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Editorial

What have we learned about the evidence-informed management of chronic low back pain?

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Introduction

This special focus issue has presented information on 24 categories of treatments that are widely prescribed for the management of chronic low back pain (CLBP) without surgery, and also provided an overview of commonly available surgical options. The authors of each of these papers have spent a great deal of time and effort discussing these treatment approaches and providing their interpretation of the evidence that is available to justify their use. The fact that there are 25 categories of treatment presented in this special focus issue, each of which has multiple subcategories, is a testament to the fact that no single approach has yet been able to demonstrate its definitive superiority. This situation makes it very challenging for clinicians, policy makers, insurers, and patients to make decisions regarding which treatment is the most appropriate for CLBP.

Although readers may be tempted to examine only those articles describing their favorite (or least favorite) treatments to find evidence that simply affirms their beliefs, it is highly recommended that the entire special focus issue be perused to compare and contrast the theories and evidence supporting all approaches. This can help overcome our natural tendencies to support only those treatments with which we are most familiar and dismiss those about which we know little. Only when reasonably informed about all available treatments will purchasers (eg, patients, insurers) and providers of care truly understand the current state of the science and art and be in a position to compare and make decisions concerning the treatment options for CLBP. This article will attempt to facilitate this task by summarizing some of the pertinent information from each of the articles presented in this special focus issue.

Articles from expert clinicians

Readers should be aware of possible biases inherent to the type of review articles contained in this special focus issue, many of which were contributed by authors known to have an interest in specific interventions. These authors are naturally more likely to be optimistic about the benefits of a procedure than others who are offering a different treatment approach. Presumably, clinicians who contributed articles on specific interventions used in their practice would not be offering them to their patients if they were not enthusiastic about their superiority over other options. This enthusiasm is seen most commonly in articles with extensive discussions about the theoretical basis of a treatment approach for which there is little available evidence of efficacy. Similarly, this zest may be at play when authors attempt to minimize or criticize the importance of clinical trials that reported negative outcomes they feel are not reflective of what is observed in their daily practice.

Articles by clinical researchers

A number of these review articles were written by authors who work primarily as researchers and are not involved in clinical practice offering the treatments about which they wrote. These authors may exhibit other biases to their interpretation of the scientific literature supporting or refuting the efficacy of a treatment approach. Whereas clinicians tend to be overly optimistic about the efficacy of an intervention based mainly on their personal experience, researchers

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(many of whom are clinical epidemiologists) tend to be overly pessimistic about interventions for which there is little, low-quality, or conflicting evidence of efficacy. This is based, in part, on medicine's long history of once promising but eventually discredited treatments, and the principle of primum non nocere. Although the former often discount research evidence, the latter often overlook clinical experience; neither viewpoint is ideal.

Systematic Reviews

Systematic reviews (SRs) conducted on intervention for CLBP that adhered strictly to the principles and rigorous methodology of evidence-based medicine (EBM) often conclude with the statement that there is insufficient evidence and more research is necessary. Although the efforts of EBM to improve the practice of health care are laudable, decisions must still be made on a daily basis in the absence of the amount and quality of evidence necessary to convince clinical epidemiologists that an intervention is beneficial. Another important reality that must be considered by readers is that funding and conducting multiple high-quality randomized controlled trials (RCTs) for each of the 200 or more individual treatment options currently available for CLBP is simply beyond the realm of possibility. Those reviewing this special focus issue must therefore decide whether they wish to rely on the enthusiasm of clinicians practicing a particular treatment approach or on the skepticism of clinical epidemiologists who rely on the evidence. A blend of both views, where possible, is perhaps the most useful current approach.

Evidence informed versus evidence based

Ideally, there would be multiple high-quality RCTs supporting each of the interventions discussed in this special focus issue to provide a solid EBM approach to CLBP. In reality, SR methodology confined to high-quality RCTs would likely find only limited evidence for many of these interventions. Given the wealth of clinical experience among invited authors, it was intended that articles in this special focus issue present evidence-informed rather than strictly evidence-based recommendations. The guiding principle behind evidence-informed management is that authors should be aware of and use research evidence when available, make personal recommendations based on clinical experience when it is not available, and be transparent about the process used to reach their conclusion. The instructions to authors made it clear that articles should not be narrative reviews founded solely on their opinions and clinical experience. Authors were asked to systematically search the biomedical literature to uncover, evaluate, and summarize recent evidence using some of the methodology recommended by the Cochrane Back Review group [1]. They were also given the liberty to make personal recommendations on specific aspects of a treatment in the absence of other available evidence.

All authors were asked to include a description of terminology surrounding that intervention, a detailed description of the intervention so that patients considering a particular intervention may know what to expect, a summary of important historical events, the qualifications required to administer that intervention, general information on costs and reimbursement policies in the United States, the theories supporting its mechanism of action, the most appropriate indications and contraindications, the ideal CLBP patient for that intervention, review methods used to uncover evidence of efficacy, appraisal and summary of available evidence by study design (clinical guidelines, SRs, RCTs, observational studies [OBSs]), and discussion of known or potential harms. Although the approach taken by each group of authors differed somewhat, most followed this format admirably and genuinely attempted to provide evidence-informed recommendations to assist stakeholders evaluating these various interventions for CLBP.

Pretreatment diagnostic testing

Table 1 summarizes recommendations by the authors regarding the diagnostic testing procedures that are required or recommended before considering each treatment approach. It should be evident to anyone reading this special focus issue that the diagnostic testing recommended before providing a treatment is, with few exceptions, almost identical. Every article in this special focus issue recommends or infers that it is important to conduct a thorough history and physical examination to rule out the possibility of serious pathology or ''red flags'' indicating organic conditions requiring immediate attention before considering any treatment for CLBP. Certain of these articles list some of the red flags whereas others use a more general term. None of the articles suggest that the treatment approach should be considered in patients with these red flags.

It is interesting to note that, despite the enormous resources devoted to daily use of diagnostic testing for CLBP, few authors reported that such testing was required before considering a particular intervention. Those who did suggest the use of specific diagnostic testing generally did not support these recommendations with citations to any studies demonstrating a change in outcomes for patients who did and did not undergo advanced diagnostic testing before receiving an intervention. This observation brings into question the routine use of laboratory testing, X-rays, computed tomography (CT), magnetic resonance imaging (MRI), discography, nerve conduction velocity, and electromyography by clinicians evaluating CLBP.

In their review of surgical options for CLBP, Don and Carragee discuss the failure of advanced imaging such as CT or MRI to delineate a clear pathoanatomic cause for

Table 1
A summary of the diagnostic testing suggested by the authors in this special focus issue before considering each treatment category

Treatment category	Summary of the diagnostic testing suggested by the authors
Adjunctive analgesics	Rule out serious pathology Radicular pain by history
Back schools, education, fear avoidance	History and clinical examination to rule out serious pathology
Cognitive behavioral therapy	History and examination to rule out serious pathology
Epidural steroid injections	Rule out spinal infection, malignancy, and acute fracture Plain film radiography or magnetic resonance imaging Lumbar provocative discography has not been critically evaluated
Facet blocks and radiofrequency neurotomy	A single screening block will identify negative patients If a screening block is positive, repeat blocks at individual levels is necessary to make the diagnosis of Z-joint pain
Functional restoration	Thorough medical history and physical examination Psychological testing
Herbal, vitamin, mineral, and homeopathic supplements	Thorough history and physical examination to rule out the possibility of serious pathology
Intradiscal Electrothermal Therapy	Fluoroscopy during procedure to confirm probe placement (Advanced imaging to identify size and location of disc bulge implied but not stated)
Lumbar extensor strengthening exercises	Thorough medical history and physical examination to rule out the possibility of serious pathology
Lumbar stabilization exercises	Diagnostic evaluation to exclude the presence of red flags
Massage	Thorough history and physical examination to rule out the possibility of serious pathology
McKenzie method	No diagnostic testing is required before this assessment
Medicine-assisted manipulation	No specific diagnostic testing is required beyond that which is necessary to establish that the primary complaint is nonspecific mechanical CLBP Preanesthesia clearance
Minimally invasive nuclear decompression nucleoplasty	(Advanced imaging to identify size and location of disc bulge implied but not stated)
Needle acupuncture	Thorough history and physical examination to rule out the possibility of serious pathology
Nonsteroidal anti-inflammatory drugs, muscle relaxants, and simple analgesics	Medical history and physical examination to rule out the possibility of serious pathology
Opioid analgesics	A thorough medical history and physical examination in an attempt to determine the specific structural cause of the pain and rule out the possibility of more serious pathology
Physical activity, smoking cessation, and weight loss	Thorough medical history and physical examination to rule out the possibility of serious pathology related to CLBP
Prolotherapy	A thorough history and physical examination to rule out the possibility of serious pathology
Spinal manipulation and mobilization	Diagnostic testing to rule out the presence of certain contraindications or red flags Manual palpation of the lumbar and sacral areas to assess local tenderness, inflammation, and identify areas of segmental dysfunction or hypomobility
TENS, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy	A thorough medical history and physical examination are required to rule out the possibility of serious pathology related to CLBP
Traction therapy	Exclude disease states such as severe osteoporosis or ligamentous instability that might compromise bone or soft-tissue integrity
Trigger point injections	Rule out other causes of CLBP such as osteoarthritis or radicular pain, and more serious pathology (eg, red flags) Palpation of trigger points. Pressure threshold also does not differentiate between trigger and tender points
Watchful waiting	A thorough history and physical examination are required to rule out the possibility of serious pathology
Surgery	Physical examination and detailed imaging techniques have failed to delineate a clear pathoanatomic cause for patients with low back pain

CLBP=chronic low back pain.

Only selected statements from the articles have been presented. For a full explanation of the diagnostic recommendations the reader should consult the full articles.

The above statements have been abbreviated and readers should read the original articles to obtain details.

a patient's symptoms. In their discussion of epidural steroid injections, De Palma and Slipman note that the use of discography—which is often touted as superior to CT or MRI—is controversial and has not been critically evaluated for CLBP. This is echoed by Don and Carragee, who report that the discography is not validated, is painful in 30% to 80% of asymptomatic subjects, and, even in a best-case scenario, has a positive predictive value of only 50% to 60% for resolution of low back pain (LBP) after surgical removal of the suspected pain generator identified by discography.

A number of articles suggested that an initial trial of treatment may be used to help customize an intervention according to patient response. This was mainly noted in articles on manual therapies including spinal manipulation, mobilization, and massage, as well as trigger point injections, which

also rely on manual palpation to identify areas to be injected. Although the logic behind diagnosis by treatment appears reasonable for these types of safe and noninvasive therapies, there were no citations provided to support these statements.

The only two treatment approaches for which authors cited evidence that the success of an intervention is dependent on examination findings were McKenzie method—which bases its treatment on findings from its customized mechanical diagnosis and therapy assessment—and radiofrequency neurotomy, which bases its treatments on findings from properly conducted diagnostic facet blocks. There is clearly no consensus that commonly used diagnostic tests hold any value in the decision-making process before offering a treatment for CLBP.

Indications for different treatment approaches

Table 2 summarizes the proposed indications and contraindications for each of the treatment categories as reported by the authors of these review articles. One of the first observations from this table is that the indications do not differ very much and provide very little information on when to consider a specific treatment approach. Indications for various interventions appear to fall into one of three broad categories: pain, nonspecific or mechanical CLBP, and failure of other treatments.

The presence of pain is noted as the main indication for articles on pharmacological approaches such as nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, simple analgesics, opioid analgesics, adjunctive analgesics, and various nutritional supplements. Authors frequently noted that many of these medications are only approved for indications other than CLBP and therefore used off label with very little or no published evidence of efficacy. Clinicians must make a leap of faith that success noted in conditions such as diabetic neuropathy or pain in patients with terminal cancer can be translated to improving the symptoms of CLBP. Although the relative advantages/disadvantages of medication classes (eg, tricyclic antidepressants vs. selective serotonin reuptake inhibitors) were discussed, very little time was spent discussing why one medication in any particular drug class should be used over its competitors. There was therefore very little guidance to clinicians or consumers as to which medication should be considered beyond the opinion and experience of the prescribing clinician. Viewed together, these articles do suggest that certain nutritional supplements, NSAIDs, simple analgesics, and muscle relaxants can be used as a first-line approach to CLBP, with the consideration of adjunctive or opioid analgesics when pain is refractory.

A number of the treatments discussed in this special focus issue list the primary indication as nonspecific or mechanical CLBP. These include spinal manipulation and mobilization, massage, acupuncture, electrotherapeutic physical modalities, prolotherapy, traction, most of the exercise therapies, back schools, and patient education. Although vague, the description of nonspecific CLBP is perhaps the most honest statement regarding the indication of any intervention for CLBP given the doubts expressed above about the usefulness of advanced diagnostic testing for identifying the exact source of pain.

The third indication stated by authors to justify a particular procedure is that the patient has failed to respond to other treatment approaches, which was noted in many of the articles on injection or minimally invasive interventional procedures. This reasoning should be viewed with some concern because it has previously been used to support dubious treatments for other health conditions which simply cannot be cured. Although compelling, the simple fact that previous treatments have failed is not sufficient justification for exposing a patient to any treatment that is supported solely by weak evidence and which is associated with considerable costs and increased risks of harms. In fact, it could be argued that the burden of scientific proof should perhaps be even higher for so-called rescue therapies to prevent exposing patients to potential harms who may simply never respond positively to any interventions.

Comparing the evidence for efficacy

Table 3 is a summary of the evidence for efficacy which was reported by the authors in the 25 articles in this special focus issue. This table also presents the conclusions and recommendations based on the best available evidence considered by those authors. This table reports the number of studies discussed and does not reflect whether the studies were positive or negative for the intervention or whether the authors agreed with the results of these studies.

It is noted that the number and type of studies that were offered to support or provide evidence of efficacy or lack thereof varied considerably among the different treatment categories. The only interventions that reported being included in clinical practice guidelines on LBP were back schools and brief education, NSAIDs and simple analgesics, the McKenzie method, needle acupuncture, spinal manipulation and mobilization, trigger point injections, and watchful waiting (for acute LBP).

The five interventions where the authors reported the highest number of SRs were back schools (seven SRs), needle acupuncture (six SRs), tricyclic antidepressants (five SRs), prolotherapy (four SRs), and traction therapy (four SRs). The five interventions that authors reported the highest number of RCTs were needle acupuncture (19 RCTs), spinal manipulation and mobilization (13 RCTs), lumbar extensor strengthening exercises (11 RCTs), brief education (11 RCTs), and epidural steroid injections (10 RCTs). The five interventions where the authors relied primarily on OBSs—which include controlled clinical trials, prospective cohorts, and case series—were Intradiscal Electrothermal Therapy (24 OBSs), minimally invasive nuclear

Table 2
A summary of the proposed indications and contraindications for each treatment category as suggested by the authors in this special focus issue

Treatment category	Proposed indications	Proposed contraindication
Adjunctive analgesics	Neuropathic pain Radiculopathy Used off label for CLBP CLBP unresponsive to NSAIDs	Adverse response to similar medications Intolerable side effects Tricyclic antidepressants should be used with caution in patients with glaucoma, urinary retention, autonomic neuropathy, and known cardiac disease
Back schools, education, fear avoidance	Nonspecific, mechanical CLBP High scores on fear-avoidance beliefs for physical activity	Serious somatic or psychiatric comorbidity, that may require tailored psychological care
Cognitive behavioral therapy	Comorbid psychiatric disorders such as anxiety, mood disorders, or pain disorder	Major cognitive deficit as a result of brain trauma or organic pathophysiology
Epidural steroid injections	Radicular pain The role of these injections to treat CLBP has not been well defined	Bleeding diathesis Local infection Uncontrolled diabetes Uncontrolled glaucoma
Facet blocks and radiofrequency neurotomy	Unresolved CLBP requiring further investigation Complete relief of pain, or near complete relief, after controlled, diagnostic, lumbar medial branch blocks	Discogenic pain or sacroiliac joint pain Allergy to local anesthetic Pregnancy Comorbidity or anatomical anomalies
Functional restoration	Patients with CLBP who have failed to respond to secondary care programs Motivated to learn to manage their pain more effectively. Compliant with the prescribed rehabilitation regimen Wishes to return to work and full activities of daily living	Active objective pathophysiology requiring immediate medical or surgical care Language barrier
Herbal, vitamin, mineral, and homeopathic supplements	First-line interventions for nonspecific mechanical CLBP when other medications are contraindicated or have failed, or based on patient preference	Many contraindications for herbal medicines, depending on the exact plant species
Intradiscal Electrothermal Therapy	From clinical trials and cohort studies: DDD with discrete annular tear Chronic nonspecific low back pain with or without leg pain	None reported
Lumbar extensor strengthening exercises	Adults with nonspecific CLBP of mechanical origin Individuals with CLBP with wide ranges of muscular capacities Good general health (physically and psychologically) Willing to take responsibility for his or her own self-care in the form of an active exercise program	Unstable angina Uncontrolled hypertension Uncontrolled cardiovascular disorders Poor left ventricular function, and angina or ischemia at low lumbosacral workloads Fractures
Lumbar stabilization exercises	CLBP with or without specific anatomic conditions. A reproducible, mechanical pattern of lumbopelvic pain that follows a specific plane of movement or functional task	Spinal or medical conditions that preclude exercise for the trunk musculature Acute neurologic compromise An unstable medical presentation Physical, social, or psychological barriers to functional recovery
Massage	Nonspecific mechanical CLBP Myofascial pain syndrome Fibromyalgia Sprains, strains	Acute inflammation Skin infection Nonconsolidated fracture Burn area Deep vein thrombosis Active cancer
McKenzie method	Centralizers Previous episodes of LBP that have resolved but keep recurring Directional preference	Atypical and nonmechanical pain responses elicited with this form of testing quickly alerts the clinician to the possibility of serious pathology
Medicine-assisted manipulation	Nonspecific mechanical CLBP that has failed to respond to more conservative treatment Patients should first try 4–8 wk of SMT and other conservative care before considering MUA CLBP with a hypomobile or soft-tissue component	Spinal malignancy Hypermobility or instability Acute inflammatory conditions Bleeding disorders Severe osteoporosis Sequestered nucleus pulposus Conditions precluding anesthesia
Minimally invasive nuclear decompression nucleoplasty	From cohort studies: Longstanding LBP with or without leg pain	From cohort studies: Protrusions greater than 1/3 the sagittal canal diameter were excluded

(*continued*)

Table 2 (*continued*)

Treatment category	Proposed indications	Proposed contraindication
Needle acupuncture	Nonspecific mechanical CLBP with or without radiating leg pain Positive expectations	Bleeding disorders Septicemia Underlying spinal pathology Needle phobia
NSAIDs, muscle relaxants, and simple analgesics	Acetaminophen: First-line treatment of mild muscular aches, backaches, and arthritis NSAIDs: Muscle aches and pains, backaches, and arthritis Muscle relaxants: Acute painful musculoskeletal conditions	Many contraindications that are dependent on specific medication Prior allergy or hypersensitivity NSAIDs: Last 3 mo of pregnancy, perioperative period for cardiac surgery, patients with high risk of bleeding, peptic ulcer disease, or congestive heart failure Celecoxib: Sulfonamide hypersensitivity Acetaminophen: Hepatic disease
Opioid analgesics	Patients with moderate to severe refractory CLBP who are psychologically healthy and have failed to respond to other forms of care Adaptive copers are the patients most likely to benefit from LTOs	Allergy to that specific opioid. Patients with a history of addictive disease are at high risk for relapse to therapeutic opioids Dysfunctional and interpersonally distressed patients tend to do poorly
Physical activity, smoking cessation, and weight loss	Smoking cessation: Patients with CLBP who are smokers Weight loss: Patients with CLBP who are overweight or obese Physical activity: All patients with CLBP	Exercise programs: Patients were not medically fit to participate
Prolotherapy	Nonspecific mechanical CLBP because of ligament or tendon injury from trauma, repetitive sprain injury, or collagen deficiency Pain relief after local anesthetic injections has yet to be validated	Non-musculoskeletal pain (eg, referred visceral pain, metastatic cancer, systemic inflammation etc.) Spinal anatomical defects that preclude deep injections (eg, spina bifida), morbid obesity, inability to perform posttreatment range of motion exercises Bleeding disorders
Spinal manipulation and mobilization	Nonspecific mechanical CLBP Characteristics that distinguish which patients may favorably respond to SMT include: 1. duration <16 d; 2. symptoms proximal to the knee; 3. FABQ scores <19; 4. hypomobility; 5. hip rotation >35 degrees	''Red flags'' as described by the AHCPR guidelines May not be the best choice for patients who cannot increase activity/workplace duties, are physically deconditioned, and have psychosocial barriers to recovery
TENS, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy	Nonspecific mechanical CLBP	TENS, EMS, and IFC: Over the anterior cervical region, carotid sinuses, heart, transthoracic area, insensate skin, pregnant abdomen, cardiac pacemaker, implanted defibrillator Ultrasound: Over malignant lesions, pregnant abdomens, plastic implants, hemorrhagic regions, prosthetic joints, ischemic regions, insensate areas, infected lesions, electronic implants
Traction therapy	Subacute or CLBP with or without leg pain No examination findings (clinical, imaging, or laboratory) that have been shown to differentiate patients who are likely to benefit from traction therapies	Spinal malignancy Spinal cord compression Local infection Osteoporosis Inflammation Spondyloarthritis Acute fracture Aortic or iliac aneurysm Abdominal hernia Pregnancy Severe hemorrhoids Uncontrolled hypertension Severe cardiovascular or respiratory disease
Trigger point injections	Clinical localization of active trigger points in CLBP patients with myofascial pain syndrome who have failed to respond to medications and/or a course of active physical therapy, or when a joint is mechanically blocked	Local infection Malignancy Anticoagulation therapy
Watchful waiting	Patients with nonspecific CLBP who, in the absence of red flags for serious pathology, do not wish to seek any form of active care and understand the principle of watchful waiting	''Red flags'' indicative of potentially serious pathology

(*continued*)

Table 2 (*continued*)

Treatment category	Proposed indications	Proposed contraindication
Surgery	Severe facet fragmentation and disc degenerative changes associated with segmental instability, spondylolisthesis, and concomitant radicular complaints	Minimum changes of disc dissecation, annular bulging with early fissuring Serious depression On-going litigation Poorly defined somatic illnesses High fear-avoidance of pain Psychological distress Compensation claims Personal injury litigation Job dissatisfaction

CLBP=chronic low back pain; NSAIDs=nonsteroidal anti-inflammatory drugs.

Only selected statements from the articles have been presented. For a full explanation of the indications and contraindications the reader should consult the full articles.

The above statements have been abbreviated and readers should read the original articles to obtain details.

decompression (nucleoplasty) (10 OBSs), medicine-assisted manipulation (6 OBSs), opioid analgesics (4 OBSs), and functional restoration (4 OBSs).

Although one might be tempted to correlate a large number of studies with a strong level of evidence from the scientific literature, this assumption would be an oversimplification. There were several possible reasons for reporting a high number of efficacy studies including 1) a few studies on each of several subtypes of interventions were combined into one broader category; 2) an intervention has a long history of use over which more studies have been conducted; 3) study eligibility criteria used by authors were more lenient; 4) multiple health databases were examined using a sensitive and comprehensive search strategy; 5) an intervention is controversial and has attracted the interest of researchers and funders; 6) conflicting results among studies perpetuate the need for additional research; or 7) lack of acceptance has motivated additional research to gain market share.

Although it appeared that studies with a higher number of SRs and RCTs generally reported positive findings supporting efficacy, best evidence syntheses from those review articles were often cautiously worded and offered only lukewarm recommendations on specific comparisons (eg, intervention vs. placebo), specific outcome measures (eg, pain but not function), or specific follow-up periods (eg, short term only). This may also have been a reflection of the experience and training in EBM of the authors involved, as mentioned earlier.

It was also noted that interventions discussing a high number of OBSs seemingly did so in the absence of higher level of evidence (eg, SRs or RCTs). Their articles also tended to make less nuanced and more positive recommendations. These findings lend themselves to two observations made regarding the interventions for CLBP reviewed in this special focus issue: 1) evidence of efficacy appears less ambiguous and more positive when based mostly on OBSs; and 2) recommendations become more restrained and conflicting when multiple SRs or RCTs are available to define boundaries regarding the conclusions that can be drawn from the scientific literature. In other words, the lower the quality and quantity of available research on an intervention, the higher the enthusiasm shown by clinicians for its efficacy. Stakeholders may wish to consider these possibilities when evaluating different treatment approaches for CLBP.

Reported harms from different interventions

Table 4 is a summary of the harms (eg, minor side effects, adverse events (AEs), serious AEs, complications) reported in the 25 articles in this special focus issue, and general estimates of their prevalence. Reported harms that have been associated with the interventions reviewed in this special focus issue varied considerably in nature, frequency, and severity. Commonly reported side effects included localized pain, soreness, or discomfort, mild gastrointestinal complaints with orally ingested therapies, and vague discomforts such as fatigue, weakness, or dizziness. The reported estimated prevalence of minor and usually brief side effects varied from 1% to 76%. More serious AEs included transient or permanent disc, vertebral, neural, or spinal cord injuries, which were more commonly reported with interventions requiring injections. All were described as rare, and usually based on isolated case reports or small case series.

It is difficult to form conclusions as to the relative safety of these interventions based on the harms reported by the authors. Although it is tempting to assume that interventions for which numerous possible harms were reported are inherently more dangerous that alternatives for which no harms are listed, this does not appear to be the case. Harms—whether theoretical or previously reported—are possible with all of the interventions reviewed in this special focus issue. The most likely explanation for this discrepancy is that those authors who put more time and effort into searching and summarizing available evidence regarding harms were more likely to fully report their existence. Interventions for which few or no harms were

Table 3
A summary of evidence for efficacy for various treatment categories suggested by the authors in this special focus issue

Treatment category	Studies reviewed by the authors	Summary or recommendations
Adjunctive analgesics	TCAs: Five SRs that included up to nine studies Selective serotonin reuptake inhibitors: Two SRs SNRIs: None for CLBP Antiepileptics: Two OBSs on carbamazepine, one OBS on topiramate, one OBS on lamotrigine	Limited evidence for CLBP TCAs for painful radiculopathy Anticonvulsants if unresponsive to other agents
Back schools, education, fear avoidance	Back schools: Seven SRs, eight RCTs Brief education: 1 SR, 11 RCTs Fear avoidance: Six RCTs	Back schools: Moderate evidence of short-term benefits Brief education: Moderate evidence of reduced sick leave Fear avoidance: Moderate evidence when incorporated in a rehabilitation program as an alternative to spinal fusion
Cognitive behavioral therapy	Two SRs on multidisciplinary pain management programs for CLBP, three SRs on CBT for other chronic pain conditions, three RCTs	CBT is an effective component in the overall treatment of CLBP It needs to be combined with other therapeutic components
Epidural steroid injections	CESIs and TLESIs: Three SRs that included up to 15 studies CESIs: Six RCTs (only three related to LBP) TLESIs: 10 RCTs (3 LBP, 7 radicular pain) TFESIs: One SR, seven RCTs (all radicular pain)	No data exist regarding predictive factors after ESI for CLBP No well-designed studies to assess the efficacy of lumbar TFESIs LESIs are a reasonable treatment option for persistent LBP unresponsive to other treatments
Facet blocks and radiofrequency neurotomy	Two SRs that included three RCTs, two RCTs, multiple OBSs	Intra-articular injections have never been tested for validity as a diagnostic test Controlled diagnostic blocks lumbar Z-joints have been validated Intra-articular steroids are no more effective than intra-articular saline Denervation of the lumbar Z-joints remains the only available treatment for Z-joint pain
Functional restoration	Two SRs, eight RCTs, four OBSs	The scientific literature has demonstrated the effectiveness of functional restoration for patients with CLBP Perceived high cost Perceptions are misguided
Herbal, vitamin, mineral, and homeopathic supplements	Two SRs, three RCTs	Although preliminary studies look promising, more data are required to determine whether any nutritional supplements are useful in controlling CLBP
Intradiscal Electrothermal Therapy	3 SRs that included up to 18 studies, 3 RCTs, 3 CCTs, 14 prospective OBSs, 7 retrospective OBSs	The procedure provides only modest improvement Would seem to be a reasonable first option with intolerable pain Even a technically satisfying procedure will not prevent a significant number of patients reporting that they have worsening of pain
Lumbar extensor strengthening exercises	3 SRs, 11 RCTs	This intervention is more effective than no treatment and most passive modalities in the short term Lumbar extensor strengthening exercise administered alone or with cointerventions is more effective than no treatment and most passive modalities The optimal dose of strengthening exercise needs to be clarified
Lumbar stabilization exercises	Three RCTs	LSE is effective at improving pain and function in a heterogeneous group of patients with CLBP There is currently no evidence that LSE is more effective than other, less specific, exercise programs
Massage	One SR, five RCTs	There is strong evidence that massage is effective for nonspecific CLBP The effects of massage are improved if combined with exercise and education Accupressure may be better than Swedish massage
McKenzie method	Four CPGs, three SRs, three RCTs	Produces better short-term outcomes than nonspecific guideline-based care and produces equal or marginally better outcomes than stabilization or strengthening exercises System of assessment and classification can help predict outcomes Noncentralization is associated with a poor behavioral response
Medicine-assisted manipulation	Two SRs, six OBSs	Methodological quality of the studies uncovered related to MUA, MUESI, and MUJA is weak There is currently insufficient evidence to make any recommendations concerning MUA, MUJA, or MUESI for CLBP
Minimally invasive nuclear decompression nucleoplasty	Eight prospective OBSs, two retrospective OBSs	Variation in published successes ranging from 80% favorable results to less than 20% average pain relief. Option that one can consider before fusion or arthroplasty for patients who have protrusions less than 4–6 mm and minimal stenosis The current nuclear decompression devices are a first iteration
Needle acupuncture	1 CPG, 6 SRs, 19 RCTs	There appears to be some evidence for the use of acupuncture for the treatment of CLBP The most consistent evidence appears to be for the addition of acupuncture to other

(*continued*)

Table 3 (*continued*)

Treatment category	Studies reviewed by the authors	Summary or recommendations
NSAIDs, muscle relaxants, and simple analgesics	NSAIDs: Three SRs, five RCTs Muscle relaxants: Two SRs, five RCTs COX-2 inhibitors: Seven RCTs Analgesics: Six RCTs Capsaicin: One SR	Mens advocates the use of an analgesic pain medication, an antidepressant, or a combination of the two for CLBP No one medication in a class is better than another It is unpredictable which patient will respond best to which medication within that class Trial and error is unavoidable
Opioid analgesics	2 SRs, 10 RCTs, 4 OBSs	Opioid analgesics are safe and effective for the treatment of patients with CLBP, at least in the short term Withdrawal rates reported in RCTs of opioids were generally high (20% to 40%) because of side effects There is no evidence of superiority among the different opioids
Physical activity, smoking cessation, and weight loss	Physical activity: Six RCTs	A number of SRs have strongly recommended staying active and avoiding bed rest in acute LBP and sciatica There is no evidence, either in the form of comparative studies or OBSs, on smoking cessation or nonoperative weight loss as an intervention for CLBP
Prolotherapy	Four SRs, five RCTs	Prolotherapy has a prolonged history of use, a reasonable but not proven theoretical base, a low complication rate, and conflicting evidence of effectiveness
Spinal manipulation and mobilization	SMT: Six CPGs, nine RCTs MOB: Four RCTs	For CLBP, there is moderate evidence that SMT with strengthening exercise is similar in effect to prescription NSAIDs with exercise in both the short and long term, that flexion-distraction MOB is superior to exercise in the short term and superior/similar in the long term, and that high dose SMT is superior to low dose SMT in the very short term There is limited to moderate evidence that SMT is better than physical therapy and home exercise in both the short and long term SMT and MOB are at least as effective as other efficacious and commonly used interventions
TENS, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy	TENS: One SR, six RCTs	Although electrotherapeutic modalities and physical agents are frequently used in the management of CLBP, few studies were found to support their use Results of these studies suggest that TENS should probably be used as an adjunct tool for immediate to short-term pain relief, with no impact on perceived disability or long-term pain
Traction therapy	Four SRs Sustained: Four RCTs Intermittent: Two RCTs Positional distraction: One RCT Distraction manipulation: Two RCTs	Literature provides more evidence against than for the use of traction therapy as a treatment for LBP Evidence indicates that sustained traction is ineffective for LBP with or without leg pain Little evidence for or against intermittent traction, which is aggressively promoted in the US healthcare market (eg, VAX-D, DRX9000)
Trigger point injections	One CPG, two SRs that included up to five RCTs, four RCTs	The objective evidence for trigger point injections and dry needling are questionable However, they remain as part of the armament for physicians to offer their patients quick relief of myofascial pain when other therapies are failing Despite the lack of overwhelming evidence, trigger point injection or dry needling may be used in the myofascial pain The high costs of botulinum toxin do not support its use
Watchful waiting	Two CPGs (for acute LBP)	Patients with CLBP often find that their symptoms will wax and wane over time, and many of them will have devised strategies for treating their symptoms when they need to
Surgery		There is insufficient evidence on the effectiveness of surgery on clinical outcomes to draw any firm conclusions Lumbar fusion for common degenerative changes appears to offer limited relative benefits Artificial disc replacements have approximately the same outcomes as fusion in the short term

CLBP=chronic low back pain; CCT=controlled clinical trial; CPG=clinical practice guidelines; OBS=observational study; RCT=randomized controlled trial; SR=systematic review; LBP=low back pain; TCA=tricyclic antidepressants.

Only selected statements from the articles have been presented. For a full discussion of the evidence and recommendations of the authors the reader should consult the full articles.

reported likely performed only a cursory search for this information, or have simply not been studied sufficiently. To fully present the risks and benefits of available alternatives during the increasingly important informed consent process, clinicians must have access to more comprehensive research and reviews of harms than those presented by most authors in this special focus issue. Additional research related to the comparative harms of common interventions for CLBP is necessary before stakeholders can even consider this aspect in their decision-making process.

Table 4
A summary of harms for various treatment categories as suggested by the authors in this special focus issue

Treatment category	Harms as reported by the authors	Prevalence
Adjunctive analgesics	TCAs: Blurred vision, cognitive changes, dry mouth, constipation, sexual dysfunction, orthostatic hypotension, and cardiovascular side effects (conduction defects, arrhythmias, tachycardia, stroke, myocardial infarction). Other side effects that may be considered potentially beneficial in certain patients include sedation, appetite stimulation, or urinary retention SNRIs: Nausea, sexual dysfunction, withdrawal problems, hypertension, somnolence, hyperhidrosis, anorexia, vomiting, and constipation Antiepileptics: Steven-Johnson syndrome, agranulocytosis, aplastic anemia, hepatic toxicity, dizziness, somnolence, peripheral edema, ataxia, infection, weight gain, vertigo, paresthesias, diarrhea	TCAs: Minor AEs 30%, major AEs 4%
Back schools, education, fear avoidance	NR	NR
Cognitive behavioral therapy	NR	NR
Epidural steroid injections	Minor and transient including injection site pain, increased radicular pain, light headedness, increased spinal pain, nausea, nonpositional headache, vomiting, facial flushing, vasovagal reaction, increased blood sugar, intraoperative hypertension, infection, dural puncture, neural trauma, vascular injury, central nervous system injury	1%–17%
Facet blocks and radiofrequency neurotomy	Blocks: None when procedure performed according to guidelines. Intrathecal injection can occur only if operator has been grossly negligent Radiofrequency neurotomy: None recorded when performed according to guidelines. Complications that can occur under general anesthesia when electrodes placed erroneously include weakness and numbness in lower limb	NR
Functional restoration	No undue complications because intervention is carefully monitored and directed by a physician and interdisciplinary team of health-care professionals	NR
Herbal, vitamin, mineral, and homeopathic supplements	Herbals: Mostly mild, transient gastrointestinal complaints. Oral capsicum can cause fullness, gas, bloating, nausea, epigastric pain and burning, diarrhea, belching; sweating, flushing of head and neck, lacrimation, headache, faintness, rhinorrhea; excessive amounts can lead to gastroenteritis and hepatic necrosis. Topical capsicum can cause burning, stinging, and erythema. Nasal capsicum can cause nasal burning and pain, lacrimation, sneezing, rhinorrhea. Inhalation of capsicum can cause coughing, dyspnea, nasal congestion, eye irritation, and allergic alveolitis Vitamins: Vitamin C $>$3,000 mg may increase half-life of acetaminophen, increase plasma estrogen when taken with oral contraceptives or hormone replacement, and possibly interfere with protease inhibitors; doses up to 16,000 mg may cause diarrhea and reduce warfarin absorption. Niacin may raise HDL when taken with simvastatin Minerals: Zinc may inactivate cisplatin and, along with manganese, potentially interfere with certain antibiotics Homeopathic supplements: Gel appears relatively safe	NR
Intradiscal Electrothermal Therapy	Nerve root injuries, disc herniations, catheter breakage, superficial skin burn, bladder dysfunction, disc infections, neural injury, transient increases in leg pain, cauda equina syndrome, end plate heat injury, accelerated disc degeneration	1–19/36,500
Lumbar extensor strengthening exercises	Delayed onset of muscle soreness, increased low back pain, dizziness, disc herniation, fracture, cardiovascular event	NR
Lumbar stabilization exercises	No serious harmful outcomes in the studies reviewed	NR
Massage	Soreness, ecchymosis, allergic reaction	6%–13%
McKenzie method	No documented side effects	NR
Medicine-assisted manipulation	Older methods of MUA associated with cauda equina syndrome, paralysis, fracture; more recent studies have not reported any AEs Temporary flare-ups in lumbosacral pain, disc herniation, respiratory distress, wet taps, vagal response	11/1,525 (including older forms of MUA)

(*continued*)

Table 4 (*continued*)

Treatment category	Harms as reported by the authors	Prevalence
Minimally invasive nuclear decompression nucleoplasty	Soreness, numbness and tingling, increased back pain, new areas of back pain. Possible risk of end plate damage and neural injury and destruction of normal annulus	15%–76%
Needle acupuncture	All were minor complications including bleeding, hematoma, worsening of pain, tiredness, drowsiness, lightheadedness, dizziness; rare complications included hepatitis, septicemia, and pneumothorax before use of sterile, disposable needles mandated by FDA in 1996	0.1%–23% (minor)
NSAIDs, muscle relaxants, and simple analgesics	NSAIDs: Renal, gastrointestinal, and cardiovascular side effects	NSAIDs: 0.4%–2%
	Muscle relaxants: Dizziness, sedation, withdrawal from chronic benzodiazepine use associated with delirium tremens and withdrawal from baclofen may result in seizures	Muscle relaxants: NR
	Simple analgesics: Fatalities from acetaminophen liver toxicity are rare when exposure less than 7.5–10 g over 8 h. Capsaicin plaster produces local skin irritation and unpleasant sensations	Simple analgesics: NR
Opioid analgesics	Gastrointestinal side effects most common, especially constipation; sedation and drowsiness, confusion, hallucinations, nightmares, dysphoria; serotonin syndrome with concomitant selective serotonin reuptake inhibitor use; seizure, tremor; hyperalgesia; opioid-related aberrant behavior; organ toxicity to liver, kidneys, brain, or other organs; tolerance, addiction and dependence; respiratory depression; androgen deficiency in men causing low libido, erectile difficulties, low energy, easy fatigue, depressed mood; decreased libido and changes in menstrual cycle in women; osteoporosis, hypothalamic-pituitary suppression	59%
Physical activity, smoking cessation, and weight loss	None of the studies reported complications or side effects	NR
	Cardiovascular events possible with exercise therapy	
Prolotherapy	Side effects include temporary increase in pain or stiffness, bruising, transient leg pain, headache, nausea, minor allergic reactions, needlestick injuries (lumbar puncture, leg pain with neurologic features), disturbed sleep because of psychological trauma, severe cough	Side effects: 5%–70%
	Rare adverse events include spinal headache, pneumothorax, nerve damage, disc injury, meningitis, hemorrhage, nerve damage, and spinal cord insult	AEs: 470 reported in survey of 171 practitioners who treated median 2,000 patients each
Spinal manipulation and mobilization	Side effects include mild localized discomfort, headache, tiredness, radiating discomfort, dizziness	Side effects: 5%–53%
	Rare AEs include disc herniation, cauda equina syndrome	AEs: 1/1–128 million
TENS, interferential current, electrical muscle stimulation, ultrasound, and thermotherapy	Skin irritation or burns possible with inappropriate prolonged continuous use, incorrect placement or settings	Infrequent (irritation), rare (burns)
Traction therapy	Cardiopulmonary side effects such as shortness of breath or hypertension, increased blood pressure, aggravation of pain or neurological signs, sudden progression of lumbar disc protrusion	6/24 trials reported AEs
Trigger point injections	Side effects include local postinjection soreness, vasovagal depression, reaction to injectate, hematoma formation, or abscess development, local muscle necrosis; excessive weakness, flu-like symptoms, transient numbness or heaviness of ipsilateral limb	NR
	Rare reports of pneumothorax, epidural abscess, intrathecal injection	
Watchful waiting	Symptoms may worsen, which could affect other aspects of health, causing psychological distress or precipitating anxiety and depression	NR
Surgery	NR	NR

NR=not reported, AE=adverse event.

Only selected statements from the articles have been presented. For a full explanation of the harms of each treatment approach the reader should consult the full articles.

Conclusions

This special focus issue contains review articles written by clinicians and researchers who summarized the evidence on 25 classes of commonly used interventions for CLBP. The wealth of information provided by these articles cannot be understated and every article must be read in its entirety to appreciate the particular strengths and weaknesses of the arguments used by the authors for each treatment approach. It is also necessary for the reader to look at the entire

special focus issue to obtain an overview of the different treatment options and place them in perspective. Although it was initially hoped that global recommendations regarding the use of specific interventions for CLBP could be made based on the information presented in each article, this goal has proven to elusive at this moment. When viewed as a whole, the articles in this special focus issue pose more questions than they answer. Taken together, these reviews demonstrate the serious deficiencies in the available research for many of the treatment approaches that are commonly used for CLBP because of either unavailable, insufficient, or conflicting research results. These articles do not present convincing evidence that it is currently possible to select one treatment approach over another for patients with CLBP and give very little guidance on when any specific treatment approach is indicated.

When viewed optimistically, the articles in this special focus issue do suggest that a reasonable approach to CLBP would include education strategies, exercise, simple analgesics, a brief course of manual therapy in the form of spinal manipulation, mobilization, or massage, and possibly acupuncture. In patients with longstanding or severe symptoms and psychological comorbidities, there is some evidence that a comprehensive multidisciplinary approach with cognitive behavioral treatment, fear-avoidance training, or functional restoration is at least as beneficial as surgery. This interpretation of the best available evidence is not materially different than the recommendations from the Practice Guidelines on Acute Low Back Pain in Adults that were published by the Agency for Health Care Policy and Research in 1994 [2]. Although potentially heartening to the many clinicians who have adopted aspects of this approach, it is somewhat disappointing to note that 14 years after dozens of highly promoted new interventions, thousand of studies, millions of lost work days, and billions of dollars spent on its care, so little has changed in the evidence available to guide stakeholders and support treatments for CLBP.

As noted in the review of the economic burden of LBP in this special focus issue, the magnitude of this problem is likely increasing in the United States and the question that needs to be answered is whether any treatment should be offered and widely used before there being sufficient research evidence to establish its efficacy, safety, and cost effectiveness. It is a generally accepted principle in most fields of health care that a treatment should not be offered to the public until there is sufficient evidence supporting its safety and effectiveness and a consensus by clinicians of different backgrounds as to its most appropriate indications and contraindications. It should be evident to most readers that this is not the norm when dealing with CLBP and additional research is required to achieve this long-term goal. In the interim, patients, clinicians, third-party payers, and policy makers have a responsibility to become thoroughly familiar with, critically appraise, compare, and openly discuss the best available evidence presented in this special focus issue. In this supermarket of over 200 available treatment options for CLBP, we are still in the era of caveat emptor (buyer beware). The enthusiastic support by providers of any treatment should be considered when reviewing available research evidence that supports its use. It is hoped that this special focus issue will provide a starting point for stakeholders desiring quality information to make decisions about the evidence-informed management of CLBP.

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