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Low Back Pain: Lumbar Traction

Assessment of variability in traction interventions for patients with low back pain: a systematic review

Abstract

Background: Previous systematic reviews have concluded that lumbar traction is not effective for patients with low back pain (LBP), yet many clinicians continue to assert its clinical effectiveness.

Objective: To systematically identify randomized controlled trials (RCTs) of traction and explore the variability of traction interventions used in each RCT.

Method: A literature search started in September 2016 to retrieve systematic reviews and individual RCTs of lumbar traction. The term "lumbar traction" and other key words were used in the following databases: Cochrane Registry, MEDLINE, EMBASE, and CINAHL. The retrieved systematic reviews were used to extract individual RCTs. The most current systematic review included RCTs from inception until August 2012. We performed an additional literature search to update this systematic review with newer RCTs published between September 2012 and December 2016. All of the identified RCTs were combined and summarized into a single evidence table.

Results: We identified a total of 37 traction RCTs that varied greatly in their method of traction intervention. The RCTs included several types of traction: mechanical (57%), auto-traction (16%), manual (10.8%), gravitational (8.1%) and aquatic (5.4%). There was also great variability in the types of traction force, rhythm, session duration and treatment frequency used in the RCTs. Patient characteristics were a mixture of acute, subacute and chronic LBP; with or without sciatica.

Conclusion: There is wide variability in the type of traction, traction parameters and patient characteristics found among the RCTs of lumbar traction. The variability may call into question the conclusion that lumbar traction has little no or value on clinical outcomes. Also, this variability emphasizes the need for targeted delivery methods of traction that match appropriate dosages with specific subgroups of patients with LBP.

Keywords: Traction, Low back pain, Sciatica, Systematic review

Introduction

Lumbar traction is a commonly used method to treat patients with low back pain (LBP) with or without sciatica. In the UK and the US, lumbar traction is used by 41 and 77% of outpatient rehabilitation providers respectively [1, 2]. Despite this common use of lumbar traction in the clinical setting, several systematic reviews have concluded that lumbar traction has little or no value on the clinical outcomes of pain intensity and functional status. The reviews also suggest that traction does not appear to lead to quicker return to work among people with LBP with or without sciatica [3–5]. These conclusions present a clear discordance between evidence-based recommendations and how lumbar traction is regarded in current clinical practice [1, 2, 6].

The earliest systematic review, conducted in 1995, included 17 randomized controlled trials (RCTs) that assessed traction on neck and low back pain [7]. Of the 17 RCTs, only 3 (2 lumbar, 1 cervical) had good quality. This systematic review concluded that traction efficacy was unclear, and called for more proper design and better methodological quality in future traction trials.

An update of the above systematic review, published in 2006, included 24 RCTs that assessed the effectiveness of traction in the management of LBP [4]. The RCTs were selected if they examined any type of traction on acute, subacute, or chronic LBP with or without sciatica. Of the 24 RCTs, only 5 were considered of high quality, and suggested that there was strong evidence that traction was not effective in the management of patients with mixed duration of LBP with or without sciatica. However, there was moderate evidence that autotraction was effective in the management of patients with mixed duration of LBP with or without sciatica.

The most recent update of the above systematic reviews, published in 2013, included 32 RCTs that assessed the effectiveness of traction in management of LBP using the same selection criteria that were used previously [5]. Of the 32 RCTs, 16 studies were considered to have low-risk of bias. The overall conclusion of this systematic review suggested that traction, alone or in combination with other interventions, has little or no impact on the clinical outcomes of pain and function on people with mixed duration of LBP with or without sciatica. However, this systematic review suggested that large, high-quality studies, were still required to make definitive conclusion about traction effectiveness.

Interestingly, rehabilitation providers are reported to be aware of the recommendations from systematic reviews against traction, yet 64% of them disagree with these recommendations and 25% remain undecided [1]. One explanation for this large amount of disagreement may be that rehabilitation providers regularly report the empirical observation that some patients are dramatic responders to lumbar traction [1]. This clinical observation may be driven by the ability of rehabilitation providers to somehow recognize certain clinical patterns that allow them to match patients' symptomatic presentations to specific traction strategies [2]. This pattern recognition of a traction subgroup has been recommended within the treatment-based classification system, which is commonly utilized by physical therapists [8–10].

Another explanation for this divergence between the continued use of lumbar traction by rehabilitation providers and the recommendations against it from systematic reviews may be related to the variability in the delivery methods of traction among the RCTs included in these systematic reviews [5]. The variability in delivery of traction interventions can stem from using different types of traction, different traction parameters, and different patient populations [5]. When RCTs with different traction methods are pooled together, the overall treatment effect size is diluted.

A number of RCTs suggest that traction can be an effective intervention in the management of patients with LBP. Fritz et al. found that mechanical traction in combination with extension exercises can result in significant improvement in disability and fear-avoidance beliefs after two weeks of treatment compared to extension exercises alone for patients with acute LBP and nerve root compression symptoms [11]. Also, Prasad et al. found that using inversion traction plus physical therapy in patients awaiting surgery for disc herniation helped 77% of them avoid surgery compared to physical therapy alone that helped only 22% avoid surgery [12]. Additionally, Kim et al. found that when prescribing the inversion traction for patients with chronic LBP, the tilt degree of the traction table matters [13]. Kim et al. found the a tilt degree of 60 resulted in improve levels of pain, spine flexibility and trunk extensors strength compared to tilt degrees of 30 or 0 (supine position) [13]. Further, Simmerman et al. found that aquatic traction resulted in significant pain reduction and centralization of symptoms compared to land-based exercises in patients with chronic LBP associated with nerve root compression symptoms [14]. Finally, Diab and Moustafa found that traction in combination with stretching and infrared radiation resulted in significant improvement of pain and disability levels compared to stretching and infrared in patients with chronic LBP at 6 months [15]. Collectively, these individual RCTs point to the potential effectiveness of traction in the treatment of patients with LBP with or without sciatica.

Given the possibility that the treatment effect size could be diluted when heterogeneous studies are pooled together, the purpose of this review is to map the evidence regarding the diversity in traction delivery methods. Specifically, this systematic review will explore the various traction intervention protocols by reporting on traction types, traction parameters, dosage and patients' characteristics. Assessing the diversity of traction delivery methods will help determine the appropriateness of conducting meta-analysis.

Methods

This is a systematic review of RCTs that have included some type of lumbar traction as a treatment intervention. The data collection of this systemic review started in September 2016. The first step was to perform a generalized search of the literature using the key words "lumbar traction" in the following databases: Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and CINAHL. The search returned several systematic reviews that directly addressed the topic of lumbar traction. The most recent Cochrane systematic review included RCTs of lumbar traction published from inception until August 2012 [5]. From this Cochrane review [5], all of the RCTs contained within the evidence tables were extracted and compared with those found in the evidence tables of the other systematic reviews [3, 7]. This step was necessary to confirm that the recent Cochrane review included all of the RCTs (or more) contained in the evidence tables of the older systematic reviews.

The next step was to update the systematic review by searching for additional RCTs published between September 2012 and December 2016. To identify new RCTs, the following keywords were used to search the same databases: "traction" OR "traction therapy" OR "traction physical therapy" OR "decompression" OR "unloading"; OR "lower back" OR "low back pain" OR lumbar pain OR sciatica OR radiculopathy OR lumbago OR backache. After these additional RCTs were retrieved, two authors (MAlr and MAlm) examined the titles and abstracts to select studies that would potentially be worthy of full text review. After that, the two authors extracted and synthesized the data about the specific traction protocols used in each RCT by reporting on the traction type, traction parameters and patient population. The authors used consensus to agree on which trials would warrant a review of the full text article for potential inclusion in this systematic review. When disagreement occurred, the third author (MS) was consulted to resolve the disagreement.

For a study to be included in this systematic review, it had to be an RCT of patients 18 years of age or older; with acute, subacute or chronic LBP; with or without sciatica. Also, the studies had to include at least one type of traction: manual, auto-traction, gravitational, aquatic and mechanical traction. The traction may or may not have been combined with other interventions such as manual therapy or exercise, with the requirement that traction was the primary intervention. Additionally, any type of comparison group was allowed including placebo, sham or active intervention. Finally, the RCTs must have included at least one clinically relevant outcome measure such as numeric pain scale, self-reported function, global measure of improvement, or return to work. These inclusion criteria are similar to those reported in the most recent Cochrane systematic review [5].

The last step was to create an evidence table that combined the RCTs extracted from the most recent Cochrane systematic review with the new RCTs identified through the updated search (Table 1). Because this review focused on extracting details about the specific traction protocols used in each RCT, there was no need to collect data on quality and risk of bias. This format was used to allow the reader to quickly visualize the similarities and differences in traction protocols across the RCTs.

Results

The most recent Cochrane systematic review included 32 individual lumbar traction RCTs published from inception through August 2012 [3, 5, 7]. Our updated search identified an additional 14 newer studies that were published between September 2012 and December 2016. Of these newer studies, 5 RCTs were combined in Table 1 with the previously identified 32 RCTs for a grand total of 37 RCTs [12, 13, 15–17]. This search process is summarized in (Fig. 1) [18].

In the columns of Table 1, the primary author and date of each RCT are organized in chronological order. In the rows of Table 1, the qualitative factors and traction parameters of each RCT were included. One study included the results of two RCTs in a single publication [19], so both of those two RCTs were included in Table 1, each reported in a separate column.

Table 2 uses descriptive statistics to summarize categories of traction parameters and patient characteristics from the included RCTs. Of the 37 RCTs, 59.5% used some type of mechanical traction while the remaining studies used auto-traction (16.2%), manual (10.8%), inversion (8.1%), or aquatic traction (5.4%). In 27% of the trials, traction was used in combination with some other type of rehabilitation intervention, such as exercise or physical agents.

The amount of force used during the traction treatment varied widely across these 37 studies, ranging from 2.3 kg in one trial to 100% of body weight in another. In 35% of the RCTs, the amount of traction force was determined by using some arbitrary percentage of the patient's body weight that varied from 20 to 100%. However, another 37.8% of studies used an arbitrary pre-determined amount of weight ranging anywhere from 2.3 kg to 60 kg as the traction force. The traction rhythm was evenly distributed between continuous and intermittent types of application, with each type of application used 43.2% of the time. In the remaining of the studies, the traction force and rhythm were not clearly described.

The traction session time and treatment frequencies were very difficult to categorize. The traction sessions lasted from 3 to 4 min in duration in some trials, to more than 30 min in other trials. The frequency of application of the traction treatments used in these trials varied from as few as one single session, to as many as 20 traction sessions applied over 6 to 10 weeks.

Other traction parameters were also found to vary widely across these 37 traction RCTs. With respect to patient positioning during the application of traction, 29.7% of the trials had the patient lie in a supine position, 16.2% used prone positioning, 5% applied traction in standing, 3% used a side-lying position, and in 43.2% of the studies there was no clear description of patient positioning.

Table 1 Characteristics of randomized trial of lumbar traction

Research parameters	Studies									
	Isner-Horobeti 2016 [17]	Thackeray 2016 [16]	Diab 2013 [15]	Kim 2013 [13]	Prasad 2012 [12]	Simmerman 2011 [14]	Schimmel 2009 [28]	Unlu 2008 [29]	Fritz 2007 [11]	
Symptom duration	Acute and Subacute	Acute, subacute and chronic	Chronic	Chronic	Acute, subacute and chronic	Acute, subacute and chronic	Chronic	Acute	Acute	
Sciatica status	+	+	–	–	+	+	–	+	+	
Traction type	Mechanical	Mechanical	Mechanical	Inversion	Inversion	Aquatic	Mechanical	Mechanical	Mechanical	
Traction rhythm	Continuous	Continuous	Continuous	Intermittent	Intermittent	Continuous	Intermittent	Intermittent	Continuous	
Traction force	50% of body weight	40–60% of body weight	Maximum tolerable force	Unknown	Unknown	2.3 kg ankle weight	50% of body weight	35–50% of body weight	40 to 60% of body weight	
Patient position	Supine	Prone	Supine	Supine	Unknown	Vertical	Supine	Supine	Prone	
Traction frequency	10 sessions, 5 per week, for 2 weeks	12 session for 6 weeks	3 min 1st session, and increased 1 min each subsequent session for a maximum of 20 min. 3 times per week for 10 weeks	Three 3-min inversions, 4 times a week for 8 weeks	Six 2-min inversions, 3 times a week for 4 weeks	1 session for 15 min	25–30 min per session, for 20 sessions for 6 weeks	15 min per session for 5 days a week for 3 weeks	12 min for 12 session for 6 weeks	
Traction combined with other interventions	No	Yes: directional preference exercises	Yes: mixed physical therapy interventions	No	Yes: mixed physical therapy interventions	No	No	No	Yes: directional preference exercises	
Comments	Patient had specific LBP (disc)				Patient had specific LBP (disc)			Patient had specific LBP (disc)		
Research parameters	Studies									
	Harte 2007 [30]	Gudavalli 2006 [31]	Ozturk 2006 [32]	Borman 2003 [33]	Sherri 2001 [20]	Guvenol 2000 [34]	Werners 1999 [35]	Beurskens 1997 [21]	Van der Heijden 1995 [36]	Letchuman 1993 [37]
Symptom duration	Acute and subacute	Chronic	Acute, subacute and chronic	Chronic	Chronic	Subacute and chronic	Acute	Subacute and chronic	Acute, subacute and chronic	Acute, subacute chronic
Sciatica status	+	+/–	+/–	Unknown	+	+	+/–	–	+/–	+/–
Traction type	Mechanical	Manual	Mechanical	Mechanical	Mechanical	Inversion	Mechanical	Mechanical	Mechanical	Mechanical
	Continuous	Intermittent	Continuous	Unknown	Intermittent	Unknown	Intermittent	Continuous	Continuous	

Table 1 Characteristics of randomized trial of lumbar traction *(Continued)*

Traction rhythm										Continuous and intermittent
Traction force	5–60 kg	Unknown	25–50% body weight	Up to 50% of the body weight	50–95 lbs	Unknown	10–20 kg	35–50% of body weight	30 to 50% of body weight maximum	50% of body weight
Patient position	Supine	Prone	Unknown	Supine	Prone	Supine	Supine	Unknown	Unknown	Prone
Traction frequency	10–20 min for 2–3 times a week for 4–6 weeks	2–4 sessions per week for 4 weeks, 9–18 min of traction	15 min per sessions, for 5 sessions per week, for 15 sessions	20 min for 5 sessions per week for 2 weeks	30 min per session for 5 sessions per week for 4 weeks, then once per week for 4 weeks.	5 min on 1st day, 8 min on 2nd day, 10 min on 3rd day and onwards through 7 days (10 days total)	6 sessions for 2–3 weeks	20 min per session, for 12 times over a period of 5 weeks	unknown session duration for 10–12 sessions for 4 consecutive weeks	6 min
Traction combined with other interventions	Yes: mixed physical therapy interventions	No	Yes: modalities	Yes: mixed physical therapy interventions	No	No	No	No	No	No
Comments			Patient had specific LBP (disc)			Patient had specific LBP (disc)		Published data only		
Research parameters	Studies									
	Sweetman 1993 [38]	Tesio 1993 [39]	Konrad 1992 [40]	Ljunggren 1992 [41]	Mathews 1988 [42]	Reust 1988 [43]	Pal 1986 [44]	Ljunggren 1984 [45]	Weber 1983a [19]	
Symptom duration	unknown	subacute and chronic	Subacute	Acute, subacute and chronic	Acute and subacute	Unknown	Acute, subacute and chronic	Subacute	Unknown	
Sciatica status	unknown	+/−	+/−	+	+	+/−	+	+	+	
Traction type	Mechanical	Autotraction	Aquatic	Manual	Autotraction	Mechanical	Mechanical	Autotraction	Manual	
Traction rhythm	Continuous	Intermittent	Unknown	Continuous	Continuous	Continuous	Continuous	Intermittent	Intermittent	
Traction force	1st week 33% body weight, 2nd week 50% body	Unknown	Participant's weight, gravity plus 3 kg weight on both sides.	300 N	45 kg	5-kg on day 1, 10 kg on day 2, 15 kg on day 3, increasing 5 kg each day up to a maximum of 50 kg	5.5–8.2 kg	Between 33 and 100% of participant's body weight	40–70 kilopond	
Patient position	Unkonwn	Unknown	Standing	Unknown	Supine or prone	Unknown	Supine	Unknown	Unknown	
Traction frequency	10 min per session, for 3 sessions per week, for	3–6 s with 1-min rest for 30–60 min/ session. 2–3	15 min, 3 times per week, for 4 weeks	10 min per day for 5–7 days	30 min per session for 5 days per week for a	10 min per day, for 12 sessions, for 12 days	Unknown	Every treatment lasted about 1 h	10–20 s followed by rest for 20 min	

Table 1 Characteristics of randomized trial of lumbar traction *(Continued)*

	unknown number of weeks	times a week for 3–10 sessions.			maximum of 3 weeks				one time per day
Traction combined with other interventions	No	No	No	No	No	No	No	No	No
Comments				Patients had specific LBP (disc).				Patients had specific LBP (disc).	Patients had specific LBP (disc).
Research parameters	Studies								
	Weber 1983b [19]	Walker 1982 [46]	Coxhead 1981 [47]	Larson 1980 [48]	Bihaug 1978 [49]	Mathews 1975 [50]	Lind 1974 [51]	Weber 1973 [52]	Lidstrom 1970 [53]
Symptom duration	Unknown	Acute, subacute and chronic	Acute, subacute and chronic	Subacute	Subacute and chronic	subacute and chronic	Acute, subacute and chronic	unknown	Subacute and chronic
Sciatica status	+	+	+	+	+	+	+/−	+	+
Traction type	Manual	Mechanical	Mechanical	Autotraction	Autotraction	Mechanical	Autotraction	Mechanical	Mechanical
Traction rhythm	continuous	Unknown	Intermittent	Unknown	Unknown	Unknown	Unknown	Intermittent	Intermittent
Traction force	30 kilopond	40–70 kiloponds	unknown	Unknown	70 Kilopond	36.3 kg	Unknown	33% of body weight	Unknown
Patient position	Unknown	Unknown	Unknown	Prone, supine, sidelying	Prone	Altered at the therapist's discretion	Unknown	Unknown	Supine
Traction frequency	10–20 s followed by rest for 20 min one time per day	20 min daily for 4–8 days.	4 weeks	up to 3 treatments within 1 week for less than 1 h	4–12 sessions per week	30 min per day, for 5 days per week, for 3 weeks.	1 h for 1–3 weeks	20 min per session for 5–7 days	Unknown
Traction combined with other interventions	No	Unknown	No	No	Unknown	No	Yes: bed rest and postural advice.	Unknown	Unknown
Comments	Patients had specific LBP (disc).		Sciatica was defined as pain as low as the buttock crease						

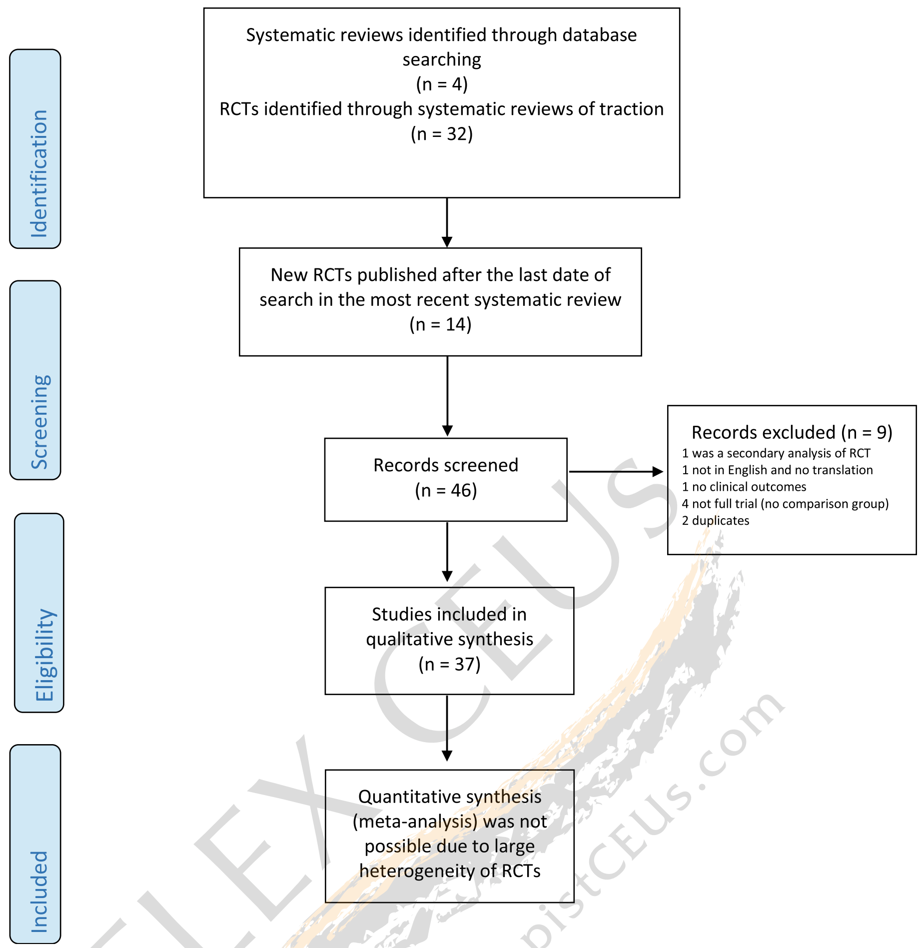

Fig. 1 Flow diagram of data searching, screening and inclusion of traction trials. RCT: Randomized controlled trial

Regarding the onset and duration of symptoms, 54% of the studies included patients with a mixed acuity of LBP, 16% included only patients with chronic LBP, 8% included only subacute cases of LBP, 8% included only acute cases, and 14% of the studies did not provide any clear description of symptom acuity. With respect to leg symptoms (e.g. sciatica), 59% of the RCTs included only patients with sciatica, 24.3% included a mixture of patients with and without sciatica, 10% included only patients without sciatica, and the remaining studies did not contain any report of leg symptom or sciatica status. In 24% of the included studies, the patients had a specific LBP diagnosis such as herniated disc, while the other 76% of studies did not report any specific pain generator or anatomical cause of the LBP (non-specific LBP).

Discussion

The results of this systematic review show that there are widespread variations in most of the traction protocols used in the RCTs found in the traction literature. When examining Table 1, each RCT appears to have a distinct combination of traction type and traction parameters applied to different populations of patients with LBP, with or without sciatica. There is no main theme or pattern that emerges about the traction parameters used in the studies included and rated in the previously published systematic reviews. This variability in traction delivery protocols represents a primary gap in the traction literature and might be a key factor that underpins the negative conclusions about traction in the most recent systematic review [5].

Mechanical and non-mechanical traction

The majority of RCTs that we reviewed used some type of mechanical traction, which involved various devices (e.g. ActiveTrac Table [11], VAX-D decompression [20], SpinaTrac [19], etc.) that used computerized algorithms to produce controlled, intermittent traction forces via motorized pulleys. Although these mechanical devices have the capacity to generate specific forces and rhythms that can be quantified, we found a serious lack of any standardized traction protocol across the RCTs that

Table 2 Descriptive statistics of traction and patient characteristics

Traction and patient characteristics	Descriptive statistics *n* (%)
Traction types	
Mechanical	22 (59.5%)
Manual	4 (10.8%)
Auto-traction	6 (16.2%)
Inversion	3 (8.1%)
Aquatic	2 (5.4%)
Traction combined with other intervention	
Traction alone	25 (67.6%)
Modalities	1 (2.7%)
Directional preference	2 (5.4%)
Mixed with physical therapy interventions	5 (13.5%)
Mixed with unknown intervention	4 (10.8%)
Traction force	
Specific amount of weight (2.3–60 kg)	14 (37.8%)
Percentage of body weight (20–100%)	13 (35.1%)
Unknown	10 (27%)
Traction rhythm	
Intermittent	13 (35.1%)
Continuous	14 (37.8%)
Mixed	2 (5.4%)
Unknown	8 (21.6%)
Patient position	
Supine	11 (29.7%)
Prone	6 (16.2%)
Standing or vertical	2 (5.4%)
Mixed	2 (5.4%)
Unknown	16 (43.2%)
Patient symptom duration	
Acute	3 (8.1%)
Subacute	3 (8.1%)
Chronic	6 (16.2%)
Mixed	20 (54.1%)
Unknown	5 (13.5%)
Patient sciatica status	
Present sciatica	22 (59.5%)
Absent sciatica	4 (10.8%)
Mixed	9 (24.3%)
Unknown	2 (5.4%)
Pathology	
Specific low back pain pathology	9 (24.3%)
Non-specific low back pain pathology	28 (75.7%)

involved mechanical traction. Instead, the RCTs were found to have great variations in the way the patients were positioned, the duration of traction sessions, the frequency of traction treatment, the amount of traction force applied and the rhythm of traction force. This lack of standardized mechanical traction protocol argues against pooling all of these RCTs under the umbrella term "mechanical traction", and further casts doubt on any conclusions derived from analyses of the pooled studies through meta-analysis.

There were also some studies that utilized non-mechanical traction interventions, such as manual traction, auto-traction, and gravitational traction. All of these interventions present a challenge when attempting to standardize the treatment because the nature of the used traction force cannot be quantified. Manual traction and auto-traction involve traction forces that are dependent on the skill and strength of the clinician and patient respectively. Gravitational (inversion) traction devices and aquatic traction involve traction forces that are dependent on the suspension effect of gravity or water which varies according to the patient's body weight and/or externally applied weight attachments. These differences in force levels exist among the patients within any one specific trial or across the RCTs. This suggests that the RCTs utilizing non-mechanical traction interventions should not be pooled together, and any conclusions drawn from these inappropriately pooled studies should be considered circumspect.

Determining the traction force

In the RCTs that involved mechanical traction devices, the traction forces were applied using either a predetermined amount of weight or a percentage of body weight. In many instances, the predetermined amount of weight was not reported (Tables 1 and 2). We could not find any consistent pattern, explanation or scientific rationale that explained the process by which the specific amount of traction force was determined; rather, the process seemed arbitrary across the RCTs.

Compared to using a predetermined amount of weight, using a percentage of body weight would seem to be a better method to individualize, quantify and standardize the traction force. However, the use of a percentage of body weight also varied widely across the RCTs. Despite the belief that a traction force of 25% of body weight (or above) is reported to create separation between lumbar vertebra [5, 21], it remains to be determined what level or range of traction force is optimal and most therapeutic.

Duration and frequency of traction session

The application time of traction during each treatment session, and the frequency/total number of treatment sessions also varied and were distinct in almost every RCT, which renders them difficult to categorize. By examining Table 1, these traction parameters of duration and frequency seem to have been chosen arbitrarily, and therefore we could not determine any consistent traction dosage protocol across the RCTs.

Patients selection for traction

With respect to patients' characteristics and selection for traction, most of the RCTs included patients with a mixture of symptom duration (i.e. acute, subacute and chronic LBP), with and without sciatica (Table 1). The RCTs did not report any responders and non-responders analyses, which are often performed as a secondary analysis in an attempt to determine if there are any baseline characteristics that might be potential predictors of treatment response. Significant predictor variables can be used to develop clinical prediction rules that can be useful to clinicians for subgrouping patients, and matching treatments with appropriate patient presentations. We only found two such studies; one that developed a preliminary prediction rule for traction and the other that tested this rule within the context of a clinical trial [11, 16]. This suggests that little attention was given to the homogeneity of LBP population that received lumbar traction within RCTs.

When traction (or any treatment) is applied to all patients without regard to subgroup matching, it is not surprising to find mixed results regarding its clinical effectiveness. This situation reminds us of the discordance between clinicians who practice manual therapy and the literature regarding the effectiveness of spinal manipulation for patients with non-specific LBP [22]. Collectively, spinal manipulation studies have been shown to have only modest treatment effect sizes on LBP when the results of those studies are pooled together in systematic reviews [23]. Meanwhile, rehabilitation providers continue to assert its clinical effectiveness, especially for patients who are matched to clinical prediction rules for manipulation [24]. Not surprisingly, when individual manipulation studies applied the concept of subgrouping and administered manipulation in a matched/unmatched design, the clinical effect sizes were much greater [24, 25]. The same principle of subgrouping has been shown to lead to greater treatment effects in trials that matched specific exercises to patients who exhibited a clear directional preference to flexion or extension movements [26, 27].

There is strong face validity to the concept of using spinal traction as a clinical tool for the treatment of LBP. Spinal traction might work by relieving the stress on a painful joint through increasing intervertebral space, loosening adhesions on facet joints and decreasing mechanical stress on the disc [5]. However, there is simply an evidence gap with respect to a validated clinical prediction rule that could guide the selection of traction for those LBP patients who are more likely to be traction responders.

Future directions for traction

We suggest that future traction research studies should strive toward standardizing the delivery method of traction for patients with LBP. This could be achieved by focusing more on efficacy trials that explore the clinical effects of different dosage parameters including the traction force level, traction rhythm, traction session duration, and traction treatment frequency. It is possible that traction trials have failed to show a treatment effect simply due to suboptimal dosage. Finding the therapeutic dosage level is key for any treatment to succeed.

Also, future traction research should attempt to provide evidence for subgroup(s) of patients as potential traction responders. This would require some modifications to the research design that focus on baseline characteristics of the patient or the clinical examination. For example, RCTs may be improved by considering the patient's response to a single traction session at first encounter. Patients who show a positive response could be considered to have a "directional preference" to an axial force, and this response could be used as a baseline independent variable in regression models. It would be important to analyze whether the presence of directional preference to an axial force is associated with improved therapeutic effect of traction.

There has been a tendency amongst the RCTs to focus on the inclusion criterion of presence of leg pain (sciatica) and/or signs of nerve root tension, with the assumption that these are important characteristics for a positive response to traction treatment. However, surveys of rehabilitation providers indicate that traction may also be successful with patients who do not present with distal leg symptoms or nerve root compression signs [1, 2]. Future trials should examine if traction force and parameters are different between patients with leg symptoms and patients without leg symptoms.

Conclusions

RCTs of lumber traction have employed a mixture of traction types, traction parameters and patient populations. The large variability in the delivery of traction intervention provides evidence that the RCTs included in systematic reviews were extremely heterogeneous. This suggests that negative conclusions about the overall clinical effectiveness of lumbar traction should be interpreted with caution. More research about the effectiveness of traction is still necessary, and future trials should consider two important points: (1) discovering optimal dosage and traction parameters to inform the development of standardized traction protocols, and (2) discovering the important baseline variables predictive of successful traction response. By standardizing the traction dosage and parameters, improving patient selection criteria, and response to axial force, more clinically meaningful traction research could be conducted.

Lumbar Traction in the Management of Low Back Pain: A Survey of Latest Results

Abstract

Introduction : Low back pain (LBP) is one of the most common complaints in the general population, affecting about 70-80% of the population at some point in life. LBP management comprises a wide range of different intervention strategies. One of the treatment options is traction therapy. The aim of our short review is to summarize and analyze the latest result reporting the use of lumbar traction in LBP treatment in order to evaluate the real effectiveness and indications of this specific physical therapy.

Materials and methods: A comprehensive search of PubMed, Medline, Cochrane, Embase, and Google Scholar databases was performed, covering the period between 2006 and 2013. 54 citations were obtained. Relevant data from each included study were extracted and recorded.

Results: A total of 14 studies were included in the review. Among these 14 studies, 11 were randomized clinical trials, 1 was a retrospective cohort study and 2 were case series. The majority of included studies used traction on patients that suffered nerve root compression symptoms. The mean number of traction sessions was 19. At most, the duration of each session was 30 min (range 3-30 min). The mean period of traction treatment was 6 weeks (range 3-12 weeks). 11 studies coupled with traction other therapies. Only 3 studies used traction as a single treatment. The mean follow up period was 16,5 weeks from the end of treatment.

Conclusion: Several biases can be introduced by limited quality evidence from the included studies. Lumbar traction seems to produce positive results in nerve root compression symptoms. Data in degenerative and discogenic pain are debatable. To date, the use of lumbar traction therapy alone in LBP management is not recommended by the best available evidence.

Keywords: Lumbar traction; Low back pain; Lumbar disc herniation; Lumbar disc disease; LBP; Physical therapy.

Introduction

Low back pain (LBP) is one of the most common complaints in the general population, affecting about 70-80% of the population at some point in life [1,2]. Moreover, LBP is a common cause of disability and work loss in developed countries, creating a large social and economic burden on society [3]. When we talk about low back pain, we have to deal with a great variety of clinical situations including acute, subacute(4 to 12 weeks) or chronic LBP. Furthermore, LBP can be due to several spine or "extra-spinal" diseases as nerve root compression, discogenic pain, rheumatologic or hip-related problems. The management of these conditions, that have to be clearly distinguished, comprises a wide range of different intervention strategies including surgery, drug therapy (NSAID's, corticosteroids, opioid) and non-medical interventions (rest, physical therapy, ozone therapy). There are numerous clinical guidelines on LBP produced worldwide, yet lack of consensus about effectiveness [4,5]. Physiotherapy (PT) interventions for the management of LBP are wide and variable, but the efficacy of many is still questionable [6,7]. One of the treatment options is traction, which may be applied in many forms: motorized lumbar traction (traction applied by a motorized pulley), autotraction (the patient exerts the traction force through a pulling or pushing action), gravitational traction (traction through a suspension device), or manual traction (forces exerted by the therapist). The supposed mechanical effects of traction are vertebral separation and widening of intervertebral foramen in order to relieve pain and recover joint function by reducing pressure on discs or nerves [8-11]. Despite a huge number of systematic reviews regarding its efficacy in lumbar pain management [11-19], the evidence of traction use is still unclear. On the contrary, many surveys have shown its continued use: with 7% of the LBP patients in the Republic of Ireland and the UK [20], with 13.7% in Northern Ireland [21], 7% in the Netherlands[22,5] 21% in the United States [23], and up to 30% of patients with acute LBP and sciatica in Canada [24]. The aim of our short review is to summarize and analyze the latest result reporting the use of lumbar traction in LBP treatment in order to evaluate the real effectiveness and indications of this specific physical therapy.

Materials and Methods

A comprehensive search of PubMed, Medline, Cochrane, Embase, and Google Scholar databases was performed, covering the period between 2006 and 2013. We used various combinations of the following keywords: "lumbar traction," " low back pain," "lumbar disc herniation," "lumbar disc disease," "LBP," and "physical therapy."

Each reference list from the identified articles was manually checked to verify that relevant articles were not missed. A total of 54 citations were obtained. The non–English-language studies were excluded. Biomechanical, cadaveric and preclinical studies were excluded as well. Reviews, case reports or case series reporting less than 20 cases were excluded. Flow diagram illustrates the number of studies that have been identified, included, and excluded and the reasons for exclusion (Figure 1). Further, each included study was evaluated for the following variables: study type, number of patients, type of LBP, traction mode, duration and frequency of sessions, traction position, weight applied, associated therapy and duration of follow up after treatment. Relevant data from each included study were extracted and recorded.

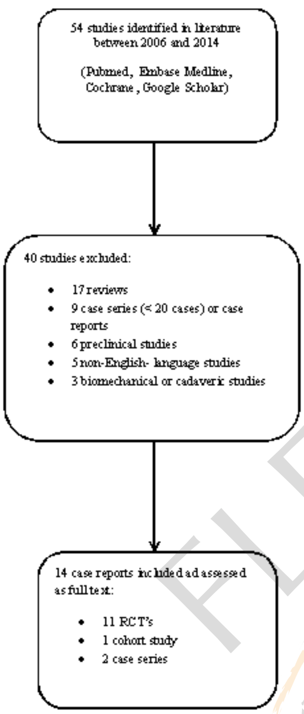

Figure 1: Flow diagram, depicting the number of studies identified, included, and excluded as well as the reasons for exclusion.

Results

A total of 14 studies published from 2006 to 2013 that reported clinical or radiological outcomes of lumbar traction treatment in LBP were finally included in the review. Among these 14 studies, 11 were randomized clinical trials [11,24-33], 1 was a retrospective cohort study [34] and 2 were case series [35,36]. The total number of patients included in our review is 1104. 12 studies were related specifically to nerve root compression symptoms [24-28,30,31,33-36], 6 took into account degenerative disc disease, mechanic pain, hypolordosis or generic "chronic low back pain" alone or in association with nerve root compression symptoms [11,25,29,32,33,35]. In 12 studies, motorized traction was used [11,24,26-30,32-36] when in 1 RTC manual traction was the declared physical therapy [25]. Inversion therapy was used only in one study [31]. In 8 studies, the preferred traction position was supine [11,27-29,32-34,36]. Patients were treated prone in 3 studies [26,30,35]. 1 prone vs supine position study was found in literature [25]. 1 RCT don't declare the traction position [24]. The mean number of traction sessions was 19. At most, the duration of each session was 30 min (range 3-30 min). In almost all studies the duration of each session increased along with the number of session. The mean period of traction treatment was 6 weeks (range 3-12 weeks). The weight applied for traction was in a range between 5 kg and 60% of the body weight. Only 1 study increased the traction weight till patient's tolerance [36]. Normally, traction weight increased along with the number of traction session. 11 studies coupled with traction other therapies (physiotherapy, manual therapy, US, hotpack, TENS, massage) [11,24-27,29-33,36]. Only 3 studies used traction as a single therapy [28,34,35]. The mean follow up period was 16,5 weeks from the end of treatment. Only 1 work evaluated patients at the end of treatment [34]. All included studies and their main features are resumed in Table 1.

Discussion

Acute and chronic LBP are complex disorders that must be managed with a multidisciplinary approach addressing physical and socioeconomic aspects of the illness. Medication and physical therapy methods including traction have proven to be useful adjuncts to an active program of exercise and education that promotes functional restoration [37].

No of study	Author	Year	Study design	No. of patients	Type of LBP	Traction mode	Duration and frequency of treatment	Trac-tion po-csition	Traction weight	Traction-associ-ated therapy	Last F.U. (weeks)
1	Ozturk et al. [24]	2006	RCT	46	Disc herniation	motorized	15 sessions of 15 min/3 weeks	not specified	25-50% of the body weight	Hotpack+US +diadynamic currents US+diadynamic currents	3
2	Beyki et al. [25]	2007	RCT	124	Degenerative/ disc herniation	manual	10 sessions/4 weeks	prone vs supine	35-50% of the body weight	Hotpack+TENS	6
3	Fritz et al. [26]	2007	RCT	64	Nerve root compression	motorized	12 sessions of 12 min/6 weeks	prone	40-60% of the	Extension-oriented treatment approach	6

									body weight		
4	Harte et al. [43]	2007	RCT	30	Nerve root compression	motorized	2-3 sessions per week of 10-20 min/ 4-6 weeks	supine	5-60 kg	Manual therapy+ exercise+advice	24
5	Apfel et al. [34]	2008	Retrospective cohort study	30	Discogenic/ disc herniation	motorized	22 sessions of 28 min/ 6 weeks	supine	4,5 kg less-9,07 more of 50% of the body weight	-	after treatment
6	Beattie et al. [35]	2008	Case series	296	Degenerative/ disc herniation	motorized	28 sessions of 30 min/8 weeks	prone	Not cleared	-	25
7	Unlu et al. [28]	2008	RCT	60 (3 groups of 20 patient)	Acute leg pain/ disc herniation	motorized	15 sessions/3 weeks	supine	35-50% of the body weight	-	12
8	Schimmel et al. [29]	2009	RCT	60	Chronic LBP	motorized	20 sessions of 25-30 min/ 6 weeks	supine	4,5 less-4,5 more of 50% of the body weight	Massage+heat+music	14 weeks
9	Kamanli et al. [36]	2010	Case series	26	Disc herniation	not specified	15 sessions of 10 min/3 weeks	supine	1/3 of the body weight-tolerance	Hotpack+US+TENS	6/4/2014 weeks
10	Fritz et al. [30]	2010	RCT	120	Nerve root compression	Motorized	12 session of 12 min/6 week	prone	40-60% of the body weight	Extension-oriented treatment approach Stretching	2/21/1900
11	Diab et al. [11]	2012	RCT	80	Chronic LBP	(lumbar extension traction)	30 sessions of 3-20 min-10 weeks	supine	not specified	exercise+infrared radiation	1/24/1900
12	Prasad et al. [31]	2012	RCT	24	Discogenic	inversion therapy	12 sessions/ 4 weeks	-	-	Physiotherapy	1/6/1900
13	Diab et al. [32]	2013	RCT	80	Chronic mechanical LBP hypolordosis	motorized (lumbar extension traction)	36 session of 3-20 min/ 12 weeks (average)	supine	not specified	Stretchingexercises +infrared radiation	1/12/1900
14	Moustafa et al. [33]	2013	RCT	64	L5-S1 disc herniation/ hypolordosis	motorized (lumbar extension traction)	30 sessions of 3-20 min-10 weeks	supine	not specified	Hot packs+interferential therapy	1/24/1900

Table 1: Summary of studies included and main features

Traction mechanism to relieve pain seems to separate the vertebrae, remove pressure or contact forces from injured tissue, increase peripheral circulation by a massage effect, and reduce muscle spasm [38]. The results of previous studies examining the efficacy of lumbar traction yielded conflicting results [6,39-41]. The aim of this short review is to discuss and analyze the latest result regarding lumbar traction in order to clarify some aspects of this specific and useful physical therapy.

The majority of included studies employed traction on patients that suffered nerve root compression symptoms (radiculopathy, sciatica, discogenic pain). Mustafa, in his randomized clinical trial, aims to investigate the effects of lumbar extension traction in patients with unilateral lumbosacral radiculopathy due to L5-S1 disc herniation. All patients has also hypolordotic lumbar spine (<39°). The control group received hot packs and interferential therapy, whereas the traction group received lumbar extension traction in addition to hot packs and interferential therapy. He concluded that traction group had better effects than the control one with regard to pain, disability, H-reflex parameters and segmental intervertebral movements [33]. Fritz et al. performed a RCT in order to identify a subgroup of patients with low back pain who are likely to respond favorably to an intervention including mechanical traction. The results of this study suggest this subgroup is characterized by the presence of leg symptoms, signs of nerve root compression, and either peripheralization with extension movements or a crossed straight leg raise [26]. Some years later, the same author conducted a preliminary study on 120 patients examining the effectiveness of a treatment protocol of mechanical traction with extension-oriented activities for patients with low back pain and signs of nerve root irritation. The authors proved that add traction to extension-oriented activities lead to a better clinical outcome. Moreover, they examine a validity of a subgrouping method based on the presence peripheralization of symptoms with extension movement and/or a positive crossed straight leg raise test. This screening will allows the identification of patients who could take advantage from traction therapy [30].

The use of mechanical traction in the management of patients with chronic low back pain/degenerative spine disorders has generally not been endorsed by evidence-based practice guidelines. Diab et al. aim to investigate the effects of lumbar extension traction with stretching and infrared radiation compared with stretching and infrared radiation alone on the lumbar curve, pain, and intervertebral movements of 80 patients with chronic mechanical low back pain (CMLBP). They stated that lumbar extension traction with stretching exercises and infrared radiation was statistically superior to stretching exercises and infrared radiation alone for improving the sagittal lumbar curve, pain, and intervertebral movement in CMLBP [11]. Beyki et al. compared the outcomes of prone and supine lumbar traction in patients with chronic discogenic low back pain. They noted that prone traction was associated with improvements in pain intensity and ODI scores at discharge but they cannot imply a long lasting relationship between the traction and outcomes [25].

Some studies tried to investigate the radiological (MRI or CT) outcome of lumbar traction therapy along with clinical ones. Unlu et al. compared the outcome of traction, ultrasound, and low-power laser (LPL) therapies by using magnetic resonance imaging and clinical parameters in patients with nerve root compression symptoms. 60 patients were randomly assigned into 1 of 3 groups equally according to the therapies applied. There were significant reductions in pain and disability scores between baseline and follow-up periods, but there was not a significant difference between the 3 treatment groups at any of the 4 interview times. There were significant reductions of size of the herniated mass on magnetic resonance imaging immediately after treatment, but no differences between groups [28]. Kamanli et al. measured the outcome of conservative physical therapy with traction, by using magnetic resonance imaging and clinical parameters in patients presenting with low back pain caused by lumbar disc herniation. Magnetic resonance imaging examinations were carried out before and 4-6 weeks after the treatment. There were significant improvement in clinical outcomes and significant increases in lumbar movements between baseline and follow-up periods. There were significant reductions of size of the herniated mass in five patients, and significant increase in 3 patients on magnetic resonance imaging after treatment, but no differences in other patients. These results suggest that clinical improvement is not correlated with the finding of MRI. Patients with lumbar disc herniation should be monitored clinically [36]. In 2006, Ozturk et al. investigated the effects of continuous lumbar traction in patients with lumbar disc herniation on clinical findings, and size of the herniated disc measured by computed tomography (CT). 46 patients with lumbar disc herniation were included, and randomized into two groups as the traction group (24 patients), and the control group (22 patients). The traction group was given a physical therapy program and continuous lumbar traction. The control group was given the same physical therapy program without traction, for the same duration of time. They achieved statistically relevant improvement in their reults concluding that lumbar traction is both effective in improving symptoms and clinical findings in patients with lumbar disc herniation and also in decreasing the size of the herniated disc material as measured by CT [24]. The goal of the study carried out by Apfel et al. was to determine if changes in LBP, as measured on a verbal rating scale, before and after a 6-week treatment period with non-surgical spinal decompression, correlate with changes in lumbar disc height, as measured on computed tomography (CT) scans. 30 patients were enrolled for this study. The concluded that non-surgical spinal decompression was associated with a reduction in pain and an increase in disc height. The correlation of these variables suggests that pain reduction may be mediated, at least in part, through a restoration of disc height. Nevertheless, authors stated that randomized controlled trials is needed to confirm these promising results [34].

The possibility of lumbar sagittal curve correction with 2 way lumbar traction has been described in literature [12]. In 2013, Diab et al. conducted an RCT to investigate the effect of extension on the , function and whole spine sagittal balance as represented in curvature, thoracic curvature, C7 plumb line, and sacral slope. Eighty patients with chronic mechanical (CMLBP) and definite hypolordosis were randomly assigned to or a control group. The control group (n=40) received stretching exercises and infrared radiation, whereas the traction group (n=40) received lumbar extension traction in addition to stretching exercises and infrared radiation three times a week for 10 weeks. They stated l extension in addition to stretching exercises and infrared radiation improved the spine sagittal balance parameters and decreased the and disability in chronic mechanical LBP.

In lumbar traction therapy, several factors has to be considered [32]. Among other (weight, number and duration of sessions, duration of treatment) the position of traction is of a paramount importance. No univocal results can be drawn from literature. 8 studies included in our review used supine traction position. According to these findings, the majority of studies found in literature employed supine position for traction therapy. Beattie et al. aim to determine outcomes after administration of a prone lumbar traction protocol in 296 consecutive patients with LBP and evidence of a degenerative and/or herniated intervertebral disk. Traction applied in the prone position for 8 weeks was associated with clinical improvements till the end of follow up (180 days after discharge). Obviously, causal relationships between these outcomes and the intervention should not be made until further study is performed using randomized comparison groups [35]. Only 1 study compared the efficacy of prone and supine lumbar traction. Beyki et al. performed a 4-week course of lumbar traction, prone or supine, in 124 patients randomly divided in case and control groups. Case group (prone traction) had statistically better clinical results compared to control group (supine traction) [25].

Separate mention has to be done for inversion therapy. In “Inversion” or “Backswing”, a tilt table is used and the weight of the entire upper half of the patient’s body assisted by gravity acts as the traction [42]. The traction forces here are likely to be more consistent and tailored to each patient than conventional traction. In our review, we detected only 1 study concerning inversion therapy. It was a prospective randomized controlled trial. 24 patients awaiting surgery for pure lumbar discogenic disease were allocated to either physiotherapy or physiotherapy and intermittent traction with an inversion device. Authors concluded that the association of inversion traction and physiotherapy resulted in a significant reduction in the need for surgery. Along with several supposed benefits, traction therapy has some adverse effects. These effects were in the main not of a serious nature (short-term exacerbation of symptoms, pain on release of traction, headache, difficulty relaxing). In contrast, episodes of cauda equina symptoms and hospitalization because of acute onset of pain are rare but possible complications [43,44].

This short review has several limitations. First of all, we included only English-language studies. Several biases can be introduced by quality of studies. Most of them were RCTs but in many cases authors don't cleared the randomization protocol. Most of these studies enrolled few patients. In consequence, clear statistical results cannot be drawn. Follow up periods were too short. Lastly, the majority of included papers associated other therapies (physiotherapy, TENS, massage, US) to lumbar traction. This consideration created an heavy bias on the evaluation of traction benefits.

Conclusion

To conclude, we identified 14 studies (11 RCTs, 1 retrospective cohort study and 2 were case series) that evaluated lumbar traction effects for patients with acute or chronic non-specific LBP. Lumbar traction seems to produce positive results in nerve root compression symptoms. Data in degenerative and discogenic pain are debatable. A subgroup of patients with low back pain (peripheralization of symptoms with extension movement and/or a positive crossed straight leg raise test) may exist for whom mechanical traction is an effective treatment. Nevertheless, the limited quality evidence from the included studies show very small effects that are not clinically relevant. The majority of included studies applied lumbar traction in association with other therapies. Therefore, authors cannot draw definite clinical result. In summary, to date the use of lumbar traction therapy alone in LBP management is not recommended by the best available evidence. For future research the focus should be on high-quality RCTs with sufficient sample size to be able to draw firm conclusions.

Multiple Impulse Therapy and Saunders Lumbar Traction Methods in the Treatment of Low Back Pain: A Randomized Controlled Trial

Abstract

Background: Low back pain is a serious medical and social problem. Despite many different research studies, no explicit standard therapy has been found so far.

Material and Methods: The study included 193 adult patients of both genders (86 females, 107 males) with low back pain and pain-induced limited spinal mobility without lumbar spinal stenosis. The controlled, randomized clinical trials were used. Patients were randomly assigned to one of the two groups. Group A (Study group, n=95) was subjected to multiple impulse therapy (MIT) and in group B (Control group, n=98) – Saunders traction device was used. The Oswestry Low Back Pain Disability Questionnaire, Oswestry Disability Index - ODI were used to observe analgesic efficacy and to the analysis of functional progress.The collected results of the trial groups were presented statistically with the Student t-test for independent samples. In turn, comparing the patients' efficiency (disability index - ODI), analysis of variance of repeated measurements immediately and 1, 3, and 6 months after the therapy, was used. The study assumed the coefficient of significance $\alpha=0.05$. The calculations were performed using IBM SPSS Statistics 22.0.

Results: Multiple impulse therapy (MIT) produces beneficial analgesic effects in significantly shorter time and improves the functional ability and performance of activities of daily living in the treated patients than in the group of patients treated by Saunders axial traction method.

Conclusions: This randomized clinical trial proves that both applied therapies are useful in the treatment of low back pain. However, MIT therapy produces beneficial analgesic effects in significantly shorter time.

Keywords: Low back pain; Multiple impulse therapy (MIT); Saunders lumbar traction

Introduction

Back pain, mainly of the lumbar region, is one of the most common complaints being a big medical and social problem. Medical literature defines this phenomenon as the rapidly growing epidemic, calling it a civilization disease [1,2]. Many activities of daily living lead to overload of the spine, particularly of the lumbar region, resulting in irreversible structural changes. Often occurring hypokinesis and stress become an additional reason for these symptoms. Evoked in this way overload of muscles, ligaments and paraspinal structures leads to the development of degenerative changes within the intervertebral disc, facet joints and to vertebral canal stenosis. These changes cause spinal pain in many people of different age [3]. Musculoligamentous disorders destabilize the spine, usually leading to degenerative and proliferative changes [4]. Deformation of the bony protection of the nervous system results in neurological complications. Increased tone in paraspinal muscles causes pain, limits spine mobility and most often results in the whole locomotor system dysfunction. The occurrence of back pain syndromes increases in an alarming rate worldwide. Undoubtedly, adversely changing lifestyle, abnormal movement patterns and the negative impact of modern achievements of civilization are the reason. Pain is the major complaint concerning the spine and induced by noxious stimuli at the site of injury indicates tissue damage [5,6].

Various methods of treatment recommended and currently used require in many cases long-term application and they are often ineffective. Thus, the search for new methods of conservative treatment of back pain syndromes is fully justified. Therapeutic effectiveness of the methods for back pain treatment depends on their effect on the cause that triggered the pain. Therefore, the decompression of the intervertebral disc, nerve root or very delicate paraspinal soft tissue structures may result in the reduction of excessive tension of adjacent muscles of the spine and in pain relief [7,8].

Back pain is a complex problem which requires individual and comprehensive management. In case of failure of the conservative therapy, there may appear neurological deficits and the need for surgical treatment. However, most patients are treated conservatively using pharmacotherapy and physical procedures [7-9].

The spinal axial traction with Saunders device is one of the therapies recommended in the conservative treatment in the field of physical medicine used in the present study. Many methods exist for the traction of the spine which have been used for a long time also in the treatment of low back pain [10]. All tractions are based on similar principles. Their main task is to decompress the nerve roots, widen the intervertebral foramina lumen, stretch the intervertebral spaces, facilitate relaxation of the tensed paraspinal muscles and to lead to protruded disc repositioning by reduction of pressure inside the disc and to help suck back in the migrating nucleus material. All this is considered to be the analgesic effect. The Saunders Lumbar Traction has a pneumatic stretching mechanism owing to which traction load of 200 kg (90.6 F) can be applied [10-14].

Multiple Impulse Therapy (MIT), which recently has gained many supporters, is another and new method of conservative treatment of back pain syndromes based on completely different principles. MIT is a modern therapeutic method, worked out in the USA, used successfully in the treatment of back pain syndromes. The results of numerous studies conducted for many years in Poland confirmed unequivocally that in all patients suffering from back pain, there is observed increased paraspinal muscle tension in the pain area [15].

Therefore, a method was proposed to reduce this pathological condition, using a repeated mechanical stimulus which may be compared to impulses or vibrations, as in the therapy with the use of a shockwave with an additional acoustic effect. The reactions of an organism to exactly that kind of a mechanical impulse is called by the creators of the method mobilization (activation) of the facet joints. PulStarFRAS device consists of an interactive head which allows registering the actual value of paraspinal muscle tension at the level of each spinal motion segment, both during the analysis and the treatment itself. The obtained objective values displayed on the screen superimpose myographs of physiological muscle tension constituting an integral part of the PulStarFRAS and they result from a computer program of that device [14].

Aim

The aim of the study was to evaluate the difference in analgesic efficacy and improvement of daily functioning in patients with chronic low back pain after application of two methods: multiple impulse therapy (MIT) provided by PulStarFRAS and axial traction of the spine with Saunders device in randomized trials.

Material and Methods

The investigated group characteristics

Initially a population of 207 individuals was enrolled into the study on the basis of confirmed diagnosis and the patient's written consent to participate in research and the therapy.

All patients had chronic low back pain resulting from disc-radicular conflict and radiation of pain to the left or right lower limb. All patients underwent MRI or CT which confirmed the pain cause. All of them were also pre-treated with standard non-steroidal analgesic and anti-inflammatory pharmacological agents (NSAIDs). As the patients complained of pain lasting more than 1 month and of motor deficits (gait impairment, diminished lower limb muscle strength and slight but already visible muscular atrophy at the area of pain), as well as a major limitation in performing activities of daily living.

All patients were referred to rehabilitation by a specialist and none of them developed disorders as a result of trauma (bone fractures, musculoligamentous injury) or neoplastic disease, which constituted criteria for exclusion from the study. Patients who had earlier undergone neurosurgery due to discopathy, those who had been diagnosed with multilevel discopathy as well as patients with spondylolisthesis, osteoporotic fractures, congenital lumbar spinal stenosis, with a history of stroke and those over 65 years of age, burdened with numerous somatic, systemic or rheumatic diseases were, in compliance with the study assumptions, excluded from the investigated group. Moreover, patients were also excluded if they were underage or due to pain were unable to come unassisted to the treatment sessions.

Finally, 12 patients were excluded from the trial as a result of inclusion criteria, and 2 patients as a result of the lack of their appropriate cooperation.

Eventually, 193 patients were included in the trial, 86 females and 107 males, aged 36 - 65 years, (mean age 50.5 years) and in order to eliminate the impact of uncontrolled variables on the results of the experiment, the patients were randomly divided into two groups (Table 1).

Number of patients		**WOMEN**		**MEAN WOMEN**	**MEN**		**MEAN MEN**	**MEAN AGE TOTAL**
193		**group A**	**group B**		**group A**	**group B**		
		42	44	43	53	54	53.5	50.5
age 36-41 years		12	11	11.5	15	14	14.5	52
age 42-47 years		10	10	10	10	12	11	44.5
age 48-53 years		9	8	8.5	13	11	12	50.5
age 54-59 years		8	10	9	11	12	11.5	56.5
age 60-65 years		3	5	4	4	5	4.5	62.5
place of Residence		WOMEN		MEAN	MEN		MEAN	MEAN TOTAL
	town	25	26	25.5	25	24	24.5	25
	village	17	18	17.5	28	30	29	23.2
professional activity								
worker	physical	20	22	21	24	29	26.5	23.7
	office	12	11	11.5	10	11	10.5	11
disability living allowance/pension		10	11	10.5	19	14	16.5	13.5
Source: Own Calculations								

Table 1: Demographic characteristics of the investigated patients.

The nature of the study (experimental but not screening) was the decisive factor in determining arbitrarily the size of both samples. Taking into account the planned use of multifactorial models of analysis of variance, attempts were made to eliminate the possible effects of any deviations from normal distribution of the examined variables, therefore a balanced study design was adopted (similar size of groups) and as large as possible size of each sample was provided [16].

Due to the fact that variables such as age and gender, according to current knowledge, have no any significant impact on the treatment of back pain, the structure of the sample was not controlled as regards these features. All patients received basic number of procedures recommended for each type of the applied therapy. Two groups were distinguished randomly.

Random assignment of patients into the groups and therapeutic sessions

All patients who met the criteria were contacted by phone. The purpose and procedures were explained to them, an interview was arranged and assessment of their physical condition was made. The medical history was taken and the patients were examined to confirm the fulfillment of all the established criteria. The selected participants signed their written consent to participate in the research. The patients were randomly assigned to treatment groups A - the Study group (95 patients) and B–the Control group (98 patients). Random assignment was made by using pre-defined schedule of treatment with random numbers generated by the function of data analysis of Microsoft Excel. The procedure for assignment to groups was kept secret in such a way that it was carried out by a person not involved in the recruitment process, the course of treatment and evaluation. The results of this procedure were stored in labeled, sealed envelopes.

Group A patients (n=95) were subjected to 5 multiple impulse therapy (MIT) sessions (MIT) with the use of PulStarFRAS device (2-3 procedures per week). At the time of the analysis single impulse force was each time 15 F, whereas during the procedure - 20 F, the impulse frequency was at the level of 2-60 Hz. The session duration depended on the outcome of the analysis of MIT system computer program and ranged from 8 to 10 minutes for procedure.

Group B patients (n=98) underwent 15 axial lumbar traction procedures with Saunders device. These sessions were performed Monday to Saturday, one procedure a day in supine position. Traction force was established individually and it was ½ of the patient's weight, mean weight of the tested patients was 88.5 kg (40.0 F). Thus, mean stretching force was 44.25 kg (20.04 F). Traction time ranged from 5 to 12 minutes, which during 15 sessions was established according to the following rules: first session -5 minutes, second -6 minutes, the 3 and 4-8 minutes each, 5 and 6-10 minutes each, 7-9-11 minutes each, the remaining procedures -12 minutes each.

The Oswestry Low Back Pain Disability Questionnaire, Oswestry Disability Index - ODI, which allows to evaluate the efficiency of patients suffering from back pain, showing their functional capabilities (restrictions), was used to observe analgesic efficacy and to the analysis of functional progress of the carried out therapy [16-19].

The evaluation of the results with the use of ODI was performed immediately prior to the sessions and at four time points after completion of the therapy (on completion of the sessions, 1 month, 3 months and 6 months afterwards). ODI serves not only for the evaluation of the intensity of a very complex phenomenon of pain sensation, but above all, it shows the patient's level of efficiency. Much better than the other scales, it allows for self-assessment of physical activity the results of which are consistent with the so-called pain behaviors. These patients personally described the state of perceptible pain and its effect on their ability to manage in everyday life. This scale consists of 10 questions concerning the activities of daily living. Each question has 6 possible answers to choose from, scored from 0-5. The subject chooses only one answer which most clearly describes his/her problem. When describing the condition, it is stated explicitly, that the present state must be described. The results of ODI are converted to (%), which allows distinguishing 5 groups of determining the efficiency of each patient. I-0-20%, no or minimal disability; II-21-40% moderate disability (the patient has problems with lifting, standing, sitting, the patient may be disabled from work); III-41-60%, severe disability, (pain restricts basic activities of daily living and patient requires detailed investigations); IV-61-80%, crippled (pain impinges on all aspects of the patient's life). V-81-100%, total disability (pain prevents self-reliance, patient is bed-bound). All patients made the same assessment five times.

The collected results of the trial for Group A (n=95), and for Group B (n=98) are presented statistically using first the basic descriptive statistics (mean - M, median - Me, standard deviation - SD, skewness coefficient, kurtosis) and then assessing the significance of differences between the groups, taking into account ODI, with the Student t-test for independent samples. In turn, comparing the patients' efficiency (disability index - ODI) prior to the therapy and at four time points after completion of the sessions (immediately, 1 month, 3 months and six months after the therapy), analysis of variance of repeated measurements was used. In addition, taking into account the time of the measurements and also the tested group of patients, assessment of the disability (ODI) was performed using two-way analysis of variance. The study assumed the coefficient of significance $\alpha=0.05$. The calculations were performed using IBM SPSS Statistics 22.0.

The study was conducted in the Fiort Clinic Rehabilitation Center-Pain and Spinal Dysfunction Treatment in Piotrkow Trybunalski, Folwarczna 38, Poland, in the period from January 2011 to December 2015.

The study protocol was approved by the Bioethics Committee of the Medical University in Lodz on 14.12.2010, NO: RNN/712/10/KB. The chairperson of the Ethics Committee is prof. Przedzisław Polakowski.

Results

Group A consisted of patients (n=95) who underwent multiple impulse therapy with PulStarFras device. Group B patients enrolled in the study (n=98) were subjected to the treatment using lumbar axial traction with Saunders device.

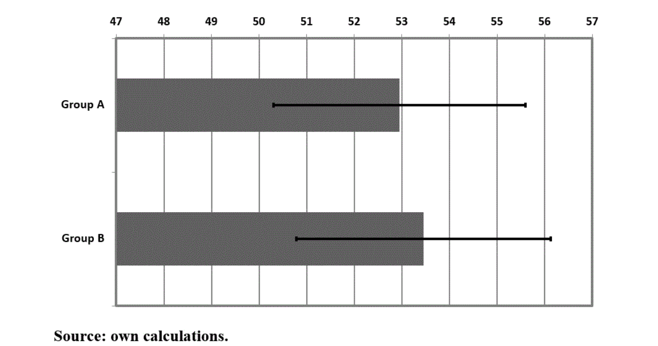

Figure 1: Mean level of ODI in Group A and B patients at baseline.

Patients selected for the trial did not differ significantly with regard to parameters of key importance for the assessment of the therapy efficacy, i.e. own assessment of the performance according to ODI (the differences were not statistically significant; in t-test $p>0.05$) Figure 1.

Before the therapy, the patients' performance assessed by ODI questionnaire was on the average approximately 53% (and thus, on the average, they were defined as patients with severe disability - pain limited their basic activities of daily living and required detailed investigation).

Both applied therapies brought significant improvement–comparing the assessment of the performance of patients before and after the therapy. We noted that each of the obtained results after completion of the therapy significantly differed, as indicated by p<0.001 in F test of the repeated measures analysis of variance. In comparison with the baseline results, the mean level of the ODI is significantly lower in all subsequent measurements; this applies to both investigated groups. Statistically significant differences were also observed between successive measurements.

After the treatment, the assessment of the performance with the use of ODI decreased to approximately 20% (this is confirmed by both the value of the arithmetic mean and median), while this decrease occurred already immediately after the treatment sessions and in subsequent periods - after 1 month, 3 months and after 6 months and it persisted. The results obtained in consecutive measurements are statistically significantly lower in both A and B groups compared to the previous measurement (Table 2).

	MIT method-5 procedures (Group A)					Saunders method - 15 procedures (Group B)				
	Baseline	0 (after therapy)	1 (1 month later)	3 (3 months later)	6 (6 months later)	Baseline	0 (after therapy)	1 (1 month later)	3 (3 months later)	6 (6 months later)
No of observations	98	98	98	98	98	95	95	95	95	95
Min	41	15	15	15	9	43	19	17	16	16
Max	63	28	27	27	22	64	33	30	30	28
Mean	52.95	21.84	20.61	20.05	18.88	53.45	23.63	22.71	21.81	20.76
Median	55	21	20	20	20	55	23	23	21	20
SD	5.485	2.551	2.218	2.212	2.022	5.546	3.142	2.637	2.655	2.513
Skewness	-0.27	0.338	0.36	0.675	-1.678	-0.323	0.719	0.406	0.574	0.581
Kurtosis	-1.291	0.537	1.189	1.312	5.035	-1.181	0.36	-0.184	0.104	0.049
Analysis of variance repetaed measures[a]	F=3326.261; df=1.456; p< 0.0001***					F=3189.045; df=1.637; p<0.0001***				
[a]Due to non- sphericity of variance -covariance matrix, the test of within -subject effect in Grenhouse-Geisser version was used.										

Table 2: ODI in the groups of patients before and after the therapy.

Thus, both therapies produced beneficial effects. First, immediately after their completion, the pain was relieved considerably (contributing to the greater efficiency of patients) and – which is important - it persisted in subsequent periods within six months after the end of the therapy. Figure 2 allows for another interesting statement - MIT method (group A) results in more measurable effects (greater decrease in the ODI scale) than the Saunders method.

The therapy with the MIT method resulted, basically already after 1 month, in restoration of physical efficiency whereas after Saunders traction it lasted longer. This is a particularly important conclusion in the context of much shorter - in the case of MIT-treatment period–5 treatment sessions are enough to restore the patient's efficiency and not, as in the case of Saunders method–15 sessions. In the case of patients treated with Saunders method, initially (0-3 months) an average patient was characterized by a moderate disability, i.e. had trouble with lifting, standing, sitting and was temporarily disabled from work. The restoration of physical efficiency occurred – on the average-six months after the therapy. However, the effect of interaction is statistically significant but at slightly higher level of significance than a standard α=0.05 (p=0.057).

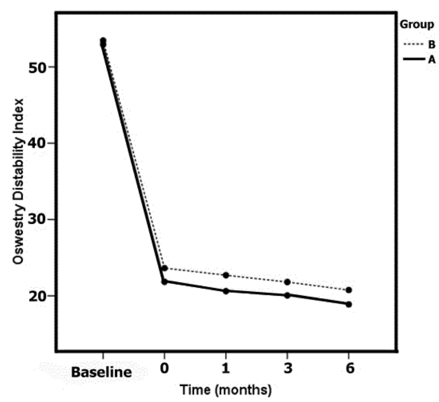

Figure 2: Boundary means for the evaluation of mobility efficiency according to ODI in patients treated by MIT method (5 procedures; Group A) and by Saunders method (15 procedures; Group B) before and after the therapy.

The standard deviation reaches about 5.5%, at weak left-sided skewness. Slightly stronger is also flattening of the distribution in relation to normal distribution; the convergence of variable distribution in relation to normal distribution is confirmed by the results of the Shapiro-Wilk test-Figure 2.

Assessing the performance of patients, in the subsequent measurements after the therapy there are observed statistically significant differences between the groups treated by MIT and by Saunders method (Table 3).

Time of measurement	Group A,M (SD)	Group B,M (SD)	Difference, M (95% CI)	p
Immediately after therapy	21.84 (2.55)	23.63 (3.14)	-0.80 (-2.21;0.98)	<0.001
1 month after therapy	20.61 (2.22)	22.71 (2.64)	-2.09 (-2.78;-1.40)	<0.001
3 month after therapy	20.05 (2.20)	21.81 (2.66)	-1.76 (-2.45;-1.07)	<0.001
6 month after therapy	18.88 (2.02)	20.76 (2.51)	-1.88 (-2.53;-1.23)	<0.001
M- mean, SD - standard deviation; 95% CI-95% confidence interval Source: own calculations				

Table 3: Comparison of ODI results in the group of patients treated by MIT method (5 procedures; Group A) and by Saunders method (15 procedures; Group B) at four time points (measurements) after completion of the therapy.

In the group of patients treated by MIT method, the results immediately after the end of the therapy, that is already after five sessions, indicate that the obtained efficiency was statistically significantly better ODI was significantly lower (M=21.84, SD=2.55) than in patients treated by Saunders method (M=23.63, SD=3.14). Importantly, the results obtained by the patients treated by MIT method were also more homogeneous than in the case of the treatment by Saunders method (although in this respect the differences are not significant). A month after the therapy, the difference between the results of ODI for both groups was more pronounced (reached 2.1 per cent points, p<0.001). At 3 and 6 months after treatment, the differences in favor of MIT treatment MIT was still maintained. Therefore, MIT is more economical and effective therapeutic method. It requires only 5 treatment sessions. In comparison with more common, better known and more widely used Saunders method, the effects of MIT therapy are also better in long-term follow-up (Table 3).

Discussion

The treatment of spinal pain, or - back pain has been one of the widely discussed medical problems for years. The issue is so serious that the ailments of the spine, especially of the lumbar region are the disease of our civilization and a real social problem. Nearly 80% of adults experience this pain, which is the most common cause of visits to a primary care physician. It is widely believed that nearly 50% of all patients coming for physical therapy is affected by just this disease [1,2,7,9,20].

In the case of back pain syndromes, it is essential to take into account biomechanical factors in their correct diagnosis and treatment. Unusual and complex biomechanical system of the spine with spinal cord and spinal nerve roots works properly only when all the components function without errors. Therefore, the injury to any construction elements of the spine causes multi-causal dysfunction manifested by pain, limitation of movement and discomfort [4]. The anatomical conditioning of the sciatic neuralgia, i.e. the piriformis syndrome, should be also considered as one of the causes inducing low back pain [21].

The opinions on the effectiveness of tractions, including Saunders device used in this study, are diverse. In the case of clinical improvement it has not been defined clearly to what extent Saunders lumbar itself traction contributed to this improvement and to what extent the applied pharmacological treatment, restrictions on lumbar spine loading or beneficial lapse of time [13]. However, Hood and Chrisman [22] demonstrated that only 52.5% of patients treated with the traction obtained good and very good results. Eie and Kristiansen [23] reported that no significant improvement was observed in 33% of patients using traction.

Komori et al. [5] using MRI to identify morphological changes in the form of lumbar disc prolapse subjected 77 patients to Saunders lumbar traction sessions. All patients were diagnosed with disc herniation with symptoms of unilateral pain radiating to the lower limb and muscle weakness on the side of pain. Relief of radicular pain and also significant improvement of neurological deficits were observed in all patients. MRI reexamination revealed a reduction of disc protrusions in 64 patients. In 13 patients there were no significant changes on MRI despite noted clinical improvement. Out of 77 patients 62 achieved very good results.

It should be remembered that in the case of very large forces during the traction procedure, there may come to the damage of bone, spinal cord or nerve roots. Saunders described lumbar traction as an effective treatment for lumbar herniated discs and radicular symptoms. He suggested 15 - 30 treatment sessions and a traction force of ½ body weight of the patient. Saunders proposed traction force of 60 pounds (27 kg) as most optimal. Numerous studies conducted by many researchers, among others by Komori, Shinomiya and Nakai [5], Gupta [12], also pointed to good results of the treatment of patients with symptoms of sciatica and furthermore they supported the use of high forces, even of 60-80 pounds.

The effectiveness of the treatment of cervical pain with Sanders device has been also described by many researchers and their results demonstrate the improvement of mobility of this part of the spine. When the X-ray findings were compared before and after traction, they revealed the increase of intervertebral disc space. There was also observed the improvement of functional ability of the examined patients on the basis of the NDI Questionnaire (Neck Disability Index Questionnaire) [24,25].

For the needs of this study, the therapy with Saunders axial traction device gave positive results in Group B (n=98), but it should be remembered that there were performed 15 treatment sessions in each patient.

However, a limitation of this study is that the assessor-blind design could not be used because patients knew in which way they were treated.

Describing in detail the procedure itself using Saunders axial traction device, the technical side of this kind of therapy cannot be ignored [26,27]. Many patients reported malaise during a few minutes' session. These were usually patients with obesity or those with gastrointestinal symptoms [1,8,25]. It seems that the need to fasten the patient with stabilization belts can further contribute to the development of these particular problems. The patients often report discomfort that results from the need to adopt a supine position which was established at the beginning and is necessary when using this kind of therapy. Sometimes persisting chronic spinal pain, often obesity, may induce malaise, which was reported during the procedure by many patients.

Unknown and not yet very popular in Poland therapeutic method for the treatment of back pain syndromes – Multiple Impulse Therapy (MIT) -was proposed to Group A patients (n=95). This therapy requires a device called PullStarFras and the creators of this method pointed to the need for the use of a tilting table for the patient to assume prone passive position. From a technical point of view in the case of the occurring back pain it makes the procedure easy to perform. This technique was fully accepted by the patients already before the procedure. The procedure itself is quick, painless, and not every day performed, which results from the recommendations of the method creators. The treatment cycle ends on five procedures [27,28]. Since this method requires carrying out a diagnostic investigation (analysis), both before and immediately after each procedure, the patient in a simple and clear way can see the differences before and after each session. The presented on the monitor of the device colored, horizontal graphs indicate the progress of the therapy. Such a graphical way to address the problem of pain has a positive influence on the cooperation with the patient and at the same time builds his confidence in the therapy. As the main goal of the Multiple Impulse Therapy is normalization of increased paraspinal muscle tension, this graphic presentation of the change coincides with the intensity of pain in many patients [28,29]. Furthermore, the investigation preceding and ending the therapy recognizes all segments of movement of the spine, showing the need for changing the intensified, pathological values of muscle tension, not only in the lumbar spine. The obtained results of the study confirm the efficacy of the multiple impulse therapy, do not produce any additional anxiety that the patient should wait patiently for the results of the therapy, as it happens in other methods of treatment. In many cases of this study group, the patients reported a significant improvement after only two or three sessions. Reduction of the intensity of pain usually translated into significantly improved lumbar spine mobility, which clearly improved the efficiency of the treated patients in everyday life, particularly in relation to household activities, which the patients themselves noticed before the end of the therapy. All participants in this study group assessed Multiple Impulse Therapy very positively. They highly appreciated the sessions and the feelings associated with this therapy. Taking into account the obtained results translating into very good opinions of the patients, their view should be shared of the wider introduction of multiple impulse therapy in the treatment program for all those who suffer from chronic back pain syndromes.

Thus, Multiple Impulse Therapy (MIT) is adapted to the expectations of many patients and it is a new method based on reliable, objective diagnostic test [29,31]. It does not require, as other conventional methods of treatment, a long time, numerous sacrifices and limitations. It is a completely safe method, significantly shortening the treatment time and of high analgesic efficacy. Definitely shorter period of treatment compared to that of patients treated with the Saunders axial traction device and thereby significantly faster return to activities of daily living and to professional work, is of great economic and social importance [28-32].

Comparing pain assessment in subsequent measurements after completion of the therapy, there were observed statistically significant differences between the group treated by MIT in relation to the Saunders group (Table 3). This applies to all measurement points-both immediately after the therapy as well as in the subsequent periods (including half a year after the end of the treatment). Lower mean levels of ODI were noted for patients treated with MIT as compared to Saunders method. This means that the MIT method gives better results than the treatment by Saunders method. The long-term follow-up demonstrated substantial persistence of the beneficial results of the MIT therapy in relation to Saunders therapy. This is even more important if we take into account the time spent on both therapies and thus - their cost. MIT treatment method is significantly shorter, more efficient and thus faster and with better effect it contributes to the improvement of the quality of life of patients with chronic lumbar pain than the applied Saunders method.

At the same time, some authors suggest that the combination of many therapeutic methods (multimodal treatment) gives the most favorable therapeutic results [33].

Conclusions

- Both physiokinetic methods: Multiple Impulse Therapy (MIT) and Saunders traction device are useful in the treatment of patients with chronic lumbar pain.
- Multiple Impulse Therapy (MIT) results in beneficial analgesic effects and functional improvement in everyday life activities in significantly shorter time compared to Saunders traction method.
- Multiple Impulse Therapy compared to Saunders traction therapy demonstrates higher effectiveness also in long-term follow-up.
- MIT therapy analgesic effect remains longer compared to Saunders traction analgesic effect, thus MIT is suggested to be more frequently in patients with low back pain when considering the application of physiokinetic methods.
- Totally pain-free and effective Multiple Impulse Therapy (MIT) enjoys popularity and approval of the treated patients.