



International Journal of Current Research and Academic Review

ISSN: 2347-3215 Volume 4 Number 9 (September-2016) pp. 156-162
Journal home page: <http://www.ijcrar.com>



Sertraline effectiveness in prevention of depression and QOL improvement in MS patients

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KEYWORDS

Multiple sclerosis;
Sertraline;
Depression;
Quality of life.

A B S T R A C T

Multiple sclerosis (MS) is a chronic disease that leads to disability and reduced function in young adults. Depression is one of the common mood disorders in MS that affects these patients quality of life. Several treatments including drug therapy and psychotherapy have been used for the treatment of depression and fatigue. In this study we aim to evaluate the role of Sertraline in prevention of depression and QOL improvement in MS patients. In this randomized clinical trial, 60 patients with MS were selected and randomly allocated into groups receiving Sertraline and placebo. 25 patients in the intervention group and 21 patients in the control group completed the study. Both groups were evaluated for milton depression score, quality of life according to SF-36 questionnaire before the study, at the end of the first, third and sixth month. There was no significant difference according to baseline findings between groups. Three and 6 months after treatment intervention group compared to control group had significantly lower depression ($p < 0.001$) and higher quality of life ($p < 0.001$). Serial changes in the above mentioned variables in time in intervention group was significantly better than control group ($p < 0.001$). Results of current study showed that treatment with sertraline in patients with MS can prevent depression occurrence and improve quality of life in these patients.

Introduction

MS is the most common chronic disorder of the central nervous system that leads to morbidity and loss of function in young people (1 and 2). This disease affects 5.2 million people worldwide and its incidence is rising (3 and 4). Depression is one of the mood symptoms in MS patients. Epidemiological reviews have confirmed a 40% prevalence of major depression in these patients (5-6).

Chronic and sometimes debilitating nature of the disease is considered as most important factors of incidence of psychiatric problems such as depression and anxiety (7). The nature of depression - Forming drugs such as interferon and corticosteroids they have been proven (8). In MS patient's Quality of life is affected by disease severity, duration and medication consumed (9) and associated depression, sexual problems and anxiety can make their own assessment of their quality of life to decline (10).

Sertraline is one of the most commonly used drugs from SSRI drug series, which is now widely and compulsorily prescribed in the treatment of depression and disease cases associated with anxiety and obsession disorders (11 and 12). According to a study by Anhoki et al, MS patients have depression scores higher than the healthy control group (13). At the same time results of the Bisk et al showed that depression is also more prevalent in MS than in other chronic diseases (14). Depending on the type of study, depression has affected 15.8 to 47 percent of the MS population and its lifetime prevalence is estimated around 50% (14-16).

Efficacy of Sertraline has been well shown in the treatment of chronic somatic diseases and the prevention and improvement of

depression in patients with stroke (17-20). However, the role of this drug in the prevention of depression in MS patients has not been investigated yet.

This study aimed at assessing the role of Sertraline in prevention of depression and improvement of the quality of life in MS patients.

Method

In a clinical trial in the Department of Psychiatry, Tabriz on MS patients, the role of Sertraline in prevention of depression and reducing morbidities and improvement of the quality of life in these patients were examined.

In this study, 60 patients with multiple sclerosis were selected based on inclusion and exclusion criteria and enrolled into two groups of intervention and control.

Sampling

Sampling was Convenience Consecutive as referred by the neurologist. In this study, randomization was based on Block design.

Inclusion criteria

1. Age of 15-60 years
2. Elementary education at minimum

Exclusion criteria

1. Having a physical and psychological disease
2. Smoking and using other drugs or alcohol

Methods of study

In this study, thirty patients were randomly assigned to each group. 50 mg of Sertraline, product of Sobhan pharmaceutical factory, was added to the drug regimen of all patients

in the case group. In the control group, placebo was added to the drug regimen.

The patients in both groups were examined at the beginning of the study, the end of the first, third and sixth months in terms of depressive symptoms, rate of patient compliance in the treatment process and the degree of remaining morbidity based on the determination of Quality of Life by SF-36 standard. Validity and reliability of SF-36 was studied by Montazeri et al and its reliability coefficient at different scales was determined 0.77 to 0.9. Kaviani & Mousavi determined the reliability coefficient of 0.92 for Beck questionnaire (21). In both groups, the patients diagnosed with depression before the beginning of intervention in every period were excluded from the study. In both group at any time, patients diagnosed with depression in the assessments were treated with appropriate medication and were excluded from the study.

Blinding

This study was double-blind, where neither the physician nor the patient were not aware of the type of drugs received. The required placebo was provided by the faculty of Pharmacy similar to the original drug in terms of the features, shape, color, size and preferably flavor. This similarity between the original drug and placebo was also applied on the packaging. Possible intervening factors in this study have been considered as follows: The type and severity of disease, gender, age and comorbidity.

To gather the information necessary to evaluate the efficacy of Sertraline in reducing morbidities in patients with multiple sclerosis admitted to Razi hospital of Tabriz patients, the following tools were used:

The quality of life questionnaire SF-36

Quality of life questionnaire (SF-36) consists of 36 questions and is composed of eight scales; each scale is made up of 2 to 10 articles. Each question is scored on the scale of 0-100 based on the questionnaire guide.

Hamilton Rating Scale for Depression

This scale is one of the first scales provided for depression. This scale is conducted by therapist and has been designed to assess the severity of depression in patients. In Iran, Gharraee, Mehryar and Mehrabi (2000) reported the reliability coefficient of this scale as 85% and 89% by test-retest method according to Hamilton Anxiety Rating Scale.

The patient was informed about his participation in this study and assured on the confidentiality of the information provided. During the study, a number was assigned for each participant, and all the data remained anonymous. These data were preserved in accordance with Data Care Rules in Iran which guarantees their confidentiality. If the patients agreed to participate in the study, an informed consent form was filled and approved by them or their guardians, and kept by the researcher. The consent form noted that the patient is eligible to be excluded at will at any time without any reason expressed.

Results and Discussion

Out of the 30 patients in each group, 9 patients in the control group and 5 patients in the intervention group refused to continue the study and the study was finally concluded with 21 patients in the control group and 25 patients in the intervention group.

Table 4-1 shows the demographic findings between the two groups. As seen, there was

no significant difference between the two groups in terms of the basic findings.

Diagram 1 show the change course in the Hamilton depression scores before and 1, 3 and 6 months after the intervention. Before and one month after the intervention, there was no significant statistical difference (p=0.06 and p=0.52). However, the intervention group had significantly better depression scores at 3 and 6 months after the intervention (p<0.001 in both cases). Using Repeated measure of ANOVA, it was observed that the change course in each group and between the two groups was significant (p<0.001 in both cases).

Diagram 2 shows the change course in quality of life score before and 1, 3 and 6 months after the intervention. Before and one month after the intervention, there was no significant statistical difference (p=0.29 and p=0.58). However, the intervention group had depression scores significantly better at 3 and 6 months after intervention (p<0.001 in both cases). Using Repeated measure of ANOVA, it was observed that the change course in each group and between the two groups was significant (p<0.001 in both cases).

Table.1 Demographics finding of patients

		Group		P
		Sertraline	Placebo	
Age		29.6±3.79	30.95±3.58	0.22
Sex	Male	5(20%)	4(19%)	0.93
	Female	20(80%)	17(81%)	
Educational state	Third grade middle school	4(16%)	4(19%)	0.8
	Diploma	9(36%)	5(23.8%)	
	associate degree	7(28%)	6(28.6%)	
	Bachelor of Arts	5(20%)	6(28.6%)	

Diagram 1: Hamilton Depression Score in before and 1, 3 and 6 months after intervention

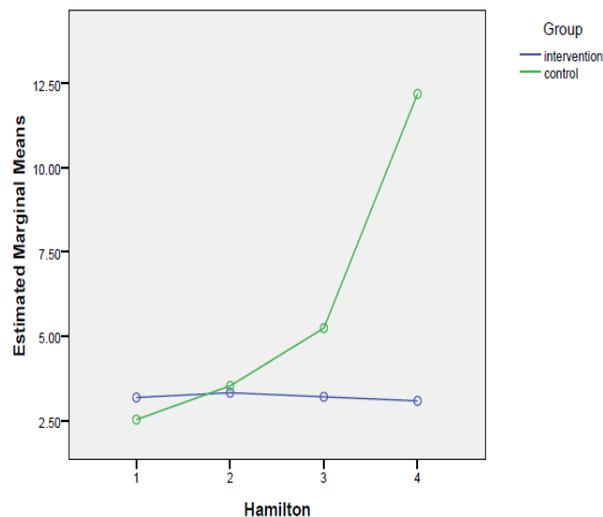
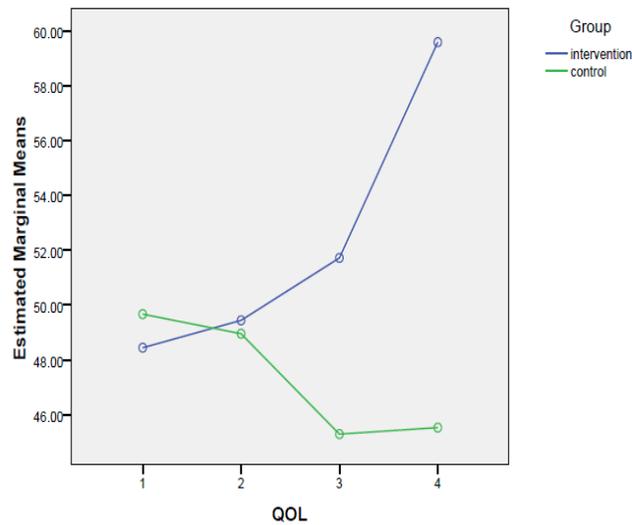


Diagram 2: Distribution of Quality of Life (QOL) in before and 1, 3 and 6 months after intervention



In the present study, the role of Sertraline in prevention of depression and fatigue, and its effect on the quality of life in MS patients were evaluated. The results showed that treatment with Sertraline was significantly associated with less depression, less fatigue and improved quality of life, and the more significant effects occurred after 3 months after beginning the treatment with Sertraline. Several treatments have been used in order to reduce fatigue and the frequent negative mood symptoms and improve the quality of life in MS patients. Sertraline is one of the medications from SSRI drug series which compared to other SSRI drugs in examinations, has higher effectiveness and tolerance and greater acceptability (12). In MS patients as well, well tolerated SSRI drugs, leaded by Sertraline, are considered as the first-line therapy for treatment of depression (22).

When selecting antidepressants for MS patients, possible side effects of these drugs should also be considered, especially if the present conditions of the patient, such as sexual dysfunction, or spasticity, may get worse.

This study is the first study evaluating the preventive role of Sertraline in prevention of depression and fatigue as well as improving the quality of life. In previous studies, MS patients with depression were treated with Sertraline and the results were evaluated.

Scott et al observed that the treatment with Sertraline contributed to significant improvement in depression symptoms in MS patients and it has been significantly effective (23). Mohr et al, examining MS patients with severe depression, observed significant improvement in measures of depression after study compared to before the study (24). Also, Hart et al showed that treatment with Sertraline in MS patients with depression was associated with significant improvements in quality of life (25).

Of course, efficacy of Sertraline in prevention of depression has been shown in other chronic diseases as well.

It is suggested that the mere treatment with Sertraline could be effective on MS disease. Taler et al in a study on rats found that Sertraline lead to improved clinical score of encephalomyelitis, and production and secretion of pro-inflammatory cytokines.

This study also suggests that Sertraline can be used as auxiliary therapy in MS (26). Previous studies on animal models as well as on humans have shown that levels of pro-inflammatory cytokines are associated with depression. Similar findings have also been reported in MS patients. It is also indicated that improvement of depression after treatment in MS patients has been associated with a reduction in levels of certain cytokines (27).

No significant side effects of the drug were observed in the previous studies. Similarly, in the present study, no unintended side effects were observed following the use of Sertraline.

Conclusion

The results showed that treatment with Sertraline in MS patients can prevent the incidence of depression, reduce fatigue and improve quality of life for these patients.

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How to cite this article:

Sepideh Herizchi Ghadim, Mohammad Asgharpour, Sheida Shaafi, Maziyar Hashemilar, Homayoun Sadeghi. 2016. Sertraline effectiveness in prevention of depression and QOL improvement in MS patients. *Int.J.Curr.Res.Aca.Rev.4(9): 156-162*.