



NSW
THERAPEUTIC
ASSESSMENT
GROUP

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LOW BACK PAIN

Rational Use of Opioids in Chronic or Recurrent Non-malignant Pain

Background

Low back pain is one of the most prevalent problems in the general population.¹ Consultations in general practice involving management of back pain are frequent. The most common presentation is non-specific lower back pain associated with decreased spinal movement. Other less common causes of back pain include trauma, disorders producing neurological lesions, infection, neoplasm and metabolic bone disease. While well over 90% of patients with **acute back pain** recover within 2 weeks, recurrence is reported in 20-60% of patients.²

Several guidelines³⁻¹⁰ have been produced to assist clinicians manage **acute back pain**. Satisfactory relief of **acute** pain may help to prevent the development of **chronic** pain.

Patients with chronic pain may present for treatment of

- acute pain from unrelated injury or illness,
- exacerbation of chronic pain, or
- ongoing management of chronic pain.

These guidelines are intended to assist general practitioners and other primary care clinicians to manage the complex medical, psychosocial, ethical and regulatory considerations involved in treating patients with **chronic low back pain**, especially where there is exacerbation of their chronic pain. They integrate key points from evidence-based guidelines with experience from general practice.

The recommendations are based, wherever possible, on published evidence. The level of evidence is noted against each treatment to assist interpretation and implementation of the guideline in practice (see Table 3).

This document deals principally with the pharmacological management of chronic non-malignant low back pain. Non-drug therapies also have an important place in pain management. Active rehabilitation is particularly important in preventing progression to a chronic condition.

Diagnosis and Management

The key to managing **acute low back pain** is assessment, which assists in distinguishing serious pathology from benign musculoskeletal causes. The latter constitute well over 90% of back pain cases.² Table 1 lists 'red flags'. These should alert clinicians to potentially serious conditions which require further investigation and possible referral.²

Where pain persists either intermittently or continuously for an extended period, there is a risk of progression to **chronic pain**.

There are psychosocial risk factors that are associated with an increase in the likelihood of progression to chronic pain. These have been referred to as 'yellow flags' and an adaptation of these is provided in Table 2.⁹ For further information on the cognitive and behavioural aspects of chronic pain, refer to *Therapeutic Guidelines: Analgesic*, 4th Edition, published by Therapeutic Guidelines Limited (2002)¹¹; which contains useful information for clinicians and patients. A self-help book which may also be helpful is *Manage Your Pain: practical and positive ways of adapting to chronic pain*, by Nicholas et al, published by ABC Books (2001).¹²

Referral to a multidisciplinary treatment program is important in managing patients with chronic low back pain,¹³ particularly those with multiple risk factors (yellow flags). Early referral is desirable for these individuals. The use of long acting oral opioids may be appropriate in a small number of patients. Ideally, pain clinic assessment should precede the prescription of oral opioids.

On occasion, a general practitioner may see a new patient who complains of severe pain, and who is already taking a mixture of opioid and non-opioid drugs and is seeking ongoing treatment. Contact should be made with the previous prescriber. Assessment by a pain clinic should be arranged as soon as possible.

Physical dependence will occur after as little as one week of continuous opioid therapy, but is usually not associated with drug-seeking behaviour.¹¹ If opioid requirements appear inappropriate based on observation of the person's behaviour, consideration should be given to referring the person to a specialist in drug dependence or a specialist pain service. If early referral is impractical, advice can usually be obtained by telephone.

For clinical advice on the management of a patient with problems related to opioid dependence, call the NSW Drug and Alcohol Specialist Advisory Service on 1800 023 687 or 02 9557 2905.

Doctors can call the Commonwealth Health Insurance Commission (HIC) on 1800 631 181 or the NSW HIC on 02 9895 3333 to check whether there is any information on a patient seeking benzodiazepines or opioids who may be seeing other doctors or obtaining multiple PBS prescriptions. However there may be limitations to the value of such information (eg it may not be current or comprehensive).

The pharmacological options for management are discussed in the following paragraphs. It is important that these options are explored in conjunction with the patient to develop a management plan. The patient should understand the goals of drug management and how these relate to the outcomes of adjunctive therapies.

The limitations of drug therapy as a means of achieving favourable outcomes are acknowledged. Although guidelines provide the best options based on available evidence, they may not ensure a successful outcome in all patients.

Evidence for Efficacy of Drug Treatments

TABLE 1

Red flags* for potentially serious conditions requiring medical intervention in acute low back pain		
Possible fracture	Possible tumour or Infection	Possible cauda equina syndrome
FROM MEDICAL HISTORY		
<p>Major trauma, such as vehicle accident or fall from height.</p> <p>Minor trauma or even strenuous lifting in an older or potentially osteoporotic patient.</p>	<p>Age over 50 or under 20.</p> <p>History of cancer. Constitutional symptoms, such as recent fever or chills or unexplained weight loss.</p> <p>Risk factors for spinal infection: recent bacterial infection (eg urinary tract infection), IV drug abuse; or immune suppression (from corticosteroids, transplant or HIV).</p> <p>Pain that worsens when supine, severe night-time pain.</p>	<p>Saddle anaesthesia.</p> <p>Recent onset of bladder dysfunction, such as urinary retention, increased frequency, or overflow incontinence.</p> <p>Severe or progressive neurological deficit in the lower extremity.</p>
FROM PHYSICAL EXAMINATION		
		<p>Peri-anal/perineal sensory loss.</p> <p>Major motor weakness: quadriceps (knee extension weakness); plantar flexors, evertors and dorsiflexors (foot drop).</p>

TABLE 2

Yellow flags* to alert to psychosocial factors which may contribute to long-term distress, disability and chronic pain	
<p>The following factors may be important in predicting poor outcomes:</p> <ul style="list-style-type: none"> • presence of a belief that back pain is harmful or potentially severely disabling • fear-avoidance behaviour (avoiding a movement or activity due to misplaced anticipation of pain) and reduced activity levels • tendency to low mood and withdrawal from social interaction • an expectation that passive treatment rather than active participation will help. 	<p>Suggested questions (to be phrased in treatment provider's own words):</p> <ul style="list-style-type: none"> • Have you had time off work in the past with back pain? • What do you understand is the cause of your back pain/ • What are you expecting will help you? • How is your employer responding to your back pain? Your co-workers? Your family? • What are you doing to cope with back pain? • Do you think that you will return to work? If so, when?

*Adapted from: New Zealand Acute Low Back Pain Guide. Wellington, 1997⁹.

Paracetamol

Paracetamol has been proposed as first line therapy in all reviewed guidelines for treatment of **acute** low back pain. Although it has not been tested in placebo controlled trials in patients with acute or chronic back pain its efficacy for a wide variety of pain is well established and it is considered relatively safe (ie it does not cause physical dependence and is not associated with gastrointestinal side effects). This view is supported by the study of Coste et al¹⁴ in which 90% of patients presenting with a first episode of back pain recovered on paracetamol and, in a few cases, rest.

Non-steroidal anti-inflammatory drugs (NSAIDs)

Evidence for the efficacy of NSAIDs in low back pain is limited. A systematic review¹⁵ of 51 randomised clinical trials evaluating NSAIDs in **acute or chronic** low back pain found treatment with an NSAID for one week provided a small but significant short term global improvement compared with placebo (relative risk 1.24; 95% confidence interval 1.10-1.41). There was not enough information to determine the effectiveness of NSAIDs over placebo in **chronic low back pain** specifically. NSAIDs were only slightly more effective than paracetamol for both acute and chronic low back pain, and none of the studies showed a difference between NSAIDs and opioids such as codeine or dextropropoxyphene. There was no difference between the various NSAIDs tested.

Because adverse effects are common with NSAIDs, they should not replace paracetamol as first line therapy. NSAIDs should be avoided in patients who are volume depleted, elderly, have renal dysfunction or a history of peptic ulcer.

NSAIDs exert an immediate analgesic effect, however their anti-inflammatory effect, which is related to the achievement of steady state, is only evident after dosing for three to five half-lives. This means that NSAIDs with shorter half-lives, such as ibuprofen and diclofenac, should be prescribed in preference to those with longer half-lives, such as piroxicam and sulindac, for non-specific low back pain due to acute injury.

Although COX-2 selective inhibitors (eg celecoxib, rofecoxib) may reduce the risk of serious gastrointestinal (GI) events,^{16,17} they are no more effective than traditional NSAIDs. They should be reserved for patients at high risk for upper GI bleeding.

Opioids

There is no place for the general use of injectable opioids such as pethidine. A single intra-muscular dose of an opioid may be beneficial when patients must be transported, and intramuscular injection in hospitalised patients may be necessary in the acute phase if pain is severe. Oral opioids may be useful in the short term management of acute back pain when early mobilisation is the goal of therapy, but there are no randomised controlled trials to support this. In chronic pain management, pethidine has no role, and patients receiving frequent pethidine injections should have their condition re-evaluated, preferably with the early involvement of a multidisciplinary pain management team.¹⁸ Attempts should be made to identify and start to address the patient's beliefs and behaviours as early as possible.

Paracetamol with codeine does not appear to be more effective than NSAIDs, but it may be better tolerated in some patients. A comparison of diflunisal and paracetamol with codeine in the treatment of acute low back strain found that both treatments provided a similar level of analgesia but that the paracetamol-codeine combination was better tolerated by patients.¹⁹ This is contrary to another study which found diflunisal (500mg twice daily) and paracetamol-codeine (650mg-60mg every 4-6 hours) to be equianalgesic but diflunisal to be better tolerated.²⁰

The published literature does not indicate a role for dextropropoxyphene in the treatment of acute or chronic back pain. Kuntz and Brossel²¹ reported a randomised double blind trial of paracetamol and caffeine versus paracetamol and dextropropoxyphene for seven days in 124 patients with osteoarthritis of the spine. There was a major reduction in pain level in both treatment groups after one week: 51% in the paracetamol-caffeine group and 47% in the paracetamol-dextropropoxyphene group. The frequency and intensity of adverse events were similar in the two groups.²¹

Tramadol is a centrally active analgesic with opioid-like effects. It appears to act by modifying transmission of pain impulses via inhibition of noradrenaline and serotonin reuptake, and also by binding weakly to mu-opioid receptors. Tramadol 100mg eight hourly has been shown to be equivalent in efficacy to paracetamol 1000mg plus codeine 60mg eight hourly in patients with refractory chronic back pain.²²

Because it has relatively weak opioid effects, constipation is less common with tramadol than with other opioids, but nausea and dizziness can be a problem. Tramadol should be used with caution in patients on monoamine oxidase inhibitors (MAOIs) or selective serotonin re-uptake inhibitors (SSRIs), because such combinations may precipitate a serotonin syndrome. The abuse potential for tramadol is low at usual recommended doses, but reports of both drug-seeking behaviour and withdrawal syndrome with tramadol have been published.²³

For a small number of patients with chronic pain, long-acting oral opioids may be appropriate where other measures have failed. Early assessment by a multidisciplinary pain clinic is important and such assessment should precede, where possible, a decision to commence oral opioids.

Antidepressants

A systematic review of randomised trials of antidepressant use in back pain reported no difference between antidepressants and placebo with respect to reported pain, antidepressant effect or functional disability.²⁴ A subsequent systematic review suggested that antidepressants could be more effective than placebo for pain associated with chronic low back pain²⁵, although there were methodological limitations. There is evidence that depression and chronic low back pain occur together, but whether they are causal, coincidental, mutually exacerbating or synergistic is not clear.²⁶ There is no evidence that selective serotonin reuptake inhibitors

(SSRIs) are more effective than noradrenergic reuptake inhibitors such as the tricyclic antidepressants, in reducing pain.

Other medications

In chronic low back pain the efficacy of drugs such as benzodiazepines, antihistamines and various sedatives has not been proven and no studies show that their use in combination with NSAIDs leads to greater efficacy. In addition, these drugs can cause dizziness in a substantial proportion of patients. A decision to use benzodiazepines for their sedative effects in the first 24-48 hours of acute pain may be appropriate for a small number of patients.

Gabapentin (in doses up to 1200mg per day) has been compared with placebo in a randomised trial in 80 patients with low back pain and associated referred leg pain. There was no significant effect on background pain, and only marginal benefit in referred pain and pain on movement.²⁷

Willow bark extract (*Salix*) contains salicin, which is the prodrug of various salicylate derivatives. It has been investigated in a randomised double-blind trial of 210 patients with exacerbations of low back pain treated for four weeks.²⁸ It was significantly better than placebo. Comparative studies with other analgesics have not been published.

Another plant extract (*Harpagophytum procumbens*) has also been evaluated in low back pain and found to be better than placebo.²⁹ Again comparative studies have not been published.

Relative cost of medicines

The following brief cost structures are provided for the information of doctors and patients:

Simple analgesics	range from \$0.20 to \$1.00 per dose
Compound analgesics	approximately \$0.34 per dose
NSAIDs (non-selective)	range from \$0.30 to \$0.50 per dose
NSAIDs (selective Cox-2 inhibitors)	approximately \$0.75 per dose
Tramadol	approximately \$0.60 per dose

Levels of evidence

Level 1	Evidence obtained from systematic review of relevant randomised controlled trials
Level 2	Evidence obtained from one or more well-designed, randomised controlled trials
Level 3	Evidence obtained from well-designed, non-randomised controlled trials; or from well designed cohort or case control studies
Level 4	Opinions of respected authorities based on clinical experience, descriptive studies, reports of expert committees

Treatment of Non-Specific Low Back Pain

TABLE 3

Initial Presentation (Acute Pain or Exacerbation of Chronic Pain)			
Education	General	Reassure the patient and answer negative questions in a positive way Distinguish between acute pain and exacerbation of chronic back pain Advise about type and likely duration of symptoms Discuss diagnosis and nature of the condition in detail Provide specific advice on lifting	Level 2
	Drug Therapy	Discuss the treatment plan and its goals	Level 2
	Exercise and Activity	Review physical fitness Recommend activity alterations to avoid back irritation, eg avoid heavy lifting Consider referral to physiotherapist and spinal mobilisation / manipulation Encourage continuation of or return to normal activities Facilitate active rehabilitation program eg attendance at 'back school' in the workplace	Level 2
Medication Provide clear guidance to patient and use regular rather than <i>prn</i> dosing. Adjust dosing frequency to observed effect. Use step-wise approach with maximum doses for 24 hours before considering a move to the next step. If unable to mobilise or tolerate medication consider combination therapy.	First Line	Paracetamol 500-1000mg every four hours (max 4g paracetamol/day)	Level 4
	Second Line	Non-steroidal anti-inflammatory agent Short course, less than 2 weeks. Avoid NSAIDs, including COX-2 inhibitors, in patients who are volume depleted, elderly or have renal dysfunction. Avoid conventional NSAIDs in patients with a history of peptic ulcer disease.	Level 2
	Third Line	Paracetamol 1000mg and codeine 30-60mg every six - eight hours (max 4g paracetamol/day) Short course, less than 2 weeks. Patient should be told of the potential for side effects (especially constipation) and that codeine is being used short term to assist early mobilisation.	Level 2
		OR Aspirin 600mg and codeine 30-60mg every four to six hours OR Tramadol 50-100mg (standard release capsules) every four to six hours or 100-200mg SR (sustained release tablets) twice daily Beware of potential for interactions, particularly with antidepressants. SR preparation is potentially useful but evidence for long term use is limited.	Level 2
Fourth Line	Oral oxycodone (immediate release) 5-10mg every six hours. If satisfactory response: Oxycodone SR 12 hourly (titrate dose) OR Morphine SR every 12 or 24 hours (depending on formulation - titrate dose) Short course (usually less than 1 week). If ongoing, reassess after 2-3 weeks. If response unsatisfactory, taper dose and discontinue. Referral may be necessary. Use SR preparations in preference once effective daily dose is determined. Explain about potential physical dependence and other side effects (especially constipation) and that it is being used short term to assist early mobilisation.	Level 3	
Bed Rest		For severe radiculopathy only (urgent referral required). Do not exceed 3 days. Prolonged bed rest may be harmful.	Level 1
Spinal mobilisation or manipulation		May be an option in selected patients (with suitably qualified and registered health professionals)	Level 2
FOLLOW UP VISIT - PATIENT REPORTS IMPROVEMENT			
Exercise		Encourage normal activities, aerobic and trunk conditioning exercise. Support return to work. Begin muscle conditioning exercises after a few weeks.	Level 2
Medication		Reduce or cease medication. Patients taking opioids should be transferred to a simple analgesic or NSAID	
FOLLOW UP VISIT - PATIENT REPORTS NO CHANGE OR WORSENING SYMPTOMS			
Review history & clinical findings		If there is no evidence of serious pathology (see Red Flags): <ul style="list-style-type: none"> Review diagnosis and consider further investigation Review management - possibly move to second or third line therapy Where pain persists there is a risk of progression to chronic pain (see Yellow Flags) Early referral for coordinated multidisciplinary pain service assessment is recommended.	

Evidence for efficacy of non-drug treatments

Bed rest and exercise

Bed rest is not recommended. Patients are advised to stay as active as possible and continue normal activities. A Cochrane systematic review evaluated 9 trials with a total of 1435 patients,³⁰ and concluded that bed rest is not effective and may have slightly harmful effects on acute low back pain. Another Cochrane review evaluated effectiveness of exercise therapy in 39 trials in low back pain³¹ and found that exercise was more effective than no exercise, but no particular exercise program was favoured.

Encouragement of exercise and physical activity should be seen as part of an active rehabilitation program. Analgesia for exacerbations of low back pain can facilitate return to normal activity. Such analgesia should be viewed as a useful interim measure rather than long term management.

Spinal mobilisation or manipulation

Spinal mobilisation or manipulation may be an option for both acute and chronic low back pain.³² However, evidence of effectiveness is limited because of less than optimal study designs, inadequate identification of patient subgroups and lack of information about details of interventions, including methods, frequency and duration of treatment.

Corsets and low back belts

These have not been shown to reduce the intensity of back pain³³ nor to be effective for primary prevention of low back pain.³⁴

Hot and cold compresses

There are no sound trials assessing the efficacy of hot or cold packs for back pain but as these are relatively safe and inexpensive therapies they have been included in several guidelines. Their use as part of an active, patient-directed management process may be positive. However, their use as a passive modality (ie one where the patient travels to a doctor or physiotherapist's rooms to have the therapy applied, or relies on a spouse to prepare such packs) is not recommended.

Back schools

Back schools generally offer group sessions on such topics as spinal anatomy, causes of lower back pain, muscle function, posture, lifting techniques, etc. These have been found to be effective in reducing time off work when conducted in the workplace but have not been effective in other environments.³⁵

Transcutaneous electrical nerve stimulation (TENS)

The use of TENS and Acupuncture-Like Transcutaneous Electrical Nerve Stimulation (ALTENS) has been reviewed as a treatment for patients with chronic back pain by the Cochrane Collaboration. One review³⁶ concluded that there is currently no evidence to support the use of TENS in the treatment of chronic low back pain. Another review³⁷ reported positive short-term benefits from TENS in 10 of the 15 studies reviewed, but was inconclusive regarding long term outcomes or optimum stimulation parameters.

TENS is a treatment that can be delivered by the patient as part of a self-directed management plan and may be of value in teaching the patient to manage their pain symptoms in a positive way. A trial of TENS may be appropriate for some patients. If effective in terms of pain relief, decreased medication use and improved activity levels, a TENS machine can be provided to the patient with training for self use. Regular visits to a doctor, physiotherapist or chiropractor for repeated application of TENS or other forms of electrical stimulation is not recommended.

Cognitive behavioural therapy

Both acute and chronic back pain can be associated with anxiety, or lead to fear and avoidance of activities that aggravate pain. Over time, these effects can lead to depression and the effects of disuse, often compounded by inappropriate drug use. Reinforcement of disability by others can perpetuate this state, especially if the patient takes a passive approach to their rehabilitation. Cognitive behavioural methods have been shown to be effective in overcoming fears and depression, changing coping styles and to result in gradual increases in goal-directed activities.^{13, 38, 39}

The importance of reassurance to the patient and the provision of information in a positive context is emphasised.⁴⁰

Other treatments

There are no published studies to support the use of the following for treatment of chronic low back pain: passive therapies such as diathermy, massage, ultrasound, cutaneous laser; vertebral traction; biofeedback; intramuscular and intra-articular injections of local anaesthetics at paravertebral trigger points; or acupuncture.

WHY PETHIDINE IS NOT RECOMMENDED²

- Pethidine has a shorter duration of action than morphine with no additional analgesic benefit
- It has similar side-effects to morphine, including increased biliary pressure
- Pethidine is metabolised to norpethidine, which has potential toxic effects (eg convulsions), especially in patients with renal dysfunction,
- Pethidine is associated with potentially serious interactions in combination with other drugs.

Because of its euphoric effects:

- Pethidine is the drug most commonly requested by patients seeking opioids, and
- Pethidine is the drug most commonly abused by health professionals.

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These guidelines were developed by the NSW Therapeutic Assessment Group Inc (NSW TAG). NSW TAG is an association of clinical pharmacologists, directors of pharmacy and other clinicians from the teaching hospitals in New South Wales. NSW TAG aims to investigate and establish therapeutic initiatives that foster high quality, cost-effective drug usage in the public hospitals of NSW and the wider community.

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