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Cooled radiofrequency for the treatment of sacroiliac joint pain – impact on pain and psychometrics: a retrospective cohort study

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Abstract

Objectives: Cooled radiofrequency (cRF) is an effective treatment for sacroiliac pain. In contrast to conventional radiofrequency denervation, this technique allows enlarging the area of denervation by cooling the radiofrequency probe. However, there is sparse knowledge about the impact of interventional procedures like cRF treatment of sacroiliac joint pain on psychological comorbidities. The aim of this retrospective study was to evaluate the outcome of cRF in chronic pain patients regarding the psychological outcomes anxiety, depression, sleep quality and pain related disability.

Methods: In this retrospective observational study 29 interventions were performed over a period of two years in 28 patients. Pre- and post-interventional pain levels, depression and anxiety scores, pain-related disability, treatment satisfaction and sleep quality were assessed by standardized and validated questionnaires. Pain medication was recorded prior to the intervention and at follow-up.

Results: Hospital Anxiety and Depression Scale (HADS-D) scores for depression showed a statistically significant reduction after therapy which did not remain significant after Bonferroni-Holm correction. Anxiety as measured by the HADS-A score did not show a statistically significant change. No statistically significant improvement was observed in the pain disability index. Patients reported fewer sleep disorders after treatment. Mean pain (NRS) was

statistically significantly reduced 1 week post intervention and at time of follow-up. There was no clear reduction of analgesic medication.

Conclusions: Besides pain reduction, our data show a positive influence on sleep quality, possibly on depression, but not on anxiety and pain disability.

Keywords: anxiety; cooled radiofrequency; depression; pain disability; psychological factors; sacroiliac joint pain.

Introduction

Chronic low back pain is a ubiquitous disease leading to disability and high costs for the health system. The sacroiliac joint is considered the pain source in 15–30% of all patients with chronic low back pain [1]. Pain deriving from the sacroiliac joint can have intra- or extraarticular, traumatic, functional, inflammatory as well as idiopathic causes [2].

Clinically, the sacroiliac joint pain is characterized by lumbar and gluteal pain with non-radicular radiation [1]. Most of the patients suffer from pain radiating into the thighs, 28% of the patients experience pain below the knee and up to 12% of the patients also have pain irradiating to the feet.

The innervation of the posterior and anterior sacroiliac joint is still a matter of discussion. With the help of cadaveric studies Roberts et al. demonstrated an innervation by the posterior sacral branches: the sacroiliac joint was innervated in all cases by S1-S2, in 88% by S3, in 8% by L5 and in 4% by S4 [3].

The therapeutic options mainly depend on the patient's particular situation and multiple factors influencing the patient's chronic pain. Conservative treatment consists of physiotherapy, manual therapy and analgesic medication.

In case of failure of conservative treatment, interventional therapy should be employed by means of sacroiliac joint blocks with local anesthetics and/or steroids. The efficacy of intra-articular steroid infiltrations for the treatment of sacroiliac joint pain has been confirmed by studies with high level of evidence (1 B+) [4]. Operative sacroiliac joint fusion as an option for refractory sacroiliac joint pain

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has also been discussed whereby the outcomes were similar to those of injection therapy [5].

The development of the cooled radiofrequency (cRF) technique has led to significant amelioration of the outcomes of radiofrequency treatment of the sacroiliac joint, not only for pain but also for pain related disability [6–8]. Technically, cooling the radiofrequency probe considerably enlarges the area of denervation, thus increasing the probability of hitting the targeted nerve branch. While the lesion diameter is about 4 mm in conventional radiofrequency, lesion diameters of 10 mm have been described in cooled radiofrequency. Internal cooling of the electrode allows the application of a higher current, which leads to an effective ionic heating at a greater distance from the probe without charring the tissue at the probe tip [9].

Low back pain frequently constitutes a component of a complex multidimensional chronic pain syndrome [10]. Chronic low back pain patients often suffer from depression, anxiety, sleep disorder and impaired function. These psychosocial factors have been studied in the context of lumbar facet joint injections but not of sacroiliac joint interventions [11].

Studies show that psychosocial factors can be correlated with poorer clinical outcomes [12–15]. Nevertheless patients with mild psychosocial impairment might also experience clinical improvement with interventional pain treatment [11, 16].

The aim of this retrospective study was to evaluate the outcome of cRF in patients with chronic sacroiliac joint pain, regarding psychological outcomes of this treatment, specifically anxiety, depression, pain-related invalidity and sleep quality.

Materials and methods

This study was approved by the Ethics Committee of the University of Freiburg (EK-Freiburg 231/13). Patients gave their written informed consent to participation in the retrospective study. All patients with chronic sacroiliac pain who had been treated with cooled radiofrequency within a period of 2 years were eligible. Questionnaires were sent by post to these patients. The questionnaires included pain scores (NRS) during the week prior to the procedure, during the week after the procedure and during the last two weeks before follow-up (on average 15.4 months after the procedure). Patients were asked to report the drugs they were taking (frequently used and well-known preparations of non-steroidal anti-inflammatory drugs [NSAIDs], low-potency opioids, high-potency opioids, muscle relaxants, anticonvulsants, antidepressants, and others). Several answers were possible under the trade names of the drugs given for selection.

Moreover, unwanted side effects of the procedure, changes in sleep quality and satisfaction with the procedure were rated by the

patients. The “Pain Disability Index (PDI)” and the German version of the Hospital Anxiety and Depression Scale (HADS-D) were used to study changes in these psychosocial items in relation to the cRF treatment of the sacroiliac pain [17–23]. HADS-D scores were divided into three groups: levels of ≤ 7 were considered normal, levels of 8–10 were considered suspicious and levels of >10 were considered indicative for the presence of an anxiety or depressive disorder.

We also used the minimal clinically important difference (MCID) as a parameter to interpret the relevance of treatment effects. Thirty percent MCID in self-reported pain is considered to be “a barometer for positive clinical change” [24].

As a matter of routine, patients completed the German pain questionnaire at their first contact with the interdisciplinary pain center [25]. The concept of the German pain questionnaire is based on a bio-psycho-social pain model. It consists of demographic data, pain variables with affective and sensory qualities of pain, previous pain treatment procedures, pain-related disability, depression test, comorbid conditions, social factors and health related quality of life [20]. PDI score, HADS scores and pain medication prior to therapy were extracted from these questionnaires for the study. Twenty eight consecutive patients had been treated with cRF, after written informed consent to the procedure. One patient had been treated twice. He received a second cRF after an interval of 14 months. Twenty patients filled in the questionnaire (Figure 1). Patients included in the study did not undergo psychotherapy, cognitive behavioral therapy or interdisciplinary pain treatment at our institution, nor did they report receiving one of these treatments elsewhere. Criteria for performing the cooled radiofrequency were low back pain with and without radiation into the leg, positive findings in the diagnostic tests (Fortin-Finger-Test, Patrick-Faber-Test, Gaenslen-Test), absence of nerve root compression on lumbar CT or MRI and at least 50% pain reduction in two intra-articular sacroiliac joint infiltrations at distinct time points with bupivacaine 0.75%. All blocks were performed under fluoroscopic guidance with the patients positioned in a prone position. Diagnostic infiltration of the sacroiliac joint was performed as described by Simopoulos et al. [26]. The pain reduction was expected to last for at least 6–8 h.

The cooled radiofrequency procedure was performed as described by Stelzer et al. [27]. Briefly, patients were placed in prone position. The intervention was performed without sedation of the patient. After skin disinfection and sterile draping, the target points were identified under fluoroscopic guidance. A stainless steel ruler (Epsilon ruler, Baylis Medical, Inc. Montreal, Canada) was placed near the insertion site. Local anesthetic (mepivacaine 1%) was applied at the entry points with an overall maximum of 10 ml. An introducer was first positioned at the dorsal ramus of the L5 root, where the first lesion was made. Three lesions were made lateral to the S1, S2 and two lesions at the S3 foramina. As the diameter of the cooled radiofrequency lesion is deemed to be about 10 mm care was taken not to place the single lesions at greater distances from each other [9]. Radiofrequency was applied for 2 min and 30 s at a temperature of 60 °C using the Pain Management SINERGY System (Kimberly Clark Corporation, Roswell, GA, USA). All interventions were performed by the same experienced interventional pain physician (TW).

The statistical analysis was performed using GraphPad Prism (Version 5.01, GraphPad Software, Inc., La Jolla, CA, USA). First descriptive statistics were applied to all items. The D’Agostini-Pearson Test was used as a normality test. The Paired *t*-test was used to compare mean pain scores (NRS), Pain Disability Index (PDI) and anxiety and depression scores pre and post cRF. A *p*-value <0.05 was

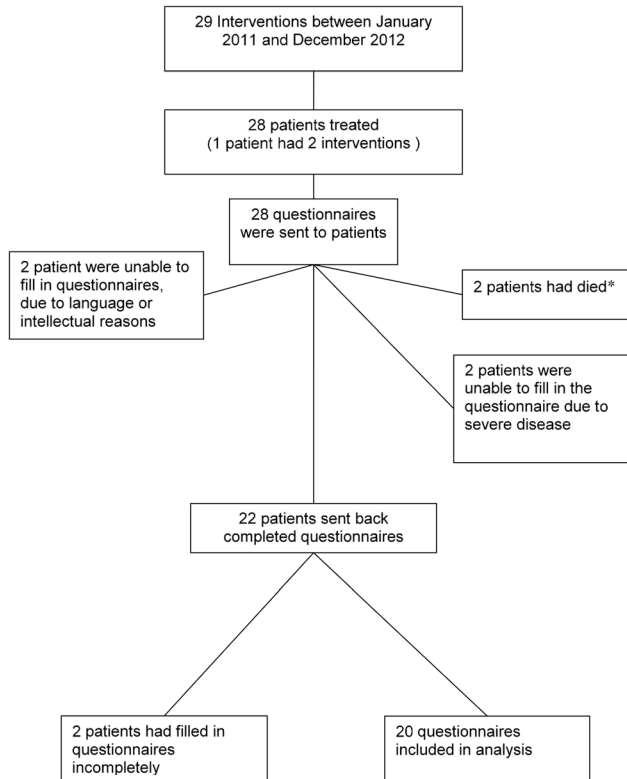


Figure 1: Patient selection and number of questionnaires analyzed. *Independent from the intervention.

considered to indicate a significant difference. As various items were studied, a sample size estimation in this study is difficult to perform. Nonetheless, we conducted a sample size estimation for depression and anxiety scores as measured by the HADS-test as the main parameter under study. With $\alpha = 0.05$ and a power of 0.8, a standard deviation of 1.5 points on the NRS for depression and anxiety levels and a detectable alternative of 1.0 points, the sample size for the Paired *t*-test was estimated to be 18. An effect size of $d = 0.6$ can be demonstrated with the sample size.

Results

Questionnaires were sent to all 28 patients on average 15.4 months after the procedure. The return rate was 78.6% (22/28 patients). As two questionnaires were incomplete, questionnaires from 20 patients (6 men, 14 women) were included in the analysis (Figure 1).

Mean age at the time of follow-up was 65.8 years. Mean follow-up was 15.4 months (Table 1). The interval between the initial assessment in the interdisciplinary pain center and the procedure was 2.6 years (31.4 months).

After treatment of sacroiliac pain with cooled radiofrequency mean depression scores improved statistically significant, but after Bonferroni–Holm correction the

Table 1: Patient characteristics and comorbidities.

Age	65.82 ± 8.90
Gender	6 m / 14 f
Duration of prior conservative pain treatment at the pain clinic	31.4 ± 30.7
Follow up/months	15.4 ± 6.8
Additional pain diagnoses:	n (%)
Lumbar spine operation including spondylodeses	5 (25%)
Fibromyalgia	3 (15%)
Restless legs syndrome	1 (5%)
Polyneuropathy	2 (10%)
Additional psychological diagnoses:	1 (5%)
Depression	7 (35%)
Anxiety	2 (10%)

change was no longer significant. There was no statistically significant change in anxiety scores. The mean scores of the HADS scale for depression dropped from 9.83 ± 5.00 to 7.75 ± 4.70 while anxiety scores dropped from 9.56 ± 4.54 to 7.70 ± 4.23 (Table 2b, Figure 3).

Also, the overall anxiety and depression score (HADS-total) attained higher values, but without statistical significance.

Pain scores (mean, minimum and maximum pain) showed significant improvements one week after the procedure and at time of follow-up compared to prior to the intervention (Figure 2).

Pre- and post-interventional pain disability questionnaires revealed no statistically significant improvement of pain-related disability in any of the tested items. Eleven of the 20 patients had a minimal clinically important difference (MCID), i.e., 30% improvement in the NRS rating [24]. The comparison of the overall PDI data showed only slightly higher values after treatment, the change was not statistically significant (Table 2b).

The patients tolerated the procedure very well, suffering only transient unwanted side-effects, such as post-procedural pain (n=6), skin irritation at the entry point of the probe (n=4) or hematoma (n=3).

One week after the procedure and at the time of follow-up, there was a statistically significant reduction of the mean, minimum and maximum pain scores. The maximum and the minimum pain level decreased accordingly (Table 2a, Figure 2).

When asked about the specific pain localization and pain quality, 20% of the patients reported being pain-free in the sacroiliac region after cooled radiofrequency. Fourty five percent of the patients reported decreased pain intensity at the same pain localization. Eleven patients

Table 2a: Overview of pre-and post-interventional HADS depression/anxiety scores (HADS-D = depression, HADS-A = anxiety) and PDI scores, \pm = SD, () = 95% confidence interval.

Item	Data derived from the pre-interventional questionnaire	Data derived from the post-interventional questionnaire ^a	p-Value*	p-Value**
HADS-D	9.83 \pm 5.00 (10.50, 6.75)	7.75 \pm 4.70 (8.00, 6.25)	0.0459	0.1836
HADS-A	9.56 \pm 4.54 (9.50, 5.75)	7.70 \pm 4.23 (5.00, 5.75)	0.2435	0.4870
HADS-total	19.39 \pm 9.140 (25.25, 11.50)	15.45 \pm 8.243 (15.50, 13.25)	0.0979	0.2937
PDI	38.85 \pm 8.47 (39.00, 17.62)	36.08 \pm 16.21 (36.00, 19.50)	0.5041	0.5041

^aat follow up.

*Paired t-test, ($p < 0.05$).

**After Bonferroni–Holm correction.

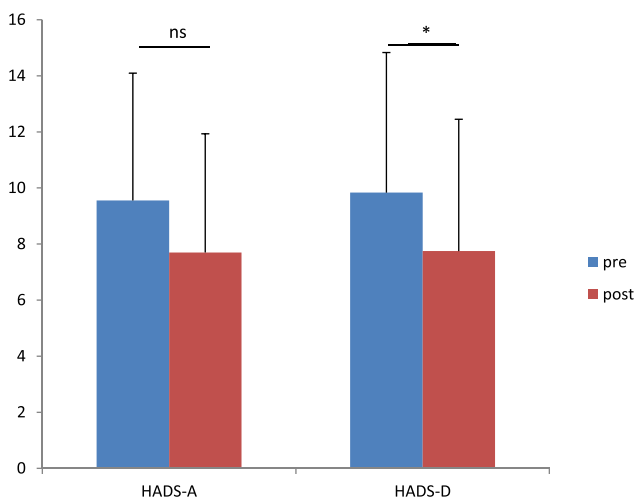


Figure 2: Pre- and post-interventional depression and anxiety scores (ns: not significant, $*p < 0.05$).

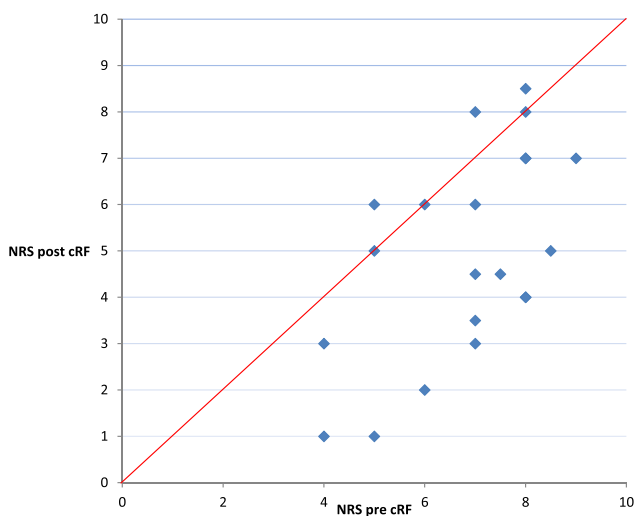


Figure 3: Scatter diagram of mean pain scores pre cRF and at time of follow-up.

reported no change in the pain quality, two patients reported different pain characteristics and six patients reported having the same pain as well as different pain of equal severity.

The pain medication included non-opioids like NSAIDs, opioids, anticonvulsants and antidepressants. On average, there was no clear reduction of typical analgesic medication such as NSAIDs or opioids and the number of different analgesic compounds used was not reduced. In contrast, 50% of those patients who had taken anticonvulsants or antidepressants could discontinue these medications after the procedure. All patients who discontinued antidepressants had been taken them for depression (Figure 4). Those patients who had received anticonvulsants mostly had additional mixed pain after lumbar spine surgery, one patient had painful restless legs syndrome (RLS) and one patient had polyneuropathy.

Half of the patients reported a significant or slight improvement in sleep quality after the procedure. For eight patients sleep quality was unchanged and two patients reported a slight deterioration. Ten patients reported an improvement in mobility. Mobility was unchanged in nine patients and slightly deteriorated in one patient (Table 3).

Twelve of the 20 patients were very or quite satisfied, three patients were undecided, three patients were slightly dissatisfied and two patients were very dissatisfied. Fourteen patients would undergo the treatment again.

Discussion

In recent years, cRF has become an established therapy for sacroiliac joint pain [28]. But up to now there are only few studies examining the question, whether successful interventional treatment of sacroiliac joint pain by cRF has a positive impact not only on pain, but also on psychological comorbidities, pain disability scores and sleep quality [8].

Table 2b: Overview of pre- and post-interventional pain, \pm = SD, () = median, IQR.

	Data derived from the pre-interventional questionnaire			Data derived from the post-interventional questionnaire		
	Pain level prior to treatment	Pain level one week after procedure	Pain level at time of follow-up	p*	p**	p**
Pain level						
Mean	7.34 \pm 1.80 (7.0, 3.50)	4.00 \pm 1.64 (4.0, 2.0)	4.95 \pm 2.28 (4.750, 3.875)	<0.0001	<0.001	0.0003
Maximal	8.39 \pm 1.14 (8.5, 1.0)	4.66 \pm 2.07 (4.0, 3.0)	5.48 \pm 2.55 (5.0, 3.0)	<0.0001	<0.001	<0.0001
Minimal	6.31 \pm 2.39 (6.0, 2.0)	3.42 \pm 1.84 (3.0, 3.0)	4.28 \pm 2.34 (4.0, 3.50)	<0.0001	<0.001	<0.0011

*at follow up.

**Paired t-test, (p < 0.05).

**After Bonferroni–Holm correction.

This study showed significant improvements in pain rating. Initially depression scores showed a significant change, but this change was not significant after Bonferroni–Holm correction. Sleep quality improved in half of the patients, worsened in 10% and remained unchanged in 40% of the patients. There was no statistically significant change in anxiety and pain disability scores after cRF.

As sacroiliac joint pain is a chronic condition, psychological factors are likely to influence treatment outcome. About 27% of the patients with chronic pain suffer from depression [29], and the prevalence of anxiety disorders is twice as high in patients with chronic pain as in the normal population [30]. In addition, anxiety can provoke and exaggerate pain [31]. Furthermore, patients with chronic pain and psychological disorders often suffer from sleep disorders [29–31].

The data of our study suggest that successful local treatment of sacroiliac pain with cRF is effective not only in terms of pain reduction but may also be effective in terms of amelioration of depression, as well as sleep disturbance. These findings cannot be compared to the majority of previous studies because psychometric variables have scarcely been determined and validated instruments have rarely been used. The present study utilized validated tests such as the PDI and the HADS Scale for the assessment of depression, anxiety and pain disability [17, 32]. The pooled outcomes in a meta-analysis of Sun et al. showed a significant relief of pain and pain disability by measuring NRS (numerical rating scale), VAS (visual analog scale), GPE (global perceived effect) and ODI (Oswestry Disability Index) [8].

The clinical efficacy of cRF was first shown by Cohen et al. in 2008 [9]. Similar results have been found by several other groups (Table 4) [7, 27, 33, 34]. The overall results of these studies are comparable and two of these studies are randomized controlled trials. All studies showed a high

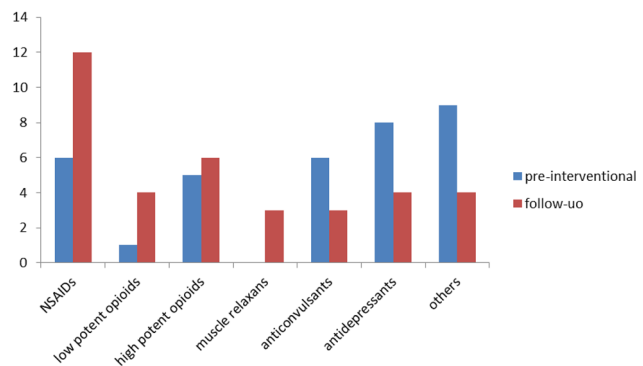


Figure 4: Number of patients with different medications: pre-interventional and at time of follow-up.

Table 3: Changes in sleep and mobility in number and percentages of patients.

	Significantly improved	Slightly improved	Unchanged	Slightly deteriorated	Significantly deteriorated
Sleep quality	9 (45%)	1 (5%)	8 (40%)	2 (10%)	0
Mobility	7 (35%)	(15%)	9 (45%)	1 (5%)	0

proportion of patients with a pain reduction of $\geq 50\%$ with a tendency towards a gradual increase in mean pain levels in the course after cRF. This is assumed to be a consequence of nerve regeneration in the course of the disease after the procedure [35].

The present study confirmed the effectiveness of cRF as an interventional therapy for pain reduction. There was a significant improvement in pain, which was, however, slightly smaller than in most of the above-mentioned studies. An MCID of 30% (according to Fishbain) was achieved in 11 of 20 patients as a parameter for a positive clinical change and the relevance of treatment effects for self-reported pain [24]. However, Olsen recently published the results of a

systematic review of empirical studies assessing the MCID in acute pain and showed a high variability of the absolute MCID (13–85%) under the influence of various factors, e.g., baseline pain, operational definition, study design and clinical conditions. This study group concluded that “there is currently no agreement on an appropriate MCID for pain and little is known about the contextual factors causing variation” [36]. Referring to our study this could imply that a higher portion than the above stated 55% (11 of 20) might have had an important improvement.

A difference in technique as a major confounder seems improbable, as we used the same technique as described previously and selected the patients in a standardized

Table 4: Overview of cRF studies.

Author/Year	n	Study design	Follow-up (months)	Parameters	Results
Patel et al. [33]	51	RCT	1, 3, 6, 9	Pain level, ^a SF-36 PF, mobility, satisfaction with cRF	Improvement of all parameters, significant pain reduction in 47% after 3 months, in 38% after 6 months and 59% and 9 months
Stelzer et al. [27]	126	Retrospective study	4–6 6–12 > 12	Life quality, medication opioid consumption satisfaction with cRF	86, 71 and 48% of the patients had pain reduction $\geq 50\%$ 96, 93 and 85% had better QoL 71% satisfaction with cRF
Ho et al. [39]	20	Retrospective study	1, 3, 24	Pain reduction ^b PGIC satisfaction with cRF	15/20 patients had pain reduction ≥ 3 points NRS mean NRS decreased from 7.4 to 3.1 80% satisfied with cRF ³ PGIC improved
Kapural et al. [40]	26	Retrospective study	3–4	^c PDI, ^d GPE-78 opioid consumption patient satisfaction	50% of the patients had pain reduction $\geq 50\%$
Karaman et al. [7]	15	Retrospective study	1, 3, 6	^e ODI	86,7% had 10-point ^e ODI reduction 80% of the patients >50% pain reduction
Cohen et al. [9]	28	RCT	1, 3, 6, 12	Pain level	79, 64, 57 and 14% of patients had pain reduction und functional improvement $\geq 50\%$
Patel [41]	51	RCT	12	Pain level ^f SF36-BP ^e ODI	Mean 2.7 drop in the NRS score 13.9 points decrease in the ^e ODI 15.8 points increase in SF-36BP

^aHealth related quality of life.

^bPatients` Global Impression of Change.

^cPain Disability Index.

^dGlobal Physiotherapeutic Examination.

^eOswestry Disability Index.

^fShort Form 36-bodily pain score.

manner with diagnostic blocks (double blocks) [26]. In our view, it is more likely that the reduced efficacy can be attributed mostly to patient selection, as this study was performed with severely affected chronic pain patients. Moreover, it might be questioned if the post-interventional improvement in pain is really clinically relevant. In order to reflect the patient's satisfaction with the treatment result the use of a self-report test method such as the Patient Global Impression of Change (PGIC) may be considered, however its validity has not yet been sufficiently assessed [37, 38].

One important finding of the study was that the pain reduction was not accompanied by a general reduction of medication intake, but certain compounds such as antidepressants and anticonvulsants were clearly reduced.

In chronic pain patients, there is a close interaction between pain, sleep quality and depression [26, 29–31, 42]. Therefore, reduction of the anticonvulsants and antidepressants might also be interpreted as a result of a possible, though not statistically significant post-interventional improvement of depression or mood.

In our opinion the lack of reduction of the typical analgesics does not necessarily lead to the conclusion, that cRF was ineffective. First, pain reduction after treatment can take several weeks. Further, some patients possibly decided to continue their analgesic medication despite reduced pain intensity in order to also improve the remaining pain level. Some patients may also be afraid of renewed deterioration of their pain level if they discontinue the medication.

Furthermore, our sample also included a number of chronic pain patients with additional pain syndromes, e.g., degenerative spine disorders, fibromyalgia, restless legs syndrome or polyneuropathy. However sacroiliac joint pain was by far the main pain problem for these patients.

In our study, cRF had no significant influence on pain disability, but led to a clear improvement in sleep quality. This again underlines the close relation between sleep quality and pain perception and pain-related conditions in these patients [29, 43]. Sleep improvement could also be the result of the reduced nocturnal pain after cRF, as the sacroiliac joint often causes pain during changes in the sleep position resulting in sleep disturbance. As antidepressants and anticonvulsants also have sleep inducing effects, the positive effects of cRF on sleep quality possibly allowed a dose reduction or discontinuation of these drugs.

Several limitations of the study have to be addressed: the retrospective study design, the lack of a control group, the small number of patients and the medication use as a possible confounding factor. The diagnosis of sacroiliac

joint pain by means of clinical tests and/or diagnostic injections is still a matter of debate. Further, concomitant pain in other locations may impede the pain assessment. Due to the small sample size, only relatively large treatment effects can be detected and the statistical findings have to be interpreted with caution. The substantial variation in pre-interventional pain duration may be regarded as another limitation. The return rate of the questionnaire with 78% is in the range of similar studies. Although it could be objected that those patients who did not benefit from therapy might not have responded, it is not formally appropriate to draw this conclusion. However, the novelty and strengths of the study include the long follow-up, the use of validated tests, the strict patient selection and the in-depth analysis of single possible factors influencing outcome using, for example, the PDI or concomitant medication.

In summary, our data suggest that cRF may be an effective and well-tolerated procedure for patients with chronic sacroiliac joint pain and that pain-related psychological comorbidities such as depression also may improve, possibly due to pain reduction. In our view the study data in addition reflect our experience in daily work. Therefore, psychological factors should remain a point of interest in treating chronic pain patients, since they seem to play an important role in the interpretation of therapy results – particularly with reference to invasive pain therapies.

There is a need for more controlled prospective studies with larger case numbers to identify valid prognostic factors for the different outcomes of this interventional treatment modality and with reliable parameters to interpret the clinical relevance of treatment effects.

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Informed consent: Before treatment, written informed consent was obtained from all individual patients described in this study. The research has been approved by the authors' institutional review board or equivalent committee.

Ethical approval: All procedures described in the study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its amendments or comparable ethical standards.

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