Research Article

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Okada Purifying Therapy in combination with duloxetine vs. duloxetine alone in patients with TMD and fibromyalgia: a randomized clinical study

https://doi.org/10.1515/jcim-2020-0116
Received March 31, 2020; accepted July 15, 2020;
published online December 31, 2020

Abstract

Objectives: This randomized study was aimed at evaluating the additional analgesic effect of Okada Purifying Therapy (OPT) when administered in combination with duloxetine in patients with Temporomandibular Disorders (TMDs) and Fibromyalgia (FM).
Methods: Patients with TMDs visited at Department of Oral and Maxillofacial Sciences, Sapienza University of Rome who were diagnosed with FM were selected for the study. The final sample was composed of 31 patients: 15 patients were treated only with duloxetine (Group I) and 16 patients underwent also OPT treatment (Group II), for eight weeks. Craniomandibular index, total tenderness score, Brief Pain Inventory Modified Short Form, Fibromyalgia Impact Questionnaire, Beck Depression Inventory and State and Trait Anxiety Inventory-1 were assessed at the beginning (T0), during the course (T1) and after therapy (T2). Descriptive and inferential statistics were performed.
Results: In all the data analyzed, both groups showed an improvement in particular between T0 and T1. No statistically significant differences were observed between the two groups during the trial, except for the interaction between treatment and time as to the ability of walking at the BPI-I ($F=7.57$, $p=0.002$). No side effects due to the duloxetine were recorded in group II compared to group I.
Conclusion: The additional complementary treatment (OPT) did not appear to give the patients with TMDs and FM any further benefit but it might improve pharmacological tolerability of the traditional medication.

Keywords: duloxetine; fibromyalgia; Okada purifying therapy; temporomandibular disorders.

Introduction

Fibromyalgia (FM) is a chronic disorder characterized by widespread musculoskeletal pain and tenderness at specific anatomic spots (so called tender points) [1, 2]. Over the years the association of FM with other comorbidities, such as Temporomandibular Disorders (TMDs) has been a trend topic among the clinicians [3, 4].

Many published studies on FM and TMDs have analyzed the effectiveness of several pharmacologic and/or non-pharmacologic treatments [5] and the ones on biofield therapies are yet few and still controversial [6]. The type of therapeutic approach to the patients with FM and associated TMDs should be considered. The treatment of the "basic" pathology before opting for any kind of gnathological auxiliary local therapy is recommended by the authors of this study. In fact, FM and TMDs are likely just not merely coexisting conditions [7]. According to the literature, the authors are led to consider that FM may lead to TMDs symptoms or at least that FM and TMDs share a common pathogenesis [8], such as the current hypothesis of Central Sensitization [9, 10].

Duloxetine hydrochloride proved to be effective for FM as evidenced in scientific literature [11, 12]. Nonetheless, the greater impact of duloxetine in FM appears to be

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lower than the one observed in other clinical conditions, suggesting the need for a more holistic approach for FM patients [13, 14]. In this regard, a multidisciplinary approach combining traditional and complementary treatments is required [15]. Therefore, Okada purifying therapy (OPT) [16–19] has been put forward in combination with duloxetine. OPT is included among the biofield therapies and it was initially formulated and developed by Mokichi Okada during 1930s in Japan. OPT is based on principles developed by a unique understanding of the human body, illness and health, and it has the purpose to allow the self-healing process through the use of subtle energy. In OPT, trained practitioners place their palms on the surface of the patient's body in order to find stiff and/or warm spots, which are sites of accumulated toxins. Then, they perform therapy with the emission of bioenergy, or qi, conveyed through their hand palm, without touching the patient, in correspondence of key areas. The distance between the practitioner's palm and the patient's body is usually 30–60 cm. Every anatomical spot was "irradiated" for 5–10 min particularly in the areas of the hot points, reported by the patients as the most painful ones. This practice might enhance natural healing abilities, possessed by any human being and toxins are purged as the natural healing ability is gradually activated. In turn, the enhancement of such abilities turns out to improve psychological and physical health [16–19].

The study aimed at evaluating the effectiveness of OPT in combination with duloxetine in improving pain, related disability and quality of life in patients with fibromyalgia and TMDs.

Methods

Study design and partecipants

To address the research purpose, the authors designed and implemented a randomized study, approved by the Institutional Human Ethics Committee, Sapienza University of Rome (Protocol No 349) and carried out during the period 2010–2015.

The sample was composed by a population derived from patients who underwent a neurological examination and who were diagnosed with fibromyalgia, then invited to be screened for temporomandibular disorders at the Department of Oral and Maxillofacial Sciences, Sapienza University of Rome, by specialized and tailored medical staff (Study Phase I-SPI).

Study variables

The following categories of variables were considered:

(1) Age (expressed in years), average disease lapse and analgesics intake (expressed in months) were considered.
(2) Pain severity, measured with the Brief Pain Inventory – short form (BPI-SF) [20]. It was the first clinical assessment.
(3) FM disability degree by using the Fibromyalgia Impact Questionnaire (FIQ) [21]. It is a self- administered questionnaire evaluating the components of the health status over the previous week.
(4) Beck Depression Inventory (BDI) [22] and the State and Trait Anxiety Inventory for the measure of anxiety state (STAI-1) [23].
(5) Craniomandibular Index (CMI), analyzing patients' craniomandibular signs and symptoms [24, 25], indicating Myofascial and Joint Dysfunctions severity.

Randomization

This study was carried out as a randomized clinical study characterized by two different phases (Figure 1).

Participants were told that they had an equal chance of being assigned to one of the two treatments.

Besides, an additional research operator, not involved with initial screening and clinical evaluations, randomized participants using a computer-generated blocked random allocation sequence with a block size of 2.

Group I or CONTROL GROUP: standard treatment with duloxetine

Group II: administration of duloxetine in combination with OPT.

During the study phase II (SPII), all subjects of the study (Group I e II) began with duloxetine 30 mg QD for the first week, while for the remaining seven weeks of SPII they were treated with duloxetine 60 mg QD.

In addition, group II was treated with two OPT sessions per week for a total of 16 treatments over a period of eight weeks. All OPT sessions were performed by a single trained certified practitioner for a period of 50 min [26].

Each patient signed the informed consent.

One operator of the study, previously tailored to it, repeated all initial clinical evaluations at T1 (after four week) and at T2 (after eight weeks). Another operator checked the reliability of all data collected.

Statistical analysis

The between-group comparison of the descriptive data was carried out by using independent samples *t*-test or with non-parametric Mann–

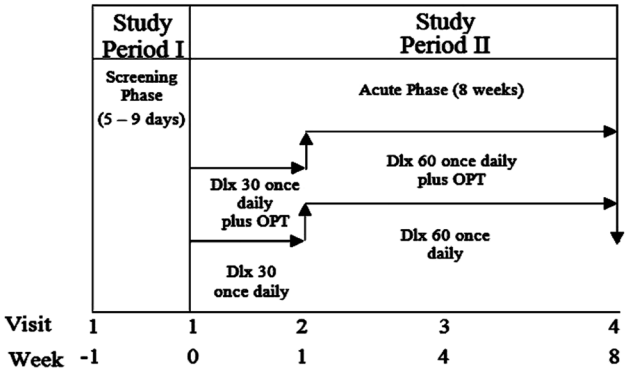

Figure 1: Study design showing all study periods.
Dlx, Duloxetine; OPT, Okada Puryfing Therapy.

Whitney U if the normality assumption was violated. The nominal variables of the descriptive data were analyzed using chi-square test. A two-way repeated measures ANOVA with time (T0, T1 and T2) as a within subjects factor and treatment (Group I or control group and Group II) as a between subjects factor was performed. Post-hoc tests were performed. A two-tailed value of $p<0.05$ was regarded as significant. All analyses were performed with JASP Version 0.8.0.1, downloadable at https://jasp-stats.org/download/. Results were controlled using SPSS 24 and no discrepancy was found.

Results

Patients who met inclusion and exclusion criteria as summarized in Table 1 were enrolled in the study.

Patient flow

The flow of patients through the study is reported in Figure 2.

The final sample was composed by 31 females (average age in years ± standard deviation, 47.71 ± 12.26).

Thirty-one patients completed the study (72%), 15 subjects were in the group of duloxetine only (Group I) and 16 subjects were in the group of duloxetine and OPT (Group II). The main reason for the suspension of the treatment was adverse side effects due to the pharmacological treatment. In particular, 7 out of the 12 patients of the group I not completing the study, dropped out because of duloxetine adverse events like nausea, drowsiness, insomnia, anorexia, headache, and stiffening of limbs, whereas five patients of the group II dropped out because they did not respect timing of the OPT sessions.

Baseline general and clinical characteristics

T0.

No statistically significant differences were found between the two groups in terms of age (p=0.52), disease span (p=0.23) and analgesic consumption (p=0.19).

As for the TMD diagnosis, no difference was found between the two groups (p=0.35). Twenty-nine (93.5%) FM patients reported myofascial pain and myofascial pain with referral and 23 (74.2%) FM patients had Temporomandibular joint Arthralgia.

Walking ability (p=0.04) and Normal work (p=0.04) were significantly altered in Group I compared to Group II.

Finally, patients of Group I turned out to be more depressed compared to the ones of Group II (Okada therapy plus duloxetine) (BDI p=0.02). Baseline general and clinical characteristics are shown in Table 2.

Effectiveness and health outcomes

As for the parameters under consideration, there was a strong effect of time, in particular T0 scores (of group 1 + group 2) were significantly different from both T1 scores (of group 1 + group 2) and T2 scores (of group 1 + group 2). T1 and T2 were not significantly different between themselves. Both groups showed an improvement of all parameters between T0 and T1, regardless of the group to which they belonged. There was no effect of treatment group and the interaction between time and group were not significant. The interaction between treatment and time

Table 1: Inclusion and exclusion criteria of the study.

Inclusion criteria	Exclusion criteria
Female outpatients ≥18 years of age	A positive history of traumatic injury or structural or regional rheumatic disease (rheumatoid arthritis, inflammatory arthritis, or autoimmune disease)
Fibromyalgia diagnosis according to American College of Rheumatology (ACR)[a]	Presence of an unstable medical or psychiatric illness, a positive history of substance abuse within the previous year, an actual suicide risk
TMD diagnosis in according to DC/TMD criteria[b]	Pregnancy or breast-feeding
Intensity of pain ≥4 on the average pain intensity item of Brief Pain Inventory (BPI)[c]	Presence of severe allergic reactions to multiple medications in the pharmacological history, a previous participation to a study of duloxetine
No previous treatment with biofield therapies consent to the study protocol	Chronic use of concomitant medications (sedatives, antiemetics, or antispasmodics), analgesics[d] and other medications or herbal agents working on the central nervous system activity.

[a]Wolfe F, Smythe HA, Yunus MB et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia. Report of Multicenter Criteria Committee. Arthritis Rheum 1990;33(2):160–172[b] Schiffman E., Ohrbach R., Truelove E., et al. Diagnostic criteria for temporomandibular disorders (DC/TMD) for clinical and research applications: recommendations of the international RDC/TMD consortium network* and orofacial pain special interest groupdagger. 2014;28(1):6–27. [c]Cleeland CS, Ryan KM. Pain assessment: global use of the brief pain inventory. Ann Acad Med Singapore 1994; 23(2):129–38[d] with the exception of acetaminophen up to 2 g/day and aspirin for cardiac prophylaxis up to 325 mg/day.

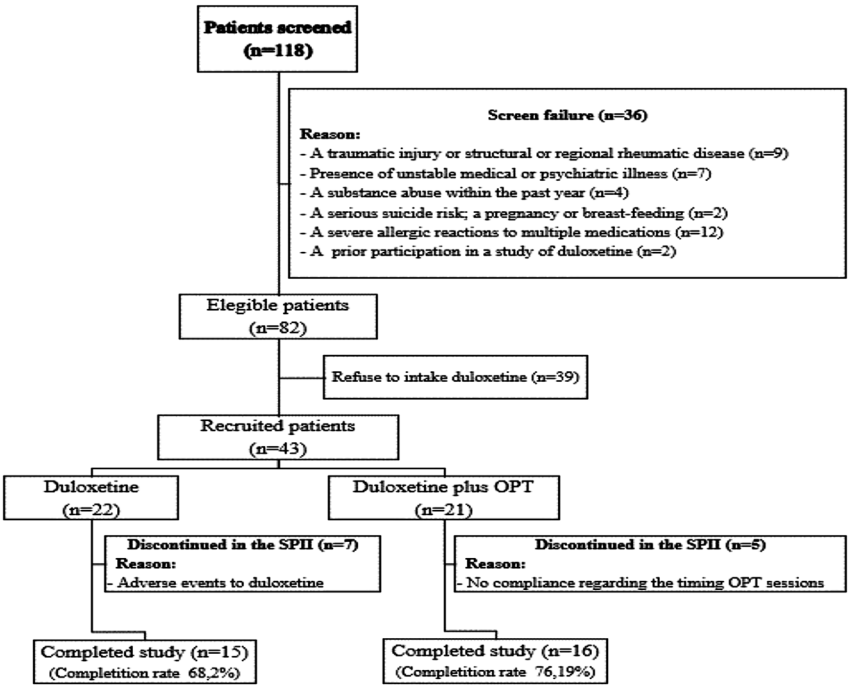

Figure 2: Flow of patients through the study.

Table 2: Baseline general and clinical characteristics for each study group.

Parameter assessed	Duloxetine		Duloxetine + OPT		p-Values *t*-student
	n	Mean (SD)	n	Mean (SD)	
Age	15	49.2 (11.8)	16	46.3 (12.9)	0.52
Disease duration (yrs)	15	9.3 (5.8)	16	13.1 (10.6)	0.23
Analgesic consumption (monthly)	15	33.1 (31.9)	16	11.9 (7.8)	0.19
***BPI severity* (0–10)**					
Average pain	15	5.9 (1.9)	16	5.9 (2.0)	1
Worst pain	15	7.5 (2.1)	16	6.9 (1.7)	0.38
Least pain	15	4.8 (2.5)	16	4.0 (2.7)	0.39
Pain right now	15	5.9 (2.9)	16	6.4 (2.3)	0.59
***BPI interference* (0–10)**					
General-activity	15	6.3 (2.3)	16	5.1 (2.4)	0.17
Mood	15	6.5 (3.0)	16	6.3 (2.8)	0.85
Walking ability	15	6.3 (2.7)	16	4.1 (3.1)	**0.04**
Normal work	15	6.4 (2.4)	16	4.5 (2.5)	**0.04**
Relationship with people	15	5.4 (3.2)	16	4.6 (2.5)	0.44
Sleep	15	6.2 (3.3)	16	6.6 (2.5)	0.70
Enjoyment of life	15	5.9 (3.9)	16	4.6 (2.9)	0.29
Fybromialgia impact questionnaire (0–80)	15	46.5 (14.4)	16	45.2 (14.2)	0.8
Beck depression inventory (0–39)	15	15.1 (9.8)	16	24.2 (12)	**0.02**
State and trait anxiety inventory 1 (20–80)	15	52.6 (13.9)	16	56.6 (12.6)	0.40
State and trait anxiety inventory 2 (20–80)	15	52.5 (11.3)	16	54.6 (12.7)	0.63

Bold type = differences between the two groups which were statistically significant (p-Values <0.05).

turned to be statistically significant, only as to one parameter, that is Ability of walking at the BPI-I; F=7.57, p=0.002. This particular outcome means that in the group I changes over time of the ability to walk were significant compared to group II, whereas the ability of walk was already statistically different in this group compared to group II, at T0 (see Table 3).

It is worth mentioning that Craniomandibular index, palpation and dysfunction index, total tenderness scores showed the same results. As for the parameters under

Table 3: A two- way repeated measures ANOVA with time (T0, T1 and T2) as a within subjects factor and treatment (Group I and Group II), as for the parameters under consideration.

	A two- way repeated measures ANOVA with time (T0, T1 and T2)	Main effect per group (Group I and Group II)	Interaction between time and group (Group I and Group II)
BPI-Severity			
Average pain in 24h	F=7.61, **p=0.001**	F=0.4, p>0.05	F=0.73, p>0.05
Worst pain in 24h	F=8.79, **p<0.001**	F=1.1, p>0.05	F=0.24, p>0.05
Least pain in 24h	F=3.91, **p=0.03**	F=0.20, p>0.05	F=1.63, p>0.05
Pain at the very moment	F=9.27, **p<0.001**	F=0.34, p>0.05	F=0.15, p>0.05
BPI-interference			
General activity	F=6.49, **p=0.003**	F=0.09, p>0.05	F=1.42, p>0.05
Mood	F=14.79, **p<0.001**	F=0.07, p>0.05	F=0.58, p>0.05
Walking	F=9.71, **p<0.001**	F=0.07, p>0.05	F=7.57, **p=0.002**
Working	F=3.54, **p=0.04**	F=0.89, p>0.05	F=2.88, p>0.05
Social abilities	F=7.52, **p=0.001**	F=0.03, p>0.05	F=0.83, p>0.05
Sleep	F=10.36, **p<0.001**	F=1.18, p>0.05	F=0.78, p>0.05
Life	F=4.61, **p=0.01**	F=0.05, p>0.05	F=2.96, p>0.05
BDI	F=7.59, **p=0.001**	F =1.84, p>0.05	F=2.76, p>0.05
STAI-1	F=18.73, **p<0.001**	F=1.58, p>0.05	F=0.12, p>0.05
FIQ	F=15.89, **p<0.001**	*F*=0.020, p>0.05	*F*=0.03, p>0.05

Bold type = statistically significant (p <0.05).

Table 4: Gnathological evaluation.

	A two- way repeated measures ANOVA with time (T0, T1 and T2)	Main effect per group (Group I and Group II)	Interaction between time and group (Group I and Group II)
PI	F=5.03, **p=0.01**	F=0.83, p>0.05	F=1.19, p>0.05
DI	F=6.4, **p=0.003**	F=1.71, p>0.05	F=2.62, p>0.05
CMI	F=7.96, **p<0.001**	F=1.78, p>0.05	F=0.77, p>0.05
TTS	F=30.84, **p<0.001**	F=0.052, p>0.05	F=0.52, p>0.05

PI, Palpation Index; DI, Dysfunction Index; CMI, Cranio-mandibular index; TTS, Total Tenderness Score. A two-way repeated measures ANOVA with time (T0, T1 and T2) as a within subjects factor and treatment (Group I and Group II). Bold type = statistically significant (p <0.05).

consideration, there was a strong effect of time, in particular T0 scores (of group 1 + group 2) was significantly different from both T1 scores (of group 1 + group 2) and T2 scores (of group 1 + group 2). T1 and T2 reported no significant difference. Both groups showed an improvement of all parameters between T0 and T1, regardless of the group to which they belonged. There was no effect of treatment group and the interaction between time and group was not significant (see Table 4).

Consumption of analgesics

Table 5: Analgesics consumption at baseline and at T2 (after eight weeks of treatment).

	Baseline (mean, SD)	T2 (mean, SD)	p-Value
Group I	33.1 (31.9)	1.9 (2.7)	**p<0.0001**
Group II	11.9 (7.8)	2.9 (3.1)	**p<0.0001**

Both treatment groups showed a significant reduction of meds consumption over the span of this study from baseline to T2 (eight weeks of treatment). No differences were observed between the two groups in terms of reduction of analgesics rate (see Table 5).

Safety and adverse events

Only 31 out of 43 patients recruited in the study, completed the eight-week of treatment (completion rate at 72%). Seven out of the 12 patients who did not complete the study were recruited in the group 1 (duloxetine) and dropped out from the study for the common adverse side effects of duloxetine such as nausea, drowsiness, insomnia, anorexia, headache and stiffening of limbs. Five patients

dropped out from the study because they did not respect the timing of the OPT sessions.

Discussion

In this *in vivo* study the authors proposed an holistic approach for the management of patients affected by FM and TMDs, consisting in the introduction of Okada Purifying Therapy alongside the traditional one used for this type of chronic diseases. In the scientific literature, the study of Sarmento et al. [27] assessed the effectiveness of OPT for patients with fibromyalgia. Despite the limitations of the study deriving from the small sample size, the research reported a decrease of depression symptoms, chronic widespread pain and tenderness, due to the administration of this type of biofield therapy. Compared to the current study, in the research of Sarmento et al. the patients did not receive any treatment other than OPT throughout the study period. Furthermore, the evaluation of temporomandibular disorders was not performed.

Among the alternative therapies proposed in the scientific literature for the treatment of FM patients, Reiki, a biofield therapy very similar to OPT in both rationale and method of energy administration, can be cited. However, compared to OPT, Reiki seems not to play an additional role in FM treatment, as suggested by Assefi et al. [6] and Langhorst et al. [28]. Such studies do not include any considerations of the impact of TMDs in patients selected for Reiki therapy and so therefore no analysis of craniomandibular indexes before and after treatments.

In compliance with the outcome of the above mentioned research studies, our results showed that the combination of OPT with duloxetine did not have any added value in terms of benefits of the clinical outcome in comparison with the treatment with duloxetine alone (Table 2, 3). Indeed in both groups, craniomandibular indexes, total tenderness scores and general parameters improved rapidly but there were not statistically significant differences between the two groups. The interaction between treatment and time was statistically significant, only as to one parameter, i.e. the Ability to walk at the BPI-I; $F=7.57$, $p=0.002$. As stated in the results section, this outcome could be explained in line of the circumstance that the ability to walk was already statistically different in this group compared to group II, at T0. The sample was certainly limited and a wider one might be required for any further investigations. Most likely, the results observed might be due to the fact that the treatment intensity and duration might have been insufficient for a chronic pain disorder, also considering the nebulous understanding of energy medicine mechanisms by the scientific community, as suggested by Assefi et al. [6].

However, an interesting aspect observed is that patients of the Group II (duloxetine plus OKADA) did not drop out for adverse side effects due to duloxetine, unlike what happened to patients of Group I (n=7 patients). This circumstance must not be random and might be explained as follows. No drop outs in the group II might be connected with the therapeutic effect of OPT in improving tolerability of duloxetine. Moreover, the high rate of drop-outs due to side effects and the decrease of duloxetine effectiveness in the medium-long term might suggest the clinicians either opting for the choice of new pharmacological solutions or non-pharmacological treatments like cognitive-behavioral therapies.

Furthermore, the data collected imply that, at least in our study population, FM patients do not easily accept traditional pharmacological treatment. The chronic assumption of preventive and symptomatic medications without a significant therapeutic success together with the chronic trend of the disease might be the underlying reason. Therefore any further future investigation could be aimed at administering OKADA therapy only in patients who do not accept pharmacological therapy with duloxetine, then at comparing results with a Control Group with a placebo therapy, or OKADA therapy in combination with other complementary treatments, such as cognitive-behavior therapy.

Study limits

Our sample was modest in quantity due to the high rate of non- participation because of the use of medication in both therapeutic arms. This did not give a greater strength to the study outcomes but it could address clinicians towards further investigation in these final directions.

Conclusion

In conclusion, the study results suggest that OPT did not improve the effectiveness of duloxetine in clinical outcomes but might increase the tolerability of medications, by improving the pharmacological effectiveness. In the future it would be interesting to try new complementary therapies or OPT in combination with interventions that currently work better in central sensitization such as cognitive behavioral therapy.

However, such results should be necessarily validated by further studies, considering the limits of the study itself.

Acknowledgement: The abstract is available also in the Journal of Osseointegration (JO).
Research funding: No financial interests exist.
Author contributions: All authors have accepted responsibility for the entire content of this manuscript and approved its submission.
Competing interests: The authors declare that there are no conflicts of interests.
Data availability statement: Data used to support the findings of this study are included within the article.

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