

Review Article

Pain measures and cut-offs – no worse than mild pain as a simple, universal outcome

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Background

A conversation overheard between a nurse and a patient in an Oxford hospital in 2011:

Nurse “How bad is your pain on a scale from 0 to 10?”

Patient “About 6.”

Nurse “Well, that’s just mild pain. You don’t need anything for that.”

Now admittedly the patient in question had undergone a life-saving operation in a brand new hospital staffed by some wonderful and talented people. However, a pain score of 6/10 is not mild, but borderline between moderate and severe, and the patient *did* need something for that.

Was the nurse ignorant of what pain scores meant, or was it just that caring professionals typically underestimate patients’ pain [1]? Both these questions are deserving of research, but for this patient, the only point is that the system failed him, and for him the reasons behind the failure were of little interest. He had pain that was borderline severe, and it was not treated. This is not uncommon. A fairly recent survey

of Italian hospital wards came to the hardly original conclusion that those wards in which less analgesic was prescribed had higher rates of patients experiencing severe pain than those where more analgesics were prescribed [2]; Fig. 1 shows the clear inverse relationship between the presence of severe pain and the percentage of patients treated for their pain.

There is a wealth of evidence that pain is poorly treated, and that significant proportions of patients suffer from moderate or severe pain, whether it is acute pain in hospital [3] or chronic pain in the community [4, 5]. Barriers to progress are many and varied, but one particular and important barrier is a degree of confusion about pain scoring systems and what they mean. How does a simple categorical verbal rating system (no pain, mild, moderate, severe) relate to a 100-mm visual analogue scale (VAS) or an 11-point numerical rating scale (NRS)? Does it matter what the anchors are at each end? Where are the boundaries for moderate or severe pain? What is the minimal clinically significant difference? Does it matter whether the scale has been ‘validated’ in Welsh, or Farsi, or Urdu? All of which makes for terrific grist for

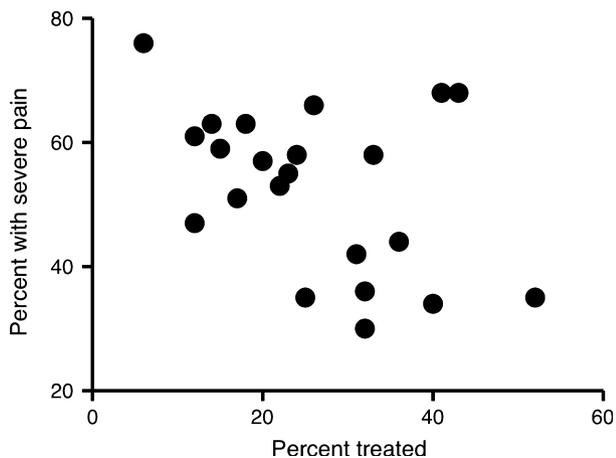


Figure 1 Inverse relationship between the presence of severe pain and the percentage of patients treated for their pain, in an Italian hospital survey (based on data published in [2]).

the mill of grant applications, but does not make things easy for clinical practice, because it suggests that there is considerable uncertainty over pain measurement. Pain scales continue to proliferate, not least because they can be copyrighted and significant sums paid to use them in clinical trials, as do academic arguments about whether, on average, a few millimetres change on a 100-mm scale represents a useful outcome [6]. One outcome of all this is additional uncertainty over which scale is ‘right’.

All this academic angst is unimportant for everyday practice, where the simple question is whether pain is present at an unacceptable level or not. It may be time to consider a divorce between all these interesting academic complexities and the theoretically simple, but practically difficult requirements for successfully treating patients with pain.

The philosophical principle of ontological parsimony, rather easier understood as keeping it simple, was suggested about 700 years ago by William of Ockham, and more recently restated as the KISS principle by Kelly Johnson [7]. We (the authors) are increasingly of the opinion that in measuring pain there should be a simple principle – that only ‘no worse than mild pain’ is acceptable in clinical practice, and the important practical outcome of ‘no worse than mild pain’ is the only outcome of interest to be taken from clinical trials. We are relaxed about just how ‘no worse than mild pain’ is measured, but take the view

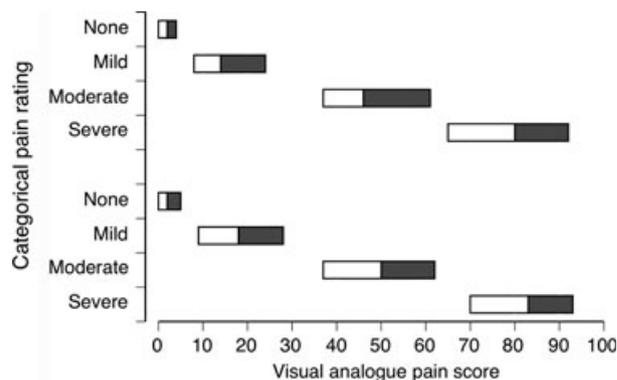


Figure 2 Data from almost 14 000 paired observations comparing categorical and visual analogue scale pain ratings taken at rest or on activity over a 48-h post-operative period in surgical patients (based on data published in [9]). Rest data are displayed at the top; activity data are displayed on the bottom. The bars represent the 95% CI of the sample, and the white/grey interface the point estimate.

that the borderline between mild and moderate pain is about 30 mm on the 100-mm VAS [8] in acute pain or 3/10 on a 0–10 NRS. Figure 2 shows data from almost 14 000 paired observations taken at rest or on activity over a 48-h postoperative period in surgical patients that would agree with 30 mm as a cut-off point (data from [9]); other analyses give similar if slightly different cut-off points [10]. There is some evidence that strict adherence to ‘no worse than mild pain’ principles can lead to virtual elimination of severe pain in hospital [11]. The same cut-off point works well for chronic pain in the community [12], and pain measures work at least as well as more complicated scales in conditions such as inflammatory arthritis [13].

There are three lines of reasoning that can be derived from the evidence available for using ‘no worse than mild pain’ as a simple, universal outcome:

- 1 What patients say when they are asked about what they want from treatment and what they say when they have been treated, linking attitude to treatment and their pain experience.
- 2 Understanding that responses to treatment are bimodal, typically with very good pain relief or none.
- 3 The link between good pain relief and improvement in associated symptoms, such as poor sleep, depression, fatigue, quality of life and function.

Literature search

Electronic searching alone is known to retrieve only a minority of observational studies relevant to a research question [14, 15]. Experience shows that broader types of searching can capture many more studies [14, 16]. We therefore conducted a search to find studies informing on the three main themes above. These searches comprised a series of different free text searches of PubMed (to November 2012), with follow-up on any potentially useful publication using the ‘related citation’ facility. For useful publications, we also checked on citations of that publication using Google Scholar™. In addition to electronic searches, retrieved articles were read for any other sources of data, as were general review articles and book chapters.

Results

What patients say about outcomes

When asked what they would consider treatment success, patients with chronic pain specify a large reduction in pain intensity, by 50% or more [17–19]. Their ideal outcome is pain intensity of 3/10 or below on a 0–10 NRS, or its equivalent when pain is rated categorically, i.e. no worse than mild pain. They also want substantial reductions in fatigue, distress and the loss of quality of life that accompanies chronic pain. Chronic pain patients want mean decrements in excess of 50% on measures of interference on either the Brief Pain Inventory (BPI) or the Multidimensional Pain Inventory (MPI) [20]. Patients in this latter study thought that an acceptable level of pain was around 3–4/10, no worse than mild pain. Much the same is true in migraine, where the outcome specified is that of complete pain relief [21].

Patients would therefore agree that a clinically important difference in pain outcomes would be at least the 33% level suggested in breakthrough pain [22], the 30/100 mm pain reduction defined as adequate pain control in acute pain [23], or a more than 40 mm reduction in pain defined as much better in musculoskeletal pain [24]. In fibromyalgia, pain severity reductions of about 40% were argued to be clinically important [25]. For painful diabetic neuropathy and fibromyalgia, patients describing themselves as much or very much better typically had pain intensity

reductions of 40% or more [26]. These are far greater than the minimally important difference of a 6% reduction in pain suggested by rheumatoid arthritis patients [27].

Pain outcomes in trials are usually described in terms of change in pain, rather than pain level at the end of a trial. As Fig. 3 demonstrates, patients can be improvement responders (50% pain reduction), state responders (have ‘no worse than mild pain’, below 30/100 mm on a 100-mm VAS), or both, or neither. There is potential complexity here, and arguments could be raised about whether pain improvement response or low pain state is better, or what ‘better’ means in this context. However, patients consistently say, when asked, that the response they want is either large reductions in pain intensity or being in a low pain state (no worse than mild pain), and ideally both, so these are patient reported outcome measures we need to take seriously.

The evidence we have is that low pain state, no worse than mild pain, is consistently rated highly by patients in clinical trials when validated against global questions of response. In fibromyalgia, for example,

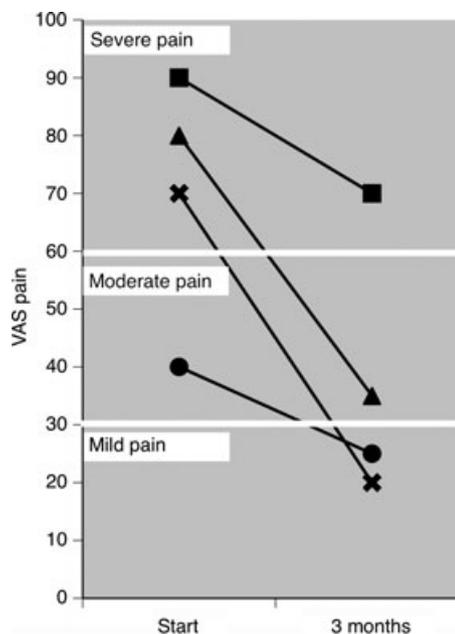


Figure 3 Theoretical patterns of pain response in chronic pain trials. Patients can be non-responders (■), improvement responders only (▲), state and improvement responders (x), or state responders only (●).

being ‘very much improved’ at the end of trials lasting 8–14 weeks was associated with a pain score of 30/100 mm or below in 1858 completers (Fig. 4; data from [28]). In the overall population of 2575 patients starting on treatment for fibromyalgia, 73% were non-responders by virtue of withdrawing from treatment or because of inadequate pain relief; only 27% were state responders only, improvement responders only, or both state and improvement responders (Fig. 5).

There are indications that some of the more complex composite outcomes are no more informative than straightforward pain scores or patient global rating in chronic pain [29], although it is clearly the case that pain itself is not the only issue for patients with chronic pain [17, 30]. In rheumatology, the patient acceptable symptom state (PASS) has been defined as the value beyond which patients consider themselves well. For osteoarthritis, the junction between satisfactory and unsatisfactory was about 32/100 mm [31], and similar results were obtained with numerical rating and function scales [32]. In acute pain also, satisfaction is associated with pain scores generally below 30/100 mm, and low analgesic requirement using intravenous fentanyl via patient-controlled analgesia [9].

In chronic pain, responders tend to keep being responders. Clinical experience is that responders typically show temporal stability in their response, as

concluded by studies to specifically test consistency in chronic pain [33] and musculoskeletal pain [34]. In fibromyalgia a long-term, enriched enrolment, randomised withdrawal study emphasised that individual response status was stable over six months [35]. In chronic low back pain, initial responders to duloxetine had further significant improvement in pain and other outcomes for another 41 weeks [36]. And in osteoarthritis, responders at two weeks overwhelmingly were responders at 12 weeks [37], and up to one year [38]. While more evidence would be welcomed, the emerging picture is that ongoing response over the long term appears to occur in those who respond initially. More-

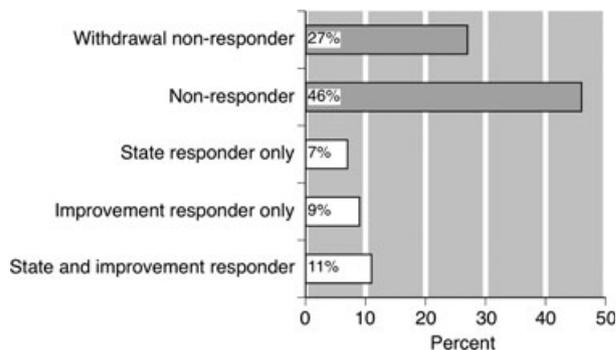


Figure 5 Type of response experienced by 2575 patients starting on treatment for fibromyalgia. Figure based on data published in [28].

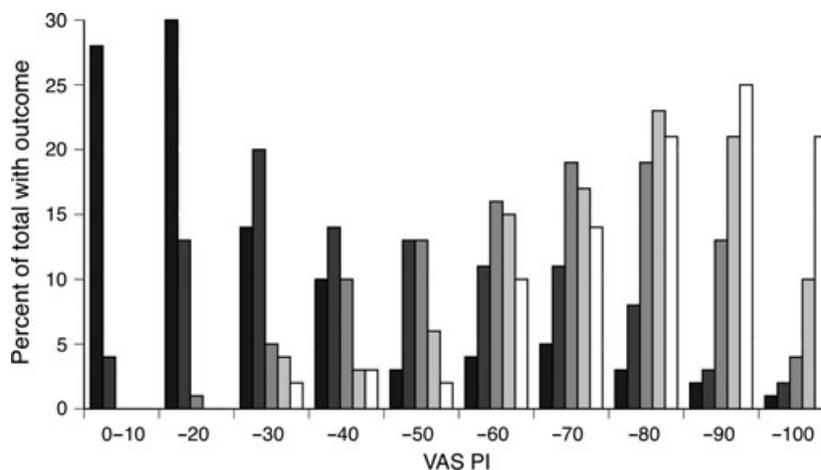


Figure 4 Visual analogue pain scores at the end of study in 1858 patients completing fibromyalgia studies lasting 8–14 weeks, comparing final pain intensity score (VAS PI) and patient global impression of improvement on a 7-point scale where 1 = very much better, 2 = much better, 3 = a little better, 4 = no change, 5 = a little worse, 6 = much worse, and 7 = very much worse. Figure based on data published in [28]: ■, very much improved; ■, much improved; ■, minimally improved; □, no change; □, any worsening.

over, current evidence indicates that in osteoarthritis [39] and fibromyalgia [28] response, or lack of response, is largely determined within 2–4 weeks from the start of treatment.

Responses to analgesia are bimodal

We are beholden to averages. As soon as we begin to learn about statistics, we are presented with a Gaussian distribution, and thereafter the implication is that distributions are always Gaussian, and the average is something applying – more or less – to most people. And that is why pain studies will almost always tell us the average pain score, or the average change in pain score, or the average postoperative analgesic requirement.

The trouble is that while the world may be Gaussian for many things – height, for instance – it isn't Gaussian for others, like hair or eye colour. Nor is it Gaussian for pain or for response to analgesics. For example, while some people have moderate or severe pain soon after surgery, for many, pain is delayed by many hours, and about one in 20 may not get pain at all [40]. Distributions other than Gaussian are found for many measures associated with pain. For example, analgesic consumption after surgery follows a highly skewed distribution in which mean, median, and mode are all very different from one another [41].

However, it is in the response to analgesics in acute and chronic pain that we find the largest deviation from Gaussian distributions. Two classic examples are the response to analgesics in acute postoperative pain or osteoarthritis (Fig. 6). They have a clearly bimodal distribution with placebo or active drug, with some people getting a very good response, whereas others get virtually none [39, 42]; few patients in either study could be described as average. The example shown in acute pain is for 120 mg etoricoxib, one of the most effective analgesics in this pain model, where good responses predominate. For most other analgesics at commonly used doses, the proportion with a good response is much less than this [43]. For chronic pain also, the same bimodal distribution applies as for osteoarthritis [39], ankylosing spondylitis [44], chronic low back pain [45] and migraine [46], as well as in neuropathic pain [47].

All these examples have used change in pain as their measure, with a reduction of at least 50%. While

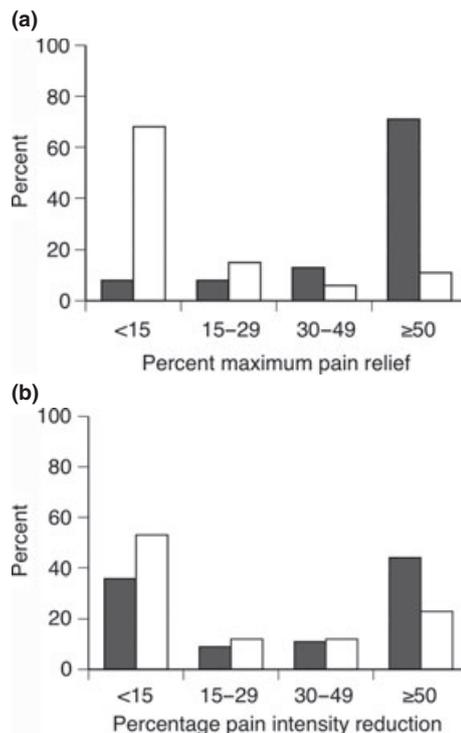


Figure 6 Distribution of response with etoricoxib (■) and placebo (□) in acute pain (120 mg) (a) and osteoarthritis (60 mg) (b).

there are few analyses directly relating the level of pain change to a pain score of 'no worse than mild pain', it is probable that this covers most patients. There are uncertainties and grey areas, as the results of analyses by improvement responders and state responders in Fig. 5 show. Interpretation at the level of the individual may not always be easy; Fig. 7 shows 200 individual patient responses over 14 weeks in patients with fibromyalgia treated with pregabalin 450 mg per day (data from [28]), some of the data from which were used to calculate the results in Fig. 5. Simple inspection demonstrates that large reduction in pain and low final pain score are highly associated. While more individual patient data analyses are needed to increase our understanding (the academic viewpoint), the broad message is that very large decrements in pain will result in a low pain state (the pragmatic take home message).

Successful pain treatment is associated with other benefits

In acute pain, inadequate pain management has substantial consequences for patients, with high pain

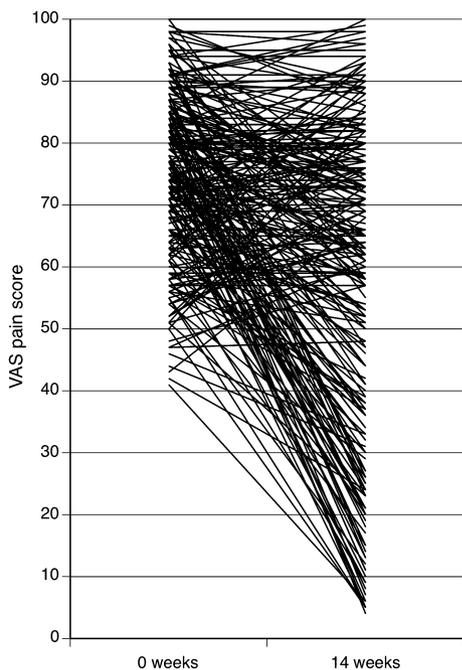


Figure 7 Two hundred individual patient responses over 14 weeks in patients with fibromyalgia treated with pregabalin 450 mg per day. Figure based on data published in [28].

scores associated with lower quality of life measures some four weeks after surgery [48, 49]. Higher pain scores substantially impaired patients' sleep, sexual function and their ability to perform physical activities during the postoperative period [50, 51]. It is also the case that there is a direct relationship between higher average postoperative pain levels and patient dissatisfaction with their postoperative experience [9]. However, it remains unclear whether techniques to improve postoperative pain result in improved sleep, function and quality of life [52].

We sought studies linking pain scores changes with quality of life changes in chronic pain treatment in a literature review; it found 13 studies with about 8000 patients treated with a variety of drugs for different chronic pain conditions (Table 1). Each individual study reported measurements of quality of life or function appropriate to the condition studied. The majority of the studies were individual patient analyses of randomised trials of appropriate duration for the condition being treated [53–64]; one was a small trial lasting four weeks [65]. Two long-duration prospective cohort studies (1387 patients) also provided some data

[66, 67]. Appropriate study duration is one important marker of clinical trial validity, as is the use of appropriate imputation methods [68, 69]. Conditions studied included migraine, fibromyalgia, neuropathic pain, osteoarthritis, rheumatoid arthritis, chronic low back pain and ankylosing spondylitis. Treatments used included tumour necrosis factor (TNF) antagonists, tramadol/paracetamol, topical diclofenac, topiramate, pregabalin, duloxetine and placebo.

Each study reported a positive association between good pain relief and measures such as quality of life, activities of daily living, function, work, enjoyment of life, global impression of benefit, depression, mood, sleep and fatigue (Table 1). A consistent finding was improvement in quality of life with successful treatment. Figure 8 shows the patterns of change in Short Form (36) Health Survey (SF-36) sections with responders experiencing at least 50% pain intensity reduction in fibromyalgia [59].

The magnitude of the changes reported is far from trivial. For example, the largest individual patient analysis in fibromyalgia, with almost a third of the total number of patients providing evidence of an additional benefit of effective pain treatment, reports that pain intensity reduction of 50% or more is associated with reversion towards population norm values for sleep, fatigue, depression, with a trend for the SF-36 section scores to return towards the population normative values [59]. Quality of life benefits were also significant, with EuroQol health status (EQ-5D) score increases over one year of 0.22 with TNF antagonists in rheumatoid arthritis [64], 0.35 for $\geq 50\%$ pain intensity reduction in painful diabetic neuropathy [58] and a one-year quality-adjusted life year (QALY) gain of 0.11 for the same outcome in fibromyalgia (Fig. 9). In an analysis of tapentadol trials, patients who tolerated the treatment with tapentadol or oxycodone and completed the trial (and therefore likely to be those with good pain benefit) had EQ-5D average increments of 0.31 [64]. Similar benefits are likely to accrue from successful non-drug interventions in pain [70].

A systematic review of QALYs for estimating effectiveness of healthcare reported the utility gains over six months to one year for various different interventions [71]. Of the 31 examples reported where interventions actually worked, and where there were

Table 1 A summary of the reviewed studies focusing on the relationship between effective pain relief, other symptoms and quality of life.

Reference (location)	Condition studied	Design	Number of patients	Main result
Data from randomised trials				
Bennett et al. [53] (USA)	Fibromyalgia	RCT (tramadol/paracetamol, placebo) analysed by different levels of pain relief over 13 weeks	313	Patients with $\geq 25/100$ mm pain intensity reduction (initial mean 72/100) experienced significant improvements in QoL scores compared with those who had lower levels of pain relief
Dahlöf et al. [54] (World)	Migraine	RCTs (topiramate, placebo) analysed by reduction in migraine headache frequency of $\geq 50\%$ as responder	756	$\geq 50\%$ responders experienced major improvements in role restriction, role prevention and emotional function $\geq 50\%$ responder experienced significant improvements in 7/8 SF-36 domains compared with non-responders
Deshpande et al. [65] (Canada)	Neuropathic pain	RCT analysed by individual patient, comparing QoL with degree of pain relief (5-week treatment periods)	41	Significant correlation between neuropathic pain reduction and improvements in QoL
Schein et al. [55] and Kosinski et al. [56] (USA)	Osteoarthritis of hip or knee	RCT examining tramadol and placebo over 12 weeks	1011	Bimodal distribution of response Stepwise increase in pain intensity reduction resulted in stepwise improvements in stiffness; physical functioning and global impression Major improvements in SF-36 domains with pain intensity reduction in $\geq 50\%$ and particularly $\geq 70\%$ Pain intensity reduction correlated with sleep improvement
Barthel et al. [57] (Germany, France, USA)	Osteoarthritis of hand	Individual patient analysis of two RCTs of topical diclofenac or placebo according to level of pain reduction over 8 weeks	783	Bimodal distribution of response Graded improvements in function, stiffness and global rating of disease with increasing degree of pain relief, with best results for ≥ 50 pain intensity reduction Initial EQ-5D of 0.4 increased by about 0.22 for RA and 0.3 for AS with 1–3 courses of treatment with anti-TNF drugs, and with at least 1 year of follow-up

Table 1 (Continued)

Reference (location)	Condition studied	Design	Number of patients	Main result
Hoffman et al. [58] (Asia, Latin America, Middle East)	Painful diabetic neuropathy	RCT of pregabalin, placebo analysed by individual patient according to degree of pain intensity reduction over 12 weeks	401	Bimodal distribution of response Stepwise increase in pain intensity reduction led to stepwise improvements in pain interference, mood, work, relationships, activity, walking, sleep and enjoyment of life. Stepwise increase in pain intensity reduction led to stepwise improvement in EQ-5D score with $\geq 50\%$ pain intensity reduction increasing EQ-5D by about 0.35 points (from initial mean of 0.45)
Moore et al. [59] and Straube et al. [60] (World)	Fibromyalgia	Four RCTs of pregabalin or placebo analysed by individual patient according to degree of pain intensity reduction and end of trial pain state, after 8–14 weeks of treatment	1858	Responder status ($\geq 30\%$ or $\geq 50\%$ pain intensity reduction (with pregabalin or placebo) resulted in significant improvement in fatigue, fibromyalgia impact, sleep, depression and anxiety, as well as each domain of SF-36 1-year QALY gain 0.07 for $\geq 30\%$ and 0.11 for $\geq 50\%$ pain intensity reduction. Significant improvement in time off work and work interference, especially with low pain state ($PI \leq 30/100$ mm) at trial end
Dworkin et al. [61] (USA)	Osteoarthritis and chronic low back pain	RCTs of lignocaine patch or placebo analysed by patient satisfaction, comparing QoL according to satisfaction with treatment over 2–12 weeks	207 OA 176 CLBP	Satisfied patients had mean reduction in pain of 29/100 mm, compared with no change with unsatisfied patients Satisfied patients had significant improvements in physical and emotional functioning and sleep interference
vanSeventer et al. [62] (Netherlands)	Post-traumatic peripheral neuropathic pain	RCT of pregabalin or placebo analysed by individual patient according to degree of pain intensity reduction over 12 weeks	254	Change in pain intensity correlated with sleep problems, disturbance and interference, and pain interference and HADS anxiety and depression scores
Arnold et al. [63] (USA)	Fibromyalgia	RCT of duloxetine or placebo analysed by individual patient according to degree of pain intensity reduction over 12 weeks	530	Responder ($\geq 50\%$ reduction in pain intensity with duloxetine or placebo) status resulted in major improvements in fatigue, activity and motivation, compared with no improvement with non-responders

Table 1 (Continued)

Reference (location)	Condition studied	Design	Number of patients	Main result
Ikenberg et al. [64] (Worldwide)	Severe non-cancer chronic pain	Data from RCTs of tapentadol, oxycodone and placebo in OA and CLBP used in cost-effectiveness analysis	Not given	Patients who tolerated treatment and completed trial with tapentadol or oxycodone had initial EQ-5D of 0.44 at baseline rising to 0.70 at end-point. Patients who experienced adverse events or who withdrew because of lack of efficacy or adverse events had no EQ-5D gain
Data from observational studies				
Kosinski et al. [66] (USA)	Chronic low back pain	Observational study of patients with CLBP on opioids converted to transdermal fentanyl for 9 weeks	131 completers	Stepped improvements for most SF-36 domains with different levels of pain relief. Main effects for physical functioning, bodily pain, social role functioning and physical role functioning.
Gülfe et al. [67] (Sweden)	Rheumatoid arthritis, ankylosing spondylitis	Comprehensive longitudinal cohort of use of TNF antagonists	1256	Initial EQ-5D of 0.4 increased by about 0.22 for RA and 0.3 for AS with 1–3 courses of treatment with anti-TNF drugs, and with at least 1 year of follow-up NNQ (NNT per QALY gained) about 4

AS, ankylosing spondylitis; CLBP, chronic low back pain; HADS, Hospital Anxiety and Depression Scale; NNT, number needed to treat; OA, osteoarthritis; QALY, quality-adjusted life year; QoL, quality of life; RA, rheumatoid arthritis; RCT, randomised controlled trial; TNF, tumour necrosis factor.

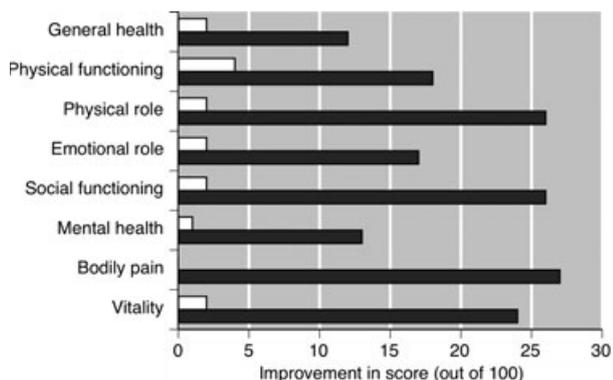


Figure 8 Patterns of changes in Short Form (36) Health Survey (SF-36) sections with responders experiencing at least 50% pain intensity reduction in fibromyalgia (■), compared with patients with little pain relief (□).

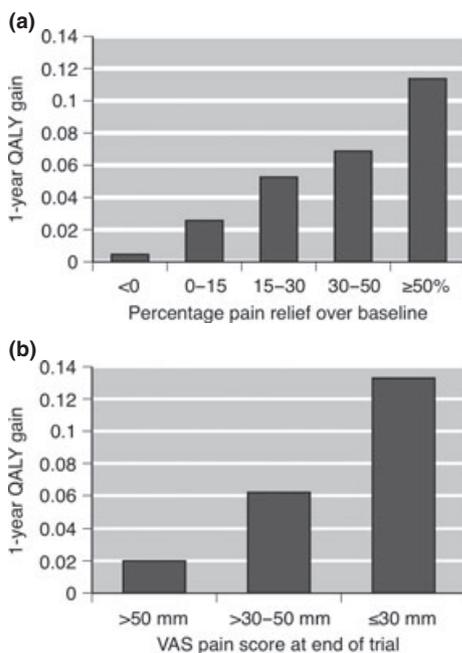


Figure 9 One-year quality-adjusted life year (QALY) gains calculated for various pain outcomes in fibromyalgia. Figure based on data published in [59].

appropriate utility measures reported, most had one-year utilities of 0.1 or below. Some (total hip replacement, cochlear implants in children or profoundly deaf adults, TNF antagonists in rheumatoid arthritis) delivered large one-year gains of 0.2 or above, but only 9/31 (29%) had one-year gains above 0.1. The quality of life or utility gains found with successful treatment

of chronic pain are clearly at least comparable, and often superior.

It is important to note that while all the studies found reported at least one positive association between effective pain treatment and some aspect of quality of life or functioning, no study was found reporting research showing the absence of any link between pain relief and benefit. It is also important to note that these studies consistently report the lack of benefits in quality of life, functioning, work, sleep, or depression in the absence of good pain relief.

Discussion

The message is that reducing chronic pain to levels equivalent to 'no worse than mild pain' carries significant health and economic benefits to patients. It should normally be both more affordable and probably cost saving, compared with ineffective treatment. Improved sleep, reduced depression, better quality of life and greater ability to function and work come with good pain relief; without pain relief, there were no improvements in these outcomes. The strength of the evidence is such as to indicate that any patient-centred treatment programme that does not include the achievement of adequate pain relief as part of its goals is likely to fail to deliver on expected benefits.

However, treating pain is clearly not easy; if it were, reports of moderate or severe acute pain in 44% of patients in hospital in the USA [72] and 91% with chronic pain living in the community in Australia [12] would not be so common. Investigations into the barriers to adequate treatment of acute pain suggest a variety of possible problems [73], but investigations into different levels of performance between centres come to no particular conclusion [74]. Guidelines for treatment of chronic pain are less or more restrictive regarding the range of therapies allowed; for example, guidelines for the management of osteoarthritis pain [75] allow a broad range of therapies to be tried, whereas for neuropathic pain, available therapies are limited to just a few [76].

It is unquestionable that there are difficulties in treating pain, regardless of its origin and mechanism. The growth in so-called evidence is not necessarily helping, as we see paracetamol ensconced in all guidance about treatment of musculoskeletal pain, despite good evidence

that its benefits over placebo are ‘of questionable clinical benefit’ [77], whereas good evidence that a simple, effective and cheap intervention for headache in adolescents works well is largely ignored [78]. Yet while different approaches to treatment are required for particular circumstances or particular patients, the goal of treatment can still be the same, irrespective of the evidence being applied. It should be ‘no worse than mild pain’ as measured by the patient, not professionals, because, to repeat, professionals often get it wrong, most often by significantly underestimating the pain [1]. If the approach is not working, or the evidence is wrong, the goal of ‘no worse than mild pain’ will not have been reached.

The academic imperative is to have trial data re-analysed using ‘no worse than mild pain’ as an outcome, to enable clinical trial results to be readily useful for clinical practice. Developments in understanding evidence, and particularly how not to be completely misled by it, are now very fully developed, and while they still use outcomes of at least 50% pain intensity reduction rather than ‘no worse than mild pain’, the two are probably closely related.

The practical imperative is to improve treatment of acute and chronic pain. There are many tools to handle, and many experienced and wise professionals able to use those tools appropriately for the incredibly heterogeneous patients in need of pain relief. It is not so much the tools that are lacking, but a clear understanding of the goal of treatment. This single unified outcome of ‘no worse than mild pain’ is simple to apply and understand, and is practical, as it can be applied with one contact with the patient; measures describing change would need at least two assessments. Any outcome worse than mild pain should be unacceptable, and should be regarded a mark of analgesic or treatment failure.

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Competing interests

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