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The effects of the number of physical therapy sessions on pain, disability, and quality of life in patients with chronic low back pain

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Background/aim: The aim of this study was to investigate and compare the effect of different physical therapy (PT) session numbers on pain, impairment. and quality of life in patients with chronic low back pain (LBP).

Materials and methods: In this prospective, randomized-controlled, single-blind trial, a total of 60 patients with chronic LBP were divided into 2 groups with simple randomization within the scope of the study. A PT program of a total of 10 sessions was applied for patients in Group 10 (n = 30) and a total of 15 sessions for patients in Group 15 (n = 30). The main outcome measures were fingertip-to-floor distance (FFD), a visual analog scale (VAS), the modified Oswestry Disability Index (mODI), and the Nottingham Health Profile (NHP).

Results: We found statistically significant differences in both groups between the before-treatment (BT) and after-treatment (AT) results in terms of all evaluation parameters. We detected significant differences between the 2 groups in terms of AT VAS, mODI, NHP Pain, and NHP Total; however, no significant differences were found in terms of FFD and the other NHP subdimension levels.

Conclusion: We determined that 15 treatment sessions were more effective than 10 sessions on pain and disability in patients with chronic LBP.

Key words: Chronic low back pain, physical therapy, number of sessions

1. Introduction

Low back pain (LBP) is an important cause of morbidity and workforce loss, affecting 80%–85% of the whole population in the course of a lifetime (1). Chronic LBP, with increased disability and decreased quality of life, causes significant healthcare costs (1,2).

The goal in chronic LBP treatment is to reduce the pain, improve activity levels, and prevent recurrence and chronicity (3). Therapeutic options include pharmacologic agents like nonsteroidal antiinflammatory drugs, antidepressants, gabapentin and pregabalin, physical therapy (PT) modalities like therapeutic ultrasound (US), transcutaneous electrical nerve stimulation (TENS), low-level laser (LLL), short-wave diathermy and traction, interventional therapies like epidural steroid and facet joint injections, therapeutic exercise, and surgery (4).

The number of PT sessions varies according to the age and sex of the patient, duration and intensity of the complaints, and the therapies applied before (5). We could not find any study in the literature comparing the efficacy of PT programs with a different number of sessions in patients with chronic LBP. Thus, we aimed to compare the effects of the numbers of conventional PT sessions on pain, disability, and quality of life in patients with chronic LBP.

2. Materials and methods

2.1. Patients

Seventy patients who had applied to the Physical Therapy and Rehabilitation Education and Research Hospital with LBP were evaluated. Patients who were 25–75 years old and who had LBP for at least 3 months were included. The exclusion criteria were: patients with certain surgical indications (motor, sensory, or reflex impairment), history of epilepsy, pregnancy, cardiac failure, respiratory failure,

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uncontrolled hypertension, major psychiatric disorder, fecal or urinary incontinence, history of physical therapy/injection for LBP in the last 1 year, history of malignant disease, history of acute trauma/fracture of the lower back, history of surgical intervention/implant for the lower back, and history of inflammatory rheumatic disease. The remaining 60 patients were enrolled in this prospective, randomized-controlled, single-blind study (Figure). Written informed consent from all of the participants and local ethical committee approval were obtained. Pretreatment workup included routine physical examination, laboratory testing, and imaging modalities like X-ray/magnetic resonance imaging.

The patients were told that they would be examined before treatment (BT) and reexamined after treatment (AT).

The treatment of the patients in the study was organized by the researcher physician.

The patients were divided into 2 groups using a random number table by the same researcher physician as a group treated with a total of 10 sessions (Group 10 (n = 30)) and a group treated with a total of 15 sessions (Group 15 (n = 30)). The demographic characteristics of the patients, fingertip-to-floor distance (FFD), visual analog scale (VAS), modified Oswestry Disability Index (mODI), and Nottingham Health Profile (NHP) levels were recorded by a researcher physician who was unfamiliar with the study. The same researcher physician carried out the AT examinations and the data were recorded.

Body mass indexes (BMI) were calculated as kg/m^2.

All patients had the same physical therapy (PT) protocol including a hot pack (HP) for 20 min/session, TENS (Fizyotens 4000, Fizyomed Medical Devices Ltd., Turkey; 50–100 Hz) for 20 min/session, therapeutic continuous US (BTL-4710 Sono Professional, BTL Medical Technologies Ltd., UK; frequency: 1 MHz, intensity: 1.5 W/cm^2) for 6 min/session, and therapeutic exercises for low back muscles. Balneotherapy treatment was added with 20 min to standard PT for 7 days in a week, with a total duration of 10 or 15 days according to the group that the patient was included in. It was applied to the patients in a spa pool in the same hospital consisting of thermomineralized water with a temperature of 38–40 °C. Water quality was tested periodically by the National Public Health and Medical Officer Service.

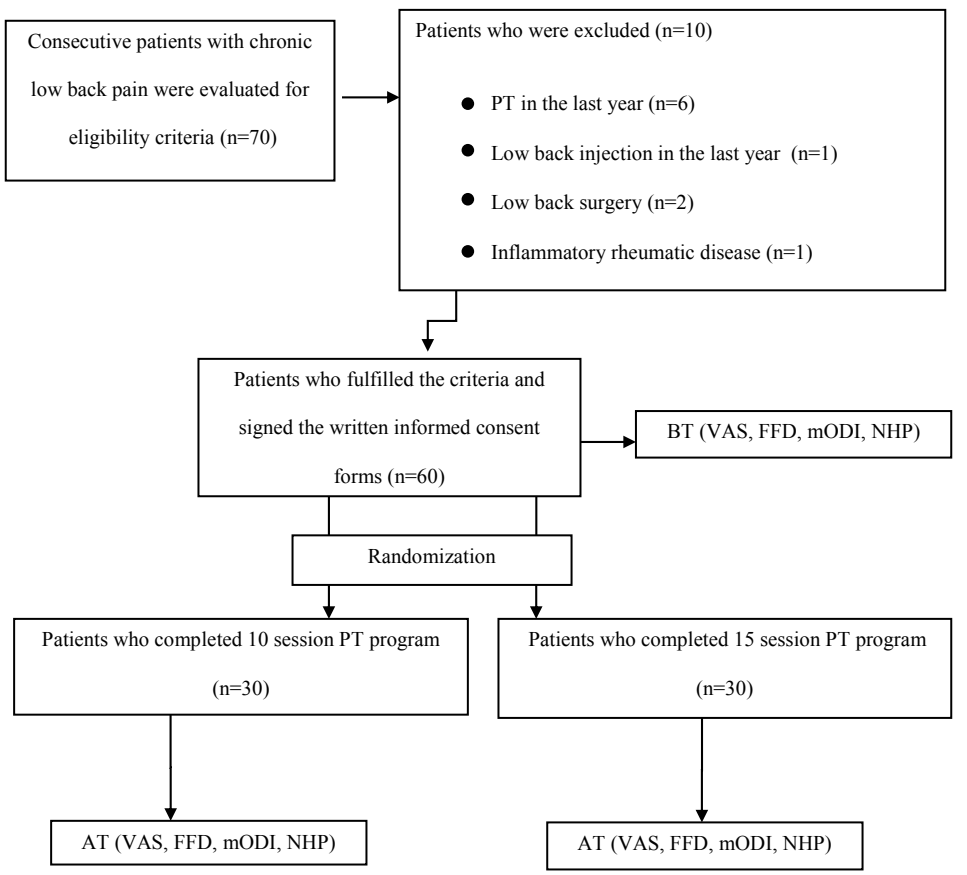

Figure. Flow chart of the study.
PT: Physical therapy, BT: before treatment, AT: after treatment, FFD: fingertip-to-floor distance, VAS: visual analog scale, mODI: modified Oswestry Disability Index, NHP: Nottingham Health Profile.

Therapeutic exercises included cat-camel exercises, posterior pelvic tilt exercises, bridge exercises, hyperextension exercises, and stretching. The exercises were taught to the patients by an experienced physiotherapist. Patients were instructed to practice 2 sets of exercises/day under supervision, each set containing 5 repetitions of all movements.

A total of 10 sessions of the abovementioned treatment days was applied for 10 days for patients in Group 10 and a total of 15 sessions for 15 days for patients in Group 15.

2.2. Main outcome measures

The patients were assessed with FFD, VAS, mODI, and NHP levels at BT and AT.

Lumbar spine range of motion was assessed by FFD. After standing in an upright position, the patients were instructed to bend and touch the floor with their fingertips without bending their knees. The distance between the floor and fingertips of the patient was measured and recorded in centimeters.

Pain intensity was measured using a VAS of 0–10 cm (0 = no pain, 10 = intolerable pain) (6).

The mODI is used to assess perceived level of functional disability. It is a self-administered questionnaire consisting of 10 questions about the activities of daily living (pain intensity and back pain during self-care, lifting, walking, sitting, standing, sleeping, social life, travel, and sexual activity) scored between 0 and 5. The total score is between 0 and 50. The final result is calculated as patient's score/maximum score × 100 (7,8). The Turkish validity and reliability was confirmed (9,10).

The NHP is a patient-reported measure of subjective health status. It was developed to estimate the physical, emotional, and social impact of diseases. It consists of 38 questions in 6 subdivisions evaluating pain, physical activity, energy, sleep, social isolation, and emotional reaction. Each subdivision is scored between 0 and 100 with 0 indicating the best and 100 indicating the worst health status (11). The Turkish validity and reliability was confirmed (12).

No drugs (including analgesics, anticonvulsants, etc.) were given to the patients throughout the study.

2.3. Statistical analyses

All statistical calculations were performed by using SPSS 21.0. Descriptive statistics (frequency, percentage, mean, standard deviation, median, min–max) were used for analyses. The Shapiro–Wilk test was used to assess conformity to normal distribution. Variables were found to be nonnormally distributed. In the comparison between groups, the Mann–Whitney U test was used. Where significant differences were detected, Tukey's HSD tests were used to identify the time point(s) responsible for such differences. The significance level was set at P = 0.05.

Power analysis was performed using the G* Power 3.1.10 program. Post hoc power 1 – β was calculated as 0.86 for $n_1 = 30$, $n_2 = 30$, $\alpha = 0.05$, and effect size (f) = 0.8.

3. Results

In our study, FFD, VAS, mODI, and NHP BT and AT levels of 60 patients with chronic LBP in Group 10 (n = 30) and Group 15 (n = 30) were statistically analyzed.

There was no statistically significant difference between patients in terms of age, sex, BMI, employment status, diagnosis, duration of pain, and smoking status (Table 1).

Table 1. The demographic characteristics of the patients.

		Group 15 (n = 30)	Group 10 (n = 30)	P
Age, mean ± SD		52 ± 13.43	55.97 ± 10.88	0.344
Sex	Female	17 (56.7%)	18 (60.0%)	0.795
	Male	13 (43.3%)	12 (40.0%)	
Employment status	No	18 (60.0%)	20 (66.7%)	0.595
	Yes	12 (40.0%)	10 (33.3%)	
Diagnosis	L. sp.	11 (36.7%)	8 (26.7%)	0.520
	LDH	15 (50%)	18 (60.0%)	
	Spinal stenosis	2 (6.7%)	2 (6.7%)	
	L. list.	2 (6.7%)	2 (6.7%)	
Pain duration, months, median (min–max)		33 (3–120)	30 (4–120)	0.493
Smoking	No	24 (80%)	24 (80%)	1.00
	Yes	6 (80%)	6 (80%)	
BMI, kg/m^2, median (min–max)		27.6 (20.30–36.3)	30.25 (21.10–43)	0.072

BMI: Body mass index, L. sp.: lumbar spondylosis, LDH: lumbar disc herniation, L. list.: lumbar spondylolisthesis.

In the intragroup assessments (Tables 2 and 3) ($P < 0.05$), FFD, VAS, mODI, and NHP levels were found to be highest BT and lowest AT (Tables 2 and 3).

In the intergroup assessments, there was no statistically significant difference in terms of BT FFD, VAS, mODI, and the NHP levels ($P > 0.05$). In the difference score analyses between BT and AT, a statistically significant difference was determined between the VAS, mODI, NHP Pain, and NHP Total subgroup values ($P < 0.05$), and the difference in the scores of patients in Group 15 was determined to be higher than in Group 10. However, in FFD and the other subgroups of NHP, no statistically significant difference was determined in the scores ($P > 0.05$) (Tables 2 and 3).

4. Discussion

As a result of the study, we aimed to compare the effects of the number of conventional PT sessions applied to patients with chronic LBP. We determined that a statistically significant improvement was achieved with both 10 and 15 sessions of PT in pain, disability, and the quality of life; however, 15 sessions were found to be more effective on pain and disability.

There have been numerous studies comparing the efficacy of different PT modalities for the treatment of chronic LBP to date (13–19). We could not find any studies in the literature aiming to detect the efficacy of different numbers of sessions with the same treatment modalities. Therefore, we present our study, in which we aimed to compare the efficacy of the number of conventional PT sessions that we applied for patients with chronic LBP.

Many methods such as US, LLLT, HILT, HP, exercise, and balneotherapy are used in the treatment of chronic LBP. The US treatment that we used in the scope of our study, as deep heating, may be used alone or additionally to other PT modalities, similarly to the literature reports (13–19).

In 2 different studies conducted to evaluate the efficacy of US, it was applied alone or in combination with different PT agents. In the first study, Unlu et al. aimed to compare the efficacy of US treatment and LLLT. They divided 60 patients with acute lumbar disc herniation diagnosis into 3 groups. They applied LLLT to the 1st group, US to the 2nd group, and traction therapy to the 3rd group for 15 sessions. As a result of this study, they reported that US was as efficient as the other agents in the treatment of LBP (13). In another study investigating the efficacy of US, Durmuş et al. included 42 patients with chronic LBP in their study. They applied HP + US + exercise therapy to the first group and HP + placebo US + exercise to the second group. They assessed the results with the mODI, VAS, 6-min walking test, Beck Depression Inventory, and Short Form-36. At the end of the treatment, although they detected a statistically significant improvement in both groups, they reported that the treatment with US was more efficient (15). We also determined US as an efficient therapy in the treatment of chronic LBP in our study. The results that they found for the US group were similar to the results of our study.

Koldaş Doğan et al., who evaluated the efficacy of combined therapy, divided 60 patients with chronic LBP into 3 groups. They applied aerobics + a home program to the 1st group, HP + TENS + US + a home program to the 2nd group, and a home program to the 3rd group, and they assessed the patients BT, AT, and 1 month after treatment. Although they found all the treatments in all groups to be effective, they stated that the improvement was statistically more significant in the group for which they applied the HP + TENS + US + home program combination (20). We

Table 2. Comparison of the before and after treatment FFD, VAS, and mODI values of the study and control groups.

		BT	AT	P	Change amount**
FFD	*Group 15 (n = 30)	12 (0–29)	3 (0–30)	0.001	–5 (–29 to 15)
	*Group 10 (n = 30)	10 (0–38)	4 (0–33)	<0.001	–3.5 (–18 to 0)
	P	0.624	0.108		0.265
VAS	*Group 15 (n = 30)	6 (3–9)	1.5 (0–8)	<0.001	–4 (–9 to –1)
	*Group 10 (n = 30)	6.5 (4–9)	4 (1–10)	<0.001	–2 (–6 to 4)
	P	0.765	<0.001		<0.001
mODI	*Group 15 (n = 30)	51 (10–80)	11 (0–80)	<0.001	–40 (–78 to 16)
	*Group 10 (n = 30)	60 (30–86)	37 (0–76)	<0.001	–16 (–40 to –2)
	P	0.594	0.060		0.001

*Median (min–max).

**Comparison of change values (Δ = BT – AT) between groups. BT: Before treatment, AT: after treatment, FFD: fingertip-to-floor distance, VAS: visual analog scale, mODI: modified Oswestry Disability Index.

Table 3. Comparison of the before and after treatment NHP values of the study and control groups.

NHP		BT	AT	P	Change amount**
P	*Group 15 (n = 30)	68.56 (5.83–100)	20.18 (0–70.18)	<0.001	–38.3 (–100 to 3.13)
	*Group 10 (n =30)	59.4 (5.83–100)	36 (0–87.09)	<0.001	–20.3 (–87.09 to 5.83)
	P	0.760	0.002		0.015
PA	*Group 15 (n = 30)	44.58 (10.79–78.70)	11.2 (0–54.47)	<0.001	–24.02 (–78.7 to 9.3)
	*Group 10 (n = 30)	43.79 (11.2–88.46)	22.9 (0–66.01)	<0.001	–12.61 (–66.47 to 2.04)
	P	0.783	0.636		0.055
F	*Group 15 (n = 30)	62 (0–100)	0 (0–100)	<0.001	–38 (–100 to 0)
	*Group 10 (n = 30)	76 (0–100)	38 (0–100)	<0.001	–24 (–100 to 24)
	P	0.312	0.361		0.111
S	*Group 15 (n = 30)	46.87 (0–100)	12.57 (0–100)	0.001	–21.7 (–77.63 to 37.80)
	*Group 10 (n = 30)	55.93 (0–100)	27.97 (0–100)	0.001	–6.29 (–65.06 to 12.57)
	P	0.503	0.918		0.439
SI	*Group 15 (n = 30)	0 (0–100)	0 (0–84.03)	0.008	0 (–62.02 to 20.13)
	*Group 10 (n = 30)	0 (0–100)	0 (0–44.54)	0.085	0 (–100 to 22.01)
	P	0.520	0.173		0.507
ER	*Group 15 (n = 30)	20.23 (0–100)	0 (0–100)	0.001	0 (–62.02 to 20.13)
	*Group 10 (n = 30)	17.11 (0–92.78)	0 (0–60.04)	0.001	0 (–100 to 22.01)
	P	0.545	0.731		0.610
T	*Group 15 (n = 30)	260.54 (33.09–502.29)	67.35 (0–435.15)	<0.001	–160.25 (–439.57 to –2.33)
	*Group 10 (n = 30)	286.55 (41.87–443.50)	134.58 (0–345.01)	<0.001	–88.68 (–402.92 to –8.96)
	P	0.894	0.028		0.028

*Median (min–max).
**Comparison of change values (Δ = BT – AT) between groups. BT: Before treatment, AT, after treatment, P: Pain, PA: Physical activity, F: Fatigue, S: Sleep, SI: Social isolation, ER: Emotional reactions, T: Total.

also applied combination therapy as HP + TENS + US + balneotherapy and exercise treatment for our patients.

The PT agents used in the scope of this study were reported to be efficient in the treatment of chronic LBP when combined with different methods or used alone. Studies related to the number of sessions, which is the main aim of our study, were discussed for different PT methods. From among a limited number of studies, Ansari et al. divided patients into 2 groups as US (n = 5) and placebo US (n = 5) to determine the efficacy of continuous US in LBP and applied a total of 10 sessions of treatment. BT and at the end of the 5th and 10th sessions the patients were assessed using the Functional Rating Index (FRI) and ROM. After the first 5 sessions of the treatment, there was no statistically significant difference in either of the two groups compared to BT, while after the second 5 sessions, they stated that the improvement in the US group was statistically significant compared to the placebo (21). However, their disadvantages were the lower number of patients and the duration of their treatment being no longer than ours. We also achieved statistically significant results in the functional assessment similarly in our study at the end of the 10th session. However, we detected that 15 sessions caused a greater statistically significant improvement in pain and functionality. The advantages of our study were the higher number of patients and the assessment of not only functionality but also pain and the quality of life.

In another study that compared the efficacy of manipulation and US in the treatment of chronic LBP in 112 patients, a significant improvement was achieved in both groups, while the improvement in the manipulation + exercise group, in which an average of 4 sessions (2–7 sessions) were applied, was reported to be significantly more significant than the US + exercise group, in which an average of 6 sessions (3–11 sessions) were applied (22). The number of the sessions not being determined and clearly applied is an indicator of the situation that the number of PT sessions applied in daily practice is determined according to the patient's pain. However, at

the end our study, we detected that the applied PT was not only effective on pain but also on functional disability and quality of life.

In our study, we tried to evaluate the efficacy of the number of sessions on the treatment results. There are many studies that have been performed with different numbers of sessions and similar treatment agents. Of these studies, in Koldaş Doğan et al.'s study, in which they evaluated the efficacy of a combination treatment, they applied a total of 18 sessions for all patients and reached statistically significant results in terms of the efficacy of the treatment (20). Similar to this study, Durmuş et al., who applied HP + US + exercise, reported that 15 sessions of treatment were effective on pain, disability, and quality of life (15). In both studies, the results achieved with 15 and 18 sessions were successful, similar to the results we achieved with 15 sessions. These results render the questioning of the efficacy of overtreatment.

As a result, there are many studies in the literature carried out with different numbers of sessions, such as 4, 6, 10, 12, 15, and 18 sessions, reporting efficient results in chronic LBP (15,16,18,20–24). However, since none of these studies were randomized-controlled studies in terms of the number of sessions, we could not compare our results in a precise manner.

We believe that the lack of long-term follow-up results is the limitation of our study.

In conclusion, we determined that both treatments with 10 and 15 sessions were effective on chronic LBP, but 15 treatment sessions were more effective than 10 sessions on pain and disability. We suggest that the PT for patients with chronic LBP should not be evaluated in terms of pain only, and the most effective treatment that would improve the disability and quality of life at the same time should be applied. In our study, we determined this effect at the 15th session. However, we agree that these periods may change with different treatment agents. We suggest that studies with longer follow-up periods, performed with different physical therapy agents and numbers of sessions, should be carried out.

Studies that are more comprehensive and with longer follow-up periods are required to determine the number of sessions that would decrease the pain and disability of patients with chronic LBP and improve their quality of life, while providing the lowest treatment costs and work power loss and the most effective treatment.

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