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Medical-legal aspects and risk management

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Complications of spinal surgery are an important source of professional liability judgments for trauma surgeons and neurosurgeons who develop this subspecialty. The disc pathology leads all the rankings of claims against these professionals. [1,2,3] This situation does not attract attention, given that lumbar and cervical disc hernias are frequent affections and more and more surgeons are turning to this activity. For the current neurosurgeon, the pathology of the spine tends to represent 50% of its benefits [4]. The high cost of agreements and sentences in cases of spinal surgeries is a reflection of the infrequent but severe damage that can occur when working millimeters from the spinal cord and nerve roots.

Spine surgery has all the ingredients that can make a trial a nightmare. In general, patients with pathologies that do not threaten life, where the main symptom (pain) has a strong subjective component and where often the opinions of experts differ between conservative and radical approaches. There are several alternatives that are not always adequately reported to the patient, who may be surprised at evolutions that were not anticipated. On the other hand, in the case of quadriplegic or paraplegic patients, the costs of lost profits and future expenses are usually millionaires [5,6,7,8]. It is an extensive, varied and complex discipline and there are many authors who suggest the need to convert it into a new specialty [4] [9,10]. Spinal surgery is technically difficult and acquiring the necessary skills demands years of learning. The margin of error is minimal and only careful attention to detail in the pre, intra and postoperative ensures consistent good results. When complications arise and judgments for professional responsibility, the rush in the surgical decision (except in cases of clear urgency) and the lack of adequate information to the patient are usually aspects widely debated by all parties.

Most malpractice claims in spinal surgeries have their origin in the inadequate selection of the patient, the lack of a psychological evaluation in cases that merit it and not having exhausted the bloodless treatments. To this the complications of surgical instrumentation are added many times [11].

Specific complications that trigger lawsuits

Table 1: Causes of malpractice lawsuits in spine surgeries.	
1	Dural tear
2	Error level
3	Vascular or visceral lesions
4	Horsetail syndrome
5	Neurological deficit added
6	Forgotten
7	Error aside
8	Amaurosis (ischemic optic neuropathy)
9	Infections
10	Failed lumbar spine syndrome

Dural tear

It is estimated that the incidence of unintentional durotomies during spinal surgery is between 0.3% to 13%, reaching 17.6% in the case of reoperations [12]. It is one of the most frequent complications of lumbar spine surgery. In a study of 146 trials against North American traumatologists, it represented the second cause of demands, second only to horsetail syndrome [12]. Although the dural tear was always considered a relatively benign occurrence, a 2005 study showed a worse long-term evolution in patients who had suffered this complication [13]. The dural injury itself is not enough to cause lawsuits. In all cases of the mentioned series the dural tear was accompanied by some sequelae (nerve damage, horsetail syndrome, CSF fistula, pain, arachnoiditis, pseudo meningocele, sphincter disorders and infections.) Damage to the dura mater is an accepted complication of lumbar spine surgery that is often difficult to avoid in complex decompressions. Its occurrence can complicate the surgery, since the loss of fluid decreases the pressure on the epidural veins, facilitating bleeding. The blood and fluid then make the surgeon's vision difficult. If the fistula occurs, the surgeon should try to repair it, if possible, which often implies greater exposure. In the case of not being able to do it, the closing of the muscular planes must be very meticulous to avoid fistulas. Most of them resolve spontaneously and on rare occasions a new intervention is required. Exceptionally, a pseudomeningocele may be developed that also requires a surgical solution. Given its relative frequency, the dural tear is a potential complication that should be discussed with the patient during the informed consent process. If it occurs, the measures taken to repair the defect should appear in the surgical part. The patient should be warned of its occurrence and postoperative control (and documentation thereof) should be intensified in order to prevent sequelae.

Level error

Although it is infrequent, the level mistake in herniated disk surgeries is a concrete possibility that in case of materializing has a chance close to 100% of becoming a trial for malpractice. Generally, these lawsuits are won by the plaintiffs. In the series of 68 claims for level error filed by Godkind and Laska [14] in 2004, 81% resulted in agreements or judgments favorable to the plaintiff. Level error is the second cause of reoperations in disc herniations (after reintervention to remove disc remains) Many times this error originates in a misinterpretation of congenital anatomical variations. Approximately 5% of the population has six lumbar vertebrae where one of the sacral segments is "lumbarized" or 4 lumbar vertebrae, where the last lumbar is "sacralized". This can confuse the surgeon and trigger the error, especially when there are no studies in the operating room, fluoroscopy is not available, or an adequate radiograph cannot be taken due to technical limitations of the table or some characteristic of the patient. The surgeon must maintain a high index of suspicion when the operative findings are not consistent with what was expected according to the semiology and studies. Although the root cause of this error can be understood, most of the specialized experts consider it unacceptable and very difficult to defend. It is therefore imperative that the surgeon adopt safety measures that guarantee the identification of the correct level. There are basically two methods. One is to expose the sacrum in the operative field. It is

possible to identify the structures through direct vision and palpation of the levels. In the case of minimally invasive surgeries, the correct level can be identified by introducing a needle at the supposedly affected level, proceeding to check it radiologically. Optionally, methylene blue labeling can be used through the same needle. It is prudent to document all the measures adopted to identify the level and, in case of radioscopic control with a needle, make and save a plate.

Vascular or visceral injuries

Vascular or visceral lesions secondary to perforation of the anterior annulus by the extractor are the most lethal complications to which a surgeon The frequency described in some works of vascular lesions (aorta, cava or iliac vessels) varies in a wide range from 1.6 to 17 per 10,000 surgeries [15,16], with an associated mortality that goes from 15 % to 62%. The visceral lesions (intestine, ureters, bladder and pancreas) are estimated at 3.8 per 10,000 cases [17]. In a review of 21 trials for malpractice as a result of this case in the USA, it was observed that nearly half (48%) were resolved in favor of the plaintiffs. (fifteen) Despite the ominous nature of these injuries, their mere occurrence is not usually considered "ipso facto" evidence of negligence on the part of the experts. What is expected in case this happens is that this complication is recognized and treated quickly. This is not always so easy. Many lesions go unnoticed in the first few minutes, since massive hemorrhage that alerts early is not observed in the surgical field. Perforation of the fibrous annulus and vascular lesion generally go unnoticed by the surgeon. It must maintain a high index of suspicion when working in radical exegesis in the anterior disc space. Hypotension or the appearance of small amounts of blood in the resection instruments are the main warning signs. The disc space is avascular and the instruments should appear dry and clean. Upon suspicion, urgent help should be sought from vascular surgeons. The tragedies occur when the spine surgeon lets himself be in the hope that the injury is minimal and resolves spontaneously. It is then too late to avoid the fatal outcome.

There is some controversy about the need to inform the patient of a risk of such low frequency in the consent process. Some surgeons consider this probability to be so low that they do not include it explicitly in the information provided to the patient, beyond including this risk in a generic way when discussing the possibility of death. Other surgeons consider it easier to explain an unplanned laparotomy if this potential complication was mentioned preoperatively.

Horsetail Syndrome

The appearance of this syndrome also usually causes medical-legal problems. It can manifest itself in the preoperative period due to the same pathology (disc or others). In these cases, the demands are usually based on the lack of diagnosis and early treatment. It can also appear exceptionally in the postoperative period as a complication, and in that case the demands are generally based on surgical malpractice. Horsetail syndrome is a rare complication of lumbar spine surgery, with a probability ranging between 0.002% and 0.3% [18,19]. In a review of 20 malpractice trials with this postoperative picture, 6 cases were associated with cerebrospinal fluid fistulas and 4 were due to epidural hematomas [20]. 16 of the 20 cases were resolved in favor of the plaintiffs. As with other low frequency but potentially serious complications, it is also controversial whether this risk should be discussed with patients. It seems prudent to do so, especially in those that refer to potential sphincteric and sexual disorders. The consultation of a patient not operated on with this symptomatology should also trigger a rapid response. Horsetail syndrome occurs in about 3% of lumbar disc hernias [21]. The recognition of this acute condition usually falls on the doctor on duty and secondarily on the specialist called in inter consultation. In these cases, a meticulous questioning and physical examination should be performed and documented, including rectal tone and peri-anal sensitivity. The assessment

of bladder function should also be established. Neurological monitoring must be performed and recorded at frequent intervals. In case of severe commitment, the response must be immediate.

Neurological deficit added

The incidence of damage to motor roots with paresis resulting in surgery of the lumbar spine has been estimated between 0.5% to 9%, with L5 being the most commonly damaged nerve root [22,23]. In their review of 109 malpractice trials for spine surgery, Godkind and Laska identified 15 cases of nerve root injuries: 14 with dorsiflexion deficits - "foot drop" - and 1 with loss of plantar flexion. One third of these cases were associated with Dural tears. Doctors lost more than half of them [12]. When these injuries occur, the defenses are usually based on disc surgery working decompressing roots that were already vulnerable and compressed in the foramen and even the most delicate retraction of the same (necessary to expose the disc or to remove the bone that compresses) can affect future function. This can happen even in the best hands and it is inevitable. However, sometimes the roots are lacerated and severely damaged by the instruments. This situation is usually the result of a poor surgical technique and is very difficult to defend. This complication is not usually expected from a competent spine surgeon. A single line of defense would consist of being able to demonstrate that the foramen was so narrow that it prevented the complete visualization of the root making inevitable the contusion of the same one. All operative difficulties should be well exposed in the surgical part. Of little use in these cases the usual phrase: "surgery according to technique ..."

Fixation with bone graft and transpedicular screws is also a possible source of root lesions. The screw insertion maneuver is usually performed blindly, with anatomical knowledge of the direction of the pedicles. Studies have shown that even in expert hands, 20% of the screws go beyond the limits of the pedicle [24]. This is not usually clinically important, but from time to time some serious deviation in the insertion may occur that ends up damaging some nerve root. This can occur when the anatomy of the spine is slightly abnormal, even going unnoticed by the surgeon. The complication is usually noticed when the patient recovers from the anesthesia complaining of pain or deficit in the leg. X-rays are not always helpful in confirming whether or not the screw has passed through the pedicle due to shadows superimposed on the plate. The clinical diagnosis is not simple either, since the postoperative pain can also be due to the manipulation and previous compression of said root and it cannot be determined in what degree the screw is badly placed responsible for this situation. If the screw has completely transfixed the root it is unlikely that the surgery will relieve the symptoms. If you only compress or irritate it, removal can be beneficial. Not necessarily the bad position of the screws is the result of the lack of skill and there are elements that allow to elaborate some line of defense if the surgeon is sued. In these cases, the position but no one disputes that they should be discussed with the patient in the process of informed consent.

Forgotten

The column has been described as one of the areas where the incidence of forgotten (gauze, cottons, compresses or instruments forgotten in the patient) is greater [27]. Almost unanimously, the judicial decisions consider the obligation as constituting negligence, understanding it as the failure to adopt the necessary precautions. It is generally considered that something else was missing to prevent the event from happening. Most of these cases are resolved in favor of the plaintiffs and are practically impossible to defend. In general, the legal principle of "res ipsa loquitor" (the thing speaks for itself) applies. The only way to prevent this error is the firm adherence to the counting protocols and the rules to follow in the event that it is inconsistent.

Side error

The side error has received in recent years the attention of surgical safety specialists around the world. It is a 100% avoidable incident and its occurrence is indefensible. These mistakes have also been described in spine surgery, favored by the confusion that sometimes generates the ventral decubitus. The immense majority of the judgments originated in this mistake are lost with important compensations. To prevent this risk is not enough to appeal to the individual responsibility of each surgeon. Undoubtedly, institutional measures must also be taken to intercept this error and prevent it from happening. Most authors agree on the need to standardize and standardize presurgical marking [28,29]. The side error is preventable when levels of check are established by the surgeon and his team and when the patient goes to the operating room with the indelibly marked site. The patient must participate actively by specifying the affected site. In turn, verification that the brand is correct is part of the checklist that all surgical equipment must perform before incising skin [30].

Amaurosis (Ischemic Optic Neuropathy)

Our legal department has received two demands for this cause in the last 5 years. The picture is devastating. Patients undergoing spinal surgeries for benign pathologies wake up blind in one eye. This very rare probability had not been noticed, generating a deep anger and anguish in the patient. The frequency described of this possibility according to some authors is 0.12% [31]. A recent work (2009) that analyzes the prevalence of this phenomenon over 10 years, reported an incidence of 3.09 / 10,000 in spinal fusions [32]. The unexpected loss of vision in these procedures is a complication that has received increasing attention from anesthesiologists, spine surgeons and ophthalmologists over the past 15 years. However, despite the greater awareness, professionals are in a difficult situation, since it is very difficult to prevent these complications when in most cases the etiology is not clear. Generally, the loss of vision is not produced by direct compression on the eyeball, although it is the first thing that tends to think. Instead, a multifactorial etiology is postulated, probably associated with large blood losses, hypotension, anemia and prolonged duration of surgery. However, amaurosis can also be caused by compression of the balloon against the head when the patient is in the ventral decubitus position. When this complication occurs, the demand is most likely based on the fact that the anesthesiologist and the surgeon did not adequately protect the eye.

From the medico-legal point of view, the plaintiff's lawyers usually also invoke in these cases the legal doctrine of "res ipsa loquitor" ("the thing speaks for itself"). Although it may be debatable, the concrete thing is that in situations of this type the burden of proof falls heavily on the professional, who must demonstrate that the care was not negligent. And the best way to do it without leaving weak flanks is to document in the anesthetic sheet the protection of the decubitus of the eyeballs. There is no unanimity among professionals about whether a risk of such low probability should be informed to the patient in the consent process. However, some authors recommend that all patients who will undergo spinal surgery be warned of this risk, which, although very low, is invalidating and intractable.

Infections

The probability of superficial or deep infection after spinal surgery, according to large published series, is close to 4%. In more than two thirds of the cases the causative organism is Staphylococcus Aureus [33]. It is tra It is an anticipated risk that the patient must be warned, notwithstanding that the doctor takes the appropriate measures to prevent infection and, if the complication occurs, attend to it with opportunity and effectiveness avoiding the aggravation of it. In trials originating in this case, the burden of proof falls heavily on the surgeon and the institution, who must demonstrate an "exquisite diligence" in the prevention of these events. All the measures tending to this should be adequately established

in the clinical history (eg: pre-surgical bath, antisepsis, controlled glycemia, suspension of smoking, etc.). There is no consensus about the need for prophylactic antibiotic therapy in surgeries without instrumentation, and routine antibiotics are rarely used. However, in case of placing prostheses, the Argentine Society of Infectious Diseases (SADI, Consensus 2009, Mar del Plata) recommends administering 1 to 2 g of cefazolin in the anesthetic preinduction and continue with 1 to 2 gr c / 8 hs. for a maximum of 24. As an alternative, the use of cephalothin 1 to 2 gr. in pre-induction, and then 1 gr. 6 hs for 24 hs. In the case of β-lactam allergy, the SADI recommends Vancomycin 1 g in anesthetic preinduction and continue with 1 g c / 12 h for a maximum of 24 h. [34].

Failed back surgery syndrome

Decompressive surgery of herniated disc is the most frequent surgical intervention at the level of the lumbar spine and one of the most common of orthopedic and neurological surgery. The success of the same varies in a wide range, finding in the literature percentages ranging from 60 to 90% [35,36]. The number of patients that do not improve or even worsen is then significantly high and they are grouped into those that evolve with the "Failed Lumbar Spine Syndrome". It is characterized by the recurrence of pain after surgery, in the absence of disc or bone pathology that justifies it. Due to the high percentage of failures, reinterventions after the first surgery are sometimes necessary, in a range that ranges from 5 to 18% of the patients, obtaining in these cases poor results regarding pain reduction and functional improvement [37].

Failed back surgery syndrome (FBSS) is a term used to define an unsatisfactory outcome of a patient who underwent spinal surgery, irrespective of type or intervention area, with persistent pain in the lumbosacral region with or without it radiating to the leg. The possible reasons and risk factors that would lead to FBSS can be found in distinct phases:

- in problems already present in the patient before a surgical approach, such as spinal instability,
- during surgery (for example, from a mistake by the surgeon),
- or in the postintervention phase in relation to infections or biomechanical alterations. [38,39]

This picture is one of the main causes of lawsuits against traumatologists and neurosurgeons. Although frequent, it is very difficult for these lawsuits to be resolved against the doctor. There are many causes that can explain this symptomatology and most are not due to malpractice on the part of the acting professionals. The main etiology (around 24% of cases) is peridural fibrosis [38], the result of a scarring response specific to each organism that is beyond the professional's control. On the other hand, there is strong evidence that psychosocial factors can have a significant influence on the perception and chronicity of pain, which could partially explain the lack of success of this surgery, even when the morphological problems have disappeared after the intervention. Another cause described of this syndrome originates in an insufficient decompression of the lateral recess with foraminal stenosis. Although someone can claim some error of judgment or execution by the surgeon, it can hardly be said that he has failed to comply with the standard of practice accepted by the average professional. The development of segmental instability after lumbar disc hernia surgery may require a posterior fixation, but this problem can also appear without necessarily implying negligence.

Conclusion

Spine surgery is a procedure with serious potential complications, even in the best hands. While the benefits of it can be considerable, all conservative approaches that are reasonable should be exhausted first. The decision of the surgical moment is difficult and requires a highly developed clinical judgment. On the other hand, the spectrum of opinions for the

same pathology among different surgeons is broad. Some prefer a radical approach, offering early surgery with the aim of accelerating recovery and facilitating labor reintegration. Others are in favor of a more conservative approach. In the long term, most spinal conditions have a benign natural history and the only absolute indication for surgery are sphincteric symptoms or severe neurological deficit. Even with severe sciatica and marked signs of root tension, surgery is not mandatory. Over time the symptoms usually resolve, perhaps not completely, but at least to a manageable level. If the duration of the symptoms has been less than two weeks, it is very difficult to predict the natural evolution. Without surgery, these patients usually recover with conservative treatment with total remission of symptoms and are able to return to work after three months. However, if the initial symptomatology persists for more than 18 weeks, the prognosis of remission is less optimistic. For this reason, many spine surgeons do not consider as good practice to operate patients with lumbosciatica less than 18 weeks of evolution, in the absence of symptoms of bladder or motor dysfunction.

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