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REVIEW

Acute Spinal Problems in the Elderly

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Abstract

The human spine has two structural and one main physiological function. The first structural function is to maintain the erect posture to allow a bipedal stance and the second is to protect the neurological elements, namely the spinal cord and the derived nerve roots. Physiologically, the spine is responsible for the majority of haematopoiesis in the skeletally mature adult. Failure of the spine can be observed as a loss of these functions; spinal deformity and neurological deficit. Clinically "spine failure" manifests like many other non-spinal pathologies in the elderly such as reduced mobility, falls and loss of independence. The management of these problems poses a challenge in this population. It is anticipated that, with an ageing population, the incidence of these issues will increase across medical specialties and so awareness of their presentation and treatment is significant. In this review, we aim to provide an overview of the diagnosis and current treatment of the most prevalent spine issues in the elderly including osteoporotic fracture, C2 fractures, myelopathy, Metastatic Spinal Cord Compression (MSCC) and lumbar stenosis.

Key words: spine; degenerative cervical myelopathy; lumbar stenosis; metastatic spinal cord compression; osteoporotic fractures

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Introduction

The human spine serves two primary purposes: first, it keeps the body upright so that people may walk on two feet; second, it protects the neurological components, such as the spinal cord and derived nerve roots (Khalil et al, 2017). Failure of the spine can be observed as a loss of these functions; spinal deformity and neurological deficit.

In the ageing spine, the most common deformities are an exaggeration of the thoracic kyphosis from osteoporotic wedge fractures and loss of the natural lumbar lordosis from degenerative disc disease (osteoarthritis). Both lead to a loss of sagittal balance or erect posture (Fig. 1).

The prevalence of adult spinal deformity is estimated to be between 8.3–68% (Edmond and Felson, 2000). Although most patients are asymptomatic, the prevalence of musculoskeletal pain in older adults ranges as high as 85% with up to 70% of them suffering from back pain (Bradford et al, 1999).

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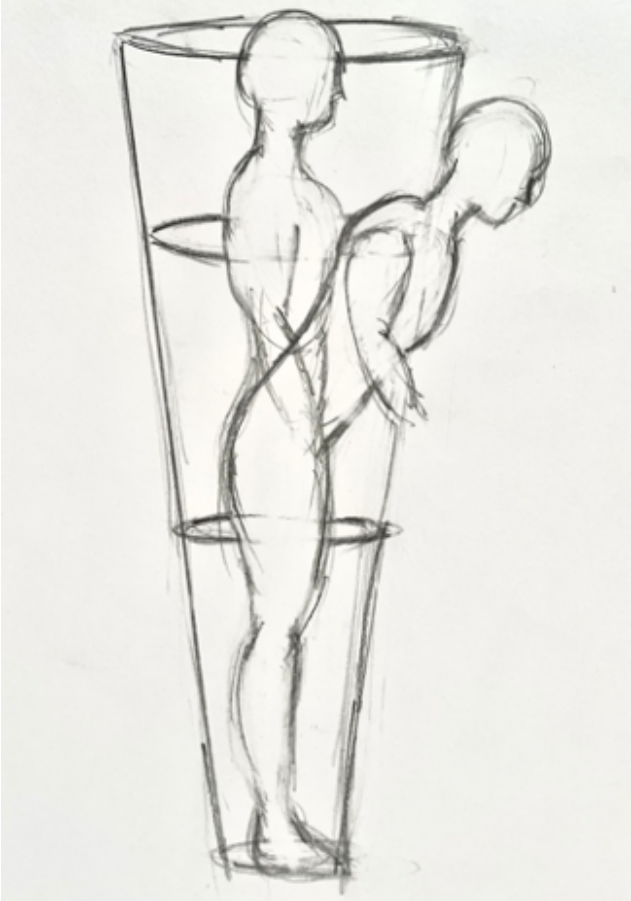

Fig. 1. The cone of economy.

The "cone of economy" concept is useful when evaluating sagittal balance in elderly patients with spinal deformities. This is a hand-drawn diagram demonstrating the gravity line within the cone of economy, where minimal muscle activation is needed to maintain balance. However, in patients with severe spinal deformity, the gravity line is outside the cone of economy. This means greater muscle energy is required to maintain a standing posture (Dubousset and Weinstein, 1994).

Patients with spinal malalignment complain of a variety of symptoms, including intermittent claudication, severe low back pain, gastroesophageal reflux disease caused by excessive pressure on the abdomen due to spinal kyphosis, depression and hence a deterioration in quality of life (QOL) (Edmond and Felson, 2000).

The most common neurological presentation pathologies are cervical myelopathy and lumbar radiculopathy (Khalil et al, 2017). Symptoms include pain, loss of power and sensation.

Clinically 'spine failure' manifests like many other non-spinal pathologies such as reduced mobility, falls and loss of independence.

The management of these problems poses a challenge in the elderly population. Once conservative measures such as analgesia and physiotherapy have failed; the next step is surgery. Surgery however has increased risks of morbidity and mortality in this group of patients (Tan et al, 2019).

In this review, we aim to summarise the diagnosis and up-to-date management of the most common spine problems in the elderly.

Osteoporotic Fractures

A vertebral fragility fracture is defined as a significant reduction in vertebral height or vertebral deformity as a consequence of structural failure. This can be precipitated by low-velocity trauma such as a fall from standing height or from straining and lifting. Occasionally there is no specific injury and fractures are picked up incidentally on X-rays, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI).

It affects 1 in 5 women over the age of 70. Vertebral fractures are powerful predictors of future fracture risk with 20% of patients sustaining another fracture in the first year and an increased relative risk of hip fracture. They incur significant care costs approximately £3400 per fracture in the first year and costs are expected to significantly increase in the future reflective of the ageing population (Royal Osteoporosis Society, 2022).

Currently, only 30% of vertebral fractures are identified. Some patients may not have any symptoms or be able to self-manage their symptoms. Back pain is the most common symptom of a vertebral fracture. Vertebral fractures are typically diagnosed from X-ray, CT or MRI scans, some may also be picked up during Dual Energy X-ray Absorptimetry (DXA).

All patients with vertebral fractures should have a holistic assessment to determine the impact of the fracture on pain, physical functioning and quality of life. Pain intensity may be assessed using a numeric rating scale (Breivik et al, 2008) (NRS) or a functional pain assessment score (Table 1). Optimisation of pain and avoidance of prolonged bedrest is important to reduce the risk of losing bone and muscle strength.

Analgesia for Vertebral Fracture Pain

Adjunct therapies in addition to the analgesic ladder should be considered carefully in the elderly patient group; muscle relaxants or centrally acting therapies such as tricyclic antidepressants and neuropathic agents should be considered depending on symptoms, along with a discussion about risks and benefits. These agents can be beneficial in treating discomfort associated with muscle spasms and neural compression, where World Health Organisation (WHO) analgesic medications may not be as effective. Attention should be given to the risk of sedation and increased falls.

There is insufficient evidence to support the use of some non-pharmacological treatments such as orthosis, Transcutaneous Electrical Nerve Stimulationa (TENS) and local heat.

However, for hospitalised patients vertebral augmentation can be a proven option. This is particularly where the patient's pain is severe after 48 hours of hospitalisation and impacting function. Such patients who have a radiologically proven acute compression fracture should be considered for referral for vertebral augmentation; this can consist of vertebroplasty or kyphoplasty (Fig. 2).

Table 1. Functional pain assessment score.

Pain level	Suggested analgesia
Mild pain (NRS <3/10)	
No/mild limitation compared with normal activity	Paracetamol ± weak opioids ± Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
Moderate pain (NRS 4–6/10)	
Mild/moderate limitation compared to normal activity	Paracetamol ± opioids ± NSAIDs ± adjunct therapy
Severe pain (NRS >6/10)	
Severe limitation compared with normal activity	Paracetamol Opioids ± NSAIDs ± adjunct therapy

NRS, numeric rating scale.

Benefits of cement augmentation include immediate pain relief from the fracture site and hence reduction in analgesic requirements. This can lead to a reduced inpatient stay and faster recovery to independence. The procedure can be done under sedation in some centres. The risks of cement augmentation include cement leak leading to paralysis and cement embolism leading to stroke, respiratory and renal failure.

Exercise following fracture has been shown to have beneficial effects on muscle strength, balance and fear of falling. In the acute setting, patients should be seen by physiotherapists if they have severe pain and loss of function. After the fracture has healed all patients should initiate a progressive balance and strength-training programme.

All patients with vertebral fractures should have fall risks assessed and consider referral to fall prevention service. They should also receive a fracture risk assessment using FRAX® or QFracture (National Institute for Health and Care Excellence (NICE), 2017). All eligible patients should be considered for initiation of appropriate therapy to reduce bone loss and risk of future fractures (Compston et al, 2017; National Institute for Health and Care Excellence (NICE), 2019; National Osteoporosis Guideline Group (NOGG), 2021; Scottish Intercollegiate Guidelines Network (SIGN), 2015).

C2 Fractures

The second cervical vertebra also known as the ‘axis’ is made up of the body, the posterior elements and the odontoid process. The latter also known as the ‘Dens’ or ‘peg’ articulates with C1, which in turn articulates with the base of the skull. The joint complex is stabilised by ligaments as illustrated in Fig. 3 (Johal et al, 2017).

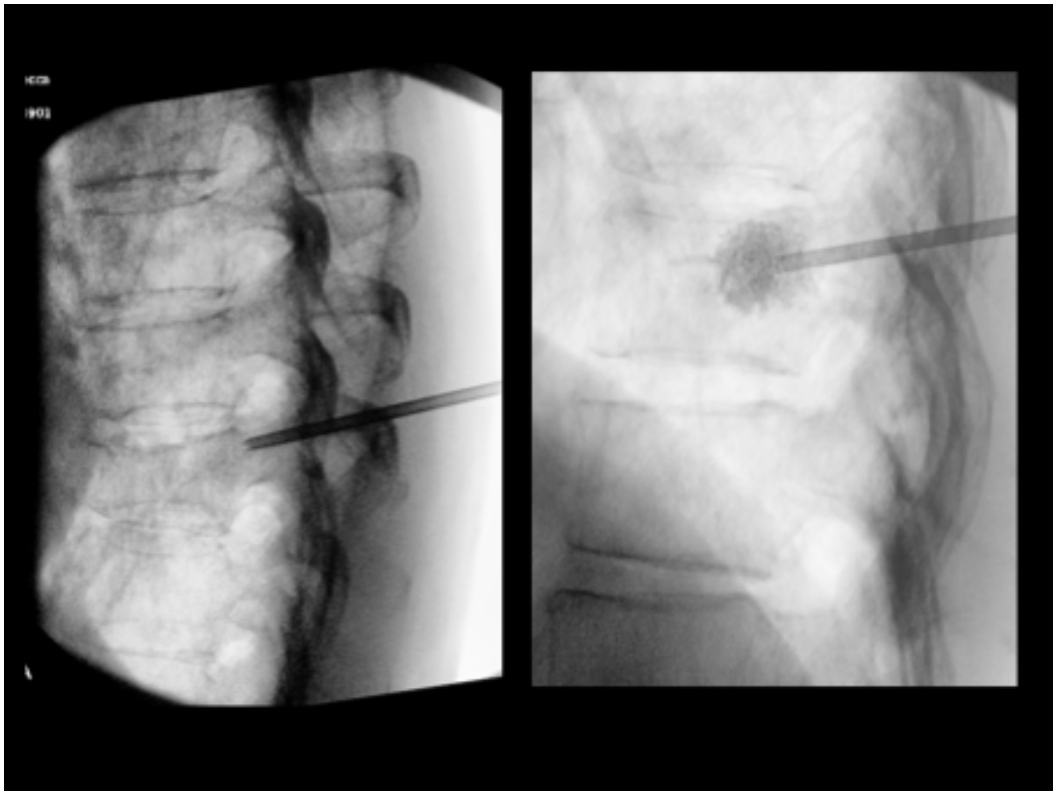

Fig. 2. Fluoroscopic imaging of vertebral augmentation. Under sedation or general anaesthetic, a canulated needle is passed into the vertebral body through the pedicle. In kyphoplasty an inflatable balloon is inserted that corrects some of the deformity. The void is then filled with cement. In vertebroplasty no attempt is made to correct and cemented is injected into the acute fracture. These are anonymised procedural X-rays from a patient, with consent for their use.

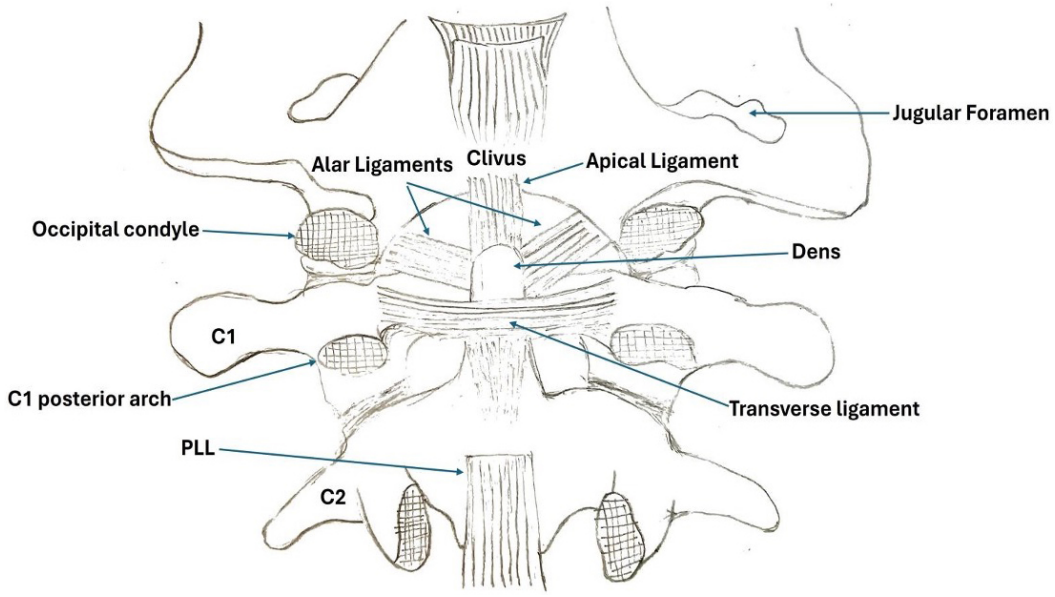

Fig. 3. Anatomy of C1-C2. Hand-drawn schematic showing the bony and ligamentous structures as viewed from posteriorly with sectioning of the laminae of C1 and C2 as well as the posterior part of foramen magnum. PLL, posterior longitudonal ligament.

C2 fractures can be classified as Odontoid fractures, Hangman's fractures and atypical fractures. C2 fractures of the odontoid are the most common and can be classified into three types (Robinson et al, 2017).

Type 1 fractures involve the tip of the Dens. This is a rare fracture and is usually stable as only the topmost part of the Dens is injured and usually heals without any intervention.

Type 2 fractures are the most common type and are around the waist of the Dens, above the level of the vertebral body. Although most are stable and are managed with a hard collar; the main complication tends to be non-union due to a tenuous blood supply compared with other vertebrae.

Type 3 fractures involve the body of the C2 vertebra and in most situations are stable injuries, not needing intervention.

C2 fractures have a biphasic age distribution, 20–30 years with high energy mechanisms and 70–80 years with mostly low energy injuries (Chen et al, 2012). High-energy injuries tend to be unstable due to significant disruption of ligaments and thus more likely to require surgical intervention. Other factors suggesting instability include neurological deficit, which at the high cervical cord is either fatal at the time of injury due to cardiopulmonary arrest or quadriparesis.

Surgical intervention, when necessary, can be broadly divided into internal fixation or external fixation. Internal fixation can be either (Chen et al, 2012):

- Anterior Odontoid Screw Fixation:
  - Placement of one or two screws directly into the odontoid process to achieve fracture fixation.
- Posterior C1–C2 Fusion:
  - This can be performed using various techniques, including wiring or screw methods to stabilise C1 to C2.
  - External fixation is usually done using a halo-vest which can be applied under local anaesthetic (Fig. 4).

Fig. 4. Person in Halo vest. Although these provide excellent support to an unstable fracture: patients with cognitive impairment tolerate them poorly. Hence the management of unstable C2 Dens fractures in the frail remains a challenge. This is a photograph of a staff member, with verbal consent to include it in publication.

Thankfully the vast majority of C2 fractures in the elderly are stable injuries. Various kinds of hard collars stabilise the fracture promoting healing and reducing pain usually over a 3 month period. However, compliance, adequate fit, personal care and pressure sores pose challenges.

Some have questioned hard collar efficacy in this group of patients for this injury (Chen et al, 2012). The Duration of External Neck Stabilisation (DENS) trial is a recently concluded, non-blinded, multi-centred UK study. It aims to evaluate the management of C2 fractures in frail and older patients ($\geq$65 years or Rockwood Clinical Frailty Scale $\geq$5); comparing treatment in a hard collar with management without a collar. It closed recruitment earlier than planned, in November 2023 after 2 years and results are awaited (Woodfield et al, 2022). An interim review of the data collected is expected as a clinical study report.

Cervical Myelopathy

Degenerative Cervical Myelopathy (DCM) is a devastating condition comparable to a spinal cord injury in slow motion. It has a greater impact on quality of life than cancer or diabetes (Oh et al, 2017). It is also very common affecting as many as 1 in 20 patients over the age of 40 (Smith et al, 2021).

It is caused by degenerative changes in the neck compressing the spinal cord. These degenerate changes may be osteophytes, degenerate discs, ligament hypertrophy or instability and movement of the cervical bones.

Patients present with a variety of symptoms most commonly weakness or numbness in the limbs; poor balance with mobility problems; difficulty performing fine motor tasks and sphincteric disturbance. These symptoms are often bilateral affecting upper and lower limbs but may be unilateral.

'Time is spine' so an early diagnosis is vital in preventing significant deterioration of function. A good history will help in the diagnosis and the severity of DCM can be quantified using a modified Japanese Orthopaedic Association scale (mJOA) (Japanese Orthopaedic Association, 1994) (Table 2).

Awareness within the medical community of DCM is low and optimising the timing of surgical treatment is fundamental to maximising its benefits (Davies et al, 2022). Patients often see several healthcare professionals over a protracted period before a diagnosis is made. Increasing awareness of DCM is obviously important.

On examination patients generally present with upper motor neurone pattern weakness with findings such as brisk reflexes, increased muscle tone, clonus, a Hoffman sign, an upgoing plantar reflex and a positive Romberg test. However, some do not display any signs and only present with subjective symptoms of gait disturbance and loss of dexterity; this is particularly so in the early stages of the disease. There are no set diagnostic criteria for DCM, patients may present with a variety or all the above clinical symptoms and signs thus making the early diagnosis of DCM challenging. An MRI showing cord compression is the gold standard for diagnosing the condition. Patients suspected of DCM should therefore undergo an urgent MRI (Fig. 5).

Table 2. mJOA scale.

	Upper limb motor	Lower limb	Upper limb sensory	Sphincter
0	I am unable to move my hands at all	I am paralysed and unable to move and feel my legs	I am unable to feel my hands	I cannot control when I pass urine
1	I can move my hands a little but unable to feed myself	I can feel my legs but unable to move them at all	I have severe pain or loss of feeling in my hands	I have marked difficulty passing urine
2	I can feed myself but am unable to button a shirt	I can move my legs but cannot walk	I have mild pain or loss of feeling in my hands	I have mild difficulty passing urine
3	I can button a shirt but it's very difficult	I can walk on the flat but require a walking aid	I have no loss of feeling in my hands	I have no difficulty passing urine
4	I can button a shirt with slight difficulty	I can walk up and down stairs but must hold a handrail	-	-
5	My hands work normally	I can walk up and down stairs without a handrail	-	-
6	-	I am a little unsteady but can walk unaided	-	-
7	-	My legs are unaffected	-	-

mJOA scale is a patient-reported composite score useful in the grading of myelopathy. Severe 11 and under, Moderate 12–14 and Mild if 14 and over.

Patients with confirmed DCM require an urgent referral to a spine surgeon for further assessment. Patients with moderate and severe mJOA grades will usually be offered surgery but may be kept under close observation.

Surgery removes the pressure from the spinal cord. The surgery can be done in the form of anterior cervical decompression and fusion (ACDF), if the compression is predominantly anterior and over a relatively short space, i.e., 3 or fewer motion segments. However, if the cord compression is extensive and across multiple spinal levels a posterior approach is often favoured. If there is associated instability, then posterior spinal fusion is sometimes necessary. Outcomes from surgery show a slight improvement in mJOA score of about 2 points 24 months from surgery (Fehlings et al, 2015).

The primary goal of surgery is to stop any further progression of the disease. In some cases, patients have been found to make some neurological improvements (Fehlings et al, 2015). However, it is important to try and operate as soon as DCM is suspected as surgery is often unable to reverse the neurological compromise in patients with a delay to treatment or significant disability at presentation due to muscular deconditioning.

There is currently little evidence for non-operative treatment of DCM. Only 1 in 5 patients report any benefit from physiotherapy (Fehlings et al, 2015).

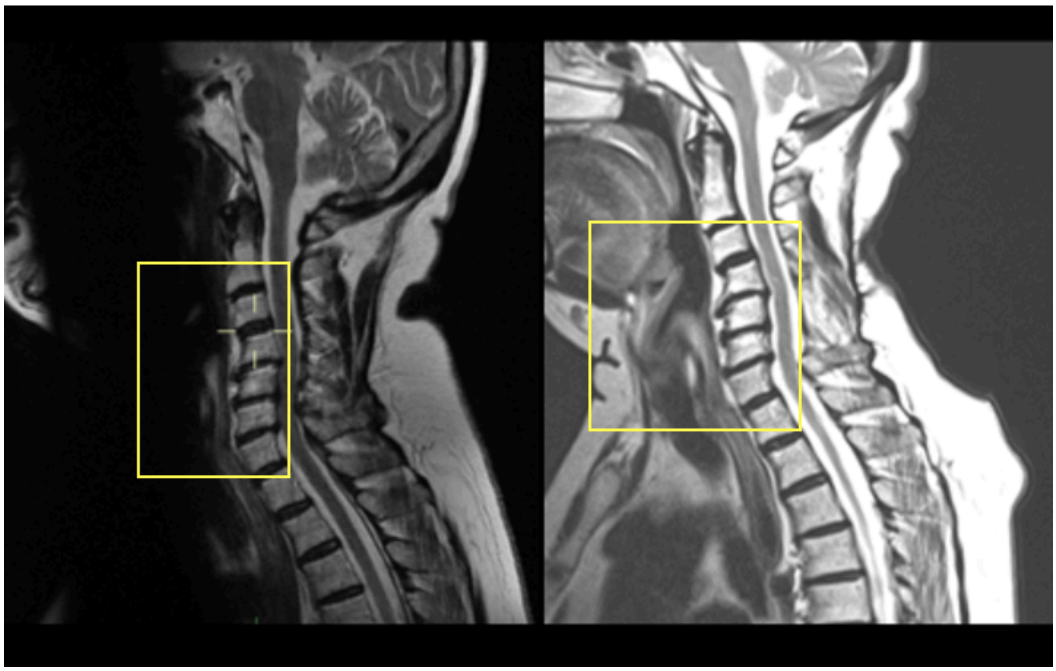

Fig. 5. T2-weighted sagittal MRI images demonstrating degenerative cervical myelopathy pre- and post-treatment. Images were anonymised and obtained from the patient with documented consent. When DCM is suspected patients require an urgent MRI of the Cervical spine looking for spinal cord signal changes, increased signal on T2 images, and narrowing of the spinal canal as seen on the left image. The right shows MRI after posterior decompression. The yellow box demonstrates that the spinal cord is no longer compressed following removal of the posterior elements, the signal change indicating cord damage is not reversed.

Lumbar Stenosis and Radiculopathy

Lumbar stenosis refers to the narrowing of the spinal canal in the lower back, which compresses the conus medularis and lumbosacral nerve roots. It is primarily an age-related degenerative condition, however, is also associated with spinal deformity and spondylolisthesis. With age, the intervertebral discs may lose height and bulge, ligaments can thicken, and bone spurs may form, all contributing to stenosis.

Lumbar radiculopathy or sciatica refers to the compression of one or more of the spinal nerve roots. This can be due to spinal stenosis, disc herniation, space-occupying lesions or infection. Symptoms of lumbar stenosis and sciatica typically include pain, and numbness in a dermatomal pattern, or myotomal weakness in the lower limbs. Patients commonly complain of pain in the buttocks and lower back.

In spinal stenosis, intermittent pain due to mechanical constriction of the nerve roots is termed neurogenic claudication. Symptoms worsen with walking or standing for prolonged periods and may be relieved by sitting or lumbar flexion, as the natural lordotic curve is straightened allowing more space within the spinal canal. In severe cases, lumbar stenosis can lead to significant mobility issues and difficulty performing daily activities. Symptoms can be confused with vascular claudication and to complicate matters further, they can co-exist. Hence vascular and neurological examination is imperative in helping to distinguish between the two (Khalil et al, 2017). Whilst there is overlap between the symptoms of neurogenic claudication

and acute cauda-equina symptoms, the key difference is the slow nature of onset and preservation of bladder and bowel function in claudication versus sudden onset and bladder and bowel involvement in acute cauda-equina syndrome (CES).

This elderly population can present with slow onset of CES symptoms with 'red flag symptoms' that develop over many months. In the younger population, CES tends to be an acute presentation happening over days and hours.

The various presenting complaints of Lumbar Canal stenosis are summarised in Table 3.

All patients need early investigation with MRI and discussion with the surgical spine team (Fig. 6). The timing of the MRI is generally dependent on the duration of symptoms. Symptoms ongoing for less than 2 weeks need emergency scanning, within 4 hours to confirm the diagnosis. The results if positive for cauda equina compression, should be emergently discussed with the local spine surgery service. The recently published GIRFT pathway is an online tool to help standardise CES care including early surgery when appropriate throughout the UK (GIRFT, 2024).

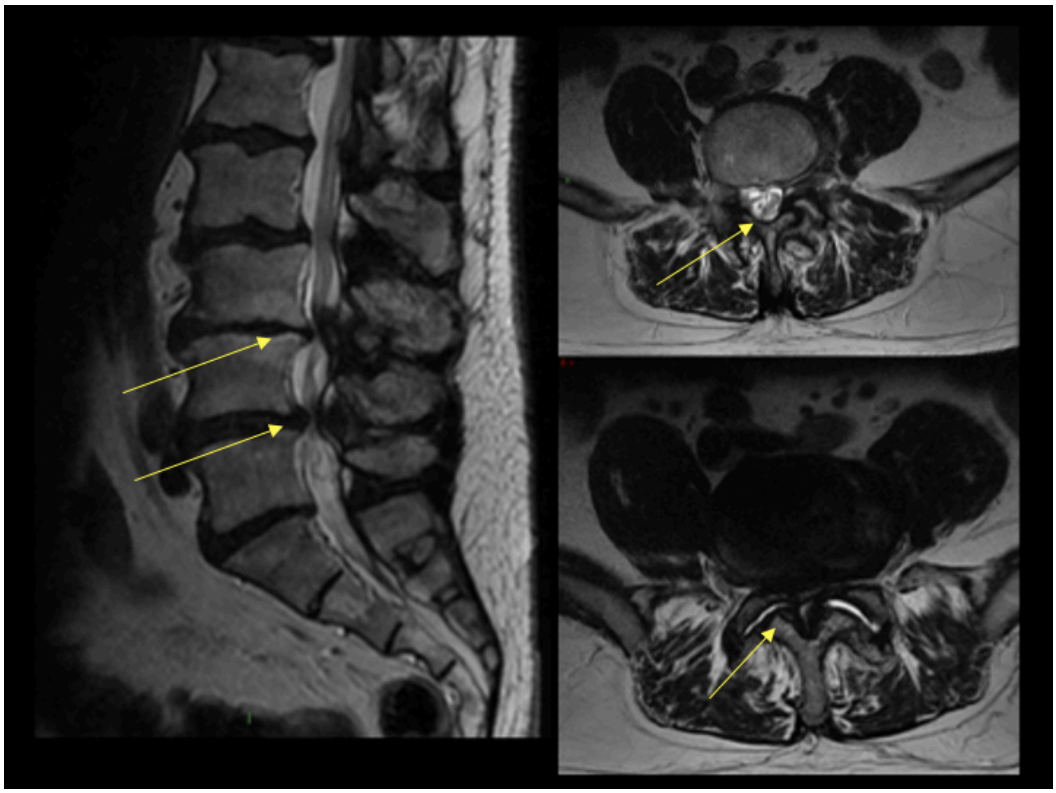

Fig. 6. Sagittal T2 weighted MRI image depicting lumbar stenosis. Secondary to disc degeneration and spondylolisthesis where one vertebral body translates (slips) over an adjacent one. The arrows in the image on the left show multilevel stenosis, particularly severe at L3/4 and L4/5. The image on the top right shows axial images comparing a level with normal space for the lumbosacral nerve roots, indicated by the yellow arrow. In the bottom right axial image the 'white' cauda-equina syndrome (CES) is completely effaced causing severe stenosis, indicated by the yellow arrow. Images from the patient were anonymised and included in the publication with documented consent.

Table 3. Comparison of presenting features in radiculopathy, neurogenic claudication and CES.

Radiculopathy	Neurogenic claudication	Cauda-equina syndrome (CES)
Unilateral	Frequently bilateral	Bilateral
Pain described as 'toothache'	Aching pain	Severe pain
Myotomal weakness	Bilateral weakness	Bilateral weakness
Hyporeflexia	Hyporeflexia	Hyporeflexia
Pain at night	Slow onset. Worse on walking/standing	Sudden or short onset and constant
Bladder/bowel preserved	Bladder/bowel preserved	Bladder/bowel involvement

The symptoms of CES are also known as red flags, which should prompt further investigation by examination and appropriately timed imaging.

Diagnosis of lumbar stenosis or nerve root compression is typically made with lumbar spine MRI with the help of a standing X-ray to determine the presence and grade of spondylolisthesis, if present (Meyerding, 1941).

Due to the degenerative nature of spinal stenosis, a trial of non-surgical management with physiotherapy, activity modification, analgesia and steroid injections is appropriate. There is spontaneous resolution of symptoms in approximately a third of patients (Atlas and Deyo, 2001). Patients who fail non-surgical management can be considered for surgical options that include simple decompressive laminectomy with or without fusion. Patients with radiculopathy due to disc herniation are amenable to discectomy and decompression, should non-operative management fail. Decompressive surgery can be performed open, via direct approach or by utilising minimally invasive endoscopic techniques. Evidence supports satisfactory outcomes in decompressive discectomy surgery using both approaches (Yang et al, 2024).

Abdel-Fattah et al (2023) performed a meta-analysis comparing decompression alone versus fusion in elderly patients with spinal stenosis and low-grade degenerative spondylolisthesis and found that there is no functional benefit with fusion. Whilst decompression alone presented better pain outcomes at 3 years and a lower risk of hospital complications.

The existing evidence suggests greater improvement in outcomes following surgical management versus non-surgical management (Abdel-Fattah et al, 2023). Despite favourable outcomes with decompressive surgery, there is a 4–9% risk of a dural tear, a 1% risk of neural injury and up to a 10% risk of the need for revision surgery (Smorgick et al, 2013).

Metastatic Spinal Cord Compression (MSCC)

MSCC refers to the compression of the dural sac and its contents by an extradural mass. As oncological treatment has improved, the incidence of MSCC has increased. Symptomatic MSCC occurs in around 10% of patients with malignancy (Quraishi et al, 2013). It is the posterior two-thirds of the thoracic vertebral bodies that are most affected, however, multiple deposits across the spine occur in 40% of

patients. The most associated primary malignancies are the lung, breast, prostate, thyroid and renal (Barron et al, 1959).

MSCC usually presents in older patients with an insidious onset, mechanical or rest pain. Some patients present with constitutional symptoms such as weight loss, fatigue and malaise. A neurological deficit may or may not be present.

Although imaging modalities include plain X-ray Antero-Posterior can be useful: whole spine MRI is the gold standard. The timing of which should be within 24 hours for patients with neurological deficits including change in mobility and 1 week for patients with suspected MSCC with normal neurological function.

Other preliminary investigations are focused on establishing the primary malignancy: These include physical examination, laboratory investigations including myeloma screen and staging CT of the thorax, abdomen and pelvis.

Technetium bone scan is sometimes utilised to detect the extent of skeletal disease: however, is of limited value in myeloma and thyroid carcinoma, which often are 'cold' on bone scan (Rougraff, 2003). When the primary malignancy is uncertain, obtaining a biopsy is necessary.

Management of MSCC usually involves oncological treatment with consideration of surgical involvement. Surgical considerations include the presence of neurological symptoms, spinal instability and the expected life expectancy of the patient. Patient longevity can be described objectively using performance status and Tokuhashi revised system (Ludwig et al, 1982; Quraishi et al, 2013).

Otherwise, fit and well patients with single metastasis and favourable prognostic tumours can be considered for en-bloc resection. Which is in general highly invasive surgery but with the intent to cure.

For the majority of patients, surgery is to preserve mobility and does not confer improved survival. The aim of most MSCC surgery is to restore the functions of the spine by stabilising with rods and screws and decompressing the neural elements. When it is deemed that surgical decompression in MSCC is a viable treatment option, Patchell et al (2005) found that decompression with radiotherapy is superior to radiotherapy alone in patients with MSCC.

Current NICE guidance suggests patients with spinal metastases and non-mechanical pain should be offered radiotherapy and surgical intervention and surgical intervention should be considered in the presence of instability or uncontrolled pain (NICE guideline, 2023).

Complications related to spinal metastases surgery have significant implications for patients and it is important to consider the complication profile. Arrigo et al (2011) performed a retrospective review of 200 patients who underwent surgery for MSCC and found a significant complication rate of 34%.

Patients with life expectancies of less than 6 months are generally for best medical management; although these are rough parameters, and all decisions are best discussed at an oncology/spine Multi-Disciplinary Team (MDT) with a good understanding of the wishes of the patient.

Conclusion

Current evidence suggests that some patients benefit from early operative intervention, particularly for cervical myelopathy. For other conditions, the approach must be customised for each patient bearing in mind their symptoms, commodities, concerns and expectations as well as the natural history of the disease.

The successful management of spinal problems in the elderly relies on early identification of the problem and an integrated approach to management, bearing in mind the wishes of the patient and family, along with the expertise of geriatricians, physiotherapy, occupational therapy and spinal surgeons.

Key Points

- All patients with vertebral fractures should have a holistic assessment to determine the impact of the fracture. For hospitalised patients where the pain is severe after 48 hours and impacting function and radiologically proven acute compression fracture, consider referral for vertebral augmentation.
- The vast majority of C2 fractures in the elderly are stable injuries; The recently concluded Duration of External Neck Stabilisation (DENS) aims to compare the management of these injuries with and without a hard.
- Degenerative Cervical Myelopathy (DCM) is comparable to a spinal cord injury in slow motion. Awareness of DCM is low and optimising the timing of surgical treatment is fundamental to maximising its benefits.
- Lumbar stenosis refers to the narrowing of the spinal canal in the lower back, which compresses the conus medularis and lumbosacral nerve roots. In the elderly population this can present with neurogenic claudication, radiculopathy and slow onset of cauda-equina syndrome (CES) symptoms with 'red flag symptoms' that develop over many months. All patients need early investigation with MRI and discussion with the surgical spine team.

Availability of Data and Materials

Not applicable.

Author Contributions

SB devised the scope of the paper and made significant contributions to reviewing and editing the chapters. MA, AF and JL participated in devising and appraising data and drafting of the manuscript. JR participated in conception and design, drafting the manuscript and editing of the manuscript. All authors revised it critically for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agree to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Written informed consent was obtained from patients for the use of anonymised imaging.

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Conflict of Interest

The authors declare no conflict of interest.

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