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Critical Review

Interventions Available Over the Counter and Advice for Acute Low Back Pain: Systematic Review and Meta-Analysis

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Abstract: **This systematic review evaluated evidence from randomized controlled trials investigating interventions available over the counter and advice that could be provided to people with acute low back pain. Searches were conducted on MEDLINE, Embase, Cochrane Database of Systematic Reviews, AMED, CENTRAL, and PsycINFO for eligible randomized controlled trials. The primary outcome measure was pain. Eligible controls included placebo, no treatment, or usual care. Two reviewers extracted data and rated study quality. A random effects model was used to pool trial effects with the overall strength of evidence described using the GRADE criteria. Thirteen randomized controlled trials (2,847 participants) evaluating advice, bed rest, simple analgesics (paracetamol, nonsteroidal anti-inflammatory drugs), heat application, and a topical rubefacient were included. There was low-quality evidence that bed rest is ineffective and very-low-quality evidence that advice is ineffective in the short, intermediate, and long terms. There was very-low-quality evidence that nonsteroidal anti-inflammatory drugs (ibuprofen and diclofenac "when required" dosing) provide an immediate analgesic effect (mean differences −10.9 [95% confidence interval = −17.6 to −4.2] and −11.3 [95% confidence interval = −17.8 to −4.9], respectively). There is very-low-quality evidence that heat wrap and a capsicum-based rubefacient provide an immediate analgesic effect (mean differences −13.5 [95% confidence interval = −21.3 to −5.7] and 17.5, $P < .001$, respectively), but there was no information on longer-term outcomes.**

Perspective: ***There is limited evidence that nonsteroidal anti-inflammatory drugs, heat wrap, and rubefacients provide immediate pain relief for acute back pain and that bed rest and advice are both ineffective. Future research is needed to provide evidence to support rational use of over-the-counter remedies and advice for people with acute low back pain.***

Key words: *Low back pain, over the counter, advice, paracetamol, nonsteroidal anti-inflammatory drugs.*

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Low back pain (LBP) is a common and costly condition worldwide,[55] with up to 84% of adults experiencing an episode at some point in their lives.[21] The Global Burden of Disease 2010 study[31] has identified LBP as the leading contributor to disability. In Australia, it is estimated that more than $1 billion is spent annually on treatments for LBP, whereas a further $8 billion is spent on indirect costs.[56] In the United States, this figure is estimated to be as high as $50 billion per year.[11]

Only around half of people with acute LBP consult a health professional,[11,23,56,57] with use of remedies

available over the counter (OTC) widespread. Findings from a 2008 U.S. National Health Interview Survey[47] identified LBP as one of the most common conditions treated with OTC medicines. Many of these OTC interventions can be provided in a community pharmacy/drug store and include nonprescription medicines and simple remedies such as heat or cold packs that can be provided to a person with LBP for self-administration.

Despite the widespread use of OTC interventions and the provision of advice to those experiencing LBP, there are no systematic reviews summarizing the clinical effectiveness of these interventions for acute LBP. The aim of this review was to investigate the effectiveness of interventions that can be accessed OTC, without the need for a prescription, and advice that could be delivered in a primary contact setting.

Methods

Data Sources and Searches

MEDLINE, Embase, Cochrane Database of Systematic Reviews, AMED, CENTRAL, and PsycINFO (inception to March 2013) were searched for randomized controlled trials (RCTs) evaluating OTC interventions and/or advice for acute LBP (full search details in the Supplementary Appendix). We also screened studies and reference lists from systematic reviews in the area to identify potentially eligible RCTs.

One reviewer (C.A.S.) screened titles and abstracts of retrieved studies. Two reviewers drawn from a pool of 3 reviewers (C.A.S., A.J.M., and C.G.M.) inspected the full manuscript of potentially eligible RCTs to determine eligibility, with disagreements resolved by consensus.

Study Selection

Studies were restricted to English language RCTs evaluating OTC remedies for acute (pain duration <12 weeks) nonspecific LBP. We restricted interventions to those that could be self-administered by a person with LBP and were readily accessible from a community pharmacy/drug store without prescription (Supplementary Appendix Tables 1 and 2). Eligible controls included placebo, no treatment, or usual care.

Eligible interventions included OTC medicines (eg, paracetamol or nonsteroidal anti-inflammatory drugs [NSAIDs]), complementary/herbal remedies (eg, comfrey), and topical applications (eg, heat or cold packs) (see Supplementary Appendix). We also included advice that could be provided to a person with LBP in an OTC setting. We excluded interventions that required a prescription (such as single-ingredient opioid analgesics, analgesic adjuvants, or muscle relaxants) and physical interventions such as spinal manipulation, acupuncture, and laser therapy.

Trials were included if they reported endpoints such as pain, disability, global perceived recovery, sickness leave, or adverse events outcomes. We considered pain as the primary outcome.

Data Extraction and Quality Assessment

Methodological quality of individual trials was assessed using the Physiotherapy Evidence Database (PEDro) scale.[10,32,34] The PEDro scale is an 11-item scale (Table 1) that has been established as a valid and reliable method of rating methodological quality of individual RCTs.[10,32,34] Each item is scored as either present (1) or absent (0). The PEDro summary score does not include the item related to external validity, thus giving a total score out of 10. Rating of trials is carried out by 2 independent raters, with disagreements resolved by an independent third rater. All PEDro raters undergo initial training, which involves practice with feedback, and raters do not begin rating trials until they pass an accuracy test. The level of disagreements for raters is monitored by the PEDro project manager, and if required additional training is provided for a rater. Finally, authors of trials are able to dispute ratings and present a case that a rating should change.[42]

Given the extensive quality control procedures used by the PEDro database, we adopted existing ratings for 12 of the 13 RCTs, with the remaining trial[12] allocated a PEDro rating by 3 reviewers (C.A.S., C.G.M., and A.J.M.) using a joint consensus approach. Trials scoring <7/10 on the PEDro scale were defined as low quality; those scoring 7 or more were considered high quality.

Two reviewers (C.A.S. and C.G.M.) extracted outcomes data from each individual study. Missing data were obtained by contacting authors or estimated using the methods endorsed by the Cochrane Collaboration.[25] We adopted median scores for missing means and used standard deviation values from baseline (or the most similar eligible study) as a substitute for missing standard deviation values.

An adapted version of the GRADE criteria[3] endorsed by the Cochrane Back Review Group was used to evaluate the strength of recommendations and the overall quality

Table 1. PEDro Ratings for Eligible Trials

Study	1	2	3	4	5	6	7	8	9	10	Total
Dreiser 2003[12]	+	+	+	+	+	+	+	–	+	+	9
Milgrom 1993[36]	+	–	–	–	–	–	+	–	+	+	4
Nadler 2003[38]	+	–	+	–	–	+	+	+	+	–	6
Nadler 2003[39]	+	–	+	–	–	+	+	+	+	–	6
Pengel 2007[43]	+	+	+	+	–	+	+	+	+	+	9
Ginsberg 1987[19]	+	–	–	+	–	+	+	–	+	+	6
Jellema 2005[28]	+	–	–	+	–	–	+	+	+	+	6
Indahl 1995[27]	+	–	+	–	–	–	+	+	+	+	6
Storheim 2003[51]	+	+	+	–	–	+	–	+	+	+	7
Gilbert 1985[18]	+	+	+	+	–	–	–	+	–	+	6
Malmivaara 1995[35]	+	+	+	–	–	+	+	–	+	+	7
Wilkinson 1995[58]	+	+	+	–	–	–	–	–	+	+	5
Rozenberg 2002[49]	+	+	+	–	–	–	+	+	+	+	5

NOTE. 1 = randomization; 2 = concealed allocation; 3 = baseline comparability; 4 = subject blinding; 5 = therapist/physician blinding; 6 = assessor blinding; 7 = adequate follow-up (>85%); 8 = intention-to-treat analysis; 9 = between-group statistical comparisons; and 10 = point measures and measures of variability.