Original Article

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Effect of fluoxetine on quality of life in patients with solid cancers: A double-blind study

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ABSTRACT

More studies showed that diagnosis of cancer lead to occurrence of emotional problems in patient and his family. Fluoxetine is an anti-depression drug that used for treatment of Depression, Obsessive compulsive disorder, Panic disorder and nervous incontinence. The aim of this study was investigate the effect of fluoxetine on quality of life in patients with solid cancers. This is a randomized controlled clinical trial that has been done on two groups of patients each with 70 patients. One group received fluoxetine for 12 weeks and another group received placebo. In baseline and end of study, SF36 questionnaire were completed for all patients and results analyzed by statistical methods in SPSS.16. The most prevalent malignancy in case and control groups was gastric cancer with 40% and 42.9%, respectively. There wasn't significant difference in QOL of patients in baseline between two groups but in the end of study, emotional-psychological health and vitality scores in case group was better than control group. In terms of physical symptoms and depression, the case group was better than control group. In start and end of study, in QOL score only difference was seen in physical activity which was better in case group than control group. Results showed that fluoxetine prescription in patients could recovery some dimensions of QOL and general health but not effect on some dimensions which probably related to short duration of fluoxetine prescription in patients.

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Keywords
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INTRODUCTION

Despite the remarkable advances in medical science, cancer is one of the most important diseases of the present century and is the second leading cause of death after cardiovascular disease. At present, more than 7 million people in the world are losing their lives due to cancer, and more than 25 million people live with cancer [1]. Although today, diagnosis of cancer is not equivalent to imminent death but many studies in Western countries and some Asian countries have shown that such a diagnosis causes deep emotional and emotional problems in the patient and his family [2,3].

Psychological status and quality of life are emphasized as one of the effective aspects in the care of cancer patients. The World Health Organization defines the quality of life as a person's perception of his or her own lifestyle based on the culture and systems of value in which he lives and how it relates to the goals, expectations, standards and priorities of the individual [4].

Cancer, in comparison with other diseases, causes worry and anxiety and more complex psychological problems.

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Almost, 85% of cancer patients experienced one mental diseases that most of them related to anxiety and depression disorders. The physiological and psychological effects of cancer on patients and their families cause profound changes in their lives [3,5-7].

Fluoxetine as an antidepressant drug from the group of serotonin reuptake inhibitors is used to treat depression, obsessive-compulsive disorder, panic disorder, and neurological abnormalities [8-9].

Higher prevalence of cancer and its side-effects have more effect on the qol in cancer patients. Since physical conditions affect the social and psychological functioning of a person, the term "quality of life" is focused on physical, psychological, economic and social factors [4].

Depression is occurred in 15% of general population and in cancer patients 2-3 time is more. Due to the complexity and limitations of caring for cancer patients, the reluctance of the patient and his family to diagnose discomfort and the presence of many other symptoms, the diagnosis of depression is often difficult in these patients [10]. Given the low cost of this drug, its availability and its benefits in treating depression and other anxiety disorders, the purpose of this study was to evaluate the effect of fluoxetine on the quality of life of patients with solid tumors.

MATERIALS AND METHODS

This is a randomized double blind clinical trial that has been done on 140 patients with solid cancer which referred to Aras clinic of Ardabil city hospital in 2013-2014.

Inclusion criteria

Patients with age>15, confirmed cancer, passed at least a year from the diagnosis of the disease and unknown psychological problems or being treated with psychosocial drugs were entered in the study.

In this study the sampling method is census and we select all patients with solid tumor under chemotherapy with stable status and non-acute during 2013-2014 and then divided in two case and control groups each with 70 patients. Case group received 20 mg fluoxetine and control group received placebo for 12 weeks. The QOL-SF36 questionnaire will completed in the start and end of study and the CHQ completed for all patients in the end of study. SF-36 questionnaire included 36 items in 8 dimensions (Physical functioning, Role limitations due to physical health, Role limitations due to emotional problems, Energy/fatigue, Emotional wellbeing, Social functioning, Pain and general health) which each item has score between 0 to 100.

This study registered in IRCT by code: IRCT2015012220751N1 and ethically approved by Ardabil University of Medical Science. In the event of drug side effects, patients withdraw from the study and drug is cut. Collected data analyzed by statistical methods such as Chi-square for determine the relation between QOL levels between two case and control groups and used T-test for compare the mean score of QOL between two groups in whiten QOL dimensions in SPSS version 16.

RESULTS

The mean age of patients in case and control groups were 57.6±12 and 55.8±13 that the difference not significant. Of

Table 1. Demographic data of patients

Variables	*Case*		*Control*	
	n	%	n	%
Illiterate	31	44.3	28	40
Smoking user	13	18	9	13.4
History of alcohol consumption	4	5	5	6.4
Age mean	55.8±13		57.6±12	

Table 2. Compare mean of QOL in patient's two groups in the beginning of study

Items	*Group*	*Mean*	*SD*	*p-value*
General mental health	Case	59.4	18.1	0.12
	Control	53.2	15.3	
General health	Case	65.1	16.4	0.2
	Control	62.1	18.3	
Physical functioning	Case	65.5	19.8	0.7
	Control	66.1	21.4	
Bodily pain	Case	66.9	16.5	0.8
	Control	67.8	14.1	
Role limitations because of physical health problems	Case	59.2	12.7	0.2
	Control	55.3	16.9	
Social functioning	Case	61.4	17.6	0.8
	Control	60.1	19.9	
Role limitations because of emotional problems	Case	67.3	21.9	0.5
	Control	66.4	20.9	
Vitality (energy/fatigue)	Case	74.1	21.4	0.08
	Control	66.9	23.6	

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all patients in two groups, 84.3% were illiterate, 31.4% were smoking user and 11.4% have the history of alcohol consumption (Table 1).

The prevalent malignancy in case group with 40% and 18% and in control group with 42.9% and 15% were gastric and colon cancer, respectively. The QOL in the beginning of study has not significant difference between two groups but in the end of study, general mental health and vitality in case group was significantly more than control group (Table 2).

By assessment the QOL in two groups separately we showed that physical functioning in case group in the end of study had a significant improvement compared to the beginning of the study but in other parameters the difference not significant and in control group no improvement were seen in any dimension. The highest frequency was related to physical functioning and general mental health of patients in the case group, which was in good range (Table 3).

In terms of general health problems and depression, the case group had a better situation than the control group but there was no significant difference between the two groups in terms of symptoms of anxiety and sleep disorders, social function and general health score (Table 4).

DISCUSSION

Some studies indicated that the severity of depression in fluoxetine-treated patients decreases and the quality of life increases. In this study, the QOL of patients in two group in the end of study after fluoxetine prescription observed that general mental health and vitality in case significantly was more than control group. Also physical functioning in case group patients in the end of study compared to the beginning of the study have significant recovery. In Fisch and et al study, results showed that the depression severity in treated patients with fluoxetine had been increased and QOL had been decreased [10].

In Holland and et al study, results the fluoxetine and Desipramine prescription reduced the symptoms of depression and anxiety in patients and the FLIC (Functional Living Index for Cancer) function was also improved [8]. In QOL study these two drugs could improvement the dimensions of general mental health and social functioning in patients which in line with our study results, because in this study fluoxetine could improve the general mental health in patients but had not significant effect on social functioning and anxiety of patients.

Passik and et al, in a study showed that the administration of fluoxetine for 12 weeks could improve the QOL of patients significantly [11]. In Navari and et al study, the depression symptoms in 79.6% of breast cancer patients which treated with fluoxetine has been decreased and QOL of patients has been increased [8,12].

Contrary to the current study, Razavi et al. found that

Table 3. Study QOL level of patients in two groups in the end of study

Items	*QOL levels* / *Group*	*Week*	*Moderate*	*Good*	*p-value*
General mental health	Case	7.1	21.4	71.4	0.001
	Control	21.4	41.4	37.2	
General health	Case	5.7	27.1	67.1	0.24
	Control	8.6	35.7	55.7	
Physical functioning	Case	2.9	22.9	74.2	0.42
	Control	7.2	21.4	71.4	
Bodily pain	Case	10	25.7	64.3	0.64
	Control	14.3	27.1	58.6	
Role limitations because of physical health problems	Case	17.1	37.1	45.7	0.8
	Control	14.3	35.7	50	
Social functioning	Case	10	31.4	58.6	0.37
	Control	7.1	40	52.9	
Role limitations because of emotional problems	Case	10	12.9	77.1	0.7
	Control	10	17.1	72.9	
Vitality (energy/fatigue)	Case	7.1	10	82.9	0.26
	Control	4.3	17.1	78.6	

Table 4. Study General Health of patients in two groups in the end of study

Items	*QOL levels* / *Group*	*Moderate*	*Week*	*Good*	*p-value*
Anxiety symptoms and sleep disorders	Case	33	44.3	23	0.8
	Control	38.5	37.2	24.3	
Social functioning	Case	24.3	58.6	17.1	0.8
	Control	27.1	58.6	14.3	
Depression symptoms	Case	27.1	68.6	4.3	0.008
	Control	37.1	41.3	21.6	
General health problems	Case	27.1	68.6	4.3	0.028
	Control	40	51.4	8.6	
Total general health score	Case	35/7	51.4	12.9	0.15
	Control	35.7	41.4	22.9	

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fluoxetine did not significantly reduce depression in patients within 5 weeks. It seems that short-term administration of fluoxetine in this study was a contradiction in the results [13].

In a full review of the articles, fluoxetine was found to be effective in depression rate and quality of life in cancer patients, which in current study the significant relation, was seen in many dimension of QOL in patients [14].

In Torta and et al study, it was observed that prescription of sertralin for 12 weeks could reduce significantly MADRS (Montgomery Asberg Depression Rating Scale) and HADS (Hospital Anxiety and Depression Scale) and in 40.4% of patients the rate of depression has improved greatly [15].

In Grassi and et al, it was observed that Administration of 8-week reboxetine significantly reduced the level of anxiety and depression in cancer patients [16]. In Pezzella and et al study, it was observed that in the 8-week amitriptyline recipient group, MARDS was reduced by more than 50% in 37.9% of patients, and this reduction was 43.7% in paroxetine recipients, which patients were more tolerant of amitriptyline [17].

In Thompson and et al study, it was observed that administration of mirtazapine could improve sleep disturbance, nausea and appetite in 19% of patients, but did not significantly reduce depression in patients [18].

In some studies, antidepressant drugs did not have a significant effect on patients' depression, for example in Musselman and et al study; it was observed that administration of 6-week Paroxetine and Dosipramine could not significantly reduce the depression rate toward placebo group [19].

In Marrow and et al study, it was observed that 8-week administration of Paroxetine couldn't reduce vitality and depression rate towards placebo group [20].

It seems that prescribing antipsychotics at a shorter duration of therapy reduces their effect on depression in patients. In the present study, it was observed that the administration of antidepressant drugs such as fluoxetine could have a significant positive effect on improving the quality of life of patients.

CONCLUSION

Results showed that Administration of fluoxetine in patients could improve some aspects of quality of life and general health, but it did not have significant effect on some aspects of quality of life and general health, that probably due to the short duration of fluoxetine administration in patients in this study which need for more studies in future.

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CONFLICT OF INTEREST

The authors declare that this research does not have any conflict of interest with anyone or any institute.

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