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Randomized sham-controlled, double-blind, multicenter clinical trial on the effect of percutaneous radiofrequency at the ramus communicans for lumbar disc pain

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Trial registration
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Abstract

Background: Investigate the effect of percutaneous radiofrequency compared to a sham procedure, applied to the ramus communicans for treatment of lumbar disc pain.
Methods: Randomized sham-controlled, double-blind, crossover, multicenter clinical trial. Multidisciplinary pain centres of two general hospitals. Sixty patients aged 18 or more with medical history and physical examination suggestive for lumbar disc pain and a reduction of two or more on a numerical rating scale (0–10) after a diagnostic ramus communicans test block. Treatment group: percutaneous radiofrequency treatment applied to the ramus communicans; sham: same procedure except radiofrequency treatment. Primary outcome measure: pain reduction. Secondary outcome measure: Global Perceived Effect.
Results: No statistically significant difference in pain level over time between the groups, as well as in the group was found; however, the factor period yielded a statistically significant result. In the crossover group, 11 out of 16 patients experienced a reduction in NRS of 2 or more at 1 month (no significant deviation from chance). No statistically significant difference in satisfaction over time between the groups was found. The independent factors group and period also showed no statistically significant effects. The same applies to recovery: no statistically significant effects were found.
Conclusions: The null hypothesis of no difference in pain reduction and in Global Perceived Effect between the treatment and sham group cannot be rejected. *Post hoc* analysis revealed that none of the investigated parameters contributed to the prediction of a significant pain reduction.
Significance: Interrupting signalling through the ramus communicans may interfere with the transition of painful information from the discs to the central nervous system. Methodological differences exist in studies evaluating the efficacy of radiofrequency treatment for lumbar disc pain. A randomized, sham-controlled, double-blind, multicenter clinical trial on the effect of radiofrequency at the ramus communicans for lumbar disc pain was conducted. The null hypothesis of no difference in pain reduction and in Global Perceived Effect between the treatment and sham group cannot be rejected.

1. Introduction

In patients with chronic low back pain, the discs represent a potential pain generator (Schwarzer et al., 1995; Pang et al., 1998; Manchikanti et al., 2001). Disc pain can occur as a result of genetic implications, together with degenerative marks and start at an early age (Boos et al., 2002; Hurri and Karppinen, 2004; Rajasekaran et al., 2004; Helm et al., 2009; Zhang et al., 2009). Low back disc pain uses the sympathetic nervous system; pain impulses coming from the intervertebral disc join the L2 spinal ganglion via the rami communicantes and the sympathetic trunk (Groen et al., 1990; Raoul et al., 2003). In patients with chronic lumbar disc pain, symptoms can show no improvement over time (Peng et al., 2009). One of the treatment possibilities is applying high frequency energy at specific sites in or around the lumbar discs. Applying radiofrequency (RF) is a possible, but not generally accepted option for chronic low back pain. When a continuous radiofrequency (CRF) current is used, the tissue heating can lead to localized destruction of neural tissue and consequent interruption of neural signalling (Erdine et al., 2009).

Interrupting signalling through the ramus communicans may interfere with the transition of painful information from the discs to the central nervous system (Zhou and Abdi, 2006). To evaluate the efficacy of a RF treatment at the ramus communicans, a few studies were performed (Oh and Shim, 2004; Levin, 2009). Methodological differences exist in these studies concerning the inclusion criteria, outcome parameters and follow-up. In a systematic review addressing RF treatment for low back pain subtypes, three sham-controlled RCT's involving lumbar disc pain (Leggett et al., 2014) were included; differences between the studies were observed regarding RF technique, duration of low back pain before entering the study, the exclusion criteria and the number of participants. The results of these studies are inconsistent and do not help to settle the continuing debate about the role of this specific treatment in chronic lumbar disc pain.

Therefore, we set up a randomized, sham-controlled, double-blind, multicenter clinical trial (Current Controlled Trials ISRCTN48011364). The aim of the study was to investigate the effect of a percutaneous RF treatment compared to a sham procedure, applied at the ramus communicans; we investigated the effect on pain intensity and on Global Perceived Effect (GPE) of this interventional treatment compared to a sham procedure. A crossover was provided for the sham-operated group after a minimum of 3 months if no significant pain relief was reported.

2. Methods

2.1 Study design

We conducted a randomized, sham-controlled, double-blind, multicenter clinical trial in patients with lumbar disc pain for more than 3 months. The medical ethics committee from Erasmus University Medical Center approved the protocol. Written informed consent was obtained from all participants.

2.2 Participants

Suitable patients for the study were recruited from a population of patients with complaints of ongoing low back pain for more than 3 months and referred to the multidisciplinary pain centres of Lievensberg Hospital (Bergen op Zoom, The Netherlands) or Franciscus Hospital (Roosendaal, The Netherlands). Conservative care (rest, analgesics and physiotherapy) had failed to improve their burden. These patients were managed according to the flow chart presented in Fig. 1. When a disc problem was suspected (Table 1) and patients met the inclusion and exclusion criteria (New Zealand Low Back Pain Guide, 1997; Table 2), and if the test injection at the ramus communicans with local anaesthetics was positive [decrease in Numerical Rating Scale (NRS) of 2 or more on a 0–10 point scale (Ostelo et al., 2008)], the patient was eligible for the RCT. Each patient received a general brochure containing information concerning scientific research involving human subjects (Ministry of Health, Welfare and Sports) and a brochure (including the questionnaires) explaining the complete procedure. After giving written informed consent patients were enrolled in the study.

2.3 Study interventions

2.3.1 Test injection at the ramus communicans

The injection was performed under fluoroscopy with 15 cm Sluijter-Mehta Kit (SMK) needles (Cotop® via Neurotherm®, Wilmington, MA, USA). The patient lies prone on the operating table with a pillow under the abdomen to flatten the lumbar lordosis. From the anteroposterior (AP) view, the c-arm is rotated obliquely to the ipsilateral side so that facet joints

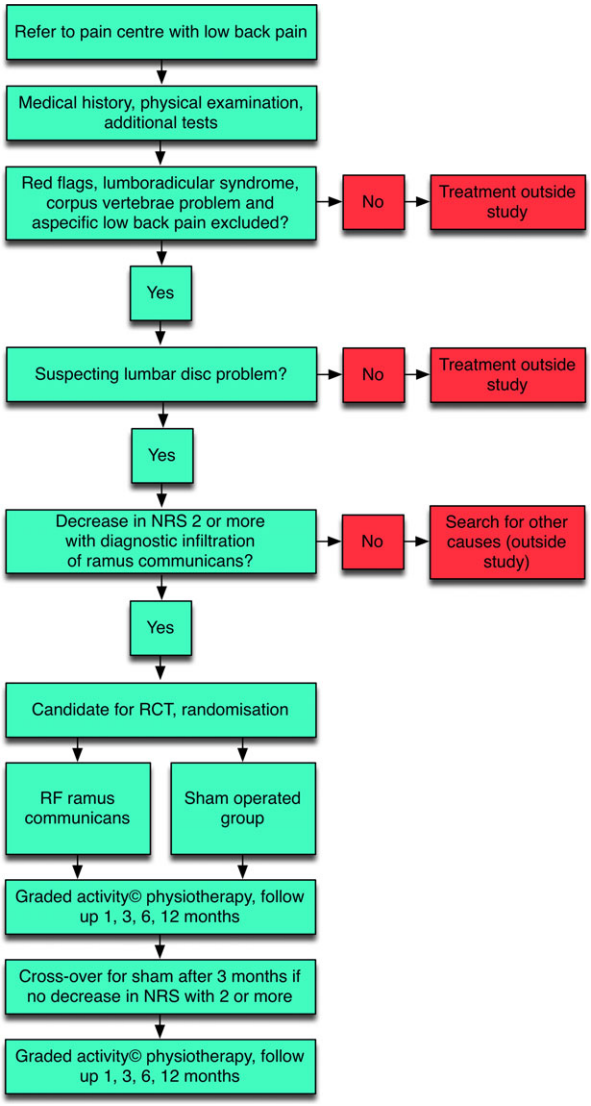

Figure 1 Study flow chart.

Table 1 Details about medical history, physical examination and additional tests in patients with disc pain.

Diagnostic criteria for disc pain
Medical history
1. Centralization of pain
2. Pain when rising from sitting
3. Low back pain, worse after prolonged sitting, flexion, coughing, sneezing
4. Referred pain to the groin, buttock and thigh
5. Chronic muscle imbalance patterns
6. Repeated episodes of low back pain (onset may be sudden or may result from overuse or unidentified causes)
7. Fear or be unable to flex during the episodes
Physical examination
1. Gait deviation
2. Abnormal sensory and motor examination, hyperactive or diminished reflexes
3. Digital interspinous pressure (DIP) test positive
4. Straight leg raising (Lasègue) positive between 30 and 70 degrees of passive flexion
Additional tests (if available and/or necessary)
1. CT (degeneration)
2. MRI (degeneration)
3. Diagnostic block at ramus communicans

Table 2 Inclusion and exclusion criteria for patients with disc pain eligible for RCT.

Inclusion
1. Age 18 years or older
2. Medical history and physical examination suggestive of lumbar disc pain
3. Decrease in NRS of 2 or more/10 on diagnostic ramus communicans block
Exclusion
1. Presence of red flags (Levin, 2009)
2. Lumboradicular syndrome
3. Aspecific low back pain
4. Corpus vertebrae problem
5. Progressive neurological defecits
6. Major psychiatric disorder (according to psychiatrists opinion)
7. Anticoagulation cannot be stopped
8. Active infection
9. Pain in other parts of the body that is more severe
10. Allergies to any medication used in the study
11. Pregnancy
12. Communication (language) difficulties (according to physicians opinion)

are projected away and the vertebral column is clearly visible. From the sagittal plane, the c-arm is rotated to let the transverse process change its location relative to the vertebral body and, as a result, the axis of the transverse process lies slightly above the middle of the vertebral body. The injection point is marked just caudally to the transverse process and somewhat medially to the lateral border of the vertebral body. Local anaesthesia with 1 mL lidocaine 2% was given for skin infiltration. The needle is advanced until contact is made with the vertebral body. On the lateral view, the tip of the needle should be somewhat ventral to the posterior side of the lateral body. After sensory (50 Hz) and motor (2 Hz) stimulation as an adjunct to confirm correct needle placement, the ramus communicans was surrounded with a total of 0.5 mL lidocaine 2%.

2.3.2 RF treatment at the ramus communicans versus sham

When patients were candidates for the trial they were randomized in two study groups:

(1) Treatment group: treatment was performed under fluoroscopy with 15 cm Sluijter-Mehta Kit (SMK) needles (Cotop® via Neurotherm®). The patient lies prone on the operating table with a pillow under the abdomen to flatten the lumbar lordosis. From the anteroposterior (AP) view, the c-arm is rotated obliquely to the ipsilateral side so that facet joints are projected away and the vertebral column is clearly visible. From the sagittal plane, the c-arm is rotated to let the transverse process change its location relative to the vertebral body and, as a result, the axis of the transverse process lies slightly above the middle of the vertebral body. The injection point is marked just caudally to the transverse process and somewhat medially to the lateral border of the vertebral body. Local anaesthesia with 1 mL lidocaine 2% was given for skin infiltration. The needle is advanced until contact is made with the vertebral body. On the lateral view, the tip of the needle should be somewhat ventral to the posterior side of the lateral body. After sensory (50 Hz) and motor (2 Hz) stimulation, the ramus communicans was surrounded with a total of 0.5 mL lidocaine 2% and a RF treatment (80 °C during 60 s per level) with a radiofrequency lesion generator (NT2000, Neurotherm®, Wilmington, MA, USA) was carried out;
(2) Sham-operated group: same procedure as in the treatment group except for the RF treatment.

A crossover was provided for the sham-operated group after 3 months if no significant pain relief was obtained.

Both groups received graded activity (Lindstrom et al., 1992; Staal et al., 2004) physiotherapy, which constitutes of an individual, submaximal, gradually increased exercise programme, with an operant-conditioning behavioural approach, based on the results of the tests and the demands of the patient's work.

2.4 Outcome parameters

The primary study parameter was pain reduction [NRS (Breivik et al., 2000; Grotle et al., 2004; Van der Roer et al., 2006; Farrar et al., 2001; Childs et al., 2005)]. The 0–10 verbal numeric rating scale (NRS-11) is a tool that enjoys widespread clinical use due to its ease of administration. When using the NRS-11, patients are asked to rate their pain on a scale from 0 to 10, where 0 represents 'no pain' and 10 represents 'the worst pain possible,' using whole numbers (11 integers including zero). Often the value of '4' is used to confirm clinical nursing judgment as to the need for further intervention or documentation that the patient's goals for analgesia have been achieved.

The secondary study parameter was the Global Perceived Effect (Fischer et al., 1999; Dworkin et al., 2005; Kamper et al., 2010). The type of rating of perceived effect is a 'transition scale'. This numerical scale asks the patient to rate how much their condition has improved or deteriorated since some predefined time point. The GPE has several qualities that make it an appealing tool for use in clinical practice and research; being a single question, it is easy and quick to administer and the results are simple to interpret. This scale is recommended for use as a core outcome measure for chronic pain trials and advocated to increase the relevance of information from clinical trials to clinical practice.

2.5 Follow-up

The results of the crossover group were analysed separately. Time periods for follow-up are presented in Table 3.

2.6 Statistical considerations

The Kolmogorov–Smirnov test was used to analyse whether or not parameters were normally distributed. Difference in patients' gender between the experimental groups was analysed using Fisher's Exact Test. Difference in age and in BMI was analysed using the Independent-Samples *T*-test. The data on NRS-11, GPE (subscales 'Satisfaction' and 'Recovery') were analysed by means of a MANOVA for repeated measurements using independent variables Group (treatment or sham) and Time (in case of the NRS-11 Period T0–T1, in case of the GPE subscales Period T1 and T2 as independent variables).

For the skewed distributed variables we nevertheless decided to use MANOVA for repeated measurements analysis of variance. We did so, because,

Table 3 Time periods for follow-up.

Period	Description
T0	Day of first consultation: medical history, physical examination, additional tests if necessary. Excluding red flags (Dworkin et al., 2005), aspecific low back pain and corpus vertebrae problems. Obtaining NRS.
T1	1 month after treatment: NRS and GPE.
T2	3 months after treatment: NRS, GPE.
T1c	1 month after treatment for crossover group: NRS and GPE.
T2c	3 months after treatment for crossover group: NRS, GPE.

NRS, Numerical Rating Scale; GPE, Global Perceived Effect.

although the MANOVA test requires that each dependent variable entered into the analysis be normally distributed it can still be used in case of skewly distributed dependent variable(s). The Monte Carlo experiments (Keppel, 1973) have shown that for sample size 3 or 5 it is still possible to analyse leptokurtic, rectangular, J-shaped, moderately and markedly skewed distributions. These experiments demonstrated that the empirically determined rejection region of the *F*-distribution would be no larger than $\alpha = 0.08$ when the usual 5% rejection is used.

The percentage of patients requesting crossover and subsequently reporting a significant pain relief was analysed using the One-Sample Binomial Test (reference probability 0.5). Only patients in the sham group could switch to the intervention.

The required a priori sample size was computed using the NRS-11 as the primary outcome parameter. A statistically detectable and clinically relevant with/between interaction effect size (f(V)) of 0.2 on the scale was chosen. The power of the study ($1-\beta$) was chosen to be 0.8, an allocation ratio of 1:1 and the two-sided level of significance (α) 0.05. The required a priori total sample size computed by this method is 60.

Data were analysed using SPSS for Mac, version 22 (International Business Machines (IBM) Corporation, Software Group, Somers, NY, USA). The primary comparison was done at T1.

2.7 Blinding

Based upon the required sample size calculation, 60 envelopes (30 'treatment group' and 30 'sham group') were prepared, sealed, mixed and placed together in a box. Patients chose an envelope randomly. Patients as well as their pain physicians were completely unaware of the content of the envelope during any stage of the investigation. The pain research nurse was the only one aware of the contents and performed the treatment accordingly. Regarding the radiofrequency generator, all sound indicators were turned off and the generator itself was visually hidden from the patient by means of a linen cloth, hung between two metal infusion poles. The pain physician left the operating theatre when the actual treatment (RF current or sham) took place. The same time period was taken for an actual, or a sham, treatment.

3. Results

Patients were included and treated between March 2012 and December 2014. Out of 116 eligible patients, a total of 56 patients resigned due to various reasons: no significant pain reduction after diagnostic block (33), not enough time (2), communication problems (4), chronic pain turned bearable (2), painful needle insertion procedure despite local anaesthetics (3), technique not possible (1), comorbidity (4), pregnancy (1) and without reporting a cause (6).

The flow chart of the progress through the phases of the RCT is presented in Fig. 2. The demographic data of the treatment and sham groups are presented in Table 4. There were no statistically significant differences in the parameters between both groups.

No statistically significant difference in pain level over time between the groups (Group × Period; $F_{(1,58)} = 0.04$; $p = 0.84$), nor in the factor Group ($F_{(1,58)} = 0.01$; $p = 0.92$) was found; however, the factor Period yielded a statistically significant result ($F_{(1,58)} = 40.68$; $p < 0.001$; Table 5). In the crossover group, 11 out of 16 patients experienced a reduction

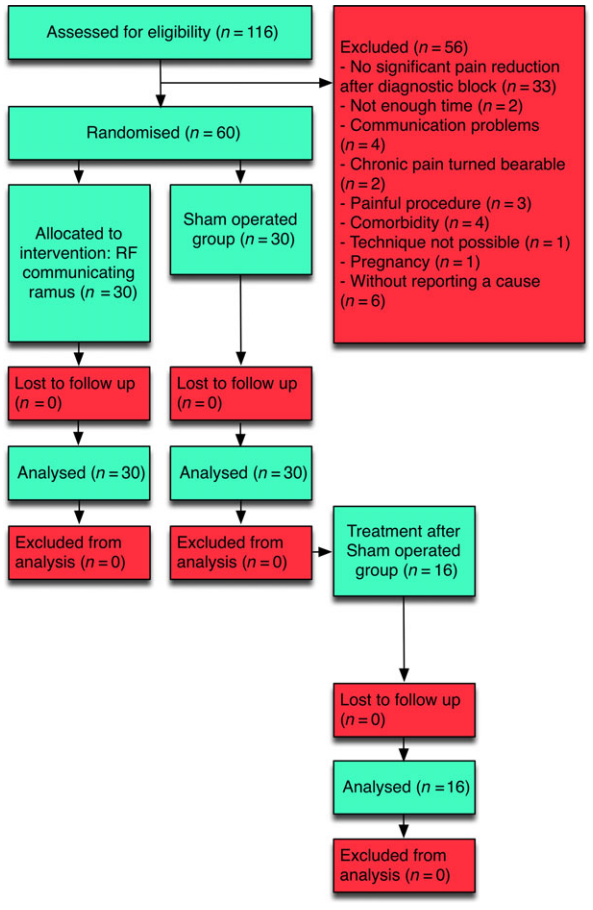

Figure 2 Flow diagram of the progress through the phases of the RCT.

Table 4 Demographic data of the verum – and sham groups.

Parameter	Treatment	Sham	*p*
Age (years), mean, (SD)	50.5 (13.9)	50.1 (12.3)	0.91
BMI (kg/m^2), mean, (SD)	27.8 (4.3)	27.8 (4.0)	0.67
Male gender (*n*, %)	10 (33.3)	11 (36.7)	1
Caucasian race (*n*, %)	30 (100)	30 (100)	1

SD, standard deviation; *p*, level of significance; BMI, Body Mass Index.

in NRS of 2 or more at 1 month crossover ($p = 0.21$).

No statistically significant difference in satisfaction over time between the groups (Group × Period) was found ($F_{(1,46)} = 0.95$; $p = 0.34$). The independent factors Group ($F_{(1,46)} = 0.80$; $p = 0.38$) and Period ($F_{(1,46)} = 0.002$; $p = 0.97$) also showed no statistically significant difference. The same applies to recovery: no statistically significant Group × Period effect ($F_{(1,46)} = 0.33$; $p = 0.57$) was found, neither an effect of Group ($F_{(1,46)} = 0.02$; $p = 0.89$) nor of Period ($F_{(1,46)} = 2.43$; $p = 0.13$; Table 5).

The duration of low back pain before entering the study (T0) in the treatment and sham groups of this RCT is presented in Table 6; the same applies to the description of the relative frequency distribution of severity of low back pain (Table 7) and patients' age (Table 8).

During the trial we noted no serious adverse events.

4. Discussion and conclusions

In this randomized, sham-controlled, double-blind, multicenter RCT we have investigated the effect of a percutaneous RF treatment compared to a sham procedure, applied to the ramus communicans for treatment of lumbar disc pain. This study does not support this type of treatment; we cannot reject the null hypothesis of no difference in pain reduction or in Global Perceived Effect between the treatment and sham group. In the crossover group, 11 out of

Table 6 Duration of low back pain before entering the study by group (T0).

Duration (years)	Treatment group *n* (%)	Sham group *n* (%)
>0.25/<0.5	4	3
0.5–1	3	1
1–5	11	11
>5	12	15
Unknown	0	0
Total	30 (100)	30 (100)

Table 7 Frequency (relative) distribution of severity of low back pain before entering the study (T0).

NRS	Treatment frequency (%)	Sham frequency (%)
≤4	0 (0)	0 (0)
5	1 (3.33)	1 (3.33)
6	3 (10)	2 (6.67)
7	3 (10)	8 (26.67)
8	18 (60)	12 (40)
9	5 (16.67)	5 (16.67)
10	0 (0)	2 (6.67)

NRS, Numerical Rating Scale.

Table 8 Patients' age before entering the study by group.

Age (years)	Treatment group *n* (%)	Sham group *n* (%)
18–29	2 (6.67)	3 (10)
30–39	5 (16.67)	3 (10)
40–49	5 (16.67)	9 (30)
50–59	13 (43.33)	6 (20)
60–69	2 (6.67)	9 (30)
70–79	3 (10)	0 (0)
Total	30 (100)	30 (100)

Table 5 Numerical rating scale (NRS) and Global Perceived Effect (GPE) scales of the treatment – and sham groups.

Outcome parameter	Treatment group mean (SD)	Sham group mean (SD)	Results MANOVAs	
NRS T0	7.8 (1.05)	7.8 (1.05)	Group	$F_{(1,58)} = 0.01$; $p = 0.92$
NRS T1	5.8 (2.28)	5.7 (2.28)	Period	$F_{(1,58)} = 40.68$; $p < 0.001$
			Group × Period	$F_{(1,58)} = 0.04$; $p = 0.84$
GPE satisfaction T1	3.5 (1.92)	3.7 (1.84)	Group	$F_{(1,46)} = 0.80$; $p = 0.38$
GPE satisfaction T2	3.3 (2.09)	3.8 (2.02)	Period	$F_{(1,46)} = 0.002$; $p = 0.97$
			Group × Period	$F_{(1,46)} = 0.95$; $p = 0.34$
GPE recovery T1	3.7 (1.48)	3.6 (1.43)	Group	$F_{(1,46)} = 0.02$; $p = 0.89$
GPE recovery T2	3.4 (1.77)	3.5 (1.70)	Period	$F_{(1,46)} = 2.43$; $p = 0.13$
			Group × Period	$F_{(1,46)} = 0.33$; $p = 0.57$

SD, standard deviation; T0, Day of first consultation; T1, 1 month after treatment; T2, 3 months after treatment.

16 patients experienced a clinically significant pain reduction at T1. This proportion is not statistically significant from chance ($p = 0.21$); this finding supports the results from the primary analysis, where we also did not find a statistically significant result from the treatment intervention compared to the sham intervention.

Considerations with respect to our findings: firstly, this RCT has possible methodological limitations: (1) having considered daily practice in pain management, we used one diagnostic test block; (2) pain scores were measured during follow-up at specific moments in time. Using average pain scores over certain time periods (e.g. past month), based on pain diaries might have led to a different result; (3) the injection of local anaesthetics is a different procedure compared to a RF treatment. So, when the RF treatment does not lead to a significant pain reduction, does that mean that the diagnostic test block was an invalid predictor of the effect of a RF treatment (i.e. a false positive)? If so, one might wonder how many false-negative results of the diagnostic block there (also) may have been. We are comparing different procedures with each other, with a diagnostic instrument being hard to validate; and (4) all patients received graded activity (Fischer et al., 1999; Dworkin et al., 2005) physiotherapy, but not at a single centre; as a consequence gaining evidence of equal quality of physiotherapy accompaniment was difficult and we therefore do not know if – and if so to which extent – this factor has confounded the treatment outcome.

It is difficult to compare our results to those of previous studies on this subject (Leggett et al., 2014) because of the many differences regarding (1) the RF technique used (intra-discal, cooled RF trans-discal biacuplasty, intra-annular discTRODE probe); (2) the duration of low back pain before entering the study (more than 6 months to more than 1 year); and (3) the exclusion criteria and the number of participants. For example, in one study the sham procedure was not the same as the actual RF treatment (Kapural et al., 2013). Besides using a different anatomical structure by Kapural et al., a positive response to diagnostic discography was used instead of a decrease in NRS of 2 or more from a diagnostic test block at the ramus communicans as an inclusion parameter, like we did in our study. Furthermore, (5) the criterion for a clinically relevant reduction in pain (after the diagnostic block and after the intervention) differed between the studies already performed: a decrease in NRS of 2 or more (Lindstrom et al., 1992), 50% pain relief or 80% pain relief were all used.

In our RCT, 48 out of 60 patients experienced a reduction in NRS of 50% or more after the diagnostic test block. *Post hoc* the predictive validity (in terms of sensitivity) of the amount of pain reduction after the diagnostic block in predicting the effectiveness of the intervention (in terms of the amount of pain reduction) after the intervention at T1 (sham or verum) was analysed. No statistically significant correlation between these parameters was found, neither in the sham group ($r = 0.02$; $p = 0.93$), nor in the verum group ($r = -0.27$; $p = 0.14$). So, in terms of predictive sensitivity, the size of the pain reduction after the diagnostic test block appears not to be related to the size of the pain reduction after the intervention (Fig. 3).

In addition, (6) the pain reduction over time of the patients pooled together, might have been due to spontaneous recovery. However, based upon the median duration of the complaints of the participating patients spontaneous recovery is not likely.

Keeping the above mentioned difference in mind, two other RCT's on this topic found no statistically significant effect either, and one RCT (Kapural et al., 2013) found a statistically significant improvement in physical function, pain and disability. In their systematic review on non-operative management for discogenic back pain Lu et al. (2014) mention the study from Oh and Shim (2004) as the only one targeting the ramus communicans. The RF treatment used in this study was the same as in our study; however, patients were eligible for this RCT only when their pain continued after intradiscal electrothermal annuloplasty (IDET). The diagnostic test block used had to generate a 50% pain reduction and not a decrease in NRS with 2 or more, as was our criterion for a clinical relevant pain reduction. Furthermore, the questionnaires used were different, as well as the number of participants.

In our RCT 34 out of 60 patients reported a significant decrease in pain of 2 or more on verbal NRS for pain. Analysis so far revealed that those patients cannot be predicted by the interventional procedure. In order to evaluate the possible contribution of other parameters than the interventional procedure to the prediction of a significant pain reduction at T1, *post hoc* a binary logistic regression analysis was performed (Backward Wald method). The parameters to be entered into this analysis were age, gender, BMI and the level of pain at baseline. To prevent over fitting of the model, we performed univariate binary logistic regression analysis of these parameters. This analysis revealed that none of the investigated parameters contributed to the prediction of a significant pain reduction.

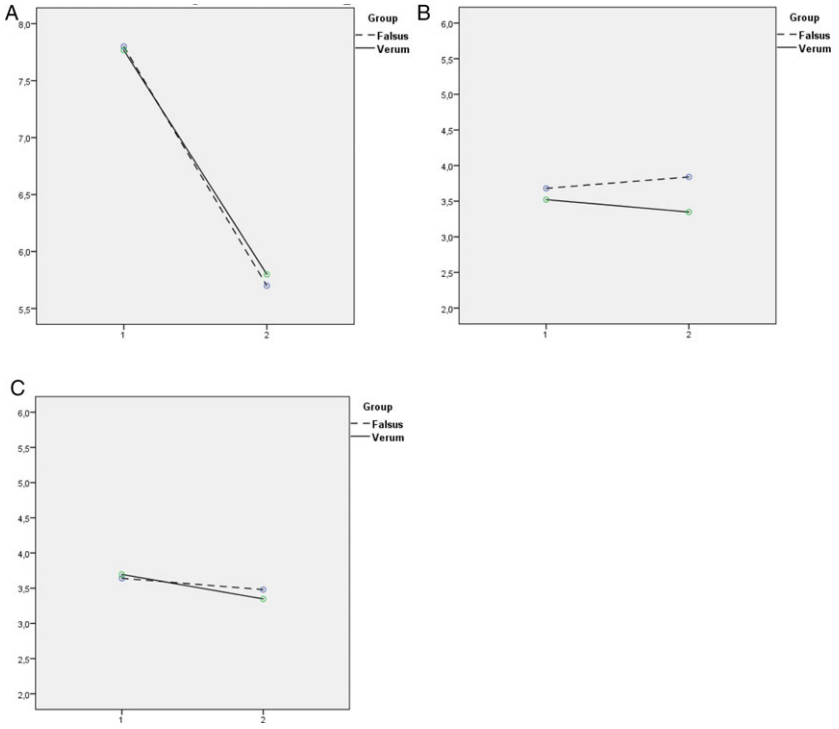

Figure 3 Comparison of the pain reduction (%) after the diagnostic block and the pain reduction at T1 after the RF or sham intervention (%).

A comprehensive understanding of spinal innervation is needed for the clinical evaluation of lumbar spinal pain. Any component that receives innervation can theoretically act as a source of pain (Bogduk, 1985). The sinuvertebral nerves that innervate the lumbar discs are formed by a somatic root from a ventral ramus and an autonomic root from a grey ramus communicans; an ascending branch passes as far as the next higher intervertebral disc, while a descending branch supplies the disc at the level of entry. Two types of rami communicantes are observed, a superior oblique ramus and a deep transverse ramus (Higuchi and Sato, 2002); sinuvertebral nerves originate from the deep transverse rami. These deep transverse rami run close to the vertebral bodies and along the lumbar arteries and veins; they run along the lateral side of each lumbar vertebral body and connect to the corresponding lumbar spinal nerve and sympathetic trunk in a segmental manner. All superficial oblique rami run upon the surface of the aponeurosis, while the deep transverse rami run beneath the aponeurosis. In this way, using fluoroscopic guidance, together with sensory and motor stimulation, we have tried to interrupt the pain impulses with high frequency energy at the site of origin.

Neural branches supplying the spinal column can arise from (1) the sympathetic trunk directly; (2) the superficial oblique rami, deep transverse rami, sinuvertebral nerves and splanchnic nerves; and (3) directly from each lumbar vertebral primary ramus. Two types of innervation co-exist, a segmental (directly from the spinal nerve) and a non-segmental type (via the sympathetic nervous system). Discogenic low back pain occurs via visceral sympathetic afferents mainly through the L2 spinal nerve root (Nakamura et al., 1996). Unilateral infiltration of this L2 nerve root was not predictive of provocative discography results; bilateral infiltration was not investigated (Mendez et al., 2005). In patients with L3 and L4 vertebral body fractures, L2 spinal nerve block was effective for 2 weeks (Ohtori et al., 2009). The results from a prospective analysis on the assessment of pulsed radiofrequency treatment at the L2 dorsal root ganglion for providing pain relief in patients with chronic low back pain with or without lower limb pain showed that the procedure is safe and effective for treating chronic low back pain (Tsou et al., 2010). Targeting the L2 nerve root can possibly be used as a diagnostic tool and treatment opportunity (Nakamura et al., 1996; Lim et al., 2013), requiring further scientific research.

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Author contributions

C.W.J.T. is the Lead author and provided greatest contribution to the project. The author took the whole responsibility for the article by rendering creative ideas, participating in design and implementation of the research data, and providing substantial intellectual contribution to the same. Both data analysis and data interpretation were carried out by the author C.W.J.T. who also had the responsibility of writing the articles. J.G.G. is the Co-promotor and coordinator of the research group who rendered creative ideas, and participated in design and implementation of the research data along with substantial intellectual contribution to the research data. The author also critically commented on parts of the intellectual concepts in the article. D.L.S. rendered creative ideas, participated in design and implementation of the research data and was responsible for statistical analysis and interpretation of data and also critically commented on the parts of the intellectual concepts in the article. F.J.P.M.H. is the promotor and the leader of the research group who rendered creative ideas, and took part in design and implementation of the research data. The author also provided substantial intellectual contribution to the research data and critically commented on the parts of the intellectual concepts in the article. All the authors discussed the results and commented on the manuscript.

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Supporting Information

Additional Supporting Information may be found online in the supporting information tab for this article:

Table S1. CONSORT 2010 statement.