ABSTRACT

Background: It is well known that Iliotibial band syndrome (ITBS) is the most frequent overuse injury in recreational runners. Given the fact that there are no clear guidelines on the optimal conservative treatment approach regarding ITBS rehabilitation, manual therapy effect by a functional joint mobilization is still unknown. The purpose of the study was to investigate whether implementation of mobilization-with-movement (MWM) and auto-mobilization had a significant short-term improvement in pain and functionality of recreational runners with ITBS.

Methods: Participants: thirty ITBS patients, were randomly assigned into two groups. Design and Settings: One group pre-test /post-test with the control group. Interventions: Runners on the treatment group followed an MWM protocol of six sessions with an additive program of auto-MWM, while the control group received a SHAM form of MWM. Outcome measurements: Pain and functionality were measured at baseline and post-treatment, via Numeric Pain Rating scale and Lower Extremity Functional Scale respectively. Mixed-ANOVA test detected possible differences among treatment phases and between groups, but also interactions among factors.

Result: The present findings revealed significant interactions between factors and significant main effects of each TIME and GROUP factors on pain and functionality. MWM-treatment group showed significant improvement in post-intervention NPRT and LEFS scores, compared to baseline scores (p<.001). SHAM-MWM group exhibited no significant differences on post-NPRT and LEFS scores, compared to baseline (p>.001). Differences between groups were significant in post-treatment scores (p<.001).

Conclusion: Our findings suggest that MWM and auto-MWM are a significant treatment approach, improving pain and functionality in recreational runners suffering from ITBS.

Keywords: iliotibial-band-syndrome, mobilization-with-movement, runners, manual therapy.
INTRODUCTION

Iliotibial band syndrome (ITBS), also known as “Runner’s Knee,” is one of the main causes of lateral knee pain in runners [1]. It is an overuse syndrome mostly seen in female recreational runners [2]. Due to the increased number of people participating in running activities, the prevalence of ITBS has been increased over the last two decades [3]. Pain is located in the outer part of the knee, that worsens with the continuance of running after 15 minutes, and also during early knee flexion. Prognostic factors are thought to be gender, age, running and injury history [4, 5]. Methodological heterogeneity of research about criteria evaluating ITBS, etiology and prognostic factors results in ambiguity of therapeutic approach and treatment goals [6, 7]. Physical therapy is often recommended, including stretching, strengthening and soft tissue mobilization [8]. However, the optimal treatment for athletes with ITBS remains undescribed, according to varied results [9]. Moreover, the conflicting evidence about ITBS pathophysiology interpretation as it is the repetitive loading of the distal part of the band [10] or the femoral epicondyle impingement [11], or more recently the mediolateral movement of ITB leading to increased compression [12], complicate the rehabilitation program.

Manual therapy (MT), as part of conservative treatment for ITBS, has been used as a soft tissue mobilization form, but not as a joint mobilization [13]. Even in that form, researchers have investigated it only in a multimodal program [9]. So there is no evidence of the effect of joint mobilization in ITBS patients. Symptoms arise during running, highlighting the need for a functional approach according to therapeutic protocols. Mobilization with Movement (MWM), is one of the fundamental methods of Mulligan concept, combined active patient movement simultaneously with passive therapist joint mobilization [14]. It is a relatively easy technique in its application resulting in immediate symptom improvement after only one session.

Under this circumstances and in the lack of research data about the relation of joint mobilization and ITBS on their common functional nature, the study objective was to identify the short-term impact of manual therapy sessions, in a form of MWM, on recreational runners suffering from ITBS in terms of pain and functionality after the acute inflammation period.

MATERIALS AND METHODS

Study Design

The study was set out in a design of the double-blind, randomized placebo-controlled trial. The first author executed all the intervention techniques. The second author was blinded of the group allocation and the MWM/SHAM protocol that each participant had to follow and conducted all measurements. In relation to CONSORT guidelines, the study design was conducted in the form of one group pre-test/post-test intervention with a control group.

A sampling of recreational runners was applied during during an eight months period from April to December of 2016. Using a random-numbers table, thirty (30) athletes were randomly allocated to the intervention (15 participants) or control group (15 participants), [15, 16]. The sample was divided into two groups, the experimental where the manual therapy intervention was implemented and the control group. Patients were asked to fulfill a short questionaire according to descriptive characteristics of gender, age, weight, height, training age, level of pain, medical and drug prescription [17]. Patients examined by an orthopedic surgeon and referred to physiotherapy in an outpatient clinic. Inclusion criteria were recreational runners presented with lateral knee pain during running that gradually worsened, local tenderness over the lateral epicondyle, reproducible pain with Noble compression test [18]. Pain features are associated with a well-localized area to the lateral femoral condyle during deceleration phase at 30˚ of knee flexion. In most case pain is worsen during downhill running due to a reduced angle of knee flexion at footstrike so the iliotibial band located in the “impingement zone” for a longer period. Moreover, a special feature of pain is that completely subsides by walking [19]. Exclusion criteria were a lateral meniscus tear, lateral collateral ligament sprain, patellofemoral dysfunction, osteochondral injury, biceps femoris tendinitis, osteoarthritis and previous supervised physical therapy [18]. A physical examination was conducted by a manual therapist, experienced in treating ITBS patients, which included Ober test assessing for ITB tightness [20], Noble's compression test is assessing tenderness and pain in 30˚ knee flexion, and a treadmill running test [21, 22].

This project received approval from the Research Ethics Committee of National and Kapodistrian University of Athens, Greece.

Intervention

We implemented six sessions of Mobilization With Movement (MWM) in a two weeks period (three sessions each week), where all participants were advised to cease every running activity. The study group followed a therapeutic protocol consisted of five (5) pre-selected MWM techniques especially in weight-bearing position in a dosage of three sets of ten repetitions (3X10) with a one-minute break between sets. MWM protocol consisted of:

A) Active hip internal rotation by the participant in upright weight-bearing position, while simultaneously the therapist applied the mobilization at a right angle of movement direction with a belt around the hip joint of the affected leg. B) Active hip abduction of the affected leg in upright weight-bearing position with the other leg on a chair and the therapist apply the mobilization via a belt in a posterior direction. C) Active hip weight-bearing extension in an upright position, with other leg on a chair, while therapist’s hip mobilization force was applied with a belt in external direction on the affected leg. D) External rotation mobilization by the therapist on the on the affected knee in an upright position, during active flexion-extension by the participant in a 30˚ ROM. E) Lateral gliding on the affected knee in a supine position during active flexion-extension...
by the patient in a 30° ROM. MWM using a belt, is the usual auxiliary therapeutic tool of mobilization application, allowing the body of the therapist to follow the movement direction of the patient properly. If discomfort was raised, a towel was placed under the belt and over patient’s thigh.

All participants in the study group followed the same MWM therapeutic protocol. In addition to this, they were taught how to implement self-mobilization (auto-mobilization) techniques at home two to three times daily, during the two week study period in a dosage of three sets of ten repetitions (3X10). Self-mobilization techniques are an important part of MWM application, contributing to the final therapeutic effect. The preselected auto-mobilization techniques were the same as of the basic protocol, using a belt for hip mobilization and by their hands on knee mobilization. Lack of pain during the MWM and self-MWM execution is a fundamental element of Mulligan concept.

In the control group, we administered a Sham-form of the therapeutic protocol, guiding on the same movements by the participants, but without therapist’s mobilization force [23].

Outcome measures
Dependent variable (DV) measures of pain and functionality were conducted through questionnaires. The pain was measured with Numeric Pain Rating Scale (NPRS), a unidimensional single eleven (11)-item scale, widely used as a generic research tool assessing pain intensity [24, 25]. Patients were asked to point their pain level during running. The concurrent, face, convergent and divergent validity has been found to be excellent, highly correlated to the Visual Analogue Scale (VAS) [26]. Test-retest reliability is excellent with a score of intra-class correlation coefficient-ICC=0.92, in musculoskeletal knee pain [24]. The Minimal Clinically Important Difference (MCID) has been determined in a reduction of 2 points, or 30%, on the NPRS scores to be clinically important by few researchers [27], while others determined a reduction of 1 point or 15% [28].

The dependent variable of functionality was measured with Lower Extremity Functional Scale LEFS, according to activities of daily living, ranking from 80 (maximum ability level) to zero (minimum ability level) [29]. The MCID is nine scale points. The reliability of the LEFS was found to be excellent (ICC=.94), [30, 31]. It has been used in research according to ITBS with good results [32, 33, 9]. As it was mentioned before, all measurements were conducted by a blinded examiner.

Statistical analysis
Data analysis was conducted via SPSS version 24. The groups were equal in size of participants. MWM therapeutic protocol was defined as the independent variable with two dimensions, GROUP and TIME. The first one is the between-subject factor (MWM-group and SHAM-group) and the second is the within-subject factor (pre-test and post-test measure). The dependent variables were pain and functionality measures. The analysis was based on a mixed-ANOVA test, where two independent groups were detected for differences, but also on repeated measures differences according to dependent variable scores. The assumptions of mixed-ANOVA that preceded the main analysis were tested via Shapiro-Wilk test for normality (normal distribution of the DV for each group), Levene's test of homogeneity of variances, Box’s M test of homogeneity of covariances. Also, the dependent variables were measured on a continues scale.

The main purpose of Mixed-ANOVA was searching for interactions between TIME factor and GROUP factor on each of the dependent variable (pain, functionality). In case of significant interaction, a pairwise comparison test would be performed to detect significant differences between levels of time measurements. Next step in the analysis, after variable interactions, was conducted on detecting the main effects each of the dimensions of the independent variable on the two dependent variables. The main effect of time was tested whether there were significant changes over time averaged across both groups. The main effect of group was tested whether on average, one group scored higher on the dependent variables than the other group. Statistical level of significance was set at α=.05 and confidence interval at 95%.

RESULTS
Both groups were equal in demographic characteristics as depicted in Table 1.

Table 1: Demographic characteristics of participants in values of Mean ± SD and percentage (%)

| Group | MWM | SHAM |
|-------|-----|------|
| Sample size, n | n=15 | n=15 |
| Gender n, (female %) | 9 (60) | 8 (53.3) |
| Age years, (mean, SD) | 33 (±7) | 30 (±8) |
| Training age in years, mean, (SD) | 4.7 (±1.1) | 6.2 (±1.6) |
| Weight, kg (SD) | 55 (±4.7) | 51.3 (±3.5) |
| Height cm, (SD) | 168 (±5.5) | 170 (±7) |
| Drugs, n, (%) | 9 (60) | 10 (66) |

Thirty-seven (37) recreational runners were assessed for eligibility criteria, but thirty (30) of them were enrolled in the two groups, 15 in the experimental group and 15 in control group. Flowchart depicts patient's recruitment and retention, as well as the reasons for ineligibility (Figure 1.)
Both groups were equal in baseline scores of dependent variables of pain and function, as depicted in Tables 2, 3.

**Table 2:** NPRT Descriptive statistics (mean, SD) for the two groups

| NPRT    | GROUP   | Mean     | Std. Deviation | N  |
|---------|---------|----------|----------------|----|
| Pre-treatment | MWM     | 5.1333   | .74322         | 15 |
|          | SHAM    | 5.1333   | 1.12546        | 15 |
| Post-treatment | MWM     | 2.0000   | .92582         | 15 |
|          | SHAM    | 4.3333   | 1.39728        | 15 |

**Table 3:** LEFS Descriptive statistics (mean, SD) for the two groups

| LEFS    | GROUP   | Mean     | Std. Deviation | N  |
|---------|---------|----------|----------------|----|
| Pre-treatment | MWM     | 49.0000  | 5.85540        | 15 |
|          | SHAM    | 46.0000  | 7.35818        | 15 |
| Post-treatment | MWM     | 65.3333  | 4.85014        | 15 |
|          | SHAM    | 50.7333  | 6.54071        | 15 |

Shapiro–Wilk test found to be non-significant (p>.05), determining the normal distribution of pain and functionality for each group (p=0.1 for MWM group and p=0.28 for SHAM group as for NPRT), (p=0.23 for MWM and p=0.20 for SHAM group as for LEFS). According to equality of variances, Levene’s test was found to be non-significant (p>0.05), (p=0.78 for NPRT and p=0.30 for LEFS). So, there was a homogeneity of variances among MWM and SHAM groups, according to dependent variables of VAS and LEFS. Box’s M test found to be non-significant (p=0.34 for NPRT, p=0.38 for LEFS), so there was an equality of covariance matrices on the dependent variables (p>.05). In accordance with the above, assumptions meeting allowed the implementation of mixed-ANOVA.

**Interactions**

Mixed ANOVA revealed a significant interaction, via profile plot (Figure 2.), among the independent variables of TIME and GROUP, according to Pain (NPRT), F (1, 28) =63.05, (p<.001), (Table 4.). Moreover, a significant interaction (Figure 3.) was found between TIME and GROUP and their effect on Functionality (LEFS), F(1, 28.=40.23, (p<.001), (Table 5.)

**Table 4:** Tests of Within-Subjects Effects on PAIN measure

| Source          | Type III Sum of Squares | df | Mean Square | F       | Sig.  |
|-----------------|-------------------------|----|-------------|---------|-------|
| Sphericity      | Assumed                 | 1  | 58.017      | 179.169 | .000  |
| Greenhouse-     | Geisser                 | 1,000 | 58.017      | 179.169 | .000  |
| Huynh-Feldt     | 1,000                   | 58.017 | 179.169      | .000  |
| Lower-bound     | 1,000                   | 58.017 | 179.169      | .000  |
| TIME * GROUP    |                         | 1  | 20,417      | 63.051  | .000  |
| Sphericity      | Assumed                 | 1  | 20,417      | 63.051  | .000  |
| Greenhouse-     | Geisser                 | 1,000 | 20,417      | 63.051  | .000  |
| Huynh-Feldt     | 1,000                   | 20,417 | 63.051      | .000  |
| Lower-bound     | 1,000                   | 20,417 | 63.051      | .000  |
| Error (TIME)    |                         | 28 | .324        |         |       |
| Sphericity      | Assumed                 | 28 | .324        |         |       |
| Greenhouse-     | Geisser                 | 28,000 | .324        |         |       |
| Huynh-Feldt     | 28,000                  | .324        |         |       |
| Lower-bound     | 28,000                  | .324        |         |       |
Table 5: Tests of Within-Subjects Effects on Functionality measure

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. |
|--------|-------------------------|----|-------------|---|------|
| LEFS   | Sphericity Assumed      | 1664,267 | 1 | 1664,267 | 132,712 | .000 |
|        | Greenhouse-Geisser     | 1664,267 | 1,000 | 1664,267 | 132,712 | .000 |
|        | Huynh-Feldt            | 1664,267 | 1,000 | 1664,267 | 132,712 | .000 |
|        | Lower-bound            | 1664,267 | 1,000 | 1664,267 | 132,712 | .000 |
| LEFS * GROUP | Sphericity Assumed | 504,600 | 1 | 504,600 | 40,238 | .000 |
|        | Greenhouse-Geisser     | 504,600 | 1,000 | 504,600 | 40,238 | .000 |
|        | Huynh-Feldt            | 504,600 | 1,000 | 504,600 | 40,238 | .000 |
|        | Lower-bound            | 504,600 | 1,000 | 504,600 | 40,238 | .000 |
| Error (LEFS) | Sphericity Assumed | 351,133 | 28 | 12,540 |
|        | Greenhouse-Geisser     | 351,133 | 28,000 | 12,540 |
|        | Huynh-Feldt            | 351,133 | 28,000 | 12,540 |
|        | Lower-bound            | 351,133 | 28,000 | 12,540 |

Figure 3: TIME-GROUP interaction on Functionality

Simple main effects
The significant interactions among independent variables lead to searching for main effects of independent variables on each dependent variable. To be more accurate, the essential finding was the simple main effect of factor Group in Pain and Functionality separately on pre and post-treatment level of within-factor of TIME. The analysis revealed a significant simple main effect of Group in Pain F(1, 28)=10.25, (p=.003), according to post-treatment measure (Table 6.). Also, a significant simple main effect of Group was also found on Functionality F(1, 28)=17.91, (p=.000), according to post-treatment measure (Table 7.).

Table 6: Tests of Between-Subjects Effects on Pain

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. |
|--------|-------------------------|----|-------------|---|------|
| Intercept | 1033,350                | 1  | 1033,350 | 519,147 | .000 |
| GROUP   | 20,417                  | 1  | 20,417 | 10,257 | .003 |
| Error   | 55,733                  | 28 | 1,990 |

Table 7: Tests of Between-Subjects Effects on Functionality

| Source | Type III Sum of Squares | df | Mean Square | F | Sig. |
|--------|-------------------------|----|-------------|---|------|
| Intercept | 167059,267              | 1  | 167059,267 | 2577,034 | .000 |
| GROUP   | 1161,600                | 1  | 1161,600 | 17,919 | .000 |
| Error   | 1815,133                | 28 | 64,826 |

DISCUSSION
This is the first study to investigate the correlation between a specific functional form of manual therapy as it is MWM, on the base of joint mobilization, apart from the widely used soft tissue mobilization techniques [13], muscle stretching [21, 34] and strengthening [8] in ITBS runners. Pain and functionality were the two variables of measuring the clinical status of runners, which are the main tools used in research due to the ease of application [35, 21, 36]. Pain and functionality score differences between pre and post-treatment measures were significant (p<.001) for MWM group, in contrast to SHAM group (p>.001). Differences between groups were also significant (p<.001), on dependent variable scores, at post-treatment measurements. Our analysis found significant pain and functionality interactions between independent variable levels and following the simple main effect analysis we came to a conclusion of significant differences between MWM and SHAM groups on the second phase of measure on each scale of NPRT and LEFS.

Up until now, only Shamus (2015) has applied a form of joint mobilization as it is high velocity and low amplitude (HVLA) manipulation in superior tibiofemoral and lumbar spine, as part of a multimodal approach, including soft tissue mobilization techniques and muscle energy intervention [9]. Many conservative therapeutic tools have been proposed in the rehabilitation protocols, but none of it has investigated manual therapy and especially a functional form like MWM in the treatment of ITBS runners. The characteristics of pain and the fact that symptoms arise after a relatively specific time of running [19] determine the functional status of pathology around the knee, in conjunction with pathologic changes on the hip joint.

Our results revealed a clear therapeutic effect in pain and functionality measurements after implementation of the treatment protocol, based on the MWM parameters that Mulligan therapists apply in clinical practice, like those of weekly frequency of therapy, duration and dosage of a single session, auto-MWM application and patient education [14].
We chose to implement joint mobilization both on the knee and hip joint as it still unknown the exact cause and effect biomechanic relationship between the two joints, even if bibliography seems that proximal deficiency is a relative prognostic factor of lower overuse musculoskeletal disorders as it is ITBS [37]. The selected techniques were mostly based on weight-bearing positions (hip-MWM), but also in non weight-bearing position (knee-MWM), combining normal open and closed kinetic chain biomechanics of iliotibial band and tensor fascia lata. The direction of hip abduction and internal rotation MWM were chosen because of the kinematic changes that ITBS patients seem to present during activity [12, 38]. Hip has the tendency of collapsing into adduction and internal rotation during hip flexion mostly in repetitive weight-bearing activities ([37, 6]. In a recent systematic review, kinematic deficiencies were present in ITBS runners, like increased peak hip adduction and knee internal rotation [5]. Even though we did not measure muscle strength, we chose to implement MWM hip extension, due to the fact that the more efficient the movement of extension, the less upright position trunk posture, resulting in less knee-extensor work during running [39]. However, it is not well understood if there is a there is a cause and effect relationship among lower extremity kinematic variables and symptoms of pain in ITBS runners [40, 41].

Given the fact that biomechanical factors are probably responsible for the etiology of runners ITBS and knowing that iliotibial band is richly innervated [42], we hypothesized that MWM intervention might alter the mechanoreceptor sensitivity in knee and hip joint, facilitating a muscle pattern that relieves pain and improves function. After six sessions of MT, runners on the experimental group were able to run with a significant pain reduction, especially after the critical mean time phase of 15 minutes of running. ITBS has similar biomechanical features with PFPS [43]. MWM found to be beneficial as part of rehabilitation protocol in PFPS patients [44], so the concept behind MWM application in ITBS, is the functional improvement of the proximal ‘tendinous’ part of the hip joint of iliotibial band insertion, additionally with mobilization on the distal ‘ligamentous’ knee joint insertion.

Since the exact mechanobiological pathways on both manual therapy and pathophysiology of ITBS are not well understood, theories, concerning the mechanism of action and immediate symptom improvements after MWM application, needs an update according to positional faults corrections [45]. More interest seems to be presented by studies investigating mechanoreceptor activity on a cellular level and physical therapy effect [46]. However, identified mechanism of action other than biomechanical, like biological or neurophysiological, are beyond the scope of the study.

Data shows that conservative therapies produced a 44% complete cure rate [47]. However, Ellis (2005) in a systematic review, points out the limited evidence to suggest conservative treatments and the possible benefit in the management of ITBS [2]. Our study showed that MWM has the potential to reduce the duration of rehabilitation resulting in the way of earlier return to activity.

MWM self-mobilization is an important additive therapeutic approach in Mulligan concept, contributing to effect consolidation and continuation of therapy at home. In our recent study [48], we found that auto-MWM as part of MWM weight-bearing treatment protocol on the hip joint, had a positive effect in patients with hip osteoarthritis, not only in short-term but also in long-term follow-up. In the absence of strong evidence about the auto-mobilization effect in the hip and knee pathology, Reiman, (2013) suggested an integrated program with a variety of hip self-mobilization techniques, in a variety starting positions, aiming to the improvement of the joint capsule and connective tissue mobility [49].

The limitations of the study are the convenient and small sample, in many starting positions the generalizability of findings compared to larger samples that would allow an extensive statistical analysis. We did not include any muscle strength measurement or kinematic analysis, so our results can not rely on possible changes in muscle patterns that connect hip and knee joint after manual therapy (MT) intervention. So, the implications for future studies would be the effect of MWM therapeutic protocol, based on muscular and kinematic parameters in pre and post-treatment phases, strengthening interpretation of clinical results and appropriately identifying the possible mechanisms of action. A follow-up study would integrate the long-term effect of MT on ITBS recreational runners.

CONCLUSION

ITBS, as an overuse syndrome with a multifactorial etiology, has been related to the unclear impact of proposed therapeutic conservative approaches, as well as their mechanisms of action. MWM is a safe and painless mobilization treatment, without contraindications, easy in application and featuring well in ITBS rehabilitation of recreational runners, as it appeared that can improve the clinical status of pain and functionality terms.

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