Individualised quality of life after pacing. Does mode matter?

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Abstract

Aims To examine the hypothesis that atrial based pacing improves Quality of Life (QoL) after pacing by undertaking a detailed QoL evaluation that includes an individualised assessment as well as disease specific evaluation.

Methods Prospective study of patients randomised to VVI(R) or atrial based pacing modes using the Schedule for the Evaluation of Individual QoL (SEIQoL), the 36-item Medical Outcomes Study Short-form General Health Survey (SF36), and a modified version of the Karolinska Cardiovascular Symptomatology Questionnaire (KCSQ).

Results Seventy-three patients completed the two-year follow up of the study. Pacing improved SEIQoL scores, cardiovascular symptoms and the physical role limitation, social limitation and mental health domains of SF36 from baseline to one month. Pacing mode had no effect on QoL the major determinants of which were baseline QoL and a history of coronary artery disease.

Conclusion Atrial based pacing does not improve QoL in the two years after pacing when compared with VVI(R) pacing.

Introduction

The initial aims of pacemaker technology were to prolong life and ameliorate the symptoms of bradycardia, predominantly syncope and heart failure. Unsophisticated pacemakers can achieve these ends and it is only since the advent of improved pacemaker technology and choice in pacemaker mode that Quality of Life (QoL) assessments have become relevant to pacemaker patients. The theoretical advantages of maintaining Atrioventricular (AV) synchrony and varying pacing rate have been demonstrated to cause acute...
haemodynamic advantages and in small, often retrospective, studies to lead to clinical advantages. Larger scale prospective studies have demonstrated significant advantages in survival, stroke risk and the development of atrial fibrillation (AF) for patients with sinus node disease, with atrial based rather than VVI(R) pacing [1–3]. These advantages however have required several years of follow up to become apparent and have not been confirmed by all subsequent multi-centre studies [4].

It is clear, therefore, that differences between pacemaker modes are not so dramatic as to cause a readily detectable change in survival, stroke or AF in the majority of patients and measuring QoL therefore provides an alternative way of investigating differences between pacing modes. QoL assessment has consequently been accepted as an integral component of the comparative evaluation of pacemaker modes. It was the primary outcome of the Pacemaker Selection in the Elderly (PASE) trial [5] and a secondary outcome measure in the United Kingdom Pacing and Cardiovascular Events (UKPACE) trial and the Canadian Trial of Physiologic Pacing [6,7]. These studies have used widely recognised generic health indices that assess health related QoL but are not specific for particular disease states. These assessment tools may be complemented therefore by the use of individualised QoL assessment and disease specific symptom scales. The former allow measurement of subjective QoL that is not confined to health related parameters while the latter assess symptoms directly related to the underlying condition.

This study was therefore designed to assess the effect of pacemaker mode on individualised QoL by comparing an individualised evaluation with a generic health index and disease specific symptom scale.

Methods

Patient selection

Patients recruited to either of two multi-centre pacemaker trials (UKPACE or STOP-AF) at the Freeman Hospital in Newcastle upon Tyne, between January 1997 and May 1999, were invited to participate in this study of QoL. UKPACE (The United Kingdom Pacing and Cardiovascular Events study) assessed the impact of pacemaker mode on the mortality of patients older than 70 years with high degree AV block [6]. Patients were randomised by hardware (i.e. by type of pacemaker implanted) to DDD, VVI or VVIR pacing in a ratio of 2:1:1. STOP-AF (the Systematic Trial of Pacing to prevent Atrial Fibrillation) assessed the impact of pacing mode on the development of AF after pacing for sinus node disease [8]. Randomisation was by software i.e. all patients were implanted with a dual chamber device which was then programmed to atrial based i.e. AAI(R) or DDD(R), or ventricular based i.e. VVI(R), pacing in a ratio of 1:1. Patients were ineligible for inclusion in the QoL study if they were visually impaired, lived more than 20 miles from the recruitment centre or had overt cognitive dysfunction that precluded informed consent.

QoL assessment

Patients underwent a QoL evaluation within 24 h of pacemaker implantation, and one month, one year and two years later. QoL evaluations prior to pacing were undertaken by the primary author (GMG). Subsequent evaluations were undertaken by a psychology research assistant at the patient’s domicile or in a tertiary referral neurocardiovascular research establishment. The QoL assessment tools used were the Schedule for the Evaluation of Individual QoL (SEIQoL), the 36-item Medical Outcomes Study Short-form General Health Survey (SF36), and a modified version of the Karolinska Cardiovascular Symptomatology Questionnaire (KCSQ).

SEIQoL [9] allows an individualised QoL evaluation that is not confined to health related matters and may therefore more accurately reflect QoL [10]. Individualisation is achieved by asking patients to evaluate those areas of life of greatest importance to them. Firstly, subjects are asked to nominate the five domains of their life which they consider to be the most important, secondly these domains (or cues) are graded by the subject on a visual analogue scale from 0 to 100 (as a measure of how well or badly that aspect of life is going) and thirdly the cues are weighted (as a measure of how important that cue area is to the subject). The SEIQoL score is derived from combining the cue score with its weighting and summing the combined scores for each cue. The maximum score is 100 and higher scores reflect better QoL.

SF36 [11] is a generic health profile covering the QoL domains of physical, emotional and social functioning, productivity, pain and self-perception of health. It provides scores in eight subsections; physical limitation, social limitation, role limitation due to physical problems, role limitation due to emotional problems, mental health,
perception, energy and pain. Responses are transformed to a score of 0–100 where a higher score represents a better QoL within that subsection.

KCSQ is one of the few QoL questionnaires validated for use with pacemaker patients [12]. It assesses severity of symptoms in the areas of breathlessness, chest pain, palpitations and dizziness. It comprises a 16-point scale [13] that originally used a visual analogue scale to respond to each question. The majority of the questions however meet the criteria for cumulative scaling and a single result therefore informs how each question is answered and furthermore eliminates the need for weighting the importance of each question [14]. For the purposes of this study therefore the response pattern was modified to a binary format providing a maximum total score of 16 with higher scores indicating more severe symptoms.

Statistical analysis

To assess the impact of pacing per se, rather than pacemaker mode, paired comparisons between baseline and one month scores were made using paired sample t tests and Wilcoxon signed ranks for parametric and non-parametric data, respectively.

Data from each of the QoL outcome measures were analysed using general linear model analysis for repeated measures (GLM-ANCOVA) using the baseline score as a covariate, to control for inter-individual variation, and pacemaker mode as a between-subjects factor. Within-subject contrasts were inspected for the effect of time and the interaction of time and pacing mode, and between-subject contrasts inspected for the independent effect of pacing mode. Only subjects who completed the two-year follow up i.e. all four assessments, were included in the analysis. Summary data were also included in a last observation carry forward analysis to assess whether missing data points may have altered the outcome of the study.

The effect of clinical variables other than pacemaker mode on QoL was assessed using independent sample t tests or Mann Whitney U tests for categorical variables and Pearson or Spearman correlations for continuous variables. Any variable found to alter QoL was then further analysed as a between-subjects factor in a General Linear Model for Analysis of Covariance (GLM-ANCOVA) analysis while maintaining baseline score as a covariate.

Categorical variables are shown as number (percentage) and continuous variables as mean (standard deviation). Analysis was conducted using SPSS version 10 with significance inferred at the 5% level.

A reverse power calculation was made using the SEIQoL data to estimate the confidence with which these data could be extrapolated.

Results

One hundred and fifty eight patients were initially enrolled into the study. Thirty-five died, 37 withdrew or were withdrawn from the study prior to its completion. SF36 was completed by 142 patients at baseline, 122 at one month, 108 at one year and 89 at two years. Only those subjects who completed each stage of QoL assessment were included in the analysis of the effect of pacing mode. Seventy-three patients completed all stages of SF36 evaluation at all four time points of the study. The baseline clinical characteristics of this group are shown in Table 1. Thirty-eight (52%) of these were paced for AV block and the remaining 35 (48%) for sick sinus syndrome. The pacing modes to which they were randomised are shown in Table 2. Prior to pacemaker implantation 51% were taking aspirin, 4% warfarin, 12% an angiotensin converting enzyme inhibitor, 7% a beta blocker and 7% an anti-arrhythmic drug (amiodarone in two, propafenone in one and sotalol in another two cases). An estimate of reliance on pacing support was made by calculating the proportion of paced ventricular beats accumulated during the follow up period. The mean percentage of paced ventricular beats was 64% for the 73 patients contributing QoL data. There was however a wide range of percentage of pacing with approximately 25% of patients experiencing 100% ventricular pacing and 5% experiencing no ventricular pacing.

| Number | 73 |
| Age | 76.2 (7.1) years. |
| Range | 55–88 years |
| Male gender | 41 (56%) |
| NYHA category at baseline | 33 NYHA I (45%) |
| 28 NYHA II (38%) |
| 12 NYHA III (16%) |
| History of: |
| Diabetes | 7 (10%) |
| Ischaemic heart disease | 24 (33%) |
| Cerebrovascular disease | 6 (8%) |
| Hypertension | 23 (32%) |
| Cardiac failure | 10 (14%) |
| Atrial fibrillation | 16 (22%) |
Eight patients were withdrawn from the study (four because of a mode change due to pacemaker syndrome or a new diagnosis of carotid sinus hypersensitivity, two because of physical frailty, one who moved away and a fourth who developed dementia). Twenty-nine patients declined to continue with the study, predominantly due to inclusion of the QoL assessment in a comprehensive neuropsychological assessment which many patients found arduous. Of these 37 patients, 26 were paced in VVI(R) mode and 27 were female. Female gender was the strongest predictor of withdrawal (OR 3.5, 95% CI 1.5–8.3) and VVI(R) pacing also had an independent association with likelihood of withdrawal (OR 2.6, 95% CI 1.1–8.3).

Baseline SF36 scores were not significantly different between patients who did or did not complete all four data points.

SEIQoL

Mean SEIQoL scores during the study are illustrated in Fig. 1. The mean score increased after pacing from 72.7 (17.4) to 81.2 (15.2), \( P < 0.001 \). There was no significant difference between mean scores at baseline and two years (75.4 (16.7) vs 76.9 (10.6), \( P = 0.5 \)) and no significant effect of pacemaker mode on SEIQoL score over the period of the study (\( P_{\text{mode}} = 0.5 \), by GLM-ANCOVA analysis).

A reverse power calculation [15] suggested that given the group size (64 patients completed SEIQoL at all four stages), there is an 80% chance of detecting, at the 5% level, a difference in SEIQoL scores of 6.5. This difference is more than that seen between healthy people and patients with peptic ulcer disease but less than that seen between healthy people and patients with irritable bowel syndrome (difference = 14.6) or healthy elderly people and patients with osteoarthritis (difference = 20.5) [16]. These estimates therefore suggest that the study was adequately powered to detect a meaningful difference.

The range of cues used in SEIQoL was considerable and is illustrated in Fig. 2. The graph has grouped cues into broad categories but no restriction was placed on cue choice and the categories include many related cues. For example, the miscellaneous category includes abstract concerns such as integrity, tolerance, violence, altruism and concrete considerations such as pets, voluntary work and a pipe. The most commonly quoted cues were those related to family, personal health, leisure activities and friends. Health comprised 15% of cues i.e. was nominated by 75% of patients (each patient nominated five cues). It is clear from this chart however that health was by no means the primary concern of the patients involved.

SF36

The mean baseline and one month scores for each domain of the SF36 are shown in Table 3. There were significant improvements in QoL in the areas of role limitation due to physical problems, social

![Table 2: Incidence of randomised pacemaker modes](https://academic.oup.com/europace/article-abstract/6/6/553/508083/65258083)
limitation, and mental health in the first month after pacemaker implantation. No significant changes were seen in the areas of physical limitation, role limitation due to emotional problems, health perception, energy or pain. Mean scores at each time point for the subjects who completed each assessment are shown in Table 4. The table confirms a significant effect of baseline function on subsequent scores and no effect of pacemaker mode on QoL as assessed by SF36.

### KCSQ

There was no significant difference in mean total symptom score between the two pacing mode groups at baseline (7.1 (3.9) for the VVI(R) vs 7.6 (4.3) for the atrial based group, \( P = 0.6 \)) but a highly significant decrease in score i.e. improvement in symptoms, after pacing (7.3 (4.0) vs 4.4 (4.1), \( P < 0.001 \)). Over the next two years symptomatology tended to worsen with a return towards pre-pacing levels, see Fig. 3. There was however no significant effect of pacemaker mode on symptom score either for the total score or the specific symptoms assessed, see Table 5. Baseline symptom score was significantly predictive of subsequent performance.

### Summary scores

There was no significant effect of pacing mode when SEIQoL, total SF36 and total KCSQ scores were further analysed by last observation carry forward analysis, see Table 6. This summary score analysis suggests that exclusion of patients with incomplete data from GLM-ANCOVA analysis has not obscured an effect of pacing mode.

### Clinical correlates with QoL

There were a number of associations between QoL and clinical variables other than pacing mode. The QoL outcome measure used to investigate clinical associations was the total SF36 score (i.e. the sum of the subsection scores) expressed as a percentage. This variable was normally distributed allowing parametric comparisons to be made. The most striking association was with coronary artery disease. This led to a progressive deterioration in QoL over the follow up period (see Fig. 4) and on GLM-ANCOVA analysis a history of coronary disease was independently associated with QoL, \( P = 0.007 \). The baseline SF36 score also remained significantly associated with subsequent scores, \( P < 0.001 \). Similarly a history of cerebrovascular disease prior to pacing was associated with a significant reduction in QoL over the follow up period, \( P = 0.04 \) on GLM-ANCOVA. There were however only six patients with a history of cerebrovascular disease in the 73 who completed all four SF36 assessments so this association may be more related to chance than that seen with coronary disease.

Diabetes, hypertension, heart failure (either as a dichotomised variable or categorised as NYHA I, II or III) and female gender were all associated with significantly reduced QoL at one or more time points. For none of these variables, however, was a significant association seen on analysis including the variation due to baseline performance. None of the other variables assessed i.e. indication for pacing, proportion of paced ventricular beats, age, AF before pacing, or use of calcium channel blockers, aspirin, warfarin, ace-inhibitors or beta-blockers affected QoL after pacing.

The impact of coronary disease was also evident in analysing the subscales of the KCSQ. Coronary disease was associated with significantly reduced scores for breathlessness (\( P = 0.006 \)) and dizziness (\( P = 0.03 \)) but not for chest pain, presumably because of the overwhelming effect of the low baseline score for people with coronary disease. Coronary disease, however, had no association with individualised QoL as measured using SEIQoL.

### Table 3  Mean SF36 scores at baseline and one month

<table>
<thead>
<tr>
<th>SF36 domain</th>
<th>Baseline score</th>
<th>One month score</th>
<th>( N )</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical limitation</td>
<td>46.3 (28.6)</td>
<td>48.0 (29.5)</td>
<td>120</td>
<td>0.1</td>
</tr>
<tr>
<td>Role limitation due to physical problems</td>
<td>22.1 (34.6)</td>
<td>36.5 (42.0)</td>
<td>120</td>
<td>0.002</td>
</tr>
<tr>
<td>Role limitation due to emotional problems</td>
<td>49.2 (45.5)</td>
<td>55.0 (43.4)</td>
<td>120</td>
<td>0.3</td>
</tr>
<tr>
<td>Social limitation</td>
<td>51.5 (25.7)</td>
<td>58.8 (26.9)</td>
<td>121</td>
<td>0.006</td>
</tr>
<tr>
<td>Mental health</td>
<td>72.8 (18.7)</td>
<td>77.5 (18.9)</td>
<td>120</td>
<td>0.003</td>
</tr>
<tr>
<td>Energy</td>
<td>41.6 (23.2)</td>
<td>54.1 (23.9)</td>
<td>118</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>63.3 (31.1)</td>
<td>65.6 (28.7)</td>
<td>120</td>
<td>0.2</td>
</tr>
<tr>
<td>Health perception</td>
<td>56.5 (23.7)</td>
<td>58.4 (23.9)</td>
<td>120</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Key: scores are shown as mean (standard deviation), \( N \) denotes the number of patients in the paired comparison, \( P \) calculated from Wilcoxon signed ranks test.
This study was designed to make an individualised assessment of QoL after pacing using a unique evaluation tool that has not previously been applied to patients with cardiovascular disease. This is not feasible in large scale trials and these data complement the findings of multi-centre trials. Pacing was shown to improve QoL as assessed by SEIQoL but this improvement was not maintained and over the following two years SEIQoL scores reverted to pre-pacing values. At one year SEIQoL scores for patients with VVI(R) pacemakers were lower than those from patients with atrial pacing systems but not significantly so (P = 0.09). Very similar results were obtained from the generic health index SF36 and the symptom scale KCSQ. For all three instruments the major factor affecting QoL throughout was the baseline QoL and in no case did mode of pacing significantly alter QoL. Thus despite using a generic health index, a pacing specific symptom scale and an individualised QoL assessment no influence of pacemaker mode could be detected.

The lack of effect of pacing mode is in contrast to the early data assessing the relationship between pacing mode and QoL. In the 1990s a number of prospective cohort studies assessed quality of life in small numbers of pacemaker patients using a range of QoL assessment tools [12,17–23].

Discussion

This study was designed to make an individualised assessment of QoL after pacing using a unique tool that has not previously been applied to patients with cardiovascular disease. This is not feasible in large scale trials and these data complement the findings of multi-centre trials. Pacing was shown to improve QoL as assessed by SEIQoL but this improvement was not maintained and over the following two years SEIQoL scores reverted to pre-pacing values. At one year SEIQoL scores for patients with VVI(R) pacemakers were lower than those from patients with atrial pacing systems but not significantly so (P = 0.09). Very similar results were obtained from the generic health index SF36 and the symptom scale KCSQ. For all three instruments the major factor affecting QoL throughout was the baseline QoL and in no case did mode of pacing significantly alter QoL. Thus despite using a generic health index, a pacing specific symptom scale and an individualised QoL assessment no influence of pacemaker mode could be detected.

The lack of effect of pacing mode is in contrast to the early data assessing the relationship between pacing mode and QoL. In the 1990s a number of prospective cohort studies assessed quality of life in small numbers of pacemaker patients using a range of QoL assessment tools [12,17–23].
The vast majority of the patients involved had AV block and were pacemaker dependent. They might therefore be expected to be sensitive to changes in pacemaker mode and, indeed, in many of these studies a detectable difference was found after only a few weeks in each mode. This may however have been a consequence of the crossover design of the studies. By definition this exposed each patient to different modes thus allowing direct comparison for each individual. While this method has merit in investigating potential differences between modes it does not reflect the reality of pacing practice.

QoL evaluation was subsequently incorporated into a number of larger scale multi-centre randomised controlled studies of which PASE [5] was the first to be published. This study compared the effects of VVIR and DDDR pacing on 407 patients requiring pacemaker implantation. The primary outcome measure of the study was health related QoL as measured by SF36 and disease specific cardiovascular status was additionally assessed using the Specific Activity Scale (SAS). PASE demonstrated that health related QoL improved after pacing but that the mode specific benefits of DDDR pacing were modest and confined to a subset of patients with sinus node dysfunction. The Mode Selection Trial (MOST) also used SF36 and SAS to assess the effect of pacemaker mode on QoL [24]. In this study of 2010 patients with sinus node disease DDDR pacing led to significant improvements in six of the eight subscales of SF36 over the 48-month follow up. No improvements in SAS scores were however seen and analysis on an intention to treat basis showed no QoL advantage of DDR pacing. QoL assessment was also a secondary endpoint in the Canadian Trial of Physiologic Pacing (CTOPP) [7]. QoL was assessed using generic health indices, pacing specific questionnaires and global measures of well being in two protocols of different intensity. No significant health related QoL difference between ventricular and atrial based pacing modes was seen.

There are many potential reasons why this study has not duplicated the modest improvements in QoL seen in PASE and MOST. Firstly it may have included too few patients followed for too short a time. Certainly the findings of PASE and MOST will have a major impact on power calculations for sample size of any future planned trials but these data were not available at the onset of this study and data that were available suggested large differences in QoL between different pacing modes. Importantly for this study, a reverse power calculation suggests that it was adequately powered to detect an important difference in SEIQoL scores. The length of follow up required to detect differences between pacing modes also remains contentious. The Scandinavian series of trials of pacing for sinus node disease have required a mean follow up exceeding five years to demonstrate significant differences between pacemaker modes [1]. Secondly the tools used to assess QoL may be too blunt to detect the impact of pacing mode. Both SF36 and SEIQoL have been criticised for having poor sensitivity in cardiac patients [25]. SF36 however is a well validated and reliable tool that has been used in a number of disease states and being too blunt to detect differences implies that the differences are too small to matter. A third possible explanation is that the gradual reduction in QoL from one month to two years after pacing, which suggests a reduction in the overall benefits of pacing per se, obscures any specific effect of pacing mode. In addition it may be the case that atrial based pacing genuinely has no benefit on QoL after pacing.

The major difference between these data and the multi-centre studies mentioned above however is the inclusion of the individualised QoL assessment SEIQoL. This complements the data from SF36 and the KCSQ but also is consistent with it, i.e. QoL improved after pacing with no subsequent effect of pacemaker mode on QoL. The additional aspect of QoL assessment that SEIQoL addresses is the individualisation of QoL. It is clear from this that while the majority of patients

<table>
<thead>
<tr>
<th>Table 6</th>
<th>Last observation carry forward ANOVA</th>
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<tr>
<td></td>
<td>Atrial based pacing</td>
</tr>
<tr>
<td>N</td>
<td>Mean (standard deviation)</td>
</tr>
<tr>
<td>SEIQoL</td>
<td>65</td>
</tr>
<tr>
<td>Total SF36</td>
<td>65</td>
</tr>
<tr>
<td>Total KCSQ</td>
<td>65</td>
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</table>

Scores are shown as mean (standard deviation).

Figure 4 Total SF36 scores dichotomised by history of coronary artery disease. Key: CAD denotes coronary artery disease. Figures underneath the chart are means for each time point, error bars show standard error of the mean.
include health as one of their five most important areas of life by no means all do so. For those who did nominate health as a baseline cue it had a mean weighting of 26.7 (possible range 0–100) and therefore was not an area of over-riding predominance. This conclusion is supported by the finding that while coronary artery disease had a significant influence on health related QoL measures (a finding that emphasises their validity) it was not related to SEIQoL scores. SEIQoL is designed to obtain a more holistic QoL evaluation that is not constrained to pre-specified or health related questions. A specific medical intervention e.g. pacemaker implantation might therefore be expected to have less impact on scores as changes in health are diluted by consistency in other life domains. It is important to note however that despite SEIQoL detecting a positive impact of pacing it was still unable to detect any effect of pacing mode.

Use of KCSQ allowed evaluation of symptoms specifically related to bradyarrhythmias and pacing i.e. breathlessness, chest pain, dizziness and palpitation. Pacemaker implantation improved symptoms in all four of these categories but, as with SF36 and SEIQoL, scores subsequently reverted towards pre-pacing levels. This probably reflects the natural progression of symptoms in an elderly population with a high incidence of cardiovascular disease. It is interesting to note that while pacing mode had no impact on QoL, the presence of coronary artery disease (defined as a history of angina or myocardial infarction) was associated with a significantly reduced QoL that was independent of baseline QoL evaluation.

The influence of clinical parameters other than pacing mode on QoL is also important to consider. The population in this study were paced for different indications through studies with different randomisation strategies and ratios. The indication for pacing however had no effect on overall QoL as assessed by total SF36 score.

Limitations

The major limitation of this study has been the unexpected high drop out rate. This will undoubtedly have reduced the ability of the study to detect an impact of pacing mode on QoL and may also have skewed the assessment of the effect of pacing mode as withdrawal from the study was more likely in patients with VVI(R) pacemakers. A retrospective power calculation however has suggested that even with this sample size the study was adequately powered to detect a meaningful change in QoL as assessed by SEIQoL.

Conclusions

Pacemaker implantation is associated with a significant increase in individualised QoL as assessed by SEIQoL. This improvement declines to pre-pacing levels over the two years after pacing and is not influenced by pacemaker mode. QoL after pacing is adversely affected by coronary heart disease but is primarily influenced by QoL at baseline.

Acknowledgements

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References


