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Original Article

Quality of life in patients with idiopathic ventricular arrhythmias treated at the Instituto Nacional Cardiovascular – INCOR

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ABSTRACT

Objective. To describe the quality of life in patients with idiopathic ventricular arrhythmias treated at the Instituto Nacional Cardiovascular -INCOR in Lima-Peru. **Materials and methods.** Analytical and cross-sectional study of patients with idiopathic ventricular arrhythmias treated by 3D ablation or antiarrhythmic therapy between July 2017 and December 2019 to whom the 36-item Short Form quality-of-life questionnaire version 2 (SF-36v2) was applied to assess health-related quality of life. **Results.** Fifty-two patients with idiopathic ventricular arrhythmias were included (34 underwent 3D ablation, and 18 received only antiarrhythmic therapy). The percentage of recurrence (14.7% vs. 50.0%, p=0.010) and adverse events (0% vs. 22.2%, p=0.011) were fewer in the 3D ablation group than the antiarrhythmic group. The mean standardized scores obtained from the Spanish version of the SF-36v2 were 85.1% vs 68.4% (p<0.001); respectively. Statistically significant differences in six of the eight components that assess health-related quality of life were found: physical function (96.0 vs. 76.0, p<0.001), physical role (93.4 vs. 61.1, p<0.001), general health (74.5 vs. 47.4, p<0.001), vitality (69.9 vs 54.7, p=0.008), emotional role (92.2 vs. 77.8, p=0.006) and mental health (73.8 vs. 60.0, p<0.001). **Conclusions.** Patients with idiopathic ventricular arrhythmias who underwent 3D ablation have a greater health-related quality of life standardized score.

Keywords: Arrhythmias, Cardiac; Quality of Life; Anti-Arrhythmia Agents; Catheter Ablation (source: MeSH-NLM).

Introduction

Idiopathic ventricular arrhythmias include extrasystoles, or ventricular tachycardias, that appear in patients without structural heart disease or absence of ventricular arrhythmic substrate measured by conventional methods [1,2]. These can be asymptomatic or have several symptoms that impact on quality of life [2], occasionally leading to extrasystolic cardiomyopathy [3] and, very rarely, associated with malignant ventricular arrhythmias or sudden cardiac death [4].

The management of ventricular arrhythmias is varied. In some cases, only clinical follow-up is required, while others, the management with antiarrhythmic drugs is necessary [2]. Several

reviews describe the presence of adverse events and low efficacy of antiarrhythmic drugs for the control of ventricular arrhythmias [5].

In recent decades, it has been made progress in the management of ventricular arrhythmias due to the development of new technologies such as catheter ablation using radiofrequency energy and three-dimensional (3D) navigator [6], which have become an effective and safe therapeutic alternative for the management of these arrhythmias [7].

Patients with symptomatic idiopathic ventricular arrhythmias, refractory or intolerant to antiarrhythmic drugs are candidates for ablation with 3D navigator [8]. This invasive strategy has shown to be more effective than antiarrhythmic drugs and has become an alternative that solves this problem definitively, reduces emergency or outpatient visits due to recurrences and leads to an improvement in patients' quality of life, as demonstrated by Huang et al. in a 3- and 12-month follow-up after 3D ablation of 58 patients who suffer from idiopathic ventricular extrasystoles [9].

Quality of life is a very complex concept, understood as a multidimensional construct according to intra-personal and socio-normative criteria of an individual's personal and environmental system, both in terms of needs and satisfaction levels, which includes different scales whose quantification requires tools that consider multiple dimensions or components [10].

The arrhythmia unit of the Instituto Nacional Cardiovascular - INCOR in the city of Lima-Peru, has been developing 3D navigator ablation for the management of different types of arrhythmias and has already registered 123 patients in the period 2017-2019. During this period, 36 cases of idiopathic ventricular arrhythmias ablation were registered (29% of the total). During clinical follow-up, they presented a recurrence rate of 23.8% in the focal idiopathic ventricular arrhythmias group and 7.1% in idiopathic ventricular arrhythmias of the conduction system group [11]; however, the effect of such procedure on patients' quality of life is not known. Therefore, the aim of this study is to describe the quality of life in patients with idiopathic ventricular arrhythmias treated at our center.

Materials and Methods

Design and study population

An analytical, cross-sectional study was performed that included all patients with symptomatic idiopathic ventricular arrhythmias treated at INCOR between July 2017 and December 2019 who met the inclusion and exclusion criteria to enter into the study. Two analysis groups were made up (Group 1: patients treated by 3D navigator ablation. Group 2: patients treated only with antiarrhythmic drugs).

Inclusion criteria

Patients aged 14 years or older and 65 years or younger with idiopathic ventricular arrhythmias of very frequent ventricular extrasystoles type, with an arrhythmic load greater than 5% or recurrent ventricular tachycardia greater than three episodes whose diagnosis and treatment type are defined at INCOR.

Exclusion criteria

Patients who do not agree to answer the 36-item Short Form quality-of-life questionnaire version 2 (SF-36v2) in Spanish [12] or have a medical history with incomplete relevant data to the study.

Procedures

Medical records were reviewed to collect data of interest, which were recorded on a collection form previously prepared by the author. Clinical and epidemiological characteristics, the procedure performed, recurrences, complications associated with 3D ablation and adverse events associated with antiarrhythmic drugs were recorded on the collection form.

Group 1 consisted of patients who underwent catheter ablation using radiofrequency energy and a and a Carto 3 three-dimensional mapping system (Biosense Webster, Johnson & Johnson).

Group 2 consisted of patients who started treatment with antiarrhythmic drugs available at our institution and included in the EsSalud pharmacological formulary. The drugs were class Ic antiarrhythmics (propafenone hydrochloride); beta-blockers (bisoprolol fumarate, propranolol hydrochloride, atenolol and carvedilol); class III antiarrhythmics (amiodarone) and class IV antiarrhythmics (verapamil hydrochloride and diltiazen hydrochloride).

In a second stage, the Spanish version of the SF-36v2™ Health Survey © 1993, 2003 [12] was applied by means of a telephone interview and verbal acceptance by the patient to participate in the present study between September and December 2022. The questionnaire is made of 36 multiple choice questions, its application provided us an initial score that needed to be recalibrated. In addition, the absent responses were recoded with a justified substitution of measures (as indicated in the questionnaire application manual), which allowed us to calculate the raw score for each health-related quality of life's component. Subsequently, we transformed the raw scores into a standardized scale between 0 and 100, where 100 corresponds to the highest quality of life and 0 to the absence of quality of life. This instrument was applied to all participants included in the study. It is worth mentioning that this instrument was validated in our country [13], so it was not necessary to carry out a pilot test.

Definition of study variables

Quality of life is a multidimensional concept, it includes several aspects of an individual's personal and environmental system, both in terms of needs and satisfaction levels [10]; for the present study, different components were included (physical function, physical role, bodily pain, general health, vitality, social function, emotional role and mental health), which will be measured through the application of the Spanish version of the SF-36v2™ Health Survey © 1993, 2003 [12].

Acute complications were defined as those occurring periprocedurally or within 24 h after procedure [14] such as pericardial effusion without tamponade; cardiac tamponade; atrioventricular block requiring pacemaker implantation; vascular complications requiring surgical intervention, among others. Adverse events or intolerance associated with antiarrhythmic drugs were considered when they were directly related to the antiarrhythmic drug used by the patient and over time [15]. The record of complications associated with 3D ablation, such as intolerance or adverse events associated with antiarrhythmic drugs, was obtained from the medical record.

Recurrence was defined as the reappearance of at least 50% of the arrhythmic load of the clinical ventricular extrasystole or 1 episode of ventricular tachycardia, which had to be reported in the medical record by means of an electrocardiographic record or Holter study.

Ethical aspects

The present study was approved by the Ethics Committee of the Instituto Nacional Cardiovascular – INCOR prior to its execution. No patient-identifying variables were collected to identify the patients.

Data analysis

Quantitative variables were classified as parametric or nonparametric, according to the distribution type, which was calculated using the Shapiro-Wilk test. Parametric variables were reported with mean and standard deviation, while nonparametric variables were reported with median and interquartile ranges. For bivariate analysis, the Student's t-test or Mann-Whitney U test were used, according to the distribution type. Qualitative variables were described by means of percentages and frequencies; for bivariate analysis, the chi-square test (X^2) or Fisher's exact test were used, according to the number of events. Quality of life was quantified by means of the total standardized score and the eight components considered by the Spanish version of the SF-36v2™ Health Survey © 1993, 2003 [12]. A value of $p < 0.05$ was considered statistically significant in all analyses. For the statistical analysis, the statistical program Stata 17.0 (StataCorp, College Station, TX, USA) was used.

Results

52 patients who met the inclusion and exclusion criteria were included in the study. The group that received 3D ablation as treatment consisted of 34 patients (65.3%) (Figure 1) and the group that received only antiarrhythmic drugs as treatment consisted of 18 patients (34.7%) (Figure 2).

The median age was 49 years; 33 were male (44.2%). According to the type of arrhythmia treated, 36 patients (69.2%) had a diagnosis of focal idiopathic ventricular extrasystole/ventricular tachycardia (VE/VT) and 16 (30.8%) had a diagnosis of conduction system or fascicular VE/VT.

Bivariate analysis according to the type of therapy received found differences in age, a median of 32 years in the 3D ablation group and 59.5 years in the antiarrhythmic group (p=0.001) were found, no complications or adverse events were reported in the 3D ablation group; however, they were reported in four patients in the antiarrhythmic group (p=0.011) (Table 1).

In the group of patients with antiarrhythmic therapy, beta-blockers were the most commonly used drugs (47.8%) followed by propafenone (30.4%), amiodarone (13%) and verapamil (8.8%). Bradycardia episodes were recorded in 2 patients, hypothyroidism in 1 patient and bronchospasm in 1 patient.

The recurrence of ventricular arrhythmias showed a statistically significant difference, being lower in the 3D ablation group than the antiarrhythmic group (14.7% vs. 50%, p=0.010) (Table 1).

The mean standardized scores obtained from the Spanish version of the SF-36v2™ Health Survey © 1993, 2003 [12] applied to the 3D ablation and antiarrhythmic groups were 85.1 vs. 68.4 (p<0.001); respectively. Bivariate analysis of the mean standardized scores obtained for each health-related quality of life's component according to the SF-36v2 questionnaire showed statistically significant differences in 6 of the 8 components, such as physical function (96.0 vs. 76.0, p<0.001), physical role (93.4 vs. 61.1, p<0.001), general health (74.5 vs. 47.4, p<0.001), vitality (69.9 vs. 54.7, p=0.008), emotional role (92.2 vs. 77.8, p=0.006) and mental health (73.8 vs. 60.0, p<0.001) when comparing the 3D ablation group to the antiarrhythmic group (Table 2).

The bivariate analysis of the mean standardized scores obtained for each health-related quality of life's component according to the SF-36v2 questionnaire by sex, showed significant differences in 3 of the 8 components, such as physical function (95.0 vs. 84.8, p=0.005), bodily pain (95.7 vs. 82.9, p=0.007), vitality (72.4 vs. 58.4, p=0.009), when comparing male to female (Table 3).

Discussion

The present study found a greater total quality of life standardized score in the group of patients with idiopathic ventricular

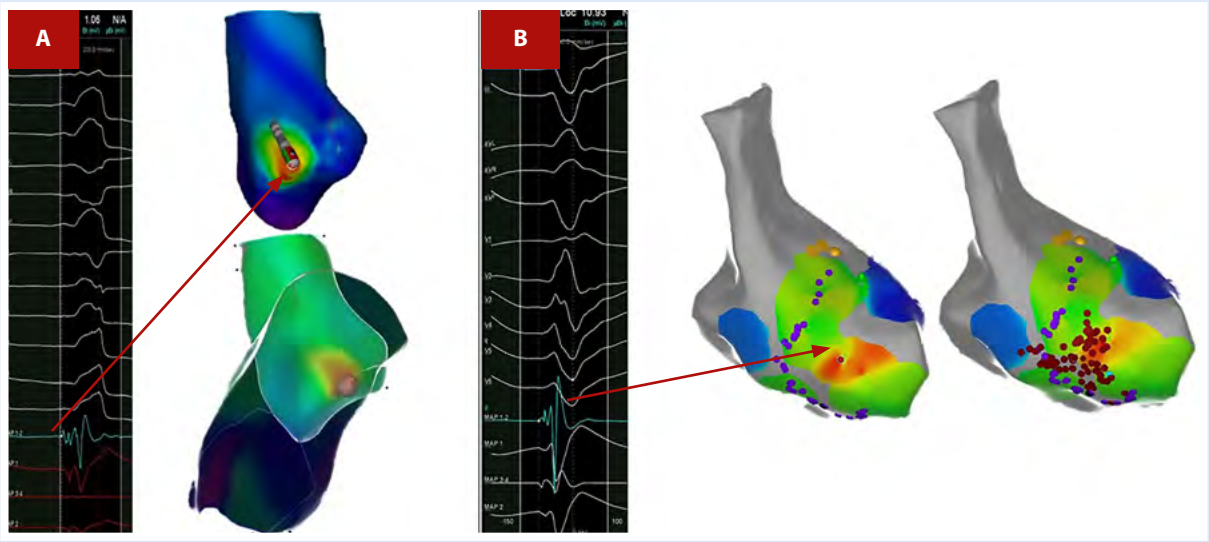

Figure 1. Example of idiopathic ventricular arrhythmia ablation.
A) 3D reconstruction and activation map of the LVOT, allowing identification of the greatest precocity zone of a focal idiopathic ventricular extrasystole meeting the criteria of the ablation target zone (bipolar EGM with a pre-QRS interval of - 30 ms and unipolar QS) located in the right cusp (red arrow). B) 3D reconstruction of the left ventricle identifying the critical zone of the macroreentry circuit of a left posterior fascicular ventricular tachycardia (red arrow) applying radiofrequency in this zone in the form of lines.

LVOT = left ventricular outflow tract, EGM = electrogram.

arrhythmias who underwent 3D ablation compared to patients on pharmacological treatment. Additionally, the rates of recurrences and complications/adverse events were fewer in the group of patients who underwent 3D ablation.

Table 1. Clinical and epidemiological characteristics of the patients included.

	Group 1 (3D ablation)	Group 2 (antiarrhythmic drugs)	P value*
Median age (IQR)	32 (21-54)	59.5 (54-61)	0.001
Male n (%)	17 (50)	6 (33.0)	0.380
Department origin n(%)	16 (47.1)	7 (38.9)	0.770
Clinical presentation n(%)			<0.001
Asymptomatic	28 (80)	0	
Palpitations	5 (14.3)	17 (68)	
Dyspnea	0	6 (24)	
Chest pain	1 (2.9)	2 (8)	
Syncope	1 (2.9)	0	
Arrhythmia type n(%)			0.031
Focal idiopathic VE/VT	20 (58.8)	16 (88.9)	
Conduction system or fascicular VE/VT	14 (41.2)	2 (11.1)	
Adverse events/ Complications n(%)	0	4 (22.2)	0.011
Recurrence n(%)	5 (14.7)	9 (50)	0.010
Median number of outpatient visits (IQR)	3 (2-3)	14.5 (12-20)	<0.001
Median number of emergency visits (minimum - maximum)	0 (0-2)	0 (0-3)	0.230

IQR: interquartile range, VE/VT: ventricular extrasystole/ventricular tachycardia.
* P-value was calculated using the Fisher's exact test or Mann-Whitney U test, according to the variable type.

Table 2. Transformed total score and quality of life components based on the SF-36v2 questionnaire of patients who underwent 3D ablation and antiarrhythmic therapy.

	3D ablation group (mean ± SD)	Antiarrhythmic group (mean ± SD)	P value*
Physical function	96.0 ± 6	76.07 ± 13.6	<0.001
Physical role	93.4 ± 20.7	61.1 ± 36.6	<0.001
Bodily pain	91.1 ± 14.7	83.6 ± 22.2	0.360
General health	74.5 ± 18.4	47.4 ± 17.3	<0.001
Vitality	69.9 ± 16.9	54.7 ± 20.9	0.008
Social function	90.1 ± 15.6	86.1 ± 18.6	0.370
Emotional role	92.2 ± 26	77.8 ± 28	0.006
Mental health	73.8 ± 14.7	60 ± 12.7	0.001
Total score	85.1 ± 13.5	68.4 ± 15.9	<0.001

SD: standard deviation.
* Calculated using the Mann-Whitney U test.

3D ablation of idiopathic ventricular arrhythmias is an effective and safe method compared to antiarrhythmic therapy [5]. Current scientific evidence recommends 3D navigator ablation of idiopathic ventricular arrhythmias in symptomatic patients, refractory or intolerant to antiarrhythmic therapy [8]. In addition, it is also considered as first line therapy in patients with focal idiopathic ventricular arrhythmias of the right ventricular outflow tract or idiopathic left ventricular fascicular tachycardia This recommendation is based on the efficacy and safety of this intervention [16], as was observed in the present study, where no acute complications were recorded.

3D ablation is long-term efficient due to the high percentage of recurrence-free survival, which allows patients to minimize outpatient or emergency visits because of ventricular arrhythmias' recurrence [17].

Huang *et al.* [9] evaluated the quality of life in 58 patients with idiopathic ventricular arrhythmias who underwent 3D ablation, who were administered the questionnaire one month before the procedure, 3 months and 12 months after 3D ablation. The results showed a significant increase in the standardized values at pre- and post-procedure for all the components that make up the health-related quality of life assessment.

3D ablation is a therapeutic method with a low recurrence rate and high efficacy [17]. These results are reflected in a significant improvement and even the elimination of the symptomatology, especially in the group of patients who underwent 3D ablation, which would allow improving the perception of their health-related quality of life, especially in physical and mental health dimensions.

85.3% of the patients who underwent 3D ablation and did not present recurrences were discharged and stopped taking antiarrhythmic medication, which would contribute to an improvement in the health-related quality of life's perception.

Half of the patients in the antiarrhythmic group presented recurrences and 22.2% presented adverse events associated with the antiarrhythmic drugs; additionally, 100% of the patients continued outpatient follow-up. All these findings contribute to a deterioration in the health-related quality of life's perception.

Table 3. Transformed score of the 8 components of quality of life based on the SF-36v2 questionnaire of patients by sex.

	Male (mean +/- SD)	Female (media +/- SD)	P value*
Physical function	95 ± 7.4	84.8 ± 14.9	0.005
Physical role	88 ± 27.0	77.58 ± 33.6	0.15
Bodily pain	95.7 ± 11.2	82.9 ± 20.0	0.007
General health	70.8 ± 20.4	60.6 ± 22.7	0.11
Vitality	72.4 ± 15.8	58.4 ± 20.4	0.009
Social function	93.5 ± 13.5	84.9 ± 18.1	0.05
Emotional role	91.3 ± 25.1	83.9 ± 29.0	0.23
Mental health	72.7 ± 14.6	66.1 ± 15.6	0.15

SD: standard deviation.
* Calculated using the Mann-Whitney U test.

Several clinical studies show differences in sex related quality of life [18]. The present study found statistically significant differences in the components of physical function, bodily pain and vitality, with higher scores found in men compared to women. These health-related quality of life components are part of physical health; however, health-related quality of life components such as mental and social health did not show differences.

As limitations, some considerations need to be taken into account when interpreting the results of the present study. This work was carried out by reviewing medical records, so that data collection could be associated with bias due to underreporting or data omission. The application of the Spanish version of the SF-36v2™ Health Survey © 1993, 2003 [12] was carried out by telephone, which leads to selection and information biases.

These results were obtained in a specialized national reference health center; therefore, they may not be extrapolated if they are performed in other lower resolution centers. However, this is the first report in our country describing the quality of life in patients with idiopathic ventricular arrhythmias at the Instituto Nacional Cardiovascular - INCOR.

In conclusion, the present study found that patients with idiopathic ventricular arrhythmias who underwent 3D ablation present a greater health-related quality of life standardized score compared to antiarrhythmic therapy.

Author contributions

RSB participated in the conception of the article, data collection, writing and approval of the final version. OAT performed the data analysis. MCS, CGC, PZC and RZC participated in the conception of the article and approval of the final version.

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