Retrospective Study

Adverse Events Associated with Fluoroscopically Guided Zygapophyseal Joint Injections

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Free full manuscript: www.painphysicianjournal.com **Background:** In spite of the widespread performance of intra-articular zygapophyseal joint (IAZJ) injections, we know of no systematic analysis to date that examines the risks and types of adverse events when IAZJ injections are performed.

Objective: To describe the type, incidence, and factors contributing to adverse events associated with fluoroscopically guided IAZJ injections.

Study Design: A retrospective, cohort study of English-speaking adults aged 18 – 90 years who underwent fluoroscopically guided IAZJ injections between March 8, 2004, and April 19, 2007. Following IAZJ injections, 3 senior researchers recorded the presence and type of adverse events. The relationship of adverse events with age, gender, fluoroscopy time, vital signs, and trainee presence was analyzed with Fisher's exact or Wilcoxon rank sum 2-sided tests. Frequency of immediate (during or immediately after the procedure) or delayed (within 24 – 72 hours following the procedure) adverse events.

Setting: Tertiary, academic, outpatient physical medicine and rehabilitation interventional spine clinic.

Results: One hundred ninety-one patients (111 men) underwent 239 procedures. The mean and standard deviation (SD) of subject age was 56.4 (16.6) years ranging from 20 to 89. The mean and SD of pre-procedure 11-point Visual Analog Pain Scale was 5.5 (2.2) ranging from 0 to 10, and for post-procedure was 2.6 (2.6) ranging from 0 to 10. Trainees were involved in 52.3% of procedures. Reported immediate adverse events were vasovagal reaction (3.8%, n = 9) and steroid clogged needle (0.4%, n = 1). Follow-up data were available for 185/239 procedures (77.4%). There were 35 adverse events reported at mean follow-up interval of 1.8 days, of which the most frequent were injection site soreness (6.0%, n = 11), pain exacerbation (4.3%, n = 8), sleeplessness (2.2%, n = 4), and transient headache (1.6%, n = 3). Patient gender, age, trainee involvement, pre-procedural pain score, systolic or diastolic blood pressure, pulse, hemoglobin saturation as measured by pulse oximetry, volume of corticosteroid injected, and duration of fluoroscopy were not found to have a significant effect on immediate or delayed adverse events.

Limitations: This study is limited by a 24- to 72-hour follow-up window, which may have also been too small to capture more delayed complications, and a sample size too small to accurately define the incidence of rare complications.

Conclusion: Fluoroscopically guided IAZJ injections have minimal adverse effects. The most common immediate adverse event was vasovagal reaction and most common delayed adverse event was injection site soreness.

Key words: Fluoroscopic injection, facet joint, zygapophyseal joint, complications, adverse effects, steroid injection

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he use of lumbosacral spinal injections has increased considerably in during the past 2 decades (1). Intra-articular zygapophyseal joint (IAZJ) injections have become widely utilized in daily interventional practice for both therapeutic and diagnostic purposes (2,3).

Rare but serious complications of IAZJ injections have been reported. Boswell et al (3,4) reviewed the existing literature between January 1966 and November 2004 and again through 2006, finding that lumbar IAZJ injections were associated with cases of dural puncture, spinal cord trauma, septic facet joint arthritis, intraarterial and intravenous injection, spinal anesthesia, neural trauma, facet capsule rupture, hematoma formation, and steroid side effects. In our literature review up to October 2013, we identified additional cases of spinal epidural hematomas in 2 patients (5), an epidural abscess causing sepsis and death (6), a paraspinal abscess complicated by endocarditis (7), radiculopathy (8), discitis (9), and bacterial meningitis in 2 patients (10) due to lumbar IAZJ injections.

However, compared with the variety of other interventional spinal procedures, IAZJ injections are considered to be relatively safe, with a far lower incidence of serious complications as evidenced by Fitzgibbon's review of 5,475 claims in the American Society of Anesthesiologists Closed Claims Project database between 1970 and 1999 (11). Additionally, the progressive adoption of image guidance appears to have resulted in increased accuracy and reduced adverse events when performing these injections (12,13). This cannot necessarily ameliorate side effects related to the procedure itself. In spite of the widespread performance of this procedure, we know of no systematic analysis to date that examines the risks and types of adverse events when IAZJ injections are performed. It is clear that such an analysis would benefit both practitioners and patients in truly and appropriately having a consent process that is "informed." In light of the recent controversy surrounding the efficacy of facet-based procedures (14-16), examination of potential adverse effects of IAZJ injections would help elucidate any risk-benefit analyses.

METHODS

This was a retrospective cohort study, approved by the Northwestern University Institutional Review Board. Patients were identified through a review of the electronic medical records for all individuals seen at an urban, academic, physical medicine and rehabilitation outpatient interventional musculoskeletal and spine center. The study included English-speaking individuals, age 18 – 90 who underwent at least one lumbosacral IAZJ injection at this facility from March 8, 2004, to April 19, 2007. There were no exclusion criteria. All injections were ordered and performed by physicians board certified in physical medicine and rehabilitation, specialized in musculoskeletal medicine. IAZJ injections were ordered if the treating physician determined that the zygapophyseal joint (ZJ) represented a possible source of pain based on clinical judgment.

Access to the ZJ was obtained via the technique described by Fenton and Czervionke (17). After informed written consent was obtained, the patient was placed in a prone position upon the fluoroscopy table. Vital signs were obtained before, throughout, and after the procedure. The skin was sterilized using povidoneiodine or chlorhexidine gluconate, and the surrounding area was covered with a fenestrated drape. The target was identified on the inferior and posterior aspect of the ZJ, using intermittent pulsed fluoroscopy. A sterile, radio-opaque marker was placed on the skin to mark the target, and a skin wheal was raised using approximately 1 mL of preservative-free 1% lidocaine via a 25 gauge, 1.5 inch needle. Again using intermittent pulsed fluoroscopy, a 22 gauge, 3.5 inch spinal needle was positioned within the inferior-posterior ZJ. Precise needle positioning was confirmed using injection of 0.2 mL of Isovue 300 contrast medium through minimal volume micro-bore tubing under real-time live fluoroscopy. Following confirmation of needle placement, usually 0.5 mL of preservative-free 1% lidocaine mixed with 0.5 mL of 40mg/mL triamcinolone or 6mg/mL betamethasone was subsequently injected into the ZJ. Injections were performed only when intra-articular contrast flow was apparent, and extra-articular injections were avoided. If satisfactory arthrography was not obtained, the injection was terminated. The spinal needle was then removed, and the patient was transported to the recovery room, where staff monitored them for at least 20 minutes. During this time, patients were observed for any new lower extremity sensory changes or motor deficits. Patients were discharged upon demonstration of stable vitals and adequate ambulation.

Data regarding patient demographics, procedure details, and adverse events were collected prior to the procedure, immediately post-procedure, as well as during a follow-up telephone call between 24 and 72 hours after the procedure. Adverse events reported during or immediately post-procedure were denoted "immediate adverse events," whereas events

Headache?	Yes	No	Explanation:
Fevers?	Yes	No	Explanation:
Rash?	Yes	No	Explanation:
Injection site swelling?	Yes	No	Explanation:
Increased pain?	Yes	No	Explanation:
New/worsening weakness?	Yes	No	Explanation:
Pain Rating?			
Do you need to make a follow-up appointment?	Yes	No	
Questions for the doctor?			
Other comments:			

Table 1. Follow-up telephone questionnaire.

reported during the follow-up telephone call were labeled "delayed adverse events." A standardized questionnaire (Table 1) was used during follow-up telephone calls carried out by nursing staff in order to facilitate rapid identification of potentially serious complications necessitating immediate evaluation (i.e., worsening weakness) and to provide reassurance for more common symptoms of IAZJ injections (i.e., worsened pain). Additionally, individuals were interviewed regarding symptoms not specifically addressed by the questionnaire. These were recorded in a field designated for "other comments." Individuals were excluded from analysis if they could not be reached by telephone. Clinical and adverse event data (Tables 2 and 3) were entered into a discrete structured clinical database (RICPLAS© - Rehabilitation Institute of Chicago Physiatric Log & Analysis System). This was used as a routine method of clinical documentation entered into the hospital medical record. De-identified data were extracted from the RICPLAS database through queries designed in Microsoft SQL Server 2000 and Microsoft Access 2003. Three senior researchers (CP, JR, WS) coded the de-identified data independently. Any discrepancies in independent coding were reconciled by consensus decision. A complication was coded as a "vagal episode," for example, if "vagal episode" was documented by a clinician or if a constellation of symptoms and signs consistent with a vagal episode were reported, such as diaphoresis, dizziness, and relative hypotension or bradycardia. The coded data were entered into Microsoft Excel 2003 and analyzed using SAS version 9.2 (Cary, N.C).

Statistical Analysis

Data were analyzed using SAS version 9.2 (Cary, N.C). A level of significance was set at 0.05. Two-sided

Table 2. List of adverse events monitored during and immediately post procedure.

Increased pain that changed or interrupted procedure Vagal • Vagal—injection completed • Vagal—injection discontinued Cardiovascular Instability • HTN (symptomatic)

• Tachycardia that changed or interrupted procedure

Motor Block

Allergic Reaction to Medication

Contrast Abnormality/Technical

- Technical —required alternate location or approach, completed
- Technical—could not position at target, not completed

Patient-related

- Patient movement/positioning that changed or interrupted procedure
- Anxiety/Patient request to stop that changed or interrupted procedure

Others

- Nausea without bradycardia or hypotension (i.e., not vasovagal)
- Dizziness/lightheadedness without bradycardia or hypotension
- (i.e., not vasovagal)
- Shakiness that changed or interrupted procedure
- Elevated, but asymptomatic BP that lead to discontinuation of procedure
- Diaphoresis without nausea or change in vital signs (i.e., not vasovagal)

Notables

- Steroid particle stopping flow through needle
- Hiccups
- Steroid clogged needle
- Face burning
- Throat fullness
- Arm numbness

tests were used for all hypothesis testing. We selected the first procedure for each subject in order to investigate demographic, clinical, and procedural factors

Headache – transient
Headache – severe
Fever
Chills
Rash
Facial Flushing/Sweating
Injection Site Swelling
Pain Exacerbation
Weak
Numbness
Cramping
Pressure
Spasms
Injection Site Soreness
Nausea/Vomiting
Diarrhea
Bowel Incontinence
Sleeplessness
Mood Fluctuation/Anxiety/Depressed/Crying
"Shakiness"/"Worked Up"/"Jittery"
Dizziness/Lightheaded
Vasovagal Reaction
Hiccups
Sneezing
Elevated Blood Sugar
Flu-like Symptoms
Ear Filled with Fluid Feeling
Fatigue
"Cold Sensation in Hands and Feet"
Elevated Blood Pressure
Hospitalization/ER Visit

Table 3. List of delayed adverse events monitored atfollow-up telephone call.

associated with adverse events. This was done in so as to assure independence of observations and valid statistical results. Fisher's exact tests were used to investigate the relationship between adverse events and categorical variables (e.g., gender). Wilcoxon rank sum tests were used to investigate the relationship between adverse events and numerical variables (such as duraTable 4. Patient description.

	Mean (SD)	n (%)			
Age	56.4 (16.6)	-			
Gender					
Male		111 (58.1%)			
Female	-	80 (42.0%)			
Number of Procedures					
1	-	154 (80.6%)			
2	-	32 (16.8%)			
3	-	1 (0.5%)			
4	-	2 (1.1%)			
5	-	2 (1.1%)			

tion of fluoroscopy).

RESULTS

One hundred ninety-one patients underwent IAZJ injection, including 111 men (58.1%) and 80 women (42.0%), totaling 239 procedures (Table 4). Mean age was 56.4 years, ranging from 20 to 89. Patient clinical and procedural details are shown in Table 5. The incidence of immediate and delayed adverse events after IAZJ injection are displayed in Table 6. The relationship of patient clinical and procedural factors to immediate and delayed adverse events after IAZJ Injection is shown in Table 7 and Table 8.

Discussion

In this cohort, we found immediate adverse events associated with fluoroscopically guided IAZJ injection to occur relatively infrequently, at an incidence of 4.1%. Nine of the 10 events were vagal episodes, while the remaining event was a needle clogged with triamcinolone. The relationship between a lower pre-procedural systolic blood pressure and immediate adverse events showed a trend toward significance (P = 0.084), which is likely explained by the dominance of vagal reactions in representing this category of adverse events.

This study showed that vasovagal episodes occur at an incidence of 3.7% during fluoroscopically guided IAZJ injection. This rate is similar to that which has been reported for fluoroscopically guided intra-articular sacroiliac joint steroid injections (2.1%) (18), the other axial joint injection that is commonly performed, and with cervical epidural steroid injection (ESI) with intravenous (IV) sedation (1.7%) (19). Compared with caudal ESI (0.8%) (20), venipuncture (0.4%) (21), fluoroscopically guided intra-articular knee (0.0%), shoulder (0.0%), and hip (0.2%) injections (22), vasovagal episodes occur

	Mean (SD)	n (%)
Pre-procedure 11-point Visual Analog Scale Pain Score	5.5 (2.2)	-
Immediate post-procedure 11-point Visual Analog Scale Pain Score	2.6 (2.6)	-
Systolic blood pressure	127.8 (19.1)	-
Diastolic blood pressure	79.3 (9.5)	-
Pulse	79.8 (12.9)	-
Fluoroscopy time (seconds)	50.8 (38.2)	-
Administration Trainee involved Attending only	-	125 (52.3%) 114 (47.7%)
Level Injected L1-L2 L2-L3 L3-L4 L4-L5 L5-S1	-	2 (0.8%) 7 (2.9%) 27 (11.3%) 165 (69.3%) 37 (15.6%)
Intravascular uptake No Yes	-	234 (98.3%) 4 (1.7%)

Table 5. Patient clinical and procedural details.

more frequently with IAZJ injection, but less frequently than with cervical interlaminar ESI without IV sedation (8.0%) (23), lumbar transforaminal ESI (0.3% – 8.7%) (23-27), and diagnostic medial branch blocks (5.1%) (22).

Immediate adverse events were more common in women (6.3%) compared to men (2.7%) and when a trainee was involved with the procedure (4.9%) as opposed to an attending only (3.4%), though these differences were not statistically significant (P = 0.2828, P = 0.7277, respectively).

Delayed adverse events were more common than immediate events, at an incidence of 18.9%. The most common reactions reported were injection site soreness (6.0%), pain exacerbation (4.3%), sleeplessness (2.2%), transient headache (1.6%), and facial flushing or sweating (1.1%). These occurrences are expected consequences of corticosteroid injections and these rates are similar to those reported for fluoroscopically guided intra-articular sacroiliac joint steroid injections (18). The incidence of injection site soreness was much lower than that reported after intramuscular vaccination (17.2% - 89.1%) (28,29) and intra-muscular placebo injection (24.1%) (30). The incidence of transient pain exacerbation was also much lower than that reported for intra-articular viscosupplement hip injection (10.0% – 29.0%) (31,32) and lumbar TFESI (37.5%) (33).

	Immediate Adverse Event	Delayed Adverse Event*
Number of patients with data available	167	144
Number of procedures with data available	239	185
Adverse event	n (%)	n (%)
Vagal episode—injection completed	4 (1.7%)	-
Vagal episode—injection discontinued	5 (2.1%)	
Steroid clogged needle	1 (0.4%)	-
Injection site soreness	-	11 (6.0%)
Pain exacerbation	-	8 (4.3%)
Sleeplessness	-	4 (2.2%)
Headache—transient	-	3 (1.6%)
Facial flushing/sweating	-	2 (1.1%)
Headache—severe	-	1 (0.5%)
Chills	-	1 (0.5%)
Fever	-	1 (0.5%)
Cramping	-	1 (0.5%)
Pressure	-	1 (0.5%)
Rash	-	1 (0.5%)
Sensation of ear filled with fluid	-	1 (0.5%)
Total Adverse Events*	10 (4.2%)	35 (18.9%)

Table 6. Immediate and delayed adverse events after IASIJ.

* In the post-procedure follow-up telephone call next business day: 153 procedures involved no adverse events, 32 involved an adverse event.

Table 7. Relationship of categorical factors to adverse events.

	Immediate Adverse Event	P-value	Delayed Adverse Event	P-value	
Gender					
Male	2.7%	0.2929	10.4%	0.0205	
Female	6.3%	0.2828	8.3%	0.8295	
Administration					
Trainee involved	4.9%	0 7077	10.4%	0.6739	
Attending only	3.4%	0.7277	8.3%		

Sleeplessness and transient headache occurred at similar rates to that of caudal, interlaminar thoracic, and interlaminar cervical epidural steroid injections (1.7% – 2.6%), while transient headache and facial flushing occurred at a lower rate compared to these procedures (2.6% – 4.5% and 1.5% – 5.1%, respectively) (34-36). Each of the following were reported once: chills, fever,

	No Immediate Adverse Event Mean (SD)	Immediate Adverse Event Mean (SD)	P-value	No Delayed Adverse Event Mean (SD)	Delayed Adverse Event Mean (SD)	P-value
Age	56.8 (16.6)	48.0 (17.3)	0.1777	58.5 (16.6)	52.9 (16.6)	0.1046
Pre-procedure 11-point Visual Analog Scale Pain Score	5.6 (2.1)	5.1 (1.6)	0.3959	5.7 (2.1)	5.2 (2.2)	0.1740
Systolic blood pressure	128.3 (19.3)	118.1 (13.6)	0.0841	129.7 (17.4)	121.5 (29.1)	0.2042
Diastolic blood pressure	79.4 (9.4)	77.0 (7.2)	0.3186	79.3 (9.3)	78.0 (9.4)	0.4390
Pulse	79.5 (13.1)	86.4 (10.1)	0.1501	79.2 (13.2)	79.9 (13.7)	0.9227
Pulse oximetry (% hgb sat)	96.7 (6.3)	96.6 (1.6)	0.2518	96.4 (7.7)	97.3 (1.2)	0.7505
Fluoroscopy time (seconds)	51.0 (37.8)	45.8 (48.6)	0.2559	56.6 (42.6)	49.1 (38.5)	0.3613
Volume of corticosteroid (mL)	0.5 (0.1)	0.5 (0.0)	0.9588	0.50 (0.10)	0.50 (0.10)	0.5014

Table 8. Relationship of numerical factors to adverse events.

cramping, pressure, rash, and a sensation of the ear being filled with fluid. Delayed events were more common in men (10.4%) compared to women (8.3%) and when a trainee was involved with the procedure (10.4%) as opposed to an attending only (8.3%), though again, these differences were not statistically significant (P =0. 8295, P = 6739, respectively).

The rate of intravascular uptake in our patients was low (1.7%) compared to previously reported rates for fluoroscopically guided lumbar IAZJ injections (6.1%) (37) and intra-articular sacroiliac joint injections (2.6%) (18).

With regards to patient clinical factors related to immediate or delayed adverse events, no significant associations were found with age, pre-procedure pain score, diastolic blood pressure, pulse, percent hemoglobin saturation by pulse oximetry, duration of fluoroscopy, or volume of corticosteroid (Table 8).

This study is limited by its retrospective design and the lack of delayed follow-up data in 24.6% of the patients injected. However, given that the routine clinical practice was to contact patients 24 – 72 hours post-procedure, inability to identify adverse event for this subset of patients was likely due to a lack of complications in most cases. Our 24 – 72 hour follow-up window may have also been too small to capture more delayed complications, such as abscess formation or other infection and metabolic or endocrine-related effects of corticosteroids. Lastly, our study was not large enough accurately define the incidence of rare complications, such as those described by Fitzgibbons et al (11) as highlighted in the introduction.

CONCLUSIONS

Fluoroscopically guided IAZJ injection is associated with a relatively low rate of adverse events both immediately and 24 – 72 hours post-procedure that are typical of other intra-articular steroid injections. The most common immediate adverse event was vasovagal reaction and most common delayed adverse events were injection site soreness, pain exacerbation, and sleeplessness. These finding can be incorporated into the informed consent process prior to IAZJ injection.

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