

# Comprehensive Fibromyalgia Treatment in Russian Private Center

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## ABSTRACT

**Background:** Several clinical trials advocate multidisciplinary approach to the treatment of fibromyalgia. A different medication to relieve pain helps only onto 30%, but much more therapeutic effect depends upon cognitive behavioral and operant behavioral therapy and physical exercise. **Aim of the study:** To assess the effectiveness of Duloxetine 30 and 60 mg and adjuvant therapies in complex therapy of fibromyalgia. **Materials and Methods:** Sixty nine patients were included in the study, 60 females and 9 males within average age  $35 \pm 19.7$  years with clinical diagnosis of fibromyalgia syndrome according to Diagnostic Criteria of American College of Rheumatology (1990). All patients were also seen by the psychiatrist. Anxiety disorder was diagnosed in 25 patients (36.2%), depressive syndrome in 25 patients (36.2%), mixed anxiety and depressive – in 5 (7.2%), irritable bowel syndrome in 26 patients (37.6%), migraine in 10 patients (14.5%), obesity in 6 patients (8.7%). Sixty five patients complained of sleep disturbances (94%). All patients were assessed by Hamilton Depression Scale (HAM-D) Forty five patients were administered Duloxetine 30 mg for two months, 20 patients were administered Duloxetine 60 mg for 2 months. Adjuvant therapy included Carnitine, Coenzyme Q 10, Vitamine C, Melatonine, Lecytine, Amber acid. **Results:** Forty five (65.2%) responded the treatment and 24 did not. Among 25 responders who were administered Duloxetine 30mg/day the number of tender points decreased down to  $9.5 \pm 0.67$  when it was initially  $11.2 \pm 0.54$  ( $p < 0.05$ ). Assessment by visual analogue scale of pain became  $6.5 \pm 1.2$  degrees when it was initially  $7.8 \pm 0.24$ . In 20 responders who were administered Duloxetine 60 mg/day the number of tender points decreased down to  $7.6 \pm 1.8$  when it was initially  $10.8 \pm 0.76$  ( $p < 0.05$ ) Assessment by visual analogue scale of pain became  $6.3 \pm 1.54$  degrees when it initially was  $7.7 \pm 1.52$ . Among 55 patients with psychiatric symptoms there were 31 responders. Among 55 patients with psychiatric symptoms there were 31 responders. They had initial degree by HAM-D  $13.7 \pm 3.2$ .

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It decreased down to  $9.5 \pm 2.1$  ( $p < 0.05$ ). Complains of gastrointestinal symptoms in the group of patients with irritable bowel syndrome also decreased in 15 of 26 patients (57.7%). **Conclusion:** Despite the multicomponent treatment of fibromyalgia syndrome in this series of patients it remained chronic and debilitating painful condition in one third of patients after 2 months of intensive care. In 65.2% of cases Duloxetine was effective (in 36.2 % in dose of 30mg/day and in 28.9% cases in dose of 60 mg/day) what confirms results of previous studies.

## INTRODUCTION

Fibromyalgia syndrome is a painful disorder which comprises musculoskeletal specific tender points over 11 across the body with non-painful syndromes such as irritable bowel syndrome, dyssomnia, depression, anxiety, migraine and other headaches, obesity and metabolic syndrome [1].

Several clinical trials advocate multidisciplinary approach to the treatment of fibromyalgia. A different medication to relieve pain helps only onto 30%, but much more therapeutic effect depends upon cognitive behavioral and operant behavioral therapy and physical exercise [2-4].

Duloxetine, milnacipran and quetiapine are the golden standard recommendation of treatment of painful syndrome and psychiatric symptoms in fibromyalgia [5,6]. In other cases pregabalin and amitriptyline are used [7,8]. Patients with fibromyalgia also use different herbal biological nutritive supplements, some of which were successfully tried in small groups of women with fibromyalgia, among them carnitine, coenzyme Q10, ascorbinogene, chlorella [9-12]. In Russia several neurologists successfully used amber acid, S-adenosylmethionin and lecycin to treat fibromyalgia [13-15]. Administration of triphosadenine is advocated due to deficiency of this substance in fibromyalgia [16].

The aim of this study was to try a comprehensive approach in management of fibromyalgia in a small group of adult patients.

## MATERIALS AND METHODS

Sixty nine patients were included in the study, 60 females and 9 males within average age  $35 \pm 19.7$  years with clinical diagnosis of fibromyalgia syndrome according to Diagnostic Criteria of American College of Rheumatology (1990) [17]. All patients were also seen by the psychiatrist. Anxiety disorder was diagnosed in 25 patients (36.2%), depressive syndrome

in 25 patients (36.2%), mixed anxiety and depressive - in 5 (7.2%), in 10 (14.5%) no psychiatric symptoms were seen, irritable bowel syndrome was registered in a way of constipation or diarrhea in 26 patients (37.6%), in 10 patients migraine was diagnosed (14.5%), in 6 with body mass index over 30 obesity was diagnosed (8.7%). Sixty five patients complained of sleep disturbances (94%). All patients were assessed by Hamilton Depression Scale (HAM-D) [18]. The initial degree in patients with psychiatric symptoms was  $15.5 \pm 3.7$ . The initial assessment by visual analogue scale of pain was  $8 \pm 0.22$  degrees.

The number of tender points in patients initially was  $12 \pm 0.77$ . It didn't differ in fibromyalgia patients with psychiatric symptoms and without them, with irritable bowel syndrome, obesity, migraine or without them.

Forty five patients were administered Duloxetine 30 mg for two months, 20 patients were administered Duloxetine 60 mg for 2 months, 4 Patients were administered Milnacipran 25 mg for 2 months. All of them were administered cognitive behavioral and operant behavioral therapy and physical stretching exercise for 30 minutes 3 times a week.

Adjuvant therapy included: 1) Melatonin 3 mg/day, 2) Chlorella 10mg + 100ml, 3) Carnitine 1 g/day, 4) CoenzymeQ 10 100 mg/day, 5) Vitamine C 1000md/day, 6) Cytoflavine (Amber acid) 10 mg in 200 ml saline 10 days IV infusion, 7) Lecytine 3g/day, 8) S-adenosylmethionine 800 mg in 200ml saline IV infusion for 10 days in depressive syndrome, 9) Cocarnite 2 ml IM injection (if no tender points were in L5-S1) for 10 days (500µg cyanocobalamine, triphosadenine 10 mg, nicotinamide 20 mg, cocarboxylase 50 mg).

In migrain Erenumab was administered in two patients in dose of 70 mg subcutaneously 1 time a month, other patients received Metoprolol 25 mg/day, Amitriptylyne 12.5 mg/day or candesartan 8-16 mg/day, for stopping of bouts Sumatriptan 50 mg was used.

## RESULTS

Forty five (65.2%) responded the treatment and 24 did not.

Among 25 responders who were administered Duloxetine 30 mg/day the number of tender points decreased down to  $9.5 \pm 0.67$  when it was initially  $11.2 \pm 0.54$  ( $p < 0.05$ ). Assessment by visual analogue scale of pain became  $6.5 \pm 1.2$  degrees when it was initially  $7.8 \pm 0.24$ .

In 20 responders who were administered Duloxetine 60 mg/day the number of tender points decreased down to  $7.6 \pm 1.8$  when it was initially  $10.8 \pm 0.76$  ( $p < 0.05$ ). Assessment by visual analogue scale of pain became  $6.3 \pm 1.54$  degrees when it initially was  $7.7 \pm 1.52$ .

Among 55 patients with psychiatric symptoms there were 31 responders. They had initial degree by HAM-D  $13.7 \pm 3.2$ . It decreased down to  $9.5 \pm 2.1$  ( $p < 0.05$ ).

Complaints of gastrointestinal symptoms in the group of patients with irritable bowel syndrome also decreased in 15 of 26 patients (57.7%).

The group of non-responders was characterized by significantly higher degree of visual analogue scale of pain  $9 \pm 0.53$  (and  $7.7 \pm 1.52$ ,  $7.8 \pm 0.24$ ,  $p < 0.05$ ), and significantly higher HAM-D degree –  $20.3 \pm 2.4$  (and  $13.7 \pm 3.2$ )

In the group of non-responders we increased dose of Duloxetine up to 60 mg/day (who had its dose 30 mg/day) and added Pregabalin 75 mg 2 times a day) for 2 months. Cognitive behavioral therapy and stretching exercise were also prolonged. Improvement was reached only in 10 patients within 2 months.

## DISCUSSION

Despite the multicomponent treatment of fibromyalgia syndrome in this series of patients it remained chronic and debilitating painful condition in one third of patients after 2 months of intensive care. In 65.2% of cases Duloxetine was effective (in 36.2 % in dose of 30 mg/day and in 28.9% cases in dose of 60 mg/day) what confirms results of previous studies [5]. Of course, we can only speculate about the role of adjuvant therapies, but the role of cognitive behavioral, operant behavioral and stretching exercise was pivotal here too. However, healing of depressive and anxiety symptoms and irritable bowel syndrome in 44.9% and 57.7% of cases respectively is the merit of antidepressant. In non-responders more aggressive therapy such as Pregabalin should be used [2,7]. Interestingly, significant differences were obtained in decreasing in tender points but not in the pain intensity, what probably reflects the necessity of longer time interval of treatment [1]. Predictive factors for non-response for Duloxetine 30 mg/day are HAM-D degree over 20 and visual analogue scale of pain degree over 9 as it is as well predictive factor not to administer adjuvant therapy for economic reason and administer Duloxetine 60 mg/day and

Pregabalin first line.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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