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Original Article

Impact of standard treatment on the quality of life of non-alcoholic fatty liver disease patients

Raika Jamali, MD [a], Atie Moghtadaie, MD [b,*], Seyed Amir Miratashi Yazdi, MD [c] and Hadie Moghtadaie, MD [d]

[a] *Research Development Center, Sina Hospital, Tehran University of Medical University, Tehran, Iran*
[b] *Internal Medicine Department, Sina Hospital, Tehran University of Medical Sciences, Tehran, Iran*
[c] *Sina Hospital, Department of Surgery, Tehran University of Medical Sciences, Tehran, Iran*
[d] *School of Pharmacy, Shahid Beheshti University of Medical Sciences, Tehran, Iran*

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الملخص

أهداف البحث: مرض الكبد الدهني غير الكحولي هو مصدر قلق كبير في الصحة العامة، ولكن تأثيره على نوعية الحياة لم يتم التحقيق فيه بشكل كاف. تقيم هذه الدراسة تأثير العلاج القياسي لمرض الكبد الدهني غير الكحولي على نوعية حياة المرضى المصابين.

طرق البحث: أجريت هذه الدراسة المستقبلية على المرضى الذين يعانون من مرض الكبد الدهني غير الكحولي، المراجعين لعيادة أمراض الجهاز الهضمي في مستشفى سينا طهران. خضع جميع المرضى لبروتوكول علاج قياسي. وتم تقييم المعالم الديموغرافية والمادية والبيوكيميائية، ودرجة الدهون في مرض الكبد الدهني غير الكحولي، ونوعية درجات الحياة من خلال استبانة منظمة الصحة العالمية بشأن جودة الحياة واستبانة أمراض الكبد المزمنة عند خط الأساس، بعد ثلاثة وستة أشهر من العلاج. تم تصنيف المرضى إلى مجموعتين; فقدان الوزن (>٥٪) وفقدان الوزن غير كبير (<٥٪)، ستة أشهر بعد بدء العلاج.

النتائج: تم تقييم ما مجموعه ٤٠٠ مريضا (٥٢.١٪ من النساء، ومتوسط العمر ٤٩.٩٣±٣.٠١سنة). لاحظنا أن ١٢٧ مريضا حققوا خسارة كبيرة في الوزن (٣١.٧٥٪) خلال فترة ٦ أشهر، في حين أن ٢٧٣ مريضا لم يحققوا هدف فقدان الوزن (٦٨.٢٥٪). ولم توجد فروق كبيرة بين الفئات في المعالم الديمغرافية. وقد أظهرت استبانة منظمة الصحة العالمية بشأن جودة الحياة واستبانة أمراض الكبد المزمنة تحسينات كبيرة في مجموعة "فقدان الوزن بشكل كبير" مقارنة بمجموعة "فقدان بسيط للوزن". وأظهر تحليل الانحدار أن درجة الدهون في مرض الكبد الدهني غير الكحولي وتحليل ناقلة أمين الألانين الأساسية كانت مرتبطة بشكل كبير بنتائج استبانة منظمة الصحة العالمية بشأن جودة الحياة. وارتبطت نتائج استبانة أمراض الكبد المزمنة بشكل كبير بمرحلة التليف، ودرجة نشاط مرض الكبد الدهني غير الكحولي ووجود داء السكري.

الاستنتاجات: خلصت هذه الدراسة إلى أن نظام العلاج القياسي وفقدان الوزن يمكن أن يحسن بشكل كبير من نوعية الحياة في مرضى مرض الكبد الدهني غير الكحولي.

الكلمات المفتاحية: مرض الكبد الدهني غير الكحولي؛ نوعية الحياة؛ أمراض الكبد المزمنة؛ فقدان الوزن؛ الكبد الدهني؛ استبانة أمراض الكبد المزمنة

Abstract

Objective: Given that non-alcoholic fatty liver disease (NAFLD) is a major concern in public health, this study evaluates the impact of a standard treatment for NAFLD on the quality of life of affected patients.

Method: We conducted this study on patients suffering from NAFLD at the gastroenterology clinic of Sina Hospital, Tehran. All patients underwent a standard treatment protocol. We collected information about the demographic, physical, biochemical parameters and the NAFLD fat and quality of life scores using the World Health Organization Quality of Life questionnaire (WHOQOL-BREF) and Chronic Liver Disease Questionnaire (CLDQ) and evaluated the data at the baseline, three months, and six months post-treatment. Patients were categorized into two groups, namely those with significant weight loss (>5%) and non-significant weight loss (<5%) six months after the start of the treatment. The statistical analysis was performed via SPSS 22.

* Corresponding address. Internal Medicine Department, Sina Hospital, Tehran University of Medical Sciences, Hassan Abad Square, Imam Khomeini Avenue, Post BOX: 1136746911, Tehran, Iran.
E-mail: atiemoghtadaie@gmail.com (R. Jamali)

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Results: A total of 400 patients (52.1% women, mean age of 49.93 ± 3.01 years) were evaluated. We noticed that 127 patients achieved significant weight loss (31.75%) during the six-month period, while 273 patients did not achieve the weight loss goal (68.25%). No significant differences in demographic parameters were found between the groups. As per the WHOQOL-BREF questionnaire and CLDQ, there were significant improvements in the significant weight loss group compared to the non-significant weight loss group. Regression analysis showed that the NAFLD fat scores and baseline alanine aminotransferase (ALT) levels were significantly correlated with WHOQOL-BREF outcomes. The CLDQ outcomes were significantly associated with the fibrosis stage, NAFLD activity score, and the presence of diabetes mellitus.

Conclusion: This study concludes that a standard treatment protocol and weight loss regime can significantly improve the quality of life of NAFLD patients.

Keywords: Chronic liver disease; Chronic Liver Disease Questionnaire; Fatty liver; NAFLD; Quality of life; Weight loss

Introduction

First recognized in 1980, the non-alcoholic fatty liver disease (NAFLD) has become one of the most common concerns in public health today.[1] It includes a spectrum of conditions from non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis (NASH) to fibrosis, cirrhosis, and hepatocellular carcinoma. Through the process of elimination, NAFLD is diagnosed after ruling out all secondary aetiologies for deposition of fat in the liver.[2]

The rise in the prevalence of NAFLD during the previous decades underscores the necessity to focus on research about this condition. Although various methods for diagnosing NAFLD have been used, and the prevalence rates vary extensively, global research estimated the prevalence rates of NAFLD at 31% and 32% for the Middle East and South American regions, respectively, and at 13.5% for Africa.[3] Estimations reveal a NAFLD prevalence rate of 24% for adult populations across the world.[3] These figures indicate that a substantial proportion of the global population is suffering from NAFLD. The clinical complications and economic consequences of NAFLD have been extensively studied. Although the negative impact of NAFLD on the quality of life (QOL) of affected patients has been proved, studies on all relevant aspects of this association are not adequate. The first study on the QOL of 106 NAFLD patients demonstrated that QOL was significantly lower for NAFLD patients compared to their counterparts with viral hepatitis.[4] Since then, several studies have presented varied or conflicting results regarding the parameters affecting QOL of NAFLD patients. A recent systematic review on QOL of NAFLD patients concluded that poor physical QOL is found in affected patients, with fatigue and cirrhosis contributing most significantly to impaired QOL.[5]

Over the years, there have been great efforts put into the treatment of NAFLD and its consequences, in the hope that this would improve the QOL of affected patients. However, a few studies on the role of treatment in improving QOL have yielded conflicting conclusions. A wide spectrum of results from "no change from baseline" to "significant change at post-treatment phase" can be observed in the literature. So, given the scarcity of studies on the effects of treatment on the QOL of NAFLD patients and the inconclusive findings of the extant studies, we aim to evaluate the impact of treatment on QOL in patients suffering from NAFLD.

Materials and Methods

This study was conducted on patients suspected to have NAFLD, referred to the Gastroenterology and Hepatology clinic of Sina Hospital in Tehran in 2019. The criteria for inclusion required all patients to be over 18 years old and diagnosed with NAFLD based on histologic assessment, ultrasonographic parameters, and serum aminotransferase levels. Those with a history or existing conditions of severe heart failure, kidney failure (where the glomerular filtration rate (GFR) < 60), consumption of hepatotoxic drugs in the previous three months, cirrhosis, malignancy, chronic obstructive pulmonary disease, intravenous drug abuse, hepatitis history, blood transfusion in the past year, and a history of alcohol abuse, opium consumption, or steroid intake were all excluded from the study. Eligible patients gave informed consent. An ultrasonography was conducted for all patients to assess the health of their livers and diagnose NAFLD. It may be noted that all ultrasonographic assessments in our study were conducted by an expert ultrasonologist.

All patients underwent standard treatment, according to the practice guidelines of the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association.[6] This protocol includes the following recommendations:

- Limiting calorie intake through a low-fat and low-carbohydrate diet
- Facilitating physical exercise in the form of 2–3 aerobic exercise sessions a week, with each session being 30–60 minutes for 6–12 weeks
- Targeting a weight loss of at least 5%
- Providing a daily vitamin E dosage of 800 units for non-diabetic patients with biopsy-proven NAFLD diagnosis
- Referring patients to the nutritionist, psychologist, and physical medicine specialist, if needed

At the baseline, patients' demographic data (age, gender, etc.) were collected, and their biochemical parameters (liver enzyme levels, fasting blood sugar (FBS), low-density lipoproteins (LDL), high-density lipoproteins (HDL), cholesterol, triglycerides, insulin), physical indices (body mass index (BMI), waist circumference), and liver fat score were assessed. The QOL of patients was assessed with a validated

Persian version of WHOQOL-BREF questionnaire and CLDQ. The former includes 26 items across four general domains including physical health, mental health, social relationships, and environmental categories. CLDQ is a tool to measure health related QOL. Assessments were all repeated three and six months after treatment for all patients. However, CLDQ was only assessed at the baseline and six months post-treatment. Patients were categorized into two groups, namely, those with significant weight loss (>5%) and non-significant weight loss (<5%) six months after the initiation of treatment. The study was approved by Tehran University of Medical Sciences' institutional review board with the code IR.TUMS.MEDICINE.REC.1396.4706 in May 2018.

To assess the severity of the condition, the NAFLD liver fat score was calculated based on the following formula:

NAFLD liver fat score = −2.89 + 1.18 * metabolic syndrome (yes = 1/no = 0) + 0.45 * type 2 diabetes (yes = 2/no = 0) + 0.15* fS-insulin (mU/L) + 0.04* fS-AST (U/L) − 0.94 * AST/ALT,[7]

where AST is aspartate aminotransferase, and ALT is alanine aminotransferase.

Liver biopsies taken from patients were evaluated by expert pathologists to determine the severity of the fibrosis. The fibrosis stage was reported in the METAVIR system (stages 3 and 4 indicate advanced liver fibrosis) and the NAFLD activity score (NAS) was also calculated. Those with NAS scores of 5−8 were diagnosed with non-alcoholic steatohepatitis (NASH).

Data analysis was performed with IBM *SPSS* Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp. Normality of data was tested using the Kolmogorov−Smirnov test. Descriptive report of data was presented as mean ± SD or median for continuous parameters, frequency, and as percentages for of categorical variables. To compare the two groups, t-test and chi-square tests were used for parametric and non-parametric variables, respectively. Furthermore, we conducted an analysis of variance (ANOVA) and paired t-test to assess the trend of parameters through follow-ups. The threshold for statistical significance was at $p < 0.05$.

Results

In our study, we analysed 400 patients (52.1% females, mean age of 49.93 ± 3.01 years), out of which 127 patients reached significant weight loss (31.75%) during a six-month period, while 273 patients did not reach the weight loss goal (68.25%). The mean ages of patients in the weight loss and non-weight loss groups were 48.11 ± 2.15 and 51.64 ± 2.68 years, respectively ($p > 0.05$). In the weight loss group, 66 (51.96%) patients had an academic education while the non-weight loss group had 130 such patients (47.61%) ($p = 0.129$). Furthermore, 90 (70.86%) and 178 patients (65.20%) in the weight loss and non-weight loss groups respectively lived in urban regions, ($p = 0.251$). We note that diabetes mellitus was present in 29 (22.83%) and 76 patients (27.83%) ($p = 0.714$) and advanced fibrosis (F3−4) was found in 32 (25.19%) and 76 patients (27.83%) in weight loss and non-weight loss groups, respectively. NAS >4 was detected in 63 patients (49.60%) from the weight loss group and 115 patients (42.12%) from the non-weight loss group.

The anthropometric and biochemical parameters for both groups were compared at three time-points. Table 1 shows the details of the anthropometric parameters, and in Table 2, we see that the trends show improvements in some parameters in the weight loss group compared to non-weight loss group.

NAFLD fat scores in the significant weight loss group were 12.9 ± 6.5, 11.9 ± 5.4, and 10.1 ± 5.6, respectively ($p = 0.011$), while those in the non-significant weight loss group were 13.7 ± 6.1, 13.1 ± 7.2 and 12.5 ± 6.8, respectively ($p = 0.073$). As shown, significant reductions in NAFLD fat scores were observed in the significant weight loss group.

The QOL was assessed with the WHOQOL-BREF questionnaire. We note that standard treatment improved all domains of WHOQOL-BREF in both groups, but the improvements in weight loss group were significantly more pronounced. The details are presented in Table 3.

Health-related quality of life was assessed with CLDQ at the baseline and six months after the initiation of treatment. Improvements across all domains of CLDQ were significant in the weight loss group compared to the non-weight loss group. The details are summarized in Table 4.

Bivariate correlation analysis revealed that data from the WHOQOL-BREF questionnaire were significantly correlated with the NAFLD fat score, age, weight, BMI, waist circumference, FBS, baseline triglyceride level, serum AST, and ALT levels (p-values< 0.05). Regression analysis revealed that the WHOQOL-BREF questionnaire was only significantly correlated with ALT (p-value = 0.002) and NAFLD fat scores (p-value = 0.001). These findings were the same across all four domains of the WHOQOL-BREF questionnaire. Figure 1 shows the relationship of NAFLD fat scores and QOL.

Table 1: Anthropometric parameters in the significant weight loss and non-significant weight loss groups.

Parameter	Group	Baseline	Three months post-treatment	Six months post-treatment
Weight	Weight loss	87.12 ± 9.61	83.91 ± 10.26	79.74 ± 8.93
	Non-weight loss	88.21 ± 10.28	87.39 ± 10.08	85.83 ± 15.65
	p-value	0.799	0.013	0.000
BMI	Weight loss	30.82.31 ± 3.34	29.71 ± 3.39	28.92 ± 4.73
	Non-weight loss	31.92 ± 4.99	31.70 ± 4.82	31.11 ± 5.96
	p-value	0.092	0.043	0.007
Waist circumference	Weight loss	107.73 ± 10.41	104.11 ± 9.44	101.66 ± 9.50
	Non-weight loss	108.20 ± 12.99	107.83 ± 11.70	106.97 ± 11.94
	p-value	0.511	0.273	0.019

Table 2: Biochemical parameters in the NAFLD and control groups.

Parameter	Group	Baseline	Three months post-treatment	Six months post-treatment
FBS	Weight loss	106.2 ± 14.9	101.5 ± 10.8	94.1 ± 11.7
	Non-weight loss	108.4 ± 11.9	104.7 ± 10.5	101.8 ± 8.7
	p-value	0.299	0.117	0.024
Triglyceride	Weight loss	164.3 ± 92.9	141.5 ± 66.1	126.8 ± 60.9
	Non-weight loss	168.6 ± 74.3	159.6 ± 52.9	151.7 ± 48.7
	p-value	0.492	0.041	0.037
Total cholesterol	Weight loss	182.3 ± 35.9	172.6 ± 29.1	161.8 ± 28.5
	Non-weight loss	179.3 ± 28.7	174.3 ± 23.3	170.2 ± 22.8
	p-value	0.529	0.493	0.031
LDL cholesterol	Weight loss	105.7 ± 31.8	99.9 ± 26.5	93.4 ± 26.4
	Non-weight loss	108.8 ± 25.4	105.1 ± 21.2	103.3 ± 21.1
	p-value	0.198	0.074	0.011
HDL cholesterol	Weight loss	37.1 ± 8.3	39.4 ± 5.2	42.8 ± 5.1
	Non-weight loss	36.2 ± 5.9	37.3 ± 4.7	38.9 ± 5.3
	p-value	0.271	0.119	0.064
AST	Weight loss	41.2 ± 7.3	39.3 ± 6.4	32.1 ± 8.2
	Non-weight loss	44.3 ± 10.1	43.1 ± 7.9	41.9 ± 9.4
	p-value	0.573	0.821	0.027
ALT	Weight loss	52.7 ± 51.7	46.8 ± 36.9	39.8 ± 32.8
	Non-weight loss	57.3 ± 8.4	51.9 ± 8.5	49.7 ± 8.3
	p-value	0.481	0.311	0.035
ALKP	Weight loss	281.7 ± 170.6	249.4 ± 126.9	221.5 ± 127.1
	Non-weight loss	293.1 ± 96.9	284.3 ± 74.2	266.4 ± 54.8
	p-value	0.077	0.048	0.006

Table 3: Group scores for quality of life assessed via WHOQOL-BREF questionnaire.

Parameter	Group	Baseline	Three months post-treatment	Six months post-treatment
Overall quality of life	Weight loss	69.4 ± 7.1	86.7 ± 4.5	99.1 ± 6.4
	Non-weight loss	65.8 ± 8.89	67.9 ± 5.7	71.8 ± 8.1
	p-value	0.239	**0.045**	**0.003**
Physical	Weight loss	19.8 ± 2.1	25.8 ± 1.4	29.6 ± 1.8
	Non-weight loss	17.1 ± 2.6	18.5 ± 1.7	21.3 ± 2.3
	p-value	0.171	**0.041**	**0.033**
Psychological	Weight loss	16.8 ± 1.4	20.6 ± 1.3	23.8 ± 1.6
	Non-weight loss	15.7 ± 1.8	16.4 ± 1.7	16.8 ± 2.1
	p-value	0.911	0.220	**0.031**
Relationship	Weight loss	10.7 ± 1.4	13.3 ± 0.5	15.4 ± 0.8
	Non-weight loss	9.1 ± 1.8	10.4 ± 0.6	10.9 ± 1.1
	p-value	0.209	0.158	**0.029**
Environment	Weight loss	22.2 ± 2.3	27.8 ± 1.5	33.3 ± 2.5
	Non-weight loss	22.5 ± 2.8	23.7 ± 1.8	24.6 ± 3.1
	p-value	0.259	0.722	**0.021**

Table 4: Health-related quality of life with CLDQ in significant weight loss and non-significant weight loss groups.

Domain	Total	Median change in significant weight loss	Median change in non-significant weight loss	*p-value*
Overall	5.5 ± 0.9	0.43	0.05	0.000
Abdominal	5.9 ± 1.2	0.71	0.06	0.005
Fatigue	5.1 ± 1.4	0.55	0.11	0.003
Systemic	5.7 ± 1.2	0.21	0.09	0.059
Activity	5.6 ± 1.3	0.32	0.08	0.013
Emotions	5.5 ± 1.1	0.37	0.11	0.042
Worry	5.6 ± 1.3	0.78	0.31	0.010

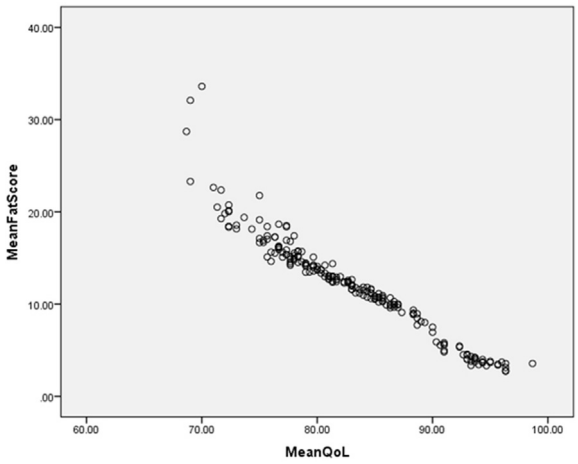

Figure 1: Relationship between NAFLD fat score and quality of life.

Further analysis showed that the results of CLDQ were significantly associated with the fibrosis stage (p-value<0.001), NAFLD activity score (p-value = 0.005), and the presence of diabetes (p-value = 0.002). Regression analysis also showed that these factors were independently correlated with CLDQ outcomes.

Discussion

Patients with NAFLD usually experience fatigue, agitation, depression, and cognitive deficits. These symptoms significantly impact the mental and physical well-being and health related QOL of patients. Despite efforts to explore the epidemiology, pathogenesis, and clinical course of NAFLD, therapeutic options are still limited.[8,9] In addition, the effect of NAFLD on patients' QOL has not been investigated extensively.

Overall quality of life and all its domains in the WHOQOL-BREF questionnaire displayed significant improvements in the significant weight loss group compared to the non-significant weight loss group. Studies reported that the QOL was significantly impaired in NAFLD patients, compared to controls.[5] The CLDQ also showed remarkable improvements in the significant weight loss group compared to the non-significant weight loss group. A comparison of sub-domains of QOL is not usually feasible due to the different tools used in the studies. A similar study that used the WHOQOL-BREF questionnaire for the evaluation of NAFLD in paediatric patients revealed that there was a significant difference between NAFLD and control groups in terms of overall QOL score and its psychological domain. Physical, relationship, and environment domains showed no significant difference in the mentioned study.[10] Among the studies that addressed the impact of treatment on QOL of NAFLD patients, only one study had evaluated the impact of standard treatment in alterations of QOL finding that 5% weight loss through exercise and dietary modifications was correlated with significant improvements in the total CLDQ score and related symptoms.[11] These findings are consistent with what we have reported in our study. Other studies have assessed specific treatments for NAFLD. One such study revealed that the administration of liraglutide significantly improves the physical sub-domain of quality of life,[12] while another study on vitamin E or pioglitazone showed no improvement in the QOL of patients. The quest for finding more precise and conclusive results on this issue continues.[13]

Demographic parameters, academic education, and urban regions were not significantly different between the weight loss and non-weight loss groups. Although age was significantly correlated with the WHOQOL-BREF questionnaire scores in univariate analysis, regression analysis did not show its independent impact on the QOL. The association of demographic variables and quality of life has yielded conflicting results in studies. On the one hand, a study on NASH patients without cirrhosis reported no association between gender or age with any domain of SF-36 and CLDQ tools in evaluation of QOL.[14] On the other hand, there are studies which have claimed that higher ages are significantly correlated with lower levels of QOL.[15,16]

Regression analysis showed no significant correlation between weight, BMI, and waist circumference and QOL. It is surprising that there was no relationship between BMI—as an indicator of obesity —and QOL in our study, although this finding has been reported in several previous studies. While some studies have ruled out the association of BMI and QOL in NAFLD patients,[11,14,17] numerous studies have posited that obesity plays a significant role in worsening the QOL of NAFLD patients. A study by David et al. (2009) has confirmed that poorer scores in the physical domain of QOL are independently a consequence of BMI levels of over 40.[15] Evaluations with CLDQ-NAFLD have also demonstrated more systemic symptoms, more prominent fatigue, and subsequently lower levels of QOL at higher levels of BMI.[4,18]

Treatment led to a significant decrease in the NAFLD fat scores in the significant weight loss group. Furthermore, regression analysis revealed that the NAFLD fat score and baseline serum ALT levels were independently correlated with the QOL of NAFLD patients. Apart from their findings on the ALT level, we see that Chawla et al. (2007)[4] and Dan et al. (2016)[14] have claimed that there was no significant association between albumin, total protein, AST, ALT, and ALKP (alkaline phosphatase) levels with QOL among NAFLD patients. This is consistent with our study. Sayiner et al. (2016)[17] and David et al. (2009).[15] have also reported that the cirrhosis and fibrosis stage were significantly and independently correlated with the QOL of NAFLD patients, similar to our study, in which the fibrosis stage was independently correlated with the CLDQ outcome.

The main limitation of our study was the lack of a healthy control group to compare the impact of weight loss in obese subjects without NAFLD, and patients suffering from NAFLD. Further investigations with the presence of adequate controls can expand our knowledge on this topic.

Conclusion

Based on our findings, we note that standard treatment and weight loss significantly improve the QOL of NAFLD patients. The NAFLD fat scores, baseline serum ALT concentrations, fibrosis stage, NAFLD activity scores, and

presence or absence of diabetes mellitus are significant and independent predictors of the QOL in these patients.

Recommendations

We recommend including a healthy control group in the future studies for a more comprehensive comparison of the outcomes.

Source of funding

This study was funded by the Tehran University of Medical Sciences.

Conflict of interest

The authors declare that there was no conflict of interest at any stage of this study.

Ethical approval

The study was approved on May 3, 2018 by the ethics committee of the Tehran University of Medical Sciences, bearing the approval code IR.TUMS.MEDICINE.REC.1396.4706.

Authors' contribution

RJ presented the idea, designed the study, and critically revised all versions of the manuscript. While AM collected the data, prepared the initial draft, and worked on revisions from the initial to the final draft, SAMY collected and analysed the data, and contributed towards writing and revising the manuscript. HM contributed to the data collection and manuscript preparation. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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