

## SPINE SECTION

### Original Research Articles

# Immediate Adverse Events in Interventional Pain Procedures: A Multi-Institutional Study

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Disclosure and conflicts of interest: Drs. Maus, Smuck and Kennedy are members of the Board of Directors of ISIS. This work was presented at ISIS 2014, the 22nd Annual Scientific Meeting Research and published in the Research Abstracts portion of *Pain Medicine*. A poster of this information was presented at the 2015 European Congress: Interventional Pain Procedures in the Era of Value-Based Care in Vienna, Austria.

### Abstract

**Setting.** Interventional procedures directed toward sources of pain in the axial and appendicular

musculoskeletal system are performed with increasing frequency. Despite the presence of evidence-based guidelines for such procedures, there are wide variations in practice. Case reports of serious complications such as spinal cord infarction or infection from spine injections lack appropriate context and create a misleading view of the risks of appropriately performed interventional pain procedures.

**Objective.** To evaluate adverse event rate for interventional spine procedures performed at three academic interventional spine practices.

**Methods.** Quality assurance databases at three academic interventional pain management practices that utilize evidence-based guidelines [1] were interrogated for immediate complications from interventional pain procedures. Review of the electronic medical record verified or refuted the occurrence of a complication. Same-day emergency department transfers or visits were also identified by a records search.

**Results.** Immediate complication data were available for 26,061 consecutive procedures. A radiology practice performed 19,170 epidural steroid (primarily transforaminal), facet, sacroiliac, and trigger point injections (2006–2013). A physiatry practice performed 6,190 spine interventions (2004–2009). A second physiatry practice performed 701 spine procedures (2009–2010). There were no major complications (permanent neurologic deficit or clinically significant bleeding [e.g., epidural hematoma]) with any procedure. Overall complication rate was 1.9% (493/26,061). Vasovagal reactions were the most frequent event (1.1%). Nineteen patients (<0.1%) were transferred to emergency departments for: allergic reactions, chest pain, symptomatic hypertension, and a vasovagal reaction.

**Conclusion.** This study demonstrates that interventional pain procedures are safely performed with

## extremely low immediate adverse event rates when evidence-based guidelines are observed.

**Key Words. Complicate Rate; Adverse Event Rate; Spinal Epidural Injections; Spine**

### Background

In the scientific literature and public press there is a heightened concern about potentially serious complications resulting from interventional pain procedures for spinal pain. Case reports and reviews describe catastrophic complications such as spinal cord infarction or infection resulting from spine injections [2–9]. A recent review concluded that the multiple types of spinal injections offered to patients are “ineffective over the longer-term, while exposing patients to major risks/complications.” The review goes on to state that “the multitude of risks attributed to these injections outweighs the benefits”[3]. However, when written without context such statements create a misleading view of the risks of interventional pain procedures. For various spine interventions, rates of adverse events vary widely, and have been reported to range from 0% to 16% [10–13]. Despite the presence of evidence-based guidelines for such procedures [1], there are wide variations in practice. However, although a given procedure may inherently carry a non-zero risk of adverse effects, that risk may be increased if improper or poor technique is used. For that reason, detailed practice guidelines have been promoted in order to minimize risk [1]. These guidelines, however, were developed on the basis of careful consideration of theory and practice experience; and have not been tested quantitatively.

The present study was, therefore, undertaken to produce quantitative data on the rates of immediate adverse events and complications for common, interventional spine procedures, as performed at three separate academic centers, at which multiple practitioners complied with the evidence-based guidelines of the International Spine Intervention Society [1]. The results paint a picture different from that portrayed in reviews of these procedures [1].

### Methods

This retrospective study was approved by the Institutional Review Boards of the parent institutions and complied with all Health Insurance Portability and Accountability Act requirements. The participating institutions were a radiology based spine procedural practice at the Mayo Clinic (Mayo), and physical medicine and rehabilitation spine based practices at the Northwestern University/Rehabilitation Institute of Chicago (RIC) and The University of Pennsylvania (Penn). The Mayo study cohort was obtained by query of a quality assurance database for all procedures ( $n=19,170$ ) from January 1, 2006 through October 1, 2013. Procedures include epidural steroid (primarily

transforaminal), facet, sacroiliac, and trigger point injections. The RIC and Penn cohorts were obtained by interrogation of a discrete structured clinical database (RICPLAS®—Rehabilitation Institute of Chicago Physiatriac Log & Analysis System). Procedures at RIC were performed between March 2004 and January 2009, consisting of 6,280 procedures. At Penn, 701 procedures were performed from September 2009 through July 2010. Procedures performed at RIC and Penn include epidural steroid injections (primarily transforaminal), medial branch block, radiofrequency neurotomies, and SI and facet injections. The time frame of the RIC and Penn cohorts was exclusively determined by the period of utilization of the structured clinical database by the parent institutions. Database termination was caused by transition to an incompatible electronic medical record by those institutions; there was no attempt to exclude complications. The tabulation of the injections performed and cohort demographics are detailed in Table 1.

### Procedures

Preprocedural clinical informed consent was received from all patients. At Mayo, primary operators were all board-certified radiologists with fellowship training, working without or with residents and fellows in training, with a range of experience of 1–13 years. At RIC and Penn, primary operators were all board certified Physical Medicine and Rehabilitation Physicians with additional fellowship training and certification in Sports Medicine or Pain Medicine, working with or without residents and fellows in training, with a range of experience of 1–10 years.

Lumbar transforaminal epidural, lumbar interlaminar epidural, medial branch blocks, radiofrequency

**Table 1** Demographics and procedure totals by institution

|                                       | Mayo        | RIC         | Penn        |
|---------------------------------------|-------------|-------------|-------------|
| <b>Age in years (SD)</b>              | 61.0 (15.8) | 54.5 (16.5) | 52.8 (15.0) |
| <b>Gender (% male)</b>                | 46.6        | 41.9        | 47.3        |
| <b>Procedures (total)</b>             | 19170       | 6280        | 701         |
| <b>Epidural</b>                       | 1054/110    | 274/160     | 82/0        |
| Cervicothoracic (TFESI/IL)            |             |             |             |
| Lumbosacral (TFESI/IL)                | 8912/1292   | 4233/120    | 404/0       |
| Caudal                                | 0           | 123         | 2           |
| <b>Medial branch block</b>            | 0           | 118         | 63          |
| <b>RF neurotomy</b>                   | 0           | 68          | 18          |
| <b>SI joint injection</b>             | 2181        | 525         | 38          |
| <b>Facet injection</b>                | 5088        | 659         | 94          |
| <b>Selective nerve block/pudendal</b> | 507/26      |             |             |

neurotomies, and cervical/thoracic/lumbar zygapophysial joint injections were all performed in accordance with International Spine Intervention Society guidelines [1]. At Mayo, cervical and thoracic transforaminal epidural and interlaminar epidural injections and select lumbar cases (2.0%) with difficult anatomy were performed with CT fluoroscopic guidance using a previously published modification of International Spine Intervention Society guidelines with proven safety and efficacy [14,15].

Lumbar transforaminal epidural steroid injections (TFESIs) and interlaminar epidural steroid injections (ILESIs) were performed under fluoroscopic guidance; CT guidance was used in select Mayo cases (2.0%) when difficult anatomy, postoperative change or body habitus precluded a safe or effective fluoroscopically guided injection. At Mayo, TFESIs were performed with 25 gauge spinal needles wherever possible; 22 gauge needles were used when additional needle length or stiffness was required. At RIC and Penn, 22 gauge spinal needles were used. Contrast injection was always performed to exclude intravascular or intrathecal flow and verify appropriate epidural flow in both anterior-posterior (A-P) and lateral planes. A test injection was performed with 1cc of 2% lidocaine at Mayo and with 1.5–2cc of 1% lidocaine at RIC and Penn. After injection, there was a standard 1–2 minute pause to assure there was no change in neurologic status.

Over the study period, the corticosteroids used included triamcinolone acetonide (Kenalog, 80 mg in 2 mL, Bristol-Myers Squibb, New York, New York, USA), betamethasone sodium phosphate/betamethasone acetate (Celestone, 12 mg in 2 mL, American Regent, Inc., Shirley, New York, USA) or preservative free dexamethasone sodium phosphate (10 mg in 1 mL, APP Pharmaceuticals, LLC, Lake Zurich, Illinois, USA). At all three institutions, betamethasone was the preferred agent for TFESIs from 2004 to 2009/2010; triamcinolone was used when betamethasone was not commercially available. In response to safety concerns, dexamethasone became the preferred corticosteroid for all Mayo TFESIs after October 2010 and all Penn lumbar TFESIs after August 2009.

At Mayo and RIC, ILESIs were performed with 20 gauge Tuohy needles. No ILESIs were performed at Penn during the study period. The dorsal epidural space was entered with loss of resistance technique. Contrast injection was always performed in A-P and lateral planes to confirm epidural flow and exclude intravascular, subdural, or intrathecal flow. The corticosteroids used for lumbar ILESIs were betamethasone preferentially, and triamcinolone when betamethasone was unavailable, at the doses noted above.

Cervical and thoracic epidural injections at Mayo were performed with CT-fluoroscopic (CT/F) guidance. Mayo cervical TFESIs were performed via either an anterolateral or posterolateral approach with 25 gauge needles

as has been previously described [14,15]. Multislice CT/F acquisitions during and following cessation of contrast injection were used to exclude vascular or intrathecal flow and assess epidural distribution. Fluoroscopic guidance without CT was used to guide cervical and thoracic epidural injections at RIC and Penn; 22 gauge needles were typically employed. As in the lumbar spine, contrast injection was always performed in A-P and lateral or contralateral oblique planes to confirm an epidural distribution and exclude intravascular, subdural or intrathecal flow. Confirmation of an appropriate flow pattern was followed by a lidocaine test injection (1 cc of 2% lidocaine or 0.5 cc of 4% lidocaine at Mayo and 1 cc of 1% lidocaine at RIC and Penn) with subsequent injection of 10 mg of dexamethasone.

Cervical and thoracic ILESIs were also performed with CT/F guidance at Mayo and fluoroscopic guidance alone at RIC and Penn using 20 gauge Touhy needles, loss of resistance technique to enter the dorsal epidural space, followed by contrast injection in all cases. Corticosteroids used for interlaminar injections were either betamethasone or dexamethasone.

Cervical, thoracic, and lumbar facet joint as well as sacroiliac joint injections were performed with fluoroscopic guidance typically with 25 gauge spinal needles or occasionally using 22 gauge needles when additional needle length or stiffness was required. Injection with contrast was always performed to exclude intravascular flow in the A-P plane. Injectate was only placed within a cervical or thoracic facet after confirmation of intraarticular location. Injectate was delivered to lumbar facets and sacroiliac joints after intravascular flow was excluded and with intraarticular or occasionally periarticular location. One cc of a 1:1 combination of betamethasone and ropivacaine (betamethasone 6mg/ml and ropivacaine 5mg/ml) was injected into each facet joint and 2–3 cc of injectate was placed in each sacroiliac joint.

At RIC and Penn, radiofrequency neurotomy (RFN) was performed according to previously detailed practice guidelines [1]. Patients were positioned prone on a fluoroscopy table. The lumbar region was sterilized with chlorhexidine and draped in a standard sterile manner. After local anesthesia to the skin and subcutaneous tissues superficial to a planned target site, a 18 gauge 10 cm RFA electrode with a 10 mm active tip, was positioned using fluoroscopic guidance at the “waist” of the articular pillar at cervical levels, at the superomedial aspect of the transverse process at the anatomic transition to the pedicle at the lumbar levels, and at the concavity of the sacral alae for the L5 medial branch. The active tip of the electrode was specifically placed parallel to the expected course of the medial branch nerve. Correct electrode position was confirmed in both anterior-posterior and oblique fluoroscopic views following negative aspiration. Motor testing was performed at 2 Hz to confirm the integrity of the corresponding exiting spinal nerve at each target. Sensory testing was performed at 50 Hz to confirm proximity to the target

medial branch nerve. After appropriate electrode positioning, 1 cc of 2% lidocaine was injected through the introducer needle for anesthesia during the ablation. Two RFA lesions were performed at each target site at 80°C for 90 seconds. Following the ablation, 0.5–1.0 cc of 0.5% bupivacaine was injected to provide post-procedure analgesia. Following the procedure, patients were observed for approximately 30 minutes and were then discharged if clinically stable.

Sedation was rarely used for epidural injections in any spine segment. The previously reported sedation rate for Mayo TFESIs was 0.1% [16]. No patients were sedated at Penn. At RIC 4.5% of all epidural injection patients were sedated. Nursing personnel who were skilled in distraction and empathetic interaction attended all patients throughout the procedure. Nursing personnel monitored patients for approximately 30 minutes after the procedure; patients were then evaluated by the treating physician prior to dismissal.

### Evaluation of Adverse Events

After the patient was discharged, the proceduralist directly entered immediate complications into the database as part of Mayo's standard record of immediate post-procedure pain and complications. At RIC and Penn, to assure accuracy all procedural data were entered via a drop down menu and free text in the electronic clinical database by the treating physician. Additional adverse events could also be entered into the clinical database immediately by nurses in the post-procedure recovery area.

Persistent leg/arm weakness was considered to be a permanent neurologic injury. Vasovagal reactions were defined as patients with signs (bradycardia, hypotension, and diaphoresis) and/or symptoms (nausea or lightheadedness) reflective of increased vagal/decreased sympathetic tone. For vasovagal reactions, the medical record was reviewed for interventions that were required. Allergic reactions were defined as patients who experienced signs (hives, erythema) or symptoms (shortness of breath requiring intervention indicating bronchospasm or laryngeal edema, for example) characteristic of a contrast reaction. Aborted procedures were those in which the intended procedure could not be accomplished and the procedure was terminated. Patients requiring transfer to an Emergency Department (ED) were tabulated. In addition, a search was performed for ED visits that occurred up to 2 days after the procedure.

New or increased weakness was defined as a documented motor deficit that arose subsequent to the injection. Increased pain was defined as documented increased pain in a radicular distribution attributable to the injection procedure. Hemorrhagic complications included any reported bleeding requiring imaging or intervention. Allergic reactions are defined above. CSF leak was defined as a postural headache requiring treatment, inclusive of but not restricted to a blood patch. Infectious complications included any documented deep

or superficial infection. Central steroid response was defined as facial flushing, non-positional headache, sleeplessness, or agitation that was self-limiting.

The quality assurance databases were interrogated for all immediate post-procedure adverse events at all three institutions. The electronic medical record was then reviewed on all positive responses to verify or refute the presence of an adverse event and ascertain its causal relationship to the procedure. Virtually all patients had documented clinical follow up that allowed verification. The only immediate complication category that was not reviewed was the presence of transient weakness immediately after a TFESI, where motor blockade was expected. Any reported aborted procedures were reviewed as to the cause. Review yielded several inappropriate recorded complications, which were then appropriately categorized.

### Results

Table 1 describes the study cohort demographics for each institution. Mayo's population was older than RIC and Penn. Mayo contributed 73% of the cases. The most common procedure performed was lumbosacral TFESI. The verified same day adverse event rate for all procedures stratified by institution is detailed in Table 2 (see *Methods* section for definitions of adverse events). The same day adverse event rate is segregated by procedure type for each institution in Tables 3–5.

There were no cases of permanent neurologic deficit or significant bleeding with any procedure at any institution. The most frequent adverse event were vasovagal reactions occurring in 1.1% of procedures (N = 289/26061) with the rate varying from 0.4%–3.2% between the institutions. The vast majority were treated conservatively (e.g., procedure stopped at least temporarily +/- oxygen and Trendelenburg positioning). Of the cases at Mayo, 8% (6/74) received IV fluids. One patient who received fluids also required atropine and had multiple prior episodes of syncope thought to be exacerbated by diuretic use for their hypertension. One patient from RIC received IV fluids. None of the vasovagal reactions required treatment from the Penn cohort.

The procedure was aborted in 0.6% (164/26,061) of cases (see Tables 6–8). The most common reasons for aborting cases include the following: vasovagal reaction 34% (55/164), pain 19% (32/164), and persistent vascular uptake 17% (29/164).

ED transfers were rare, occurring in <0.1% of cases (19/26,061; 14/19 from Mayo and 5/19 from RIC). Reasons for patients being transferred to an ED or an ED visit in the first 24 hours from RIC include: increased pain (2/5); gastroenteritis (1/5); delayed allergic reaction (1/5) and dizziness (1/5). Reasons for patients being transferred or an ED visit in the first 24 hours from Mayo include: chest discomfort (5/14); increased pain (4/14); allergic reaction (3/14); gastroenteritis (1/14); headache

**Table 2** Verified same day adverse events—all procedures (N = 26,061)

| Institution | # Procedures | Neurologic deficit | Vasovagal | Allergic reaction | Bleeding | Procedure aborted | ED transfer | Dural puncture | Total AE  |
|-------------|--------------|--------------------|-----------|-------------------|----------|-------------------|-------------|----------------|-----------|
| Mayo        | 19170        | 0                  | 74        | 9                 | 0        | 30                | 14          | 4              | 131       |
| RIC         | 6190         | 0                  | 199       | 1                 | 0        | 116               | 6           | 6              | 318       |
| Penn        | 701          | 0                  | 16        | 0                 | 0        | 12                | 0           | 0              | 28        |
| Total       | 26061        | 0                  | 289 (1.1) | 10 (<0.1)         | 0        | 164 (0.6)         | 19 (<0.1)   | 10 (<0.1)      | 493 (1.9) |

**Table 3** Same day adverse event rate for Mayo by procedure type (N = 19,170), N (%)

| Injection type | Vasovagal | Allergic reaction | Procedure aborted | Dural puncture | ED transfer |
|----------------|-----------|-------------------|-------------------|----------------|-------------|
| IL             | 4         | 0                 | 5                 | 4              | 2           |
| TFESI          | 34        | 4                 | 17                | 0              | 9           |
| Facet          | 36        | 5                 | 8                 | 0              | 3           |
| SI Joint       | 0         | 0                 | 0                 | 0              | 0           |
| Total:         | 74 (0.4)  | 9 (<0.1)          | 30 (0.2)          | 4 (<0.1)       | 14 (<0.1)   |

**Table 4** Same-day adverse event rate for RIC by procedure type (N = 6,190), N (%)

| Injection type | Vasovagal | Allergic reaction | Procedure aborted | Dural puncture | ED transfer |
|----------------|-----------|-------------------|-------------------|----------------|-------------|
| IL             | 4         | 0                 | 2                 | 1              | 0           |
| TFESI          | 156       | 1                 | 85                | 5              | 5           |
| Caudal         | 2         | 0                 | 2                 | 0              | 0           |
| Facet          | 22        | 0                 | 16                | 0              | 0           |
| SI             | 10        | 0                 | 2                 | 0              | 0           |
| MBB            | 5         | 0                 | 6                 | 0              | 0           |
| RFN            | 0         | 0                 | 3                 | 0              | 0           |
| Total:         | 199 (3.2) | 1 (<0.1)          | 116 (1.8)         | 6 (<0.1)       | 5 (<0.1)    |

**Table 5** Same-day adverse event rate for Penn by procedure type (N = 701), N (%)

| Injection type | Vasovagal | Allergic reaction | Procedure aborted | Dural puncture | ED transfer |
|----------------|-----------|-------------------|-------------------|----------------|-------------|
| TFESI          | 13        | 0                 | 8                 | 0              | 0           |
| Caudal         | 0         | 0                 | 0                 | 0              | 0           |
| Facet          | 3         | 0                 | 1                 | 0              | 0           |
| SI             | 0         | 0                 | 0                 | 0              | 0           |
| MBB            | 0         | 0                 | 2                 | 0              | 0           |
| RFN            | 0         | 0                 | 0                 | 0              | 0           |
| Total:         | 16 (2.3)  | 0 (0)             | 11 (1.7)          | 0 (0)          | 0 (0)       |

(1/14). No sequelae relating to the procedure performed were associated with any of the transfers.

Dural punctures were rare, occurring in <0.1% (10/26,061) of cases. Allergic reactions were also rare occurring in <0.1% (10/26,061) of cases. These patients developed hives +/- pruritus with three requiring 50 mg of Benadryl administered orally, one of these was a delayed reaction and presented to the ED later in the day.

**Discussion**

Prospectively collected data were available for 26,061 consecutively performed procedures from three different teaching institutions with practices based in two different medical specialties, with multiple practitioners at each institution. Amongst all of these procedures, there was not a single instance of a major adverse event. Specifically, there were no cases of permanent neurologic deficit or clinically significant bleeding (e.g., epidural or subdural hematomas). This study demonstrates that interventional pain procedures are safely performed with extremely low immediate adverse event rates when evidence-based guidelines are observed.

Overall adverse event rate was low, at less than 2% (493/26,061). The most frequently encountered events were vasovagal reactions. The treatment of the majority of these reactions required no medications or intervention. The overall rate of aborted procedures was 0.6% occurring primarily in epidural injections. The most common reasons for aborting the procedure were for vasovagal reactions, vascular uptake or pain. None of these cases had any sequelae from the etiology prompting the cessation of the procedure.

While there is variability in the reporting of minor adverse events, the results of this large study of prospectively collected consecutive cases demonstrate results comparable to other smaller retrospective and prospective reports. Specifically, major adverse events are very rare for spine interventional pain procedures and essentially exist only as case reports. In addition, minor adverse events (e.g., vasovagal reactions) are also relatively uncommon and infrequently, if ever, have clinical consequence.

There are several smaller studies that report adverse event rates. For example, a retrospective chart review of epidural steroid injections from an academic physiatry

**Table 6** Cause for aborted cases by spine segment and procedure type at Mayo (N = 30), N (%)

| Spine segment | Procedure type | Vascular uptake | Vasovagal | Pain | Positive test injection | Lack of route | Intrathecal filling | Anxiety | Lack of target specificity |
|---------------|----------------|-----------------|-----------|------|-------------------------|---------------|---------------------|---------|----------------------------|
| Cervical      | TFE            | 2               | 3         | 1    | 1                       | 1             | 0                   | 0       | 0                          |
|               | IL             | 0               | 0         | 0    | 0                       | 0             | 0                   | 1       | 0                          |
|               | Facet          | 0               | 0         | 0    | 0                       | 0             | 0                   | 0       | 5                          |
| Lumbar        | TFE            | 3               | 5         | 2    | 1                       | 0             | 1                   | 0       | 0                          |
|               | IL             | 0               | 0         | 0    | 0                       | 1             | 3                   | 0       | 0                          |
| Total         |                | 5               | 8         | 3    | 2                       | 3             | 4                   | 1       | 5                          |

**Table 7** Cause for aborted cases by spine segment and procedure type at RIC (N = 116), N (%)

| Spine segment | Procedure type | Vascular uptake | Vasovagal | Pain | Lack of route | Dural puncture | Hypertension | Anxiety | Defective RFA probe | Lack of target specificity |
|---------------|----------------|-----------------|-----------|------|---------------|----------------|--------------|---------|---------------------|----------------------------|
| Cervical      | TFE            | 2               | 2         | 1    | 0             | 0              | 0            | 0       | 0                   | 0                          |
|               | IL             | 0               | 0         | 0    | 0             | 0              | 0            | 0       | 0                   | 0                          |
|               | Facet          | 1               | 3         | 1    | 0             | 0              | 0            | 1       | 0                   | 0                          |
|               | RFA            | 0               | 0         | 0    | 0             | 0              | 0            | 0       | 1                   | 0                          |
| Thoracic      | IL             | 1               | 0         | 0    | 0             | 0              | 0            | 0       | 0                   | 0                          |
| Lumbar        | TFE            | 12              | 30        | 21   | 0             | 4              | 3            | 5       | 0                   | 5                          |
|               | IL             | 0               | 0         | 1    | 0             | 0              | 0            | 0       | 0                   | 0                          |
|               | Facet          | 1               | 7         | 1    | 0             | 0              | 0            | 1       | 0                   | 0                          |
|               | RFA            | 0               | 1         | 0    | 0             | 0              | 0            | 1       | 0                   | 0                          |
|               | MBB            | 1               | 1         | 2    | 0             | 0              | 1            | 1       | 0                   | 0                          |
| Caudal        |                | 0               | 1         | 0    | 1             | 0              | 0            | 0       | 0                   | 0                          |
| Sacroiliac    |                | 0               | 2         | 0    | 0             | 0              | 0            | 0       | 0                   | 0                          |
| Total         |                | 18              | 47        | 27   | 1             | 4              | 4            | 9       | 1                   | 5                          |

**Table 8** Cause for aborted cases by spine segment and procedure type at Penn (N = 12), N (%)

| Spine Segment | Procedure type | Vascular uptake | Pain | Positive test injection | Lack of route | Dural puncture |
|---------------|----------------|-----------------|------|-------------------------|---------------|----------------|
| Cervical      | TFE            | 2               | 0    | 0                       | 0             | 0              |
|               | IL             | 0               | 0    | 0                       | 1             | 0              |
| Lumbar        | TFE            | 3               | 1    | 1                       | 1             | 1              |
|               | Facet          | 1               | 0    | 0                       | 0             | 0              |
| Sacroiliac    |                | 0               | 1    | 0                       | 0             | 0              |
| Totals        |                | 6               | 2    | 1                       | 2             | 1              |

practice yielded a total of 4,265 injections. This series identified no major adverse events (defined as infection, hematoma, paralysis and nerve root injury) with a minor adverse event rate (defined as increased pain, numbness, local pain and other) of 2.4% with the most common complication being increased pain [12]. A prospective study of 10,261 epidural procedures reported no major complications (spinal cord infarct, infection, abscess, or epidural hematoma) and a minor adverse event rate of

approximately 8% [11]. A randomized, double-blind study to compare RFA and facet injections with 56 patients had no major adverse events [17]. A prospective study of 7,482 patients for facet joint nerve blocks also reported no major adverse events [10]. While their reported minor adverse event rate was high, this was due to reporting local bleeding (70% of cases of minor adverse events) which could be interpreted as an expected part of the procedure rather than an adverse event.

Case reports of serious adverse events such as paralysis and infection do exist [2,4,6,7,18]. Practitioners should minimize these risks to the best of their ability by following the evidence-based guidelines that have been published by ISIS [1]. We believe that the very low overall adverse event rate in these practices are as a result of adherence to these guidelines.

Although data were collected prospectively, tallying of adverse events relied on the operators to record these events with the potential for missing these events if not appropriately logged in the clinical or quality assurance database. Strengths of this study include a very large patient population and prospectively gathered data with standardized reporting for adverse events.

### Conclusion

Interventional spine procedures are safely performed when utilizing evidence-based practice guidelines. No significant adverse events were seen in more than 26,000 consecutively performed procedures. The minor adverse event rate was less than 2% with no sequela from any of the events.

### Acknowledgments

The authors would like to thank Angela Majerus and Kristina Schmidtke for their contributions in editorial assistance.

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