Audit of MRI protocol, referral pattern and appropriateness of clinical indications for lumbar spine MRI use for adult low back pain: A singlecentre study in Ghana.

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Abstract

A guideline for MRI request is nonexistent in Ghana. This study is to evaluate the local lumbar spine MRI protocol, clinical indications, referral sources, imaging findings and the appropriateness of the request using the Appropriateness Criteria (AC) of the American College of Radiology (ACR) for MRI of Lower Back Pain (LBP) patients. Using a Ghanaian tertiary hospital's MRI centre, we evaluated the local MRI protocol used for lumbar spine imaging, reviewed the referral sources of adult patients (18 years and above) within a six-month period. The age, gender, clinical indication, imaging findings and the appropriateness of lumbar spine MRI for low back pain (LBP) was descriptively analyzed using Excel 2013. A total of 242 patients (females 140, males 102) underwent MRI for LBP within a six-month period. The existing MRI protocol was justified. Using the AC of ACR, about 39% of MRI requests were "usually appropriate", 36% "may be appropriate", and 25% were "usually not appropriate". Most referrals were from the OPD (58%). Most common indication was LBP/sciatica (52.1%); the most common imaging finding was degenerative changes (65.0%). The local MRI protocol for LBP was justified. Judicious request for MRI is very necessary to avoid wastefulness. MRI centers must prioritize requests coming from Orthopedic Specialists and not the OPD. The main imaging finding was degenerative bone disease which plain radiography can diagnose. This study may serve as a reference for local lumbar spine MRI practice, and inform local practice.

Keywords: MRI protocol, Lower back pain, Sciatica, Degenerative disease, Osteoporosis, Lumbar spine.

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Introduction

Low Back Pain (LBP) is a global public health problem characterized by health-related quality of life impairments, neuropsychological impairments, and has enormous socioeconomic impact. It is the most prevalent musculoskeletal condition and one of the most common outpatient hospital referrals [1-3]. Roudsari et al. estimated that, 80% to 90% of the population will experience LBP at some stage in life [4]. Patients with LBP are asked to undergo one or more imaging examinations in the form of plain radiography, Computed Tomography (CT), and/or Magnetic Resonance Imaging (MRI).

Plain radiographs are the simplest, cheapest and most accessible diagnostic imaging workup for LBP, however, it shows a very low correlation between patients' complaints and physical findings. Its sensitivity in the early diagnosis of cancer

or infection is low [5,6]. Computer Tomography (CT) is more sensitive for the detection of early spinal infections, neoplasm and is the imaging method of choice for infection, cancer, or persistent neurologic deficit [7,8].

The superiority of MRI for imaging the lumbar spine includes its ability to demonstrate spinal infections, intraspinal tumours, and identify degenerative discs based on decreased water content. It is well established that CT and MRI have similar accuracy in detecting herniated disks and spinal tumours [9,10], but MRI is more sensitive [8].

To guarantee excellent images of the lumbar spine, standardized protocols with appropriate choice of imaging planes, weightings, and pulse sequences tailored to the available equipment are required. In addition, the clinical indication for the examination should be appropriate. The appropriateness of MRI is increasingly being debated, due to its high cost and impact on clinical outcome.

According to a European Commission [11] Report, main causes of wasted imaging investigations are: repetitions, inaccuracy in the diagnosis, investigations unlikely to affect patient management, and unavailability of clinical information and questions that the imaging investigation should answer. Due to the ever-increasing amount of evidence on appropriateness (and inappropriateness) of imaging utilization, there are established clinical guidelines aimed at optimizing quality and minimizing waste [12], (Ludwig Boltzmann Institute 2014). One of such guidelines is the Appropriateness Criteria (AC) of the American College of Radiology (ACR) which is widely acceptable for use in many clinical settings.

This study seeks to evaluate the local lumbar spine MRI protocol, clinical indications, referral sources, imaging findings and the appropriateness of the request using the AC of the ACR for MRI of LBP patients in a tertiary hospital's MRI centre in Ghana.

Materials and Methods

Study design and setting

A descriptive cross sectional study was conducted at the MRI centre at the Korle-Bu Teaching Hospital in Accra. The hospital is a tertiary institution and a premiere referral hospital in Ghana. The MRI centre is one of the few MRI centres in the country.

Study population

The study population consisted of all patients 18 years and above who were referred to the MRI centre with LBP within the period of 1^{st} January to 30^{th} June 2018.

We evaluated the local MRI protocol for lumbar spine imaging. A review of all lumbar spine MRI examinations performed was done.

The age, gender, referral source and clinical indication, Appropriateness of lumbar spine MRI for LBP and the imaging findings were collected for analysis.

Data analysis

Microsoft Excel 2013 was used in the entering, cleaning and analysis of data. The age, gender, clinical indication, imaging findings and the appropriateness of lumbar spine MRI for LBP was descriptively analyzed.

Results

A total of 242 patients (140 females and 102 males; age 18 years and above) underwent lumbar spine MRI between during the study period. The details of the age and sex distribution are shown in Table 1. The lumbar spine MR images were acquired on a 1.5T Toshiba Titan using a 16-channel phased-array spinal coil. The routine lumbar spine MRI protocol used in this MRI suite was analyzed. This is shown in Table 2. A total of 6 pulse sequences were acquired, mainly in the sagittal and axial

planes Contrast administration was not routinely used, except in the suspected cases of infection and tumour.

Table 1. Distribution of LBP patients by age and sex.

Age (years)	Female	Percent (%)	Male	Percent (%)
18 – 25	9	6.4	3	2.9
26 – 35	13	9.3	9	8.8
36 – 45	28	20	21	20.6
46 – 55	43	30.7	32	31.4
56 – 65	31	22.1	24	23.5
≥ 66	16	11.4	13	12.7
Total	140	100	102	100

From table 1, out of the 242 patients that underwent MR imaging secondary to LBP, 140 (57.9%) were females and 102 (42.1%) were males. Patients between ages 18 to 25 were 12 representing 9.3%, 9 (6.4%) were females and 3 (2.9%) males. The ages of 26 to 35 years were a total of 22 (18.1%) patients, 13(9.3%) were females and 9 (8.8%) were males. The age 36 to 45 were 49 patients representing 40.6%, 28 (20.0%) were females and 21(20.6%) were males. There were 75 patients representing 62.1% between the ages 46 to 55, which had 43(30.7%) females and 32(31.4%) were males. Those aged 56 to 65 were 55 patients representing 45.6% of which 31(22.1%) were females and 24(23.5%) males. Patients of 66 years and above that underwent MR imaging were 29(24.1%) of which 16(11.4%) were females and 13(12.7%) were males.

Sagittal T1W FSE
Sagittal T2W FSE
Sagittal STIR FSE
Axial T2W FSE
Post-contrast Axial T1W-FatSat
Post-contrast Sagittal T1W-FatSat
W: Weighted; FSE: Fast Spin-Echo; STIR: Short Tau Inversion Recovery; Fat Sat: Fat Saturation.

Table 2. Routine Lumbar spine MRI protocol at local center (Ghana).

Table 2 shows the existing MR imaging protocols employed at the imaging center for LBP. The protocol consisted of 6 pulse sequences, acquired mainly in the sagittal and axial planes with T1W and/or T2W T1W and T2W which are core sequences of any MRI protocol, therefore the acquisition of these sequences in this protocol is justified. The acquisition of sagittal T1W-FSE images in this protocol is important for demonstrating the anatomical structures of the lumbar spine at a faster speed than using a conventional spin-echo (SE). STIR-Short tau Inversion Recovery, sequences also called 'search and destroy' in this protocol helps to null the signal from normal bone marrow in order to increase the conspicuity of bone lesions i.e. osseous and ligamentous lesions. Fat Sat-Fat saturation, this protocol facilitates such that, fat-composing structures or lesions will be suppressed for an improved visualization.

The AC of ACR used as a reference in this study is illustrated in Table 3. The clinical conditions, imaging procedure, rating, and comments as presented in the table were those established for MRI of the lumbar spine (Table 3). The appropriateness of lumbar spine MRI cases presented was compared and analyzed using the AC of ACR (Table 4). It was shown that only 39% of the cases were "usually appropriate", 36% "may be appropriate", and 25% were "usually not appropriate".

 Table 3. Clinical condition: Low back pain (ACR Appropriateness Criteria®).

Variant	Imaging Procedure	Rating	Comments
1. Acute, subacute, or chronic uncomplicated low back pain or radiculopathy. No red flags. No prior management.	MRI lumbar spine without IV contrast	2	-
2. Acute, subacute, or chronic uncomplicated low back pain or radiculopathy. One or more of the following: low velocity trauma, osteoporosis, elderly individual, or chronic steroid use.	MRI lumbar spine without IV contrast	7	CT is preferred. MRI can be useful to evaluate for ligamentous injury or worsening neurologic deficit. MRI can depict marrow edema in these scenarios.
3. Acute, subacute, or chronic low back pain or radiculopathy. One or more of the following: suspicion of cancer, infection, or immunosuppression.	MRI lumbar spine without and with IV contrast MRI lumbar spine without IV contrast	8 7	Contrast is useful for neoplasia patients suspected of epidural or intraspinal disease. Noncontrast MRI can be sufficient if there is low risk of epidural and/or intraspinal disease.
4. Acute, subacute, or chronic low back pain or radiculopathy. Surgery or intervention candidate with persistent or progressive symptoms during or following 6 weeks of conservative management.	MRI lumbar spine without IV contrast MRI lumbar spine without and with IV contrast	8 5	This procedure is indicated if noncontrast MRI is nondiagnostic or indeterminate. Contrast is indicated if patient has history of prior lumbar surgery. See variant 5.
5. Low back pain or radiculopathy. New or progressing symptoms or clinical findings with history of prior lumbar surgery.	MRI lumbar spine without and with IV contrast	8	This procedure can differentiate disc from scar.
 Low back pain with suspected caudaequina syndrome or rapidly progressive neurologic deficit. 	MRI lumbar spine without IV contrast MRI lumbar spine without and with IV contrast	9 8	Use of contrast depends on clinical circumstances Use of contrast depends on clinical circumstances

Rating Scale: 1, 2, 3 usually not appropriate; 4, 5, 6 may be appropriate; 7, 8, 9 usually appropriate. For the purpose of this study, only MRI procedures for each variant were included in the table.

Table 3 shows the appropriateness or otherwise of MR imaging of Lumbar Spine for lower back pain, using the American College of Radiologist (ACR) appropriateness criteria. Using a rating scale of 1 to 9, the appropriateness or otherwise can be justified according to the nature of the presenting clinical complaint.

A rating score of 1, 2 and 3 for a particular clinical presentation is deemed usually not appropriate for imaging studies.

A rating score of 4, 5 and 6 for a set of clinical presentation is deemed may be appropriate for imaging studies.

A rating score of 7, 8 and 9 for a set of clinical presentation is deemed to be usually appropriate for imaging studies.

Appropriateness Rating Category	Number of Cases (percentage)
Usually not appropriate (1, 2, 3)	61 (25%)
May be appropriate (4, 5, 6)	87 (36%)
Usually appropriate (7, 8, 9)	94 (39%)

Total	242 (100%)		
Distribution of Appropriateness Rating Cate represent usually not appropriate; 4, 5, 6 represent 8, 9 represent usually appropriate.			

Table 4 shows the distribution for the 242 patients which were seen at the imaging center and using the ACR appropriateness criteria the justification for performing MR imaging studies of the Lumbar Spine for lower back pain gave the following results; 61 (25%) patients were deemed to have had MR imaging which was usually not appropriate whereas, 87 (36%) patients underwent MR studies which may be appropriate and 94 (39%) patients underwent MR imaging which was usually appropriate.

Further descriptive analysis of the data showed the distribution by age and sex of all lumbar MRI during the period, referral pattern and appropriateness of clinical indications for lumbar spine, MRI imaging findings for adult low back pain. Figure 1 represents distribution of low back pain patients by age and sex, the figure shows that there is a gradual increase in the incidence of LBP in both sexes from 18 years with a peak in patients' age between 46-55 years in both sexes. There were 32 (30.7%) males and 43 (31.4%) females.



Figure 1. Distribution of low back pain patients by age and sex.

There was a steady decline in LBP in patients aged 56 years and above. Figure 2 indicates Source of referrals of LBP patients, Referral pattern to the centre showed the out-patient department (OPD) referred the largest number for imaging representing 58.3%. The lowest number came from the accident and emergency unit with 7.9%. The details of the other sources of referral are as shown in the figure. Figure 3 is Indications for lumbar spine MRI, Low back pain/sciatica represented the most common indication for MRI accounting for 51.7% of patients. The details of the other indications are shown in the figure. Figure 4 is the Imaging findings of patients had undergone MRI, The most common imaging finding of the lumbar spine was degenerative changes representing 65.0% Even though significant findings were only 10.0% of the total, and they included tumours and infections.



Figure 2. Source of referrals of LBP patients.

Discussion

This study documents for the first time and evaluates lumbar spine MRI protocol, referral pattern and appropriateness of clinical indications for lumbar spine MRI use for adults with low back pain in Ghana. The role of MRI in interrogating LBP is well established in clinical practice. In this study, lumbar spine MRI was carried out using a 1.5 T scanner, and multiple array spine coils. The advantage of the multiple array spine coils is that it returns high signal, however flare from adipose tissue of the buttock may degrade the image (Westbrook 2014).

The protocol consisted of 6 pulse sequences, acquired mainly in the sagittal and axial planes with T1W and/or T2W T1W and T2W are core sequences of any MRI protocol, therefore the acquisition of these sequences in this protocol is justified. The acquisition of sagittal T1W-FSE images in this protocol is important for demonstrating the anatomical structures of the lumbar spine at a faster speed than using a conventional spinecho (SE). This is because with FSE, several lines of K space are filled at every repetition time (TR) instead of one line as in CSE. Therefore, as K space is filled more rapidly, in effect the acquisition time decreases. In addition, with FSE, reduced flow of CSF means flow artifact will not be problematic. Another important sequence acquired is T2W which best depicts the pathology as most pathologies have increased water content which demonstrates hyper intensity signal on T2W. By acquiring T2W-FSE, the pathology can be easily demonstrated with increased T2 weighting, high resolution imaging, at short scan times.

The acquisition of fat-suppressed T2W-FSE is also invaluable for evaluating spinal bone marrow for tumour [13]. However, because the multiple 180° RF pulses used in FSE sequences cause lengthening of the T2 decay time of fat, the signal intensity of fat on T2-weighted FSE images tend to be higher than in CSE, even with longer TE times (Westbrook 2014). Therefore marrow pathology, such as tumours or fractures, may not be adequately visualized on T2W-FSE sequences, a situation which requires the application of STIR. It is therefore impressive to note that STIR is routinely acquired applied? As part of the lumbar spine MRI protocol. The advantage of obtaining STIR sequences also called 'search and destroy' in this protocol was to null the signal from normal marrow in order to increase the conspicuity of bone lesions i.e. osseous and ligamentous lesions (Westbrook 2014) and (ACR practice guideline 2017). Short Tau Inversion Criteria or other T2weighted fat-suppressed FSE sequences are also recommended for evaluating soft tissues after trauma or surgery (ACR practice guideline 2017).

The acquisition of post-contrast sagittal- and axial T1-weighted FSE images with fat saturation for some clinical indications of the lumbar spine is justified. This is because, by acquiring post-contrast T1W alone, pathologies such as extra osseous extension of a neoplastic process can also be demonstrated [13]. By further combining with fat saturation, fat-composing structures or lesions will be suppressed for an improved visualization. In postoperative cases, for differentiating a scar from a disk, post-contrast sagittal and axial T1- weighted sequences with or without fat suppression have also been found to be useful [13].

The study revealed that the prevalence of LBP in women increased from the youngest age of 18 to 55 years and then decreased thereafter (Figure 1). This is supported by earlier research which suggests that LBP prevalence progressively increases from teenage [14] to 60 years of age and then declines [15,16]. Notably, women within the age range of 46-55 years formed the majority with LBP. This age range. defined as a postmenopausal period has been reported to be the age group in which 80% of women suffer from various symptoms, including physical symptoms such as spine and joint pains, hot flashes, night sweats and chronic tiredness. They also have psychological symptoms such as irritation and anxiety, mood swings, depression and sleep disorders [17,18]. Kozinoga et al., their review of available studies on perimenopausal women with LBP reported that the perimenopausal stage of life is associated with an increased incidence of LBP. This is supported by [19].

Our study also revealed that women accounted for the majority of the referrals for lumbar spine MRI consisting 57.9% of the total (Table 1). This has been confirmed in a number of studies that reported that women tend to have a higher prevalence of LBP, are severely affected and have a worse prognosis than men by [20-22]. Epidemiological studies have reported a high prevalence of musculoskeletal pain in the adult general population, particularly in women [23,24].

In the context of chronic LBP, it is well-established that females are more susceptible than males regardless of age [25], and are two times more likely to develop chronic LBP than men [24]. This high prevalence of chronic pain in females, according to some authors may be attributed to genetic sensitivity, pain coping [26], and a higher vulnerability to develop temporal summation of chemically [27] or mechanically evoked pain [28,29]. In addition, women commonly have a higher number of concomitant chronic diseases such as osteoporosis, osteopenia, and osteoarthritis, which are known to be risk factors for developing chronic LBP [30]. Again, LBP has been reported to be associated with hormonal changes, irregular or prolonged menstrual cycles, different pain perception and recall of symptoms in women [24,31].

In Ghana, women form a significant proportion of the workforce in the informal sector, and are routinely involved in heavy physical workload, as well as different types of strenuous manual activities which include carrying of heavy loads on the head, frequent bending and twisting particularly within their domestic settings. These factors have long-term cumulative deleterious effect on their lumbar spine resulting in LBP.

The sources of referrals for lumbar spine MRI revealed that 58% of the referrals were from the OPD compared to 19% from specialists (Figure 2). Low back pain is probably one of the major reasons for outpatient referral [3]. The high number of referrals from OPD recorded in this study might be due to the fact that these referrals are often received from private, standalone diagnostic imaging centres, and other public clinics/ hospitals.

The referral patterns of this study is in contrast with a retrospective study by Yu et al. [32] who reported that 64.1% of all lumbar spine MRI were ordered by orthopedic surgeons, 21.7% by various specialists of internal medicine, 7.2% by neurologists and neurosurgeons, and the remaining 7.0% by the practitioners at health assessment centres which specifically provide routine health evaluation service. Their study [32] was however a multicentre study of 10 hospitals hence a larger sample size as compared to our study which involved only one facility. Inappropriate referral for lumbar MRI can affect patient outcome.

For instance, in a study [33] to examine the appropriateness of lumbar spine referrals made by neurosurgeons, it was reported that 44.0% of the referrals were inappropriate, that is, they contained no mention of leg symptoms or signs of neurological deficit, and/or had no description of nerve root compression on imaging for surgical assessment. In conclusion, the authors [33] advised that physicians seeking specialist consultations for patients with lumbar spine complaints need to be better informed of the criteria which indicate an appropriate referral for surgical treatment, namely clinical and radiological evidence of nerve root compression.

It is therefore clear that inappropriate referrals for lumbar spine MRI can negatively affect how physicians further manage patients with LBP. Inappropriate referral to specialists can also lead to a waste of time for the patient, increased workload for the specialists, and also increase healthcare costs. In a study by Piersson, et al. [34] they found the availability and accessibility of MRI services in Ghana is limited. Therefore the judicious request for MRI is very important.

An important aspect in MRI referrals is the justification–which often requires that referrers have adequate knowledge to justify the need for the use of MRI for interrogating a particular examination–as well as consideration for alternative imaging modalities which are relatively cheaper and can offer somewhat similar findings as compared to MRI methods.

Consistent with previous studies by [32], LBP/sciatica was the most common indication 125(52%) for lumbar spine MRI (Figure 3). In developed countries there are referral guidelines for diagnostic imaging examinations, none of such currently exists in Ghana. The clinical information provided on referral forms for lumbar spine MRI must justify the need for the examination. An important recommendation with regards to the request of imaging for LBP is that it should be discouraged [19] as studies have shown that, imaging in acute low back pain has not been shown to yield significant new findings [35], or alter outcomes [5,36].



Figure 3. Indications for lumbar spine MRI.

Another important issue which was investigated in this study was the appropriateness of lumbar spine MRI. Apart from a previous study [34] which was the first to be carried out on the appropriateness of clinical indication of brain MRI in Ghana, this current study is also the first to report on the appropriateness of lumbar spine MRI use in Ghana. The study revealed a relatively high current rate of inappropriateness (Table 4) use of lumbar spine MR imaging. Some studies from other countries have also reported on the appropriateness of lumbar spine MRI using ACR criteria [37], expert opinion [38], or other criteria [39]. The rates of inappropriateness of lumbar MRI from these studies ranged from 2.6% to 56.7% [37,39], depending on the patient sample size, and type of clinical guidelines used.

The definition of appropriateness of a diagnostic imaging procedure, in particular MRI, for an individual indication is complex as it may vary with patient characteristics (age and gender) as well as with the patients' condition and symptoms. In addition, the appropriate use of MRI is affected by structural conditions such as the availability of the technology, qualified staff, rapid development of imaging technologies, and increasing patient demand, medical liability concerns, and economic motivation (Ludwig Boltzman institute), [40]. There is already evidence [41] that many practitioners request a lumbar MRI to meet the patients' expectations.

Finally, our study also revealed degenerative changes as the most common imaging findings, representing 65% of the total. This was followed by normal lumbar spine (18%), significant findings (10%) and (7%) osteoporosis/compression fractures (Figure 4). This contradicts previous study [42] which reported normal lumbar spine as the most common (32.7%) followed by lumbar disc bulging and lumbar disc herniation. Degenerative changes often affect the muscles, ligaments, zygapophyseal joints, facets, nerve roots, the lumbar dura mater, musculature, vertebral body, endplate and the sacroiliac joints. These changes lead to the development of different pathologies including disc bulge, disc desiccation, disc protrusion, disc extrusion, hyper intense zone/annular tear and Schmorl's nodes [43].



Figure 4. Imaging findings of patients had undergone MRI.

Magnetic Resonance Imaging is clearly superior in the detection of disc degeneration, tumours, and infections. However, studies have shown that degenerated, bulging, and herniated disks are frequently incidental findings, even among patients with LBP, and may lead to over diagnosis, anxiety on the part of patients, and dependence on medical care, a conviction about the presence of disease, and unnecessary tests or treatments [8].

Furthermore, the correlation between anatomic abnormalities of the lumbar spine detected at MR imaging, clinical history, and patient outcome remains controversial [8,19]. This is because the determination of a patho-anatomic origin of LBP is made difficult by the rate of frequent false positive and negative findings on imaging studies, thereby limiting the utilization of imaging modalities in the identification of active anatomic pain generators [19]. Previous studies [35,44] have revealed a high prevalence of spine abnormalities in asymptomatic patients. In their study, Savage et al. [44] reported that 32% of their asymptomatic participants had "abnormal" lumbar spines (evidence of disc degeneration, disc bulging or protrusion, facet hypertrophy, or nerve root compression) and only 47% of their participants who were experiencing LBP had an abnormality detected. Therefore, the association between clinical indications and concurrent pathological examination with imaging findings must be cautiously interpreted [19].

Limitations of Study

The general application of this study may be limited. First it was a study from only one MRI centre in Accra, Ghana. The use of lumbar spine MRI may vary in different geographic regions, it may not be applicable to all MRI centres. A multicentre MRI study is important to get more precise results [45-49]. Secondly, the present study was a retrospective study of lumbar spine MRI use in Ghana. A prospective study is therefore needed to confirm the findings of this study. Again, we did not evaluate MRI parameters of the sequences employed in the protocol. Moreover, only lumbar spine MRI requests of patients18 years and above were analyzed. This is because patients below age 18 years, form a negligible percentage of the entire patient population reporting with LBP at the study centre.

Conclusion

In conclusion, the choice of local MRI protocol employed for lumbar spine MRI use for diagnosis of LBP is justified. The study revealed that women accounted for the majority of the referrals for lumbar spine MRI, and the prevalence of LBP in women increased from 18 to 55 years and then decreased afterwards. OPD accounted for the majority of the referrals for lumbar spine MRI. Low back pain/sciatica was the most common indication for lumbar spine MRI. The study also revealed that 25% of lumbar spine MRI cases were deemed usually not appropriate and degenerative changes were the most common imaging findings. The judicious request for any imaging investigation must be guided by the cardinal principle of how useful that investigation would really be to the client.

Theoretical and Practical Implications

This research documents for the first time the non existence of specific guidelines that regulates the practice of MR imaging and safety for patients with lower back pains in Ghana and can serve as a guide in imaging practice and to most likely a number of developing countries.

Awareness by clinicians of the appropriateness criteria of ACR for Lumbar MRI. This can very much lead to the judicious application of MR imaging for lower back pain, especially because availability of MR is very limited. This can go a long way to save money and resources for patients and cut cost in general healthcare delivery.

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