

DO PELOIDS HAVE A ROLE IN THE TREATMENT OF CHRONIC NON-SPECIFIC LOW BACK PAIN?

IMAJU LI PELOIDI ULOGU U LIJEČENJU KRONIČNE NESPECIFIČNE KRIŽOBOLJE?

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ABSTRACT

Introduction. Non-specific low back pain (NSLBP) is a type of pain that cannot be associated with a specific pathology and is likely to have a mechanical cause. Mineral mud (MM) is a form of peloids used for therapeutic purposes. The aim of this study was to evaluate the efficacy of standard kinesiotherapy and hydrotherapy for chronic NSLBP patients, treated with and without peloid therapy. **Patients and methods.** In this prospective randomized study, 64 patients were included: 33 received standard kinesiotherapy treatment and hydrotherapy five times a week, while 31 received additional MM therapy three times a week, instead of hydrotherapy, for three weeks. Measurements included Thomayer's distance test, sagittal mobility (Schober's test), bilateral lateroflexion, and indices such as the Rolland-Morris Disability Questionnaire (RMDQ), the Clinical Functioning Information Tool (ClinFit), the Depression, Anxiety, and Stress Scale (DASS 21), the EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) quality of life questionnaires, and the visual analogue scale (VAS) for pain. Paired t-tests or Wilcoxon signed-rank tests were used depending on the data's normality distribution. Delta changes were examined using the analysis of variance (ANOVA) in order to assess the effects of treatment type, age, and sex of patients, along with the correlation analyses. Significance was set at $p < 0.05$. **Results.** Overall, all measurements significantly improved after therapy, as indicated by paired tests. Univariate analyses showed treatment type to be associated with lateroflexion ($p < 0.05$), sex with Schober's test ($p < 0.05$), and age with VAS pain ($p < 0.05$). Multivariate analyses revealed a significant difference in delta changes for Thomayer's test ($p < 0.01$), left lateroflexion ($p < 0.01$), and RMDQ ($p = 0.01$), with greater improvement in the group receiving additional peloid therapy compared to the standard therapy group. Pain reduction (VAS pain) was significantly greater in patients under 55 years of age compared to those over 55 ($p = 0.03$). Correlation tests showed the expected improvements in patient status. **Conclusion.** Additional treatment with MM instead of standard kinesiotherapy and hydrotherapy leads to significantly increased mobility and improved daily functioning in patients with chronic NSLBP.

KEYWORDS: low back pain, peloid, balneotherapy, hydrotherapy, kinesiotherapy

SAŽETAK

Uvod. Nespecifična križobolja (NK) je bol koja se ne može povezati s određenom patologijom, a vjerojatno ima mehanički uzrok. Mineralno blato (MB) je oblik peloida koji se koristi u terapijske svrhe. Cilj ovog istraživanja bio je procijeniti učinkovitost kinezioterapije i hidroterapije u liječenju bolesnika s kroničnom NK, s dodatnom terapijom

peloida i bez nje. **Ispitanici i metode.** U ovoj prospektivnoj randomiziranoj studiji sudjelovala su 64 bolesnika. Tijekom tri tjedna, 33 bolesnika primilo je standardnu kinezioterapiju s hidroterapijom pet puta tjedno, a 31 bolesnik je imao terapiju MB-om tri puta tjedno umjesto hidroterapije. Ispitivane varijable bile su: Thomayerova mjera (udaljenost prsti – pod), sagitalna pokretljivost lumbalne kralježnice (Schoberova mjera), bilateralna laterofleksija, vizualna analogni ljestvica (VAS) boli te upitnici *Rolland Morris Disability Questionnaire* (RMDQ), *Clinical Functioning Information Tool* (ClinFit), *Depression, Anxiety and Stress Scale* (DASS 21) i *EuroQol-5 Dimensions-5 Levels* (EQ-5D-5L). Sve varijable procijenjene su prije i nakon tretmana. Ovisno o distribuciji podataka, korišten je zavisni t-test ili Wilcoxonov test. Razlike u vrijednostima prije i nakon tretmana ispitane su ANOVA testom s obzirom na vrstu tretmana, dob i spol pacijenata te korelacijskim testovima. Alfa pogreška postavljena je na $p < 0,05$. **Rezultati.** Sve mjere pokazale su značajno bolje rezultate nakon tretmana MB-om. Univarijatna analiza pokazala je da su delta promjene laterofleksije ($p < 0,05$) značajno povezane s vrstom tretmana, Schoberova mjera ($p < 0,05$) bila je povezana sa spolom, a dob s VAS boli ($p < 0,05$). Multivarijatna analiza pokazala je značajno bolje rezultate u delta promjenama Thomayerove mjere ($p < 0,01$) i lijeve laterofleksije ($p < 0,01$) i RMDQ ($p = 0,01$) u skupini bolesnika tretiranoj peloidom u usporedbi sa standardnom terapijom. Također je uočeno značajno smanjenje boli (VAS boli) kod bolesnika mlađih od 55 godina u usporedbi s onima starijima od 55 godina ($p = 0,03$). Korelacijski testovi pokazali su očekivana poboljšanja u zdravstvenom statusu bolesnika. **Zaključak.** Dodatni tretman MB-om umjesto standardne kinezioterapije s hidroterapijom dovodi do značajnog povećanja opsega pokreta te boljeg funkcioniranja u svakodnevnim aktivnostima kod bolesnika s kroničnom NK.

KLJUČNE RIJEČI: križbolja, peloid, balneoterapija, hidroterapija, kinezioterapija

INTRODUCTION

Low back pain is most often defined as pain between the rib cage and the lower fold of the buttocks, which can (but does not have to) spread to the legs (1). If this pain is caused by a specific pathophysiological mechanism, we speak of specific low back pain. However, in cases where we are talking about pain without a clear nociceptive-specific cause and no indication for further interventions (apart from the conservative treatment method) (2), that is the case of non-specific low back pain (3). If low back pain lasts up to 12 weeks, it falls into the category of chronic low back pain. (1)

The greatest non-pharmacologically proven effect on non-specific chronic low back pain, according to several studies, is shown with the use of kinesiotherapy (4,5) such as the McKenzie method (6) or dynamic neuromuscular stabilization (7) and hydrotherapy (8). Mineral mud (MM), a peloid used as a form of balneotherapy, was mainly used in previously conducted research to show the effect of mud on specific joints, e.g. the knee (9) or small joints of the hands (10) as well as to show its effect on specific conditions such as fibromyalgia (11,12) or seronegative spondyloarthritis (13).

The term balneotherapy originates from the Latin words “balneum” and “logos” (literally translated, *the science of bathing*), and is most often defined as the science of natural thermal mineral waters (14). Balneotherapy also includes treatment using natural water sources, thermal/mineral springs, as well as the methods of using said waters, which also includes mineral mud (MM) (14). Thermal mineral waters are natural waters that contain over 1 g of mineral substances and/or gases in one liter of water, which are not regularly found (or are significantly less present) in “normal”

UVOD

Križbolju možemo definirati kao bol između rebrenog luka i donje glutealne brazde, s propagacijom u nogu ili bez nje (1). Ako je ta bol uzrokovana specifičnim patofiziološkim mehanizmom, govorimo o specifičnoj križbolji dok, ako se radi o boli bez jasnog nociceptivno-specifičnog uzroka i bez indikacija za daljnje intervencije (osim konzervativnog liječenja) (2), govorimo o nespecifičnoj križbolji (3). Ako križbolja traje preko 12 tjedana, kategoriziramo je kao kroničnu (1).

Najveći nefarmakološki dokazani učinak na nespecifičnu kroničnu križbolju, prema više studija, predstavlja upravo kineziterapija (4,5) poput metode McKenzie (6) ili dinamičke neuromuskularne stimulacije (7) te hidroterapija (8). Mineralno blato (MB) – peloid, kao oblik balneoterapije, u dosadašnjim se istraživanjima uglavnom orijentira na učinak blata na specifične zglobove, npr. koljeno (9) ili male zglobove šaka (10) kao i na specifična stanja kao što su fibromialgija (11,12) ili seronegativni spondiloartritis (13).

Balneoterapija kao pojam potječe od izraza „balneum“ i „logos“ (doslovno prevedeno, znanost o kupanju), a najčešće je definiramo kao znanost o zdravim vodama (14). Također, balneoterapija podrazumijeva liječenje pomoću prirodnih izvora vode, termomineralnih izvora, kao i načine korištenja navedenih voda, što uključuje i MB (14). Termomineralne vode su prirodne vode koje u jednoj litri sadrže više od 1 g mineralnih tvari i/ili plinova kojih nema (ili ima znatno manje) u običnoj vodi te na izvoru imaju temperaturu iznad 20°C (15). Učinci termomineralnih voda dijele se na mehaničke, kemijske i toplinske, a sve one dovo-

water and that have a temperature above 20°C at the source (15). The effects of thermal mineral waters are divided into mechanical, chemical and thermal, all of which lead to changes in the physiological reactions of the body (16). The thermal mineral waters at "Daruvarske toplice" show excellent balneological properties (17) and have been used since Roman times as a form of hydrotherapy, but also as peloid therapy, or mud enriched with thermal mineral water. The analysis showed that, according to their composition, the above-mentioned springs in Daruvar contain a mixed type of geothermal waters: CaMgNa-HCO₃ (calcium, magnesium, sodium-hydrogen carbonate type of water). The measured water temperature ranges from 24.6°C to 47.1°C. The above mentioned values show that these are geothermal waters, due to the fact that their temperature is significantly higher than the average annual temperature of the area used for the replenishment of springs, wells and shafts. In addition to that, it is possible to analyze and classify these waters as mineral waters because their total dissolved solids range is in concentrations between 0.92 and 1.9 g/l (17). Even though each thermal mineral water is specific and it is difficult to objectively compare the effects of individual peloid therapies used in other regions, several studies have shown the positive effect of treating patients suffering from non-specific low back pain with peloid therapy (18,19), and they also proved that peloid therapy has a better effect on the patients' condition in comparison to kinesiotherapy and/or hydrotherapy (20,21). Several review articles have highlighted the need for further research to be conducted on this topic, given that some studies have not shown a significant effect of balneotherapy (22,23). Chronic non-specific low back pain is a major public health issue (1) and its pharmacological treatment is based primarily on the use of nonsteroidal anti-inflammatory drugs (NSAIDs) (24) combined with numerous non-pharmacological modalities such as the use of pain relief creams (25) and massages (26) with the ultimate result of pain reduction and mobility improvement.

One of the forms of non-pharmacological treatment is certainly the mineral mud (MM) treatment, which is still considered controversial and insufficiently researched.

MATERIALS AND METHODS

This prospective randomized study included 64 subjects (40 women and 24 men) who were divided into two treatment groups.

The first group, which consisted of thirty-one patients, received kinesiotherapy treatment five times a week, hydrotherapy twice a week, and mineral mud from Daruvar was applied to the patients' lumbar spine three times a week. The control group, which consisted of 33 patients, received kinesiotherapy treatment and

de do promjena u fiziološkim reakcijama organizma (16). Termomineralne vode u Daruvarskim toplicama pokazuju odlična balneološka svojstva (17) te se koriste još od rimskog doba u obliku hidroterapije, ali i kao peloid, odnosno blato obogaćeno termomineralnom vodom. Analiza je pokazala da prema svom sastavu navedeni izvori u Daruvaru sadrže geotermalne vode koje pripadaju miješanom tipu – CaMgNa-HCO₃ (kalcijsko, magnezijsko, natrijsko-hidrogenkarbonatnom tipu voda). Izmjerena temperatura voda nalazi se u intervalu od 24,6°C do 47,1°C. Iz navedenih vrijednosti vidljivo je da je riječ o geotermalnim vodama jer je njihova temperatura znatno viša od srednje godišnje temperature područja prihranjivanja izvora, zdenaca i šahtova. Također, analizom je moguće navedene vode klasificirati kao mineralne jer se ukupne otopljene tvari kreću u koncentracijama između 0,92 i 1,9 g/l (17). Premda je svaka termomineralna voda specifična i teško je objektivno uspoređivati učinke pojedinih peloida iz drugih krajeva, u više radova je dokazan pozitivan učinak liječenja bolesnika s NK peloidom (18,19), kao i bolji učinak u odnosu na samu kineziterapiju i/ili hidroterapiju (20,21). U nekoliko preglednih radova istaknuta je potreba za daljnjim istraživanjima s obzirom na to da dio radova nije pokazao značajan učinak balneoterapije (22,23).

Kronična NK velik je javnozdravstveni problem (1) čije se farmakološko liječenje zasniva prvenstveno na korištenju nesteroidnih antireumatika (24), čemu su pridruženi brojni nefarmakološki modaliteti poput korištenja krema za relaksaciju (25) i masaža (26) s krajnjim rezultatom smanjenja boli i poboljšanja pokretljivosti.

Jedan od oblika nefarmakološkog liječenja zasigurno je i tretman MB-om koji je i dalje kontroverzan i nedovoljno istražen.

MATERIJALI I METODE

U ovom prospektivnom randomiziranom istraživanju sudjelovala su 64 ispitanika (od čega 40 žena i 24 muškarca) podijeljena u dvije terapijske skupine.

Prva skupina, koja se sastojala od trideset i jednog bolesnika, provodila je kineziterapiju pet puta tjedno, hidroterapiju dva puta tjedno, a daruvarsko MB aplicirano je na lumbosakralnu regiju bolesnika tri puta tjedno. Kontrolna skupina sastojala se od 33 bolesnika te je provodila kineziterapiju i hidroterapiju pet puta tjedno. Svi tretmani provedeni su prema prethodno utvrđenim kriterijima (hidroterapija i kineziterapija 20 minuta uz standardizirane vježbe istezanja i stabilizacije trupa te aplikacija peloidnih obloga u trajanju od 30 minuta) kroz tri tjedna. Od ukupnog broja bolesnika, 37 ih je imalo 55 godina ili više godina, a 27 manje od 55 godina.

hydrotherapy five times a week. All treatments were carried out in accordance with the previously established criteria (hydrotherapy and kinesiotherapy treatment in the duration of 20 minutes with standardized trunk stretching and stabilization exercises and the application of peloid wraps in the duration of 30 minutes) during the course of three weeks. Out of the total number of patients, 37 of them were 55 years old or older, and 27 of them were younger than 55.

The study was conducted at the Special Hospital for Medical Rehabilitation "Daruvarske toplice" in accordance with the 1967 Helsinki Convention and its subsequent amendments, as well as the principles of good clinical practice. All subjects have signed an informed consent before participating in the study, and were previously informed in detail about the study itself, its objectives and risks. The approval for this study was granted by the Ethics Committee of Daruvarske toplice at a meeting held on March 9th, 2021. The inclusion criterion was chronic non-specific/mechanical low back pain (27). Patients with febrile conditions of any type of cause, patients with previous lumbar spine or hip surgery, patients with neurological diseases and conditions that could interfere with the study and consequently affect its results, as well as those who could not follow the study protocol for any somatic or psychosocial reason were excluded from the study.

During the course of the treatment, only paracetamol (1 to 2 tablets of 500 mg, for a maximum of 2 days) could be used as an analgesic. It was not allowed to use this drug on the first day and one day after the last treatment, as evaluation was being conducted at that time.

On the first day of treatment and one day after the last intervention, the patients completed the EQ-5D-5L, a validated questionnaire for assessing the quality of life with domains of mobility, self-care, usual activities, pain and anxiety/depression (28); the Rolland-Morris Questionnaire (RMDQ) as a standardized instrument of functional capacity in patients with low back pain (29) and the ClinFit questionnaire for classifying patient functioning, disability and health in daily activities using a set of 30 questions, ranked on a scale of 1 – 10 (30).

As measures of spinal mobility, we used the Thomayer's fingertip-to-floor distance test at maximum inclination of the trunk and arms extended towards the floor (31), the modified Schober's test as a standard measure of sagittal mobility for the lumbar spine (32), and the measure of spinal lateroflexion, expressed in centimeters (with one decimal place for millimeters). A tailor's tape measure was used for performing all length measurements. When testing lateroflexion, the subject stands upright with his legs together, flexes the trunk to one side and then to the other, sliding the outstretched palm along the body (leg), and then the dis-

Studija je provedena u Specijalnoj bolnici za medicinsku rehabilitaciju „Daruvarske toplice“ u skladu s Helsinškom konvencijom iz 1967. godine i njezinim kasnijim dopunama, kao i s načelima dobre kliničke prakse. Svi ispitanici potpisali su informirani pristanak prije sudjelovanja u istraživanju, a prethodno su detaljno informirani o samom istraživanju, ciljevima i rizicima. Odobrenje za ovo istraživanje donijelo je Etičko povjerenstvo Daruvarskih toplica na sjednici održanoj 9. ožujka 2021. godine. Uključni kriterij bila je kronična nespecifična/mehanička križobolja (27). Isključeni su bolesnici s febrilnim stanjima bilo koje geneze, bolesnici s prethodnim kirurškim zahvatima na slabinskoj kralježnici ili kukovima, bolesnici s neurološkim bolestima i stanjima koja bi mogla ometati provođenje istraživanja i samim time utjecati na njegove rezultate, kao i oni koji iz bilo kojih somatskih ili psihosocijalnih razloga nisu mogli slijediti protokol istraživanja.

Tijekom cijelog tretmana, kao jedina analgetska farmakoterapija, mogao se koristiti samo paracetamol (1 – 2 tablete od 500 mg i to maksimalno do dva dana). Navedeni lijek nije bio dozvoljen prvoga dana i jedan dan nakon zadnjeg tretmana jer se tada provodila evaluacija.

Prvoga dana i jedan dan nakon zadnje intervencije bolesnici su ispunjavali validirani upitnik EQ-5D-5L za ocjenu kvalitete života s domenama mobilnosti, samozbrinjavanja, uobičajenih aktivnosti, boli te anksioznosti/depresije (28); upitnik Rolland Morris (RMDQ) kao standardizirani instrument funkcionalne sposobnosti kod bolesnika s križoboljom (29) te upitnik ClinFit za klasifikaciju funkcioniranja, nesposobnosti i zdravlja u aktivnostima svakodnevnog života uz pomoć seta od 30 pitanja, rangiranih ljestvicom od 1 do 10 (30).

Od mjera mobilnosti kralježnice koristili smo Thomayerovu mjeru udaljenosti prsti – pod kod maksimalne inklinacije trupa i ruku ispruženih prema podu (31), modificiranu Schoberovu mjeru (Schoberov klinički test) kao standardnu mjeru sagitalne gibljivosti za slabinsku kralježnicu (32) i mjeru laterofleksije kralježnice, izražene u centimetrima (s jednim decimalnim mjestom za milimetre). Za sva mjerenja dužine korišten je krojački metar. Prilikom ispitivanja laterofleksije ispitanik stoji uspravno sa skupljenim nogama, flektira trup u jednu pa u drugu stranu povlačeći ispruženi dlan uz tijelo (nogu) te se pritom mjeri udaljenost između vrška srednjeg prsta i poda (33).

Sva mjerenja provodila su dva specijalista fizikalne i rehabilitacijske medicine (DK i AK) koji su se izmjenjivali pri svakom mjerenju, a podatci za svaku pojedinu mjeru upisivani su u posebne dijelove upitnika, bez uvida u prethodna mjerenja. Mjerenja su vršena uvijek u istoj prostoriji i u isto doba dana, prvo neposredno

TABLE 1. Overall results in 64 patients treated for non-specific lumbar pain
 TABLICA 1. Ukupni rezultati u 64 pacijenta liječena radi nespecifične križobolje

Test		Median (interquartile range, min – max range) mean/sd /Medijan (interkvartilni raspon, min. – maksimalni raspon) srednja vrijednost/sd		
		Before therapy/Prije terapije	After therapy/Nakon terapije	Delta change†/Delta promjena†
Thomayer (cm)****		9.5 (18.25, 0 – 36) 11.34 / 10.37	5 (12, 0 – 49) 7.67 / 9.53	-3 (6, -21 – 22) -3.66 / 7.52
Schober (cm)**		6 (2.12, 3 – 11.5) 6.07 / 1.71	6.25 (2.62, 3 – 11) 6.53 / 1.7	0.5 (1.5, -3 – 3.6) 0.46 / 1.3
Rolland Morris (1-100)**		8 (8, 0–18) 8.16 / 4.93	6 (8.25, 0–20) 6.78 / 5.41	-0.5 (2, -16 – 6) 1.38 / 3.63
Lateroflexion (cm)/Laterofleksija (cm)				
Right/Desno*		51 (6.25, 40 – 66) 51.24 / 5.15	50 (6, 39–61) 49.86 / 4.94	-1.25 (5.25, -15 – 9) -1.38 / 4.74
Left/Lijevo*		52 (6, 42 – 64) 52.1 / 5.05	51 (6.25, 41–58) 50.82 / 4.09	-1 (4, -14 – 8) -1.28 / 4.35
EQ-5D (1-5)	Pain****/Bol	3 (1, 1 – 5) 3.12 / 0.79	3 (1, 1 – 4) 2.53 / 0.78	-1 (1, -3 – 1) -0.59 / 0.75
	Mobility***/Mobilnost	3 (1, 1 – 4) 2.5 / 0.96	2 (2, 1 – 4) 2.14 / 0.83	0 (1, -2 – 1) -0.36 / 0.65
	Activity***/Aktivnost	3 (1, 1 – 4) 2.59 / 0.92	2 (1, 1 – 4) 2.19 / 0.83	0 (1, -3 – 1) -0.41 / 0.79
	Self care**/Briga o sebi	2 (2, 1 – 4) 2.08 / 0.96	2 (1, 1 – 3) 1.8 / 0.8	0 (1, -3 – 1) -0.28 / 0.77
	Anxiety*/Anksioznost	2 (2, 1 – 4) 2.06 / 0.96	1.5 (2, 1 – 4) 1.81 / 0.91	0 (0.25, -2 – 2) -0.25 / 0.76
ClinFit***		75 (92.5, 14 – 232) 96.72 / 59.63	75 (66, 2 – 228) 82.94 / 56	-4 (16, -133 – 75) -13.78 / 35.47
DASS-21****		10 (13.75, 0 – 59) 12.81 / 12.26	5 (9.25, 0 – 36) 7.98 / 8.09	-2.5 (7, -47 – 6) -4.83 / 8.57
VAS (1-100)	Pain****/Bol	6 (2, 2 – 10) 5.33 / 1.94	4 (3.25, 0 – 8) 4.09 / 2.02	-1 (2, -5 – 2) -1.23 / 1.58
	Health****/Zdravlje	60 (21.25, 10 – 95) 57.34 / 17.55	70 (30, 30 – 95) 66.3 / 17.7	10 (15, -20 – 45) 8.95 / 14.43

*Significant difference between test results before and after the treatment with *p*-values of paired two-sample *t* or Wilcoxon signed-rank tests reported as *(*p*≤0.05), **(*p*<0.01), ***(*p*<0.001), ****(*p*<0.0001), and without the symbol if not significant (*p*>0.05). † Delta changes in test results per patient were calculated as after – before. / Značajna razlika između rezultata ispitivanja prije i nakon tretmana s *p*-vrijednostima uparenih dvaju uzoraka *t* ili Wilcoxonovi testovi rangiranja s predznakom prijavljeni su kao *(*p*≤0.05), **(*p*<0.01), ***(*p*<0.001), ****(*p*<0.0001) i bez simbola ako nije značajno (*p*>0.05). † Delta promjene u rezultatima ispitivanja po pacijentu izračunate su kao poslije – prije.

tance is measured between the tip of the middle finger and the floor (33).

All measurements were performed by two physical medicine and rehabilitation specialists (DK and AK) who took turns at performing each measurement, and the data for each individual measure were recorded in separate sections of the questionnaire, without any insight into previous measurements. The measurements were always performed in the same room and at the same time of day. The first measurement was performed immediately before the first treatment and the final measurement was performed one day after the last treatment.

The exploratory data analysis included standard measures of central tendency and variability for numerical data. The Shapiro-Wilk test was used to test for normal distribution of data. In accordance with that, the dependent Student's *t*-test was used to test the dif-

prije prvog tretmana te završno jedan dan nakon zadnjeg tretmana.

Eksplorativna analiza podataka uključivala je standardne mjere centralne tendencije i varijabilnosti za numeričke podatke. Za ispitivanje normalne distribucije podataka korišten je Shapiro-Wilk test. Prema tome, za ispitivanje razlika u rezultatima prije i poslije terapije korišten je zavisni Studentov *t*-test za normalno distribuirane podatke te zavisni Wilcoxonov rang test za podatke s nenormalnom distribucijom. Nakon toga provedena je univarijatna i multivarijatna ANOVA kako bi se ispitalo jesu li delta promjene rezultata bile značajno povezane s dobi (bolesnici < 55 godina starosti i bolesnici ≥ 55 godina starosti), spolom (muški i ženski) i tipom tretmana (dodatni MB tretman). Korelacije između varijabli analizirane su Spearmanovim korelacijskim testovima uz primjenu Bonferronijeve korekcije *p*-vrijednosti za više-

TABLE 2. Delta changes in test results by treatment type, sex and age of 64 patients treated for non-specific lumbar pain
TABLICA 2. Delta promjene rezultata testa prema vrsti liječenja, spolu i dobi 64 bolesnika liječenih radi nespecifične križbolje

Test		Delta change = after – before / Delta promjena = poslije – prije Median (interquartile range, min – max range)* / Medijan (interkvartilni raspon, min. – maks. raspon)*		
		Sex/Spol Female/Žene (n = 40) Male/Muškarci (n = 24)	Age/Dob < 55 years/< 55 godina (n = 27) ≥ 55 years/≥ 55 godina (n = 37)	Treatment/Liječenje Control/Kontrola (n = 33) mud/blato (n = 31)
Thomayer (cm)		-2 (6, -21 – 22) -3 (4.75, -15 – 2.5)	-3 (10, -15 – 22) -3 (5, -21 – 9)	-2 (5, -21 – 22) -3 (11, -20 – 2.5)**
Schober (cm)		0.5 (1.5, -3 – 3) 0.5 (1.5, -3 – 3)*	0.5 (1.5, -3 – 2.5) 0.5 (1.5, -1.5 – 3.6)	0.5 (1.5, -3 – 3) 0.5 (1.75, -2.5 – 3.6)
Rolland Morris (1-100)		0 (2, -12 – 6) -1 (2, -16 – 0)	-1 (3, -16 – 6) 0 (2, -9 – 5)	0 (1, -4 – 6) -1 (3.5, -16 – 2)*
Lateroflexion (cm)/Laterofleksija Right/Desno		-1 (6, -9 – 9) -3 (6.25, -15 – 4)**	-2 (6.5, -12 – 8) -1 (4, -15 – 9)	-1 (4, -11 – 9) -2 (5.5, -15 – 8)
Left/Lijevo		-1 (4, -9 – 7) -2 (6.25, -14 – 8)**	-0.5 (7.25, -11 – 8) -1 (2, -14 – 7)	0 (3, -9 – 8) -2 (6, -14 – 5)**
EQ-5D (1-5)	Pain/Bol	-1 (1, -3 – 1) -1 (1, -2 – 0)	0 (1, -3 – 1) -1 (1, -2 – 1)	-1 (1, -2 – 1) 0 (1, -3 – 1)
	Mobility/Mobilnost	0 (1, -2 – 1) 0 (1, -2 – 1)	0 (1, -1 – 0) 0 (1, -2 – 1)	0 (1, -2 – 1) 0 (1, -2 – 1)
	Activity/Aktivnost	0 (1, -3 – 1) 0 (1, -2 – 1)	0 (1, -2 – 1) 0 (1, -3 – 1)	0 (1, -2 – 1) 0 (1, -3 – 1)
	Self care/Briga o sebi	0 (1, -3 – 1) 0 (0.25, -2 – 1)	0 (1, -2 – 1) 0 (0, -3 – 1)	0 (1, -2 – 1) 0 (1, -3 – 1)
	Anxiety/anksioznost	0 (0.25, -2 – 2) 0 (0.25, -2 – 1)	0 (1, -2 – 1) 0 (0, -2 – 2)	0 (0, -2 – 2) 0 (0.5, -2 – 2)
ClinFit		0 (16.75, -133 – 75) -5 (15.25, -74 – 48)	-5 (23, -133 – 21) 0 (13, -83 – 75)	0 (10, -83 – 48) -11 (17.5, -133 – 75)
DASS-21		-3 (7.25, -47 – 6) -1 (5, -15 – 2)	-3 (8, -47 – 6) -1 (5, -30 – 4)	-3 (6, -30 – 6) -1 (7, -47 – 3)
VAS (1-100)	Pain/Bol	-1 (2, -5 – 2) -1 (2, -5 – 0)	-2 (3, -5 – 2) 0 (1, -4 – 2)*	-1 (2, -4 – 2) -1 (2.5, -5 – 2)
	Health/Zdravlje	10 (20, -20 – 45) 9.5 (12, -20 – 45)	10 (20, -15 – 45) 5 (10, -20 – 45)	10 (15, -20 – 45) 10 (13, -20 – 45)

*Significant difference in delta change from the multivariate linear regression with all three variables (Treatment, Sex, Age) as independent effects only and tested using ANOVA with p-values depicted using symbols: *(p<=0.05), **(p<0.01), *** (p<0.001), ****(p<0.0001), and without the symbol if not significant (p>0.05). / *Značajna razlika u delta promjeni u odnosu na multivarijatnu (linearnu regresiju) sa sve tri varijable (liječenje, spol, dob) samo kao nezavisni učinci i testirana pomoću ANOVA-e s p-vrijednostima prikazanim pomoću simbola: *(p<=0,05), **(p< 0,01), *** (p<0,001), ****(p<0,0001) i bez simbola ako nije značajno (p>0,05).

ferences in pre- and post-treatment scores for normally distributed data and the dependent Wilcoxon signed-rank test was used for non-normally distributed data. Univariate and multivariate ANOVA methods were then performed to examine whether delta score changes were significantly related to age (patients < 55 years of age and patients ≥ 55 years of age), sex (male and female), and type of treatment (additional MM treatment). Correlations between variables were analyzed using Spearman’s correlation tests with Bonferroni correction of p-values for multiple cross-comparisons. All tests had a significance level set at < 0.05. The R Statistical Software (v4.1.2; R Core Team 2021) was used for exploratory and statistical data analysis (34).

struke usporedbe. Svi testovi imali su razinu značajnosti postavljenu na < 0,05. Za eksplorativnu i statističku analizu korišten je R softver v.4.1.2 (R core team 2021) (34).

REZULTATI

Svi ispitanici imali su značajno promijenjene rezultate nakon intervencije u svim praćenim parametrima (varijablama) i to u smjeru poboljšanja (tablica 1). Najveća razlika uočena je u vrijednostima EQ-5D-5L varijabli VAS zdravlja, upitniku ClinFit te Thomayerovoj mjeri (tablica 1). Univarijatna analiza pokazala je da je tretman MB-om značajno povezan s lijevom laterofleksijom (p = 0,046), dob pacijenata s VAS boli (p =

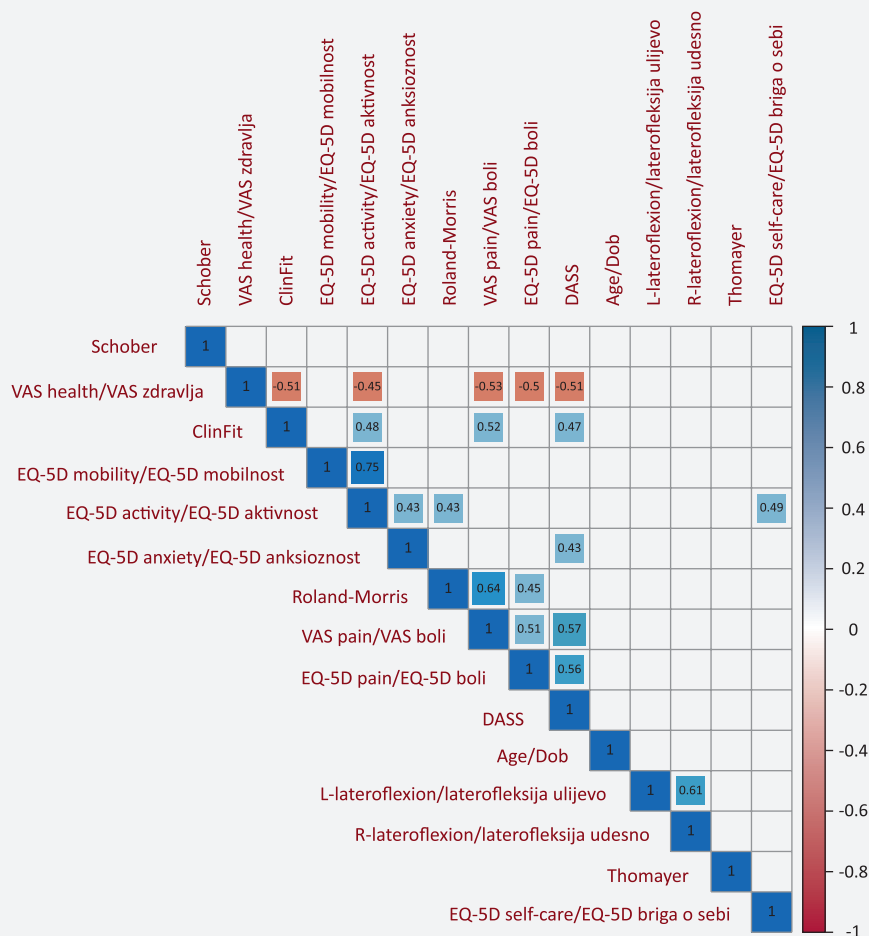


FIGURE 1. Correlogram of delta changes in test results after finishing the treatment and age of patients
PRIKAZ 1. Korelogram delta promjena rezultata testova nakon završetka liječenja i dobi bolesnika

RESULTS

All subjects had significantly different results after the intervention in all monitored parameters (variables) and the results have significantly improved (Table 1). The largest difference was observed in the values of EQ-5D-5L variables VAS scores, ClinFit questionnaire and Thomayer's test (Table 1). Univariate analysis showed that the MM treatment was significantly associated with left lateroflexion ($p = 0.046$), the age of patients was associated with VAS pain ($p = 0.01$) and gender was associated with Schober's test ($p < 0.05$). After including the variables of age and sex in the multivariate analysis, the type of treatment (MM) was still significantly associated with delta changes in left lateroflexion measures ($p < 0.01$), but also with significant differences in Thomayer's test ($p < 0.01$) and RMDQ questionnaire ($p = 0.01$) (Table 2).

When sex and treatment type were included in the analysis as constant variables, multivariate analysis found an association between age and delta changes in VAS pain scores ($p = 0.03$), with better results in indi-

0,01) te spol sa Schoberovom mjerom ($p < 0,05$). Nakon uvrštavanja varijable dobi i spola u multivarijatnu analizu, tip tretmana (MB) i dalje je bio značajno povezan s delta promjenama u mjerama lijeve laterofleksije ($p < 0,01$), ali i sa značajnim razlikama u Thomayerovoj mjeri ($p < 0,01$) i RMDQ upitniku ($p = 0,01$) (tablica 2).

Uključujući spol i tip tretmana kao konstantu, multivarijatna analiza utvrdila je povezanost dobi s delta promjenama u rezultatima VAS boli ($p = 0,03$) s boljim učinkom kod osoba ispod 55 godina (tablica 2). Uključujući pak dob i tip tretmana kao konstantu, utvrđena je povezanost spola s lijevom ($p < 0,01$) i desnom laterofleksijom ($p < 0,01$) te Schoberovom mjerom ($p = 0,049$), s boljim rezultatima u muškoj populaciji (tablica 2). Sve korelacije bile su blage do umjerene jačine (prikaz 1).

Značajno negativne korelacije uočene su između EQ-5D-5L VAS zdravlja s ClinFit ($p < 0,0001$), DASS 21 ($p < 0,0001$), EQ-5D-5L aktivnosti ($p < 0,0024$), VAS boli ($p < 0,0001$) te EQ-5D-5L boli ($p < 0,0001$),

viduals under 55 years of age (Table 2). When age and treatment type were included in the analysis as constant variables, sex was found to be associated with left ($p < 0.01$) and right lateroflexion ($p < 0.01$) and Schober's test ($p = 0.049$), with better results in the male population (Table 2). All correlations were mild to moderate in strength (Figure 1).

Significant negative correlations were observed between EQ-5D-5L VAS health with ClinFit ($p < 0.0001$), DASS 21 ($p < 0.0001$), EQ-5D-5L activity ($p < 0.0024$), VAS pain ($p < 0.0001$), and EQ-5D-5L pain ($p < 0.0001$), while there were 14 significant positive correlations (Figure 1). Age, Schober's, and Thomayer's test were the only variables that did not correlate with any other variable (Figure 1).

DISCUSSION

Due to the significantly better statistical results of the left lateroflexion variables, Thomayer's test, and RMDQ questionnaire in the group treated with MM, this study demonstrated greater effectiveness in the treatment of chronic non-specific low back pain with the application of peloid wraps in comparison to hydrotherapy and kinesiotherapy treatments. Through the use of univariate analysis of variance, the only significant difference found was increased left lateroflexion in the group treated with MM therapy, which could be explained by the predominantly unilateral mechanical low back pain which was present in the majority of subjects. However, we did not examine the specific side on which the lumbar pain was present (predominantly present on the left or right side). In addition to the lateroflexion, multivariate analysis confirmed a significant difference in the RMDQ questionnaire and Thomayer's test results (Table 2), indicating that patients treated with MM therapy also experienced more ease in the performance of their daily activities as well as greater mobility due to increased range of motion in the lumbar spine.

Multivariate analysis also revealed interesting data: the results have shown a significant reduction of pain in the younger population, as well as an increased range of motion in the male population (Table 2). We were not able to find these data in literature to date, but we can associate them with a better recovery of the younger patients and potentially more persistent exercise in the male population.

Although there are numerous studies that question the superiority of hydrotherapy over kinesiotherapy (22, 23, 35), the use of mineral waters as a form of conservative treatment for patients with chronic low back pain has been confirmed in several studies (8, 21). The advantage of their use over kinesiotherapy has also been confirmed, whether it be the case of additional hydrotherapy (36, 37) or the use of MM peloid treatment (18, 38). In addition to improved mobility and

dok je bilo 14 značajnih pozitivnih korelacija (prikaz 1). Dob, Schoberova i Thomayerova mjera bile su jedine varijable koje nisu korelirale ni s jednom drugom varijablom (prikaz 1).

RASPRAVA

S obzirom na statistički značajno bolje rezultate u varijablama lijevostrane laterofleksije, Thomayerove mjere te RMDQ upitnika u skupini tretiranoj i MB-om, ovim istraživanjem dokazali smo veću učinkovitost liječenja kronične nespecifične križobolje uz aplikaciju peloidnih obloga u usporedbi sa samom hidroterapijom i kineziterapijom. Korištenjem univarijatne analize varijance, jedina utvrđena značajna razlika bila je povećana lijevostrana laterofleksija u skupini tretiranoj MB-om, što bi moglo biti objašnjeno pretežno jednostranom mehaničkom križoboljom kod većine ispitanika. Međutim, podatak o specifičnoj strani lumbalne boli (pretežito lijevo ili desno) nismo ispitivali. Osim laterofleksije, multivarijatnom analizom potvrđena je značajna razlika i u RMDQ upitniku te Thomayerovoj mjeri (tablica 2), što ukazuje da su bolesnici tretirani MB-om, osim veće pokretljivosti zbog povećanog opsega kretnji u lumbalnoj kralježnici, imali i olakšane aktivnosti u svakodnevnom životu.

Multivarijatna analiza također je otkrila zanimljive podatke – rezultati pokazuju značajno smanjenje boli u mlađoj populaciji, kao i povećani opseg kretnji kod muškaraca (tablica 2). Navedene podatke nismo pronašli u dosadašnjoj literaturi, ali ih možemo povezati s boljim oporavkom kod mlađih pacijenata te potencijalno upornijim vježbanjem kod muške populacije.

Premda postoje brojni radovi koji dovode u pitanje prednost hidroterapije nad kineziterapijom (22, 23, 35), korištenje mineralnih voda kao oblika konzervativnog tretmana za bolesnike s kroničnom križoboljom potvrđeno je u nekoliko istraživanja (8, 21). Također, utvrđena je i prednost njihovog korištenja u odnosu na samu kineziterapiju, bilo da se radi o dodatnoj hidroterapiji (36, 37) ili upotrebi MB peloida (18, 38). Osim olakšane pokretljivosti i smanjenja boli, istraživanja o učinkovitosti hidroterapije i terapije MB-om promatrala su i druge varijable poput maksimalnog primitka kisika (VO_{2max}) i postotka masnog tkiva (39, 40).

Pojedini radovi koriste varijable poput VAS boli, RMDQ upitnika i Schoberove mjere (41, 42) kao pokazatelje učinkovitosti, no do sada nismo pronašli studije koje obuhvaćaju sve varijable korištene u našem istraživanju, a koje se odnose na pokretljivost lumbalne kralježnice, funkcionalni status i aktivnosti svakodnevnog života. Uspoređujući naša istraživanja s prethodnim radovima, možemo zaključiti da većina radova (18, 40, 41, 42) potvrđuje olakšanu pokretljivost lumbalne kralježnice nakon terapije.

pain reduction, studies on the effectiveness of hydrotherapy and MM therapy have also looked at other variables such as maximal oxygen uptake (VO_2 max) and percentage of body fat (39, 40).

In some studies, variables such as VAS pain, RMDQ questionnaire and Schober's test (41, 42) are used as indicators of effectiveness, but so far, we have not found any studies that include all the variables used in our study, which relate to lumbar spine mobility, functional status and patients' daily activities. By comparing our research with research performed in previously conducted studies, we can conclude that most studies (18, 40, 41, 42) confirm facilitated lumbar spine mobility after therapy.

We were able to confirm the expected results of the study with correlation analysis. Negative correlations were in line with the assumptions: in cases where there is a higher level of health (observed in the VAS pain and EQ-5D-5L questionnaire scores) there is a decrease in pain (monitored through the use of the VAS pain and EQ-5D-5L pain methods) (Figure 1). Positive correlations indicated that a better level of health leads to greater activity (EQ-5D-5L questionnaire) and better daily functioning (RMDQ questionnaire) (Figure 1). Interestingly enough, lumbar spine mobility tests (Thomayer's and Schober's test) and age did not correlate with any other variable (Figure 1), although we expected a correlation with the VAS pain variable, for example.

The causes of non-specific low back pain are mainly mechanical in nature (43), which was one of the reasons why we expected that an increase in mobility would significantly affect other variables. Working and socioeconomic conditions, whose influence on low back pain symptoms is possible but still debatable (1), were not the subject of this study. A shortcoming of this study is the inability to compare these treatment methods with a peloid of the same composition, as each thermal mineral water is unique, making it difficult to compare its chemical effects. Another limitation of this study could also be the small number of subjects ($n=64$), as well as the lack of the patients' health status follow-up after treatment (e.g. after 6 months), which would allow for an assessment of the long-term effectiveness of the treatment to be performed.

CONCLUSION

In this study, measures of lumbar spine mobility (lateroflexion, Thomayer's test) and functional abilities (RMDQ) showed significant improvement after three weeks of therapy (in comparison to baseline values) in the group of patients additionally treated with peloids in comparison to the control group that only received standard hydrotherapy and kinesiotherapy treatments. Additional studies with a larger number of subjects and long-term follow-up are needed in order to assess the long-term effectiveness of the treatment. Based on

Analizom korelacija potvrdili smo očekivane rezultate istraživanja. Negativne korelacije bile su u skladu s pretpostavkama, s većim stupnjem zdravlja (promatranim u VAS zdravlja EQ-5D-5L upitnika) dolazi do smanjenja boli (praćenima u VAS boli i EQ-5D-5L boli) (prikaz 1). Pozitivne korelacije ukazale su na to da bolji stupanj zdravlja dovodi do veće aktivnosti (EQ-5D-5L upitnik) i boljeg funkcioniranja u svakodnevnom životu (RMDQ upitnik) (prikaz 1). Zanimljivo je da mjere pokretljivosti lumbalne kralježnice (Thomayer i Schober) i dob nisu korelirale ni s jednom varijablom (prikaz 1), iako smo očekivali povezanost, primjerice, s VAS boli.

Uzroci nespecifične križobolje uglavnom su mehaničke prirode (43), što je bio jedan od razloga zašto smo očekivali da će povećanje pokretljivosti značajno utjecati na druge varijable. Radni i socioekonomski uvjeti, čiji je utjecaj na simptome križobolje moguć, ali još uvijek diskutabilan (1), nisu bili predmet ovog istraživanja. Kao nedostatak istraživanja može se izdvojiti nemogućnost usporedbe s peloidom istog sastava jer je svaka termomineralna voda jedinstvena pa je teško usporediti njezin kemijski učinak. Ograničenje ovog istraživanja mogao bi biti i mali broj ispitanika ($n=64$), kao i nedostatak praćenja njihovoga zdravstvenog stanja nakon tretmana (npr. nakon šest mjeseci), što bi omogućilo procjenu dugoročne učinkovitosti tretmana.

ZAKLJUČAK

U ovom istraživanju mjere pokretljivosti lumbalne kralježnice (laterofleksija, Thomayerova mjera) i funkcionalne sposobnosti (RMDQ) pokazale su značajno poboljšanje nakon tri tjedna terapija (u usporedbi s početnim vrijednostima) u skupini bolesnika dodatno tretiranoj peloidom u odnosu na kontrolnu skupinu koja je provodila samo standardnu hidroterapiju i kineziterapiju. Potrebna su dodatna istraživanja s većim brojem ispitanika i dugoročnim praćenjem kako bi se procijenila dugoročna djelotvornost tretmana. Na temelju novih spoznaja moguće je izraditi preporuke za fizikalno-terapijske tretmane kod bolesnika s kroničnom nespecifičnom križoboljom.

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new findings, it is possible to give recommendations for physical therapy treatments in patients with chronic non-specific low back pain.

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