A pilot cohort study of lumbar facet joint denervation in patients with chronic low-back pain

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ABSTRACT

INTRODUCTION: Radio-frequency (RF) denervation of the facet joints is a procedure aimed at the nociceptive median branch nerves of the lumbar dorsal rami. Pain signals from the facet joints are carried through these fibres; by ablating these fibres, central signalling can be prevented. This pilot study investigated the clinical effect and feasibility of the procedure at our institution, the Spine Centre of Southern Denmark.

METHODS: Patients with at least 50% pain relief after initial medial branch diagnostic blocks were candidates for RF denervation. Patients were divided into two groups: 1) patients with at least 80% pain relief and 2) patients with between 50% and 79% pain relief after diagnostic blocks. Denervation was performed bilaterally on the three lowest facet joints in the lumbar spine. The primary outcome parameter was visual analogue scale (VAS). Follow-up questionnaires were answered after one week and after three, six and 12 months.

RESULTS: For the whole sample, we found a mean reduction of 43 VAS points after one week. At three months, we found a mean reduction of 25 points. Six-month data showed a mean 19-point reduction. Twelve-month data showed a mean reduction of 17 points. Group 1 showed superior improvements at all follow-up points and after 12 months, we found a mean VAS reduction of 22 points for this group.

CONCLUSIONS: This pilot cohort study found RF denervation of the facet joint to be a promising alternative for patients with chronic low-back pain. The effect persisted at the one-year follow-up; however, the effect diminished over time.

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TRIAL REGISTRATION: The study protocol was approved by the ethical committee of Southern Denmark with registration number S-20160070.

Low-back pain can originate from multiple structures in the lumbar spine. The facet joints, intervertebral discs and sacroiliac joints are thought to be the most clinically relevant pain sources. It is estimated that up to 31% of chronic low-back pain originates from the facet joints [1]. However, pain is often multimodal; and no clinical test or imaging modality (X-ray, computed tomography or magnetic resonance imaging) can accurately determine if the pain originates from the facet joints [2-6]. Current best practice to test for facet joint pain is to perform a medial branch block with an anaesthetic agent. If pain is reduced by 50-80% following this, the facet joint is considered the underlying cause of a patient's back pain [7, 8].

In Denmark, many patients with chronic low-back pain try conservative treatments such as physiotherapy, chiropractic or analgesic medications. If these treatments fail and patients are not surgical candidates, there are typically no conventional treatment options left, and patients must learn to live with their pain. Radio-frequency (RF) denervation of the facet joints is a procedure aimed at the nociceptive median branch nerves of the lumbar dorsal rami. Pain signals from the facet joints are carried through these fibres, and central signalling can be prevented by denervating these fibres.

A recent systematic review [9] of lumbar facet joint RF denervation included nine moderate-to-high-quality randomised controlled trials (RCTs) of facet joint RF denervation. The authors concluded that there is Level I evidence for the short-term effectiveness of RF denervation up to six months, and Level II evidence for long-term pain relief exceeding six months. Despite these promising results, a more recent Cochrane review [10] concluded that moderate evidence suggests that facet joint RF denervation has a greater short-term effect on pain than placebo. Low-quality evidence indicated that facet joint RF denervation is more effective than placebo for function in the short and long term. Overall, the review concluded that current evidence for RF denervation for chronic low-back pain is of a very low-to-moderate quality. Since the publication of the Cochrane review, more studies have been published with conflicting results. Juch et al [11] found no effect of RF denervation when compared with a standard exercise programme, whereas Odonkor et al [12] and Moussa & Khedr [13] found a significant effect of RF denervation. Regardless of these conflicting results, high-quality evidence is lacking and RCTs with larger

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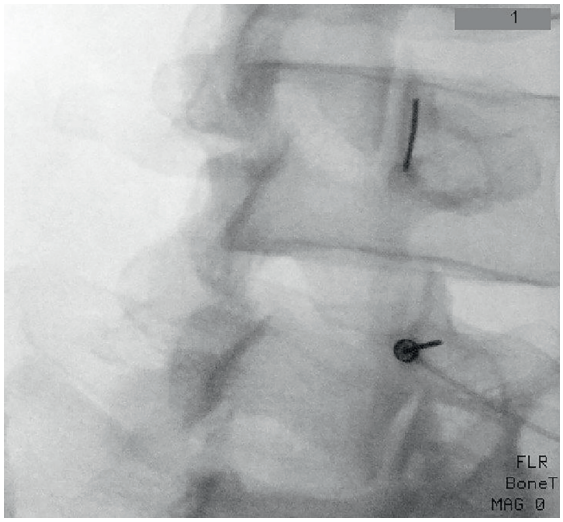
FIGURE 1

The "scotty dog" sign and canulla placements when performing denervation of the facet joint.



patient samples and long-term follow-up are needed. To facilitate the performance of an RCT, our institute needed experience with patient selection and the performance of RF denervation. With this study, we sought to investigate the clinical effect and feasibility of the procedure in a clinical setting at our institution, the Spine Centre of Southern Denmark.

METHODS

This study was designed as a pilot prospective observational cohort study with patient inclusion and treatment from September 2016 to December 2016. Patients were referred from primary care to surgical consultation at our department. Patients with no regular treatment option available and primary back pain were assessed for eligibility by the primary investigator. The inclusion criteria were age above 18 years, low-back pain for at least six months, failure of conservative treatments and no clear surgical indication as assessed by an experienced spine surgeon. The exclusion criteria were inability to speak and write Danish language, use of corticosteroids or presence of psychiatric disease.

After meeting the initial inclusion and exclusion criteria, prospective patients had two sessions of medial branch blocks. Medial branch block was performed as follows: Fluoroscopy with oblique lateral view was used to ensure correct placement of the cannula, which was at the lateral part of the facet joint at the notch between the superior articular process and the transverse process. After establishing correct needle placement, 1.5 ml of bupivacain 20 mg/ml was administered bilaterally at each of the three lower facet joints in the lumbar spine. Patients were asked to record their back pain before and after each block for up to seven days or as long as pain relief was observed. Diagnostic blocks were performed with at least a seven-day interval. If patients reported at least 50% pain relief after the medial branch blocks, they were candidates for RF denervation. Based on their response to the medial branch blocks, patients were divided into two groups: 1) patients with at least 80% pain relief after both initial blocks and 2) patients with between 50% and 79% pain relief after both initial blocks.

Fluoroscopy guidance was used for the RF denervation procedure using an oblique lateral view to clearly visualize the "scotty dog" sign (Figure 1). 1 ml of bupivacain 20 mg/ml was applied before denervation was initiated. Denervation was performed at 90 °C for 60 seconds at two locations of the facets. The locations were at the distal and the proximal lateral part of the facet joints capsule (**Figure 1**). For this study, we used the Stockert Inomed n50 generator with a 20G 150-mm isolated cannula with a 5-mm active tip. No stimulation was used as we did not aim directly for the medial branch.

All patients answered questionnaires covering standard baseline characteristics, health information, visual analogue scale (VAS), the European Quality of Life – 5 Dimensions (EQ5D) and the Oswestry Disability Index (ODI). All patients recorded their post-intervention back pain for seven days on VAS. Our primary outcome was VAS, and the secondary outcomes were ODI and EQ5D. Follow-up questionnaires were answered after three, six and 12 months.

The baseline characteristics were analysed as categorical data with Fisher's exact test in STATA and presented with percentages and p values comparing subgroups to each other.

The assumption of normality for PRO data was checked by Q-Q plots. Patient-reported outcome (PRO) data were analysed as normally distributed data with paired and unpaired t-test. PRO data are presented with means and 95% confidence intervals. For PRO data, we defined a minimal clinically important difference (MCID) of 20 mm for VAS, ten points for ODI and 0.17 points for EQ5D [14, 15].

Trial registration: The study protocol was approved by the ethical committee of Southern Denmark with registration number S-20160070.

RESULTS

Fifty-seven patients were included in the initial screening with medial branch blocks. In all, 22 patients had at least 50% pain reduction on each of the two diagnostic blockages. Eleven of these patients experienced at least 80% pain relief and were placed in Group 1, whereas

another 11 patients experienced 50-79% pain relieve and were placed in Group 2. Three patients from Group 2 were excluded post-intervention. Two patients had spine surgery due to new disc herniation, and another was lost to follow-up immediately post-intervention. After one year, we had 100% (19/19) follow-up. No statistical differences were observed between the two groups at baseline (**Table 1**).

When analysing the total sample, we found a statistically significant improvement in VAS back at all follow-up points. Group 1 showed improvements achieving MCID at all follow-ups, whereas Group 2 showed no statistically significant improvements in VAS except after one week (**Table 2**).

For the total sample, we found a significant improvement in ODI at the three-month follow-up of 5.8 points; and at six months, we found a 0.10-point EQ5D improvement in Group 1. No other improvements were seen in ODI or EQ5D during follow-up (Table 2).

Preoperatively, 17 patients (89.5%) had regular use of pain medicine. At the one-year follow-up, 11.8% had completely discontinued their use of pain medicine. The use of synthetic opioids diminished by 36% and the use of paracetamol diminished by 18% for the entire sample.

Of the total sample, 58% reported a persisting effect after 12 months. Subjective outcomes are presented in **Table 3**.

DISCUSSION

The aim of this pilot study was to investigate the effect and feasibility of RF denervation for low-back pain. The RF treatment is not a conventional procedure for low-back pain in Denmark, so we needed to obtain the relevant knowledge and experience with RF denervation before considering its im plementation.

For pragmatic reasons and to omit the time expenditure, we only treated 22 patients, which is a strong limitation to this study and our conclusions. We found a relatively large spread of data within each group with wide confidence intervals. This may be explained by our small sample size. Despite the small sample, we did find a statistically significant reduction in VAS back at all follow-up time points.

The pain reduction was 17 points on a VAS scale at the one-year follow up for the entire sample. This is not clinically relevant and does not correlate with other larger studies, which report up to 41 points of pain reduction on a VAS scale after one year [16]. However, when analysing Group 1, we found differences of statistical and clinical relevance with a mean VAS improvement of 22.5 points. This is consistent with the study by Nath et al [17]. During the research done for the preparation of this manuscript, we identified various areas of possible improvements regarding the technique that we used for RF denervation. Some studies report a possible improvement of the effect from longer denervation times for up to 180 seconds [18, 19]. In the present study, each denervation lasted 60 seconds. The findings by Cosman et al [18] and Provenzano et al [19] may imply that a longer RF denervation time is needed to ensure that the nerves are denervated. The number of denervation points also varies between studies. The most current literature indicates the use of 2-6 points on each facet during the procedure. In our

TABLE 1

Baseline characteristics compared between groups.

	Group 1	Group 2	p-value[a]
n	11	8	-
Male, %	54.5	75.0	0.633
Smoking, %	54.5	25.0	0.352
Back pain > 2 yrs, %	100	88	0.421
Previous spine surgery, %	9.1	25	0.546
BMI, mean, kg/m^2	25.4	29.5	0.099
VAS, points, mean	71.2	65.4	0.502
ODI, points, mean	31.4	39.8	0.156
EQ5D, points, mean	0.65	0.63	0.815

BMI = body mass index; EQ5D = European Quality of Life - 5 Dimensions; ODI = Oswestry Disability Index; VAS = visual analogue scale.
a) Unpaired t-test comparing continuous outcomes and Fisher's exact test comparing categorical outcomes.

TABLE 2

Differences in patient-reported outcome data compared with baseline, unpaired t-test comparing continuous outcomes to the baseline value. The values are mean points (95% confidence interval).

	Group 1	Group 2	Combined
1 wk			
VAS	55.7 (44.3-67.1)*	26.6 (7.2-46.0)*	43.5 (31.8-55.2)*
3 mo.s			
VAS	37.0 (23.8-50.2)*	9.4 (-13.6-32.4)	25.4 (12.6-38.2)*
ODI	6.82 (-1.2-14.9)	4.5 (-3.1-12.1)	5.8 (0.71-10.9)*
EQ5D	0.10 (-0.02-0.22)	-0.03 (-0.22-0.16)	-0.05 (-0.05-0.14)
6 mo.s			
VAS	28.3 (10.3-46.4)*	7.6 (-20.6-35.9)	*19.6 (4.7-34.5)
ODI	5.9 (-5.9-17.7)	3.4 (-5.5-12.2)	4.8 (-2.3-11.9)
EQ5D	0.10 (0.01-0.19)*	-0.07 (-0.22-0.07)	0.03 (-0.05-0.12)
12 mo.s			
VAS	22.5 (2.5-42.6)*	11.1 (-19.9-42.1)	17.7 (2.0-33.5)*
ODI	3.9 (-5.5-13.4)	4.3 (-5.5-14.0)	4.0 (-2.1-10.2)
EQ5D	-0.05 (-0.22-0.12)	0.07 (-0.27-0.13)	0.06 (-0.17-0.06)

EQ5D = European Quality of Life - 5 Dimensions; ODI = Oswestry Disability Index; VAS = visual analogue scale.
*) p < 0.05.

TABLE 3

Subjective changes after one year. The values are %.

	Group 1	Group 2
Lasting effect	72.7	37.5
No back pain anymore	0.0	12.5
Much better	45.5	12.5
Better	27.3	12.5
Unchanged	0.0	37.5
Worsening	27.3	25.0
Initial improvement, but pain has returned	100	100
Would consider radio frequency denervation again	90.9	75.0

study, we only denervated two points on each facet. We targeted the capsule laterally at its proximal and distal aspects, which is supported by a recent study suggesting that ablating the capsule instead of the medial branch directly has a more lasting effect [13]. We did not target the medial branch directly. However, if both the capsule and main medial branch had been denervated, this could potentially result in outcome improvements. We did not use sensorial stimulation in our treatment, which is thought to increase the risk of hitting the nerve. Taking these factors into consideration might have improved our results. Despite these technical flaws, 58% of the total sample experienced a significant pain reduction at the one-year follow-up.

We found a significant improvement of ODI at the three-month follow-up for the total sample. Furthermore, an EQ5D improvement was observed in Group 1 after six months, but no other significant differences in ODI or EQ5D were observed in the study sample. We hypothesise that if patients had less back pain, their functionality and quality of life would also improve. However, our sample had a relatively good score in both ODI and EQ5D compared with patients with spinal stenosis or disc herniation who are surgical candidates, and therefore have less room to improve. Other studies [13, 16, 20] report statistically significant ODI improvements of 10-34 at one-year follow-up. For us to obtain such results, we must include more patients, develop our technique and implement the above-mentioned technical features.

High-quality evidence for the treatment effectiveness of denervation is still lacking. However, several of the studies that found no evidence of treatment effectiveness have been criticised for poor patient selection and technical flaws.

One must be very careful in the selection of patients and in performing correct diagnostic blocks. In this study, we divided the candidates into two groups depending on their response to the two initial diagnostic blockages. We found that patients who experienced at least 80% pain relief during the diagnostic block had a consistently significant and clinically meaningful improvement of low-back pain at all follow-up time points, whereas the patients with only 50-79% pain relief showed no statistical improvements except after one week. The response to the initial blockages might help us to define stronger inclusion criteria for future treatments and studies at our department.

A recent study from 2018 [12] reported inciting events to be connected to facet joint pain, and these may also be a predictor of a good outcome. In our study, it was not possible to investigate this, but it should be taken into consideration when planning future studies.

Our study found the use of analgesics to diminish during the follow-up period. Our small sample makes it difficult to draw valid conclusions, but previous studies also showed results supporting this finding [17, 20].

In the entire sample, 84% reported that they would undergo treatment again if possible; and 58% still experienced some treatment effect at the one-year follow-up. This means that some patients experienced an initial effect that subsequently disappeared during follow-up period. Table 3 shows that a total of five patients reported worsening of their back pain at the one-year follow up. However, when analysing these five patients, it becomes clear that four of these patients experienced pain relief during follow-up, but that their pain had returned. The same four patients replied that they would like a new treatment if possible. The fact that some patients experience good results in the initial phase of the study but had increasingly more pain during follow-up may be due to the neural regeneration of the facets and the natural course of a degenerative low-back disease. Despite the diminishing effects, 84% from the entire sample wanted new treatment, if possible, which implies that the discomfort associated with the RF denervation is outweighed by the improvement in their symptoms. One must keep in mind that this is an outpatient procedure requiring neither hospitalisation nor sedation. Generally, each procedure took around 40 minutes to complete and patients tolerated the procedure well without complications. This taken into consideration makes RF denervation attractive to the group of patients that have no other treatment options left for their chronic back pain.

CONCLUSIONS

This pilot study found RF denervation of the facet joints to be a safe and promising supplementary treatment that is feasible for larger clinical studies in the future.

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