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An investigation into the incidence of pain flare in patients undergoing radiotherapy for symptomatic bone metastases

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ABSTRACT

Introduction: External Beam Radiotherapy (EBRT) is a recognised intervention for symptomatic pain relief from bone metastases. Pain flare is a reported EBRT toxicity, described in 16–41% of steroid-naïve patients. This study aimed to determine incidence and duration of pain flare amongst patients within one Oncology Centre.

Methods: Patients receiving EBRT for bone metastases were recruited to a prospective cohort study. Baseline pain scores and a daily pain/analgesia diary were recorded during EBRT and for 14 days thereafter. Pain flare was defined as a two-point increase on a pain scale or 25% increase in analgesia intake, with a return to baseline.

Results: Of the thirty-two participants, 69% (n = 22) completed the diary. 41% (n = 9) patients experienced pain flare, the median duration being 3 days. Of the evaluable patients, 55% (n = 12) were male, 45% (n = 9) female. The median age was 73 years (range 40–83). The common primary sites of disease were Breast (32%) and Prostate (32%), with other sites making up the remaining 36%. The most frequent EBRT site was the spine (63%), with other treatment sites including pelvis (23%) and extremities (14%). EBRT regimes were restricted to 20 Gy in 5 treatments, received by 32% (n = 7) of patients and 8 Gy in 1 treatment (68% (n = 14)). Of these two regimes, pain flare was reported by 29% and 47% respectively.

Conclusion: Pain flare is a common toxicity of EBRT for bone metastases. Taking the small sample size into consideration, the incidence and duration of pain flare in patients within this single-centre study are comparable with those found in international studies.

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Introduction

Cancer incidence is rising due to longer life expectancy, and an improvement in systemic anti-cancer therapy (SACT) has led to greater numbers of patients living longer with metastatic disease.[1] In particular, bone metastases are a frequently occurring complication of many cancers, predominantly breast, prostate and lung, and are known to be experienced by approximately 70% of patients.[2] These can lead to poor quality of life (QoL), with patients experiencing many symptoms, including pathological fractures, hypercalcaemia and metastatic spinal cord compression (MSCC), some of which may require surgical intervention.[3–5] The main systemic management options for bone cancer are SACT (including bisphosphonates), surgery, chemotherapy and hormone manipulation, supported by analgesia. External Beam Radiotherapy (EBRT) provides a useful local treatment for pain relief. EBRT is widely used with approximately 23,000 episodes delivered to metastatic bone cancer in England in 2013.[6] It has been evidenced to provide symptomatic relief and loco-regional control for approximately 50–80% of patients, and complete response for 30–50%.[7]

Toxicities due to palliative EBRT vary, with patients experiencing erythema, fatigue and local side effects, e.g. nausea, diarrhoea. Furthermore, prospective studies have recognised that pain flare may be observed in up to 41% of patients in the period immediately post-treatment.[8] Pain flare is identified as a transitory increase of pain experienced within the irradiated site, and is thought to be caused by oedema of the periosteum compressing on nerves or the release of inflammatory cytokines.[9] Flare is generally quantified using Chow's definition of i) an increase of 2 points on a numerical rating scale (NRS) with no increase in analgesia, or ii) a 25% increase in analgesia to maintain the previous pain levels, with a return to baseline.[8,10]

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Limited evidence evaluating incidence of pain flare is available from within the literature, thus a corresponding pilot study was undertaken to identify and evaluate the experience within one UK Oncology Centre and subsequently compare the results with published literature. The pilot study and proposed subsequent research aim to inform service development within the Oncology centre by analysing whether the identified patient group is receiving appropriate clinical care to manage EBRT-induced pain flare.

Materials and methods

Ethical approval was obtained from the Regional Ethics Committee (REC) and from the participating NHS Trust to undertake the study.

A prospective cohort study was undertaken with participation confined to one Oncology Centre within a 9 month period from December 2015 to August 2016. Patients were aged 18 years or over and capable of providing informed consent. A histological-proven diagnosis of any primary cancer or haematological malignancy was required, with radiologically-proven osseous metastases. Patients who were prescribed either 8 Gy in a single treatment or 20 Gy in five fractions of EBRT were eligible, conforming to the protocol within the Oncology Centre for prescription of EBRT to painful lesions. Participants were required to be assessed as having a performance status (PS) of 0–3 inclusive using the criteria developed by the Eastern Cooperative Oncology Group.[11] Due to differing EBRT protocols and treatment intent, patients prescribed EBRT for pathological fracture of a bone, MSCC, an area previously irradiated or non-proven osseous metastases were excluded.

Prior to EBRT, a questionnaire was completed using the Oncology Centre's electronic patient records and treatment management system, to ascertain baseline demographic data. The variables within this included gender, age, primary disease site, site and prescribed dose of current EBRT and any previous EBRT received. Participants provided informed consent, receiving full written information regarding the study. Baseline pain burden was assessed by the patient's completion of the Brief Pain Inventory (BPI) and regular analgesia consumption registered.[12] The patient was provided with a pain diary, with written and verbal instructions regarding its completion, to record the worst pain score experienced each day on an NRS and any supplementary analgesia required. The diary was completed daily from the first day of treatment until 14 days following completion of EBRT. Patients were provided with a postage-paid envelope in which to return the diary and were contacted by telephone towards the end of the diary period to encourage them to do so.

Chow's definition of pain flare was used by the majority of the published studies, and was thus used within this study to enable comparison of results.[10]

Data from the completed diaries were collected on an excel® (Microsoft, Redmond, WA) spreadsheet to ascertain incidence of pain flare amongst the study population. Descriptive statistics were gathered to report percentages of the population experiencing pain flare; this was compared directly with the published studies. Demographic data was evaluated to ascertain statistical significance in gender, primary disease site, dose received, etc. Pearson's chi-square analysis was used to test any associations between these variables, with the approximate p-value giving the probability of the observed differences happening by chance. A statistical significance threshold was agreed at 5%. Yates' continuity correction factor was applied to improve the accuracy if the cell values were less than 5. Incomplete data was analysed and assessed for suitability to be included in the overall results. Inclusion was dependent on the aspects of the data missing, for example, no indication on the NRS may be negated if the analgesia record was complete as this included the pain level at the time the medication is taken. Non-completion of the diary led to exclusion of the participant and therefore omission from the overall analysis.

Results

Thirty two patients were recruited into the study between December 2015 and August 2016, of which 47% (n = 15) were males and 53% (n = 17) were females. Of those enrolled, 69% (n = 22) completed their daily pain diary to provide evaluable data which has been statistically analysed. Table 1 demonstrates the relevant data of the appraisable participants. Reasons for exclusion from the study included decline in patient condition or death during the study period, patient withdrawal from the study, non-return of the diary or insufficient data to allow for evaluation.

Daily pain levels were recorded by the participants using the BPI. Pain flare incidence was calculated, with the independent variables of pain experiences in the evaluated group indicated in Table 2. Ten of the evaluable patients experienced an increase of at least 2 points on the pain scale at some stage in their study period, however, using the Chow definition, 41% (n = 9) of these actually experienced pain flare.[8] The 10th patient's pain did not revert back to the original level and thus cannot be recorded as a flare. Severity and duration varied between participants. Pain flare occurred within the first 5 days in all of the patients (100%). 3 patients experienced intermittent pain flare and therefore provided more than one set of data, resulting in 13 reported episodes of flare in total. The mean duration of flare was 3 days (range 1–10 days).

Data was gathered regarding systemic and steroidal treatments, radiation dose and site as indicated in Table 2. The analysis of patients also receiving SACT, including Abiraterone and Tyrosine-kinase inhibitors, and steroid treatment was introduced part-way through the study period. Retrospective data was gathered where possible for early participants; however it was not possible to elicit this information from some annotations and records, reducing quantifiable data.

The age range of the evaluable patients within this study was between 40 and 83 years (median age 73 years). Of those experiencing pain flare, the range was 43–82 years, with an overall mean age of 67.4 years. Further analysis indicates that the male age range was 57–82 years, with a mean age of 73.8 years; the female population range was 43–72, the mean being 59.5 years. There was no statistical difference between patients who did or did not experience pain flare for the majority of variables, including gender, age range, primary cancer site, EBRT site, EBRT dose or SACT when using a significance of $p < 0.05$. However, using Pearson's chi-square test for independence, a significant difference was found in pain flare experience between those who did and did not receive steroids during their evaluation period, with a probability (p-value) of 0.0253 ($p < 0.05$). When the Yates correction factor was applied due to the small cell values, the p-value was recalculated at 0.0935; the statistical significance cannot be confirmed. The calculations do not take into consideration the unknown steroidal status of 7 patients.

Discussion

This study provided further evidence that pain flare is experienced by patients receiving EBRT to secondary bone cancer, with 41% (n = 9/32) of evaluable patients in the Oncology Centre reporting an increase in pain which conformed to the definition used.[10] The overall result is equivalent to the highest within the range identified in the reviewed publications (16–41%),[2,5,8,10] although it is acknowledged that the results in our study may have been affected by imprecise patient annotation within the research tool and also the inclusion of participants who were also

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