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Evaluating the Therapeutic Synergism of Pregabalin and Physiotherapy in Fibromyalgia–A Case Report

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Abstract: ***Background: Fibromyalgia (FM) is exemplified by chronic pervasive musculoskeletal pain, which remains a difficult clinical entity worldwide and the management of this condition is a challenge for the health providers. Numerous treatment options are available to improve the symptoms of fibromyalgia, but a specificity tailored to particular patient is still missing. Thus, in this study we tested the combination of pregabalin with physiotherapy techniques would bring any changes on the fibromyalgia symptoms. Method: A 36 year female reported to the psychiatry department with complaints of continuous pain all over the body, with more than 4 year history of stiffness and functional disability. The patient met the 2010 fibromyalgia diagnostic criteria. Visual analogue scale, Pain pressure algometer, revised fibromyalgia impact questionnaire and shortform-36 health surveys were used as the outcome measures to document the changes. The patient was managed for a period of 3 months using pregabalin along with Physiotherapy techniques. Results: After three months we found positive results on the management of fibromyalgia. Conclusion: Pregabalin combined with Physiotherapy may be synergistic in the treatment of FM had an effect to reduce the severity of pain and improve the pressure threshold and quality of life on fibromyalgia.***

Keywords: Fibromyalgia, Fascial release, Pregabalin, Myofascial release, Pain threshold

1. Introduction

Fibromyalgia (FM) is recognized as a common chronic musculoskeletal pain disorder in the clinical scenario and a major cause of morbidity worldwide. It is a multidimensional disorder that is unpredictable in its course [1], [2] and the management of this condition is a challenge for the health provider [3]

The estimated overall prevalence of FM in Europe was 4.7% of chronic widespread pain, and was 2.9% when stronger pain and fatigue criteria were simultaneously used [4]. It affects 4% of US population, approximately 6 -10 million Americans [5], [6], with strong female predominance[7] between the age of 20 and 50 [8].

The 2010 criteria for diagnosing the FM syndrome recommended by the American College of Rheumatology (ACR) include a history of "widespread pain index (WPI) at ≥7 and symptom severity (SS) scale score ≥5 or WPI 3-6 and SS scale score ≥9" and the symptoms have been present at similar level for at least 3 months and the patient does not have a disorder that would otherwise explain the pain [9].

The alpha-2-delta ligand pregabalin was the first drug to be approved by US food and drug administration (FDA) for the treatment of fibromyalgia [10]. But FM patients have a different constellation of symptoms resulting in different responses to therapeutic interventions. So, medication alone is not generally sufficient for the treatment of Fibromyalgia.

Myofascial Release (MFR) is one of the manual soft tissue release technique, which applies the principles of biomechanical loading of soft tissue and the neural reflex modifications by stimulation of mechanoreceptors in the fascia [11], [12]; It represents a widely employed manual technique specific for fascial tissues, to reduce adhesions, restore and/or optimize fascia sliding mobility in both acute and chronic conditions.[13]-[15] There are dearth of studies reporting synergism of physiotherapy and pregabalin in different constellation of symptoms in FM. Thus, we reported a case of FM treated with the combination of Pregabalin and novel physiotherapy techniques.

2. Methods: Case Presentation

A 36 year female reported to the psychiatry outpatient department of tertiary teaching hospital of North India with complaints of continuous pain all over the body, with more than 4 year history of stiffness and functional disability. Area of pain described by the patient was the upper trapezius, neck, hip and abdomen, with characteristic of pain as sharp aching and induced while washing the vessels.

Functional capacity of the patient was restricted to a great extent, such that patient had complaints of difficulty to prepare homemade meal and lift and carry a bag of full of groceries, also patient had disturbance in the quality of sleep. Patient reported depressive features not amounting to syndromal depression. Patient was diagnosed as somatoform disorder according to ICD-10 DCR.

The patient satisfies the 2010 fibromyalgia diagnostic criteria such as widespread pain index (WPI) 8 and the symptom severity scale score was 7. Symptoms have been present at the similar level for at least 3 months, and the

patient does not have a disorder that would otherwise explain the pain. Written informed consent was obtained from the patient for this case report.

Outcome measure: Visual analogue scale and Pressure algometric measurements were carried out for quantification of pain response. Eight areas were selected for measurement of algometric readings –shoulder girdle (left and right), hip (buttock) left and right, chest, abdomen & lower back. The areas were chosen based on the complaint. Also, revised fibromyalgia impact questionnaire (FIQR) and quality of life (QOL) was recorded from the baseline (prior to treatment), first month, and second month and at the end of third month. Rater was blinded to the treatment.

The patient was managed for a period of 3 months. A dosage of 150 mg pregabalin drug was administered continuously for 3 month along with the physiotherapy treatment on alternate days. The physiotherapy treatments included in the study are moist heat, ultrasound therapy, deep transverse friction and fascial release.

The moist heat therapy was the first treatment applied over the cervical and the low back area for 10 minutes. The Ultrasound (US) treatment was administered in a circular manner over the area of 2 x the size of the transducer (Ultrasound head) with a frequency of 3 MHZ in a continuous mode and a dose of 1.5 W/Cm^2 was delivered at each tender point. The duration of the US treatment is 3 minutes of 3 session / week for 4 weeks.

Deep friction massage has been performed through the therapist fingers perpendicular to the exact site of lesion, with the depth of friction tolerable to the patient. The duration of the treatment 5 minutes of 3 session / week for 12 weeks at each tender point.

Myofascial release (MFR) technique was applied using the cervical release, cranial base release, and leg pull over the point of restriction for at least 3 minutes. Enough rest time given in between the treatment repetitions to avoid any unnecessary fatigue.

3. Results

The subject improved in all the measures (Table 1). Marked improvement was reported on Pain pressure threshold (Fig.1), VAS, FIQR and SF-36 survey (Fig.2).

Table 1: Summary of all the variables

Variables	Baseline Pre Treatment		1st Month	2nd Month	3rd Month
VAS (Pain)	8		5	3	3
FIQR	55.8		31.1	26	20.5
SF – 36	PCS	28.1	29.7	31.8	40.5
	MCS	32.7	43.2	41.8	44.4
Pain Pressure Threshold (Kg)					
Shoulder girdle (R)	0.7		1.3	1.2	2.0
Shoulder girdle (L)	0.5		0.8	1.0	1.4
Hip (Buttock, trochanter) Right	0.8		1.0	1.7	2.4
Hip (Buttock, trochanter) Right	0.9		1.2	1.6	1.8
Lower back	1.0		1.6	1.8	2.2
Chest	0.6		2.4	2.4	2.6
Abdomen	1.8		2.0	2.4	3.0
Neck	0.9		1.2	1.2	1.9

PCS = Physical Component Summary, MCS = Mental Component Summary.

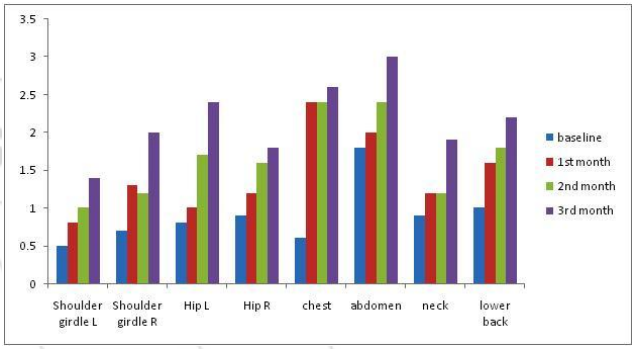

Figure 1: Measurements of pain pressure threshold from baseline to 3rd month.

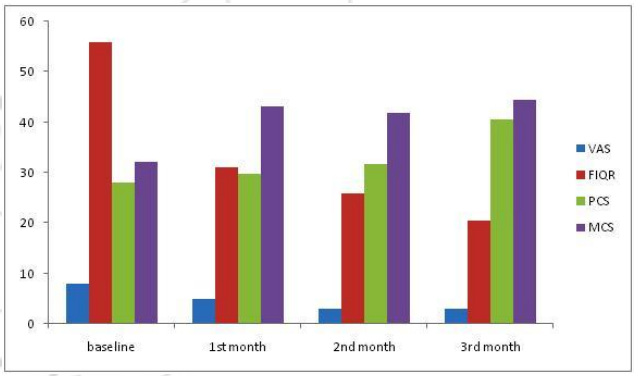

Figure 2: Measurements of other variables from baseline to 3rd month

4. Discussion

This case study has shown a significant improvement on all the outcome measures. To our knowledge, this is the only research which combines both pharmacology and novel physiotherapy techniques in the treatment of fibromyalgia. Pregabalin has a proven efficacy under chronic neuropathic pain conditions and fibromyalgia. Pregabalin binds to the α – δ subunit six times more potently than gabapentin and thereby reduces the release of several neurotransmitters like glutamate, norepinephrine, serotonine, dopamine, and substance P; also pregabalin produces dizziness and somnolence [16], so it is our liability to find an alternative treatment to resolve these symptoms.

In this study, the use of ultrasound improves sustained muscle contraction by increasing the permeability of the cell

membrane; improves intracellular energy consumption; increases angiogenesis in ischemic tissues; and promotes tissue repair [17].

MFR facilitate the release of fascial restrictions [18] and inhibit the gamma spindle response that causes the muscle to shorten when rapidly stretched [19].

Deep cross-friction massage facilitates the proliferation of fibroblasts and results in the facilitation of soft tissue healing and realignment as pressure applied to the muscle is increased [20].

Therefore, it appears that improvement in this index patient could be attributed to the synergism between favorable neurotransmitter changes influencing messenger systems and cellular changes (with tissue healing) due to physiotherapy techniques.

5. Conclusion

Pregabalin with physiotherapy synergism is safe and effective, providing long lasting effects on the symptoms of fibromyalgia over a period of 3 months on pain, pressure threshold and quality of life. There is need for systematic trials exploring this synergism in future.

6. Consent

Written informed consent was obtained for the publication of this case report.

7. Conflicts of Interest

Authors confirm that they have no potential conflicts of interest during the study and publication of this research.

8. Clinical Registry Trial India Acknowledgement Number

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9. Acknowledgement

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