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Original Article

Effect of Lower Limb Strengthening Exercises on Severity of Restless Leg Syndrome among Diabetic Patients: A Time Series Study

Amina Sadaqat[1], Kainat Ahmar[2], Hafiza Rabia Javed[3], Ayesha Hamid[4] and Hira Shahid[5]

[1]Department of Physiotherapy, Life Care Hospital, Lahore, Pakistan
[2]University of South Asia, Lahore, Pakistan
[3]Life Care Institute of Pharmacy and Medical Sciences, Daska, Pakistan
[4]Muhammadi Eyecare Hospital, Lahore, Pakistan
[5]Abasyn University, Islamabad, Pakistan

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***Corresponding Author:**

Amina Sadaqat
Department of Physiotherapy, Life Care Hospital, Lahore, Pakistan
aminasadaqat57@gmail.com

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ABSTRACT

A disorder characterized by aching or burning sensations in the lower and rarely the upper extremities that occur prior to sleep or may awaken the patient from sleep. **Objective:** To evaluate the effect of lower limb strengthening exercises on the severity of restless leg syndrome (RLS) symptoms among diabetic patients. **Methods:** The time series Quasi experimental study design was conducted in the government sector (Services hospital) of Lahore for a sample size of 77 diabetic patients who were also suffering from RLS. In order to compensate dropout's data were collected from 150 patients, from March 2018 to September 2019. IRRLSG Criterion was used to screen out presence of RLS in diabetic patients. After taking written informed consent, baseline data were collected through a questionnaire of close ended questions and proformas with pictures of lower limb muscle strengthening exercises was given to all patients. Follow-ups were taken twice through phone calls after every four weeks and the difference in the scores was noted down in both groups. **Results:** Patients who performed strengthening exercises reported reduced symptoms of RLS whereas those who didn't perform exercises were excluded from the study. 96% patients reported reduced symptoms. While 4 patients did not have any improvement in their symptoms. At the end of 8 weeks majority had a significant improvement in the severity of their symptoms. **Conclusions:** It is concluded that an exercise program consisting of different strengthening exercises was effective in improving symptoms of RLS. No effort was made to discontinue medications that may aggravate RLS symptoms.

INTRODUCTION

Restless leg syndrome or Willis Ekbom disease is a sensorimotor disorder with an irresistible urge to move legs along with the uncomfortable sensations in lower extremities and a diurnal variation which is relieved with movement [1]. The patients complain of a burning sensation, of worms moving, of a sudden pulling movement of the leg, or of ants crawling within the legs. The sensations range from uneasiness to irritation and pain [2]. Mostly RLS symptoms arise at dusk but different studies showed an impact of RLS on daytime functioning. Problems are daytime sleepiness, physical dysfunction of both extremities and concentration problems [3]. A person with RLS does not need to be a couch potato he can reduce his symptoms through stretching exercises like calf stretch, front thigh stretches, hip flexor stretches. Yoga, cycling and swimming are additional exercises for RLS [4]. According to Aliasgharpour who conducted the study in Tehran confirmed stretching exercises by a sports

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medicine specialist and applied to the legs including hip rotation to the sides, quadriceps stretch, knee to chest stretch, hamstring stretch, gluteal stretch, straight leg raise, side-lying leg lift and so on. Each muscle was stretched to three sets often and duration of each was 5 seconds and these proved positive results in relieving the symptoms of RLS [5]. The prevalence rates of RLS have been reported to be approximately 10% in white populations of Europe and North America [6]. While in the general population it ranges from 5-10% that rises with age at least up to the eighth decade of life. The prevalence of RLS was generally approximately twice as high for women as it was for men [7]. The global prevalence of RLS is 2.5% to 15%. The diagnosis of RLS is purely based on the patient's history and symptoms; nevertheless, when the history and symptoms are too ambiguous, it is frequently ignored [8]. Dopamine antagonists have been used as first-line treatments for RLS, although they have been reported to aggravate symptoms in some patients a condition known as paradoxical worsening of symptoms [9]. Primary and Secondary are two types of RLS. Another disorder that can lead to RLS is Periodic Limb Movement Disorder (PLMD) that results in spasm of lower extremities during sleep. For instance, there are 2-types of RLS. Primary, or Idiopathic RLS-It has an unknown cause and is most probably inherited. It usually starts in childhood and is lifelong, while the symptoms typically worsen with age. Secondary RLS-Onset is sudden, and generally due to any medication, or other disease. It typically begins in mid-forties, and symptoms do not worsen with age. Symptoms can be due to arthritis, diabetes, pregnancy, iron deficiency kidney disease, different medications and many other causes [10]. Comorbidities of RLS are Pain: polyneuropathy, Somatoform pain disorder, Rheumatoid arthritis, and Fibromyalgia, Depressive and anxiety disorders, Insomnia [11]. A prospective study explained that people suffering from RLS more than three years were prone to get coronary heart problems [12]. Active smokers are 50% more prevalent to get RLS [13]. According to Dr Thompson, (pregnancy, obesity, smoking, and different medications) are major risk factors for RLS. Environmental factors like sleep deprivation and alcohol consumption also intensify the condition [14]. In 1995 International Restless Legs Syndrome Study Group (IRLSSG) along with its 28 members advanced the diagnostic criterion from clinical consensus RLS/WED. These points are used for screening of RLS [15]. Desire to move the legs not always associated with and uneasiness in the legs. An urge of moving legs along with uncomfortable sensations. Starts or worsens at the time of rest like lying. Relieves with mobility like stretching or walking or as long as movement is continued. Worsens especially during evening or at dawn. These characteristics can differ if it relates to another medical condition like arthritis. The urge to move the legs and any accompanying unpleasant sensations are partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues [15]. Dopamine precursors (Levodopa), Ergot-derived dopamine agonists (Ergotamine), Non-ergot- derived dopamine agonists (pramipexole), gabapentin clonazepam, opioids, and pregabalin. IRLS scores were significantly improved in those who received iron replacement therapy [16]. Different Exercises are used to alleviate symptoms of RLS. According to a supposition that reduction of blood flow to the limbs plays a significant role in this respect, pneumatic compression device is an alternative therapy for it. Massage therapy, sclerotherapy and Endovenous laser ablation are short term relieving treatment options [17]. These therapies reduce tissue hypoxia and have no side effects and are of less cost [16]. Conventional treatment for RLS is pharmacological in current practices. As per literature and search in data bases only one RCT and no Controlled trial have been conducted yet to determine effectiveness of physiotherapy exercises e.g. resisted exercises (strength training) etc. Our aim of this study was to assess the effect of lower limb strengthening exercises on the severity of RLS symptoms in diabetic patients.

METHODS

This Time Series study was initiated after taking the approval from institutional ethical review committee (IERC) with the objective to assess the effect of lower limb strengthening exercises on reducing the severity of RLS symptoms among diabetic's patients**.** It was conducted in diabetic government sector; Services hospital. The duration of the study was 7 months. The baseline data were collected within 1 month and first follow up was taken on phone call after 4 weeks and second follow up was taken after 8 weeks Analysis and writeup was done within 3 months. The sample size of 77 participants suffering from RLS (screened out from Diabetic patients according to literature-based criterion named as IRLSSG International Restless Leg Syndrome Study Group, while severity of RLS was measured through Restless Leg Syndrome Rating Scale in week 1, week 4 and week 8 using 5% margin of error, 95% confidence level and population proportion 11% response. Sample size was calculated through n4 studies app. Non-probability convenient sampling technique was used to recruit diabetic patients. Patients were informed about the study aims and that by completing a questionnaire they were provided with informed consent to participate in the study. Proformas of strengthening exercises as illustrated in (figure1) were also provided and according to inclusion & exclusion criteria, purposive

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sampling was used to screen out patients having RLS symptoms out of those diabetic patients the target population was diabetic patients and then out of them RLS patients were recruited. Data were collected from 150 patients and after covering drop outs the final sample size was 77 patients. All RLS Screened male and female diabetic patients both of type 1 and type 2 diabetes mellitus were included in the study of age 30-70. Diabetic patients suffering from related comorbidities like hypertension, Ischemic Heart disease etc. were also included in the study. Participants having Gestational diabetes and those suffering from recent injuries of low back pain, trauma, injuries, falls, gangrene, and amputation were excluded from the study. Dependent Diabetic patients with limited mobility or Diabetics suffering from major organ dysfunction like renal failure, Multiple sclerosis, arterial & venous insufficiency were also excluded from the study. Descriptive statistics like mean and standard deviation was calculated for quantitative variables. Frequency and percentages were calculated for categorical variables. Freidman test was applied to evaluate the differences between pre interventional and first and second post interventional readings. Wilcoxon test was used to evaluate the pairwise differences between pre interventional and first and second post interventional readings. The p-value <0.05 was taken as significant. The analysis of the data was done by the help of IBM SPSS (Statistical Package for the Social Sciences) version 21.0.

RESULTS

As Table 1 shows that out of 77 participants 10.4% were having age between 30-40, whereas 35.1% were having age between 41-50, 29.9% were having age between 51-60 years and 24.7% were having age between 61-70%. There were 35 males (45.5) and 42 females (54.5). 76 persons were married (98.7) and one was unmarried (1.3).

Table 1: Descriptive Statistics of Age, Gender & marital status

Variables		Frequency (%)
Age (years)	30-40	8(10.4)
	41-50	27(35.1)
	51-60	23(29.9)
	61-70	19(24.7)
Gender	Male	35(45.5)
	Female	42(54.5)
Marital status	Married	76(98.7)
	Unmarried	1(1.3)

Table 2 shows Forty-four patients (57.1) were suffering from type I and thirty-three (42.9) from type II. Thirty-nine persons (50.6) were having diabetes from less than 5 years. Twenty persons (26.0) were having diabetes from more than 5 years. Eight persons (10.4) were having diabetes from less than 10 years. Ten persons (13.0) were having diabetes for more than 10 years.

Table 2: Descriptive Statistics of type duration and treatment of diabetes

Descriptive Statistics		Frequency (%)
Type	Type-I	44(57.1)
	Type -II	33(42.9)
Duration	<5 years	39(50.6)
	>5 years	20(26)
	<10 years	8(10.4)
	>10 years	10(13)
Treatment	Oral hypoglycemics	45(58.4)
	Insulin	19(24.7)
	Both	13(16.9)

In table 3 the results show that patients had significant differences among themselves in terms of intensity of RLS symptoms during the pre-intervention period and post-intervention period of 8 weeks the intensity of RLS symptoms decreased with the lower limb strengthening program as per guidance. So, p-value (p=0.001) showed the results are highly significant.

Table 3: Difference between pre intervention and post intervention values in terms of Intensity of RLS

Variables	z-value	Mean Rank	Chi-square Value	p-value
Intensity of RLS	-	-	129.72	0.001
Intensity of RLS – Pre-intervention	-	2.88	-	-
Intensity of RLS after 4 weeks -Post Intervention	-	1.92	-	-
Intensity of RLS after 8 weeks -Post Intervention	-	1.18	-	-
Pairwise comparison				
Intensity of RLS after 4 weeks-Intensity of RLS	-7.47	-	-	0.001
Intensity of RLS after 8 weeks -Intensity of RLS	-7.75	-	-	0.001
Intensity of RLS after 8 weeks -Intensity of RLS after 4 weeks	-6.94	-	-	0.001

*Significant value is p>0.05
**Friedman test of comparison
***Wilcoxon Signed Ranks Test of differences

Table 4 states that patients had significant difference in term of relief of RLS symptoms after performing strengthening exercise as per guided. The symptoms decrease after 8 weeks of intervention plan and p-value (p=0.001) indicates that the results were highly significant. So lower limb strengthening exercises have great impact on RLS symptoms.

Table 4: Difference between pre intervention and post intervention values in terms of Relief of RLS from movement

Variables	z-value	Mean Rank	Chi-square Value	p-value
Relief of RLS from movement	-	-	82.46	0.001
Relief of RLS from movement-Pre- intervention	-	2.65	-	-
Relief of RLS from movement after 4 weeks-post intervention	-	1.97	-	-
Relief of RLS from movement after 8 weeks-post intervention	-	1.38	-	-

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Pairwise comparison				
Relief of RLS from movement after 4 weeks- Relief of RLS from movement	-5.77	-	-	0.001
Relief of RLS from movement after 8 weeks-Relief of RLS from movement	-6.74	-	-	0.001
Relief of RLS from movement after 8 weeks-Relief of RLS from movement	-5.51	-	-	0.001

Leg extension, abduction, straight leg press, calf press, leg curls, ankle dorsiflexion and ankle plantarflexion are the exercise regime of strengthening exercises that were Prescribed to patients to improve the symptoms that were arising from RLS(Figure 1).

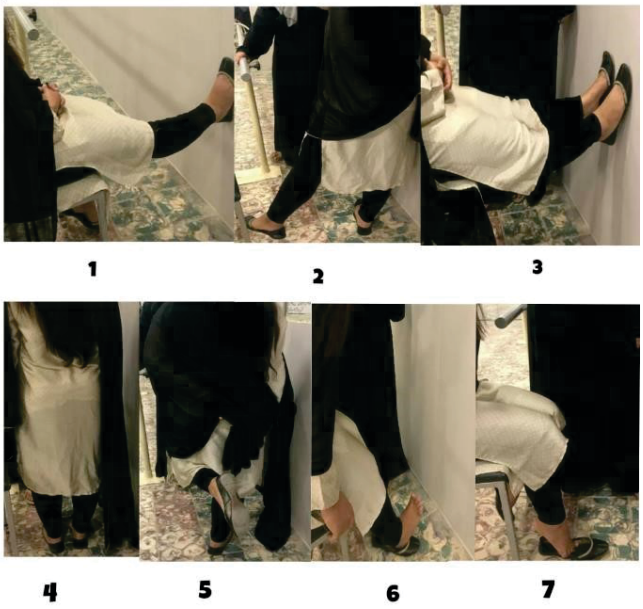

Figure 1: Exercise program prescribed to the patients

DISCUSSION

Our study was conducted in government sectors (Services and Jinnah hospital) of Lahore while the sample size was 77 but we took data of 150 patients to cover up dropouts. Our study design was quasi experimental design (time series design). For the first time, we visited patients and after diagnosing RLS according to the criterion given by International RLS study group and knowing the severity, we gave them proformas for strengthening exercises for the improvement of RLS symptoms. After this we contacted the patients after four weeks through calls to know about their improvement and got positive results and some dropouts. Last reading was taken after next four weeks that gave us remarkable improvement in relieving symptoms of RLS. A randomized control trial published by Aukerman *et al.*, examined how the exercise program reduces symptoms of RLS. The results were remarkably effective in the exercise group relative to the control group. The technique mentioned in each of these trials, however, was different, namely Aerobic activity and Leg Strengthening exercise. There is a one-third discrepancy in the number of participants. In our study, individuals who were provided training sessions improved significantly as well [18]. A meta-analysis was performed by Song *et al.*, RN who investigated either exercise is effective in relieving the symptoms of RLS. It was reported that strength training, resisted exercises combined with different regimes reduced the symptoms so it was recommended. And in our study patients who performed strengthening exercises also got relieved from severe symptoms of RLS [19]. An observational study directed by Daniele *et al.*, on diabetic patients to investigate association between physical activity and quality of life. It was concluded that active lifestyle overcomes the pain and physical limitation in diabetics with RLS. Our study is also similar to these results. In Thiago's trials, however, no specific intervention was employed, and physical mobility was the sole focus; however, in this study, specific exercise was prescribed for each patient, and the outcomes improved; therefore, it is preferable for diabetic patients with RLS to adopt a particular pattern of exercise rather than a general one [20]. Dinkins and Stevens-Lapsley examined the effect or enhancement of the traction straight led test on RLS patients in a study. His investigation involved 13 participants. It was determined that patients who followed the straight leg test subsequently improved. In addition to the straight leg test, other interventions such as abduction, pressing, plantar and dorsiflexion training regimes were included in our study, and the results were identical to those obtained by Dinkins. In the future, it will be possible to draw a conclusion based on a comparison between the straight led test and leg strengthening activities that combine only the straight leg test along with other exercise regimens [21].

CONCLUSIONS

During the 8-week intervention period, the results of this study indicate that following a lower limb strengthening exercise program significantly reduced RLS symptoms. Patients reported statistically significant reductions in both the severity and alleviation of RLS symptoms. It suggests that leg strengthening exercises can have a significant beneficial influence on the symptoms of restless legs syndrome.

Authors Contribution

Conceptualization: AS
Methodology: KA, HRJ, AH, HS
Formal Analysis: KA, HRJ, AH, HS
Writing-review and editing: AS, KA, HRJ, AH, HS

All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interest.

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