Research Paper

Comparative Effectiveness of the Corticosteroid Injection and Prolotherapy in Patients With Hallux Rigidus: A Clinical Trial

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ABSTRACT

Objectives: Hallux rigidus is one of the main etiologies of disability in the elderly. It is a degenerative disease of the first metatarsophalangeal joint causing restriction of movement as well as pain and swelling. This study was conducted to evaluate the effectiveness of methylprednisolone and dextrose prolotherapy in pain reduction and functional improvement of patients with hallux rigidus.

Methods: A randomized double-blind control trial was designed with the inclusion of 32 patients assigned to the two groups. Group one received a mixture of 1 cc methylprednisolone 40 mg with 1 cc lidocaine 2% while the second group received a combination of 1 cc dextrose 50% with 1 cc lidocaine 2%. Standard questionnaires, including visual analog scale (VAS) and Manchester-Oxford foot questionnaire (MOXFQ) were completed by all patients at baseline and 1, 4, and 8 weeks after injections.

Results: Both groups revealed significant improvement in VAS and MOXFQ scores 1, 4, and 8 weeks post-injection with no difference between the two groups in the follow-up.

Discussion: Both corticosteroid injections and prolotherapy are effective in pain reduction and functional improvement in patients with hallux rigidus but neither is superior to the other.

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Highlights

• Hallux rigidus is one of the main etiologies of disability in the elderly.

• We conducted this research to evaluate the effectiveness of methylprednisolone and dextrose prolotherapy in pain reduction and functional improvement of patients with hallux rigidus.

• Both corticosteroid injections and prolotherapy are effective in pain reduction and improvement of function in patients with hallux rigidus but neither is superior to the other.

Plain Language Summary

Hallux rigidus is one of the main etiologies of disability in the elderly. We conducted this research to evaluate the effectiveness of methylprednisolone and dextrose prolotherapy in pain reduction and functional improvement of patients with hallux rigidus. Both corticosteroid injections and prolotherapy are effective in pain reduction and improvement of function in patients with hallux rigidus but neither is superior to the other.

1. Introduction

Hallux rigidus is one of the leading etiologies of disability in the elderly. It is a degenerative disease of the first metatarsophalangeal joint (MTP) causing restriction of movement as well as pain and swelling [1-3]. This swelling is initially due to synovitis secondary to the progression of osteophytes around the joint [4-6]. It has a prevalence of 1 in 60 people in cases aged 31-60 years or 1 in 45 people over 60 years. Elsewhere, the prevalence is reported to be 2.5% in people over 50, which is twice as common in women as in men [7, 8]. As the disease progresses, periods of acute pain intensify and the duration of pain increases so that it can be sometimes misdiagnosed by gout or infection [9]. The underlying cause of hallux rigidus is not clearly known. Although most cases are probably idiopathic, some predisposing factors mentioned in previous articles include age, trauma, female gender, positive family history, inflammatory and metabolic conditions, such as gout, rheumatoid arthritis, seronegative arthropathies, hallux valgus, and structural factors, like elevated metatarsus, hyperactivity of the first toe, pes planus, high arches of the foot, and longer first metatarsus in contrast to the second one. Improper shoes, poor foot mechanics during walking or running, strenuous exercise, and being overweight also play a role [2, 6, 10].

Standard treatment for foot pain is usually conservative starting with appropriate shoes or orthoses. If the pain does not improve, nonsteroidal anti-inflammatory drugs (NSAIDs), intra-articular injections, and physical therapy may be used. Patients can be candidates for surgery if conservative managements are not effective [7, 11]. One of the injectable drugs is a corticosteroid, which is widely used in the treatment of various problems, such as osteoarthritis and gout. However, it may have side effects and short-term advantages due to the previous studies [12, 13]. For example, Grice et al. performed a retrospective review of the clinical results after steroid injections in 365 patients with foot or ankle problems. They showed that it was a safe and effective choice for the treatment of different foot and ankle disorders. It also reduced the requirement for surgery. However, it did not cause a significant improvement in pain for periods longer than three months, especially in patients with plantar fasciitis and hallux rigidus [13]. Prolotherapy is another method, which is primarily used for controlling pain in tendinopathies and ligament strains as well as destructive arthritis of the spine and joints. In this method, a solution is injected into the tendons and ligaments, which stimulates the production of collagen, fibrous tissue, and new bone cells, and ultimately strengthens these structures as well as increases joint staility. Dextrose is the most common drug used in prolotherapy as it is more available and cheaper than other proliferators [14-16]. Ross et al. investigated the outcomes of 19 patients undergoing dextrose prolotherapy treatment for unresolved foot and toe pain. They showed 100% improvement in their pain, stiffness, and quality of life (QoL) [2]. Nowadays, the grading of the hallux rigidus is based on the system designed by Shurnas and Coughlin combining radiology and clinical findings as the gold standard method (Table 1) [12].

In summary, Hallux rigidus can cause antalgic gait and secondary musculoskeletal problems that will have great socio-economic costs for the patients. Using a proper treatment method can help reduce pain and increase the QoL. The aim of this research was to investigate the effect of intra-articular injections of 50% dextrose using methylprednisolone and prolotherapy on reducing pain and improving function in these patients. Steroids are one of the cheapest and most widely used drugs for joint injections. We compared it to prolotherapy because it is safe and cost-effective, and provides tissue renewal without any side effects.

2. Materials and Methods

This research was a double-blind clinical trial, which was conducted on patients referring to physical medicine and rehabilitation units affiliated with the Shiraz University of Medical Sciences (SUMS). Written informed consent was obtained from each patient. In 2021, a total of 32 patients (16 cases in each group) were randomly allocated to two groups by block randomization assignment and double-blind techniques to receive either prolotherapy or corticosteroid injections. The randomization sequence was made using excel 2007 (Microsoft) with a 1:1 allocation as well as a random block size of six. Both patients and statisticians were blinded to treatment allocation. Patients aged 30-65 years and complaining of pain or decreased range of motion in the first MTP for at least three months without any response to other conservative therapies were included. The exclusion criteria were patients with the severe stage of the degenerative disease in the first MTP according to the anterior-posterior and lateral views of radiography performed before treatment (grades III and IV). Moreover, patients with diabetes, rheumatologic disease, history of previous trauma or operation of the first MTP, infections, lumbar radiculopathies, anomalies, nonsteroidal anti-inflammatory drug consumption, coagulopathies, pregnancy, and history of previous local injection of this joint in recent six months were excluded. The demographic variables, such as age, sex, and side of injection (right or left first MTP) were evaluated. Two types of questionnaires were considered for each patient before injection, one, four, and eight weeks after injection by the researcher's questioning verbally. These questionnaires were the visual analog scale (VAS) and Manchester-Oxford foot questionnaire (MOXFQ). The validity and reliability of both questionnaires were confirmed [17, 18]. The former included zero to ten scores indicating zero scores for no pain and ten for the worst pain. The latter was also a 16-item questionnaire to assess the patient's pain and functional performance, walking and standing, which has good evidence in assessing foot and ankle problems [19]. The mechanism of the disease, various approaches of treatment, prognosis, the study process, and case selection was described for each patient. The injection was performed under sterile conditions with a 2 cc syringe (23 gauge), which was inserted from the medial side of the joint while the solution was injected in both plantar and dorsal directions. Treatment of group A was performed with a mixture of 1 cc methylprednisolone acetate (40 mg) and 1 cc of lidocaine 2%. For group B, a mixture of 1 cc dextrose 50% and 1 cc of lidocaine 2% was injected. The injection was given in one session only. Recommendations and precautions after the injection were described and each patient was followed in the first, fourth, and eighth weeks after the injections. Figure 1 shows the consort diagram.

Statistical analysis

Analysis was conducted for each of the outcome measures (score from VAS and MOXFQ) by SPSS software, version 18 (IBM Corp., 2011, IBM SPSS Statistics for windows, NY, EUA). The Mean±SD were used to show quantitative variables. Frequency variables as well as percentages were used to reveal qualitative variables. According to the result of the Kolmogorov-Smirnov test, the data distribution was not normal. Therefore, the Mann-Whitney test was used to compare quantitative variables between the two groups while the Chi-square and Fisher's exact tests were used to compare qualitative variables between the two groups. Mann-Whitney test was used to compare VAS scores between the two groups and the Kruskal-Wallis test was used to compare VAS within the group. To compare the score of the MOXFQ questionnaire according to its normal distribution, a t-test was used for between-group comparison and repeated-measures ANOVA was used for within-group comparison. A $P<0.05$ was defined as a significant value statistically.

3. Results

In this research, 32 cases participated (16 cases were in group A with methylprednisolone injection while the other 16 patients were in group B with 50% dextrose injection). The age range of patients was 33-64 years. The demographic characteristics of the two groups are summarized in Table 2. Comparing the mean age and sex factors between the two groups revealed no significant difference. The comparison of VAS scores within each group was significant, which was due to the significant reduction of the post-injection VAS score compared to

Table 1. Coughlin and Shurna's classification of hallux rigidus

Grade	X-ray Radiography	Clinical Findings
0	Normal	Tolerable stiffness and partial lack of range of motion
I	Osteophytes as cardinal finding, minimal metatarsal head flattening and joint space narrowing	Mild or intermittent pain and stiffness, pain elicited at maximum degrees of range of motion
II	Periarticular osteophytes with mild to moderate joint space narrowing, flattening, and sclerosis	Moderate to severe pain and stiffness with more obvious frequency, pain elicited near end degrees of range of motion
III	Similar to grade II with cystic changes subchondral and sesamoid irregularities	Approximately constant pain and stiffness with the pain evoked with the end range of motion
IV	Similar to grade III	Pain presents at mid-range of motion

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Table 2. Demographic characteristics of both methylprednisolone and prolotherapy groups

Demographic Characteristics		Mean±SD/No. (%)			P
		Methylprednisolone (n=16)	Prolotherapy (n=16)	Total	
Ag (y)		46.87±9.77	49.81±9.31	48.37±9.54	0.36
Gender	Male	3(18.8)	2(12.5)	5(15.6)	0.50
	Female	13(81.3)	14(87.5)	27(84.4)	

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the pre-injection one (Table 3). Furthermore, there was no statistical difference between the VAS scores of the two groups before injection, and after the first, fourth, and eighth weeks (P: 0.491, 0.323, 0.305, and 0.699, respectively) (Figure 2). A comparison of MOXFQ scores also showed a significant reduction in the post-injection scores (Table 4). Moreover, no statistical difference was detected in the MOXFQ scores of the two groups before injection, and one, four, and eight weeks after injection (P: 0.254, 0.930, 1.000, and 0.825, respectively) (Figure 3). During follow-up of patients after the injections, no specific complication was observed except for slight pain at the injection site lasting for a few days. No bruising or infection was reported by any of the patients.

4. Discussion

The first toe maintains the inner arch of the sole of the foot, and indeed, it is the most important weight-bearing part that bears 40 to 60% of the body weight during walking. Hallux rigidus is seen in 10% of people over the age of 60 [3-6]. It causes antalgic gait. It means that with the exacerbation of the disease, the person puts pressure on the outer part of the foot, which limits activity, reduces balance, and increases the risk of falling [5, 8]. Pain and stiffness worsen as the joint becomes dorsiflexed while climbing stairs or running. The patient may have numbness in the medial side of the thumb due to the entrapment of the superficial inner branch of the nerve by dorsal osteophytes [1, 4, 20]. In this study, the effects of methylprednisolone injection and 50% dextrose were compared in terms of reducing pain and improving pa-

Table 3. Comparing the VAS score within each group of methylprednisolone prolotherapy

VAS Score	Methylprednisolone	Prolotherapy
Before and 1 week after injection	P<0.001	P<0.001
Before and 4 weeks after injection	P<0.001	P<0.001
Before and 8 weeks after injection	P=0.004	P=0.001

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Table 4. Comparison of the MOXFQ within each group of methylprednisolone and prolotherapy

MOXFQ Score	Methylprednisolone	Prolotherapy
Before and 1 week after injection	P=0.045	P=0.047
Before and 4 weeks after injection	P=0.015	P<0.001
Before and 8 weeks after injection	P<0.001	P=0.012

tients' functions. The MOXFQ was used to evaluate the improvement of patients' performance and the VAS was used to assess the severity of pain. There was no statistically significant difference between the two groups in terms of demographic factors, including age and sex. In both groups, the desired factors were evaluated before injection and one, four, and eight weeks after injection. In each group, following the injection, factors measured with both VAS and MOXFQ significantly improved compared to the time before injection. Therefore, it can be concluded that the injections of both methylprednisolone and dextrose 50% reduced pain and improved patients' performance for at least eight weeks. A comparison of the results obtained between the two groups showed no significant difference in the scores achieved from both questionnaires before the injection as well as one, four, and eight weeks after the injection. This indicated that both treatments had a positive effect on reducing pain and improving patients' performance, but there was no significant difference between them. In previous studies, the effects of these two drugs on the treatment of hallux rigidus were not compared.

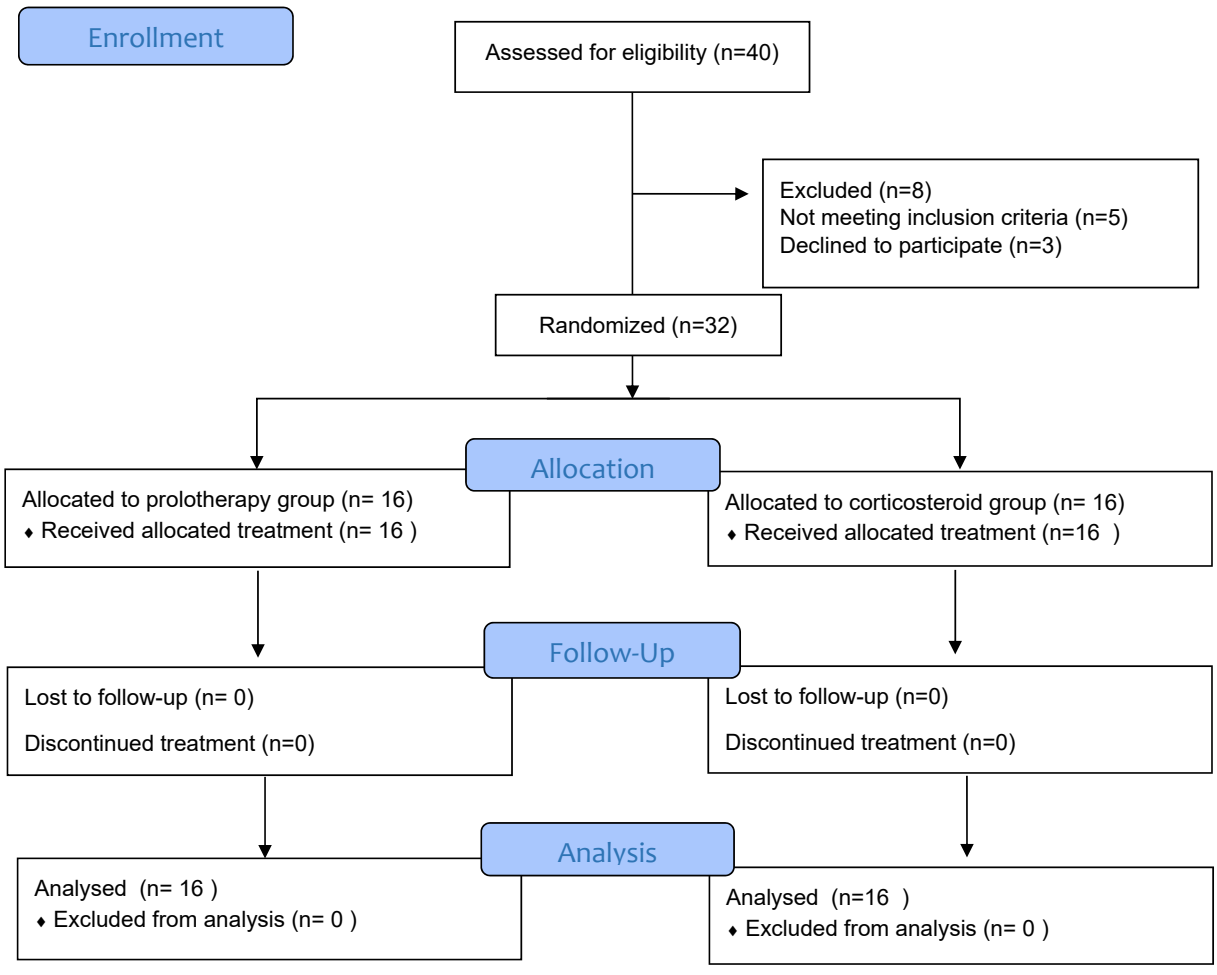

Figure 1. CONSORT 2010 flow diagram

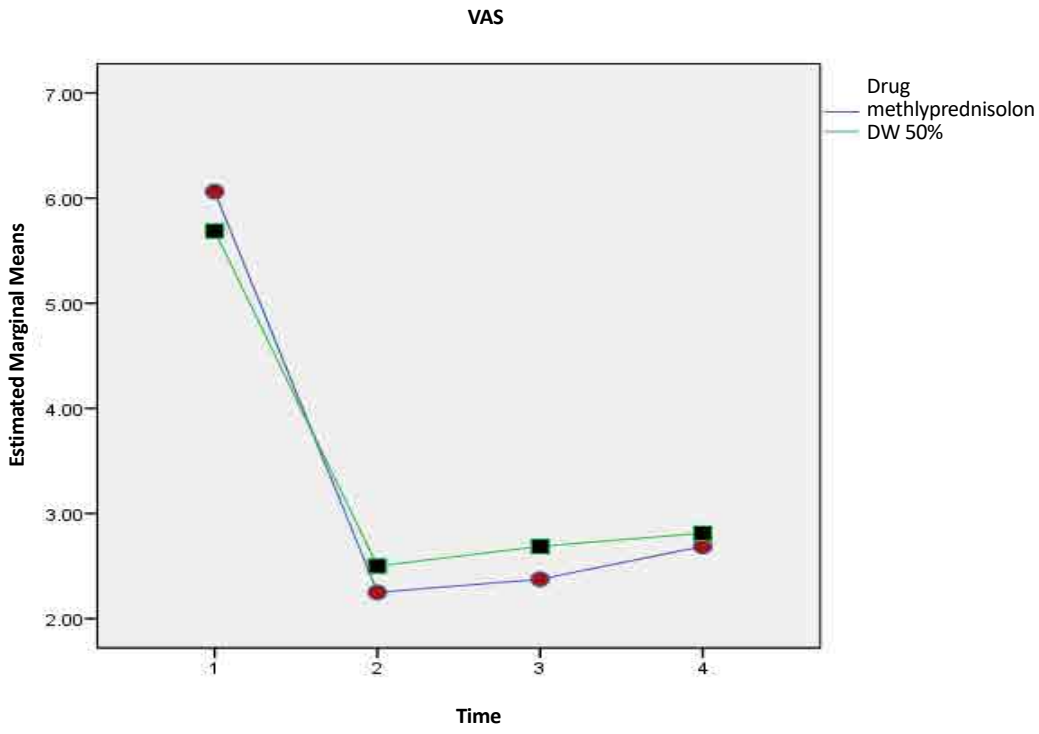

Figure 2. Comparison of the VAS scores between the methylprednisolone injection and dextrose 50% prolotherapy groups pre-injection, and 1, 4, and 8 weeks after injection.

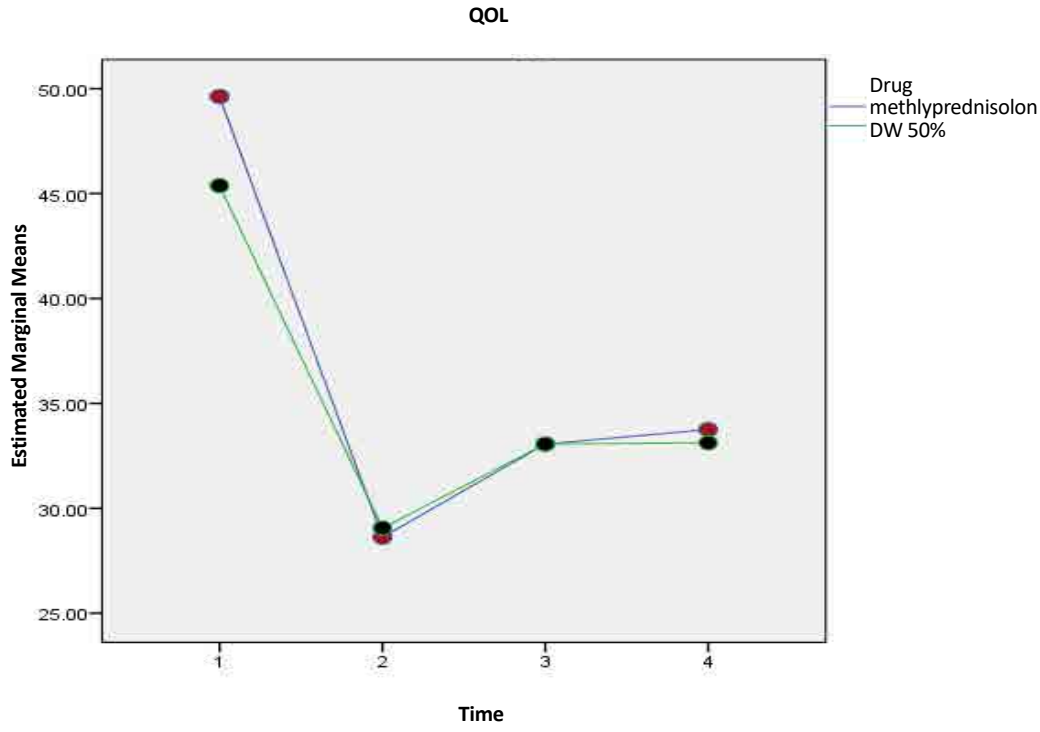

Figure 3. Comparison of the MOXFQ scores as a quality of life (QoL) questionnaire between the methylprednisolone injection and dextrose 50% prolotherapy groups pre-injection, and 1, 4, and 8 weeks after injection.

Rather, one of the two drugs was usually used or the two drugs were compared to treat other musculoskeletal problems. For example, Ross et al. evaluated the effect of prolotherapy injection on foot problems, such as hallux rigidus, and showed a significant difference before and after dextrose injection. This effect was also seen up to 18 months of follow-up [2]. In our study, the same result was obtained but it was not comparable in terms of follow-up time. In another study, the effect of prolotherapy and corticosteroids on the treatment of lateral epicondylitis was compared and the two drugs showed a similar effect, which is consistent with our results [21]. In the other study by Jahangiri et al., the effect of these two drugs on the osteoarthritis of the first metacarpophalangeal joint of the hand was evaluated. During the first month, the effect of corticosteroids was better, but after six months, the effect of dextrose was greater than that of corticosteroids [22]. The results of this study did not match the results of our study, which showed no significant difference between the two groups for up to eight weeks. In the studies by Grice et al. and Grady et al., corticosteroid injection was effective in hallux rigidus. In the study by Grady et al., this effect remained until a year later, but in the study by Grice et al., this effect lasted for three months [13, 23]. The result of our study in terms of corticosteroid injection in a short period is consistent with these studies. However, in the long period, it was not comparable due to shorter follow-up.

One of the shortcomings of this study was the short-term follow-up. Moreover, to more accurately evaluate the effect of drugs on the treatment of hallux rigidus, patients could be classified according to the severity of hallux rigidus and the desired indicators that would be accurately checked. The economic and cultural conditions of patients were other factors that could affect the results of the work. The lack of standard shoes in the market was another factor that could aggravate hallux rigidus and affect the therapeutic response of patients. Therapeutic effects have also been evaluated subjectively. If the recovery process was evaluated with the objective findings, such as radiographic manifestations before and after the procedure or the use of laboratory markers and clinical examinations (like a more objective assessment of patient ability over a specified distance via treadmill testing), comparison of scientific findings would be reported more accurately. Furthermore, the older age of some patients and the presence of possible depression due to chronic pain might reduce the accuracy of the answers received from the patients. Decreased patient cooperation following the passage of time was also a problem that had arisen in such studies. Therefore, future studies with larger sample sizes, longer follow-ups, objective evaluations of patients, categorization of patients' response to treatment based on the severity of hallux rigidus, administration of different doses of drugs, and obtaining the most appropriate prescribed dose are recommended.

5. Conclusion

Corticosteroid and dextrose prolotherapy are both effective in the management of hallux rigidus with neither having superior to the other. Therefore, dextrose prolotherapy can be an alternative option for corticosteroids injection due to the low price, the absence of specific side effects, and the mentality of patients towards the side effects of corticosteroids that may cause rejection by the patients.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the vice-chancellor of research, Shiraz University of Medical Sciences, Shiraz, Iran. Furthermore, the study method was approved by the Medical Ethics Committee of SUMS with the reference number "IR.SUMS.MED.REC.1398.489" and the Iranian Registry of Clinical Trials (IRCT) (Code: IRCT20210308050637N1).

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

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References

[1] Frontera WR, Silver JK, Rizzo TD. Essentials of physical medicine and rehabilitation e-book. Amsterdam: Elsevier Health Sciences; 2018. [Link]

[2] Hauser RA, Hauser MA, Cukla JK. A retrospective observational study on Hackett-Hemwall Dextrose Prolotherapy for unresolved foot and toe pain at an outpatient charity clinic in rural Illinois. Journal Prolotherapy. 2011; 3(1):543-51. [Link]

[3] Kon Kam King C, Loh Sy J, Zheng Q, Mehta KV. Comprehensive review of non-operative management of hallux rigidus. Cureus. 2017; 9(1):e987. [DOI:10.7759/cureus.987] [PMID] [PMCID]

[4] Welsh BJ, Redmond AC, Chockalingam N, Keenan AM. A case-series study to explore the efficacy of foot orthoses in treating first metatarsophalangeal joint pain. Journal of Foot and Ankle Research. 2010; 3(1):1-9. [DOI:10.1186/1757-1146-3-17] [PMID] [PMCID]

[5] Roddy E, Menz HB. Foot osteoarthritis: Latest evidence and developments. Therapeutic Advances in Musculoskeletal Disease. 2018; 10(4):91-103. [DOI:10.1177/1759720X17753337] [PMID] [PMCID]

[6] Park CH, Chang MC. Forefoot disorders and conservative treatment. Yeungnam University Journal of Medicine. 2019; 36(2):92-8. [DOI:10.12701/yujm.2019.00185] [PMID] [PMCID]

[7] Lam A, Chan JJ, Surace MF, Vulcano E. Hallux rigidus: How do I approach it? World Journal of Orthopedics. 2017; 8(5):364-71.[DOI:10.5312/wjo.v8.i5.364] [PMID] [PMCID]

[8] Ho B, Baumhauer J. Hallux rigidus. EFORT Open Reviews. 2017; 2(1):13. [DOI:10.1016/S0899-3467(07)60025-1] [PMID]

[9] Becker BA, Childress M. Common foot problems: Over-the-counter treatments and home care. American Family Physician. 2018; 98(5):298-303. [Link]

[10] Galois L, Hemmer J, Ray V, Sirveaux F. Surgical options for hallux rigidus: State of the art and review of the literature. European Journal of Orthopaedic Surgery & Traumatology. 2020; 30:57-65. [DOI:10.1007/s00590-019-02528-x] [PMID]

[11] Maher A, Price M. An audit of the use of sodium hyaluronate 1%(Ostenil [R] Mini) therapy for the conservative treatment of hallux rigidus. British Journal of Podiatry. 2007; 10(2):47-52. [Link]

[12] Caravelli S, Mosca M, Massimi S, Pungetti C, Russo A, Fuiano M, et al. A comprehensive and narrative review of historical aspects and management of low-grade hallux rigidus: Conservative and surgical possibilities. Musculoskeletal Surgery. 2018; 102(3):201-11. [DOI:10.1007/s12306-018-0530-3] [PMID]

[13] Grice J, Marsland D, Smith G, Calder J. Efficacy of foot and ankle corticosteroid injections. Foot & Ankle International. 2017; 38(1):8-13. [DOI:10.1177/1071100716670160] [PMID]

[14] Heidari N, Ashraf A, Mohamadi Jahromi LS, Parvin R. Efficacy of perineural hypertonic saline injection versus acupoints of foot in the management of diabetic neuropathy: A multicenter, double-blinded randomized controlled trial. Pain Management. 2023; 13(1):35-43. [DOI:10.2217/pmt-2022-0042] [PMID]

[15] Reilly I. Palpation-guided intra-articular injection of the first metatarsophalangeal joint: Injection technique and safe practice for novice practitioners. SN Comprehensive Clinical Medicine. 2021; 3(1):136-44. [DOI:10.1007/s42399-020-00719-w]

[16] Nasiri A, Jahromi LS, Vafaei MA, Parvin R, Fakheri MS, Sadeghi S. Comparison of the effectiveness of ultrasound-guided prolotherapy in supraspinatus tendon with ultrasound-guided corticosteroid injection of subacromial subdeltoid bursa in rotator cuff-related shoulder pain: A clinical trial study. Advanced Biomedical Research. 2021; 10:20. [DOI:10.4103/abr.abr_181_20] [PMID] [PMCID]

[17] Boonstra AM, Preuper HR, Reneman MF, Posthumus JB, Stewart RE. Reliability and validity of the visual analogue scale for disability in patients with chronic musculoskeletal pain. International Journal of Rehabilitation Research. 2008; 31(2):165-9. [DOI:10.1097/MRR.0b013e3282fc0f93] [PMID]

[18] Ponkilainen VT, Miettinen M, Sandelin H, Lindahl J, Häkkinen AH, Toom A, et al. Structural validity of the Finnish Manchester-Oxford Foot Questionnaire (MOXFQ) using the Rasch model. Foot and Ankle Surgery. 2021; 27(1):93-100. [DOI:10.1016/j.fas.2020.02.012] [PMID]

[19] Dawson J, Doll H, Coffey J, Jenkinson C. Responsiveness and minimally important change for the Manchester-Oxford Foot Questionnaire (MOXFQ) compared with AOFAS and SF-36 assessments following surgery for hallux valgus. Osteoarthritis and Cartilage. 2007; 15(8):918-31. [DOI:10.1016/j.joca.2007.02.003] [PMID]

[20] Massimi S, Caravelli S, Fuiano M, Pungetti C, Mosca M, Zaffagnini S. Management of high-grade hallux rigidus: a narrative review of the literature. Musculoskeletal Surgery. 2020; 104:237-43. [DOI:10.1007/s12306-020-00646-y] [PMID]

[21] Carayannopoulos A, Borg-Stein J, Sokolof J, Meleger A, Rosenberg D. Prolotherapy versus corticosteroid injections for the treatment of lateral epicondylosis: A randomized controlled trial. PM&R. 2011; 3(8):706-15. [DOI:10.1016/j.pmrj.2011.05.011] [PMID]

[22] Jahangiri A, Moghaddam FR, Najafi S. Hypertonic dextrose versus corticosteroid local injection for the treatment of osteoarthritis in the first carpometacarpal joint: A double-blind randomized clinical trial. Journal of Orthopaedic Science. 2014; 19(5):737-43. [DOI:10.1007/s00776-014-0587-2] [PMID]

[23] Grady JF, Axe TM, Zager EJ, Sheldon LA. A retrospective analysis of 772 patients with hallux limitus. Journal of the American Podiatric Medical Association. 2002; 92(2):102-8. [DOI:10.7547/87507315-92-2-102] [PMID]