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Perspective Review

Root Cause Analysis of Paraplegia Following Transforaminal Epidural Steroid Injections: The 'Unsafe' Triangle

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The utilization rate of transforaminal epidural steroid injections (TFESIs), an elective diagnostic and therapeutic spinal procedure, has risen dramatically over the past decade. In 2006 alone, greater than 300,000 thoracolumbar TFESIs were performed on Medicare beneficiaries. Despite the purported superiority of the transforaminal route, compared to other modes of epidural injection, TFESIs are associated with potential hazards.

The artery of Adamkiewicz (ARM) might enter any mid thoracic, lower thoracic, or lumbar foramen; the exact level, in a specific patient, will be unknown to the proceduralist· The authors propose that the "safe triangle" approach to transforaminal epidural injections is not safe (TFESIs).

Injury to the ARM can lead to paraplegia, independent of operator skill or adjuvant safety initiatives (digital subtraction angiography, local anesthetic test dose). Injury to the ARM is a "black swan" event. The authors believe that catastrophic injury may be averted when performing TFESIs by avoiding the "un-safe," superoanterior triangle in the foramen and that transforaminal injections should be performed at the inferior aspect of the foramen, known as Kambin's triangle.

Key words: transforaminal, spinal cord, artery of Adamkiewicz, paraplegia, foramen, radiculomedullary, root cause analysis, patient safety, medico-legal, black swan

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The utilization rate of transforaminal epidural steroid injections (TFESIs), an elective diagnostic and therapeutic spinal procedure, has risen dramatically over the past decade. In 2006 alone, greater than 300,000 thoracolumbar TFESIs were performed on Medicare beneficiaries (1). Despite the purported superiority of the transforaminal route, compared to other modes of epidural injection (2-7), TFESIs are associated with potential hazards: 1) intravascular injection, 2) air emboli, 3) vascular trauma, 4) particulate emboli, 5) cerebral thrombosis; and 6) epidural hematoma (2,3,7-9). Neurological or spinal cord injury poses the gravest concern (7-22). Estimating the incidence of these catastrophic complications is impossible; the confidential nature of the legal process and hesitancy among physicians to report complications preclude accurate estimation.

Despite the lack of transparency in reporting these complications, at least 12 cases of severe neurological damage following a thoracic or lumbar TFESI have been reported in the literature. One prominent expert witness has reviewed at least 20 such severe complications following lumbar or low thoracic TFESIs. Glaser et al (22) published a case of a left T12-L1 TFESI performed in 2001 that was complicated by paraplegia. Non-ionic iodinated contrast was injected, under live fluoroscopy, through a needle placed within the "safe triangle." Venous uptake was detected. The needle was repositioned posteriorly and was placed at the midpoint of the pedicle as viewed on a lateral view. Contrast instillation then demonstrated flow along the nerve root, with cephalo-medial spread towards the epidural space on AP view. A mixture of triamcinolone, bupivacaine, and preservative free normal saline was injected under live fluoroscopy. The washout image demonstrated appropriate dilution of the epidurogram. Unfortunately, this patient immediately developed paraplegia. The extent and rapid onset of paraplegia implicated a thoracolumbar spinal cord infarction, secondary to profound ischemia. An MRI performed 2 days later confirmed extensive infarction of the thoracic and lumbar spinal cord. The patient has not had any significant recovery of neurological function. Glaser et al (22) was the first to contend that the root cause of paraplegia, following lumbar and thoracic TFESIs, stems from placement of needles in the "safe" triangle.

Since this case report, the first author has been consulted to review 3 cases of paraplegia following lumbar TFESIs performed in the "safe" triangle. One is sub judice and cannot be discussed secondary to confidentiality. In the second case, an 83-year-old woman developed paraplegia immediately following a right L2-3 TFESI. Fluoroscopic images were unfortunately unavailable for this case. The rapid onset of paraplegia and spinal cord signal abnormalities on follow-up MRI points to an artery of Adamkiewicz (ARM) injury as the etiology.

The third case is a 62-year-old triathlete that developed paraplegia following a right sided L4-5 TFESI. This patient initially presented with right lower extremity pain secondary to a far lateral, right sided L4-5 disc protrusion. Due to a lack of improvement at 4 weeks, the patient underwent a lumbar TFESI to facilitate pain relief and return to training. A right sided, "safe triangle" L4-5 TFESI was performed. The fluoroscopic images demonstrated needle placement within the anterosuperior foramen. Following the injection of contrast, a static fluoroscopic image demonstrated dye flow alongside the exiting nerve root that ended just medial to the L4 pedicle. Paraplegia developed immediately and the patient has had only mild improvement, despite vigorous rehabilitation.

This particular topic has generated a great deal of interest and concern among interventional pain physicians. The unique association of paraplegia with TFESIs has generated considerable debate and controversy. The TFESI is most commonly performed utilizing the "safe triangle" approach (Fig. 1). The "safe" triangle refers to a fluoroscopic region just lateral to the inferior margin of the pedicle, dorsal to the vertebral body, and cephalad to the nerve root. This zone is regarded as safe, since needle placement in this region avoids the nerve root. Under fluoroscopy, the inferior endplate of the cephalad-vertebral body and the superior endplate of the caudad vertebral body are aligned with the gantry angle of the C-arm, i.e., "squared" off. The C-arm is then rotated obliquely until the "Scotty Dog" view is obtained. This oblique angle "moves" the ipsilateral pedicle towards the middle of the vertebral body. The needle is then directed through the skin towards the inferolateral boundary of the pedicle. The needle is

Fig. 1. *Saggital MRI of lumbar spine revealing enlarged radiculomedullary artery traversing body of vertebra.*

coaxial to the long axis of the fluoroscope beam. The needle is advanced until bony contact is made with the vertebral body. Needle placement is within the antero-superior intervertebral foramen. Needle depth is monitored with a lateral view. The final needle tip location is at the 6 o'clock position of the pedicle—assuming an imaginary clock is superimposed on an A-P view of the pedicle. A lateral view will demonstrate the needle tip to be immediately posterior to the vertebral body. This is described as the "safe" triangle (23,24).

The "safe triangle" approach to thoracolumbar TFESIs is advocated as the standard of care by the International Spinal Intervention Society (ISIS) (25). This has been disseminated via publications that include guidelines, seminars, and videotapes (26,27). Needle placement in the "safe" triangle is widely assumed to be the correct way to perform a thoracolumbar TFESI. Unfortunately, the popularity of this technique outstrips concerns about risk. The vascular anatomy of the "safe triangle" and the implications for TFESIs were not fully understood, as this procedure quickly evolved to become de riguer for the interventionalist. According to Bogduk et al (21), more disconcerting is that arterial puncture can occur even with correct placement of the needle at recommended target points. This is due to the close proximity of the radicular artery to the spinal nerve. Nonetheless, most practitioners continue to practice the "safe" triangle technique with perceived impunity.

TFESI-associated paraplegia meets the criteria for a "black swan event," as described by Taleb (28): 1) the event is a surprise (to the observer) or outlier, 2) the event has a major impact, and 3) after the fact, the event is rationalized by hindsight, as if it had been expected. TFESI-associated paraplegia is a rare event, it has a major impact (paraplegia), and the event is rationalized by hindsight, as if it had been expected (litigation, expert testimony). Different practitioners have developed strategies to protect against TFESI-associated paraplegia. However, many of these practitioners suffer from "survivorship bias" — the logical error focusing on the millions of survivors of TFESIs and not on the rare paraplegias stemming from TFESI. There is an overconfidence that this "black swan" event can be eliminated vis a vis procedural modifications: digital subtraction angiography, lidocaine challenge, avoidance of particulate steroids, live fluoroscopy, or blunt/short beveled needles. The latter approach has been investigated in an article demonstrating the reduced capability of a blunt needle in puncturing an arterial wall, relative to a sharp needle (29). Taleb (28), however, contends "Black Swans being unpredictable, we need to adjust to their existence (rather than naively try to predict them)."

Notably absent from the classic depiction of the "safe" triangle (Fig. 1) is the vascular anatomy. The anterior thoracolumbar spinal cord is heavily dependent upon the anterior spinal artery. In turn, the anterior spinal artery is highly dependent on the contribution from a large and variably located radiculomedullary artery, the artery of Adamkiewicz. Interruption of the blood supply through this individual radicullomedullary artery may be responsible for paraplegia following aortic bypass procedures. Avoiding this vital artery is paramount during the performance of an interventional pain procedure.

Radiculomedullary arteries are found bilaterally at every vertebral foraminal level. In the thoracic spine, radiculomedullary arteries are formed by posterior intercostal arteries. In the lumbar spine, radiculomedullary arteries are formed by paired lumbar arteries. At the thoracic levels 6-8, posterior intercostal arteries pass laterally and then, posteriorly along the anterolateral margin of the vertebral body towards the intervertebral foramen (30). This is the shortest route between the aorta and spinal cord. After the intercostal artery wraps around the lateral vertebral body groove, it passes medially under the pedicle. In the lumbar spine, the arteries originate more cephalically as they pass from the aorta en route to the foramen. Hence, they lie close to the superior endplate of the lumbar vertebral body (31) (Fig.2).

Each artery divides into a series of major branches (abdominal wall, intermediate or spinal canal, and the posterior body wall branches) just outside the level of the intervertebral foramina. The spinal canal (intermediate) branches divide into the anterior spinal canal, the nervous system, and the posterior spinal canal branches. The nervous system branches are the radiculomedullary arteries and they arise from this segmental artery, located just outside of the spinal canal. These radiculomedullary arteries are vulnerable during the performance of "safe" triangle TFESIs (Fig.3) .

As the segmental artery courses around the posterior aspect of the vertebra, the arterial branches that comprise the radicullomedullary arteries course upwards towards the pedicle. They reach the superior edge of the adjacent nerve root, located just outside or within the foramen; they run along the dural nerve root sleeve for a short distance (31). These arteries supply blood to the spinal cord via direct cord pen-

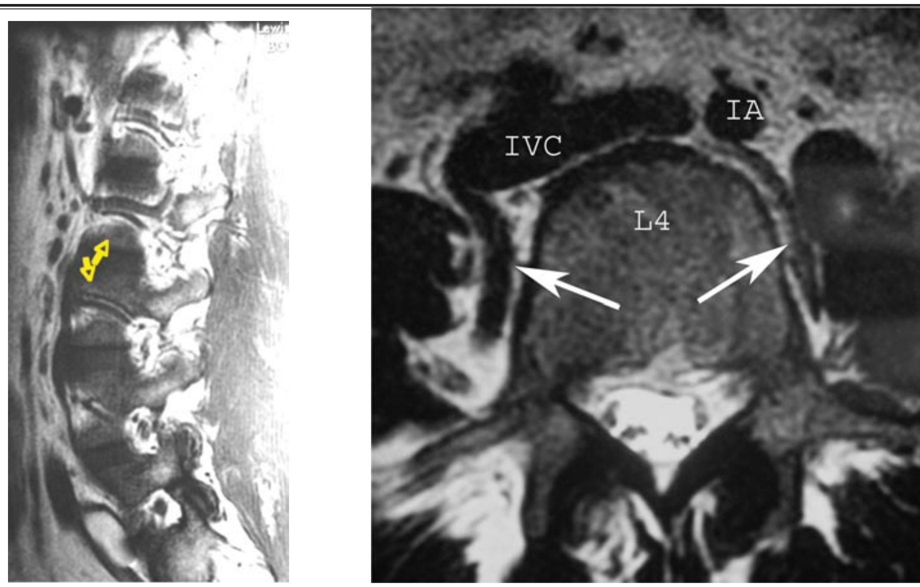

Fig. 2. *Left: parasagittal T1 weighted MRI demonstrating segmental arterial vessels and Right: axial T2 weighted MRI with right arrow pointing to segmental arterial vessel and left arrow pointing to segmental vein*

etration or regional anastomoses with the anterior spinal artery. However, one radiculomedullary vessel is unique: arteria radicularis magna or artery of Adamkiewicz. This vessel is the major contributor to the anterior spinal artery. This is a remote, not regional, anastomosis. After passing through the foramen, the ARM turns sharply and travels cephalad for several segments. Then this vessel makes a characteristic downward "hairpin" turn to anastomose with the anterior spinal artery (Fig. 4) (33).

The ARM may enter the spinal canal at any intervertebral foramen, spanning T5 to L5. In greater than two-thirds of cadavers, the ARM was found along the lumbar nerve roots (34). This anatomic study highlighted the "remarkable variability of the ARM origin." The ARM enters the spinal canal on the left 69-85% percent of the time, based on anatomic and radiologic studies; it enters the right side 15-31% of the time. The ARM might be duplicated in some individuals. It might be split ipsilaterally between adjacent foramina or bilaterally between contralateral foramina (35). In summary, the ARM can be found in any lumbar or thoracic foramen. Knowledge of radiculomedullary and segmental arterial anatomy is of paramount importance when performing TFESIs. However, anatomic studies can only demonstrate the statistical odds of encountering the ARM in one foramen versus another. Practitioners will not know ahead of time if their planned "safe" triangle TFESI will encounter the ARM.

In contradistinction to the variable foraminal level of the ARM, the anatomic relationship of the radiculomedullary arteries and ARM to individual foraminal landmarks is constant. Radiculomedullary arteries travel in a path proximate to and within the foramen; this path has negligible inter-individual variability. The arteries join the nerve root at the foramen; the artery then courses medially through the superoanterior or midportion of the foramen, in close juxtaposition to the dorsal root ganglion-ventral root complex (36,37).

The "safe" triangle is a busy vascular region wherein the radiculomedullary arteries and ARM become predictably invested within the superior and anterior aspect of the nerve root sleeve. These radiculomedullary vessels or ARM may become accessed or injured as soon as the needle is advanced into the "safe" triangle. Direct injury ranges from vasospasm and/or intimal flap formation, to the transection of the vessel. Indirect injury includes inadvertent embolization with injectate. All of these events can impair perfusion and lead to paraplegia, if the involved artery happens to be the ARM. A practioner cannot predict which foramen contains the ARM and one cannot know, in an a priori manner, about the collateral supply to the anterior spinal artery. As a "black swan event," paraplegia

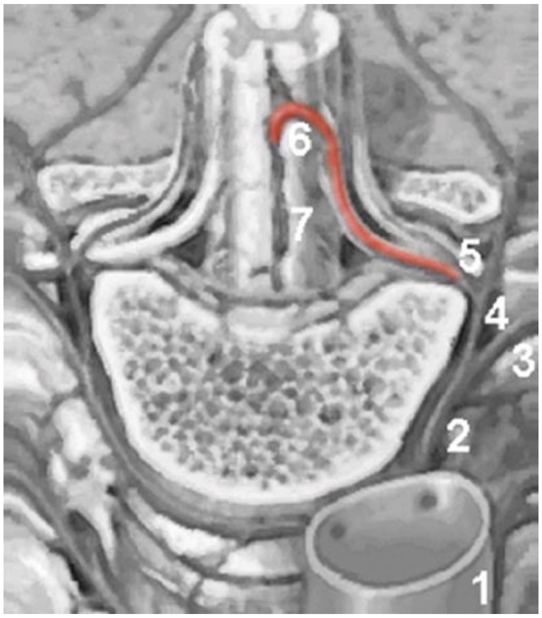

Fig. 3. *Course of artery of Adamkiewicz (red) and its feeding arteries. Schematic drawing originating from thoracic aorta (1), intercostal artery (2) subdivides into anterior (3) and posterior (4) branches. Posterior branch courses to spine and enters vertebral foramen as radiculomedullary artery (5). AAdapted from Boll et al (35) Angiography of the Spinal Vasculature and the Artery of Adamkiewicz. Am. J. Roentgenol. 2006 187: 1054-1060*

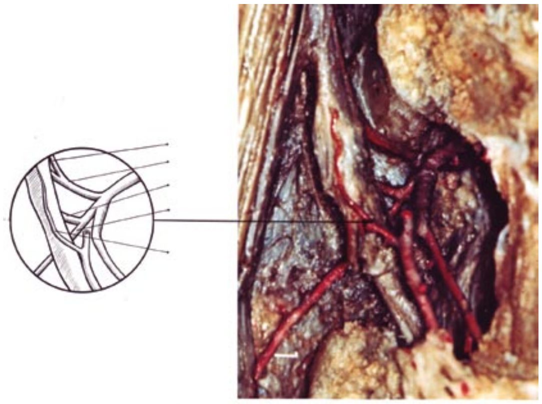

Fig. 4. *A detailed photograph shows the anterior spinal canal branches lying anterior to the emerging lumbar nerve root at the intervertebral foramen, together with the ascending anterior and posterior nerve root branches (neural branches) of the lumbar artery. Reprinted with permission from Crock et al. The blood supply of the vertebral column and spinal cord in man. RR Donnelly & Sons, Chicago, 1977 (32).*

is a disastrous outcome with a finite probability. We contend that the 'safe' triangle is not safe. There is a non-quantifiable risk of paraplegia due to the regional vascular anatomy of the foramen. The authors contend that an alternative location within the foramen, such as Kambin's triangle, should be considered. In the interest of patient safety, the authors advise that the 'safe' triangle be avoided.

Alternatively, the TFESI can be performed at the caudal aspect of the foramen—underneath the nerve root. In this technique, the endplates bounding the intervertebral foramen should be aligned with the fluoroscopy beam "squared off." Under an oblique projection, the skin is entered just lateral to the superior articular process of the caudad vertebral body at the intervertebral disc level. The needle is advanced with intermittent lateral projections to monitor depth. The superior articular process might be contacted. This is a retrodiscal foraminal approach and one can avoid an intradiscal injection (38). Close monitoring with contrast injectate allows early recognition of an intradiscal injection (39). Intradiscal injections are not complications. Furthermore, the morbidity of disciitis is negligible as compared to paraplegia.

The retrodiscal approach is utilized to create a surgical roadmap for posterolateral endoscopic discectomy. This retrodiscal zone has been described by Kambin: Kambin's triangle (40,41). This is a right triangle overlying the dorsolateral disc. The triangle is defined by the hypotenuse, base, and height. The hypotenuse is the exiting nerve; the base is the caudad vertebral body; and the height is the traversing nerve root. According to Kambin (40,41), "As the spinal nerve descends diagonally across the intervertebral disc, the annulotomy site is defined inferiorly by the proximal vertebral plate, and posteriorly by the articular process of the lower segment. Departing from the foramen, the exiting root moves anteriorly, distally, and laterally, and forms the anterior boundary of the triangular working zone. Within the triangle, there is generally ample room for introduction of the coaxial instruments." Several references (40,41) have attested to the safety of endoscopic foraminotomies with or without laser assistance; instrumentation in this space typically includes trephines, lasers, curettes, forceps, and rasps. There is limited visualization and a need for live fluoroscopy. Many of these techniques demand pre-procedural placement of a needle and guidewire with fluoroscopic guidance (40,41). The safety of endoscopic foraminotomies bears direct relevance to the safety of a TFESI performed in this triangular working zone. A Kambin triangle TFESI (KT-TFESI) uses less manipulation and smaller caliber needles, as compared to an endoscopic foraminotomy.

The relative safety of an endoscopic foraminotomy implicitly may support the safety of the Kambin triangle TFESI with respect to nerve root and vascular injury. Furthermore, the purpose of a TFESI is to target the disc nerve root interface and the Kambin triangular working zone targets this interface. We hypothesize that targeting Kambin's triangle instead of the "safe triangle" might improve the efficacy of TFESI (Fig. 5). In this Kambin triangle technique steroids are instilled directly at the nerve-disc interface. The "safe" triangle TFESI does not directly target the nerve-disc interface, but instead delivers steroids distal to the nerve-disc interface.

Despite the anatomic vulnerability of the radiculomedullary vessels, most physicians continue to believe the "safe" triangle technique is safe and that complications are due to malfeasance by the proceduralist. Physicians hired as experts for the plaintiff focus on searching for operator-dependent errors. Once these purported errors are identified, these hired physicians will try to establish a cause and effect relationship using hindsight analysis. One typical line of attack is that the proceduralist failed to recognize an intra-arterial injection. However, recognition of intra-arterial needle placement requires that the needle remain fixed in a constant intraluminal position for the duration of the procedure. "Safe" triangle needle placement is virtually perpendicular to the artery. Small movements, by the patient or operator during syringe transfers, can dislodge the needle by a few millimeters. An initially negative vascular uptake on live fluoroscopy or digital subtraction angiography will be moot, i.e., become a false negative, if the needle migrates intraluminally just prior to steroid instillation. Needle trauma can create an intimal flap and/or arterial spasm—this will also be a false negative. Partial or complete transection of the artery may occur — the outer diameter of the ARM according to Alleyne et al (37) is comparable to the outer diameter of the 22-gauge spinal needle. This would be comparable to placing a 12-gauge needle into the radial artery; radial artery injury and vasospasm is a well established phenomenon even with smaller guage cannulation procedures the authors believe that these are more plausible explanations, as compared to blaming the operator, for the development of a devastating neurovascular complication. We contend that expert testimony that blames the operator for failing to recognize intravascular uptake as the root cause of TFESI-paraplegia is tantamount to sophistry.

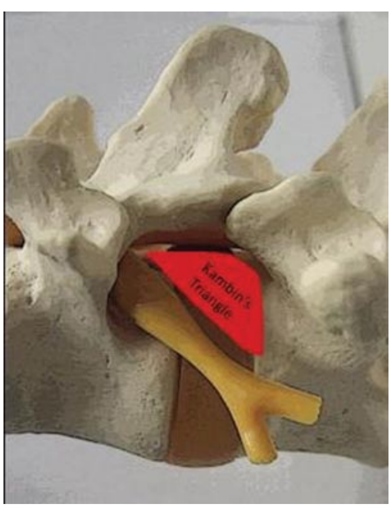

Fig. 5. *Illustration of Kambin's triangle.*

Thoracic and lumbar sympathetic nerve blocks deserve mention, since these procedures may also endanger blood flow through the ARM. Sympathetic nerve blocks require placement of the needle at the anterolateral aspect of the vertebral body, as is the case for celiac plexus blocks, splanchnic nerve blocks, lumbar paravertebral sympathetic nerve blocks, and superior hypogastric plexus blocks. Knowledge of the path of the arteries off of the aorta is imperative so as to avoid them while performing these procedures. In the lower thoracic and upper lumbar spine, one must avoid the middle of the vertebral body. In the lower lumbar spine, the middle and upper aspects of the vertebral body should be avoided. The artery sweeps posteriorly and caudally from a position close to the superior endplate. Datta et al (42), described this vascular anatomy in their cadaveric study of the lumbar sympathetic plexus and the surrounding structures.

In summary, the ARM is highly variable with respect to the lumbar or thoracic foramen traversed. The location of the ARM is highly consistent relative to the vertebral body, foramen, and nerve roots. Considering these indisputable anatomic facts, We contend that there is only one conclusion: if interventionalists continue to place needles/devices in the inappropriately named "safe" triangle, cases of paraplegia will accrue due to statistical likelihood. Since this is a "black swan" event, a patient safety checklist or technique modification will not prevent these complications. However, if this elective TFESI is performed in another location, such as Kambin's triangle, then the incidence of paraplegia, due to vascular injury, will decrease or perhaps, disappear. We contend that attempts to salvage the "safe" triangle TFESI because of its "iconic" value will not prevent paraplegia and will serve as fodder for speculative, plaintiff expert testimony. It is incumbent that interventionalists make every effort to avoid and therefore defend the radiculomedullary artery from injury.

Conclusion

Primum non nocicerum — firstly, do no harm. We contend that by avoiding the "safe" triangle when performing a TFESI, and utilizing alternate methods such as the Kambin triangle approach, that this procedure can be performed in an efficacious and safer manner.

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