Patients’ views on the PulMiCC trial information: Results from a survey

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Introduction

- Pulmonary metastasectomy is an established treatment for surgically treated colorectal cancer patients (pts) with newly diagnosed, asymptomatic, lung metastases but the benefit of this operation is uncertain
- Surgery can involve the removal of significant amounts of lung tissue, leading to compromised lung function and poor quality of life (QoL)
- The Pulmonary Metastasectomy in Colorectal Cancer (PulMiCC) trial aimed to investigate the benefits and harms of pulmonary metastasectomy compared to active monitoring
- The trial was anticipated to be challenging for both HCPs and pts so a feasibility study was conducted to ascertain the trial’s acceptability
- We produced a HCP training DVD, with examples of best practice trial information discussions with actor pts, and a pt DVD to accompany the patient information leaflet (PIL)

Trial design

- Pt with known colorectal cancer found to have one or more pulmonary nodules
- Stage 1: Consent for evaluation
  - Evaluation according to local practice plus any additional investigations required by protocol
  - MDT recommend metastasectomy
  - Results reviewed by MDT
  - Pt matches local criteria for uncertainty
  - MDT recommend against metastasectomy
  - Discuss Stage 2 with pt
  - Pt declines Stage 2 Offered 'Accept/Decline' clinical trials questionnaire
  - Pt consents to Stage 2 randomisation Offered 'Accept/Decline' clinical trials questionnaire
- Continued active monitoring and QoL questionnaires
- Pulmonary metastasectomy followed by continued active monitoring and QoL questionnaires

Methods

- Potentially eligible pts were given information via discussion with the HCP, the PIL and PulMiCC DVD
- Pts who consented to Stage 1 underwent tests to confirm fitness for surgery and absence of widespread disease
- If test results revealed uncertainty regarding the benefit of pulmonary metastasectomy, pts were invited to participate in PulMiCC Stage 2
- All pts eligible for PulMiCC Stage 2 were offered an ‘Accept/Decline’ clinical trials questionnaire after they had decided whether or not to proceed to randomisation

Accept/Decline clinical trials questionnaire*

- 16 item, Likert scale, self-report questionnaire exploring
  - Aspects of trial information provision
  - Pts’ concerns about their illness
  - Influence of friends, family and doctor in their decision making
  - Concerns regarding randomisation
- Pts also identified their most important reason for accepting or declining randomisation

*V. Jenkins, L. Fallowfield. Reasons for accepting or declining to participate in randomised clinical trials for cancer therapy. Br J Cancer. 2000; 82(11): 1783-1788

Results

- 60 randomised pts and 68 who declined randomisation completed the questionnaire
- We found the ‘Accept/Decline’ questionnaire easy to administer and acceptable to patients

Most important reason for accepting or declining randomisation

- All pts had taken part in PulMiCC Stage 1
- (40/128) 31.3% of pts indicated their most important reason to be ‘I feel that others with my illness will benefit from the results of the trial’ (20 of whom accepted randomisation and 20 who declined)
- A further 31.7% pts who accepted randomisation indicated their most important reason to be ‘I thought the trial offered the best treatment available’ (10/60, 16.7%), ‘I wanted to help with the doctors research’ (9/60, 15.0%) while pts who declined indicated ‘I trusted the doctor treating me’ (8/68, 11.8%), ‘The idea of randomisation worried me’ (7/68, 10.3%)

Conclusion

The ‘Accept/Decline’ clinical trials questionnaire is an inexpensive and efficient tool for collecting relevant views from patients regarding potential drivers and barriers to recruitment

Acknowledgements

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Table 1-3 show proportions of pts who ‘strongly agree/agree to some extent’ with statements

1. Trial Information

<table>
<thead>
<tr>
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<th>Accept (n=60)</th>
<th>Decline (n=68)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The doctor told me what I needed to know about the trial</td>
<td>100% (60)</td>
<td>98.5% (67)</td>
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<tr>
<td>I was given enough information to read about the trial</td>
<td>96.7% (58)</td>
<td>91.2% (62)</td>
</tr>
<tr>
<td>I was given too much information to read about the trial</td>
<td>16.7% (10)</td>
<td>16.2% (11)</td>
</tr>
<tr>
<td>I knew I could leave the trial at any time and still be treated</td>
<td>98.3% (59)</td>
<td>94.1% (64)</td>
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2. Study design and randomisation

<table>
<thead>
<tr>
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<th>Accept (n=60)</th>
<th>Decline (n=68)</th>
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</thead>
<tbody>
<tr>
<td>I trusted the doctor treating me</td>
<td>98.3% (59)</td>
<td>97.1% (66)</td>
</tr>
<tr>
<td>I thought the trial offered the best treatment available</td>
<td>61.7% (49)</td>
<td>41.2% (28) (p &lt;.001)</td>
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<tr>
<td>I believed the benefits of treatment in the trial would outweigh the side-effects</td>
<td>75.0% (45)</td>
<td>39.7% (27) (p &lt;.001)</td>
</tr>
<tr>
<td>I was satisfied that either treatment in the trial would be suitable for me</td>
<td>90.0% (54)</td>
<td>42.6% (29) (p &lt;.001)</td>
</tr>
<tr>
<td>The idea of randomisation worried me</td>
<td>40.0% (24)</td>
<td>64.7% (44) (p =.003)</td>
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<tr>
<td>I wanted the doctor to choose my treatment rather than be randomised by computer</td>
<td>43.3% (26)</td>
<td>75.0% (51) (p =.001)</td>
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3. Other considerations

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<tr>
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<tbody>
<tr>
<td>I wanted to help with the doctors research</td>
<td>98.3% (59)</td>
<td>89.7% (61)</td>
</tr>
<tr>
<td>I feel that others with my illness will benefit from the results of the trial</td>
<td>98.3% (59)</td>
<td>88.2% (60)</td>
</tr>
<tr>
<td>The doctor wanted me to join the trial</td>
<td>66.7% (40)</td>
<td>36.8% (25) (p =.003)</td>
</tr>
<tr>
<td>Others, e.g. family or friends wanted me to join the trial</td>
<td>60.0% (36)</td>
<td>33.8% (23) (p =.001)</td>
</tr>
<tr>
<td>I did not feel able to say no</td>
<td>13.3% (8)</td>
<td>10.3% (7)</td>
</tr>
<tr>
<td>I was worried that my illness would get worse unless I joined the trial</td>
<td>23.3% (14)</td>
<td>19.1% (13)</td>
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- A small proportion of pts (15/128) 11.7% did not feel able to say ‘No’ and (27/128) 21% were worried that their illness would get worse unless they joined the study.