



Metastatic Bone Disease: A Guide to Good Practice.

PREFACE

This document sets out a statement of good practice in the Orthopaedic and Neurosurgical management of patients with metastatic bone disease. It represents a consensus statement from the British Orthopaedic Association and the British Orthopaedic Oncology Society.

It is hoped that this guide, which is an interim statement, will inform Surgeons, Trusts and Purchasers and also improve the care of patients with bone metastases.

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Key Points

- The prognosis for Patients with Metastatic Bone Disease (MBD) is steadily improving. Many patients will survive three or more years.
- Never assume that a lytic lesion, particularly if solitary, is a metastasis.
- Metastatic pathological fractures rarely unite, even if stabilized.
- Prophylactic fixation of long bone mets is generally easier for the surgeon and less traumatic for the patient. Use the Mirels scoring system.
- Fixation of pathological fractures or lytic lesions, especially around the hip /proximal femur have a high failure rate. Cemented hip prostheses (either standard or tumour prostheses) have a low failure rate.
- Never rush to fix a pathological fracture. Traction or splintage will suffice while investigations are performed and surgical intervention discussed with the lead clinician for MBD and other appropriate colleagues.
- When surgery is indicated for spinal metastases, both decompression **and** stabilization are generally required.
- Constructs, whether spinal or appendicular, should allow immediate weightbearing and aim to last the lifetime of the patient.
- Solitary renal metastases should, where possible, be radically excised.
- Each trauma group requires a lead clinician for MBD.
- Treatment should be within the context of a multi-disciplinary team.

1. INTRODUCTION.

- 1.1 This document is a statement of good practice in the orthopaedic management of patients with metastatic bone disease (MBD) and has been approved by the British Orthopaedic Association and the British Orthopaedic Oncology Society.
- 1.2 The incidence of MBD is difficult to determine accurately. Metastases may develop in two-thirds of cancer patients. It has been estimated that in the UK approximately 9000 women with breast cancer develop bone metastases each year. This suggests that the total for all cancers is in excess of 20,000 cases per year. Tumours which metastasise to bone most frequently are prostate, breast and kidney, followed by lung and thyroid.
- 1.3 Despite the Calman Initiative in the recognition of site-specific oncology services there has been a singular failure (a) to recognise the final common pathway of many of these patients and (b) to define adequate levels of provision of service and appropriate funding.
- 1.4 Despite the advances in oncology and spinal surgery, there remains a low level of awareness in the hospital and primary care settings of what can be achieved. A recent review of patients with breast carcinoma by Galasko documented that in only 45 of 207 patients with painful skeletal metastases and in only 6 of 51 patients with spinal instability was an orthopaedic opinion sought. A similar review by O'Donoghue documented that in only half the instances where orthopaedic review would have been indicated was this undertaken and in only half of those in whom spinal surgery may have been beneficial was this undertaken.

- 1.5 There is a widespread and, we believe, a significant variation in the standard of management of MBD and the surgical techniques and implants used. Poor outcomes are due to a variety of reasons including the following:
- a. failure to intervene prophylactically where appropriate, often due to late referral.
 - b. lack of understanding of the biomechanical basis of orthopaedic implants, leading to inappropriate surgery and high failure rates.
 - c. delays inherent in the organisation of cancer and orthopaedic services including a relative shortage of orthopaedic and spinal surgeons.
 - d. failure to appreciate the options available, particularly in more advanced cases of MBD.
- 1.6 From available data, this document identifies the best practice in general terms and the emphasis is therefore on process rather than precise techniques. It is not a statement which claims to be applicable to all patients or in all circumstances. Each consultant, or those working under the supervision of a consultant, must continue to take into account the individual requirements of each patient. Presently, there is a lack of auditable standards for the treatment of MBD. Standards can only be set by the widespread collection of uniform data, centred on NHS Trusts and made available for regional and national audit.
- 1.7 The prognosis for patients with MBD, and particularly those without visceral disease, has significantly improved in recent years due principally to advances in medical therapy including hormonal treatment, bisphosphonates and, to a lesser extent, chemotherapy. In the 1970s the average survival following recognition of bone metastases was 7 months . By 1990 this had increased to 2 years This improvement has been most marked in breast and prostate cancer,

and of these, breast cancer provides the great majority of cases which merit orthopaedic intervention due to the frequency of lytic bone lesions. This improvement places an increased burden of responsibility on orthopaedic surgeons treating MBD.

- 1.8 The poor outcome figures for some oncological treatments in the United Kingdom are likely to reflect, at least in part, the failure adequately to address skeletal metastatic disease
- 1.9 This document should be read in conjunction with ‘The British Association of Surgical Oncology Guidelines for the Management of Metastatic Bone Disease in the UK’, which gives additional information with regard to non-surgical aspects of treatment.

2. EVIDENCE LEVEL.

- 2.1 This is a subject where there has, until recently, been a relative paucity of reliable scientific data. Controlled prospective trials in this field are difficult to construct, and in many cases unethical. Treatment with radiotherapy, for example, is historical rather than evidence-based, but nonetheless very effective. Despite this we consider that a sufficient volume of data and clinical experience exists to regard this guide as an evidence-based approach to MBD.

3. COST BENEFIT AND IMPLICATIONS.

- 3.1 We consider that the prompt and appropriate surgical management of skeletal metastases along broadly agreed principles detailed in this guide is highly cost-effective in terms of the overall management of cancer patients. The cost of even specialised implants is recouped within days if a previously immobile patient is enabled to walk and live independently.
- 3.2 There is, however, no doubt that this places extra demands on trauma, elective orthopaedic and spinal services, and this burden must be recognised by health care managers and purchasers. Savings, however, are often not within the Orthopaedic budget, but in the field of nursing care and community cancer services. Re-allocation of budgets may be necessary.
- 3.3 Inadequate orthopaedic treatment frequently leads to costly revision surgery, causing suffering and potential complications in addition to the financial cost.

4. PRESENTATION TO THE ORTHOPAEDIC SURGEON.

- 4.1 This is typically in one of three modes:
- a. acute admission with pathological fracture or neurological compromise
 - b. referral to clinic with unexplained musculoskeletal pain

c. referral from oncologist/breast care team (surgeon, radiologist or oncologist).

4.2 Pain is the most frequent clinical symptom, ranging from a dull ache to a deep intense pain that is exacerbated by weight-bearing, and is sometimes worse at night. The aetiology of this pain is not fully understood, but probably involves the release of chemical mediators of pain including substance p, prostaglandins, growth factors, bradykinin and histamine.

5. THE ROLE OF THE ORTHOPAEDIC SURGEON.

5.1 The role of the orthopaedic surgeon in the management of MBD falls into three principal categories:

- a) prophylactic fixation of metastatic deposits where there is a risk of fracture.
- b) stabilisation or reconstruction following pathological fracture.
- c) decompression of spinal cord and nerve roots and/or stabilisation for spinal instability.

6. AIMS OF SURGERY.

6.1 The aims of surgery are to relieve pain and restore function. The general orthopaedic principles underlying the management of impending or actual pathological fractures through metastases are as follows:

- a) The procedure should provide immediate stability, allowing weight bearing.
- b) The surgeon must assume that the fracture may not unite.
- c) The fixation should aim to last the lifetime of the patient.
- d) All lesions in the affected bone should, where possible, be stabilised.

We consider that all patients requiring surgery must be admitted under the care of a surgeon who is on the Specialist Register. The Consultant Surgeon need not see all the patients nor carry out all procedures, but may delegate aspects of patient care to appropriate members of the team, appropriate to their skills and competence.

7. ADJUVANT THERAPY.

7.1 Radiotherapy is generally palliative, and often given as a single fraction. It can produce effective bone healing and sclerosis and, when given prophylactically, can prevent pathological fracture occurring. It will not, however, cure pain of a 'mechanical' nature, and only 30-40% of pathological fractures will unite even after radiotherapy. It is recommended that following nailing or other surgical procedures in patients with MBD, radiotherapy to the affected bone and operative field (unless field sizes are excessive) should be considered by the appropriate specialist within the context of the multidisciplinary team. The spinal cord is radiosensitive, and this may limit the scope for adjuvant treatment of the axial skeleton.

7.2 Endocrine therapy, bisphosphonates and chemotherapy may all have a role in the management of patients with MBD. The indications are beyond the scope of this document but should be addressed by the multi-disciplinary team.

8. FRACTURE RISK ASSESSMENT

8.1 Where fracture is likely to occur then prophylactic fixation should be performed prior to the administration of radiotherapy. It is essential therefore to have a reliable method of predicting the risk of a pathological fracture occurring.

- 8.2 Plain radiographs are often unreliable as a measure of cortical destruction. As a rule of thumb, where 50% of a single cortex of a long bone (in any radiological view) has been destroyed, pathological fracture should be regarded as inevitable. In addition, avulsion of the lesser trochanter is an indication of imminent hip fracture.
- 8.3 In an effort to provide a more reliable and reproducible measure of the risk of pathological fracture, Mirels devised a scoring system (Table 1) which we regard as a useful aid to management, both for the orthopaedic surgeon, and for the breast care team and oncologists monitoring patients with MBD. For scores of eight or above, the risk of fracture is high and prophylactic fixation should be carried out prior to radiotherapy being administered.

9. MECHANISM OF FRACTURE.

- 9.1 With respect to the appendicular skeleton, the mechanism of fracture is significantly different in pathological bone when compared to 'normal' traumatic fractures. Bone destruction may produce a 'stress riser' or an 'open section' defect in a long bone. Low energy fracture will then occur following minor trauma or a twisting movement. Soft tissue injury is minor compared to that seen in traumatic fractures in healthy bone.

10. PRE-OPERATIVE ASSESSMENT.

- 10.1 It is essential that the general condition of the patient is addressed prior to surgery. A full medical history and examination is mandatory.
- 10.2 Electrolyte Imbalance including hypercalcaemia must be assessed and, if possible, corrected prior to surgery and fluid balance monitored.

10.3 Staging studies and investigations appropriate to the clinical situation should be performed. Plain radiograph of the entire affected bone is a minimum requirement.

10.4 Patients with a life expectancy of less than six weeks rarely gain useful benefit from major reconstructive surgery. However, an accurate prognosis cannot always be given in MBD and decisions regarding the appropriateness of surgery, or indeed any other interventions, should be discussed within the context of the multidisciplinary team and an informed patient and family.

11. SURGICAL TREATMENT - 'APPENDICULAR SKELETON'

11.1 Hip.

Fractures about the hip present most frequently. Management differs significantly from that of purely traumatic fractures. When a case of suspected pathological fracture is admitted to a Trauma Unit, a full medical and radiological assessment should initially be made, speed of surgery being less important than planning and the use of an appropriate implant. Whilst there is clearly no virtue in undue delay, these patients are usually haemodynamically stable, and can be nursed comfortably in bed (\pm skin traction) for several days if necessary while appropriate investigations are carried out.

Where destruction is limited to the femoral neck or head, a cemented hemiarthroplasty or total joint replacement is recommended as a primary procedure. Long stem femoral implants should be considered. Subtrochanteric fractures or lesions with limited bone loss are best stabilised by 'reconstruction' nails with locking screws up the femoral neck. This greatly reduces the risk of subsequent femoral neck fracture.

11.2 Pelvis and Acetabulum.

The majority of pelvic lesions are treated with prophylactic palliative radiotherapy alone. Peri-acetabular lesions, however, may lead to central dislocation of the hip with migration of the femoral head into the pelvis. Patients who have undergone radiotherapy to this area may occasionally suffer pain due to radiation necrosis of the femoral head or articular cartilage. Total hip replacement with acetabular reconstruction using threaded rods, reinforcement rings and bone cement can be highly effective in restoring or maintaining mobility.

11.3 Shoulder Girdle and Upper Limb.

Metastatic lesions or fractures of the scapula and clavicle are usually managed with radiotherapy alone. In the humeral head, significant destruction is, in most cases, best treated by hemiarthroplasty. In the forearm, however, where stresses are relatively low, plate fixation with cement augmentation can be highly effective.

11.4 Shafts of Major Long Bones (humerus, femur, tibia).

Intramedullary nailing is the procedure of choice with locking screws to give rotational stability and to prevent telescoping. Apart from the case of solitary renal metastases, the potential spread of tumour cells within the medulla by nailing is acceptable within the context of palliative treatment. The entire bone and operative site should be included in the post-operative radiotherapy field. Since these fractures are unlikely to unite, load bearing, rather than load sharing, devices should be used, and solid nails, of a greater diameter than may be used for purely traumatic fractures, may be considered. Packing of major bone defects with methylmethacrylate bone cement is useful in maintaining stability in some cases. All of the lesions in the affected bone should be stabilised to minimise the risk of further surgery being required.

Reconstruction nails, stabilising the femoral neck, are recommended in the femur. Lesions of the humerus, particularly the distal humerus, can present a difficult reconstructive problem, and in some instances a cast brace and radiotherapy may be a useful approach.

11.5 Endoprosthetic Surgery.

Extensive bone destruction at the metaphyses of major long bones is sometimes so great that reconstruction can only be achieved using custom or modular endoprostheses (sometimes called 'megaprostheses'). This is particularly applicable in the proximal femur, but lesions of the distal femur, proximal tibia and proximal or distal humerus can also be successfully treated this way. Endoprostheses are principally used in the management of primary bone tumours, but are increasingly used in MBD. They are highly effective in maintaining function, with a low re-operation rate. Referral to a supra-regional centre of orthopaedic oncology should be considered, but it is anticipated that endoprosthetic surgery will also be carried out in regional centres specialising in the management of MBD.

12. SURGICAL TREATMENT - SPINE.

12.1 Incidence

The spine is the commonest site for MBD and whilst not all spinal metastases are symptomatic, pain is frequently disabling. Paresis or paralysis may be the presenting feature. Untreated, high levels of dependency result, with high human and financial costs.

12.2 Background

Historically, surgical management of spinal MBD has been widely considered inappropriate due to poor outcomes for surgical and oncological reasons. Decompressive laminectomy in the presence of anterior column deficiency

frequently led to further destabilisation and early instrumentation had significant design faults.

12.3 Recent Improvements

Over the last two decades there has been considerable improvement in the implants available to manage structural deficiency of the spine, notably pedicle screws, cages and plating or rodding systems. Even in the hospital sector there remains a low level of awareness regarding spinal reconstruction techniques, and a consultant spinal surgical opinion should be obtained before spinal surgical intervention is dismissed.

12.4 Presentation

This is generally in one or more of the following ways:

a. Back pain in isolation.

In some it may be apparent that symptoms are similar to previous episodes of degenerative origin. In others *de novo* pain of mechanical type may be suggestive of pathological fracture. In either case neurological examination must be performed. It is suggested that plain radiographs be obtained in all those with a past history of malignancy. Whole spine sagittal MRI should ideally be performed but availability and cost precludes this at present.

b. Incipient Neurological Compromise

All patients with partial neurological deficit should be assumed to be at risk of sudden deterioration, and should be referred to a Spinal Surgeon/Unit capable of assessment. MRI should be performed.

c. Complete Neurological Deficit

If gradual in onset and within hours of becoming complete, surgery may be considered. If rapid in onset or with complete deficit of more than 12 hours' duration the probability of significant recovery, particularly in the elderly, is low.

N.B. If pain is severe or there is a partial neurological deficit it may be appropriate to treat the patient as a potentially unstable spine until imaging confirming reasonable structural integrity is obtained.

If instability is confirmed, spinal beds are recommended (with collar, if cervical) to assist in nursing prior to definitive management. Nursing staff should be familiar with care of the unstable spine.

12.5 Patient Factors Influencing Management

- a. biological, as opposed to chronological, age.
- b. general medical condition.
- c. patient motivation. Some patients may not wish to consider surgery in a palliative context, and sensitive discussion with patients and relatives is essential.

12.6 Spinal Factors Influencing Management

- a. whether compression is due to tumour in isolation or spinal fracture needs to be established. If the latter then radiotherapy will be ineffective, and surgery is the only option for neurological improvement.
- b. extent of spinal involvement. This can only be adequately be established with MRI
- c. level and direction of compression. This is important for surgical planning.

- d. duration and degree of neurological compromise.

12.7 Tumour Factors Influencing Management

- a. tumour type. This will affect prognosis.
- b. adjuvant sensitivity to chemotherapy, radiotherapy or hormonal manipulation.
- c. staging.

12.8 Clinical Assessment.

A complete history and examination with particular attention to neurological status is mandatory. Fluid balance charts to monitor sphincter function and neurological charts are required.

12.9 Laboratory Investigations

In addition to standard haematological and biochemical analysis, the coagulation profile is essential. Site-dependent tumour markers may also be valuable, but their role is beyond the scope of this document.

12.10 Imaging Requirements

Plain radiographs of spine

MRI - Whole spine saggital views/projections, T1 & T2 axial projections of involved levels.

Chest X Ray

Chest CT

Liver imaging (CT or US)

Isotope bone scan

(Those in italics represent desirable staging investigations, but should not delay appropriate surgical intervention if neurology is deteriorating).

12.11 Biopsy of Spinal Lesions

General principles are as for non spinal tumours. Biopsy of an apparently solitary lesion should not be undertaken without prior discussion with a spinal centre. Biopsy generally requires imaging control in the form of CT or bi-planar image intensifier, and should normally be performed by trephine. Multiple samples should be obtained, particularly with blastic lesions, in view of the difficulty in obtaining diagnostic material.

12.12 Spine Scoring Systems.

A number have been reported and some validated as clinically useful. Their use is recommended (Tokuhashi, Tomita) but no system has been universally adopted.

12.13 Treatment Selection

a. Indications for Radiotherapy

No spinal instability

Radiosensitive tumour

Stable or slowly progressive neurology

Multi-level disease

Surgery precluded by general condition

Poor prognosis

Post operative adjuvant treatment

b. Indications for Surgery

Spinal instability evidenced by pathological fracture, progressive deformity,

and/or neurological deficit

Clinically significant neurological compression especially by bone.

Tumour insensitive to radiotherapy, chemotherapy or hormonal manipulation

Patients who have reached spinal cord tolerance after prior radiotherapy Intractable pain unresponsive to nonoperative measures (eg radiotherapy, chemotherapy or hormonal manipulation.)

12.14 Objectives of Surgery

- a. Maintenance of or restoration of spinal cord/nerve root function
- b. Preservation of or restoration of spinal instability
- c. Preservation of as many normal motion segments as possible

12.15 Principles of Surgery of Particular Significance in Spinal Disease.

- a. The magnitude of the procedure should not exceed the patient's ability to survive it or the surgeon's level of competence. The surgeon requires familiarity with anterior and posterior approaches to all spinal levels. Junctional areas may require specialised approaches.
- b. All constructs will eventually fail unless replaced by living tissue. If the prognosis exceeds six months, adjunctive fusion should be considered.
- c. Implants should provide immediate stability
- d. Ideally, either anterior or posterior constructs alone should be sufficient to provide decompression and stability
- e. Surgical implants should be Titanium for MRI compatibility
- f. Posterior constructs should be based on pedicle screws, and rectangular for maximum stability
- g. An adequate range of implants for posterior and anterior reconstruction at all levels should be available in-house

12.16 Theatre Requirements for Spinal MBD

- a. Recognition of the surgical priority of these cases and displacement of other less pressing cases when necessary.
- b. Surgery during normal hours with full support, including appropriately trained theatre staff.
- c. Spinal operating table permitting biplanar imaging, and trained radiographers.

12.17 Anaesthesia Requirements

- a. Consultant Anaesthetist
- b. Facility for biluminal intubation

12.18 Post Operative Requirements

- a. High Dependency Unit (HDU) facilities are mandatory. If it is anticipated that patients will require ITU facilities in terms of their general condition then it is questionable whether they should be undergoing surgery for this indication.
- b. Physiotherapy and hydrotherapy are particularly desirable in assisting mobilisation and recovery following spinal procedures.

13. WHEN IS BIOPSY NECESSARY?

13.1 If there is the slightest doubt as to the underlying pathology, and in particular where there is a solitary bony lesion, then further investigations including scintigraphy, MRI scan of the lesion and percutaneous bone biopsy should be carried out before definitive surgery. This will avoid so-called ‘whoops’ procedures where a specimen of histology is sent only at the time of definitive surgery and it turns out that an inappropriate procedure has been performed. Nailing of a long bone lesion which proves to be a primary bone tumour can

be a disaster, spreading tumour cells throughout the marrow cavity, and frequently precluding limb salvage surgery.

13.2 Biopsy should generally be carried out by an experienced surgeon using percutaneous biopsy instruments and under X-ray control. If biopsy is carried out by a radiologist, there should be prior discussion with the surgical team, so that the creation of inappropriate biopsy tracts can be avoided.

13.3 Patients with a solitary renal metastasis have a good prognosis if the lesion is treated as a primary neoplasm and radically excised. Referral to a regional centre is recommended.

14. HOSPITAL FACILITIES REQUIRED FOR THE MANAGEMENT OF MBD.

14.1 Facilities should include a dedicated orthopaedic ward, consultant-led trauma or elective theatre lists, clean air theatre enclosure and an adequate inventory of trauma, spinal and arthroplasty implants.

14.2 A skilled and prompt pathology service and anaesthetists familiar with the metabolic disturbances commonly associated with MBD are essential.

15. SERVICE DELIVERY AND THE MULTI-DISCIPLINARY TEAM.

15.1 The management of MBD requires input from a wide range of specialists, including pathologists, radiologists, oncologists, radiotherapists, palliative care specialists, cancer nurses and pain specialists. The Chief Medical Officer has instructed that cancer care in England and Wales be concentrated into Cancer Centres and Cancer Units in order to improve outcomes. There must be orthopaedic input to these multi-disciplinary teams in order to provide optimum care for patients with MBD.

- 15.2 We consider that a lead orthopaedic surgeon for appendicular MBD should be designated in each trauma group as an integral part of the multidisciplinary team. The skills of the named individual need to be maintained by CPD and this added burden must be acknowledged by Trusts. Where workload is significant, a sessional commitment may be required.
- 15.3 The lead orthopaedic surgeon for MBD will not, in most cases, be skilled in all aspects of trauma, arthroplasty and spinal surgery, but will liaise with a network of colleagues and regional or supra-regional centres as necessary to optimise the management of more complex cases.
- 15.4 Within each Health Region, clear definition of those responsible for the provision of reconstructive spinal surgery for MBD is required. This will normally be the remit of those charged with the management of spinal trauma/infection. The relative contribution of orthopaedic spinal surgeons and neurosurgeons will be determined at local level.
- 15.5 A regular weekly conference is the most appropriate vehicle for contact between members of the team. A weekly combined clinic specifically for patients with bone pain or known MBD may however be a satisfactory alternative. Access to an orthopaedic opinion is widely perceived to be inadequate, and without a regular clinic or conference, we do not consider that this concern will be met.
- 15.6 Appropriate audit of referral, surgical requirement and outcome should be compiled and made available for national comparison. In particular, details of those in whom no intervention is undertaken and the reasons for this should be

included. Financial and administrative support for this should be made available.

15.7 It is imperative that sufficient and timely access to the appropriate imaging facilities is made available , notwithstanding that this may mean significant alteration to current custom and practice in on-call availability . With the recent provision of MRI facilities in most DGHs, it is no longer acceptable to transfer patients in pain and at risk of neurological deterioration to a centre for consideration of surgery only for them to be returned to the referring DGH when it has become apparent there is no surgical option.

15.8 Education of what can now be achieved for many of these patients remains a priority. The orthopaedic and spinal surgical community needs to inform professional colleagues, both in primary and secondary care, of the possibilities that now exist. Patients should be aware at the outset of their disease of the possibility of skeletal involvement and that this event can often be addressed effectively.

16. TABLE 1.

MIRELS' SCORING SYSTEM FOR METASTATIC BONE DISEASE.

VARIABLE	SCORE		
	1	2	3
<i>SITE</i>	UPPER LIMB	LOWER LIMB	PERITROCHANTERIC
<i>PAIN</i>	MILD	MODERATE	FUNCTIONAL
<i>LESION</i>	BLASTIC	MIXED	LYTIC
<i>SIZE*</i>	<1/3	1/3 - 2/3	>2/3

*As seen on plain X-Ray, maximum destruction of cortex in any view.

*Maximum possible score is 12. If lesion scores 8 or above, then prophylactic fixation is recommended **prior** to radiotherapy.*

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