



Description of a clinical stream of back-pain patients based on electronic medical records



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A B S T R A C T

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Back pain consists of a spectrum of conditions, with no common etiology and therefore no dominant method of treatment. The purpose of this study is to describe the complexity of a collection of 8000 back pain patients who appeared in an integrative medicine clinic, as a prelude to conducting comparative effectiveness research on CAM alternatives to conventional therapy.

Approximately 23% of all clinic patients were diagnosed at some time with back pain. Nearly half had treatment periods of less than one month, while more than 25% were treated for back pain for more than two years. Women were represented more than twice as often as men. The initial diagnosis categories that occurred most frequently were lumbar symptoms, cervical symptoms, and a general category, with smaller numbers having lumbar anatomic, thoracic symptom, brachial neuritis, or sciatica diagnoses. There were few strong relationships between initial diagnosis pattern and length of back pain treatment period.

While 77% of back pain patients presented with diagnoses in only a single category, there were many composite categories each of which was sparsely represented. Between 50% and 75% of patients used some CAM service, depending on their initial diagnosis pattern. Patients with complex initial diagnosis patterns strongly tended to chose CAM, and among CAM-users those with complex diagnoses tended toward chiropractic, as opposed to acupuncture or bodywork. The CAM usage patterns of men and women were highly similar. Again among CAM users, 82% used only a single type of CAM service, and multiple service uses tend to be combined at random. Between two-thirds and three-quarters of multiple CAM service users had very simple temporal patterns of use, dominated by use of one type of CAM at a time.

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1. Introduction

Back pain is one of the conditions most frequently seen by primary care providers, and one which makes a substantial contribution to chronic health care utilization. The research literature on back pain consists primarily of relatively small studies of highly selected patient subgroups, directed toward testing the efficacy of specific therapies. It is unclear whether this research strategy is making much progress in reducing the back pain burden and its clinical costs.

In its deliberations on how to use economic stimulus research funding for comparative effectiveness research (CER), the Federal

Coordinating Council on CER emphasized the importance of obtaining medical effectiveness information from “real world” situations, as opposed to somewhat artificial clinical trials. It also pointed to the need for integrated electronic medical records as a potential source of such information.¹¹ There has, however, been little federal funding for the development of methods for extracting valid therapeutic information from clinical data where there are no research interventions. It is therefore not surprising that the literature on medical records-based comparative effectiveness studies is quite thin. Back pain seems to be a nearly optimal topic within which such methods can be developed, due to the large fraction of the patient population that presents with back pain, the complexity of the condition, and the relative lack of evidence about the multiple strategies that have been proposed to treat it.^{2,7,9,10,12,13,16–19,22,23,25–27,29,30,33,35,38,39,43,45,49,50,52,53,55}

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The purpose of this article is to introduce a new research strategy for back pain, with implications for the study of chronic conditions more generally. This approach is based exclusively on the data that are available in an electronic medical record (EMR) system. It encompasses essentially all outpatients who present for treatment, and who have sufficient clinical follow-up for an attempted evaluation of their conditions over time.

Since this is the first report from a patient-centered, clinical EMR-based program of research, we restrict ourselves to data related to the challenges we have encountered and the techniques that can be mobilized to undertake this kind of project. Many of the challenges flow from the fact that EMRs are not designed to facilitate clinical research. While this fact limits what can be accomplished with current EMR structures, we feel that it is possible to make more progress in this setting than is generally realized in the medical research community.^{1,3,28,51,54}

It is not our aim here to present comparative effectiveness analyses; this will be the subject of a subsequent report, as part of the federally funded SPICER project (Studies in Patient-oriented Informatics for Comparative Effectiveness Research). Instead we focus on characterizing back pain patients according to demographics, their initial diagnoses, their length of back pain treatment, and their use of medications and complementary and alternative medicine (CAM) approaches, all in the context of a conventional/integrative medicine clinic. We also spend some time describing our approaches to the methodological challenges of EMR-based research.

2. Back pain

In 1983 Roland and Morris wrote: “Treatment of low-back pain is unsatisfactory. The physician often has little scientific basis for his choice of treatment for a particular patient...Because of problems in establishing diagnoses in patients with back pain, it is difficult to select homogeneous groups of patients on which to test the effect of a treatment...and conventional outcome measures are very crude.”⁴⁰ Lack of consensus among physicians about the treatment of back pain⁵ has made it difficult to recommend therapeutic approaches, and hard for patients to make informed decisions. A review of the current literature make it apparent that little has changed over the past three decades.²⁴ For example, the American College of Physicians makes a number of strong recommendations for conventional approaches on the basis of moderate evidence, but weak recommendations for alternative approaches based on the same level of evidence,⁶ thereby neither improving confidence in guidelines nor making the patients’ choices any easier.

In general, back pain is a symptom and so the diagnosis does not identify the pathophysiology associated with it. The common teaching in medical school is that increased back pain with flexion indicates a disc problem and increased back pain with extension indicates facet pathology, but this fails to encompass the multitude of possible etiologies and the actual pain generators in particular cases. There is a rich clinical literature written by physiatrists, osteopaths, chiropractors, and orthopedic surgeons that focuses on structural and biomechanical sources of pain, in addition to applied work on myofascial pain.^{21,41,47} The level of detail in the history and physical examination needed to reveal the underlying causes of generic “low back pain” has often not been reflected in the day-to-day allopathic approach or in the corresponding research. Radiological tests clarify only a few items on the diagnostic menu while leaving the majority of back pain cases without a specific diagnosis. In fact, the disparity between the clinical and radiological diagnoses is often startling. As reported in the *Journal of Neurosurgery: Spine*¹⁵ an underwhelming

3.6% of the patients diagnosed with sciatica (being treated with the standard of care for disc bulges and herniation) actually had disc herniations.

Back pain is the most common cause of disability for those under age 45.³⁷ It is a serious and costly problem and the published studies are inadequate to delineate all the costs involved. One researcher has estimated total back pain costs in the US at \$600 billion annually.⁴⁸ Some of the costs include conventional medical and surgical care, costs of CAM practices, medication, lost time from work, or loss of productivity at work. Rarely do the studies address the impact on quality of life factors.

Back pain clinical trials are numerous but largely inconclusive. Studies often use heterogeneous or nonspecific inclusion criteria, and outcome measures range over clinical symptoms, radiological diagnosis, or speculation about causative factors. Acute and chronic pain are often not distinguished. Moreover, there is a lack of long term follow-up. It is exceptional to have follow-up measures at one year, and since low back pain is characteristically relapsing and remitting, it is difficult to judge from the current state of the research whether the interventions have any impact on long term outcomes.

The non-intervention literature on back pain focuses on specific conditions and treatments, and again has limited follow-up. This makes it difficult to elucidate the overall scope of back pain patients as they present in primary care offices, the specific pathophysiological processes associated with different categories of back pain, the natural history of the different kinds of back pain, and the appropriateness of therapies.

Because back pain is an inhomogeneous diagnostic category it is difficult to design clinical studies and hard to interpret the results. Researcher Mark Erwin DC, PhD (personal communication) points to a recent study that “looked at exercise vs SMT (spinal manipulative therapy) in chronic back pain patients (more than three months of back pain)”. The inclusion criteria here were so vague that it surely had a number of sub-groups, all of which would surely have variable response rates to any therapy ‘built in’. For example, the “chronic sore back in an otherwise fit and healthy individual” may have a different response than “the chronic sore back in the 250 lb, sedentary 2 pack/day smoker”; yet they may well be within the same treatment group.

A review of the current state of affairs⁴ concluded that “quality evidence about what is good clinical practice in pain treatment is buried in the medical literature among large quantities of conflicting information.” For example, Manchikanti’s³² meta-analysis found 1200 references recommending the use of a variety of interventions in chronic spinal pain, while Geurts et al.²⁰ found only moderate evidence and Slipman et al.⁴⁴ found no evidence for the use of these interventions in chronic low back pain. “Thus,” concludes Cahana, “practically speaking, evidence-based medicine gives little guidance to practitioners desperately seeking to do their best for their patients.”

3. The Marino Clinical Centers

The data presented here come from The Marino Center for Integrative Health, a not-for-profit organization that manages two integrative medical clinics, located in Cambridge and Wellesley MA. The clinics are associated with the Mount Auburn Hospital, Cambridge, MA, and the Newton-Wellesley Hospital, Newton, MA respectively. In addition to clinical work, the Marino Center sponsors research and education opportunities for medical professionals and the community for those interested in learning about integrative medicine. The Center has approximately 35,000 active patients, representing almost 60,000 visits per year.

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