Evidence-to-Recommendation Framework

This document outlines the underpinning evidence and rationale for the recommendations in the ACE Clinical Guideline (ACG) "When to order MRI for low back pain".

In ACGs, the strength of a recommendation reflects the confidence that the desirable effects of the recommended practice outweigh undesirable effects across the range of patients for whom the recommendation applies, based on the best available evidence:

- A strong recommendation is usually made when benefits clearly outweigh the risks, based on at least moderate-certainty evidence.
- A weak or conditional recommendation may be needed when there is a closer balance between benefits and harms, evidence is of low certainty, there is significant variability in patients' values and preferences, or important concerns with resourcing and feasibility of the recommended practice[1].

Recommendation 1	**Patients with non-specific low back pain with or without radicular symptoms – MRI is not indicated**
Recommendation 2	**Patients with non-specific low back pain despite 4 to 6 weeks of conservative management – MRI may be indicated**

Strength of recommendation 1	**Strong**	Conditional
Strength of recommendation 2	Strong	**Conditional**

Summary:

MRI of lumbar spine for patients with non-specific low back pain is associated with overall unfavourable benefit/risk ratio and significant resource utilisation. While patients with low back pain perceive MRI of lumbar spine as useful, clinical evidence does not support routine MRI use (moderate certainty of evidence). A strong recommendation against MRI of lumbar spine for acute, non-specific low back pain is proposed. On the other hand, the benefit/risk balance is closer for patients with persistent non-specific low back pain despite adequate conservative management and MRI may be indicated for the evaluation of the underlying cause of the persistent pain.

Balance of benefits and harms

Acute non-specific low back pain

Early imaging in patients with non-specific low back pain is not associated with clinically significant improvements in patient reported outcomes, such as pain, function, quality of life and mental well-being.[2] In addition, early MRI of lumbar spine in patients with non-specific low back pain may be associated with more invasive and costly management without a corresponding improvement in low back pain.[3] In a meta-analysis of randomised controlled trials evaluating the difference in outcomes between patients with non-specific low back pain with early imaging compared to those without early imaging, there was no significant difference in short and long-term pain, function, quality of life, mental health and overall improvement.[2] In a retrospective matched cohort study, it was noted that patients with non-specific low back pain who underwent early MRI of lumbar spine experienced worse pain (pain score 3.99 vs 3.87) at follow-up compared to patients who did not have an early MRI of lumbar spine, despite undergoing more lumbar spine surgery (1.48% vs 0.12%), having more prescription opioid use (35.1% vs 28.6%) and incurring a higher medical cost ($8082 vs $5560), $p< 0.001$ for all comparisons.[3]

Persistent non-specific low back pain

MRI of lumbar spine may be able to identify an underlying cause for patients with persistent non-specific low back pain, such as degenerative disc disease.[4,5] In a prospective study evaluating the MRI findings of patients with non-specific back pain who had failed conservative management, among patients aged 30 to 40 years old, prevalence of severely degenerated discs was 56.6% compared to 40% in asymptomatic patients in the same age group.[4] In a meta-analysis done to evaluate the diagnostic accuracy of imaging in identifying the cause of low back pain, the likelihood ratio that MRI evidence of disc degeneration was associated with discogenic low back pain was 2.20 (95% CI 1.61-3.01).[5]

Certainty of evidence	**Values and preferences**
Acute non-specific low back pain The certainty of evidence (CoE) for the association between the use of MRI of lumbar spine and patient reported outcomes is moderate. The meta-analysis by Chou et al[2] had moderate to substantial heterogeneity among the studies included, with I^2 ranging from 0% to 78% depending on the outcome measured. The retrospective matched cohort study by Jacobs et al[3] provided moderate CoE for the higher rates of spine surgery, use of opioid medication, and healthcare cost, and a higher pain score among patients non-specific back pain with early MRI of lumbar spine. The inclusion criteria for participants was clear and efforts were made in the statistical analysis to account for confounding. Persistent non-specific low back pain The CoE for the association between patients with persistent non-specific low back pain and MRI findings of disc degeneration is low to moderate. The prospective study by Leonova et al[4] did not include a control population in their study and did not account for confounding. The systematic review by Han et al[5] had concerns regarding the risk of bias in the studies used and there was moderate heterogeneity (I^2 = 44.4%) in the pooled analysis that was conducted.	A systematic review of qualitative studies conducted in Europe, North America, Australasia and Asia to evaluate patients' beliefs about diagnostic imaging for low back pain found that patients believe that imaging is an important tool for evaluating the underlying cause of their low back pain and they feel that the findings on imaging help legitimise the pain they experience.[6] These findings were consistent among the studies included in this systematic review. A comprehensive search strategy in identifying relevant studies was used and it included high quality studies that were conducted in Asia, which improves the local applicability of its findings. Systematic reviews have shown that patients desire having a diagnosis for their low back pain[7] as it allows for the development of appropriate management strategies to resolve the pain they experience and allow them to regain their pre-pain quality of life.[8]
Resources and feasibility	**Acceptability and other considerations**
MRI of lumbar spine is not available in the primary care setting within Singapore's public healthcare system and requires a referral to a specialist in the tertiary care setting. This will lead to additional waiting time and cost for the patient. The median waiting for a referral to a specialist clinic in a public hospital is 35 days for subsidised	Evidence synthesis from qualitative studies conducted in Europe, North America, Australasia and Asia have found that physicians generally believe imaging is a useful tool for the evaluation of the underlying cause of low back pain, a normal imaging can reassure patients of the absence of serious pathology and imaging

patients in Singapore, with earlier appointments provided in cases that are assessed as urgent.[9] Subsidies are available for patients to reduce the cost of outpatient MRI scans.[10] Early MRI of lumbar spine in patients with non-specific low back pain may be associated with higher healthcare resource utilisation, such as an increase in hospital admissions, outpatient consultations, physiotherapy reviews, additional investigations (e.g. electromyography and nerve conduction study) and lumbar spine injections and surgeries. This may lead to higher (unwarranted) healthcare costs.[11]	reduces the risk of missing the diagnosis of a serious spinal pathology.[6] Patients may also request for imaging and declining it may have a negative impact on the doctor-patient relationship.[12,13] Physicians may also not have the time during a clinic consult to explain to the patients about their diagnosis and why imaging is not indicated.[12] MRI of lumbar spine may be contraindicated in some patients, such as patients with metal implants that are not MRI compatible.[14] An alternative imaging modality will be required in such cases. Claustrophobia may be exacerbated in patients undergoing MRI of lumbar spine due to the confined space in the scanner and the prolonged immobility required for the imaging. These patients may require additional measures such as sedation in order to undergo the MRI scan.[15]

Recommendation 3	**Patients with low back pain and progressive neurological symptoms or signs – MRI is indicated**
Recommendation 4	**Patients with low back pain and suspected cauda equina syndrome – MRI is indicated**
Recommendation 5	**Patients with low back pain and cancer or infection (suspected or known) – MRI is indicated**
Recommendation 6	**Patients with new or progressive low back pain following an invasive procedure on the lumbar spine – MRI is indicated**

Strength of recommendation 3	**Strong**	Conditional
Strength of recommendation 4	**Strong**	Conditional
Strength of recommendation 5	**Strong**	Conditional
Strength of recommendation 6	**Strong**	Conditional

Summary:

Strong recommendations are proposed for using MRI of lumbar spine in patients with low back pain and features of underlying spinal pathologies. This is underpinned by overall moderate certainty of evidence for favourable benefit/risk ratio and in alignment with patients' values or preferences.

Balance of benefits and harms

Low back pain can be the symptom of serious specific spinal pathologies, such as cauda equina syndrome, spinal cancer and spinal infection. These conditions warrant urgent evaluation with imaging, for which MRI of lumbar spine, with its multiplanar imaging capability and excellent soft tissue resolution, is the imaging modality of choice.

Low back pain and progressive neurological symptoms or signs

Progressive neurological symptoms or signs in patients with low back pain are associated with serious spinal conditions such as cauda equina syndrome (CES)[16] or spinal infection[17], for which MRI of lumbar spine plays an important role in the evaluation and diagnosis of these conditions (refer to sections on suspected CES and infection for further elaboration on role of MRI in these conditions). In a retrospective cohort study done to evaluate the clinical features of CES, it was noted that the odds ratio for MRI-proven cauda equina syndrome among patients with severe or progressive bilateral neurological deficit was 14.97 (95% CI 4.15-96.79, p< 0.001).[16] There are various stages of spinal epidural abscess. Initial neurological deficits are seen in the third stage with clinical features such as weakness of the voluntary musculature, faecal or urinary incontinence and sensory deficits. This then progresses to the fourth stage, where muscle weakness develops into paralysis. In a meta-analysis conducted to evaluate the clinical features associated with spinal epidural abscess, it was noted that for initial neurological deficit, 26% of patients had muscle weakness, 24% had incontinence and 13% had sensory deficit. For advanced neurological deficit, 31% of patients had paraparesis or paraplegia.[17]

Low back pain and suspected cauda equina syndrome

MRI of lumbar spine allows for early diagnosis of patients with suspected CES for which the clinical signs and symptoms have poor diagnostic accuracy.[18,19] Early management of these patients will lead to improvements in clinical outcomes such as the resolution of motor and sensory deficits, and bladder and rectal dysfunction.[20,21] In a systematic review conducted to evaluate the diagnostic accuracy of clinical features in patients with MRI-proven CES, it was noted that the pooled sensitivity for the signs and symptoms ranged from 0.19 (95% CI 0.09-0.33) to 0.43 (95% CI 0.30-0.56) while the pooled specificity ranged from 0.62 (95% CI 0.59-0.73) to 0.88 (95% CI 0.85-0.92). The clinical features evaluated all showed higher specificity compared to sensitivity in the diagnosis of CES, which suggest a high risk of missing the diagnosis based on the clinical features alone.[18]

A meta-analysis conducted to evaluate the correlation between the time to decompression after the onset of cauda equina syndrome and clinical outcomes after surgery showed that in patients with decompression of CES within 48 hours compared to after 48 hours, there was significant improvement in the resolution of sensory deficit (OR 3.45, 95% CI 1.45-8.33), motor deficit (OR 9.09, 95% CI 2.56-33.33), urinary deficit (OR 2.50, 95% CI 1.19-5.26) and rectal dysfunction (OR 9.09, 95% CI 2.13-33.3).[20] Another meta-analysis showed similar findings, with patients with decompression of CES after 48 hours having a higher incidence of bladder dysfunction after surgery compared to patients who had decompression within 48 hours (50.3% vs 24.6%).[21]

Low back pain and cancer or infection (suspected or known)

MRI of lumbar spine is an accurate imaging modality for the evaluation of patients with concerns of malignancy.[22] In addition, MRI is able to provide important information regarding the underlying malignancy, such as the type of malignancy and the extent of bony, marrow, soft tissue and neural involvement.[23] In a systematic review conducted to evaluate the diagnostic accuracy of imaging for patients with low back pain in the primary care setting, in comparison to other imaging modalities such as plain radiography, computed tomography and bone scan, MRI had the highest sensitivity (0.83 to 0.93) and specificity (0.90 to 0.97) for the diagnosis of spinal metastases.[22]

In addition, early diagnosis and management of patients with concerns of spinal malignancy is associated with improvements in patients function and quality of life.[24] In a prospective study to assess the relationship between delayed treatment and functional status and quality of life among patients with symptomatic spinal metastases, it was found that patients with delayed treatment had lower EuroQoL-5 Dimensions (0.24 vs 0.57) and Karnofsky Performance Score (60 vs 70) compared to patients who had timely treatment ($p < 0.001$).[24]

MRI of lumbar spine is also able to diagnose spinal infections accurately[25] and is also able to detect early spinal infection and delineate the extent of the infection.[26] In a systematic review conducted to evaluate the diagnostic accuracy of imaging for patients with low back pain in the primary care setting, the sensitivity and specificity of MRI in diagnosing spinal infections were found to be 96% and 92% respectively.[22]

Early diagnosis of spinal infections is important as delays are associated with an increased risk of developing persistent pain which can contribute to greater disability and poorer physical and mental well-being.[27] A retrospective observational study found that patients with residual back pain following spondylodiscitis had a significantly longer duration of symptoms prior to diagnosis compared to patients without residual back pain (48 days vs 24.5 days, $p = 0.002$). In addition, it also found patients with residual back pain after suffering from spondylodiscitis had significantly lower SF-36 physical function (27.3 vs 40.6, $p < 0.001$), SF-36 mental function (39.55 vs 46.7, $p < 0.002$) scores, and a higher Oswestry Disability Index (58 vs 26, $p < 0.001$) compared to patients who did not have residual back pain.[27]

New or progressive low back pain following an invasive procedure on the lumbar spine

MRI of lumbar spine is a useful imaging modality for the evaluation of patients with low back pain and concerns of possible complications following lumbar spine surgery, such as a haematoma from postoperative haemorrhage, cerebral spinal fluid (CSF) collection from incidental durotomy and spondylodiscitis.[28,29] Identification of the underlying cause of low back pain in these patients will assist in guiding appropriate management.[30] A retrospective study found that unenhanced T2-weighted MRI had a sensitivity of 92.3% (95% CI 83.0%-97.5%) and specificity of 93.5% (95% CI 78.6-99.2%) in detecting epidural CSF.[31] A prospective study showed that MRI had a sensitivity of 71% (95% CI 51%-87%) and specificity of 83% (95% CI 59%-96%) for the diagnosis of postoperative spine infection.[32]

MRI can also identify other potential abnormalities in patients with low back pain and previous invasive lumbar spine procedure,[30,33] for example in distinguishing scar tissue from recurrent disc herniation.[34,35] Prospective studies have shown that MRI of lumbar spine with gadolinium contrast had a 96% to 100% accuracy in differentiating epidural fibrosis from recurrent disc prolapse.[34,35] However, MRI findings might not correlate accurately with the patient's clinical symptoms[36] and might under-report the severity of scar tissue.[37] A prospective study found that there was no correlation between the pain score of patients with previous lumbar spine surgery and the severity of epidural fibrosis noted on contrasted MRI scan ($p > 0.05$).[36] Another prospective study found that 80.1% of patients with severe epidural fibrosis noted on epiduroscopy did not have such findings noted on the contrasted MRI scan.[37]

Certainty of evidence	Values and preferences
Low back pain and progressive neurological symptoms or signs The CoE for the relationship between progressive neurological signs and symptoms and serious spinal conditions is moderate. The retrospective observational study by Zeb et al[16] addressed concerns on confounding with the use of multivariable analysis. The meta-analysis by Reihsaus et al[17] had concerns regarding the risk of bias of the studies included. Low back pain and suspected cauda equina syndrome The CoE for the importance of MRI of lumbar spine in the early diagnosis and management of cauda equina syndrome is moderate. The systematic review by Dionne et al[18] had concerns regarding the risk of bias and heterogeneity of the studies included. The meta-analysis by Anh et al[20] had concerns regarding the risk of bias and inconsistency of the results of the studies included. The meta-analysis by Kumar et al[21] had concerns regarding substantial heterogeneity (I^2 = 96.19) of the studies included. Low back pain and cancer or infection	A systematic review of qualitative studies conducted in Europe, North America, Australasia and Asia to evaluate patients' beliefs about diagnostic imaging for low back pain found that patients believe that imaging is an important tool for evaluating the underlying cause of their low back pain and they feel that the findings on imaging help legitimise the pain they experience.[6] These findings were consistent among the studies included in this systematic review. A comprehensive search strategy in identifying relevant studies was used and it included high quality studies that were conducted in Asia, which improves the local applicability of its findings. Early diagnosis of the various specific spinal conditions with imaging allows for prompt and appropriate management, which can improve patient reported outcomes such as the residual low back pain, function, disability, physical and mental well-being and quality of life.[24,27]

The CoE for the importance of MRI of lumbar spine in patients with concerns of spinal malignancy or infection is moderate. The systematic review by Jarvik et al[22] had concerns regarding of the risk of bias and heterogeneity of the studies included. The prospective study by van Tol et al[24] had appropriate eligibility criteria, accurate measurement of both exposure and outcome, addressed concerns on confounding in their analysis of the results and had an adequate follow-up period. The retrospective observational study by Ascione et al[27] had appropriate eligibility criteria and accurate measurement of the outcomes.

<u>New or progressive low back pain following an invasive procedure on the lumbar spine</u>

The CoE for the importance of MRI of lumbar spine in patients with new or progressive low back pain following an invasive procedure on the lumbar spine is low.

The retrospective study by Dobrocky et al[31] had an accurate measurement of the outcome and also had almost perfect inter-rater agreement in the MRI evaluation of CSF leak. However, there was no control group in this study. The prospective study by Paez et al[32] had an accurate measurement of the outcome and was a multicentre study which improves the generalisability of its findings.

The prospective studies by Fan et al[34] and Hueftle et al[35] regarding the role of MRI in distinguishing scar tissue from recurrent disc herniation had concerns regarding selection bias and had a small sample size (n=11 and n=44 respectively). The prospective study by Coskun et al[35] had an accurate measurement of outcomes and an adequate period of follow-up. The prospective study by Bosscher et al[37] had an accurate measurement of outcomes.

Resources and feasibility	Acceptability and other considerations
MRI of lumbar spine is not available in the primary care setting within Singapore's public healthcare system and can only be obtained via a referral to a specialist in the tertiary care setting or via the emergency department.	MRI of lumbar spine may be contraindicated in some patients, such as patients with metal implants that are not MRI compatible.[14] An alternative imaging modality will be required in such cases.

Referral to a specialist will lead to additional waiting time and cost for the patient. The median waiting for a referral to specialist clinic in a public hospital is 35 days for subsidised patients in Singapore, with earlier appointments provided in cases that are assessed as urgent.[9] Subsidies are available for patients to reduce the cost of outpatient MRI scans.[10] If the patient's condition is assessed to be critical and requires immediate evaluation with MRI of lumbar spine, referral to the emergency department will be required. Emergency MRI services are available during and outside of office hours in most public hospitals.	Claustrophobia may be exacerbated in patients undergoing MRI of lumbar spine due to the confined space in the scanner and the prolonged immobility required for the imaging. These patients may require additional measures such as sedation in order to undergo the MRI.[15] The quality of the images obtained from MRI of lumbar spine may be affected by imaging artefacts in patients who had previous lumbar spine surgery with metal implants. There are numerous metal artefact reducing sequences that are available to reduce the size and intensity of the artefacts to allow for adequate radiological evaluation with MRI.[33]

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