Shoulder Function After Cardioverter-Defibrillator Implantation: 5-Year Follow-up

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Background. **Implantable cardioverter-defibrillator (ICD) represents the main tool for prevention of sudden cardiac death. Different kinds of postimplant complications have been described; however, little is known about shoulder functional impairment and its impact on quality of life.**

Methods. **Patients with standard indications for elective prepectoral subcutaneous ICD insertion were enrolled during a 1-year period. The impact of ICD implantation on shoulder motility, pain, general disability, and quality of life was evaluated prospectively at baseline, and after 2 weeks, 3 months, 1 year, and 5 years using the Constant score, the Numeric Pain Rating Scale, the Disabilities of the Arm, Shoulder, and Hand scale, and the Short Form-36 Health Survey questionnaire.**

Results. **A total of 50 patients underwent insertion of single, dual chamber, or biventricular ICDs. Two weeks after implantation, functional impairment and mild pain were observed in ipsilateral shoulder movements, with a reduction in the Short Form-36 Health Survey score. Shoulder functional impairment improved at the third-month evaluations, with almost normalization at 1-year and 5-year assessments, as well as pain and quality of life.**

Conclusions. **Prepectoral subcutaneous ICD implantation may be associated with ipsilateral shoulder functional impairment that regresses partially after 3 months and completely at 1-year and 5-year assessments. The less invasive implantation technique and the relatively small size of modern ICDs, independently from types and volumes, may be relevant to the degree of post-implantation shoulder functional impairment and recovery time. Shoulder function should be assessed at routine checks, especially soon after ICD implantation because of potential functional impairment and subsequent impact on quality of life.**

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The implantable cardioverter-defibrillator (ICD) represents the main tool for primary and secondary prevention of sudden cardiac death due to ventricular arrhythmias in selected patients affected by cardiac dysfunction.[1,2] The ICD insertion can be performed by four approaches on the basis of leads and device placement. (1) Epicardial leads are placed surgically around the heart, and the ICD is positioned in the abdominal wall or subclavian region; this is a fully surgical open approach, usually used when other approaches are not possible.[3,4] (2) For the transvenous subcutaneous prepectoral approach, pacing-sensing and shock leads are inserted transvenously through cephalic or subclavian vein; the ICD is placed in the subclavian region, subcutaneously, above the pectoral muscle.[5] (3) For the transvenous subcutaneous subpectoral approach, pacing-sensing and shock leads are inserted transvenously through cephalic or subclavian vein; the ICD is placed in the subclavian region under the pectoral muscle.[6] (4) For the totally subcutaneous approach, the sensing-shock lead is placed along the sternum margin; the ICD is placed in the lateral chest wall, generally intermuscular.[7] Currently, the transvenous subcutaneous prepectoral approach represents the most frequent technique of ICD insertion.[5,6]

Because ICD strategy aims for a substantial gain in life expectancy, in clinical practice patient candidates for

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ICDs are also selected on the basis of presence or absence of comorbidities and midterm to long-term probability of nonarrhythmic death. Numerous reports have described different types of early or late complications in ICD carriers: lead dislodgment or fracture, inappropriate shocks, pocket hematoma, and pocket or lead infections.[8-11] Another possible but underestimated complication for ICD recipients may be temporary or permanent disability due to the ICD system either in terms of functional limitation of both arm and shoulder of the same side of implantation and in terms of changes in quality of life.[12-14]

The aim of this prospective study was to evaluate the impact of ICD insertion with transvenous lead placement and subcutaneous device pocket in terms of shoulder motility and pain, and overall disability affecting quality of life 2 weeks after implantation and after 3 months, 1 year, and 5 years.

Patients and Methods

Eligibility Criteria and Device Implantation

We considered all consecutive patients who underwent transvenous ICD insertion (single, dual chamber, or biventricular). To properly assess the impact of ICD placement on shoulder function, patients affected by neuromuscular diseases or with fractures or shoulder joint surgery before implantation would have been excluded from the study. The ICD insertion was performed by four qualified electrophysiologists at our hospital (with similar surgical ability), according to the current guidelines.[15,16] The device type was chosen on the basis of patients' clinical needs.

In all patients, ICDs were implanted in the left subclavian region, where a prepectoral subcutaneous pocket was created. The leads were inserted through the left cephalic vein whenever possible; the subclavian vein was used when cephalic vein was not available or when a more complex device (dual chamber or biventricular) had to be implanted. The leads were always secured to the muscular fascia by means of dedicated sleeves, and all devices were tied underneath pectoral muscle by means of a non-reabsorbable suture.

Twelve-hour bed rest was recommended for all patients after ICD implantation. Paracetamol (for mild pain) or tramadol (for severe pain) were prescribed as analgesic treatment; nonsteroidal antiinflammatory drugs were not used owing to possible interference with anticoagulants and antiplatelet drugs, which are frequently prescribed for ICD carriers. Patients were warned against extreme abduction or extrarotation of the ipsilateral shoulder to prevent catheter dislodgments, but no slings were recommended; tiny movements of the left arm were encouraged soon after implantation to avoid painful muscular contractures of the shoulder. Moreover, patients were not forbidden to drive but were strongly advised against any major car maintenance (eg, wheel replacement, and so forth). Likewise, all heavy work was discouraged for at least 15 days after implantation.

Clinical Evaluations and Impairment Evaluations of Shoulder

All patients underwent baseline evaluation of clinical status and of New York Heart Association functional class. Moreover, each patient underwent clinical and echocardiographic assessment at each follow-up to tailor pharmacologic therapy. Checks of the ICD were regularly performed to ascertain correct function of the device and to determine arrhythmic burden.

For the main purpose of this study, all patients underwent a comprehensive evaluation of the following issues by means of appropriate scoring systems to obtain quantitative data, comparable at each evaluation, at each scheduled follow-up, namely, at baseline, and at 2 weeks, 3 months, 1 year, and 5 years after ICD insertion.

PAIN. Pain was measured by means of the Numeric Rating Scale (NRS), which is a 10-point scale used to quantify the patient's pain at the time of evaluation (1 for the least pain ever experienced, 10 for the worst pain).[17,18]

QUALITY OF LIFE. Quality of life was evaluated by means of the Short Form-36 Health Survey (SF-36), which is a complete questionnaire that segments quality of life in eight domains—physical and social function, emotional and physical role, bodily pain, general health, vitality, and mental health—and within each subsection, the score can range between 0 and 100 (the higher the result, the better the quality of life for the investigated item).[19-22]

DISABILITIES OF THE ARM, SHOULDER, AND HAND. The Disabilities of the Arm, Shoulder and Hand (DASH) score was obtained by use of a questionnaire designed to measure specific variables—such as physical, social, and psychological function—in patients with musculoskeletal disorders of the upper limb at each evaluation. The DASH score can range between 0 (best performance with absence of disability) and 100 (worst performance with complete disability).[23,24]

CONSTANT SCORE. To provide a more complete assessment of the disability induced by ICD insertion, each patient was also evaluated by means of the Constant score.[25,26] It supplies objective information about overall dysfunction, power and range of shoulder and arm motion (forward and lateral elevation, internal and external rotation); moreover, it provides subjective information about shoulder pain.

Statistical Analysis

The Shapiro-Wilk test was used to discriminate normal distribution of continuous variables; parametric/nonparametric statistic was adopted accordingly. Continuous variables with normal distribution are expressed as mean and standard deviation, and variables without normal distribution are reported as median and interquartile range. Categoric variables are expressed in terms of fraction and percentages. Comparisons between baseline and postprocedure follow-ups were performed using one-way analysis of variance (ANOVA) for repeated measurements for normally distributed variables, and the Friedman test followed by the Wilcoxon test when appropriate (the second for ordinal variables

and for variables not normally distributed). Any P values less than .05 were considered significant. Patients who died during follow-up were excluded from 1-year and 5-year analyses; that was also taken into account for ANOVA and the Friedman test.

Ethical Considerations

The Local Ethics Committee approved this observational study, and all patients gave informed consent to participate. The investigation complies with the principles outlined in the 1975 Declaration of Helsinki.

Results

Fifty consecutive patients were referred to our hospital for elective ICD insertion from June 2010 to June 2011, and all patients were eligible for the present study. At the time of implantation, none of them was already hospitalized for any other reason; the ICD insertion was performed during a specific hospitalization. After informed consent given before implantation, they were enrolled in the present study (approved by the Local Ethics Committee).[13]

Forty-nine patients received an ICD for primary prevention of sudden cardiac death or treatment of congestive heart failure in addition to pharmacologic therapy; only 1 patient received an ICD for secondary prevention. All patients who underwent device implantation were right handed. The main clinical characteristics of patients at baseline are summarized in Table 1.

For all patients, it was the first transvenous subcutaneous prepectoral left side implantation. According to clinical needs, 21 patients were implanted with a single-chamber ICD, 5 with a dual-chamber ICD, and 24 with a biventricular ICD for cardiac resynchronization therapy. The mean volume of implanted devices was 37.9 ± 1.6 mL. In particular, for single-chamber ICDs, the mean volume was 35.7 ± 1.3 mL; for dual chamber, 37.6 ± 1.2 mL; and for biventricular, 39.5 ± 1.8 mL. After implantation, the administration of analgesic drugs was necessary only in 12 cases: paracetamol 1000 mg intravenously was sufficient to control mild postoperative pain, and no patient needed any type of analgesic drugs 24 hours after the procedure. All patients were discharged 1 ± 1 day after device implantation. Patients employed before implantation (20% of patients) were able to restart their work 2 weeks after the procedure. Of note, none of them performed heavy work.

All patients underwent all scheduled follow-up evaluations within 1 year; 11 patients died during follow-up, and they were excluded from 1-year and 5-year analyses (this was taken into account in ANOVA and Friedman test). Death causes were severe congestive heart failure in 6 patients, stroke in 3, ST-segment elevation myocardial infarction in 1 patient, and pneumonia in 1 patient. No patient had local ICD pocket infection or pocket skin erosion during follow-up.

Prospective functional assessments were evaluated by means of NRS, DASH, and Constant score. Two weeks after ICD insertion, shoulder-related pain measured by NRS (Figure 1) significantly increased compared with before implantation (Freidman test $P < .001$; Wilcoxon test $P < .001$). A trend toward progressive reduction of shoulder-related pain started after 2-week evaluation; indeed, no significant differences in pain were seen after 3 months. The evaluations at 1 year and 5 years confirmed the absence of significant differences in terms of pain in comparison with baseline. The upper extremity related disability evaluated by DASH score increased significantly at 2-week evaluation with respect to baseline, and a slow but progressive regression of the impairment was noted at 3 months. At 1-year and 5-year evaluations, the upper extremity related disability completely regressed to values similar to baseline, without any significant differences (Figure 2). Notably, differences in terms of sex, age, and body mass index were not associated with differences in functional impairment. Moreover, differences of device volume were also not associated with differences in functional impairment.

The mental components of SF-36 did not show significant changes in short-term, midterm, and long-term follow-up (Table 2). The evaluations of overall shoulder dysfunction, power and range of motion, and pain during movement, measured by means of the Constant score, paralleled the results obtained with the two previous scores. Predictably, no significant differences in right shoulder Constant score were observed at any follow-up. As far as left shoulders were concerned, a significant decrease of Constant score was observed after 2 weeks

Table 1. Baseline Clinical Characteristics of Enrolled Population

Characteristics	Values
Population	
Age, y	62 ± 12
Male	38 (76)
Weight, kg	75 ± 14
Height, m	1.7 ± 0.9
Body mass index, kg/m^2	25.6 ± 3.6
Body surface area, m^2	1.88 ± 0.23
LVEF, %	31 ± 12
Primary prevention	49 (98)
Heart disease	
Dilated cardiomyopathy	25 (50)
Ischemic cardiomyopathy	20 (40)
Hypertrophic cardiomyopathy	3 (6)
Other	2 (4)
NYHA functional class	
I–II	26 (52)
III–IV	24 (48)
ICD type	
Single chamber	21 (42)
Dual chamber	5 (10)
Biventricular	24 (48)

Values are mean ± SD or n (%).

ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.

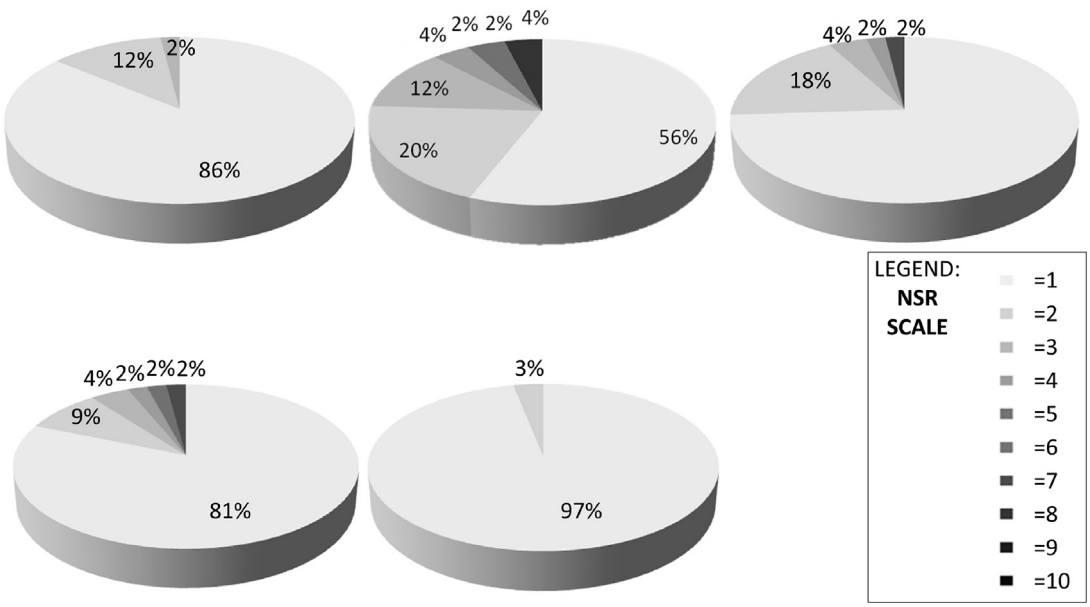

Figure 1. Longitudinal shoulder-related pain variation measured by means of the Numeric Rating Scale (NRS) before and after implantable cardioverter-defibrillator insertion. The scores from 1 to 10 are indicated by shades of gray from lightest (1) to darkest (10).

with respect to baseline; a trend to normalization was observed at 3-month evaluation, with no significant difference with respect to baseline. A complete normalization of left shoulder dysfunction measured by Constant score was observed both at 1-year and 5-year evaluations in comparison with baseline (Figure 3).

Comment

The efficacy of ICDs in preventing sudden cardiac death led to their worldwide spread despite the risk, albeit small, of complications.[9] Numerous reports focused on device-related complications (such as lead dislodgment or fracture, ICD malfunction, inappropriate shocks, and pocket or lead infections)[27,28] but to date, little is known about ipsilateral shoulder functional impairment due to ICD placement and its consequences on quality of life.

Implantable cardioverter-defibrillators usually provide a considerable extension of life expectancy because of reduction of sudden cardiac death due to suppression of ventricular arrhythmias: consequently, in clinical practice, ICD candidates are selected not only according to the

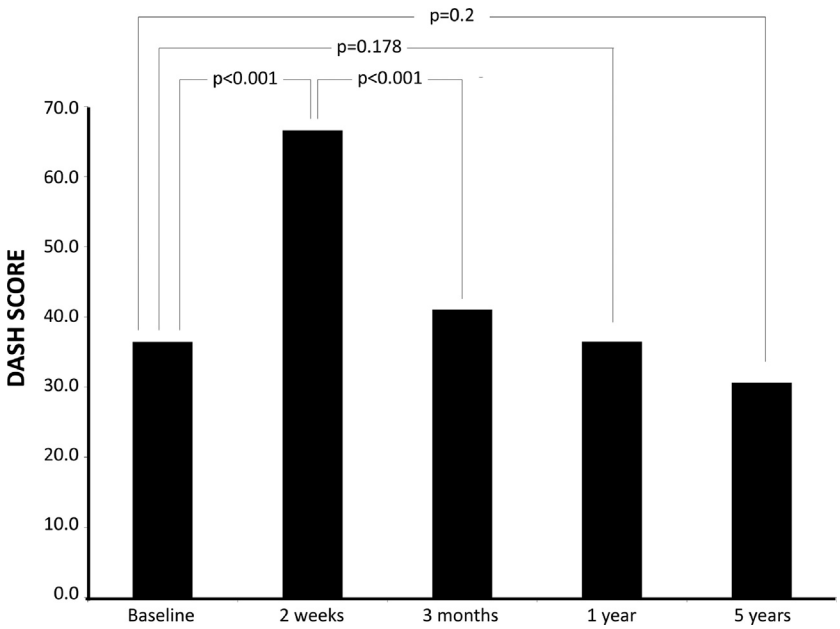

Figure 2. Longitudinal upper extremity related disability variation measured by means of the Disabilities of Arm, Shoulder, and Hand (DASH) score before and after implantable cardioverter-defibrillator insertion.

Table 2. Values Obtained for Short Form-36 Domains Among Enrolled Patients at Baseline, 2 Weeks, 3 Months, 1 Year, and 5 Years

Domain	Baseline	2 Weeks	3 Months	1 Year	5 Years	Wilks' Lambda	*P* Value[a]	*P* Value[b]	*P* Value[c]	*P* Value[d]
PF	71 ± 21	67 ± 22	76 ± 23	70 ± 22	71 ± 17	<0.001	NS	.009	NS	NS
PR	51 ± 43	44 ± 40	67 ± 36	53 ± 36	56 ± 39	<0.001	NS	.001	NS	NS
BP	81 ± 27	72 ± 24	81 ± 25	80 ± 25	82 ± 26	0.017	.011	.001	NS	NS
GH	59 ± 17	59 ± 22	59 ± 23	59 ± 25	58 ± 25	NS	NS	NS	NS	NS
VT	64 ± 19	69 ± 19	68 ± 21	68 ± 18	69 ± 19	NS	NS	NS	NS	NS
SF	72 ± 27	74 ± 27	81 ± 24	77 ± 24	76 ± 21	0.007	NS	NS	.001	NS
ER	65 ± 43	65 ± 44	67 ± 44	64 ± 32	65 ± 21	NS	NS	NS	NS	NS
MH	68 ± 19	71 ± 18	71 ± 22	69 ± 19	70 ± 19	NS	NS	NS	NS	NS
PCS	44 ± 9	42 ± 10	47 ± 9	43 ± 10	46 ± 12	<0.001	.010	<.001	NS	NS
MCS	47 ± 11	49 ± 11	48 ± 12	49 ± 11	48 ± 12	NS	NS	NS	NS	NS

[a]Results of paired sample Student's *t* test: between [a]baseline and 2-week follow-up; [b]between 2 weeks and 3 months; [c]between baseline and 1 year; [d]between baseline and 5 years.

Values are mean ± SD.

BP, bodily pain; ER, emotional role; GH, general health; MCS, mental component summary; MH, mental health; NS, nonsignificant; PCS, physical component summary; PF, physical function; PR, physical role; SF, social functioning; VT, vitality.

main cardiac disease but also on the basis of comorbidities and midterm to long-term probability of nonarrhythmic death. Potentially, that leads to select ICD candidates among patients with a low level of whole physical impairment. Therefore, the issue of shoulder functional impairment of ICD recipients might be potentially relevant,[29] and few studies have focused on this topic.

Our study has investigated, prospectively and in the long term, a large series of variables involving both shoulder function and quality of life in a multidimensional way. A study by Korte and colleagues[14] evaluated shoulder functional limitations and pain issues in 50 patients who underwent subpectoral ICD insertion with 1-year follow-up. Three months after subpectoral device implantation, 40% of patients had a reduction in ipsilateral shoulder abduction movements, 60% in forward flexion, and 16% in external rotation; moreover, 38% reported shoulder-related pain 3 months after implantation. After 1 year, only 8% of patients still had reduced active abduction, forward flexion, and external rotation, and 6% had shoulder-related pain. Now, the subpectoral approach represents an almost outdated mode of implantation, owing to reduction of ICD volumes and to improvement in surgical techniques that have led to the more common and less invasive subcutaneous prepectoral approach. More recently, another study evaluated the potential impact on shoulder function of subcutaneous prepectoral ICD insertion, investigating its short-term to midterm effects.[13]

In accordance with previous studies, we found that the main impairment of shoulder function was observed within the first 2 weeks after surgery, independently from the number of implanted leads, with a progressive recovery in the following period. Three months after ICD insertion, there was still an impairment of shoulder function, albeit modest; however, after 1 year, the level of shoulder functional impairment was comparable to baseline. Finally, after 5 years, no further significant differences in shoulder function were observed in our population, in comparison with neither baseline nor 1-year assessment. Even with the limitation of the different assessments of shoulder functional impairment, our study population showed less impairment, especially 3 months after implantation, than in the study by Korte and colleagues[14] (Table 3). This result could depend on the different surgical technique. Unlike patients described in the Korte study (who underwent subpectoral implantation), in our population, the prepectoral subcutaneous technique (regardless of device type and volume) avoided the surgical damage of pectoral muscles with a lower impact on shoulder function in the short term, and with a shorter duration of postprocedure pain. Notably, in our patients, a mild level of shoulder functional impairment and pain were already detected before ICD insertion (preimplantation data are not available in the Korte study). Moreover, the lower level of shoulder function impairment in case of subpectoral implantation technique compared with subcutaneous after 1 year (Table 3) may be due to the comparison with a population (from

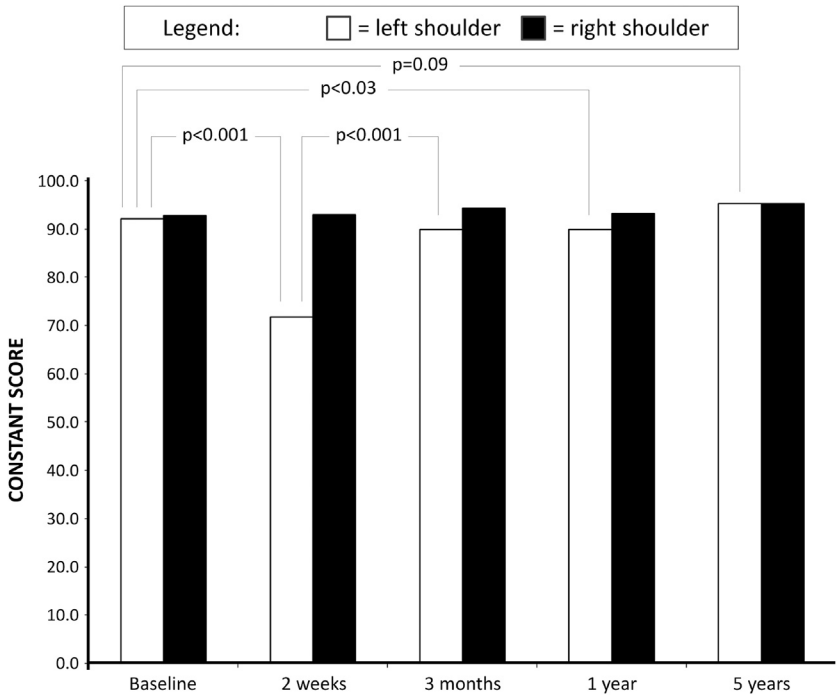

Figure 3. Longitudinal Constant score variations between left shoulder (white bars) and right shoulder (black bars) before and after implantable cardioverter-defibrillator insertion.

the Korte study), where no baseline data are available. Finally, late favorable results on shoulder function could also depend on both the small size of modern ICDs and the progressive familiarity of ICD recipients with their device over time, as well as on the sparing of pectoral muscles. Our surgical technique consists of shaping large device pockets, and the way in which ICDs are placed inside them allows any type of movement without mechanical hindrance, even in the short to mid term after implantation, regardless of device type and number of leads.

Study Limitations

The size of this study population is limited, and that could hamper the identification of statistically different levels of disability over time; however, it is one of the largest studies in the field of shoulder function after ICD insertion with a long-term follow-up (5 years). Another limitation is the lack of a specific assessment of patient frailty before ICD insertion.

Conclusion

Insertion of ICD is frequently associated with ipsilateral shoulder impairment, which tends to recover after 3 months in nearly all patients and becomes complete after 1 year. It is possible that the less invasive surgical technique used in the subcutaneous prepectoral approach, coupled with a reduction of ICD sizes, play a relevant role for a rapid, complete, and stable recovery. In case of transvenous subcutaneous prepectoral left side ICD placement, functional impairment of the ipsilateral shoulder is independent of age, sex, and body mass index

Table 3. Comparison Between Subpectoral and Prepectoral Implantable Cardioverter-Defibrillator Implantation Regarding Pain and Different Domains of Shoulder Function at 3-Month and 1-Year Follow-up

Impairment	Baseline Subpectoral[a]	Baseline Prepectoral[b]	3 Months Subpectoral[a]	3 Months Prepectoral[b]	1 Year Subpectoral[a]	1 Year Prepectoral[b]
Abduction	NA	7 (14)	20 (40)	13 (26)	4 (8)	11 (23)
Forward flexion	NA	4 (8)	30 (60)	11 (22)	4 (8)	6 (12)
External rotation	NA	1 (2)	8 (16)	6 (12)	4 (8)	3 (6)
Pain	NA	8 (16)	19 (38)	13 (26)	5 (6)	9 (19)

[a]Data derived from Korte et al[14]; [b]Data derived from present study.

Values are n (%).

NA, not available.

in right-handed patients. Furthermore, the different features of implanted devices, such as volumes and types (single, dual chamber, or biventricular ICDs), were not associated with different results.

After ICD insertion, the assessment of shoulder function should not be neglected during routine clinical examinations, particularly in the short term, because of the impact that impairment may have on physical well-being and quality of life.

References

1. Boriani G, Cimaglia P, Biffi M, et al. Cost-effectiveness of implantable cardioverter-defibrillator in today's world. *Indian Heart J*. 2014;66(suppl 1):101-104.
2. Fumagalli S, Gasparini M, Landolina M, et al. Determinants of all-cause mortality in different age groups in patients with severe systolic left ventricular dysfunction receiving an implantable cardioverter-defibrillator (from the Italian Clinical Service Multicenter Observational Project). *Am J Cardiol*. 2014;113:1691-1696.
3. Mellert F, Schneider C, Esmailzadeh B, et al. Implantation of left ventricular epicardial leads in cardiosurgical patients with impaired cardiac function—a worthwhile procedure in concomitant surgical interventions? *Thorac Cardiovasc Surg*. 2012;60:64-69.
4. Suzuki S, Motohashi S, Matsumoto M. Surgical techniques for implanting implantable cardioverter defibrillators in children and infants. *Surg Today*. 2014;44:1801-1806.
5. Block M, Hammel D, Borggrefe M, Scheld HH, Breithardt G. [Transvenous subcutaneous implantation technique of the cardioverter/defibrillator]. *Herz*. 1994;19:259-277.
6. Manolis AS, Chiladakis J, Vassilikos V, Maounis T, Cokkinos DV. Pectoral cardioverter defibrillators: comparison of prepectoral and submuscular implantation techniques. *Pacing Clin Electrophysiol*. 1999;22:469-478.
7. Ziacchi M, Corzani A, Diemberger I, et al. Electrocardiographic eligibility for subcutaneous implantable cardioverter defibrillator: evaluation during bicycle exercise. *Heart Lung Circ*. 2016;25:476-483.
8. Diemberger I, Biffi M, Martignani C, Boriani G. From lead management to implanted patient management: Indications to lead extraction in pacemaker and cardioverter-defibrillator systems. *Expert Rev Med Devices*. 2011;8:235-255.
9. Diemberger I, Mazzotti A, Giulia MB, et al. From lead management to implanted patient management: systematic review and meta-analysis of the last 15 years of experience in lead extraction. *Expert Rev Med Devices*. 2013;10:551-573.
10. Kratz JM, Toole JM. Pacemaker and internal cardioverter defibrillator lead extraction: a safe and effective surgical approach. *Ann Thorac Surg*. 2010;90:1411-1417.
11. Rusanov A, Spotnitz HM. A 15-year experience with permanent pacemaker and defibrillator lead and patch extractions. *Ann Thorac Surg*. 2010;89:44-50.
12. Burke MC, Drinan K, Kopp DE, et al. Frozen shoulder syndrome associated with subpectoral defibrillator implantation. *J Int Card Electrophysiol*. 1999;3:253-256.
13. Diemberger I, Pegreffi F, Mazzotti A, et al. Implantation of cardioverter-defibrillator: effects on shoulder function. *Int J Cardiol*. 2013;168:294-299.
14. Korte T, Jung W, Schlippert U, et al. Prospective evaluation of shoulder-related problems in patients with pectoral cardioverter-defibrillator implantation. *Am Heart J*. 1998;135:577-583.
15. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure: the task force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC) developed with the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur Heart J*. 2016;37:2129-2200.
16. Priori SG, Blomstrom-Lundqvist C, Mazzanti A, et al. 2015 ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: the task force for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death of the European Society of Cardiology (ESC). *Eur Heart J*. 2015;36:2793-2867.
17. Bolton JE, Wilkinson RC. Responsiveness of pain scales: a comparison of three pain intensity measures in chiropractic patients. *J Manipulative Physiol Therapeut*. 1998;21:1-7.
18. Breivik H, Borchgrevink PC, Allen SM, et al. Assessment of pain. *Br J Anaesth*. 2008;101:17-24.
19. Coons SJ, Rao S, Keininger DL, Hays RD. A comparative review of generic quality-of-life instruments. *Pharmacoeconomics*. 2000;17:13-35.
20. Schron EB, Exner DV, Yao Q, et al. Quality of life in the antiarrhythmics versus implantable defibrillators trial: impact of therapy and influence of adverse symptoms and defibrillator shocks. *Circulation*. 2002;105:589-594.
21. Ware JE, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) project. *J Clin Epidemiol*. 1998;51:903-912.
22. Ware JE, Gandek B, Kosinski M, et al. The equivalence of SF-36 summary health scores estimated using standard and country-specific algorithms in 10 countries: results from the IQOLA project. International quality of life assessment. *J Clin Epidemiol*. 1998;51:1167-1170.
23. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH (Disabilities of the Arm, Shoulder and Hand) [corrected]. The Upper Extremity Collaborative Group (UECG). *Am J Indust Med*. 1996;29:602-608.
24. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the shoulder. *Arthroscopy*. 2003;19:1109-1120.
25. Constant CR, Gerber C, Emery RJ, Sojbjerg JO, Gohlke F, Boileau P. A review of the Constant score: modifications and guidelines for its use. *J Shoulder Elbow Surg*. 2008;17:355-361.
26. Constant CR, Murley AH. A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res*. 1987;214:160-164.
27. Providencia R, Kramer DB, Pimenta D, et al. Transvenous implantable cardioverter-defibrillator (ICD) lead performance: a meta-analysis of observational studies. *J Am Heart Assoc*. 2015;4:e002418.
28. Tarakji KG, Ellis CR, Defaye P, Kennergren C. Cardiac implantable electronic device infection in patients at risk. *Arrhyth Electrophysiol Rev*. 2016;5:65-71.
29. Boriani G, Artale P, Biffi M, et al. Outcome of cardioverter-defibrillator implant in patients with arrhythmogenic right ventricular cardiomyopathy. *Heart Vessels*. 2007;22:184-192.