Original Article

# Comparison of Ultrasound-Guided Local Dexmedetomidine Injection vs. Corticosteroid Injection in the Treatment of Chronic Plantar Fasciitis: A Randomized Clinical Trial

**Mahshid Ghasemi[1], Mehrdad Taheri[2], Fatemeh Nazari[2*], Artadokht Khoshooei[3], Alireza Amanollahi[4], Hadi Ali Anvari[5]**

[1]Department of Anesthesiology and Pain Management, Akhtar Hospital, Shahid Behesthi University of Medical Sciences, Tehran, Iran
[2]Department of Anesthesiology and Pain Management, Imam Hossein Hospital, Shahid Behesthi University of Medical Sciences, Tehran, Iran
[3]Department of Anesthesiology, Jundishapur University of Medical Sciences, Ahvaz, Iran
[4]Department of Epidemiology, Faculty of Medicine, Shahid Behesthi University of Medical Sciences, Tehran, Iran
[5]Department of Anesthesiology, Zahedan University of Medical Sciences, Zahedan, Iran

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## Abstract

**Background:** Heel pain is commonly caused by chronic plantar fasciitis, associated with pain and activity limitation in patients. Although steroid injection is a popular method to treat this disease, it has side effects and provides short-term pain relief. The study was designed to investigate the effects of dexmedetomidine and corticosteroid injection in treating chronic plantar fasciitis.

**Materials and Methods:** A total of 70 participants were divided into two groups. The intervention group received a mixture of dexmedetomidine (1µg/kg) with 1 ml of lidocaine 2%. The control group received a combination of 1ml of corticosteroid (40mg triamcinolone) with 1ml of lidocaine 2%. Outcome measures were evaluated with Numerical Rating Scale (NRS) and Maryland foot score (MFS) before, one, and three months after the intervention.

**Results:** Significant improvements in NRS and MFS were observed in both groups at 1 and 3 months of follow-up compared to baseline($P<0.001$). NRS score improvement in the first month was more significant in the corticosteroid group compared to the dexmedetomidine group. However, after three months, the dexmedetomidine group experienced greater pain reduction ($P=0.012$) and higher functional ability ($P<0.001$) than the corticosteroid group.

**Conclusion:** Local injection of dexmedetomidine provided significant and long-term effects on pain severity and physical activity. Corticosteroids caused an immediate but short-term effect, whereas sustained improvement in the dexmedetomidine group was observed during the follow-up.

**Keywords:** Plantar fasciitis, Dexmedetomidine, Corticosteroid, Numerical rating scale, Maryland foot score

***Corresponding Author:** Fatemeh Nazari, Department of Anesthesiology and Pain Management, Imam Hossein Hospital, Shahid Behesthi University of Medical Sciences, Tehran, Iran. Email: F.nazari1983@yahoo.com, ORCID: 0009-0007-6054-0999

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# Introduction

Plantar fascia is a thick fibrous sheet on the plantar surface of the foot that originates from the internal appendage of the calcaneus tubercle and connects to the plantar part of the front foot, and absorbs shock powerfully[1-5.] Plantar fasciitis (PF), the inflammation of this facia, is the leading cause of chronic heel pain, accounting for approximately 11-15% of all foot pain causes among adults. The site of involvement is near the junction of the plantar fascia with the medial part of the calcaneal tuberosity. It induces considerable pain and activity limitations[1-8]. While the specific pathology of PF is not known yet, there are some possible causes, such as obesity, foot deformity (pes planus, pes cavus, shortened Achilles tendon), repetitive microtrauma, degeneration, chronic inflammation, etc[1-6,8,9]. Plantar fasciitis pain occurs more in the early morning and after prolonged immobility. This pain is accompanied by symptoms of point sensitivity along the medial tuberosity of the calcaneus[1-6,10-13]. Like most inflammatory disorders, nocturnal pain and paresthesia can be detected in more serious conditions[8,13]. Medical history and physical examination can certainly diagnose plantar fasciitis[1-5,13]. Ultrasound is a valuable method for the detection of chronic PF and for ruling out other problems. In ultrasound, the proximal thickness of the plantar fascia is measured, and if it is more than 4 mm, it is associated with the diagnosis of PF[7,8,13].

Treatment of PF is mainly conservative, and 80–90% of patients respond well to this type of treatment[13]. A Conservative approach includes non-steroidal anti-inflammatory drugs, heel cushions, stretching exercises, physiotherapy, local injections[1,7,8,13], extracorporeal shockwave therapy[1], low-power laser therapy[4], and tibial nerve blocks[5]. Some injectable agents are available, including hyperosmolar dextrose (prolotherapy)[1], local anesthetics[7,13], botulinum toxin[2], autologous platelets[1], and regional ozone (O2-O3) injections[3]. Steroid injections are a widespread method of treatment[1-17]. Injection of corticosteroids provides rapid pain relief. Most family physicians can prescribe it as an outpatient treatment. A potential corticosteroid injection complication may offset this treatment modality's benefits. There is an increased risk of plantar fascia rupture[6,9,10,16], heel fat cushion atrophy[10], limited physical activity in the first two weeks following injection, lateral nerve injury secondary to injection[6,8,10], calcaneal osteomyelitis[14], change in skin pigmentation, post-injection flare (worsening of heel pain), pain after injection[7,12,13], increase in blood glucose, and infection[14,17]. Studies found limited evidence supporting the selection of a particular corticosteroid for local injection. There is no difference in clinical efficacy between various corticosteroid types, according to systematic reviews[7]. Triamcinolone, a relatively insoluble fluorinated steroid, has a greater anti-inflammatory effect[8]. In most clinical trials, corticosteroids and local anesthetics were used, among which lidocaine was most commonly used[7].

Dexmedetomidine is an imidazole derivative routinely used sedative-hypnotic, anxiolytic, and analgesic agent[18]. Combining Dexmedetomidine with local anesthetics can be used for lengthening the duration of local anesthetic effects as a result of local vasoconstriction and direct impact on peripheral nerve activity[18,19]. In addition, local injections of dexmedetomidine suppress acute inflammatory response[18-20]. Due to the increased secretion of cytokines in inflammatory conditions, the normal balance between the production of inflammatory and anti-inflammatory cytokines is disturbed. Activation of the central α2-adrenoceptor by dexmedetomidine inhibits sympathetic excitation, thus enhancing the cholinergic anti-inflammatory pathway and reducing proinflammatory factors' expression[21,22]. Additionally, it has been reported that dexmedetomidine regulates proinflammatory factors like Interleukin-6, Interleukin-8, and Tumor necrosis factor one(TNF-1) by modifying NF-kB (Nuclear factor kappa-light-chain-enhancer of activated B cells)[22,23]. Without human dose–response studies, Dexmedetomidine doses varied between 30, 100μg or 0.75, 1μg/kg for the peripheral route[18].

Regarding the lack of well-designed investigations on these patients considering the use of Dexmedetomidine, we aimed to assess ultrasound-guided local dexmedetomidine and corticosteroid injection for the treatment of chronic PF to determine the safety and

effectiveness of these drugs for the treatment of plantar fasciitis.

## Methods

This single-blinded randomized controlled trial was performed from 1st July 2022 to 10th March 2023 in the pain clinic at Imam Hossein and Akhtar Hospitals. It was ethically approved and registered in the Iranian registry (ethical code: IR.SBMU.RETECH.REC.1401.532, clinical trial registry: IRCT20170423033615N2).

The study was conducted on 70 patients with chronic PF. These criteria were used to select participants: 1) Minimum age of 18 years old; 2) Sharp heel pain and local tenderness at medial calcaneal tuberosity that lasted for more than three months and refused to respond to conservative treatment; 3) Pain score (NRS) of at least 4; 4) Thickness of plantar fascia exceeding 4mm, having hypoechoic changes in the area of calcaneus insertion. The following criteria were used to exclude: 1) Pregnancy; 2) History of consuming oral corticosteroids during the past two weeks or injection of steroids in the plantar fascia within six months; 3) Infections at the injection site; 4) Pain in the heels associated with Neuropathy or radiculopathy; 5) Past medical history of diabetes; 6) Bone fractures in the surrounding area; 7) Heel pain caused by ankylosing spondylitis, ankle joint inflammation, previous surgical treatment of the plantar fascia; 8) Coagulopathies; 9)

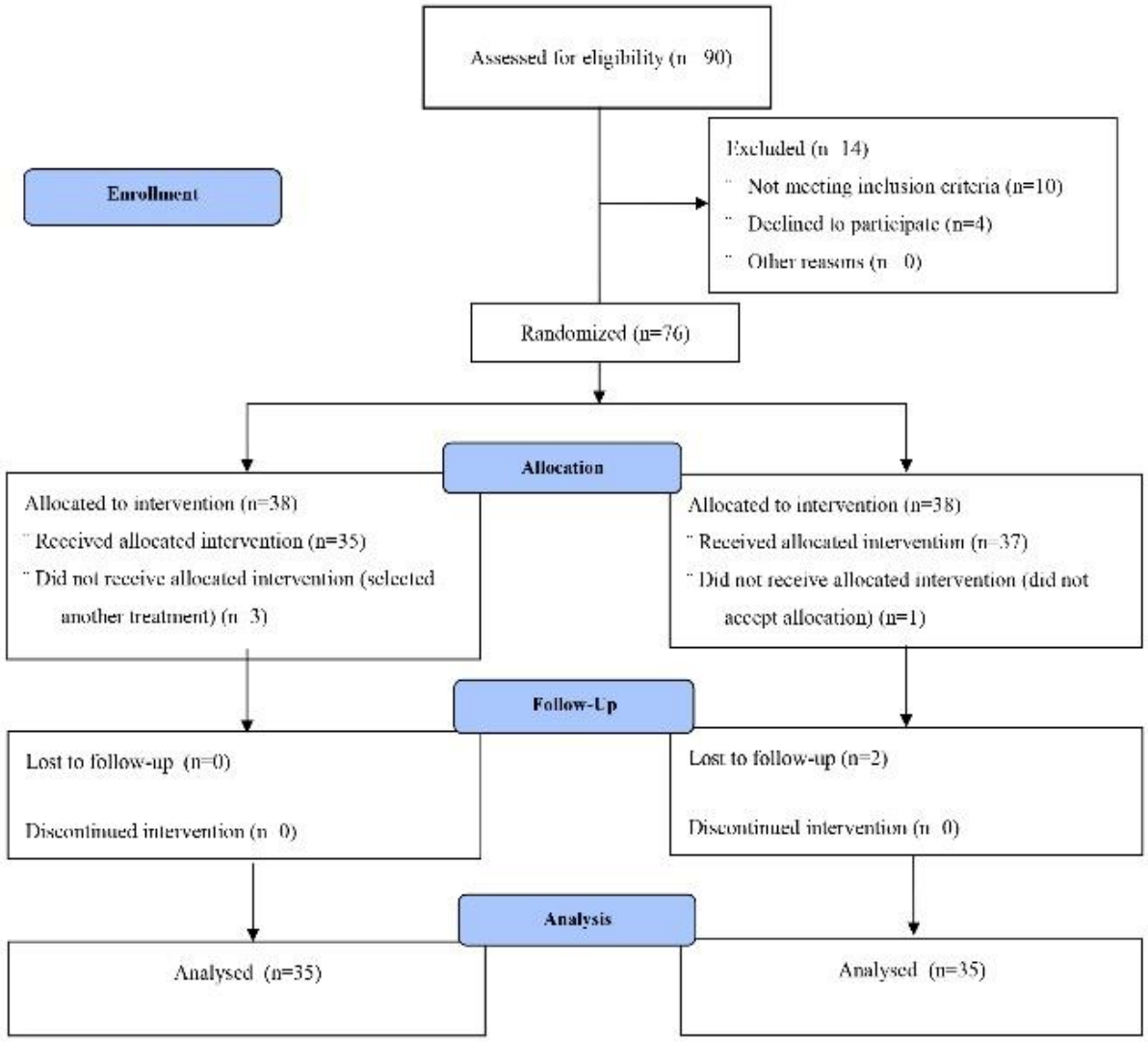


**Figure 1.** Consort flow chart of participants.

Allergic reaction to corticosteroids.

Upon obtaining written informed consent, we took a complete medical history from each participant and performed a complete physical examination. Some demographic statistics were collected, including date of birth, gender, height, weight, and duration of pain. Subjects were randomly assigned to intervention groups using block randomization. The ultrasound-guided injection technique was used in this study to confirm the diagnosis and ensure the accuracy of the application. The combination of triamcinolone acetonide and lidocaine was selected for this study.

In the operating room, a safe intravenous line was taken with A 20 G catheter. Blood pressure (NIBP), pulse rate (HR), and peripheral oxygen saturation (SpO2) were recorded. Patients were placed in a prone position so their feet hung over the edge of the examination table. Antiseptic was used to prepare the skin of the injection site. We placed the high-frequency linear transducer in a longitudinal direction over the plantar fascia in its insertion site to the calcaneus. Then a 90-degree rotation was made to place the probe in a transverse position. Using an in-plane approach, medial to lateral insertion of a 23-gauge needle was performed, and the subcutaneous tissue was anesthetized with lidocaine. The needle was advanced to reach Between the plantar fascia and the calcaneal periosteum. The control group received a combination of 1mL corticosteroid (40mg triamcinolone) and 1 mL lidocaine 2%, and the intervention group received a mixture of

Dexmedetomidine (1μg/kg) and 1 mL lidocaine 2%. For the first 48 hours, patients were recommended to use a cold pack as much as possible. The usual treatment was also given to both groups, such as custom-made orthotics, arc support, and stretching exercises. In addition, corticosteroids or NSAIDS were not allowed, and paracetamol was prescribed for severe pain. A follow-up telephone interview was conducted one month and three months following the injection. All outcome measures were evaluated with a numerical rating scale for pain intensity (NRS) and Maryland foot score for functional ability (MFS) before.

An NRS was used to measure pain severity. The NRS is a 0–10 scale in which a pain score of 0 implies no pain, while a score of 10 represents the most painful experience you have ever had. The effect of pain on patients' function was assessed using the Maryland foot score (MFS). A Maryland Foot Score assesses a patient's foot condition based on pain intensity, gait disturbance, functional activities, and foot appearance. It has a minimum point value of 0 and a maximum point value of 100. A total score of <50 is considered poor, 50–74 points as fair, 75–89 as good, and 90–100 as excellent. The outcome was assessed from baseline to one and three months following the start of the study by the same physician.

This study used the SPSS software version 26 (SPSS Inc., Chicago, IL, USA) to analyze data. Analysis and comparison of categorical data between groups were made with the Chi-square test. We used the Student's t-test to compare continuous variables between groups before treatment and in follow-up visits. A repeated measure test was used to evaluate the improvement of variables compared to baseline levels. Finally, a linear mixed model was applied to evaluate post-treatment improvement between groups. Statistical significance was noted by the p-value <0.05.

According to the Declaration of Helsinki issued by the World Medical Association, investigators received ethics approval from Ethics Committee of Shahid Beheshti University of Medical Sciences (No.IR.SBMU.RETECH. REC.1401.532). The trial was registered in the Iranian Registry of Clinical Trials (registration ID:IRCT20170423033615N2). Informed consent was obtained from all individual participants included in the study.

## Results

Among 90 patients enrolled, 38 patients in each group were assessed, and 14 were excluded. Three participants in the corticosteroid and one in the dexmedetomidine group were unwilling to continue the study after being randomized. However, they were excluded from the trial before receiving their allocated intervention. Three chose another treatment, and one subject refused to accept the allocation. Two subjects in the dexmedetomidine group missed follow-up visits. Therefore, the results 70, including 35 in each group, were finally analyzed (Figure 1).

In this study, 35 participants (50%) were females, and 35(50%) were males with a mean age of 54.31±10.35 years (29–75 years). The average of body mass index

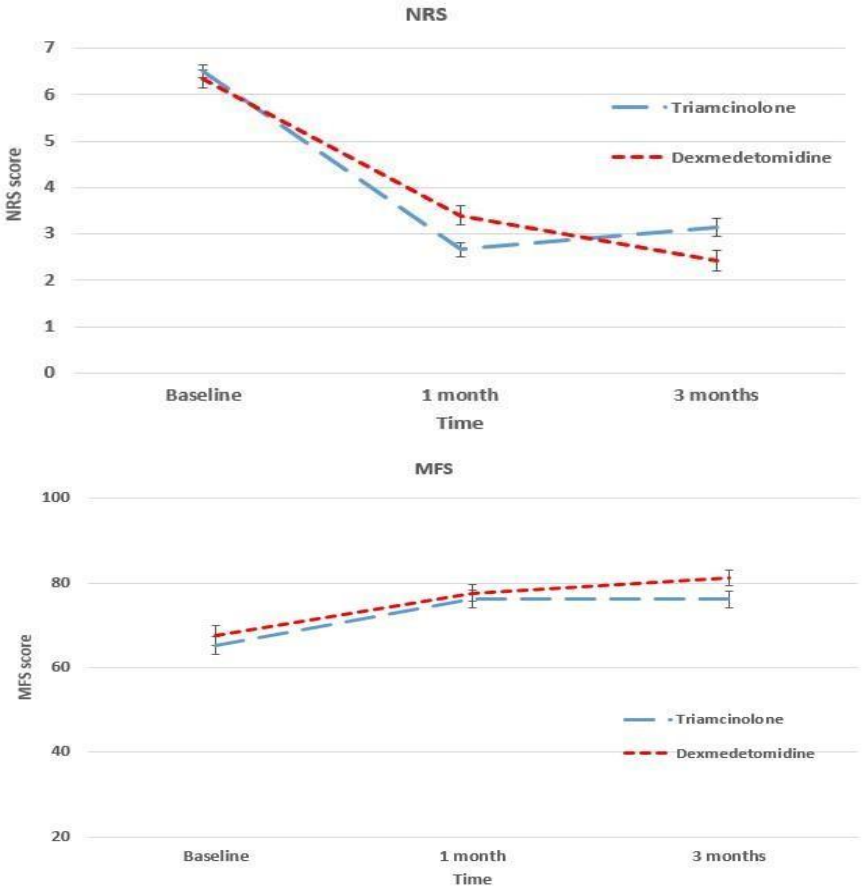


**Figure 2.** The trend of mean changes in NRS and MFS at follow-up.

(BMI) calculated as weight/(height)$^2$ was 24.75±2.48 kg/m$^2$(17.96–33.29 kg/m2). The mean duration of pain was 27.60±13.97 weeks (12–53 weeks). There was no significant difference in demographic characteristics between groups (Table 1).

There was no significant difference between the Corticosteroid and dexmedetomidine group regarding NRS at baseline (P=0.471). Both groups showed significant improvement in NRS at one month of follow-up compared with baseline(P<0.001). However, a greater reduction in pain score was seen in the steroid group (Mean difference=-3.85±0.65) compared to the dexmedetomidine group (Mean difference=-2.94±0.91) at one month of follow-up, which was statistically significant (P<0.001).

Similarly, both groups had a considerable improvement in NRS score three months after injection compared with the baseline score (P<0.001), but NRS changes at three months were slightly higher in the dexmedetomidine (Mean difference=-3.91±0.88) compared to the steroid group (Mean difference=-3.37±0.87). Despite the statistical difference, that was not clinically important between them (P=0.012) (Table 2, Figure 2).

Figure 2. The trend of mean changes in NRS and MFS at follow-up.

Results showed that steroid injection provided no greater reduction in pain intensity at three months of follow-up compared to one month (Mean difference=0.48±0.85). However, there was a significantly greater reduction in pain score in the dexmedetomidine group at the same time points (Mean difference=-0.97±0.82) (P<0.001) (Table 3).

Besides, there was not any significant difference between the steroid and dexmedetomidine group in terms of MFS at baseline (P=0.434), one month after injection (P=0.606), and three months after injection (P=0.068) (Table 2). Although significant

**Table 1:** Demographic data of patients in the two groups*.

| Characteristic | Dex. | Cor. | Mean difference | Total | p-value** |
|---|---|---|---|---|---|
| **Age (y)** | 52.14±10.89 | 56.49±9.44 | -4.343 | 54.31±10.35 | 0.079 |
| **Body Mass Index (kg/m2)** | 24.95±3.03 | 24.54±1.81 | 0.403 | 24.75±2.48 | 0.502 |
| **Duration of Symptoms (Weeks)** | 27.37±14.5 | 27.82±13.63 | -0.457 | 27.60±13.97 | 0.892 |
| **Female (n %)** | 19 (54.3%) | 16 (45.7%) | -- | 50% | 0.473 |

*Values are expressed as mean ± SD. **P value <0.05 shows significant differences between groups. DEX: Dexmedetomidine, Cor: Corticosteroid.

**Table 2:** Mean changes in NRS and MFS during follow-up.

| Outcomes | Groups | Baseline | 1 month | 3 month | Coefficient (Std.Error) P-value* | P-value** |
|---|---|---|---|---|---|---|
| **NRS** | **Dex.** | 6.34± 1.13 | 3.40± 1.17 | 2.43± 1.22 | β= -0.08(0.22) 0.723 | <0.001 |
| | **Cor.** | 6.51± 0.81 | 2.66± 0.94 | 3.14± 1.09 | | |
| **MFS** | **Dex.** | 67.69± 13.65 | 77.63± 10.87 | 81.14± 10.99 | β= 6.45(2.67) 0.016 | <0.001 |
| | **Cor.** | 65.29± 11.79 | 76.23± 11.74 | 76.17± 11.48 | | |

$Values are expressed as mean ± SD. *Between groups. **Between times. Dex: Dexmedetomidine, Cor: Corticosteroid.

**Table 3:** Within-group comparisons for NRS and MFS in three-time points*.

| Outcome | Compare times | Dex. | Cor. | P-value |
|---|---|---|---|---|
| **NRS** | **Baseline vs. 1 Month** | -2.94 ± 0.91 | -3.85 ± 0.65 | <0.001 |
| | **Baseline vs. 3 Month** | -3.91 ± 0.88 | -3.37 ± 0.87 | 0.012 |
| | **1 Month vs. 3 Month** | -0.97 ± 0.82 | 0.48 ± 0.85 | <0.001 |
| **MFS** | **Baseline vs. 1 Month** | 9.94 ± 5.17 | 10.94 ± 3.48 | 0.346 |
| | **Baseline vs. 3 Month** | 13.45 ± 5.47 | 10.88 ± 4.02 | 0.028 |
| | **1 Month vs. 3 Month** | 3.51 ± 2.39 | -0.06 ± 2.96 | 0<0.001 |

* Values are expressed as mean difference ± SD. Dex: Dexmedetomidine, Cor: Corticosteroid.

improvements in MFS were observed in both groups at one and three months of follow-up compared to baseline (P<0.001), corticosteroid injection provided no greater improvement in physical ability at three months of follow-up compared to one month (Mean difference=-0.06±2.96). But in the dexmedetomidine group, further improvement in MFS was seen at the same time-point (Mean difference =3.51±2.39). Three

months after the initial intervention, the dexmedetomidine group showed higher functional ability than the other group, which was clinically important (P<0.001) (Table 3, Figure 2).

## Discussion

Our study was the first to assess the effectiveness of ultrasound-guided local dexmedetomidine injection compared with corticosteroid injection for PF with a three-month follow-up. Results showed that both groups significantly improved NRS and MFS at one and three months of follow-up. One month after injection, NRS improved significantly after corticosteroid injection, compared to dexmedetomidine injection. Inversely, NRS changes at three months of follow-up were slightly higher in the dexmedetomidine group compared to the steroid group.

Similarly, after three months, the dexmedetomidine group had better physical ability and higher MFS. In the dexmedetomidine group, there was an increasing trend of functional activity in addition to decreasing trend of pain severity during three months, but after 3rd month of follow-up, the NRS score increased in the corticosteroid group, and the useful effect of corticosteroid on reducing pain was only noted within one month. A quick but short-term effect was achieved through corticosteroids compared with dexmedetomidine, whereas sustained improvement in the patients treated with dexmedetomidine was observed during the follow-up.

Although there is no previous study that assessed the effect of dexmedetomidine on chronic PF, consistent with our findings, Sukegawa et al. found that local injection of dexmedetomidine had an inhibitory effect on the production of leukocytes, COX-2 and TNFα at the site of injection. They reported the anti-inflammatory effect of this drug against local inflammation[19]. According to Rushuang Chen et al., dexmedetomidine administration inhibited surgery-induced inflammation in patients undergoing intestinal surgery[24]. Nesioonpour et al. also mentioned that intra-articular injection of 2μg/kg dexmedetomidine relieved postoperative pain, reduced NRS, and increased the time of first analgesic request after knee arthroscopy[25].

Most studies also showed corticosteroids' short-term but quick effect, similar to our observation. In a meta-analysis comparing the effect of steroid injection with placebo on heel pain, Li et al. reviewed four RCTs (N=289). Compared to placebo, steroid injection produced significant improvements in pain after the first month; but no significant difference was found after two or three months. Therefore, steroid injection is effective for pain reduction in the short-term[13]. In five RCTs(N=292), Crawford et al. compared steroid injection effectiveness with alternative treatment options, such as orthoses. Steroid injection was not more effective or only effective in the short term at reducing heel pain[12].

In our study, the adverse effects of corticosteroid injection were not observed. Corticosteroids provide a rapid effect on pain relief in patients with PF, but these drugs must be used cautiously because of the possibility of rupturing the plantar fascia. It is important to note that a ruptured fascia and atrophy of the fat pad are serious problems. An injection to the plantar fascia can cause fascial rupture[6,10,16], and a mis-injection into the fat pad can cause fat pad atrophy, which reduces subcalcaneal cushioning and makes the fascia more susceptible to injury[10]. In two retrospective studies, the rupture rate of plantar fascia was 2.4% to 6.7%[10]. As a result of suppressing proteoglycan synthesis in cultured human tenocytes, glucocorticoids may result in spontaneous rupture after steroid injections. Treatment of plantar fascia rupture remains unclear[26]. Acevedo et al., who evaluated 765 patients with PF, noted 51 plantar fascia ruptures. Among these, 44 were related to corticosteroid injection. Thirty had a sudden beginning of heel tearing (68%), and 14 (32%) had a gradual onset[10]. Lee et al. assessed the risk of plantar fascia rupture in 286 patients with PF. Their results noted that only steroid injection with an odds ratio of 32.96 was the significant risk factor[15].

Corticosteroid injections may have long-term adverse effects since few studies have assessed outcomes after three months. Dean BJF et al. found that local corticosteroid administration severely impacted collagen organization in vivo. There is also a significant reduction in the mechanical properties of the tendon. According to this review, corticosteroid injections have significant long-term effects on tendon tissue and cells[9]. Kennedy and Willis found that steroid injection in physiologic dose (0.25 cc betamethasone) weakens

normal Achilles tendons strength for 14 days in vitro due to collagen necrosis[11].

In our study, patients did not experience the side effects of dexmedetomidine, such as hypotension or bradycardia. A meta-analysis of nine RCTs (N=516) by FW Abdallah et al. demonstrated the perineural adverse effects of dexmedetomidine. The incidence of hypotension was similar between the dexmedetomidine and the control groups. Transient bradycardia was more common in patients who received dexmedetomidine and reversed with atropine. There was no respiratory depression among the patients in these trials[27].

The result of this study matches with other trials that, although steroid injection is the most common local injection in the treatment of plantar fasciitis, but is not the only way to pain relief. Dexmedetomidine injection should be advised as a choice of therapy in resistant heel pain, especially for cases with contraindications to steroid therapy. In dexmedetomidine injection therapy, there is less involvement of instruments/machines (ozone, ESWT, laser therapy, PRP) and less exposure to blood products (PRP, orthokin). Also, dexmedetomidine injection needs less expertise in comparison to other treatments.

The main limitation of this study was the small number of participants, which may have affected the accuracy of the results. In this experiment, we used a single dosage of dexmedetomidine.

Different dosages may affect the effect of dexmedetomidine on the inflammatory response. Along with clinical scoring systems, using the ultrasonography parameters such as the thickness of the plantar fascia can help assess the improvement of pain and disability in patients. Further multicenter studies should be done to evaluate the long-term effectiveness of dexmedetomidine with a larger number of patients.

## Conclusion

The present study mentioned that locally injected dexmedetomidine provides long-lasting pain relief and improvements in physical activity comparable to corticosteroid injection in treating plantar fasciitis. Furthermore, dexmedetomidine is a safe drug in patients with contraindications to steroid therapy and is an alternative therapy for patients referred for surgical interventions.

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## Conflict of interest

The authors further declare that they have no conflict of interest.

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