Prospective Evaluation

Complications of Fluoroscopically Directed Facet Joint Nerve Blocks: A Prospective Evaluation of 7,500 Episodes with 43,000 Nerve Blocks

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: None.

Manuscript received: 02/01/2012
Accepted for publication: 02/27/2012

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Background: Chronic spinal pain is common along with numerous modalities of diagnostic and therapeutic interventions utilized, creating a health care crisis. Facet joint injections and epidural injections are the 2 most commonly utilized interventions in managing chronic spinal pain. While the literature addressing the effectiveness of facet joint nerve blocks is variable and emerging, there is paucity of literature on adverse effects of facet joint nerve blocks.

Study Design: A prospective, non-randomized study of patients undergoing interventional techniques from May 2008 to December 2009.

Setting: A private interventional pain management practice, a specialty referral center in the United States.

Objectives: Investigation of the incidence in characteristics of adverse effects and complications of facet joint nerve blocks. The study was carried out over a period of 20 months including almost 7,500 episodes of 43,000 facet joint nerve blocks with 3,370 episodes in the cervical region, 3,162 in the lumbar region, and 950 in the thoracic region. All facet joint nerve blocks were performed under fluoroscopic guidance in an ambulatory surgery center by 3 physicians. The complications encountered during the procedure and postoperatively were evaluated prospectively.

Methods: This study was carried out over a period of 20 months and included over 7,500 episodes or 43,000 facet joint nerve blocks. All of the interventions were performed under fluoroscopic guidance in an ambulatory surgery center by one of 3 physicians. The complications encountered during the procedure and postoperatively were prospectively evaluated.

Outcomes Assessment: Measurable outcomes employed were intravascular entry of the needle, profuse bleeding, local hematoma, dural puncture and headache, nerve root or spinal cord irritation with resultant injury, and infectious complications.

Results: There were no major complications. Multiple side effects and complications observed included overall intravascular penetration in 11.4% of episodes with 20% in cervical region, 4% in lumbar region, and 6% in thoracic region; local bleeding in 76.3% of episodes with highest in thoracic region and lowest in cervical region; oozing with 19.6% encounters with highest in cervical region and lowest in lumbar region; with local hematoma seen only in 1.2% of the patients with profuse bleeding, bruising, soreness, nerve root irritation, and all other effects such as vasovagal reactions observed in 1% or less of the episodes.

Limitations: Limitations of this study include lack of contrast injection, use of intermittent fluoroscopy and also an observational nature of the study.

Conclusion: This study illustrate that major complications are extremely rare and minor side effects are common.

Key words: Spinal pain, facet joint nerve blocks, cervical medial branch or facet joint nerve blocks, thoracic medial branch or facet joint nerve blocks, lumbar facet joint nerve blocks, L5 dorsal ramus block complications

Pain Physician 2012; 15:E143-E150

Chronic spinal pain in the United States is highly prevalent with substantial economic impact (1-7) with increasing prevalence of chronic spinal pain. Various modalities applied to manage this pain also have been increasing exponentially (8-23). Epidural injections and facet joint nerve blocks are the 2 most commonly utilized interventions in managing chronic spinal pain (8-16,24-30). The literature addressing the effectiveness of facet joint nerve blocks is highly variable and debated and facet joint nerve blocks may be associated with significant complications (14-16,24-32). Facet joint nerve blocks include intraarticular injections, facet joint nerve blocks, and facet joint nerve ablation. Even though, complications with facet joint nerve blocks are rare, the most common and worrisome complications are related to needle placement and drug administration. These complications include issues related to bleeding with or without intravascular entry, infection, dural puncture and spinal anesthesia, neural trauma, spinal cord trauma, pneumothorax, radiation exposure, hematoma formation, and steroid side effects (14-16,24-64). Most of the complications have been only case reports, while intravascular injections, bleeding, infection and role of fasting have been evaluated systematically (63-69). In an evaluation of the incidence of intravascular penetration and medial branch blocks in cervical, thoracic, and lumbar regions, Verrills et al (63) after evaluation of 14,312 separate medial branch blocks over a period of 3 years demonstrated that the overall incidence of intravascular penetration in medial branch blocks was rare with an overall rate of 3.5%. They also showed differential intravascular injection for various levels of the spine with the cervical spine 3.9%, lumbar spine 3.7%, and the thoracic spine with 0.7%. Lee et al (64) in evaluation of 1,433 injections of lumbar medial branch blocks illustrated 6.1% per nerve block. Sullivan et al (66) also showed 6.1% intravascular injections in the lumbar spine. This study was undertaken to evaluate adverse events of facet joint nerve blocks in a prospective, non-randomized evaluation.

Methods

The study was conducted in the United States in a private interventional pain practice and specialty referral center based on Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (67-70). The Institutional Review Board (IRB) approved the study protocol. This study was conducted with internal resources of the practice without any external funding either from industry or from elsewhere. The study is registered with the U.S. Clinical Trial Registry NCT00625248. The study results on bleeding risk, infection, and necessity of fasting have been published (67-69). This study was conducted with internal resources of the practice without any external funding either from industry or from elsewhere. The present evaluation includes data analysis for complications related to fluoroscopically directed facet joint nerve blocks.

Participants

All the participants undergoing facet joint nerve blocks were assigned for evaluation from May 2008 to December 2009.

Interventions

This study was performed prospectively on patients without change in their normal course of treatment. Thus, the IRB waived the requirements for specific consent for inclusion in the study. However, all the patients were informed about the nature of the study with adherence to all confidentiality and Health Insurance Portability and Accountability Act (HIPAA) requirements.

Pre-Enrollment Evaluation

The patients provided the history of their antithrombotic therapy or lack thereof, including whether the antithrombotic therapy was stopped or not, for evaluation of bleeding. Further, they also have provided the history with regards to previous adverse effects related to facet joint nerve blocks.

Inclusion and Exclusion Criteria

All the patients receiving facet joint nerve blocks in any region during the time period were included.

Description of Interventions

Either diagnostic or therapeutic facet joint nerve blocks were performed in cervical, thoracic, and lumbar regions. Interventions were performed by 3 physicians in sterile operating rooms located in an ambulatory surgery center (ASC) using fluoroscopy.

Objectives

The study investigated the incidence and characteristics of adverse effects and complications of facet joint nerve blocks.

Outcomes

Measurable outcomes employed were intravascular entry of the needle, profuse bleeding, local bleed-

ing, local hematoma, oozing, bruising, dural puncture and headache, nerve root or spinal cord irritation with resultant injury, infectious complications, numbness, postoperative soreness, and increased pain.

Eight nurses were trained to evaluate the above outcomes. Each participant was contacted postoperatively within 48 hours. If there were any side effects or complications, repeat contact was made and they were managed by the physician involved in the care.

Statistical Analysis

Data were recorded in a database using Microsoft Access (Microsoft Corporation, Redmond, WA) by a person not participating in the study. The SPSS 9.0 statistical package (IBM Corporation, Armok, NY) was used to generate the frequency tables. Pearson chi-square test was carried out in the comparisons of proportion between antithrombotic with no antithrombotic. Results were considered statistically significant if the P-value was less than 0.05.

Results

Participant Flow

Table 1 illustrates the baseline characteristics. The study period lasted from May 2008 to December 2009 (20 months) with a total number of participants 1,793 with 5,717 encounters.

Procedural Characteristics

The total number of facet joint nerve block episodes or encounters was 7,482 with 3,370 in cervical region, with 950 in thoracic region, and 3,162 in the lumbar region.

Outcomes

Table 2 illustrates the results of various outcomes observed in this study by type of procedure. Cervical

Table 1. *Patient demographics based on facet joint encounters.*

Gender	Male	32.3% (1,849)
	Female	67.7% (3,868)
Age	Mean ± SD	50.5 ± 12.99
Height	Mean ± SD	66.2 ± 3.81
Weight	Mean ± SD	184.8 ± 51.57
Smoking	Yes	60.2% (3,441)
	Quit	4.5% (160)
	None	35.3% (2,016)

Table 2. *Analysis of intraoperative side effects and complications of spinal facet joint nerve blocks.*

	Cervical Encounters (3,370)	**Lumbar Encounters (3,162)**	**Thoracic Encounters (950)**	**Total Encounters (7,482)**
Total Number of Levels	20,544	15,645	5,821	43,010
Local Bleeding	66.9% (2,255)	72.7%* (2,298)	75%* (710)	70.3% (5,263)
Oozing	28.9% (974)	10.2%* (324)	18%*# (172)	19.6% (1470)
Intra-Vascular	20.0% (673)	4.0%* (125)	6%*# (58)	11.4% (856)
Local Hematoma	2.3% (77)	0.1%* (3)	1%* (13)	1.2% (93)
Profuse Bleeding	0.7% (24)	0.4% (12)	0.03% (3)	0.5% (39)
Bruising	0.2% (8)	0.3% (9)	0.04% (4)	0.3% (21)
Nerve Root Irritation	0.15% (5)	0.1% (3)	0.1% (1)	1% (9)
Nerve Damage	0	0	0	0
Spinal Cord Irritation	0	0	0	0
Epidural Hematoma	0	0	0	0
Infection	0	0	0	0
Vasovagal Reaction	0	0.03% (1)	0	0.1% (1)
Facial Flushing	0	0	0	0

* indicates significant difference ($P < 0.05$) with cervical facet joint # indicates significant difference ($P < 0.05$) with lumbar facet joint

facet joints (66.9%) had significantly lower percentage of local bleeding complications compared to lumbar and thoracic facet joint nerve blocks. Cervical facet joint nerve blocks had significantly lower percentage of oozing, intravascular, return of blood, and local hematoma compared to lumbar and thoracic facet joint nerve blocks.

Figure 1 illustrates the proportion of intraoperative adverse events based on the region for facet joint nerve blocks.

No major complications were identified in performance of over 7,482 facet joint procedures. However, in reference to minor events, there was 1.1 incidence per episode of facet joint nerve block procedures per region. However, if this is translated to per facet joint nerve block or medial branch block, it will be reduced to one minor event for 6 blocks including local bleeding, which is expected in over 70% of the population. Of importance is the intravascular penetration which was observed in a total of 11.4% of the patients with 20% in the cervical region, 4% in the lumbar region, and 6% in the thoracic region which was significantly higher in the cervical region. However, if one considers per medial branch or facet joint nerve block, the prevalence will be reduced substantially to approximately 3% of the nerves blocked in the cervical spine and 1% in thoracic and lumbar regions.

Discussion

This prospective evaluation assessed the patterns of adverse events in a large group of patients undergoing spinal medial branch or facet joint nerve blocks. The adverse events included intravascular penetration of overall 11.4% with 20% in cervical region, 4% in lumbar region, and 6% in thoracic region, significantly higher in the cervical region per encounter or episode. However, considering that average cervical medial branches blocked were 6 with 20,544 blocks, thoracic medial branches blocked were 6 with 5,821 blocks, and lumbar medial branches blocked were 5 with 15,645. Based on the per nerve, intravascular entry would be 3.3% in the cervical region, with 5 average nerves blocked in lumbar region, translating to 0.8% per nerve and 6 average nerves blocked in the thoracic region, translating it to 1% based on the number of nerves involved. Even then, it is significantly higher in cervical region compared to thoracic and lumbar regions. Local bleeding was observed in a substantial proportion of patients; however, there was no difference among the regions with a total of 70.3% . However, oozing was observed in less than 20% of the encounters and the highest was noted in cervical region, followed by thoracic and lumbar regions, which was significantly different. Even though local bleeding appeared similar, it was significantly higher in the thoracic and lumbar regions compared to

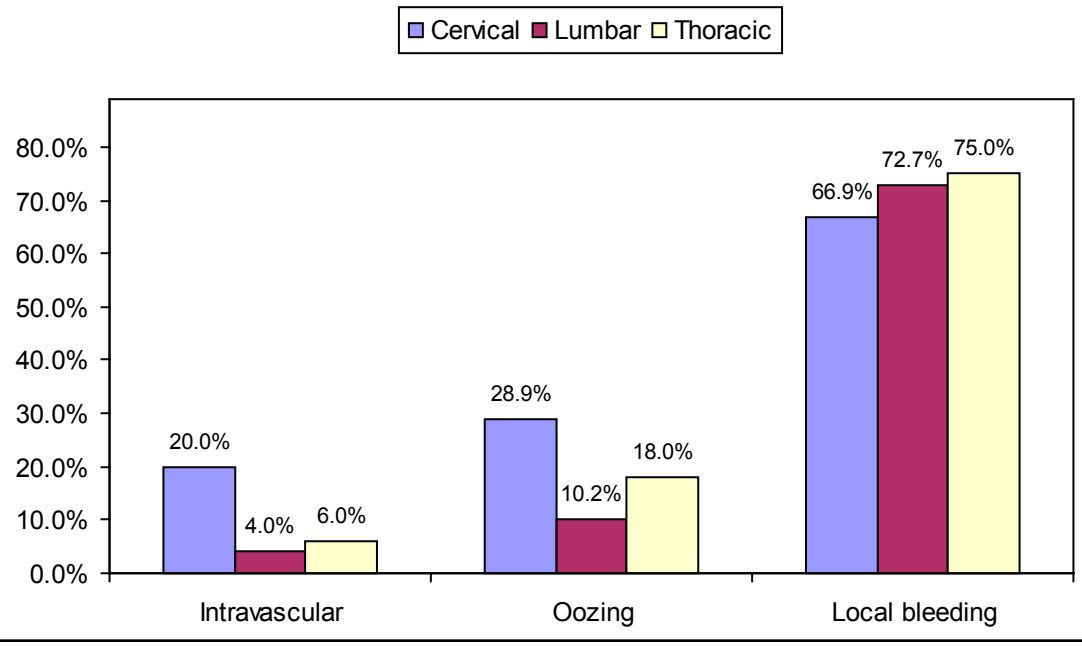

Fig. 1. *Proportion of intraoperative adverse events based on the spinal region.*

cervical region. All other adverse events were noted in a very small proportion of patients; however, of note is the nerve root irritation which was observed in 5 patients or 0.15% in cervical region, 3 patients or 0.1% in lumbar region, and one patient or 0.1% in thoracic region, with a total of 9 patients or 0.1%. There was no lumbar puncture headache or infections noted. There was only one vasovagal reaction whereas there was no facial flushing in this study.

This is the first study to evaluate over approximately 7,500 episodes of medial branch or facet joint nerve blocks over a period of 20 months involving approximately 43,010 nerve blocks with an average of 5.7 nerve blocks. The procedures were performed over a period of 20 months in an ambulatory surgery center under fluoroscopy by 3 physicians. Our results may be considered similar to other publications even though there are multiple variations and also the majority of the complications are minor. Kaplan et al (65) showed the inadvertent intravascular injection in lumbar facet joint nerve blocks at 8%. Further, Lee et al (64) in evaluation of 1,433 injections of lumbar facet joint nerves reported an overall incidence of intravascular uptake of 6.1 per nerve block. Verrills et al (63) in an evaluation of the incidence of intravascular penetration in medial branch blocks in all 3 regions demonstrated that overall incidence of intravascular penetration in medial branch blocks was rare with an overall rate of 3.5% in 14,312 separate medial branch blocks. They also showed that cervical spine was likely to be more vascular 3.9% of the time and the lumbar spine 3.7%, whereas thoracic spine was significantly lower with just 0.7% injections reported as intravascular. They concluded that the false-negative rate for medial branch blocks is likely to be lower than previously reported. In contrast, involving 7,482 facet joint nerve blocks in this study, intravascular penetration was observed in 11.4% of the episodes with highest in the cervical region, followed by thoracic and lumbar regions. However, per nerve, these rates were lower compared to the previous studies with 45% in cervical, 12.7% in thoracic, and 42.3% in lumbar. Further, thoracic was observed at a higher level in this study than in the previous study (63).

All other complications were minor; however, the nerve root irritation which was not reported by any of the previous investigators was also seen in a total of 9 or 0.02% facet joint nerve blocks of the 43,010 total blocks. Thus, even though it is extremely rare, it calls for caution. Relatively low incidence of intravascular penetration shows that the false-negative results reported in the past may be somewhat higher. There were no infections noted even though infectious complications have been reported in a number of patients in the past, though mostly related to intraarticular injections.

The limitations of this study include lack of contrast injection and use of intermittent fluoroscopy. It still has not been proven to utilize contrast for each and every facet joint nerve block and also use of continuous fluoroscopy or other sophisticated modalities to detect intravascular injections as in transforaminal epidural injections. Thus, cost-effectiveness of contrast injection or safety of high radiation exposures associated with continuous fluoroscopy or other modalities has not been demonstrated. Rather, it has proven to be expensive and involves significant amounts of radiation without increased effectiveness (71-84). Other limitations include that it was a single site study involving the experience of only 3 physicians.

This is the first study to evaluate over 43,000 facet joint nerve block procedures in 20 months performed by 3 physicians under fluoroscopy. While our results are similar to the previous publications in many aspects with the majority being minor complications, there are also some differences.

Conclusion

This large study of prospective nature illustrates that major complications are extremely rare whereas minor side effects are common. Overall intravascular penetration was observed in 11.4% of episodes with 20% in cervical region, 4% in lumbar region, and 6% in thoracic region; with local hematoma seen only in 1.2% of the patients with profuse bleeding, bruising, soreness, nerve root irritation, and all other effects such as vasovagal reactions observed in 1% or less of the episodes.

Acknowledgments

The authors wish to thank Sekar Edem for assistance in the search of the literature, Tom Prigge, MA, for manuscript review, and Tonie M. Hatton and Diane E. Neihoff, transcriptionists, for their assistance in preparation of this manuscript. We would like to thank the editorial board of Pain Physician for review and criticism in improving the manuscript.

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