Ultrasound-guided versus Computed Tomography-controlled facet joint injections in the middle and lower cervical spine: a prospective randomized clinical trial.

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Abstract

Objectives: A prospective randomized clinical trial was conducted to evaluate accuracy, time-saving, radiation doses and pain relief of ultrasound-guided (US) facet joint injections versus Computed Tomography (CT)-controlled interventions in the cervical spine. Material and methods: Forty adult patients were consecutively enrolled and randomly assigned to the US- or CT group. US-guided facet joint injections were performed on a standard ultrasound device using a broadband linear-array transducer. The corresponding comparison group underwent CT-guided instillations which were performed under standardized procedures using the CT-positioning laser function. Results: The accuracy of ultrasound-guided interventions was 100%. The mean time (min:sec) to final needle placement in the US group was 04:46 versus 11:12 (p<0.05) in the CT group for one injected level, and 05:49 in the US group versus 14:32 (p<0.05) in the CT group for two injected levels. The mean dose-length product (DLP, mGy*cm) radiation dose, including CT confirmation for study purposes only, was 27.6 for the US group versus 88.2 in the CT group (p<0.05) for one injected level, and 32.5 in the US group versus 205.0 in the CT group (p<0.05) for two injected levels. Both groups showed the same significant visual-analog-scale (VAS) relief in pain (p<0.05), without any “inter-methodic” differences (p>0.05). Conclusions: US-guided intra-articular injections show the same therapeutic effect as CT-guided intra-articular injections and result in a significant reduction of procedure duration without any exposure to radiation. Keywords: facet joints injections, cervical spine, ultrasound, computed tomography, radiation dose

Introduction

Injection therapies play a major role in the management of various pain conditions [1,2]. With a 12-month prevalence that varies between 30% and 50%, neck pain is common in the general population. It occurs more often in women and shows a peak of prevalence at middle age [3]. Facet joints are well innervated by the medial branches of the dorsal rami and contain free and encapsulated nerve endings, nociceptors and mechanoreceptors [4]. They have been shown to be a source of pain in the neck and related pain in the head and upper extremities [5-10]. In 2% to 10% of the cases, facet-joint-associated pain results in incapacity to perform daily activities. If, despite non-steroidal anti-inflammatory drug administration and nonspecific physical therapy measures, pain becomes unremitting, it may be managed by intra-articular injections or medial branch blocks [2,4,11]. The majority of such infiltrations is performed under fluoroscopy- or computed tomography (CT) control [12]. Recently, various groups, including ourselves, have shown the reliability of ultrasound (US) guidance for different infiltrations, and US has been demonstrated to facilitate the locali-
zation and imaging of spinal nerve roots and also bony parts of the spine such as facet joints [13-22]. US-guided approaches tailored for spinal interventions are already available but only proven for their topographic feasibility [1,13-22].

The aim of this study was to show the feasibility and accuracy of a methodological US-based approach – as described by Galiano et al 2006 [13] – for inter-articular instillations in the middle to lower cervical spine in a prospective randomized clinical trial.

Materials and methods

The protocol of this prospective randomized study was reviewed and approved by the ethical committee of the Innsbruck Medical University (IMU, Protocol UN3959). The patient selection was performed consecutively during daily routine at the Department of Neurosurgery at IMU and was performed on the basis of standard neurological diagnostics and clinical methods by neurosurgical specialists following evidence-based-medicine recommendations [3]. Forty adult patients (24 women and 16 men) were prospectively enrolled, after having given written informed consent. All subjects had to fulfill the following inclusion criteria: (1) subacute-chronic facet-joint-associated neck pain of the middle or lower cervical spine; (2) available recent CT or MRI of their cervical spine; (3) aged over 18 years old. Exclusion criteria were (1) neurological deficit, (2) local or systemic infections and discitis (3) running anticoagulation therapy or uncorrectable coagulopathy, (4) allergies to steroids, anesthetics or contrast agents, (5) diabetes, (6) pregnancy or (7) spinal tumors. After recording the subjects' demographic data, preceding surgeries, body-mass-index and visual analog scale (VAS) score regarding their neck pain, patients were assigned to one of two groups by chance, using a computer-generated randomization-table. One group consisted of candidates for US-guided infiltrations (US group), the other group consisted of candidates for Computed Tomography (CT group). To guarantee for patient safety the study was planned to be aborted if in more than two patients of the US group the target was not visible or CT-control scans showed an incorrect needle position after US-guided intervention.

Ultrasound-Guided-Procedure

Ultrasound interventions were performed on a standard US device (iU22; Philips Ultrasound, Bothell, Washington), using a 12-5 broadband linear array transducer, by a radiological specialist with relevant experience of more than 10 years in musculoskeletal US imaging and spinal injection therapies. Under sterile circumstances and after covering the US probe with a sterile wrap, patients were placed in prone position and the region of interest was washed sterile and covered accordingly. The time was taken from the moment the investigator touched the skin the first time with the probe after sterile US gel was applied. Following the systematic procedure described by Galiano et al. [13], the facet joint of interest was sought through a paraxial scan position, and the sonographer classified the target as clearly visible, partially visible or not visible. If clearly or partially visible, a spinal needle (20 GA 3.00 IN, 0.9 x 75 mm; BD Spinal Needle, Becton Dickinson, Madrid, Spain) was inserted from dorsal exactly within the echo plane (fig 1). When the sonographer was sure to have placed the needle tip directly at the inter-articular space of the targeted facet joint, the elapsed time was recorded. Then the accuracy of the positioning was verified by CT (Somatom - Sensation Open, Siemens, Erlangen, Germany). If the sonographer classified the target as partially visible, the time of the following CT verification was included in the procedure time measurement. To keep the radiation dose as low as possible, a topogram centered on the needle tip and a few axial slices - using a low dose protocol (120 kV, 120 mA) - were obtained. If the needle placement was correct, 1 mL mixture of betamethasone (CELESTAN® solubile 4 mg/ml; essex-pharma GmbH, Munich, Germany) and bupivacainehydrochloride (Bucain® 0.25%, 2.5 mg/ml, Delta Select GmbH, Pfullingen, Germany) was injected. If the needle tip was not in correct position, it was replaced again under ultrasound guidance followed by CT control, with the time measurement running on.

Computed-Tomography-Controlled Procedure

The CT-guided interventions were performed with the same CT device as used for the verification of the US procedure and were executed by a radiology specialist with more than 10 years of relevant experience in CT-guided interventions. After placing the candidates in a prone position, a radio-opaque marker was positioned on the skin.
of the area of interest. Consistent with the US procedure, elapsing time was recorded with the start of the initial scan. For a precise calculation of the needle pathway, a topogram through the targeted area was obtained with a low-dose protocol (120 kV, 120 mA) at 3 mm slice thickness. The point of entry, the angle and the depth of approach were selected and calculated. The needle entry point was marked on the patient’s skin using the obtained calculations and the CT-positioning laser function. Then a spinal needle (20 GA 3.00 IN, 0.9 x 75 mm; BD Spinal Needle, Becton Dickinson, Madrid, Spain) was advanced toward the facet joint of interest, according to the preliminary calculations. To control the present and final needle tip position, several CT scans were obtained repeatedly, i.e. after each reposition, until the needle was estimated to be in the incorrect position. At that time the elapsing time was recorded. Exactly as in the US procedure, 1 mL mixture of betamethasone (CELESTAN® solubile 4 mg/ml; essex-pharma GmbH, Munich, Germany) and bupivacaine hydrochloride (Bucain® 0.25%, 2.5 mg/ml, Delta Select GmbH, Pfullingen, Germany) was injected.

Measurements and Statistics

For both groups the periods of intervention time and the radiation doses (as dose-length products; DLPs) are reported. Time and radiation dose were compared separately for one- and two-leveled injections. To follow up the clinical benefit, neck pain was assessed via a visual analog scale (VAS) before, 30 minutes after and 4 weeks after the intervention. Feasibility of the US procedure was defined as percentage of patients with clearly, partially, or invisible targets (respectively inter-articular space). Accuracy was calculated as CT-verified exact needle tip placement. The number of repositions, unexpected problems and complications were also recorded for both groups. Statistical analyses were done according to the intention-to-treat principle [23]. The primary outcomes were accuracy and time to final needle placement. The number of repositions, unexpected problems and complications were also recorded for both groups. Statistical analyses were done according to the intention-to-treat principle [23]. The primary outcomes were accuracy and time to final needle placement. For the evaluation of VAS changes we used the comparison of percentage VAS reduction from pre- to 30-minutes post-interventional and from pre- to 4-weeks post-interventional interval. The trial was designed to detect an absolute difference of one standard deviation with a power of 80% at a two-sided significance level of 0.05 and a maximum dropout rate of 20%. Comparisons between groups were performed with an unpaired t-test, or in case of nonparametric values, with a Mann-Whitney U-test.

Results

After randomization there were no significant differences between the two groups (table I). All patients who were randomly assigned to the US group were judged to be feasible for the US-guided procedure. In 20 patients the inter-articular space of the targeted facet joint, as well as the bony landmarks, were clearly depicted by US (100%). In 19 of these patients (95%) the intervention was performed as planned and the needle was positioned correctly, as also confirmed by CT (95%). In one case (5%) the intervention was aborted because of the patient’s missing compliance (the patient was unable to deal with the pain of needle positioning). In the US group no needle had to be repositioned (accuracy = 100%). In the CT group a needle reposition was necessary in 13 cases (65%): in 3 cases (15%) the respective needle position was changed once, in 6 cases (30%) twice, in 2 cases (10%) three times and in another 2 cases (10%) even four times. Regarding the necessary needle repositions the US-guided procedure statistically showed a significantly higher accuracy (p<0.05). The mean duration (min:sec) to needle placement for one-leveled injections was 4:46 in the US group and 11:12 in the CT group. The US group showed significant time savings (p<0.05). The mean duration (min:sec) of two-leveled injections was 5:49 for US-guided and 14:32 for CT-controlled procedures. US guidance again showed statistically significant time savings (p<0.05). The mean DLP radiation doses, including CT confirmation for study purposes only in the US group, were 27.55 mGy*cm (one level) and 32.5 mGy*cm (two levels) for US-guided interventions, versus 88.2 mGy*cm (one level) and 205 mGy*cm (two levels) for CT-guided procedures. US guidance

<table>
<thead>
<tr>
<th>LEVELS</th>
<th>CT-guided</th>
<th>US-guided</th>
</tr>
</thead>
<tbody>
<tr>
<td>One level injected</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Two levels injected</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>C2/3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>C3/4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>C4/5</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>C5/6</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>C6/7</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>C7/Th1</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

NOTE. Gender, age, BMI and VAS are reported as mean ± standard deviation. Other values are numbers of patients for each subgroup. There were no significant differences between the groups (p>0.05)
showed a significant DLP saving for one- (p<0.05) and two-leveled (p<0.05) injections. Both groups showed a significant benefit from inter-articular injections 30 minutes (p<0.05) and one month (p<0.05) after the injection: 30 minutes post-interventional there was a mean VAS reduction of 72% (one level) and 69% (two levels) in the US group versus 50% (one level) and 52% (two levels) in the CT group. One month post-interventional, US guidance showed a mean VAS reduction of 91% (one level) and 50% (two levels) versus 59% (one level) and 55% (two levels) under CT guidance (table II). There were no significant differences between the US and CT groups (p>0.05) after two-leveled injections (table II). However, there was a procedure-dependent benefit for the US group with one-leveled injections (p<0.05).

There were no complications or unexpected side effects.

**Discussion**

The aim of this study was to demonstrate and to compare accuracy, efficacy, time saving, radiation doses, safety and pain relief of US-guided intra-articular facet joint injections in the middle to lower cervical spine to CT-guided interventions in a prospective randomized clinical trial. Although the pain relief was significant after a 30-minute- and one-month follow-up in both groups and a possible significance of an inter-modality difference was assessed in a prospective randomized manner, the study was neither intended to evaluate the overall effectiveness of intra-articular injected steroids (as in a drug study) nor to compare intra-articular injections to medial branch blocks, which are popular as well.

According to clinical studies evaluating lumbar facet joint and lumbar periradicular injections under US-guidance and according to anatomical studies in which accuracy of US-guided cervical facet joint injections has been analyzed, the present study demonstrated that in 100% of the performed US-guided procedures the needle placement was correct, as the procedure mainly relied on the visibility of cervical facet joints [1,13-17,20-22]. The study population showed BMI-values ranging up to 33.2 and different anatomical conditions, e.g. short necked patients.

An important consideration is that all cervical injection therapies can be technically challenging, as accidental puncture of paraspinal vessels may lead to severe and irreversible spinal complications [24-29]. This is particularly relevant for cervical injections performed under fluoroscopic control, where the needle placement is more or less a blind flight until contrast agent is administered [27,30]. Following current recommendations for cervical spinal injections, the application of contrast agent under real-time digital subtraction fluoroscopy should thus be

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**Table II. Results**

<table>
<thead>
<tr>
<th></th>
<th>CT-guided</th>
<th>US-guided</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time (min:sec)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One level</td>
<td>11:12 (± 03:43)</td>
<td>04:46 (± 02:49)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Two levels</td>
<td>14:32 (± 02:58)</td>
<td>05:49 (± 02:16)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><strong>Radiation dose (mGy*cm)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One level</td>
<td>88.2 (± 58.2)</td>
<td>27.6 (± 21.4)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Two levels</td>
<td>205.0 (± 199.7)</td>
<td>32.5 (± 29.2)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><strong>Needle repositions (total)</strong></td>
<td>13</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1 repositions</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 repositions</td>
<td>6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 repositions</td>
<td>2</td>
<td>&lt;0.05</td>
<td></td>
</tr>
<tr>
<td>4 repositions</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VAS reduction (30 min)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One level</td>
<td>50.1 % (± 13.8)</td>
<td>72.0 % (± 14.0)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Two levels</td>
<td>52.0 % (± 19.7)</td>
<td>69.2 % (± 19.7)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td><strong>VAS reduction (1 month)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One level</td>
<td>58.6 % (± 44.7)</td>
<td>91.3 % (± 24.5)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Two level</td>
<td>55.3 % (± 40.0)</td>
<td>50.3 % (± 40.3)</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

NOTE. Time, radiation dose and VAS reduction are reported as mean ± standard deviation. Other values are numbers of patients for each subgroup.
performed to reduce the risk of unintentional injection in such paraspinal, e.g. radicular, vessels [27]. In the present US technique, the advantage of utilizing a real-time “in-plane” needle access from dorsal is striking: any relevant vessel is so avoided, as – based on normal topography – none usually crosses the needle pathway. Also, if the target is clearly visible under US guidance, no further radiographic control and no systemic application of contrast agents or other ionizing modalities are necessarily required. In this context, the use of Duplex-mode US imaging as a further guidance tool is conceivable, but was not used in the present study because of its questionable additional benefit.

In this trial, CT controls in the US group were performed only for study purposes. The recordings of these DLPs showed that the mean radiation dose in the US group was significantly lower than the mean dose of patients who had undergone CT-guided-only interventions, which implies a benefit of US guidance even if performed with subsequent CT control (maybe due to forensic necessities). Although the necessary radiation dose for single CT-guided intervention may be rather low, our study showed that cumulative effects have to be taken into account, as some CT-guided instillations in our trial required up to four CT scans. For such repeated and multilevel injections, which are quite popular, US guidance would be the recommended procedure.

A further benefit of US guidance is that it helps to minimize the risk of unexpected side effects, as those are often associated to the application of contrast agents required for the positioning control under CT- or fluoroscopy-guided procedures. The fact that US-guided injections can be performed rather easily is mostly based on the direct depiction of the structures of interest, i.e. cervical facet joints, by US. Thus, with a little exercise, a needle can be advanced to the target structure itself in just a few seconds under safe and real-time controlled conditions [1,13,16]. If such an intervention is performed under CT-guidance, calculations on access angles and entry points of the needle are based on landmarks, followed by an actually blind needle-positioning which is then controlled by a subsequent scan and often followed by multiple repositions. Control scans, if necessary, are potentially harming to the patients, as described above, but are also laborious and costly compared to the US procedure presented here. US-guided facet joint instillations may even be performed very efficiently under “bed-side” conditions, e.g. in outpatients. This saves time and resources, as US is comparatively inexpensive and broadly available, and does not imply any therapeutic compromises for the patient, as accuracy is obviously sufficient for the purpose described here [13].

According to the analysis on increasing numbers and costs of spinal injection therapies, published by Carrino et al 2002 [11], the overall cost-effectiveness of cervical instillations must be evaluated as well. This is however beyond the scope of this study.

Limitations

Limiting factors might be that outcome was only measured by patient satisfaction and that the long-term follow-up was only performed four weeks after the instillation.

Conclusion

The US-guided facet joint injection in the middle and lower cervical spine is accurate, feasible, and bears minimal risk. It results in a significant pain reduction, not different from CT-guided instillations. Additionally, a reduction of time, radiation dose and resources is highly evident. However, as with any form of instillation therapy needing practice for good results, a specific and mandatory learning curve to achieve good visualization and guidance of the instillation needle has to be taken into account with US guidance. Upcoming projects are supposed to evaluate this and the value of the US-guided procedure during daily routine.

Conflict of interest: none

References