Prospective Evaluation

Quality Assurance for Interventional Pain Management Procedures in Private Practice

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Background: A recent study has indicated that quality assurance for interventional pain management procedures (IPMPs) can be achieved in university pain clinics. However, the issue of quality assurance for IPMPs in private practice has not yet been addressed.

Objective: This study was designed to monitor the quality of IPMPs in a private pain practice in north Florida.

Methods: From November 2005 to July 2006, we monitored the quality of IPMPs in a private pain practice in north Florida. Questionnaires regarding degree of pain relief, patient satisfaction, and complications were handed to patients immediately after the completion of each IPMP. Follow-up phone calls were also made to patients 1 day after the IPMPs.

Results: A total of 771 (male: 249, female: 522) patients with a mean age of 58.1 years participated in the study. Office-based IPMPs included lumbar and cervical epidural steroid injections, lumbar and cervical facet joint blocks, selective nerve root blocks, lumbar and cervical sympathetic nerve blocks, sacroiliac joint injection, and large joint injections. Seven-hundred patients (90.8%) reported various degrees of pain relief immediately following IPMPs. Average pain score decreased by 4.3 on a 0 to 10 scale (p=<0.001). Number needed to be treated (NNT) to reach 50% or more pain relief immediately after IPMPs was 1.4. Six-hundred ninety-two (89.7%) patients were satisfied or very satisfied with the results of IPMPs. sixty-two patients (8%) developed headaches after IPMPs, which lasted from 30 minutes to 4 days. None of these patients required a blood patch. Five patients developed moderate vasovagal responses during IPMPs, in which their heart rates decreased to <45/min, BP <90/60mmHg. The IPMPs were aborted immediately. All of these patients recovered uneventfully within a few minutes. No other serious adverse events were reported.

Conclusions: The results of the current study suggest that high quality private interventional pain programs with high efficacy, high patient satisfaction, and low complication rates can be achieved through appropriate staff training, proper monitoring of patients during IPMPs, and adequate handling of patients after the IPMPs.

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

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Quality assurance for interventional pain management has yet to be established. Interventional pain management is a relatively new field with a history of less than 2 decades. Even though it has gained a rapid development over the last decade and multiple evidence-based guidelines for interventional pain management procedures (IPMPs) have been published (1-3), the issue of quality assurance in interventional pain management has not been well addressed. According to the Medicare database, from 1998 to 2005, there was a 179% increase of IPMPs in the USA (1,406,417 in 1998 and 3,925,467 in 2005, respectively). The majority of IPMPs are performed in private practices. Serious complications, such as quadraparesis and cardiovascular arrest have been reported as the results of IPMPs (4,5). Patient safety standards during the IPMPs have yet to be established.

Zhou et al (6) published the first research study on quality assurance in a university pain clinic in 2006. In that study, the authors used 3 indexes to measure the quality for IPMPs. These criteria included degree of immediate relief, patient satisfaction, and rate of adverse effects. Various degrees of pain relief was reported in 92% of patients immediately after IPMPs, with an average pain score decrease of 4.7 on a 0 to 10 scale. The percentage of patients who were satisfied or highly satisfied with the immediate outcome of IPMPs, was 91.8%. No major complications were reported for that group of patients. The authors concluded that quality assurance for IPMP could be achieved in university pain clinics. The program can be used to train fellows and residents to be aware of the importance of quality assurance for IPMPs before the majority of them leave the training programs and join teams of private practices in the community.

"Pay for performance" has been well addressed over the last decade and has been promoted by Medicare and several large health insurance carriers (7,8). The goal of the "pay for performance" program is to improve the quality of care, recognize practitioners who provide higher-quality care, and help providers align their practices with national standards (9). The main component of "pay for performance" is quality of care. During the next few years, some portion of physician reimbursement will be increasingly based on the quality and efficiency of services. Private payers are already rewarding primary care physicians for practices that adhere to quality standards, are efficient, involve information technology, and result in high patient satisfaction. The Centers for Medicare and Medicaid Services have completed the development of performance measures to be used in Medicare payment strategies for all specialties by the end of 2006, and anticipates phasing in the program by 2008 (10).

With the increasing numbers of IPMPs performed in private practices, possibility of serious consequences of adverse effects from IPMPs, and developing trend of "pay for performance," quality assurance for IPMPs in private practice has the potential to become a part of routine clinical practice in the near future. However, to date, studies addressing quality assurance for IPMPs in private pain practices have been very scant.

The current study was designed to monitor quality assurance for IPMPs in a private pain practice in north Florida. The study used degree of immediate pain relief, patient satisfaction, and risks associated with IPMPs as measures for the quality assurance for IPMPs, with the purpose of enhancing the efficacy of IPMPs, improving patient satisfaction, and reducing possible risks associated with IPMPs in private pain practice.

Methods

From November 2005 to July 2006, we monitored the quality of IPMPs in a private pain practice in north Florida. To ensure the quality of care, the following steps were taken before, during, and after IPMPs:

1) each patient was seen by an attending physician with a board certification in pain medicine;
2) a complete history, detailed physical examination, and reviewing of MRI/CT reports and films of the spine were all performed by a board certified physician before a diagnosis was formulated;
3) an IPMP was prescribed according to the patient's diagnosis following the procedure indication in the second edition of the *Massachusetts General Hospital Handbook of Pain Management*;
4) each procedure was explained to the satisfaction of the patient;
5) a pre-procedure instruction was handed out to each patient;
6) on the day of the IPMPs, vital signs, pain severity, medications, possible contraindications, diagnosis, name, and site of the procedure were re-checked prior to taking the patient into the procedure room (Table 1);
7) procedures were rescheduled or canceled if any of the conditions listed in Table 2 were present;
8) an intravenous access was obtained for all cervical procedure and sympathetic blocks;

Table 1. *Pre-procedure and post-procedure check list.*

Pre-procedure:

1. Diagnosis_____
2. Procedure to be done_____, side_____, level_____
3. Vital signs:
   a. Blood pressure _____mmHg
   b. Heart rate_____/m
   c. Respiration rate__ /m
   d. Temperature _____F
   e. Pain score_____/10
4. Allergy:
   a. Latex Yes__ No__
   b. Betadine Yes__ No__
   c. Contrast Yes__ No__
   d. Steroid Yes__ No__
   e. Lidocaine Yes__ No__
   f. Other Yes__ No__
5. Risk factors
   a. Local or systemic infection. Yes__ No__
   b. BP > 155/95 mmHg or below 90/50 Yes__ No__
   c. Eat solid food within 6 hours or drink within 2 hours. Yes__ No__
   d. Recent history of chest pain or shortness of breath Yes__ No__
   e. Take Coumadin with 5 days Yes__ No__
   f. Take Plavix, or other anticoagulant medications for at least 7 days prior to the procedure. Yes__ No__
   g. Taking Glucophage (metformin) Yes__ No__
   h. Person to drive home. Yes__ No__
   i. Date of last period for female _____

Post Procedure:

1. Pain score: /10
2. Complications:

Physician Signature_____

9) a "time out" was called immediately by the attending physician prior to IPMPs to confirm the patient's name, diagnosis, type, and site of the procedure;
10) during the procedure, blood pressure, heart rate, pulse oximetry, and mental status were continuously monitored. The physician performing IPMPs was constantly talking with the patients to monitor the cognitive status of the patients. Patients were instructed to report any abnormal feelings, such as increased local pain, dizziness, chest pain, metallic taste in the tongue or feeling of fainting to the physician immediately.
11) fluoroscopy was used to ensure the correct final locations of the needle tips for IPMPs;
12) upon completion of the IPMPs, patients were sent to a recovery room and observed for at least 15 minutes prior to discharge with an adult. Patients were not allowed to drive after the IPMPs.

Table 2. *Conditions for which IPMPs were rescheduled or canceled*

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

The study was conducted in a private pain practice in north Florida even though the principle investigator has a courtesy faculty position in a local state university. However, the facility where the research was conducted was not officially affiliated with the university. So no IRB was submitted to the local university for approval. However, every effort was taken to ensure that the research protocol follows the Ethical Principles for Medical Research Involving Human Subjects by the

Table 3. Post procedure survey.

(Please circle your answers)

1. **Select the phrase that indicates how satisfied or dissatisfied you are with the way you were treated by our staff before, during and after the procedure?**
   - **(a) Very satisfied**
   - **(b) Satisfied**
   - **(c) Slightly satisfied**
   - **(d) Slightly dissatisfied**
   - **(e) Dissatisfied**
   - **(f) Very dissatisfied**

2. **Select the phrase that indicates how satisfied or dissatisfied you are with the results of the pain relieving procedure.**
   - **(a) Very satisfied**
   - **(b) Satisfied**
   - **(c) Slightly satisfied**
   - **(d) Slightly dissatisfied**
   - **(e) Dissatisfied**
   - **(f) Very dissatisfied**

3. **Were the procedure and the consent adequately explained to you?**
   (a) Yes (b) No If no, please explain…

4. **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**

5. **On this scale, how much anxiety did you have right before the procedure (0: no anxious, 10: most anxious)?**
   0 1 2 3 4 5 6 7 8 9 10

6. **On this scale, how painful was the procedure itself (0: no pain, 10: worst pain)?**
   0 1 2 3 4 5 6 7 8 9 10

7. **On this scale, how much pain were you having just before the procedure (0: no pain, 10: worst pain)?**
   0 1 2 3 4 5 6 7 8 9 10

8. **On this scale, how much pain are you having now, following the procedure (0: no pain, 10: worst pain)?**
   0 1 2 3 4 5 6 7 8 9 10

THANK YOU VERY MUCH FOR ANSWERING THESE QUESTIONS

World Medical Association Declaration of Helsinki. Following measures were exercised throughout the study:

1) the principle investigator was a well trained physician with years of experience and a history of publications and research involving human subjects;
2) an informed consent was obtained from each subjects participating the research. The subjects were informed regarding the purpose, benefit, and possible risks of the study. The subjects had the right to chose whether to participate in the study without affecting their treatment;
3) all subjects had no extra medical risks or financial burden by participating the study;
4) all research related documents were initially kept in a locked drawer controlled by the principle investigator. Then the data was entered into a password-protected computer only accessible to the principle investigator;
5) no patient identity was revealed or patient privacy was violated due to participating of the study.

Immediately following the IPMPs, patients were asked to complete a questionnaire (Table 3). There were a total of 8 questions grouped into 3 categories:

1) efficacy of the procedure;
2) adverse effects experienced during and immediately after the IPMPs; and
3) patient satisfaction.

Data were collected before patients were discharged. Physicians reevaluated the patient's VAS pain score within 10 minutes after the procedure and documented any adverse reaction on the pre- and post procedure check list

(Table 1). Each patient was contacted by a medical assistant through a phone call the day after the procedure regarding the efficacy of and any side effects from the IPMPs.

Patients' pain scores immediately prior to and following the IPMPs were utilized to measure the short-term efficacy of the treatment. Pain was assessed on a 0 to 10 scale (0: no pain, 10: worst pain) (Q7 and Q8, respectively).

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 (Q3); and did they understand what to expect after the procedure, and how to contact the physician (Q4).

For discomfort and anxiety associated with the procedure, patients were asked to rate the level of pain during the IPMPs and anxiety level immediately before the procedure on a 0 to 10 scale (Q5 and Q6, respectively).

Statistics

Statistical software StatGraphics™, version XV, was used for data analysis. Analysis of variance (ANOVA) and unpaired t-tests were conducted to examine the pain score before and after procedures among the various groups. Correlation between pain during IPMPs and degree of pain relief after IPMPs was also tested.

Results

A total of 771 (male: 249, female: 522) patients with a mean age of 58.1 years participated in the study. Office-based IPMPs included lumbar, thoracic, and cervical epidural steroid injections (ESI); lumbar and cervical facet joint blocks; selective nerve root blocks; lumbar and cervical sympathetic nerve blocks, sacroiliac joint injections; and large joint injections. Other spine procedures such as discograms, spinal cord stimulator trials and implantations, intrathecal pump implantations, disc decompressions, and vertebroplasty were performed in a hospital during the same period of the research. These patients were not included in the Q&A study for the office based IPMPs. Table 4 lists the names of the IPMPs.

Pain Relief

Of 771 patients, 700 (90.8%) reported various degrees of pain relief immediately following IPMPs. Mean VAS pain score was 6.7 ± 1.99 and 2.4 ± 2.5 before and after IPMPs, respectively. The average pain score decreased by 4.3 on a 0 to 10 scale after IPMPs ($t = 37.2$, $P<0.001$) (Fig. 1). Among 771 patients, 537 (69.7%) reported 50% or more pain relief immediately after IPMPs. The number needed to be treated (NNT) to reach 50% or more pain relief immediately after IPMPs was 1.4.

Table 4. *Procedures performed in the study.*

Name of procedure	Numbers
Blood patch	1
Cervical ESI	110
Lumbar/caudal ESI	425
Thoracic ESI	17
Cervical facet joint block	4
Lumbar facet joint block	101
Hip joint injection	7
Lumbar sympathetic block	2
Stellate ganglion block	5
Sacroiliac joint injection	67
Lumbar selective nerve root block	32
Total	771

ESI: epidural steroid injection

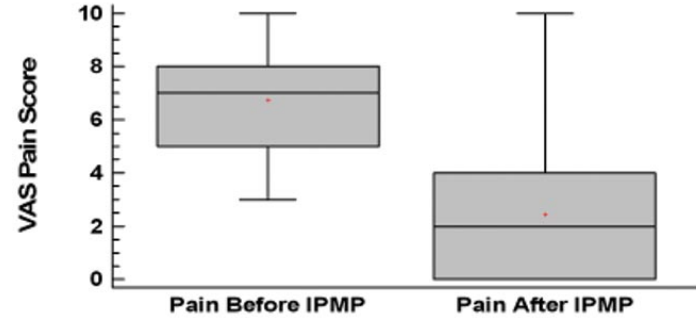

Fig. 1. *Mean VAS pain score changes before and after IPMPs. There was a significant decrease of pain scores after IPMPs. (Mean ± SD)*

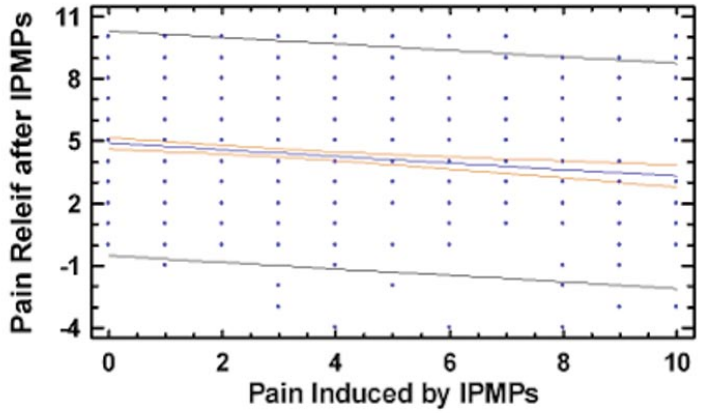

Fig. 2. *Negative correlation between pain during IPMPs and pain relief after IPMPs. Patients experiencing more pain during the IPMPs tend to have less pain relief after the IPMPs.*

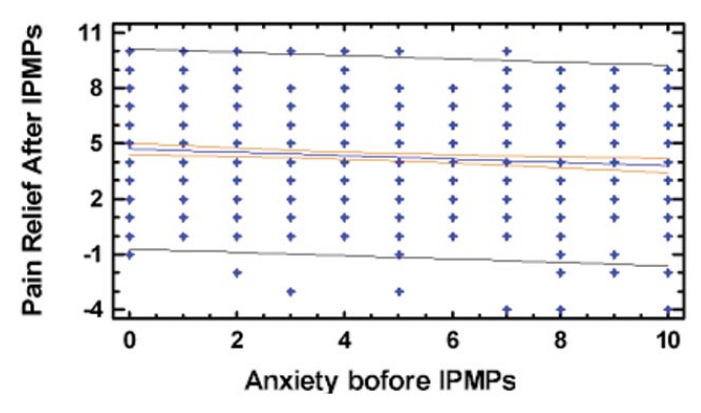

Fig. 3. *Negative correlation between anxiety before the IPMPs and pain relief after the IPMPs. Patients with a higher score of anxiety before the IPMPs were more likely to have less pain relief after the IPMPs.*

Six hundred fifty-six (85%) of 771 patients reported some degree of procedure-induced pain during IPMPs with an average pain score of 3.55 on a 0 to 10 scale, with 0 for no pain and 10 for the worst pain. There was a negative correlation between pain during IPMPs and pain relief after IPMPS (Correlation Coefficient = -0.148388, *P*=0.0000). Patients experiencing more pain induced by IPMPs tend to have less pain relief after IPMPs (Fig. 2).

Six hundred seventeen (80%) of 771 patients reported some degree of anxiety immediately before IPMPs, with an average anxiety score of 5.18. There was a negative correlation between anxiety immediately before IPMPs and pain relief after IPMPs (Correlation Coefficient = -0.108842, *P*=0.0000). Patients with a higher anxiety level before IPMPs tend to have less pain relief after IPMPs (Fig. 3).

Patients had slightly different immediate responses to different IPMPs, but without statistical significance. The average VAS pain score decreased immediately by 3.9, 5.0, 4.3, 4.4, 4.6, and 4.2 for cervical ESI, thoracic ESI, lumbar ESI, lumbar facet joint block, SI joint injection, and lumbar selective nerve root block, respectively. ANOVA revealed no significant differences for results of immediate pain relief among these six IPMPs (F=0.98, *P*=0.42).

Patient Satisfaction

Of 771 patients, 736 (95%) were slightly satisfied to very satisfied with the results of the

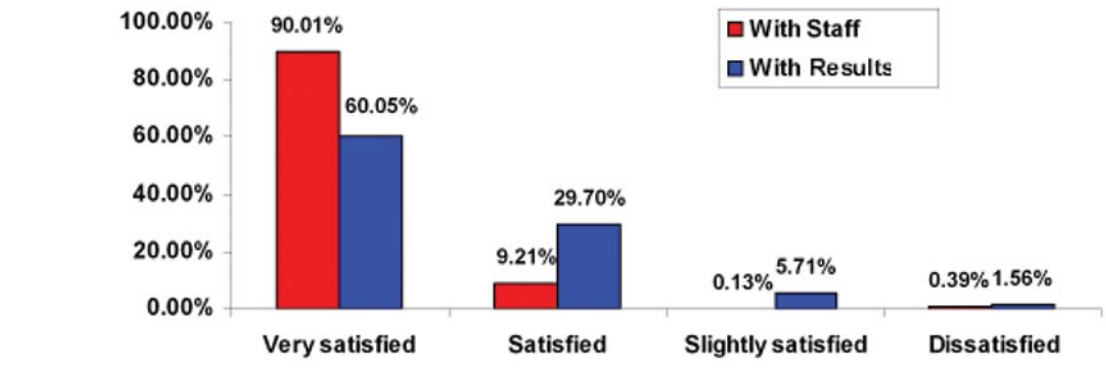

Fig. 4. *Patient satisfaction with the staff and the results of the IPMPs. Majority of patients were very satisfied with both the staff and the results of IPMPs. More patients were very satisfied with the staff than with the results of IPMPs.*

Fig. 5 *Relationship between level of satisfaction and degree of pain relief. Patients with a higher level of pain relief tend to be more satisfied with the results of the IPMPs*

Fig. 6. *Relationship between levels of satisfaction with the results of IPMPs and pain induced by the IPMPs. Patients who experienced less pain during IPMPs tend to be more satisfied with the results of the IPMPs.*

IPMPs. Among them, 463 (60%) were very satisfied, 229 (29.7%) were satisfied, and 44 (5.77%) were slightly satisfied. Thirteen (1.56%) patients were slightly dissatisfied to very dissatisfied with the results of the IPMPs (Fig. 4).

The level of satisfaction with the results of the IPMPs was related to the degree of pain relief. ANOVA revealed that there was significant difference for the average scores of pain relief among patients with different levels of satisfaction (F=35.75, *P*=0.000) (Fig. 5). Patients with a high level of pain relief tend to be more satisfied with the results of the IPMPs.

The level of satisfaction with the results of the IPMPs was also negatively related to the severity of pain induced by IPMPs. ANOVA revealed that there was a significant difference for the average scores of pain during IPMPs among the groups with different levels of satisfaction (F=23.83, *P*=0.000) (Fig. 6). Patients who experienced more pain during IPMPs are less likely to be satisfied with the results of IPMPs. The group with slight satisfaction for the results of IPMPs had significantly higher pain scores during IPMPs than those in the satisfied group (t = 2.4203, *P* = 0.016). While those highly satisfied with the results had significantly less pain during IPMPs than both the slightly satisfied and satisfied groups (*P*<0.05). There is no statistical difference between the pain score for the dissatisfied group and any of the other 3 groups, possibly due the fact that only 12 patients were in the

Fig. 7. *Relationship between patient satisfaction and anxiety immediately before the IPMPs. Patients with higher score of anxiety immediately before the IPMPs tend to be less satisfied with the results of IPMPs*

dissatisfied group leading to a very small sample and less statistical power (Fig. 6).

The level of satisfaction with the results of the IPMPs was also negatively related to the degree of anxiety immediately before IPMPs (Fig. 7). ANOVA revealed a statistically significant difference for the average anxiety scores among the patients with different levels of anxiety immediately before IPMPs (F=4.28, *P*=0.0052). Patients with higher levels of anxiety tended to be less satisfied with the results of the IPMPs. The mean anxiety score for the satisfied group was significantly higher than that of the highly satisfied group (*t*=3.02958, *P*=0.002). The mean anxiety score for the slightly satisfied group was significantly higher than that of the satisfied group (*t*=2.252, 38 *P*=0.02).

In response to the question of how satisfied they were with the way they were treated by our staff, 99.27% were satisfied to very satisfied. Among them, 90.01% were very satisfied; 9.2 % were satisfied; and 0.13% were slightly satisfied (Fig. 2). More people expressed a higher level of satisfaction with the way they were treated by our staff than with the results of the treatment (90.01% vs. 60.05%), (x^2 =195.562, *P*=0.0000).

Adverse Reactions

Fifteen patients had a mild decrease in heart rate to below 60/min during the IPMPs, with no other symptoms of vasovagal response such as dizziness, flushing, palor, diaphoresis, or piloerection. These patients were all instructed to take deep breaths. Ten patients responded successfully and their heart rate returned to above 60/min. The IPMPs were finished without complications.

Psychological distraction may decrease the stress level and reverse the bradycardia during IPMPs. One patient had a baseline heat rate of 65 to 70/m. However, when the cervical epidural needle was inserted, her heart rate decreased to 45/m. The patient was nervous but not feeling dizzy or hot. There were no diaphoresis or piloerection. The treating physician was almost ready to abort the procedure. However, the physician asked the patient about her grandchildren. The tone of patient's voice improved immediately and sounded less nervous when she started to talk about her grandchildren. At the same time, her heart rate increased from 45/min to 60/min. The procedure was finished without any adverse consequences.

Five patients developed vasovagal responses during the IPMPs, in which their heart rates decreased to <45/min, BP <90/60mmHg. The patients all felt dizzy, hot, or sweaty. Needles were pulled out immediately and the IPMPs were aborted. All of these patients recovered uneventfully within a few minutes. No patient needed IV fluid or intravascular medications, such as epinephrine or atropine, to treat their hypotension or bradycardia. No other serious adverse events, such as cardiovascular arrest, loss of consciousness, infection, or paralysis, were noticed during and after the IPMPs.

Sixty-two patients (8%) developed headaches, which lasted from 30 minutes to four days. Fifty-six (7.2%) of them had mild headaches. Six (0.8%) of these patients had severe headaches. Most of these patients responded to oral acetaminophen or bed rest. None of these patients required a blood patch. The only blood patch performed during the study was for a case after a spinal cord stimulator trial, on a patient with a history of

TESI: Thoracic epidural steroid injection
CESI: cervical epidural steroid injection
LESI: lumbar epidural steroid injections
L Facet: lumbar facet joint block
SI Inj: sacroiliac joint injection
SNRB: lumbar selective nerve root block.

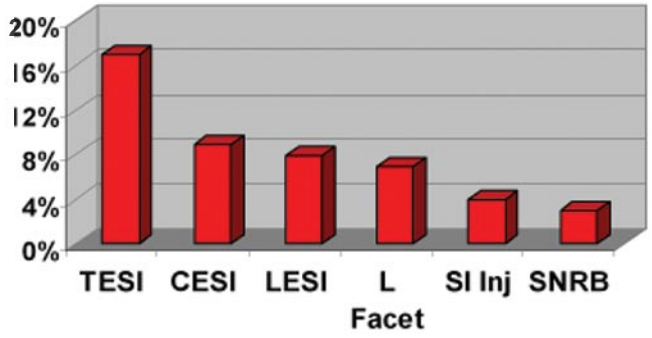

Fig. 8. *Risks of headache after IPMPs. Note that not only patients after epidural steroid injections had headaches after the IPMPs. Patients with lumbar facet joint block, SI joint injection, and selective nerve root block also had headaches after IPMPs. There were numerical differences among 6 groups for the risks of headaches after the IPMPs. However, there was no statistical significance.*

multiple lumbar spine surgeries. Apparently, there was scar tissue formation in the epidural space involving the dura. Epidural placement of the electrode resulted in dura puncture and subsequent spinal headache.

Headache was common after IPMPs. It could occur after epidural steroid injections, as well as other procedures, such as lumbar facet joint blocks or SI joint injections. Two of the 4 patients with cervical facet joint blocks had headaches after the procedures. However, their headaches were pre-existing. For other procedures, the risks of headache were 17%, 9%, 8%, 7%, 4%, and 3% for TESI, CESI, LESI, lumbar face joint block, SI joint block, and lumbar selective nerve root block, respectively (Fig. 8). There was no statistical significance among the 6 groups (x^2 =14.1, *P*=0.2912) for the risks of headache after IPMPs.

Discussion

The results of the current study indicate that quality assurance for interventional pain management can be achieved in private practice, with the purpose of enhancing the efficacy of IPMPs, increasing the patient satisfaction, and decreasing the risks associated with IPMPs. The current study found that 90.8% of patients reported various degrees of pain relief immediately following IPMPs with an NNT of 1.4 for IPMPs. The average pain score decreased by 4.3 on a 0 to 10 scale. 89.7% patients were satisfied or very satisfied with the results of IPMPs. The current study also found that headache is common (8%) after epidural steroid injections, as well as other IPMPs. Vasovagal response is another common and potentially serious complication during IPMPs. Special attention must be paid and swift reactions are needed to treat vasovagal response during IPMPs.

Clinical Efficacy

Immediate pain relief after IPMPs has been proposed as the first indicator for the quality assurance for IPMPs (6). The degree of immediate pain relief after IPMPs reflects the accuracy of pretreatment diagnosis, appropriate utilization of procedure indications, as well as the correctness of needle placement. In the current study, the authors implemented a series of measures to ensure the accuracy of clinical diagnosis, appropriate selection of patients for IPMPs, and accuracy of needle placement as described in the methodology section. With these measures, the current study found that 90.8% patients reported various degrees of pain relief immediately following IPMPs. The results are comparable to what has been reported (92% immediate pain relief) from a university pain clinic (6).

The results of the current study also suggest that a high rate of immediate pain relief can be achieved in private pain practices as long as practitioners in private practices take appropriate measures to ensure the quality of their care, even though physicians in private practices usually have to see a higher volume of patients and are required to perform more IPMPs in a given time unit.

The current study also found 2 major factors that can affect the results of IPMPs. Patients with higher anxiety levels before IPMPs and those who experienced more

procedure-induced pain during IPMPs tend to have less pain relief after IPMPs. These results confirm the findings of Zhou et al's previous report (6). These findings also suggest that treating physicians should enhance their skills to decrease patient anxiety levels and procedure-induced pain in order to increase the efficacy of their treatment.

Immediate pain relief after IPMPs is often the results of the blockage of sodium channels and nerve conduction by local anesthetics. Most fluoroscopy-guided IPMPs deliver local anesthetics, frequently with corticosteroid, to an assumed pain source, such as a nerve root or a joint. Immediate pain relief could be expected if both clinical diagnosis and needle placement are accurate, regardless of the source of pain. The current study found that the degrees of immediate pain relief are comparable for various types of IPMPs, such as CESI, TESI, LESI, lumbar facet joint block, SI joint injection, and lumbar selective nerve root blocks. This result probably reflects the equal accuracy of the diagnosis and needle placement for various IPMPs by the same treating physician.

The concept of number needed to treat (NNT) to reach 50% or more pain relief has been used to evaluate the clinical efficacy of various medications for pain management. However, NNT has not yet been used to evaluate the results of immediate pain relief in interventional pain management. The current study found an NNT of 1.4 for IPMPs in the private practice. This result indicates that the concept of NNT can be used as an index of quality assurance to evaluate the immediate results of various IPMPs, and could be potentially used to compare the efficacy of treatment between different practices.

Patient Satisfaction

In the current study, 89.7% patients were satisfied to very satisfied with the immediate results of the IPMPs. The degree of satisfaction is correlated with the degree of pain relief. Patients with a high level of pain relief tend to be more satisfied with the results of the treatment. This finding further confirms Zhou et al's previous report (6). The current study also found that patients' satisfaction with the results of IPMPs was negatively related to both the anxiety level immediately before IPMPs and procedure-induced pain during IPMPs. Patients with higher anxiety levels before IPMPs and those who experienced more procedure-induced pain tended to be less satisfied with the results of IPMPs. These results suggest that treating physicians should not only pay attention to enhance the efficacy of IPMPs, but they should also try to decrease the anxiety level before IPMPs and enhance their skills to decrease the procedure-induced pain during IPMPs, in order to increase the level of patient satisfaction with the results of IPMPs.

Patient satisfaction with the results of IPMPs can be affected by the limitation of current technology. However, patient satisfaction with the staff of the clinic is related more to human factors. To ensure the patients' satisfaction with the staff of our pain clinic, all the staff members were appropriately trained to follow the measures illustrated in the methodology section. Weekly noon pain conferences were conducted in our pain clinic throughout the year to educate the physicians, physician's assistants, medical assistants, secretaries, and other supporting staff. All the staff members were instructed to treat patients with care and respect. As a result of these efforts, 99% of patients were satisfied to highly satisfied with the way they were treated by our staff. More patients were highly satisfied with our staff than the results of IPMPs (90.01% vs. 60.05%). This finding indicates that despite the limitation of current technology, patients can still be highly satisfied with the staff in the pain clinic even if they may not be highly satisfied with the results of IPMPs. Our results further confirm Hirsh et al's previous findings (11). Satisfaction with treatment of chronic pain is not merely a matter of pain relief. The interpersonal aspects of the health care provider-patient relationship appear critical to the overall satisfaction with the quality of health care.

Patient Safety

Vasovagal responses (VVR) are common during IPMPs and can lead to serious consequences if they are not handled on time and appropriately. The authors believe that the severity of vasovagal response during IPMPs can be divided into 3 classes according to their severity: mild, moderate, and severe (Table 5). Patients with mild VVR usually have their heart rates decrease to between 45 to 60 min without feeling dizziness, hotness, or sweating. Their heart rates may return to normal after deep breaths, psychological distraction, or temporarily holding the manipulation of needles during IPMPs. Moderate VVR can decrease a patient's heart rate to below 45/min; they may feel dizzy, hot, or sweaty; their blood pressure may be below 90/50 mmHg. However, these patients are still awake. It is critical for treating physicians to continuously monitor patients and find the critical conditions in this stage. These patients' symptoms can usually be reversed if the IPMPs are aborted immedi-

Table 5. *Severity of vasovagal response during IPMPs and treatment.*

Severity	Symptoms	Handling
Mild	Heart rate: 45 to 60 min. BP: normal No dizziness, flushing, palor, diaphoresis or piloerection	Deep breathing, distracting, continue monitoring Temporary holding the procedure
Moderate	HR: <45 min, BP <90/50 Patient feels hot, dizzy, flushing diaphoresis and/or piloerection	Pulling the needle out, immediately discontinue procedure, O2, IV fluid
Severe	Cardiovascular arrest, BP: 0	Cardiovascular resuscitation

ately. These moderate VVR have been reported in both the current study and Zhou et al's previous report (6). Severe vasovagal response can lead to cardiovascular arrest and other serious consequences.

Ahmed et al (12) performed a survey among 105 pain practices in the U.S. 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. Six percent of respondents have dealt with cardiopulmonary arrest in the previous year, with a mean of 4.3 affected patients per practice. According to Ahmed, only 89% to 92% of patients had blood pressure monitoring and 79% to 87% patients had pulse oximetry monitoring during cervical ESI and facet joint blocks. It is not known whether the practices with a high percentage of vasovagal responses and cardiopulmonary arrest have low rates of cardiovascular monitoring during IPMPs. However, results of the current study and Zhou et al's previous report (6) both indicate that bradycardia is a common early sign of vasovagal response during IPMPs, and that bradycardia during IPMPs can be easily reversed by pulling out the needle immediately after they are noticed. It is possible that untreated bradycardia and vasovagal response during IPMPs could lead to cardiovascular arrest. Due to continuous monitoring of the patients and swift response to bradycardia, none of the patients in the current study developed cardiovascular arrest as a result of untreated vasovagal response. The authors believe that each patient undergoing IPMPs should have their cardiovascular system monitored so that the treating physician can make a quick reaction to a vasovagal response before the cardiovascular arrest occurs.

Risk of vasovagal response during the IPMPs was a major concern and a focus of the current study. In the current study, 15 of 771 patients (1.9%) had a mild decrease in heart rate to below 60/min during the IPMPs without other symptoms of vasovagal response and fluctuation of blood pressure (mild vasovagal response). Only 5 out of 771 patients (0.6%) developed moderate vasovagal response with heart rate <45/min, BP <90/60mmHg. No patients developed cardiopulmonary arrest. Zhou et al published the first QA study for IPMPs in 2006. The study was conducted in a teaching hospital at the University of Miami. In that study, 1.4% patients had a fluctuation of blood pressure and heat rate during IPMPs (moderate vasovagal response). In Ahmed et al's study, 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. Six percent of respondents have dealt with cardiopulmonary arrest in the previous year, with a mean of 4.3 affected patients per practice. In both Zhou et al's and Ahmed et al's studies, the rate of mild vasovagal response (mildly decreased heart rate without other symptoms of vasovagal response and fluctuation of blood pressure) were not specifically studied and reported. Comparing all the available data, the authors believe the rate of moderate to severe vasovagal response is not high in the current study (0.6% in the current study vs. 1.4% in Zhou et al's study in 2006). Actually, by actively monitoring the patients and quickly and appropriately handling the mild vasovagal response, we may have prevented possible serious consequences such as cardiopulmonary arrest.

Headache after spine injections have been well documented (13-15). The common assumption is that epidural insertion of the spinal needle causes a small dural puncture, which leads to a positional headache. In rare cases, pneumocephalus and headache have been reported as a result of epidural steroid injections (16,17). In the current study, it was found that not only patients with epidural steroid injections may develop headaches, patients with other spine injections, such as lumbar facet joint block and SI joint injection, can also develop mild headaches. There was a numerical difference without statistical significance among risk of headaches after various types of IPMPs, including

lumbar facet joint block, SI joint injection, and lumbar selective nerve root blocks. Headaches after lumbar facet joint blocks and SI joint injections have not been well documented. The results of the current study indicate that 7% and 4% of patients may develop mild headache after lumbar facet joint blocks and SI joint injections, respectively. These headaches are usually mild and respond to oral acetaminophen and bed rest, and resolve within few days without major consequences. The mechanism of the headaches after lumbar facet joint blocks and SI joint injections remains unclear. Possible explanations include stress associated with the procedure, or medications used in the procedures such as triamcinolone (18,19). The results of the current study also suggest that not all of the headaches after epidural steroid injections are the result of a dura puncture, because other spine injections such as lumbar facet joint blocks and SI joint injections can also induce headache. As long as the headaches respond to oral acetaminophen and rest, and resolve within less than 3 to 4 days, no blood patches are indicated.

In the current study, 8% patients reported headaches after IPMPS. This incidence may seem high. It is probably related to the method of data collection. We obtained the number of 8% by actively calling the patient the day after the procedure. The majority of headaches were mild (56 of 60 patients reporting headaches). Only 4 out of 771 patients reported severe headaches. If patients were not actively contacted the day after IPMPs, most of them would likely not call and report a mild headache. The incidence of headaches may be much lower. To the date, no other systemic prospective study data regarding the incidence of headaches after IPMPs is available. It will be possible to compare the rate of headaches between different studies and decide whether the incidence of headaches in this study is higher or lower when more data are available.

In this study, none of the 62 (8%) patients with headaches after IPMPs required blood patches. Stojanovic et al (20) found that during epidural steroid injections, there is a 30% chance that the tip of the epidural needle may land in an inaccurate space by using a loss of resistance technique alone. In the current study, all epidural steroid injections were performed under guidance of fluoroscopy. Epidural steroid injections were performed after the needle reached the epidural space and were confirmed by AP and lateral fluoroscopy. The fact that none of the patients needed blood patches indicates that none of the patients had severe dura puncture due to inappropriate needle placement. It is possible that the fluoroscope guidance of the spine procedure cannot only increase the accuracy of needle placement, but also decrease the risks of adverse effects, such dura puncture and subsequent headaches.

Conclusion

The results of the current study suggest that quality assurance programs for IPMPs in private pain practices can be implemented. High quality private interventional pain management programs with high efficacy, high patient satisfaction, and low complication rates can be achieved through appropriate staff training, proper monitoring of patients during IPMPs, and adequate handling of patients before,

References

1. Boswell MV, Trescot AM, Datta S, Schultz DM, Hansen HC, Abdi S, Sehgal N, Shah RV, Singh V, Benyamin RM, Patel VB, Buenaventura RM, Colson JD, Cordner HJ, Epter RS, Jasper JF, Dunbar EE, Atluri SL, Bowman RC, Deer TR, Swicegood JR, Staats PS, Smith HS, Burton AW, Kloth DS, Giordano J, Manchikanti L. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111.
2. Manchikanti L, Heavner JE, Racz GB, Mekhail N, Schultz DM, Hansen HC, Singh V. Methods for evidence synthesis in interventional pain management. *Pain Physician* 2003; 6:89-111.
3. Boswell MV, Shah RV, Everett CR, Sehgal N, Brown AM, Abdi S, Bowman RC, Deer TR, Datta S, Colson JD, Spillane WF, Smith HS, Lucas LF, Burton AW, Chopra P, Staats PS, Wasserman RA, Manchikanti L. Interventional techniques in the management of chronic spinal pain: Evidence-based practice guidelines. *Pain Physician* 2005; 8:1-47.
4. Bose B. Quadriparesis following cervical epidural steroid injections: case report and review of the literature. *Spine J* 2005; 5:558-563.
5. Cicala RS, Westbrook L, Angel JJ. Side effects and complications of cervical epidural steroid injections. *J Pain Symptom Manage* 1989; 4:64-66.
6. Zhou Y, Furgang FA, Zhang Y. Quality assurance for interventional pain management procedures. *Pain Physician* 2006; 9:107-114.
7. Hagland M. Rewarding good behavior. With Medicare as a major proponent, pay-for-performance programs are gaining traction across the country. *Healthc Inform* 2007; 24:36, 38.
8. Pham HH, Schrag D, O'Malley AS, Wu B, Bach PB. Care patterns in Medicare and their implications for pay for perfor-

mance. *N Engl J Med* 2007; 356:1130-1139.

9. Van Swol MA. Does pay-for-performance improve the quality of health care? *Ann Intern Me* 2007; 146:538-539.
10. Moser JW, Wilcox PA, Bjork SS, Cushing T, Dennis M, Greissing JE, Keysor K, McKenzie J, Weinreb JC. Pay for performance in radiology: ACR white paper. *J Am Coll Radiol* 2006; 3:650-664.
11. Hirsh AT, Atchison JW, Berger JJ, Waxenberg LB, Lafayette-Lucey A, Bulcourf BB, Robinson ME. Patient satisfaction with treatment for chronic pain: Predictors and relationship to compliance. *Clin J Pain* 2005; 21:302-310.
12. Ahmed SU, Tonidandel W, Trella J, Martin NM, Chang Y. Peri-procedural protocols for interventional pain management techniques: A survey of US pain centers. *Pain Physician* 2005; 8:181-185.
13. Datta S, Candido KD. Incidental discovery of carotid artery dissection as a cause of horner's syndrome and headache in a patient presenting for follow-up of lumbar epidural steroid injection: A case report with a three year follow-up. *Pain Physician* 2004; 7:483-485.
14. Imarengiaye C, Ekwere I. Postdural puncture headache: A cross-sectional study of incidence and severity in a new obstetric anaesthesia unit. *Afr J Med Med Sci* 2006; 35:47-51.
15. Brull R, McCartney CJ, Chan VW, Liguori GA, Hargett MJ, Xu D, Abbas S, El-Beheiry H. Disclosure of risks associated with regional anesthesia: a survey of academic regional anesthesiologists. *Reg Anesth Pain Med* 2007; 32:7-11.
16. Hawley JS, Ney JP, Swanberg MM. Subarachnoid pneumocephalus from epidural steroid injection. *Headache* 2005; 45:247-248.
17. Simopoulos T, Peeters-Asdourian C. Pneumocephalus after cervical epidural steroid injection. *Anesth Analg* 2001; 92:1576-1577.
18. Weber R, Garcia J, Faruqi R, Banerji D, Georges G. Safety and clinical relief over 1 year with triamcinolone acetonide hydrofluoroalkane-134a nasal aerosol in patients with perennial allergic rhinitis. *Allergy Asthma Proc* 2006; 27:243-247.
19. Jeal W, Faulds D. Triamcinolone acetonide. A review of its pharmacological properties and therapeutic efficacy in the management of allergic rhinitis. *Drugs* 1997; 53:257-280.
20. Stojanovic MP, Vu TN, Caneris O, Slezak J, Cohen SP, Sang CN. The role of fluoroscopy in cervical epidural steroid injections: An analysis of contrast dispersal patterns. *Spine* 2002; 27:509-514.