



Pain Relief Foundation

The controversy surrounding the NICE guidelines for persistent non-specific low back pain

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Introduction

Back pain is a common medical complaint. The point prevalence of back pain ranges from 12% to 33%, with the one year prevalence ranging from 22% to 65%, and the lifetime prevalence ranging from 11% to 84% (1). It has been estimated that around 20% of the consultations in general practice (GP) in the United Kingdom (UK) each year involves patients seeking help or advice about back pain (2). The NHS currently spends a staggering £1 billion per year on back pain related costs, including £512 million on hospital costs, £141 million on GP consultations and £150 million on physiotherapy treatment (3).

For most patients with back pain, substantial pain and disability is short lived and they are soon able to return to normal activities of daily living and work. In a small number of patients however, chronic, or persistent, back pain and disability can develop. It has been suggested that up to 62% of patients still have pain one year after their first episode and importantly, that 16% of those who were initially unable to work due to back pain are still unable to work one year later (4). Back pain therefore has a significant economic impact on society. The Health and Safety Executive estimates that musculoskeletal disorders, which includes back pain, costs UK employers between £590 million and £624 million per year (5).

In 2005 the National Institute for Health and Clinical Excellence (NICE) were given the task of cutting the huge socioeconomic cost of non-specific low back pain (NSLBP) (see below). Their objective was to develop a simple guideline that would enable practitioners “to ensure that an episode of low back pain [did] not result in long term withdrawal from normal activities, including sickness absence from paid employment” (6). Earlier this year, in May 2009, NICE published their recommendations. Almost immediately they caused much debate within the NHS and the media because, for the first time since NICE had been established, they recommended the use of “alternative medicine” such as acupuncture. This essay aims to consider the complexity of diagnosing NSLBP as well as briefly outlining the recently published NICE guidelines, and discussing the debate which has since been taking place with the NHS and the media.

Low back pain

The lower back occupies the dorsal aspect of the torso from the 12th ribs to the gluteal folds. The lower back has substantially more motion than the thoracic spine and carries the weight of the torso, making it the most frequently injured part of the spine. In all patients that present with a new episode lower back pain (LBP) doctors should undertake simple diagnostic triage as a basis for diagnosis and subsequent management. LBP can be categorised according to: a) duration

(into acute [less than 6 weeks], sub-acute [between 6 and 12 weeks], and chronic [more than 12 weeks]), and; b) pathology (into non-specific and specific causes e.g. nerve root compression¹). If suspicion of a serious cause of low back pain is raised (e.g. fracture, infection, cancer and inflammation) enquiry must be directed to eliciting characteristic “red flag” symptoms². The management of specific causes of LBP will not be covered in this essay.

Non-specific low back pain (NSLBP) is the most common form of LBP accounting for approximately 80-90% of GP cases in the UK (7). The condition commonly presents as pain distributed in the low back, gluteus and thighs, with a varying degree of intensity, but which is normally alleviated by rest. The majority of patients are in good general health. There are usually few clinical signs on examination other than reduced mobility. The neurological examination is often normal.

There are several structures in the back that could contribute to the symptoms of LBP including joints, discs, and connective tissues,

¹ In patients with nerve root compression pain commonly radiates to one or several dermatomes and numbness/parathesia occurs to a variable degree. Pain may be reproduced by coughing and/or sneezing (although not in spinal stenosis). If patients describe pain and paresis in one or both legs when walking, which does not terminate by stopping, then spinal stenosis should be considered. In addition, such patients may describe numbness and a feeling of heaviness in their and pain cessation when flexing their backs. Spinal stenosis is more commonly seen in patients aged over 60 years old. In the much rarer of Cauda Equina syndrome, where significant narrowing of the spinal canal compresses the nerve roots below the level of the spinal cord, patients will classically present with additional loss of sensitivity/paresis in the perineum, urine retention or progressive paresis and/or paralysis.

² Red flag symptoms include constant pain that has been increasing over time, pain whilst at rest, thoracic pain, a general feeling of illness and/or loss of weight; injury, previous/family history of cancer; use of steroids, immunosuppressant's or drug abuse; widespread neurological signs and deformity of the spine. In addition, if symptoms occur in patients aged less than 20, or more than 50 years old, serious spinal pathology must be considered.

however there is little evidence to suggest that NSLBP has a distinctive patho-anatomical cause, and most cases are attributed to either skeletal degeneration or musculo-ligamentous injury. In addition, a number of psychosocial risk factors have been linked to back pain, including fear avoidance beliefs, depression and anxiety (8).

Non-specific LBP has traditionally been categorised according to duration into: acute (less than 6 weeks), sub-acute (between 6 and 12 weeks), and chronic (more than 12 weeks). There is a well accepted approach to managing patients with acute NSLBP involving a combination of pharmacological (e.g. analgesia and muscle relaxants) and non-pharmacological therapies (e.g. spinal manipulation), in addition to providing educational information, reassurance, and advise to stay as active as possible (9). However, until recently, there was no guidance available about how to treat chronic, or persistent, NSLBP.

NICE guidelines

In May 2009, NICE published guidance for the early management of persistent NSLBP in primary and secondary healthcare (6). Persistent, or recurrent, NSLBP was defined as tension, soreness and/or stiffness in the low back region that had lasted for more than 6 weeks and less than 12 months, but in which it was not possible to identify a specific cause. In their guidance, NICE effectively set out a clear management plan for all patients with NSLBP, which utilised a series of stepwise approaches to patient care.

The key initial recommendation made was to promote self management by advising people with NSLBP to exercise, remain physically active, and attempt to carry on with their normal activities of daily living as far as possible. In addition, they recommended first line treatment should included appropriate analgesia in combination with up to two specific treatments including, either: an exercise programme (e.g. aerobic activity or postural control), a course of manual therapy

(e.g. spinal manipulation) or a course of acupuncture lasting up to 12 weeks. For those patients with poor outcome following first line treatment, or significant psychological distress and/or high disability NICE recommends prompt referral for a combined physical and psychological treatment consisting of 100 hours of treatment over 8 weeks, and additional cognitive behavioural therapy. The last line of treatment recommended for patients if they were still left with severe pain despite first and second line treatments, was referral to a specialist spinal service for consideration for spinal fusion surgery.

In their report NICE also recommended that practitioners did not treat patients with NSLBP using serotonin selective reuptake inhibitors, or other non-pharmacological treatments such as laser therapy, therapeutic ultrasound, transcutaneous electrical nerve stimulation *etc.* In addition, NICE also controversially did not recommend the currently widely accepted treatment of spinal injection therapy.

The debate

Since its publication, the NICE guideline for early intervention of persistent NSLBP has caused controversy and much public debate. A large body of healthcare workers have opposed their use in standard practice. Their argument centres on three seminal points; firstly that there is limited robust clinical evidence to suggest that either acupuncture or spinal manipulation are effective in patients with persistent NSLBP. Secondly, that early surgical intervention in patients that may benefit from less invasive procedures, such as spinal injection therapy, will place patients at unnecessary risk. And finally, that the limited resources currently available in the NHS to provide alternative medicines, such as acupuncture, may prevent patients being efficiently treated and subsequently lead to spiralling costs as care is shifted into the private sector.

In their guidance, NICE reported in detail their inclusion/exclusion criteria when evaluating acupuncture and spinal manipulation therapies (6). For acupuncture, a total of five clinical studies were included, including four randomised control trials (RCTs) and one systematic review (10-14). The conclusion reached in all but one of these studies suggested that acupuncture does provide pain relief and can improve function in patients with NSLBP, but only over a short time period (less than 3 months). Only one RCT suggested a significant improvement in pain occurred in patients with NSLBP over a longer period of 24 months (13). Furthermore, one of the RCTs evaluated; assessing conventional treatment versus sham therapy, showed no significant difference in pain scores between patient groups ($p=0.39$) (12). Recently, the NHS Quality Improvement Scotland have also concluded that adding acupuncture to “usual care” (or specific treatment) is more effective than “usual care” (or specific treatment) alone in patients with chronic LBP (15). The evidence presented appears to suggest acupuncture can improve persistent NSLBP in the short term, in comparison to standard care, however persistent NSLBP by its very definition can occur for up to 12 months (NICE guidelines) and therefore, as this treatment is not curative, patients may re-present with similar symptoms relatively soon after one course of acupuncture. There is also limited evidence currently available to suggest a difference in the clinical outcome between patients who receive conventional and sham therapy, suggesting acupuncture may act through a placebo effect. Moreover, it is clear that even the data presented here is limited in scope, as none of the trials compared the effectiveness of acupuncture versus other forms of therapy used in NSLBP.

For spinal manipulation therapy NICE evaluated seven RCTs (16-22). Three of these trials showed no significant difference in clinical outcome between standard and osteopathic care (16-18) and a two further trials showed only moderately better outcomes over a short time period (less than 1

month) (19-20). NICE must therefore have based their decision to recommend spinal manipulation on the two final RCTs. One of these trials includes the UK Back Pain Exercise and Manipulation (UK BEAM) clinical trial (n=1334), which reported that spinal manipulation improved back function by a small to moderate margin at three months and by a smaller but still significant ($p<0.05$) margin at one year, in comparison to “best usual care” (21). A number of reservations have been made about the inclusion of the UK BEAM trials and possible affect it had on the outcome of NICE’s decision, considering the fact that the chairman of the NICE Guideline Development Group (GDG), Professor Martin Underwood, was also lead author of the UK BEAM trial. Such rhetoric has been vehemently denied, and remains pure speculation. The last RCT used showed that manual therapy provides pain relief but without simultaneous reduction in disability and handicap (22).

Spinal surgery is a well established and effective treatment in few patients with chronic LBP. NICE assessed the indication for referral (only) for lumbar fusion surgery using two systematic reviews (23-24). Both reviews suggested surgical procedures do have a more efficacious effect on persistent NSLBP when compared with “unstructured” nonsurgical care. Both systematic reviews analysed a combination of four different RCTs in total (25-28). Little objection has been raised about the use of spinal surgery in NSLBP, however, objections has been made about the ease by which patients can be referred after only two previous alternate treatment steps. Traditionally, invasive procedures such as spinal surgery have been deemed “last resort” treatments, having tried less invasive treatments such as injection therapy first. Indeed, as part of pre-guideline standard practice GPs would have often referred patients to a pain specialist for spinal injection therapies such as facet-joint injections and epidurals. However, NICE have since recommended that patients are not referred from primary care for spinal injection

therapy, and instead referred directly for surgical opinion. This has lead a large body of Consultants in Pain Medicine objecting to such practice. By excluding spinal injection therapy NICE have effectively given practitioners no other option than to refer for surgical opinion in those patients who second line treatments fail. This could mean that as many as 400,000 patients are referred for surgery each year (currently only around 20,000 spinal operations are performed each year) (29). It is believed that such recommendations will place a significant number of patients at an unnecessary risk. Furthermore, it appears idiosyncratic that NICE have specifically recommended spinal fusion surgery, as opposed to e.g. spinal decompression *etc*, to treat NSLBP even though by its very definition NSLBP has no recognisable patho-anatomic cause.

NICE did analyse the use of spinal injection therapy in patients with NSLBP, and came to the conclusion that such therapies should not be recommended. Its recommendation was based on a single RCT (n=101) that took place around 20 years ago (1991), which evaluated the efficacy of injecting corticosteroids or isotonic saline into the facet-joints of patients with NSLBP (30). The results indicated that there was no significant difference between clinical outcomes at one month ($p=0.53$) and six months ($p=0.19$). A number of specialists in Pain Medicine however believe that NICE could not accurately assess the effectiveness of injection therapy by using a single RCT. However unfortunately, although spinal injection therapy is widely used by many pain management specialists, there is very limited scientific evidence to support its use in clinical practise. Pain specialists have argued that this is merely because LBP is such a complex condition that it is virtually impossible to design and implement double blind, randomised control trials to assess treating it. Moreover, greatest opposition has come against the lack of special expertise in spinal injection therapy on the GDG, in comparison to the inclusion of experts in spinal manipulation and acupuncture. This key factor is why many Consultants in Pain

Medicine currently believe the guideline lacks any usefulness in setting standards of care in patients.

The final point raised in the current debate involves the availability of resources within the NHS. NICE have accepted in their guidelines that “there are insufficient numbers of trained practitioners in the NHS to meet the demand and [that] it would take a few years to train people up” (6). This may mean one of two possible outcomes: either, a) patients are forced to wait longer for available treatment, or that; b) the NHS will be obliged to utilise the private sector to ease patient demand. Evidence has been presented that estimates the NHS will make an annual saving of £33 million on spinal injections and £11 million on MRI scans by following its guidelines (6), however, more recently figures suggest it will spend upwards of £24 million extra pounds on acupuncture and £16 million extra on manual therapy (plus additional costs of training staff to provide the service) meaning such cost-cutting is negligible (31). In addition, in some areas of the country, patients will undoubtedly get good access to such care in comparison to other areas which struggle to recruit staff and fund treatment.

The public criticism shown towards NICE following the release of their guidelines for patients with NSLBP has become more hostile recently. In an unprecedented show of opposition, the British Pain Society (BPS), which represents the views of over 1,500 healthcare workers involved in all aspects of pain management voted to force its president, Professor Paul Watson, out of office because he helped to develop the NICE guidelines. Sir Michael Rawlins, Chairman of the NICE, and Professor Peter Littlejohn, a member of the GDG on early back pain, have express outrage over the decision taken by the BPS. However, with the BPS and the Faculty of Pain Medicine within the Royal College of Anaesthetists and many others condemning the guideline whilst NICE reject any policy

change, this debate is likely to continue for some time.

Summary

Non-specific low back pain is a complex medical condition. There is currently little evidence to suggest an underlying pathology, and various psychosocial risk factors have been associated with the condition. It currently causes significant morbidity in numerous patients as well as a substantial economic burden to society. In order to combat this NICE were given the task of developing guidelines that could prevent acute episodes of NSLBP from becoming persistent and leading to long term disability. The guidelines were welcomed by some experts and charities, and yet bitterly disputed by others. Their decision to incorporate “alternative” medical treatment, such as acupuncture, was always likely to cause controversy not only because of the limitation of available evidence on such practice, but also because this was the first time in NICE’s history that such treatment had been recommended. However, the choice to dismiss the experience of so many interventional pain specialists and rely instead on the findings of one clinical trial undertaken almost 20 years, when deciding on the use of spinal injection therapy, must be questioned. In addition, the scale of such a decision is only made worse by the fact that those patients who would have been treated with injection therapy will instead be referred for surgery, which could potentially put a large number of patients, who are not eligible for surgery, at further risk. Whether this “one size fits” all approach will satisfy patients and cut the costs of back pain on society is debatable, however, from the opinions raised so far it clearly does satisfy the medical community and the fierce debate between pain specialists and NICE is likely to only worsen. treatment