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Evaluation of a Robotic Assistance-System For Percutaneous Computed Tomography-Guided (CT-Guided) Facet Joint Injection: A Phantom Study

Authors' Contribution:

Study Design A Data Collection B

Statistical Analysis C

Data Interpretation D

Manuscript Preparation E

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Background:

The aim of this study was to compare robotic assisted and freehand facet joint puncture on a phantom mod-

el in regards to time requirements and puncture accuracy.

Material/Methods:

Forty facet joints were punctured, 20 using a robotic guidance system and 20 using a freehand procedure. Side and height of the facet joints were randomized and identical for both groups. Procedural accuracy, defined as axial and sagittal deviation, as well as the number of corrections were assessed. Procedure times for each step were documented and time requirements for pre-positioning, reconstruction, planning, and total intervention were calculated.

Results:

Total procedure time for robotic guidance was 259±111 seconds versus 119±77 seconds for freehand procedure (p=1.0). Procedural accuracy for robotic guidance was significantly higher with 0 corrections versus 1.3 corrections for freehand procedure (p=0.02). Needle deviation in the robotics arm was 0.35 ± 1.1 mm in the axial and 2.15±1.2 mm in the sagittal reconstruction.

Conclusions:

Robotic assisted puncture of the facet joint allowed accurate positioning of the needle with a lower number of needle readjustments. Higher procedural accuracy was marginally offset by a slightly longer intervention time.

MeSH Keywords:

Pain Management • Radiology, Interventional • Robotics

Full-text PDF:

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Background

According to the 2010 Global Burden of Disease study, lower back pain causes more morbidity than any other conditions. It globally ranks first in the YLD (years lived with disability) ranking and is responsible for 83.0 million DALYs (disability-adjusted life years). In the upcoming years, the number of people with lower back pain will likely increase because of the ageing population [1].

Facet joint injection (FJI) defined as the precise installation of local anaesthetic and/or corticosteroid into a facet joint or around its nerve supply with the aim to relieve both pain and inflammation is a common treatment option in the case of lower back pain. FJI is commonly used in clinical practice and for the patient often is considered the last hope for pain improvement [2]. Good clinical outcome is highly dependent on accurate deposition of the anaesthetic and/or corticosteroid. This may partially explain the varied outcomes reported from different FJI studies. Recently, new procedures using laser or electromagnetic tracking, have been introduced [3,4] to allow for better needle placement during FJI.

Image CT-guided, robotic assisted interventions may allow for higher FJI accuracy, therefore lower complication rates and achieving higher clinical efficacy. Robotic navigation might also reduce radiation dose exposure and procedure time, because fewer control scans need to be performed [5,6].

Hence, this phantom model study aimed to investigate the benefits of CT-guided, robotic assisted facet joint puncture compared to the conventional freehand approach.

Material and Methods

Study design

In this phantom model study, we performed 40 facet joint punctures, 20 using a robotic targeting system and 20 using a freehand procedure, controlled by stepwise CT-scans. The primary endpoint of the study was the time required from planning the CT scan to the correct intra-articular placement of the 21-gauge puncture needle. Secondary endpoints were the accuracy of the needle placement, measured as axial and sagittal deviation, and the number of required needle adjustments.

Prior to the acquisition of a lateral topogram (Somatom Sensation 16, Siemens Healthcare, Forchheim, Germany), the phantom model (Siemens Healthcare, Forchheim, Germany) was immobilized in a vacuum fixation system (iSYS Medizintechnik GmbH, Kitzbühl, Austria). Segment and side of the punctured facet joints were randomized but identical for robotic navigated



Figure 1. Setup of the study with the phantom device, the robotic device, and the workstation.

approach and freehand approach. An experienced interventional radiologist (more than 200 facet joint punctures per year) carried out the procedures. Time requirements, number of corrections, and needle deviation were documented in an Excel spreadsheet.

Robotic assisted puncture

For robotic-assisted puncture the iSYS 1.3 (iSYS Medizintechnik GmbH, Kitzbuehel, Austria) robotic targeting system was used. The phantom model and vacuum fixation system were mounted on a holding platform and placed on the CT examination table. An adjustable multifunctional arm with the connected robotic device was attached to the holding platform. The mobile CT workstation, which was connected to the local network, was placed next to the examination table (Figure 1).

In order to manually pre-position the robotic targeting system at the approximate position of the percutaneous entry point, a lateral topogram was acquired, which was used to define the height of the facet joint in the z-axis. The examination table was moved to the defined height and, using the gantry laser, the robot was manually locked into position at the presumable percutaneous entry point. After positioning of the device, a CT scan was acquired and sent to the workstation, where an automatic registration of the robotic device and its 13 radio-opaque markers was performed by the navigation software (RoboNav, MedCom Gesellschaft für medizinische Bildverarbeitung GmbH, Darmstadt, Germany). The robotic device has a range of motion of ± 2 cm in both axes and of -32° in every direction. The navigation software displays all reachable target and entry points, determined by the registered position of the robotic device (Figure 2). Target and percutaneous entry points were defined by the physician. Afterwards, the needle guidance of the robot was moved into position. The needle was then manually placed through the needle guidance, whereby the depth of the needle was calculated after defining

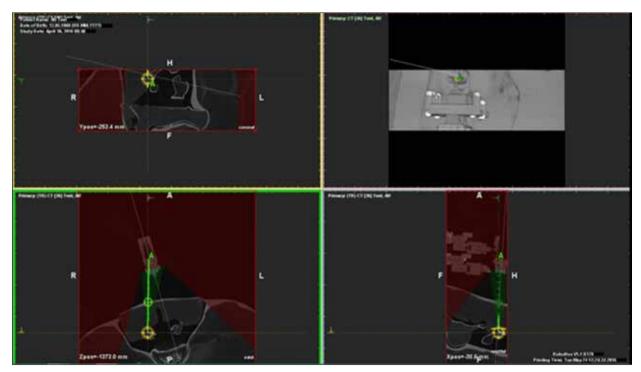


Figure 2. Planning screen of the workstation. Reachable target and entry points are automatically calculated based on the registration of the robotic device and can be set within the green conic field.

the target and entry point. After injection, another CT scan was performed and sent to the workstation. Axial and sagittal deviation between planned and conducted punctures were noted.

Free hand puncture

According to the navigated puncture, a lateral topogram was acquired to define the height of the facet joint. A grid was placed on the presumed percutaneous entry point and a CT scan was acquired. The percutaneous entry point and the needle trajectory were planned by the physician at the CT workstation. The examination table was moved to the defined position. The gantry laser marked the height of the facet joint and the needle was placed freehand. A 3-slice biopsy scan was performed to control the position of the needle. If not placed intra-articular, the position of the needle was corrected and another biopsy scan was performed stepwise until the facet joint was reached.

Time requirements

During robotic assisted and freehand needle placement procedures, the times were documented (Figure 3). The following time intervals were calculated for the robotic assisted procedure: time required for pre-positioning of the robotic device, time required for reconstruction, time required for transfer to the workstation (measured from the CT scan to the start of the planning), and time required for planning needle trajectory

at the robotic workstation. Total intervention time (measured from the CT scan until the final needle position was reached) was calculated for robotic assisted and freehand procedure.

Statistical analysis

The JMP statistics software package (SAS Institute, Cary, NC, USA) was used to perform all statistical calculations. The Shapiro-Wilk test was used to assess the normality of the distribution of investigated parameters. Data are expressed as mean \pm standard deviation (SD). Differences between total intervention times were compared using the paired t-test, reported with degrees of freedom in parentheses, the t statistic, and the significance level. The number of required needle corrections were compared using Pearsons' chi-squared test, reported with degrees of freedom and sample size in parentheses, the Pearson chi-square value, and the significance level. A p-value of $p \le 0.05$ was considered the cut-off point of statistical significance.

Results

Segment and side of the punctured facet joint are listed by their frequency in Table 1.

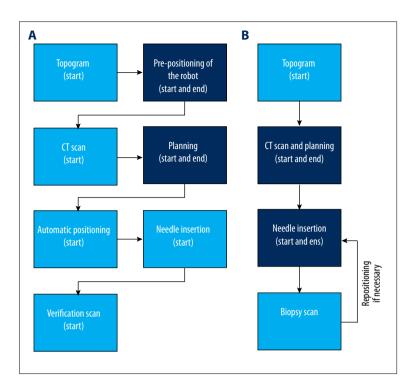


Figure 3. Workflow of the robotic-assisted (A) and freehand approach (B) with the documented time points

Table 1. Identical segment and side of the punctured facet joint for robotic assisted and freehand technique.

Segment	Left side	Right side
L1	2	2
L2	2	1
L3	0	3
L4	3	4
L5	2	1

The facet joint was reachable by the robotic device after initial pre-positioning in all cases (20 of 20, 100%), no position adjustments after the registration were necessary.

Table 2 shows the measured time intervals in seconds. Differences between the total intervention time were not significant (t (19)=4.64, p=1.0). Using the robotic device, the facet joint was reached within the first puncture in all cases (20 of 20, 100%; Figure 4). For the freehand approach, a maximum of four corrections was necessary (median, 1 correction), the frequencies are shown in Table 3. The number of required corrections was significantly greater in the freehand group (c^2 (4, N=40)=11.61, p=0.02).

In the robotic assisted group, the mean deviation from the planned trajectory to the documented needle position was: 0.35 ± 1.1 mm (minimum 2, maximum 3) in the axial

Table 2. Measured time spans in seconds in robotic assisted and freehand approach.

Time span	Robotic assisted (sec)	Freehand (sec)
Device pre- positioning	57±20 (min. 23, max. 97)	-
CT reconstruction	130±66 (min. 42, max. 314)	-
Trajectory planning	70±36 (min. 29, max. 189)	-
Total intervention time	259±111 (min. 118, max. 517)	119±77 (min. 40, max. 344)

and 2.15 ± 1.2 mm (minimum 0, maximum 4) in the sagittal reconstruction.

Discussion

Nowadays, injections into the facet joint are performed using a freehand technique and under CT control. Hence, frequent repositioning of the needle is necessary. This causes higher radiation doses for the patients and increases their risk for related complications [7]. Correspondingly, we observed up to four needle repositions with a median of one in our study.

Robotic assisted punctures on the other hand have been associated with higher accuracy compared to the freehand

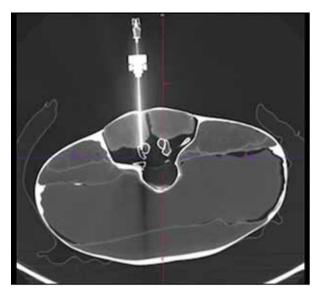


Figure 4. Verification scan showing correct intra-articular needle placement in the robotic-assisted group.

Table 3. Frequency of required needle corrections resp. biopsy scans in the freehand approach.

Number of required corrections	Frequency
0	11
1	4
2	2
3	2
4	1

technique, especially for complex needle trajectories [8]. With fewer readjustments, the required radiation dose can also be reduced [9]. Our study confirmed these results; using the robotic guidance system, the needle was placed intra-articular at the first attempt and no repositioning of the needle was required. Exact positioning of the needle intra-articular with minimal axial and sagittal deviation might increase therapeutic efficiency. Further studies with patients have to be conducted to confirm this benefit.

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The intervention time was longer, although not significantly, using the robotic guidance system. On average, the procedure took 259 seconds (minimum 118 seconds, maximum 517 seconds) within the robotic assisted group, and 119 seconds (minimum 40 seconds, maximum 344 seconds) when performed freehand. This difference might be explained by the long reconstruction times, which were primarily caused by the required 1 mm CT slice thickness and the low computing power of our CT scanner. The planning itself, defining target and entry point within the reachable range of the robot, took on average only 70 seconds. In no case did the robot have to be re-pre-positioned because the target could not be reached.

Even though the procedure took longer using the robotic guidance system, it is, with approximately four minutes, still fast and a recommendable technique especially for inexperienced interventional radiologists.

The study had several limitations, being a phantom model study the high accuracy reached within the robotic assisted group might not be reached in a real world patient setting. A further limitation was that only one interventional radiologist performed all robotic assisted and freehand punctures. Especially the freehand puncture is highly depend on the experience of the interventional radiologist and might therefore vary considerably.

Conclusions

The high accuracy achieved when using the robotic targeting system can allow even an inexperienced interventional radiologist to place the needle intra-articular without repositioning. We believe this advantage outweighs the fact that the robotic intervention takes slightly longer.

Conflict of interest

No conflict of interest to declare.

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