



EFFECTS OF ACTIVE RELEASE TECHNIQUE VERSUS MULLIGAN TECHNIQUES ON PAIN, RANGE OF MOTION AND FUNCTIONAL DISABILITY IN PATIENTS WITH DEEP GLUTEAL SYNDROME

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ABSTRACT

Background: Deep gluteal syndrome is characterized by pain or loss of sensations in the hip, posterior thigh and buttock area, affects people of age 18-50 years. This syndrome is mostly under diagnosed and thus not get proper treatment, for this active release and Mulligan techniques, used as a co-adjuvant treatment with conventional physical therapy and found to be effective but the literature lacks the effectiveness between the two techniques.

Purpose: To compare the effects of active release versus Mulligan technique on pain, range of motion, and functional mobility in patients deep gluteal syndrome. **Methods:** Twenty-four individuals (13 females and 11 males) with deep gluteal syndrome pre-diagnosed by an orthopedic, were assessed from Rehab Max Clinic Layyah. After fulfilling the inclusion criteria, the participants were randomly divided into two groups receiving active release and Mulligan along with conventional physiotherapy. Outcome measures were pain (NPRS), range of motion (UG), and function (LEFS) collected at the baseline, 6th session, and 12th session. **Results:** The mean age for participants was 30.58 ± 5.64 years. The within-group analysis showed a statistically significant improvement in pain, range of motion, and function among active release and Mulligan group (P<0.05). The between group analysis showed that both the groups active release and Mulligan group had equal effects on pain, ROM and function at the baseline, 6th and 12th session among patients with gluteal syndrome as the difference was not significant (P>0.05). **Conclusion:** Both the active release and Mulligan group had equal effects in alleviating pain, increasing range of motion as well as function among individuals with gluteal syndrome.

KEYWORDS: Deep Gluteal Syndrome, Active Release Technique, Mulligan Technique.

CHAPTER 1

INTRODUCTION

Deep gluteal syndrome (DGS) is characterized by pain or loss of sensations in hip, posterior thigh and buttock area. It comes with radicular pain which originates due to non-discogenic entrapment of sciatic nerve specifically in the gluteal space.^[1] Presence of pain in buttock area other than discogenic origin is mainly due to extra pelvic entrapment of sciatic nerve that includes structures like piriformis muscle, fibrous band containing blood vessels, space occupying lesions, gluteal muscles and hamstrings muscles.^[2] Due to diversity of multiple structures present

in gluteal space, cause of sciatic nerve entrapment could be of any reason, that is why now the term deep gluteal syndrome is preferred over piriformis syndrome.^[3]

The DGS is common in population among subjects with age group between 18-50 years.^[4] It is very important to diagnose DGS correctly as its symptoms highly mimic with sciatica and piriformis syndrome.^[5] General diagnostic pathway for DGS should be composed of detailed history taking (posterior hip pain, difficulty sitting for 30 min, radicular pain etc.) physical examination (positive seated piriformis test, positive

pace sign and tenderness in deep gluteal space) and imaging tests (spine MRI, Pelvic MRI and pelvic radiographs).^[6]

Buttock region has various muscles but gluteus maximus, gluteus medius and gluteus minimus are well known among them.^[7] Deep to the gluteus maximus muscle lies the piriformis muscle underneath which sciatic nerve courses. Piriformis muscle sometimes entraps or irritates the sciatic nerve which also causes pain in buttock, hence called piriformis syndrome, which is over-diagnosed by the most of the practitioners according to the recent literature.^[8] Most recent literature also enlightens the fact that piriformis is not the only muscle that can entrap sciatic nerve or pudendal nerve, obturator internus, coccygeus, gemelli and levator ani can also pinch nerves in buttock area to cause pain and dyesthesias. Hence the term 'deep gluteal syndrome' invented.

As far as the pain pattern and other symptoms are concerned, they are same as in piriformis syndrome. In the absence of radiological imaging or other objective evidence that piriformis is entrapping the nerve, clinical differential diagnosis of DGS should be used to find out the possibility that buttock pain can also arise from the irritation of nerve in different structures in gluteal space not only due to entrapment in piriformis muscle. Most people who are diagnosed with DGS have pain in posterior hip which aggravates upon sitting longer than twenty or thirty minutes. Other symptoms also include tenderness in buttock area when pressed. According to the perspective of researchers, initially imaging is not required to move forward with a recovery plan to treat the condition. If symptoms persist and do not subside even after treatment, perhaps then imaging might be needed in which it is also important to rule out if the nerve is entrapped at spinal levels or irritated in gluteal space. Other than imaging, nerve conduction studies and injections can also help in making diagnosis but usually are not necessary.^[9]

DGS is most common non-discogenic cause of sciatica yet most unidentified and under-diagnosed entity. Females highly suffer from DGS as compared to male population with symptoms of pain, restricted range of motion and disability.^[10] The reason behind the increased female to male ratio is the anatomical structure of the female, the broad pelvis, increased fat ratio among females, the hormonal imbalance that might affect the bones and the muscles.

Activities like hip flexion on the affected side such as sitting and walking are more likely to increase pain in DGS. An antalgic position may be observed often in patients when sitting for longer periods of time. If pain is induced by adducting an internally rotated hip in the seated position with the hip flexed at 90° and the knee is in extension then seated piriformis stretch test is positive. On resisted abduction with external rotation of the hip,

pain and tenderness provokes then active piriformis test is positive. Pudendal nerve entrapment could be possible, if tenderness is present medial to ischium and is localized.^[11]

There are many studies that discuss different aspects of piriformis syndrome but reports including term 'Deep Gluteal Syndrome' are limited in radiological and orthopedic journals and make DGS an under-diagnosed entity which in turn makes it difficult for most practitioners to diagnose in first place. Proper diagnosis is possible after comprehensive history, detailed physical examination (including special tests and palpation of gluteal structures) and imaging if needed. Conservative treatment should always be the first line of treatment which includes rest, muscle relaxant, NSAIDs and Physiotherapy for a six-week period.^[12]

Mobilization techniques on lumbar spine, hip and sacroiliac joint restores normal joint function, range of motion and mobility. Reports of several clinical cases and case series show the success of movement with mobilizations (MWMs) to manage various musculoskeletal conditions. A manual therapy technique called Mulligan's therapy was developed by Brian Mulligan for treatment of musculoskeletal problems. A sustained force which also called accessory glide is performed while painful movement is performed.^[13]

Manual therapist uses non-invasive and patented soft tissue mobilization technique called Active Release Technique (ART). It helps to locate and breakdown the adhesions and scar tissues which causes pain, weakness, numbness and stiffness.^[14] The adhesions are the result, if the muscles are kept under continuous stress and stretch with repetitive overuse. The numbness, tightness of muscle as well as fascia, weakness and even aching or in some cases tingling can be caused by these adhesions. So, in order to breakdown these adhesions, the active release technique is found to be effective as it strengthens the muscle by breaking down the adhesions as well as by improving the blood circulation.

There is limited literature detailing the conservativemanagement of DGS. Many experimental studies include multiple treatments approach while treating patients with DGS which make it hard to understand the role of physiotherapy alone in managing DGS. As per our knowledge there is no sufficient literature where effects of mulligan and active release technique on symptoms of patients with DGS are compared. In this study, Mulligan and active release techniques (ART) were performed in conjunction with conventional therapy to compare their effects in alleviating pain, increasing ROM and other functional outcomes in patients with DGS. Results from this comparison were also help to provide a better understanding of how best to treat patients with DGS.

METHODOLOGY

This study employed a randomized controlled trial (RCT) design, conducted at the Rehab Max Clinic, Layyah, with a duration of three months following synopsis approval. The required sample size was calculated as 24 (12 per group), with a 20% dropout adjustment, resulting in 14 participants per group. A non-probability convenient sampling technique was used. Inclusion criteria included individuals aged 18-50 with a prior medical diagnosis of deep gluteal syndrome and pain/tenderness in the gluteal space. Exclusion criteria encompassed degenerative spine disorders, fractures, myofascitis, and other musculoskeletal disorders. Ethical guidelines of Government College University Faisalabad, Layyah Campus were followed. Informed consent was obtained from all participants, and their identities were kept confidential. Participants were informed of their right to withdraw at any time.

Participants were randomized into two groups: Group A received active release technique (ART) with conventional therapy, while Group B received Mulligan mobilization technique with conventional therapy. Data collection occurred at baseline, 6th session (2 weeks), and 12th session (4 weeks) using NPRS, universal goniometer, and LEFS. Data was analyzed using SPSS version 26. Quantitative variables were analyzed using mean $\pm$ SD, while qualitative data was expressed as frequencies and percentages. Statistical comparisons used Friedman and Mann-Whitney tests with a significance level of $p \leq 0.05$.

CHAPTER 4

RESULTS

Table 1: Age of Participants.

Group	Mean $\pm$ SD. Deviation
Active Release	30.58 $\pm$ 5.64
Mulligan	34.75 $\pm$ 5.77

The mean age of the participants of the active release group was 30.58 $\pm$ 5.64 and of Mulligan group 34.75 $\pm$ 5.77.

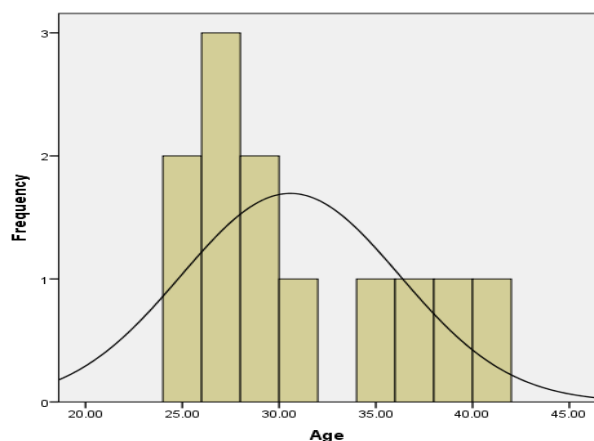


Figure 1: Frequency of Age of Participants in Active Release Group.

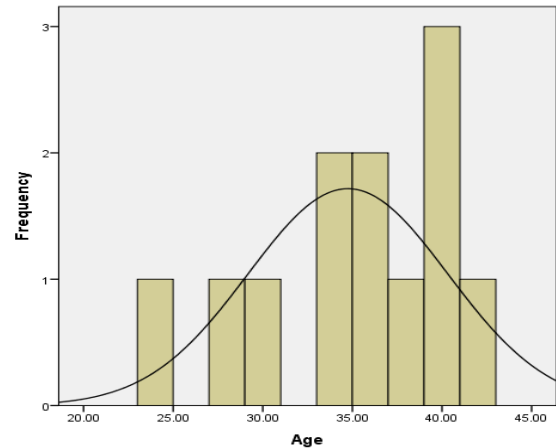


Figure 2: Frequency of Age of Participants in Mulligan Group.

Table 2: Gender Distribution among Groups.

Groups	Gender	Frequency
Active Release	Male	7
	Female	5
Mulligan	Male	6
	Female	6

Out of 24 participants, 5 were females and 7 were males in the active release group and Mulligan there were 6 females and 6 males.

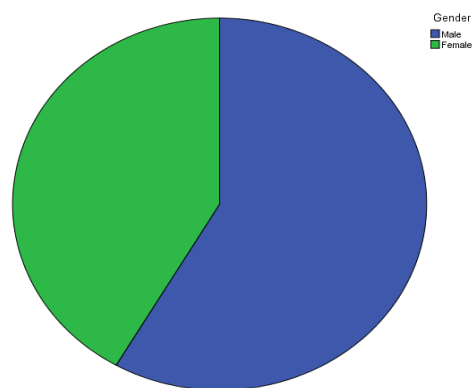


Figure 3: Pie Chart Showing Gender Distribution in Active Release Group.

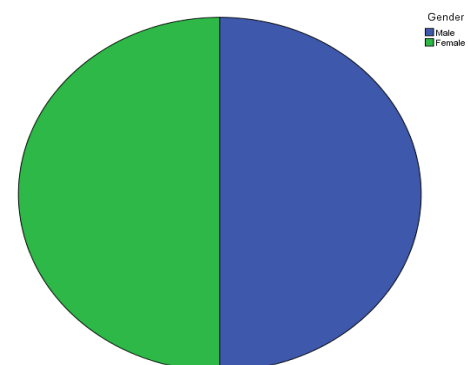


Figure 4: Pie Chart Showing Gender Distribution in Mulligan Group.

Table 3: Normality Test.

Variables	Kolmogorov-Smirnov		Shapiro-Wilk	
	Statistic	Sig.	Statistic	Sig.
Pain Baseline	0.35	0.001	0.637	0.000
Pain 6 th Session	0.44	0.004	0.573	0.000
Pain 12 th Session	0.37	0.000	0.629	0.000
LEFS Baseline	0.18	0.038	0.882	0.009
LEFS 6 th Session	0.13	0.020	0.888	0.012
LEFS 12 th Session	0.22	0.002	0.918	0.025
Flexion Baseline	0.20	0.008	0.813	0.000
Flexion 6 th Session	0.22	0.002	0.795	0.000
Flexion 12 th Session	0.28	0.010	0.784	0.000
Extension Baseline	0.28	0.020	0.848	0.002
Extension 6 th Session	0.30	0.012	0.821	0.001
Extension 12 th Session	0.29	0.000	0.800	0.000
Adduction Baseline	0.29	0.020	0.788	0.000
Adduction 6 th Session	0.29	0.040	0.788	0.010
Adduction 12 th Session	0.38	0.000	0.723	0.021
Abduction Baseline	0.30	0.000	0.848	0.002
Abduction 6 th Session	0.29	0.030	0.788	0.020
Abduction 12 th Session	0.38	0.000	0.711	0.012
External Rotation Baseline	0.30	0.034	0.848	0.002
External Rotation 6 th Session	0.29	0.000	0.788	0.025
External Rotation 12 th Session	0.38	0.041	0.711	0.041
Internal Rotation Baseline	0.30	0.000	0.848	0.002
Internal Rotation 6 th Session	0.29	0.000	0.788	0.010
Internal Rotation 12 th Session	0.38	0.043	0.711	0.020

The p-value is less than 0.05 so the data was not normally distributed.

Table 4: Clinical and Descriptive Statistics of Active Release Technique Group.

Variables		Mean	Std. Deviation	Maximum	Minimum
Baseline NPRS		2.50	0.52	3	2
Base line ROM	Flexion	113.75	7.72	100	120
	Extension	110.41	5.41	100	115
	Adduction	40.83	2.88	35	45
	Abduction	40.85	2.80	35	40
	External Rotation	40.83	2.57	35	40
	Internal Rotation	42.08	3.01	35	120
Baseline LEFS		96.25	5.47	90	110
6 th Session NPRS		1.66	0.49	2	1
6 th Session ROM	Flexion	114.16	6.33	100	120
	Extension	112.91	2.57	110	115
	Adduction	40.83	2.88	35	45
	Abduction	41.83	2.89	35	45
	External Rotation	40.87	2.86	35	45
	Internal Rotation	40.84	2.88	35	45
6 th Session LEFS		115.0	3.97	110	120
12 th Session NPRS		1.41	0.51	2	1
12 th Session ROM	Flexion	117.08	4.50	110	120
	Extension	110.61	5.54	100	115
	Adduction	41.66	2.46	40	45
	Abduction	42.08	2.57	40	45
	External Rotation	40.97	2.61	40	45
	Internal Rotation	40.08	2.57	40	45
12 th Session LEFS		127.0	4.9	120	135

Table 5: Clinical and Descriptive Statistics of Mulligan Group.

Variables		Mean	Std. Deviation	Maximum	Minimum
Baseline NPRS		2.41	0.51	2	3
Base line ROM	Flexion	107.50	7.53	100	120
	Extension	100.62	7.17	90	110
	Adduction	37.08	2.57	35	40
	Abduction	36.25	3.76	30	40
	External Rotation	36.25	3.76	30	40
	Internal Rotation	36.29	3.66	30	40
Baseline LEFS		97.08	3.14	90.00	100
6 th Session NPRS		1.75	0.45	1	2
6 th Session ROM	Flexion	112.91	8.38	100	120
	Extension	101.67	7.27	90	110
	Adduction	37.90	2.30	35	40
	Abduction	37.08	2.61	35	40
	External Rotation	37.18	2.56	35	40
	Internal Rotation	37.15	2.53	35	40
6 th Session LEFS		117.66	1.72	115.0	120
12 th Session NPRS		1.37	0.55	1	2
12 th Session ROM	Flexion	110	7.38	100	120
	Extension	110.41	3.34	105	115
	Adduction	39.00	1.95	35	45
	Abduction	39.16	1.94	35	45
	External Rotation	39.14	1.91	35	40
	Internal Rotation	39.42	1.97	35	40
12 th Session LEFS		128.83	3.29	124.0	136

Table 6: Within-group comparison using Friedman for Active Release Technique Group.

Variables		Mean Rank	P-Value
NPRS Baseline		2.82	0.00
NPRS 6 th Session		1.73	
NPRS 12 th Session		1.45	
ROM Baseline	Flexion	20.18	0.00
	Extension	19.05	
	Adduction	9.14	
	Abduction	9.12	
	External Rotation	9.16	
	Internal Rotation	9.12	
ROM 6 th Session	Flexion	20.59	
	Extension	19.05	
	Adduction	9.20	
	Abduction	9.24	
	External Rotation	9.19	
	Internal Rotation	9.16	
ROM 12 th Session	Flexion	21.23	
	Extension	19.59	
	Adduction	10.23	
	Abduction	10.31	
	External Rotation	11.01	
	Internal Rotation	11.03	
LEFS Baseline		16.09	0.00
LEFS 6 th Session		20.32	
LEFS 12 th Session		23.91	

Non-parametric Friedman test was used for comparison within the active release technique group based on NPRS, ROM and LEFS. The p-value was 0.00 when NPRS compared within group for baseline, 6th and 12th

session. The p-value was 0.00 when ROM compared within group for baseline, 6th and 12th session. For the LEFS when compared at baseline, 6th and 12th session the p-value was 0.00.

Table 7: Within-group comparison using Friedman for Mulligan Group.

Variables		Mean Rank	P-Value
NPRS Baseline		2.75	0.00
NPRS 6 th Session		1.83	
NPRS 12 th Session		1.42	
ROM Baseline	Flexion	19.58	0.00
	Extension	18.00	
	Adduction	8.92	
	Abduction	8.25	
	External Rotation	8.28	
	Internal Rotation	8.25	
ROM 6 th Session	Flexion	21.02	
	Extension	18.02	
	Adduction	8.96	
	Abduction	8.92	
	External Rotation	8.99	
	Internal Rotation	8.92	
ROM 12 th Session	Flexion	20.25	
	Extension	20.33	
	Adduction	11.04	
	Abduction	11.21	
	External Rotation	11.29	
	Internal Rotation	11.24	
LEFS Baseline		16.54	0.00
LEFS 6 th Session		22.21	
LEFS 12 th Session		24.00	

Non-parametric Friedman test was used for comparison within the Mulligan group based on NPRS, ROM and LEFS. The p-value was 0.00 when NPRS compared within group for baseline, 6th and 12th session. The p-

value was 0.00 when ROM compared within group for baseline, 6th and 12th session. For the LEFS when compared at baseline, 6th and 12th session the p-value was 0.00.

Table 8: Between Groups Comparison for NPRS using Mann Whitney Test.

Variables	Groups	Mean Rank	P-value
NPRS base line	Active Release	13.00	0.68
	Mulligan	12.00	
NPRS 6 th Session	Active Release	12.00	0.66
	Mulligan	13.00	
NPRS 12 th Session	Active Release	12.50	0.60
	Mulligan	12.00	

Non-parametric Mann Whitney U test was applied for comparison between active release group and Mulligan based on NPRS. The results show that there was not any statistically significant difference between the groups

with the p-value <0.05. According to the results, the active release group and Mulligan group have equal effects in decreasing pain among individuals with deep gluteal syndrome.

Table 9: Between Groups Comparison for ROM using Mann Whitney Test.

Variables	Groups		Mean Rank	P-value
ROM baseline	Flexion	Active Release	15.13	0.81
		Mulligan	10.88	
	Extension	Active Release	16.50	0.60
		Mulligan	10.89	
	Adduction	Active Release	16.13	0.62
		Mulligan	18.88	
	Abduction	Active Release	16.09	0.51
		Mulligan	18.78	
	External Rotation	Active Release	16.21	0.60
		Mulligan	18.79	

	Internal Rotation	Active Release	15.73	0.61
		Mulligan	16.42	
ROM 6 th Session	Flexion	Active Release	12.67	0.903
		Mulligan	9.25	
	Extension	Active Release	17.67	0.61
		Mulligan	15.33	
	Adduction	Active Release	16.13	0.65
		Mulligan	18.88	
	Abduction	Active Release	16.10	0.62
		Mulligan	18.79	
	External Rotation	Active Release	16.15	0.64
		Mulligan	18.89	
	Internal Rotation	Active Release	16.13	0.62
		Mulligan	18.88	
ROM 12 th Session	Flexion	Active Release	17.75	0.54
		Mulligan	19.25	
	Extension	Active Release	13.17	0.58
		Mulligan	15.83	
	Adduction	Active Release	15.50	0.52
		Mulligan	17.50	
	Abduction	Active Release	15.53	0.72
		Mulligan	16.42	
	External Rotation	Active Release	15.51	0.71
		Mulligan	16.39	
	Internal Rotation	Active Release	15.58	0.19
		Mulligan	15.42	

Non-parametric Mann Whitney U test was applied for comparison between active release group and Mulligan group based on ROM. According to the results, the active

release group and mulligan group have equal effects in range of motion among individuals with deep gluteal syndrome.

Table 10: Between Groups Comparison for LEFS using Mann Whitney Test.

Variables	Groups	Mean Rank	P-value
LEFS base line	Active Release	10.79	0.23
	Mulligan	14.21	
LEFS 6 th Session	Active Release	11.96	0.44
	Mulligan	15.04	
LEFS 12 th Session	Active Release	12.58	0.50
	Mulligan	13.42	

Non-parametric Mann Whitney U test was applied for comparison between active release group and Mulligan based on LEFS. According to the results, the active release group and Mulligan group have equal effects on function among individuals with deep gluteal syndrome.

CHAPTER 6 DISCUSSION

This study compared the effects of active release technique versus mulligan technique in patients with deep gluteal syndrome which has little evidence available so far. Results showed that there was not any statistically significant difference between the groups getting both treatments. According to the results, the active release group and Mulligan group have equal effects on pain, range of motion and function among individuals suffering from deep gluteal syndrome. Patients in both groups showed equally significant improvement to both treatments individually.

According to previous studies, hip pathologies were found more prevalent in housewives and office workers. This is mainly because of poor posture, cross legged and prolonged sitting habits imposing excessive stress on deep gluteal structures. Attiq Ur Rehman et al (2021) compared the effects of ART and post isometric technique in patients suffering from piriformis syndrome. 30 patients were treated with mean age of 41.30±4.99. Group A (active release technique) and Group B (post isometric relaxation) showed significant improvement within groups in all outcome measures. ART and PIR were equally effective in improving pain, hip internal rotation and functional disability. However, ART compared to PIR is more effective in improving functional disability in piriformis syndrome.^[28]

A Review was conducted by Neha Chitale Jr. et al (2022) on treatment approaches for Chronic low back pain via Mulligan movement with mobilization and physical

therapy. She explained Mulligan as a technique in which arthrokinematics and osteokinematics of the joint can be brought to normal by performing mobilization with movement, as sometimes the issue cannot be corrected just by mobilization in a still position. Mulligan's concept says that pain is due to a minor positional fault to the joint which leads to the restriction. Postural fault leads to biomechanical changes leading to pain. The principles of Mulligan mobilization are that the movement should be pain-free. In this review, she found that Mulligan mobilization is a better treatment approach over other manual therapy techniques to reduce chronic LBP. Pain stiffness and disability were the points considered while concluding the review.^[29]

When body tissues are damaged due to some injury, poor posture, excessive pressure or any other reason there are always healing responses in them. They are accomplished by immune system. The immune system protects them from infection. Wound tissues and connective tissues block blood flow and limit movement. Therefore, enough movement should be made by using methods such as ART. ART restore movement of the soft tissues, recover elasticity and proper function of soft tissues and relaxes the entrapped nerves, blood vessels and lymph nodes.

Active release technique (ART) is a popular soft tissue mobilization techniques used by manual therapists. It is a patented, non-invasive, soft tissue treatment technique that both locates and breaks down the adhesions and scar tissue which cause pain, stiffness, weakness, numbness, and dysfunctions. Sajin Tak et al (2013) conducted a study to determine the effects of ART on gluteus medius for pain relief in patients with chronic low back pain. Subjects in ART group received 2 times a week treatments with ART on gluteus medius muscle trigger points for 3 weeks. Therapist applied deep digital tension to the affected site as the tissue is moved both actively and passively from a shortened position to a lengthened position or from a lengthened to shortened. The results showed that patients suffering from back pain due to gluteus medius had significantly reduced pain with ART.^[30]

Most studies have shown improvement with stretching on different regions of body but there is no much literature to know the effect of mulligan on gluteal region. In 2016 Samahir Abuaraki Elbkheet et al conducted a comparative study to know the effectiveness of mulligan with movement versus stretching in patients with piriformis syndrome. The objective of this study was to compare the above mentioned two measures in the management of pain relief and movement dysfunction in unilateral piriformis syndrome. In this experimental study, 40 patients with piriformis syndrome were selected and divided into two groups. One group was given only stretching for the tightened muscle and the other group given Mulligan mobilization for lumbo sacral joints. VAS and lower limb functional index were

taken to compare before and after the treatment regime of 4 weeks. Results showed no significant difference between the two groups in both pain scale and lower limb mobility and function. But there was significant improvement in pain relief and LLFI after the treatment regime in both groups compared to the pre-treatment status.^[31]

Unlike the bilateral tightness of the muscle, the one sided shortening can cause dysfunctions either in hip mechanics or lumbo-sacral movements or both. Hence, in this study between the two groups of patients taken, one group is treated with active release technique targeting the tightened structure and the other group received lumbo sacral mobilization with movement (Mulligan's). We can find from the results that there is no marked difference in the baseline values of pain (NPRS), ROM (universal goniometer) and LEFS between the two groups. When compared within the same group pre and post interventions, there is considerable improvement in both groups regarding pain relief, range of motion and functional improvement. However, the table of comparison between the two groups shows that there is no statistically significant difference between either of the treatment approaches. Analysis from the results found that when means was compared between the mulligan mobilization group and active release group, there is no statistically significant difference in means of Numeric pain rating score for pain, ROM on Goniometer and LEFS score for functional disability pre intervention to post intervention means. Therefore, neither group showed a statistically greater difference when comparison was made between the groups.

CONCLUSION

The novelty of this study was to compare the two known treatment program for deep gluteal syndrome and to find out which is superior. The present study concluded that both ART and mulligan mobilization were found to be effective as an exercise program for patient with deep gluteal syndrome to provide additional benefits and better outcomes. A decrease in pain and increases in functional performance and mobility were noted in both cases at the end of 12th sessions.

Detailed analysis showed that ART and MWM are equally effective in improving pain, range of motion and functional disability. Additional studies should be conducted with similar treatment along-with advanced technological and radiological considerations in individuals with deep gluteal syndrome.

7.2: LIMITATIONS

- Sample size is small.
- This review included only articles written in English and published in peer review journals.
- This might have limited the evidence by not including article written in other languages that may have been eligible for inclusion.

7.3: RECOMMENDATIONS

- Systematic review must be done.
- Further studies should be conducted with large sample size.

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