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Research Article

Which is a more Efficacy Method between Manual Therapy, Traction, or Laser in Low Back Pain without Neurological Deficiency? A Randomized Controlled Trial

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Abstract

Background: The conservative treatment of Low Back Pain (LBP) is the generally accepted standard of care at least in its initial phase. A myriad of modalities are offered but optimal management is still a matter of debate.

Objective: Efficacy comparison of selected methods of conservative LBP treatment.

Methods: Ninety patients with LBP were allocated randomly to three groups each containing 30 participants with a different method of treatment. Manual therapy (MT), Traction Therapy (TT), or High-Intensity Laser (HIL) were implemented twice a week for five weeks. Assessment: Baseline (T0), 4 (T1), and 12 (T2) weeks after last intervention. Primary outcomes: Visual Analogue Scale (VAS, 0-10), Oswestry Disability Index (ODI, 0-50), Modified Laitinen Questionnaire (MLQ, 0-16). Secondary outcomes: Seat and reach test (SaR) and range of motion (ROM).

Results: No significant statistical differences (SSD) between groups for primary outcomes at T1. At T2 noted SSD in ODI for HIL (12.27) versus MT and TT (6.87, 7.03 respectively), p = 0,002. In all groups, SaR and ROMs directions improved at T1, but during follow-up, only side-bending right was maintained.

Conclusion: MT, TT, and HIL are comparable methods in terms of efficacy for LBP treatment.

Keywords: Low Back Pain; Conservative Treatment; Rehabilitation; Physical Therapy Modalities; Laser Therapy

Introduction

Low Back Pain (LBP) is a serious health problem with a global scope, a kind of epidemic of our times. It is assumed that the incidence of a first-ever episode of pain in the lumbar spine ranges from 6.3% to 15.4%. On the other hand, the incidence, considering the first and subsequent episodes during the year (1-year incidence of any episode), ranges from 1.5% to 36%, with the frequency of annual episodes reaching even from 54% to 90%. The LBP prevalence is reported by various literature sources within very wide range of values, between 1.0% and 58.1% (mean: 18.1%; median: 15.0%), and the annual prevalence between 0.8% and 82.5% (mean: 38.1%; median: 37.4%) [1]. The prevalence of LBP increases with age, which is related to both exposures to environmental factors (labor burden, physical activity), as well as natural degenerative processes that occur in the intervertebral disc only from the second decade of life. In the meta-analysis, by Meucci., *et al.* the prevalence of LBP in the age group of 24-39 years, was determined at the level of 4.2%, and in the group of 20-59 years, it was 19.6% [2].

In addition to non-measurable losses associated with impaired patient activity and a significant reduction in their quality of life, LBP is the greatest burden on the world economy. It is measured by the ratio of years lived with disability (years lived with disability, YLD) due to a significant reduction in the productivity and professional abilities of patients suffering from LBP [3].

Due to the ubiquitous and global scope of LBP and still a real risk of complications related to surgical treatment (despite significant advances in technology), conservative treatment is the generally accepted standard of care in the initial phase of LBP patient care supposing that neurological deficits are absent. There is consensus that only sudden neurological deficits or constant worsening of symptoms despite intensive conservative treatment for several weeks are an indication for surgery and only if there is a pathology correlating with the clinical signs and imaging tests. Otherwise, surgical treatment is not justified, as there are numerous meta-analyses confirming that the results of surgical and conservative treatment are roughly the same after 12 months of observation and are worse in longer observations due to possible scarring, loosening of implants, or their intolerance [4].

Most cases (approximately 90%) represent non-specific LBP related to any stage of Lumbar Degenerative Disc Disease (LDDD) which seems to be the core factor for further spondylosis development. Thus, the aim of the treatment in the acute period is to alleviate pain and reduce inflammatory oedema around the facet joints, soft tissues, and elements of the nervous system affected due to disc–related pro-inflammatory agents [5-7]. In the chronic period, the aim is shifted to stimulate the healing and regeneration of already existing injuries and restore the patient's functional capabilities.

As can be observed in the natural course of non-specific LBP, most cases tend to be self-limiting and spontaneously resolve after 1-3 months. Hence, besides any chosen treatment of LBP, it is fundamental to reassure the patient, instruct on how to avoid pain and its recurrence in terms of work and sports activities ergonomics, and work out a coping strategy against stress resulting from a temporary inability to work. Although the majority of cases can be effectively treated conservatively, optimal management is still a matter of debate and at least three concurrent concepts i.e., lymph-venous drainage, mechanical decompression, or direct anti-inflammatory (anti edematous) action have their ardent proponents among caregivers [8].

Own clinical observations, and at the same time the lack of clear guidelines on how to use physical therapy modalities more specifically and reproductively, prompted the authors to research comparing three concepts of LBP treatment in terms of efficacy and safety: manual therapy oriented toward spinal lymph-venous drainage, mechanical spinal decompression by lumbar traction and direct anti-inflammatory action by targeted laser stimulation.

Materials and Methods

The study was designed as a single-center open randomized controlled trial. The Bioethics Committee operating at the Military Medical Chamber in Warsaw approved the protocol of the trial (Resolution No. 146/17 of 27/01/2017). All experiments were performed in accordance with and following the Declaration of Helsinki Principles. Written informed consent was obtained from all participants before any intervention. The study was performed in Sutherland Medical Center (SMC), Warsaw, Poland, and all data were collected and stored there.

The study included ninety patients in three groups of thirty participants. Patients meeting the inclusion criteria were allocated randomly according to the computer-generated randomization list (block randomization; block size = 6). No changes in allocation and no changes in the methodology of the study took place throughout the study and all procedures were performed in the SMC clinic.

Manual Therapy (MT) is oriented toward the release of venous and lymphatic congestion in the region of the lumbar spine obtained by facet joints and Sacroiliac Joint (SIJ) mobilization and manipulation, soft tissue release techniques, especially iliopsoas muscles, diaphragm, pelvic floor according to spotted dysfunction, two 30-minute sessions a week, ten treatments in total, 5 weeks of therapy plus instruction for a patient about self-therapy at home. The therapy was performed by the same experienced physiotherapist as an individual therapy face to face (T.Z).

Traction therapy (TT) on the 3D traction table (model Platinium Technomex,) in flexion position with the following parameters: 6-10 degrees of flexion, traction force 10-15% of body weight (according to individual tolerance), duration 15 minutes, two sessions a week, ten treatments in total, 5 weeks of therapy. The therapy was performed by the same experienced physiotherapist as an individual therapy face-to-face (W.R).

High-Intensity Laser (HIL, model BTL-6000 HIL 12W, BTL) - two sessions a week with the following parameters: analgesia program 50 Hz, power 7 W, area of action - 2 cm^2 ultrasound-guided treat-

ment with beam targeting at the intervertebral joints (facet joints) and biostimulation program power 7W on area 2 cm^2 targeting the beam at the intervertebral joints of the affected spinal segment, ten treatments in total, 5 weeks of therapy. The therapy was performed by the same experienced physiotherapist as an individual therapy face-to-face (W.R).

Figure 1: Ultrasound-guided HIL therapy targeted at lumbar facet joints.

Inclusion criteria

- Informed consent of the patient to participate in the study.
- Patients aged from 18 to 60 years.
- The presence of non-specific LBP with LDDD confirmed by MRI, without neurological deficits (i.e. sphincter dysfunction, sensory or motor deficits, absent tendon reflexes).

Exclusion criteria

- LBP of another origin (post-traumatic lesions, autoimmune, neoplastic, and infectious diseases).
- Neurological deficits.
- Other physiotherapeutic procedures performed in the last 8 weeks before the start of the study.
- No consent.

During the trial, patients were allowed to take paracetamol in the case of exacerbation of symptoms during the therapy or during the follow-up period in a standard dose.

Assessment: Baseline (T0), immediately after accomplishing therapy (T1), eight weeks after last intervention (T2).

Primary outcomes: Mean values evolution for Visual Analogue Scale (VAS, 0-10), Oswestry Disability Index (ODI, 0-50), Modified Laitinen Pain Questionnaire (MLPQ, 0-16).

Secondary outcomes: Functional tests - Seat and reach (SaR) functional test, range of motion (ROM) in the direction of extension, rotation, and lateral flexion in the lumbar spine.

Methodology of functional tests

- Seat and Reach test (SaR) - a modified toe-floor test to determine flexion mobility of the spine. Performed in a sitting position with the lower limbs straightened at the knees and the command to bend forward with hand range measurement towards the feet by moving the standardized pointer on the centimeter (cm) scale. The result is the difference between the measurement at the maximum possible range of motion position and the measurement at the starting position.

- Standing rotation right or left test (SRR or SRL), test with measurement of the distance between the Anterior Superior Iliac Spine (ASIS) and the xiphoid process of the sternum in centimeter (right rotation - measurement from the left ASIS). The result is the difference between the measurement at the maximum possible range of motion position and the measurement at the starting position.

- Standing side-bending right or left test (SSBR or SSBL) test with measurement of the distance between the highest point of the axillary fossa and the anterior superior iliac spine (ASIS) in centimeters. The result is the difference between the measurement at the maximum possible range of motion position and the measurement at the starting position.

- Standing extension (SE) test with measurement of the distance between the highest point of the pubic symphysis and the xiphoid process of the sternum. The result is the difference between the measurement at the maximum possible range of motion position and the measurement at the starting position.

Statistical method

Descriptive statistics were used for the demographic characteristics of the treated group. For checking the comparability of the

groups at T0 the statistical significance of the differences between the mean values of VAS, ODI, MLQ, and ROMs by the one-way ANOVA test with Tukey's post hoc test at the significance level $p < 0.05$ was used. The same test was used to compare the results at T2.

At points T0 and T2, in some cases the assumption of homogeneity of variance in the studied groups was not met, then it was decided to use the Brown-Forsythe test (no homogeneity of variance at T0: ODI, SaR, SRR, at T2: VAS, ODI, SRL). Post-hoc tests were used to determine between which groups there were statically significant differences, In the case of comparisons where the assumption of homogeneity was not met, the Games-Howell test was used, in other cases the Tukey HSD test.

A power analysis was used to estimate the minimum sample size required for an experiment, given the desired significance level, effect size, and statistical power. The power of the test was set at 0.8 and the significance level at 0.05, assuming that the effect size was $f = 0.35$. This allowed us to establish that the research sample for the three compared groups should not be smaller than 90 subjects altogether.

All calculations and graphics were performed using IBM SPSS version 27.

Results

One hundred thirty-six patients were screened for eligibility. Thirty-eight patients occurred ineligible because of lumbar spine comorbidities. Out of ninety-eight patients meeting inclusion criteria, 8 patients refused to participate in the trial, and 90 patients were enrolled. The inclusion and follow-up process presents in figure 2.

At the T0 treated groups turned out to be comparable because the one-way analysis of variance (ANOVA) test with Tukey's post hoc test at the significance level of $p < 0.05$ found the only statistically significant difference between the groups concerning the mean values of ROM regarding bilateral SSB and SE between HIL and MT groups ($p = 0{,}005$ for SSBR, $p = 0.006$ for SSBL, and $p = 0{,}002$ for SE). Another ROM directions ($p = 0.12$-0.49), SAR ($p = 0.56$), age ($p = 0.26$) and mean values of the VAS ($p = 0.34$), ODI ($p = 0.41$), MLQ ($p = 0.09$) did not show statistically significant differences. Summary of mean baseline values for individual treatment groups presents figure 3.

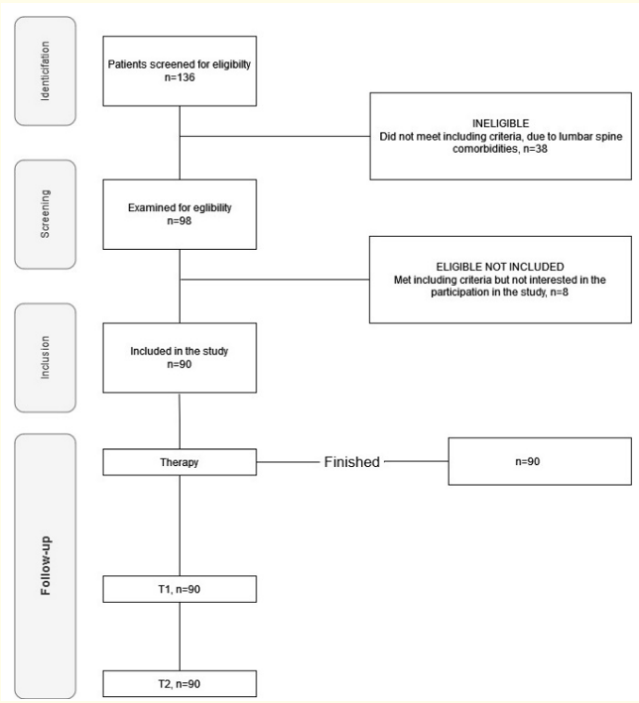

Figure 2: Inclusion and follow-up process.

Total number of patients,	n = 90
Women, n (%)	59 (65.6)
Age, years, mean ± SD (range)	40.50 ± 12.33 (18-60)
Disease phase, n (%):	
Acute	3 (3.3)
Subacute	10 (11.1)
Chronic	77 (85.6)
Dominant side of complaints	
Right	29 (32.2)
Left	54 (60)
Both	7 (7.8)
Dominant segment, n (%):	
L1 / L2	1 (1.1)
L2 / L3	1 (1.1)
L3 / L4	3 (3.3)
L4 / L5	14 (15.6)
L5 / S1	71 (78.9)

Table 1: Demographic characteristics.

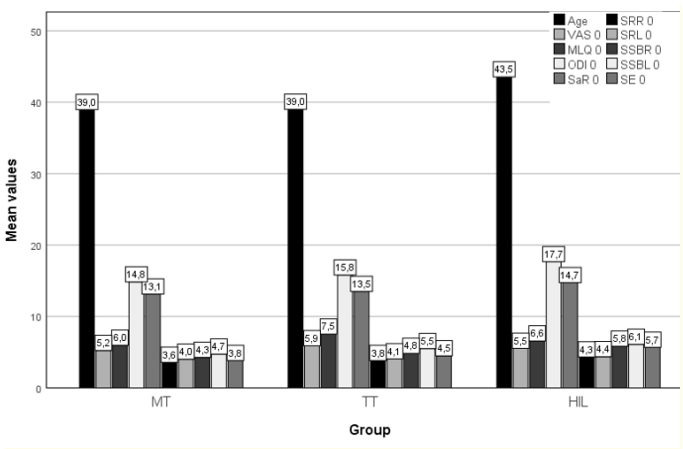

Figure 3: Summary of mean baseline values for individual treatment groups.

All patients completed the full course of therapy and all of them had follow-up visits T1 and T2.

The improvement in the VAS scale at point T1 was reported by seventy-six patients (MT, n = 26, TT, n = 27, HIL, n = 23).

The slightly better effectiveness in reducing pain after therapy was demonstrated in the TT (2.9 points), compering to MT and HIL (both 2.7 points). During the observation period, both the MT and HIL showed a slight regression (by 0.4 points), while the values remained unchanged in the TT.

Seventy-seven patients improved in the ODI at T1 (MT, n = 26, TT, n = 24, HIL, n = 27). The greatest mean values improvement was noted in the TT group (7.6 points) and in the remaining groups HIL and MT (6.9 and 6.7 points respectively). During the observation period in the HIL group, the results deteriorated slightly - by 1.5 points, while in the MT and TT group they improved – in both cases by 1.2 points.

Seventy-two patients improved in the MLQ at T1 (MT, n = 23, TT, n = 22, HIL, n = 27). The highest difference between mean values was noted in TT (3.1 points) and in the remaining groups HIL and MT (2.6 and 2.7 points respectively). During the observation period in the HIL group the result did not change, it has slightly deteriorated in the MT (by 0.6 points), and slightly improved in the TT group (by 0.5 points). No significant statistical differences were spotted comparing primary outcomes at T1 between the groups. One-way ANOVA showed statistically significant differences between the groups at T2 for the ODI. The Games-Howell test was used to determine between which groups there were differences.

There is a statistically significant difference in the score at T2 between the HIL (M = 12.27, SD = 8,26) and MT (M = 6.87, SD = 3,71) in favor MT, p = 0,006 and between HIL (M = 12.27, SD = 8,26) and TT (M = 7.03, SD = 4,48) group, in favor TT p = 0,010. No significant statistical differences were spotted comparing other primary outcomes between the groups by ANOVA test.

The evolution of VAS, ODI, and MLQ mean values for individual therapies are presented in figure 4-6.

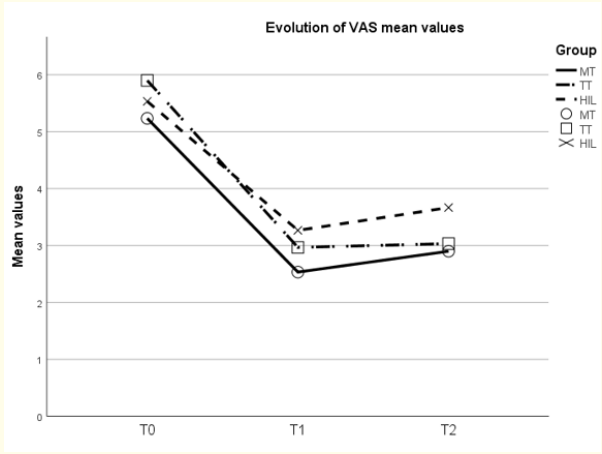

Figure 4: Evolution of VAS mean values.

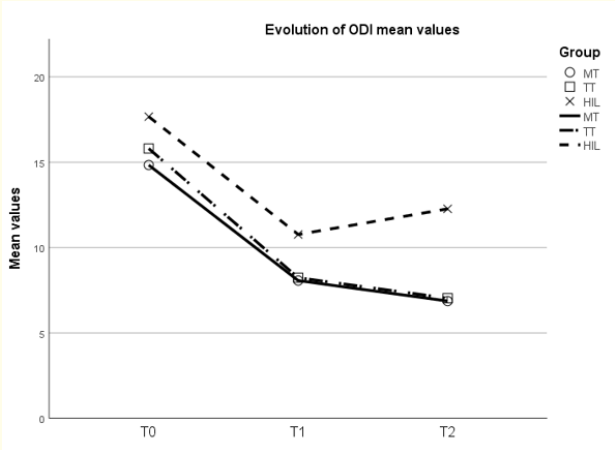

Figure 5: Evolution of ODI mean values.

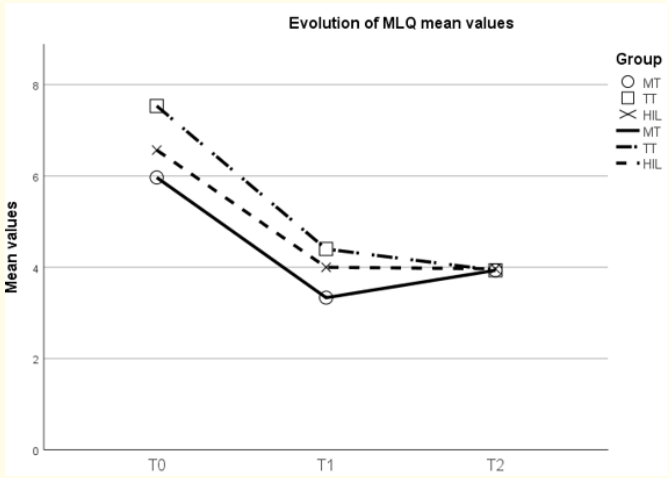

Figure 6: Evolution of MLQ mean values.

The SaR test and ROMs mean values in individual directions improved between T0 and T1, but only SSBR did not deteriorate during the observation period. The evolution of SaR test mean values in specific groups and ROMs during follow-up is presented in figures 7 and 8.

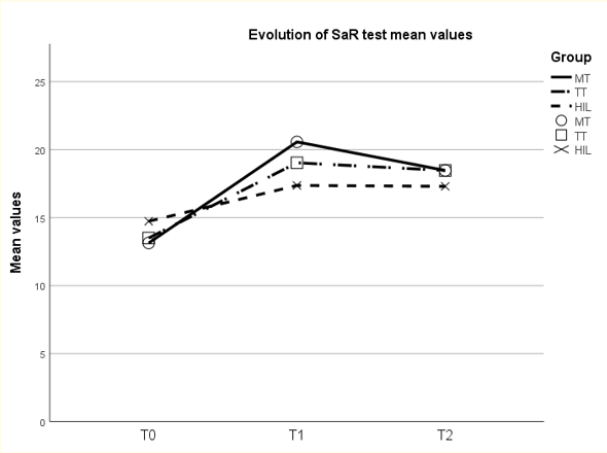

Figure 7: Evolution of SaR test mean values in specific groups.

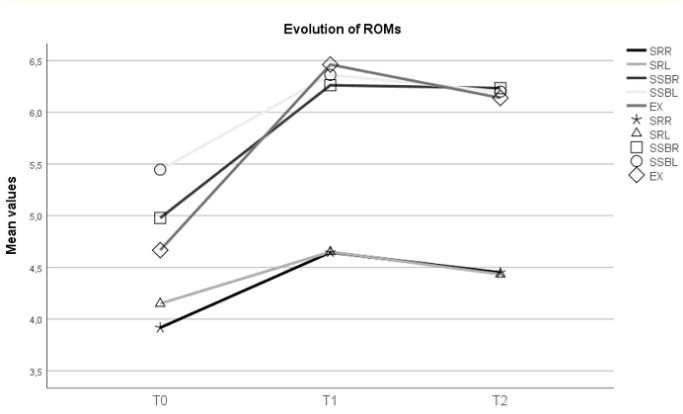

Figure 8: Evolution of mean ROMs during follow-up.

Deterioration of the mean values at T1 was reported by five patients regarding the VAS scale (MT, n = 2, TT, n = 1, HIL, n = 2), by three patients regarding MLQ (MT, n = 1, TT, n = 2, HIL, n = 0), and by ten patients regarding ODI (MT, n = 3, TT, n = 4, HIL, n = 3). No serious complications or intolerance during treatment were reported.

Deterioration of the mean values at T2 was reported also by five patients regarding the VAS scale (MT, n = 1, TT, n = 3, HIL, n = 1), by ten patients regarding MLQ (MT, n = 6, TT, n = 2, HIL, n = 2), and by twelve patients regarding ODI (MT, n = 1, TT, n = 5, HIL, n = 6).

Discussion

Due to the good prognosis of non-specific LBP, conservative treatment is still the mainstay, hence the robust literature analyzing its various forms. Nevertheless, to the best knowledge of the authors, no analogous report exists that would confront three forms of treatment: mechanical venous-lymphatic drainage, mechanical spinal decompression, and targeted treatment with a physical stimulus. The analysed literature presents numerous observational studies providing information on the effectiveness of specific LBP conservative treatment algorithms. Unfortunately, it is very difficult to build a coherent algorithm on their basis, because

the pathogenetic basis of the pain syndrome is rarely specified, so in fact, we do not know what process we are dealing with out of the three main pathogenetic forms of LBP (spondylosis, radicular syndrome, spinal canal stenosis). Meta-analyses are more valuable as they allow to compare reports that can meet the rigors of EBM and build recommendations for therapists based on them, but they are also very often contradictory.

The 2018 meta-analysis by Coulter., *et al.* on the use of manipulation and mobilization in the treatment of chronic LBP concluded that there is only moderate-quality evidence that these treatments can alleviate pain, although manipulation is attributed to greater efficiency. The authors also emphasized the safety of using these methods [9].

These conclusions seem to be confirmed by the work of Krekoukias., *et al*. (2017), where MT was compared to conventional rehabilitation (stretching, TENS, massage) and sham therapy in the group of patients with chronic LBP due to LDDD. It turned out that MT had a clear advantage over the two others (even though the sessions were extremely short - 10 minutes long and took place once a week), and the results of sham therapy and conventional rehabilitation did not differ significantly after the end of the five-week therapy [10]. Of course, we are dealing here with a very short observation period covering only the early effects. However, Aure., *et al*. assessed similar methods after one year in a comparative study of MT and exercise therapy and observed significantly better results in both the short and long follow-up periods in favour of MT [11].

However, the meta-analysis conducted by Assen delft., *et al.* based on 39 randomized trials belies the above-mentioned very favourable opinions about MT. The authors compared the results of MT with many other forms of treatment (sham therapy, family doctor care, pharmacology, physical therapy, back school), and even therapies that, according to the authors, are not only ineffective and even harmful (traction, corset, bed rest, local anti-inflammatory gels, diathermy, massage). They stated that MT does not show any advantage over the above methods, except for mock therapy, neither in acute nor chronic low back pain [12]. In our study, MT was effective in reducing pain in 26 patients (86.7%) and had a high safety profile (only 2 cases with worsening pain after therapy), although during the observational period there was a slight regression in primary outcomes.

Traction therapy in LBP treatment is one of the most popular therapies. It is assumed to be performed in the United Kingdom and the United States in 41-77% of patients with non-specific LBP, even in the presence of radicular symptoms [48,49]. The popularity of the method completely contradicts the negative assessment of its effectiveness based on large analyses cited by the Cochrane database as a method with very little (if any) influence on the natural course of LBP and shortening the time of work incapacity [13,14]. The authors of another large meta-analysis conducted by Clarke., *et al.* expressed a similar thesis based on 24 randomized studies (a total of 2,177 patients with LBP and radicular symptoms). It was found that there was no significant difference in short and long observations between treatment and placebo (sham therapy) regardless of the technique of traction performance (continuous, pulsed) and that adding traction to other conventional rehabilitation procedures does not bring new quality or increase the effectiveness of LBP treatment [15]. Just as it is difficult to assess the objective effectiveness of manual therapy in LBP because this term covers its different schools, methods of practicing, and experience of the person performing the therapy, the same concerns a fair assessment of TT. In terms of LBP, there are various treatment protocols and many differences among devices. In addition to professional tools, the so-called home traction, where the patient performs them only after a cursory instruction or even reading the manual for the equipment just purchased. These doubts are expressed in the meta-analysis conducted by Alrwaily., *et al.* where 37 randomized trials with the use of the TT in the treatment of LBP were analyzed. Among these methods, there was significant heterogeneity in the protocols: mechanical (57%), auto-traction (16%), manual traction (10.8%), gravity (8.1%), and water traction (5.4%), as well as traction force, duration sessions and even the frequency of its application, varied even within the same method. Due to the above factors, also in this analysis, it was not possible to conclude the effectiveness of TT, therefore it remains an "unpredictable friend" in LBP therapy [16].

In our study, TT with a standardized patient position and reproducible treatment protocol proved its effectiveness in reducing pain in the case of most patients (90%), maintaining, as the only

one of the examined methods, the VAS score during the observational period, with only one patient declaring worsening of pain at the T1, which significantly differs from the negative or at least sceptical assessments of the literature cited above.

The use of laser therapy in the treatment of LBP has been analyzed by many authors. So far, however, the meta-analyses of the Cochrane database from 2003 and its update from 2008 regarding the use of Low-Level Laser Therapy (LLLT) in the treatment of non-specific LBP did not bring arguments in favor of recognizing it as an effective method [17-20].

We have only several observational and comparative studies on the effectiveness of HIL versus ultrasound or conventional rehabilitation, and the results show much greater effectiveness in reducing pain after HIL procedures, even in three-month follow-up [21,22]. A meta-analysis conducted by Alayat., *et al.* concerning the use of HIL in the field of spine diseases (10 randomized in total, including 6 related to the lumbar section), where the level of recommendation for this type of therapy was defined as low or very low, has a similar effect, but the fact is that only two publications met the strict formal requirements. Nevertheless, the authors concluded that HIL is certainly a more effective treatment than placebo and when combined with conventional rehabilitation, it is more effective than itself [23].

In our study, the laser beam was guided by ultrasound very precisely on the intervertebral joints (mimicking the technique in-plane used during spinal injections). The procedure was also easy to normalize and reproduce in every single patient in contrast to very unspecific treatments guided usually on the painful or trigger point. Thus, in our study HIL turned out to be an effective and safe tool for reducing the intensity of LBP pain in 23 patients (76.7%), with only two patients declaring worsening pain at the T1.

To the best of our knowledge up to date, there is no report of RCT comparing the three above-mentioned treatment methods in such a reproducible protocol for LBP, so the strength of our study lies in presenting the evaluation and comparison of this approach for the first time. Additionally, the new safe and very precise technique of ultrasound-guided laser therapy can be implemented in clinical practice.

Undoubtedly the limitation of our study is a small group of participants, limited period of observation, and use of subjective questionnaires for analyzing the outcomes.

Conclusions

Manual therapy, traction table, and High-Intensity Laser are comparable methods in terms of their efficacy in LBP treatment.

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Authors Statement

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Authors' Contribution

All authors contributed to the study's conception and design. Material preparation and data collection were performed by Wojciech Rucinski, data analysis was performed by Piotr Godek. The first draft of the manuscript was written by Piotr Godek and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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