



Effect of Intradermal Local Anesthetics on Pain and Functionality Following Persistent Spinal Pain Syndrome Type 2

Persistan Spinal Ağrı Sendromu Tip 2'de İntradermal Lokal Anestezik Uygulamasının Ağrı ve Fonksiyonelliğe Etkisi

Mustafa Hüseyin Temel, Duygu Geler Külcü*, Nilgün Mesci*, Dilara Dilik*

Üsküdar State Hospital, Clinic of Physical Medicine and Rehabilitation, İstanbul, Turkey

*University of Health Sciences Turkey, İstanbul Haydarpaşa Numune Training and Research Hospital, Clinic of Physical Medicine and Rehabilitation, İstanbul, Turkey

Abstract

Objective: To examine the effect of intradermal local anesthetic (LA) injection as an adjunct to physical therapy and rehabilitation (PTR) on pain and functionality in patients with persistent spinal pain syndrome type 2 (PSPS-T2).

Materials and Methods: A total of 80 patients aged between 18 and 75 years were included and randomized in this prospective, randomized, single-blind study. The first group (n=40) received PTR, while the second group received 3-sessions of intradermal LA injection at painful locations and scar areas in addition to PTR. Patients were assessed using the visual analog scale (VAS), Oswestry Disability index (ODI), Hospital Anxiety and Depression scale (HADS), and finger to ground distance. All tools were administered before, immediately after treatment, and 1 month after completion of treatment.

Results: The VAS and ODI scores were significantly reduced in both groups and were maintained at the 1-month follow-up visit. The HADS scores and finger to ground distance did not change significantly in either group (p>0.05).

Conclusion: PTR was associated with improved pain and functionality in patients with PSPS-T2, with no additional therapeutic contributions from intradermal LA injections.

Keywords: Persistent spinal pain syndrome type 2, local anesthetic, intradermal injection

Öz

Amaç: Persistan spinal ağrı sendromu tip 2 (PSPS-T2) hastalarında fizik tedavi ve rehabilitasyon (FTR) programına ek olarak uygulanan intradermal lokal anestezik (LA) enjeksiyonunun ağrı ve fonksiyonelliğe etkisini arařtırmaktır.

Gereç ve Yöntem: Prospektif randomize ve tek kör olarak tasarlanan çalışmamıza 18-75 yaş arası toplam 80 hasta alındı ve 2 gruba randomize edildi. İlk gruba FTR programı, ikinci gruba FTR programına ek olarak 3 seans operasyon skarını ve ağrılı alanları çevreleyecek şekilde intradermal LA enjeksiyonu yapıldı. Hastalar Ağrı vizüel analog skala (VAS), Oswestry Dizabilite indeksi (ODİ), Hastane Anksiyete ve Depresyon skalası (HADS) ve parmak zemin mesafesi ile tedavi öncesi, tedavi sonrası ve tedaviden 1 ay sonra değerlendirildi.

Bulgular: Her iki grupta da VAS ve ODİ değerlerinde anlamlı derecede düşüş saptandı ve bu düşüş 1 ay sonraki kontrolde de devam etti. İki grup arasında tedavi sonrası istatistiksel olarak anlamlı bir fark görülmedi. Her iki grupta da HADS skorunda ve parmak zemin mesafesinde istatistiksel olarak anlamlı bir değişim görülmedi (p>0,05).

Sonuç: Çalışmamız sonucunda PSPS-T2'de FTR programının ağrı ve fonksiyonelliği iyileştirdiği, ek olarak uygulanan intradermal lokal anestezik enjeksiyonunun ek bir katkı sağlamadığı görülmüştür.

Anahtar kelimeler: Persistan spinal ağrı sendromu tip 2, lokal anestezik, intradermal enjeksiyon

Introduction

Persistent spinal pain syndrome type 2 (PSPS-T2) is described as lumbar and/or cervical pain of unknown origin either persisting despite surgical intervention or appearing after surgical intervention for spinal (origin) pain originally in the same topographical distribution (1). PSPS-T2 may occur due to pre-operative, intra-operative, and post-operative factors. Manifestations of PSPS-T2 include back and/or leg pain and difficulty in daily activities after surgery. The pain may be of mechanical or neuropathic origin (2).

Rehabilitation represents a mainstay of conservative management in PSPS-T2 patients. Rehabilitation of PSPS-T2 starts with careful history taking and complete physical examination, followed by an individualized rehabilitation program aiming at pain reduction, restoration of functionality, active participation in daily activities, and improved quality of life. Such rehabilitation programs have been shown to be associated with improvements in muscle strength, physical functions, posture, and gait (3,4).

Previous studies showed that spinal surgery may damage the multifidus muscle, with subsequent atrophy, the degree of which correlates with chronic low back pain and functional incapacity (5). Flexor and extensor muscles stabilizing the spine are generally weakened in patients with chronic low back pain (6). On the other hand, patients with postoperative back pain experience difficulties in performing exercise due to both kinesiophobia as well as pain itself, leading to a vicious cycle consisting of pain, limitation of motion, and impaired quality of life.

Local anesthetic (LA) injections have long been used successfully in the management of chronic painful conditions such as pelvic pain, fibromyalgia, myofascial pain, and non-specific chronic low back pain (7). Intradermal drug administration is known to provide more prolonged local pharmacological activity, as compared to oral and intramuscular routes of administration (8). Lidocaine can lead to selective and partial block in A-delta and C fibers via the blockade of sodium channels in peripheral nerves, hence its use as an analgesic agent. Also, lidocaine is known to possess anti-nociceptive and analgesic effects, to cause endogenous release of opioids, and to contribute wound healing. Also, with decrease in peripheral sensitization and hyperalgesia; lidocaine injection can also alter the course of central sensitization (9,10). In light of these data, we carried out this study to investigate whether intradermal LA injections as an adjunct to electrotherapy and exercise program would lead to more effective or more rapid alleviation of pain in PSPS-T2 patients, and whether it would be associated with more quick improvement in terms of functions and disability.

Materials and Methods

This prospective and single-blind study was carried out between 01 June 2019 and 01 June 2020 at the Physical Medicine and Rehabilitation Unit, Haydarpaşa Training and Research Hospital of the Health Sciences University after Ethics Committee

approval (decision no: KAEK 2019/23, date: 08.04.2019). All patients provided written informed consent. Eligible patients were diagnosed with PSPS-T2, were between 18 and 75 years of age, and had low back pain severity of visual analogue scale (VAS) >4. Exclusion criteria were the presence of mental disorders, conditions affecting the central or peripheral nervous system, previous fixation surgery on the back, physical therapy or injection at the low back within the past 3 months, known allergy to lidocaine, needle phobia, presence of spinal stenosis, lesions at the site of injection (e.g., wounds, infection, rash etc.) and malignancy.

A power analysis to determine the minimum required number of patients assuming a type 1 error level of 5%, a statistical power of 80%, and a drop-out rate of 20%, 37 patients in each group were required. The power analysis was carried out using the G*Power software.

A total of 80 patients attending to the Physical Medicine and Rehabilitation Unit of Haydarpaşa Research and Training Hospital were included and assigned into treatment and control groups using the sealed envelope randomization method. In each patient, detailed medical history was obtained and locomotor system examination was performed. Demographic data as well as the number, date, type, level, and side of previous surgeries were recorded. The study was completed by 31 and 35 patients in the treatment and control groups, respectively. The flow diagram for the study is shown in Figure 1.

Patients in the treatment group received of hotpack (Fizyopack 7000) (20 min/day) + transcutaneous electrical nerve stimulation (TENS) (Fizyotens 4000, clinical TENS device with 4 independent channels) (20 min/day) + lumbar range of motion and strength exercises 5/weekly for a total of 15 sessions, in addition to 3 sessions of intradermal lidocaine injections, one session per week.

Intradermal lidocaine (2% lidocaine) injections were administered to painful areas and around the surgical scar. The intradermal injections were performed with a needle (0.4 mm, 25G) angle of 5-15 degrees and without penetrating beyond the superficial layer of the skin (the needle was not advanced more than 3 mm) (11). A total of 2 cc of lidocaine was used, with 0.2 cc of lidocaine in each injection. The lidocaine preparation was diluted with physiological saline at a ratio of 1:1, and injections were performed with 1 cm intervals starting from an injection point 1 cm distal to the painful scar area.

Control patients received of hotpack (Fizyopack 7000) (20 min/day) + TENS (Fizyotens 4000, clinical TENS device with 4 independent channels) (20 min/day) + lumbar range of motion and strength exercises 5/weekly for a total of 15 sessions.

Assessment Parameters

Pain

VAS: In VAS, patients mark their severity of pain on a linear scale from 0 to 10. Pain before treatment, after treatment, and at 1-month follow-up examination was assessed using VAS (12).

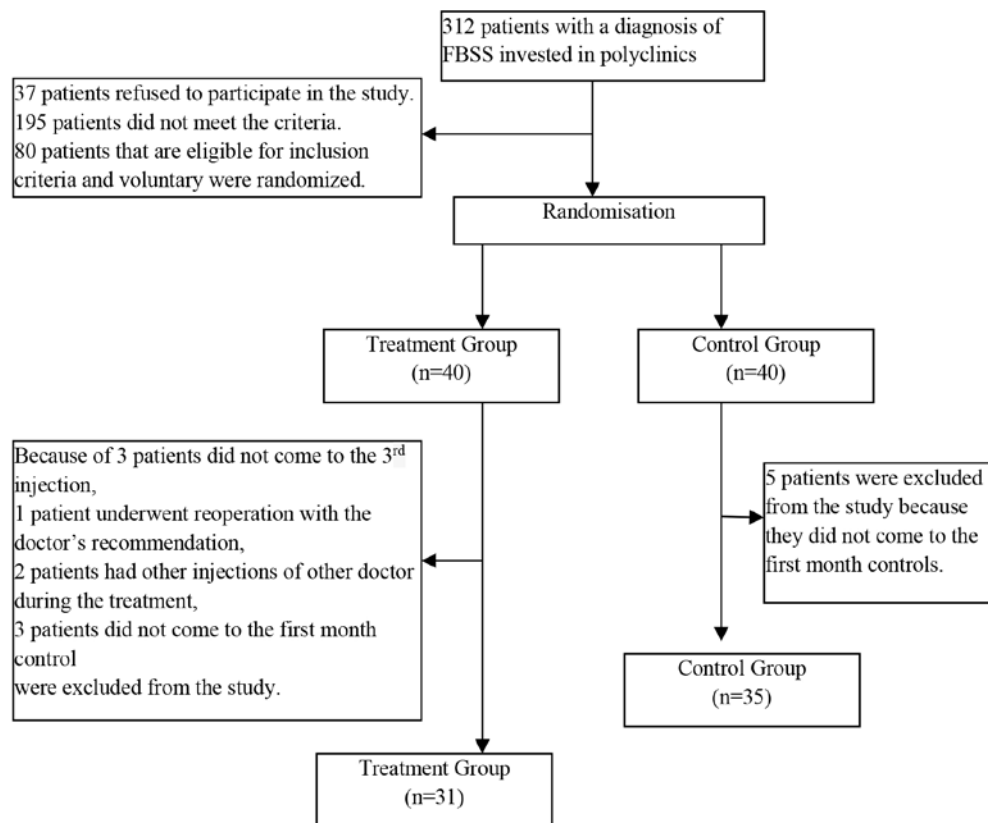


Figure 1. Flow diagram

Flexibility

Finger to ground distance (FGD): In this method, the patient is asked to perform a lumbar flexion with knees at full extension. A finger to ground distance of up to 10 cm is considered normal. FGD provides information on the lumbar range of flexion (13).

Functionality and Disability

Oswestry Disability index (ODI): This tool consisting of 10 questions scored between 0 and 5 points assesses the severity of pain, self-care, difficulties associated with weight bearing, problems experienced during walking, standing, sitting, or traveling, and the effect of pain on social life. The maximum score is 100 and minimum score is 0. Increasing scores indicate worsening disability. The reliability and validity studies of the Turkish version were performed in 2004 (14).

Depression and Anxiety

Hospital Anxiety and Depression scale (HADS): Consisting of 14 items, HADS is used to evaluate the severity of depression and anxiety in patients with physical conditions. There are 7 questions each for anxiety and depression. Each question is given a score between 0 and 3 points. A total score between 0 and 7, 8 and 10, and >11 is considered normal, marginally normal, and abnormal, respectively. The validity and reliability studies for the Turkish version were performed in 1977 (15).

The above-listed assessments were performed at the start of treatment (T0), completion of treatment (T1), and one month after treatment (T3).

Statistical Analysis

Statistical analysis of the study data was performed using IBM SPSS Statistics 22 (IBM SPSS, Turkey) software pack. Normal distribution of the study data was assessed with Shapiro-Wilks test. Descriptive data (mean, standard deviation, frequency) and quantitative data were compared between the two groups using Student's t-test for parameters with normal distribution, and Mann-Whitney U test for parameters without normal distribution. Within group comparisons for parameters with normal distribution were performed with variance analysis, and the Bonferroni test was used to determine the time-point responsible for the difference. Within group comparisons for parameters without normal distribution were carried out with Friedman's test, and the time-point responsible for the difference was evaluated by Wilcoxon signed-rank test. The qualitative data were compared with chi-square, Fisher's Exact test, Fisher Freeman Halton test, and Continuity (Yates) correction. Statistical significance was accepted at a p<0.05.

Results

Demographic data: A total of 66 patients completed the study, 43 female (65.2%) and 23 male (34.8%). The mean age of the subjects was 54.2±11.86 years. The two groups were comparable in terms of age, gender distribution, body mass index, cigarette smoking, duration symptoms, occupational status, education level, and number, side, and level of previous surgery (Tables 1, 2).

VAS: Treatment and control groups did not differ significantly in pre-treatment, post-treatment, and 1-month VAS scores ($p>0.05$). Serial VAS scores showed significant differences in both groups ($p<0.0001$). Post-hoc analyses showed that these were due to the differences between T0 and T1 ($p<0.0001$, $p<0.0001$), and between T0 and T2 ($p<0.0001$, $p<0.0001$) in both groups (Table 3).

FGD: Treatment and control subjects did not differ significantly in pre-treatment, post-treatment, and 1-month FGD ($p>0.05$). Also, repeated measurements did not exhibit any differences in either group (Table 3).

ODI: Pre-treatment ODI was significantly lower in the treatment group than in controls ($p=0.031$). However, post-treatment and 1-month ODI were comparable between treatment and control groups ($p>0.05$). Repeated ODI measurements showed significant differences in the treatment group ($p=0.038$), which was due to the difference between T0 and T2 as shown in a post-

hoc analysis ($p=0.032$). Similarly, repeated ODI measurements showed significant differences between time-points in controls as well ($p<0.0001$) which were due to the differences between T0 and T1 ($p<0.0001$) and between T0 and T2 ($p<0.0001$) (Table 3).

HADS: Treatment and control groups had comparable pre-treatment, post-treatment, and 1-month follow up HADS Depression and Anxiety scores ($p>0.05$). Also, repeated HADS measurements did not show significant differences in either group (Table 3).

Discussion

In this study exploring therapeutic contribution of intradermal LA injection as an adjunct to PTR in PSPS-T2 patients showed no additional therapeutic benefit in terms of pain, functionality, and flexibility.

Intradermal drug injections offer certain advantages such as slower distribution, longer duration effect, and higher local drug concentrations. Also, it avoids systemic exposure and providing mostly local effects (16). Due to such advantages, we decided to test the efficacy of intradermal injections in this setting. To the best of our knowledge, no previous studies examined the effects of lidocaine injections on pain and functions in PSPS-T2 patients. Our initial hypothesis was that intradermal lidocaine injections could have an impact on the myofascial component of the

Table 1. Evaluation of demographic characteristics among groups

		Treatment group	Control group	p
		Mean ± SD	Mean ± SD	
Age (mean ± SD)		53.13±11.08	55.14±12.59	0.495 ¹
BMI (kg/m ²) (mean ± SD)		29.66±4.81	28.74±6.46	0.521 ¹
Symptom duration (month)(median)		18.13±26.32 (6)	15.83±35.46 (4)	0.122 ²
Number of surgeries performed (median)		1.35±0.55 (1)	1.23±0.55 (1)	0.197 ²
		n (%)	n (%)	
Gender	Female	19 (61.3%)	24 (68.6%)	0.718 ³
	Male	12 (38.7%)	11 (31.4%)	
Work status	Not working	15 (48.4%)	19 (54.3%)	0.584 ⁴
	Worker	15 (48.4%)	13 (37.1%)	
	Officer	1 (3.2%)	3 (8.6%)	
Education status	Uneducated	1 (3.2%)	4 (11.4%)	0.498 ⁴
	Primary school	21 (67.7%)	21 (60%)	
	Middle School	3 (9.7%)	1 (2.9%)	
	High school	5 (16.1%)	6 (17.1%)	
	University	1 (3.2%)	3 (8.6%)	
Smoking habit	No	22 (71%)	24 (68.6%)	1.000 ³
	Yes	9 (29%)	11 (31.4%)	
Alcohol habit	No	30 (96.8%)	33 (94.3%)	1.000 ⁵
	Yes	1 (3.2%)	2 (5.7%)	

¹Student's t-test, ²Mann-Whitney U test, ³Continuity (Yates) correction, ⁴Fisher Freeman Halton test, ⁵Fisher's Exact test, BMI: Body mass index, SD: Standard deviation

Table 2. Evaluation of surgery types between groups

Types of surgery			Treatment group	Control group	p
			n (%)	n (%)	
Laminectomy	L2	Right	0 (0%)	2 (7.4%)	0.495 ¹
	L3	Right	1 (4.5%)	3 (11.1%)	0.617 ¹
	L4	Right	3 (13.6%)	7 (26.9%)	0.307 ¹
		Left	10 (45.5%)	7 (25.9%)	0.260 ²
	L5	Right	7 (31.8%)	3 (11.1%)	0.090 ¹
		Left	5 (22.7%)	11 (40.7%)	0.302 ²
	S1	Right	2 (9.1%)	0 (0%)	0.196 ¹
Left		1 (4.5%)	2 (7.4%)	1.000 ¹	
Flavectomy	L2	Right	0 (0%)	1 (3.7%)	1.000 ¹
	L3	Right	0 (0%)	1 (3.7%)	1.000 ¹
		Left	1 (4.5%)	0 (0%)	0.449 ¹
	L4	Right	2 (9.1%)	0 (0%)	0.196 ¹
		Left	3 (13.6%)	0 (0%)	0.084 ¹
Foraminotomy	L5	Right	1 (4.5%)	1 (3.7%)	1.000 ¹
		Left	1 (4.5%)	0 (0%)	0.449 ¹
	S1	Right	1 (4.5%)	0 (0%)	0.449 ¹
Discectomy	L3-L4		1 (4.5%)	1 (3.7%)	1.000 ¹
	L4-L5		4 (18.2%)	7 (25.9%)	0.732 ¹
	L5-S1		3 (13.6%)	4 (14.8%)	1.000 ¹
Microdiscectomy	L4-L5		3 (13.6%)	2 (7.4%)	0.646 ¹
	L5-S1		3 (13.6%)	1 (3.7%)	0.314 ¹

¹Fisher's Exact test, ²Continuity (Yates) correction

pain in PSPS-T2 patients. We assumed that lidocaine injections around the surgical scar would suppress the nociceptor activity by achieving local anesthesia in the cutaneous tissues, leading to the interruption of the nociceptor hyperactivity, which is the first stage of central sensitization. Also, the drug could have a diffusing effect toward the degenerated disc and facet joint arthropathy. However, despite these assumptions, we observed no additional therapeutic effects. In a study by Sihvonen et al. (17) involving PSPS-T2 patients, presence of scar formation in segments adjacent to surgery, dorsal root injury, as well as atrophy and fatty degeneration of the paraspinal muscles at the level of surgery were found. The lack of additional therapeutic effects from intradermal lidocaine may at least partly be related with the confirmed iatrogenic tissue injury and scar formation in PSPS-T2, leading to impaired circulation and reduced diffusion of the drug into the tissues. Again, the injury in the dorsal roots may have prevented the expected LA effect of lidocaine involving nociceptor blockade and interruption of the central sensitization cascade.

In Park et al.'s (18) study comparing intravenous lidocaine with physiological saline in PSPS-T2 patients, efficacy was observed in both groups with no significant differences. Although lidocaine was administered via a different route in that study, results may be considered comparable.

In another study, Imamura et al. (19) observed significantly better improvement in pain and functionality with LA injection at trigger points in 387 patients with chronic non-specific low back pain, with maintenance of improvement at 3-month follow up. In the current study, significant and similar improvements in pain and disability were observed in both treatment and control groups that were maintained at 1 month of follow up. Absence of the iatrogenic tissue injury in patients with non-specific chronic low back pain may explain the absence of such difference in PSPS-T2 groups.

Egli et al. (20) administered local anesthesia to 280 patients, most of whom had chronic low back pain. Patients received 9 sessions of therapy on average, and 74% of the participants reported reduced analgesic use with this approach, with most patients totally discontinuing their medical therapy at their follow-up visit. In that study, these injections were repeated on an as-needed basis for 1 year, some patients receiving up to 40 injections (20). Since ours was a randomized study involving PSPS-T2 patients with 1 month follow-up, a direct comparison between these two studies is not feasible. On the other hand, a similarly designed study by Valencia Moya et al. (21), intramuscular corticosteroid injections administered 3-4 cm lateral to the spinous processes were compared with intradermal local anesthesia in PSPS-T2 patients, and LA therapy given for 4 sessions was found to

Table 3. Comparison of pain, functionality and disability parameters within and between groups

		Treatment group	Control group	p
		Median ± SD	Median ± SD	
VAS (0-10)	T0	7.06±1.77 (7)	7.14±1.7 (7)	0.849 ¹
	T1	5.03±2.06 (5)	5±2.38 (5)	0.995 ¹
	T2	4.87±1.91 (5)	4.77±2.34 (5)	0.845 ¹
	p ²	<0.0001*	<0.0001*	
	T0-T1p ³	<0.0001*	<0.0001*	
	T0-T2p ³	<0.0001*	<0.0001*	
	T1-T2p ³	0.398	0.445	
Oswestry Disability index	T0	43.77±18.26	54±19.19	0.0314 ⁴ *
	T1	37.48±21.49	41.06±18.08	0.466 ⁴
	T2	36.42±18.55	39.14±19.82	0.568 ⁴
	p ⁵	0.038*	<0.0001*	
	T0-T1p ⁶	0.082	<0.0001*	
	T0-T2p ⁶	0.032*	<0.0001*	
	T1-T2p ⁶	1.000	1.000	
HADS-Depression scale	T0	7.9±4.33	8.23±3.62	0.741 ⁴
	T1	7.58±4.77	6.69±3.72	0.403 ⁴
	T2	7.1±4.33	7.23±3.63	0.893 ⁴
	p ⁵	0.441	0.058	
HADS-Anxiety scale	T0	9.58±5.14	9.49±5.07	0.940 ⁴
	T1	8.48±4.4	8.49±4.83	0.999 ⁴
	T2	8.39±3.61	8.8±4.73	0.690 ⁴
	p ⁵	0.144	0.274	
Finger ground distance	T0	21.42±13.34	26.57±20.19	0.222 ⁴
	T1	21.74±12.45	22.74±16.27	0.782 ⁴
	T2	19.65±11.39	21.69±13.63	0.515 ⁴
	p ⁵	0.149	0.088	

¹Mann-Whitney U test, ²Friedman test, ³Wilcoxon signed-rank test, ⁴Student's t-test, ⁵Analysis of Variance in Repetitive Measurements, ⁶Bonferroni test, *p<0.05. VAS: Visual analog scale, HADS: Hospital Anxiety and Depression scale, SD: Standard deviation, T0: Before treatment, T1: After treatment, T2: After treatment 1st month

be superior to corticosteroid injections, with improvements maintained after 1 year. In that study, intradermal LA was administered 2 cm lateral to spinous processes, and patients also received facet joint injections (21). In a case report by Hines et al. (22) involving 4 PSPS-T2 patients, lidocaine patch therapy added to the existing pain-management strategy resulted in an improvement of pain. Intradermal injections utilized in our study and lidocaine patch administered to these patients share common mechanisms of action. However, comparisons between case reports and randomized controlled studies are not feasible. Use of placebo in our control group could have provided a better means for such comparisons.

Our study was carried out by the inclusion of PSPS-T2 patients, in whom pain may arise from the disc complex, facet joints, and myofascial tissues. Chronic strain due to the postoperative impairment in posture, or denervation and atrophy resulting

from the retractor utilized during surgery may also lead to pain. Factors that complicate the management of PSPS-T2 patients include the requirement to achieve coordination between osteo-ligamentous and neuromuscular structures for a pain-free range of motion as well as the differential responses of the tonic and phasic muscles to muscular injury. In these patients, variations in load distribution in joints may also cause articular micro-trauma and inflammation, in addition to laxity of the ligaments. In PSPS-T2 management, it is imperative to strengthen the supportive framework for the lumbar vertebra, which consists of an interconnection between diaphragm and pelvic muscles and which involves a number of anatomical structures such as the multifidus, thoraco-lumbar fascia, and transverse abdominal muscles (23,24). In line with this notion, our comprehensive exercise program in both groups included the pelvic tilt, strengthening of abdominal muscles, cat-camel

exercises, hamstring stretch, strengthening of extensor muscles and plevic flexors, cross-training involving leg and arm raises, range of motion exercises, and posture exercises.

Application of TENS during exercise and hot-packs prior to exercise might have increased the efficacy of our treatments, leading to challenges in demonstrating the additional therapeutic contribution of the intradermal lidocaine injections. On the other hand, if one group had received injections only and the other group had received PTR, this would have complicated the comparison between the PTR group receiving a total of 15 sessions (5 sessions per week) and injection group receiving 3 injections (1 per week), due to patient perception.

In a previous study by Sahin et al. (25) comparing pain, quality of life, and level of depression between patients with PSPS-T2 and chronic non-specific low back pain, PSPS-T2 patients were found to be more depressed. Also, the lack of pain control and functional improvement in PSPS-T2 patients as opposed to those with non-specific low back pain suggests that these patients were more severely depressed and had lower pain thresholds than those without surgery (25). In the current study, patients were assessed at three time-points: before treatment, after treatment, and at 1-month follow up. Following treatment, HADS scores did not differ significantly in both groups. This might have resulted from the long-term impact of adverse experiences in pre-surgery and post-surgery periods on anxiety and depression. On the other hand, ODI scores showed significant improvements in both groups.

There were some limitations on this study. First; although there was no statistically significant difference between the two groups at the end of the study; this study was performed single-blindly and without placebo control. Also, patients were not assessed with a neuropathic pain scale, thus the effect of LA injection on neuropathic pain cannot be investigated. Although there was no significant difference between the types of the spinal procedures between control and intervention group, different types of surgical procedures were not categorized and thus, the impact of severity of the spinal procedure is unknown.

Conclusion

Our results suggest that intradermal LA injections as an adjunct to rehabilitation program has no therapeutic contributions in terms of pain and functionality in PSPS-T2 patients. To the best of our knowledge, this is the first study to examine local intradermal anesthetic injections in such a patient population. On the other hand, irrespective of injections, PSPS-T2 patients received significant benefits from the rehabilitation programs administered. We recommend comprehensive PTR programs for PSPS-T2 patients.

Ethics

Ethics Committee Approval: University of Health Sciences Turkey, Haydarpaşa Training and Research Hospital Clinical Research Ethics Committee approval was obtained for the study with the number of KAEK 2019/23 (date: 08.04.2019).

Informed Consent: All patients provided written informed consent.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: M.H.T., Concept: M.H.T., D.G.K., N.M., Design: D.G.K., Data Collection or Processing: N.M., D.D., Analysis or Interpretation: M.H.T., N.M., Literature Search: M.H.T., D.D., Writing: M.H.T., D.G.K.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study has received no financial support.

References

1. Thomson S. Failed back surgery syndrome - definition, epidemiology and demographics. *Br J Pain* 2013;7:56-9.
2. Fritsch EW, Heisel J, Rupp S. The failed back surgery syndrome: reasons, intraoperative findings, and long-term results: a report of 182 operative treatments. *Spine (Phila Pa 1976)* 1996;21:626-33.
3. Delitto A, Piva SR, Moore CG, Fritz JM, Wisniewski SR, Josbeno DA, et al. Surgery versus nonsurgical treatment of lumbar spinal stenosis: a randomized trial. *Ann Intern Med* 2015;162:465-73.
4. Keller A, Brox JI, Gunderson R, Holm I, Friis A, Reikeras O: Trunk muscle strength, cross-sectional area, and density in patients with chronic low back pain randomized to lumbar fusion or cognitive intervention and exercises. *Spine* 2004;29:3-8.
5. Ohtori S, Orita S, Yamauchi K, Eguchi Y, Aoki Y, Nakamura J, et al. Classification of Chronic Back Muscle Degeneration after Spinal Surgery and Its Relationship with Low Back Pain. *Asian Spine J* 2016;10:516-21.
6. Maddalozzo GF, Aikenhead K, Sheth V, Perisic MN. A Novel Treatment Combination for Failed Back Surgery Syndrome, With a 41-Month Follow-Up: A Retrospective Case Report. *J Chiropr Med* 2018;17:256-63.
7. Couto C, de Souza IC, Torres IL, Fregni F, Caumo W. Paraspinal stimulation combined with trigger point needling and needle rotation for the treatment of myofascial pain: a randomized sham-controlled clinical trial. *Clin J Pain* 2014;30:214-23.
8. Chen L, Li D, Zhong J, Qiu B, Wu X. Therapeutic Effectiveness and Safety of Mesotherapy in Patients with Osteoarthritis of the Knee. *Evid Based Complement Alternat Med* 2018;2018:6513049.
9. Weinberg L, Peake B, Tan C, Nikfarjam M: Pharmacokinetics and pharmacodynamics of lignocaine: A review. *World J Anesthesiol* 2015;4:17-29.
10. Krumova EK, Zeller M, Westermann A, Maier C. Lidocaine patch (5%) produces a selective, but incomplete block of A and C fibers. *Pain* 2012;153:273-80.
11. Arora S: Elsevier's Clinical Skills Manual: Child Health Nursing, 1SAE - e-Book. Elsevier Health Sciences 2020.
12. Carlsson AM. Assessment of chronic pain. I. Aspects of the reliability and validity of the visual analogue scale. *Pain* 1983;16:87-101.
13. Omata J. Clinical value of finger flör distance in lumbar spinal disorders: GP104. In *Spine Journal Meeting Abstracts*. 2010.
14. Yakut E, Düger T, Oksüz C, Yörükan S, Ureten K, Turan D, et al. Validation of the Turkish version of the Oswestry Disability Index for patients with low back pain. *Spine (Phila Pa 1976)* 2004;29:581-5.
15. Aydemir O. Hastane Anksiyete ve Depresyon Ölçeği Türkçe Formunun Geçerlilik Güvenilirlik Çalışması. *Türk Psikiyatri Dergisi* 1997;8:280-7.

16. Mammucari M, Gatti A, Maggiori S, Sabato AF. Role of mesotherapy in musculoskeletal pain: opinions from the italian society of mesotherapy. *Evid Based Complement Alternat Med* 2012;2012:436959.
17. Sihvonen T, Herno A, Paljärvi L, Airaksinen O, Partanen J, Tapaninaho A. Local denervation atrophy of paraspinal muscles in postoperative failed back syndrome. *Spine (Phila Pa 1976)* 1993;18:575-81.
18. Park CH, Jung SH, Han CG. Effect of intravenous lidocaine on the neuropathic pain of failed back surgery syndrome. *Korean J Pain* 2012;25:94-8.
19. Imamura M, Imamura ST, Targino RA, Morales-Quezada L, Onoda Tomikawa LC, Onoda Tomikawa LG, et al. Paraspinal Lidocaine Injection for Chronic Nonspecific Low Back Pain: A Randomized Controlled Clinical Trial. *J Pain* 2016;17:569-76.
20. Egli S, Pfister M, Ludin SM, Puente de la Vega K, Busato A, Fischer L. Long-term results of therapeutic local anesthesia (neural therapy) in 280 referred refractory chronic pain patients. *BMC Complement Altern Med* 2015;15:200.
21. Valencia Moya A, Navarro Suay R, Fernández González JA, Gutiérrez Ortega C, Panadero Useros T, Mestre Moreiro C. Selective local anesthesia versus corticosteroid infiltration on low back pain: a randomized clinical trial. *Rev Esp Anesthesiol Reanim (Engl Ed)* 2020;67:1-7.
22. Hines R, Keaney D, Moskowitz MH, Prakken S. Use of lidocaine patch 5% for chronic low back pain: a report of four cases. *Pain Med* 2002;3:361-5.
23. Shapiro CM. The failed back surgery syndrome: pitfalls surrounding evaluation and treatment. *Phys Med Rehabil Clin N Am* 2014;25:319-40.
24. Cho JH, Lee JH, Song KS, Hong JY, Joo YS, Lee DH, et al. Treatment Outcomes for Patients with Failed Back Surgery. *Pain Physician* 2017;20:E29-43.
25. Sahin N, Karahan AY, Devrimsel G, Gezer IA. Comparison among pain, depression, and quality of life in cases with failed back surgery syndrome and non-specific chronic back pain. *J Phys Ther Sci* 2017;29:891-5.