Patient Reported Outcomes Measures (PROMs) in Cardiac Ablation

Patients – a NICE Commissioned Pilot

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Background: Disease
Patients with cardiac arrhythmias often suffer recurring symptoms including nausea, blurred vision, fainting and chest pain. Many of these can be difficult to quantify, but have a significant adverse effect on quality of life. Several treatment options are available, including cardiac ablation which is reported to have a high success rate. Currently patients are not routinely followed up after treatment, leading to the loss of useful data.

Cardiac arrhythmias are abnormal heart rhythms. Some arrhythmias are caused by abnormal electrical activity within the heart. During ablation, a catheter is inserted into a blood vessel in the groin and guided to the heart. Here radiofrequency energy is used to destroy the small area of heart tissue causing the abnormality.

Background: PROMs
Patient Reported Outcome Measures (PROMs) are used increasingly to measure patient experience. They typically comprise of questionnaires administered before and after a procedure to assess fields such as pain, mobility and impact on daily routine, allowing changes in these parameters to be identified and measured. This provides evidence of the effectiveness of the procedure which can support decision making for patients and clinicians.

Problem:
Currently in the UK there are no nationally recognised disease specific tools to assess PROMs following cardiac ablation procedures in patients with symptomatic cardiac arrhythmias. Important outcomes are therefore being neglected.

Strategy for change:
In November 2010, Cedar, part of Cardiff and Vale UHB, was commissioned by the National Institute of Health and Clinical Excellence (NICE) to pilot the use of two new disease-specific questionnaires alongside EQ5D5L. These new tools were based on work carried out in the US by Wood et al (2009), and were developed in conjunction with a multidisciplinary team led by Dr Griffith at University Hospitals, Birmingham.

Aim: To explore the feasibility of using questionnaires to assess patient reported outcomes following cardiac ablation at specialist UK centres.

Methods: A retrospective audit design was chosen. Three specialist ablation centres were identified and confidentiality, data protection and Welsh language requirements met.

A total of 791 subjects were contacted: 397 from Queen Elizabeth Hospital, Birmingham, 200 from University Hospital Wales, Cardiff and 194 patients from Freeman Hospital, Newcastle. Each patient was sent a pack containing a participant information sheet, a consent form and two sets of questionnaires, one of these sets asked them to recall how they felt before the procedure and the other set asked them how they felt after the procedure.

Results: Excellent response rate
Responses were received from 74% of participants, and anonymised data were logged onto the national Central Cardiac Audit Database for data linkage and analysis. A scoring system applied to the questionnaires enabled changes in quality of life following cardiac ablation treatment to be measured and assessed.

Eight domains were assessed:
- Expectations
- Symptom severity
- Days impact on social activity
- Days off work/school
- Physician visits
- Impact on life
- EQ5D visual analogue scale (VAS)
- EQ5D index value

Responses illustrated a significant change in symptoms following ablation. Data showed:
- An improvement in all eight domains
- Improvement in EQ5D index value score in 70% of respondents.
- Reduced anxiety about general health in 69% of cases
- Expectation met in 71% of patients

<table>
<thead>
<tr>
<th>Proms</th>
<th>Pre ablation</th>
<th>Post ablation</th>
<th>Change</th>
<th>Percentage Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days Impact on Social Activities</td>
<td>9.67</td>
<td>2.98</td>
<td>6.69</td>
<td>69%</td>
</tr>
<tr>
<td>Days Missed at Work / School</td>
<td>7.50</td>
<td>2.19</td>
<td>5.31</td>
<td>70%</td>
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<tr>
<td>GP / Hospital Visits</td>
<td>1.64</td>
<td>0.51</td>
<td>1.13</td>
<td>69%</td>
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<tr>
<td>EQ5D5L VAS Score (Average / Patient)</td>
<td>51.62</td>
<td>70.82</td>
<td>19.20</td>
<td>37%</td>
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</tbody>
</table>

Effects of Change:
The success of this audit has illustrated the feasibility of collecting PROMs from patients with cardiac arrhythmias treated with ablation. Although a small retrospective study, the high response rate has demonstrated a potential to expand this project further, while patient feedback has enabled the questionnaires to be improved. The data gathered in this audit have demonstrated the significant benefit to patients treated with ablation, and the ability to calculate reduction in days lost at work and school allow societal costs to be considered.

Lessons learnt:
Patients responded with great enthusiasm and were keen to have the opportunity to voice their opinions and share experiences. This provided useful data which would otherwise have been lost. Patient feedback highlighted weaknesses in the process allowing areas for improvement to be identified. This will improve clarity and ensure inclusion of areas most important to the service users in the future.

Message for others:
Health-care provision is intended to improve patient quality of life. While traditional measures of clinical effectiveness are important, patients are able to provide data which are unavailable from any other source. Patient reported outcomes are a valid and useful tool for service measurement and improvement which should not be overlooked.

Future Aims
Ongoing work is being undertaken by the study team with the aim of developing and validating the disease specific PROMs to be suitable for use on a national level. This process will include further patient involvement such as patient interviews to allow continued iterative improvement of the questionnaires.

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