MR-guided lumbar facet radiofrequency denervation for treatment of patients with chronic low back pain in an open 1.0 Tesla MRI system

Georg Böning¹, Tony Hartwig², Patrick Freyhardt¹, Maximilian de Bucourt¹, Ulf Teichgräber⁴, Florian Streitparth¹

¹Department of Radiology, Charité-Universitätsmedizin Berlin, corporate member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Berlin, Germany; ²Department of Musculoskeletal Surgery, Vivantes Hospital Spandau, Berlin, Germany; ³Faculty of Health, School of Medicine, University Witten/Herdecke, Witten, Germany; ⁴Department of Radiology, Friedrich-Schiller-University, Jena, Germany; ⁵Department of Radiology, Ludwig-Maximilians-University, München, Germany

Contributions: (I) Conception and design: F Streitparth, T Hartwig; (II) Administrative support: U Teichgräber; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: T Hartwig; (V) Data analysis and interpretation: F Streitparth, T Hartwig, G Böning; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Prof. Dr. Florian Streitparth, MD, PhD. Department of Radiology, Ludwig-Maximilians-University, München, Germany. Email: florian.streitparth@med.uni-muenchen.de.

Background: To evaluate the feasibility, safety and efficacy of magnetic resonance imaging (MRI)-guided lumbar facet joint radiofrequency denervation (FRD) in patients with chronic low back pain.

Methods: The study consisted of two parts. First, a preclinical analysis using an ex vivo animal model was performed to define optimal technical parameters for ablation. Then, 17 patients with chronic lumbar facet joint pain syndrome were prospectively included and underwent MRI-guided FRD in an open 1.0-Tesla MRI. We analyzed technical feasibility and complications as well as clinical outcome in terms of subjective pain assessed on a numerical visual analogue scale (VAS) before and after 1 week/6 months after FRD. Clinical assessment was complemented by measurement of paravertebral muscle volume and fat content before the intervention and at 6-month follow-up.

Results: All interventions were technically successful without major complications. Initial VAS scores (median: 8, IQR: 1, range: 6–9, CI: 7.14–8.04) decreased significantly both after one week (median: 4, IQR: 5, range: 0–7, CI: 1.9–4.69, P=0.003) and after 6 months (median: 1, IQR: 6, range: 0–7, CI: 1.06–4.23, P<0.001). Mean multifidus muscle volume increased significantly in the patient population (from 366.8±130.8 cm³ before to 435.4±146.7 cm³ after FRD, P=0.031).

Conclusions: This proof of principle study shows MRI-guided FRD in an open 1.0-Tesla MRI system to be a potential therapy option for patients with chronic low back pain.

Keywords: Open MRI; MRI interventions; lumbar facet joint radiofrequency denervation; low back pain

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ORCID: Georg Böning, 0000-0002-8819-6209; Patrick Freyhardt, 0000-0001-9705-8513; Maximilian de Bucourt, 0000-0002-6244-0496; Ulf Teichgräber, 0000-0002-4048-3938; Florian Streitparth, 0000-0003-1007-4057.
Introduction

Chronic low back pain is one of the most commonly diagnosed conditions in developed countries with an enormous socioeconomic burden. In many patients, the condition is attributed to the facet joint pain syndrome with or without radiologically proven spondylarthrosis (1). For patients with a history of frustrating analgetic and physical therapy, corticoid/analgesic infiltration of affected facet joints represents an adequate approach for supplementary diagnosis and first-line minimally invasive treatment (2). In patients who respond to infiltration, treatment can be extended to denervation of the facet joints to achieve a sustained therapeutic effect (3,4). Facet joint radiofrequency denervation (FRD) using fluoroscopy or computed tomography (CT) for image guidance is an established method (5,6).

However, there are several technical issues with fluoroscopy- and CT-guided FRD such as the radiation exposure for patient and interventionalist and poor soft tissue contrast. Higher radiation may be caused by difficult access to the nerve course of the medial dorsal ramus due to degeneratively enlarged facet portions, which can make denervation difficult in some cases. The lack of full three-dimensional angulation of the CT image plane to monitor the position of the thermal applicator may limit the extent of medial dorsal ramus denervation and can thus result in insufficient facet denervation.

Successful magnetic resonance imaging (MRI)-guided interventions in the area of the spinal column have been reported for several indications, such as spinal injection and laser disc decompression (7-13). However, MRI has not yet been used for radiofrequency denervation of the facet joints. In this study, we therefore investigated the feasibility and clinical outcome of multiplanar MRI-guided lumbar FRD in an open 1.0 Tesla MRI scanner.

Methods

Study design/patient cohort

This prospective, exploratory single-center study was conducted in accordance with the Declaration of Helsinki (as revised in 2013), approved by the institutional ethics committee of our university hospital (EA1/071/09, EA1/301/12) and written informed consent was obtained from all patients.

Inclusion criteria: only patients with a preinterventional lumbar pain score of at least 6 on a visual analog scale (VAS), spondylarthrosis detected by MRI (≥ Fujiwara 2–3°), and multiple positive facet joint infiltrations (>75% pain relief) were included (14). At least 2 of the following 4 symptoms of facet joint pain syndrome were present: local pressure and knocking pain over one or more facets, worsening of low back pain with hyperextension and rotation of the lumbar spine, morning stiffness in the lumbar spine or increased pain in the morning with pseudoradicular radiation into the buttocks or thigh. Exclusion criteria were: progressive neurological deficits due to neuroforaminal and spinal canal stenosis, evidence of lumbosacral radiculopathy, spinal and zygapophyseal cysts, spondylolisthesis, pre- or postinterventional surgery of the lumbar spine, BMI >40 kg/m², skin infection, circulatory disorders, allergic reactions to local anesthesia, and relevant neurological, cardiological or malignant disease. Indications for facet joint denervation were jointly established by orthopedic surgeons and interventional radiologists.

MRI system and MR-compatible interventional equipment

All interventions were performed in an open 1.0-Tesla MRI system with vertical orientation of the main magnetic field (Panorama HFO, Philips, Best, Netherlands). The open configuration allows almost 360° patient access in the magnetic isocenter and thus provides good conditions for MR-image-guided interventions. The equipment used in the open MRI system included a workstation with complete scanner control, an MRI-compatible in-room monitor, and an MRI-compatible wireless PC mouse for starting interventional acquisitions and switching imaging planes. A flexible solenoid superficial coil (Multipurpose L, Philips, Best, Netherlands) with a diameter of 21 cm was used for all procedures.

All facet denervations were performed using a bipolar radiofrequency (RF) system (CelonLab POWER, Celon AG medical instruments, Teltow, Germany) with a maximum output power of 250 W and a frequency of 470 kHz. The MRI-compatible RF applicator (CelonProSurge MR 150-T20, Celon AG medical instruments, Teltow, Germany) has an electrode length of 20 mm, a shaft length of 150 mm, and a diameter of 15 gauge (1.79 mm).
model to identify the optimal power, energy, and application duration to be selected in relation to the size of the ablation area to be achieved. For this purpose, radiofrequency ablations at 5 W and different target energy inputs of 100–200 J (in 20 J steps) were combined with different application durations, and the ablation areas/shapes achieved in the animal muscle were subjectively evaluated by two experienced interventionalists in consensus. The aim was to determine the optimal energy input regarding area/shape in terms of denervation effectiveness and maximum protection of surrounding tissue such as paravertebral muscles.

**Clinical application**

Denervation treatment was performed on an outpatient basis. The interventions were uneventful, and all patients left the hospital after circulatory monitoring for one hour after the procedure.

The interventional team included an MRI technician for coil positioning and pre- and postinterventional imaging, a nurse for sterile patient and equipment preparation, an interventional radiologist, and an orthopedic surgeon. Patients were positioned in 90° lateral position, and the lumbar interventional area was covered steriley in the usual manner (Figure 1). In order to achieve optimal image quality, the radiofrequency coil was positioned as close as possible to the lumbar puncture site in a position orthogonal to the main magnetic field (B0).

The MRI sequence protocol is presented in Table 1. Multislice T1- and T2-weighted (w) fast spin echo (FSE) sequences were used for preprocedural planning and localization of the target anatomy (Figure 2). An interactive proton density (PD)-w FSE sequence was used to determine the exact skin entry point using the finger-point technique and to direct the applicator needle toward the target anatomy in near real-time (acquisition time: 2 s) (Figure 2). A local anesthetic (2 mL prilocaine 1%, Xylonest™ 1%, AstraZeneca, Wedel, Germany) was administered subcutaneously in the area of the predetermined puncture sites and around the facet joints to be treated.

After a small skin incision, the RF applicator was positioned parallel to the medial branch of the respective dorsal ramus in approx. 15° inferosuperior puncture direction with posterolateral access. Here, the medial dorsal ramus is located in a groove along the medial-posterior surface of the transverse process (15). For upward advancement of the RF applicator, a puncture site approximately one level below the target site was used. First, the needle should be used to establish bone contact with the transition of the lateral surface of the superior articular process and the transverse process. After this step, the probe was brought into the final position—parallel to the nerve.

For the RFA procedure, a 2W test application was carried out for approx. 2–3 s to rule out irritation of the nerve root after applicator positioning. Each facet joint was treated until the defined autostop settings of the RF generator were reached, and a strongly T2-w fat-saturated SPIR sequence was acquired for assessment of postinterventional effects.

**Technical feasibility and safety**

Image quality of real-time MRI was evaluated subjectively
regarding accurate and safe RF applicator guidance by two experienced interventional radiologists in consensus. The procedure was defined as technically successful when the applicator reached the corresponding target position at the level of the respective medial dorsal ramus branch with MR fluoroscopy for guidance, and FRD was accomplished. Complications were recorded according to the Society of Interventional Radiology (SIR) clinical practice guidelines (16).

Clinical outcome
Back pain was evaluated clinically using follow-up questionnaires with a VAS for subjective assessment of low back pain ranging from 0 (0= no pain) to 10 (10= maximum pain intensity). VAS scores were obtained before the intervention and at follow-up after one week and six months.

Volumetric assessment
To complement the results of subjective pain assessment, we measured paravertebral muscle volumes and fat content. Diagnostic MRI examinations using the same protocols were performed for intervention planning and for follow-up at 6-month intervals. All volumes were measured manually by an experienced reader, and results over time were compared.

The volumetric measurements were performed as described before by Hartwig et al. using Amira v.5.2.0 (Visage Imaging, San Diego, CA, USA) (17). The cranio-caudal extent of volumetric measurement was defined according to the treated segments following the definition of Hartwig et al. were the middles of intervertebral discs in the sagittal plane were used to define the superior and inferior margins of the region of interest (17). For example, if segment L4/5 was treated, the region of interest was defined from the center of the L3/4 disc to the center of the L5/S1 disc. The measurements were than performed in the axial T2w with 3mm slice thickness.

Table 1 Imaging protocols in open 1.0-T MRI system

<table>
<thead>
<tr>
<th>Sequence application</th>
<th>Sequence name</th>
<th>Sequence parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic MRI</td>
<td>T2-w FSE (axial/sagittal)</td>
<td>TR/TE 3,000/120 ms, FOV 240 mm, matrix 268×210 mm, SL 3 mm, 6 acq., TA 3 min 12 s</td>
</tr>
<tr>
<td></td>
<td>T1-w FSE (sagittal)</td>
<td>TR 400/400 ms, TE 10/10 ms, FOV 180×240 mm, matrix 180×180/272×270 mm, SL 3/3 mm, 6/4 acq., TA 3 min 2 s/2 min 59 s</td>
</tr>
<tr>
<td>Real-time MRI for RF</td>
<td>Interactive PD-w FSE</td>
<td>TR/TE 600/10 ms, DRIVE pulse, FOV 200×157 mm, matrix 224×72 mm, SL 5 mm, TA 2 s</td>
</tr>
<tr>
<td>applicator guidance</td>
<td>(multiplanar)</td>
<td></td>
</tr>
<tr>
<td>Post interventional control</td>
<td>Fat-saturated (SPAIR) T2-w FSE (axial)</td>
<td>(TE/TR 100/1,500 ms, FOV 200×200 mm, NOS 6, Rec matrix 400×400 mm, Acq matrix 224×216 mm, TF 24, SL 3 mm, TA 4.16 min</td>
</tr>
</tbody>
</table>

Drive, driven equilibrium RF reset pulse; FOV, field of view; FSE, fast spin echo; MRI, magnetic resonance imaging; NSA, number of signal averages; PDw FSE, proton density weighted fast spin echo; SL, slice thickness; SPAIR, spectral attenuated inversion recovery; SPIR; spectral presaturation with inversion recovery; TA, acquisition time; TE, echo time; TR, repetition time. Table reprint from Streitparth et al. with kind permission from Springer Nature (11).

Statistical analysis
Graphics were created with GraphPad Prism v.5® (GraphPad Software, San Diego, CA, USA). Statistical analysis was performed with IBM SPSS Statistics 26 for Windows 10 (IBM Corp., Armonk, NY, USA). Descriptive evaluation of the data was done using common measures of location (median, mean), dispersion measures [standard deviation (SD), range from minimum (min) to maximum (max), interquartile range (IQR)], and frequency tables. For exploratory data analysis, we used the Wilcoxon signed-rank test (interval scaled data) and Friedman’s two-way analysis of variance by ranks (ordinal scaled data). Statistical significance was assumed for P<0.05, and Bonferroni correction was used.

Results
Patient population
In this study, 17 patients (7 women/10 men; median age: 58 years, range: 37–83 years) with chronic lumbar facet joint pain syndrome underwent MRI-guided facet joint radiofrequency denervation. Due to the dual nerve supply of
each individual segment by descending fibers, the adjacent cranial segment was always treated as well. Segments L2/3 (n=1), L3/4 (n=5) and L4/5 (11) were primary targets. In 11 patients, two segments (n=66 ablations) and in four patients, three segments (n=32 ablations) were denervated in the same session, resulting in a total of 106 facet joint ablations. Further patient details are summarized in Table 2.

**Technical feasibility and safety**

Optimal ablation settings identified experimentally were: 5W, 100J, and 20s application duration, resulting in an oval ablation area of 4 mm x 7 mm.

All procedures were technically successful. No major complications occurred during or after the interventions. Mild injection site pain was observed in all patients.

Image quality of the interactive PD-w FSE sequence was adequate, allowing identification of the targeted anatomical landmarks and confirmation of correct needle positioning parallel to the medial dorsal ramus in all patients.

**Clinical outcome**

Subjective pain scores were improved after the intervention. Preinterventional initial scores (median: 8, IQR: 1, range: 6–9, CI: 7.14–8.04) decreased significantly both after one
week (median: 4, IQR: 5, range: 0–7, CI: 1.9–4.69, P=0.003) and after 6 months (median: 1, IQR: 6, range: 0–7, CI: 1.06–4.23, P<0.001) (Figure 3).

**Volume measurement**

Mean multifidus muscle volume before/after the intervention increased significantly in our patient population (366.8±130.8 cm³/435.4±146.7 cm³, P=0.031). No significant differences were observed for the other volumes analyzed (Figure 4).

**Discussion**

This proof-of-principle study describes the feasibility of real-time MRI-guided bipolar radiofrequency denervation of lumbar facet joints in patients with chronic lumbar pain syndrome in an open 1.0-Tesla MRI system. Facet joint pain is thought to be mediated by the neural supply of the facet joint capsule. The joints have a rich innervation arising from the medial and lateral branches of the dorsal rami with dual innervation from the medial branches arising from the...
posterior rami (18). Studies have shown that image-guided
denervation of the facet is a safe and effective therapeutic
option when indicated and can prevent or postpone
surgical treatment (2). In addition to alcohol ablation,
radiofrequency denervation using X-ray fluoroscopy or
CT guidance has become an established treatment option
(3,4,19). Significant pain reduction after denervation for
chronic lumbar pain syndrome was reported for a 6-month
interval (19) and is confirmed by the results of our study.

Previous studies suggest that MRI-assisted facet
infiltration is safe and effective (7-9). The lack of
ionizing radiation is advantageous for both patients and
interventionalists. Furthermore, MRI navigation has
additional advantages. For example, the better soft tissue
contrast and especially the multiplanar imaging capabilities
of MRI make it easier to position the RF applicator
compared to fluoroscopy and CT. MR imaging allows 15°
inferosuperior angling of the RF applicator with complete
visualization of the applicator. This allows a higher
contact length to the medical dorsal ramus for optimized
denervation.

We achieved technically successful MR-guided RF
denervation of the facet joints in all patients without major
complications. The real-time PD-w FSE sequence enabled
precise multiplanar applicator positioning with good
visualization of spinal structures and optimal artifact properties
for applicator imaging. This was accomplished by a complex
interaction of material and alignment of the applicator to the
main magnetic field (B0), the sequence type, and parameters
applied for the vertically oriented magnetic field strength of 1.0
Tesla (7). In comparison to CT, MRI depicts spinal anatomy
in greater detail and facilitates applicator positioning due
to multiplanar navigation with unlimited selection of image
planes (20). In our study, interventions were performed with
patients in lateral position, which allows the best possible
coil positioning and hence optimal signal amplification (7).
In addition, an MRI quadrupole imaging coil (butterfly)
was developed for spinal interventions in a vertical 1.0-T
MRI system and the use of this surface coil may allow spinal
interventions to be performed in a prone position comparable
to CT (21). Prone positioning ensures access to a larger
area for spinal interventions and might be more familiar to
interventionalists, especially to those with little to moderate
experience. The durations of interventions were not recorded
in this study. The interventionalist performing the procedures
estimated the time to be comparable to that of fluoroscopy-
or CT-guided denervation after an initial learning curve,
due to real-time MR fluoroscopy navigation. Furthermore,
the development of dedicated sequences can improve the
benefit and safety of MRI-guided interventions (22). Real-
time thermometry was reported to technically optimize
MRI-guided thermoablation (11,12,23-25). Other technical
advances may enable new applications in the future (26,27).

The use of a bipolar RF applicator contributed to the
safety of the interventions performed in this study (28).
Known risks such as current flow across a patient-neutral
electrode (monopolar systems) are prevented by the use of
a coaxial electrode (29). Current flow in a bipolar system
solely occurs in the distal portion of the applicator. The fact
that very low power is required for effective denervation
further reduces the risk of unwanted thermal damage.
Finally, the autostop function of the applicator which
we defined in a preclinical experiment prevents damage
to adjacent subcutaneous and muscle tissue as well as to
structures at risk such as the nerve root.

A disadvantage of MRI-guided interventions is the
currently still limited availability of open MRI scanners.
However, techniques for performing interventional MRI
guidance in closed-bore systems have been reported. In
short wide-bore systems, needles can be advanced with
the extended arm using real-time imaging. In standard
magnets, control and workflow may be improved by remote
operation using robotic or manual driving elements (30).

Regarding clinical outcome, we observed significant
pain relief (median VAS scores of 8 to 1), which correlated
with an increase in muscle volume (multifidus muscle) after
6 months. The underlying mechanism for this observation
is that pain can lead to a sparing of the corresponding
segments with subsequent hypotrophy of muscles and
increasing fat content (31). Consequently, successful pain
therapy is expected to reverse hypotrophy (32). This
underlines the benefit of MRI-guided FRD with prompt
pain relief (median VAS scores of 8 to 4 one week after
denervation), allowing the patient to undergo optimized
physiotherapy aimed at improving spinal muscle volume
and ensuring sustained pain control.

Besides ethanol and radiofrequency denervation, there
are other treatment options such as MRI-guided focused
ultrasound ablation or cryoneurolysis that have shown
promising results in animals and humans (33,34). Studies
comparing different procedures would be desirable and
should be performed in the future.

Our study has some limitations. First, we used
subjective pain scores without further verification. In
addition, patients were asked to report the response to
treatment by telephone (not blinded), which could have
affected outcome results. Second, a follow-up period of 6 months is relatively short, as pain is bound to recur due to nerve regeneration, and a longer follow-up period would be helpful to analyze the duration of the therapeutic effect and the time when patients may need a repeat procedure. Third, as this was a preliminary study, we did not include a control group to compare MRI guidance with fluoroscopy or CT. Fourth a prospective case number planning was not performed because valid data on the expected effect size are available for CT-guided RFA, but it was not possible to predict with certainty whether comparable effects could be achieved with the MRI-guided procedure. However, the rough estimation of the effect size for this procedure, which is possible from the data of this pilot study, can be used to prospectively generate a sufficient number of cases at adequate test power in following studies. Fifth, this study was performed in an open MRI system, which is not the most common type available. Nevertheless, our experience is transferable to state-of-the-art wide- and short-bore tunnel systems, which are most appropriate for performing MR interventions. For this transfer, some requirements should be considered, such as modifications in patient and coil positioning and possible parameter modifications of the interactive MR sequence. Future studies in larger patient populations should investigate the clinical significance of the achieved pain reduction and long-term efficacy.

In conclusion, this proof-of-principle study shows that MRI-guided facet joint radiofrequency denervation (FRD) in an open 1.0-Tesla MRI system is a promising treatment option for patients with chronic lumbar pain syndrome.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the institutional ethics committee of Charité – Universitätsmedizin Berlin (EA1/071/09, EA1/301/12), and informed consent was obtained from all study participants.

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