexion ROM was significantly greater in both exercise groups compared with controls, with mean differences of +9.0° (95% CI: 3.9–14.1) for PE and +11.0° (95% CI: 5.4–16.6) for SSE. Similarly, abduction ROM differences were +7.0° (95% CI: 1.9–12.1) for PE and +8.0° (95% CI: 2.2–13.8) for SSE versus controls.

At the 3-year follow-up, flexion and abduction ROM remained significantly greater in the PE and SSE groups compared with controls. Mean differences in flexion ROM were +10.0° (95% CI: 6.0–14.0) for PE and +11.0° (95% CI: 6.3–15.7) for SSE, and abduction ROM differences were +7.0° (95% CI: 2.4–11.6) for PE and +7.0° (95% CI: 1.7–12.3) for SSE versus controls. No significant differences were observed between the two exercise groups. Within-group analysis showed sustained preservation of ROM from 2 months to 3 years in the exercise groups, whereas recovery in the control group remained incomplete (Fig. 2B and 2C).

Pain assessment

VAS scores were comparable among groups at baseline and at 2 weeks. At 2 months, pain scores were significantly lower in both exercise groups compared with the control group, with no difference between PE and SSE.

At 3 years, pain scores had decreased in all groups, and no significant between-group differences were observed, indicating convergence of pain levels over long-term follow-up (Fig. 3A).

Table 1. Comparison of demographic and clinical characteristics between groups.

Variables	Control Group (n = 27)	PE Group (n = 29)	SSE Group (n = 26)	<i>P</i> [*]	<i>P</i> [#]	<i>P</i> ^{&}
Age, years	67 ± 10	64 ± 9	63 ± 11	0.346	0.129	0.488
Male gender, n (%)	15 (55.6)	17 (58.6)	15 (57.7)	0.999	0.999	0.999
Smoking status, n (%)	6 (22.2)	3 (10.3)	4 (15.4)	0.288	0.728	0.696
Left-handed, n (%)	1 (3.7)	2 (6.9)	1 (3.8)	1.000	1.000	1.000
Body mass index, kilogram/square meter	26.2 ± 3.8	26.4 ± 3.3	26.1 ± 3.2	0.521	0.741	0.352
Illiterate, n (%)	2 (7.4)	4 (13.8)	3 (11.5)	0.671	0.669	1.000
Hypertension, n (%)	14 (51.9)	11 (37.9)	11 (42.3)	0.420	0.586	0.788
Diabetes mellitus, n (%)	9 (33.3)	12 (41.4)	10 (38.5)	0.589	0.779	1.000
Hypothyroidism, n (%)	2 (7.4)	1 (3.4)	2 (7.7)	0.605	1.000	0.598
Coronary artery disease, n (%)	9 (33.3)	10 (34.5)	12 (46.2)	1.000	0.406	0.420
Heart failure, n (%)	8 (29.6)	9 (31.0)	10 (38.5)	1.000	0.569	0.584
New York Heart Association functional class, n (%)						
I-II	24 (88.9)	26 (89.7)	22 (84.6)	1.000	0.704	0.696
III-IV	3 (11.1)	3 (10.3)	4 (15.4)			
Left ventricular ejection fraction, %	50 ± 9	51 ± 10	47 ± 8	0.514	0.416	0.318

*Control vs. PE; #Control vs. SSE; &PE vs. SSE.

Table 2. Comparison procedural characteristics between groups.

Variables	Control Group (n = 27)	PE Group (n = 29)	SSE Group (n = 26)	<i>P</i> [*]	<i>P</i> [#]	<i>P</i> ^{&}
Device type, n (%)						
Pacemaker	23 (85.2)	23 (79.3)	21 (80.8)	0.731	0.728	1.000
Defibrillator	4 (14.8)	6 (20.7)	5 (19.2)			
Number of leads	1 (1-3)	1 (1-3)	1 (1-3)	0.551	0.352	0.488
Incision length, centimeters	4.1 ± 0.6	4.4 ± 0.8	4.3 ± 0.8	0.198	0.254	0.748
Transvenous Access type, n (%)				0.288	0.728	0.696
Subclavian vein	21 (77.8)	26 (89.7)	22 (84.6)	0.416	0.782	0.511
Axillary vein	6 (22.2)	3 (10.3)	4 (15.4)			
Procedural duration, minutes	55 (40-90)	60 (35-95)	55 (40-80)			
Generator position, centimeters (at 3-year)						
Generator-Clavicle	5.1 ± 1.4	4.9 ± 1.3	5.0 ± 1.1	0.242	0.416	0.448
Generator-Acromion	8.7 ± 3.5	8.6 ± 3.1	8.4 ± 3.3	0.644	0.218	0.304
Lead dislodgement, n (%) (2-month to 3-year)	0 (0.0)	0 (0.0)	0 (0.0)	N/A ^a	N/A ^a	N/A ^a

*Control vs. PE; #Control vs. SSE; &PE vs. SSE. ^aNo events occurred in any group during this period; statistical comparison was not applicable.

Functional disability

QuickDASH scores were similar among groups at baseline and at 2 weeks. At 2 months, both exercise groups demonstrated significantly lower QuickDASH scores compared with controls, with mean differences of -6.0 points (95% CI: -7.9 to -4.1) for PE and -5.0 points (95% CI: -6.9 to -3.1) for SSE versus controls, without differences between PE and SSE.

These between-group differences were sustained at 3 years. QuickDASH scores remained significantly lower in the PE and SSE groups than in the control group, with mean differences of -5.0 points (95% CI: -6.7 to -3.3) for PE and -6.0 points (95% CI: -7.7 to -4.3) for SSE versus controls, indicating long-term preservation of upper limb function. Functional gains observed at 2 months were maintained at 3 years in the exercise groups, whereas no comparable improvement was seen in the control group (Fig. 3B).

Quality of life

MCS scores of the SF-36 did not differ significantly among groups at any time point (Fig. 4A).

In contrast, PCS scores of the SF-36 were significantly higher in both exercise groups at 2 months compared with the control group, with mean differences of +12.0 points (95% CI: 8.0-16.0) for PE and +13.0 points (95% CI: 9.4-16.6) for SSE versus controls. This difference persisted at the 3-year follow-up, with mean differences of +9.0 points (95% CI: 5.2-12.8) for PE and +10.0 points (95% CI: 6.7-13.3) for SSE versus controls, with no significant difference between the PE and SSE groups. Improvements in physical health-related QoL observed at 2 months were preserved at long-term follow-up in the exercise groups, whereas the control group did not demonstrate a comparable improvement (Fig. 4B).

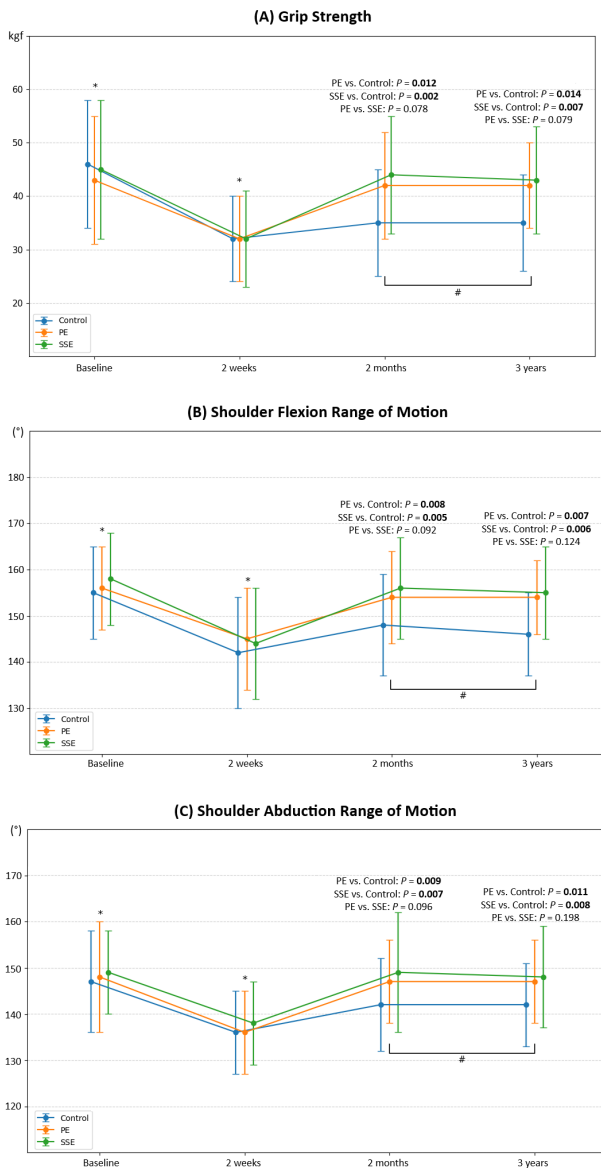


Fig. 2. Changes in (A) grip strength (kilogram-force), (B) shoulder flexion range of motion ($^{\circ}$), and (C) shoulder abduction range of motion ($^{\circ}$) over time in the control, pendulum exercise (PE), and stretching & strengthening exercise (SSE) groups from baseline to 3-year follow-up.

*No significant between-group difference at baseline ($P > 0.05/3$, Bonferroni correction). #No significant within-group difference between 2 months and 3 years ($P > 0.05$). Error bars represent standard deviation ($\pm$ SD).

Safety outcomes

One case of lead dislodgement was observed in the control group within the first 2 months after implantation. During the subsequent 3-year follow-up period, no lead-related complications (including lead fracture and dislodgement) were observed in any of the study groups.

Accordingly, there were no statistically significant differences among the three groups with respect to lead-related complications, and no adverse events attributable to the prescribed exercise interventions were identified during long-term follow-up (Table 2). Given the absence of events during the 2-month to 3-year period, formal

between-group comparison was not performed. The one-sided 95% upper confidence bound for the lead-related complication rate was 9.8% for the PE group, 10.9% for the SSE group, and 10.5% for the control group, reflecting the limited statistical power of this study to detect rare safety events.

DISCUSSION

The results demonstrate that early shoulder exercise after CIED implantation yields durable functional benefits without compromising device safety. Our findings indicate that a structured 6-week exercise intervention initiated shortly after implantation leads to preserved grip strength, shoulder mobility, upper-limb function, and physical health-related QoL at the 3-year follow-up, more effectively than standard postoperative care. Importantly, these advantages were not accompanied by an increased incidence of lead-related complications.

Shoulder dysfunction after CIED implantation is increasingly recognized, although it is still often underestimated in clinical practice^{9,10}. Despite the relatively low level of surgical trauma associated with the procedure, many patients report weakness, reduced mobility, and discomfort in the ipsilateral upper extremity. These observations are in line with previous studies showing that functional limitations may occur even after an uncomplicated implantation^{10,14,27}.

In the present study, a clear distinction emerged between subjective and objective recovery. While shoulder pain decreased over time in all groups, patients in the exercise groups maintained better muscle strength, shoulder mobility, and upper-limb function. This suggests that improvement in pain does not necessarily reflect full functional recovery^{25,27}. In fact, relying solely on symptom relief may overlook persistent deficits that develop in the absence of structured rehabilitation^{14,19,20}.

One possible explanation is that restricting shoulder movement early after implantation may lead to deconditioning and capsular stiffness^{14,19}. Over time, these changes can contribute to ongoing functional limitations. In contrast, early activation of the shoulder may help preserve muscle function and joint mobility by preventing disuse-related changes^{23,28,29}. While most previous investigations have focused on short-term outcomes^{11,22,23,26}, our findings support the idea that early mobilization has not only short-term benefits but also lasting effects, as demonstrated by the sustained differences observed at 3 years. In this context, Martignani et al. reported spontaneous improvement in shoulder function over a 5-year observational follow-up after ICD implantation²⁵; however, that study did not include a structured exercise intervention or a randomized comparison group. The present study extends these findings by demonstrating that early structured exercise yields superior and sustained functional outcomes compared with standard care alone over 3 years²⁵.

Another notable finding was that the two exercise approaches resulted in similar outcomes. Both PEs and SSEs were effective in maintaining strength, mobility, and

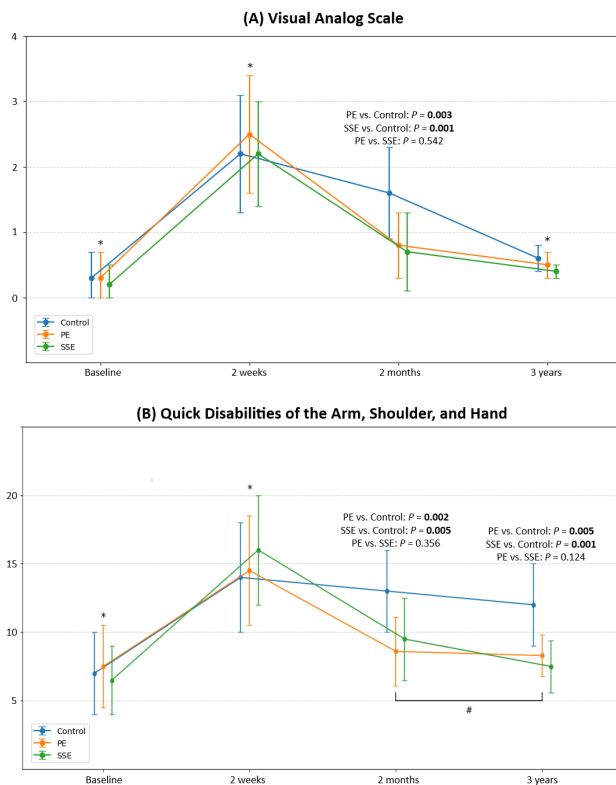


Fig. 3. Changes in (A) Visual Analog Scale pain scores and (B) Quick Disabilities of the Arm, Shoulder, and Hand scores over time in the control, pendulum exercise (PE), and stretching & strengthening exercise (SSE) groups from baseline to 3-year follow-up.

*No significant between-group difference at baseline ($P > 0.05/3$, Bonferroni correction). #No significant within-group difference between 2 months and 3 years ($P > 0.05$). Error bars represent standard deviation ($\pm$ SD).

upper-limb function. This suggests that the timing of mobilization may be more important than the specific type of exercise performed^{18,24}. From a practical standpoint, this is encouraging, as it indicates that relatively simple and accessible exercise programs may be sufficient to achieve meaningful long-term benefits^{23,28}.

Importantly, no exercise-related lead complications were observed during follow-up. This finding may help address concerns about lead dislodgement, which have traditionally led to cautious postoperative movement restrictions. Overall, these results support a more active rehabilitation approach¹⁵⁻¹⁷.

To contextualize the clinical relevance of these findings, the observed between-group differences were compared with published minimal clinically important differences (MCIDs) for each outcome measure. The between-group differences in grip strength at 3 years (PE: +9.0 kgf; SSE: +9.0 kgf) exceeded the reported MCID of 5.0–6.5 kgf for grip strength dynamometry, indicating clinically meaningful preservation of muscle strength in the exercise groups³⁰. For shoulder ROM, the improvements in flexion (PE: +10.0°; SSE: +11.0°) reached the reported MCID range for active forward flexion ($12^\circ \pm 4^\circ$), while the improvements in abduction (PE: +7.0°;

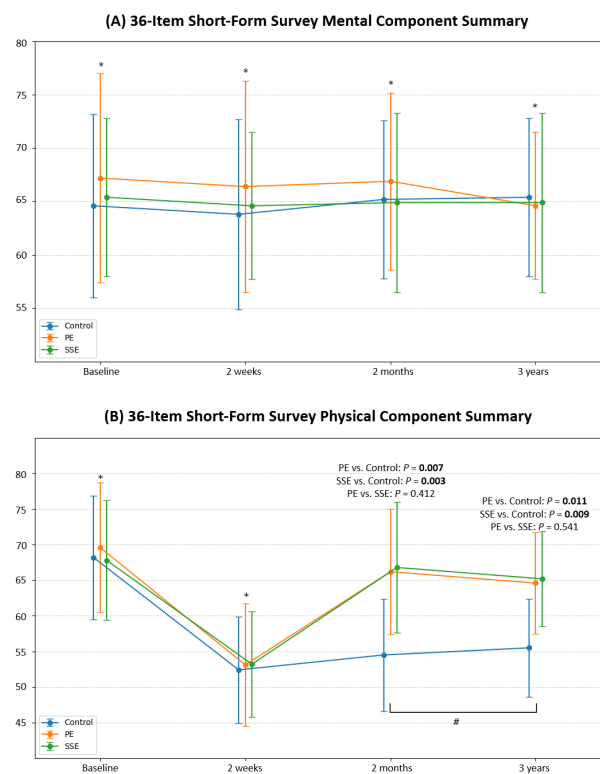


Fig. 4. Changes in (A) 36-Item Short-Form Survey Mental Component Summary scores and (B) Physical Component Summary scores over time in the control, pendulum exercise (PE), and stretching & strengthening exercise (SSE) groups from baseline to 3-year follow-up.

*No significant between-group difference ($P > 0.05/3$, Bonferroni correction). #No significant within-group difference between 2 months and 3 years ($P > 0.05$). Error bars represent standard deviation ($\pm$ SD).

SSE: +7.0°) also reached the reported MCID threshold for shoulder abduction ($7^\circ \pm 4^\circ$) (ref.³¹). Regarding SF-36 PCS, the between-group differences at 3 years (PE: +9.0 points; SSE: +10.0 points) substantially exceeded the reported MCID of 4.9 points, supporting the clinical significance of the observed improvements in physical QoL (ref.³²). In contrast, although QuickDASH differences were statistically significant (PE: –5.0 points; SSE: –6.0 points), they did not reach the reported MCID of 15.91 points, suggesting that the magnitude of functional improvement may not have been clinically perceptible at the individual patient level³³. Collectively, these findings suggest that early shoulder exercise after CIED implantation provides sustained and clinically meaningful benefits in muscle strength, shoulder ROM, and physical QoL, whereas the clinical relevance of improvements in functional disability should be interpreted cautiously. It should be noted that CIED-specific MCID thresholds have not been established in the literature; the values applied here were derived from the closest available populations and should therefore be interpreted with appropriate caution.

Taken together, the results of this study highlight the importance of early postoperative shoulder rehabilitation. While many patients experience gradual symptom

improvement over time²⁵, spontaneous recovery alone may not be sufficient to restore optimal function. Early rehabilitation strategies that encourage safe, controlled shoulder movement may avoid immobilization and help preserve long-term functional capacity and physical QoL.

Limitations

Several limitations of this study should be acknowledged. First, the sample size was relatively modest, with 82 participants completing the 3-year follow-up across three groups. This may have limited the statistical power to detect smaller between-group differences, and caution is warranted when interpreting safety-related outcomes given the limited number of events. Although this cohort represents one of the few randomized studies with 3-year follow-up data on structured shoulder exercise after CIED implantation, larger studies are needed to provide more definitive estimates of both functional and safety outcomes. Furthermore, no formal power calculation was performed for the long-term follow-up; the observed convergence of VAS and SF-36 MCS scores across groups may reflect either a true absence of between-group differences or insufficient power to detect small but clinically meaningful effects for these endpoints.

Second, although validated clinical instruments were used to assess shoulder pain and function, subjective measures may be influenced by individual perception. To minimize this variability, all assessments were conducted by a single, blinded, experienced physiotherapist using standardized protocols.

Third, adherence to the exercise programs beyond the initial supervised intervention period could not be objectively monitored. Furthermore, long-term physical activity levels, lifestyle changes, and other rehabilitation-related behaviors during the 3-year follow-up were not systematically assessed. These unmeasured confounding factors may have influenced the observed outcomes, and it is possible that participants in the exercise groups remained more physically active over time, independently contributing to the sustained functional differences.

Finally, as a single-center study, the generalizability of these findings may be limited. Future multicenter studies with larger cohorts are warranted to confirm these findings and further refine postoperative rehabilitation strategies.

CONCLUSION

Early postoperative shoulder exercise following CIED implantation provides sustained preservation of grip strength, shoulder mobility, and upper-limb function over long-term follow-up. Although shoulder pain tends to decrease over time irrespective of intervention, objective functional recovery remains significantly superior in patients who engage in early, structured mobilization, underscoring that pain resolution alone does not reflect full functional restoration. Importantly, no lead-related complications were observed in either exercise group, which is reassuring; however, given the modest sample size, larger

studies are needed before definitive safety conclusions can be drawn. Incorporating simple, structured shoulder exercise programs into routine post-implantation care may therefore represent a safe, practical, and effective strategy to optimize long-term functional outcomes and physical QoL in this patient population.

ABBREVIATIONS

ANOVA, analysis of variance; CIED, cardiac implantable electronic device; kgf, kilogram-force MCS, mental component summary; PCS, physical component summary; PE, pendulum exercise; QoL, quality of life; QuickDASH, Quick Disabilities of the Arm, Shoulder, and Hand; ROM, range of motion; SF-36, 36-Item Short-Form Survey; SSE, stretching & strengthening exercises; VAS, Visual Analog Scale.

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