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# Shoulder girdle function in patients with subcutaneous implantable cardioverter-defibrillator

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**Shoulder girdle function in patients with subcutaneous implantable cardioverter-defibrillator**

**Short title:** Shoulder function in S-ICD patients

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## INTRODUCTION

Disabilities of shoulder girdle affect up to 76% of patients with cardiac implantable electronic devices (CIED), particularly shortly after procedure. Pain related to surgery, local impact of CIED placed in subclavicular region, routine recommendations to refrain from movements that involve shoulder girdle within few weeks after procedure, as well as self-restriction from movement beyond recommended period, are considered as major factors determining chronic shoulder dysfunction [1].

Subcutaneous cardioverter-defibrillator (S-ICD) emerged as a novel solution to overcome intracardiac lead-related infectious complications. The pulse generator of S-ICD, double as large and heavy as conventional transvenous CIEDs, is implanted in the pocket on the lateral wall of the

chest and defibrillation lead is tunneled under the skin parallel to sternum [2]. Whether shoulder girdle disabilities related to a large size device exist in S-ICD patients has never been investigated. We aimed to evaluate subjective complains of S-ICD patients related to shoulder girdle as well as to objectively assess shoulder joint movements.

## METHODS

Studied population consisted of consecutive single-center patients implanted with S-ICDs at Department of Electrocardiology within one year (2021) and seen at routine follow up ambulatory visits for regular device control one year after procedure. In order to avoid bias related to the influence of dominant hand the same examination was performed in a control group of non-CIED, sex and age matched patients. Patients with neuromuscular, rheumatological or /and orthopedic disorders were excluded. All patients were implanted with Boston Scientific S-ICD system that consists of Emblem MRI S-ICD A219 generator and tripolar subcutaneous defibrillation lead. All implantations were performed by the same experienced electrophysiologist with two-incision technique with intermuscular placement of the generators as described by Winter [3]. Similarly to conventional CIED, patients were instructed to avoid excessive abduction or extrarotation of ipsilateral shoulder and to protect chest wall from potential mechanical impact.

Data on shoulder functioning was based on self- assessment questions that described pre- and post-surgery physical activity level, reported discomfort related with S-ICD device (0 — none, 1 — mild, 2 — moderate, 3 — severe), pain in shoulder region (yes/no) and sensation of asymmetric arms strength (yes/no). Objective evaluation of shoulder girdle included assessment of pain, range of movement (ROM) and muscle strength. Shoulder ROM were measured according to SFTR system for flexion, abduction, internal and external rotation using goniometer and categorized as normal versus abnormal according to ISOM normal values. Hand function in terms of muscle strength was assessed using electronic dynamometer (AXIS FC50). Surface electromyography (sEMG) by means of sEMG NeuroTrac ® MyoPlus was used to assess muscle activation. During sEMG examination S-ICDs were deactivated.

Study complies with the principles of Declaration of Helsinki and was approved by Bioethical Committee of Medical University of Lodz, Poland (RNN/395/18/KE). All participants signed provided informed consent to participate.

***Statistical methods***

Data are presented as median (Q1–Q3) for continuous values or as number (percentage) for categorized variables. All continuous data had non-normal distribution, which was tested with Shapiro-Wilk test, and therefore non-parametric test for between groups comparison was used (Wilcoxon rank test). *P* wave of <0.05 was considered as statistically significant. Data was analyzed using IBM SPSS Statistics (IBM Corp, Armonk NY, US).

## RESULTS AND DISCUSSION

Final population consisted of 15 patients (12 males), median age 47 (Q1–Q3: 30–64) years after S-ICD implantation (10 subjects in primary prevention) and 15 control patients (12 males), median age 48 (Q1–Q3: 34–65). All devices were positioned left-sided and all studied patients reported dominant contralateral right arm. No peri- and postprocedural complications related to surgical procedures were reported in the studied group.

Regarding overall physical activity 7 patients reported no changes, 6 patients indicated improvement and 2 decrease in activity as compared post to pre-implantation period. At the time of examination no patient reported pain in shoulder region. However, 10 subjects complained on discomfort related to a chest location of a device (mild in 5 subjects and moderate in 5).

None of the studied patients reported pain during passive shoulder movement, while only one patient from S-ICD group and one control subject reported on left shoulder pain during active movement on physical examination. Physical examination of ROM as well as detailed evaluation of muscle strength did not reveal any significant difference between left and right side within S-ICD group and in a control group. Furthermore, no differences in ROM and muscle strength between the same side arms were observed between S-ICD patients and control group. Detailed results are summarized in Table 1 (Part A). Even though two S-ICD patients reported on sensation of unequal strength between two arms during hand grip, sEMG evaluation revealed no asymmetry in movements. No difference between subgroups representing overall chest discomfort was observed in terms of ROM, and only trend toward lower muscle flexion and abduction strength in left arm was observed in S-ICD patients who felt mild to moderate discomfort ($P = 0.055$ for both measures) (Table 1, Part B).

Chronic shoulder disability has been constantly reported in CIED patients independently on the technique of implantation. Initial reports in patients with subpectoral CIED placement documented

that shoulder impairment was present in up to 60% of patients at 3 months and persisted in 37% of subjects at 6 months of follow up [4]. Similar impairment was reported in case of subcutaneous placement (76% of patients at 2 weeks and 28% at 3 months post-surgery) [5]. Significantly lower shoulder flexion and abduction ROM as well as grip strength loss on the site of CIED implantation were the most frequently reported [6]. Device size, type and length of incision were determined as significant predictors of shoulder dysfunction [7, 8]. Data on long term follow up documented that ipsilateral shoulder impairment regressed after 1 year [9].

So far, no data on S-ICD impact on shoulder function exists, however one could hypothesize that similar mechanisms that those observed in case of traditional CIED can contribute to some degree of shoulder girdle impairment. Large S-ICD pulse generator and lead tunneled subcutaneously across the chest even though located far from shoulder may indirectly impact shoulder mobility via pressure and interaction with chest fascia. Patients in postoperative period are in fact given similar recommendations as to arm mobility to prevent from early lead and pocket complications.

In everyday life the sensation of a device that limits some activities is reported, even though this perception is highly variable depending on a study population, ranging from non-existing to significantly impacting everyday life [10, 11]. Thienel at al. documented that two-thirds of their patients reported on daily routine restrictions, pain and device-related discomfort [11]. Large device located on the lateral wall of the chest almost always changes sleeping behavior into one side night position due to discomfort related to a device [12].

## CONCLUSIONS

We documented that despite discomfort related to the presence of large S-ICD device located on the chest wall, objective detailed evaluation did not show any signs of shoulder girdle dysfunction after one year from device implantation. Our findings in a small single site population should be considered as preliminary results. Further investigation documenting shoulder function in post- vs. pre-procedural periods is needed. Nevertheless, is important to increase awareness that physiotherapy should be considered as an essential part of post-procedural patients' assessment after any CIED implantation.

## Article information

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**Table 1.** Comparison of muscle strength between right and left arm in S-ICD patients vs. control group (Part A) and comparison of muscle strength in S-ICD subgroups according to reported discomfort related with a device (Part B)

| **Part A. Comparison of muscle strength between right and left arm in S-ICD patients and in a control group** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Muscle strength** (Newton) | **S-ICD group n = 15** | | **Control group n = 15** | | ***P*-value[a]** | | | |
| | Right arm | Left arm | Right arm | Left arm | A | B | C | D |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Flexion | 117 (101–144) | 114 (80–123) | 117 (90–143) | 104 (79–128) | 0.10 | 0.13 | 0.71 | 0.74 |
| Abduction | 113 (88–139) | 100 (83–127) | 113 (83–140) | 105 (82–125) | 0.39 | 0.28 | 0.90 | 0.93 |
| External rotation | 109 (84–120) | 110 (86–126) | 103 (88–120) | 103 (88–120) | 0.43 | 0.40 | 0.84 | 0.78 |
| Internal rotation | 100 (86–123) | 100 (78–119) | 102 (81–112) | 102 (81–112) | 0.53 | 0.73 | 0.84 | 0.90 |

**Part B. Muscle strength in subgroups of S-ICD patients according to reported discomfort related with a device**

| | **No discomfort (n = 5)** | **Mild to Moderate Discomfort (n = 10)** | ***P*-value** |
|---|---|---|---|
| **Left arm** | | | |
| Flexion | 101 (132–184) | 100 (79–118) | 0.055 |
| Abduction | 127 (104–169) | 94 (71–111) | 0.055 |
| Extrernal rotation | 126 (80–130) | 101 (84–117) | 0.25 |
| Internal rotation | 100 (81–125) | 115 (87–130) | 0.77 |
| **Right arm** | | | |
| Flexion | 165 (100–170) | 115 (97–139) | 0.16 |
| Abduction | 148 (96–152) | 112 (79–130) | 0.16 |
| External rotation | 112 (89–122) | 107 (84–122) | 0.95 |
| Internal rotation | 100 (75–104) | 115 (87–130) | 0.16 |

Data presented as median (Q1–Q3)

[a]Part A. *P*-values provided for the following comparisons: A — S-ICD group: right vs left arm; B — control group: right vs. left arm; C — right arm: S-ICD vs. control group; D — left arm: S-ICD vs. control group