Acta Neurochir (2004) [Suppl] 92: ■■■–■■■

Printed in Austria

Surgical radio-frequency epiduroscopy technique (R-ResAblator) and FBSS treatment: preliminary evaluations

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Summary

Failed back surgery syndrome represents a heterogeneous situation that suggests a fibrosis or neuroinflammatory genesis. The social cost related to this issue are enormous. Several surgical techniques have been applied to FBSS patients with controversial effectiveness. In 1998 we evaluated the efficiency and limits of epiduroscopy treatment; it proved to be effective in 75% of cases, but in 45% of cases it needed to be repeated after 12 months. Therefore we subjected 14 patients, who had previously experienced a short temporary benefit by using a traditional epiduroscopic approach, to a new epiduroscopy fibrolysis using a radio-frequency device named "R-Resablator Epiduroscopy". Clinical evaluation was performed before myeloscopy and after 1–3–6 months. After myeloscopy, 93% of patients reported a general improvement. Among the latter, pain was reduced by 90% in 8 patients, by 60–70% in 5, and by less than 30% in 1.

Conclusion. It can be concluded that RF-Epiduroscopy offers greater therapeutic benefit than traditional epiduroscopy or other surgical techniques. Furthermore, RF-Epiduroscopy is more easily performed and repeated.

Keywords: Epiduroscopy neurolysis; back pain; epiduroscopy FBSS treatment.

Introduction

Despite the improvement of surgical practices for painful spine pathology, there is still a high percentage (10–40%) of pain recurrence [1], called "Failed Back Surgery Syndrome" (FBSS). The expression Failed Back Surgery Syndrome groups up very different clinical situations (pain in lumbar axial site – radicular pain with or without claudication – instability of the posterior compartment) which only have in common persistent pain and radiological iconography (MRI-CT) characterised by the presence of fibrous tissue. According to Burton [7], however, only among 24% of patients suffering from FBSS does pain have an etiogenesis from fibrosis, with the formation of adhesions among tissues and compression or "tethering" of nerve roots; no evidence is reported in the literature of linear correlation between epidural scars and radicular pain, unless the fibrosis is very large [16]. It can therefore be assumed that other mechanisms as well as the described mechanical-compressive one, are responsible for pain in FBSS [4]. Neuro-inflammatory factors play a more substantial role [21], even when there are no compressive causes [20]. This has been detected in an interesting way, by means of myeloscopic investigation [13]. Our experience has shown how morphological pictures of the epidural area in FBSS patients are much more complex and heterogeneous than what can be identified with traditional investigation. The relation between pain and fibrosis depends on fibrosis distribution within the epidural specum and the strain generated on the surrounding tissue. Recurrence of pain-free intervals suggest that the phenomenon is biochemical and is generated by stress in an area which is made anatomically sensitive by adhesion fimbria.

Nevertheless, pain persistence, negative economical impact, and patients' poor quality of life do not seem to be affected by pharmacological approach [7–11–19]. The social cost related to this issue is still huge [5]. Several surgical techniques have been applied to FBSS patients displaying controversial effectiveness [6–8–22], while Spinal Cord Stimulation (SCS) seems to be more effective [12]. As for the latter, one must bear in mind that tolerance, especially in young adults, may develop in 6 to 8 years. Which therapy should be implemented [9] and with what progression? Based on our experience, we have evaluated in 1998 the effectiveness and limits of this method [18]. Myeloscopy proved to be effective in 75% of FBSS cases, but in

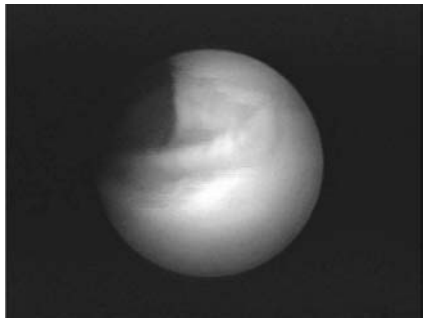

Fig. 1. Dura with false septa. The surface of the dura appears wrinkled (see arrows) with 'sail-like' aspects as dura was probably pulled by above or underlying fibrous traction

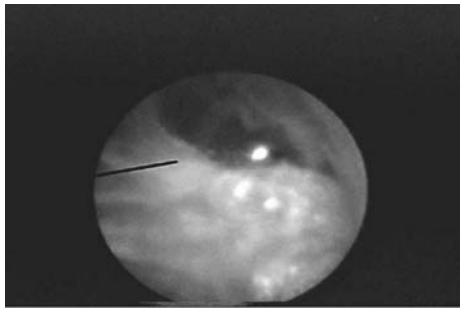

Fig. 2. Jagged or cotton-candy-like structures. Fibroid elements of transparent nature like bluish flaps interfere with the view of the dura. These structures adhere onto the surrounding tissues while exhibiting low adhesiveness onto the dura

45% of cases [13–14–15] it needed to be repeated after a 12-month period, so we introduced a new technique for the lesion of strangulation fimbria by using an RF thermo-knife inserted by means of the endoscope in order to improve the outcome.

Morphologic considerations [13–14]: endoscopic pictures (Figs. 1, 2): myeloscopy shows that there are very different morphological pictures, but they can be classified according to the presence of inflammatory situations and vessel alterations, which normally generate an axial lumbar pain, or scarring and adhesion bands with no flogosis element. The fibrotic component can also be divided into four subgroups based on the distribution of the pattern adhesion fimbria in the epidural channel: median connective sedimentation, diffused "honeycomb", blind transversal fimbria with total or partial stenosis, parallel to the side walls.

It can then be divided into 2 categories based on adhesiveness on dural structures: it adheres to the dura with painful distension of meninges and perineural tissue from traction that we have defined as "functional instability" or it can adhere to inert tissue without any distension, defined as "stable stenosis".

Table 1. *The morphological features %*

Morphological features	%
Fibrosis	55
Flogosis and hyperaemia	37
Stasis	29

The morphological features in our experience show the presence of functional stenosis from fibrosis in 55% of cases, flogosis and hyperaemia in 37%, alteration of microcirculation with stasis in 29% (Table 1).

Depending on the prevalence of the two pictures there will be a different therapeutic response to the procedure. The possibility of pain relief just with the infusion of liquids (antibiotics and saline) justifies a neurochemical-bacterial pathogenesis, which could be generated by the structural pericicatrical strain, since after different lengths of time there is a reappearance of the same pain. *Sacral pathology*. We would also like to stress an important factor which regards the scarce consideration often given by authors to the sacral component as site of pain genesis and presence of pathology. The presence of structural anomalies in the sacral compartment is common (50%) which can be the cause of a portion of the clinical pictures in FBSS patients, due to the co-existence in clinical correspondence areas, when they are subject to liquid dilation.

Materials and method

Patients. We have studied 14 patients (average age: 48 years). Primary pathology: secondary FBSS resulting from multiple spine surgeries (a minimum of two, discectomy/emilaminectomy – stabilization). Inclusion criteria were: presence of persistent radicular back pain related to previous rachis operations. Pain duration: at least two years after surgery.

Pain intensity: VAS > 5 (average VAS: 7).

Patients

- Had no pain relief after physical or invasive analgesic treatments, such as administration of drugs (NAISDs-weak Opioids) on a twice a week basis;
- Were subject to a first traditional epiduroscopy with a transitory (less than 3 months) partial pain relief;
- Displayed epiduroscopic morphological evidence of connective fibrosis with "Functional Instability";
- Responded well to active drug after "Intrathecal tests" (injection in the subarachnoid space of anaesthetic-opioids/paravertebral placebo) which excluded psychological pathology;
- Did not display imaging (MRI-CT) and electrophysiological (EMG) red flags.

Subjective evaluation of methods' outcomes. Patients before epiduroscopy (T0) and at the first (T1), third (T2) and sixth (T3) month after it, were evaluated by a blinded investigator. Patients were asked to estimate pain intensity by using an analog scale (VAS), and whether they had any benefit from epiduroscopy (yes/no). Those who responded in the affirmative were asked to rate their pain reduction using three categories: over 70%, 70–50%, 50%. Less than 50% was recorded as a negative result. A second question regarded reduction in analgesic drug consumption (100% – more than 50%).

Materials and technique

Optical fibre instruments commonly used are: single use with re-sterilizable optic fibre and protection single use videocatheter – manufactured by Myelotec (0.8 mm).

Patient preparation: Pre-anaesthesy with fentanyl and atropine (intra-operative use of propofol at sub-hypnotic doses); prone position on the radio transparent bed.

Sacral-elective approach to ease and lower invasiveness of execution [14–19]: identification and insertion in the iatus sacrale, after the fluoroscopy L/L guide of the dilation instrument through which a video-catheter with the optic fibre is positioned. If it is impossible to use the sacral path (due to a blocked stenosis iatus or to sacro-coccygeal ligament's ossification), one has to use a cranio-caudal interlaminar lumbar approach, two metamers above the site of the pathology (this is a more invasive technique) [13]. Dilation of the channel by means of liquid: infusion with a 20 ml syringe, with individual bolus at time intervals every 3–4 boluses (perforaminal diffusion time) – total dose from 180 to 350 ml – average dose 220 ml. Contrastography with Iopamiro (5 ml) after identification of the pathological space – purpose: to assess how the fluids are distributed and identify the presence of total channel stenosis and patency of sacral foramens.

Raffaeli-Righetti Technique (RR Myeloscopy technique)

1st phase adhesion subsidising

Preparation of the site by cleaning the channel structures by mechanical dilation and skeletization, removal of fat and low-adhesivity fimbria by selective pressure of fluids in situ and traction/dilation with Fogarty 3 F float.

Mechanical dissection of connective structures: by dragging with the endoscope tip in rotation and dilation of the fogarty float (Fig. 3).

Fig. 3. Fogarty float

2nd phase – resection by radio frequency ablation

Surgical instrument: Res-ablator 50. Introduction through the video-catheter's operative channel. Ablative fibre type 0.8 mm reseflex. Spherical ablative tip. Modulated 4 Mhz output frequency in coagulation. Working depth: 1 mm beyond the tip.

Technique: Preparation of the channel and visualization of tissues by means of the first procedural phase. Identify, by means of skeletization with video-catheter tip, the newly-formed vascular component which appears blurred with the scar connective network/reticulum and proceed to insulating the individual fibrous septa with the application of RF, in the median fibrosis site for 2/3 times, until complete resection and disconnection from the base. Cleaning with fluids and float to isolate the fibroses in progression. Do not proceed to lesion if the dura/fimbra interconnection point is not visible. Avoid lesion of the structures at the insertion base with dural pannus. Proceed to removing septa and dilation of the channel until completely isolating the dural pannus from fibrous shoots. Dilation with float – cleaning with liquids and assessing any bleeding sites to be selectively coagulated by RF and removal of system after local application in inflammatory sites of steroids – (80 mg) and antibiotics – 100 mg (Ciprofloxacina).

Surgical time: 35 minutes.

Results

Anatomical effects: As we can see in Fig. 4 the Resablator epiduroscopy technique permits to remove the connective tissue totally in those conditions in which traditional epiduroscopical approach is not effective.

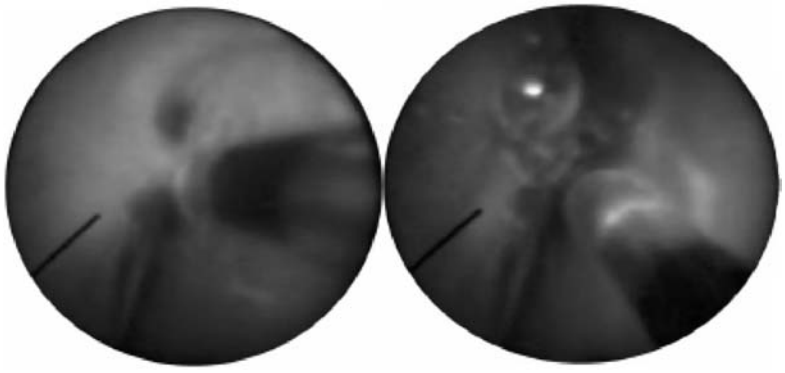

Fig. 4. During and post RF lesion

Table 2. *Pain reduction*

Pain reduction %	n. patients
<30%	1
60–70%	5
>90%	8

Subjective evaluation.

Compliance with the clinical investigation was total as all patients responded to the questionnaire. After myeloscopy, 93% of patients (n = 13) reported a general pain relief. Among the latter, pain reduction was over 90% in 8 patients, of 60–70% in 5, and less than 30% in 1 patient. For a quarter of patients [5] benefit lasted <1 month; for the other groups benefit was over 80% at the sixth month. Six patients: all patients stopped weekly analgesic use and half of them used weekly opioids sporadically (less than 10 days in a month): tramadol (9.4%) (Table 2).

Complications: short-long term: none.

Discussion

Surgical approach to FBSS patients is reported to have a low success rate. Some authors [2] report that repeated surgery in FBSS cases fails to give any pain relief in 60% of cases, worsening in another 20% of cases and sufficient benefit in only 20% of cases. Similar results were found more recently [11] making this approach highly inadvisable, except when instability of the rachis is involved. As previously reported [14–15] we believe that fibrosis is not the only cause of persistent pain in FBSS. So in our series, patients in whom fibrosis was not removed reported pain relief as just the same. Thus we are in agreement with those authors who attribute pain to fibrosis only in 24% of cases [1]. Hence, fibrosis generation by itself is not a synonym of FBSS [18]: often, before symptoms arise, there is a pain free window during which alongside fibrosis, other painful neuro-inflammatory phenomena and local fibrous impairments may develop. We have described extensively these phenomena in the epidural space and reported in accordance with other authors [10–15–16] the effective pain relief obtained by traditional epiduroscopy [13–15–16]. The peridural scar, especially when extensive, has widely been considered responsible for FBSS by Ross [16] who found that increasing scar scores led to an increased likelihood of experiencing recurrent radicular pain. We know that epidural structures upon which fibrous tissue anchors may determine during some conditions (e.g. increased SCF pressure) a traction on the inflamed dura and elicits pain (''dynamic instability''), so in this morphological condition we think it is indispensable to remove the fibrosis, otherwise there would not be persistent benefit. Epiduroscopy results proved to be effective in FBSS pain relief [15–16] but is poor in more than half over the years and the technique is no longer indicated.

Our preliminary findings show that in patients with dynamic instability it is important to remove the link with the dura to obtain a prolonged pain relief.

We need to gain further experience to find out which is the best epiduroscopy approach and select the patient patterns.

Conclusion

It has been shown that epiduroscopy has a specific therapeutic value. The effectiveness in FBSS patients

proved to be not inferior than other non-surgical techniques, with the advantage of easy implementation, limited invasiveness and repeatability. Given the variability of the identified pathological features, the technique is essential for a morphological diagnosis.

The set-up phase of the new technique allowed us to verify its limits and advantages as well as to define its technical features and to facilitate interventions. We think that introduction of the RF lesion method will lead to higher therapeutic benefits; it must be implemented in all conditions (Raffaeli) named ''functional instability'' in which fibrotic/connective banding takes place in the epidural space, causing traction on the dural pannum and where its perinervous structures increase or cause traction on the roots during intracanicular pressure. Rf myeloscopy represents a further development which allows to increase and optimize the positive results obtained with traditional myeloscopy, especially as regards reduction of long-distance pain recurrence. Compared with traditional surgical procedures, it has the advantage of easy execution and repeatability. We tend to recommend this method as first procedural step in patients with persistent FBSS pain with no signs of instability of the posterior compartment.

Using the Resablator Epiduroscopy Technique we can reduce the quantity of fluid used and avoid excessive fluid irrigation of the ES, taking care not to forget monitoring patients' cervico-cranial discomfort [10].

Hence epiduroscopy can be considered as a feasible and safe method when avoiding excessive fluid irrigation of the ES and preventing patients cervico-cranial discomfort.

Ethics

The study was approved by the Hospital Ethics Committee and conducted according to the Helsinki declaration principles on human clinical studies. All the patients were thoroughly onformed of the procedure and the study written consent was obtained.

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