

Am Board Fam Med. Author manuscript; available in PMC 2010 January 1.

Published in final edited form as:

*J Am Board Fam Med.* 2009; 22(1): 62–68. doi:10.3122/jabfm.2009.01.080102.

## Overtreating Chronic Back Pain: Time to Back Off?

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#### **Abstract**

Chronic back pain is among the most common patient complaints. Its prevalence and impact have spawned a rapidly expanding range of tests and treatments. Some of these have become widely used for indications that are not well-validated, leading to uncertainty about efficacy and safety, increasing complication rates, and marketing abuses. Recent studies document – over approximately a decade – a 629% increase in Medicare expenditures for epidural steroid injections; a 423% increase in expenditures for opioids for back pain; a 307% increase in the number of lumbar MRIs among Medicare beneficiaries; and a 220% increase in spinal fusion surgery rates. The limited studies available suggest that these increases have not been accompanied by population-level improvements in patient outcomes or disability rates. We suggest a need for a better understanding of the basic science of pain mechanisms; more rigorous and independent trials of many treatments; a stronger regulatory stance toward approval and post-marketing surveillance of new drugs and devices for chronic pain; and a chronic disease model for managing chronic back pain.

Pain complaints are a leading reason for medical visits. The most common pain complaints are musculoskeletal, and back pain is the most common of these. The prevalence and impact of back pain have led to an expanding array of tests and treatments, including injections, surgical procedures, implantable devices, and medications. Each is valuable for some patients, but use may be expanding beyond scientifically validated indications, <sup>2-4</sup> driven by professional concern, patient advocacy, marketing, and the media.

More tests and treatments do not simply reflect a greater incidence of back pain. The proportion of office visits attributed to back pain has changed little since 1990.<sup>5</sup> In recent National Health Interview Surveys, about a quarter of U.S. adults reported back pain in the past three months, broadly consistent with previous surveys.<sup>5</sup>

There are important implications of expanded testing and treatment for back pain. Innovation has often outpaced clinical science, leaving uncertainty about the efficacy and safety of many common treatments. Complications and even deaths related to pain management are increasing. <sup>6,7</sup> Despite uncertainties, manufacturers aggressively promote new drugs and devices. However, trust in the science supporting these products is eroded by revelations of misleading advertising, <sup>8</sup> allegations of kickbacks to physicians, <sup>9</sup> and major investments by surgeons in the products they are investigating. <sup>10</sup>

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Conflicts of interest: The research program of Drs. Deyo and Mirza has benefited from a gift to the University of Washington from Synthes, a surgical device manufacturer. They have not received any personal financial support from this source. Mr. Martin has received partial salary support from this source. Dr. Turner has no conflicts to declare.

We focus here on common management decisions in primary care, related to imaging, medication, and referral for injections or surgery. Our goal was not to conduct systematic reviews of each of these or to provide a treatment guide, but to summarize data on recent trends, highlight certain risks, provide conclusions from systematic reviews on efficacy, and comment on practice patterns.

### Imaging for low back pain

Despite guidelines recommending parsimonious imaging, use of lumbar magnetic resonance imaging (MRI) increased in the Medicare population by 307% during a recent 12-year interval (Figure 1a, previously unpublished data). Others have described rapid increases in spine imaging, and for imaging procedures in general. Spine imaging rates vary dramatically across geographic regions, and surgery rates are highest where imaging rates are highest. When judged against guidelines, one-third to two-thirds of spinal computed tomography (CT) and magnetic resonance (MR) imaging may be inappropriate. Alarm factors probably underlie the growth of imaging, including patient demand, he compelling nature of visual evidence, see factors and financial incentives.

One problem with inappropriate imaging is that it may result in findings that are irrelevant but alarming. Positive findings, including herniated disks, are common in asymptomatic people. <sup>20-22</sup> In a randomized trial, there was a trend toward more surgery and higher costs among patients receiving early spinal MR than those receiving plain films, but no better clinical outcomes. <sup>23</sup> Six other randomized trials, involving a total of 1,804 patients from primary care without features suggesting a serious underlying disease, compared some form of lumbar spine imaging with none. <sup>24-29</sup> In these studies, imaging was not associated with an advantage in subsequent pain, function, quality of life, or overall improvement.

Based on an extensive systematic review, the joint guidelines of the American College of Physicians and the American Pain Society (ACP/APS) explicitly recommend against routine imaging in patients with nonsepcific low back pain (i.e., no severe or progressive neurologic deficits or evidence of serious underlying conditions).<sup>30</sup>

## **Opioid analgesics**

Prescription opioid use is steadily increasing, overall and for musculoskeletal conditions in particular. <sup>4,7,31-35</sup> Among patients with spinal disorders, the National Medical Expenditure Panel Survey showed a 108% increase in opioid prescriptions from 1997 through 2004 (Figure 1b). The combination of increasing use and higher drug prices resulted in a 423% inflation-adjusted increase in expenditures. <sup>31</sup> These trends have been driven at least partly by concern for undertreatment of pain in the past, especially among patients with cancer or terminal illness.

Emergency department reports of opioid overdose parallel the numbers of prescriptions.<sup>4</sup> Deaths related to prescription opioids have increased, so that by 2002 there were 4,451 deaths related to opioid analgesics: more than the combined total involving cocaine or heroin alone. <sup>7</sup> Diversion of prescription opioids is increasingly common, with broad societal impacts.<sup>4,36</sup>, <sup>37</sup>

Unlike advanced cancer or postoperative pain, chronic back pain often persists for years or decades. In this setting, the efficacy and safety of long-term opioid use remain controversial. Nonetheless, more than half of "regular" prescription opioid users have back pain. <sup>38</sup> A systematic review concluded that for chronic back pain, short-term advantages over non-opioid analgesics were modest, while data beyond 16 weeks were unavailable. <sup>39</sup>

The Cochrane Collaboration review of opioids for chronic low back pain similarly concluded that "Despite concerns surrounding the use of opioids for long-term management for chronic LBP, there remain few high-quality trials assessing their efficacy...Based on our results, the benefit of opioids in clinical practice for the long-term management of chronic LBP remains questionable." In population-based studies, many patients receiving opioids for non-cancer pain have persistent high levels of pain and poor quality of life. 41

Ironically, patients with major depression and other psychiatric disorders are more likely than others to initiate and to continue opioid therapy, <sup>42</sup> yet they also are more likely to misuse medication, <sup>43,44</sup> and may be less likely to experience analgesic benefit. <sup>45</sup> Although depression and other psychiatric disorders are common among patients with chronic back pain, <sup>42,46-48</sup> patients with such disorders are commonly excluded from trials of opioid therapy, <sup>42</sup> raising questions about the generalizability of efficacy studies to routine practice.

Some adverse effects of opioid use may be underappreciated, including hyperalgesia, <sup>49,50</sup> which may result from changes in the brain, spinal cord, and peripheral nerves. <sup>51-53</sup> In short, opioid use may paradoxically increase sensitivity to pain. Hypogonadism is another underappreciated consequence of chronic use, resulting in reduced testosterone levels, diminished libido, and erectile dysfunction. <sup>54-56</sup>

The ACP/APS guidelines conclude that "Opioid analgesics are an option when used judiciously in patients with acute or chronic low back pain who have severe, disabling pain that is not controlled (or is unlikely to be controlled) with acetaminophen and NSAIDs. Because of substantial risks...potential benefits and harms of opioid analgesics should be carefully weighed before starting therapy. Failure to respond to a time-limited course of opioids should lead to reassessment and consideration of alternative therapies or referral for further evaluation."

## Spinal injections

The efficacy of spinal injections is limited. Epidural corticosteroid injections may offer temporary relief of sciatica, but both European and American guidelines, based on systematic reviews, conclude they do not reduce the rate of subsequent surgery.<sup>57,58</sup> This conclusion is based on multiple randomized trials comparing epidural steroid injections with placebo injections, and monitoring subsequent surgery rates.<sup>59-62</sup> Facet joint injections with corticosteroids appear no more effective than saline injections.<sup>57,63</sup>

Despite the limited benefit of epidural injections, Medicare claims showed a 271% increase during a recent seven-year interval (Figure 1c). Facet joint injections increased 231%. Earlier Medicare claims analyses also demonstrated rapid increases in spinal injection rates. 12,64 For patients with axial back pain without sciatica there is no evidence of benefit from spinal injections; 57 yet many injections in the Medicare population appeared to be for axial back pain alone. 2

After inflation, charges per injection rose 100% during the past decade, and the combination of increasing rates and charges resulted in a 629% increase in fees for spinal injections.<sup>2</sup> During this time, the Medicare population increased by only 12%.

# Spine surgery

Although spine fusion surgery has a well-established role in treating fractures and deformities, four randomized trials indicate that its benefit is more limited when treating degenerative discs with back pain alone (no sciatica).<sup>65</sup> Despite no specific concurrent reports of clarified indications or improved efficacy, there was a 220% increase in the U.S. rate of lumbar spine

fusion surgery from 1990 to 2001 (Figure 1d).<sup>3</sup> The rise accelerated after 1996, when fusion cages, a new type of surgical implants, were approved.<sup>3</sup> Their promotion may have contributed to both the rise in fusion rates and increased use of implants. In the last five years of the 1990s, Medicare claims demonstrated a 40% increase in spine surgery rates, a 70% increase in fusion surgery rates, and a 100% increase in use of implants.<sup>66</sup>

Higher spine surgery rates are sometimes associated with worse outcomes. In the state of Maine, the best surgical outcomes occurred where surgery rates were lowest; the worst results occurred in areas where rates were highest.<sup>67</sup> Multiple randomized trials suggest that adding surgical implants to bone grafting slightly improves rates of solid bone fusion, but may not improve pain or function.<sup>68-70</sup> Implants increase the risk of nerve injury, blood loss, overall complications, operative time, and repeat surgery.<sup>68,69</sup> In a large study of injured workers, the rapid increase in use of intervertebral fusion cages after 1996 was associated with increased complications but not with improved disability or reoperation rates.<sup>71</sup> We recently found that reoperation rates following initial spine surgery were higher in the late 1990's than earlier in the decade, despite greater use of fusion procedures and implants.<sup>6</sup>

### Are we improving outcomes?

Jumps in imaging, opioid prescriptions, injections, and fusion surgery might be justified if there were substantial improvements in patient outcomes. Even in successful trials of these treatments, though, most patients continue to experience some pain and dysfunction. Population-level data on back-related dysfunction are sparse. However, despite a rise in costs related to spine problems, the U.S. Medical Expenditure Panel Survey showed that self-reported functional limitations, mental health, work limitations, and social limitations were worse among people reporting such problems in 2005 than in 1997.<sup>31</sup>

Furthermore, Social Security Disability Insurance (SSDI) statistics suggest that disability from musculoskeletal disorders is rising, not falling. Work disability attributed to musculoskeletal disorders – much of which is back pain -- increased from 20.6% of beneficiaries in 1996 to 25.4% in 2005 (Figure 2).<sup>72</sup> This was not a growing proportion of a shrinking pie; the number of SSDI recipients increased over these years. Though it is unclear exactly what proportion of musculoskeletal disability is from back pain, the data suggest that current management of musculoskeletal pain is not highly successful. In contrast, for conditions where effective prevention and treatment have emerged, such as circulatory and respiratory diseases, the proportion of disabled beneficiaries fell.

### Implications and possible responses

Prescribing yet more imaging, opioids, injections, and operations is not likely to improve outcomes for patients with chronic back pain. We must rethink chronic back pain at fundamental levels. Our understanding of chronic back pain mechanisms remains rudimentary, including our knowledge of spinal biology, central nervous system processing, genetic factors, and psychosocial and environmental influences. Greater investment is needed in this basic science research.

Clinicians may often be applying an acute care model to a chronic condition. There are no "magic bullets" for chronic back pain, and expecting a cure from a drug, injection, or operation is generally wishful thinking. These approaches risk overlooking the psychosocial, occupational, and lifestyle dimensions of chronic pain. Although evidence remains incomplete, and the magnitude of benefits may be modest, data support the benefits of interventions that promote patient involvement and activity (e.g. graded exercise programs and group support). 73-77 These therapies also have the advantage of being low risk.

A "chronic care model" would acknowledge that chronic back pain, like diabetes or asthma, is a condition we can treat but rarely cure. As with other chronic conditions, care of chronic back pain may benefit from sustained commitment from health care providers, involvement of patients as partners in their care, education in self-care strategies, coordination of care, and involvement of community resources to promote exercise, provide social support, and facilitate return to work. <sup>78,79</sup> Patients need realistic expectations, despite product marketing, media reports, and medical rhetoric that promise a pain-free life.

Each treatment and test discussed here has a role in managing back pain, but the evidence base for judicious use remains inadequate. Greater federal involvement in research on therapies and devices may be necessary, to provide independent assessments. Initiatives in comparative effectiveness research would be particularly welcome in this regard. Research emphasis should shift from studying fine points of procedural technique to determining who benefits most. Instead of measuring only technical success (solid bony fusion or properly placed injection), research should clarify a treatment's safety and its effects on pain, function, and return to work. Serious complications and unclear benefits highlight the need for more rigorous approval and better post-marketing surveillance of both drugs and devices for treating pain. Without stronger evidence, insurers may reasonably question coverage of newer drugs, devices, and procedures. <sup>80</sup> In the meantime, we should fully inform patients about available treatment options, including the best available evidence for effectiveness, uncertainties, and risks, and encourage them to play an expanded role in therapeutic decision-making. <sup>77</sup>

### Acknowledgments

Supported in part by grants # 5P60-AR48093 and #5K23AR48979 from the National Institute of Arthritis, Musculoskeletal and Skin Diseases

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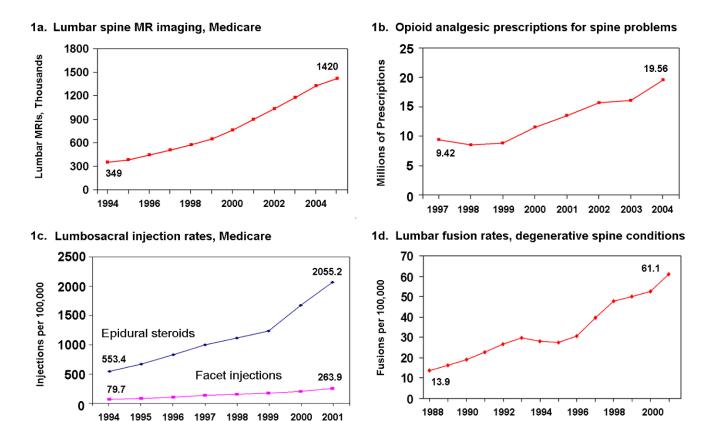


Figure 1. Increases in Use of Various Services for Low Back Pain (1a.) Lumbar spine magnetic resonance imaging (CPT codes 72148, 72149, 72158), numbers of scans among Medicare beneficiaries, from Part B claims; (1b.) Numbers of opioid prescriptions for spine conditions, national data from the Medical Expenditure Panel Survey, reference 11 (1c.) Rates of lumbosacral injections in the Medicare population, age- and sexadjusted. Data are from reference 1, adapted with permission.(1d.) Lumbar spine fusion rates for degenerative conditions, age- and sex-adjusted, National Inpatient Sample, from reference 2, reproduced with permission.

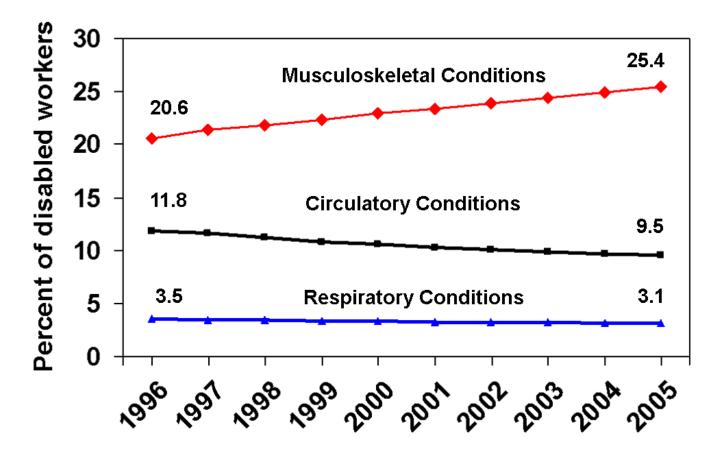


Figure 2. Percentage of individuals with permanent work disability (Social Security Disability Income beneficiaries) disabled by various medical conditions. Data are from reference 24.