UNDERSTANDING ADVERSE EVENTS IN INJECTION CARE FOR SPINE PATIENTS

The impetus for research at Penn Medicine’s Department of Physical Medicine and Rehabilitation can arise from a variety of sources. For Christopher T. Plastaras, MD, Assistant Professor of Physical Medicine and Rehabilitation, the research he pursues often develops from questions asked by patients.

Injections for spine-related pain are a common mode of treatment for many patients. Although the treatments can be helpful in alleviating pain and disabling spine conditions, patients frequently worry about the process, safety and dangers of the injections. In his research, Dr. Plastaras has investigated the type and incidence of adverse events (AEs) in injection treatments, factors that may predict higher risk, and ways to ensure safety.

Dr. Plastaras’ passion for PM&R research began when he was a fourth-year student at the Perelman School of Medicine at the University of Pennsylvania and working on spine-centered research projects. He was particularly interested in the emphasis of exercise as a treatment, and how injection care could be used to complement treatment for spine-related pain and disability. He soon realized how much in the field was not yet known. After an internship at Albert Einstein Medical Center, he went on to a PM&R residency at Northwestern University Feinberg School of Medicine and practiced for nine years at the Spine & Sports Rehabilitation Center of Northwestern University/Rehabilitation Institute of Chicago. In 2009, Dr. Plastaras returned to Penn Medicine to continue to apply his clinical interest in interventional spine medicine management of musculoskeletal conditions. Since 2009, he has also served as the Director of the Spine, Sports, & Musculoskeletal Medicine Fellowship.

To facilitate Spine research, Dr. Plastaras created a way to collect data without much expense. Through self-study, he devised and programmed a relational database that captured daily clinical care and patients’ questions that could be analyzed subsequently to answer research questions. Information obtained from the database has been used for research for the past six years.

“The main focus of my research has revolved around the most common questions asked by our patients. The patients have driven the questions and I have applied my research methods accordingly.”

—Christopher T. Plastaras, MD
Evidence for Treatment Decision-making
Recently, Dr. Plasteras has co-authored several studies addressing key concerns related to AEs in injection therapies as well as the clinical implications of this research.

◆ Adverse Events (AEs) Associated with Fluoroscopically Guided Lumbosacral Transforaminal Epidural Steroid Injections (TFESI)

TFESI is commonly used to treat lumbosacral radicular pain. While AEs related to TFESI had been previously described, no study had systematically obtained patient reports to gather an accurate range and incidence of problems.

This study of 2,025 procedures found that fluoroscopically guided lumbosacral TFESI produced short-lived minor AEs. These included vasovagal episodes, intravascular flow that changed or interrupted the procedure, and pain exacerbation. There were no serious permanent complications. AE type and rate was similar to other axial corticosteroid injections.

• Clinical Implications: Male patients and younger patients are more likely to experience a vasovagal episode. Female patients more often have delayed AEs, including headache and facial flushing. Physicians might reduce patient anxiety by providing them with information about what to expect from TFESI, the possibility of common AEs, and this study’s findings.


◆ AE Rates for TFESI and Interlaminal Epidural Steroid Injection (ILESI): A Multi-Institutional Study

This research study resulted in an incredible opportunity to collaborate with other experts at peer institutions, including the Mayo Clinic and Stanford University. In this study, TFESI has shown efficacy and effectiveness in treating radicular pain. Some clinicians use ILESI as primary therapy for radicular pain because they perceive it to be safer since it is not placed near the exiting nerve, as TFESI is. In the largest study of its kind, this multi-institutional study of 16,638 consecutive procedures found that both routes (TFESI and ILESI) are safe when performed using evidence-based procedural guidelines and showed low AE rates, with no major or permanent AEs.

• Clinical Implications: Because both injection types are safe when performed according to guidelines, this study suggests that physician choice can be based on demonstrated efficacy and effectiveness, not on safety concerns. Future research could examine which patients are more likely to benefit from which types of injections.

**AEs Associated with Fluoroscopically Guided Intra-articular Zygapophyseal Joint (IAZJ)**

Although IAZJ injections are widely performed to alleviate pain in spinal facet joints, there was no systematic analysis of AEs related to treatment. This study found minimal associated AEs. Most common were vasovagal reaction and injection site soreness.

- **Clinical Implications:** Fluoroscopically guided IAZJ injections have a low rate of AEs immediately and 24-72 hours after the procedure. Physicians can provide these findings to patients as part of the informed consent process.


In conclusion, Dr. Plastaras’ research has shown that not only are these procedures safe, but his team is also committed to finding ways to reduce and manage the AEs that are known to cause anxiety in patients.

"IT IS REASSURING FOR OUR PATIENTS TO KNOW THAT NOT ONLY ARE WE USING THE BEST AND SAFEST TREATMENTS KNOWN, BUT THE MEDICAL TEAM THAT THEY ARE ENTRUSTING THEIR CARE TO IS PART OF CREATING THE RESEARCH THAT HAS DEVELOPED THESE PRACTICES. WE ARE TRULY LOOKING OUT FOR OUR PATIENTS’ SAFETY AND WELL-BEING."

—Christopher T. Plastaras, MD

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**RESEARCH INITIATIVES**

In 2016, Dr. Plastaras will collaborate with investigators at University of Colorado, Cleveland Clinic, and the University of Florida to investigate patients with lumbar disc herniation that resulted in leg weakness. This study will describe the evolution of strength recovery featuring non-surgical treatments.