

A PROSPECTIVE EVALUATION

QUALITY ASSURANCE FOR INTERVENTIONAL PAIN MANAGEMENT PROCEDURES

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Background: Over the last decade various guidelines for quality assurance in pain medicine have been published for cancer pain, acute postoperative pain and other pain conditions. However, quality assurance for interventional pain management procedures has yet to be addressed. An interventional pain program should at least evaluate 1) efficacy of pain relief; 2) complication rate; and 3) patient satisfaction.

Objective: This study was designed to monitor the quality of interventional pain management procedures in a university teaching hospital.

Study Design: A prospective survey.

Methods: From January 1, 2004, to June 30, 2004, the quality of interventional pain management procedures in a university teaching hospital in Miami, Florida was monitored. Questionnaires assess-

ing immediate pain relief, patient satisfaction, and complications were provided to each patient and physician immediately after completion of each procedure. Data was collected before patients were discharged.

Results: A total of 566 patients with a mean age of 52.9 years participated in the survey. Interventional pain management procedures included epidural steroid injections, facet joint blocks, transforaminal epidural injections, sympathetic nerve blocks, lumbar discography, nucleoplasty, percutaneous disc decompression, spinal cord stimulator trial, and intravenous regional blocks, etc. Among 528 patients who reported their pain scores before and after procedures, 487 (92%) patients reported various degrees of pain relief immediately following their procedures. The

average pain score decreased 4.7 on a 0 to 10 scale after treatment ($p < 0.001$). No major complications were reported for this group of patients. Among 442 patients who answered the question regarding satisfaction, 406 (91.8%) were satisfied, or highly satisfied, with the immediate outcome of their procedures.

Conclusion: The results of the current study indicate that quality assurance of interventional pain management procedures in terms of immediate pain relief following the procedure, low complication rate, and high patient satisfaction can be achieved through application of a quality assurance program.

Key Words: Interventional pain management procedures, quality assurance, efficacy, patient safety, patient satisfaction

The purpose of a Quality Assurance program in pain medicine is to provide a mechanism for reviewing patient-related activity on a continuous basis in order to monitor, analyze, and improve patient outcomes. Over the last two decades quality assurance in pain management has gained increasing attention from the medical community, as well as from governmental agen-

cies, which oversee pain management in hospitals and other health care facilities. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published an official statement for the purpose of improving the quality of pain management in 2003. U.S. hospitals(1) and other patient care facilities, such as nursing homes (2, 3), have subsequently utilized more resources and efforts to improve the quality of pain management. Various guidelines, consensus statements and suggestions for quality assurance have been published for pain management in patients with cancer (4), acute postoperative pain (5), obstetrical pain (6), palliative care (7, 8), intensive care units (9), rheumatologic pain (10, 11) and in managed care settings (12). Quality assurance projects have been applied in multiple health care facilities (2, 13, 14). As a result, a better quality of care has been re-

ported as indicated by a significantly reduced prevalence of pain in institutionalized patients, and higher levels of patient satisfaction(2).

Interventional pain management procedures have been growing rapidly since 1990 and have become one of the major tools in treating chronic pain (15). The National Uniform Claims Committee (NUCC) defined interventional pain management as the discipline of medicine devoted to the diagnosis and treatment of pain and related disorders with the application of interventional techniques in subacute, chronic, or intractable pain, independently or in conjunction with other modalities of treatment. In 2003, CMS designated specialty code "-09" for interventional pain management. It has been estimated that among Medicare recipients, the frequency of interventional pain management procedures in-

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creased by 95% from 1998 to 2003 (15). The American Society of Interventional Pain Physicians (ASIPP) has developed evidence-based guidelines for interventional pain management procedures for the purpose of improving compliance and quality of care (16). Numerous reports have been published to investigate the long-term efficacy of interventional pain management procedures; these studies have provided critical evidence of their usefulness. However, literature regarding the application of quality assurance techniques to interventional pain management procedures is scant. As a part of the quality assurance program at Jackson Memorial Hospital's Pain Management Center (PMC) we evaluated the results of our interventional pain management procedures program from January 1, 2004, to June 30, 2004. We evaluated 1) efficacy of pain relief; 2) patient safety or complication rates; and 3) patient satisfaction.

METHODS

From January 1, 2004, to June 30, 2004, we monitored the quality of interventional pain management procedures in the pain management center (PMC) of Jackson Memorial Hospital, the primary teaching hospital of the University of Miami Miller School of Medicine. Exclusion criteria are illustrated in Table 1.

To ensure the quality of care, the following steps were taken before, during and after interventional pain management procedures: 1) each patient was seen by a resident or fellow under the direct supervision of an attending physician; 2) a diagnosis was formulated; 3) an interventional pain man-

agement procedure was prescribed as indicted by the patient's diagnosis; 4) each procedure was explained to the satisfaction of the patient; 5) a pre-procedure protocol was handed out to each patient; 6) on the patient's return to the PMC for their procedure, vital signs, pain severity, medications, possible

contraindications, diagnosis, name and site of the procedure were re-checked prior to taking patients into the procedure room; 7) procedures were re-scheduled if any of the exclusion criteria were present; 8) intravenous access was obtained for all cervical procedures, sympathetic blocks, discography,

Blood pressure >160/95
Any sign or symptom of infection
Coumadin within 5 days or clopidogrel (Plavix) within 7 days
Solid food consumption within 6 hours or liquids within 2 hours
Failure to bring along an accompanying adult

POST-PROCEDURE SURVEY
(Please circle your answers)

1. Were you treated courteously by our staff before, during and after the procedure?
(a) Yes (b) No
2. Select the phrase that indicates how satisfied or dissatisfied you are with the results of your pain overall.
(a) Very satisfied
(b) Satisfied
(c) Slightly satisfied
(d) Slightly dissatisfied
(e) Dissatisfied
(f) Very dissatisfied
3. Do you have any undesirable reaction resulting from the procedure?
(a) Yes (b) No If yes, please explain...
4. Were the procedure and the consent adequately explained to you?
(a) Yes (b) No If not, please explain...
5. Do you understand what to expect after the procedure and how to contact the clinic physician if you have a problem?
(a) No instructions were given
(b) Instructions are unclear to me or I forget
(c) Instructions are somewhat clear
(d) Instructions are absolutely clear
6. On this scale, how much pain did you have during the procedure?
0 1 2 3 4 5 6 7 8 9 10
7. On this scale, how uncomfortable (other than pain) were you during the procedure?
0 1 2 3 4 5 6 7 8 9 10
8. On this scale, how much anxiety did you have during the procedure?
0 1 2 3 4 5 6 7 8 9 10
9. On this scale, how much pain were you having just before the procedure?
0 1 2 3 4 5 6 7 8 9 10
10. On this scale, how much pain are you having now, following the procedure?
0 1 2 3 4 5 6 7 8 9 10
11. List all procedures that you had done today
(a)
(b)
12. Assuming that these procedures helped your pain, would you be willing to undergo them again, sometime in the future?
(a) Yes (b) No, if not, explain: _____

Fig. 1. Post-procedure survey of interventional pain management procedures for patients

disc decompression, spinal cord stimulator trial and vertebroplasty procedure; light intravenous sedation with 1-2 mg of midazolam was only administered to those patients undergoing disc decompression, discography, spinal cord stimulator trial and vertebroplasty; 9) a “time out” was called immediately prior to the interventional pain management procedures to confirm the patient’s name, diagnosis, type and site of the procedure; 10) during the procedure, blood pressure, heart rate, pulse oximetry, and EKG were continuously monitored; fluoroscopy was used to guide the needle placement for all spine procedures; 11) each procedure was performed by a resident or fellow

under the direct supervision of an attending physician; 12) and upon completion of interventional pain management procedure(s), patients were sent to a recovery area and observed for at least 30 minutes prior to discharge.

Immediately following interventional pain management procedure(s), patients were asked to complete a list of quality assurance questionnaires (Fig. 1). There were a total of 12 questions grouped into three categories: 1) efficacy of each procedure. 2) adverse effects experienced during and immediately after the procedure(s), and 3) patient satisfaction. Data was collected before patients were discharged home. Physicians completed a separate quali-

ty assurance worksheet regarding efficacy of the procedure and adverse events (Fig. 2).

Patient’s pain score immediately prior to, and following the interventional pain management procedures was determined to evaluate the short-term efficacy of treatment. Pain was assessed by an 11-point Numeric Pain Scale (0 = no pain and 10 = worst pain).

To evaluate patient satisfaction, they were asked how they were treated by the staff (Q1); how satisfied they were with the results of the procedure (Q2); whether the procedure and the consent were adequately explained to them (Q4); and did they understand what to expect after the procedure and how to contact the physician (Q5).

For discomfort associated with each procedure, patients were asked to rate the level of overall discomfort, as well as pain and anxiety during the procedure(s) on a 0 to 10 scale.

Statistical Analysis

Unpaired *t* test was used to measure significance of pain scores before and after procedures. Correlation between pain during the procedure and degree of pain relief after the procedures was also tested with Wilcoxon matched-pairs test (by using the Prism 3 statistic software).

RESULTS

A total of 566 patients (male: 262; female: 304; mean age: 52.9 years old) had the interventional pain management procedures during the period of survey. All of these patients participated in the survey. Patients were involved in a wide variety of pain relieving procedures as listed in Table 2.

Effectiveness

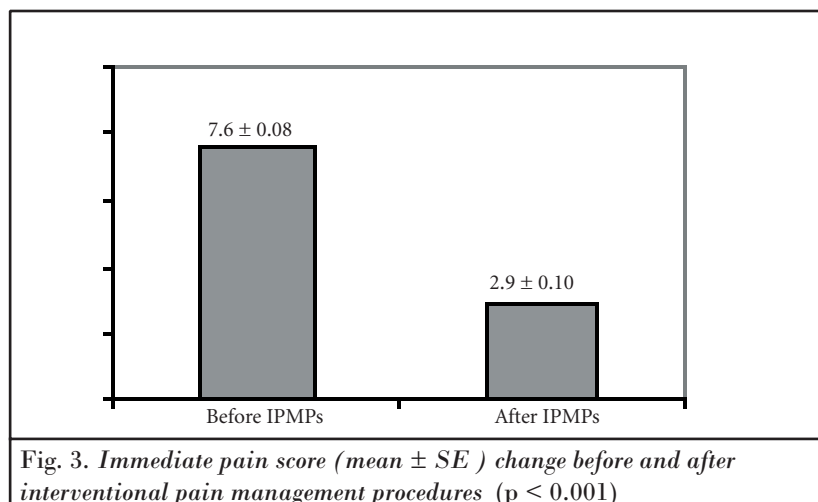
Eight patients had lumbar discography; since lumbar discography is a provocative diagnostic procedure, these patients were excluded from statistical tests for pain relief. Of the remaining 528 patients who reported their pain scores both before and after their interventional pain management procedures, 487 (92%) had various degrees of pain relief immediately following their interventions. Mean pain score

<u>Pain Management Center</u> <u>Anesthesia Quality Assessment</u>										
Procedure(s): _____										
Numeric Scale for Effectiveness of Therapy										
Pre-procedure: Pain scale 0 = no pain 10= worst pain										
0	1	2	3	4	5	6	7	8	9	10
Post-procedure: Pain scale 0 = no pain 10= worst pain										
0	1	2	3	4	5	6	7	8	9	10
Complications:										
<input type="checkbox"/> 1 No incidents <input type="checkbox"/> 2 Inadvertent subarachnoid puncture <input type="checkbox"/> 3 Inadvertent subarachnoid spinal analgesia <input type="checkbox"/> 4 Failed block <input type="checkbox"/> 5 Pneumothorax <input type="checkbox"/> 6 Seizure <input type="checkbox"/> 7 Coma <input type="checkbox"/> 8 Motor deficits in extremities <input type="checkbox"/> 9 Persistent sensory deficits in extremities <input type="checkbox"/> 10 Hypoxemia <input type="checkbox"/> 11 Hypotension <input type="checkbox"/> 12 Equipment failure <input type="checkbox"/> 13 Allergic or Anaphylactic reactions <input type="checkbox"/> 14 Unplanned RR or ICU admission <input type="checkbox"/> 15 Cardiac arrest <input type="checkbox"/> 16 Other (specify)										
Signature and ID# _____										
Date: _____										

Fig. 2. Post-procedure survey for physicians

Table 2. *Procedural characteristics*

Name of Procedure	Frequency
Bier block	4
Celiac plexus block	4
Lumbar disc decompression	5
Discography	8
Cervical epidural injection	37
Caudal epidural injection	24
Lumbar epidural injection	191
Thoracic epidural injection	5
Cervical facet joint block	5
Cervical facet radiofrequency	5
Lumbar facet block	39
Lumbar facet radiofrequency	6
Gasserian Ganglion block	5
Hip joint injection	2
L2 rami communicans block	5
L2 rami communicans radiofrequency	2
Lumbar sympathetic block	22
Nucleoplasty	3
Occipital nerve block	8
Orbital nerve block	2
Pyriformis muscle injection	10
Percutaneous adhesiolysis	13
Suprascapular nerve block	6
Saphenous nerve block	2
Spinal cord stimulator trial	8
Stellate ganglion block	8
Sacroiliac joint injection	36
Sphenopalatine ganglion block	2
Splanchnic nerve block	2
Cervical transforaminal epidural injection(s)	3
Lumbar transforaminal epidural injection(s)	78
Trigger point injection(s)	11
Vertebroplasty	5
Total	566



was 7.58 ± 0.08 before, and 2.87 ± 0.10 after interventional pain management procedures ($t=35.75$, $p<0.0001$) (Fig. 3). Average pain score decreased 4.7 after treatments. Forty-one (8%) patients reported no change or increased pain after interventional pain management procedures.

There was a negative relationship between pain during interventional pain management procedures and the degree of pain relief after interventional pain management procedures ($R^2=0.01431$, $p=0.013$). Patients who experienced more pain during the interventional pain management procedures were more likely to have less pain relief following treatment.

Adverse Effects and Patient Safety

Eight patients (1.4%) had fluctuations of blood pressure and heart rate during procedures, which required immediate action. Four patients (0.7%) had blood pressure elevation to over 200/100 mmHg during interventional pain management procedures; these procedures were canceled. The other four patients developed bradycardia and/or hypotension during the procedures. All patients were treated immediately and stabilized without long-term consequences (Table 3). A 37-year-old female developed chest pain immediately after a lumbar epidural steroid injection; her vital signs remained normal during the procedure. She was sent to the emergency room where tests ruled out myocardial infarction. A 48-year-old male had excessive cutaneous bleeding during a thoracic epidural steroid injection. Two patients had acute migraine attacks prior to lumbar epidural steroid injection. Procedures were canceled for all these three patients. A Gasserian ganglion block, a cervical epidural steroid injection, and a lumbar facet joint block had to be canceled due to patient discomfort.

No major adverse events defined as wrong patient, wrong needle insertion site, inadvertent intrathecal injection, intravascular injection, seizure, infection, paralysis, or death were reported in any patient.

Patients were NPO for six hours

Table 3. Cardiovascular Instability during interventional pain management procedure(s)

Age	Gender	Procedure	Event	Action
55	F	Lumbar epidural steroid injection	BP 218/122 during procedure	Procedure canceled
58	M	Lumbar sympathetic block	BP 218/122 during procedure	Procedure canceled
55	M	Lumbar epidural steroid injection	BP 218/122 during procedure	Procedure canceled
49	M	Lumbar epidural steroid injection	BP 218/122 during procedure	Procedure canceled
30	M	Cervical transforaminal epidural injection	HR below 50/m and BP below 90/40 mmHg	Procedure canceled. BP and HR return to normal within 2 min.
47	M	Cervical epidural steroid injection	BP 80/50 mmHg, HR 50/m	One liter of normal saline and 5mg of ephedrine were given. procedure canceled
55	F	Lumbar epidural steroid injection	HR below 50/m	Procedure canceled
28	M	Lumbar epidural steroid injection	Mild hypotension	Procedure completed

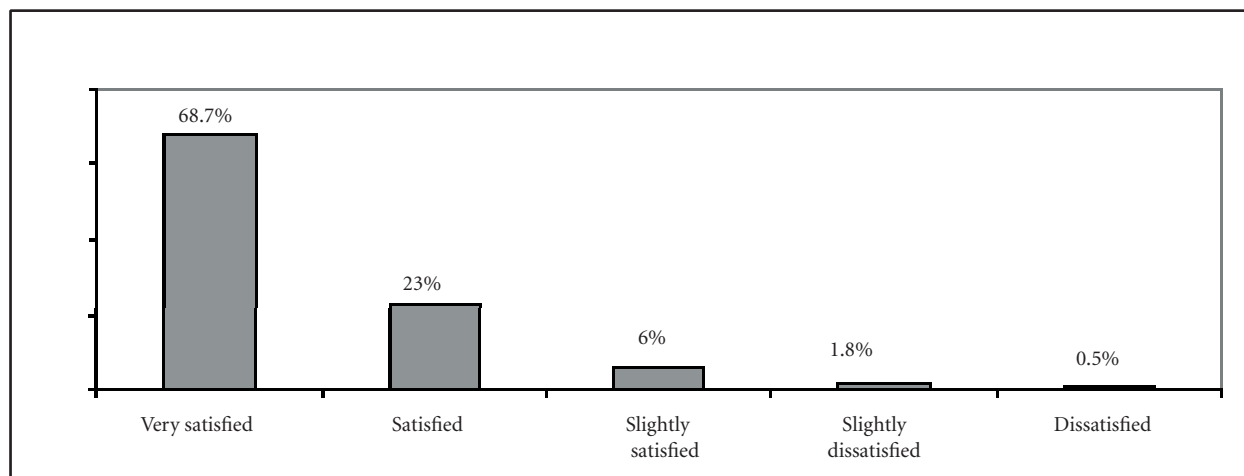


Fig. 4. Patient satisfaction with the immediate outcome of interventional pain management procedure(s)

for solid food and two hours for clear liquid, except for trigger point injections. None of the patients vomited or aspirated during interventional pain management procedures.

Patient Satisfaction

Four hundred forty-two patients answered the question regarding satisfaction. Four hundred six (91.8%) were satisfied or very satisfied with the results of interventional pain management procedures. Three hundred four (68.7%) patients were very satisfied; 102 (23%) satisfied; 28 (6%) slightly satisfied. Eight (1.8%) patients indicated they were unsatisfied with the result of interventional pain management procedures (Fig. 4). There is a significant correlation between decrease

of pain score and patient satisfaction ($R^2=0.05644$, $P<0.0001$). Patients with a higher level of pain relief tended to be more satisfied with the results of their treatment.

DISCUSSION

Results of the current study indicate that quality assurance techniques can be applied to interventional pain management procedures. A high quality interventional program with high rates of pain relief, low rates of complications and high patient satisfaction can be achieved through efforts to monitor, analyze and adjust the process of care.

Traditionally, studies on efficacy of chronic pain management have focused on long-term effects (16). How-

ever, the immediate effect of treatment is also critical for success in the management of chronic pain. Local anesthetics block the sodium channel and inhibit the conduction of pain information into the CNS. Most fluoroscopy-guided interventional pain management procedures deliver local anesthetics, frequently with corticosteroid, to an assumed pain source, such as a nerve root. Immediate pain relief could be expected if both clinical diagnosis and needle placement are accurate. Thus, the rate of immediate pain relief should be an indication of the accuracy of the clinical diagnosis as well as the correctness of needle placement. Furthermore, it could also reflect the appropriateness of patient selection. We believe that immediate pain re-

lief should be the first indicator for the quality of interventional pain management procedures.

Our data showed that 92% of patients had various degrees of pain relief immediately after procedures with a mean numeric pain score reduction of 4.7. Even though placebo effect plays a role in the results of treatment, the high rate of immediate pain relief in this study reflected our efforts to obtain an accurate diagnosis prior to interventional pain management procedures, strict control of procedure indication, as well as emphasis on the accuracy of needle placement. In interventional pain management procedures, immediate pain relief is usually the result of local anesthetic use, while long-term pain reduction appears to be the result of other components of the treatment, such as the anti-inflammatory effect of steroids for lumbar radicular pain (17, 18). A high rate of immediate pain relief could potentially forecast better long-term pain reduction. However, more studies are needed to confirm this hypothesis.

Patient safety has drawn major attention over recent years (19, 20). In interventional pain management procedures, many factors can affect the incidence of complications and patient safety. These factors include underlying medical conditions, medications, type of interventional pain management procedures, and the particular drugs injected, physician skill level, and patient preparedness, among others.

Various adverse reactions have been reported in interventional pain management procedures. For epidural steroid injection, these include spinal headache, abscess formation (21), epidural hematoma (22), acute retinal necrosis (23), meningitis, arachnoiditis and inadvertent subdural or subarachnoid injection, temporary quadriplegia (24), spinal cord infarction (25) and cerebellar infarction (26). Serious life threatening side effects can occur for many other interventional pain management procedures.

With the help of strict pre-procedure preparation and continuous monitoring of patients, as described in the methodology section, no major com-

plications were noted in our patient series. However, cardiovascular fluctuation was common in our study as has been reported by other investigators (27). The exact causes of cardiovascular fluctuation in this group of patients are not clear. However, age and history of hypertension may play a role. The four patients who developed critical hypertension in our study had a history of hypertension, and the mean age of these four patients was 54.3 years. The mean age of those who developed vasovagal response including bradycardia and hypotension was 40 years. None of these patients had history of hypertension. Because of the small sample (four patients in each group), age difference was not statistically significant. However, it is worthy of future research whether those with hypertension history and old age are more likely to develop critical hypertension and those with no history of hypertension, and young age are more likely to develop vasovagal response.

Ahmed et al (27) performed a survey among 105 pain practices in the US. In the 12 months prior to survey completion, 72% of responding pain physicians treated patients with vasovagal responses with a mean of 7.3 reactions occurring per practice (median 5, range 1-50). Six percent of respondents have dealt with cardiopulmonary arrest in the previous year, with a mean of 4.3 affected patients per practice. In the current study, four patients developed serious hypertension over 200/100 mm Hg. Two patients had bradycardia and hypotension. Two patients developed hypotension without bradycardia. Due to continuous monitoring, we were able to abort the pain procedure and start treating bradycardia and hypotension immediately. None of these patients developed a life threatening event.

To help avoid major complications, the authors have established the following rules: 1) avoid interventional pain procedures for those patients with serious cardiovascular risks, such as recent chest pain, MI, severe heart failure, respiratory failure, uncontrolled hypertension or hypotension; 2) continuous monitoring of heart rate, EKG and oxygen saturation throughout the proce-

cedure; 3) continuous verbal communication with patients during the procedure to disclose any symptoms such as dizziness, shortness of breath or severe pain; 3) immediate discontinuation of the procedure if there is any sign of cardiovascular instability, such as uncontrolled hypertension, bradycardia, hypotension, hypoxia and; 4) immediate treatment of any adverse reaction. By continuous monitoring of patients and immediate response, all four cases of vasovagal responses were stabilized within a few seconds to minutes. No one developed cardiovascular arrest.

Ahmed et al (27) reported various rates of cardiovascular monitoring during interventional pain management procedures across the nation. According to Ahmed et al (27), 89% to 92% of patients had blood pressure monitoring and 79% to 87% patients had pulse oximetry monitoring during cervical epidural steroid injections and facet joint blocks. Due to the potential seriousness of vasovagal reaction and cardiopulmonary arrest induced by interventional pain management procedures, it is suggested that all the patients undergoing spine procedures have continuous blood pressure, heart rate and pulse oximetry monitoring. An IV line should be inserted for high risk patients or procedures more likely to develop cardiovascular instability, such as cervical or lumbar sympathetic blocks.

Guidelines for interventional pain management procedures are needed to improve patient safety, decrease adverse reactions, and to increase the quality of care for patients undergoing interventional pain management procedures. Guidelines for peri-procedural protocols including NPO status, peri-operative monitoring and post-procedural care for all the interventional pain management procedures are essential.

Patient satisfaction is another critical indicator of the quality of health care. A positive relationship between the degree of patient satisfaction and the overall evaluation of the quality of health care has been reported (28). In our study, we utilized patient satisfaction as an outcome measure of quality. It was found that patient satisfaction is correlated with the overall pain decrease

after interventional pain management procedures; patients with greater pain relief after a procedure tend to be more satisfied with their treatments. There is no correlation between pain/discomfort during the procedures and patient satisfaction. The result suggests that patients are likely to forgive the discomfort or pain during the procedure as long as the treatment can provide adequate pain relief when it is finished. However, there is a negative relationship between pain during the procedure and pain relief after the procedures. Patients who experience more pain during the procedure are more likely to have less pain relief after the treatment. These results require practitioners to enhance their skills and reduce the pain during interventional pain management procedures in order to achieve a better treatment outcome.

The current study used pain relief, adverse reaction/patient safety and patient satisfaction as the main indicators for quality assurance for interventional pain management procedures. The study found that quality of interventional pain management procedures can be measured through systematic monitoring. A high quality interventional pain management procedures program, with a high rate of pain relief, a low rate of complications, and high patient satisfaction can be achieved through appropriate selection of patients, pre-procedural preparation, skillful execution of interventional pain management procedures, continuous monitoring of patients and post procedural care. However, results of the current study only reflect the quality of the interventional pain management program in one university teaching hospital pain center. Major differences most likely exist among various practices in the quality of patient care for interventional pain management procedures across the nation (27). Currently, no universal guidelines are available for the measurement of quality of interventional pain management procedures. We believe such guidelines are needed. The quality assurance methods described here may be used to monitor long-term efficacy and satisfaction of interventional pain

management procedures. Ultimately, this approach may improve long-term efficacy, reduce complications, and enhance patient satisfaction.

CONCLUSION

Quality of interventional pain management procedures can be monitored. Because no other quality assurance study on interventional pain management procedures were found through the literature search, data comparison is not possible until more data is published. However, the results of the current study indicate that quality assurance of interventional pain management procedures in terms of immediate pain relief following the procedure, low complication rate, and high patient satisfaction can be achieved through application of a quality assurance program.

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