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Review

The role of the pharmacist in low back pain management: a narrative review of practice guidelines on paracetamol vs non-steroidal anti-inflammatory drugs

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Abstract

Low back pain (LBP) is a common and costly condition and a leading cause of disabilities across the globe. In Australia and other countries, there has been changes in LBP management guidelines and evidence in recent years, including the use of pharmacotherapy. Inadequately treated LBP is a burden with significant health and economic impacts. Although there is some variability, non-steroidal anti-inflammatory drugs (NSAIDs) have largely replaced paracetamol as the first-choice analgesic for non-specific LBP in many international clinical guidelines, including the current Australian Therapeutic Guidelines. More recent clinical evidence also supports that targeting LBP with the use of NSAIDs can provide superior and more effective relief of LBP symptoms compared with paracetamol. Community pharmacists are one of the most accessible and frequently visited health professionals that offer vital primary healthcare services aimed to provide enhanced clinical outcomes for patients. The position of a community pharmacist is pivotal in LBP assessment and management, from both a pharmacological and non-pharmacological standpoint, including the use of clinical guidelines, yet their roles are often not fully utilized in LBP therapy. Studies investigating the community pharmacist's views, practices, knowledge, and roles, specifically in LBP management in Australia are variable and limited. This narrative review will briefly cover the impacts of LBP, and to provide a summary on recent evidence, updates and a comparison of the Australian and international low back pain management guidelines on paracetamol vs NSAIDs in LBP, as well as pharmacists' roles and interventions in a primary healthcare setting in this context.

Keywords

Low Back Pain; Pain Management; Guidelines as Topic; Anti-Inflammatory Agents, Non-Steroidal; Acetaminophen; Pharmacies; Pharmacists; Australia

INTRODUCTION

Low back pain (LBP), defined as pain that is localised below the costal margin and above the inferior gluteal folds, is one of the most commonly presenting complaints encountered in the Australian healthcare system.[1] Approximately 25% of Australians suffer from LBP and this number is set to rise with the aging population.[2,3] Furthermore, it has been identified that around four in five Australian adults lived will experience LBP symptoms at some point in their lives, and approximately 50% of Australians who experience LBP discomfort seek medical care.[2,3]

Many LBP sufferers seeking symptomatic relief will present to community pharmacies, sometimes for large quantities of analgesic medicines.[2] Community pharmacists are an important primary healthcare resource that contributes to patient care, yet their roles in LBP management are often not fully utilized. Although serious pathology is not common in patients with LBP symptoms, it is imperative that health professionals recognize and identify the presence of alerting features which may potentially lead to serious systemic and neuropathic consequences.[4] However, clinical guidelines and evidence are also constantly being updated and evolving, including for LBP, thus reinforcing the importance for pharmacists to manage accordingly based on best practice and best clinical evidence.

This narrative review will first briefly cover the impacts caused by LBP. Additionally, this review will also provide an overview on recent updates and comparisons of the Australian and several international LBP management guidelines on paracetamol and non-steroidal anti-inflammatory drugs (NSAIDs) for LBP, including a brief summary of their current clinical evidence, as well as pharmacists' roles and interventions in a primary healthcare setting in this context.

With the aim of providing insights into the assessment and management of LBP and the role of pharmacists in this space, systematic searches of the following electronic databases were carried out: Pubmed, Medline, Science Direct, Proquest and Google Scholar. Results were limited to January 2000 to February 2020. Search items used for each database included: 'low back pain', 'chronic low back pain', 'low back pain management', 'low back pain burden', 'low back pain guidelines, 'low back pain evidence', 'paracetamol', 'acetaminophen', 'non-steroidal anti-inflammatory drugs', 'NSAIDs', and 'community pharmacist'. References from identified journal articles were also screened to identify relevant articles and studies. Studies and books were included if they reviewed the global burden of LBP, as well as the guidelines and evidence on the management and assessment of LBP.

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CONSEQUENCES OF INADEQUATELY TREATED LOW BACK PAIN

Cases of LBP symptoms encountered in primary care settings are often attributed to acute local musculoskeletal injuries and strains. These presentations of LBP (termed non-specific LBP) are typically self-limiting and primarily require non-pharmacological strategies to manage symptoms.[4] However, as is the case with all acute pain in general, inadequate treatment of LBP can potentially lead patients to experience persistent and ongoing symptoms, with 10-15% of cases leading to chronic pain.[5,6] There are reported cases of patients who develop chronic non-specific LBP which can be severe and disabling.[7] It is essential that sufferers of LBP are provided with holistic and evidence-based therapy in order to minimise the risk of symptoms developing into chronic cases.[4,5] Failure to adequately treat LBP symptoms can impact the quality and functionality of life of patients who experience these symptoms.

In a 2010 study that investigated the global burden of LBP, results showed that out of the 291 conditions that were included in the study, LBP was found to cause more global disability than any other condition.[8,9] Further retrospective analysis of this study increasingly heighten these findings by confirming that in 2010, LBP was ranked as the 6th leading contributor to years lived in ill health compared to 1990 in which LBP was ranked 11th.[8] It appears that the rate that individuals experience LBP in their day-to-day lives is unquestionably on the rise. LBP sufferers, and in particular those who experience chronic and persistent symptoms, express the desperate need to pursue assistance from numerous healthcare providers for targeted pain relief.[4,5] Unfortunately, from a therapeutic perspective, pain collectively is often inadequately treated. Poor assessment and treatment give rise to clinical as well as practical health concerns for pain sufferers. Failure to adequately manage pain in general results in significant costs to the healthcare system as well as posing financial strains on sufferers and their families in dealing with the pain management.

The economic consequences

In addition to being common, LBP is also among the most costly conditions encountered in primary care. One study reported that in 2001, there was a AUD 1.02 billion dollar direct cost of treating LBP in Australia.[10] These direct costs included charges for diagnosis, treatment and rehabilitation, and more than 70% of these costs are attributed to physical treatment provided by massage therapists, physiotherapists and chiropractors.[10] A more recent study reported that in 2011, the direct and indirect costs associated with LBP management in Australia had not improved. The estimated direct costs of LBP treatment were still sitting at approximately AUD 1 billion with a further AUD 8 billion on indirect costs.[3]

There are currently limited reports on the exact economic burden associated with inadequate pharmacological LBP management. However, it is suggested that less than optimal management can also result in an increased economic burden. A secondary analysis study published in 2018 reported that there was an increase in healthcare costs associated with inadequate pharmacological management of LBP.[11] It was found that there was a substantially lower healthcare cost to patients who did not receive paracetamol compared to those who did as part of first-line care.[11] This is indicative of the fact that taking paracetamol as part of first-line care for acute LBP increases the economic burden overall, whilst also providing patients with suboptimal LBP relief.[11] It is therefore essential from both a health and economic perspective that primary healthcare professionals can correctly assess, identify and characterise the different aetiologies of LBP as this is often the first step in providing appropriate tailored therapeutic strategies to patients.

ASSESSMENT AND MANAGEMENT: A LOOK AT CLINICAL LOW BACK PAIN GUIDELINES

When healthcare professionals who practice in primary care settings (such as general practitioners and community pharmacists) encounter LBP presentations, one of the initial aims of assessment is to exclude serious pathologies. Examples of cases warranting an immediate clinical response include pyelonephritis, prolonged morning stiffness, pain with recumbency or significant neuropathic pain or numbness.[2,12,13] These warning signs of serious causes of LBP can be uncovered with the use of correct and targeted questions by healthcare professionals, such as pharmacists.[2] In this context, clinical practice guidelines can be essential tools for promoting evidence-based practice, as they integrate clinical expertise and research findings in order to support therapeutic decision-making.[6,14,15]

Australian healthcare professionals such as pharmacists have an advantage in that they can readily access clinical and up-to-date resources that can be used as tools to aid in their assessment, diagnosis and treatment of health conditions. Resources such as the Australian Medicines Handbook and the Australian Therapeutic Guidelines provide pharmacists with therapeutic information in the context of LBP management.[4,16] According to these guidelines, management of LBP is dependent on the aetiology as well as whether the flare up of symptoms is acute or chronic in nature.[4,17] According to the current Australian Therapeutic Guidelines, treatment of LBP begins with the implementation of non-pharmacological strategies where appropriate. This is consistent with many other international guidelines.[15,18-20] Clinical resources are conflicting with regards to the use of passive physical therapies such as acupuncture and transcutaneous electrical nerve stimulation (TENS) in LBP cases.[4,21] However there are cases of patients reporting temporary pain relief from thermotherapy and remedial massage.[4,14,22] Clinical guidelines highlight that health professionals may consider and recommend a trial of these non-pharmacological treatments as part of an overall management approach inclusive of patient education and pharmacological therapy.[4] After non-pharmacological options, a number of current international guidelines suggest the simple analgesic paracetamol to be the first-line treatment for acute and localised non-specific LBP. The mechanism of action is complex and it is suggested that paracetamol reduces the severity of pain symptoms via inhibition of prostaglandin synthesis and modulation of inhibitory descending serotonergic pathways.[16] Despite paracetamol's limitation in analgesia, the aim of pharmacological management according to Australian

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clinical resources is to not only reduce the severity of symptoms but to also minimise the risk of acute cases transforming into chronic cases leading to physical disabilities.[4,5] Guidelines also emphasise that patients ought to be educated on the benefits of regular dosing (as opposed to when required dosing) of paracetamol, given that this dosing regimen increases the analgesic potential of the drug.[4,5] In light of this recommendation, one Australian study published in 2011 found that 82% of LBP patients who were self-managing their symptoms with paracetamol were under-dosing.[23] This highlights the need for primary healthcare professionals, such as community pharmacists to openly engage with patients and provide education around the quality and effective use of analgesic medicines.

In almost all cases, LBP does not have a known pathoanatomical cause and as a result there are no specific LBP treatments.[22] However, LBP often results in inflammation in the surrounding muscle layers which can further exacerbate and worsen the symptoms.[1,13] Therefore, much current clinical evidence suggest that targeting LBP with the use of NSAIDs can provide superior and more effective relief of symptoms, especially in comparison to the analgesic effect paracetamol offers. A number of studies have reported that paracetamol use did not affect recovery time compared with placebo treatment in LBP patient groups.[24-26] Interestingly, further research also showed that patients who experience LBP symptoms typically respond well to the use of NSAIDs such as ibuprofen, aspirin, and diclofenac. Australian clinical resources have recently been updated to reflect the position of NSAIDs as first-line treatment options, however, resources also emphasise the importance of health professionals using their professional judgment and ruling out potential contraindications before recommending NSAIDs. Additionally, in cases where healthcare professionals deem NSAIDs suitable, resources highlight that NSAIDs are to be used in as low dosages as possible and for the shortest time possible in order to minimise potential complications.[4] This in part is due to the fact that NSAIDs carry undesirable adverse effects profiles, potentially causing gastrointestinal ulcerations, renal impairment and cardiovascular complications.[2,4,16] Despite these adverse effects, results from another Australian study reported that around 37% of patients were provided with NSAIDs by their medical professional compared to 17% of patients who were given paracetamol for LBP.[27] This is possibly due to the fact that primary healthcare professionals are aware of NSAIDs' superiority in providing LBP relief, however, clinical guidelines suggest that medical professionals must be mindful of the fact that all patients should be screened to rule out contraindications and drug-drug interactions as a result of using NSAIDs.[4]

Many international clinical resources also reinforce that although NSAIDs are more effective, they are not without harm. Numerous literature investigating clinical pain management guidelines in North America, Asia, Africa and Europe found that many countries actually favour the use of NSAIDs in LBP.[15,18,20,28,29] One study published in 2018 highlighted that of the 15 countries involved in analysis, 14 countries recommended NSAIDs in their clinical guidelines for the management of LBP.[15] Despite there being 8 international clinical guidelines that support the use of paracetamol, Belgium, Denmark, Germany, United Kingdom and the United States of America hold clinical guidelines that advise against the use of paracetamol in LBP casses.[18,20,29-31] A summary of this information is provided in Table 1. New Zealand clinical guidelines on the management of LBP suggest the use of either paracetamol or the NSAID aspirin as a first-line option, however, these clinical guidelines also suggest that from a therapeutic perspective, all NSAIDs are equally effective and health professionals can recommend whichever NSAID they deem suitable.[19] In contrast to this, while the NICE guidelines which are adopted in the United Kingdom strongly advise against the use of paracetamol alone, these guidelines highlight that the choice of NSAID is crucial.[32] Health professionals are advised to profile the patient's risk factors in relation to gastrointestinal, cardiovascular and renal function and recommend the most appropriate NSAID at the lowest dose according to these risk factors.[32] LBP guidelines adopted in the United States (e.g. American College of Physicians) and Canada are also consistent with this argument, emphasising that the use of the most appropriate NSAID for a specific patient is recommended with the core aim of allowing the patient to return to normal activities and work as soon as possible.[33,34] It is interesting to highlight that clinical guidelines have evolved

Table 1. Summary of current international clinical guidelines on the pharmacological management of low back pain[16]

Geographical region	Paracetamol	NSAIDs	Favour NSAIDs over Paracetamol
Africa		✓	✓
Australia	✓	✓	✓
New Zealand	✓	✓	
Brazil	✓	✓	
Belgium		✓	✓
Canada	✓	✓	✓
Denmark		✓	✓
Finland	✓	✓	
Germany		✓	✓
Malaysia	✓		
Mexico	✓	✓	
Netherlands	✓	✓	
Philippines	✓	✓	
Spain	✓	✓	
USA		✓	✓
London/UK		✓	✓

NSAID: Non-steroidal anti-inflammatory drug

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over the past 20 years. As is the case with Australian therapeutic guidelines, many international clinical guidelines historically showed favour in the recommendation of paracetamol as a first-line treatment option, with NSAIDs reserved as second line options.[7,35,36] The negative profile associated with NSAIDs appears to have shifted in light of the fact that NSAIDS seem to be more widely adopted in clinical guidelines in the area of LBP management.

NSAID FOR LBP – A BRIEF SUMMARY OF SOME RECENT EVIDENCE

Disease state management should be holistic and evidence-based, incorporating both pharmacological and non-pharmacological approaches where possible. For acute LBP, the efficacy of analgesics remains unclear, however NSAIDs have largely replaced paracetamol as the first-choice analgesics for non-specific LBP in many guidelines due to the latest evidence.

In a 2014 systematic review and meta-analysis of randomised controlled trials on acute LBP, Abdel Shaheed *et al*. reported very low quality evidence that NSAIDs (ibuprofen and diclofenac "when required" dosing) provides an immediate analgesic effect, however suggested more research is needed.[37] This followed similarly from a 2011 systematic review by Kuijpers *et al*. where they also reported low quality evidence that NSAIDs and opioids produces higher pain relief on the short term, as compared to placebo, in patients with non-specific chronic LBP; however both types of medication showed more adverse effects than placebo.[38]

In a 2016 Cochrane review by Enthoven *et al*., it was concluded that NSAIDs reduced pain and disability in people with chronic LBP compared to placebo, however the differences were small and the quality of evidence was low.[39] Further, the authors added that the number of adverse events was not significantly different between the people receiving NSAIDs and people receiving placebo; that different types of NSAIDs did not show significantly different effects; and that there were no differences found between NSAIDs and paracetamol in either effect or adverse events. However, the authors also did suggest the need for additional larger studies of longer duration.[39]

In 2017, Machado *et al*. published a systematic review and meta-analysis of randomised placebo controlled trials looking at efficacy and safety of NSAIDs for spinal pain (neck or LBP). The authors reported that NSAIDs reduced pain and disability, but only provided clinically unimportant effects over placebo, however NSAID use did increase the risk of gastrointestinal reactions by 2.5 times.[40] Lastly, a recent paper by Yabuki *et al*. in 2019 (following a review of the evidence and expert discussions) provided the general recommendation that oral NSAIDs should be considered as a first-line pharmacological treatment for chronic LBP based on recent evidence in the Asian context.[41] Taken together, these above studies appear to be more supportive of NSAIDs use as a pharmacotherapeutic option in LBP management, however it is clear that more research is needed.

PARACETAMOL FOR LBP - A BRIEF SUMMARY OF SOME RECENT EVIDENCE

As indicated above, the role of paracetamol in LBP management has changed in recent years. Previously, the simple analgesic paracetamol was suggested to be a first-line treatment option for acute and localised non-specific LBP in Australian as well as numerous international guidelines despite its efficacy in LBP being a constant subject of debate.

In a double-blind, randomised controlled trial (the Paracetamol for Low-Back Pain Study (PACE)) looking at paracetamol for acute LBP, it was reported that that regular or as-needed dosing with paracetamol does not improve recovery time compared with placebo in LBP, with the authors further questioning the use of paracetamol in this patient group.[26]

In 2015, Machado *et al*. published a systematic review and meta-analysis of randomised placebo controlled trials looking at efficacy and safety of paracetamol for spinal pain (neck or LBP) and osteoarthritis. The authors concluded from high quality evidence that paracetamol was ineffective in reducing pain intensity or improving Quality of Life in the short term in people with LBP. Similarly, the authors also went on to suggest that the results should further put into question the recommendations to use paracetamol for patients with LBP in clinical practice guidelines.[42]

In a 2016 Cochrane review, it was concluded that paracetamol (4g per day) did not lead to better outcomes than placebo for people with acute LBP (from high-quality evidence), and it is unclear if it has any effect on chronic LBP (low-quality evidence).[43] The authors also reported about one in five people reported side effects, though few were serious; however, they also reported that most of the participants studied were middle-aged.[43] The lack of effectiveness of paracetamol (acetaminophen) for acute LBP was also reported in another systematic review from 2017.[33] Similarly, a recent paper by Yabuki *et al*. in 2019 also suggested that long-term use of paracetamol for chronic LBP is not recommended based on recent evidence and expert discussions for the Asian context.[41] Interestingly, a recent paper in Japan by Miki *et al*. in 2018 reported that acetaminophen has comparable analgesic effects on acute LBP, based on at least a noninferiority margin, compared with loxoprofen (a traditional NSAID in Japan) at 4 weeks.[44]

THE PHARMACIST'S ROLE IN LOW BACK PAIN MANAGEMENT AND FUTURE CONSIDERATIONS

Many Australian adults will experience LBP symptoms at some point in their lives. For many chronic illnesses, medicines remain the major modality of treatment, and LBP is no different in this context. LBP sufferers seeking symptomatic relief will present to community pharmacies, sometimes for large quantities of analgesic medicines.[2] Therefore, it is no surprise that Australian community pharmacies are considered to be one of the most frequently accessed primary healthcare services and is regularly the first point of contact for most patients due to convenience, accessibility and availability of analgesic medicines at reasonable costs.[45-47] The role of an Australian

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community pharmacist is pivotal in the area of LBP management from both a pharmacological and non-pharmacological standpoint, including providing education, counselling, assess the patient condition, assess the appropriateness of interventions, and advice on key therapeutic strategies to patients experiencing LBP symptoms. The important role of pharmacists in the quality use of medicines is further heightened when appreciating the fact that patients who experience chronic back pain symptoms are often on multiple analgesic medicines long term. As primary healthcare professionals, pharmacists can address this health concern by effectively engaging with the patient at each encounter, thereby improving patient knowledge and minimising misuse and overuse of analgesic medicines.[45,48] Additionally, appropriate diagnostic questioning is necessary for pharmacists to select the safest and most appropriate NSAID for each patient, which includes a thorough holistic therapeutic consideration of the suitability, risks and benefits of using medications such as NSAIDs. This once again emphasises the important need for community pharmacists to familiarise themselves with the correct clinical assessment, diagnosis and management of LBP, including staying up-to-date with the latest clinical guidelines and evidence.

The pharmacist's role is also critical given the recent legislative changes to over-the-counter (OTC) analgesics that have occurred in the Australian community. For example, due to ongoing concerns with the misuse of codeine in the Australia, as of February 2018, codeine that was once available in fixed low dose combinations with simple analgesics can no longer be supplied by Australian community pharmacists without a valid prescription from an authorised prescriber.[49] There has been substantial research aimed at investigating the impact this codeine restriction will have on community pharmacists.[50-52] One study published in 2019 reported that there were mixed views of Australian community pharmacists concerning the codeine upscheduling.[52] Pharmacists who opposed the codeine up-scheduling highlighted that community pharmacies are now limited in the pain management area now that fewer OTC analgesics that can be supplied to patients.[52] Results also showed that pharmacists conveyed that patients who are unable to regularly see their medical practitioners are now forced to excessively use simple analgesics such as paracetamol or NSAIDs in order to obtain the same amount of pain relief, and this overuse of medicines may cause further harm.[52] Conversely, there were many pharmacists who were in favour of the codeine restriction, emphasising that the codeine content in the OTC fixed combinations was subtherapeutic and provided inadequate pain relief.[52] Despite the diversity of opinions, the unanimous opinion expressed by community pharmacists in this space is that patient education in the area of pain management is important and necessary.[51,52] Research in patient education has demonstrated that pharmacists who appropriately educate patients (in the area of pain management) enables them to manage their pain more effectively.[53,54] Although codeine is not recommended as a first-line option for LBP, the recent codeine restrictions in Australia has reinforced that pharmacists are in an ideal position to interact with their patients and offer alternative pain management strategies that may provide more effective LBP relief. In a study by Abdel Shaheed *et al*., it was reported that community pharmacists are indeed suitability placed and are receptive to optimising the primary care management of LBP patients.[55] However, it was also identified that adequate remuneration and staff training were critical factors to its implementation.[55] A more recent study published in 2020 also demonstrated that community pharmacists are ideally placed to provide first-line care for LBP, which can be aided by clinical decision support systems that enhances LBP care.[56]

Lastly, in appreciation of the newer evidence regarding effective pharmacological management of LBP, community pharmacists have the opportunity to effectively engage with patients and assess whether pharmacological management of pain symptoms are attuned to the latest clinical evidence and guidelines. The views and opinions of Australian community pharmacists in generalised pain management is well documented, however, there are less studies investigating the community pharmacist's role and knowledge, specifically in the context of LBP management in Australia.[14,52] Australian community pharmacies are routinely the first point of contact for primary healthcare related inquiries, thus understanding and appreciating community pharmacists' opinions with regards to LBP assessment and management can serve to identify inconsistencies from what the Australian clinical guidelines and evidence recommends. Whilst clinical guidelines are important and are critical therapeutic resources, research suggests that they are not always followed by health professionals.[57,58] For example, investigating precisely what Australian community pharmacists recommend as therapeutic strategies in the context of LBP management, and why, is research worth exploring, given the limited published literature in this space.

CONCLUSIONS

LBP is currently one of the leading causes of disability worldwide. It is one of the most commonly presenting conditions seen in the Australian healthcare setting. Failure to adequately assess and manage LBP can give rise to clinical, health and economic consequences. LBP has been shown to respond well to NSAIDs, and as such, current Australian clinical guidelines have demoted the position of paracetamol as a first-line treatment option, replacing it with NSAIDs. Additionally, there is a growing shift towards the adoption of NSAIDs in LBP treatment across the world, with more emerging evidence supporting its use. Since many cases of LBP are treated with the use of OTC analgesics, Australian community pharmacists are ideally placed to engage with patients and identify whether there is room for improvement in the way patients manage their symptoms. However, it is unclear what community pharmacists recommend specifically in the context of LBP. Research in this space can identify whether there are opportunities for pharmacists to promote additional education and evidence-based strategies to further optimise LBP management in the community.

CONFLICT OF INTEREST

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