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Original Contribution

Effectiveness of Clinical Guidelines in Interventional Pain Management

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Many commissions and groups throughout the world have proposed clinical guidelines on the management of low back pain, spinal pain, and chronic pain. Practice guidelines are systematically developed statements to assist the practitioner and patient decisions about appropriate healthcare for specific clinical circumstances. The American Society of Interventional Pain Physicians developed practice guidelines for interventional techniques which are professional practice recommendations for practices for prevention, diagnosis and treatment of acute and chronic painful disorders, and in some cases, disability management. The effectiveness of so-called evidence-based guidelines has not proven.

This study was designed to evaluate a total of 300 patients with 100 randomized patients seen in the month of January 1999, 2000 and 2001, in one private pain management practice in a non-university setting. The study was retrospective for 1999 and 2000, whereas it was prospective for 2001. The results showed that there were no significant differences in patient demographics or their psychological status. The results consistently showed decrease in number of visits from 1999 to 2000 and 2001 with 5.5 + 0.18, 5.1 + 0.17, and 4.3 + 0.15 respectively. The average expenditure also decreased from per visit of $872 in 1999 to $891 in 2000, to $810 to 2001. further, the average expenditure per year also decreased as expected due to decrease in frequency of visits, as well as the average expenditure per visit from $4751 + $231 in 1999 to $4505 + $214 in 2000 and to $3514 + $193 in 2001 even without consideration of inflation. Thus, it is concluded that guidelines describing the interventional techniques in the management of chronic pain are effective in reducing the cost and frequency of visits with improvement or at least maintenance of similar outcomes, physician decision making abilities, and patient preferences.

Keywords: Interventional pain management, interventional techniques, clinical guidelines, outcomes, cost effectiveness

Evidence-based medicine is about solving clinical problems (1). Guyatt et al (2) described evidence-based medicine as a shifting medical paradigm (2). In contrast to the traditional paradigm of medical practice, evidence-based medicine acknowledges that intuition, unsystematic clinical experience, and pathophysiologic rationale are insufficient grounds for clinical decision making; and it stresses the examination of evidence from clinical research. Further, evidence-based medicine suggests that a formal set of rules must compliment medical training and common sense for clinicians to interpret the results of clinical research effectively (2). Finally, evidence-based medicine places a lower value on authority than the traditional medical paradigm does (2). As a distinctive approach to patient care, evidence-based medicine involves two fundamental principles (2). First, evidence alone is never sufficient to make a clinical decision. Decision makers must always trade the benefits and risks, inconvenience and costs associated with alternative management strategies, and in doing so, considered the patient's values (1). Second, evidence-based medicine posits a hierarchy of evidence to guide clinical decision making. However, rather than denigrating clinical expertise (3, 4), evidence-based medicine acknowledges expertise as the basis for all clinical practice (5). In contrast to the popular belief, evidence-based medicine provides enormous value for patient values, points out a thorough and deep understanding of the evidence rather than promoting cookbook medicine (4, 6) and assists the practitioner to make valid judgments about the course of action (5). The most commonly perceived misconception is that only randomized controlled trials are systematically reviewed constitute the "evidence" in evidence-based medicine (7, 8). In contrast, evidence-based medicine suggests that clinicians should seek evidence about the prognosis of a disease or health state from natural history studies and acknowledges that physiologic stud-

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ies and individual clinical experience are important evidence sources (5).

Since the publication by Spitzer et al (9) in 1987, five years prior to development of the concept of evidence-based medicine, many commissions throughout the world have proposed clinical guidelines on the management of low back pain (10-27). However, the use of practice or clinical guidelines is not new medicine. The first guidelines were specific to the practice of anesthesia, concerned themselves with overall patient safety and effective technique for preventing anesthetic mishaps and were developed in the 1840s, shortly after the use of anesthesia was first demonstrated. Practice guidelines are systematically developed statements to assist the practitioner and patient decisions about appropriate health care for specific clinical circumstances (17). These are professional practice recommendations for practices for prevention, diagnosis and treatment of acute and chronic painful disorders, and in some cases, disability management. The diffusion of the guidelines in managing chronic pain, spinal pain, and low back pain and their everyday application by interventional pain physicians is a significant problem (9-13, 19-27). A serious examination of the guidelines shows that about 85% of the recommendations are not based on any significant evidence (28). In addition, numerous guidelines are prepared by entrepreneurial technological companies, insurers, as well as individuals and organizations.

The American Society of Interventional Pain Physicians published these guidelines in 2000 and updated them in 2001 (17, 18). One question always raised is if evidence-based medicine or clinical guidelines either improve patient outcomes or provide cost-effective care? Further, one may even ask if evidence-based medicine or clinical guidelines will result in superior, or even different, patient management strategies. Even then, several countries and agencies have promoted evidence-based guidelines for the management of low back pain and chronic pain. Such guidelines have been promoted in the belief that they should and will work. However, they have been launched without any accompanying evidence that they do, in fact, work.

McGuirk et al (29) in a case-controlled study involving parallel benchmarking compared the safety, efficacy and cost effectiveness of evidence-based medical care and usual care for acute low back pain. They compared the patients in two settings with outcomes of patients managed by their own general practitioners compared to special clinics, at which trained medical practitioners managed patients with acute low back pain according to evidence-based guidelines. They concluded that the immediate results from evidence-based care are marginally better than those from good usual care, but in the long term, evidence-based care achieves clinically and statistically significant gains, with fewer patients requiring continuing care and remaining in pain.

In contrast, Rao et al (37) in evaluating the impact of guidelines on ordering of magnetic resonance imaging studies by primary care providers for low back pain concluded that orders for MRI did not decrease offer education on the guidelines. Further, several clinical studies (31-33) indicated that implementation of selective ordering criteria proposed by Deyo et al (34) in 1986, resulted in increased utilization of lumbar spine radiographs. In addition, it was also shown that implementation of the AHCPR Guidelines would actually increase utilization of imaging studies 3-fold (35).

The effectiveness of clinical guidelines for various modalities of treatments specifically interventional techniques has not been evaluated. Hence, the present study was undertaken to evaluate effectiveness of clinical guidelines in interventional pain management utilizing practice guidelines entitled "Interventional Techniques In The Management Of Chronic Pain." Our purpose was to determine whether utilization of interventional techniques would reduce the cost of the management of the patients per year, and frequency of application of interventional techniques and physician behavior has changed after implementation of guidelines in part or comprehensively. We hypothesized that with utilization of interventional techniques, frequency of interventional techniques, and cost of care of patients would decrease from 1999 with management without clinical guidelines, to 2000 with partial application of guidelines, and 2001 with comprehensive application of guidelines.

METHODS

This study was designed to evaluate a total of 300 patients, with 100 randomized patients seen in the month of January 1999, 2000, and 2001, in one private pain management practice in a non-university setting. Of all the patients undergoing interventional techniques in the month of January in each year, 100 patients were randomly allocated into the study group. The study was retrospective for 1999 and 2000, whereas it was prospective for 2001. During this time, 550 to 600 patients underwent interventional techniques for pain management in the month of January each year. However, the inclusion of these pa-

tients was not known either to the treating physicians, patients or nurses involved. Patients undergoing spinal cord stimulation, intradiscal electrothermal annuloplasty, percutaneous disc decompression with nucleoplasty, spinal cord stimulation, intrathecal implantation of drug delivery systems, and patients with metastatic carcinoma not expected to live through the study were excluded.

Of the 100 patients included in the study for 1999, 22 were new patients; for 2000, 24 patients were new patients; for 2001, 26 patients were new patients. The remaining patients were in therapeutic phase. All the patients underwent interventional pain procedures as deemed necessary based on the relief (greater than 50% of pain relief), and improvement in functional status and complications. All patients were evaluated with demographic characteristics, psychological status evaluating depression, generalized anxiety disorder, and somatization disorder, and analysis of interventions with the average number of visits per year, average number of visits per year, average expenditure per year, and average expenditure per visit.

In 1999, 2000, and 2001 were selected for multiple reasons. First, no guidelines were followed in 1999. Second, guidelines were developed in 1999 and were published in January 2000. However, these guidelines were followed only partially. Third, in late 2000, the guidelines were revised and were published in January 2001. These updated guidelines were more comprehensive, detailed, and were utilized in the practice in their entirety.

Data were recorded on a database using Microsoft®, Access®. The SPSS Version 9.0 statistical package was used to generate the frequency tables, and the chi – squared statistic was used to test the significant difference between groups. Fisher's Exact Test was used wherever expected value was less than 5. Students t-test was used to test mean differences between groups. Results were considered statistically significant if the *P*-value was less than 0.05.

RESULTS

Patient Characteristics

Demographic characteristics of all patients studied in 1999, 2000, and 2001, are shown in Table 1, with no significant differences noted between groups in terms of gender, age, weight, height, duration of pain in years, history of previous surgery, and mode of onset of pain.

Psychological Status

Table 2 illustrates the psychological status of all patients. They were evaluated for the presence of depression, generalized anxiety disorder, and somatization disorder. The evaluations were performed on all the patients at the time of admission and the same data were utilized. The data does not represent the evaluation of the psychological sta-

Table 1. *Demographic characteristics*

		Year		
		1999	**2000**	**2001**
Gender	Male	39%	36%	40%
	Female	61%	64%	60%
Age (yrs)	Mean + SEM	44 + 1.36	47 + 1.44	46 + 1.46
Weight (lbs)	Mean + SEM	173 + 4.56	184 + 4.70	181 + 4.11
Height (inches)	Mean + SEM	66.7 + 0.39	66.2 + 0.39	66.7 + 0.39
Duration of pain (yrs)	Mean + SEM	11 + 1.08	11.4 + 0.85	10.6 + 1.02
Previous surgery		51%	47%	43%
Mode of onset of pain	Occupational	30%	27%	31%
	Non-occupational	13%	10%	15%
	Motor vehicle injury	18%	18%	19%
	Gradual onset	39%	45%	35%

Table 2. *Psychological status of patients at the time of admission*

	Year		
	1999	2000	2001
Depression	68%	76%	65%
Generalized anxiety disorder	80%	71%	74%
Somatization disorder	20%	23%	29%

tus for some patients at the time of the study. However, there were no significant differences noted between the groups and their psychological status at the time of admission into the program.

Intervention Characteristics

Table 3 shows results of analysis in interventions of 100 patients for one year during 1999, 2000, and 2001. The results consistently showed decrease in number of visits from 1999 to 2000 and 2001. Similarly the average expenditure also decreased from per visit $872 in 1999 to $891 in 2000, to $810 in 2001. Further, the average expenditure per year also decreased as expected due to decrease in frequency of visits as well as the average expenditure per visit from $4751 + $231 in 1999 to $4505 + $214 in 2000 and to $3514 + $193 in 2001. However, this evaluation has not considered the influence of inflation will only increase the significance of reduction in frequency of visits as well as expenditures per visit as well as per year.

DISCUSSION

Interventional techniques in the management of chronic pain have been applied since 1901, yet continue to be controversial (17, 18). The rationale for diagnostic and therapeutic interventional techniques has been described. The practice guidelines describing interventional techniques in managing chronic pain are comprehensive utilizing evidence-based and consensus-based approaches. In spite of the great potential of the clinical practice guidelines, and the involvement of numerous medical societies and physician groups, there is still great debate within the profession, not only about the pros and cons of development and usage of guidelines, but also conflicting and controversial opinions on both sides of the issue, ie, providers and patients versus payors. Many interventional professionals see the guidelines as the best hope for accommodating the demands, not only for the quality of care at the lowest possible price, but also getting involved in the development of these guidelines. Many considered the practice guidelines not as a threat to professional autonomy but as a valuable addition or adjunct to the complex task of medical decision making. Eddy (36) observed that, "practice policies present a powerful solution to the complexity of medical decisions. They free practitioners from the burden of having to estimate and weigh the pros and cons of each decision. They can connect each practitioner to a collective consciousness, bringing order, direction and consistency to their decisions." Eddy (36) also stated that practice policies not only provide an intellectual vehicle through which the profession can distill the lessons of research and clinical experiences and put the knowledge and preferences of many people into conclusions about appropriate practices, but also provide a natural pathway to convey that information to practitioners. Thus, interventional pain management practice policies, along with other policies, may be considered as a central component to effective quality medical practice as what a conductor is to an orchestra. Walker et al (37) stated that practice guidelines,

Table 3. *Analysis of interventions*

	Year 1999	Year 2000	Year 2001
Average number of visits per year	5.5 + 0.18	5.1 + 0.17	4.3* + 0.15
Average expenditure per visit ($)	872	891	810*
Average expenditure per year ($)	4751 + 231	4505 + 214	3514* + 193

* Indicates significant difference with year 1999 and 2000

"are in effect, what the clinician would create personally if he or she had the time and resources to accomplish a full evaluation alone. . . guidelines summarize the collective as determined scientifically."

This study showed significant decrease in frequency of visits, expenditure per visit, and expenditure per year per patient from 1999 to 2000 to 2001 with incremental effect based on utilization of clinical guidelines.

This study may be criticized for the combined nature of retrospective and prospective comparison of patients. To obtain reasonable comparisons, this was necessitated. However, the study was randomized both for retrospective and prospective purposes from a large group of patients. There were no differences noted in patient demographic characteristics and psychological status. Further, the involvement of patients, even in the prospective phase was not known to either the patients, nurses, or treating physician, thus, maintaining a double-blind nature of the study, as well as avoiding any type of bias in providing number of interventions. The study may also be criticized for not taking into consideration the inflation in economic evaluation, however, with consideration of inflation, the cost of each procedure will only increase the difference and potentiate the results of improvement in care. Further, decrease in cost may be also attributed to lower reimbursement. However, the decrease in cost of the procedures was coupled with frequency of procedures, hence, this does not appear to be a valid concern. Cost was calculated by the net expense to the patient or insurer as paid to physician services, as well as ambulatory surgery center services. Further, reimbursement rates were somewhat higher in 2000 and 2001 compared to 1999 for Medicare; whereas they decreased for Medicaid and finally, decreases and increases were observed with commercial carriers.

The limitations of our study include a single interventional pain management practice involving only three physicians. Further limitations include this was not performed in a university or academic setting, which may be rather advantageous in certain situations as most patients are treated in community settings rather than academic settings, thus reflecting the nature of interventional pain management practices in the United States. We have also utilized only one set of guidelines, rather than blend of numerous guidelines with controversies available in managing chronic pain. However, the present guidelines utilized in this study are the most comprehensive available describing interventional techniques in managing chronic pain with a description of pathophysiology, indications for various techniques, as well as description of frequency of application of interventional techniques.

This evaluation provides preliminary evidence to the effectiveness of guidelines in application of interventional techniques in management of chronic pain. This study not only shows that outcomes are improved, they also show that efficiency of care is increased by reducing the visits, thus reducing patient care time and finally, with reduction in costs of care without deterioration in physician independence and patient preferences.

CONCLUSION

This study evaluated effectiveness of guidelines in managing chronic pain with interventional techniques over a period of three years. In the study of 300 patients, with 100 patients for each year of 1999, 2000 and 2001, the results showed that there was significant improvement in patient outcomes with decrease in number of visits per year, average expenditure per visit and per year. We conclude that practice guidelines detailing interventional techniques in managing chronic pain are effective in reducing frequency of visits and reducing the costs while improving or at least maintaining similar outcomes, physician decision making abilities, and patient preferences.

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