

Application of Pulsed Radio Frequency to the Dorsal Horn and Dorsal Roots

Description of a Device for Functional DREZectomy

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Abstract

A newly developed multifunctional electrode (PASHA-electrode[®]) combines diagnosis of the level at which afferences enter the spinal cord with treatment at these levels by applying PRF at the dorsal root entry zone, making functional DREZectomy.

Background: The traditional idea of preventing the conduction of nociceptive impulses by burning a nerve appears overly mechanistic. Sluijter developed the Pulsed Radio Frequency (PRF) technique whereby a high electrical field is applied without overheating. Unlike radiofrequency thermocoagulation (RFTC), treating chronic pain with PRF has few side effects. Histochemical investigations revealed enzyme-like protein induction in PRF treated nerve cells which was not seen in cells treated with continuous RF. Moreover, histological analyses showed no significant tissue damage to the treated nerve cells. The technical limitations of instrumentation designed mainly for extraspinal use are preventing PRF treatment from reaching its full effective potential.

PRF using the new multifunctional electrode with a stimulation period of 240 sec appears effective in the treatment of chronic pain patients. The flexible device enables us to develop new algorithms for the diagnosis and treatment of pain. Since we are treating the transmission and translation of pain and are modulating the dorsal horn entry zone, the origin of the nociceptive input is not a primary consideration.

Introduction

The treatment of chronic pain remains a challenge in modern medicine. Whenever pharmacologic and other conservative treatments of chronic pain fail, ablative and interventional methods are attempted on the assumption that interrupting nerve conduction prevents central pain cognition. High-end therapies such as spinal cord stimulation or intrathecal drug infusions are expensive and not free from complications. There is still a large gap between the standard therapies and these high-end methods. When using the thermosurgical approach, radiofrequency thermocoagulation (RFTC) is the method of choice. The temperatures applied usually reach 70 °C-80 °C [1].

Since pulsed radiofrequency (PRF) technology has been shown to be effective in the management of chronic pain, it is an interesting option for the invasive treatment of chronic pain and has a much lower rate of side effects compared to other techniques. The temperature in the treated tissue does not rise above 42-43 °C and there is thus no tissue destruction. Histochemical investigations showed enzyme-like protein induction in PRF-treated nerve cells which is not observed in cells treated with continuous RF. Moreover, histological analyses have not revealed any significant tissue damage to the treated nerve cells [2]. Maintaining a safety distance from the treated nerves is no longer

necessary, on the contrary distance diminishes the outcome.

Since only rigid electrodes and the thin electrodes developed in the 1980's were available, interventions had to be restricted to stimulating the nerves in or peripheral to the intervertebral foramina. A closer approach to the roots or treatment of (sacral or thoracic) ganglia in the spinal canal was only achievable by drilling burr holes, an intervention eschewed by many pain specialists.

In 2003, a flexible multifunctional electrode was developed.

The rationale underlying this approach is that the dorsal horn plays a central role in modulating all nociceptive inputs on their way to the central nervous system. We developed a flexible probe which allows us to apply PRF without restriction to almost any target. This flexible multifunctional electrode is a combination of a catheter with two electrodes located at the tip.

With this device we can perform the following procedures:

- Stimulate any nerve or spinal nerve root at any frequency, e.g. 80 Hz test stimulus for sensory stimulation, in order to determine the exact level

- Apply PRF at the dorsal root entry zone, the dorsal roots and conus medullaris peripheral nerves and any other structures
- Injection of medications and agents
- Online measurement of the temperature at the tip to avoid damage to surrounding tissues
- Accurate placement without the need for radiopaque contrast materials, due to the visibility of the device in radiography and test stimulations
- SCS trial stimulation
- The multifunction device can be left in place for repetition of PRF or injections

This paper summarises these results and presents technical conclusions. After treating more than 1000 patients, new algorithms have been developed for the management of chronic pain patients.

2 Methods

The flexible multifunctional electrode is a combination of a catheter and two electrodes placed at its distal end (each 3 mm long and 4 mm apart). The distal opening of the catheter is situated between the two electrodes. The catheter is 60 cm long and has a maximum outer diameter of 1.38 mm (4F), the stylet diameter is 0.35 mm.

Stimulation parameters: The duration of the active phase is 20 msec and the pause between active phases lasts 480 msec, resulting in two active phases per second. Each nerve root is stimulated for 240 sec. The temperature at the electrode tip measured online does not exceed 42 °C. The generator power output is in the range 0.1 – 5 watts (in a few cases above 10 watts). The conductivity of electrical current in epidural fat is very low ($0.04 \Omega^{-1} \cdot \text{m}^{-1}$) compared to $1.4 \Omega^{-1} \cdot \text{m}^{-1}$ in the CSF.

3 Practical implementation

The goal is to achieve the closest possible proximity to nervous structures.

The patient is placed in the prone position with a cushion under the abdomen to reduce the lordosis. The return electrode (ground plate) is positioned cranial to the area we intend to stimulate. The introducing cannula is advanced until we feel the intervertebral ligaments. A small suture incision is made and the epidural space is accessed using the loss-of-resistance technique. X-ray visualization is recommended. This is done under Local anaesthesia. We use 14G introducing cannula familiar to us from introducing spinal cord stimulation (SCS) electrodes. If the dura is unintentionally punctured, the introducer is not retracted, and the procedure is continued

Approximately 1.5 cm proximal to the tip, we bend the electrode slightly to make navigation easier. The

electrode is introduced through the cannula and advanced smoothly towards craniolateral. The curved tip acts as a guiding mechanism facilitating advancement to the levels above the area to be treated.

We do not place the multifunctional electrode over the dorsal column as in SCS. When treating the lumbar and sacral area, our target is the dorsolateral parts of the spinal cord.

The dorsal roots are stimulated with 80 Hz and the electrode tip is moved until the stimulation is sensed by the patient at its lowest voltage threshold. It should be attempted to produce perceptible stimulation in the patient with voltages $< 0.8 \text{ V}$ to ensure that the tip of the electrode is close enough to the nerve roots, which considerably enhances the effect of the PRF. If the electrode is accidentally or intentionally positioned intraspinally, the stimulation is perceived at considerably lower currents – sometimes as low as 0.1 V. However, the currents required vary according to where the electrode is positioned in the spinal canal. If the dura is thick or calcified, higher currents may be required.

The identified nerve roots are then treated by PRF. The electrode is gently withdrawn applying continuous stimulation until the following caudal root is localized, which is identified in the same manner by test stimulation and treated by PRF. In this way the roots can be located and treated in succession.

There are different targets when treating the spinal cord and its nerve roots:

- 1- By introducing the electrode using a paramedian approach and entering the epidural space between the 3rd and 4th intervertebral space, we can treat all the lumbar roots and the upper sacral roots. Using this approach we are also able to treat the conus. The electrode can be advanced, if required, to the thoracic and even cervical parts of the spinal cord. Usually, if our target is the thoracic region, we prefer to enter between the 2nd and 3rd vertebra. When treating the cervical spine we usually introduce the electrode between the 3rd and 4th thoracic vertebra.
- 2- Treating the DREZ region at the conus medullaris or at the levels of the lower thoracic spine appears to have a similar outcome as treating the dorsal nerve roots directly.
- 3- The electrode can be introduced via the sacral hiatus. The primary indication for this method is treatment of the sacral nerves which are difficult to approach in the lumbar spine because they are concealed ventral to the lumbar roots. For the management of mononeuropathy, e.g. affecting the pudendal or obturator nerves, we chose the sacral approach.

4 Indications

The indications established to date for pulse radiofrequency (PRF) treatment and/or infiltration by means of the multifunction electrode are:

- Neuropathic pain
- CRPS 1 and CRPS 2
- “Failed Back Surgery Syndrome”
- Cervical and thoracic spinal pain syndromes. Here this approach is safer and avoids the complications of the conventional needle puncture techniques - Mixed pain: back and radicular pain - All indications suitable for facet joint denervation (specifically thoracic and cervical).
- Multi level spinal stenosis - Restless legs syndrome - Visceral pain?

Since we are treating the transmission and translation of pain and are modulating the dorsal horn entry zone, the origin of the nociceptive input is not a primary consideration.

The multifunctional origin of chronic pain sometimes makes it necessary to combine different procedures and apply them successively. The multifunction electrode allows multiple procedures to be completed in a single step, minimizing possible complications, treatment time and costs.

Causal treatment should self-evidently be the goal of every treatment, but where it fails multifunctional electrode PRF can be used to modulate the input of the spinal cord at the dorsal root entry zone before considering the use of destructive techniques, SCS, intrathecal drugs or even initiating the use of morphine.

The new approach is not intended to replace SCS, but is merely a step in the therapeutic algorithm, and may help patients without implanting expensive devices or attempting other invasive techniques.

In addition to the benefits described above, there is no need for all the test infiltrations usually performed to identify pain pathways. The levels can be mapped more accurately with the electrode – and with fewer complications. In fact there are no complications except those also observed with any other catheter or electrode.

It is not yet possible to predict the treatment outcome. There still is a lack of knowledge as to how the pain processing system functions and what physical and psychological parameters may alter the effect of the treatment.

5 Results

Pain reduction: In 95 of the first 101 treated patients, post-treatment pain ratings were obtained after 6 months. Mean age 59.7 years (max. 94, min. 32). Females 71, males 27. 88 patients lumbar pain – 1 patient thoracic pain – 11 patients cervical pain.

75 patients had back pain – 55 patients leg pain – 15 patients had neuropathic pain.

The mean VAS score before treatment was 8.5 ± 1.3 units with a minimum 5 units and a maximum 10 units, indicating severe pain. The mean post treatment pain score was 4.3 ± 2.8 units, with a minimum 0 units and a maximum 10 units, indicating that some patients did not benefit from the treatment. Nevertheless, the pain reduction in the pre-post comparison is highly significant ($p < 0.0001$). Mean pain reduction was 48.3 %.

Dividing the group according to the duration of PRF stimulation (60 sec, 120 sec, 240 sec), the pre-post comparison for pain reduction in each subgroup is still highly significant (60 sec, N=21, $p = 0.0002$; 120 sec, N=28, $p < 0.0001$; 240 sec, N=46, $p < 0.0001$).

Pain reduction in the subgroup with a 240 sec stimulation period was a mean $54.7 \% \pm 33.0 \%$,

The analysis showed a highly significant treatment effect. Using a 240 sec stimulation period, 47.8 % of the patients experienced a pain reduction $\geq 70 \%$.

PRF treatment of 101 patients was found to provide definite pain reducing effects without evidence of neuronal lesions. The only side effects were headache in 4 patients due to accidental intrathecal puncture. The main parameter influencing the pain reducing effect was the stimulation period. With a stimulation period of 60 sec, which is also used in RFTC, 3 of 21 patients (14.3 %) had a pain reduction of more than 70 %, and when the stimulation period was increased to 240 sec, 22 of 46 patients (47.8 %) responded with a pain reduction of more than 70 %.

Long-term follow up: 123 patients had a pain reduction of 64% after 18 month. The long-term follow up of 64 patients: mean VAS score before treatment of 8.85. After >3 Years the mean VAS was 3,12.

6 Conclusions

The new multifunctional electrode presented in this article, together with the associated procedure described above, considerably extends the range of therapeutic options for the management of chronic pain. Besides the definite therapeutic effect, the lower rate of complications and side effects, further factors also make this new procedure and device appear an attractive diagnostic and therapeutic modality.

7 References

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