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

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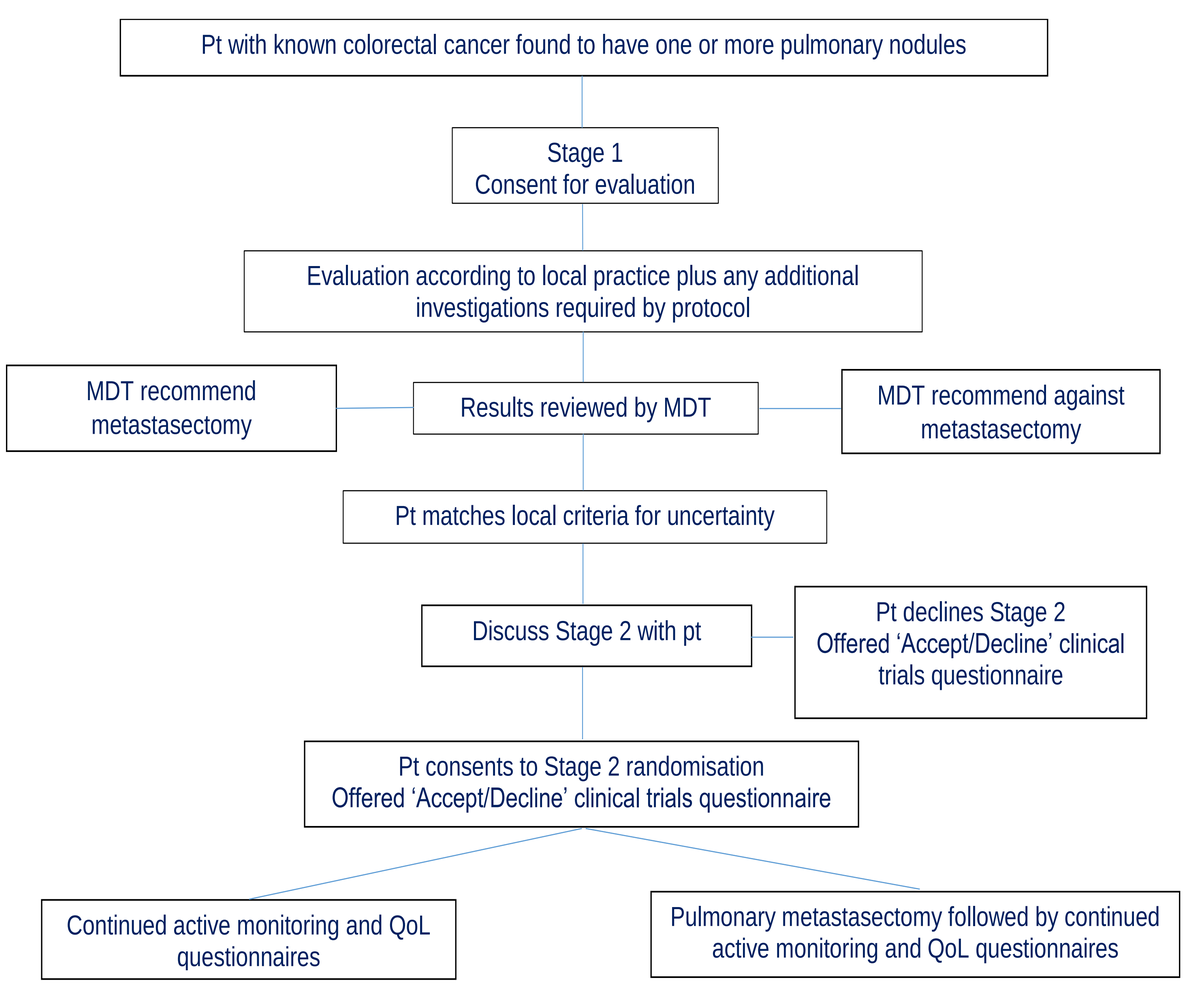
Introduction

- 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



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

Tables 1-3 show proportions of pts who 'strongly agree/agree to some extent' with statements

1. Trial Information	Accept (n=60)	Decline (n=68)
The doctor told me what I needed to know about the trial	100% (60)	98.5% (67)
I was given enough information to read about the trial	96.7% (58)	91.2% (62)
I was given too much information to read about the trial	16.7% (10)	16.2% (11)
I knew I could leave the trial at any time and still be treated	98.3% (59)	94.1% (64)

- Irrespective of accepting or declining, the majority felt well informed about the study

2. Study design and randomisation	Accept (n=60)	Decline (n=68)	
I trusted the doctor treating me	98.3% (59)	97.1% (66)	
I thought the trial offered the best treatment available	81.7% (49)	41.2% (28)	(p <0.001)
I believed the benefits of treatment in the trial would outweigh the side-effects	75.0% (45)	39.7% (27)	(p <0.001)
I was satisfied that either treatment in the trial would be suitable for me	90.0% (54)	42.6% (29)	(p <0.001)
The idea of randomisation worried me	40.0% (24)	64.7% (44)	(p =0.003)
I wanted the doctor to choose my treatment rather than be randomised by computer	43.3% (26)	75.0% (51)	(p =0.001)

- Pts who declined were significantly more worried about the trial design and whether it offered the best treatment
- They were also significantly more worried about randomisation

3. Other considerations	Accept (n=60)	Decline (n=68)	
I wanted to help with the doctors research	98.3% (59)	89.7% (61)	
I feel that others with my illness will benefit from the results of the trial	98.3% (59)	88.2% (60)	
The doctor wanted me to join the trial	66.7% (40)	36.8% (25)	(p =0.003)
Others, e.g. family or friends wanted me to join the trial	60.0% (36)	33.8% (23)	(p =0.001)
I did not feel able to say no	13.3% (8)	10.3% (7)	
I was worried that my illness would get worse unless I joined the trial	23.3% (14)	19.1% (13)	

- 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.

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

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