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Case report

Use of intraoperative neurophysiological monitoring during epiduroscopy as a safety measure

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ABSTRACT

Objective: In this study, we present the first 12 cases of the use of intraoperative neurophysiological monitoring (IONM) during therapeutic epiduroscopy in patients with clinical canal stenosis.
Methods: IESS was performed using two working instruments: an epidural balloon to dilate the epidural space without damaging the nerve structures (Resaloon®) and an element to perform flavotomy of the ligamentum flavum (Resaflex®). The procedure was performed at levels of the greatest stenosis, as detected using preoperative magnetic resonance imaging.
Results: Of the 12 cases that used IONM, 2 patients presented neurotonic activity in roots during ligamentum flavum ablation, 1 patient presented neurotonic activity while using Resaloon® in a root contralateral to the level at which the procedure was conducted, and other presented neurotonic activity in a root below the level at which the ligamentum flavum was ablated. In all cases, potentially harmful discharges stopped when the procedure was interrupted momentarily.
Conclusions: Intraoperative neurophysiological monitoring detected alterations in surgical field and roots below and/or contralateral to the field, which disappeared with complete recovery after interrupting the procedure; this can avoid the possible prolonged or even permanent complications postoperatively.
Significance: Intraoperative neurophysiological monitoring during epiduroscopy is safe, thus optimizing surgical outcomes.

1. Introduction

Epiduroscopy or spinal endoscopy [interventional endoscopy spinal surgery (IESS)] is a minimally invasive surgical procedure in the spinal epidural space, which through the use of a directable flexible endoscope, allows for the direct visualization of the epidural space with diagnostic as well as therapeutic possibilities.

Development of epiduroscopy techniques began in the early 1930s, and Pool in 1937 performed the first epiduroscopy (Pool, 1938). The technique was reassessed in the 1990s, and various groups began using it for the treatment of spinal pain of diverse origins through the caudal approach, as it is currently known (Saberski and Kitahata, 1995). The most important advances in this field have been achieved through the development of various tools used for working within the lumbar epidural space, such as the Fogarty balloon modified for use in the epidural space, called Resaloon®, and the subsequent development of an ablation system using the quantum molecular resonance (QMR®) technology, called Resaflex®. This is a minimally invasive device used with the epiduroscope for the treatment of adhesions in case of epidural fibrosis or for the treatment of ligamentum flavum in case of lumbar canal stenosis due to ligamentum flavum hypertrophy (Periduroscopy, 1998; Raffaeli and Righetti, 2005).

The use of epiduroscopy represents one line of action for cases of chronic refractory lumbar pain and pain in the lower limbs due to post-laminectomy syndrome as well as for cases of stenosis of the central or foraminal canal before the use of more aggressive procedures, such as reoperation or neurostimulator or intrathecal pump implantation. Thus, the main indications for the use of this technique include post-laminectomy syndrome and lumbar canal stenosis (Kallewaard et al., 2014; Igarashi et al., 2004; Sabersky, 2001).

Degenerative stenosis of the lumbar canal has been estimated to affect 400,000 individuals in the United States (Kallewaard et al., 2014), with prevalence of absolute and relative stenosis esti-

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mated at 19.4% and 47.2% in patients older than 60 years, respectively (Kalichman et al., 2009). This constitutes the most frequent indication for spinal surgery in individuals older than 65 years (Deyo, 2010). Although the causes underlying this syndrome are multiple and the etiology is sometimes multifactorial, ligamentum flavum hypertrophy remains one of the main causes (Kallewaard et al., 2014). Clinical symptoms presented by patients, depending on their type of stenosis (central or foraminal), constitute changes in the cauda equina, bilateral radicular pain, alterations in saddle sensitivity, or motor alterations in the legs, which become worse with walking and prolonged standing. In most cases, the symptoms disappear when patients are resting, sitting, or lying in the prone position and are relieved by trunk flexion (Chad, 2007).

Although epiduroscopy using the new QMR® technology may be useful in patients with lumbar canal stenosis (to reduce hypertrophy of the ligamentum flavum), it is not a risk-free technique. Complications as transient neurological symptoms, dural puncture, visual disturbances, urinary and/or faecal incontinence are possible in such patients (Trescot et al., 2007). The need to perform epiduroscopies as safely as possible arises to avoid potential complications. Therefore, we propose the use of intraoperative neurophysiological monitoring.

In this article, we present the first cases in the literature involving the use of intraoperative neurophysiological monitoring to avoid or reduce the rate of complications in patients with lumbar canal stenosis as well as to contribute information to the etiopathogenesis of this type of complications.

2. Methods

We present the first cases of the use of intraoperative neurophysiological monitoring during therapeutic epiduroscopy in patients with clinical symptoms of canal stenosis to reduce the possible complications of the technique. In all cases, the monitoring was conducted after obtaining the informed consent, and the study was registered at ClinicalTrials.gov with number NCT03863067 and approved by the Ethics Committee (Comité de Ética de la Investivgación de la Fundación Jiménez Díaz, Madrid, Spain).

In all patients, the technique was performed as described by other authors, together with the use of the latest safety tools that are currently available (Abejón et al., 2017).

2.1. Technique

Epiduroscope (Resascope®) is a system designed for diagnosis and surgical endoscopic treatment of the epidural space (IESS) (Fig. 1A). Resascope® and its components have been specially designed for a percutaneous approach through the sacral hiatus of the epidural canal with an external diameter of 3.3 mm and two open internal canals with a diameter of 1.25 mm and length of 30 cm.

Resaloon® is an inflatable balloon catheter for adhesiolysis during epiduroscopy (Fig. 1B) and Resaflex® comprises a flexible electrode for surgical lysis (Fig. 1C) with the QMR® technology (Fig. 1D). Resaflex® is a minimally invasive device, which through Resascope® enables to reach and coablate of scar tissue and treat epidural fibrosis in patients with post-laminectomy syndrome. It can also be used to perform ligamentum flavum ablation in patients with ligamentum flavum hypertrophy and canal stenosis (Fig. 2).

The technology applied for IESS operates through the emission of a main waveform with a very well-defined harmonic at 4 MHz, followed by others of 8, 12, and 16 MHz with decreasing intensities. The combination produces a series of energy quanta calibrated for biological tissues, whose intensity is sufficient to break the tissue bonds without increasing the temperature and denaturing the structure of the fibrinogen protein in fibrin (Raffaeli and Righetti, 2005; Raffaeli et al., 2010; Raffaeli et al., 2007).

In all cases, other non-invasive and invasive treatments were used prior to the intervention, following the SAFE principle published by Krames et al. (2009), and epidurolysis was performed before the epiduroscopy. Nuclear magnetic resonance and electrophysiological examinations were conducted for all patients before performing the technique in order to verify the diagnosis of the pathology, to confirm the existence of the ligamentum flavum hypertrophy, and to rule out the existence of any anatomical variant that may contraindicate the technique. The diameter of the epidural canal at the entrance to the sacral hiatus was measured to confirm that the approach could be applied without any complications to all cases.

The technique was always performed in the operating room with strict aseptic measures and under conscious sedation. Intravenous cefazolin (2 g) was used as antibiotic prophylaxis 1 h before the procedure, which was performed on an ambulatory basis.

After preparation of the field and cleaning with chlorhexidine, a caudal approach was used with the help of a fluoroscope, with the patient in the prone position. The midline of the sacral hiatus was located with an AP projection of the radiological C-arm, and the sacral hiatus was approached in the lateral projection. The entry point in the sacral hiatus and the floor of the sacral canal were infiltrated with local anesthetics using a needle (25G,

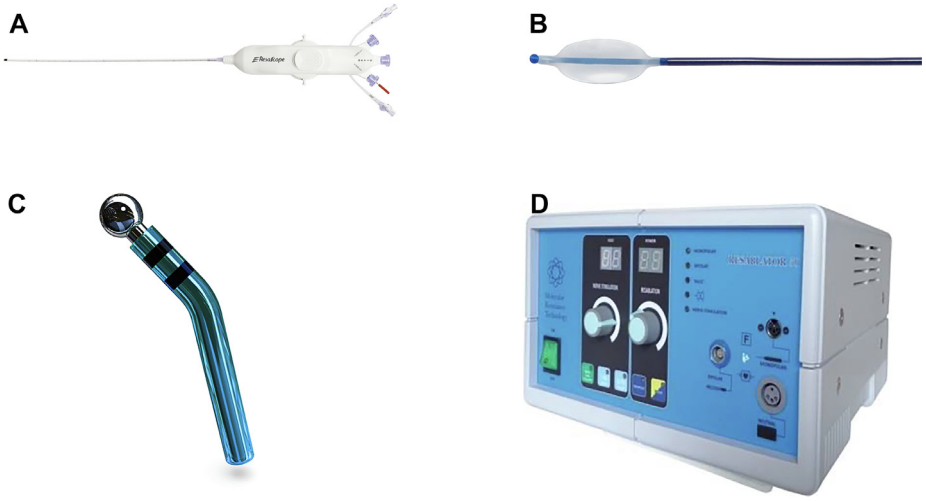

Fig. 1. A. Resascope® B. Resaloon® C. Resaflex® D. Resablator®.

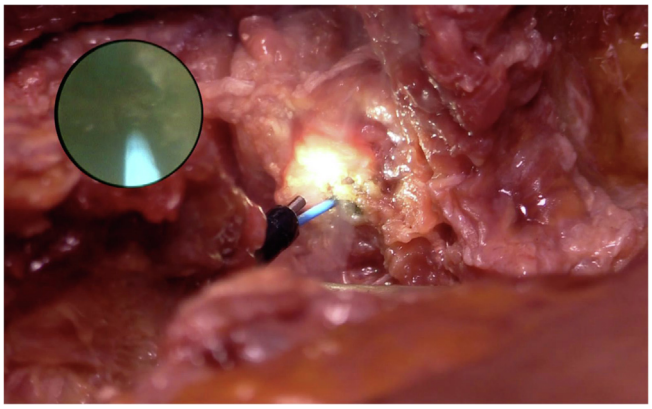

Fig. 2. L4–L5 dissection and laminectomy of a cadaver to visualize ligamentum flavum ablation with Resaflex® using macroscopy and epiduroscopy.

0.5 × 16 mm). The caudal epidural space was accessed using an 18G Tuohy needle and confirmed with two radiological projections, one AP and another lateral; no contrast was used in any case. The needle was removed after confirming the correct epidural position while keeping the guide inside the canal. From this point on, the Seldinger technique was used.

The next steps in the technique were aimed at dilating the entrance for introducing the Resascope®. The entrance was enlarged with a #11 cold knife to place the dilator and introducer (9 Fr) (Kit introductor vascular TERUMO CORPORATION), through which the Resascope® was placed in the caudal epidural space.

Subsequently, 0.9% saline solution was used to distend the canal and to visualize the epidural structures better. Serum was heated to 37 °C in all cases to obtain better tolerance by the patients, and a constant infusion rate was maintained to prevent serum boluses, thus avoiding rise in pressure.

2.2. Neurophysiological monitoring

Neurophysiological monitoring was conducted through continuous electromyographic recording (free-running EMG). For this, paired monopolar needle electrodes were inserted into the muscles depending on different lumbosacral roots studied. In our case, monitoring was carried out from L3 to S4. The following areas were monitored achieve these measurements: L3–L4 (quadriceps), L5 (anterior tibial/long peroneus), S1–S2 (lateral and medial gastrocnemius), S3–S4 (external anal sphincter), all bilaterally (Fig. 3).

A 32-channel Eclipse Intraoperative Neurophysiological Monitoring System (Medtronic) of was used for recording and analysis.

Neurophysiological control enables identification of the manipulated roots (their mechanical manipulation determines the generation of nerve action potentials, which are translated into muscle action potentials in the free-running EMG) as well as of electromyographic activities that could be correlated with harmful maneuvers (generation of high-frequency electromyographic activities, such as the appearance of neuronal discharges, as neurotonic activity or trains).

Free-running EMG was chosen over SEP – Somatosensory Evoked Potentials – and MEP-Motor Evoked Potentials because the patient was under conscious sedation, and these kind of monitorization need high intensity electric stimulation, which may be difficult to tolerate in patients who are not under general anesthesia.

3. Results

We present the first cases of intraoperative neurophysiological monitoring in patients diagnosed with lumbar canal stenosis who were subjected to epiduroscopy. Bilateral lumbosacral root monitoring was performed in all patients through continuous EMG recording, and spontaneous activity was verified while the patients were awake to check for proper functioning of the roots studied.

Of the 12 cases studied, 8 did not present potentially pathological discharges (Table 1), whereas 4 presented with electrophysiological abnormalities during the intervention, although all were completely resolved. Of the 4 patients with neurophysiological alterations, neurotonic activity was recorded in the left S1 territory in 1 patient during maneuvers for opening the working field with Resaloon® at the level of right L5–S1, which may correspond to pathological activation, with subsequent recovery when the procedure was discontinued in the contralateral area. Potentially injurious neurotonic activity in the right L5 root, which lasted 200–300 ms, was detected in another patient, coinciding with the use of Resaflex®, in ligamentum flavum at the level of the right lateral recess L5. Another patient presented with neurotonic activity, which suggested potentially harmful maneuvers in the neural tissue in the right L5 territory, when working on the same level with Resaflex®. Finally, depolarization of non-damaging mechanical causes was detected in roots S1–S4 in another patient, although neurotonic activity was observed in the right S1 territory, when working at the level of right L4–L5 (Fig. 4).

All potentially harmful activities cease when momentarily interrupting the procedure, with all patients presenting normal neurological examination at the end of the procedure.

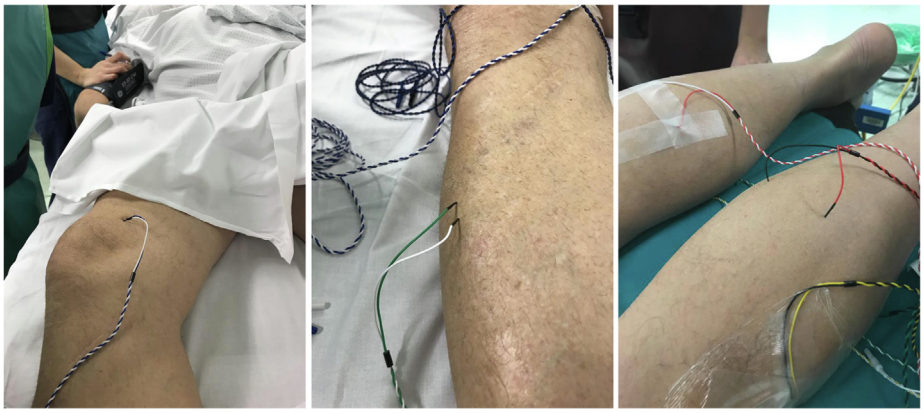

Fig. 3. Intraoperative neurophysiological monitoring.

Table 1
Results of intraoperative neurophysiological monitoring.

Patient	Epiduroscopy level	Epiduroscopy volume (ml)	EMG pre data	EMG intra data
1	L4, L5, L5, and S1 central	180	Subacute neurogenic changes in L3 and L4 left and chronic changes in L5 and S1 left compatible with radicular damage to these levels, mild, showing denervative activity at rest in L3 and L4 left but no loss of motor units	No neurotonic activity
2	L5 and S1 right	190	Chronic neurogenic changes in L5–S1 right and L4–S1 left with moderate degree of higher left affection. Compatible with radiculopathy of L5, S1 bilateral, and L4 left chronic motor	Neurotonic activity in S1 left territoty while working with Resaloon® at level L5 and S1 right
3	L5 and S1 left	190	Normal	No neurotonic activity
4	L5 and S1 bilateral	180	S1 bilateral radiculopathy	No neurotonic activity
5	L4 and L5 right	240	Chronic neurogenic changes of axonal character in L5 to L5 right of moderate grade and L5 left of moderate level	Neurotonic activity in L5 right, lasting 200–300 ms
6	L4, L5, and S1 left	210	Loss of motor units from L3–L4 to L5S1 above all L4, L5 left	No neurotonic activity
7	L4–L5, Y, and L5–S1 right	200	Chronic radiculopathy at L5 right	Neurotonic activity in L5 right territory, coinciding with Resaflex® use in recess L5 right
8	L4 and L5 right	300	Sub-chronic neurogenic changes of axonal character in territory L2, L3 bilateral of mild grade, compatible with radiculopathy L2 and L3 sub-chronic motor bilateral	Neurotonic activity in territory S1 right for activity at level L4, L5 right with Resaflex®
9	Fibrosis grade IV, which prevents the passing of epidurosocpe over S2	80	Chronic neurogenic changes in territory L5 and S1 bilateral compatible with radicular chronic damper moderate in L5 and mild in S1	No neurotonic activity
10	L4 and L5 right	160	Chronic neurogenic changes in territory L5 right and S1 bilateral	No neurotonic activity
11	L5 and S1 left	220	Chronic neurogenic changes in territory L3–S1 right and L5 left	No neurotonic activity
12	L5 and S1 left	190	Chronic radiculopathy in L5 left	No neurotonic activity

4. Discussion

Epiduroscopy is mainly indicated for lumbar canal stenosis and post-laminectomy syndrome. Although the procedure is safe and complications are typically minor, safety measures must be applied to reduce the incidence of complications considering the risk of subsequent potential major complications (Manchikanti, 2000).

The complications of epiduroscopy can be determined by the technique itself or by distension of the epidural space with saline solution (Marchesini et al., 2018). Distension of the epidural space can elicit two effects: affectation of the local perfusion and increase

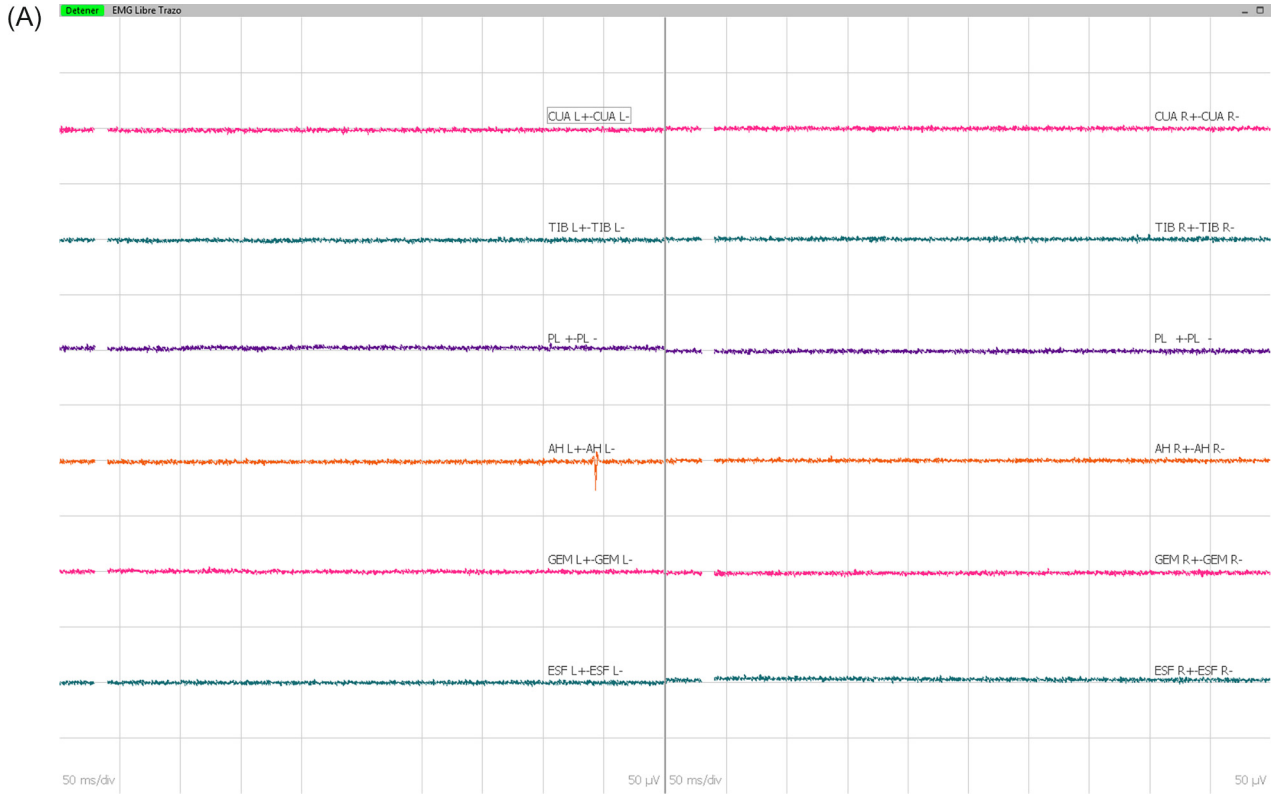

Fig. 4. A: Normal; B: Neurotonic discharges in the right L5 territory; C: Neurotonic discharges in the left S1 territory; D: Neurotonic discharges in the right S1 territory.

(B)

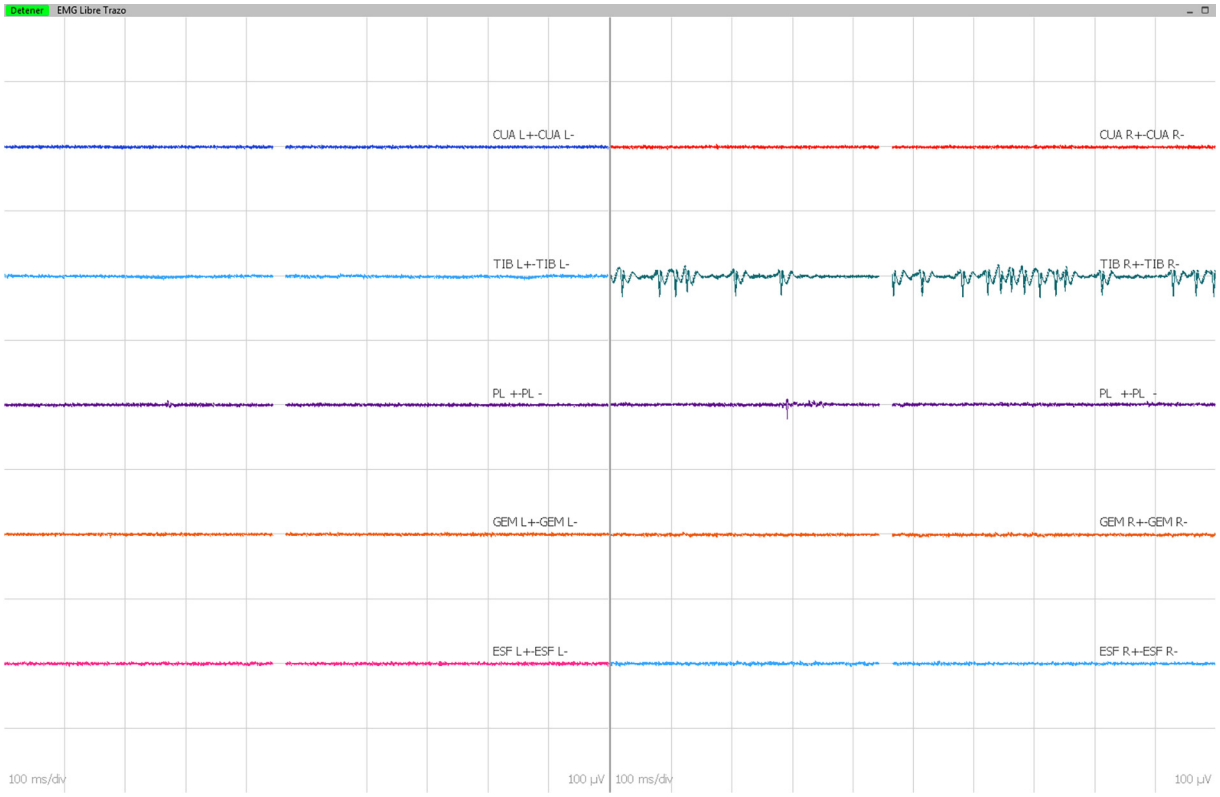

Fig. 4 (*continued*)

(C)

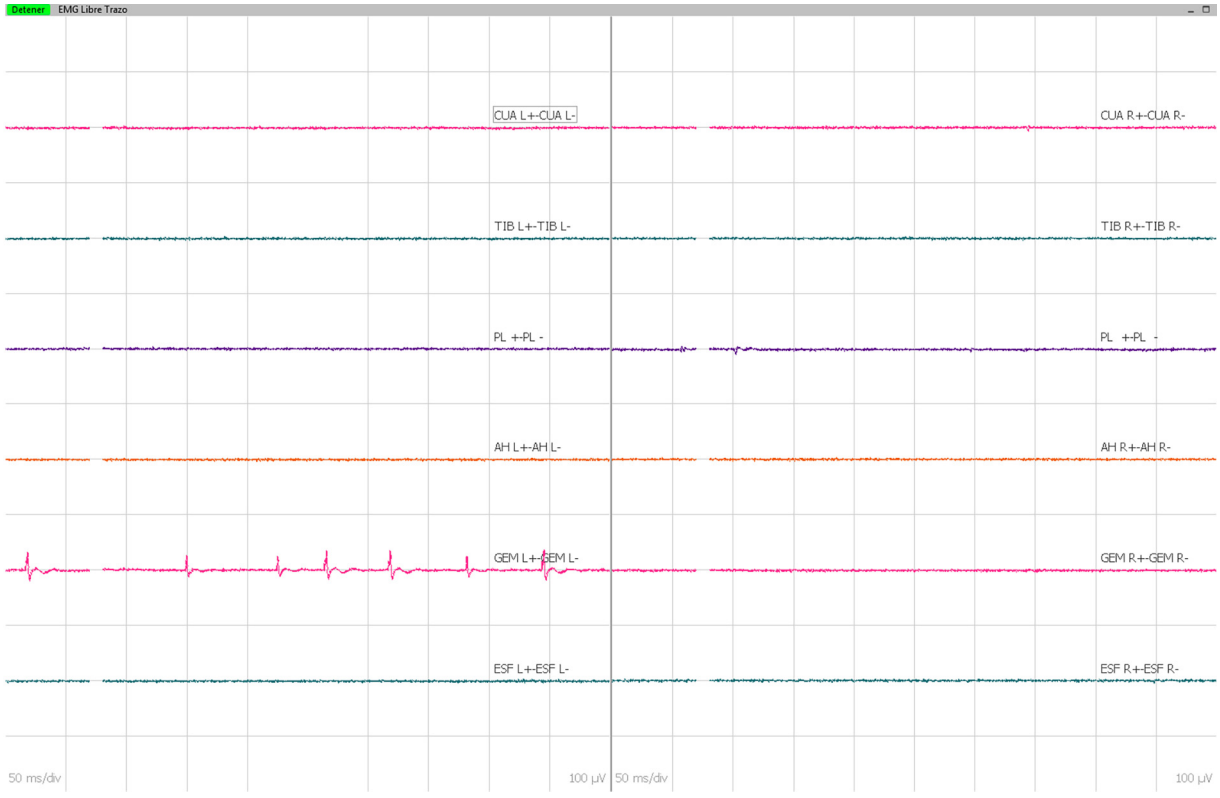

Fig. 4 (*continued*)

in pressure in the space that can be transmitted by the cerebrospinal fluid (CSF) (Mizuno et al., 2007). The primary complications arising from the technique include pain at the puncture site, dural puncture with or without post-puncture headache, par-

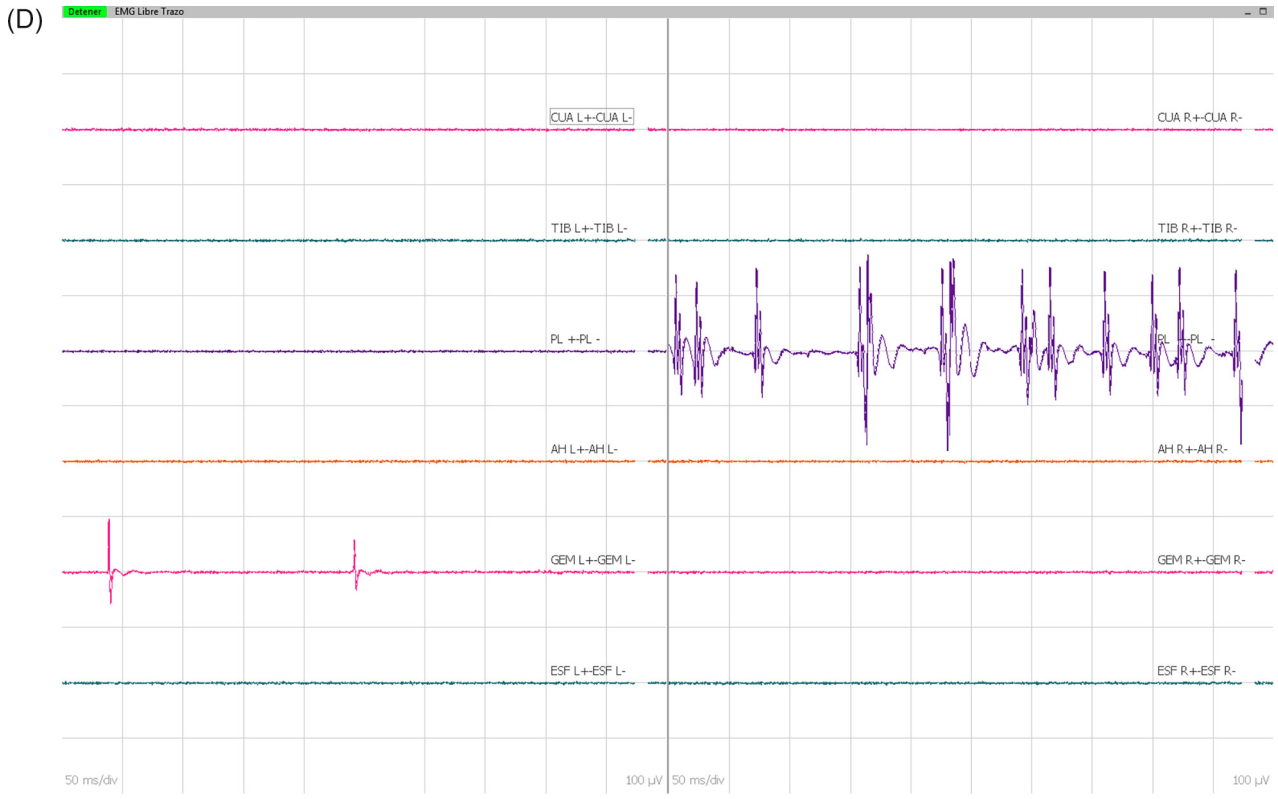

Fig. 4 (*continued*)

tial catheter shearing, paresthesia, transient subarachnoid block, and infection. Other types have also been described, such as nerve root injury, epidural bleeding and hematoma, meningitis or arachnoiditis, and abscesses (Table 2) (Trescot et al., 2007), although majority of the studies have been performed with percutaneous epidurolysis and complications have been comparable to those described in epiduroscopy (Talu and Erdine, 2003; Perkins et al., 2003; Wagner et al., 2006). Severe problems with vision after epiduroscopy have also been described, possibly due to increased pressure in CSF due to the formation of saline solution boluses during the procedure, as well as retinal hemorrhages and blindness, although with complete recovery in 79% of the cases according to Gill and Heavner (2005) and Heavner et al. (2007). All these complications of the procedure are generally minor and can be prevented with careful technique and proper handling of the amount and rhythm of the liquid infused (Hayek et al., 2009).

Table 2
Main complications arising from IESS.

Category	Adverse event
Related to Hardware	Additional surgery due to malfunction of the device: extension
	Additional surgery due to malfunction of Resaloon®
	Additional surgery due to the use of Resaflex®
	Additional surgery due to rupture/fracture of the device
Biological	Hematoma
	Infection
	Seroma
	Skin erosion
	Complications at the lesion site
	Persistent pain and/or numbness in the spinal area
	Pain related to trauma or inflammation of the side
	Allergic reaction to surgical materials ((sutures, antibiotics, and anesthesia)
	Changes in subcutaneous tissue at the site of introduction of the device
Related to Resaflex®	Inexplicable changes in headaches (with regard to intensity, type, or frequency)
	Decrease or loss of motor or muscular-skeletal control
	Nerve lesion
	Puncture or rupture of the dura mater

Complications regarding sphincter control in the form of faecal and urinary incontinence related to bladder or faecal dysfunction have been described as a consequence of a possible nerve injury at the level of the sacral plexus, which can be increased when performing large-volume injections in the epidural space (Kao and Lin, 2017). We did not find publications that can explain whether the reasons for this type of complications are the volume used, caudal entry into the epidural space with damage to the sacral plexus, or the use of Resaflex®. The lesion of the plexus does not seem logical at the entrance due to caudal access to the epidural space, although lesions may be formed by traversing the posterior to the anterior space, at the level of S3. This cause could be corroborated by means of electrophysiological studies. No changes were detected in neurophysiological monitoring conducted after this complication in patients who developed this type of complications. Conversely, using a new system within the coablative radio-frequency generator, sensory and motor stimulations were performed before each use of Resaflex® to avoid direct damage to the roots at which the procedure was performed; therefore, the location at which this tool was employed and safety measures taken before the procedure (Abejón et al., 2017) do not seem the most possible causes of these complications. Despite these safety measures, in our experience, there had been 5 cases of urinary incontinence from among more than 250 procedures, 4 of which fully recovered at 3–5 months after the procedure. Finally, the most possible cause for this type of complication could be increase in pressure and ensuing transient ischemia in the sacral plexus or cauda equina.

To reduce the possible causes, utmost care must be taken when accessing the epidural space without the use of large volumes, as recommended in the literature (Raffaeli et al., 2010; Abdi et al.,

2017) as well as when infusing without boluses to avoid all complications arising from this type of procedure.

To avoid this type of complications, we have started to perform intraoperative neurophysiological monitoring, which allows us to detect the presence of pathological discharges at different roots. These may indicate a potential lesion, so ceasing the maneuver over the nerve root, we can avoid the establishment of a neurogenic lesion. In fact, the existence of pathological neurogenic discharges on the side contralateral to the location at which Resaloon® was being used was detected in only 1 patient. This is an indication that increase in pressure on the contralateral side may be the origin of this type of complication and not necessarily either the volume used or the use of elements that can damage the sacral plexus or the passage of the epiduroscope through the caudal epidural canal. In 3 of the 12 patients in whom the monitoring was performed, neurotonic activity was detected in the roots when working with Resaflex®, 1 of which was detected at a lower level than that being treated, although in this case the activity did not seem to be pathological.

Increase in pressure in the epidural space, given the distensibility of the system, is transmitted via the caudal, cranial, and foraminal spaces (Usubiaga et al., 1967), and although studies by Hirabayashi et al. (1990) have shown an increase in the said distensibility of the epidural space associated with age due to the loss of epidural fat, the fact of working in patients with canal stenosis (anteroposterior distance <10 mm or cross-sectional area <100 mm^2) (Steurer et al., 2011) may justify the appearance of transient ischemia (due to increased pressure transmitted to CSF) in roots where the vascular supply may be compromised and trapping that may justify urinary or faecal incontinence after the technique. This causes urinary incontinence in patients, which is difficult to manage and predict because there is no intraoperative symptom that we can correct. Thus, we have started using a technique with monitoring to identify patients at a risk of such complications who would not be otherwise discovered.

We could detect changes in the surgical field as well as in roots below and/or contralateral to the surgical field through intraoperative neurophysiological monitoring, which would have otherwise gone unnoticed; however, these changes disappeared with complete recovery after stopping the procedure, which allowed us to avoid possible prolonged or even permanent complications in postoperatively.

5. Conclusions

Monitoring all types of constants throughout history has always been initially controversial because of the added cost to the technique and the lack of evidence of its benefit.

Intraoperative neurophysiological monitoring is a known security measure that may help to reduce potential neurological insults and can optimize outcomes during epiduroscopy. Moreover, it enables the surgeon to work for long periods and discover changes within the epidural space where we work in real time. Advances in patient safety must be considered in all interventional procedures that we perform to improve results and reduce the incidence of complications.

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None.

Conflict of interest

David Abejon is a consultant for Boston Scientific, PRIM, Cardiva, Abbott, and Medtronic. Eva M. Monzón and Pedro Moreno have no conflicts of interests.

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