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The efficacy of radiofrequency lesioning of the cervical spinal dorsal root ganglion in a double blinded randomized study: no difference between 40°C and 67°C treatments

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Abstract

The efficacy of radiofrequency lesion treatment of the cervical dorsal root ganglion (RF-DRG) in cervicobrachialgia was investigated in 61 patients by a randomized prospective double blinded study. Before lesion treatment the putative pain provoking spinal root was identified by diagnostic blocks with a local anesthetic agent. One group of patients ($n = 32$, group I) was treated with a radiofrequency lesion of 67°C and in a control group ($n = 29$, group II) a temperature of 40°C was applied. Three months after treatment a significant reduction in VAS scores was demonstrated in both groups. The outcome of the treatments was identical (VAS reduction: group I, 1.7; group II, 1.9; $P = 0.001$). In group I a VAS reduction of 3 or more occurred in 11/31 (34%) and in group II in 11/29 (38%) of patients. A VAS reduction of 2 or more occurred in group I in 15/31 (47%) and in group II in 15/29 (51%) of patients. This study suggests that treatment with 40°C radiofrequency application of the dorsal root ganglion is equally effective as treatment at 67°C. Further appraisal of this treatment is required. © 1997 International Association for the Study of Pain. Published by Elsevier Science B.V.

Keywords: Radiofrequency lesion; Dorsal root ganglion; Cervicobrachialgia; Pain

1. Introduction

Annually in the Netherlands radiofrequency lesion treatments of the dorsal root ganglion (RF-DRG) are applied in about 3000–4000 patients suffering from chronic benign pain. About 1000 of these patients are treated for cervicobrachialgia. Although the value of RF-DRG has been clearly demonstrated in cancer patients (Lahuerta et al., 1990), the usefulness of the technique is questioned in patients with pain of chronic benign origin (Koning et al., 1991). Good results are claimed as long as the technique is applied properly and in carefully selected patients (Sluyter, 1981; Nash, 1986; Vervest and Stolker, 1991). A main cause of the current discord can be attributed to the shortage of critical clinical research.

RF-DRG is performed in patients with cervicobrachialgia of monosegmental origin established by preceding prognostic root blocks with a local anesthetic agent.

The method requires meticulous attention to detail since cases of irreversible neurological damage have been reported (Lahuerta et al., 1990).

A prospective randomized double blind study was performed to compare the effectiveness of RF-DRG at two temperatures in patients with intractable cervicobrachialgia.

2. Methods

The study was approved by the ethics committees of the participating hospitals. This multicenter study was performed in three hospitals: University Hospital Nijmegen (pain treatment: Professor B.J.P. Crul, anesthesiologist), St

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Anna Hospital, Oss (pain treatment: G.J.J. Braak, anesthesiologist) and University Hospital, Utrecht (pain treatment: J.W. Geurts, anesthesiologist).

2.1. Treatment of patients with cervicobrachialgia

All patients with cervicobrachialgia were examined by an anesthesiologist during their first visit to the pain clinic. They were also seen by a neurologist and an orthopedic surgeon. A neurosurgeon or rheumatologist was also consulted when indicated. CAT scans were obtained in all patients. Depending on the history and the results of psychological questionnaires (SCL 90 symptom check list; Derogatis, 1977) completed by the patient, a psychologist was also involved.

After the intake procedure a therapeutic protocol was established, which consisted of conventional measures, e.g., analgesics, triggerpoint injections with local anesthetics, physical therapy, transcutaneous nerve stimulation, psychological intervention and social support. Only when definitive therapy was not possible (orthopedic or neurosurgery) and conventional therapy was not effective was the patient advised to undergo RF-DRG. Psychological intervention was not a contraindication for RF-DRG.

2.2. Study design

When paravertebral mechanical pain was present suggestive of cervical facet joint syndrome a radiofrequency lesion of the ramus dorsalis on the side corresponding to the painful segments was performed to achieve facet joint denervation in the painful segments. When the patient thereafter still complained of unilateral cervicobrachialgia, diagnostic blockades were performed to identify the putative pain provoking cervical spinal root. These blocks included the levels C3 to C7. After a clearly identified cervical spinal root was identified by the prognostic blockades, patients were asked to participate in the study and to provide written

informed consent. Inclusion and exclusion criteria are summarized in Table 1.

Patients were assigned at random to two study groups, a treatment group (group I), and a control group (group II). Both groups were treated with a radiofrequency lesion limited to one spinal root; group I received a radiofrequency lesion at a temperature of 67°C for 90 s, and group II received a radiofrequency lesion at a temperature of 40°C for 90 s. An independent investigator operating the radiofrequency lesioning generator (Radionics® RFG 3C lesion generator) adjusted the temperature to the values. In both groups the timer ran for 90 s. Neither the patient nor the therapist were able to observe which procedure was being performed. For ethical reasons the double blinded period was limited to 3 months, after which the code was broken. If the pain was still present, patients of group II were offered the possibility of RF-DRG treatment with a temperature of 67°C.

2.3. Evaluation

In both groups the first evaluation was done before RF-DRG was performed, and included: (i) pain measurement (Visual Analogue Scale (VAS), a pain scale between 0 and 10, where 0 indicates no pain and 10 indicates maximum pain); (ii) subjective changes (better, equal or worse than before RF-DRG treatment); and (iii) side-effects (impairment of motor function, sensory impairment or other). After 6 weeks and 3 months (before the double blinded code was broken) measurement of pain, and prevalence of side-effects was assessed by a questionnaire and a visit to the pain clinic.

2.4. Diagnostic blockade of the cervical spinal ganglion

To identify the putative pain provoking spinal root, three to four diagnostic blockades of different cervical spinal roots were performed. Diagnostic blockades were performed using fluoroscopy with a C-arm. The C-arm was positioned parallel to the axis of the intervertebral foramen. Under direct vision an electrode (Top-XE electrode, 23-gauge needle with 4-mm bare tip, Radionics®) was introduced parallel to the beam of the X-rays into the selected cervical foramen (tunnel vision). Anatomically, the (dorsal) caudal part of the foramen is where the sensory nerve fibers are located. A physiologically correct placement was obtained by 50-Hz stimulation of the needle tip. A tingling sensation in the corresponding cervical dermatome was obtained between 0.3 and 0.7 V. After correct physiological placement, the anatomical placement of the needle was controlled making use of a contrast dye (iohexol 240 mg/ml, Omnipaque® 240). The correct position of the needle tip was at the lateral edge of the facet column, injected contrast dye imaging the corresponding cervical root (Fig. 1).

In addition to the cervical foramen view, the anterior posterior view was also used in all cases to identify any

Table 1

Inclusion and exclusion criteria

Inclusion criteria

- Patients suffering from unilateral pain in neck, shoulder or arm of chronic benign pain origin
- Age between 20 and 60 years
- Pain duration of at least 6 months
- Conventional therapeutic approach not effective
- No indication for surgical therapy as validated by X-ray and CAT scan of the cervical spinal column
- Positive diagnostic blockade for monosegmental pain

Exclusion criteria

- Evidence of deafferentation pain (hyperpathia, hypoesthesia, dysesthesia) in the upper extremity involved
- Previous surgery of the cervical spinal column
- Hypersensitivity to radiopaque dye solutions and/or local anesthetics
- Clotting disorders, major mental disease

Table 2

Group I and II demographic and patient data

	Group I (67°C)	Group II (40°C)
Number of patients	32	29
Male/female	11/21	10/19
Mean age	46.3 (11.3)	43.9 (14.0)
Mean number of analgesics used	0.88 (1.0)	0.66 (0.76)
Duration of pain before RF-DRG treatment (years)	7.4	7.6
Involved cervical spinal ganglion (<i>n</i>)	C3 (3) C4 (14) C5 (9) C6 (5) C7 (1)	C3 (4) C4 (10) C5 (7) C6 (5) C7 (3)
Mean level motor response RF-DRG (V)	1.07 (0.46)	1.28 (0.81)
Mean level sensory response RF-DRG (V)	0.43 (0.18)	0.46 (0.14)

3. Results

In total 314 patients with cervicobrachialgia visited the pain clinic from January 1993 to June 1995 in the participating hospitals. After diagnostic blockades of the cervical spinal ganglion 63 patients with a clearly identified pain provoking spinal root were finally included in the study. One patient refused to continue to participate in the study 3 months after RF-DRG. In another patient the record of the applied temperature was missing. Finally the results in 61 patients could be analyzed.

Demographic data are summarized in Table 2. Overall, both groups are comparable.

After diagnostic blockade of the eventually treated spinal ganglion, the mean VAS score decreased to 0.5 in both groups. In all these patients VAS scores returned to baseline values within 1 week. In both groups, following RF-DRG a highly significant reduction of mean VAS scores was observed (Table 3).

There were no significant differences in reduced pain scores between group I and II. Three patients in group I had an increase in pain (increase VAS score >3 points) 3 months after RF-DRG, in contrast to group II, where no patient had an increase in VAS score.

In order to investigate if any variables were related to the change in VAS score after 3 months, a stepwise linear regression analysis of the VAS score changes was done with this change as the dependent variable and the following independent variables: treatment, gender, treatment and gender interaction, age, sensory threshold, motor threshold, number of medications at baseline, sleep pattern (sleeping pattern score: 0 = undisturbed, 1 = moderate without sedative, 2 = moderate with sedative, 3 = bad with sedative) and baseline VAS score. From these, only the last one, baseline VAS score appeared to be related to the change after 3 months ($P = 0.03$), with higher baseline values

resulting in larger decreases (Fig. 4). The relationship was rather weak with only 8% of the total variation in VAS change explained by the relationship with baseline VAS. Females showed a decrease of 1 point more on the VAS scale than males, in both groups (overall: 2.2 versus 1.2). This difference was, however, not statistically significant.

Complaints of neuritis in the treated spinal nerve were present in group I ($n = 6$) and group II ($n = 5$) 6 weeks after RF-DRG. These disappeared completely 3 months after RF-DRG. Three patients complained of slight loss of muscle strength in the hand or arm on the treated side. In group I, two patients presented with a decreased pinch force 3 months after RF-DRG. The pinch force measured in the hand decreased from 16 to 12 mmHg (treated spinal root C5), and from 24 to 8 mmHg (treated spinal root C4). In group II there was one patient with a decreased pinch force 3 months after RF-DRG. The pinch force measured in the hand decreased from 20 to 14 mmHg (treated spinal root C4). There were no other reported side-effects or complications in either group.

4. Discussion

Following treatment in both groups a significant pain reduction was demonstrated. Mean VAS scores at 6 weeks and 3 months after treatment were significantly lower than pre-treatment values.

In this study no significant difference in pain reduction between treatment group I and control group II was demonstrated. This raises the question as to whether the control

Table 3

Pain scores in groups I and II before and after RF-DRG

	Group I (67°C)	Group II (40°C)
Number of patients	32	29
Mean VAS score before RF-DRG	6.7 (1.6)	6.3 (2.1)
Mean VAS score 6 weeks after RF-DRG	4.8 (3.5)	4.9 (2.7)
Mean VAS score 3 months after RF-DRG	5.0 (2.9)	4.4 (2.9)
VAS score between 0 and 1, 3 months after RF-DRG (%)	$n = 4$ (12.5)	$n = 3$ (10.3)
VAS reduction >3, 3 months after RF-DRG (%)	$n = 11$ (34)	$n = 11$ (38)
VAS reduction >2, 3 months after RF-DRG (%)	$n = 15$ (47)	$n = 15$ (51)
VAS increase >3, 3 months after RF-DRG	$n = 3$	$n = 0$
Subjective pain at the involved area 3 months after RF-DRG	Better, $n = 15$ Equal, $n = 15$ Worse, $n = 2$	Better, $n = 15$ Equal, $n = 12$ Worse, $n = 2$

RF-DRG, radiofrequency lesion of the dorsal root ganglion.

* $P < 0.01$. P -values refer to differences between values at 3 months minus baseline values.

Expected decrease in VAS-score

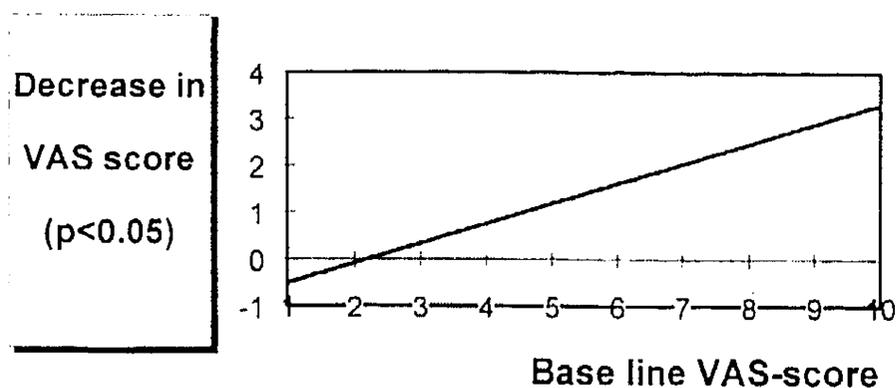


Fig. 4. VAS change related to baseline VAS score.

group (group II) represents placebo treatment. Although minimal increases in temperatures (45°C) can induce damage to nervous tissue (Smith et al., 1981), it was not expected that 40°C procedures would provoke long-lasting changes in nervous function, e.g., nociception. For that reason we expected to have a minimal pain reduction in the control group (40°C radiofrequency lesion). In a recently published study (van Kleef et al., 1996) on patients with cervicobrachialgia treated with RF-DRG, using a sham lesion (no radiofrequency current applied) in the control group, only two out of nine patients of this group reported pain relief (VAS decrease 2 points or more) after an 8-week follow-up period. Furthermore we consider the effect of a no current blockade to be identical to the effect obtained after a diagnostic blockade in which, after needle positioning, only local anesthetics (and contrast dye) are injected. In contrast to the effects of the 40°C procedure, none of our patients reported a pain-free interval of more than 24 h was observed after a mere diagnostic blockade. Thus a placebo effect of 51% (VAS decrease >2 points) was not expected in case a true placebo treatment had been used in this group. Our findings therefore raise a question about the mechanism of action of RF-DRG. Is it the current or the temperature that determines the pain relief after RF-DRG? When comparing the results of van Kleef et al. (1996) with those obtained in our study the use of radiofrequency current seems to be responsible for the effect seen in our 40°C control group. In the study of van Kleef et al. a decrease in VAS of 2 points was registered in 22.2% (placebo without current, 8 weeks follow-up). In our 40°C group this number was 51% (control, 40°C radiofrequency lesion, 3 months follow-up). Although temperature rise is known to have a selective anatomical effect on small myelinated and unmyelinated nerve fibers (Smith et al., 1981), long-term effects on nerve action potentials have not been studied in these settings. In other fields of medicine electrical current is known to have long-lasting effects on neuronal function, e.g., cardioversion where several rhythm disorders of the heart can be perma-

nently converted to a sinus rhythm. Further support for the assumption that current rather than temperature determines outcome of treatment are the results obtained in non-responders of the control group who were offered the possibility of an RF-DRG treatment with a temperature of 67°C. Only two out of fifteen patients (13.3%) opting for subsequent treatment with 67°C, reported a 2-point decrease on VAS scale after a 3-month follow-up.

This study suggests that 40°C lesion is an active treatment and should not be considered as a sham lesion. We found the same effectiveness with the 40°C lesion as the 67°C lesion. An important advantage of the 40°C lesion is that the incidence of nerve damage related side-effects, such as sensory deficits and loss of motor power, presumably will be lower, although this could not be demonstrated in this study. The findings of this study warrant a critical reappraisal of the mechanisms and the mode of action of radiofrequency lesions.

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