

Health-related quality of life and arrhythmic risk in patients with Brugada syndrome

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ABSTRACT

Background. Brugada syndrome (BrS) is associated with an elevated risk of sudden cardiac death (SCD). This study investigated health-related quality of life (HRQoL) among patients with BrS and examined whether clinical features and indicators of arrhythmic risk are related to patient-reported well-being.

Methods. The study included 70 patients who were divided into three groups: spontaneous or sodium channel blocker test (SCBT) induced type 1 BrS electrocardiogram pattern (T1BrP), patients with negative SCBT, and control group. All patients completed the Short Form Health Survey version 2 (SF-36v2) questionnaire and underwent detailed SCD risk stratification.

Results. The HRQoL of patients with T1BrP (median Modified Shanghai score was 4 [3.5–4.5], median Sieira score = 1 [0–2] points) did not differ compared with those with negative SCBT. In patients with T1BrP the

Sieira score correlated with a poorer self-assessment of health ($p = 0.014$, $R = 0.50$), increased limitations in lifting or carrying groceries ($p = 0.004$, $R = -0.57$) and a stronger disagreement with the statement that they are as healthy as anybody they know ($p = 0.019$, $R = 0.48$). Moreover, Sieira score correlated negatively with Physical Functioning scale score ($p = 0.025$, $R = -0.47$). Among patients with T1BrP, those who experienced syncope, showed lower scores on the General Health scale compared to the remainder (51 [27–57] vs. 67 [57–82] points, $p = 0.032$).

Conclusions. The diagnosis of BrS, especially among patients at low risk of SCD, does not significantly affect HRQoL. However, patients with T1BrP and higher clinical risk tend to feel less healthy and more limited in their daily lives.

1. Introduction

Brugada syndrome (BrS) predisposes to arrhythmogenesis and is associated with distinctive electrocardiographic (ECG) abnormalities. Its characteristic ECG presentation includes a coved ST-segment elevation and subsequent T-wave inversion in the right precordial leads, particularly V1 and V2. Patients with BrS are susceptible to ventricular tachyarrhythmias, which may manifest clinically as syncope or sudden cardiac death (SCD) [1,2]. The genetic background of BrS is complex and involves considerable heterogeneity [3]. Among the genetic variants associated with BrS, alterations in *SCN5A*, encoding the α -subunit of the cardiac voltage-gated sodium channel, are identified most frequently. Such variants are found in approximately 14–34% of diagnosed patients [4–7]. Currently, over 40 different genes have been identified as involved in BrS pathogenesis [6]. Population-based ECG studies suggest that BrS may affect about 0.5 individuals per 1,000 people, although its frequency varies across geographical regions [8]. Ventricular arrhythmias in BrS commonly are observed at rest, during sleep and may be precipitated by fever which should be treated by early administration of antipyretics. Moreover, BrS patients should avoid drugs known to induce or aggravate type 1 Brugada ECG pattern (T1BrP) or arrhythmias in BrS (a list of these drugs is available at www.brugadadrugs.org) [9,10]. In addition, excessive alcohol consumption is contraindicated in BrS. An effective therapy to prevent SCD among selected BrS patients is placement of implantable cardioverter-defibrillator (ICD) [9].

Cardiovascular disorders may substantially reduce patients' quality of life (QoL), and may

also affect their families. This impact has been documented among hypertrophic cardiomyopathy (HCM), familial dilated cardiomyopathy (FDC), long QT syndrome (LQTS) and catecholaminergic polymorphic ventricular tachycardia (CPVT) [11, 12]. Evidence on the impact of BrS diagnosis on health-related QoL (HRQoL) is limited. A diagnosis of BrS may have negative psychological effect among patients and their relatives, which persists for 2 years after diagnosis [13]. It was also shown that about one-sixth of BrS patients experienced symptoms of depression or anxiety after diagnosis of BrS [14]. Moreover, mental distress and Type D (distressed, 32.7% of BrS patients) personality were observed more frequently among patients with BrS, than in the general population [15].

Detailed clinical assessment, including evaluation of HRQoL in various diseases is important because it provides a greater view of the impact of specific factors on a patient's health and functioning [16,17]. These assessments help understand how patients perceive their health, how they cope with their disease or disorder and how the disease affects their lives. The Short Form Health Survey (SF-36) questionnaire is one of the most popular tools used to assess HRQoL. The origins of its use were in the 1980s. Since then it has been translated into many languages and validated [18].

Despite increasing interest in the psychological and psychosocial aspects of BrS, there is a lack of studies assessing HRQoL using standardized instruments, such as the SF-36, in well-characterized patient groups with varying levels of arrhythmic risk. In particular, little is known about how specific clinical factors—including the presence of a type 1 BrS electrocar-

diagram pattern (T1BrP), history of syncope, family history or risk stratification scores—may influence different dimensions of HRQoL. Therefore the aim of this study was to assess the impact of a diagnosis of BrS on HRQoL and to identify factors that may affect HRQoL in BrS patients.

2. Material and methods

2.1. Patients

We studied adult patients diagnosed with BrS and those with a negative sodium channel blocker provocative test (SCBT). There were no restrictions as to the time since the diagnosis of BrS or to the performance of SCBT. Patients were assigned to three groups:

- T1BrP: patients with a positive SCBT or with spontaneous T1BrP,
- non-T1BrP: patients with a negative SCBT,
- control group: patients without a history of genetic heart diseases and other significant chronic diseases matched to the study group in terms of age and sex.

BrS was diagnosed according to the appropriate European Society of Cardiology (ESC) guidelines [9,19]. After the diagnosis, observed findings, the possible course of the disease, the risk of serious arrhythmias and possible further management were thoroughly discussed with the patients. Patients could additionally benefit from an interview with a psychologist. Patients diagnosed with BrS were referred to genetic testing to assess genetic background of BrS. Interestingly, in one of the surveyed families, both parents were diagnosed with BrS [20,21].

2.2. Risk stratification

Risk stratification was assessed on the basis of the Sieira score, which incorporates several clinical factors, including a history of aborted SCD, sinus node dysfunction, prior syncope, inducible electrophysiological study (EPS), early familial SCD and spontaneous T1BrP [22,23]. Based on the total score, patients were classified into three groups reflecting their likelihood of future arrhythmic events: low (score 0–1), intermediate (score 2–4), and high-risk (score ≥ 5) [24]. Most of the patients did not have EPS performed, so this parameter was not taken into account when calculating the Sieira score. Moreover, the recently

proposed Modified Shanghai Score, which provides updated and refined diagnostic criteria was calculated. This scoring system classifies individuals as probable/definite BrS (>3.5 points), possible BrS (2–3 points), or nondiagnostic (<2 points) [4]. ICDs were implanted in patients according to the ESC recommendations in force at the time of qualification for the procedure. Patients diagnosed with BrS remain in the care of the outpatient cardiology clinic.

2.3. HRQoL status evaluation

HRQoL status was evaluated using the SF-36 version 2 (SF-36v2) questionnaire, standard version. The SF-36v2 measures eight dimensions of health (Supplementary Methods) [25]:

- Physical Functioning (PF),
- Role-Physical (RP) – role limitations due to physical health,
- Bodily Pain (BP),
- General Health (GH),
- Vitality,
- Social Functioning (SF),
- Role-Emotional (RE) – role limitations due to emotional health,
- Mental Health (MH).

A total of 35 questions from the questionnaire are assigned to the above scales. The remaining one is about self-assessment of change and refers to the question of how health is now compared to how it was a year earlier (Self-Evaluated Transition [SET]; question 2).

The eight domains of the SF-36v2 can be summarized into two composite indices: the physical component score (PCS) and mental component score (MCS) (Supplementary Methods). Analysis of responses to individual SF-36v2 questions was also performed.

The collected data was analyzed in the Software QualityMetric PRO CoRE Smart Measurement System Version 2.4. The software, using the T-Score parameter, also called Norm-based scoring (NBS), allows the results obtained to be compared with data from the QualityMetric 2009 General Population Sample. The T-score is calculated based on the mean and standard deviation of scores in a reference population. The T-score scale has a mean of 50 and a standard deviation of 10.

T-score = 50 is a score equal to the average of the reference population.

T-score > 50 means a score better than the average of the reference population.

T-score < 50 means a score worse than the average of the reference population [25].

2.4. Statistical analysis

Variables following a normal distribution are presented as means $\pm$ standard deviations (SD), while data not meeting the criteria of normality are expressed as medians and interquartile ranges (IQR, 25th–75th percentile). The normality of continuous-variables distributions was assessed using the Shapiro–Wilk test. Categorical variables are summarized as numbers and percentages. Depending on data distribution, group comparisons were performed with an unpaired t-test or the Mann–Whitney U test, with Levene's test used to verify the homogeneity of variances for normally distributed variables. Between variables correlation was analyzed using Pearson's or Spearman's rank correlation, as appropriate for the data distribution. Tests were two-tailed, and a P value <0.05 indicated statistical significance. All statistical calculations were performed with Statistica TIBCO Software inc. (version 13).

Results

We analyzed 70 patients (53 male and 17 female patients) in mean age 40.7 ± 14.7 years. Among these patients, 23 had T1BrP, 27 did not reveal T1BrP during SCBT, while 20 patients consisted

the control group. The age of patients with T1BrP did not significantly differ from patients with negative SCBT and control group (42.1 ± 14.2 vs. 36.5 ± 14.1 vs. 44.8 ± 15.4 years; $p = 0.15$). The groups also did not differ in terms of sex and history of previous syncope (26.1% vs. 14.8% vs. 35%; $p = 0.27$ and 26.1% vs. 40.7% vs. 35.3%; $p = 0.55$) (see **Table 1**). Family history of BrS was noted in 19 patients (9 in T1BrP group and 10 in negative SCBT group).

Among patients with T1BrP median Modified Shanghai score was 4 (3.5–4.5), while median Sieira score was 1 (0–2) points. A correlation analysis was conducted between Sieira score values and SF-36v2 questionnaire scores. Due to the character of this model, it was analyzed only in the T1BrP group. In response to question 1, the number of points on the Sieira score correlated with patients' poorer assessment of their own health ($p = 0.014$, $R = 0.50$, see **Figure 1A**). The Sieira score was also correlated with the limitations associated with lifting or carrying groceries (question 3c, $p = 0.004$, $R = -0.57$, see **Figure 1B**). Patients with higher Sieira scores rated the sentence that they are as healthy as anybody they know as more false (question 11b, $p = 0.019$, $R = 0.48$, see **Figure 1C**). Among the health domain scales, the number of points on the Sieira score correlated negatively with PF scale ($p = 0.025$, $R = -0.47$, see **Figure 1D**). There were no significant correlations between the Modified Shanghai scoring system and the SF-36v2 questionnaire results.

Table 1. Patient characteristics

	All (n = 70)	T1BrP (n = 23)	Non-T1BrP (n = 27)	Control group (n = 20)	p-value
Age, year	40.7 ± 14.7	42.1 ± 14.2	36.5 ± 14.1	44.8 ± 15.4	0.15
Female sex, n (%)	17 (24.3)	6 (26.1)	4 (14.8)	7 (35)	0.27
Syncope, n (%)	23 (34.3)	6 (26.1)	11 (40.7)	6 (35.3)	0.55
Family history of BrS, n (%)	19 (27.1)	9 (39.1)	10 (38.5)	0 (0)	0.005
Early (<45 years) SCD or aborted SCD in FDR, n (%)		4 (18.2)	1 (4.5)	ND	0.15**
Modified Shanghai scoring system		4 (3.5–4.5)	1 (0–2.0)	ND	<0.001**
Sieira score*		1 (0–2)	0 (0–0)	ND	<0.001**
Implantable cardioverter-defibrillators, n (%)	9 (12.9)	9 (42.9)	0 (0)	0 (0)	<0.001
Spontaneous type I BrS ECG changes, n (%)		11 (47.8)	0 (0)	0 (0)	<0.001

Values are presented as means $\pm$ standard deviations, medians (interquartile ranges) or numbers (percentages). BrS – Brugada syndrome, ECG – electrocardiogram, FDR – first-degree relative, ND – no data, SCD – sudden cardiac death, T1BrP – type 1 Brugada syndrome electrocardiogram pattern, Non-T1BrP – patients with negative sodium channel blocker test.

* Most of the patients did not have EPS performed, so this parameter was not taken into account when calculating the Sieira score, ** only two groups were compared.

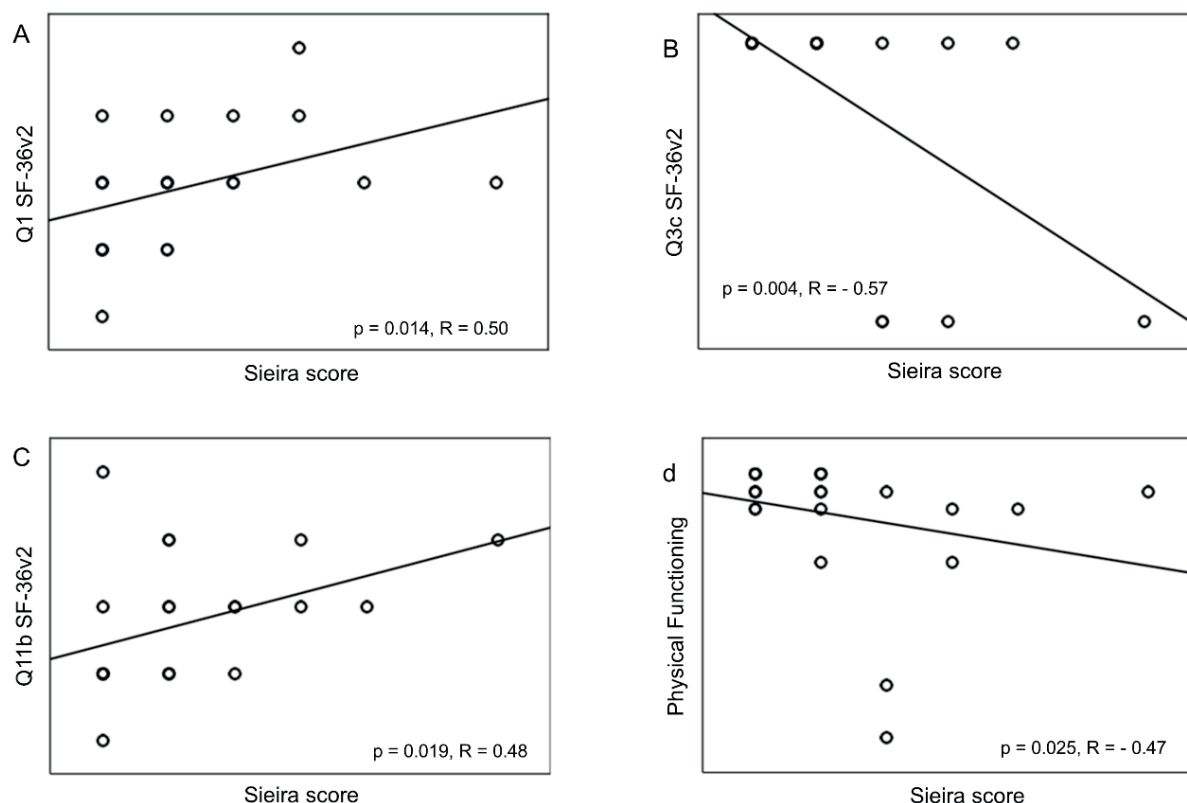


Figure 1. Spearman rank correlations between Sieira score and the Short Form Health Survey version 2 (SF-36v2) questionnaire in type 1 Brugada syndrome electrocardiogram pattern group. Q1: In general, would you say your health is: 1 – Excellent, 2 – Very good, 3 – Good, 4 – Fair, 5 – Poor. Q3c: Does your health now limit you in lifting or carrying groceries? If so, how much? 1 – Yes, limited a lot; 2 – Yes, limited a little; 3 – No, not limited at all. Q11b: 'I am as healthy as anybody I know' – How TRUE or FALSE is this statement for you? 1 – Definitely true; 2 – Mostly true; 3 – Don't know; 4 – Mostly false; 5 – Definitely false

Among BrS patients 11 had spontaneous T1BrP. They estimated in response to question 4a that they are more likely to reduce the time spend on work or other activities because of physical health problems than patients without spontaneous T1BrP (4.0 [3.0–5.0] vs. 5.0 [5.0–5.0] points, $p = 0.049$). Nine patients diagnosed with BrS had an ICD implanted (8 as a primary prevention and 1 as a secondary prevention following cardiac arrest). These patients reported greater limitations associated with the lifting or carrying groceries compared to BrS patients without ICD (question 3c, median 3.0 [2.0–3.0] vs. 3.0 [3.0–3.0] points, $p = 0.014$). There were no statistically significant differences regarding the other survey questions between above mentioned groups.

We compared SF-36v2 questionnaires scores in patients with T1BrP and in those with negative SCBT and observed no significant differences in any of the health domains measured or in

the answers to individual questions (see **Table 2** and **Table 3**). Comparison with the control group also showed no statistically significant differences in any of the health domains (see **Supplementary Table 1**). In the single-question analysis, there was a statistically significant difference in the answer to question 9b regarding feelings of nervousness in the past 4 weeks. Surprisingly, patients in the control group reported feeling nervous more frequently than those in the T1BrP group (3.0 [2.5–3.0] vs. 4.0 [3.0–4.0] points, $p = 0.005$), see **Supplementary Table 2**.

Syncopal occurred in 23 patients. In 6 patients with T1BrP and 11 with negative SCBT (see **Table 1**). Among patients with a history of syncope, BrS patients, compared with patients with negative SCBT, found the claim that they were as healthy as others they knew to be less true (question 11b, median 3.5 [3.0–4.0] vs. 2.0 [2.0–3.0] points, $p = 0.049$, see **Figure 2A**). Among patients with T1BrP, those who experienced syncope,

Table 2. Health dimensions measured by the Short Form Health Survey version 2 (SF-36v2) questionnaire

	T1BrP (n = 23)	Non-T1BrP (n = 27)	p-value
Physical Functioning	95 (90–100)	100 (85–100)	0.29
Physical Functioning NBS	55.6 (53.7–57.5)	57.5 (51.8–57.5)	
Role-Physical	87.5 (63–100)	100 (69–100)	0.58
Role-Physical NBS	52.7 (43.7–57.2)	57.2 (45.9–57.2)	
Bodily Pain	84 (41–100)	84 (62–100)	0.70
Bodily Pain NBS	55.6 (38.2–62)	55.6 (46.7–62)	
General Health	57 (50–77)	67 (52–77)	0.41
General Health NBS	46.1 (42.7–55.6)	50.8 (43.7–55.6)	
Vitality	62.5 (44–75)	68.8 (56–75)	0.40
Vitality NBS	52.6 (43.7–58.5)	55.6 (49.6–58.5)	
Social Functioning	87.5 (75–100)	87.5 (75–100)	0.90
Social Functioning NBS	52.3 (47.3–57.3)	52.3 (47.3–57.3)	
Role-Emotional	100 (75–100)	100 (83–100)	0.31
Role-Emotional NBS	56.2 (45.7–56.2)	56.2 (49.2–56.2)	
Mental Health	70 (55–85)	75 (60–85)	0.40
Mental Health NBS	48.3 (40.4–56.1)	50.9 (43–56.1)	
Physical Component Summary	53.9 (45.4–58.8)	55.7 (47.4–58.7)	0.62
Mental Component Summary	51.1 (40.6–55.5)	51.8 (41.2–56.6)	0.48

Values are presented as medians (interquartile ranges). NBS – norm-based scoring (T-score), T1BrP – type 1 Brugada syndrome electrocardiogram pattern, Non-T1BrP – patients with negative sodium channel blocker test.

Table 3. Responses to all questions in Short Form Health Survey version 2 (SF-36v2) questionnaire among patients with type 1 Brugada syndrome electrocardiogram pattern and in patients with negative sodium channel blocker test

Question number	Question content	T1BrP (n = 23)	Non-T1BrP (n = 27)	p-value
1	In general, would you say your health is: 1 – Excellent, 2 – Very good, 3 – Good, 4 – Fair, 5 – Poor	3 (2–3)	3 (2–3)	0.50
2	Compared to one year ago, how would you rate your health in general now: 1- Much better, 2- Somewhat better now than a year ago, 3- About the same as one year ago, 4- Somewhat worse now than one year ago, 5- Much worse now than one year ago	3 (3–4)	3 (3–4)	0.74
	The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? 1 – Yes, limited a lot; 2 – Yes, limited a little; 3 – No, not limited at all.			
3a	Vigorous activities, such as running, lifting heavy objects, participating in strenuous activities.	2 (1–3)	3 (2–3)	0.07
3b	Moderate activities, such as moving a table, pushing a vacuum cleaner, swimming, light work in the garden	3 (3–3)	3 (3–3)	0.43
3c	Lifting or carrying groceries	3 (3–3)	3 (3–3)	0.93
3d	Climbing several flights of stairs	3 (2–3)	3 (2–3)	0.93
3e	Climbing one flight of stairs	3 (3–3)	3 (3–3)	0.88
3f	Bending, kneeling, or stooping	3 (3–3)	3 (3–3)	0.73
3g	Walking more than a kilometer	3 (3–3)	3 (3–3)	0.73
3h	Walking several hundred meters	3 (3–3)	3 (3–3)	0.24
3i	Walking one hundred meters	3 (3–3)	3 (3–3)	0.48
3j	Bathing or dressing yourself	3 (3–3)	3 (3–3)	0.48
	During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health? 1 – All of the time; 2 – Most of the time; 3 – Some of the time; 4 – A little of the time; 5 – None of the time			
4a	Cut down on the amount of time you spent on work or other activities	5 (3–5)	5 (4–5)	0.55
4b	Accomplished less than you would have liked	5 (3–5)	5 (3–5)	1.00
4c	Were limited in the kind of work or other activities	5 (4–5)	5 (3–5)	0.75

Table 3 – continued

Question number	Question content	T1BrP (n = 23)	Non-T1BrP (n = 27)	p-value
4d	Had difficulty performing the work or other activities (for example, it took extra effort)	4 (4–5)	5 (4–5)	0.56
	During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? 1 – All of the time; 2 – Most of the time; 3 – Some of the time; 4 – A little of the time; 5 – None of the time			
5a	Cut down the amount of time you spent on work or other activities	5 (4–5)	5 (5–5)	0.21
5b	Accomplished less than you would like	5 (4–5)	5 (4–5)	0.45
5c	Did your work or activities less carefully than usual	5 (4–5)	5 (4–5)	0.46
6	During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? 1 – Not at all; 2 – Slightly; 3 – Moderately; 4 – Quite a bit; 5 – Extremely	1 (1–2)	1 (1–2)	0.82
7	How much bodily pain have you had during the past 4 weeks? 1 – None; 2 – Very mild; 3 – Mild; 4 – Moderate; 5 – Severe; 6 – Very severe	2 (1–4)	2 (1–3)	0.52
8	During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? 1 – Not at all; 2 – A little bit; 3 – Moderately; 4 – Quite a bit; 5 – Extremely	1 (1–3)	1 (1–2)	0.96
	These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the Past 4 weeks.... 1 – All of the time; 2 – Most of the time; 3 – Some of the time; 4 – A little of the time; 5 – None of the time			
9a	Did you feel full of life?	2 (2–3)	2 (2–2)	0.15
9b	Have you been very nervous?	4 (3–4)	3 (3–4)	0.37
9c	Have you felt so down in the dumps that nothing could cheer you up?	4 (3–5)	4 (4–5)	0.21
9d	Have you felt calm and peaceful?	2 (2–3)	2 (2–3)	0.47
9e	Did you have a lot of energy?	3 (2–4)	2 (2–3)	0.12
9f	Have you felt downhearted and depressed?	4 (3–4)	4 (3–5)	0.55
9g	Did you feel worn out?	4 (3–4)	4 (3–4)	0.88
9h	Have you been happy?	2 (2–3)	2 (2–3)	0.32
9i	Did you feel tired?	3 (3–4)	3 (3–4)	0.76
10	During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? 1 – All of the time; 2 – Most of the time; 3 – Some of the time; 4 – A little of the time; 5 – None of the time	5 (4–5)	5 (4–5)	0.90
	How TRUE or FALSE is each of the following statements for you? 1 – Definitely true; 2 – Mostly true; 3 – Don't know; 4 – Mostly false; 5 – Definitely false			
11a	I seem to get sick a little easier than other people	4 (3–4)	4 (3–5)	0.25
11b	I am as healthy as anybody I know	3 (2–3)	2 (2–3)	0.34
11c	I expect my health to get worse	4 (3–5)	4 (3–5)	0.52
11d	My health is excellent	3 (2–5)	3 (2–4)	0.94

T1BrP – type 1 Brugada syndrome electrocardiogram pattern, Non-T1BrP – patients with negative sodium channel blocker test. In the current study patients completed Polish language version of SF-36v2 questionnaire

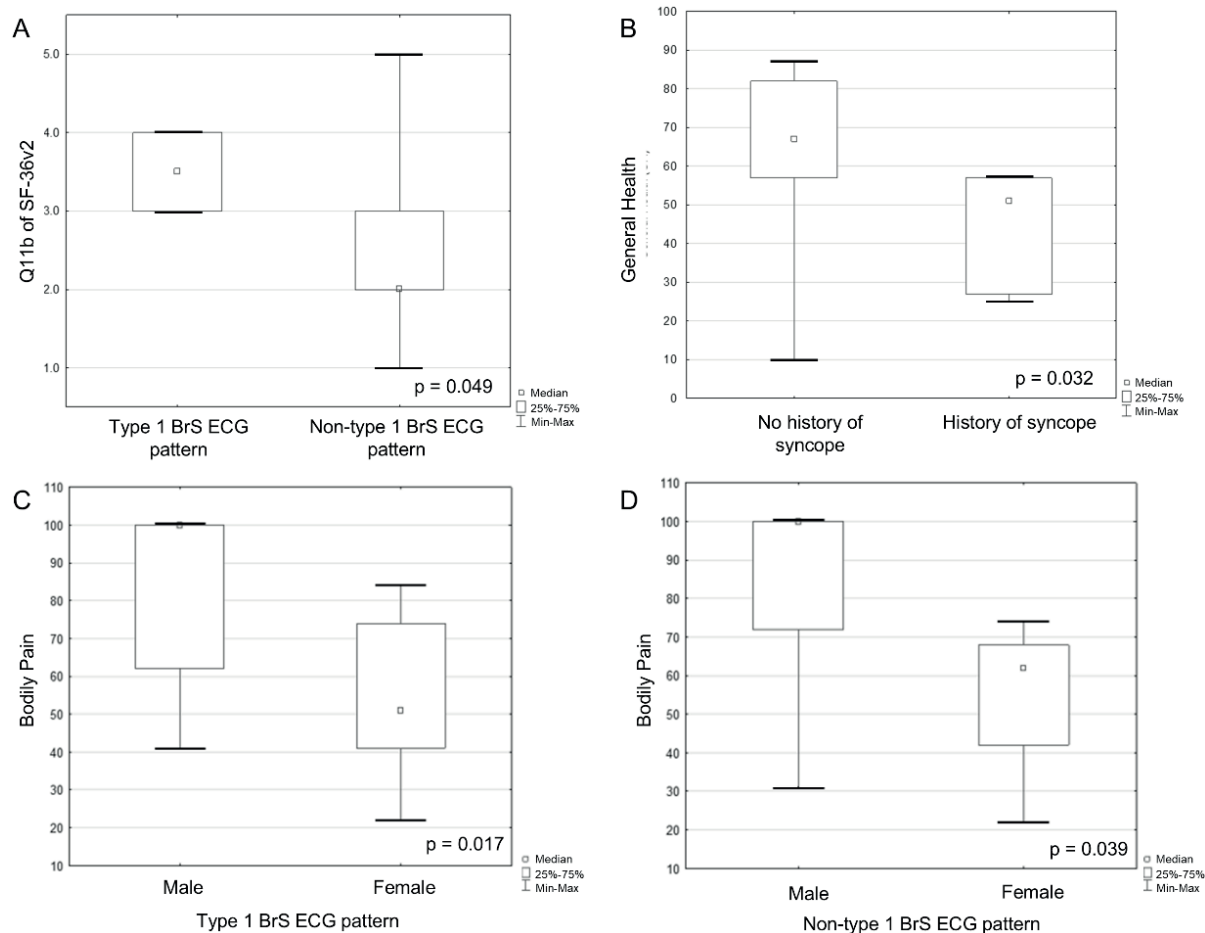


Figure 2. Differences in the Short Form Health Survey version 2 (SF-36v2) questionnaire results. Panel A – answer to the question of how true or false is the statement ‘I am as healthy as anybody I know’ among patients with syncope in type 1 Brugada Syndrome (BrS) electrocardiogram (ECG) pattern and with negative sodium channel blocker test (non-type 1 BrS ECG pattern) group (available responses: 1=Definitely true; 2=Mostly true; 3=Don’t know; 4=Mostly false; 5=Definitely false). Panel B – General Health scale score among type 1 BrS ECG pattern patients with and without history of syncope. Panel C – Bodily Pain scale score among type 1 BrS ECG pattern patients according to sex. Panel D – Bodily Pain scale score among non-type 1 BrS ECG pattern patients according to sex

compared to those who never had such a symptom, reported:

- greater limitations in lifting or carrying groceries (question 3c; 2.5 [2.0–3.0] vs. 3 [3.0–3.0] points, $p = 0.019$)
- more frequent lack of agreement with the statement that they were as healthy as other people they know (question 11b; 3.5 [3.0–4.0] vs. 2.0 [2.0–3.0] points, $p = 0.011$)
- a higher agreement with the statement that they expect their health to get worse (question 11c; 3.0 [1.0–3.0] vs. 5.0 [3.0–5.0] points, $p = 0.012$)
- lower scores on the GH scale (51 [27–57] vs. 67 [57–82] points, $p = 0.032$) (see **Figure 2B**).

Family history of BrS did not significantly affect SF-36v2 questionnaire results. On the other

hand, women had lower scores on BP scale than men within the patients with T1BrP (51 [41–74] vs. 100 [62–100] points, $p = 0.017$) and with negative SCBT (62 [42–68] vs. 100 [72–100] points, $p = 0.039$) (see **Figure 2C, 2D**). In patients who had negative SCBT result, there was also a difference in the RP scale (female 69 [56–75] vs. male 100 [69–100] points, $p = 0.043$). The control group showed no sex-related differences in any of the eight health domain scales.

The time from diagnosis or SCBT to questionnaire completion in the T1BrP group was variable (median 1193 [4–1648] days). In patients who had negative SCBT result, the majority completed the questionnaire shortly after the SCBT (median 1 [0–46] days). Among patients with T1BrP the time from diagnosis to questionnaire completion

correlated with limitations in vigorous activities (question 3a, $p = 0.037$, $R = -0.44$). It correlated also with limitations in the kind of work or other activities and with difficulties in performing them (question 4c: $p = 0.014$, $R = -0.50$ and question 4d: $p = 0.048$, $R = -0.42$). Moreover, the time elapsed between diagnosis and questionnaire completion correlated with assessing the claim 'I seem to get sick a little easier than other people' as more false (question 11a: $p = 0.019$, $R = 0.48$).

Discussion

In this study, we found that a diagnosis of BrS does not necessarily affect patients' assessment of their own health on the SF-36v2 questionnaire. The main potential reasons of this observation should be considered. First of all, the good general condition of the patients studied who had T1BrP. A thorough discussion with the patient about the course of the disease and possible treatments is also probably not without significance. All of this, in our opinion, might contribute to a softer perception of one's own disorder or potential predisposition to arrhythmogenesis. Patients' QoL assessment may be affected by the background of the BrS diagnosis. The suspicion of this disorder is frequently incidental during a routine ECG assessment performed for another reason, in people who consider themselves healthy and who have no symptoms. BrS may be suspected after BrS diagnosis in a family member or after SCD in a relative. The anxiety associated with the disease is more intense and lasts longer in people who have experienced the unexpected death of a relative [26,27].

Sieira score was presented in 2017 as a score model to predict risk of events in patients with BrS [23]. Its usefulness was evaluated in one of the largest databases of patients with BrS to assess the risk of SCD. The 10-year follow-up showed that SCD occurred more often in those with Sieira score of 5 (26.4%) than in those with scores of 0 (0.9%) or 1 (1.1%). Importantly, the Sieira score may not provide sufficiently accurate arrhythmic risk stratification for patients in the intermediate-risk category, in whom decisions regarding the most appropriate management strategy remain challenging [24]. Among studied by us patients with T1BrP median Sieira

score was 1 (0–2) points. As many as 82.6% of the patients had a score of 0–1 and can be classified as low-risk patients. Only one patient had a score ≥ 5 (4.3 %). We have shown that the Sieira score can be potentially also useful in aspects other than SCD risk assessment. In our study the Sieira score correlated with several HRQoL measures. Patients with T1BrP and higher scores rated their health as worse, reporting poorer self-rated health (question 1), greater limitations in activities requiring physical effort (question 3c), and being more likely to disagree with the statement 'I am as healthy as anybody I know' (question 11b). The number of points in the Sieira score also correlated negatively with PF scale, suggesting a possible association with greater limitations in physical activities. The analysis of the individual components of the Sieira score demonstrated a potential association between syncope and the responses to questions 3c and 11b. For question 1 and the PF scale, statistical significance was observed only when considering the total Sieira score. These findings should be interpreted in the context of the relatively favorable clinical risk status of the studied patients (only one patient had a history of ventricular fibrillation) and the exclusion of EPS results due to the insufficient number of available data. These findings imply that the Sieira score may be associated with psychological and behavioral aspects beyond its traditional prognostic use—possibly because a higher score reflects a more symptomatic or clinically complex phenotype, which in turn shapes patients' perceptions of vulnerability and physical capability. Notably, several comparisons yielded p -values between 0.01 and 0.05, suggesting that some clinically relevant differences may exist. However, these findings should be interpreted with caution given the limited sample size and multiple comparisons. There were no significant correlations between the scores on the Modified Shanghai Score and the SF-36v2 questionnaire results. In line with our findings, an analysis of 1,613 patients with BrS conducted by Probst et al. showed that the Shanghai Score provided no additional benefit in arrhythmic risk stratification [24].

The SF-36v2 questionnaire has been used to evaluate patients with genetic heart diseases. Ingles et al. in their publication evaluated the results of this questionnaire in patients with the inherited cardiomyopathies such as HCM, FDC,

arrhythmogenic right ventricular cardiomyopathy (ARVC) and primary arrhythmogenic disorders such as LQTS, CPVT and BrS [12]. However, due to the small number of patients with BrS (two patients), data of patients with this disease were not analyzed. Of the other diseases, significantly reduced PCS was shown in the HCM (44.91 ± 10.6), FDC (44.89 ± 8.2) and CPVT (44.2 ± 12.3) groups compared to the general Australian population. On the other hand, MCS was significantly lower only in patients with LQTS (43.1 ± 11.3). PCS scores above 50 in genetic heart disease studied by Ingles et al. were observed in patients with LQTS (50.8) and ARVC (52.1). In none of the diseases they studied was the MCS above 50. In our study, among patients with T1BrP, PCS and MCS were above 50 (53.9 and 51.1, respectively). Another research that used the SF-36 questionnaire to assess patients with BrS was conducted by Sutjaporn et al. [28]. In a single center study from Thailand, the authors evaluated 29 highly symptomatic patients with BrS. PCS for this group of patients was 49.8 ± 6.4 and MCS 52.9 ± 6.3 . However, based on all the questionnaires conducted and their analysis, the authors concluded that patients with BrS had a moderate QoL, and anxiety may play an important role in QoL of BrS patients. It should be noted that the group of patients studied by Sutjaporn et al. largely differed from the patients studied by us: asymptomatic patients 20.6% vs. 73.9%, history of SCA 62.1% vs. 4.3%, ICD implantation 86.2% vs. 39.1%, ICD shock since placement of ICD 48.3% vs. 0%. The above-mentioned publication does not provide information on the time interval between the diagnosis and questionnaire completion. In another study utilizing SF-36 questionnaire by Probst et al., BrS patients were divided into 3 groups: symptomatic patients with ICD (32.1%), asymptomatic patients with ICD (40.5%) and asymptomatic patients without ICD (27.4%) [29]. The time interval between the diagnosis and questionnaire completion was 5.7 ± 2.7 years. They did not identify any difference between the three groups in any of eight dimensions of health in SF-36 questionnaire, which is in line with our results. The authors did not provide an analysis of the questionnaire's individual questions. Comparison of BrS patients with and without ICDs, of all the questions in the questionnaire, we showed a potential difference only in question

3c – patients after ICD placement reported greater limitation associated with the lifting or carrying groceries. On the other hand, in Probst et al. publication, BrS patients compared to the general French population had higher PF and lower RP, GH, vitality, RE and MH [29]. There was no difference when comparing patients with an implanted ICD versus a control group in our study which could result from the absence of appropriate and inappropriate ICD shocks in our study group, which were found previously to affect psychological well-being and HRQoL [30]. In summary, it should be noted that the patient populations described in the cited studies were considerably more symptomatic. Furthermore, the studies by Sutjaporn et al. and Probst et al. do not provide clear information regarding which version of the SF-36 questionnaire was used (SF-36 version 1 or version 2). This distinction is relevant, as these two versions differ in terms of response formats and scoring algorithms.

HRQoL is important and should be assessed among patients. The frequent absence of symptoms among BrS patients may have a significant impact on HRQoL results. In our study, patients with a T1BrP who experienced syncope, therefore reflecting a more symptomatic phenotype and increased Sieira score, reported lower GH scores, which may influence the psychological impact of such events. It may be hypothesised that syncope may intensify fear of recurrence and illness-related anxiety, resulting even in low-risk patients, to perceive their overall health more negatively.

Previous studies have indicated various effects of a BrS diagnosis on patients' mental state. Six et al. found that individuals diagnosed with BrS experienced greater psychological distress than members of the general population [15]. Interestingly, BrS patients tested before diagnosis showed a significantly higher mental distress scores compared to patients tested after the diagnosis of BrS [15]. This may suggest that individuals awaiting diagnostic clarification experience greater emotional strain compared with patients whose BrS diagnosis has already been established. As in our study, they showed no significant difference between BrS patients and those with negative SCBT (regardless of the timing of the test). Similarly, Berne et al. showed a significant reduction in the mental QOL score but only in a group of patients evaluated 1

month after diagnosis [13]. Most of our patients with T1BrP filled out the SF-36v2 questionnaire long after diagnosis. It should be emphasized that the time elapsed between diagnosis and questionnaire completion correlated with treating the claim 'I seem to get sick a little easier than other people' as more false.

An interesting observation in our analysis is the more frequent feelings of nervousness among patients in the control group compared to patients in T1BrP group. In our opinion (confirmed by conversations with some patients), the answer to such a result may be that the diagnosis of a chronic disease, such as BrS, can change the approach to life, leading to a decrease in nervousness in response to stressful everyday situations, often of little importance in the perspective of the experience of the disease. This interpretation is consistent with studies on posttraumatic growth in cardiovascular disease and potentially could be explained, at least in part, by cognitive adaptation theory. A systematic review by Lee et al. [31] showed that many cardiac patients undergo positive psychological changes following diagnosis of a disease or after experience of cardiac event, including greater appreciation of life, reprioritization of values, and increased personal strength. Such positive psychological changes may lead patients to place everyday stressors into a broader perspective, making them appear less emotionally significant. Although patients with inherited arrhythmia syndromes were not included in the reviewed studies [31], similar mechanisms may also occur in BrS.

Another noteworthy finding is the difference in the BP domain between women and men among patients with T1BrP and those with negative SCBT ($p = 0.017$ and $p = 0.039$, respectively). This may reflect a higher level of pain affecting daily activities in women than in men. These findings are consistent with previous reports demonstrating sex-related differences in pain perception [32] and potentially also illness experience.

Limitations of the study

The results of our study should be considered in light of several limitations. The relatively small sample size could limit the statistical power to detect differences between subgroups and suggests some of marginal findings as hypothesis-generating rather than confirmatory. However,

we performed various statistical tests, as reliance on a single measures may provide an incomplete picture of the results [33]. The heterogeneity of the interval between BrS diagnosis or SCBT and completion of the SF-36v2 questionnaire (due to psychological adaptation to a diagnosis, which can evolve over time, patients assessed shortly after diagnosis may report different HRQoL than those assessed years later). EPS data were not available for all patients and therefore could not be incorporated into the Sieira score and consists rather a systematic limitation. In addition, the cross-sectional design precludes assessment of temporal changes in HRQoL and does not allow causal relationships between clinical characteristics and questionnaire outcomes, which remain to be established.

Conclusions

The diagnosis of BrS, especially among patients at low risk of SCD, does not significantly affect HRQoL. Less frequent feelings of nervousness among patients with T1BrP may result from a change in their approach to life after being diagnosed with a chronic disorder. However, patients with T1BrP and higher clinical risk tend to have lower HRQoL, feel less healthy and more limited in their daily lives.

Perspectives

Conducting a prospective study evaluating a larger group of patients with at least two assessments of HRQoL, before and during the follow-up after BrS recognition or occurrence of events, could better assess the impact of BrS diagnosis or BrS-related events on HRQoL.

Statements

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Author Contributions

Study conception and design: PTM, PB. Data collection and curation: PB, PTM, MSz, RK. Data analysis and

interpretation: PB, PSM, PP and PTM. The first draft of the manuscript was written by PB. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by local ethics committees (opinions numbers: 53/KBL/OIL/2016 and 1072.6120.125.2018). Informed consent was obtained from all individual participants included in the study.

Conflict of interest

PTM: received speech honoraria from Lilly, Polpharma and NDG Medical; and having participated in educational activities, which were supported by cardiac implantable electronic device manufacturers, as well as Polpharma. Other authors declare no competing interests.

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