

Quality of life benefits from arrhythmia ablation: A longitudinal study using the C-CAP questionnaire and EQ5D

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Abstract

Aims: To investigate long-term efficacy of cardiac ablation for symptomatic arrhythmia by gathering generic and arrhythmia-related quality of life data using patient-reported outcome measures before and after ablation.

Methods: Consecutive patients undergoing cardiac ablation procedures at three sites in the United Kingdom were enrolled ($n = 561$). Data were collected at baseline, at 8–16 weeks, and 12 months after the ablation with responses from 390 patients received at all three time points. Nonparametric tests were used to identify any changes in patient outcomes due to nonnormal data.

Results: There were significant improvements in symptom severity, impact on life scores, EQ-5D-5L indices, and visual analogue score (VAS) scores at pre- versus 3 months and at preablation versus 1 year. Impact on life score showed additional improvement at 1 year versus 3 months, while improvements in symptom severity, EQ-5D-5L indices, and VAS scores continued to be maintained between 3 months and 1 year.

Conclusion: Cardiac ablation provides patients with arrhythmias relief from symptoms, and results in an improvement in quality of life. Improvements observed at 3 months are maintained at 1 year follow-up.

KEYWORDS

atrial fibrillation, cardiac ablation, cardiac arrhythmia, PROMS, quality of life, symptoms

Condensed Abstract

Questions remain regarding the long-term efficacy of cardiac ablation. We enrolled 561 consecutive patients undergoing ablation procedures at three UK sites. Data were collected at baseline, and at 3 and 12 months. Improvement in symptoms was reported following treatment, with patients continuing to maintain or show continued improvement at 1 year.

1 | INTRODUCTION

With over 2 million people in the United Kingdom suffering from cardiac arrhythmias, they are a significant burden to the healthcare system and patients themselves.¹ In 2015–2016, Hospital Episode Statistics recorded over 2.3 million inpatient finished consultant episodes that included a diagnosis of arrhythmia in the English NHS, and over 245,000 of these listed arrhythmia as the primary diagnosis.²

The overall aim of ablation therapy in patients with cardiac arrhythmias is to reduce or abolish arrhythmia-related symptoms, improving the patient's quality of life (QoL).³ For many patients, living with cardiac arrhythmias can be a significant burden, adversely affecting work, daily routine, and social activities with a resulting negative impact on QoL.⁴ While first-line management has traditionally been via the often combined use of antiarrhythmic or rate control drugs and cardioversion, the use of catheter ablation is now recommended as primary treatment for many arrhythmias in current treatment guidelines.^{3,5} However, questions still arise regarding the long-term efficacy of ablation in some patient groups particularly those with atrial fibrillation (AF).⁶

In current clinical practice in the United Kingdom, there is a general reliance on hospital clinic visits to assess and monitor patient symptoms and outcomes, yet there is no consistency in the way that centers do this. Not all NHS ablation centers routinely follow-up patients after the procedure, and some have a policy to only see those who develop complications or a recurrence of symptoms. In those centers that do routinely follow-up postprocedure, the follow-up generally takes place relatively soon after treatment and usually consists of a single follow-up appointment unless further treatment is required. This means there are little data available on the longer-term outcomes of ablation and the resulting QoL of these patients.

The regular use of Patient Reported Outcome Measures (PROMs) has the potential to improve patient engagement when used as an integrated part of clinical practice. As a means of identifying the issues which are most troublesome to individual patients, they can be useful in initiating clinical discussions and in managing patient expectations. They can allow patients to feel more involved in their care, facilitate shared decision making, and can potentially improve patient monitoring, management, and outcomes.⁷ The use of PROMs supports the principles of coproduction, which focuses on achieving the outcomes which matter to individuals, with patients and clinicians working together in equal partnership.⁸ Evidence suggests that used appropriately, PROMs have the potential to improve patient QoL by facilitating appropriate treatment selection.⁹

Our research team has previously developed and validated a disease-specific PROM tool for use in UK patients with symptomatic cardiac arrhythmias.¹⁰ The purpose of the current report is to assess patient-reported outcomes over a longer follow-up period.

2 | METHODS

In this multicenter, prospective, observational cohort study, consecutive patients enrolled between March 2013 and August 2014, who had consented for a cardiac ablation procedure, were enrolled from three sites in the United Kingdom. Patients were invited to complete PROMs pre- and postablation and data were analyzed to identify any changes in symptom occurrence and severity, frequency and duration of symptoms, and impact on life.

2.1 | Ethics and funding

The study protocol was reviewed and approved by the Nottingham 1 Research Ethics Proportionate Review Sub-Committee (reference: 12/EM/0164). The study is registered on the UK Clinical Research Network Study Portfolio (reference 13148). The research was facilitated by Cedar, Cardiff & Vale UHB, on behalf of NICE (The National Centre for Health and Care Excellence). The clinical work was funded by the NHS under normal arrangements for clinical governance and consent.

2.2 | Study population

Patients aged 18 or over were eligible for inclusion if they had a symptomatic cardiac arrhythmia and had consented to their first or subsequent cardiac ablation procedure. Patients were excluded if they were aged less than 18 years of age; not able to read, write, or understand English or Welsh; or unable to provide informed written consent. Informed written consent was obtained from all individual participants included in the study. Additional details of the study methods have been previously published.¹⁰

2.3 | Questionnaire administration

In brief, the PROMs study uses the previously validated disease-specific Cardiff Cardiac Ablation PROM (C-CAP) tool¹⁰ and the generic EQ-5D-5L tool.¹¹ The C-CAP tool was validated as part of this current study with the tool showing good internal consistency with a Cronbach alpha of >0.7, and acceptable test-retest reliability for all of the scales

as assessed using intraclass correlation coefficient (ICC) of ≥ 7 . The C-CAP consists of three common scales which measure symptom severity, frequency, and duration (i.e., burden) of symptomatic episodes and impact on life of the arrhythmia. The symptom severity scale includes those symptoms which most commonly affect arrhythmia sufferers including palpitations, fatigue, dizziness, and headache, while the frequency and duration section quantifies how often episodes of arrhythmias occur and how long each episode lasts. The impact of life section assesses how arrhythmias affect, for example, the participants' everyday activities, social activities, confidence, and family. Within these scales, high values relate to worse symptoms/longer episodes/greater impact on life. There is an additional scale preprocedure which measures the patient expectations of how their symptoms will change following treatment. This is matched by a postprocedure scale measuring the actual changes in symptoms, with a "Yes / No" question which asks "Did the outcome of the procedure meet or exceed your expectations?" Each of the C-CAP PROMs tools also has additional domains exploring comorbidities and arrhythmia medication. The postprocedure tool has an additional domain on adverse events related to the ablation procedure. The C-CAP tool is freely available to use and is accessible via <http://www.cedar.wales.nhs.uk/ccap/>.

EQ-5D-5L consists of a visual analogue scale and a descriptive system comprising five dimensions each with five levels of response. These can be combined in a 5-digit profile describing the respondent's health state which can be converted to a single index value where a score of 1 represents perfect health and 0 represents death. The scoring permits scores of less than 0, implying that some health states may be worse than death.

At each of the sites, patients were invited to enroll and complete postal PROM surveys preprocedure. Enrolled patients were sent additional surveys at 8–16 weeks and at 1 year postprocedure. Patients were asked to complete and return these to the study group using a prepaid envelope. Nonresponders were sent reminders with replacement surveys and return envelopes 2–3 weeks after the initial mailing.

2.4 | Responses

A total of 561 patients enrolled onto the study, and 517 were subsequently treated with cardiac ablation at one of the three participating hospitals. Of these, 390 (75%) completed and returned valid questionnaires at all of the three measurement time points (preablation, postablation, and 1-year follow-up). Data from these 390 patients are included in this analysis.

2.5 | Data management and statistics

Patient responses were entered into the National Audit of Cardiac Rhythm Management (NACRM) database administered by the National Institute for Cardiovascular Outcomes Research (NICOR) at University College London. Data were exported and IBM SPSS® Statistics software version 21 (IBM Corp., Armonk, NY, USA) was used for all statistical analyses. The results for impact on life, symptom severity, visual analogue score (VAS), and EQ-5D-5L were compared

for differences over time (baseline vs 1 year, 3 months vs 1 year, and baseline vs 1 year).

Patients who undergo ablation for AF sometimes experience an increase in atrial arrhythmias during the initial 3 months after the procedure (often referred to as the blanking period) that is not seen among patients undergoing ablation for other indications which can delay recovery.³ Therefore, the patients were analyzed as two groups based on whether they underwent an ablation procedure for AF or non-AF. Some patients did not complete all questions within a multi-item scale. These missing data were not imputed but instead participants were removed from analysis for a specific scale if any data items were missing; for example, a patient who did not complete all questions on the impact on life scale was excluded from that section of analysis but was included in other analyses if he or she completed all the questions within that scale. Data were not normally distributed and transformations did not make the data normal. Therefore, the data were analyzed using the nonparametric Friedman test and results were deemed significant if $P < 0.05$. *Post hoc* analyses were carried out using the Wilcoxon signed rank test. Due to multiple comparisons being carried out, a Bonferroni correction was applied to P-values. Results were deemed significant if $P < 0.017$. To test gender differences in scores, data were analyzed using the Mann-Whitney U test and results were deemed significant if $P < 0.05$. Figures were generated using R statistical software with the ggplot2 package.^{12,13}

3 | RESULTS

3.1 | Patient characteristics

The characteristics of patients who completed the pre-, post-, and 1-year follow-up C-CAP questionnaires are presented in Table 1. A total of 56.4% of the patients were male, and the mean age was 62.04 years. The majority of patients underwent left atrial ablation for AF (50.8%), and most were treated using either radiofrequency (RF) ($n = 316$) or cryothermal energy ($n = 21$). The proportion of patients with other tachycardia mechanisms is listed in Table 1. Details on ablation procedures for other types of tachycardias have been previously published.¹⁰

3.2 | Changes in QoL following treatment

Results from the pre-, post-, and 1-year follow-up questionnaires are presented in Table 2. Friedman tests were conducted to determine if there were significant differences in EQ-5D-5L indices, VAS, impact on life scores, symptom severity scores, and frequency and duration of episodes observed in pre-versus post- and pre-versus 1-year follow-up scores. Friedman tests were significant for EQ-5D-5L (χ^2 (2, $n = 367$) = 60.159, $P < 0.001$), VAS (χ^2 (2, $n = 378$) = 130.18, $P < 0.001$), impact on life score (χ^2 (2, $n = 317$) = 304.26, $P < 0.001$), symptom severity scores (χ^2 (2, $n = 254$) = 162.89, $P < 0.001$), and the frequency and duration of episodes (χ^2 (2, $n = 362$) = 270.17, $P < 0.001$). *Post hoc* analyses showed a significant increase in median EQ-5D-5L index (preprocedure = 0.77, 1-year follow-up = 0.84; $Z = -7.051$,

TABLE 1 Demographic and clinical characteristics of sample at baseline

Characteristic	Patients analyzed (n = 370) N (%)
Gender - male	220 (56.4%)
Mean age (years)	62.04 (SD ± 11.83)
Median age (years)	64.58 (range: 19.75-90)
Arrhythmia substrate	
Atrial fibrillation	198 (50.8%)
AVNRT	63 (16.2%)
Atrial flutter	56 (14.4%)
Uncommon atrial flutter	8 (2.1%)
Accessory pathway	22 (5.6%)
Ventricular extrasystoles/ectopics	7 (1.8%)
Ventricular tachycardia	9 (2.3%)
Not recorded	27 (6.9%)
History of prior cardiac procedures	
Previous ablation	93 (23.8%)
Pacemaker	15 (3.8%)
Coronary angioplasty	5 (1.3%)
Cardiac surgery	10 (2.6%)
Other	1 (0.3%)
Energy	
Radiofrequency	316 (81%)
Cryothermal	21 (5.4%)
Radiofrequency and cryothermal	3 (0.8%)
Laser	1 (0.3%)
Unknown	49 (12.5%)

Note: AVNRT = atrioventricular nodal reentry tachycardia; SD = standard deviation.

$P < 0.001$) and median VAS (preprocedure = 70, 1-year follow-up = 80; $Z = -9.689$, $P < 0.001$) following ablation, indicating an improvement in QoL following treatment. Similarly, improvements were seen in symptom severity following ablation with median symptom severity score being significantly lower (preprocedure = 14, 1-year follow-up = 6; $Z = -10.918$, $P < 0.001$). Additionally, median impact on life scores were significantly lower following catheter ablation (preprocedure = 13, 1-year follow-up = 3; $Z = -13.574$, $P < 0.001$). The median

impact on life scores observed at 1-year follow-up were lower than those observed at postprocedure (postprocedure = 4, 1-year follow-up = 3; $Z = -4.424$, $P < 0.001$), indicating a continued improvement. The median frequency and duration of episodes was significantly lower following treatment (preprocedure = 5, 1-year follow-up = 2; $Z = -13.741$, $P < 0.001$).

3.3 | AF versus non-AF

Patients were divided into two groups for analysis, an AF group ($n = 198$) and non-AF group ($n = 165$). For those cases where no arrhythmia mechanism was recorded on ablation records ($n = 27$), data were not included in the present analysis. For both AF and non-AF groups, EQ-5D-5L indices and VAS were significantly higher following ablation (higher = better QoL) while impact on life and symptom severity scores significantly decreased (lower = less impact, less severity) following ablation (Table 3).

Data on PROMs scores for patients with AF undergoing RF ablation were also analyzed separately ($n = 159$). There was a significant increase in median EQ-5D-5L index (preprocedure = 0.75, 1-year follow-up = 0.84; $P < 0.001$) and median VAS (preprocedure = 65, 1-year follow-up = 80; $P < 0.001$) following ablation. Median impact on life scores significantly decreased (preprocedure = 15, 1-year follow-up = 4; $P < 0.001$) and median symptom severity scores significantly decreased (preprocedure = 15, 1-year follow-up = 7; $P < 0.001$) following ablation. These changes all suggest that AF ablation had a significant impact in improving QoL. Other patients with AF were treated with cryoablation ($n = 19$); laser ($n = 1$); and RF and cryo ($n = 2$); while in 17 cases the technology group was unknown.

3.4 | Does the outcome of ablation meet patient expectation?

At 8-16 weeks' follow-up, 364 of the 390 patients responded to the stand-alone question "Did the outcome of the procedure meet or exceed your expectations?" Of the responders, 268 patients (68.7%) answered "Yes," with 96 responders (24.6%) indicating that the procedure had not met their expectations. At the 1-year time point, 321 patients responded to this question with 250 of these (64.1%) reporting their expectations had been met.

TABLE 2 Pre-, post-, and 1-year follow-up questionnaire results

Domain	Number of patients with data at all time-points	Preprocedure questionnaire	Postprocedure questionnaire	1-year follow-up questionnaire	P-value (pre- and postprocedure comparison)	P-value (preprocedure and 1-year follow-up comparison)
Median EQ-5D-5L index (IQR)	367	0.77 (0.23)	0.84 (0.3)	0.84 (0.3)	$P < 0.001^*$	$P < 0.001^*$
Median VAS (IQR)	378	70 (30)	80 (25)	80 (25)	$P < 0.001^*$	$P < 0.001^*$
Median impact on life score (IQR)	317	13 (13)	4 (10)	3 (7)	$P < 0.001^*$	$P < 0.001^*$
Median symptom severity score (IQR)	254	14 (12)	6 (9)	6 (9)	$P < 0.001^*$	$P < 0.001^*$

Note: IQR = interquartile range; VAS = visual analogue score.

*Significant result ($P < 0.017$) as determined through *post hoc* analyses using the Wilcoxon signed rank test with a Bonferroni correction.

TABLE 3 Pre-, post-, and 1-year follow-up questionnaire results for AF and non-AF patients

Domain	Number of patients completing the domain at all time-points	Preprocedure questionnaire	Postprocedure questionnaire	1-year follow-up questionnaire	P-value (pre- and postprocedure comparison)	P-value (preprocedure and 1-year follow-up comparison)
Atrial fibrillation						
Median EQ-5D-5L index (IQR)	187	0.77 (0.24)	0.84 (0.24)	0.84 (0)	P < 0.001*	P < 0.001*
Median VAS (IQR)	193	65 (30)	80 (22.5)	80 (25)	P < 0.001*	P < 0.001*
Median impact on life score (IQR)	151	15 (14)	6 (13)	4 (9)	P < 0.001*	P < 0.001*
Median symptom severity score (IQR)	131	14 (13)	7 (11)	7 (10)	P < 0.001*	P < 0.001*
Nonatrial fibrillation						
Median EQ-5D-5L index (IQR)	154	0.77 (0.18)	0.85 (0.27)	0.84 (0)	P < 0.001*	P < 0.001*
Median VAS (IQR)	159	70 (25)	80 (20)	80 (22)	P < 0.001*	P < 0.001*
Median impact on life score (IQR)	131	11 (10)	2 (6)	2 (5)	P < 0.001*	P < 0.001*
Median symptom severity score (IQR)	105	14 (12)	4 (8)	5 (8)	P < 0.001*	P < 0.001*

Note: IQR = inter-quartile range; VAS = visual analogue score.

*Significant result (P < 0.017) as determined through *post hoc* analyses using the Wilcoxon signed rank test with a Bonferroni correction.

3.5 | Gender differences

No difference in median EQ5D index scores and VAS was observed between males and females at preprocedure, postprocedure, and at 1-year follow-up. There was a significant difference in preprocedure median impact on life scores between males and females (males = 13, females = 16.5; $U = 14349.5$, $P = 0.029$). There was no significant difference in median impact on life scores observed between males and females at postprocedure (males = 4, females = 4; $U = 14913.5$, $P = 0.990$) and 1-year follow-up (males = 2, females = 3; $U = 15860.5$, $P = 0.470$). There was a significant difference in preprocedure median symptom severity scores between males and females (males = 12, females 14; $U = 10388.5$, $P < 0.001$). Median postprocedure symptom severity scores were not significantly different between males and females (males = 6, females = 7; $U = 11385$, $P = 0.074$). However, a significant difference was observed at 1-year follow-up (males = 5, females = 7; $U = 11761$, $P = 0.009$) (Figure 1). The results highlight that females with arrhythmia had worse symptoms, which impacted upon their lives, at baseline than males.

4 | DISCUSSION

Patients undergoing ablation for non-AF substrates show an immediate improvement in QoL scores, symptom severity scores, and impact on life scores. These improvements, seen at 8–16 weeks following treatment, were maintained at 1-year follow-up. Similarly, patients undergoing AF ablation also indicate an improvement in these scores. However, in this patient group the impact on life score continues to improve with higher scores at 1 year than at 8–16 weeks. This is consistent with observations seen in clinical practice that are related to

the early postoperative inflammatory period. Importantly, in our study, the majority of responders felt that their expectations had been met at both time points with no suggestion that there is a decrease in patient satisfaction with outcome over time.

Improvements in impact of life and EQ5D Index scores suggest that as well as improving arrhythmia-specific symptoms, catheter ablation also improves overall QoL. This correlates with the results of the INTRINSIC RV ICD Trial which reported a range of benefits beyond the direct effects of arrhythmia.¹⁴ Our study also saw similar gender differences to the INTRINSIC Trial with lower baseline scores observed in female responders. Although improvements were seen in both genders following ablation, females saw larger improvement in impact on life scores than males, suggesting females may derive more benefit from the ablation procedure.

While data suggest that patients undergoing AF ablation have a high rate of arrhythmia recurrence, a recent meta-analysis demonstrates that repeat ablations allow approximately 80% of patients to achieve long-term freedom from arrhythmias.¹⁵ Our study will continue to collect additional PROMs data with a final survey taking place at 5-year postablation. This will allow us to identify long-term changes in symptoms and QoL and will also allow us to identify those who have undergone additional repeat procedures. This will add to the existing evidence base as data on very long-term follow-up is currently sparse. Brabandt and colleagues¹⁶ noted that further research into long-term outcomes is required. The routine use of PROMs by all ablation centers could help fill this evidence gap and facilitate improved quality of care across centers.

The results of our study illustrate how the use of longitudinally collected PROMs data can monitor patient symptoms, QoL, and even satisfaction with their treatment. Successful treatment is particularly important for AF where a natural progression from paroxysmal to

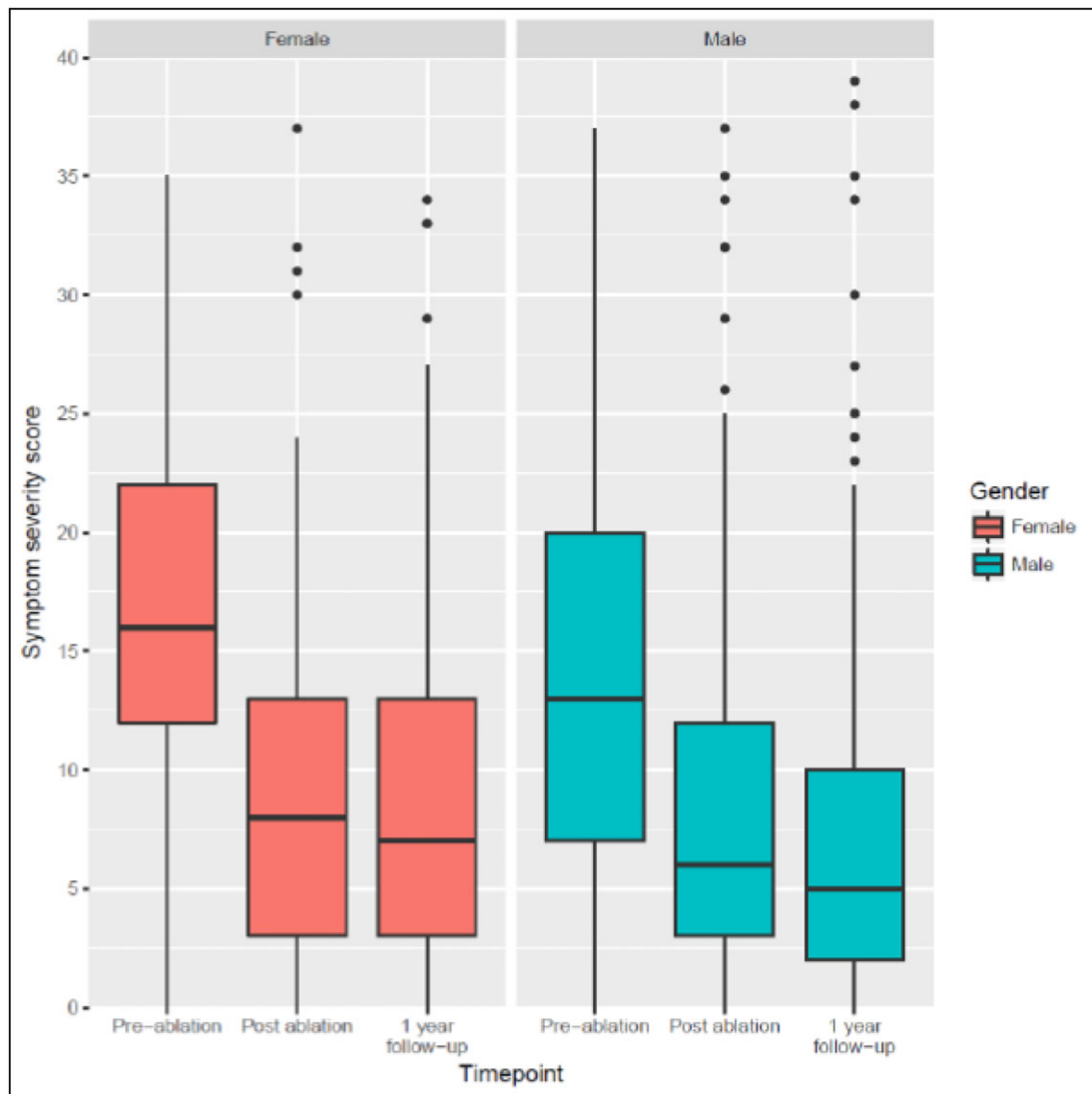


FIGURE 1 Symptom severity, preablation, postablation, and 1-year follow-up by gender [Color figure can be viewed at wileyonlinelibrary.com]

sustained AF is common. This increase in frequency and duration of arrhythmic episodes over time is associated with increased symptoms and morbidity.¹⁷ Use of individually collected PROMs can easily be adopted into the patient pathway to facilitate clinic consultations. Used in conjunction with the existing evidence base, they can allow clinicians to identify those areas which are most troublesome for patients and discuss patient expectations. This may help identify those patients who will benefit most from catheter ablation as well as providing an opportunity to manage patient expectation. It would be useful for further research to look into whether routine use of PROMs by all ablation centers could improve quality of care and achieve consistently high outcomes in all centers.

4.1 | Study limitations

As a noncomparative study, we are unable to show that the improvements in QoL are entirely due to the ablation procedure. It is possible that the patients included in the study are not representative of the general arrhythmia population. However, although arrhythmias

can be self-limiting over time, untreated AF is usually progressive, and evidence suggests that patient symptoms usually deteriorate over a period of time.¹⁸ We would therefore expect patients enrolled to report a worsening of symptoms with a reduced quality of life over the study period.

Additionally, we have only included data from those patients who responded at all three time points. One 2014 study found that those participants who did not provide PROMs at each review point were younger, and with lower baseline scores and lower satisfaction than those who responded at all time points.¹⁹ Another recent study which contacted those lost to follow-up found that this group were younger with lower EQ5D, but there was no difference in patient satisfaction or improvement in pain to those who has responded at all time points.²⁰ It is possible that the patients who did not respond at all time points in our study may be those with the poorest outcomes following the procedure.

Due to the relatively large sample size included for each individual question, we did not impute data but excluded individual scales from analysis. We do not believe that this will have had a significant effect

on the outcomes of the study, but acknowledge that it may potentially have a minor impact on some findings. Overall, we feel that the findings of this study are robust and generalizable to the general arrhythmia population.

4.2 | Conclusion

The Cardiff Cardiac Ablation PROMs study has illustrated that catheter ablation for symptomatic arrhythmias provides effective relief from arrhythmia related symptoms for many patients with both AF and non-AF arrhythmias. Our data suggest that cardiac ablation leads to a reduced impact on life and improved QoL scores. Results show improvements reached at 8–16 weeks continue to be maintained at 1 year, and that the results of the procedure meet or exceed expectation for most patients.

CONFLICTS OF INTEREST

None declared.

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DECLARATION OF HELSINKI

The authors confirm that this study complies with the declaration of Helsinki, and the research protocol has been approved by the appointed ethics committee. Informed consent has been obtained from all patients.

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