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

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INTRODUCTION

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

The subcutaneous cardioverter-defibrillator (S-ICD) emerged as a novel solution to overcome intracardiac lead-related infectious complications. The pulse generator of the S-ICD, twice as large and heavy as in conventional transvenous CIEDs, is implanted in the pocket on the lateral wall of the chest, and defibrillation lead is tunneled under the skin, in parallel with the sternum [2]. Whether shoulder girdle dysfunction related to a large-size device exists in S-ICD patients has never been investigated.

We aimed to evaluate subjective complaints of S-ICD patients related to shoulder girdles as well as to objectively assess shoulder joint movements.

METHODS

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

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

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

Part A. Comparison of muscle strength between the right and left arm in S-ICD patients and the 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 the subgroups of S-ICD patients according to reported device-related discomfort								
	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 medians (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

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

Statistical analysis

Data were presented as medians (Q1–Q3) for continuous values or as numbers (percentages) for categorized variables. All continuous data had non-normal distribution, which was tested with the Shapiro-Wilk test, and therefore non-parametric test for between-group comparison was used (Wilcoxon rank test). A *P* value of <0.05 was considered statistically significant. Data were analyzed using IBM SPSS Statistics (IBM Corp, Armonk NY, US).

RESULTS AND DISCUSSION

The 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 on the left side, and all studied patients reported a 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 decreased in activity as compared post to pre-implantation period. At the time of examination, no patient reported pain in the shoulder region. However, 10 subjects reported discomfort related to the location of the device in the chest (mild in 5 subjects and moderate in 5).

None of the studied patients reported pain during passive shoulder movement, while only one patient from the S-ICD group and one control subject reported 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 the left and right sides in the S-ICD and control groups. Furthermore, no differences in ROM and muscle strength between the same side arms were observed between S-ICD patients and the control group. Detailed results are summarized in Table 1 (Part A). Even though two S-ICD patients reported the 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 a trend toward lower muscle flexion and abduction strength in the left arm was observed in the S-ICD patients who felt mild to moderate discomfort ($P = 0.055$ for both measures) (Table 1, Part B).

Chronic shoulder dysfunction has been constantly reported in CIED patients independently of the implantation technique. 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 the case of subcutaneous placement (76% of patients at 2 weeks and 28% at

3 months after surgery) [5]. Significantly lower shoulder flexion and abduction ROM as well as loss of grip strength 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 exist; however, one could hypothesize that similar mechanisms as those observed in the case of traditional CIEDs can contribute to some degree of shoulder girdle impairment. A large S-ICD pulse generator and lead tunneled subcutaneously across the chest, even though they are located far from the shoulder, may indirectly impact shoulder mobility via pressure and interaction with the chest fascia. Patients in the postoperative period are in fact given similar recommendations on arm mobility to prevent early lead and pocket complications.

In everyday life, the sensation that the device limits some activities is reported, even though this perception is highly variable depending on the study population, ranging from no activity limiting sensation to significant impact of the device on everyday life [10, 11]. Thienel et al. documented that two-thirds of their patients reported daily routine restrictions, pain, and device-related discomfort [11]. A large device located on the lateral wall of the chest almost always changes sleeping behavior into one side night position due to device-related discomfort [12].

CONCLUSIONS

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

Article information

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