Učinki ambulantne fizikalne terapije pri bolnikih s kronično bolečino v križu

Outcomes of physical therapy in patients with chronic low back pain

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Izvleček

Namen: *Ugotoviti učinek 10–dnevnega programa fizikalne terapije na nivo bolečine in z zdravjem povezano kakovost življenja pri bolnikih s kronično enostavno bolečino v križu.*

Metode: *Zaporeden vzorec odraslih (N = 129) s kronično enostavno bolečino v križu je bil ocenjen glede na izboljšanje stanja po 10–dnevnem programu fizikalne terapije. Bolniki so bili na fizikalno terapijo napoteni s strani svojih zdravnikov družinske medicine. V povprečju so imeli 3 različne fizioterapevtske postopke. Pred začetkom in po zaključku 10–dnevnega programa so izpolnili lestvico VAS in vprašalnik EuroQol (EQ–5D in EQ–VAS).*

Rezultati: *Jakost bolečine po 10–dnevnem fizioterapevtskem programu je bila v povprečju nižja za 1,7 ± 1,8 točk (P < 0,001). Ocena z zdravjem*

Abstract

Purpose: *To assess the outcomes of a10–treatment sessions program of physical therapy regarding the level of pain and health–related quality of life in patients with chronic, non–specific, low back pain.*

Methods: *A consecutive sample of adults (N = 129) with chronic, non–specific, low back pain was assessed for improvement after a 10–day physical therapy program, consisting of an average of 3 different physical modalities, as prescribed by family physicians. A visual analog pain scale and EuroQol questionnaire (EQ–5D and EQ–VAS) were completed by patients before and after physical therapy.*

Results: *The intensity of pain after 10 days of physical therapy was on average lower (1.7 ± 1.8 points; P <*

povezanega stanja na lestvici EQ–VAS je bila v povprečju boljša za 10,3 ± 15,2 točk (P < 0,001). Seštevek točk vprašalnika EQ–5D je bil v povprečju nižji za 0,8 ± 1,2 točke (P < 0,001). Bolniki, ki v času izvajanja fizikalne terapije niso bili na bolniškem dopustu, so poročali o večjem zmanjšanju bolečine (P = 0,03). Bolniki z ITM 29 kg/m2 ali več so dosegli večje izboljšanje ocene na lestvici EQ–VAS (P = 0,022). Bolniki, ki so se udeležili telovadbe, so dosegli večje izboljšanje ocene na lestvici EQ–VAS (P = 0,036). Bolniki z anksioznostjo oz. depresijo in tisti, ki so imeli ITM 29 kg/m² ali več, so poročali o večji spremembi seštevka točk vprašalnika EQ–5D (P = 0,013; P = 0,013).

Zaključek: *Ambulantna fizikalna terapija ima vpliv na kratkotrajno izboljšanje stanja bolnikov s kronično enostavno bolečino v križu, vendar je smiselnost njene uporabe pri tovrstni populaciji vprašljiva.*

0.001). The assessment of overall health on the EQ–VAS was on average better (10.3 ± 15.2 points; P < 0.001). The score of the EQ–5D was on average lower (0.8 ± 1.2 points; P < 0.001). The patients that were not on sick leave during the physical therapy reported a greater lowering of the intensity of pain than those on sick leave (P = 0.03). Patients with a BMI ≥ 29 kg/m² had a significantly higher change in the assessment of overall health on the EQ–VAS (P = 0.022). The patients that had group exercise in the set of procedures reported a greater improvement in overall health on the EQ–VAS compared to the patients that did not have group exercise (P = 0.036). The patients with anxiety and depression had a significantly higher change in the composite score of the EQ–5D (P = 0.013). Patients with a BMI ≥ 29 kg/m² had a significantly higher change in the composite score of the EQ–5D (P = 0.013).

Conclusion: *Physical therapy has some effect in the short–term treatment of patients with chronic, non–specific, low back pain, but the viability of such procedures in this population of patients is questionable.*

INTRODUCTION

Chronic, non–specific, low back pain is defined as pain in the low back region that is not attributed to a recognizable pathology (such as infections, tumors, osteoporosis, rheumatoid arthritis, fractures, or inflammation), and lasts for more than 12 weeks (1). Chronic, non–specific, low back pain is a common medical and social problem, with a 1–year prevalence in the general population estimated to be 44% (2). Chronic, non–specific, low back pain is an important cause of disability and poor quality of life of patients in Western countries (3).

Many non–pharmacologic treatments are available for low back pain, but the evidence on their efficacy is scarce and inconsistent (4). A recent systematic review showed that the therapies with good evidence of moderate efficacy for chronic low back pain include cognitive–behavioral therapy, exercise, spinal manipulation, and interdisciplinary rehabilitation (5).

Direct family physician referral to physical therapy has been shown to provide several advantages for patients. Specifically, direct family physician referrals result in a significant reduction in waiting time, greater convenience, reduced costs for the patients, lower costs per treated patient, and a shorter recovery time (6). Several factors have been found which affect the referral pattern, such as type of referral, communication between patients and physicians, physician's previous experience with physiotherapy, and patient's expectations (7). Little is known about the referral patterns of Slovenian family physicians to physical therapy (8). Also, the data on outcomes of such referrals are scarce (6, 7, 9).

In Slovenia, basic sets of health care services are provided by means of compulsory health insurance. The employer and employee finance compulsory health insurance, which is required by law for all citizens and permanent residents on an equal basis. Through voluntary insurance, additional services (plastic surgery and some drugs) can be provided to the consumer. If the insuree does not pay the voluntary insurance premium, the insuree will be charged an additional rate for almost all regular services based on actual out–of–pocket costs (10). Payment for physical therapy services is combined; 85% of the costs are paid through the compulsory insurance and the remaining 15% through voluntary insurance (11).

Physical therapy takes place in outpatient physical therapy departments of health resorts, health care centers, hospitals, and in some private centers. Health insurance coverage for physical therapy is regulated by national contract agreement. Patients with chronic, non–specific, low back pain are covered for 10 treatment sessions, consisting of 3–4 different physical modalities per year. The physical modalities that are paid through compulsory and voluntary insurance are only accessible after referral by a physician, who prescribes the physical modalities and the number. Greater 90% of patients are directly referred by their family physician. The remaining patients are referred by clinical specialists (12).

The primary aim of this study was to assess the outcomes of a ten treatment sessions' program of physical therapy regarding the level of pain and the health–related quality of life in patients with chronic non–specific low back pain. The secondary aim was to evaluate the effect of individual physical modalities on the level of pain and the health–related quality of life in patients with chronic non–specific low back pain.

MATERIAL AND METHODS

Type of study

We performed a prospective study in the physical therapy department in the health resort of Topolsica, which is one of several providers of physical therapy in the northeast region of Slovenia. We got approval of the National Ethics Committee.

Study population

We included consecutive patients who were referred for physical therapy by their family physician from 1 March 2008 to 28 February 2009. The inclusion criteria were as follows: ≥ 18 years of age; non–specific, low back pain that lasted for ≥ 12 weeks prior to beginning physical therapy; and signed oral informed consent for participation in the study. The exclusion criteria were as follows: < 18 years of age; underlying pathology for chronic back pain (infections, tumors, osteoporosis, rheumatoid arthritis, fracture, inflammation, previous vertebral surgery, and intervertebral disc herniation); duration of pain < 12 weeks; and patient disapproval for participation in the study. Patients that were unable to attend all 10 treatment sessions were excluded from the study.

Data collection

The physician in the Department of Physical Therapy gave a questionnaire to all eligible patients on the 1st day before beginning physical therapy and on the 10th day after the end of physical therapy. The questionnaire at the beginning of physical therapy consisted of a visual analog pain scale (VAS; 13), the EuroQol questionnaire (14), the Duke anxiety–depression scale (Duke–AD; 15), and a sheet with the following demographic and clinical data: gender; age; education (primary, secondary, and university); employment status (employed, unemployed, and retired); body mass index (BMI); the duration of low back pain (in months); whether or not a patient is on sick leave; and type of physical modality (Table 1). The questionnaire at the end of physical therapy consisted of the VAS (13) and EuroQol questionnaire (14).

The VAS is a 10–point scale for marking the level of pain, ranging from 1 (no pain) to 10 (worst pain imaginable; 13). The EuroQol questionnaire is a widely accepted questionnaire for health–related quality of life and consists of two components. The first component (EQ–5D) consists of five dimensions

Table 1. *Demographic and clinical characteristics of the patients*

Characteristic	Number (%) of patients
Gender	
Men	61 (47.3)
Women	68 (52.7)
Education	
Primary	23 (18.7)
Secondary	83 (67.5)
University	17 (13.8)
Employment status	
Employed	91 (70.5)
Unemployed	3 (2.3)
Retired	35 (27.1)
Sick leave	
Yes	47 (37.0)
No	80 (63.0)
Anxiety and depression	
Yes	60 (51.3)
No	57 (48.7)
Physical modality	
Group exercise (duration: 20 min)	75 (58.1)
Diadinamic currents (duration: 15 min, frequency: 50 Hz)	49 (38.0)
Interference currents (duration: 15 min, frequency: 4,000 Hz)	28 (21.7)
TENS (duration: 15 min, frequency: 100 Hz)	71 (55.0)
Magnetotherapy (duration: 15 min, density: 10 mT, frequency: 50 Hz)	14 (10.9)
Ultrasound (duration: 15 min, frequency: 1,000 Hz, intensity: 1 W/cm2)	14 (10.9)
Thermo therapy (warm padding (55 `C), duration: 20 min)	61 (47.3)
Massage (duration: 20 min)	107 (82.9)
Lumbar traction (duration: 10 min)	22 (17.1)
Thermal water gymnastics (duration: 20 min)	45 (34.9)
No group exercise or thermal water gymnastics	32 (24.8)

TENS – transcutaneous electrical nerve stimulation

(mobility, self–care, usual activity, pain/discomfort, and anxiety/depression). For each dimension there are three answer categories (no problem, 0;some problems, 1; and severe problems, 2). The composite score ranges from 0–10 points. The second component is a VAS (EQ–VAS), providing the respondents with the option to describe their current overall health status on a thermometer–type scale ranging from 0 (the worst health imaginable) to 100 (the best health imaginable; 14). Duke–AD is a brief, self–administered scale for the detection of anxiety and depression. The Duke–AD consists of 7 questions about health and feelings, which are scored from 0–2 points. A composite score of ≥ 5 points of 14 indicates the presence of anxiety and depression (15).

Statistical analysis

We included only the patients who completed both interviews. We calculated the descriptive statistics. In the univariate analysis we used an independent samples t–test, paired samples t–test, and χ^2 test. The statistical significance was set at a $P < 0.05$. For the

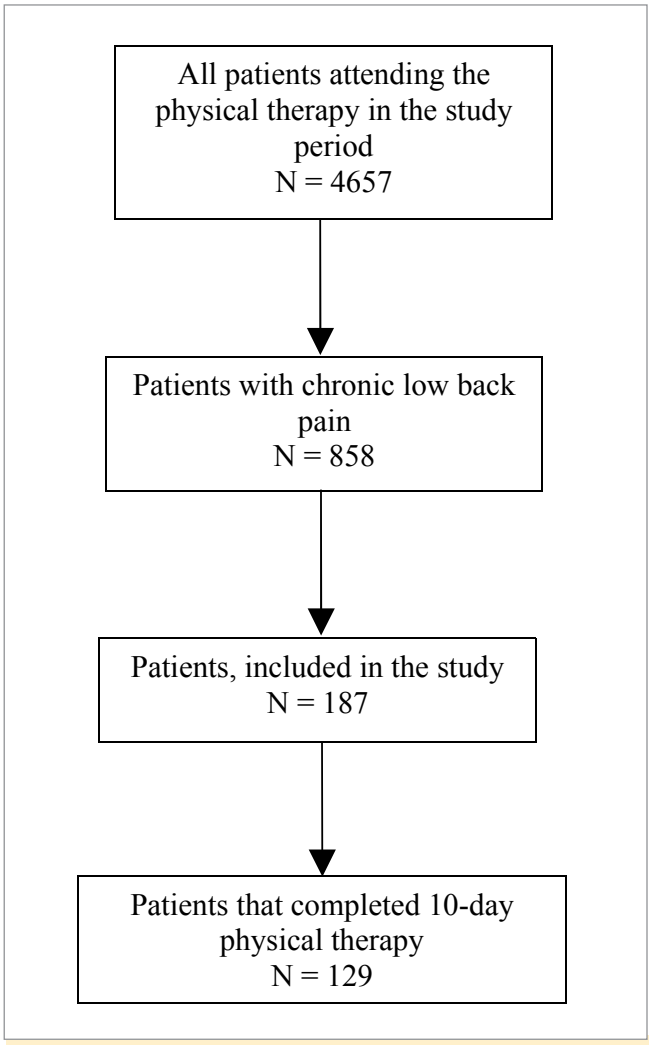

Figure 1. *The flow–chart of the patients' recruitment.*

cut–point in continuous variables to dichotomize the variables, we used median values of the variables. For calculating the change in scores of VAS, EQ–VAS, and EQ–5D, we defined three new variables based on the following equations: VAS (difference) = VAS (beginning) – VAS (end); EQ–VAS (difference) = EQ–VAS visual analog scale (end) – EQ–VAS (beginning); and EQ–5D (difference) = EQ–5D (beginning) – EQ–5D (end).

RESULTS

Demographic and clinical characteristics

The final sample consisted of 129 patients (Figure 1), of which 61 (47.3%) were men (Table 1). The mean age ± SD of the patients was 50.1 ± 10.2 years, ranging from 24–77 years. The mean BMI was 27.5 ± 4.6 kg/m^2, ranging from 18.1–48.1 kg/m^2. The mean duration of low back pain was 115.6 ± 110.0 months, ranging from 3–480 months. Patients had 3.7 ± 0.7 different physical modalities per day, ranging from 2–5. The mean VAS score at the first interview was 6.2 ± 1.9 points, ranging from 1–10 points, and 4.4 ± 2.0 points at the second interview, ranging from 0–10 points. The mean score on the EQ–VAS at the first interview was 53.4 ± 16.1, ranging from 10–90 points, and 63.8 ± 15.5 at the second interview, ranging from 25–95 points. The mean score of the EQ–5D at the first interview was 3.8 ± 1.5, ranging from 0–8 points, and 3.0 ± 1.5 at the second interview, ranging from 0–8 points. The mean score of the Duke–AD was 5.0 ± 2.7, ranging from 0–12 points.

Pain

The intensity of pain after a 10–day physical therapy program was on average lower (1.7 ± 1.8 points; 95% C.I. 1.4–2.1; $P < 0.001$). Nine patients reported worsening of pain, 20 patients had no change in the intensity of pain, and the others patients reported a decrease in the intensity of pain (minimum change, –2; maximum, 8 points). The decrease in the intensity of pain was not significantly correlated with gender, age, education, employment status, BMI, the duration of pain, and the presence of signs of anxiety and depression. The patients that were not on sick leave during the physical therapy program reported a greater decrease in the intensity of pain than those on sick leave (2.1 ± 1.9 vs. 1.4 ± 1.8, $P = 0.03$). Individual sets of procedures of physical therapy did not have an effect on decreasing the level of pain.

Health–related quality of life

The assessment of overall health on EQ–VAS after a 10–day physical therapy program was on average improved (10.3 ± 15.2; 95% C.I. 7.3–13.3; $P < 0.001$). Ten patients reported a worsening of overall health, 16 patients reported no change at all, and the other patients reported a better overall health status (minimum change –75 and maximum –55

points). The difference in the assessment of overall health between both interviews was not significantly correlated with gender, age, education, employment status, the duration of pain, whether or not the patient was on sick leave, and the presence of signs of anxiety and depression. Patients with a BMI ≥ 29 kg/m^2 had a significantly higher change in the assessment of overall health on the EQ–VAS (15.0 ± 18.6 vs. 6.5 ± 16.4, P = 0.022). The patients that had group exercise in the set of procedures reported a greater improvement in overall health on the EQ–VAS compared to the patients that did not have group exercise (12.8 ± 16.2 vs. 5.5 ± 18.2, P = 0.036). The patients that did not have any type of exercise therapy had a lower improvement in the EQ–VAS score in comparison to the other patients (4.1 ± 19.3 vs. 11.9 ± 16.2, P = 0.039).

The score of the EQ–5D scale after a 10–day physical therapy program was on average lower (0.8 ± 1.2 points; 95% C.I. 0.5– 1.0; P < 0.001). Nine patients reported a lower score, 53 patients reported no change, and the rest of the patients reported a higher score (minimum change –2 and maximum 5 points). The patients who did not have any type of exercise therapy had lower improvement in the EQ–5D score (0.3 ± 0.9 vs. 1.0 ± 1.3, P = 0.002). The patients with the presence of anxiety and depression had a significantly higher change in the composite score of the EQ–5D (1.0 ± 1.3 vs. 0.5 ± 0.9, P = 0.013). Patients with a BMI ≥ 29 kg/m^2 had a significantly higher change in the composite score of the EQ–5D (1.1 ± 1.3 vs. 0.6 ± 1.2, P = 0.013).

DISCUSSION

Patients with chronic, non–specific, low back pain that are referred for physical therapy by their family physicians reported a better health–related quality of life after a 10–day physical therapy program. The most effective physical modalities were group exercise and thermal water gymnastics. Sick leave, higher BMI, and the presence of anxiety and depression had a significant impact on the level of pain and on the health–related quality of life after a 10–day physical therapy program. The level of pain was significantly lower after a 10–day physical therapy program, but this change in VAS score was not clinically relevant.

The effectiveness of physical therapy in chronic, non–specific, low back pain has previously been shown (16). Previous studies have also reported on exercise therapy as the only effective procedure of physical therapy (4, 16), which is consistent with our findings. However, the absolute level of pain relief and of quality of life improvement was low and the dispersion of the results was large. Therefore, we can conclude that the value of patient referrals to physical therapy for chronic, non–specific, low back pain is questionable.

The finding that patients with anxiety and depression and those with higher BMIs reported a greater improvement in pain and health–related quality of life are new and conflicting. It is known that chronic low back pain is multi–factorial and connected to psychosocial characteristics of the patients (17). Also, the patients with chronic, non–specific, low back pain have significantly more anxiety and depression than the general population (18). In general, the treatment outcomes of the patients with chronic, non–specific, low back pain are worse in patients that have anxiety and depression (19).

On the other hand, depressed patients with chronic, non–specific, low back pain that went through a multimodal treatment program reported better treatment outcomes (20). However, the limited literature on the response of patients with chronic, non–specific low back pain to various physical modalities (18) hinders tour ability to judge our findings in light of the current knowledge. It is possible that a 10–day physical therapy program acts as a positive short–term psychological stimulus that improves their psychological status, and therefore the symptoms of chronic, non–specific, low back pain because the psychological status of the patients was found to be highly associated with chronic, non–specific, low back pain (21).

This assumption is supported by our finding that group exercise was the only one effective physical therapy procedure because it is known that physical activity in depressed patients acts positively both in the prevention and treatment of anxiety and depression (22). This pattern has also been previously recognized, but the clinical use of positive effects of exercise on depression and anxiety in the form of an adjunct to established treatment approaches, such as psychotherapy or pharmacotherapy, is still at the beginning stage of development (22). Nevertheless, depressed patients with co–morbid pain are often frequent users of the health care system (23, 24), but infrequent users of mental health services (24), and as such they might also benefit from physical modalities. It has been speculated that obesity is a causal factor for low back pain, but no firm clinical evidence exists to support this notion (25).

It has been proven that various forms of exercise reduce pain and increase the quality of life in obese patients with musculoskeletal disorders (26). Studies have shown that exercise therapy has the potential to significantly improve psychopathologic outcomes in obese adolescents in comparison to usual care (27).

These findings are supported with our findings that the patients with a BMI $\geq$ 29 kg/m^2 reported a significantly higher change in the health–related quality of life. It appears that obese patients benefit more from physical therapy in comparison to non–obese patients. This might also be due to the previously stated assumption about the positive effects of exercise on depression and anxiety, which are often co–morbid conditions in obese patients (28).

Prior participation in physical therapy has been reported to be a risk factor for non–return to work in patients with chronic, non–specific, low back pain (29). Our results showed that patients who were not on sick leave during physical therapy reported a greater lowering of pain intensity. This might be because patients on sick leave usually have a longer period of pain that is difficult to treat, usually because of a co–morbid mental illness (30).

The strengths of our study were its prospective design, the inclusion of all consecutive patients that fit inclusion criteria, and the use of valid and reliable instruments. Also, the age and gender of the patients were similar to the patients in a national sample of family practice attendees (31). A limitation was the inclusion of patients in only one department of physical therapy, which might contribute to selection bias. The study also lacked a control group, so the effect of each individual physical modality and the effect of other factors (emotional) were not studied.

The assessment of anxiety and depression at the end of physical therapy would give us more data about the effect of physical therapy on the mental status of patients. The study also lacked long–term follow–up. For studying of the effect of family physicians' referrals to physical therapy, these patients should have been compared to patients referred by clinical specialists (orthopedic surgeons or rehabilitation specialists). Another limitation was the possible selection bias due to unresponsiveness of some patients at the second interview.

Further studies should focus on a long–term assessment of the effect of physical therapy, larger representative samples of patients should be used, and the studies should be done with control groups.
The results of our study showed us that physical therapy has some short–term impact on the level of pain and also on the health–related quality of life in patients with chronic, non–specific, low back pain, but the value of such referrals is questionable.

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