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Original Research Article

The Immediate Adverse Events of Lumbar Interventional Pain Procedures in 4,209 Patients: An Observational Clinical Study

Savas Sencan, Rekib Sacaklidir, and Osman Hakan Gunduz

Division of Pain Medicine, Department of Physical Medicine and Rehabilitation, Faculty of Medicine, Marmara University, İstanbul, Turkey

Correspondence to: Rekib Sacaklidir, Marmara Üniversitesi Pendik Eğitim ve Araştırma Hastanesi, Fevzi Çakmak, Muhsin Yazıcıoğlu Cd No: 10, 34899 Pendik/İstanbul. Tel: +90- (0216) 625 45 45; E-mail: rakipsacakli@hotmail.com.

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Abstract

Objective. Lumbar interventional pain procedures (LIPPs) are frequently used in low back pain and have shown an increasing trend in recent years. LIPPs are highly effective when performed by properly trained physicians. However, some adverse events are seen during interventional procedures. Our aim in this study is to determine the immediate adverse event rates of LIPPs and to inform our colleagues about possible adverse events. **Study Design**. Retrospective, observational study. **Setting**. A university hospital pain management center. **Methods**. After approval by the institutional ethics committee, a retrospective evaluation of patients who received fluoroscopy-guided LIPPs between January 2015 and December 2020 was performed. This observational study was conducted with 4,209 patients who underwent LIPPs, including epidural steroid injection, sacroiliac and facet joint injection, medial branch block or radiofrequency ablation, application of pulsed radiofrequency to the dorsal root ganglion, epidural catheter placement, or spinal cord stimulator application. **Results**. No major adverse events were detected during the procedures. Minor adverse events were detected in 60 patients, and the adverse events rate was found to be 1.4% (95% confidence interval: 1.0–1.8%). Minor adverse events rates varied between 0.7% and 2.3% according to the procedure type. The most common adverse events were determined to be vasovagal reactions (26/60). Facial numbness, cramps, and seizures were detected as rare adverse events. **Conclusion**. No major adverse events were seen in 4,209 patients. The rate of minor adverse events was 1.4%, with no sequelae in any of the events. When evidence-based guidelines are followed, interventional pain procedures can be performed safely.

Key Words: Spine; Lumbar; Back Pain; Fluoroscopy; Safety

Introduction

Low back pain is one of the leading causes of disability worldwide and is associated with a significant personal, social, and economic burden [1]. Therefore, low back pain treatment is important for public health. Conservative, interventional, and surgical treatments are included in the treatment of low back pain. Interventional pain procedures are used in cases that do not respond to conservative treatment. Lumbar interventional pain procedures (LIPPs) include epidural steroid injections (caudal, transforaminal, interlaminar), facet joint injections, medial branch blocks or radiofrequency (RF) ablations, sacroiliac joint injections, applications of pulsed RF to the dorsal root ganglion, epidural catheter placements, and spinal cord stimulator applications. Interventional procedures for low back pain are highly effective when performed by properly trained physicians [2]. However, some adverse events are seen in interventional procedures.

Adverse events associated with interventional pain procedures described in the literature include headache, syncope, dural puncture, epidural hematoma, bacterial meningitis, epidural abscess, and corticosteroid side effects. Chang et al. found a complication rate of 2.4% to 9.6% in patients who received lumbar epidural steroid injections [3]. According to Kim et al., the incidence of

facet joint–related adverse events requiring hospitalization or an emergency visit was 0.84% [4]. The dorsal root ganglion pulsed RF complication rate was found to be 2% in one study [5]. Although adequate precautions are taken due to increasing interventional procedures, the number of complications is gradually increasing. As reported in previously published large cohort studies, the current understanding is that the major complication rate is less in interventional pain procedures, yet more studies are needed to support this result [6,7]. Our aim in the present study is to determine the immediate adverse event rates of LIPPs and to inform our colleagues about possible adverse events.

Methods

After approval by the institutional ethics committee (2021-518), a retrospective evaluation of patients who received fluoroscopy-guided LIPPs between January 2015 and December 2020 in a tertiary hospital pain management center was performed. This observational study was conducted with 4,209 patients ≥18 years of age who underwent LIPPs, including epidural steroid injections (caudal, transforaminal, interlaminar), sacroiliac joint injections, facet joint injections, medial branch blocks or RF, dorsal root ganglion pulsed RF, epidural catheter placement, or spinal cord stimulator applications. The exclusion criterion was accepted as the absence of adverse events information in the hospital registry system. All LIPPs were done by using evidence-based guidelines for reducing the risk of adverse events [8,9].

Evaluation of Adverse Events

All adverse events related to procedures were recorded during or after the process. Afterward, all records were transferred to the clinical data system on the same day. Adverse events were arranged on the basis of the study in the literature [10,11]. Immediate adverse events were defined as events occurring during or immediately after the procedure in the recovery room within 2 hours [12]. These events were divided into two categories: minor and major. Death, paralysis, and nerve root injury were accepted as major adverse events. Minor adverse events were increased pain, foot numbness, vasovagal reactions, dural puncture, pain occurring in the opposite leg, drop foot (temporary), chest pain, intradiscal injection, facial numbness, seizure, and leg cramps [10].

Vasovagal reactions were defined as patients with signs (sweating, hypotension, and bradycardia) or symptoms (dizziness or nausea) reflecting increased vagal tone. Persistent leg weakness was accepted as neurological damage. Neurological damage was defined as a new or increasing motor deficit relative to the pre–epidural steroid injection muscle strength and persistence of this deficiency despite the termination of the effect of local anesthetics. Electromyography evaluation was planned to confirm the diagnosis in patients who were thought to have neurological damage. Dural puncture is a risk of epidural procedures and occurs when the needle or catheter punctures the dura mater, which is confirmed by contrast spread pattern [13].

Aborted procedures are those in which the intended procedure could not be performed and the procedure was terminated [10]. The procedures that could not be performed after the needle entered the skin were considered aborted procedures and were recorded.

Procedures

All procedures were performed by pain medicine resident fellows, in the same fluoroscopy unit (GE Healthcare OEC 9900 Elite), with intermittent imaging and under the guidance of interventional pain medicine specialists having at least 10 years of experience.

Sedation was applied only during spinal cord stimulator and epidural catheter applications. All other procedures were performed with local anesthesia.

All procedures were performed with the patient in the prone position. A pillow was placed under the abdomen to flatten the lumbar lordosis. For epidural procedures, 3 cc of the mixture (40 mg triamcinolone, 1 cc bupivacaine, and 1 cc saline solution) were used. Transforaminal epidural steroid injection (TFESI) was made by using a 22G Quincke spinal needle, and caudal and interlaminar epidural steroid injections were made by an 18G Tuohy needle.

Facet joint and sacroiliac joint injections were made by using a 22G Quincke spinal needle. A 1:1 combination of triamcinolone and bupivacaine (1 cc) was injected into each facet joint, and 2 cc of injectate was placed in each sacroiliac joint.

For the medial branch conventional RF and dorsal root pulsed RF, the correct point was determined after sensory and motor stimulation. After appropriate electrode positioning for facet medial branch conventional RF, 1 cc of 2% lidocaine was injected through the 20G needle for anesthesia during the ablation, and RF lesions were performed at each target site at 80 C° for 90 seconds. Dorsal root ganglion pulsed RF stimulation was applied for 240 seconds at 42°C with a 20G needle.

Results

Interventional procedures were performed in 4,209 patients. The most common procedure was found to be TFESI (3,077). Caudal (470) and interlaminar (289) epidural steroid injections were the most common after TFESI (Table 1).

No major adverse events were detected during the procedures. Minor adverse events were detected in 60 patients (60/4,209), and the adverse event rate was found to be 1.4% (95% confidence interval [CI]: 1.0–1.8%). Minor adverse events rates varied between 0.7% and

Table 1. Types of lumbar interventional procedures and the number of adverse events

	Patients, n	Adverse Events, n	Adverse Events, % (95% CI)
Transforaminal epidural	3,077	48	1.6% (1.2–2.0%)
Caudal epidural	470	5	1.1% (0.2–2.0%)
Interlaminar epidural	289	2	0.7% (0.3–1.7%)
Facet intra-articular joint	170	2	1.2% (0.4–2.8%)
Sacroiiliac joint	98	1	1.0% (0.2–5.5%)
Dorsal root ganglia RF	52	1	2.0% (0.0–5.7%)
Facet medial branch block / RF	43	1	2.3% (0.0–6.8%)
Spinal cord stimulation / epidural catheter	10	–	–
Total	**4,209**	**60**	**1.4% (1.0–1.8%)**

2.3% according to the procedure type. The adverse event rate for sacroiliac joint injection was 1.0% (95% CI: 0.2–5.5%), and for interlaminar epidural steroid injection, this rate was 0.7% (95% CI: 0.3–1.7%) (Table 1). The most common adverse events were determined to be vasovagal reactions (26/60). Facial numbness, cramps, and seizures were detected as rare adverse events (Table 2).

Aborted procedures, which were procedures that could not be completed, constituted 0.76% (95% CI: 0.5–1.0%) of all patients (32/4,209). Anatomic difficulty (17/32) was found to be the most common cause in patients in whom the procedure was not completed. Other causes were vasovagal reaction, patient incompatibility (the patient was constantly moving despite the starting of the procedure and prevented the procedure from being performed), the patient not lying on the operating table, and hypertension (Table 3).

Discussion

Retrospectively, 4,209 patients were examined. Major adverse events such as death, paralysis, and nerve root injury were not detected, and the minor adverse event rate was found to be 1.4%. This study shows that LIPPs can be performed safely with reasonably low adverse event rates when evidence-based guidelines are followed.

Table 2. Adverse events occurring during lumbar interventional procedures

Adverse Event Type	n
Vasovagal reactions	26
Drop foot (temporary)	17
Numbness in leg	4
Dural puncture	2
Pain in the opposite leg	2
Conversion	2
Chest pain	2
Intradiscal injection	1
Facial numbness	1
Seizure	1
Leg cramps	1
Hypertension	1
Total	**60**

In the present study, the adverse event rate was found to be 1.4%, and the adverse event rate varied between 0.7% and 2.3% according to the procedure type. Vasovagal reactions were the most common adverse event type. Most of these adverse events were followed up without medical treatment. Carr et al. found an adverse event rate of 2% in interventional pain procedures in their study, and they did not find any major adverse events. Most frequently, vasovagal adverse events were found, such as in our study [10].

There are many studies in the literature on adverse events associated with interventional pain procedures [3–5,10]. In a study that retrospectively examined the complications of epidural steroid injections in more than 10,000 procedures, no major complications were observed, while minor complications varied between 2% and 8% according to the type of procedure [11]. In another study on facet joint injections, data of 11,900 patients were analyzed retrospectively, and the rates of minor and major adverse events were found to be 0.63% and 0.07%, respectively [4]. In another study on sacroiliac joint injections, the immediate adverse event rate during the procedure was found to be 2.6%, and no major adverse events were detected [12].

Major adverse events seen in interventional pain procedures are rare; they are usually found as case reports in the literature. In these case reports, it was reported that particular steroids were a significant risk factor for major adverse events, although they were used in all lumbar procedures for long-term well-being [14–16]. In spite of this, no major adverse events were observed in our study. We think there are several reasons. First, all procedures were performed

Table 3. Cause of aborted cases

Cause	n
Anatomic difficulty	17
Vasovagal reactions	5
Patient incompatibility	4
The patient refused procedures	2
The patient could not lie on the procedure table	2
Hypertension	1
Vascular uptake	1
Total	**32**

under sterile conditions with real-time fluoroscopy imaging. Second, all procedures were performed under the supervision of interventional pain medicine specialists having at least 10 years of experience. Finally, patients' anticoagulation was arranged in accordance with the relevant guidelines [17]. Minor adverse events (e.g., vasovagal reactions) are also relatively rare and have rare clinical consequences requiring hospitalization [10,11]. In our study, the rate of minor complications was found to be 1.4%, and these complications were followed up with a conservative treatment that did not require hospitalization.

Patients whose procedures could not be completed constituted 0.76% of all patients (32/4,209). Anatomic difficulties were the cause of the aborted procedure in the majority of patients whose procedures aborted. In the literature, anatomic abnormalities that cause difficulties include achondroplasia, foraminal stenosis, congenital adolescent scoliosis, and spina bifida [18]. In addition, a closed hiatus also prevents epidural processes, and closed hiatus was found in 3% of cases [19]. Vasovagal reactions and patient incompatibility were other causes. Carr et al. found an aborted procedure rate of 0.6% in their study, and the most common cause was found to be vasovagal reaction [10].

Because of adverse events, the use of non-particle steroids has been recommended instead of particulate steroids in recent years. In particular, dexamethasone is currently used as a first-line steroid in spinal interventional pain procedures [20]. Despite this, Clements et al., in a study of 314 physicians, reported that approximately 41% of physicians used particulate steroids for lumbar TFESI and 74% for lumbar interlaminar epidural injections [21]. Chatterjee et al. reported that the use of particulate steroids provided significantly longer pain relief than did the use of non-particle steroids [22]. Therefore, it can be said that there is variability in clinical practice with regard to the type of steroid, depending on the risk of complications and the duration of pain relief.

As reported in previously published large cohort studies, the current understanding is that the major complication rate is less in interventional pain procedures, and our study also supports this result. Nevertheless, this study has a number of limitations. First, it was a study in which data were evaluated retrospectively. Second, the procedures were not performed by a single physician. Finally, only immediate adverse events were evaluated. Hence, adverse events that might develop in the long term were not evaluated.

In conclusion, no major adverse events were seen in 4,209 patients. The rate of minor adverse events was 1.4%, with no sequelae in any of the events. When evidence-based guidelines are followed, interventional pain procedures can be performed safely. However, more observational and prospective studies are needed to inform our colleagues about possible adverse events.

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