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Comparison of clinical outcomes of ultrasonography-guided and blind local injections in facet syndrome: A 6-week randomized controlled trial

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Abstract.
BACKGROUND: Facet syndrome is defined as pain that arises from any structure of the facet joints, including the fibrous capsule, synovial membrane, hyaline cartilage, and bone.
OBJECTIVES: To compare the effectiveness of US-guided and blind injections on clinical outcome in facet syndrome.
MATERIALS AND METHODS: Forty-seven patients with the diagnosis of facet syndrome were included. Patients were consecutively randomized into one of the two groups. The patient's history, physical examination and routine laboratory parameters were obtained and diagnose was established based on physical findings. Two injections (mixture of 2 ml of 1% lidocaine hydrochloride and 20 mg of triamcinolone, to a single or maximum two sites depending on the clinical characteristics of the facet joint) were performed with 15 days apart, as blinded or US-guided manner. Clinical outcome assessments were carried out at 0, 2nd and 6th weeks, using Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and State-Trait Anxiety Inventory (STAI).
RESULTS: The patients' initial VAS and ODI were not significantly different. When the two groups were compared in the 6th week in terms of VAS scores, improvement was more pronounced in the US-guided injection group (US-guided group ($n = 23$) before 7.6 (2.2) cm, after 3.0 (1.7) cm $P = 0.0001$ vs blind group ($n = 24$) before 7.2 (1.3) cm, after 5.2 (2.0) cm, $P = 0.0001$). The improvement in initial and 6th week ODI was statistically significant in the US-guided injection group ($P = 0.006$). Except STAI I for US-group, trait anxiety scale scores was significant in both groups.
CONCLUSION: The US-guided local injections offer better clinical outcome in the treatment of facet syndrome.

Keywords: Facet joint, injection, ultrasound, low back pain

1. Introduction

Facet syndrome is defined as pain that arises from any structure of the facet joints, including the fibrous capsule, synovial membrane, hyaline cartilage, and bone. The prevalence rate ranges between 5% and 15% of the population with axial low back pain. Because arthritis is a prominent cause of facet joint pain, the prevalence rate increases with age [1].

Ultrasound (US) is becoming increasingly important in visualizing the musculoskeletal system [2]. It is used as a diagnostic guide and in local injection procedures but is less frequently applied in visualizing deep joints and injections [3]. Local injections are a good alterna-

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tive in medical treatment for soft tissue disorders. That effectiveness is enhanced if these are accompanied by imaging. US is a very good guide for local procedures in the musculoskeletal system [2–4].

Facet syndrome treatment consists of conservative and interventional approaches [5,6]. Local steroid injections are widely used in the treatment of facet syndrome. This procedure is generally performed accompanied by fluoroscopy and computerized tomography (CT) [7]. However, these procedures expose patients to radiation and also increase costs [8]. One contemporary study compared fluoroscopy and US as guides in steroid injection to the facet joint, and reported similar outcomes from both [9].

Well-designed studies are needed for accurate patient selection and the development of appropriate procedures for the application of US in the lumbar region. Therefore, this prospective study was aimed to evaluate the effectiveness of US-guided facet joint injections and to compare them with blinding injection in lumbar facet syndrome.

2. Material and methods

Forty-nine patients diagnosed with facet syndrome were randomized into two groups according to the order of admission to the outpatient clinic. A detailed physical examination was performed. Lumbar region movements were measured. Fifteen females and 34 males with clinical diagnosis of chronic low back pain were included in our study. Facet joint injection was performed under US to the patients in group I ($n = 23$), whereas blinded injection was done in group II ($n = 24$). Two of the patients in group I did not complete the study by their will.

The study was approved by the local ethics committee. Written informed consent was obtained from all participants who were included in the study.

Inclusion criteria for the study were as follows: pain for at least 6 weeks, pain extending to gluteal region and thigh, presence of pain with lumbar hyperextension and lateral flexion, paravertebral tenderness at the facet joint localization, negative straight leg raising test and normal neurological examination findings [10].

The exclusion criteria were as follows: being < 20 and $\geqslant 50$ years of age (degenerative osteoarthritis), Body Mass Index (BMI) $\leqslant 30$ kg/m^2 (because of the difficulty in deep tissue imaging), current anticoagulant therapy, malignancy, presence of any scar tissue in the area of application, inflammatory with low back pain, lumbar spine fractures and steroid hypersensitivity.

2.1. Blind facet injection procedure

A mixture of 2 ml of 1% lidocaine hydrochloride and 20 mg of triamcinolone was injected to maximum two sites, detected by palpation depending on the clinical characteristics of the facet joint by 15-day intervals. Patients with single point tenderness received only half a volume of this injection material. This application was performed about 2 cm lateral to the spinous process at L4-5 level (the line joining the superior aspect of the iliac crests posteriorly, Tuffier's lines) [11] and 2.5 cm lateral to the spinous process with a 3–5 cm depth at L5-S1 level. These applications were performed by an experienced physiatrist (İ.B.) with 10 years' experience in the field of spinal diseases and musculoskeletal interventional procedures.

2.2. US evaluation and facet injection procedure

All subjects were examined with commercial, real-time equipment (Esaote, Mylab 60, Genoa, Italy) using a 3- to 8-MHz convex transducer following a standardized scanning method. The patient was placed in prone position with a pillow under the abdomen to decrease lumbar lordosis. Firstly, transverse process was obtained in paramedian sagittal view. Then the probe was moved slightly medial to see the facet joint. The probe was rotated 90 degrees to get the transverse view to scan facet joint better (Fig. 1). Under transverse US imaging of the facet joint, a 22 G spinal needle was inserted lateral to the probe with a 45–60 degrees angle using a direct in-plane technique (under aseptic conditions). The needle was advanced until establishing contact with the bony surface of the facet joint. If there is one point tender, half of the solution was injected [2,12]. US-guided injections were performed by one expert (M.K).

A Visual Analog Scale (VAS) was applied to assess pain, and the State-Trait Anxiety Inventory (STAI) form was applied to determine anxiety levels, both before and after injection. The STAI form used was developed to measure anxiety levels in 1964 and adapted into Turkish by Oner et al. [13]. The STAI consists of two subscales measuring state anxiety (STAI-1) and trait anxiety (STAI-2) levels, containing 20 items each. Items take the form of a Likert-type scale. Total scores from both scales range from 20 to 80 [14].

The Oswestry Disability Index (ODI) was used to determine the degree of disability. The scale consists of 10 items. Each item is rated between 0–5. Total points increases the level of disability increases. The maxi-

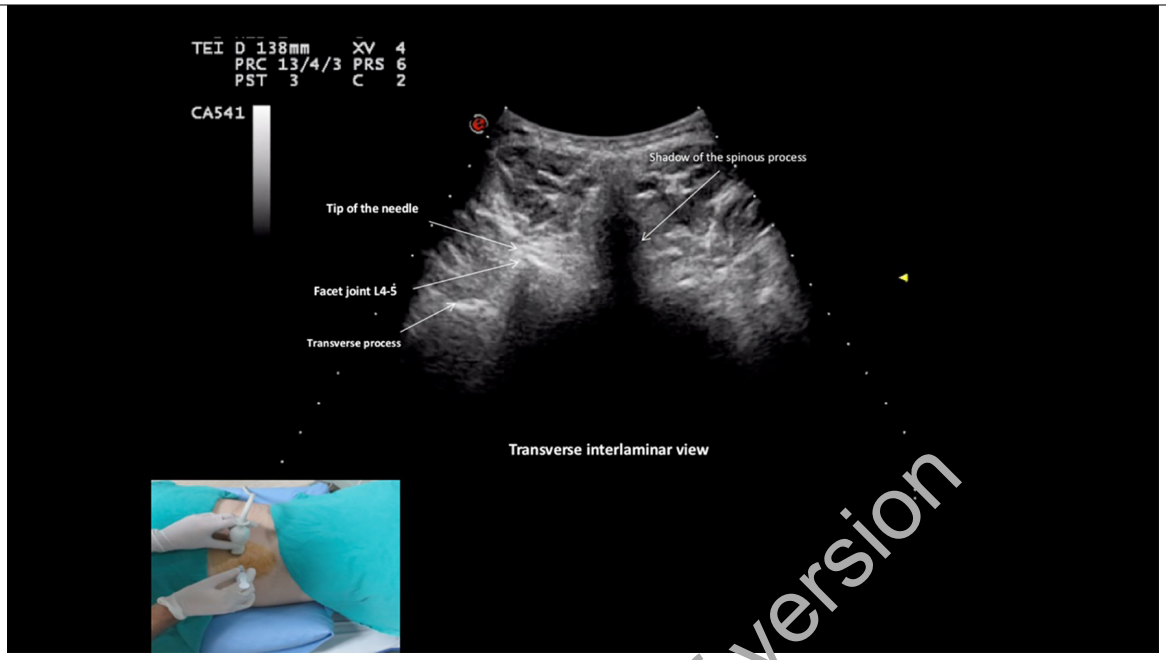

Fig. 1. US-guided injection of the right lumbar 4–5 facet joint. Inset shows the positioning of the probe.

mum score is 50 points; 31–50 points between severe, moderate between 11–30 points, 1–10 points is considered mild. The disability percentage computed by the percentage of total points system obtained from patients [15].

2.3. Statistical analysis

Compatibility with normal distribution of data obtained by measurement was examined using the Kolmogorov Smirnov test. Student's *t* test was used in the comparison of normally distributed data from the two groups, the Mann Whitney-U test for non-normally distributed data, the paired *t* test in the comparison of normally distributed data in repeated measurements within the groups and the Wilcoxon test in the comparison of non-normally distributed data. The chi-squared test was used in the comparison of qualitative data. Measurement data were expressed as mean $\pm$ standard deviation and arithmetical data as percentages (%). Significance was set at $p < 0.05$.

3. Results

The demographic characteristics of the patients are summarized in Table 1.

The baseline VAS values were comparable between the groups ($P = 0.4$). The VAS values were significantly improved after injection in both groups. But, the improvement in VAS score was better in group I compared to group II [(baseline *vs* score at 6th week); 7.6(2.2) cm *vs* 3.0(1.7), $P = 0.0001$ for group 1; 7.2(1.3) cm *vs.* 5.2 ± 2.0 mm, $P = 0.0001$ for group 2, respectively]. The effect on VAS was time-dependent as the difference between the groups I and II became more significant at 6th week post-injection evaluation (see the methods section and Table 2).

The baseline ODI of the groups were comparable ($P = 0.4$). The ODI were significantly improved after injection in both groups, being more prominent in group I ($P = 0.006$ for group 1; $P = 0.178$ for group II, Table 2).

When the groups were compared with regard to the STAI 2 questionnaire scores; statistically significant improvement was obtained in both groups. However, the improvement in STAI 1 scores was significant only for the group II.

4. Discussion

The results of this study indicates that the US-guided local injections have a potential to provide better clinical outcome in the treatment of facet syndrome as evident by VAS and ODI.

The treatment of facet syndrome consists of conservative and interventional approaches. The interven-

Table 1
The demographic characteristics of the patients

Characteristics	Group I ($n = 23$)	Group II ($n = 24$)	P
Age, mean (SD), yrs	38.2(11.6)	37.1(9.1)	0.876
Sex (male/female), n	15/8	17/7	0.337
Physical examination			
Lumbar extension, mean (SD) (°)	27.5(5.3)	26.6(5.3)	0.898
BMI (kg/m^2), mean (SD)	26.7(3.8)	26.0(2.1)	0.580
Injections of level, n			
Unilateral L4-5, L5-S1	13	15	
Unilateral L5-S1	3	1	
Unilateral L4-5	5	4	
Bilateral L5-S1	2	3	
Bilateral L4-L5	–	1	

Values are expressed as mean (standard deviation), BMI; Body mass Index.

Table 2
Comparison of the treatment groups

	Group I ($n = 23$)	Group II ($n = 24$)	
VAS (cm), mean (SD)			
1st injection (initial)			
Before	7.6 (2.2)	7.2 (1.3)	0.400
After	3.5 (1.7)	4.8 (1.1)	*0.007*
P	*0.002*	*0.048*	
2nd injection (2 week)			
Before	4.2 (1.9)	4.8 (1.8)	0.293
After	2.5 (1.8)	3.3 (2.2)	0.196
P	*0.000*	*0.001*	
6 week	3.0 (1.7)	5.2 (2.0)	*0.001*
$P*$	*0.000*	*0.000*	
ODI, mean (SD)			
Initial	6[illegible].1 (14.9)	65.3 (13.3)	0.366
6 week	[illegible]3.3 (14.7)	60.1 (10.2)	*0.083*
P	*0.006*	*0.178*	
STAI (1,2), mean (SD)			
STAI 1			
Before injection	45.1 (10.6)	44.1 (9.5)	0.731
After injection	39.3 (9.4)	39.1 (7.0)	0.958
P	*0.135*	*0.003*	
STAI 2			
Before injection	42.5 (5.9)	44.3(5.7)	0.319
After injection	40.2(6.1)	40.3(5.2)	0.902
	0.000	*0.000*	

Group I: US-guided injection, Group II: Blind injection, VAS: Visual Analog Scale, STAI: State-trait anxiety inventory, ODI: Oswestry Disability Index. *Initial vs 6. Weeks. Values are expressed as mean (standard deviation). $P < 0.05$ (significantly) is the significance of values in italics.

tional treatment options are injection therapies and radiofrequency treatment [5]. Facet injections are implemented for different purposes with different techniques such as diagnostic blocks, intraarticular steroid injection , blocking of the medial branch and blocks before radiofrequency [6]. In our study intraarticular steroid injection was applied to our patients. Pain and disability scores of patients improved significantly.

In a study comparing radiofrequency and injection therapy, injection is proposed as the first choice and if sufficient effect cannot be obtained or the complaints repeat radiofrequency can be the alternative [7]. These applications are commonly performed by fluoroscopy or CT guidance. This increases the patient's exposure to radiation [16]. Moreover, Kim et al. [8] reported emergence of skin lesions after repeated injections administered under fluoroscopy. This procedure also constitutes an additional cost to social security system and time to medical staff. Ha et al. [9] reported the 6-month results of the facet joint injections in 105 patients. In this retrospective study, the preference of US was emphasized due absence of the radiation risk of

facet joint blockade, and easy administration in outpatient clinic as a minimally invasive procedure. Galiano et al. [17] had also brought forth that facet joint injections with US-guide are easily applicable with minimal risks. Being radiation-free, cost effective and easily repeatable applications which helps to obtain many images in multiple planes are the main advantages of US [1,3,16]. We also applied the injections in consideration of similar advantages of ultrasound.

In a recent study performed by Yun et al. [12], 57 patients with facet syndrome were randomized into two groups. Facet joint injections were applied to one group under fluoroscopy and the other group with US guidance. Visual Analog Scale, patient's global assessment and modified ODI were used for the assessment of the patients. Significant improvement was shown in all parameters within 1 week, 1 month and 3 months. However, they did not detect any statistically significant difference between the two methods. Similarly in another retrospective study indicated that the US-guided procedure did not show significant difference in treatment outcomes for pain reduction and functional improvements compared with the fluoroscopy-guided procedure [18]. In both studies, it was concluded that fluoroscopy had no superiority to ultrasound but the radiation risk of fluoroscopy was emphasized as a disadvantage.

In one study, the accuracy and clinical efficacy of US-guided and blinded-fashion nerve block in lumbar facet joint pain was investigated. They evaluated the accuracy of the procedures by confirming the location of needle tip by CT. There were 37 facet joint blocks guided by US, in which 32 were correctly targeted with the first puncture yielding a success rate of 86.5%. This rate was 31.4% in blinded group. After 6 weeks of follow-up, the overall remission rates were $72.3 \pm 14.0\%$ in US group and $56.7 \pm 11.0\%$ in blind injection group [19]. Similarly, in our study, it was concluded that ultrasound guide facet injection was superior in locating the target site than blinded facet injection. Also, significant improvement was shown in pain reduction and functional improvements in US group. In another study involving with non-specific low back pain patients, significant reduction in back pain has been obtained 3 months after treatment with lidocaine alone for 3 weeks to the paravertebral region, while a group of the patients received only sham-injection to the lumbar region. A significant reduction of pain was obtained in both groups [20]. Hence, subjectivity of patients satisfaction should be considered when evaluating the clinical effectiveness of these procedures. The placebo effect might have contributed to the blinded injection group; although its impact on US-guided injection group could not be ruled out.

Our study has some limitations. Among these, we did not confirm the accuracy of the injection by imaging of the tip of the needle. However, as mentioned above, accuracy of US guided applications has been shown with a high rate in several studies [16]. The research personnel who performed the injections are experienced in this procedure [2]. The relatively short follow-up time of our study is another limitation.

5. Conclusion

Results from this prospective clinical study indicate that utilization of US-guidance in local injections offer significant potential to improve clinical the outcome in the treatment of facet syndrome. Considering the additional cost and effectiveness of this procedure, further larger scale clinical studies with longer-term follow-up are warranted for a more definitive conclusion on the use of US-guided injections as a standard protocol for facet syndrome management.

Conflict of interest

The authors have no competing interests.

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