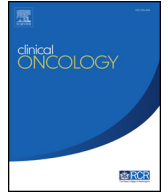




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Original Article

Evaluation of Quality of Life Outcomes Following Palliative Treatment of Bone Metastases with Magnetic Resonance-guided High Intensity Focused Ultrasound: An International Multicentre Study

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Abstract

Aims: To determine quality of life (QoL) outcomes after palliation of pain from bone metastases using magnetic resonance-guided high intensity focused ultrasound (MR-guided HIFU), measured using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C15-PAL and the QLQ-BM22 questionnaires.

Materials and methods: Twenty patients undergoing MR-guided HIFU in an international multicentre trial self-completed the QLQ-C15-PAL and QLQ-BM22 questionnaires before and on days 7, 14, 30, 60 and 90 post-treatment. Descriptive statistics were used to represent changes in symptom and functional scales over time and to determine their clinical significance. QoL changes were compared in pain responders and non-responders (who were classified according to change in worst pain score and analgesic intake, between baseline and day 30).

Results: Eighteen patients had analysable QoL data. Clinically significant improvements were seen in the QoL scales of physical functioning, fatigue, appetite loss, nausea and vomiting, constipation and pain in the 53% of patients who were classified as responders at day 30. No significant changes were seen in the 47% of patients who were non-responders at this time point.

Conclusion: Local treatment of pain from bone metastases with MR-guided HIFU, even in the presence of disseminated malignancy, has a substantial positive effect on physical functioning, and improves other symptomatic QoL measures. This indicated a greater response to treatment over and above pain control alone. MR-guided HIFU is non-invasive and should be considered for patients with localised metastatic bone pain and poor QoL.

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Key words: Bone metastases; cancer-induced bone pain (CIBP); high intensity focused ultrasound (HIFU); magnetic resonance imaging; quality of life (QoL); thermal ablation

Introduction

Advances in cancer treatment confer increased survival on patients with bony metastatic disease, but often leave

them experiencing chronic metastatic bone pain, which can impact significantly on their quality of life (QoL) [1]. When systemic therapies are inadequate for controlling metastatic bone pain, external beam radiotherapy (EBRT) is offered as a local palliative treatment [2]. This is a well-established and effective treatment that can be delivered non-invasively in an outpatient setting, without immediate side-effects. However, delayed side-effects (including mucositis, fibrosis, gastrointestinal symptoms, fatigue, pathological

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fractures and neuropathies [3]) can negatively affect patient QoL, even in the 60–80% who experience a pain response [2]. Analysis of the Dutch Bone Metastasis study ($n = 956$, where $>70\%$ patients responded to treatment) [4] showed that most QoL domains did not improve after radiotherapy. However, several studies have reported better QoL in radiotherapy responders than non-responders [5–7]. A literature review of 18 studies [8] concluded that EBRT may provide some improvement or stabilisation in QoL for those who respond to treatment, but did not specify which areas of QoL actually improved.

The non-invasive thermal ablation technique of magnetic resonance-guided high intensity focused ultrasound (MR-guided HIFU) has growing evidence to support its efficacy as a palliative treatment for painful bone metastases [9–13], with early reports indicating that $>70\%$ of patients with radiotherapy refractory metastatic bone pain experienced significant pain reduction within 3 months of HIFU treatment. The largest, phase III study found that 72 of 112 patients (64%) responded to MR-guided HIFU, compared with seven of 35 (20%) reporting a response after a sham treatment [12]. There was a corresponding improvement of 2.4 points (out of 10) in QoL, but this was only briefly summarised using the Brief Pain Inventory Short Form (BPI-SF), a tool that does not differentiate between the multiple factors that influence QoL [14]. As MR-guided HIFU is localised, there is minimal risk of toxicity to normal healthy tissue, potentially conserving a range of QoL measures.

An International consensus panel on clinical trial end points for bone palliation with radiotherapy recommends the QLQ-C15-PAL [15] and the QLQ-BM22 [16] questionnaires as instruments for providing a comprehensive evaluation of QoL [17]. They are validated tools [18–20] developed by the European Organization for Research and Treatment of Cancer (EORTC). To date, no studies have used these questionnaires to assess QoL after MR-guided HIFU treatment. The purpose of this study, therefore, was to determine the relationship between pain response and specific QoL measures after MR-guided HIFU using both the QLQ-C15-PAL and the QLQ-BM22 questionnaires.

Materials and Methods

Study Population

Participants were recruited to an international, prospective, single-arm study, designed to determine the efficacy of MR-guided HIFU for the palliation of painful skeletal metastases (NCT01586273) [21]. Thirty-six patients with bone metastases were assessed, of whom 20 met eligibility criteria (worst pain $\geq 4/10$ on the BPI-SF, corresponding to a bony metastatic site accessible by MR-guided HIFU) and received treatment between May 2012 and July 2016. Recruitment ran across three sites: The Royal Marsden Hospital, Sutton, UK ($n = 10$); University Medical Centre Utrecht, Utrecht, the Netherlands ($n = 5$); and the Samsung Medical Center, Seoul, South Korea ($n = 5$). Patients at all sites provided written informed consent, following

approval from an Institutional Review Board (REC number: 12/LO/0424, Samsung Medical Center IRB code: 2013-04-050). The study was conducted in accordance to the principles of the Declaration of Helsinki, Good Clinical Practice and the study protocol. Treatments were carried out using the Philips Sonalleve MR-guided HIFU device. Participants were followed-up on days 7, 14, 30, 60 and 90 days after treatment. All patients included in this QoL analysis had previously received radiotherapy to their painful bone metastases and had experienced differing levels of response. Baseline patient characteristics are presented in Table 1.

Questionnaires

Assessment of baseline QoL occurred on the day of MR-guided HIFU treatment before treatment was administered. A further QoL assessment was completed at each follow-up time point. The QoL questionnaires were self-completed by patients during their hospital visits at baseline, 30, 60 and 90 days, and at home at the 7 and 14 day time points.

The QLQ-C15-PAL [15] is a shortened version of the EORTC QLQ-C30 [22] and contains 15 items. It was developed as an abbreviated tool to assess QoL in patients treated palliatively. Data collection in advanced cancer patients is facilitated by reducing the burden of completing the longer, more time-consuming QLQ-C30. The QLQ-C15-PAL contains seven symptom scales (dyspnoea, pain, insomnia, fatigue, appetite loss, nausea and vomiting, and constipation) and three functional scales (physical functioning, emotional functioning, and overall QoL), which were identified as being relevant to the palliative population.

The QLQ-BM22 [16] was developed as a specific module for assessing QoL in patients with bone metastases. It is a 22-item questionnaire comprising two multi-item symptom scales: painful sites (five items) and painful characteristics (three items) and two multi-item functional scales: functional interference (eight items) and psychosocial aspects (six items).

Items on both the QLQ-C15-PAL and QLQ-BM22 questionnaires were rated on a four-point Likert scale and were rated from 1 (not at all) to 4 (very much), with the exception of the overall QoL status item, which was rated from 1 (very poor) to 7 (excellent). A higher score for the symptom scales represents a higher level of symptomatology and, therefore, a decreased QoL. By contrast, a higher score for the functional scales represents a higher level of functionality and, therefore, an increased QoL. Each scale was transformed to a score ranging from 0 to 100, according to their respective scoring manual.

Magnetic Resonance-guided High Intensity Focused Ultrasound Response Classification

Patients were categorised as responders to MR-guided HIFU treatment if they experienced a complete response or a partial response at day 30 after treatment, and non-responders if they experienced no response or pain

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