



Systematic Reviews of Physical and Rehabilitation Medicine Cochrane Contents. Part 1. Disabilities due to spinal disorders and pain syndromes in adults

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Background. This article is the first in a series presenting the strongest published evidence for physical and rehabilitation medicine (PRM) to date coming from the Cochrane Collaboration. The intent of the series is to stimulate ideas for reviews and research in neglected areas of PRM.

Aim. To systematically review the rehabilitation contents of the Cochrane Collaboration on disabilities due to spinal disorders or pain syndromes in adults.

Methods. The Cochrane Database of Systematic Reviews was searched at the end of June 2013 for articles relevant for PRM about disabilities resulting from spinal disorders or pain syndromes in adults. Retrieved papers were classified according to the PRM approach: active therapies, which require active participation by patients to achieve treatment goals, and passive treatments, which rely on the application of external forces. The quality of the reviews was checked against the AMSTAR checklist.

Results. Reviews on spinal disorders or pain syndromes were found in the Cochrane Back Group (CBG) and in the Pain, Palliative and Supportive Care Group (CPPSCG). Thirty-eight (42.8%) of 89 Cochrane reviews in the CBG and 7 (2.4%) of 293 Cochrane reviews in the CPPSCG were included. All were of high quality (range, 8-11 points out of 11 on the AMSTAR checklist). The contents of the reviews are given in detail.

Conclusion. This review presents an overview of the current evidence for PRM in the treatment of disabilities due to spinal disorders or pain syndromes in adults. Within PRM there is ample space for research in the Cochrane Collaboration and for producing original studies (randomized controlled trials [RCTs]).

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Clinical Rehabilitation Impact. To apply evidence-based clinical practice, clinicians must be familiar with the current best evidence.

KEY WORDS: Spinal diseases - Pain management - Pain.

This article is the first in a series presenting the strongest published evidence for physical and rehabilitation medicine (PRM) to date coming from the Cochrane Database of Systematic Reviews. The intent of the series is to stimulate ideas for reviews and research in neglected areas of PRM.¹ This article follows on a series of papers the European Journal of Physical and Rehabilitation Medicine (EJPRM) has published on the Cochrane contents.²⁻⁷

Here we focus on disabilities due to spinal disorders or pain syndromes in adults.

As reported by Cimmino,⁸ musculoskeletal pain affects between 13.5% and 47% of the general population, with a prevalence of chronic widespread pain (C-WP) between 11.4% and 24%. Despite the huge economic burden associated with this group of conditions, including C-WP, chronic back pain (C-

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BP), and fibromyalgia syndrome (FMS), the origin of these problems is poorly understood.⁹

Because of its social and economic impact, low back pain (LBP) is a major problem that up to 70% of people will experience during their lifetime. Despite its clinical impact, LBP is often of benign origin, with more serious underlying problems accounting for only 1-5% of cases.¹⁰⁻¹² Koes reported that, in general, the clinical course of an episode of acute LBP (A-LBP) seems favorable and that most pain and related disability will resolve within a couple of weeks: about 90% of patients with LBP in primary care stop consulting their doctor within 3 months. Only a small proportion (5%) of people with A-LBP develop chronic LBP (C-LBP) and disability. Subacute LBP (SA-LBP) occurs when the disability doesn't resolve within 1 month because of other factors that perpetuate the problem.¹⁰

The worldwide prevalence of neck pain (NP) is high, but with differences depending on the study and the country of origin. Some studies report a prevalence from 26% to 71% during adulthood, with a prevalence of 75% according to recent data. The associated disability varies between 6-7 and 40% depending, again, on the evaluation tools and definitions.¹³

PRM plays an important role in the approach to disabilities ensuing from LBP, NP and other pain syndromes. They are among the most frequent cause of visits to outpatient facilities for PRM services. An evidence based approach to these problems is mandatory. The Cochrane Collaboration offers the actual best evidence in medical literature.^{1, 2} The aim of this paper is to check the actual best evidence on physical and rehabilitation medicine of disabilities due to spinal disorders or pain syndromes in adults through a systematic review of the contents of the Cochrane Database of Systematic Reviews.

Materials and methods

A systematic search of the Cochrane Collaboration Database was performed at the end of June 2013 to find articles relevant to PRM on disabilities due to spinal disorders or pain syndromes in adults. Articles on pain secondary to specific musculoskeletal disorders other than spinal pain or due to neurological diseases or other pathologies were not considered.

Articles were reviewed only if relevant to PRM. Consequently, only drugs commonly used by PRM doctors to treat disabilities and improve outcomes were considered. Psychotherapy or educational approaches performed by specialists not part of a PRM team were excluded, as were specific techniques (e.g., music therapy) proposed alone, outside a PRM team approach.

The contents of the retrieved studies were classified according to the PRM approach: active therapies, which require active participation by the patient to achieve treatment goals, and passive therapies, which rely on the application of external forces.

Active therapies included: exercises, education and prevention, multimodal rehabilitation, other PRM active therapies.

Passive therapies were defined as: physical modalities, manual therapies, reflex therapies, assistive devices, drugs, other PRM passive therapies.

Review quality was checked against the AMSTAR checklist¹⁴ developed for systematic reviews.

The contents of the reviews are summarized in the text. Detailed tables with the contents of each single review have been produced but are not published with the article due to space constraints. They will appear in a book that will be published by Minerva Medica in June 2014.¹

Results

Numerical results

Articles on PRM for disabilities due to spinal disorders can be found in the Cochrane Back Group and those on pain syndromes in the Cochrane Pain, Palliative and Supportive Care Group.

Out of a total of 89 Cochrane reviews retrieved in the Back Group, 52 (58.4%) were initially considered as being relevant for PRM; after reading the abstracts and full texts, 14 were excluded because the study involved children or was not pertinent to PRM; 38 (42.7%) reviews were included in the final analysis (Figure 1). The PRM contents of the Cochrane Back Group are summarized in Table I, divided according to the main conditions: BP and NP.

Out of a total of 293 Cochrane reviews in the Pain, Palliative and Supportive Care Group, 18 (6.1%) were deemed relevant for PRM; after reading the

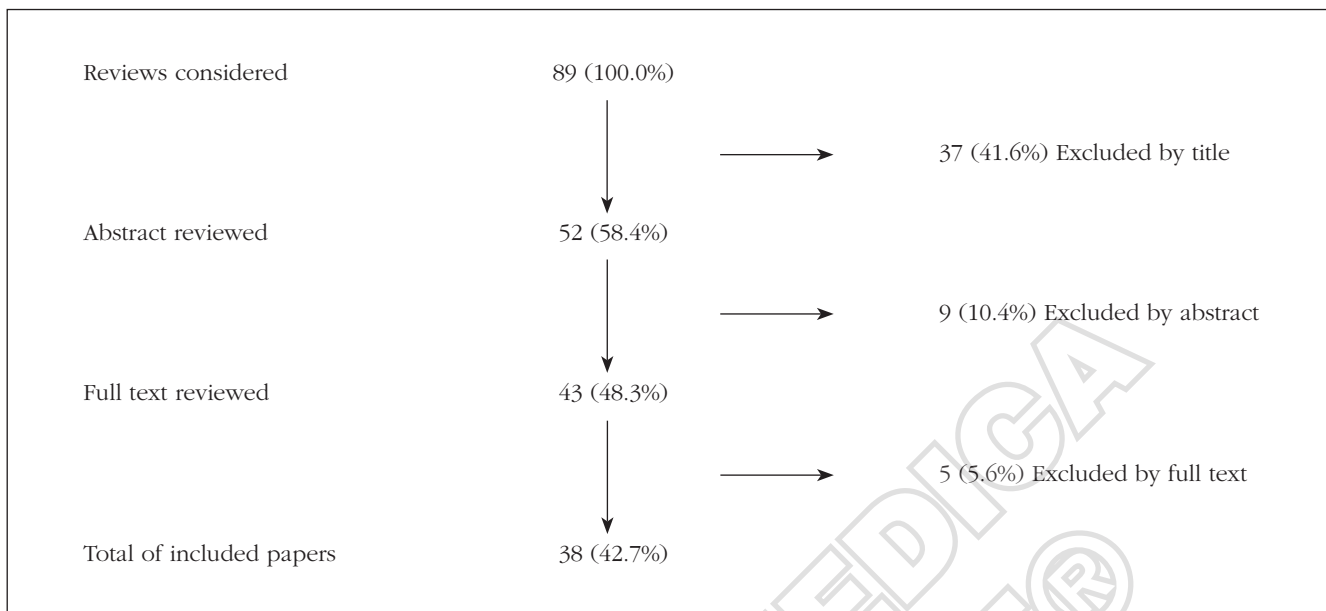


Figure 1.—Systematic reviews of the Cochrane Back Group relevant to Physical and Rehabilitation Medicine included in the final analysis.

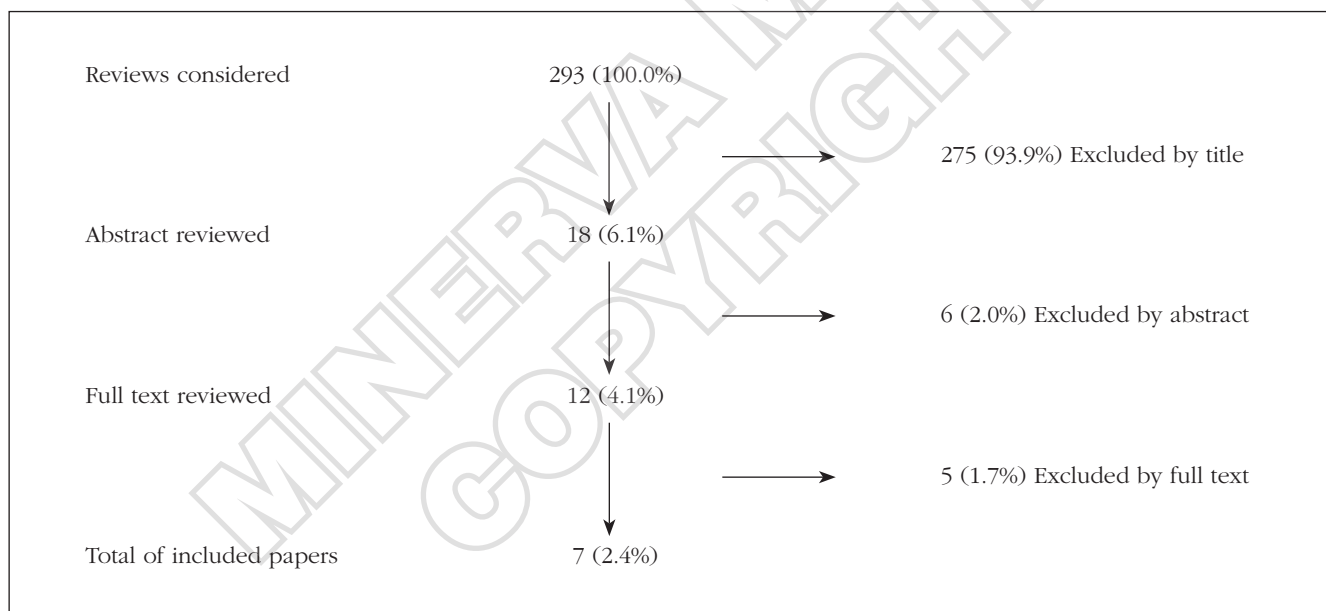


Figure 2.—Systematic reviews of the Cochrane Pain, Palliative and Supportive Care Group relevant to Physical and Rehabilitation Medicine included in the final analysis.

abstracts, 6 were excluded because unrelated to pain syndromes in adulthood (1 on children and 5 on cancer); after reviewing the full texts, 7 papers (2.4%) were included in the final analysis (Figure 2).

The PRM contents of the Cochrane Pain, Palliative and Supportive Care Group (Table II) were grouped according to the main types of pain syndromes: chronic or recurrent pain, and cancer pain.

TABLE I.—Number of Cochrane reviews of PRM interest on back disorders.

		Back pain	Neck pain
Active therapy	Exercises	4	1
	Education and prevention	3	2
	Multimodal rehabilitation	1	1
	Other	1	0
Passive therapy	Physical modalities	4	3
	Manual therapies	4	2
	Reflex therapies	2	1
	Assistive devices	2	0
	Drugs	5	2
	Other	0	0
TOTAL		26	12

All Cochrane reviews had a minimum of 8 out of 11 points as measured against the AMSTAR checklist, so they could be considered of high quality.

Contents of the reviews

EXERCISES

Hayden JA *et al.*¹⁵ (date of bibliographic search [DoBS]: October 2004; 61 RCTs, 6390 subjects) investigated the effectiveness of exercise therapy for LBP. They found it to be slightly more effective at decreasing pain and improving function in C-LBP in healthcare populations (patients) than in the general population recruited through advertising. In SA-LBP there is some evidence that a graded activity pro-

gram improves absenteeism outcomes, though the evidence for other types of exercise is unclear. In A-LBP, exercise therapy is as effective as either no treatment or other conservative treatments.

Schaafsma F *et al.*¹⁶ (DoBS July 2008; 23 RCTs, 3676 workers) focused on the role of physical conditioning programs for improving work outcomes in workers with BP. They concluded that the effectiveness of such programs in reducing sick leave in workers with BP remains uncertain as compared to usual care or other exercises. In workers with A-BP, these programs probably have no effect on sick leave, but there may be a positive effect on sick leave for workers with SA- and C-BP. Workplace involvement might improve the outcome.

Choi BK *et al.*¹⁷ (DoBS July 2009; 13 studies, 1113 participants) examined the role of exercise in the prevention of LBP recurrence. The studies were divided in two groups: post-treatment intervention programs and treatment studies; the recurrence of BP or time to recurrence was measured. They concluded that there is moderate-quality evidence that post-treatment exercise programs can prevent the recurrence of LBP, while conflicting evidence was found for treatment exercise.

Ostelo RW *et al.*¹⁸ (DoBS May 2007; 14 studies) evaluated the effectiveness of rehabilitation after lumbar disc surgery. They concluded that exercise programs starting 4 to 6 weeks post-surgery seem to lead to a faster decrease in pain and disability as compared to no treatment. High-intensity exercise programs seem to lead to a faster decrease in pain and disability than low-intensity programs. There

TABLE II.—Number of Cochrane reviews of PRM interest on pain syndromes.

		Chronic or recurrent pain	Cancer pain
Active therapy	Exercises	0	0
	Education and prevention	0	0
	Multimodal rehabilitation	0	0
	Other	0	0
Passive therapy	Physical modalities	3	1
	Manual therapies	1	0
	Reflex therapies	0	0
	Assistive devices	0	1
	Drugs	1	0
	Other	0	0
TOTAL		5	2

were no significant differences between supervised and home exercises for pain relief, disability or global perceived effect. They also found no evidence that active programs increase the reoperation rate after first-time lumbar surgery.

Kay *et al.*¹⁹ (DoBS February 2012; 21 RCTs) evaluated the role of exercises for NP. They concluded that low-to-moderate quality evidence supports the use of specific cervical and scapular stretching and strengthening exercises for C-NP in the immediate post-treatment and intermediate periods and cervicogenic headache in the long term. Low-to-moderate evidence suggests no benefit for upper extremity stretching and strengthening exercises or a general exercise program.

EDUCATION AND PREVENTION

Heymans MW *et al.*²⁰ (DoBS May 2003; 19 RCTs, 3584 patients) studied the role of back schools for LBP. They found moderate evidence suggesting that back schools, in an occupational setting, reduce pain, and improve function and return-to-work status in the short and intermediate term as compared to exercises, manipulation, myofascial therapy, advice, placebo or waiting list controls, for patients with C-LBP and recurrent LBP.

Engers A *et al.*²¹ (DoBS July 2006; 24 studies) studied the effectiveness of individual patient education for LBP. They concluded that, for patients with acute or SA-LBP, intensive patient education (2.5 hours) seems to be effective, but not a less intensive regimen. For patients with C-LBP, the effectiveness of individual education is still unclear.

Dahm KT *et al.*²² (DoBS May 2009; 10 RCTs) focused on advice to rest in bed versus advice to stay active for A-LBP and sciatica. They concluded that there is moderate-quality evidence that patients with A-LBP may experience small benefits in pain relief and functional improvement from advice to stay active as compared to advice to rest in bed; patients with sciatica experience little or no difference between the two approaches. They also added that low-quality evidence suggests little or no difference between those who received advice to stay active, exercises or physiotherapy.

Gross A *et al.*²³ (DoBS July 2010; 15 trials) studied the role of patient education for NP. One trial found moderate-quality evidence that an educational video of advice focusing on activation was more beneficial

for acute whiplash-related pain as compared to no treatment at the intermediate term but not at long-term follow-up. With this exception, they concluded that their review did not show any effectiveness for educational interventions, including advice to activate, advice on stress-coping skills, workplace ergonomics and self-care strategies.

Aas RW *et al.*²⁴ (DoBS July 2009; 10 RCTs, 2745 workers) investigated the effectiveness of workplace interventions for NP in workers. They found low-quality evidence that neither supported nor refuted the benefits of any specific workplace interventions for pain relief and moderate-quality evidence that a multiple-component intervention reduced sickness absence in the intermediate term which was not sustained over time.

MULTIMODAL REHABILITATION

Karjalainen K *et al.*²⁵ (DoBS November 2002; 2 RCTs) evaluated multidisciplinary biopsychosocial rehabilitation for SA-LBP among working-age adults. They concluded that there is moderate evidence for the positive effectiveness of multidisciplinary rehabilitation for SA-LBP and that a workplace visit increases its effectiveness.

Karjalainen K *et al.*²⁶ (DoBS November 2002; 1 RCT and 1 CCT) evaluated multidisciplinary biopsychosocial rehabilitation for NP and shoulder pain among working-age adults. They similarly concluded that there is little evidence for the effectiveness of multidisciplinary biopsychosocial rehabilitation as compared with other rehabilitation facilities for NP and shoulder pain.

OTHER PRM ACTIVE THERAPIES

Henschke N *et al.*²⁷ (DoBS February 2009; 30 RCTs, 3438 subjects) studied behavioral treatment for C-LBP. They distinguished three behavioral approaches, operant, cognitive, and respondent, although these are often combined in a single treatment package. They concluded that there is moderate-quality evidence that, in the short-term, operant therapy is more effective than waiting list and that behavioral therapy is more effective than usual care for pain relief, but no specific type of behavioral therapy is more effective than another. They found little or no difference between behavioral therapy and group exercises for pain or depressive symptoms in the intermediate to long term.

PHYSICAL MODALITIES

French SD *et al.*²⁸ (DoBS October 2005; 9 RCTs, 1117 subjects) compared superficial heat or cold therapy for LBP. They concluded that there is moderate evidence in a small number of trials that heat wrap therapy provides a small short-term reduction in pain and disability in a population with a mix of A-LBP and SA-LBP and that the addition of exercise further reduces pain and improves function. The evidence for the application of cold treatment to LBP is even more limited, with only three poor-quality studies. No conclusions can be drawn about the use of cold therapy for LBP. There is conflicting evidence for the differences between heat and cold therapies for LBP.

Khadilkar A *et al.*²⁹ (DoBS July 2007; 4 high-quality RCTs, 585 patients) evaluated transcutaneous electrical nerve stimulation (TENS) versus placebo for C-LBP. They concluded that the evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of C-LBP.

Kroeling P *et al.*³⁰ (DoBS December 2008; 18 RCTs, 1043 patients) evaluated electrotherapy for NP. They concluded that it was not possible to make any definite statements on the efficacy and clinical usefulness of electrotherapy modalities for NP since the quality of evidence is low or very low. They found that current evidence for pulsed electromagnetic field (PEMF), repetitive magnetic stimulation (rMS), and TENS shows that these modalities might be more effective than placebo but not other interventions; galvanic current, iontophoresis, electric muscle stimulation (EMS), and static magnetic field did not reduce pain or disability.

Nnoaham KE and Kumbang J³¹ (DoBS April 2008; 25 RCTs, 1281 subjects) investigated TENS for chronic pain. They concluded that the published literature lacks the methodological rigor or robust reporting needed to make confident assessments of the role of TENS in chronic pain management.

Hurlow A *et al.*³² (DoBS November 2011; 3 RCTs, 88 subjects) investigated TENS for cancer pain. They found that the results are inconclusive due to a lack of suitable RCTs.

Yousefi-Nooraie R *et al.*³³ (DoBS November 2007; 7 RCTs, 326 patients) evaluated low-level laser therapy for LBP. They concluded that, due to the heterogeneity of the populations, interventions and comparison groups, there are insufficient data to draw

firm conclusions on the clinical effect of low-level laser therapy for LBP.

Clarke JA *et al.*³⁴ (DoBS November 2004; 24 RCTs, 2177 patients) evaluated traction for LBP with or without sciatica. They found that traction is probably not effective. Neither continuous nor intermittent traction by itself was more effective in improving pain, disability or work absence than placebo, sham or other treatments for patients with a mixed duration of LBP, with or without sciatica. They also found moderate evidence that autotraction was more effective than mechanical traction.

Graham N *et al.*³⁵ (DoBS March 2008; 7 RCTs, 958 subjects) compared mechanical traction for NP with or without radiculopathy. They concluded that their results do not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function or global perceived effect as compared to placebo traction, tablet or heat or other conservative treatments in patients with C-NP.

O'Connell NE *et al.*³⁶ (33 trials, 937 subjects; 19 trials on repetitive transcranial magnetic stimulation [rTMS], 8 on cranial electrotherapy stimulation [CES], and 6 on transcranial direct current stimulation [tDCS]) compared the effectiveness of non-invasive brain stimulation techniques for chronic pain. They concluded that single doses of high-frequency rTMS of the motor cortex may have small short-term effects on chronic pain, even if the effects do not clearly exceed the predetermined threshold of minimal clinical significance. Low-frequency rTMS is not effective in the treatment of chronic pain. There is insufficient evidence from which to draw firm conclusions regarding the efficacy of CES or tDCS. The available evidence suggests that tDCS applied to the motor cortex may have short-term effects on chronic pain and that CES may be ineffective.

Verhagen AP *et al.*³⁷ (DoBS November 2006; 23 studies, 2344 subjects) evaluated the effectiveness of conservative treatments for whiplash. They concluded that the current literature is of poor methodological quality and insufficiently homogeneous to allow the pooling of results. Individual studies demonstrated the effectiveness of one treatment over another but the comparisons were varied and the results inconsistent. Therefore, the evidence neither supports nor refutes the effectiveness of either passive or active treatments to relieve the symptoms of whiplash-associated disorders.

Bronfort G *et al.*³⁸ (DoBS November 2002; 20

studies, 2628 patients) evaluated non-invasive physical treatments for chronic/recurrent headache. They concluded that some non-invasive physical treatments may be effective as prophylactic treatment for chronic/recurrent headache; they appear to be associated with little risk of serious adverse effects. They also added that the heterogeneity of the studies included in the review means that the results of a few additional high-quality trials in the future could easily change the conclusions of the review.

MANUAL THERAPIES

Rubinstein SM *et al.*³⁹ (DoBS March 2011; 20 RCTs, 2674 subjects) reviewed the effectiveness of spinal manipulative therapy (SMT) for A-LBP. They concluded that SMT is no more effective than inert interventions, sham SMT, or when added to another intervention. SMT also appeared to be no better than other recommended therapies.

Rubinstein SM *et al.*⁴⁰ (DoBS June 2009; 26 RCTs, 6070 patients) evaluated SMT for C-LBP. They concluded that high-quality evidence suggests no clinically relevant difference between SMT and other interventions in reducing pain and improving function in these patients.

Walker BF *et al.*⁴¹ (May 2009; 12 studies, 2887 subjects) compared combined chiropractic interventions for LBP. They found that pain and disability improved slightly in the short term and pain in the medium term for A-LBP and SA-LBP. However, there is currently no evidence that supports or refutes that these interventions provide a clinically meaningful difference for pain or disability in people with LBP as compared to other interventions.

Gross A *et al.*⁴² (DoBS July 2009; 27 trials, 1522 subjects) compared the effectiveness of manipulation or mobilization for NP. They concluded that cervical manipulation and mobilization produced similar changes. Either may provide immediate - or short-term change; no long-term data are available. Thoracic manipulation may improve pain and function. Optimal techniques and dose are unresolved.

Furlan AD *et al.*⁴³ (13 randomized trials) investigated the effectiveness of massage for LBP. They found that it might be beneficial for patients with SA-LBP and C-LBP, especially when combined with exercises and education. The evidence suggests that acupuncture massage is more effective than classic massage, but this needs confirmation.

Patel KC⁴⁴ (DoBS February 2012; 15 trials) studied massage for NP. They concluded that no recommendations for practice can be made at this time because the effectiveness of massage for NP remains uncertain. As a stand-alone treatment, massage for NP was found to provide immediate or short-term effectiveness or both in pain and tenderness.

Finally, So PS *et al.*⁴⁵ (24 studies, 1153 subjects) found that touch therapies (Healing Touch, Therapeutic Touch and Reiki) may have a modest effect on pain relief.

REFLEX THERAPIES

Urrútia G⁴⁶ (DoBS October 2002; 3 RCTs, 273 subjects) studied the application of neuroreflexotherapy for LBP. They concluded that it appears to be a safe and effective intervention for the treatment of C-LBP, while its efficacy is less clear for SA-LBP. However, they added that these results are limited to three RCTs conducted by a small number of specifically trained and experienced clinicians in a limited geographical location.

Furlan AD⁴⁷ (DoBS February 2003; 35 RCTs) evaluated acupuncture and dry-needling for LBP. They concluded that the data do not allow firm conclusions about the effectiveness of acupuncture for A-LBP. For C-LBP, acupuncture is more effective for pain relief and functional improvement than no treatment or sham treatment immediately after treatment and in the short term only. Acupuncture is not more effective than other conventional and “alternative” treatments. The data suggest that acupuncture and dry-needling may be useful adjuncts to other therapies for C-LBP.

Trinh KV *et al.*⁴⁸ (DoBS February 2006; 10 RCTs or quasi-RCTs) evaluated the effectiveness of acupuncture for NP. There were no studies on A-NP or SA-NP and all existing ones were on C-NP. They concluded that there is moderate evidence that acupuncture relieves pain better than some sham treatments, as measured at the end of treatment. They also found moderate evidence that those who received acupuncture reported less pain at short-term follow-up than those on a waiting list; acupuncture was also more effective than inactive treatments for relieving pain post-treatment and this was maintained at short-term follow-up.

ASSISTIVE DEVICES

Verbeek JH *et al.*⁴⁹ (DoBS February 2011; 9 RCTs, 20,101 employees and 9 CCTs, 1280 employees) compared manual material handling advice and assistive devices for the prevention of BP. They concluded that there is moderate-quality evidence that manual material handling advice and training with or without assistive devices does not prevent BP or BP-related disability as compared to no intervention or alternative interventions. There is no evidence available from RCTs for the effectiveness of manual material handling advice and training or manual material handling assistive devices for treating BP.

Sahar T *et al.*⁵⁰ (DoBS February 2007; 6 RCTs: 3 on BP prevention, 2061 subjects and 3 on treatment, 256 subjects) evaluated the use of insoles. They concluded that there is strong evidence that insoles are not effective for the prevention of BP, while the current evidence for insoles as treatment for LBP does not allow any conclusions.

Lee SH *et al.*⁵¹ (DoBS February 2012) compared patient positioning (mobilization) and bracing for pain relief and spinal stability in metastatic spinal cord compression in adults. They found no RCT on patient positioning or on bracing.

DRUGS

Roelofs PD *et al.*⁵² (DoBS June 2007; 65 trials, 11,237 patients) investigated the effectiveness of non-steroidal anti-inflammatory drugs (NSAIDs) in patients with LBP. They concluded that the evidence suggests that NSAIDs are effective for short-term symptomatic relief in patients with A-LBP and C-LBP without sciatica, even if the effect sizes are small. They added that there does not seem to be a specific type of NSAID which is clearly more effective than others, and that selective COX-2 inhibitors showed fewer side effects as compared to traditional NSAIDs, although studies have shown that COX-2 inhibitors are associated with increased cardiovascular risk in specific patient populations.

van Tulder MW *et al.*⁵³ (DoBS October 2001; 30 RCTs or double-blinded prospective CCTs) evaluated the use of muscle relaxants in the management of LBP. They concluded that benzodiazepines, non-benzodiazepines and antispasticity muscle relaxants are effective in the management of LBP, but the adverse effects require that they be used with caution.

The various muscle relaxants were found to be similar in performance.

Deshpande A *et al.*⁵⁴ (DoBS May 2007; 4 trials) studied the effects of opioids for C-LBP. Although achieving high internal validity scores, the trials were characterized by a lack of generalizability, inadequate description of study populations, poor intention-to-treat analysis, and limited interpretation of functional improvement. They concluded that the benefits of opioids in clinical practice for the long-term management of C-LBP remains questionable.

Urquhart DM *et al.*⁵⁵ (DoBS June 2006; 10 trials) evaluated the use of antidepressants in the management of C-LBP. They concluded that there is no clear evidence that antidepressants are more effective than placebo. They also added that their findings do not imply that severely depressed patients with BP should not be treated with antidepressants.

Peloso P *et al.*⁵⁶ (DoBS May 2006; 36 trials) evaluated the effectiveness of medicinal and injection therapies for NP. They found moderate evidence for the benefit of intravenous methylprednisolone given within 8 hours of acute whiplash. Two trials claimed that a single dose of lidocaine injection into myofascial trigger points appears effective. There is moderate evidence that botulinum toxin A is not superior to saline injection for chronic NP. Muscle relaxants, analgesics and NSAIDs had limited evidence and unclear benefits.

Langevin P *et al.*⁵⁷ (DoBS September 2010; 9 trials, 503 patients) evaluated botulinum toxin for SA-NP and C-NP. They concluded that current evidence fails to confirm either a clinically important or a statistically significant benefit of botulinum toxin A injection for C-NP with or without associated cervicogenic headache. Likewise, no benefit was seen for disability and quality of life at 4 weeks and 6 months.

Waseem Z *et al.*⁵⁸ (DoBS August 2009; 3 RCTs, 123 patients) reviewed the use of botulinum toxin injections for C-LBP (1 study) and sciatica (2 studies involving a mixed population). They concluded that there is low-quality evidence that botulinum toxin injections improved pain, function, or both better than saline injections and very low-quality evidence that they were better than acupuncture or steroid injections.

Soares A *et al.*⁵⁹ (DoBS December 2011; 4 studies involving 233 participants) evaluated the use of botulinum toxin for myofascial pain syndromes in

TABLE III.—Number of Cochrane Reviews of PRM interest and number of Trials (mainly, but not only Randomised Controlled Trials) that have been evaluated in these Cochrane Reviews.

		Spinal disorders		Pain	
		Cochrane Reviews	Trials	Cochrane Reviews	Trials
Active therapy	Exercises	5	142	0	0
	Education and prevention	5	78	0	0
	Multimodal rehabilitation	1	30	0	0
	Other	2	4	0	0
Passive therapy	Physical modalities	7	92	4	81
	Manual therapies	6	113	1	24
	Reflex therapies	3	48	0	0
	Assistive devices	2	24	1	0
	Drugs	7	92	1	4
	Other	0	0	0	0
	TOTAL		38	621	7

adults. One study demonstrated a significant improvement in pain and its daily duration versus placebo; the three other studies showed no statistically significant difference versus placebo in pain intensity. They concluded that evidence supporting the use of botulinum toxin is inconclusive.

Discussion

This systematic review focuses on the contents of the Cochrane Database of Systematic reviews, offering readers a complete overview of the PRM literature on disabilities ensuing from spinal disorders and pain. Generally speaking, the quality of evidence is medium to low, a sure signal that research sorely needs improvement. Tables I and II illustrate topic coverage; Table III lists the studies involved. Interestingly, pain syndromes received much less attention than pain associated with back disorders.

Current evidence

As a mainstay of PRM, exercise has been far more widely assessed in the treatment of spinal disorders than for general pain syndromes. Exercise regimens have a confirmed role in C-NP, C-LBP, and cervicogenic headache but not in A-LBP, while evidence for their utility in SA-LBP remains controversial. Exercise training in physical conditioning programs can be helpful in preventing recurrence and reducing work absenteeism. Moreover, exercise is

useful after surgery for LBP. As far as we can state today, exercise is useful only when applied after a LBP episode with the aim to prevent its recurrence, while exercise *per se* showed conflicting results as regards prevention.

Though sometimes overlooked, education and advice to patients play a key role in the PRM approach to disabilities. In a modern understanding of the specialty, PRM is a learning process⁶⁰ where education is fundamental for therapeutic outcome and prevention. For it to be effective, education should be appropriate for the stage of the disorder or condition. For instance, advice is considered useful for patients with A-LBP, while a more intensive approach should be taken to those with SA-LBP. Individual education in patients with C-LBP and NP appears to be less important than group education, as provided by back schools for C-LBP. Adjusting the message contents to patients seems to work if differentiated according to the condition: the advice to remain active has been shown to improve recovery in those with A-LBP but not in those with sciatica; similarly, advice for whiplash-related pain to stay active is useful mainly in the short term only. Finally, there is proof of efficacy for manual material handling advice for workers. We did not find any Cochrane review on education and prevention for pain syndromes.

A multidisciplinary biopsychosocial rehabilitation approach is a cornerstone of PRM clinical practice in both inpatient and outpatient settings. The only available evidence for its use in SA-LBP and NP is

partially positive, albeit based on trials with methodological shortcomings. Nevertheless, caution in LBP is warranted due to the costs involved. No Cochrane reviews on general pain syndromes in this context were found.

A psychological approach is basic to PRM and is ordinarily part of the general context of generalized biopsychosocial rehabilitation approaches. We found only one study dealing directly and specifically with psychological topics relevant for PRM doctors. Current evidence favors this approach in C-LBP, while there are no studies (nor a real rationale) in A-LBP and SA-LBP patients, apart from advice and individual education. Again, pain syndromes were not evaluated.

Physical modalities are among the most familiar conventional treatments in PRM; in fact, the word "physical" refers to this part of our specialty, though with much broader meaning.⁶¹ Today, there are two mainstream lines of thinking within PRM: one claims that traditional physical therapy is not useful and so focuses on rehabilitation instead; the other supports traditional methods even if the evidence for their effectiveness is apparently weak. The present stage of research suggests that heat therapy can potentially help relieve A-LBP and SA-LBP in the very short term, with an added on effect on exercise, whereas there is no reliable evidence for the benefit of cold therapy. TENS has been extensively studied, without evidence for its use in C-LBP, chronic and cancer pain, though it could reduce NP. Traction, continuous or intermittent, is not effective for LBP or NP with associated radiculopathies; however, there is some evidence in favor of autotraction. Finally, looking at the new non-invasive brain stimulation techniques, some evidence exists for the use of high-frequency rTMS for chronic pain.

Manual therapies (MT) make up the clinical background of PRM physicians and professionals. And though widely used, MT is not so widely studied. Today, may be stated that there is no real evidence in favor of manipulation in A-LBP and C-LBP, while there is some for NP, where its effectiveness is similar to simple mobilization. Conversely, there is some evidence supporting massage for SA-LBP and C-LBP, and only in the short-term for NP. The combination of manual treatments increases the effectiveness of massage and manipulation (chiropractic interventions) for LBP. Finally, touch therapy also seems to have a role in pain management.

Neuroreflexotherapies, derived from either modern age philosophies or traditional medicine (*e.g.*, Chinese acupuncture), have found their place in PRM. There is some degree of evidence for the benefit of neuroreflexotherapy, dry-needling and acupuncture in C-LBP, as also for acupuncture in C-NP. No studies on these methods have been conducted in patients with A-LBP, SA-LBP or NP.

Assistive devices for pain are mainly orthoses, that are commonly used in both the prevention and treatment of spinal disorders and pain; nevertheless, at the present state-of-the-art there is only evidence for their use in prevention: insoles are not useful, as well as assistive devices for workers. It is not possible to say anything about orthotic treatment for LBP pain due to metastatic tumors of the spine.

Sometimes PRM doctors see patients under drug treatment for a condition that usually requires another type of approach when not real detoxification. Oftentimes, however, drugs are associated with PRM treatment or prescribed as a stand-alone therapy. Inextricably linked to the drugs industry's pre- and post-marketing needs, drug therapy is far more extensively studied than any other approach. Consequently, study results in this area predominate by number and strength. According to available data, current evidence clearly shows the effectiveness of NSAIDs, without substantial claims for the superiority of one product over another, for A-LBP and C-LBP but not for NP. The same holds true for centrally acting muscle relaxants (associated with numerous adverse effects). Conversely, from the limited research basis to date there is no favorable evidence for the use of opioids and antidepressants. Botulinum toxin, a drug widely used in PMR, has been extensively studied, with some favorable evidence for its use in C-LBP but not in NP or myofascial pain syndromes.

Research indications

Tables I-III give an overview of the best literature on pain and spinal disorders issues relevant for PRM. Generally speaking, the PRM-specific reviews in the Back Group far outnumber those in the Pain, Palliative and Supportive Care Group. Another review in this series¹ will cover the topic of pain in musculoskeletal disorders, that is not considered here. Importantly, the topic of general pain deserves far more research attention than it has received till now. The reason for this imbalance is difficult if not pos-

sible to explain: is the difference between the two Groups due to a lack of primary studies or a lack of interest from the Cochrane Group itself? Unquestionably, there is a need for more systematic reviews by PRM researchers to cover the missing topics and better summarize the current evidence.

The effect of therapeutic and preventive exercises on pain syndromes has not been evaluated in the Cochrane systematic reviews. There is a paucity of RCTs on NP, particularly trials conducted under similar protocols which would allow for cross-comparison. Also, SA-LBP is not very well studied. Aside from the diagnostic problems in identifying candidates eligible for exercise treatment for NP and LBP, at this stage of research, and given the 9 years since the last Cochrane review published on the topic, it should now be possible to distinguish between the effect of different types of exercise regimens for LBP. Furthermore, long-term outcome research in the prevention of recurrence and reduction of work absenteeism is desirable.

Apparently, patient education has not been studied in other kinds of pain syndromes, apart from LBP and NP. This is an open field for PRM research, at least in Cochrane terms; whether this can be done with RCTs is beyond the scope of this article. There is quite a good amount of scientific work on the role of advice to stay active in A-LBP, which is not true for sciatica where more research is needed. The role of education in NP still needs to be elucidated; improving on the low quality of the current evidence will require specific effort. The review on back schools is outdated, though it cannot be excluded that new studies have been published in the meantime.

As regards psychological therapies connected with PRM, further research is likely to have an important impact on our current knowledge. Pain in spinal disorders has been studied but not specifically in other conditions. Research on multidisciplinary programs in the treatment of SA-LBP, C-LBP, and NP is lacking. In common use around the world, usually on an inpatient basis, these approaches carry high costs and merit critical examination.

Convincing evidence for physical modalities is scanty: RCTs are few and study populations are small. There is a strong need for research in this specific field, which could help in the treatment of spinal and general pain syndromes. The results on physical treatment for chronic/recurrent headache

are promising: this is a good reason to produce good quality research on this topic. Moreover, the present Cochrane review is quite old, and an update, perhaps distinguishing between different types of headache, could be interesting. The same is true for whiplash-associated disorders. The results of the two Cochrane reviews seem to differ more in the individual approach and the authors' attitudes than in any real basis of evidence.

Manual therapies are a paradigmatic situation that shows how the weight of evidence can shift as the research basis widens. With each systematic review, the results differ as more recent studies appear, though the situation is apparently stabilizing. Because of the small number of studies, further research in this field could improve comparison between outcomes. Future RCTs should also examine specific subgroups; finally, cost/benefit analysis is crucial where pain relief is concerned, with meaningful comparison among treatment options.

Reflex therapies open new perspectives for research: neuroreflexotherapy and dry-needling for C-LBP, and acupuncture for C-LBP and C-NP appear particularly promising, but their effectiveness needs to be evaluated by other researchers. These approaches have not been attempted on other pain syndromes, or at least we did not find Cochrane studies on this topic that deserves exploration.

Research on assistive devices (orthosis) for spinal disorders is another open field; the existing reviews underscore the almost complete absence of good quality research about treatment. Something has been done about prevention, but there is still ample space for research. More RCTs are really needed.

Drug therapy has been extensively studied; nevertheless, many questions remain open. Centrally acting muscle relaxants and corticosteroids are widely used but not studied. Despite concerns about the use of opioids for the long-term management of C-LBP, there are few high-quality trials assessing their efficacy. Trials are therefore needed to determine whether muscle relaxants are more effective than analgesics or NSAIDs. Meta-analyses of studies on botulinum toxin drugs are not feasible because of the heterogeneity between studies. We suggest that future studies adopt the same methodology to assess pain, a standardized dose of treatment, a follow-up of at least 4 months (to observe the maximum/minimum curve of the

drug's effect) and appropriate data presentation. More high-quality RCTs on botulinum toxin for treating the myofascial pain syndrome need to be conducted before firm conclusions on its effectiveness and safety can be drawn.

Conclusions

Cochrane reviews offer the state-of-the-art of the best evidence in medicine.^{1, 2} This is especially important for all medical specialties. The absence of a PRM-specific group, due to the peculiarities of our specialty, makes for sparse evidence that is difficult to collect. The EJPRM series will try to reduce this gap, with the aim to provide PRM specialists with a complete overview of the best evidence to date on PRM issues.

This first article has focused on disabilities due to spinal disorders and pain in adults. The reviews examined here can be found in the Cochrane Back Group and the Pain and the Palliative and Supportive Care Group. The article has depicted the current situation in PRM and delineated the space for PRM research either within the Cochrane Collaboration or for conducting original studies (RCTs).

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