Atrial fibrillation (AF) is a frequent and costly health care problem. In patients with AF, the restoration and maintenance of sinus rhythm is the primary therapeutic goal. The most frequent strategy for maintaining sinus rhythm after restoration is the use of antiarrhythmic drugs. The efficacy of therapy in AF has been predominantly measured using objective criteria such as mortality and morbidity. In recent years, the importance of quality of life (QoL) as an outcome measure has been recognized. However, few studies in the literature have examined QoL in patients with AF using properly validated tools. In addition, the specific impact of antiarrhythmic drug treatment on QoL in patients with AF has not been assessed. These issues are now being addressed in several ongoing studies. This article attempts to define QoL, makes recommendations on how QoL might be assessed, reviews our current knowledge regarding QoL in patients with AF, and discusses new clinical trials currently assessing QoL in patients with AF.

Atrial fibrillation (AF) is the most frequently experienced cardiac arrhythmia, affecting an estimated 2.2 million people in the United States. The prevalence of AF increases with age, ranging from less than 1% at 50 to 59 years to nearly 9% at 80 to 89 years. In addition to palpitations, patients with AF have an increased risk of stroke and can develop decreased exercise tolerance and left ventricular dysfunction. All of these problems may be reversed with restoration and maintenance of sinus rhythm. Thus, treatment of AF is warranted in the hope of eliminating symptoms, preventing complications, and possibly decreasing the excess mortality associated with this arrhythmia. The primary intervention for maintaining sinus rhythm after restoration is use of antiarrhythmic drugs. However, many of the existing drugs have only limited efficacy and are associated with considerable unexpected adverse effects. Current treatment is therefore suboptimal.

Assessment of the efficacy of therapy in patients with AF has been based primarily on objective criteria such as mortality and morbidity. Despite the prevalence of AF, its impact on quality of life (QoL) has not been evaluated widely, and of the relatively small number of studies in this area, few have defined QoL in a comprehensive manner or used validated methods. Most information about QoL in patients with AF has come from a group of highly symptomatic patients who were intolerant of or refractory to standard antiarrhythmic drug therapy and were therefore referred for definitive therapy, such as ablation of the atrioventricular (AV) node or junction. More important, none of the reported studies examined QoL in typical, minimally symptomatic patients with AF who are responsive to specific antiarrhythmic drug treatment. However, these shortcomings are currently being addressed by several groups, including an international group of investigators from the United Kingdom, Germany, and Canada (International Quality of Life Investigators).

This article (1) explains the importance of assessing QoL, (2) defines the term QoL, (3) describes the construction of QoL measurement scales, (4) reviews published clinical studies that have assessed QoL.
Quality of life in atrial fibrillation is a multidimensional construct. The illustrated flow pattern of anxiety shows interactions among anxiety, muscle tension, and atrial fibrillation (center) affected by anticipatory anxiety, avoidant behavior, and lack of social activities. Concerning quality of life, family interactions, coping strategies, and personal structure.

Quality of life in patients with AF, and (5) outlines the design of new trials currently evaluating QoL in patients with AF.

**IMPORTANCE OF ASSESSING QoL**

In recent years, interest has increased in the measurement of QoL in relation to health care. Several factors have contributed to this growing interest. Advances in medical care have made available an array of therapeutic options, with QoL being the only differentiating factor affecting treatment choice. Quality-of-life issues are becoming central to the management decisions of chronic conditions in an aging population. Increasingly, patients expect to participate as partners in therapeutic decisions, and QoL data facilitate informed choice in making these decisions. Finally, regulatory authorities are requesting QoL outcome data as part of new drug or device approval. These factors highlight the need for a more comprehensive assessment of therapies, which includes a range of variables referred to collectively as QoL. The rationale for QoL assessment in clinical research should be outlined in an analytic model that describes the relationship between predictor variables and response variables and the time frame during which the effects on QoL are elicited.

**DEFINITION OF QoL**

Quality of life is a multidimensional construct, illustrated in the Figure using AF as an example. Multidimensional end points such as QoL present particular problems of design, analysis, and interpretation. Although the concept of QoL is inherently subjective and definitions vary, there is growing consensus that it can be assessed on the basis of 4 principal components: physical condition, psychological well-being, social activities, and everyday activity. These 4 dimensions can be further subdivided. For example, physical condition includes mobility and self-care; social activities include intimacy, support, and family contact; and psychological well-being includes anxiety and depression. Each of these subdivisions can be measured quantitatively.

**CONSTRUCTING QoL MEASUREMENT SCALES**

Quality of life is generally measured with a complex collection of items, scales, domains, and instruments. An item is a single question, and a scale contains the available categories or other mechanisms for expressing the response to the question. A domain identifies a particular focus of attention, such as digestion or functional capacity, and it may comprise the response to a single item or responses to several related items. An instrument is the collection of items used to obtain the desired data. The instrument can contain a single global question or multiple items that may or may not be categorized into separate domains.

The measurement of QoL should address each objective and subjective component that is important to members of the patient population and susceptible to being affected, positively or negatively, by interventions. To compare QoL with other patient groups, it is recommended that standardized instruments be used. Many new instruments reflect the multidimensionality of QoL. The selection of appropriate instruments allows an extensive description of QoL. One of the most important areas for further development is making quantitative change scores for QoL more clinically meaningful. To ensure that the QoL measure used is the most appropriate, the health problem and likely range of impacts of the treatment being investigated need to be carefully considered. Established instruments cannot be assumed to be the most appropriate.

Several factors affect the selection of appropriate instruments to assess QoL. The most important being how well the instrument will perform in the required situation. This can be assessed from the instrument’s psychometric properties, which include reliability, validity, responsiveness, sensitivity, appropriateness to question, and use or practical utility.

Reliability means that the QoL instrument must produce the same
results on repeated use under the same conditions.

Validity is a measure of how appropriate the QoL tool is to the patient population.

Responsiveness is a measure of the association between the change in the observed score and the true value of the construct. Responsiveness is a crucial requirement for most applications, especially in clinical trials.

Sensitivity refers to the ability of the measurement to reflect true changes or differences in QoL.

The instruments and techniques used to assess QoL vary according to the identity of the respondent, the setting of the evaluation, the type of questionnaire used, and the general approach to evaluation.

Generic instruments are used in general populations to assess a wide range of domains applicable to a variety of health states, conditions, and diseases. They are usually not specific to any particular disease state or susceptible patient population and are therefore most useful in conducting general survey research on health and making comparisons between disease states.

Disease-specific instruments focus on the domains most relevant to the disease or condition under study and on the characteristics of the patients in whom the condition is most prevalent. Disease-specific instruments are most appropriate for clinical trials in which specific therapeutic interventions are being evaluated.

Batteries of scales and modular instruments combine the generic and disease-specific approaches by maintaining a core module of questions applicable to diverse disease states and patient populations, to which the questions most relevant to the disease and therapy in question are added as required. Studies have shown that clinicians' and patients' judgment of QoL differ substantially; systematic assessment can overcome this problem.

PREVIOUS STUDIES OF QoL IN PATIENTS WITH AF

Methods that have been used to measure QoL in patients with AF are summarized in Table 1.

Patient Interview

In a long-term follow-up study of 42 patients with supraventricular arrhythmia who were treated with direct current catheter ablation, 35 (83%) reported an improved activity level at interview. The percentage of patients with an improved activity level was significantly lower in patients with preexisting heart disease (P < .001).

In another study, follow-up interviews were conducted with patients undergoing either direct current or radiofrequency catheter ablation of the AV junction; 84% (n = 38) of those treated with radiofrequency catheter ablation and 80% (n = 10) of those treated with direct current catheter ablation reported improvement in their condition. Both these studies have similar limitations. The exact questions used in the interview are not specified, and improved activity or condition are clearly generic constructs. Although the patient perspective was a valuable addition to these studies, the lack of detail makes the findings difficult to interpret. Finally, neither study offered a definition of QoL.

Self-reported Symptoms

A study from the Flecainide Supraventricular Tachycardia Study Group included patient self-report of symptoms as part of a randomized drug trial for treatment of paroxysmal AF. Patients reported significant symptomatic events, which were then validated by transtelephonic monitoring. The symptoms most predictive of paroxysmal AF were palpitations, dizziness, dyspnea, tachycardia, and diaphoresis. A descriptive study by the same group also included patient self-report of symptoms and transtelephonic monitoring in an attempt to establish a link between symptoms and episodes of paroxysmal supraventricular tachycardia or AF. The most frequently reported symptoms in the 64 patients with AF were tachycardia, palpitations, dyspnea, chest pain, and dizziness.

In a 2-phase study by Brignole et al, 23 patients with chronic AF who were refractory to drug therapy were assigned to catheter ablation and VVI-R (ventricular-inhibited rate-adaptive pacing) pacemaker implantation or to VVI-R pacemaker implantation only. Quality of life was assessed by a self-administered, semiquantitative questionnaire. Patients were asked to quantify the extent to which they had experienced palpitations, rest dyspnea, effort dyspnea, exercise intolerance, and asthenia using a scale from 0 (absence) to 10 (maximum). The results showed that ablation therapy was associated with improved functional capacity as classified by the New York Heart Association and improved exercise duration. At the end of 90-day follow-up, patients had significantly lower scores for symptoms of palpitations and effort dyspnea.

In another study, patients underwent AV junctional ablation and pacemaker therapy for drug refractory AF. Self-administered, semiquantitative questionnaires were completed before and after the procedure to (1) score general QoL (1, very bad; 5, very good); (2) assess the frequency and impact of intermittent symptoms; (3) score impairment of ability to perform activities of daily living; and (4) evaluate health care consumption in terms of number of emergency department visits, hospital admissions, and times patients contacted their attending physicians. This study showed that after radiofrequency catheter ablation of the AV node and permanent pacing for established or paroxysmal AF, there were statistically significant positive outcomes in terms of QoL, performance of daily activities, and consumption of health care resources.

In a more recent study, 60 patients with refractory AF were randomly assigned to either complete AV junction ablation with permanent pacing or AV junction modification. All patients kept a detailed diary that included general QoL, frequency of significant symptoms, symptoms during attacks, and ability to perform activities of daily living. Subjective perception of QoL was assessed by a semiquantitative questionnaire before and 1 and 6
months after ablation. The assessment of general QoL before and after ablation was scored on a scale from 0 (very good) to 4 (very bad). The frequency of AF was scored on a scale from 0 (none) to 3 (very frequent). Symptoms resulting from AF were scored on a scale from 0 (no symptoms) to 3 (severe symptoms). Activity limitation was scored on a scale from 0 (not limited) to 3 (severely limited).

Both treatments were associated with a significant improvement in general QoL and a significant reduction in the frequency of major symptoms and symptoms during attacks. However, patients who received complete ablation of the AV junction had significantly greater improvement in general QoL and significantly greater reduction in the frequency of major symptoms and symptoms during attacks. Ability to perform daily tasks improved significantly in both treatment groups.

The studies by Brignole,16 Fitzpatrick,17 and Lee18 and their colleagues all defined good QoL as improved functional capacity and decreased symptoms. However, although questions specific to patients with AF were used, the measures were not validated.

Multidimensional Assessment of QoL

In a study by Hamer et al.,19 69 patients with paroxysmal supraventricular tachycardia or paroxysmal AF were asked to complete a comprehensive psychometric test battery designed to assess a variety of psychological functions, including mood, personality functioning, social and work adjustment, and behavior.
Two thirds of patients considered that the symptoms of paroxysmal AF or supraventricular tachycardia were moderately disruptive to their lives. However, patients who reported a high level of impairment of QoL on direct questioning were not found to score significantly differently on many of these rating scales compared with those whose symptoms were less disruptive. Patients were found to be well adjusted and not emotionally disturbed by their symptoms.

This study demonstrates the feasibility of using an extensive battery of instruments to measure selected dimensions of QoL. However, a major limitation of this study was its cross-sectional design. All patients had been symptomatic for many years, modes of treatment were not reported, and transtelephonic monitoring confirmed that 97% of patients were in sinus rhythm when they completed the QoL tests. Further limitations include the relatively small sample size and the heterogeneity of the arrhythmia groups.

Longitudinal studies enable measurement of QoL variations before and at selected points after therapy is initiated. One such study systematically evaluated rate-adaptive pacing therapy in 12 patients with paroxysmal AF. Psychosocial and physical dimensions of QoL were measured with validated instruments 1 day before and 6 weeks after catheter ablation of the AV junction. In addition, objective assessment of physical function was accomplished by treadmill testing before ablation and 6 weeks later. Scores on both measures increased significantly 6 weeks after the ablation procedure.

Table 1. Summary of Methods Used to Measure Quality of Life in Patients With Atrial Fibrillation (AF)* (cont)

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients, No.</th>
<th>Design</th>
<th>QoL Measure(s)</th>
<th>Main Results</th>
<th>Study Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamer et al,19 1994</td>
<td>69 (n = 43 PSVT and n = 26 PAF)</td>
<td>Cross-sectional, multidimensional QoL assessment</td>
<td>Coping Strategies Questionnaire, Health Locus of Control Scale, Hopkins Symptom Checklist, McGill Pain Inventory, Psychosocial Adjustment to Illness Scale, and State-Trait Anxiety Inventory</td>
<td>No significant differences were found between scores of patients with the 2 types of arrhythmias; patients were described as basically well adjusted</td>
<td>Relatively small sample size, heterogeneity of arrhythmias, lack of a control group, and most patients were in sinus rhythm when they completed the questionnaire</td>
</tr>
<tr>
<td>Kay et al,20 1988</td>
<td>12</td>
<td>Longitudinal study of DC ablation</td>
<td>McMaster Health Index Questionnaire and Psychological General Well-being Index</td>
<td>Scores on both measures increased significantly from before ablation to 6 wk after ablation</td>
<td>Small sample size, no control group, and DC rather than RF ablation</td>
</tr>
<tr>
<td>Bubien et al,21 1996</td>
<td>159 (n = 22 AF)</td>
<td>Longitudinal study, multidimensional QoL assessment, and definition of QoL</td>
<td>Medical Outcomes Study Short-Form Health Survey, Symptom Checklist: Frequency and Severity, perceived impact, perceived effects</td>
<td></td>
<td>Highly selected symptomatic patients, influence of anxiety is unknown, the potential negative impact of AAD on QoL is unknown, and no control group</td>
</tr>
<tr>
<td>Brignole et al,22 1997</td>
<td>43 severely symptomatic PAF</td>
<td>Randomized to AVN ablation and DDD-R PM or to drug treatment</td>
<td>Minnesota Living With Heart Failure Questionnaire and Specific Symptoms Scale</td>
<td>After 6 mo, ablation and DDD-R PM treatment is highly effective and superior to drug therapy in controlling symptoms and improving QoL</td>
<td>Small sample size, the negative impact of AAD on QoL is unknown, and highly symptomatic patients with PAF</td>
</tr>
<tr>
<td>Brignole et al,23 1998</td>
<td>66 CAF and heart failure</td>
<td>Randomized to AVN ablation and VVI-R PM or to drug treatment</td>
<td>Minnesota Living With Heart Failure Questionnaire and Specific Symptoms Scale</td>
<td>After 12 mo, ablation and VVI-R PM treatment is effective and superior to drug therapy in controlling symptoms but to a lesser extent than that observed in uncontrolled studies; cardiac performance is not modified</td>
<td>Highly symptomatic patients with CAF and a significant crossover rate (30%)</td>
</tr>
<tr>
<td>Kay et al,24 1998</td>
<td>156 AF</td>
<td>Prospective, multisite registry</td>
<td>Global Health Status Questionnaire, Quality of Life Index for Cardiac Patients, and Symptom Checklist: Frequency and Severity</td>
<td>After 12 mo, ablative and PM treatment is associated with improved QoL and left ventricular dysfunction</td>
<td>Highly selected severely symptomatic patients with AF; no randomized controlled trial, effect of AAD is unknown, and most patients with a PM had no sophisticated mode-switching algorithms</td>
</tr>
</tbody>
</table>

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* Aflut indicates atrial flutter; CAF, chronic atrial fibrillation; PAF, paroxysmal atrial fibrillation; PSVT, paroxysmal supraventricular tachycardia; QoL, quality of life; DC, direct current; RF, radiofrequency; PM, pacemaker; AAD, antiarrhythmic drug treatment; AVN, atrioventricular node; DDD-R, dual-chamber rate-adaptive; and VVI-R, ventricular-inhibited rate-adaptive.
More recently, a longitudinal study \(^{21}\) assessed the impact of radiofrequency catheter ablation on QoL in 159 patients with a variety of tachyarrhythmias. In this study, the term QoL was used according to the definition of Wenger et al. \(^{22}\) ie, encompassing total well-being of the person, including psychosocial and physical aspects. A battery of 4 QoL measures was used before ablation and 1 and 6 months after ablation. The Medical Outcomes Study Short-Form Health Survey (SF-36) \(^{23}\) was used to assess 8 dimensions of health status and well-being. A disease-specific instrument, the Symptom Checklist: Frequency and Severity, was applied to measure the patient’s perception of the frequency and severity of arrhythmia-related symptoms. Two investigator-developed, brief instruments were also included: Perceived Impact of the Arrhythmia and Effects of Arrhythmias on Activities of Daily Living. Patients with AF had the lowest scores at baseline on the SF-36. Catheter ablation was associated with significant improvement in the generic SF-36 health status questionnaire and the disease-specific Symptom Checklist scores and with increased performance of activities of daily living and a marked decrease in the consumption of health care resources.

Although this study provided a great deal of information, there were several limitations. Patients were symptomatic and highly selected, raising the possibility that the results might not be applicable to a less symptomatic population. Furthermore, because patients were withdrawn from prestudy medication treatment, it is unclear whether the marked improvements in measurements of QoL were related solely to catheter ablation. The removal of drug-related adverse effects might have had some effect. Finally, a control group of untreated patients was not included in the study.

Two more recent studies from Brignole et al. \(^{24,25}\) used validated tools to measure QoL in patients with AF treated with AV junction ablation and an implantable pacemaker or standard drug therapy.

In the first of these studies, \(^{24}\) 43 patients with severely symptomatic paroxysmal AF were randomized to treatment with either AV ablation and a DDD-R (dual-chamber rate-adaptive pacing) mode-switching pacemaker or standard drug therapy. A comprehensive evaluation of the patient’s QoL was made using the Minnesota Living With Heart Failure Questionnaire, the reliability and validity of which are well established. \(^{26}\) This 21-item, self-administered questionnaire comprehensively covers physical, socioeconomic, and psychological impairments. A score based on how each person ranks each item on a common scale is used to quantify the extent of impairment and how it is affected by therapeutic intervention. In addition, the Specific Symptoms Scale was used to measure the patient’s perception of the frequency and severity of arrhythmia-related symptoms. Palpitations, effort dyspnea, rest dyspnea, exercise intolerance, easy fatigue at rest, and chest discomfort were all rated on a scale from 0 to 10.

At the end of the 6-month study, the ablation-and pacemaker-treated patients showed significantly better scores on the Minnesota Living With Heart Failure Questionnaire, palpitations, effort dyspnea, exercise intolerance, and easy fatigue compared with the drug group. In this small population with severely symptomatic paroxysmal AF, ablation and pacemaker treatment is highly effective and superior to drug therapy in controlling symptoms and improving QoL.

In the second study by Brignole et al. \(^{25}\) 66 patients with heart failure and chronic AF were randomized to treatment with either AV junction ablation and an implantable VVI-R pacemaker or standard drug therapy. The same QoL tools were used as in the previous study. At the end of the 12-month study, the ablation and pacemaker group had significantly better scores in palpitations and effort dyspnea than the drug group. There were no significant differences in Minnesota Living With Heart Failure Questionnaire scores, with both methods of treatment demonstrating improvement over baseline.

The recently completed Ablate and Pacem Trial \(^{27}\) was a prospective, multisite registry study that assessed the effects of catheter ablation of the AV conduction system and permanent pacemaker implantation on health-related QoL in 156 patients with AF. A consecutive series of patients with AF who remained highly symptomatic despite standard drug therapy was included. Quality of life was defined as individually perceived, dynamic, multidimensional, and quantifiable by individual self-report of patients. A tiered approach to assessing QoL was used, which incorporated the following instruments: the Global Health Status Questionnaire, the Quality of Life Index for Cardiac Patients, \(^{28,29}\) and the Symptom Checklist: Frequency and Severity. The QoL measures were performed at baseline and 3 and 12 months after catheter ablation.

A preliminary study showed that, at baseline, all subscale scores of the Global Health Status Questionnaire were significantly lower for patients with AF compared with normative scores for patients with congestive heart failure or a recent myocardial infarction. \(^{30}\) The scores of the Quality of Life Index and the Symptom Checklist were lower in the AF group than in other cardiac groups. Although this study was limited to a select group of highly symptomatic patients, it is apparent that the disease burden of AF can be considerable.

After ablation and implantation of a pacemaker, significant improvements in QoL scores were noted for all 8 subscales of the Global Health Status Questionnaire, for the overall rating of the Quality of Life Index, the Health and Function subscales, and arrhythmia-related symptoms were markedly reduced as measured by the Symptom Checklist: Frequency and Severity scale.

Again, this study had several limitations. First, it was a prospective registry rather than a randomized, controlled trial. This makes it impossible to be certain that all the improvements in QoL were the result of catheter ablation and pacemaker implantation. In addition, patients included in this registry were highly selected and severely symptomatic. The results, therefore, cannot be extrapolated to less severely compromised patients.
A new international study has been set up to address the lack of informative trials are currently examining the impact of AF on QoL.

Two important large-scale prospective trials are currently examining the impact of AF on QoL.

Table 2. Quality of Life in Atrial Fibrillation (AF): Timing of Questionnaire Administration

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Timing of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic data</td>
<td>Baseline, 3 mo, 6 mo, 12 mo, After Shock, After AF</td>
</tr>
<tr>
<td>Life Orientation Test</td>
<td>X</td>
</tr>
<tr>
<td>Barsky Somatization Scale</td>
<td>X</td>
</tr>
<tr>
<td>Atrial Fibrillation Severity Scale</td>
<td>X</td>
</tr>
<tr>
<td>Medical Outcomes Study</td>
<td>X</td>
</tr>
<tr>
<td>Short-Form Health Survey</td>
<td>X</td>
</tr>
<tr>
<td>Goldman Specific Activity Scale</td>
<td>X</td>
</tr>
<tr>
<td>Symptom Checklist: Frequency and Severity</td>
<td>X</td>
</tr>
<tr>
<td>Illness Intrusiveness Scale</td>
<td>X</td>
</tr>
<tr>
<td>Impact of Events Scale</td>
<td>X</td>
</tr>
</tbody>
</table>

Table 3. Symptoms for Different Types of Atrial Fibrillation (AF) Recorded on the Atrial Fibrillation Severity Scale

<table>
<thead>
<tr>
<th>Symptom Score</th>
<th>Paroxysmal AF</th>
<th>Persistent AF</th>
<th>Permanent AF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of last episode (0-10)</td>
<td>5.0</td>
<td>4.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Severity of average episode (0-10)</td>
<td>5.5*</td>
<td>4.5</td>
<td>3.2</td>
</tr>
<tr>
<td>Total symptoms (0-6)</td>
<td>3.7†</td>
<td>2.7</td>
<td>2.9</td>
</tr>
</tbody>
</table>

*P = .001 vs other types of AF
†P < .001 vs other types of AF.

ONGOING STUDIES OF QoL IN PATIENTS WITH AF

Two important large-scale prospective trials are currently examining the impact of AF on QoL.

International Quality of Life Investigators

A new international study has been set up to address the lack of information on the effect of AF on systematically measured QoL. This study will attempt to measure QoL systematically in patients with AF (and in an age- and sex-matched healthy control group) using validated generic measures and specifically constructed disease scales. This approach might help identify the types of measures that may be useful in assessing QoL in patients with AF.

The questionnaires to be used and related information about the severity of the disease are listed in Table 2. Patients will complete the following instruments at baseline only: (1) A Standard Demographic Instrument will be used to record the patient’s age, sex, education level, social contacts, and socioeconomic status. In addition, 2 predictive scales will be used to identify subsets of patients who might be more or less responsive to various interventions. (2) The Life Orientation Test (13 items) is a measure of optimism and has been shown to have good internal consistency and good discriminatory validity with respect to related constructs. (3) The Barsky Somatization Scale is a 10-item measure of somatization and has been used in a variety of cardiac populations, including patients with paroxysmal AF.

The following outcome scales will be given to patients at baseline and at 3, 6, and 12 months: (1) The SF-36, which has been used and validated in a diverse spectrum of disease states, in general cardiac populations, and in patients with implantable cardioverter defibrillators. (2) The 20-item modified Goldman Specific Activity Scale is a functional status scale for patients with cardiovascular diseases. Evaluation in a small sample of patients with pacemakers suggests good convergent validity and high test-retest reliability. (3) The Symptom Checklist (16 items) quantifies symptom frequency and severity of symptoms related to arrhythmias. (4) The Illness Intrusiveness Scale is a 13-item scale designed for patients with chronic illnesses. This scale has been validated in several diverse disease states.

A summary score will then be used to classify the patient’s clinical burden of AF as mild, moderate, or severe. The Clinical Disease Burden Score will reflect objective and subjective portions of the clinical disease burden and severity obtained from the patient. The physician or study coordinator will record objective assessments, and these variables will be combined with patient self-report items to provide a matrix of clinical disease severity and a summary score, the Atrial Fibrillation Severity score.

Preliminary results from this group of investigators have started to answer some of the questions concerning AF and QoL. For example, the effect of clinical type of AF on QoL has been assessed in a group of 147 patients with AF.33 Atrial fibrillation was categorized as paroxysmal (n = 79), persistent (n = 51), or permanent (n = 17). The specifically designed Atrial Fibrillation Severity Scale was used to assess symptom distress and health-related QoL. Patients with paroxysmal AF who often have frequent, highly symptomatic recurrences seem to have a higher incidence of more severe symptoms (Table 3) and a significantly lower QoL than those with persistent or permanent AF.

When a similar group of patients (paroxysmal, n = 85; persistent, n = 50; and permanent, n = 25) was assessed using the SF-36 and the Symptom Checklist, no significant differences were noted across the AF subgroups.34 The difference between these 2 results highlights the value of disease-specific measures of QoL.

More recently, the long-term impact of AF on QoL was assessed in 175 patients who completed the questionnaires (the SF-36 and the Symptom Checklist) at baseline and at 3-, 6-, and 12-month intervals. At baseline, the scores on the SF-36 demonstrated health dysfunction for patients with AF compared with pre-
Recently completed prospective study\(^35\) focused on the international QoL study. The results of a re-parameterized, large-scale clinical trial that intends to randomize 5,300 patients for an average of 3.5 years to a strategy of ventricular rate control or antiarrhythmic drug therapy with a primary end point of total mortality. Quality of life is a secondary end point in this study. The SF-36, the Quality of Life Index for Cardiac Patients, and the Symptom Checklist: Frequency and Severity are being used to collect data at baseline, at intervals during the first year of follow-up, and annually.

**LIMITATIONS**

Regarding only the above-reviewed studies on QoL in patients with AF, it can be stated that generally the sample sizes are too small and often limited to symptomatic patients who might be drug refractory. All but 1 of the studies were prospective; however, control groups frequently were not used. So far no study focused on the international aspect of QoL. The results of a recently completed prospective study\(^35\) showed similar QoL findings in 4 countries on 2 continents. Based on these results, it seems that the effect of AF on QoL is consistent across diverse populations and transcends any cultural or language differences that were present in the 4 centers that participated in the international QoL study.

There are other limitations that are inherent to measurement of QoL. Although the items in most of the QoL instruments were specifically constructed to minimize response bias, and although response bias is decreased with the use of anonymous mail surveys, self-reporting methods might be confounded by underreporting of undesirable characteristics and overreporting of socially desirable characteristics. In addition, participants who undergo an invasive procedure may report improvements in QoL simply as a result of being part of a treatment group.

In studies with a multidimensional approach, various instruments were applied to assess QoL. One can easily understand how difficult it is to compare QoL across studies given the variation in instruments selected. Selection of appropriate instruments to measure QoL is a challenge. Attention must be given to the psychometric measures—in particular, reliability and validity—as well as to the design of QoL studies. As can be seen from the information presented from the studies reviewed, much has yet to be learned about QoL in patients with AF. Quality of life can be suitably measured only by determining the preferences of the patients and by supplementing (or replacing) the authoritative opinions contained in statistically validated and approved instruments. Unless greater emphasis is placed on the distinctive sentiments of patients, QoL might continue to be measured with a psychometric statistical elegance that is accompanied by unsatisfactory face validity.

**CONCLUSIONS**

It is apparent that the disease burden of AF can be considerable. However, much additional information should be learned about QoL in patients with AF over the next few years. The InControl Quality of Life Investigators will provide comprehensive information about various aspects of AF using validated QoL tools. In addition, the Atrial Fibrillation Follow-up Investigation of Rhythm Management will provide valuable knowledge about the impact of specific drug therapy on QoL in patients with AF. It seems likely that QoL assessments will become increasingly important in the development of new antiarrhythmic drugs and other nonpharmacological treatments for AF. Finally, it is clear that rigorous yet practical approaches are needed to facilitate a comprehensive understanding of QoL in patients with AF.

**REFERENCES**


