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ORIGINAL PAPER

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# Quality of Life Assessment in Antidepressant Treatment of Patients with Depression and/or Anxiety Disorder

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## ABSTRACT

**Introduction:** The concept of quality of life (QoL) is becoming an increasingly important criterion in the assessment of treatment outcomes, health outcomes and in the assessment of the benefit-to-load ratio of drugs or therapies that have equivalent mechanisms of action. **Aim:** The aim of the study was to evaluate the improvement of quality of life, tolerability of therapy and patient compliance in patients with depression and/or anxiety disorder treated with antidepressants.

**Methods:** The study was designed as a clinical, multicenter, prospective, cohort study involving 682 patients of both sexes diagnosed with depression and/or anxiety disorder observed over the 9 months period. The study was conducted from January to December 2017 in six research centers of the PI Health Center of the Canton of Sarajevo. The patients were divided into three groups: depressive, anxious and mixed anxiety-depressive disorder, and the therapy administered was, paroxetine or escitalopram. MOS (Medical Outcomes Study) sleep scale and Q-LES-Q-SF (Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form) scale were used for quality of life evaluation. Patients were observed six times over the course of the study. **Results:** The results of the MOS questionnaire showed that more than 90 percent of patients with depression and/or anxiety disorder who had taken fluoxetine, paroxetine or escitalopram for 36 weeks experienced an improvement in the sleep problem index. Sleep duration was greatly improved in all patients regardless of the antidepressants used. The results of the Q-LES-Q-SF questionnaire showed a significant improvement in quality of life as well as overall pleasure and satisfaction with life due to the use of antidepressants. **Conclusion:** Therapy with fluoxetine,

paroxetine and escitalopram leads to a significant improvement of all recorded parameters, along with the overall quality of life, which makes them very effective in the treatment of depression and/or anxiety disorders.

**Keywords:** quality of life, depression, anxiety disorder, antidepressants.

## 1. INTRODUCTION

The concept of quality of life (QoL) is becoming an increasingly important criterion in the assessment of treatment outcomes and health outcomes and in the assessment of the benefit-to-load ratio of drugs or therapies that have equivalent mechanisms of action (1). According to the latest data, depression is the main cause of health problems and inability to work, and in the last ten years, the number of patients has increased by more than 18 percent. According to the World Health Organization (WHO) estimates, depression will become the second most important health problem in the world by 2020 (2). Empirical findings from various studies indicate that anxiety disorders and major depression are associated in various areas and have a negative impact on quality of life (1,3,4). The importance of measuring health - related quality of life (HRQoL) has strongly increased according to the Medical Outcomes Study (5). Several large - scale studies on depression and anxiety disorders affecting subsequent quality of life showed that subjects had significant quality of life impairment (1,6). Treatment with antidepressants can improve both anxiety and depression symptoms. Many antidepressants are available, but none is clearly preferred for all patients. In recent years, selective serotonin

reuptake inhibitors (SSRIs) have been the first line of treatment for these disorders (1,7). Escitalopram, fluoxetine and paroxetine are well-known SSRIs that have shown consistent efficacy and rapid symptom relief in the treatment of anxiety disorders.

Multiple studies demonstrated the superior effect of these antidepressants compared with placebo (7–11). A study by Simon et al. points out that patient and physician preferences are the most important factors in treatment decisions for patients with depression. However, the available data do not show whether SSRIs and the more recent antidepressants show better outcomes, such as better quality of life, less mental stress and better mental health (6,12). When analyzing HRQoL, studies usually focus on the way the disease or disorder affects quality of life. While clinical studies have provided sufficient data on the safety and efficacy of the various antidepressant classes, there is a lack of information on the effects on HRQoL and mental health in real environments (6). The goal for mental disorders is now shifting from a mere remission to the complete recovery of the individual (6). Therefore, there is an increased need for studies that can further investigate the influence of antidepressants on quality of life.

## 2. AIM

The aim of this study is to investigate the potential improvement of quality of life in patients with depression and/or anxiety disorder who used antidepressants during the study, as well as the tolerability of the treatment administered and the compliance of patients during the study.

## 3. METHODS

### Patients

This clinical, multicenter, prospective, cohort study involved 682 adult patients diagnosed with depression and/or anxiety disorder, validated by Beck Depression Scale (13) and Beck Anxiety Scale (14), and followed up for nine months. The study was carried out in six research centers in the Public Institution Health Centre of Sarajevo Canton, from January to December 2017. Patients with severe depression and/or anxiety disorder, patients with symptoms of psychosis, patients with anamnestic angioedema, patients taking concomitant treatment with monoamine oxidase inhibitors, patients who had clinical conditions that could affect the pharmacokinetics of antidepressants, patients who showed hypersensitivity to components of the drugs and patients who were pregnant were excluded from the study.

Patients were divided into three groups based on their conditions: depressive, anxious and mixed anxiety-depressive disorder. During the course of the study, patients used the following treatment: fluoxetine 20 mg film-coated tablets (Flusetin®, Bosnalijekd.d.), paroxetine 20 mg film-coated tablets (Dipresan®, Bosnalijekd.d.) and escitalopram 10 mg film-coated tablets (Citalea®, Bosnalijekd.d.).

The study was submitted to and approved by the Agency for medical products and medical devices of Bosnia and Herzegovina, according to the Law on medicines of Bosnia and Herzegovina.

### Methods

During the study, MOS (Sleep Scale from the Medical Outcomes Study; MOS Sleep Scale) and Q-LES-Q-SF

(Quality of Life and Satisfaction Questionnaire) questionnaires were translated to Bosnian language for the purpose of the study and used for evaluation. The assessment of sleep quality was assessed using the MOS questionnaire (15), which measures the index of sleep problems using six variables: sleep disorder, sleep deprivation, daily somnolence, snoring, waking up breathless or with headache and total sleep. The answers are based on a retrospective evaluation of sleep in the last 4 weeks. The variables are measured as a total score of 0-100, whereby the higher result means better sleep. The amount of sleep is measured as the average number of hours of sleep during the night (16). Life enjoyment and satisfaction were measured using the Q-LES-Q-SF questionnaire (17), which consists of 16 variables (questions) and evaluates the overall joy and satisfaction of patients with physical health, mood, occupation, housework, social relationships, family relationships, leisure activities, daily functioning, sexual life, economic status, living conditions, the possibility of physical activity without feeling dizzy and/or unstable, sight during work or with hobbies, general well-being and medication. Answers are measured on a scale of 14-70, after which the results are converted to a maximum percentage (% maximum). Higher result indicates better enjoyment and satisfaction with life. The first 14 variables give the overall result of the questionnaire. The last two variables (general well-being and medication) are considered separately (18).

Patients were observed at six points: baseline and five additional assessments. The first assessment was made three weeks after the baseline, the second assessment was made seven weeks after the baseline, the third assessment was made 11 weeks after the baseline, the fourth assessment was made 24 weeks after the baseline and the fifth assessment was made 36 weeks after the baseline.

The safety of the study was ensured by monitoring the frequency of adverse reactions of the drug with the evaluation of the relationship between the use of drugs and the reporting of adverse reactions (certain, likely, possible, unlikely, unclassified relationship and unclassifiable) and compliance with the assessment basis in the application of therapy (number of tablets).

### Statistical analysis

Statistical analysis was performed by SPSS (Statistical Package for Social Sciences), version 21.0. The distribution of data from the study was tested by Kolmogorov-Smirnov test for normality and then described by measurements of central tendency and variability (median and interquartile range). A comparison of the mean values between the two groups was performed by the student t-test for independent samples, i.e. the ANOVA test for several independent groups of variables following the normal distribution. To measure the significance of differences in variables measured at time intervals, a Student-t test for dependent samples or ANOVA for repeated measurements was used. Calculation was done by  $\chi^2$  test with the level of significance of 95% ( $p=0.05$ ).

## 4. RESULTS

This study included 682 patients that met the inclusion criteria. Majority of the study sample were females 447 (65.5%), while 235 (34.5%) were males. Out of the total number, 339

Type of disorder	Antidepressant	MOS questionnaire			
		Sleep problem index		Amount of sleep	
		Observation		Observation	
		Baseline	Last	Baseline	Last
Depression	Fluoxetine	63.9±16.2	24.9±16.1*	5.1±1.3	6.6±1.3*
	Paroxetine	61.2±15.9	23.1±17.1*	5.1±1.2	6.8±1.1*
	Escitalopram	63.1±16.5	21.5±15.9*	5.3±1.4	6.8±1.1*
Anxiety disorder	Fluoxetine	52.0±21.9	19.0±16.2*	5.5±1.4	7.4±1.1*
	Paroxetine	61.3±19.0	17.1±13.8*	5.3±1.5	7.0±1.2*
	Escitalopram	54.0±21.2	16.6±12.0*	5.3±1.5	7.0±0.9*
Depression and anxiety disorder	Fluoxetine	60.4±14.7	21.5±14.8*	5.9±1.4	7.5±0.6*
	Paroxetine	63.3±11.7	25.1±13.8*	5.7±1.6	6.9±0.9*
	Escitalopram	59.7±17.2	21.1±14.4*	5.2±1.2	6.9±0.9*

Table 1. Results of sleep problem index and the amount of sleep in all three patient groups during the baseline and last observation. Note: Variables are measured as the total score ranging from 0-100, where the higher result means better sleep. The amount of sleep is measured as the average number of hours of sleep during the night. \* p<0.001 compared with the values at the baseline observation before the start of treatment

Type of disorder	Antidepressant	Q-LES-Q-SF questionnaire Enjoyment and life satisfaction	
		Observation	
		Baseline (%)	Last (%)
Depression	Fluoxetine	13±11	43±13*
	Paroxetine	17±11	46±14*
	Escitalopram	16±13	46±13*
Anxiety disorder	Fluoxetine	25±12	54±14*
	Paroxetine	22±13	52±13*
	Escitalopram	27±12	52±12*
Depression and anxiety disorder	Fluoxetine	16±12	49±18*
	Paroxetine	12±14	45±17*
	Escitalopram	17±12	43±15*

Table 2. Changes in scores of enjoyment and life satisfaction in patients with depression and/or anxiety disorder during the use of antidepressant therapy. Note: Variables are shifting as the maximum percentage (% maximum) ranging from 0-100%, where the higher result means better enjoyment and life satisfaction. \* p<0.001 compared with the values at the baseline observation before the start of treatment

(49.7%) patients had depression, 250 (36.7%) had anxiety disorders and 93 (13.6%) had depression and anxiety disorders. Of the total number of patients with anxiety disorder, 115 (40.9%) had generalized anxiety disorder, 72 (25.6%) had post-traumatic stress disorder, 64 (22.8%) panic disorder, 64 (22.8%) obsessive-compulsive disorder, and 13 (4.6%) had social phobia.

In the group of patients with depression, 94 (27.7%) used fluoxetine, 92 (27.1%) paroxetine and 153 (45.1%) used escitalopram. In the group of patients with anxiety disorder, 51 (20.4%) of them used fluoxetine, 84 (33.6%) paroxetine, while 115 (46.9%) used escitalopram. In the group of patients with depression and anxiety disorder, 18 (19.4%) of them used fluoxetine, 31 (33.3%) paroxetine and 44 (47.3%) used escitalopram. Most commonly prescribed antidepressants in all three groups was escitalopram.

sants in all three groups was escitalopram.

**MOS questionnaire**

The examination of the MOS questionnaire for the evaluation of sleep quality showed that the average score for all six variables (sleep disturbance, snoring, shortness of breath, sleep disorders, somnolence) decreased significantly in all three patient groups (p<0.001). A significant decrease in the average sleep problem index and a significant increase in the average amount of sleep were also observed in all three groups of patients (p<0.001). The displayed decrease in all six variables was observed regardless of the type of therapy used (Table 1). In patients with depression and/or anxiety disorders, the drop rate was between 50 and 70 percent for various parameters. All three drugs were equally effective.

**Q-LES-Q-SF questionnaire**

Examining the rate of enjoyment and life satisfaction during the use of these antidepressants showed that the values increased significantly in all three groups of patients (p<0.001) (Table 2).

**5. DISCUSSION**

This study investigated the long-term efficacy and effect on quality of life (QoL) of antidepressant therapy in the treatment of patients with depression and/or anxiety disorder. QoL measurement has gained increasing importance in medicine and is increasingly being implemented in clinical studies and health policy (19). It includes a more comprehensive picture of people’s health that is necessary to explain that treatment to restore health has been successful (19).

Based on the results of our study, we can conclude a few points. Demographic data showed that there was no significant difference in the use of antidepressants compared to sex, age, work status or previous use of antidepressants. In our study, the results of the MOS questionnaire on sleep quality in our study showed that over 90 percent of patients with depression and/or anxiety disorder experienced a significant improvement in their sleep problem index after 36 weeks of fluoxetine, paroxetine and escitalopram therapy. In addition, sleep duration was significantly increased for all patients regardless of the antidepressant used. These results indicate an improvement in sleep quality with antidepressant therapy. Q-LES-Q-SF questionnaire showed a significant improvement in enjoyment and life satisfaction in all three groups of patients, indicating improvement in quality of life with antidepressant therapy.

The QoL assessment enabled the comparison of the effects of various mental disorders. When diseases and their impact on society need to be compared, disease - specific scales are not appropriate to enable this comparison, and generic scales are needed. The combination of mental disorders, which are widespread and associated with a significant reduction in quality of life, could help to place patients with mental disorders higher on the scientific and financial agenda (19). A study on relapse prevention with escitalopram in patients with social anxiety disorder, evaluated with the MOS scale, showed that long-term treatment with escitalopram, which effectively prevents relapse, is associated with a significant benefit in terms of HRQoL (20).

Escitalopram has shown high efficacy and tolerability with high remission rates and a significant improvement in symptoms of depression, anxiety and overall quality of life (21). It appears to be beneficial for the treatment of sleep problems in depression and generalized anxiety disorder (22). Escitalopram was significantly more effective than placebo in the treatment of anxiety and depression symptoms and depressed patients with a high degree of anxiety (7). The quality of life study of depressed inpatients treated with fluoxetine showed that fluoxetine improved not only depressive symptoms but also most aspects of HRQoL in hospitalized patients with depression (23). Another study by Kroenke et al. showed that the SSRI antidepressants paroxetine, fluoxetine and sertraline were similar in efficacy in depressive symptoms as well as in several areas of health-related quality of life over the 9 months period (24). In a randomized, controlled study with paroxetine evaluated on the MOS scale, the results showed that all areas of HRQoL, with the exception of physical function, improved with successful acute and follow-up treatment. Maintenance antidepressant pharmacotherapy was superior to placebo in preserving improvements in overall well-being achieved with treatment response in late-life depression (25). A meta-analysis by Hofmann et al. on the effect of pharmacotherapy on quality of life in anxiety disorders showed that pharmacological therapy is effective in improving quality of life in anxiety disorders, and greater symptom reductions are associated with greater improvement in quality of life (26). The results of our study may be limited by the type of questionnaires used for QoL measures. All questionnaires were self-disclosures with a potential risk of misrepresentation or bias in the responses. Clinician-reported outcome assessments could give a greater insight into patients' antidepressant therapy-related QoL. Another limitation of this study is that it did not investigate how involved patients were in treatment decisions or the patient-physician relationship, that could further explain the results of patients' adherence to therapy or treatment satisfaction.

## 6. CONCLUSION

Our study shows that fluoxetine, paroxetine and escitalopram are equally effective in treating depression and/or anxiety disorders. All three antidepressants led to a significant improvement in all monitored parameters, which led to a significant improvement in the patient's quality of life, improved the sleep quality index in over 90 percent of patients, prolonged sleep duration, and resulted in a comprehensive improvement in life satisfaction.

- **Author's contribution:** A.D.Z., R.R., M.H., A.C. and E.M. gave substantial contribution to the conception or design of the work and in the acquisition, analysis and interpretation of data for the work. E.M., E.A.G., E.M., A.H. and A.S. had role in drafting the work and revising it critically for important intellectual content. Each author gave final approval of the version to be published and they are agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
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