Ultrasound-guided versus computed tomography-controlled periradicular injections in the middle and lower cervical spine: a prospective randomized clinical trial

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Abstract

Purpose We conducted this study to evaluate accuracy, time saving, radiation doses, safety, and pain relief of ultrasound (US)-guided periradicular injections versus computed tomography (CT)-controlled interventions in the cervical spine in a prospective randomized clinical trial.

Methods Forty adult patients were consecutively enrolled and randomly assigned to either a US or a CT group. US-guided periradicular injections were performed on a standard ultrasound device using a broadband linear array transducer. By basically following the osseous landmarks for level definition in “in-plane techniques”, a spinal needle was advanced as near as possible to the intended, US-depicted nerve root. The respective needle tip positioning was then verified by CT. The control group underwent CT-guided injections, which were performed

under standardized procedures using the CT-positioning laser function.

Results The accuracy of US-guided interventions was 100 %. The mean time to final needle placement in the US group was $02:21 \pm 01:43$ min:s versus $10:33 \pm 02:30$ min:s in the CT group. The mean dose-length product radiation dose, including CT confirmation for study purposes only, was 25.1 ± 16.8 mGy cm for the US group and 132.5 ± 78.4 mGy cm for the CT group. Both groups showed the same significant visual analog scale decay ($p < 0.05$) without “inter-methodic” differences of pain relief ($p > 0.05$).

Conclusions US-guided periradicular injections are accurate, result in a significant reduction of procedure expenditure under the avoidance of radiation and show the same therapeutic effect as CT-guided periradicular injections.

Keywords Periradicular injections · Cervical spine · Ultrasound · Computed tomography · Radiculopathy

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Introduction

Cervical radiculopathy caused by disk herniation or cervical spondylosis is a common entity in clinical practice. At least transient cervical radiculopathy occurs in almost 40 % of the population at some time during their lives [1, 2]. In 10–20 % of these patients, radiculopathy becomes unremitting—despite oral corticosteroid dose packs, non-steroidal anti-inflammatory drugs, and nonspecific physical therapy measures [3]. When conservative treatment fails, interventional treatment may be considered. In cases of clear neurologic deficit or associated myelopathic signs, surgical intervention is recommended [3]. Evidence supports the efficacy and the safety of interlaminar cervical

epidural corticosteroid injections for subacute cervical radicular pain without neurological symptoms [4].

The reasons to permit injections via a transforaminal route rather than the interlaminar route are to deliver the injectate directly at the target nerve, periradicularly near the ganglion of spinal nerve, to ensure that the medication reaches the region of interest in maximum concentration [5]. Because of the anatomy of the cervical spine, cervical transforaminal injections may be technically challenging, and associated with potential morbidity and mortality [5]. Currently, procedures for cervical periradicular injections are preferentially radiographically controlled interventions [2, 6]. In the past, ultrasound (US) has been demonstrated to facilitate the localization and imaging of peripheral nerves, spinal nerve roots and also bony parts of the spine such as facet joints. US-guided approaches tailored for spinal interventions are already available, but only proven for their topographic feasibility [7–11].

The aim of this study was to show the feasibility and accuracy of a methodological US-based approach [12–15] and to analyze possible differences concerning procedure time, radiation dose, and pain relief for periradicular injections in the middle to lower cervical spine in a prospective randomized clinical trial.

Materials and methods

The study protocol of this prospective randomized analysis was reviewed and approved by the Ethical Committee of the Innsbruck Medical University (IMU) (Study Number UN3269). The patient selection was performed consecutively during daily routine at the Department of Neurosurgery (IMU) and was performed on the basis of standard neurological diagnostics and clinical methods by neurosurgical specialists. Forty adult patients (19 women and 21 men) were prospectively enrolled after given written informed consent. All subjects had to fulfill the following inclusion criteria: (1) subacute to chronic radiculopathy of the middle or lower cervical spine, (2) availability of a

recent computed tomography (CT) or magnetic resonance imaging (MRI) study of their cervical spine, and (3) at least 18 years of age. Exclusion criteria were (1) neurological deficit, (2) local or systemic infections and/or discitis, (3) running anticoagulation therapy or uncorrectable coagulopathy, (4) allergies to steroids, anesthetics or contrast agents, (5) diabetes, (6) pregnancy, and (7) spinal tumors. After recording of the subjects' demographic data, preceding surgeries, body mass index (BMI), and visual analog scale (VAS) score regarding their radiculopathic pain, patients were assigned to one of two groups by chance, using a computer-generated randomization table. One group consisted of candidates for ultrasound-guided infiltrations (US group), the other group consisted of candidates for computed tomography (CT group). In order to ensure patient safety, the study was planned to be aborted if the target was not visible in more than two patients of the US group, or if CT control scans showed an incorrect needle position after a US-guided intervention in more than two subjects.

Ultrasound-guided procedure

Ultrasound interventions were performed with a standard ultrasound device (iU22; Philips Ultrasound, Bothell, WA, USA), using a 12–5 MHz broadband linear array transducer, and were performed by a radiologist having relevant experience of more than 10 years in musculoskeletal US imaging including intervention. 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 recording was started at the moment the investigator touched the skin with the probe for the first time. Following the systematic osseous landmark based procedure, the root of interest was sought with a paraxial scan orientation, and the sonographer classified the target as clearly visible, partially visible or invisible. If clearly or partially visible, a spinal needle (20 GA 3.00 IN, 0.9×75 mm; BD Spinal Needle, Becton–Dickinson, Madrid, Spain) was inserted from dorsal exactly within the scanning plane (Figs. 1, 2).

Fig. 1 US-guided periradicular injection for the 6th cervical nerve root (**a**); *at* tuberculum anterior, *pt* tuberculum posterior, *ARROW* needle pathway, *C6* 6th nerve root, *detected vessel; and CT control (**b**)

When the sonographer was sure to have placed the needle tip within 5 mm of the targeted root, the time recording was stopped. Then—to objectify sonographer's work for study purposes—the accuracy of the positioning was verified with a subsequent CT scan (Somatom—Sensation Open, Siemens, Erlangen, Germany). If the sonographer classified the target as partially visible, the duration of this CT scan was included in the procedure time measurement, as the needle placement was deemed not to have been completed by US alone. 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 (4 mg) of betamethasone (CELESTAN®

Fig. 2 Illustration showing sonographer's hand position and the placement of the spinal needle—inserted from dorsal exactly within the scanning plane of the US probe (▼)

solubile 4 mg; essex-pharma GmbH, Munich, Germany) was injected. In cases where the needle tip was not in its correct position, a replacement under US guidance followed by CT control was scheduled—also under time commissioning. If the target was classified as not visible, the US procedure was—according to the study protocol—planned to be stopped and the intervention to be completed under CT guidance.

Computed tomography-controlled procedure

The CT-guided interventions were performed using the same CT device as for the control of the US procedures and was performed by a radiologist with more than 10 years of relevant experience in CT-guided interventions. After placing the candidates in supine or lateral position, a radio-opaque marker was positioned on the skin of the area of interest, and a venous access was placed to bring in contrast agent for a better depiction of the cervical blood vessels in the CT slices. According to the US procedure, elapsing time recording was started with the initial scan. Topograms of the targeted area were obtained by a low-dose protocol (120 kV, 120 mA) at 3-mm slice thickness for a precise calculation of the intended needle pathway (Fig. 3). The point of entry, the angle, and the depth of approach were defined and calculated. The needle entry point was marked on the patient's skin using the obtained calculations and the CT-positioning laser function. Subsequently, a spinal needle (20 GA 3.00 IN, 0.9×75 mm; BD Spinal Needle, Becton–Dickinson, Madrid, Spain) was advanced toward the nerve root of interest, according to the preliminary calculations. To monitor the ongoing and final needle tip positions, several CT scans were obtained repeatedly, i.e., for each repositioning, until the needle was esteemed to be in correct position. Until that point the elapsed time was recorded. Then, as in the US procedure,

Fig. 3 CT-guided periradicular injection for the 7th cervical nerve root. **a** CT scout with radio-opaque marker on patient's skin and CT localizer at the level C6/7. **b** Calculations of point of entry, the angle

and depth of the approach. **c** Control scan after final needle placement showing needle tip

1 ml (4 mg) of betamethasone (CELESTAN® soluble 4 mg; essex-pharma GmbH, Munich, 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. To follow-up the clinical benefit, pain due to cervical radiculopathy was assessed via a visual analog scale (VAS) before and 4 weeks after the intervention. Feasibility of the US procedure was defined as percentage of patients with clearly, partially or invisible target (respective cervical root). 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 [16]. 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 4 weeks post-interventional interval. Because of the fact that no local anesthetic drugs have been used for the injections, the measurement of immediate pain reduction was not carried out. 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 maximal dropout rate of 20 %. Comparisons between groups were performed with the use of an unpaired *t* test, or in case of nonparametric values with a Mann–Whitney *U* test.

Results

There were no significant demographic or clinical differences between the two randomized groups and in both groups both pathologies (discal herniation and foraminal stenosis) have been treated (Table 1). All subjects (20 patients) of the US group were judged suitable for the US-guided procedure. In 19 of these patients (95 %), the intervention was performed as planned, in one case (5 %) the intervention was aborted because of the patient's missing compliance. In 18 patients (90 %), the targeted osseous landmarks as well as the nerve roots were depicted clearly by US and the needle was positioned as intended, which was confirmed by CT. In one subject (5 %), a female patient with a BMI of 28.7, the nerve root was only partially visible, but the needle was nevertheless positioned correctly using the above-mentioned landmarks. In the US group, no needle had to be repositioned and in no case the procedure had to be finished under CT guidance. In the CT group, a needle reposition was necessary in seven cases (35 %); in three cases, the respective needle position was changed even twice (15 %), and in one case three times

(5 %). Regarding the necessary needle repositions, the US-guided procedure statistically showed a significantly higher accuracy ($p < 0.05$) (Table 2). The mean duration to needle placement was $02:21 \pm 01:43$ min:s for the US group and $10:33 \pm 02:30$ min:s for the CT group (Table 2). The time saving in the US group was significant ($p < 0.05$) (Table 2). The mean radiation dose (DLP) was 25.1 ± 16.8 mGy cm for the US group control scans versus 132.5 ± 78.4 mGy cm for the CT group ($p < 0.05$) (Table 2). Both groups showed a significant benefit from periradicular injection ($p < 0.05$) with no inter-methodical or inter-pathological difference. The mean VAS reduction in the US group was 68 % (± 34 %) versus 51 % (± 46 %) in the CT group. The difference between the two groups was not statistically significant ($p > 0.05$) (Table 2).

Complications

In the CT-guided group, one patient suffered from numbness in the upper extremity after intervention, which was

Table 1 Patient-related pre-interventional data for both groups

	CT-guided	US-guided
Male/female	9/11	12/8
Age (years)	51.9 ± 11.3	49.4 ± 9.6
BMI	25.4 ± 3.5	23.5 ± 7.0
Visual analog score	5.65 ± 2.1	6.83 ± 1.74
Levels		
C5	2	1
C6	7	10
C7	6	7
C8	5	1
Pathologies		
Discal herniation	11	13
Foraminal stenosis	9	7

Gender, age, BMI and VAS are reported as mean $\pm$ standard deviation

Other values are numbers of patients for each subgroup

There were no significant differences between the groups ($p > 0.05$)

Table 2 Results

	CT-guided	US-guided	<i>p</i> value
Time (min:s)	$10:33 \pm 02:30$	$02:21 \pm 01:43$	<0.05
Radiation dose (mGy cm)	132.5 ± 78.4	25.1 ± 16.8	<0.05
Needle repositioning	11	0	<0.05
VAS reduction	51 % (± 46)	68 % (± 34)	>0.05

Time, radiation dose, and VAS reduction are reported as mean $\pm$ standard deviation

Other values are numbers of patients for each subgroup

self-limiting within 1 week. Another subject showed nausea, vertigo, and flush reaction immediately after the CT-guided intervention. It was not clear if these symptoms were a side effect of steroids or of the contrast agent. There were no unexpected side effects or complication during the US-guided interventions.

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 periradicular injections in the middle to lower cervical spine to CT-guided Interventions. Although the pain relief was significant after a 1-month follow-up in both the US and CT groups and a possible significance of an inter-modality difference was assessed in a prospective manner, the study was not intended to evaluate the overall effectiveness of periradicular injected steroids (as in a drug study). The study demonstrated that in 100 % of our US-guided procedures the intended needle placement was correct, as the procedure was mainly relying on the visibility of cervical nerve roots.

An important consideration is that all cervical injection therapies can be technically challenging, as accidental puncture of pararadicular vessels may lead to severe and irreversible spinal complications [17–23]. That 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 [17–19]. Following current recommendations for cervical periradicular injections, the application of contrast agent under real-time digital subtraction fluoroscopy should, thus, be performed to reduce the risk of unintentional injection in such pararadicular vessels [19, 20, 23]. 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 cross the needle pathway. In addition, if the target is clearly visible under US guidance, no further radiographic control and no systemic application of contrast agents or other ionizing modality are necessarily required. In this context, the use of Duplex-mode US imaging—which was not used in the present study—has been shown to be a further guidance tool for injections near potential feeder vessels to the cord or brainstem and might additionally help to minimize the risk of rare but devastating complications [24].

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 interventions solely, 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 one 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 needed up to four CT scans. For such repeated and multilevel injections, which are quite popular, US guidance would be the recommended procedure. Accuracy of final needle placement was shown to be the same in both groups, but especially the missing real-time visualization under CT guidance and the resulting number of needle repositions and rescans are one of major disadvantages of the CT-guided 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 periradicular injections can be performed rather easily is mostly based on the direct depiction of the structures of interest, i.e., cervical roots, 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 [10, 12]. 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 periradicular 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 [10].

According to the analysis on increasing numbers and costs of lumbar injection therapies, the overall cost-effectiveness of cervical injections must be evaluated as well [25]. This is however beyond the scope of this study.

Limitations

Because of the small number of subjects, an inhomogeneous distribution of the targeted levels was found in the US group. Another limiting factor might be that outcome was only measured by patients' satisfaction and only 4 weeks after the injection.

Conclusion

The US-guided periradicular injection in the middle and lower cervical spine is feasible, as accurate as the CT-guided injection, and bears minimal risk. It results in as a significant pain reduction not different from CT-guided instillations. Additionally a reduction of time, radiation dose, and resources are 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.

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Conflict of interest The authors declare that there are no conflicts of interest.

References

- Smith MD (1995) Cervical radiculopathy: causes and surgical treatment. *Minn Med* 78:28–50
- Cyteval C, Thomas E, Decoux E, Sarrabere MP, Cottin A, Blotman F, Taourel P (2004) Cervical radiculopathy: open study on percutaneous periradicular foraminal steroid infiltration performed under CT control in 30 patients. *AJNR Am J Neuroradiol* 25:441–445
- Ellenberg MR, Honet JC, Treanor WJ (1994) Cervical radiculopathy. *Arch Phys Med Rehabil* 75:342–352
- Van Zundert J, Huntoon M, Patijn J, Lataster A, Mekhail N, van Kleef M (2010) 4. Cervical radicular pain. *Pain Pract* 10:1–17
- Benny B, Azari P, Briones D (2010) Complications of cervical transforaminal epidural steroid injections. *Am J Phys Med Rehabil* 89:601–607
- Vallee JN, Feydy A, Carlier RY, Mutschler C, Mompoin D, Vallee CA (2001) Chronic cervical radiculopathy: lateral approach periradicular corticosteroid injection. *Radiology* 218:886–892
- Galiano K, Obwegeser AA, Bodner G, Freund M, Maurer H, Kamelger FS, Schatzer R, Ploner F (2005) Real-time sonographic imaging for periradicular injections in the lumbar spine: a sonographic anatomic study of a new technique. *J Ultrasound Med* 24:33–38
- Loizides A, Gruber H, Peer S, Brenner E, Galiano K, Obernauer J (2011) A new simplified sonographic approach for paravertebral injections in the lumbar spine: a CT-controlled cadaver study. *AJNR Am J Neuroradiol* 32:828–831
- Loizides A, Gruber H, Peer S, Galiano K, Bale R, Obernauer J (2013) Ultrasound guided versus CT-controlled paravertebral injections in the lumbar spine: a prospective randomized clinical trial. *AJNR Am J Neuroradiol* 34:466–470
- Galiano K, Obwegeser AA, Bodner G, Freund MC, Gruber H, Maurer H, Schatzer R, Fiegele T, Ploner F (2006) Ultrasound-guided facet joint injections in the middle to lower cervical spine: a CT-controlled sonoanatomic study. *Clin J Pain* 22:538–543
- Galiano K, Obwegeser AA, Bodner G, Freund M, Maurer H, Kamelger FS, Schatzer R, Ploner F (2005) Ultrasound guidance for facet joint injections in the lumbar spine: a computed tomography-controlled feasibility study. *Anesth Analg* 101:579–583 (table)
- Galiano K, Obwegeser AA, Bodner G, Freund MC, Gruber H, Maurer H, Schatzer R, Ploner F (2005) Ultrasound-guided periradicular injections in the middle to lower cervical spine: an imaging study of a new approach. *Reg Anesth Pain Med* 30:391–396
- Narouze SN (2006) Ultrasound-guided cervical periradicular injection: cautious optimism. *Reg Anesth Pain Med* 31:87–88
- Narouze SN, Vydyanathan A, Kapural L, Sessler DI, Mekhail N (2009) Ultrasound-guided cervical selective nerve root block: a fluoroscopy-controlled feasibility study. *Reg Anesth Pain Med* 34:343–348
- Gofeld M (2008) Ultrasonography in pain medicine: a critical review. *Pain Pract* 8:226–240
- Lachin JM (2000) Statistical considerations in the intent-to-treat principle. *Control Clin Trials* 21:167–189
- McLean JP, Sigler JD, Plastaras CT, Garvan CW, Rittenberg JD (2009) The rate of detection of intravascular injection in cervical transforaminal epidural steroid injections with and without digital subtraction angiography. *PMR* 1:636–642
- Jasper JF (2003) Role of digital subtraction fluoroscopic imaging in detecting intravascular injections. *Pain Physician* 6:369–372
- Verrills P, Nowesentz G, Barnard A (2010) Penetration of a cervical radicular artery during a transforaminal epidural injection. *Pain Med* 11:229–231
- Windsor RE, Storm S, Sugar R, Nagula D (2003) Cervical transforaminal injection: review of the literature, complications, and a suggested technique. *Pain Physician* 6:457–465
- Baker R, Dreyfuss P, Mercer S, Bogduk N (2003) Cervical transforaminal injection of corticosteroids into a radicular artery: a possible mechanism for spinal cord injury. *Pain* 103:211–215
- Huntoon MA (2005) Anatomy of the cervical intervertebral foramina: vulnerable arteries and ischemic neurologic injuries after transforaminal epidural injections. *Pain* 117:104–111
- Brouwers PJ, Kottink EJ, Simon MA, Prevo RL (2001) A cervical anterior spinal artery syndrome after diagnostic blockade of the right C6-nerve root. *Pain* 91:397–399
- Narouze SN (2012) Ultrasound-guided cervical spine injections: ultrasound “prevents” whereas contrast fluoroscopy “detects” intravascular injections. *Reg Anesth Pain Med* 37:127–130
- Carrino JA, Morrison WB, Parker L, Schweitzer ME, Levin DC, Sunshine JH (2002) Spinal injection procedures: volume, provider distribution, and reimbursement in the U.S. medicare population from 1993 to 1999. *Radiology* 225:723–729