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Complications of Spine Surgery and Litigations – Managing Malpractice Risk

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Abstract

Complications of spine surgery are common in surgical practice and practitioners should be aware of the multiple risks related to these operations as well as of the means to prevent them. To present day in Belgium, the patient has to support the evidence of a fault resulting from medical malpractice in case of legal dispute.

The authors remind the foundations of the medical responsibility applied to the surgery of the spine in Belgium, although it is well known that any surgical damage does not necessarily result from an error or from a surgical misconduct, and that therefore, the surgeon is not always responsible for the damage in the absence of a proven fault in the legal sense.

Keywords: Spine surgery; Complications; Malpractice; Litigation; Informed consent

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Introduction

Spine surgery has made huge progresses, particularly in the analysis, understanding and realization of spinal osteosynthesis and fusions. In addition, multiple minimally invasive approaches provide answers to many problems encountered by spinal surgeons whether of orthopedic or neurosurgical backgrounds. In spine surgery, there are basically two main surgical options with many different techniques supporting them. The first consists in the decompression of the neural elements of the spine from tightness. The second aims to stabilize the spine in order to protect the nerves and eliminate the pain resulting from abnormal loading from the different movements. Any indication for surgery has to be well documented since the expected results are far less predictable if the actual indication for one of these surgical options is not clear. Let us beware then when the phrase "unindicated surgery" is pronounced during a litigation process because it is often referring to the lack of reasonable identification of the surgical problem. In order to draw the practitioners' attention on the multiple risks related to these operations, we will describe some complications of usual spine surgery as well as the means to prevent their unwanted side-effects or to have them discontinued.

Complications of Spine Surgery

Neurologic complications can be classified according to onset (per- vs. postoperative) and surgical site (cervical vs. thoracolumbar). Onset may be at any stage of treatment, and complications may be classified by period of onset as well as by the underlying mechanism [1]. The overall incidence of complications or adverse events in spinal surgery is not sufficiently documented. In a systematic review of the literature on complications in spinal surgery, Nasser et al. (2010) analyzed 105 articles. They found that of the 79,471 patients, 16.4% presented a complication of one type or another and the incidence was twice as high in thoracolumbar surgery (17.8%) than for the neck (8.9%) [2]. General complications include mortality, deep venous thrombosis and pulmonary embolism, chest/urinary infections. Local complications are most often related to incorrect positioning or during the surgical procedure and they may include: nerve injury, dural tear, bleeding, infection, improper use of instrumentation, and pseudoarthrosis. **Table 1** lists the major complications in cases of first-time lumbar micro discectomy, anterior cervical discectomy and fusion, and lumbar stenosis decompression [3]. In his excellent review article [4], Garreau de Loubresse has analyzed and discussed the major risks and complications of these surgical procedures.

Neurologic Compression of the Limbs

Peripheral nerve injuries occurring postoperatively due to patient malpositioning have been described in the literature for nearly a century, probably with a strong bias toward underreporting, and they still constitute a frequent cause for malpractice claims

Table 1 Major complications in cases of first-time surgical procedures of the spine.

Procedure			
Complication, Number (%)	Lumbar Microdiscectomy (n=9,692)	ACDF * (n=6,735)	Lumbar Stenosis Decompression (n=10,329)
Dural tear	156 (1.6)	11 (0.2)	321 (3.1)
Wound infection	45 (0.5)	13 (0.2)	93 (1.0)
Superficial	34 (0.4)	9 (0.1)	111 (1.1)
Deep	57 (0.6)	24 (0.4)	9 (0.01)
Other	28 (0.3)	19 (0.3)	62 (0.6)
Acute neurologic	11 (0.1)	19 (0.3)	51 (0.5)
Wound hematoma	5 (0.05)	3 (0.04)	0
Delayed neurologic	3 (0.03)	3 (0.04)	7 (0.01)
Cardiorespiratory	2 (0.02)	6 (0.09)	13 (0.01)
Pulmonary (not PE**)	2 (0.02)	3 (0.04)	9 (0.01)
Pulmonary embolism	2 (0.02)	2 (0.03)	0
Nonfatal hematologic	1 (0.01)	1 (0.01)	8 (0.01)
DVT***	0	4 (0.06)	13 (0.01)
Death	0	2 (0.03)	0
Brachial plexus injury	0	1 (0.01)	1 (0.001)
Sepsis	0	0	0
Visual acuity change Implant related Dysphagia	NA	17 (0.3)	21 (0.2)
Recurrent laryngeal nerve injury	NA	14 (0.2)	NA
Total complications	NA	8 (0.1)	NA
Percent complications*	346	159	719
	3.6%	2.4%	7.0%

*ACDF=Anterior Cervical Discectomy and Fusion; **PE=Pulmonary Embolism; ***DVT=Deep Venous Thrombosis; ****Percent complications=Total complications/number of patients.

Number of major complications in cases of first-time lumbar micro discectomy, anterior cervical discectomy and fusion, and Lumbar stenosis decompression that were reported from the "Scoliosis Research Society Morbidity and Mortality Committee Procedures from the Year 2004 to 2007" (after Smith et al., 2010). The respective ratios in percent are in brackets. For each surgical procedure, the main complications consisted of dural tear and wound infection. Only the ACDF procedure evidenced a mortality of 0.03%.

[5,6]. Any positioning may induce peripheral nervous damage, especially in the brachial plexus. Prognosis is usually favorable. Recovery takes several weeks to months and requires lengthy rehabilitation [6]. Nerve trunk involvement may affect all 4 limbs. The ulnar nerve may suffer compression at the elbow, at the upper-limb pressure point. Median nerve involvement is uncommon.

Peroneal nerve compression at the fibular neck is possible in any patient positioning, inducing simple paresthesia or severe motor impairment with drop foot. Femoral cutaneous nerve involvement results in meralgia paresthetica following ventral decubitus with compression of the anterior superior iliac spine region. A prospective study [7] reported 20% prevalence of femoral cutaneous nerve damage after spinal surgery. In half of the patients, involvement was bilateral, secondary to compression of the framework supporting the anterior superior iliac spines. More rarely, there was neurological damage due to retroperitoneal hematoma or sustained during iliac crest graft harvesting. In 89% of cases, recovery was complete within 3 months.

Ocular Complications

A prolonged prone position during spinal surgery can cause external compression of the eye, causing serious and irreversible injury to the orbital structures [5,8]. This is a rare but disastrous complication that has an estimated incidence of 0.01-1% after non-ocular surgery [2]. By precaution, positioning should be adapted to a much longer surgery time than planned. All possible compression and traction points on the face, trunk and limbs should be inventoried. Positioning should be made with the patient's head raised, in order to minimize facial and per orbital edema. Obviously, eyeball compression must be avoided. If such a complication occurs, both surgeon and anesthesiologist could face litigation [9].

Importance of Stable Hemodynamics

One cause of medullary insult is ischemia by hypo perfusion. Therefore, the anesthesiology team must maintain a stable hemodynamic and any blood loss should be rapidly compensated during hemorrhagic procedures.

Neurologic Risk According to Surgical Site

There is always a risk of medullary and radicular lesion to the spine and spinal contents during the surgical approach. There may result from direct instrumental trauma, faulty implant positioning or faulty preparation of the implant site.

Cervical Spine: Medullary Lesions

The incidence of medullary lesion during anterior and posterior approaches is estimated at 0.2 to 0.9% [10]. Risk factors identified are myelopathy, medullary atrophy or ossification of the posterior longitudinal ligament. Correction of severe kyphosis with release and extensive fusion and also major instability are further risk factors. Prevention of these severe complications requires good medullary perfusion maintained by arterial pressure>80 mm Hg. Excessive cervical spine flexion or extension is to be avoided [11].

Cervical Spine: Radicular Lesions

Disc surgery is associated with the lowest risk, while medullary decompression for myelopathy entails elevated risk. The reported incidence varies greatly, from 0.2 to 3.2%, due to differences in study populations. It is the C5 root that is the most often affected, in 2.3 to 6.7% of cases, depending on the procedure [12-14]. This root has a short sheath and may be subject to traction by medullary mobilization after decompression. It is particularly at risk during surgical interventions restoring lordosis, inducing spinal cord retraction. A C5 located in mid-lordosis and possible fixation in foraminal stenosis are also risk factors. The result is deltoid impairment, with recovery possibly lasting several months [14-19].

Cerebral Lesions Following Vertebral Artery Trauma

The risk of surgical trauma to the vertebral artery is estimated at 0.3% [15]. The risk of stroke following iatrogenic vertebral artery lesion is estimated at 3.8% on the left and 1.8% on the right [16], whence the need for angiography ahead of any arterial ligature or embolization. In case of vertebral artery lesion, a direct approach is possible by raising the longus colli muscle and opening the transverse canal. Vascular repair may be slightly postponed after packing, and be dealt with by a vascular surgeon [15,18].

Inferior Laryngeal Nerve Lesion

Dysphonia is a common postoperative complaint following anterior cervical spine surgery (ACSS) [17].

A retrospective study [19] found that the most common cause of vocal cord paralysis after anterior cervical spine surgery is compression of the RLN within the endolarynx therefore, releasing the retractor regularly diminishes this risk.

Sympathetic Trunk Lesions

Horner syndrome due to injury to the cervical sympathetic trunk is a very rare complication of anterior cervical decompression and fusion [6]. The incidence is between 0, 2 to 4% [20] mainly after revision surgery. Knowledge of the anatomical relation between the CST and the LCM is very important to avoid Horner syndrome in ACDF. Prevention involves approaching the anterior cervical spine in the mid part, raising the medial edge of the longus colli muscle without excessive traction [21].

Thoracic and Lumbar Spine

By its poorer vascularization compared to the cervical or upper lumbar cord, the thoracic spine is more exposed to neurological complications by hypo perfusion. Exposing vertebral bodies may require vascular ligature. This may damage the radiculomedullary spinal nutrient arteries, inducing severe ischemic neurologic deficit. Spinal deformity of the thoracic and lumbar spine, requires complex surgical procedures. The rate of complete or partial paraplegia in published results could reach 0, 55% to 1, 78% [22-24]. Correction of sagittal deformity may require three-column resection osteotomies (3CO), including pedicle subtraction osteotomies and vertebral column resections. These procedures have high rates of reported complications [25]. Corrective surgery for high grade lumbar spondylolisthesis is credited with 11, 8% neurologic complications with regards especially to the L5 root [23]. Risk of retrograde ejaculation from damage to the hypo gastric plexus during anterior approach of the lumbar spine is estimated between 0, 42 to 4, 1% [26-28]. Although the most common etiology of cauda equina lesions is lumbar intervertebral disc herniation, iatrogenic lesions may also be the cause. According to Jensen [26] this syndrome following decompression for spinal stenosis appears to occur more commonly than the literature suggests. A large series of spinal stenosis decompressions was reviewed and the rate of occurrence was for an incidence of 2.8%.

Neurologic Risk and Spinal Implants

Whatever material is used (screws, hooks or inter body cages implanted via a posterior, trans-foramen, trans-psoas or anterior approach), the cord or roots may be damaged by poor positioning or per- or postoperative implant mobilization. The rate of wrong positioning is estimated at 4.2%, but is found to be 15.7% on control CT. Nevertheless, the rate of major neurovascular complications in the literature is very low [27]. A systematic review by the Scoliosis Research Society and the Pediatric Orthopaedic Society of North America task force reported 91.5% good positioning of thoracic pedicular screws in scoliosis in adults and 94.9% in pediatrics. The low complications rate and significantly better efficacy of screwing as compared to the use of hooks or hybrid assemblies are sufficient for pedicular screws to be formally recommended [29,30].

Bleeding

Abnormal bleeding during discectomy should orient toward a breach of a major vessel during the manoeuver.

In such a case, immediate vascular exploration by vascular surgeon is always mandatory.

Dural Tear

Incidental durotomy is an underestimated and relatively adverse event during spinal surgery. McMahon et al. reported a 7.7% rate of neurological complications with dural tear, versus 1.5% without. The risk of dural tear is three-fold higher in revision surgery [31,32]. Careful suturing may if necessary be backed up by a muscle fascia patch or interposition of a muscle or fat graft, fibrin or glue. Postoperative drainage after dural tear is controversial; some authors recommend non- aspirate or supra-Apo neurotic drainage after hermetic closure of the various planes [33].

Postoperative Complications

They include the occurrence of an epidural hematoma, a cauda equina syndrome, spondylodiscitis, epidural scaring, recurrent disc prolapse, nonunion of the fusion or pseudoarthrosis, implant failure, and later on junctional degeneration/instability (fusion disease).

Vertebroplasty Complications

Leakage of cement inside the vertebral canal may harm the medulla; outside leakage would harm vascular or neural elements. Cement embolization in the lungs has also been reported.

Litigations and Malpractice

Medical litigation in spine surgery, as with any medical treatment, involves breach of standard of care, negligence, and causation. Although any surgical treatment is a field of endeavor, both the patient and the surgeon should naturally agree to achieve their common goal of improving the patient's condition; but adverse events can still occur. As surgery is a joint venture, requiring both the patient's compliance and the surgeon's skills, communication about expectations is a key component of the process. Medical error is defined as a failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Medical negligence claims are an increasing feature of clinical practice in Belgium. Although medicine in Belgium is still much less litigious than in the United States, medical negligence is on the increase. It is reported that an important number of patients (by the hundreds for a country of 10 million inhabitants) die or are seriously injured every year as a result of medical errors and 1 in 10 suffers an 'adverse effect' due to hospital accidents, diagnostic errors and operating mistakes .

Definition of Medical Malpractice

Medical malpractice occurs when a physician fails to act as any reasonable physician would have acted under the same circumstances. This standard may be stated somewhat differently as follows: a physician must exercise the same level of skill, diligence and judgment that any reasonable physician would have exercised under the same or similar circumstances. While a doctor's failure to meet this standard constitutes 'negligence', the mere fact that the doctor was negligent does not necessarily result in liability. Technically unsuccessful surgery does not automatically mean a breach of standard of care. For example, if the surgeon injures an anterior thoracic or abdominal organ while performing posterior spine surgery without appropriate precautions, that would be a breach of standard of care. However, if the patient develops a nerve injury after undergoing surgery of the spine, that is unfortunately a recognized possible adverse event during surgery, which requires dissection, retraction, and manipulation of the neural elements during surgery. Sometimes, once the neural function has taken the downward path to deterioration, this may continue before settling to a lower baseline after surgery. Moreover patients with these conditions may have a lower threshold for further nerve function compromise.

Legal Framework of Medical Responsibility

In Belgium, the plaintiff in suits for damages resulting from alleged malpractice could turn easer to civil courts or penal tribunals. The plaintiff bears the burden of the proof that the doctor has actually breached his duty to the patient by not abiding to the common standard of care. Typically, although not always, this standard will be ascertained by appointed experts who will contrast the liable medical conduct to existing practice guidelines, statements of professional organizations and societies, use of leading books, scientific treaties and published articles.

Liability

In order for the doctor to be liable, the complaining patient must prove four things in the legal sense:

1. Duty (Did a physician-patient relationship exist?);
2. Breach of duty (Did the physician fail to meet the required standard of care?);
3. Causation (Did the physician's breach cause the patient's injury?);
4. Damages (Did the patient incur medical expenses, pain, suffering, or loss of wages as a result of the breach?).

Inappropriate Decisions

Some of the leading causes to litigations are inappropriate delegation of procedures to junior doctors, lack of expertise or adequate knowledge of the procedure, failure to recognize the clinical signs and symptoms of complications, inappropriate patient selection and an inadequate preoperative evaluation. It is also important for the surgeon to consider pre-existing medical conditions in elderly patients and the need for careful preoperative assessment and consideration of these factors before embarking on surgery.

Failure to Obtain Consent

Patients frequently alleged that they would not have agreed to undergo the procedure if they had known all the risks associated with it. Before laying hands on a patient even for the most fleeting

of physical examinations, one must always obtain his or her implied or express consent, otherwise one would be vulnerable to a civil claim in medical negligence or, rarely, civil or criminal proceedings in assault. For the consent to be legally valid, three conditions must be met:

- The patient must be capable of giving legal consent;
- The patient should be sufficiently informed to make a considered decision;
- The consent must be given knowingly, freely and voluntarily.

New Procedures in Belgium

According to the Belgian law on the 'Patients' rights' that was published on August 22th, 2002, 'The patients have a legal right to information about their condition and about all the treatment options that are available to them.' On 31/03/2010, a new law was published but came into effect only on 1/09/2012. By this law, a Fund for Medical Accidents (FMA) was instituted to centralize the management of claims made against medical professionals. The FMA is essentially functioning under the authority of the Belgian Institute for Sickness and Disablement. The files submitted to the FMA are to be dealt quickly by medical specialists. Within six months, an opinion has to be issued. If the FMA concludes to medical malpractice, the file will be sent to the doctor's insurance company which will proceed with the patient's complaint. If the FMA concludes to a therapeutic accident without the physician's responsibility, it will give compensation to the victim provided that the patient has at least 25% of permanent disability or an incapacity for working for six months, or if death has occurred. If the FMA considers that there is no fault or accident, the file will be closed and the patient is not compensated.

Conclusion

The indications for spine surgery are wide and many. Any indication for surgery should always be well documented in order to improve the expected results since these are far less predictable if the actual indications for surgical options are less clear. We present the major complication rates associated with spine surgery. We hope that these data provide surgeons with potentially useful information for preoperative patient counselling. Medical malpractice or negligence may occur during spine surgery. It is always difficult to know if a medical accident actually results from fate or from a medical error, and unsuccessful surgery does not automatically mean a breach of standard of care. In many cases, the litigation process is an exhausting and painful experience for both the surgeon and the plaintiff. In Belgium, the patient has to prove that his surgeon has actually committed a fault, which, in the legal sense, will consist in a breach of duty. Due to the patient's legal rights, before considering a surgical procedure, the surgeon has to make sure beforehand that the patient is capable of giving legal consent, has been sufficiently informed, and that the consent has been given knowingly, freely and voluntarily. In Belgium, the procedure established by the FMA (Fund for Medical Accidents) under the authority of the Belgian Institute for Sickness and Disablement assures that the patient receive financial compensation in case of therapeutic accident without the physician's responsibility; in all the complaints, the FMA provides rapid answers to the plaintiff's questions about what went wrong during medical therapeutic procedures. However, if the FMA finds any breach of duty on behalf of the surgeon, the case would then be transferred to a court of justice.

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