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ORIGINAL PAPER

Percutaneous cryodenervation of lumbar facet joints: a prospective clinical trial

C. Birkenmaier · A. Veihelmann · H. Trouillier · J. Hausdorf · C. Devens · B. Wegener · V. Jansson · C. von Schulze Pellengahr

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Abstract Facet joint pain is an important aspect of degenerative lumbar spine disease, and radiofrequency medial branch neurotomy remains an established therapy, while cryodenervation has still been poorly examined. This study was undertaken to examine the effects of medial branch cryodenervation in the treatment of lumbar facet joint pain. This was a prospective clinical case series. Patient selection was based on the history, physical examination and positive medial branch blocks. Percutaneous medial branch cryodenervation was performed using a Lloyd Neurostat 2000. Target parameters were low back pain (VAS), limitation of activity (McNab) and overall satisfaction. Fifty patients were recruited, and 46 completed the study. The follow-up time was 1 year. At 6 weeks, 33 patients (72%) were pain free or had major improvement of low back pain; 13 (28%) had no or little improvement. Including failures, mean low back pain decreased significantly from 7.7 preoperatively to 3.2 at 6 weeks, 3.3 at 3 months, 3.0 at 6 months and 4.2 at 12 months ($P<0.0001$). Limitation of the activities of daily living improved parallel to reduced pain. Our results suggest that medial branch cryodenervation is a safe and effective treatment for lumbar facet joint pain.

Résumé But de l'étude : les douleurs facétaires articulaires sont un élément important de la pathologie dégénérative de la colonne lombaire et la neurotomie par radio fréquence de la branche médiale est un traitement classique, alors que les résultats de la cryodénervation ne sont pas considérés comme évidents. Cette étude a pour but d'examiner les effets de la cryodénervation des rameaux médians dans le traitement des douleurs facétaires. L'étude a été menée de façon prospective. Les patients ont été sélectionnés selon leur histoire, l'examen physique et la positivité de la réalisation d'une infiltration des rameaux médians. La cryodénervation par voie percutanée a été réalisée par un appareil Lyod Neurostat 2000. Les paramètres étudiés ont été les lombalgies (VAS), la limitation d'activité (McNab) et la satisfaction. Cinquante patients ont été recrutés pour ce traitement, 46 sujets ont été spécialement étudiés et suivis pendant au moins un an. Résultats : à 6 semaines, 33 patients (72%) ne présentent aucune douleur et ont une grande amélioration de leur lombalgie, 13 (28%) n'ont pas ou simplement ont une petite amélioration. Malgré les échecs, les douleurs lombaires diminuent de façon significative avec une échelle de 7.7 préopératoire à 3.2 à 6 semaines, de 3.3 à 3 mois, de 3.0 à 6 mois et 4.2 à 12 mois ($P<0.0001$). En conclusion, nous pouvons affirmer, aux vues de nos résultats que la cryodénervation des rameaux médians est un procédé donnant de bons résultats réguliers dans le traitement des syndromes facétaires douloureux.

C. Birkenmaier (✉) · J. Hausdorf · B. Wegener · V. Jansson · C. von Schulze Pellengahr
Department of Orthopaedic Surgery,
Grosshadern Medical Center, University of Munich,
Marchioninistr 15,
81377 Munich, Germany
e-mail: doctor-b@web.de

A. Veihelmann
Medical Park Bad Wiessee St. Hubertus,
Sonnenfeldweg 29,
83707 Bad Wiessee, Germany

H. Trouillier
Franziskus Hospital,
Chirurgie II, Kiskerstr 26,
33615 Bielefeld, Germany

C. Devens
Praxisklinik Leopoldstr 25,
80802 Munich, Germany

Introduction

Chronic low back pain with its various origins is a medical, social and economic challenge. The significance of lumbar zygapophyseal joints as a source of low back pain has been discussed since Ghormely [9] in 1933 coined the expression "facet joint syndrome." In 1975, Shealy [17] reported on successful percutaneous radiofrequency denervations, but other investigators failed to achieve comparable results. Based on neuroanatomical studies, Bogduk interpreted these failures as a result of lacking anatomical understanding and published several papers on facet joint sensory innervation that are the basis of the denervation techniques used today [2–4]. Dreyfuss and Bogduk validated the technique of medial branch blocks in a CT-controlled study and were able to show technical success of medial branch blockade by multifidus muscle EMG in 90% of cases [5, 6]. Only recently, cryodenervation was introduced as an alternative method for facet joint denervation [1, 16]. The aim of our study was to investigate the effectiveness of medial branch cryodenervation using the medial branch technique in patients with lumbar facet joint pain.

Methods

Patient selection

We recruited all patients from our spine clinics to which they had been referred by general practitioners or orthopaedic surgeons. All patients had exhausted conservative treatments such as physical therapy, back braces, NSAIDs and analgesics. Inclusion criteria were non-sciatic low back pain that was unresponsive to conservative therapy for at least 3 months, absence of sitting intolerance suggestive of discogenic pain and positive diagnostic medial branch blocks. Exclusion criteria were sciatic pain, previous lumbar spine surgery except nucleotomies, relevant spinal canal stenosis, activated erosive spondylochondrosis, malignancies, chronic inflammatory disease, a history of depression and pending workman's compensation cases. The additional presence of referred pain responsive to diagnostic blocks was not considered an exclusion criterion. When meeting these criteria, patients were asked to participate in the study. Prospectively, we entered 50 patients (19 male and 31 female) from June 2002 through December 2003. The average age was 56 years (range: 28 to 74). Four patients had to be excluded: one was diagnosed with a malignant tumour, another underwent nucleotomy for a lumbar disc prolapse, and two had moved and could not be contacted. As a consequence, 46 of the original 50 patients were available for evaluation.

Study design and parameters

The study design was a prospective case series. Beyond the standard informed consents for the diagnostic blocks as well as for the denervation treatment itself, patient consent to use the medical data anonymously for study purposes was obtained. The main outcome parameter was low back pain as measured by the visual analogue scale (VAS 0–10). In addition, we evaluated the subjective limitation in activities of daily living caused by low back pain as measured on a four-step scale (simplified McNab: 3= severe; 2= medium; 1= light; 0= none); satisfaction with the therapy was also assessed by the question: "Given the same level of low back pain as prior to the procedure, would you choose to have it performed again?" Data were collected prior to denervation as well as at 6 weeks and 3, 6 and 12 months. Treatment success or failure was determined at 6 weeks: full success when pain was reduced to 50% or less of the pre-treatment levels, partial success when pain was reduced to between 51 and 69% of the pre-treatment levels and failure when pain was only reduced to 70% of the pre-treatment levels or above.

Diagnostic algorithm and blocks

Patients with suspected unilateral or bilateral lumbar facet joint pain were selected as described above, and informed consent for the diagnostic blocks was obtained. Under fluoroscopy, diagnostic blocks were performed on the medial branches supplying the painful facet joints using the method described by Dreyfuss and Bogduk [5]. For each block, 1.0 ml bupivacaine 0.5% (Carbostesin®, AstraZeneca GmbH, Wedel, Germany) was used. Blocks were considered positive when there was a definite improvement in the patients' specific low back pain of 50% or more for at least 3 h. We did not perform placebo-controlled blocks.

Denervation procedure

Patients had intravenous access and ECG monitoring throughout the procedure. They were positioned prone on the operating table. After adjusting the fluoroscopy unit, surgical skin preparation was performed, and the operative field was draped with sterile sheets. Local anaesthesia at the incision sites as well as in the expected trajectory of the cryoprobe was performed with 1% mepivacaine (Scandicain, AstraZeneca). We used a Lloyd Neurostat 2000 cryo unit and a 2-mm cryoprobe with an uninsulated trocar tip that can be used for neurostimulation (Spembly Medical Systems, Andover, UK). A small incision was made lateral to the joint (about at the tip of the transverse processes), and the cryoprobe was advanced under fluoroscopy control onto the transverse process and then into the angle between

the superior articular and the transverse process. After accurate positioning of the probe, sensory stimulation (concordant pain at <0.5 V) and motor stimulation (multifidus, but no leg muscle contractions) were performed to confirm the proximity to the nerve. The tip of the cryoprobe reaches a temperature of −50°C when using medical grade CO_2 at the suggested flow rates [14]. Cryodenervation was performed for 2 min at each location and after removal of the probe, incisions were closed with a steristrip, and a sterile adhesive dressing was applied. Patients were advised to refrain from strenuous activity for the rest of the day; beyond that, no specific aftercare was required.

Statistical methods

Data were obtained from all individuals and then grouped according to the time point. We assumed that the statistical variances of the pre- and post-treatment groups were comparable, since all groups represented the same individuals. Analysis for statistical significance was performed using the two-sided Student's *t*-test for paired samples for pain data and for data on the limitation of activity. A *P* value of less than 0.05 was accepted as significant.

Results

At 6 weeks, 33 patients had a significant reduction of low back pain (success and partial success); 13 patients were not or were only slightly improved (data displayed in Table 1). When analysing the combined data of all patients including failures (Fig. 1), we found a statistically significant improvement in mean low back pain of 50% or more ($P<0.0001$) at all time points when compared to pre-treatment pain levels. Since pre-denervation pain levels differed quite strongly between individuals, we calculated the individual improvements expressed as the percentage level of pain compared to pre-denervation levels (equalling 100%). These results did not differ from the mean low back pain results in magnitude or trend (data displayed in Table 1). All patients were categorised as having success, partial success or failure at 6 weeks. When only the patients that were categorised as having succes and partial success were considered, the improvement in mean low back pain would have reached 75% at 6 weeks and at 3 and 6 months (Fig. 2). At 3 months, one patient with partial success reported a return of pain to pre-treatment levels, and one "success" patient reported a pain increase to partial success. At 12 months, four "success" patients reported a pain increase back to failure levels and two to the partial success level. At the termination of the study, 21 patients qualified as having success, 5 as having partial success and 20 as having failure, with the mean low back pain again increasing slightly (Figs. 1, 4). In summary, success or partial success was achieved in 72% of patients at 6 weeks, 70% of patients at 3 months and 57% of patients at 12 months. With regards to the limitation in the activities of daily living, the results were inversely parallel to the improvement of back pain when a limitation had been present prior to therapy, and improvement was significant at all times (Fig. 3). There were some patients, however, who reported pain levels as high as 7 and 10 prior to cryotherapy and yet did not complain of being limited in their regular daily activities. At 12 months, the question "Given the same level of low back pain as prior to the procedure, would you chose to have it performed again?" was answered "yes" by 30 patients and "no" by 12 patients. Four patients remained undecided. Our only complication was a vagus-induced syncope, which was easily controlled by the administration of atropine. No haematoma or wound infections were observed.

Discussion

There are a significant number of treatment failures with low back pain patients, regardless of whether the treatment modality is physical therapy, lumbar fusion, disc replacement or a minimally invasive procedure. In our study, we found a success and partial success rate of 72% at 6 weeks. The pain reduction we observed was slightly superior to that in the treatment group of van Kleef's [19] placebo-controlled trial with a similar ratio of successes and failures. We did not, however, reach the same level of pain reduction achieved by Dreyfuss et al. [6] in a highly selected group of 15 patients. This is discussed in more detail below. Our results were quite well maintained throughout the follow-up period until 12 months, when some patients reported an increase in low back pain and the failure rate rose to 43%. Nevertheless, only 12 out of 46 patients (25%) would not have wanted the procedure performed again, which may be explained by the comparably little discomfort experienced during cryodenervation. Van Kleef did not publish VAS pain data beyond 8 weeks, but stated a failure rate of 8 out of 15 patients at 12 months, which is higher than we observed. There are two previous publications on lumbar facet joint cryodenervation, one of which is a paper by Schuster [16], who did not use the medial branch technique. Baerlocher et al. [1] reported a 62% success rate after 1 year using slightly different target points than those suggested by Bogduk. In addition, 14 out of the 50 patients (28%) in this study required a repeat procedure within 2.5 months. Including those repeatedly treated patients in their analysis, Baerlocher and colleagues achieved a reduction in low back pain similar to our results. If one were to count the 14 patients that received repeat denervation as failures, their failure rate would have been much

Table 1 Individual low back pain as VAS values and as percent of pre-denervation levels

	VAS: absolute values					Percent of pre-denervation				
Pt.	0	6 weeks	3 months	6 months	12 months	0	6 weeks	3 months	6 months	12 months
1	7	0	0	0	0	100	0	0	0	0
2	9	1	1	3	2.5	100	11	11	33	28
3	9	2	2	2	4.5	100	22	22	22	50
4	3	3	3	3	3	100	100	100	100	100
5	10	9	10	0	9.5	100	90	100	0	95
6	10	0	0	0	10	100	0	0	0	100
7	8	5	5	5	5	100	63	63	63	63
8	7	7	7	7	7	100	100	100	100	100
9	8	1	1	1	1	100	13	13	13	13
10	10	4	4	4	4	100	40	40	40	40
11	10	0	0	0	0	100	0	0	0	0
12	8	0	0	0	0	100	0	0	0	0
13	8	6	5	5	2	100	75	63	63	25
14	6	6	6	6	6	100	100	100	100	100
15	9	0	0	0	0	100	0	0	0	0
16	8	2	2	2.5	2.5	100	25	25	31	31
17	5	5	5	5	5	100	100	100	100	100
18	8.5	8.5	8.5	2	7.5	100	100	100	24	88
19	5	0	0	0	0	100	0	0	0	0
20	10	4	4	4	4	100	40	40	40	40
21	8.5	0	0	0	0	100	0	0	0	0
22	9	0	0	0	0	100	0	0	0	0
23	9	9	9	9	9	100	100	100	100	100
24	7	0	0	0	7	100	0	0	0	100
25	10	5	5	5	5	100	50	50	50	50
26	10	1	1	1	2	100	10	10	10	20
27	8	3	3	3	3	100	38	38	38	38
28	6	6	6	6	6	100	100	100	100	100
29	6	2	2	2	6	100	33	33	33	100
30	7.5	2.5	2.5	2.5	2.5	100	33	33	33	33
31	5.5	2	2	2	3	100	36	36	36	55
32	8	4	5	3	6.5	100	50	63	38	81
33	7.5	2	4	6.5	7.5	100	27	53	87	100
34	10	2.5	2.5	2.5	2.5	100	25	25	25	25
35	5.5	3	3	3	3	100	55	55	55	55
36	10	5	5	5	5	100	50	50	50	50
37	7	3	3	3	4	100	43	43	43	57
38	10	10	8	8	9	100	100	80	80	90
39	7	0	0	0	3	100	0	0	0	43
40	5	0	0	0	8	100	0	0	0	160
41	5	3	5	7	5	100	60	100	140	100
42	7.5	7.5	7.5	7.5	7.5	100	100	100	100	100
43	7.5	0	0	0	0	100	0	0	0	0
44	4	4.5	4.5	4.5	5	100	113	113	113	125
45	8	0	0	0	0	100	0	0	0	0
46	8	8	8	8	8	100	100	100	100	100
Mean	7.7	3.2	3.3	3.0	4.2	100	43	45	43	58
SD	1.8	2.9	2.9	2.7	3.0					

Pt.= patient number, 0= pre-denervation

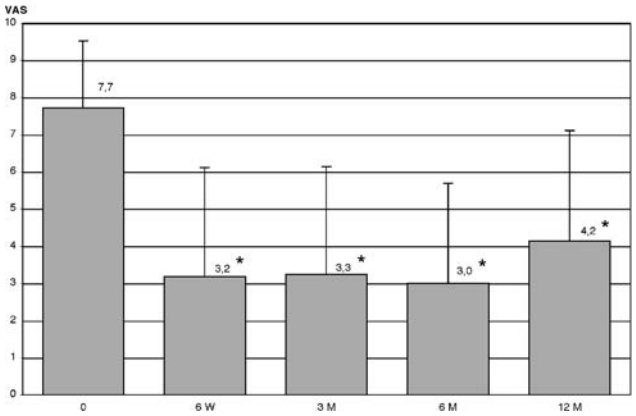

Fig. 1 Mean low back pain before and after cryodenervation as measured on visual analogue scale: data of all patients, including failures (0 = before therapy; 6 W =6 weeks after therapy; 3 M =3 months after therapy; 6 M =6 months after therapy; 12 M =12 months after therapy; error bars reflect standard deviation; *P<0.0001)

higher. There are several possible explanations as to why cryodenervation failed in some of our patients.

Other sources of low back pain

Most patients with lumbar facet joint pain suffer from degenerative disc disease with a loss of disc height and sometimes early instability, resulting in chronic overloading and progressive osteoarthritis of lumbar facet joints. There are other potential pain sources beyond the facet joints, such as discogenic pain, pain from (active) spondylochondrosis, instability pain and muscular pain. There have been many attempts to assign specific qualities of pain and specific tests to the various sources of low back pain; however, there are no reliable clinical tests to confirm lumbar facet joints as the predominant source of pain [10, 15]. In addition, pain may be referred to the legs [8]. Pain originating from the lowest lumbar facet joints can be mistaken for sacroiliac joint pain and vice versa. There are limitations to the diagnostic power of selective blocks and hence to the accuracy of the conclusions derived from the results.

False-positive diagnostic blocks

Intra-articular injections cannot be reliably performed in severely osteoarthritic joints, and their diagnostic value as opposed to medial branch blocks are subject to interpretation [7], with medial branch blocks remaining the gold standard for diagnosing facet joint pain [5, 10, 18]. Kaplan et al. found a false-negative rate of 11% [11]. There is discussion, however, about whether single blocks are reliable enough to diagnose lumbar facet pain. Most patients in our study group had been suffering from low back pain for a long time and therefore had great hopes for improvement of their complaints through facet joint denervation. Some of them may consequently have over-interpreted the pain relief experienced with the diagnostic blocks. The use of either placebo-controlled blocks or controlled blocks with a long- and a short-acting local anaesthetic is capable of increasing the diagnostic power in such situations [7, 13, 15]. Selecting a small group of 15 patients with controlled blocks, Dreyfuss et al. [6] achieved 60% pain relief in 87% of patients at 12 months after RF denervation. This shows that results can be outstanding when one is willing to sacrifice sensitivity for the sake of specificity. However, performing placebo-controlled blocks separately and in combination for possibly several neighboring facet joints is unrealistic in a routine clinical setting.

Inadequate technique

There are several technical differences between RF denervation and cryodenervation: The lesions created by both RF probes and cryoprobes do not extend far beyond the probe tips, but rather from the tip backwards [14]. Consequently, both types of probes should ideally be positioned somewhat parallel rather than perpendicular to the bone at the target point, a problem that is well recognised [12]. In the presence of hypertrophic facet joint osteophytes, care has to be taken to approach the target point on a latero-medial trajectory. Despite such precautions, it may be impossible to position the probe correctly in some cases. There are several relevant differences between the lesions created by RF probes and cryoprobes: RF probes are thin and flexible and require an introduction canula; the lesions they create are about 3 mm in diameter, which leaves little margin for errors in targeting. In contrast, the cryoprobes used for facet joint denervation have a slightly larger diameter (up to 2 mm) and are much easier to manipulate because of their rigidity. They create a lesion with a typical diameter of around 6 mm [14], which makes them more forgiving with regards to

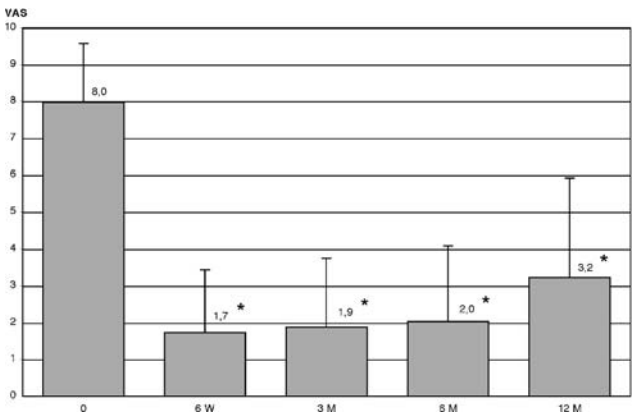

Fig. 2 Mean low back pain before and after cryodenervation as measured on visual analogue scale, excluding "failures" at 6 weeks (0= before therapy; 6 W =6 weeks after therapy; 3 M =3 months after therapy; 6 M =6 months after therapy; 12 M =12 months after therapy; error bars reflect standard deviation; *P<0.0001)

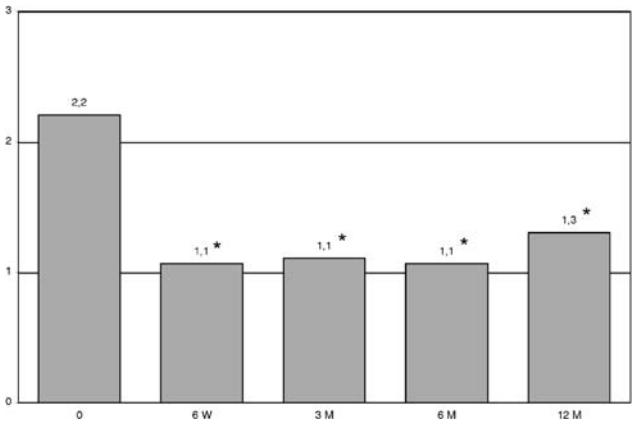

Fig. 3 Mean limitation of activities of daily living before and after cryodenervation: data of all patients, including failures at 6 weeks (simplified McNab score; y-axis: 3= severe, 2= moderate, 1= light, and 0= none; x-axis: 0= before therapy, 6 W =6 weeks after therapy, 3 M =3 months after therapy, 6 M =6 months after therapy, and 12 M =12 months after therapy; *P<0.0001)

targeting. The shape of RF lesions is dependent on the location of the neutral electrode and the electrical conductivity of the surrounding tissues, which is not the case with cryolesions [14]. When using a cryoprobe, the neutral electrode is exclusively required for neurostimulation, which allows for continued stimulation during denervation to confirm cessation of pain or multifidus activity. In conclusion, we were able to demonstrate that percutaneous medial branch cryodenervation is a safe and reasonably effective treatment for lumbar facet joint pain and that it is not inferior to RF denervation. Our results compare favourably to those of other studies using uncontrolled diagnostic blocks, cryodenervation as well as RF denervation, but did not reach the level of effectiveness achieved in patient populations selected by using controlled blocks. We would like to suggest that facet joint diagnostics (and, if test blocks are positive, medial branch denervation) should be tried prior to more invasive measures in low back pain patients.

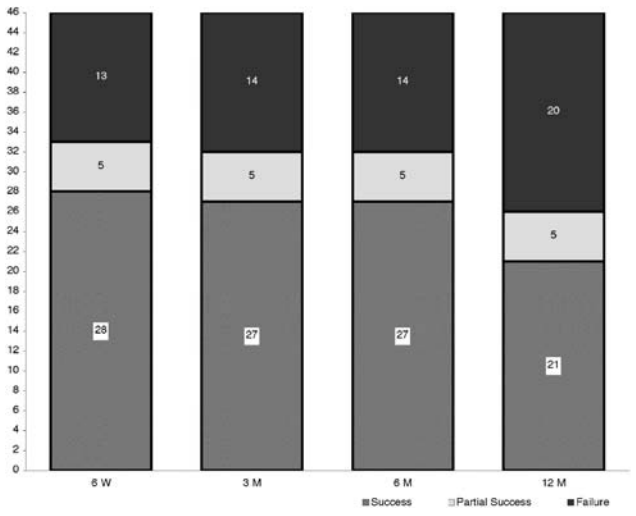

Fig. 4 Patient distribution in success, partial success and failure categories (6 W =6 weeks after therapy; 3 M =3 months after therapy; 6 M =6 months after therapy; 12 M =12 months after therapy)

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