Ultrasound-guided versus computed tomography-controlled periradicular injections of the first sacral nerve: a prospective randomized clinical trial

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Introduction

In today’s clinical routine a selective nerve root block has become an important non-surgical treatment option that – beside physiotherapy and analgesics – is increasingly offered to patients with radicular compression neuropathy [1,2]. Steroids directly injected locally at the affected nerve root provoke an anti-inflammatory effect [3] by stabilizing cellular membranes, suppressing immune responses, enhancing neuronal blood flow, releasing fibrosis and washing out inflammatory substances [4]. Many different opinions regarding the imaging guidance techniques, the agents to be injected, the dose and the timing of repeated injections exist [5,6]. Besides the “blind” access, which is not regarded as a valid option, several imaging modalities are used to reach the compressed nerve root. These include fluoroscopy, computed tomography (CT) and ultrasound [7]. Due to anatomic precision and spatial resolution CT is currently the preferred method [8-10] and is therefore regarded the “gold standard” imaging tool. However, potential benefits of ultrasound guidance, including real-time needle control and avoidance of radiation seem to be attractive. Meanwhile, comparative clinical studies between CT and ultrasound exist for periradicular injection therapies (PRT) in the cervical [11] and lumbar spine [12]. The lumbosacral region as a mechanic transition zone is prone to injuries [13] and degeneration changes: disc herniation, spinal or foraminal stenosis can provoke relatively common, radicular compression neuropathy of the first sacral nerve (S1 radiculopathy) [14]. Moreover, in a previous

Abstract

Aim: To compare ultrasound (US)-guided versus computed tomography (CT)-controlled periradicular injections of the first sacral spinal (S1) nerve in a prospective randomized clinical trial. Materials and methods: Thirty-nine patients with S1-radiculopathy were consecutively enrolled for 40 periradicular injections and assigned to an US or CT guided group. Needle position after US-assisted placement was controlled by a low-dose CT-scan. Accessibility, accuracy, and intervention time were compared. The overall effect on pain was matched evaluating the visual analog scale (VAS) decrease before and one month after the intervention. Results: The mean intervention time was lower in the US-group compared to the CT-group: 4.4±3.46 min (1.3-13.2) vs. 6.5±3.03 min (2.4-12.5). Using CT-controlled infiltration the mean number of needle passes was with 1.15 higher than utilizing US-guidance. The therapeutic effect (mean difference between pre- and post-intervention, VAS scores) for the CT-group was 4.85±2.52 and for the US-group 4.55±2.74 with no significant difference between the two groups (p=0.7). Conclusion: US-controlled infiltrations of the first sacral nerve show a similar therapeutic effect to the time consuming, and ionizing CT-controlled injections and result in a significant reduction of procedure expenditure and avoidance of radiation.

Keywords: image-guided; infiltration; injection; pain; ischialgia
cadaver study the accuracy of US-guided needle placement within the dorsal sacral foramen has already been proven [15].

The aim of this study was the comparison of US-guided versus CT-controlled S1 periradicular injections in a prospective randomized clinical trial evaluating accessibility, accuracy, and intervention time as well as overall effect on pain relief of US-guided periradicular S1 injections compared with the standard CT-controlled approach. The primary objective of this trial is to prove that US-guided S1 periradicular injections have the same treatment results as the standard CT-controlled approach.

**Material and methods**

This prospective randomized clinical trial was approved by the local institutional Ethics Board of the Medical University of Innsbruck. (Innsbruck EK Nr: 1099/2019).

**Patients**

Thirty-nine patients, based on a standard clinical neurological examination and functional testing, were consecutively enrolled by the department of Neurosurgery of the Medical University of Innsbruck between 06/2020 and 05/2021 for 40 image guided PRT of S1 (1 patient was injected on both sides). Inclusion criteria were clinical and radiological (MRI images) signs of a radicular S1-compression (radiculopathy), age over 18 and informed consent for study participation. Contraindications included a known allergy to the applied medical agent (1 ml Solucelestan, 4 mg Betamethasone), any disease or medication which exclude or are critical for injection therapies such as diabetes, local, spinal, or systemic infection, a spinal tumor, a current anticoagulation therapy or uncorrectable coagulopathy, a present or not excludable pregnancy as well as all patients with an appointed guardian or a patient’s provision against study participation. Further, for US guided procedures a body-mass index over 36 kg/m² [16] counted as a further exclusion criterion. The recruited 39 patients were randomized into equal sample sizes with the permuted block randomization method and assigned to the 2 treatment groups.

**VAS (visual analog scale)**

To evaluate the patient’s harm and pain relief a paper-based VAS concerning the actual perception of pain at rest graded from 0 (no pain) to 10 (maximum pain) was documented before randomization and one month after the intervention.

The difference between pre- and post-intervention VAS scores was interpreted as therapeutic effect deviation. In addition, pain relief medications before as well as 1 month after the infiltration were noted.

**Image-guided infiltrations**

The patients were randomized using a computer-generated randomization table Microsoft Excel (Version 21, Redmond, Washington, USA) into two groups (US-group vs CT-group):

1. **US-guided infiltration**

   For all US-guided interventions a standard US-device under default settings (Canon Medical Systems GmbH, Aplio i800) with a convex I8CX1 curved array transducer was used. Infiltrations were performed by two radiologists (HG and ALL) with long-lasting experience in US-guided musculoskeletal interventions.

   The patient was placed in a prone position on the CT table. Based on similar preceding studies [11,12] time recording was started with the first US-transducer’s contact of the patient’s skin. The injection material was prepared under aseptic conditions including the sterile coverage of the US transducer. The lower back was cleansed and covered sterile. The periradicular area of S1 was identified using landmarks as previously described [15]. Thereby the first sacral foramen was depicted by positioning the transducer in a cranially tilted median-transversal orientation to assess the typical transition from the fifth lumbar to the first sacral spinous process as described by Loizides et al [12]. By moving the transducer laterally, the respective fifth lumbar and first sacral facet joints were identified. Moving the probe slightly caudally the first sacral foramen was identified as a bony gap. Following, a spinal needle (BD Quincke Point spinal anesthesia needle 20G 3.50 IN 0.9x90 mm – yellow; 405253, GIMA S.p.A, Gessate, Milan, Italy) was introduced in-plane technique under real-time visualization (fig 1) and advanced into the foramen S1 on the respective side until the tip reached the medial osseous border of the first sacral foramen (estimated tip depth about 1cm under the bone surface). Time recording was stopped with the needle in place. Subsequently a low-dose CT scan (Somatom Confidence®; Siemens, Erlangen, Germany) was obtained to document the final needle position and evaluate accuracy. Adopted parameters (scan with tube current at 80kV, 30 mAs), a scan level of 28 mm with the tip in the center, a field of view of 150 and a gantry tilt parallel to the positioned needle were used. In case of wrong level or if the needle tip did not reach the aimed periradicular position, the needle had to be repositioned under US-guidance and the respective time was added to the aforementioned. If the correct needle level was confirmed additional axial scans in a low-dose protocol were obtained for exact control of the needle tip position (fig 2). Once CT documented the correct needle tip position, 1 ml of Solu-Celestan (4 mg betamethasone) was injected into the periradicular compartment. After removing
the needle and cleansing the punctured skin a dressing was applied at the puncture side.

2. CT-controlled infiltration

Injections were performed on a Somatom Confidence®; Siemens, Erlangen, Germany CT-scanner by one radiologist with distinctive and long-standing experience in CT-controlled interventions (BR). Patients were placed in prone position at the CT table and preparation of sterile material as well as patient’s cleansing were performed in the same manner as already described for the US-guided group. Additionally, a linear radio-opaque marker was attached at the lumbosacral region of patients assigned to this group. Time recoding was started with the low-dose CT scan (Somatom Confidence; Siemens, Erlangen, Germany). First, a topogram of the lumbosacral region was carried out. Thereafter, a small section of axial images with a scan level of 28 mm with the first sacral foramen in the center and a slice thickness of 2.4 mm were acquired for the planning CT. Based on these data the needle access pathway to reach the periradicular S1 region in the sacral foramen was planned. Using the CT-positioning laser function the entrance point was marked on the skin with a sterile pen. The same spinal needle as described above, was introduced along the planned access to the periradicular compartment of S1. Once the needle was estimated to be positioned correctly, the time recording was stopped. Time recording was recontinued just when the control CT scan for verification of the needle tip started. If the needle tip was in an unsatisfactory position, a repositioning was carried out until a correct needle placement was documented (fig 3).

At this timepoint recording was stopped and again 1 ml of betamethasone (4 mg Solucelestan) was injected into the periradicular compartment. After removing the needle, a plaster was applied to the skin’s puncture side.

After the infiltration all patients of both groups were observed for 15 minutes subsequently for potential complications.

Measurements and statistics

For both groups the following parameter were evaluated and compared: intervention time (in minutes); radiation dose report (dose-length product in mGy*cm); accuracy of needle tip position (correct level, potential repositioning); V AS before and one month after the infiltration including the difference between pre- and post-intervention V AS scores; underlying pathology (discal hernia, discal recessus stenosis, bony recessus stenosis, luxated discal hernia)
The statistical analysis contained basic mean value calculations including standard deviations, Pearson coefficient calculation between needle repositioning and difference between pre- and post-intervention VAS scores as well as intervention time and difference between pre- and post-intervention VAS scores, both for CT und ultrasound. Further, Student’s t-test for the difference between pre- and post-intervention VAS scores of patients undergoing CT and sonography (p-value≤0.05 estimated as significant) was performed.

Given a standard deviation of 1 for the measure and assuming a drop-out rate of 16%, an estimated total of 22 patients were required in each group for the study to have a power of 90% at a 2-sided α level of 0.05.

Results

Common data
Forty image-guided periradicular injections, 20 US-guided (10 men and 9 women, one female patient received an injection on both sides, 15 left and 5 right) and 20 CT-controlled (11 left, 9 right on 13 men and 7 women) were performed in 39 patients (23 male) aged between 20 to 82 years (mean age female 45±14.2; mean age male 48±15 years).

Intervention time
The mean intervention time for the US-guided treatment group was 4.4±3.46 min (between 1.3-13.2 min) and for CT-controlled treated group it was 6.5±3.03 min (between 2.4-12.5 min), respectively.

Radiation exposure dose
Using CT as an image-guidance, the mean dose length product (DLP) contained 25.405±32 mGy*cm (between 7-149.1 mGy*cm).
For the ultrasound-guided group the CT-based needle verification induced a DLP mean value of 8.165±4.93 mGy*cm (between 3-25 mGy*cm).

Accuracy of needle tip position
Using US guidance, in 6 cases the CT-based needle verification revealed an initial needle position at the second sacral level, whereby in two cases this was observed again after the first repositioning. A repositioning of the needle in the CT-group was necessary in 12 cases. Finally, in all 40 infiltrations a correct needle tip position could be achieved. Details regarding required repositioning are listed in figure 4. The mean value of required repositioning attempts using CT-controlled infiltration was 1.15±1.27 and applying US-guidance 0.4±0.68, respectively.

VAS
In 3 cases (2 of the US group and 1 of the CT group) the VAS did not change; in the other 37 it decreased. The mean difference between pre- and post-intervention VAS scores (interpreted as therapeutic effect) for the CT group was 4.85±2.52 and for the US group 4.55±2.74, respectively. Comparing the two groups no significant difference of therapeutic effect (difference between pre- and post-intervention VAS scores) could be found (t-test 0.7). The flow chart in figure 5 reveals an overview of difference between pre- and post-intervention VAS scores for both groups regarding needle repositioning.

Before injection therapy all besides 3 patients received pain medication (NSAIDs such as ibuprofen, diclofenac, naproxen, and/or metamizole). The used drug and the dosage were chosen by their family doctor. One month after infiltration 21 patients (9 of the CT group
and 12 from the US group) had no need of further pain medications, 3 patients of the CT group only if required. The others had reduced the use of medication. Of note, 5 patients (1 of the CT group, 4 of the US group) underwent surgery within one month after the infiltration with persisting pain intensity.

**Underlying pathology**

The underlying pathology was in 33/40 cases (82.5%) a disc herniation, whereby a fragmented type could be found in 15/40 (37.5%) cases. In 11/40 cases (27.5%) a herniation associated lateral stenosis and in 9/40 cases (22.5%) a bony lateral recess stenosis was the causative reason.

**Correlation analysis**

Correlation analysis regarding repositioning and mean difference between pre- and post-intervention VAS scores (CT group Pearson ρ=0.24, US group Pearson ρ=0.24) was similar. As well as intervention time and the difference between the VAS scores (CT group Pearson ρ=0.18, US group Pearson ρ=0.26) showed no relevant effect on each other.

Also, when correlating the underlying pathologies, no relevant linear associations could be found, such as discal hernia to discal recessus stenosis (Pearson ρ= 0.28) or to fragmented type hernia (ρ = 0.36). Also, for patients with discal herniation the association with the pre- and post-intervention VAS scores concerning CT (ρ=0.03) as well as regarding US (ρ=0.18) were not significant. For patients with discal recessus stenosis the correlation to pre- and post-intervention VAS scores showed no significance (ρ=0.13). It was the same for disc herniation and VAS before infiltration (ρ= 0.02), for discogenic recessus stenosis and VAS before infiltration (ρ=0.01), for bony or ligamentous recessus stenosis and VAS before infiltration (ρ=0.07) and for the fragmented disc herniation and VAS before infiltration (ρ=0.1).

**Discussion**

This prospective study is the first clinical trial comparing US-guided versus CT-controlled infiltrations of S1, evaluating accessibility, accuracy, needed intervention time, and the overall effect on pain relief for both imaging methods.

Like previously published studies in the cervical und lumbar spine [11,12,17] we could prove accessibility and potential accuracy of US-guided periradicular injections in patients with S1 radiculopathy. In all 40 injections accessibility was granted by a finally correct needle position without difference between US-guided versus CT-controlled periradicular injections. The number of required repositioning attempts was higher using CT-guidance; however, the wrong level (S2) was initially addressed 6 times under US-guidance. We hypothesize that an increased lordosis of the lumbosacral transition zone may result in a local “collapse” of the lumbosacral area and induce an incorrect interpretation of the spinal level. Further, degenerative changes may worsen the sonographic overview. Therefore, the importance of a correct placed role over a cushion underneath the lower abdomen must be emphasized which seems essential for patient positioning and the definition of the correct level under ultrasound guidance.

Optionally, it can be discussed from a therapeutic point of view: it is anatomically irrelevant to catch the second rather than the first sacral foramen, as we know that a perineural spread of the applied medication reaches the intraspinal epidural space and therefore potentially reaches adjacent nerve structures. This phenomenon was described in a preceded cadaver study [15] where an injection in the sacral spine induced a fluid dispersal along this virtual cavity. However, this query was beyond the scope of our study and should be evaluated in further clinical trials. Nevertheless, the injections of the S2 sacral foramen were obviously a mis“target” probably due to the mentioned hyperlordosis described above. This was adapted during the course of this study using a roll over cushion and should be implemented in every US-guided injection of the sacral spine.

Altogether using CT guidance first puncture success was lower and repositioning was more often required. This fact seems reasonable based on real-time target and intervention visualization only in the case of US guided interventions [18]. Once the first sacral foramen is recognized simple needle advancement provides “live” monitoring of the insertion along the entire length and path. On the other side, if CT-controlled imaging is used, once the pathway is planned, any patient’s movement may inevitably result in a discrepancy of the planned target point and a correction of the inserting needle could be necessary.

As is known ultrasound is a radiation free modality: this is an important advantage, especially if injections are necessary in young adults or even more important in children or in cases during pregnancy. Also, the cumulative radiation dose should not be underestimated considering that periradicular injections are often performed repeatedly.

Moreover, the ultrasound technique is a bedside method and can be performed anywhere, in contrast to the CT-technique where a patient needs to appear in a specialized center to undergo PRT which also provokes higher costs by in comparison limited availability.

Time to perform was also shorter when using US-guidance compared to the CT-controlled method. Of
course, the duration of an intervention does not state final success, but patients with radiculopathy are often in pain and have difficulties staying in a prone position.

No significant difference of the therapeutic effect (difference between pre- and post-intervention VAS scores) was found comparing the two image-based methods. Nevertheless, problems with US-guidance may arise - as we know based on physical properties – with severe obesity (this was a contraindication for inclusion to the ultrasound study group) and in case of previous spine surgery including the insertion of osteosynthetic material, so that the landmarks for US-intervention are not fully visible or freely accessible. In our study, all patients included did not present such problems.

One limit of the study is related to the fact that the first sacral nerve root cannot be visualized in detail by ultrasound. However, a previous cadaver study [15] has already proven that it is sufficient to position the needle tip at the proposed landmark (inner medial bone surface of the respective dorsal sacral foramen) to achieve adequate accumulation of the applied fluid in the S1-periradicular space. Comparable to previous studies in the cervical and lumbar spine, only steroids for periradicular injections were used. In our study, the aim was not to evaluate the effect of steroids for periradicular injections, but to reveal a new and safe method for an US-guided approach to the periradicular compartment of the S1 root.

In “real life” no CT control is performed after US-guided injections, so that potential “mistargeting” of the S2 sacral foramen might be overlooked using this modality. However, as discussed above, the usage of a roll over cushion should prevent potential hyper lordosis and ensure an optimal overview of lumbosacral transition. In addition, the possibility of a lumbosacral transitional vertebra should always be confirmed or ruled out by prior imaging, which in this study was provided by available MRI images [19].

The number of patients included (n=39) is considerable small but increasing use in routine clinical practice will provide further experience on practicality and elucidate the necessity for additional larger comparative studies regarding the two modalities in the future.

Another limiting factor could be the lack of determination of the therapeutic effect based on subjective satisfaction by VAS on the actual pain sensation of the patients at rest, before injection, and briefly 4 weeks after the intervention.

In conclusion, our study proves the feasibility of US-guided PRT of the first sacral nerve and reveals the similar therapeutic effect (difference between pre- and post-intervention VAS scores) as the CT-based procedure in patients with S1 radiculopathy. An injection performed under ultrasound guidance is generally radiation free, allows for bedside therapy even in outpatients and should be considered as an alternative to CT-guided injections.

Conflict of interest: none

References


