CoRIPS Research Award 089
Beverley Atherton
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Can the early signs and symptoms suggestive of spinal cord compression be identified by radiographers during bone scans by gathering clinical information about back pain from patients?

Lay summary
The study aims to find out if radiographers who perform bone scans can gather information from patients about back pain which may identify early signs and symptoms suggestive of Metastatic Spinal Cord Compression (MSCC). This is not currently routine practice and there is no evidence that radiographers will be able to successfully collect this sort of clinical information. If data can successfully be obtained it may be possible to use it in conjunction with other clinical information to identify patients at high risk of developing MSCC. These patients may benefit from prompt referral for medical assessment or Magnetic Resonance Imaging (MRI) scanning.

The project will assess back pain using two questionnaires in 200 patients or over four months, whichever is reached first. An existing, validated pain questionnaire, the Brief Pain Inventory (BPI) will be used as well as a new questionnaire which has been developed for use in this study. The new questionnaire is based on the early signs and symptoms of spinal pain and neurological symptoms as defined by the National Institute for Health and Clinical Excellence (NICE). The data from the questionnaires and other clinical information acquired during the bone scan visit will be compared with clinical follow up of the patients 5 months after their visit, to see if any have required treatment for malignant spinal disease. Each element of the collected data will be compared to see if any relationship exists. The project is the first stage in exploring the possibility of developing a risk assessment tool for use in an imaging setting.

Description of the project:

Principal aim of the study
The study aims to find out if radiographers involved in performing radioisotope bone scans can gather clinical data from patients regarding back pain which may identify early signs and symptoms suggestive of Metastatic Spinal Cord Compression (MSCC). Currently this is not routine practice and there is no evidence that radiographers will be able to successfully do this. If data can be collected it may be possible to use it in conjunction with standard clinical data to identify those patients at high risk of developing MSCC and those who may benefit from prompt referral for medical assessment or Magnetic Resonance Imaging (MRI).

Primary research question
Is it feasible and acceptable for radiographers to gather clinical information from patients regarding back pain during a bone scan procedure which may be indicative of metastatic spinal disease using i) a new questionnaire which has been designed, based on NICE indications and ii) a standardised pain questionnaire, the Brief Pain Inventory (BPI)?

Secondary research questions

1. Is there a relationship between data collected using the BPI and that collected using NICE signs and symptoms questionnaire?
2. Is there any relationship between questionnaire data, standard clinical data acquired during a routine bone scan procedure and clinical outcome in terms of requirement for treatment of metastatic spinal disease?

Outcomes / Deliverables

The study will determine if data can be collected which may provide evidence of the early signs and symptoms of MSCC in a group of patients who may all be at potential risk. Based on the outcome of this project, a wider future study may provide scoping information regarding the feasibility of developing and validating a risk assessment tool. This could potentially be used routinely in clinical practice to identify high risk patients at an early and opportune time. By grouping risk tool scores it may be possible to signpost patients at an early stage to an appropriate interventions thus potentially sparing them from developing disabling clinical complications. The study fulfils the requirements of a feasibility study by evaluating acceptability and practicality (Bowen et al 2009). A risk assessment tool could have particular value in settings where oncology patients are infrequent and the knowledge of early signs of MSCC are less well established.

Review of the literature and identification of the current gap in knowledge

What is MSCC?

MSCC is an oncological emergency which occurs in some patients with cancer. NICE defines it as pathological vertebral body collapse or direct tumour growth causing compression of the spinal cord or cauda equina. Treatment includes radiotherapy and/or surgery.

Why is it important?

Without timely treatment MSCC can cause irreversible neurological damage, permanent disability or premature death. Early diagnosis and treatment makes a significant difference to quality of life but there is substantial evidence that late presentation is not uncommon (Husband 1998). The neurological status at the time of diagnosis of MSCC is a significant predictor of outcome in terms of survival (Husband 2001, Levack et al 2002). Evidence from several seminal observational studies indicates that once MSCC is suspected, it is essential that investigation, planning and treatment takes place before any further loss of neurological function (Helweg-Larsen et al 1996, Husband et al.1998, Levack et al. 2002, Maranzano et al. 1995, Solberg et al.1999, Turner et al. 1993).

What is the size of the problem?

An estimated 3-5% of all patients with cancer will develop spinal metastases (NICE 2008), most commonly in cases of breast, prostate or lung cancer, in whom the incidence may be as high as 19 %. These high risk cancers account for over 50% of cases of MSCC (Loblaw et al 2003, Levack et al 2002). However, 23% of patients with MSCC have no prior cancer diagnosis (NICE 2008) and the onset of neurological symptoms is often insidious (IAEA 2007). NICE issued guidance in Nov 2008 regarding the diagnosis and management of patients at risk of or with MSCC followed by regional guidance in Sept 2010.

What are the key signs, symptoms and risk factors?

Back pain is the most frequent first symptom of MSCC, occurring in 95% of patients (Levack et al 2002) but it is also a common complaint in the general population. NICE have identified a specific list of features of back pain and neurological symptoms that are better predictors of MSCC. They recommend that health care professionals should be aware of the signs and symptoms of MSCC but acknowledge that those which are taught often relate to later neurological stages of the condition (Bucholtz 1999). Regional guidance states that the professional who recognises that cord compression is a potential complication should undertake to make patients aware of potential signs (MCCN 2012). NICE suggest that standardised written information is given to patients identified as being at risk about the symptoms and details of what they, or their families/carers, should do if they develop them. An agreed plan to disseminate such information has yet to be implemented and anecdotal evidence suggests that clinicians have difficulty in reaching an agreement as to which patients and at which stage of treatment patients should recieve risk information as it may cause an unnecessary burden of concern.

The role of imaging - an opportunity

Radioisotope bone scanning is not used to diagnose MSCC but is a routinely performed examination on the same group of patients who may potentially be at risk of developing the condition. The visit to the hospital for the bone scan therefore, presents an opportunity to assess if patients are demonstrating any early symptoms. Bone scans are commonly used as a routine investigation to assess the whole body for bony metastases. The procedure does not, however, demonstrate the extent of soft tissue compression or reliably detect the level of a MSCC. Locally, a recent audit showed that 34% of bone scans performed on patients with known or suspected cancer demonstrated metastases, with 28% having spinal metastases (83% of cases with metastases had spinal metastases). MRI is the imaging

modality of choice for diagnosing MSCC (Cook 1998) and is central to NICE guidance to the diagnosis, staging and planning of treatment. Regular MRI imaging of the spine to detect early disease is not, however, recommended if patients are asymptomatic (NICE 2008). It is not uncommon that patients having MRI scans for suspected of MSCC may have previously undergone a radioisotope bone scan. A recent audit within this unit indicated this was the case in almost 62% of patients. 26% of these patients had bone scans within the previous month, 48% within the previous six months and 65% within the previous year. The actual number may be higher as bone scans may have also been performed at hospitals whose records are not included in the local shared computer system.

Bone scans referrals may be received from a variety of referral routes, oncology consultants, the local district general hospital, some GPs and private practice. An audit indicated that 96% of the total referrals to the department had a known or suspected cancer (91% with a known cancer, 5% with a suspected cancer). Of these with known or suspected cancers, 68% were referred from oncology consultants and 32% from outside the oncology setting. Of the total number of cases with known or suspected Cancer 85% had known primaries defined as being high risk of developing metastatic spinal disease (NICE).

The request to perform a bone scan rather than MRI implies that the clinician was not suspicious of MSCC at the time of referral. Symptoms may, however, have altered by the time the patient attends for their appointment or the referral may be from a clinician whose primary specialism is outside oncology and the risk of MSCC may not have been promptly considered.

Method
The study is of quantitative, descriptive and exploratory cohort design. Patients will be asked to complete two questionnaires during their visit for a nuclear medicine bone scan.
Sample - Patients will be recruited from those referred for whole body bone scanning who have a known history or suspicion of cancer.

Inclusion criteria
- Patients referred for whole body bone scans with a known or suspected cancer.
- Over eighteen years of age.
- Able to communicate in English.
- Capable of giving written informed consent.

Exclusion
- Known existing or previous MSCC
- Patients not having been given appropriate time to consider the study
- Patients who have already participated in the study. If patients attend for a second bone scan whilst the study is being conducted they will be ineligible to participate.

Data will be collected from a 200 patients or over a period of four months, whichever occurs sooner. Approximately 75 patients per month with a known or suspected cancer are currently referred for bone scans. If 50 (66%) of eligible patients per month can be recruited then 200 patients can be entered in the study over approximately four months.

Recruitment
The project will be led by the Diagnostic Research Radiographer who together with the Nuclear Medicine Clinical Specialist will identify eligible patients from referral forms. An invitation to participate in the study and a patient information leaflet will be posted to the patient with their appointment letter. Patients will be given a telephone number to contact staff should they require further information. Approximately five whole time equivalent staff will be available to participate in the study. Patients will be consented by qualified, trained staff on arrival in the department before the clinical procedure.

Staff
Experienced oncology, nuclear medicine radiographers with Good Clinical Practice research (GCP) and research project training will undergo a short education training session (approximately one/two hours). The training will be provided by the local clinical lead for MSCC management. This will include information and training regarding:

- Completion of the BPI
- The NICE related back pain questionnaire which has been developed
- NICE and regional MSCC guidance
- Clarifying the early clinical symptoms suggestive of spinal metastases and the neurological symptoms suggestive of MSCC.

Data collection
Patients will be asked to complete two questionnaires during their visit.

i) NICE based back pain questionnaire -this will be completed by the radiographer during the routine patient interview conducted prior to the bone scan injection. The patient is asked a specific set of questions about back pain based on NICE indications. The responses will be recorded as “yes” or “no” with an opportunity to comment when a definitive response cannot be established. Both radiographers and patients are then asked to score the questionnaire for ease/difficulty of completion using a linear 1-10 scale and a free text area is also available for either to comment in.

ii) BPI- A bone scan involves a wait of three hours between injection and imaging. Patients will be asked to complete the BPI independently during this waiting time but assistance will be offered and available if required.

iii) Clinical Data - Clinical data will be recorded by the radiographer. This will include:

- Site of primary cancer if known / suspicion of cancer
- Whether back pain is mentioned on the referral form
- Radiographer opinion on reviewing the scan images (presence of metastases, presence of spinal metastases)

The radiologist report will be noted.
On line case notes and data from the regional MSCC co-ordinator will be reviewed after five months to assess if any patients have required treatment for metastatic spinal disease.

Data analysis
The Research Radiographer will perform all the following data analysis.
i) Analysis of Primary aims

a) Feasibility will be assessed by:

- Percentage of patients eligible for the study who participated.
- Analysis of the reasons patients did not participate if they were eligible but not invited
- Percentage of eligible and invited patients who agreed to take part and consented
- Percentage of questionnaires fully completed (both questionnaires)
- Percentage of partially completed questionnaires (both questionnaires)
- Analysis of which questions were not answered where questionnaires are incomplete.
- Analysis of the percentage of patients completing just one questionnaire and reasons why
- Percentage of questionnaires not completed at all and reason why.

b) Acceptability will be assessed by:

- Analysis of the mean and range of scores given to the NICE based questionnaire for ease of use by radiographers
- Analysis of the mean and range of scores given to the NICE based questionnaire for ease of use by patients

A mean score of less than 5 would indicate the questionnaire was no more than moderately difficult to complete. Acceptability of use scores for both patients and staff will also be compared with clinical outcome, as a higher score may eventually be classed as acceptable should the questionnaire prove to have good predictive value.

- The mean and range of the time estimated that it took to complete the NICE questionnaire will be assessed.

ii) Analysis of Secondary aims

a) Results from the NICE based questionnaire will be compared to results from the BPI.

b) Clinical data collected at the time of the scan will be compared with clinical outcome

c) Questionnaire scores will be compared with clinical outcome

A comparison of the mean values and standard deviation of the scores from both questionnaires will be made. Relationships will be investigated using chi-square tests and logistic regression.

Ethical issues

Data collected for the purpose of the study will be compliant with the Data Protection Act, Caldicott principles and good research practice standards. No recruitment will commence until independent ethical, University and Trust R&D approval is granted.

Potential Anxiety/Distress

It could be argued that for some, the study title and the topic may cause unnecessary anxiety. The eligible patients are, however, already being managed for a serious disease or suspicion of cancer and therefore, questions about their symptoms would probably be expected by them. The patient information sheet and staff explanations will be explicit in reassuring patients that the questions are standardised for all patients and are not asked because of any individual clinical concern. The potential of creating unjustified anxiety for patients is, therefore, not expected to be problematic but patients will be cared for by experienced oncology radiographers, familiar with and sensitive to, discussing cancer with patients. As per normal practice, on site support from clinical nurse specialists and the Macmillan support team is available for any cases where additional counselling may be identified as required during the visit.

Management of High Risk Patients

It is not intended for the purpose of this study that any additional clinical action or intervention will take place for any patients but it is standard practice that staff advise patients to seek medical review if minor symptoms have changed since referral. When radiographers suspect a patient is displaying neurological symptoms which require urgent medical attention urgent referral to the on site oncology team is arranged.

Dissemination strategy

The results of the study will be shared within the Trust to the appropriate specialist groups, the Trust MSCC clinical lead and the regional MSCC working group. Submission for presentations will be made at the British Nuclear Medicine Society annual meeting and submission for publication in the radiographers' professional body journal.

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