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Case report

Spinal cord ischemia complicating treatment of abdominal aortic aneurysms: a medical-legal overview

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Abstract. *Background and aim:* The aim of this work is to report on the occurrence of spinal cord ischemia following open and endovascular repair of abdominal aortic aneurysms and its legal consequences, exemplified by a dramatic case report and supported by a review of the current literature on the subject. *Methods:* we will focus on whether this rare and fearsome complication is predictable or unpredictable, whether it is attributable to specific professional guilt and if and how it can be prevented and treated. *Results:* Unpredictability of SCI is part of the dramatic consequence of having an AAA, whose natural history yields to rupture and, in most cases, death. Preventive OAR or EVAR represents the only alternative to this course, and all the diagnostic and therapeutic efforts should aim first of all to detect and treat as many AAAs as possible before they rupture. *Conclusions*: the correct compilation of the medical record, and in particular of the operating register, assumes a fundamental role even in the case of infrequent adverse events, in order to demonstrate that, despite the implementation of all the precautions codified by the specialist discipline, it was a matter of adverse event which, however foreseeable, was not concretely preventable in the present case, thus including the event in the realm of "complication" unrelated to profiles of professional responsibility. (www.actabiomedica.it)

Key words: abdominal aortic aneurysm, spinal cord ischemia, malpractice lawsuits

Running Title:

Introduction

Abdominal aortic aneurysms (AAAs) are focal, permanent dilations (>50% of the native diameter) of all the three layers of the abdominal aorta. It is an extremely common disease, with an estimated prevalence ranging between 1% and 3% among men aged over 65 years and accounting for the tenth cause of death worldwide (1). The natural history of the disease is characterized by continuous dimensional increase, which is usually silent and asymptomatic, leading to sudden rupture, sometimes preceded by nonspecific abdominal or back pain: in this last phase, emergent surgical treatment represents the only chance of survival, but with a mortality rate as high as 50% (1). On the contrary, early detection of AAAs during their silent growth, can lead to safe elective treatment with mortality rates ranging from 1% to 4% depending on baseline clinical conditions (1). Treatment of AAAs can be open surgical (OAR), through laparotomy, aortic cross-clamping and aneurysmectomy and reconstruction with a prosthetic graft, or endovascular

(EVAR), consisting in aneurysm exclusion by an endograft placement through the femoral arteries (1). In elective settings, both techniques have an extremely low mortality and morbidity compared with the treatment of ruptured AAAs, but complications are possible and should always be taken into account.

Spinal cord ischemia (SCI), albeit extremely rare, is one of the most fearsome complications that can arise following both OAR and EVAR (2). In fact, it has a dramatic impact over the patient's quality of life, is often permanent and, on account of its rare occurrence, it is seldom foreseen by surgeons and patients (3). For these reasons, paraplegia due to SCI following AAA treatment is the cause of a number of legal disputes involving vascular teams and other medical staff, accused of having caused, or not prevented nor treated such complication.

The aim of this work is to discuss the legal aspects of SCI following AAA treatment by reporting an exemplary case of a typical and dramatic onset of neurological deficits after OAR.

Case report

A 72-year-old male, affected by hypertension, had an US incidental finding of an aneurysm involving the abdominal aorta and the iliac arteries (maximum transverse diameters 65 and 25 mm respectively), confirmed by Computed Tomography Angiography (CTA). The patient was asymptomatic but the aneurysm size required elective treatment, and, in absence of significant comorbidity and contraindications, OAR was proposed. Pre-operative examinations included cardiological and anesthesiologic evaluations, Duplex scan of the supra-aortic trunks and lower limbs arteries, and Magnetic Resonance Angiography (RMA), focusing on the lumbar and spinal network. The patient received full information regarding the treatment options, the choice of open surgery and its alternatives, and the risk of complications including that of postoperative SCI and paraplegia, and he signed written informed consent to OAR.

Aneurysmectomy and reconstruction with a bifurcated aorto-biiliac graft was performed as planned, respecting all the competent guidelines and good clinical practice, and during the intervention no complications nor technical difficulty occurred. The postoperative course was regular, with normal stepwise recovery and restoration of the abdominal canalization.

However, on post-operative day II, hyposthenia of the left lower limb appeared, followed within 24 hours by paresthesia of the right lower limb. The vascular examination revealed no pathologic finding, with normal temperature, and presence of both proximal and distal pulses, as confirmed by the Duplex scan of the lower limbs. The abdominal evaluation was also negative, nor were any clinical or laboratory signs of blood loss of cerebral affection. On postoperative day IV, after removing the urinary catheter, acute urinary retention appeared, in absence of urinary stimulus, which obliged the physicians to catheterize the patient again. The patient also reported anesthesia of the groin and genital regions and loss of sphincter control with fecal incontinence. The neurologist prescribed a spinal cord MR, which found an ischemic lesion of the apex of the medullary conus. Meanwhile, the patient began his physio-kinetic rehabilitation program and started to mobilize with the auxilia, but he complained of severe difficulty in doing so, due to the persistent hyposthenic left lower limb. Based on the clinical and instrumental findings, the neurologist made a diagnosis of cauda equina syndrome. Follow-up MR, six days later, showed no changes in the findings compared to the previous one, confirming the presence of an ischemic sequelae in the same region.

At the end of the rehabilitation program, 45 days after surgery, the patient was discharged home in clinical conditions defined as improved, and thereafter he underwent all clinical and instrumental follow-up controls and a further cycle of neuromuscular rehabilitation. However, five months after surgery, the patient still had persistent sensitive and motor impairment of the lower limbs, especially the left one, mild fecal incontinence and permanent urinary catheter, due to the lack of stimulus, which led him to develop a severe status of frustration and depression. Moreover, he was no longer able to do his previous working activity, with a heavy impact on his productive capacity.

For these reasons, the patient pleaded with the hospital for an economic refund of the damages sustained as consequence of the intervention. Any mediation attempt

failed to find a satisfactory solution and the parts came into judgement after a preventive technical consultancy, as prescribed by the Italian Legislation (art. 696 bis c.p.c).

The Expert Witnesses College, which included specialists in Legal Medicine, Vascular Surgery, Neurology and Neurosurgery, examined the clinical documents and stated that the intervention was necessary and undelayable, due to the life-threatening vascular diseases affecting the patient, and that it was carried out following the principles of evidence-based medicine and good clinical practice, regarding both the therapeutic choice and its execution.

The College also observed that the patient had no pre-existing vascular or neurological spinal cord diseases before surgery, and that all due preoperative exams to rule it out and to identify potential risk factors for this complication (CTA, RM) had been correctly prescribed and carried out, but, if they failed to identify any of such conditions, it was not for technical defects or lack of diagnostic skills. It was also ascertained that medical and nurse assistance in the postoperative period had done, *lege artis,* all that could be done to manage and treat the neurological complications, including the prompt demand for an early neurological consultancy.

Finally, the outcome of surgery was considered favorable regarding the prognosis *quoad vitam*, while, as for the prognosis *quoad valetudinem* and *quoad functionem*, the Judge and the Expert Witnesses acknowledged the occurrence of an adverse event, which was predictable and causally related to the intervention, but in no way preventable.

In conclusion, the College of Court Appointed Expert Witnesses agreed upon the causal relation between SCI and the neurological deficits, but it could not find any element of responsibility imputable to the Hospital or the Medical Staff. Thus, the Judge rejected the recurrent's requests, following the clear line of jurisprudence marked by the Supreme Italian Court, stating that predictable but unpreventable complications rule out medical malpractice (artt. 1218 and 1228 c.c.).

Discussion

SCI is a rare event complicating both OAR and EVAR with a reported incidence ranging between 0.1% and 0,25% in elective treatment, reaching to 1.4% following urgent treatment (4). Its clinical presentation is extremely variable, from a mild hyposthenia to a complete flaccid paralysis, either uni- or bilateral. Sensory disturbances generally involve the gross tactile sensation, leaving untouched the epicritic, thermic and pain sensitivity, and urinary and/or fecal incontinence is present in 30% cases (5). The onset is generally immediate, although late presentation is also described, arising from II to XXI postoperative day, as in the present case. Although there are some treatment options upon early recognition (cerebro-spinal fluid drain, steroids, neuromuscular rehabilitation), only 25% of patients recover, 50% only experience small improvement over time and 25% have none at all (5).

Because of the heavy prognostic impact of this complication in terms of quality of life, the risk of SCI should be anticipated to the patient and every effort should be made to minimize its occurrence. While this is routinely done in open or endovascular repair of the thoracic and thoraco-abdominal aorta, when the risk is higher, the medullary aspect is often overlooked when treating only the abdominal aorta. However, as we show in this report, the risk is not negligible, and neglecting this aspect can have dramatic consequences on the patient's life and also from the legal standpoint.

The most important elements to consider during preoperative planning to assess the risk of SCI are the origin of the Adamkievicz artery (AKA), or great anterior radicolo-medullary artery, the occlusion of the hypogastric arteries and previous ischemic or traumatic affection of the spinal cord (6).

The AKA is considered the main artery providing supply to the spinal cord network and, in 80% of cases, it stems from the descending thoracic aorta at a variable level, between T5 and L2, but 20% of subjects have an abdominal AKA, originating from the lumbar vessels (7). Preoperative identification of abdominal AKA can be extremely helpful in anticipating SCI following OAR or EVAR, but because of the great variability of its anatomical location and dimension, this artery is difficult to identify, even with the most sophisticated imaging, and reimplantation is rarely a feasible option. As for the hypogastric arteries, their occlusion is more frequent following EVAR than OAR, and the preservation of at least one of them is important not only for

the spinal cord, but also to avoid buttock claudication, erectile dysfunction and bowel ischemia (8). Another element increasing the risk of SCI is a prolonged aortic cross-clamping during OAR, reducing the blood supply to the pelvic circulation.

By virtue of the technological evolution that has characterized the last decade, in the recent period numerous studies relating to medullary ischemia are available in the literature, however largely referring to endovascular procedures, where the preoperative study aimed at identifying the artery of Adamkievicz is of increasing importance. Further studies published in the last decade also focus attention on medullary ischemic events resulting from microembolization phenomena, but always very rare and comparable in frequency of onset to traditional surgery.

The preoperative investigation for these risk factors, as the vascular surgeons did in the present case, is advisable to reduce the risk of SCI and to show a correct diagnostic and therapeutic conduct in case of a legal dispute, but unfortunately it is not enough to prevent postoperative paraplegia, which is still widely unpredictable.

From a medico-legal point of view, it is therefore essential to differentiate the cases in which the injury represents a foreseeable but not concretely preventable adverse event ("complication"), from those in which an inadequate surgical practice is at the basis of the iatrogenic event.

It should be remembered that in the jurisprudential context the current orientation excludes the legal relevance of the concept of "complication" *strictu sensu*, since even if an event -considered as predictable by literature - occurs, the Healthcare sector has the burden of concretely prove the exact fulfillment of one's obligation, and it is not sufficient that the exclusion of guilt can only be theoretically conceivable.

In this regard, we report what was established by a Supreme Court Judgment: "... *With the term" complication", clinical medicine and forensic medicine usually designate a harmful event, which arose during the therapeutic process, which, although abstractly predictable, is not it would be avoidable. This concept is useless in the legal field. When, in fact, during the execution of an operation or after its conclusion, a worsening of the patient's condition occurs, either: - or this worsening was foreseeable and avoidable, and in this case it must be ascribed to fault of the doctor, not at all, noting that clinical statistics theoretically include it among the "complications"; - or this worsening was not foreseeable or was not avoidable: and in this case it integrates the details of the "non-attributable cause" referred to in Article 1218 of the Civil Code, noting at all that the clinical statistics do not theoretically include it among the "complications"...*" (Civil Cassation, section III, sentence 30 June 2015, no. 13328).

In other words, if following a surgical intervention an adverse event occurs that is included among the possible operating risks, the nature and extent of the lesion and its causal relationship with the surgical act must first be ascertained, and subsequently if - also and above all from the point of view of documentation - all the precautions recommended by the specialist discipline to prevent similar events are respected.

Preliminarily, an exhaustive description of the preoperative physical examination must be reported in the medical record, in order to verify whether already before the surgery there were clinical signs indicative of spinal pain, suitable to increase the vulnerability of the nervous tissue also for insults of small entity.

It is therefore essential that the maneuvers aimed at identifying, isolating and possibly protecting the most delicate anatomical structures are expressly recorded in the operating register, so as to provide suitable evidence that can be used in any court.

Further, any changes in the anatomy and course of the nerve with respect to the norm must be reported, which could account for the inevitability of the iatrogenic lesion.

In the absence of an adequate description in the medical record, it may be impossible for the Surgeon to demonstrate that he has performed the surgery in a technically flawless manner, and that he has implemented all the precautions aimed at preventing and / or amending the unwanted event.

In this regard, we report what was established by further legal rulings, which essentially attribute an autonomous role to the lack of medical records for the purposes of the obligation to pay compensation in the event of adverse events, according to the assumption that: "... *when it is not possible to establish with absolute certainty if the damage suffered by a patient was caused by the inexperience of the treating doctor and the uncertainty*

derives from the incompleteness of the medical record, the physician is responsible for the damage, when his conduct is abstractly suitable to cause it... ".

The same concept is also unequivocally confirmed by a recent ruling by the Supreme Court, which states: "*... the hypothesis of incompleteness of the medical record must be considered a factual circumstance that the trial judge can use to consider the existence of a valid causal link between the doctor's work and the damage suffered by the patient, making the following necessary double check so that the incompleteness is relevant for the purpose of deciding or, on the one hand, that the existence of the causal link between the doctor's conduct and damage to the patient cannot be ascertained precisely because of the incompleteness of the file; on the other hand, that the doctor has in any case put in place a conduct that is abstractly suitable to cause the damage, incumbent on the health facility and on the doctor to demonstrate that no non-fulfillment is attributable to them or that it was not the cause of the damage, loming over them the risk of lack of proof ...* " (*Cassazione Civile*. sez. III. *Ordinanza* 23/03/2018, n. *7250*).

Conclusion

Unpredictability of SCI is part of the dramatic consequence of having an AAA, whose natural history yields to rupture and, in most cases, death. Preventive OAR or EVAR represents the only alternative to this course, and all the diagnostic and therapeutic efforts should aim first of all to detect and treat as many AAAs as possible before they rupture. In this context, rare unpreventable treatment complications, as disabling as they can be, are part of the disease consequences and can happen even without any medical malpractice. It is important, however, to fully inform the patient about risks and benefits of the treatment, including the low, but existing risk of SCI and paraplegia, and to do all that can be done to prevent it and treat it, despite the poor results that have been described.

From the point of view of forensic medicine, the correct compilation of the medical record, and in particular of the operating register, assumes a fundamental role even in the case of infrequent adverse events, in order to demonstrate that, despite the implementation of all the precautions codified by the specialist discipline, it was a matter of adverse event which, however foreseeable, was not concretely preventable in the present case, thus including the event in the realm of "complication" unrelated to profiles of professional responsibility.

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References

1. Wanhainen A, Verzini F, Van Herzeele I, et al. Editor's Choice - European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms. Eur J Vasc Endovasc Surg. 2019;57(1):8-93.
2. Gloviczki P, Cross SA, Stanson AW, et al. Ischemic Injury to the Spinal Cord or Lumbosacral Plexus after Aortic-Iliac Reconstruction. Am J Surg. 1991;162:131-6.
3. Rosenthal D. Spinal Cord Ischemia after Abdominal Aortic Operation: is it Preventable? J Vasc Surg, 1999;30:391-7
4. Berg P, Kaufmann D, van Marrewijk CJ, Buth J, Spinal Cord Ischaemia After Stent-graft Treatment for Infra-renal Abdominal Aortic Aneurysms. Analysis of the Eurostar Database. Eur J Vasc Endovasc Surg. 2001;22(4):342-347.
5. Moulakakis KG, Alexiou VG, Karaolanis G, et al. Spinal Cord Ischemia following Elective Endovascular Repair of Infrarenal Aortic Aneurysms: A Systematic Review. Ann Vasc Surg. 2018;52:280-291.
6. Szilagyi DE, A Second Look at the Etiology of Spinal Cord Damage in Surgery of the Abdominal Aorta J Vasc Surg. 1993:17(6):1111-1113.
7. Yamada N, Okita Y, Minatoya K, et al. Preoperative Demonstrations of the Adamkievicz Artery by Magnetic Resonance Angiography in Patients with Descending or Thoracoabdominal Aortic Aneurysms. Eur J Cardiothorac Surg. 2000;18(1):104-11.
8. Shilya N Wakasa S, Matsui K, Sugiki T, Shingu Y, Yamakawa T, Matsui Y. "Anatomical pattern of feeling artery and mechanism of intraoperative spinal cord ischemia". Ann.Thorac Surg 2009;88(3):768-71; discussion 772.
9. Hudorovic N. "Detecting the Adamkiewicz artery it is really necessary in everyday practice?" Eur J Cardiothorac Surg 2007; 32: 183—190.
10. Nijenhuis RJ. Mull M, Wilmink JT, Thron AK, Backes WH. MR Angiography of the Great Anterior Radiculomedullary Artery (Adamkiewicz Artery) validated by digital subtraction angiography Am J Neuroradiol 2006;27(7):1565-72.
11. Jacobs MJ. Jacobs MJ, van Engelshoven JM, et al. MR angiography artery and anterior radiculomedullary vein: postmortem validation Am J Neuroradol 2006;27(7):1573-5.

12. Backes WH. Nijenhuis RJ. Advances in spinal cord MR angiography. Am J Neuroradiol 2008;29(4):619-31.
13. Kwok PC, Chung TK, Chong LC, et al. Neurologic Injury after Endovascular Stent-Graft and Bilateral Internal Iliac Artery Embolization for Infrarenal Abdominal Aortic Aneurysm. J Vasc Interv Radiol 2001;12(6):761-3.
14. Trib. Roma, 16 gennaio 2004, in Foro It., 2004; I: 909.

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