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THERAPEUTIC EFFICACY OF MYOFASCIAL RELEASE FOR PATIENTS WITH KNEE OSTEOARTHRITIS: A RANDOMIZED CLINICAL TRIAL

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Abstract: *The study compared the effect of Myofascial release (MFR) on Quadriceps, Gastrocnemius, and Iliotibial (IT) Band along with conventional care (MFRC) and conventional care (CC) alone in patients with Knee Osteoarthritis. Sixty-four (n=64) patients between the ages of 40 and 70 who had been given an ICD-10-based diagnosis of osteoarthritis. By hospital randomization and concealed allocation, participants were equally distributed between the MFR with conventional treatment (n=31) and conventional care (n=32) groups. In this assessor-blinded randomized clinical trial, MFRC and CC groups received 12 sessions of treatment over 4 weeks. The numerical pain rating scale (NPRS) was used to measure pain and universal goniometer to measure ROM, Manual muscle testing (MMT) to measure muscle strength, and The Western Ontario and McMaster Universities Arthritis Index (WOMAC) scale to measure disability. The result shows that both groups had significant outcomes compared to baseline (p<.05) in pain, disability, ROM, and muscle strength except for the hamstring. The experimental group's outcome was superior to the conventional group in all outcome measures (p<.05). The study reveals Myofascial release combined with conventional care is more effective than conventional care alone for patients with Knee Osteoarthritis.*

Keywords: Knee Osteoarthritis, Myofascial Release, Physiotherapy, Pain, Disability.

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1.0 Introduction

The global burden of disease study in 2010 reports, hip and knee osteoarthritis (OA) is the eleventh prime reason for disability [1]. It is a chronic joint disorder affecting more than 250 million individuals globally with a significant impact on health care and social issues [2]. In addition to the knee, OA mainly affects the lower back and smaller peripheral joints including the hands and ankle [3]. Statistical studies comparing the incidence of osteoarthritis found that women tend to have severe knee and hip OA compared to men, especially those above 55 years of age [4]. While OA may be inherited, its growth is connected with several risk factors such as aging, body mass index, extreme mechanical loading, bodily activities, and an insufficient supply of nutrients. [5]. At first, osteoarthritis used to view as a syndrome which has been affected the articular cartilage only but later research has shown that the condition includes the whole joint of the knee [6, 7]. The frequency of osteoarthritis is intensifying due to the elderly population and the wide-ranging of obese individuals that lead to management including therapeutic, pharmacological, and operative methods [8]. The whole management program for knee OA is usually established after the assessment of the patient, according to the signs and symptoms of the disease state, disease phase, therapeutic and clinical history of the patient, and his/her condition health [9]. Suitable knee OA management is generally incorporated with biomechanical procedures, intra-articular corticosteroids, ground, and water-based exercises, education as well as self-management, strengthening exercises, and management of weight [10].

However, the main goal of OA treatment is to control these joints' uncomfortable and severe symptoms as well as to improve their functionality and quality of life, for which non-pharmacological treatments should always be used as the first line of defense [11]. Exercise and physiotherapy are one of the foremost talked about and disputable non-pharmacologic administration methodologies for OA [12]. As pain and physical dysfunction of knee OA can also occur due to myofascial pain or dysfunctions, the physiotherapist generally provides myofascial releases [13]. Myofascial release (MFR) is one of the frequently applied mechanical approaches that generally enhance soft tissue extensibility with the help of compression or reestablishing the limited fascia/ordinary muscle length by mechanical forces of low load and lengthy duration [14]. Among the distinct methods that operate on the structures of fascial tissue, the method of myofascial Release technique (MRF) was regarded to have pain lessening potentiality, improvement of flexibility, reduction of disability, and hence the improvement of function in daily living activities [15, 16].

2.0 Objectives of the Study

2.1 General objective

To identify the efficacy of Myofascial Release on Quadriceps, Gastrocnemius, and Iliotibial (IT) Band in knee osteoarthritis.

2.2 Specific objectives

1. To explore the socio-demographic related information of knee OA patients with myofascial trigger points.
2. To find out the comparisons of pain status in experimental and control group after introducing myofascial release.
3. To determine the range of motion and muscle power in experimental and control group after providing myofascial release.
4. To estimate the status of disability in experimental and control group after applying myofascial release.

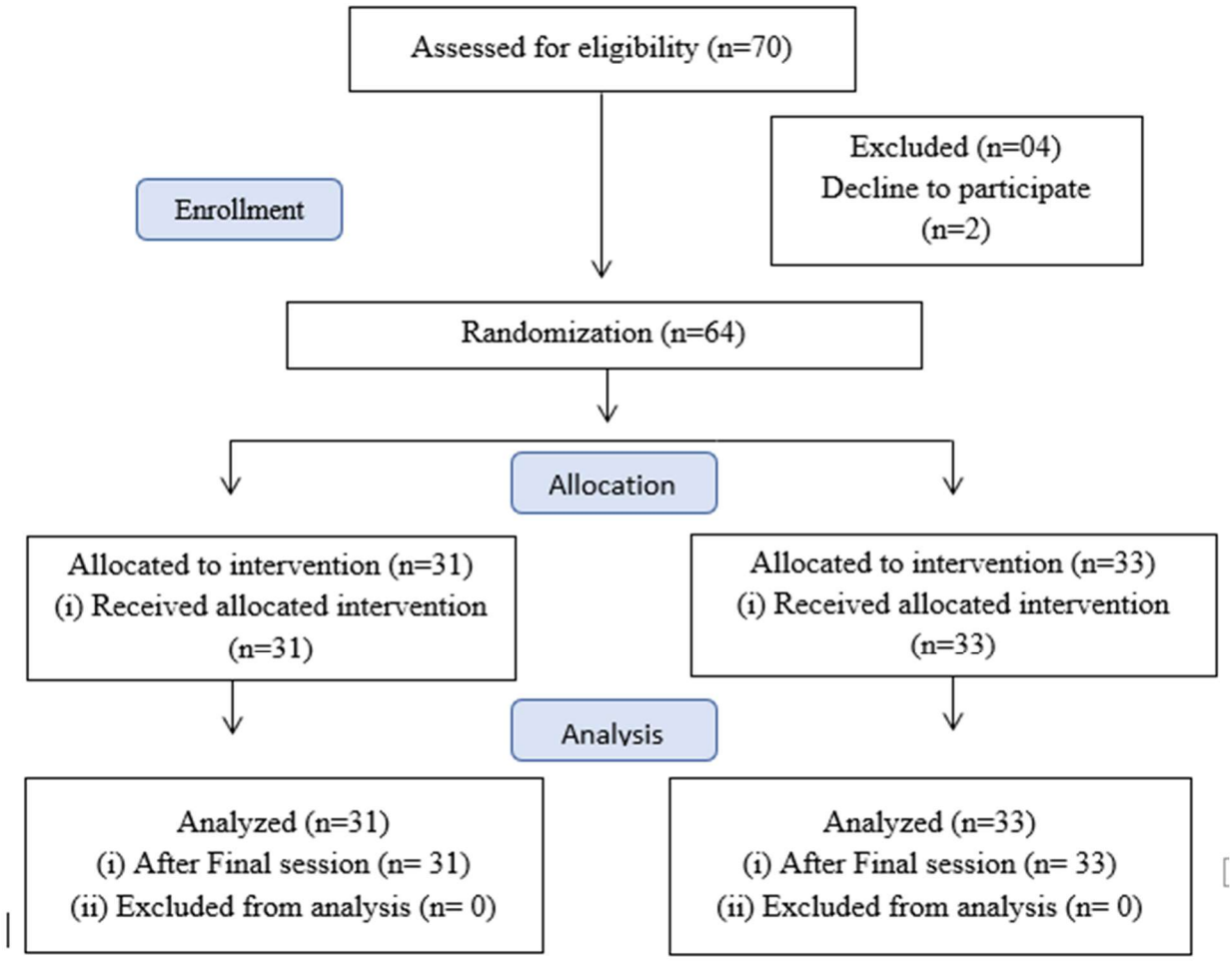
3.0 Limitations of the Study

In this study the sample size was really very small, so the result is difficult to generalize among whole population and the subjects with wide age range group between 40 to 70 years, thus results could not be generalized to individual age. This research was carried out in CRP, Savar such a small environment, so it was difficult to keep confidential the aims of the study for blinding procedure. Therefore, single blind method was used in this study. Moreover, there was no available research done this area in Bangladesh. So, relevant information about knee osteoarthritis patient with specific myofascial intervention for Bangladesh was very limited in this study. Though Ethical Review Board (ERB) permission has been achieved, clinical registration trial needed to be taken either.

4.0 Methodology of the study

4.1 Objects and Methods

A 12-month randomized clinical trial with assessor blinding was conducted at the Centre for the Rehabilitation of the Paralyzed in Savar, Bangladesh. The BHPI Institutional Review Board (IRB) gave its approval to the study. The study followed to CONSORT (Consolidated Standards of Reporting Trials) criteria (Figure 1).



4.2 Patients

70 patients aged 40-70 years with a diagnosis of Osteoarthritis in accordance with ICD-10 were enrolled in the trial using hospital randomization. Sixty-four (n=64) subjects were assigned after giving their voluntary written agreement and meeting the eligibility criterias, to either MFR with the conventional care (MFRC) group or only the conventional care (CC) group by computer-generated concealed allocation. The Sixty-four (n=64) subjects who meet the inclusion criteria's (diagnosis of Knee OA according to American College of Rheumatology, bilateral knee OA pain who have myofascial trigger points in lower extremities and age range between 40-70 years, Both male & female patients) and exclusion criteria's (Clinical conditions that may have deteriorated with myofascial release such as skin disease, dermatitis, eczema, any history of rheumatic diseases or severe impairment, such as the inability to walk without crutches, contraindications on using physical modalities or with neurological impairments, mentally unstable and had previous history of taking injection of intra-articular corticosteroids within the previous six months) were assigned as samples by using the simple random sampling technique from musculoskeletal unit of physiotherapy department of CRP, Savar, after voluntary written consent, to either MFR with

conventional care group or only conventional care group by computer-generated concealed allocation.

4.3 Interventions

A standard intervention program was carried out for both groups as conventional physiotherapy (CC) that consists of Stretching, Muscle strengthening such as static quad sets in knee extension, Manual therapy technique (Mobilization grades, Soft tissue mobilization), and Cryotherapy which is the most frequently used intervention for knee OA patients. In addition, for the experimental group, the myofascial release (MFRC) was applied along with the conventional physiotherapy by the clinical physiotherapists of CRP, musculoskeletal unit. The duration of the treatment session ranged between 20 to 30 min per day for 3-4 days per week for 12 sessions (Table 1) (Figure 3) [13, 17, 18]. A skilled physical therapist with extensive in-service training who follow the particular treatment plan of interventions. All of the assessments were completed by one assessor who was blind of the assignment. Prior to treatment, baseline data were gathered, and they were repeated after 12 sessions (3 sessions, 4 weeks) of therapy in a hospital setting.

Table 1: Treatment for CC and MFRC Groups

CC group treatment protocol		**MFRC group treatment protocol**	
Treatment Options	**Duration/Repetitions**	**Treatment Options**	**Duration/Repetitions**
Sustain Manual Stretching	15-35 sec hold with 3-5 repetitions	Vastus medialis release	5 minutes per session with 3-4days per week
Static quad sets in Knee extension	10-sec contraction with 10 repetitions	Vastus lateralis release	5 minutes per session with 3-4days per week
Maitland mobilization	Grade I, II, and III for 10 repetitions	Iliotibial band release	5 minutes per session with 3-4days per week
Soft tissue mobilization	1-3 repetitions with 30sec hold per area	Gastrocnemius release	5 minutes per session with 3-4days per week
Cryotherapy	5-10 minutes for 5 days per week	Vastus Intermedialis release	5 minutes per session with 3-4days per week

4.4 Outcome measurements

The Numeric Pain Rating Scale (NPRS) was used as a measurement tool for measuring the primary outcomes such as pain intensity and the Goniometer was also used as a measurement tool for a range of motion. For secondary outcomes, The Western Ontario and McMaster Osteoarthritis Index (WOMAC) was used as a measurement tool for measuring functional disability, and the Manual muscle testing scale (MMT) was for measuring the estimated muscle strength by a 10-point manual muscle testing process. With the help of an independent data collector, an assessor

who was blind to the randomization evaluated the baseline and post-test data to guarantee reliability.

5.0 Analysis, Result & Discussion of the Study

5.1 Statistical analysis

Data entry and checking the quality of data were surveyed by a different operator who was blinded to the process of data collection. All statistical analysis was performed using SPSS statistical software version 22. As the data were not normally distributed for between-group comparisons that were determined through Kolmogorov–Smirnov test (P<.05). Considering non-parametric analysis, Mann Whitney "U" test was used to analyze the pain, disability, range of motion, and muscle strength of both control and trial groups and for within-group comparison of the pain, disability, range of motion and muscle strength, was analyzed by Wilcoxon signed rank test. For all the tests, a 5% level of significance was set.

5.2 Results

All the study objectives were fulfilled as the result shows that both groups had significant outcomes compared to baseline (p<.05) in pain, disability, ROM, and muscle strength except for the hamstring. The experimental group's outcome was superior to the conventional group in all outcome measures (p<.05).

In total sixty-four (n=64) participants, the mean age range of the experimental group was 57.65±7.81 years and the mean age range of the control group was 53.70±8.42 years and in terms of gender, in the experimental group 61.3% (n=19) was male and 38.7% (n=12) was female and in control group among 33 participants 48.5% (n=16) was male and 51.5% (n=17) was female. Among 31 participants in the experimental group, the highest number of participant's educational level was Primary school 29% (n=9), then secondary school was 22% (n=7) and 16.1% (n=5) was Illiterate and in the control group, 30.3% (n=10) was finished primary school, 27.3% (n=9) was completed secondary school, 6.1% (n=2) accomplished Masters and 15.2% (n=5) was Illiterate. The demographic characteristics and differences between the groups' baselines have been shown in Table 2.

Table 2: Baseline compatibility of the respondents

Variables		Experimental	Control	P
		n=31	n=33	
Age [a]	Mean (SD), years	57.65±7.81 years	53.70±8.42 years	.3
Gender [b]	Male Female	19 (61.3%) 12 (38.7%)	16 (48.5%) 17 (51.5%)	.28

Education [b]	Primary	9 (29%)	10 (30.3%)	.33
	Secondary	7 (22%)	9 (27.3%)	
	Higher Secondary	2 (6.5%)	2 (6.1%)	
	Bachelors	4 (12.9%)	2 (6.1%)	
	Masters	4 (12.9%)	5 (15.2%)	
	Illiterate	5 (16.1%)	5 (15.2%)	

[a] Pearson Correlation test, [b] Chi-square test; P<.05

Table 3 shows pre-post-intervention among different variables values and between-group changes scores with associated 95% CI. Mann Whitney U test analysis in post-test pain variable, the observed value of U is 121 in between group and Z value 5.23 where the p-value is < .00 in two-tailed hypothesis, so the result is significant at p < .05 and it can be concluded that pain reduction score on the Numerical Pain Rating Scale (NPRS) in the experimental group was statistically significantly higher than the control group. In the post-test disability variable, the observed value is 5.5 in between groups and the Z value is 6.79 where the p-value is <.00 in the two-tailed hypothesis, so the result is significant at p < .05 which can be concluded that the Disability score on Womac Index Scale in the experimental group was statistically significantly higher than the control group. In post-test ROM in the knee flexion variable, the observed value is 301.5 in between groups and the Z value is 2.81 where the p-value is <.00 in the two-tailed hypothesis. In post-test ROM in the knee extension variable, the observed value is 244 in between groups and the Z value is 3.58 where the p-value is <.00 in the two-tailed hypothesis.

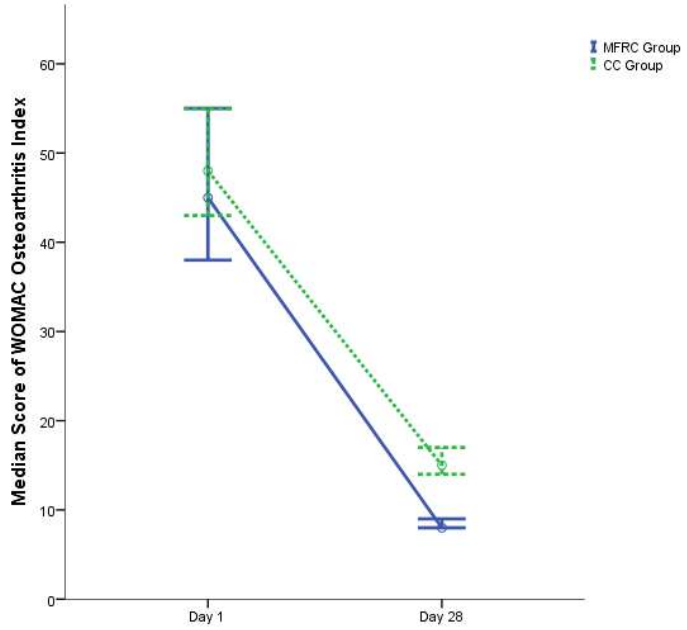
Table 3: The Outcome Analysis

Variables		Between Group [a]		MFRC Group [b]		CC Group	
		U Value	P	Z Value	P	Z Value	P
Pain		121	0.001**	-4.89	0.001**	-5.05	0.001**
Disability		5.5	0.001**	-4.86	0.001**	-5.01	0.001**
ROM	Knee Flexion	301.5	0.001**	-4.66	0.001**	-4.24	0.001**
	Knee Extension	244	0.001**	-4.76	0.001**	-2.81	0.001**
Muscle Power	Quadriceps	381	.04*	-4.50	0.001**	-1.13	.25
	Hamstring	423	.20	-4.14	0.001**	-4.00	0.001**

[a] Mann Whitney U test, [b] Wilcoxon test; Significant with * <.05, ** <.01

In the post-test Quadriceps Muscle power variable, the observed value is 381 in between groups and the Z value was 1.74 in the two-tailed hypothesis. So, it can be concluded that the null hypothesis was rejected and the alternative hypothesis was accepted at a 5% level of significance for pain, disability, and ROM during knee flexion, extension, and quadriceps muscle power. On the other hand, in the post-test Hamstring Muscle power variable, the observed value is 423 in between groups and the Z value was 1.18 where the p-value is 0.20 in the two-tailed hypothesis which is larger than the observed U value. So, it can be concluded that the Hamstring muscle power score in the experimental group was not statistically significant than the control group. So, the null hypothesis was accepted and the alternative hypothesis was rejected at a 5% level of significance. Examining the final test statistics by Wilcoxon signed-rank test it was found that the intervention group combined with the usual treatment course showed a statistically significant change in current pain (Z= -4.89, p= 0.00), functional ability (Z= -4.86, p= 0.00), range of motion during knee flexion (Z= -4.66, p= 0.00) and knee extension (Z= -4.76, p= 0.00) as well as in Quadriceps muscle strength (Z= -4.50, p= 0.00) and hamstring muscle strength (Z= -4.14, p= 0.00) among individuals with knee OA. Figure 2 shows the median changes in disability in two groups. Wilcoxon signed-rank test of the control group with usual care also showed a statistically significant change in current pain (Z= -5.05, p= 0.00), functional ability (Z= -5.01, p= 0.00), range of motion during knee flexion (Z= -4.24, p= 0.00), knee extension (Z= -2.81, p= 0.00) as well as in hamstring muscle strength (Z= -4.00, p= 0.00). However, the result was not significant during Quadriceps muscle strength (Z= -1.13, p= 0.25) among individuals with knee OA.

Figure 2: Median changes of Osteoarthritis related disability in WOMAC



MFRC, Myofascial release, and Conventional care group
CC, Conventional care group

5.3 Discussion

The findings of this study revealed that among the 64 knee OA participants, the experimental group included 19 patients who were male (61.3%) and 12 patients who were female (38.7%) whereas, 16 were male (48.5%) and 17 were female (51.5%) in Control Group. Moreover, the mean age range of the experimental group was 57.65±7.81 years and the control group was 53.70±8.42 years. In contrast, Rahbar et al. (2013) examined the effectiveness of myofascial trigger point therapy where in the experimental group, 83.3% of patients (25 patients) were female and 16.7% (5 patients) were male, similarly, in the control group, 80% of patients (n = 24) were female and 20% (6 cases) were male. The mean ages of the control and intervention groups, respectively, were 59.13 ± 0.30 and 56 ± 5.44 [13].

Joshi et al. (2018) found that hamstring flexibility improved after the therapist gave interventions (p 0.05) in all three groups (Group A (n=19) received static stretching, Group B (n=20) received remote MFR, and Group C (n=19) received both SS and remote MFR whereas, additional benefits which are related to the significant level of hamstring muscle power of this study [16]. This study reveals that the pain reduction score on the Numerical Pain Rating Scale (NPRS) in the experimental group was statistically significantly higher than the control group (U = 121, p = 0.00) at a %5 level of significance which is similar to Rahbar et al.'s study that found different types of myofascial release methods that have the effectiveness to decrease pain (p<0.0001 for right knee pain and p<0.01 for left knee pain) and enhance function (P< 0.001 in both groups) in osteoarthritis patients [13] and which is also found to be similar with Paul & Selvabharathi's study where showed significant improvement during functional activities (p<0.0001) [19].

In this matter, according to certain research, myofascial release therapy is highly beneficial in lowering pain-related disability (P<0.05) [20], and ITB flexibility, patellar alignment, and PPT improvement in KOA patients (P <0.05) [17].

In between group analysis of Mann Whitney u test, it concluded that the range of motion score on the goniometer during Knee flexion in the experimental group was statistically significantly higher than the control group (U = 301.5, p = 0.00) as well as in knee extension ROM in the experimental group was also significantly higher than the control group (U = 244, p = 0.00). In this regard, Kuruma et al. (2013) reported that the effects of myofascial release and stretching technique on a range of motion and reaction time have been identified in increasing quadriceps (p<0.05) and hamstrings ROM (p<0.05) as well as it eases the movements of the knee joint [21].

In this study Hamstring, Muscle strength analysis did not show a statistically significant change (U=423, p=0.20) which is common to some studies that found that ROM (p < 0.001) increased by 10 degrees after applying MFR but it does not inhibit or improve muscular performance which showed the significant (p< 0.05) negative correlation between quadriceps force and knee joint ROM [22].

However, the myofascial release technique has been demonstrated to be effective to improve pain (P < 0.001) and respectively, 72.4% and7.4% reduction in pain and functional disability in week

4 which is common with this study [23]. Arun (2014) showed that in a similar approach, based on the results of this study, the following application of various myofascial release therapy, the pain-related disability was 24.9 ($p<0.05\%$), quality of sleep and depression level was 21.3 ($p<0.05\%$) which are considerably reduced after application of Myofascial release combined with usual interventions [24].

6.0 Findings of the Study

1. Both groups had significant outcomes in pain, disability, ROM
2. Except for the hamstring, both trial and control groups had significant outcomes muscle strength.
3. Though both groups had positive results, myofascial release with conventional care showed more efficacy than only conventional care group.

7.0 Recommendations of the Study

In order to formulate a concrete treatment plan, unusually large and high-quality RCTs are mandatory. Double blinding procedure with more participants as the sample of this study should be done in future. As well as the specific stage in which patient will start this exercise and the specific protocol of home exercises should be included.

8.0 Conclusion

In patients with knee osteoarthritis, conventional care alone has been effective in reducing pain and enhancing the motion and function of the joint range. But the addition of myofascial trigger point and dysfunction therapy and applying for myofascial release enhances the effectiveness of physiotherapy and helps to decrease pain and disability and improve range of motion, muscle power, and physical performance even more. Though within-group analysis showed a relevant significant improvement, between groups analysis findings gave a clear idea that myofascial release along with conventional care is a more effective therapeutic approach for patients with knee OA than only conventional care.

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