Randomized Trial

Piriformis Syndrome: Comparison of the Effectiveness of Local Anesthetic and Corticosteroid Injections: A Double-Blinded, Randomized Controlled Study

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Background: Piriformis syndrome (PS), which is characterized by pain radiating to the gluteal region and posterior leg, is accepted as one of the causes of sciatalgia. Although the importance of local piriformis muscle injections whenever PS is clinically suspected has been shown in many studies, there are not enough studies considering the clinical efficacy of these injections.

Objective: To investigate the differences between local anesthetic (LA) and LA + corticosteroid (CS) injections in the treatment of PS.

Study Design: A prospective, double-blinded, randomized controlled trial.

Setting: Physical medicine and rehabilitation department of a university hospital.

Methods: Fifty-seven patients having unilateral hip and/or leg pain with positive FAIR test and tenderness and/or trigger point at the piriformis muscle were evaluated. Out of 50 patients randomly assigned to 2 groups, 47 patients whose pain resolved at least 50% from the baseline after the injection were diagnosed as having PS. The first group (n = 22) received 5 mL of lidocaine 2% while the second group (n = 25) received 4 mL of lidocaine 2% + 1 mL of betametazone under the guidance of ultrasound.

Outcome Assessment: Numeric Rating Scale (NRS) and Likert Analogue Scale (LAS).

Results: No statistically significant difference ($P > 0.05$) was detected between the groups in NRS score values at resting ($P = 0.814$), night ($P = 0.830$), and in motion ($P = 0.145$), and LAS values with long duration of sitting ($P = 0.547$), standing ($P = 0.898$), and lying ($P = 0.326$) with evaluations at baseline, first week, and first and third months after the injection. A statistically highly significant ($P < 0.005$) reduction of pain was evaluated through NRS scores at resting ($P = 0.001$), in motion ($P = 0.001$), and at night ($P = 0.001$) and LAS values with long duration of sitting ($P = 0.001$), standing ($P = 0.001$), and lying ($P = 0.001$) in both of the groups.

Limitations: Presumed limitations of this study include having a relatively small sample.

Conclusion: LA injections for the PS were found to be clinically effective. However, addition of CS to LA did not give an additional benefit. This gives us the idea that PS is mostly muscular in origin and responds well to both LA and LA+CS injections.

Key words: Piriformis muscle syndrome, injection, ultrasound, pain, local anesthetics, steroids, rehabilitation

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Piriformis syndrome (PS) is an underdiagnosed cause of buttock and leg pain, possibly because it is thought to be a rare cause of sciatica (1). In the literature, PS has been used to denote 4 different entities (2). These are 1) "proximal sciatic neuropathy" defined as the injury of the proximal sciatic nerve by lesions in the vicinity of the piriformis muscle (PM) such as endometriosis, tumors, hematomas, fibrosis, aneurysms, false aneurysms, or arteriovenous malformations; 2) compressive injury of the proximal sciatic nerve by the anatomical variations of the PM itself; 3) "post-traumatic PS" defined as the injury of the sciatic nerve by the scar tissue of the PM and adjacent tissues from trauma of the gluteal region; 4) chronic buttock pain caused by the musculoskeletal pathologies of the PM such as myofascial pain or pinching of the sciatic nerve by the PM during certain leg and hip maneuvers. In most cases, however, PS is widely believed to be myofascial in origin (3).

Treatment of PS starts with conservative pharmacotherapy with nonsteroidal anti-inflammatory drugs, muscle relaxants, and neuropathic pain agents and continues with physical therapy, which includes stretching of the PM to correct the underlying pathology (4). If the conservative regimen fails, then more aggressive therapy, such as local injection of PM, which may reconfirm the diagnosis through therapeutic success, should be performed (5).

Local anesthetic (LA) injection that is done into the PM is accepted as a reference diagnostic test. The dramatic and almost immediate relief of pain produced by infiltration of the PM is considered to be a diagnostic aid for PS (5). So, to increase the reliability of the injection, various methods such as nerve stimulator technique, electromyography, fluoroscopy, computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound (US) have been described as a guide for infiltration of the PM (6-10). LA with or without corticosteroid (CS) may be injected into the PM to relieve pain upon diagnosing PS (2,11-15). However, in reviewing the literature on PS, it is seen that most of the LA injections are done with CS so as to enhance the therapeutic effect (5-7,13,16,17).

In our department, we perform US-guided injection of the PM for diagnostic and therapeutic purposes. The goal of our study was to investigate the differences between LA and LA+CS injections in the treatment of PS.

Methods

A prospective double-blinded, randomized controlled trial was conducted with approval of the Medical Ethics Committee prior to the study. All patients were competent to provide consent and signed informed consent forms prior to the initial assessment.

Patients

Fifty-seven (n = 57) patients between the ages of 18 and 70, having unilateral hip and/or leg pain with positive FAIR (flexion, adduction, internal rotation) test and tenderness and/or trigger point at the PM were enrolled in our study. The exclusion criteria were having a neurological deficiency, limited lumbar and/or hip range of motion, operation history at the lumbar and/or hip region, being in gestational or lactational period, history of allergic reaction to the substance to be applied as LA, history of anticoagulation use, body mass index of greater than 35, and history of inflammatory or infectious disease, active psychiatric disease, uncontrolled hypertension,uncontrolled diabetes mellitus, noncompensated chronic heart/liver/renal deficiency, or vascular/tumoral disease.

Baseline assessments were done by the first physiatrist (TOM) who was blinded to group allocation. A detailed history including duration of pain, pain aggravating factors, possible causative factors, history of trauma, and medical history was obtained. Physical examination of the hip, lumbar, and sacroiliac regions was meticulously assessed to exclude other causes of pain. In neurologic examination, muscle strength, cutaneous sensation, deep tendon, and pathologic reflexes were assessed. Pain as well as its radicular character on palpation of the PM at the symptomatic side and reproduction with maneuvers such as applying downward pressure to the symptomatic flexed knee while maximizing the adduction and internal rotation in the symptomatic flexed hip in the lateral decubitus position (FAIR test) (17), forcefully internally rotating the extended thigh on the affected side in the supine position (Freiberg's maneuver) (18), actively abducting the thigh on the affected side in the lateral decubitus position (Beatty's maneuver) (19), and actively abducting both thighs against resistance in the seated position (Pace's maneuver) (12) were noted. At the end of the physical examination, in cases when other causes of sciatica could not be excluded, x-ray and/or MRI of the lumbar spine and hips were ordered.

Of the 57 patients who had been enrolled to the study, 7 patients not meeting the inclusion criteria after the clinical and radiological assessments were excluded. Fifty patients (8 men, 42 women) having a pre-diagnosis of PS were randomized into 2 groups for the test thera-

peutic intervention of the PM by the second physiatrist (MGE). PS was diagnosed in patients whose pain resolved at least 50% from the baseline after the injection.

Patients randomized to the first group (the LA group) (n = 25) received 5 mL of lidocaine 2% while the second group (the LA+CS group) (n = 25) received 4 mL of lidocaine 2% + 1 mL of betametazone. Three patients from the LA group whose pain did not resolve at least 50% from the baseline were also excluded. Forty-seven patients completed the study including the LA group of 22 cases and the LA+CS group of 25 cases.

The procedure in all cases was carried out by the third physiatrist (KA) who was experienced with interventional procedures under the guidance of US. All the patients who were included in the study were warned about pain exacerbating activities such as prolonged sitting, standing, and walking; squatting; crossing legs; and sitting with a large wallet in the affected side's rear pocket. Treatment of conservative pharmacotherapy with meloxicam 10 mg (1x1) and paracetamol 500 mg (3x1) for 10 days was given to all patients. At the end of the first week, piriformis stretching exercise which involved hip and knee flexion, hip abduction, and external rotation in supine position was started and aimed to be done as far as the patients could tolerate.

Objectives

The objective of this trial was to evaluate the effectiveness of US-guided LA injections into PM with or without CS for managing PS.

Outcomes

Patients were re-assessed one week (first evaluation), one month (second evaluation), and 3 months (third evaluation) after the injection, by the first physiatrist (TOM), who was not involved in patients' injection procedures and who was blinded to group allocation. Numeric Rating Scale (NRS) (at resting, at night, and during activity) and Likert Analogue Scale (LAS) values (pain in daily living activities: with long duration of sitting, standing, and lying) were used as outcome measures while responses to clinical maneuvers (FAIR position, Beatty's maneuver, Pace's maneuver, and Freiberg's maneuver) were also assessed during the follow-up period.

All procedures were performed with a 5 – 10 MHz linear probe (Diasus Dynamic Imaging, Livingston, UK). During the procedure, all the patients assumed a prone position. The sacral hiatus was identified first, and afterwards the transducer was moved in a lateral direction towards the greater trochanter. After locating the PM as a hyperechoic band between the sacrum and the greater trochanter deep under the gluteus muscle, injection was performed in a lateral-to-medial approach to the point of maximum tenderness with a 22-gauge 88 mm Spinocan (Figs. 1-3).

Sample Size

The expected values to calculate the sample size were 5 and 3, the standard deviations was assumed to be 2, and the power was determined to be 0.90 at an

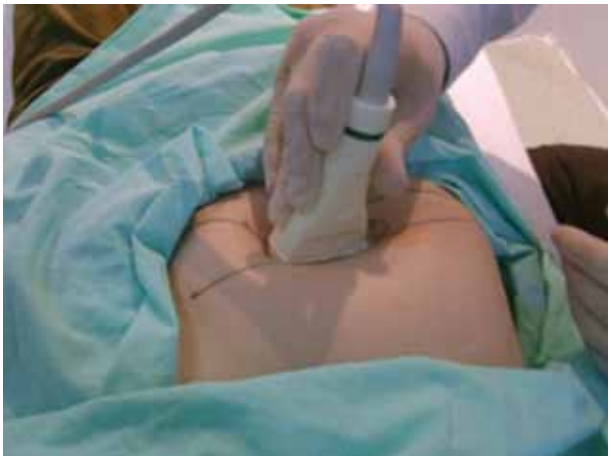

Fig. 1. Longitudinal placement of the US probe over the PM before the injection. Left PM is illustrated extending from the sacrum to the greater trochanter.

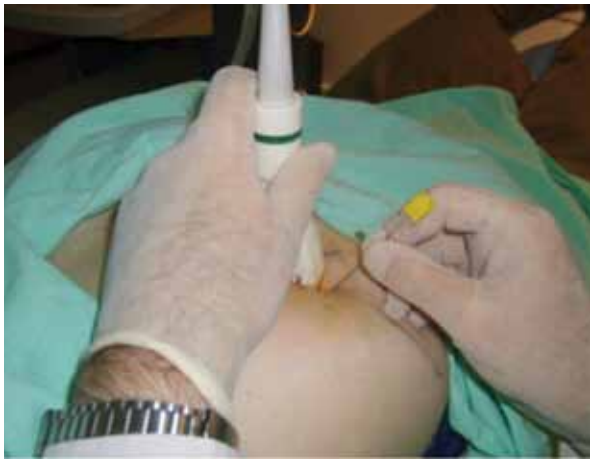

Fig. 2. *US guided injection of the left PM. Physician's one hand holds the transducer while the other one moves the 22-gauge spinal needle into the PM.*

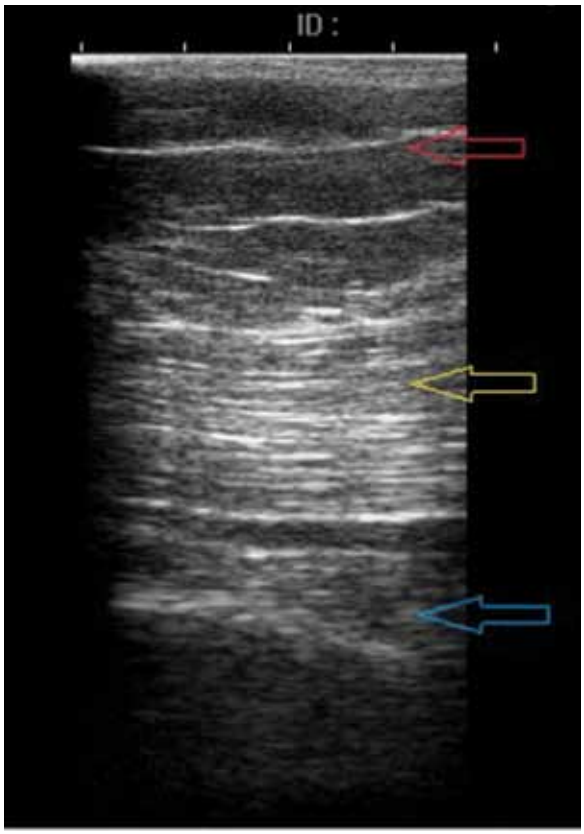

Fig. 3. *US image of the PM (blue arrow). The PM appears as a hyperechoic band deep under the gluteus maximus muscle (yellow arrow). Red arrow indicates subcutaneous fat tissue.*

alpha level of 0.05 with a sample size of 22 for each group.

Intention-to-treat Analysis

All dropouts occurred prior to data collection; i.e., no dropouts occurred while the study was being carried out, eliminating the need for an intention-to-treat analysis.

Randomization-sequence Generation

The block randomization method was used for the randomization of the patients who were also blinded to group allocation.

Randomization-allocation Concealment

All the assessments were done by the first physiatrist (TOM), who was not involved in patients' injection procedures. The randomization was performed by the second physiatrist (MGE) who was not involved in patients' assessment and injection procedures. After preparing the drugs and providing them to the ultrasonography room, MGE did not take part in the clinical part of the study. All medical personal involved in the care of the patients as well as the patients were blinded to the treatment. Injections for both groups were clear and indistinguishable from each other. US-guided injection of PM was carried out by the third physiatrist (KA) who did not take part in the assessments. Both KA and TOM were blinded to group allocation.

Statistical Methods

Each group was analyzed with the Friedman test for non-parametric repeated measures comparisons. Wilcoxon signed-ranks test was used to analyze each group's pre- and post-injection scores in pairs. We compared the NRS and LAS values of the LA group with the LA+CS group with Pillai's Trace for multivariate analysis from general linear models. P value < 0.05 was considered statistically significant.

All statistical analyses were performed using SPSS statistical software for Windows, version 14.0.

Results

Patient Flow

The flow of patients in this study is presented in Fig. 4.

Recruitment

The trial recruitment period lasted from September 2010 through May 2011.

Baseline Data

The mean ages ± SD in the 2 groups were 45.5 ± 14.1 and 47.2 ± 13.4, respectively (P > 0.05). The LA group consisted of 17 women and 5 men, while there were 23 women and 2 men in the LA+CS group (P > 0.05). The mean symptom duration was 17.4 ± 28.6 months in the LA group and 23.6 ± 30.5 months in the LA+CS group (P > 0.05). Pain characteristics and physical findings of our patients diagnosed with PS are given in Table 1.

Numbers Analyzed

Of the 57 patients who had been enrolled to the study with a pre-diagnosis of PS, 7 patients not meeting the inclusion criteria after the clinical and radiological assessments were excluded. Fifty patients were randomized to 2 groups containing 25 patients in each

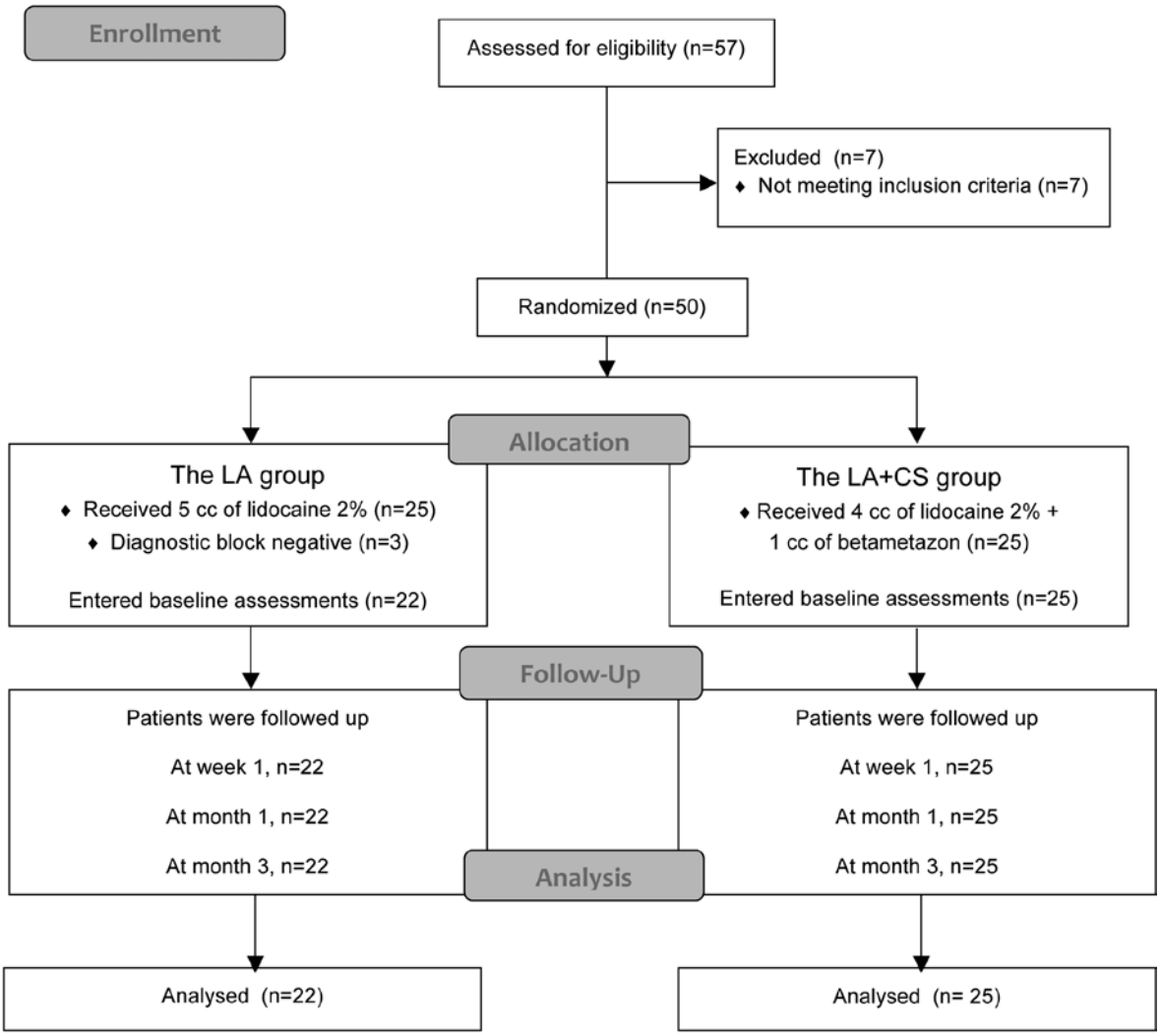

Fig. 4. *Flow of patiens in the study.*

group. The diagnosis of PS was excluded in 3 patients from the LA group whose pain did not resolve at least 50% from the baseline after the injection. Finally, 22 patients from the LA group and 25 patients from the LA+CS group completed the study.

Outcomes and Estimation

No significant difference was found between the groups in terms of age, gender, and symptom duration at the beginning of our study. Baseline values of pain measured by NRS and LAS were all comparable among the groups ($P > 0.05$). When compared with the baseline values, significant improvements in terms of all pain parameters measured by NRS were observed at the first (one week later), second (one month later), and third (3 months later) evaluations after the injection in both of the groups ($P < 0.05$) (Table 2). The same significant improvements from the baseline values were observed in the LAS scores at the first, second, and third evaluations for both of the groups ($P < 0.05$) (Table 3). The group comparisons revealed no significant difference in reduction of pain of any parameters among the groups at the first, second, and third evaluations after the procedure ($P > 0.05$) (Table 2-3).

Table 1. *Characteristics and physical findings of our patients diagnosed with PS.*

	The LA group (n = 22)	The LA+CS group (n = 25)
Side of pain (right/left)	9/13	10/15
Character of pain (constant/occasional)	9/13	17/8
Local/radiating pain	4/18	4/21
History of trauma (+/-)	9/13	11/14
Bad sitting habits (+/-)	17/5	20/5
Sitting with wallet in the rear pocket of the affected side (+/-)	2/20	1/24
Tenderness with deep palpation of PM (+/-)	22/0	25/0
Radiating pain with deep palpation of PM (+/-)	13/9	17/8
FAIR test (+/-)	22/0	25/0
Beatty test (+/-)	11/11	14/11
Pace test (+/-)	9/13	13/12
Freiberg test (+/-)	5/17	5/20

Table 2. *Pain values measured by NRS in the groups. Data presented are NRS values (mean ± SD). Differences of all baseline values among the groups are not significant (P > 0.05).*

	The LA group (n = 22)				The LA+CS group (n = 25)			
	Before the procedure	First week	First month	Third month	Before the procedure	First week	First month	Third month
Rest pain	2.8 ± 3.1	1.0 ± 2.1*	0.5 ± 1.1 *	0.4 ± 1.1 *	3.6 ± 3.1	1.4 ± 2.7 *	1.7 ± 2.9 *	1.6 ± 2.1*
Activity pain	7.2 ± 2.0	3.5 ± 2.6 *	1.9 ± 1.5 *	1.7 ± 2.3 *	7.4 ± 2.4	4.6 ± 3.0 *	3.9 ± 2.9 *	3.0 ± 2.7 *
Pain disturbing sleep	3.3 ± 3.2	1.3 ± 1.9 *	0.6 ± 1.5*	0.4 ± 1.0 *	3.8 ± 3.9	2.1 ± 3.2 *	1.0± 1.9 *	1.0 ± 2.0 *

*A significant change between one week, one month, and 3 months after and before the procedure for both of the groups ($P < 0.05$).

Table 3. *Pain values measured by LAS in the groups. Data presented are LAS values (mean ± SD). Differences of all baseline values among the groups are not significant (P > 0.05).*

	The LA group (n = 22)				The LA+CS group (n = 25)			
	Before the procedure	First week	First month	Third month	Before the procedure	First week	First month	Third month
Standing	3.0 ± 1.0	2.0 ± 0.9*	1.8 ± 0.7*	1.6 ± 0.8*	3.4 ± 1.2	2.4 ± 1.2*	2.1 ± 1.1*	1.9 ± 1.2*
Sitting	3.1 ± 1.2	2.2 ± 1.1*	1.7 ± 0.6*	1.7 ± 1.0*	3.3 ± 1.2	2.1 ± 1.2*	2.1 ± 1.2*	1.9 ± 0.8*
Lying	2.2 ± 1.2	1.5 ± 0.78*	1.3 ± 0.5*	1.3 ± 0.6*	2.7 ± 1.3	1.9 ± 1.2*	1.6 ± 0.9*	1.5 ± 0.8*

*A significant change between one week, one month, and 3 months after and before the procedure for both of the groups ($P < 0.05$).

Adverse Events

Procedural technical success was achieved in all 50 patients who were treated with US-guided injection of PM. Sciatic nerve block was observed in 12 patients (6 patients from LA group and 6 patients from LA+CS group) after intramuscular injection, which resolved some hours after the procedure. No complications or side effects were observed.

Discussion

Lack of standard diagnostic criteria for the diagnosis of PS gives rise to arguments on whether PS is an under- or over-diagnosed cause of sciatica (2). There are still ongoing debates about the diagnostic and treatment methods since there are many different theories described for the ethiopathogenesis of the syndrome. When PS is suspected clinically, LA injection can be done into the PM and at least 50% decrease in patient's symptoms following the injection is accepted as an important diagnostic aid by many authors (2,6,14,15,20). However, there is some recently published literature advocating diagnostic scores (21) and electromyographic signs (22,23) in the diagnosis. In our clinics, we

accept the diagnostic block as the golden standard and we think imaging and electrophysiologic studies should be done in order to see if there is a causative or accompanying lesion.

Many different injection techniques have been described in the literature. These are injections into the muscular belly, the perisciatic nerve infiltration, or injections into the medial aspect of the muscle or in the side (7,13,24). There are still no conclusive studies about which of the techniques is the superior one. In our study, we preferred to make our injections into the point of maximum tenderness.

Starting with the blinded injections, many different methods such as nerve stimulation, electromyography (EMG), fluoroscopy, CT, MRI, and US have been used to improve the accuracy of needle placement into the PM. Among these, the nerve stimulation method was found to be inappropriate for patients who have anatomic variations of PM (13). The injections done under the guidance of fluoroscopy and EMG were successful at identifying the PM accurately. However, these techniques were found to be insufficient in measuring the needle depth needed to reach the PM (8). In a study done by Smith et al (25) injections done under US guidance were proposed to be superior to EMG, fluoroscopy, CT, and MRI. They described the advantages of this method as easily accessible, fast, simple, and economical. Compared with the other methods, it was reported that US had no known contraindications, produced no ionizing radiation, did not require contrast, and was well-accepted by patients. In addition to providing excellent soft tissue resolution, identifying bony landmarks, nerves, and vessels, US provided real-time visualization of needle passage toward an intended target. It was also found superior to the other methods, since it can be easily done by the physiatrist with appropriate training and experience in a clinical setting (26-29).

In the literature, LA and CS are the most commonly used drugs for the PM injections. Injection of these drugs into the site of nerve compression was shown to reduce nerve swelling, reduce ectopic discharge, and facilitate the recovery of nerve conduction following nerve injury (13). In another study, it was also shown that steroids selectively block the transmission of nociceptive fibers, whereas anesthetics can relax the PM and break the cycle of pain and spasms (7).

In a study conducted by Fishman et al (17), the use of lidocaine and CS injections for treating PS had been investigated. The patients who were found to have 2 out of the 3 following clinical features: (1) pain where the sciatic nerve travels below the piriformis muscle in the FAIR position, (2) tenderness to palpation at the same location, and (3) positive Lasegue sign and or 3-SD prolongation of the H-reflex in the FAIR position were included in the study. An average of 71.1% of the 537 patients diagnosed as PS were reported to improve after corticosteroid and lidocaine injection combined with physical therapy.

Botulinum toxin (BTX) for treatment of PS has also been found efficient by many authors (30). It may be responsible for a reduction of nerve compression exerted by a normal or hypertrophied PM and relieving pain by relaxing the muscle. While in some studies, injections of BTX, when used as an adjunct to physical therapy, have been shown to produce more pain relief than lidocaine with steroids or placebo (31,32), there are also other studies that have found no statistically significant differences between either (30,33). Therefore, considering the high cost of the drug, the use of BTX as a first line of treatment is not advised.

To our knowledge, this is the first study that has investigated the differences between LA and LA plus CS injections under the guidance of US. We wanted to reveal whether the patients get benefit from the addition of CS to LA injections of PM. Participant recruitment and treatment adherence were considered successful, and there were no serious adverse events related to the intervention. Twelve patients developed sciatic nerve block following the injection, which can be due to high concentrations of LA. As recommended by Hanania and Kitain (13), we may consider using lower amounts of LA in order to prevent sciatic nerve blocks especially in patients with a lesser amount of adipose tissue in the gluteal region.

Our study groups were all comparable in terms of age, gender, and symptom duration. The mean age ± SD of our patients was 46.4 ± 13.6, which was an expected result since PS is said to occur mostly in middle-aged patients in their fourth or fifth decades (19,34). Eighty-five percent of our patients were woman, which was also compatible with the literature. Woman:man ratio in PS was reported as 6:1 in the literature (12). History of trauma to the gluteal region was present in 42.5% of the patients in our study. In the literature, the frequency of gluteal trauma in PS was also reported as 50% (12,19,24). While bad sitting habits such as sitting crossed-legged and squatting down were present in 78.7% of our patients, carrying a wallet in the rear pocket which is the most known

risk factor in the etiology of PS was observed in 42.8% of our male patients.

In physical examination, tenderness by deep palpation of the PM was elicited in 100% of our patients. Radiation of pain with deep palpation of the PM was present in 63.8% of the patients. In a retrospective study of 26 patients with sciatica due to PS, sciatica was reproduced in 92% of the patients upon deep digital palpation and in 100% of the patients upon rectal or pelvic examination (35). Among the clinical tests that we performed for the diagnosis of PS, the FAIR test was positive in 100%, Beatty test was positive 53.1%, Pace test was positive in 46.8%, and Freiberg test was positive in 21.2% of the patients. In the literature, none of these tests have had their sensitivity and specificity clearly validated (23). From our standpoint and clinical experience, we believe that the most helpful clinical test suggesting PS is the FAIR test and the deep palpation of the PM triggering the typical symptoms of the patient. After the physical examination, these patients should be the candidates for the diagnostic PM injection test.

The outcomes of our injections were assessed with NRS score values (at resting, night, and in motion) and LAS values (pain on daily living activities: with long duration of sitting, standing, and lying). All of the pain parameters improved significantly at the first week, first month, and third month evaluations in both groups. However, addition of CS to LA did not make an additional difference between the groups. This may confirm the hypothesis that PS is mostly muscular in origin (21) and responds well to both LA and LA+CS injections.

In the literature, although some of the investigators consider PS as a form of myofascial pain syndrome (3,5,30), what is widely believed is that PS results mainly from the entrapment of the sciatic nerve by inflammation and swelling of the PM (1,11). Our study showed that our treatment protocol was successful in both groups regardless of the injection material. As a result, for the PS injections, we suggest using LA alone in order to get use of its therapeutic as well as its diagnostic effect.

Presumed limitations of this study include having a relatively small sample. More studies including more patients are needed to support our results.

Conclusion

Local anesthetic injections for the PS were found to be clinically effective. However, addition of CS to LA did not give an additional benefit. This gives us the idea that PS is mostly muscular in origin and responds well to both LA and LA+CS injections. Besides, it is reasonable to do these injections with LA alone considering the possible side effects of corticosteroids.

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