Efficacy of Pilate's Exercise with Postural Advice in the Management of Low Back Pain for Lower Limb Amputee Patients: A Randomised Control Trial

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Abstract:

Objective: To observe the effectiveness of Pilate's exercise, with postural advice to reduce low back pain for lower limb amputee patients.

Material and Methods: An assessor-blind, randomised control trial design has been used wherein sixty-two patients were divided into two groups by simple random allocation. The experimental group received the Pilates' Training Program with postural advice, and the control group received usual care at the prosthetic department. There were thrity-one participants in both groups that completed the study. Both groups attended a 15-minute specialized, supervised session; 5 days a week, for 4 weeks. Outcomes were measured in terms of pain by a numeric pain rating scale and specific function & disability of the lumbo-pelvic region by the Roland-Morris Low Back Pain and Disability Questionnaire. Descriptive (median and inter quartile range, IQR) and inferential statistics (Pearson Chi-square test, Mann-Whitney U test and Wilcoxon Signed Rank Test) were performed to analyse the data through the Statistical Package for Social Sciences (SPSS), Windows version 25 (IBM, Armonk, NY, USA).

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Results: Average age of participants was 33 (29.75 to 47.50) years; whereas, the average duration of amputation in the experimental group was 11 (7 to 13) months compared to 8 (6 to 11) months in the control group. Both groups showed significant improvement in terms of pain intensity and functional ability in intergroup analysis (p-value<0.05); additionally, in intra-group analysis participants that received Pilate's exercise with postural advice had better outcomes than participants who received only postural advice (p-value<0.05).

Conclusions: It was concluded that Pilate's exercise with postural advice is effective in the rehabilitation of patients with lower limb amputee-induced low back pain. Additionally, Pilate's exercises with postural advice also led to better improvement in mechanical correction of the lumbo pelvic region.

Keywords: Pilate's exercise, postural advice, low back pain, lower limb amputee

Introduction

Amputation, one of the earliest surgical treatment options, is the removal of a part or complete limb as a result of disease or accident, having first appeared in the sixteenth century¹. On average, lower limb amputations have occurred more frequently than upper limb amputations². Additionally, the incidence rate varies significantly by nation and depends on elements; such as: socioeconomic position, location, severity of trauma, how long people wait to seek medical attention and the clinical staff's judgement³⁻⁵. Globally, the incidence rate of lower limb amputation has been estimated to be 5.8 to 31.0 per 100,000 civilians⁶. However, as improvised explosive device (IED) injuries are so penetrating, this rate is substantially higher among military personnel⁷.

People having had lower leg amputation frequently experience persistent pain, which may be considered as a significant factor in subsequent disability. Even if lower-limb amputations are associated with phantom pain and uncomfortable stumps⁸, recent studies have also show that lower limb amputees have low back discomfort more frequently than the general population⁹. Low back pain affects lower-limb amputees 71% of the time, which is a significant percentage. In a United States survey of amputees, it was shown that 52% of those with lower limb amputations suffer from chronic, unpleasant back pain, with

25% saying the discomfort is frequent and significantly limits daily activities¹⁰. The mechanism behind this phenomenon can be aberrant trunk and pelvis motor behavior, secondary to lower-limb loss, which potentially alters trunk postural control and increases demands on the trunk musculature for stability¹¹.

Currently, there are several different therapeutic approaches that may be used to address persistent low back pain¹². A generally accepted Spine Exercise Program is a multidisciplinary exercise program that incorporates flexibility exercises, ergonomic recommendations, posture correction, strength training for superficial and deep spinal muscles, and awareness of the condition^{13,14}. Another is the comprehensive body training program for the growth of the body and mind that encourages improved posture and body awareness, which was initially created by Joseph H. Pilates^{15,16}. It is founded on the concept of: "Contrology", also known as the Pilates technique, which, while being relatively new, is increasingly being used to improve both the aesthetics and therapeutic effects of the body¹⁷. Its methods primarily use isometric contractions of the core muscles, often known as the: "powerhouse", in order to particularly train them¹⁸. These act as the body's stabilizing muscle center, which controls both the body's static and dynamic stability¹⁹ and these exercises are said to be comparable to spinal stabilization exercises²⁰.

Numerous studies have examined treatments for low back pain in healthy people, but none have examined the impact of this kind of exercise on low back pain in amputees, who have lost their lower limbs. Hence, the purpose of this study was to enumerate that the Pilate's exercise and posture instruction effectively can treat low back pain in individuals with lower limb amputees.

Material and Methods

This was a single-blinded randomized controlled clinical trial, conducted in the Prosthetics & Orthotics unit of the Physiotherapy Department of Centre for the Rehabilitation of the Paralysed (CRP), Savar, Dhaka, Bangladesh; from October to December, 2022. Eighty lower limb amputee patients with back pain were screened from the Prosthetics & Orthotics unit of the physiotherapy department of CRP, Savar. The simple random sampling technique was used to draw out the samples from the population in this study. When considering an 80% power (β) and 5% margin of error (δ), a total of sixty-two lower limb amputee patients with back pain were selected from the outdoor Prosthetics and Orthotics department of CRP, Savar, Dhaka, Bangladesh; after conducting the sample size calculation. After sample collection, the researcher used a computerised random allocation technique to assign participants into either the experimental or control group. From this, 31 patients were randomly assigned to the experimental group comprising of Pilate's exercise with postural advice, and the same number were assigned to the control group without any specific back care management for this study. The participants were first screened in accordance with the inclusion and exclusion criteria, and simple random sampling improved the internal validity of this experimental research. Informed consent was obtained from the parents or legal guardians of all individuals included in this study.

Inclusion criteria were: male patients having had unilateral lower limb amputation with back pain; age range was 10-50 years, and new or follow-up prosthetic users. Exclusion criteria were: patients who were in their trial version of prosthesis fitting, had any upper limb disability, evidence of phantom pain and history of pathological disease.

The trial study was approved by the Institutional Review Board (IRB) of BHPI (CRP/BHPI/IRB/10/2022/661), the academic Institute of CRP, Bangladesh. The trial has been registered with Clinical Trial Registry – India (CTRI) (CTRI/ 2022/11/047000), which is a Primary trial registry of the WHO, and affiliated with the International Committee of Medical Journal Editors (ICMJE).

Outcome measurement tools were: the Numeric Pain Rating Scale for pain intensity and the Roland–Morris Low Back Pain and Disability Questionnaire to measure level of disability.

The Numerical pain rating scale is a simple and accurate way of subjectively assessing pain along a continuous visual spectrum. It comprises of a straight line, on which the person being assessed marks the level of pain. The ends of the straight line are the extreme limits of pain with: 0 representing no pain, 1–3 mild pain, 4–6 moderate pain and 7–10 representing the worst pain ever experienced²¹.

The Roland-Morris Low Back Pain and Disability Questionnaire is a 24-item self-reporting questionnaire in concerns to how low-back pain affects functional activities. Each question is worth one point, so scores can range from: 0 (no disability) to 24 (severe disability)²².

Statistical analysis was conducted via IBM SPSS v. 25 software. The Kolmogorov–Smirnov test was used to determine the normal distribution of data. A Mann–Whitney test was used to compare scores in between groups and a Wilcoxon Signed Rank test was used to compare within– group changes. Statistical significance level was set at 0.05. No intention to treat protocol was followed in this study.

Participants in the experimental group received Pilate's exercise (10 repetitions of four exercises, for 15 minutes of specialized, supervised session; 5 days a week, for 4 weeks), with postural advice during sitting, standing, walking and weight lifting. The participants were trained for all exercises on the first day of initial assessment and the Pilate's exercise was performed at the centre under supervision of a physiotherapist with prosthetic training (Figure 2). The control group, participants only received prosthetic training; as per the guidelines of the prothetics and orthotics (P&O) outpatient department of CRP, for four weeks. Each participant received 20 sessions during the rehabilitation period.



Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flowchart of the study







Figure 2 Pilate's exercise of amputee patients in different positions

Results

The socio-demographic and clinical information of the participants for both groups is summarised in Table 1. The average age of the total participants was 33 (29.75 to 47.50) years. The average duration of amputation in the experimental group was 11 (7 to 13) months; whereas, in the control group this was 8 (6 to 11) months. In the experimental group the mean duration of wearing prosthesis was 2 (2 to 3) months; in contrast, in the control group this was 2 (2 to 2) months. Most of the participant, in the both groups, had higher secondary certificate (HSC) and a higher level of education (50%, n=3). Most of the

participants in the experimental group were unemployed (40%, n=4); whereas, most in the control group were waged employees (50%, n=5). Approximately, 70% (n=7) had transfemoral amputation, followed by 50% (n=5) in the experimental group. Most of the participants in both groups had complained about pain in both lower limbs: 40% (n=4) in the experimental group and 30% (n=3) in the control group, respectively, and most of them, within both groups, had a burning type of pain.

From the intergroup analysis, between both groups, there was significant improvement (p-value<0.01) in pain intensity and functional ability (Table 2). The mean difference between baseline and after treatment was higher in the experimental group than in the control group.

From intragroup analysis, there was significant improvement of pain intensity and functional ability found among the experimental group participants (p-value<0.01); however, there were no significant changes found in the

Table 1 Socio-demographic and clinical characteristics of participants

Variables	Experimental % (n)	Control % (n)	p-value
Age of the participants (years) Median (IQR)	33 (29.75 to	0 47.50)	
Duration of amputation (months) Median (IQR)	11 (7 to 13)	8 (6 to 11)	0.067 ^ª
Duration of using prosthesis (months) Median (IQR) Education	2 (2 to 3)	2 (2 to 2)	0.378ª
Illiterate	19.4 (6)	29.0 (9)	0.246 ^b
Up to SSC and SSC	38.7 (12)	19.4 (6)	
HSC and above Occupation	42.0 (13)	51.6 (16)	
Waged employed	29.0 (9)	51.6 (16)	0.860 ^b
Self employed	51.6 (16)	19.4 (6)	
Unemployed	19.4 (6)	29.0 (9)	
Level of amputation		(-)	
Transtibial	58.1 (18)	29.0 (9)	0.490 ^b
Transfemoral	41.9 (13)	71.0 (22)	
Site of amputation		. ,	
Right leg	38.7 (12)	51.1 (18)	0.197 ^b
Left leg	51.6 (16)	41.9 (13)	
Bilateral	9.7 (3)	-	
Use of prosthesis device			
Only prosthesis	71.0 (22)	41.9 (13)	0.490 ^b
Prosthesis with other mobility aids	29(9)	58.1 (18)	
Location of pain			
Back and one L/L	19.4 (6)	29.0 (9)	0.543 ^b
Back and both L/L	38.7 (12)	61.3 (19)	
Only back	42.0 (13)	9.7 (3)	
Characteristics of pain			
Burning	80.6 (25)	51.6 (16)	0.197 ^b
Paresthesia	19.4 (6)	48.4 (15)	

IQR=interquartile range, SSC=secondary school certificate, HSC=higher secondary certificate, L/L=lower limb a=Mann-Whitney U test, b=Pearson Chi-square test

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Numeric pain rating scale	Experimental (n=31) Median (IQR)		Control (n=31) Median (IQR)		p-value
	Baseline	After treatment	Baseline	After treatment	p tuite
Pain right now	5 (5 to 7)	2 (2 to 2)	6 (6 to 7)	5 (5 to 6)	0.001*
Usual Pain in last week	5 (5 to 6)	2 (2 to 2)	5 (5 to 6)	4 (4 to 5)	0.001*
Best level of pain in last week	4 (4 to 5)	1 (1 to 2)	5 (5 to 6)	5 (5 to 5)	0.001*
Worst pain in last week	7 (7 to 8)	4 (3 to 4)	8 (8 to 9)	7 (7 to 8)	0.001*
Roland-Morris Low Back Pain and Disability Questionnaire	5 (4 to 6)	2 (1 to 2)	6 (6 to 6.25)	6 (5 to 6)	0.001*

Table 2 Intergroup analysis of pain intensity of the participants, after completing rehabilitation (Mann-Whitney U test)

*significant at 95% confidence level, IQR=interquartile range

Table 3 Intragroup analysis of pain intensity of the participants (Wilcoxon Signed Rank Test)

Numeric pain rating scale	Experimental (n=31)		Control (n=31)	
	z	p-value	z	p-value
Pain right now	2.850	0.004*	2.460	0.064
Usual Pain in last week	2.840	0.005*	1.520	0.317
Best level of pain in last week	2.842	0.004*	1.537	0.397
Worst pain in last week	2.972	0.003*	1.080	0.560
Roland-Morris Low Back Pain and Disability Questionnaire	2.823	0.005*	1.890	0.059

*significant at 95% confidence level

control group (p-value>0.05). Hence, Pilates training with postural advice was shown to have better outcomes than that of the standard care provided from the prosthetics and orthotics department of CRP (Table 3).

Functional improvement level of low back pain and disability for people with lower limb amputation after treatment (Roland-Morris Low Back Pain and Disability Questionnaire)

Figure 3: showing the percentage of an individual's improvement whom are suffering from low back pain and disability. Around 33.9% (n=21) participants had 91 to 120 percent improvement after taking treatment for LBP and disability, which is the highest among all others. Meanwhile, 1 to 30 percent improvement and 31 to 60

percent improvements have been reported among 29% (n=18) and 21% (n=13) of participants, respectively. The least amount of participants, which was 16.1% (n=10) had 61 to 90 percentage improvement.

Discussion

In this study, firstly the researcher observed some socio-demographical and clinical characteristics of patients. Significant improvements were found (p-value<0.01) in pain intensity and functional improvement in between the experimental group and control group (Table 2). Additionally, observed was the mean difference for withingroup participants on the scale of pain and functional improvement. The value does not represent a clinically significant improvement if a minimum difference is less



Overall improvement level of low back pain and disability

Figure 3 Overall improvement level of low back pain and disability

than 2 points^{23,24}. This study outcome showed a significant improvement in pain intensity and functional ability via the mean difference between the experimental and control groups. Furthermore, the mean difference of the experimental group was greater than 2 points, for every numeric pain rating scale, and was, therefore, greater compared to the control group of patients. This approach results in better motor control, because they focus on trunk muscles and breathing control that ultimately facilitates the activity of muscles involved in lumbopelvic stability²⁵, and as it is supported with Pilates-based activities it may have reduced discomfort²⁶. Gladwell et al. stated that the 8-week Pilates exercises significantly improved lumbopelvic motor control and spinal muscle flexibility²⁷. The increased recruitment and co-contraction of core muscles; such as the transverse abdominis and multifidus which increase effective control of both local and global spinal stability, may be the cause of the pain reduction²⁸⁻³⁰; as this action reduces compressive overloads and eliminates pain perception.

It is well acknowledged that muscle dysfunction in LBP is caused by altered neuromuscular control processes, which decrease the trunk's muscular stability and movement effectiveness. Improved neuromuscular coordination results from the Pilates movements' adherence to the Centring, Control, Concentration, Precision, and regular breathing principles. Additionally, avoiding sloppy, uncontrolled motions improves motor control even more. This may be the cause of increased stability³¹. According to Norris, the body expects the commencement of the limb load in Pilate's exercises since it is predictable. As a result, the transverse abdominis is pre–set, which may again improve stability³².

The Pilate's method is a combination of static and dynamic stretching exercises that are proper and safe to provide increased flexibility, based on the neurophysiological properties of contractile tissue²⁴. In this study, significant improvement (p-value<0.01) was found in the experimental group of patients; however, there was no significant improvement found in the control group patients (p-value>0.05). From this significant result, it was observed that Pilate's exercise with postural advice is effective for low back pain of lower limb amputee patients.

This is supported by the overall improvements; wherein: 33.9% of participants had 91 to 120 percent improvement after getting treatment, 29% of participants had an improvement of 1 to 30 percent, 21% of participants had an improvement of 31 to 60 percent and the last amount of 16.1% participates had improvement 61 to 90 percent. Pilates routines, on the other hand, emphasize maintaining the contraction of the core throughout the whole activity. This might account for the Pilates group's much greater gain in core muscular endurance as compared to the Conventional Exercise Group³³.

There are only a few restrictions affecting this study's strength; including its small sample size and that the multicentre was double-blind in nature. Nevertheless, this study was still adequately powered, despite its small sample size.

Conclusion

It was concluded that Pilate's exercise with postural advice is effective in the rehabilitation of patients with lower limb amputee-induced low back pain. However, Pilate's exercises lead to better improvement in disability, pain and flexibility that focused on core stability, control of muscle, breathing, strengthen stretching, posture and conscious use of core muscles to stabilize the lumbo-pelvic region.

Conflict of interest

All the authors declare that they do not have any conflicts of interest.

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