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ORIGINAL PAPER

Health-related quality of life changes in patients undergoing repeated catheter ablation for atrial fibrillation

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Abstract
Objective Pulmonary vein isolation (PVI) for paroxysmal or non-paroxysmal atrial fibrillation (AF) should increase health-related quality of life (QOL).
Design Retrospective cohort study of consecutive patients scheduled for PVI.
Setting University Medical Center.
Main outcome measures QOL was assessed using the physical (PCS) and mental (MCS) component summary scores from the SF-12v2 in patients undergoing PVI (mean 50, range 0–100, with higher scores indicating greater QOL). SF-12v2 was obtained at initial presentation (3-months) before PVI and after PVI at the end of follow-up (mean 1.7 ± 1.4 years) which included: (1) Clinical status, ECG, and 24-h ECG every 3 months, (2) trans-telephonic ECGs for 4 weeks every 3 months, or (3) continuous ECG via implanted devices. A recurrence was any atrial arrhythmia >30 s.
Results Out of 229 patients (73 % males; 58 ± 11 years), 72 % returned SF-12v2 regarding 187 PVI procedures: 56 % for 1st PVI, 48 % for 2nd PVI, 71 % for 3rd PVI, and 44 % for 4th PVI. The mean difference between before and after PVI was 10 for PCS and 9 for MCS. History of paroxysmal or non-paroxysmal AF did not influence QOL ($p = 0.724$). Patients with an estimated PCS improvement ≥10 or an estimated MCS improvement ≥9 had the best outcome after repeated PVI. Success rates were 72 or 82 % after 1 year compared to 20 and 22 % in patients not achieving this improvement, respectively ($p < 0.0001$).
Conclusion Improvement in QOL correlates with success of AF ablation after single and repeated PVI. Assessment of QOL pre- and post-PVI can complement ECG techniques for PVI success monitoring.

Keywords Quality of life · Atrial fibrillation · Pulmonary vein isolation · Rhythm control · Ablation

Introduction

Atrial fibrillation (AF) affects up to 2 % of the general population [1]. Patients with symptomatic AF have a substantially reduced quality of life (QOL) when compared to the normal population [2]. QOL is similar to those who have survived a myocardial infarction [3]. Even in so-called clinically asymptomatic AF patients, a negative impact of AF on QOL has been described: these patients seem to be truly asymptomatic (normal activity scores), but their QOL scores are significantly reduced [4]. The efficacy of current treatment strategies, including antiarrhythmic drugs and catheter ablation in AF rhythm control, is quite variable and suboptimal [5]. While interventions for suppressing AF have not been shown to prevent strokes or reduce mortality [6–8], the primary goal of rhythm control should be reduction in symptoms and improvement of QOL. Outcomes after pulmonary vein isolation (PVI), the standard catheter technique for drug-refractory, and/or symptomatic AF were less favorable in the long term with a substantial number of late recurrences after PVI [9, 10]. In addition, very few data on QOL with long-term follow-

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up are available [11, 12], and there are virtually no data available on patients with repeated PVI procedures.

We used the SF-12v2 questionnaire for this retrospective analysis and assessed QOL before and after PVI in patients with both paroxysmal and non-paroxysmal AF. The goal of this study was to assess an increase in QOL parameters at the end of follow-up compared to initial presentation before PVI. This increase should be dependent on the procedural success but independent from the number of PVIs applied.

Methods

Study design and study population

This was a retrospective analysis of patients scheduled for routine PVI at the Medical University of Vienna, Department of Cardiology between 2009 and 2013. The diagnosis of paroxysmal, persistent, or longstanding persistent AF was established using current guidelines [13]. The local ethics committee approved the planned retrospective data extracting for publication. Inclusion criteria are symptomatic AF refractory or intolerant to at least one Class I or III antiarrhythmic drug. Exclusion criteria are contraindications to anticoagulation, presence of a left atrial (LA) thrombus, life expectancy <1 year, or overt thyroid dysfunction.

Pre-procedural imaging and catheter ablation

All patients underwent pre-procedural imaging to exclude left atrial thrombi and to acquire left atrial anatomy. PVI study techniques and system functions have been described in detail elsewhere and where intra-procedure was adapted based on the operator's decision [14–17]. Overall, the procedural end point was achievement of PV entrance and exit block.

Post-ablation management, monitoring, and follow-up

The recommended initial follow-up regime was to see patients at 1, 2, 6, 9, and 12 months and thereafter every half-year post-ablation at the outpatient department. Routine clinical checks with 12-lead ECGs were done at every visit. If patients had no implanted device capable of loop monitoring, patients received event recorders post-PVI at week 1–4, 13–16, 25–28, and 37–40. Patients were instructed to send an ECG at least twice a day and additionally when they felt any discomfort. Twenty-four-h ECG recordings post-PVI at week 5, 17, 29, 41, and 52 were done. After 52 weeks, additional ECG recordings (24-h ECGs, event recorders) at least every half-year were done.

Quality of life (QOL) assessment

Health-related QOL was assessed using the Short-Form 12 Health Survey, version 2 (SF-12v2) [18]. The SF-12v2 is a multipurpose short-form survey with 12 questions, all selected from the Short-Form 36 Health Survey. In the assessment of QOL by the SF-12v2, eight dimensions are used. These include physical functioning, physical role limitation, body pain, general health, vitality, social functioning, emotional role limitation, and mental health. Physical (PCS) and mental health (MCS) composite scores are normed to the US population (mean 50, SD 10) and vary from 0 to 100, with higher scores indicating greater health-related quality of life [18]. Scores above 50 indicate that a person is likely to be well, scores of 40–49, likely to have mild disability, 30–39, likely to have moderate disability, and below 30, likely to have severe disability. The SF-12v2 was recently evaluated in the US National Health and Wellness Survey in AF patients [19]. As part of our clinical routine program, we obtained SF-12v2 at initial presentation (3-months) before PVI and after PVI at the end of follow-up. The latter were collected after the 2-month blanking period for early PVI failures or at the end of follow-up with a minimum of 12-month follow-up for all others. Patients were encouraged to answer the SF-12v2 at home to exclude any bias referring from the hospital environment. SF-12v2s were either delivered at the next scheduled visit or were returned per mail. Returned, anonymized surveys were sent to Testzentrale®, Göttingen, Germany. Calculation was done using Hogrefe Testsystem (HTS®). Quality of life scores were based on the SF-12 US general population t scores. For calculation of normalized values, z-transformation was used. PCS and MCS scores were returned from Testzentrale® and combined with the pre-calculated endpoints.

Endpoints

Two primary outcomes were analyzed in this study: quality of life (QOL) and procedural success. QOL was measured as PCS and MCS using the SF-12v2 questionnaire 3 months before and 12 months after PVI. PVI is not considered a permanent cure for AF. The observed time after the last PVI is regarded as right censored, since the requirement for an additional PVI cannot be ruled out, while the time to that event is unknown. The main endpoints were the difference in QOL before PVI and after PVI and the effect of that difference on the procedural success. Success was defined as freedom from any atrial arrhythmia: after the blanking period (2 months), a single

episode of atrial fibrillation, -flutter, or -tachycardia lasting >30 s considered a recurrence (= PVI failure). Secondary endpoints were (1) the effect of age at PVI, (2) gender, body mass index, history of AF, ejection fraction, and antiarrhythmic drug treatment (class I–IV) on the difference in QOL following PVI, (3) the impact of history of AF on procedural success, and (4) the impact of baseline characteristics on the return/non-return of SF-12v2 questionnaires.

Statistical analysis

For descriptive purposes, mean and standard deviation (SD) were calculated for metric variables and absolute frequencies and relative frequencies for categorical variables. Differences between groups were analyzed by *t* tests for metric variables, and Chi-squared test or Fisher's exact test for categorical variables. Pearson correlation coefficients were calculated to describe the correlations between the PCS and MCS. To evaluate the first endpoint, the individual development of the quality of life scores was plotted for each patient, and the mean scores of all patients at a given PVI incidence were added. Linear mixed models were calculated to explain PCS and MCS values by the number of PVIs and the factor pre/post-PVI. Guided by the graphical representations, the number of PVI was included as a linear predictor. Correlations between repeated observations within the same patient were accounted for by including a random intercept term for each patient. For stable estimation, these calculations were based on data from PVI 1 to 3.

The first null hypothesis was that there is no difference between mean pre- and post-PVI QOL scores at any time point. The second null hypothesis was that there is no change in mean pre-PVI scores and no change in mean post-PVI scores with increasing number of PVI. The denominator degrees of freedom for the tests were estimated by the method of Kenward and Roger [20]. Since no significant effect of number of PVI was found, final models were calculated including only the factor pre- versus post-PVI as independent variable.

Univariable and multivariable linear mixed models for the difference in PCS or MCS before and after PVI were calculated to analyze the potential effect of age at PVI, gender, body mass index, history of AF, ejection fraction, and antiarrhythmic drug treatment (class I–IV) on the difference in QoL. In these models, the averaged effect across all PVIs was analyzed. To avoid an increased risk for false positive conclusions for this question, the Bonferroni-Holm method was used to adjust *p* values for multiple testing.

Conditional gap time Cox regression models according to Prentice, Williams, and Peterson were calculated to explain the risk for a new PVI using the QOL measurement from the previous PVI. These models utilize the information from all recurrent PVIs. The effect of history of AF was analyzed from multiple gap time Cox models. For Kaplan–Meier estimates, patients were stratified according to their health scores improvements at PVI 1 into two groups, using the overall mean PCS or MCS improvement as cut-off. Software: SAS® Version 9.3, (SAS Inst., Cary, NC, USA).

Results

This study included baseline data of 229 patients (73 % males; mean age 58 ± 11 years) undergoing PVI for drug-refractory symptomatic paroxysmal (48 %), persistent (37 %), or longstanding persistent (15 %) AF. One-hundred-sixty-three patients (71 %) responded the SF-12v2 and 66 (29 %) did not. Patients' clinical characteristics stratified according to the SF-12v2 response status are summarized in Table 1. The most frequent comorbidity was hypertension (81 %) followed by coronary artery disease (11 %). Only 3 % of patients had more than mild reduction in left ventricular ejection fraction, and 20 % had more than mild mitral regurgitation. The mean left atrial diameter was 46 ± 6 mm (enlarged).

PVI and follow-up data

In summary, 129 out of 229 at 1st PVI (56 %), 37 out of 77 at 2nd PVI (48 %), 15 out of 21 at 3rd PVI (71 %), 4 out of 9 at 4th PVI (44 %), 1 out of 3 at 5th PVI, and 1 out of 1 at 6th PVI returned the SF-12v2 questionnaire. Clinical follow-up with 12-lead ECGs, 24-h recordings, trans-telephonic ECGs, and implanted monitoring devices were performed in 100, 63, 51, and 16 % of all cases, respectively. The mean overall follow-up time was 1.7 ± 1.4 years per PVI procedure.

Effect of PVIs on QOL scores

The graphical representation of individual and mean QOL development in Fig. 1 clearly suggests an average increase in both PCS and MCS after each PVI. Within the time period to the next PVI, QOL scores are declining to their original level. The analysis using linear regression confirmed that there is a significant difference between pre- and post-PVI values for QOL scores ($p < 0.0001$ for both, PCS and MCS). There was no significant change of mean pre-PVI or post-PVI QOL scores with increasing number of PVIs ($p = 0.967$ for MHS and $p = 0.323$ for PHS). Considering only the first PVI, the mean PCS was 37.3 (SD

Table 1 Clinical and echocardiographic data stratified according SF-12 response status

	Total $n = 229$	SF-12 never responded $n = 66$	SF-12 ever responded $n = 163$	p for trend
Baseline characteristics				
Age (years)	58.1 ± 11	57.2 ± 12	58.5 ± 11	0.435
Male (*n*)	167 (73 %)	50 (76 %)	117 (72 %)	0.6531
Body mass index	28.0 ± 4.6	27.0 ± 4.5	28.4 ± 4.5	0.0358
History of atrial fibrillation				
Paroxysmal	109 (48 %)	29 (44 %)	80 (49 %)	0.7331
Persistent	85 (37 %)	27 (41 %)	58 (36 %)	
Longstanding persistent	35 (15 %)	10 (15 %)	25 (15 %)	
Comorbidities				
Hypertension	186 (81 %)	60 (91 %)	126 (77 %)	0.0277
Coronary artery disease	26 (11 %)	6 (9 %)	20 (12 %)	0.6478
Chronic renal failure	5 (2 %)	1 (2 %)	4 (2 %)	1*
History of stroke	16 (7 %)	2 (3 %)	14 (9 %)	0.1626*
COPD	11 (5 %)	2 (3 %)	9 (6 %)	0.5184*
Diabetes	17 (7 %)	6 (9 %)	11 (7 %)	0.581*
Echocardiographic parameters				
Ejection fraction				
Normal LVEF	200 (87 %)	58 (88 %)	142 (87 %)	0.1403*
Mild LVEF reduction	22 (10 %)	4 (6 %)	18 (11 %)	
Moderate LVEF reduction	6 (3 %)	3 (5 %)	3 (2 %)	
Severe LVEF reduction	1 (0 %)	1 (2 %)	0 (0 %)	
Valves				
Regurg./stenosis (non-mitral)	17 (8 %)	5 (8 %)	12 (8 %)	0.808
Mitral valve status				
Normal mitral valve	99 (46 %)	30 (47 %)	69 (46 %)	0.8666*
Mild mitral regurgitation	71 (33 %)	22 (34 %)	49 (33 %)	
Moderate mitral regurgitation	39 (18 %)	10 (16 %)	29 (19 %)	
Severe mitral regurgitation	5 (2 %)	2 (3 %)	3 (2 %)	
Left atrium/IV wall (mm)				
A.p. parasternal long axis	46 ± 6	45 ± 5	46 ± 7	0.5054
Interventricular wall	12.6 ± 1.8	12.6 ± 1.8	12.7 ± 1.8	0.8559
Antiarrhythmic drug treatment				
AA class I	25 (11 %)	9 (14 %)	16 (10 %)	0.5447
AA class II	139 (61 %)	45 (68 %)	94 (58 %)	0.1849
AA class III	80 (35 %)	21 (32 %)	59 (36 %)	0.6338
AA class IV	27 (12 %)	11 (17 %)	16 (10 %)	0.2188

p values are from two-sample t tests for metric variables, Chi-squared test or Fisher's exact test (indicated by *) for categorical variables

10.6) before and 47.4 (SD 8.8) after the intervention. The mean MCS was 39.7 (SD 12.0) before the first PVI and 48.9 (SD 10.3) afterward. The mean difference between pre- and post-PVI estimated from the final mixed model for PCS and MCS including all PVIs was 10.0 [95 % confidence interval (8.3; 11.6)] for PCS and 8.9 [95 % confidence interval (7.1; 10.6)] for MCS, respectively. Both differences are significantly different from zero ($p < 0.0001$).

Correlation between PCS and MCS

The correlation between PCS and MCS was calculated to confirm the independent measure ability of these two component scores. PCS and MCS measured before the first PVI had a Pearson correlation coefficient of 0.35, PCS and MCS obtained after the first PVI had a correlation of 0.40, and the improvements in MCS and PCS due to the first PVI had a correlation of 0.35. Thus, there is a moderate positive

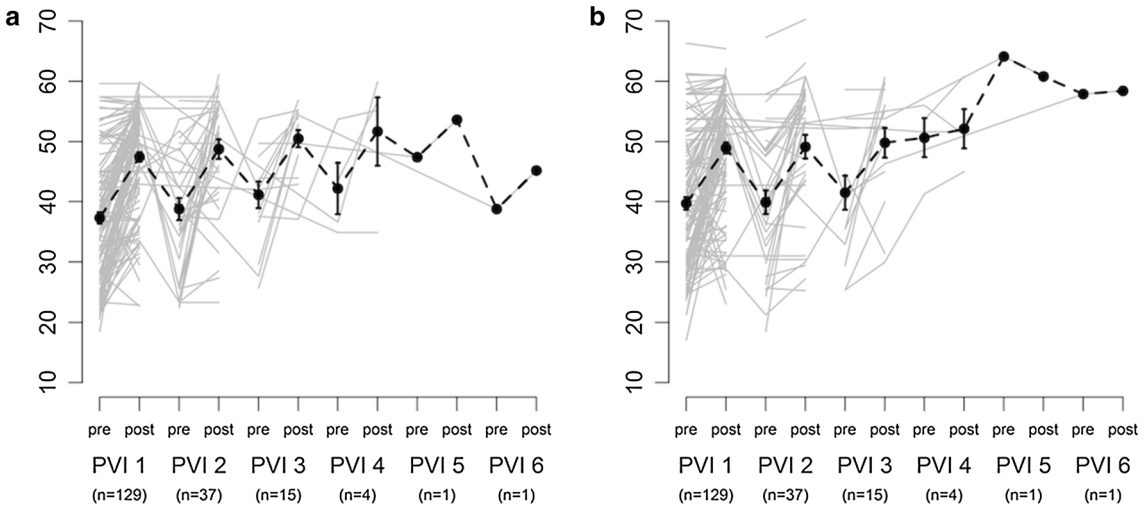

Fig. 1 Development of PCS (**a**) and MCS (**b**) values pre- and post-repeated PVI. Individual traces are shown in *gray color*. Mean values at given PVI points are shown by *black circles*. A *dashed line* indicates the trace of means. The mean PCS was 38 and 48, and the mean MCS was 40 and 49 pre- and post-1st PVI, respectively

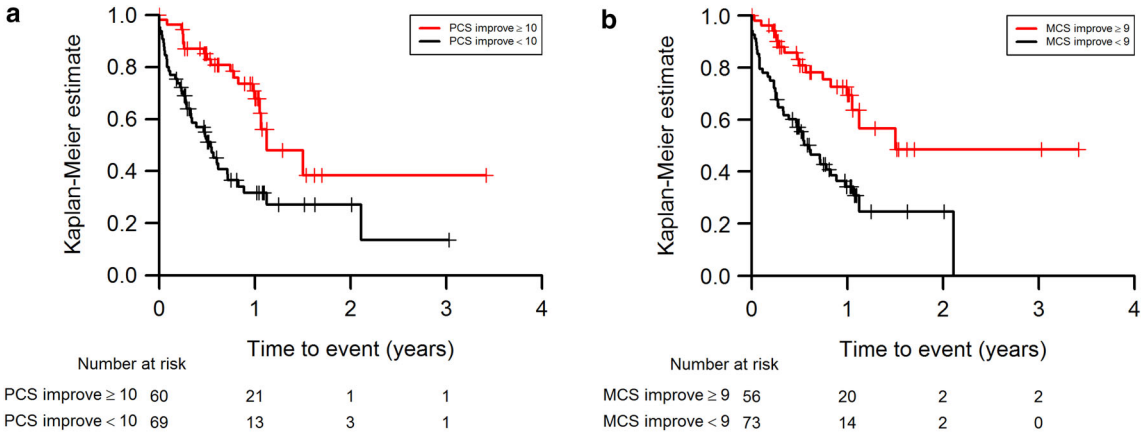

Fig. 2 Kaplan-Meier estimate for the time between 1st PVI and 2nd PVI, stratified by PCS improvement (**a**) and MCS improvement (**b**). Absolute numbers of patients at risk are outlined. An improvement in either health scores above the mean improvement results in longer time periods until an additional PVI is required

correlation between the two component scores justifying separate analyses.

Association between PCS and MCS improvements and time to next PVI

The risk for a redo PVI was significantly decreased with increased QOL scores post-PVI. The hazard ratio per unit of PCS improvement was 0.944 [95 % confidence interval (0.923; 0.964), $p < 0.0001$]. This equals a reduction in the instantaneous risk for a redo PVI at any time by approximately 94 % with each increase of PCS improvement by one point. Thus, a 56 % risk reduction is expected for each increase in PCS improvement by 10 points. The effect of MCS improvement was similar with a hazard ratio of 0.964 [95 % confidence interval (0.947; 0.982), $p < 0.0001$]. The results are visualized by plotting Kaplan–Meier curves (Fig. 2a, b). These graphics illustrate that an improvement in either health scores above the mean improvement results in significantly longer time periods until an additional PVI is required. Patients with a PCS improvement ≥10 or an MCS improvement ≥9 have an estimated success rate (i.e., the probability of not requiring a new PVI) of 72 and 39 or 73 and 49 % at 1 or 2 years after 1st PVI, respectively. Similar results were found for repeated PVIs (Fig. 3a, b): patients with a PCS improvement ≥10 or an MHS improvement ≥9 had success rates of 72 and 82 % at 1 year post-2nd PVI, respectively. Patients with a PCS improvement <10 or an MCS improvement <9 had worse outcomes with 2nd PVI success rates of 20 and 22 % after

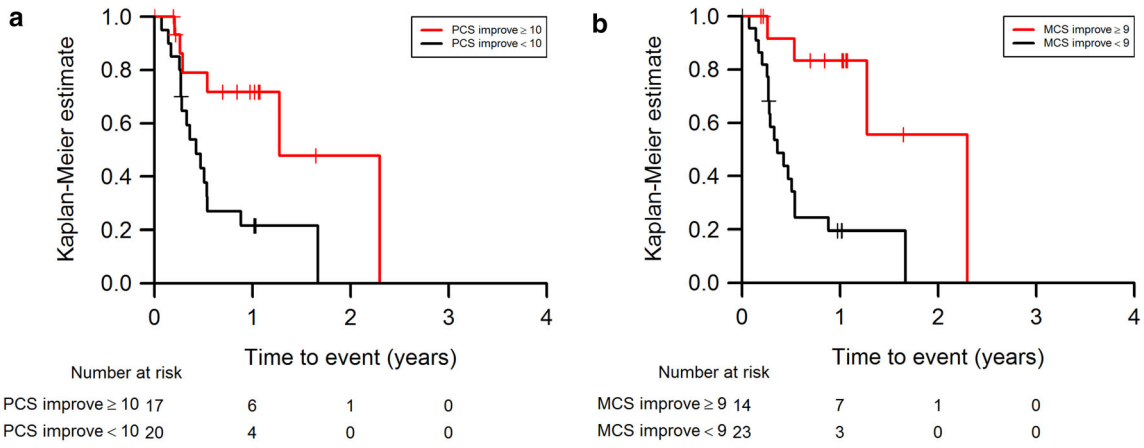

Fig. 3 Kaplan-Meier estimate for the time between 2nd PVI and 3rd PVI, stratified by PCS improvement (**a**) and MCS improvement (**b**). Absolute numbers of patients at risk are outlined. An improvement in either health scores above the mean improvement results in longer time periods until an additional PVI is required

1 year of follow-up, respectively. There was no significant influence of history of AF (with the three groups paroxysmal, persistent, and longstanding persistent) on the risk for a new PVI ($p = 0.4906$ and $p = 0.3640$ for models including PCS or MCS improvement, respectively).

Regression analysis for possible influences of baseline parameters on the outcome

Univariable and multivariable linear mixed models for the difference in PCS or MCS before and after PVI were calculated to analyze the potential effect of age at PVI, gender, body mass index, history of AF, ejection fraction, and antiarrhythmic drug treatment (class I–IV). In these models, the averaged effect across all PVIs was analyzed. Body mass index was found to be predictive in the univariate model for change in PCS before adjustment for multiple testing. Following the adjustment, no significant effects could be inferred, see Table 2. None of the investigated variables was found significant in the multivariable models including all variables at the same time.

Discussion

We found that PVI results in a significant improvement in QOL and that the extent of individual improvement is positively associated with procedural success, both after

Table 2 Effect of covariables on the increase in QoL after PVI estimated from univariable models

Variable	Effect on PCS change				Effect on PCS change			
	Estimate	SE	p	p value	Estimate	SE	p	p value
Male	1.11	1.86	0.5514	1	1.32	2.11	0.533	1
History atrial fibrillation			0.0711	0.5688			0.0583	0.5247
Paroxysmal	0				0			
Persistent	−1.74	1.82			−2.88	2.06		
Longstanding persistent	−5.61	2.43			−6.30	2.74		
Normal LVEF			0.9683	1			0.1933	1
Mild LVEF reduction	0				0			
Moderate LVEF reduction	−0.68	2.70			−5.42	3.02		
Severe LVEF reduction	0.05	6.36			1.51	7.05		
Age	−0.010	0.080	0.9033	1	−0.045	0.090	0.619	1
BMI	−0.44	0.18	0.0177	0.1593	−0.05	0.21	0.8058	1
AA Class I	−3.06	2.47	0.2188	1	−0.56	1.95	0.7736	1
AA Class II	1.31	1.57	0.406	1	−1.41	1.27	0.2699	1
AA Class III	−2.52	1.63	0.1242	0.8694	−0.82	1.40	0.5577	1
AA Class IV	−2.91	2.43	0.2323	1	−0.37	2.01	0.8528	1

Multiplicity adjusted p values are calculated using the Bonferroni-Holm method for each

single and repeated PVI. This finding is clinically important because the individual improvement in QOL impacts on further ECG monitoring and treatment strategies.

Hospitalizations are frequent in AF patients and may contribute to reduced QOL. Measurement of patient-assessed outcome has been proven to be reliable [18]. The SF-12 is an efficient instrument where a short generic measure providing summary information on physical and mental health status is required [21]. Long-term QOL has been evaluated after single PVI and was found significantly improved in successful treated patients [11]. With increasing number of patients undergoing PVI, the number of redo procedures is growing. The underlying study reflects on this new patient setting and investigates long-term QOL changes in patients undergoing repeated PVI procedures.

General role of common AF treatment strategies on QOL

It is commonly believed that the restoration and maintenance of sinus rhythm can improve QOL. Although QOL associated with AF may be decreased, it has not often been conclusively demonstrated that QOL significantly is improved by a particular treatment strategy. In both AFFIRM [22] and AF-CHF [23], there was no significant difference in QOL when comparing rhythm control with rate control. However, AFFIRM patients who remained in sinus rhythm had a better QOL. The treatment strategy of stricter heart rate control does not seem to influence QOL either [24]. Overall, the impact of drug therapy on QOL in patients with AF seems to be only modest. According to current guidelines, PVI is recommended for patients with symptomatic paroxysmal and persistent AF after failure of antiarrhythmic drug therapy [13]. To date, there is only limited data available on QOL following PVI [11, 25–29].

Placebo effect of PVI?

Mean PCS and MCS for US residents aged 65–74 without AF are 43 and 53, respectively [22]. Our study population initially presented with depressed PCS and MCS scores (mean PCS 38, mean MCS 40 before the 1st PVI). After the 1st PVI, mean PCS and MCS values normalized to the US average. Our data do not suggest differences in the effect of PVI on QoL in regard to different periods of follow-up until the first recurrence, as the effect across repeated PVI events stays remarkably constant. We could also clearly demonstrate this apparent positive effect of PVI after repeated PVIs ($p < 0.0001$). The Cox models clearly demonstrate a reduction in the instantaneous risk for a redo PVI at any time by approximately 94 %.

Health-related QOL measures are important clinical outcome measures of therapy of chronic disease, and based on the data of the PROTECT AF trial [30], QOL indicators are important for evaluating these strategies. However, QOL impairment has been found not related or only weakly correlated with indices of disease burden, frequency of episodes and illness duration [31]. In PVI the reported success rate very much depends upon the monitoring technique applied. The 70 % freedom from AF in a clinical symptom-only (yes/no) based follow-up regime dropped to a success rate of 50 and 45 % only when 7 days ECG and trans-telephonic monitoring had been added, respectively [32]. One explanation for the higher success rate on a symptom-based follow-up may be the marked increase in the percentage of asymptomatic AF episodes early after PVI [33]. This observation explains results of studies assessing QOL after PVI showing an improved QOL regardless of the ablation outcome but that possible placebo effects early after PVI "dilute" during longer periods of follow-up [11]. Alternatively, those with recurrent AF and improved QOL could represent a group of patients where either a reduction in AF burden sufficiently treats the patient or true placebo effect is evident [28, 29]. The actual contribution of placebo effect is hard to study given the invasiveness of PVI procedures. At least, the present study shows an independent association between recurrences and reduction in mean QOL scores.

Repeated PVI and history of AF

Currently, to the best of our knowledge, this is the first study analyzing QOL questionnaires before and after repeated PVIs. We are in line with others [11, 26, 27, 34, 35] who demonstrated that both paroxysmal and persistent AF patients gained better QOL when maintaining in SR by means of a single PVI. The underlying study demonstrates that this is also true for repeated PVI, which was performed up to six times in some patients. Due to the presence of censored observations, the most useful model to predict the risk of future events is QOL measurement. Patients with a PCS improvement $\geq$10 or an MCS improvement $\geq$9 had the best outcome at 1st PVI with success rates of 72 or 73 % after 1 year of follow-up, respectively. This was also true for patients with repeated PVIs: patients with an PCS improvement $\geq$10 or an MCS improvement $\geq$9 had the best outcome at 2nd PVI with success rates of 72 and 82 % after 1 year of follow-up, respectively. This implicates that a "delta" in PCS and MCS somehow conditions the magnitude of the individual response to a recurrence.

Limitations

Patients were treated and data were analyzed in a consecutive manner, not in a randomized fashion. So we cannot completely rule out bias. It cannot be ruled out that AF

treatment is limited by the ability to record all asymptomatic episodes of AF. Therefore, our findings may have overestimated the efficacy of PVI.

Conclusion

Considering the high impact of AF on QOL, the aim of repeated PVI must be an increase in QOL. Changes in QOL highly significantly correlate with the success of AF ablation irrespective of the number of PVIs applied. Thus, assessment of QOL pre- and post-PVI can complement ECG techniques for ablation success monitoring.

Conflict of interest None.

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