ORIGINAL ARTICLE

Eastern Journal of Medicine
East J Med 23(4): 289-297, 2018
DOI: 10.5505/ejm.2018.66933

The alteration of life quality between hormone treatment-receiving and non-receiving early-stage prostate cancer patients who underwent radiotherapy

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ABSTRACT

The purpose of this prospective study was to compare the life qualities of radiotherapy-receiving early-stage prostate cancer patients during their controls done prior to, at the last week of, and 3 months after, the radiotherapy procedure.
Curative surgery or radiotherapy is the treatment of choice in localized prostate cancer. Androgen deprivation therapy, which is performed according to the risk groups, is effective in the downsizing of the prostate. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire EORT-QLQ C30 is an effective means of evaluating the quality of life on the basis of the individual's physical and functional scales.
35 prostate cancer patients who had not undergone surgery and who received curative radiotherapy were included in the study. The study was performed prospectively. The life qualities and weights of prostate cancer patients were evaluated before, at the end of, and 3 months after, the radiotherapy sessions, by means of the EORTC-QLQ 30 Test.
The alterations encountered in hormone-receiving patients on the basis of physical, emotional, perceptional, and social scores, in addition to fatigue, nausea, vomiting and pain evaluations, done on the basis of the EORTC-QLQ 30 measurements performed prior to, at the end of and 3 months after, the radiotherapy sessions, were found to be statistically significant ($p<0.001$). Patients who did not receive hormone therapy in the emotional and pain scores demonstrated statistically significant changes during the same evaluations $p=0.006$, and $p=0.019$, respectively.
It was concluded at the end of the study, that radiotherapy, in general, does not impose a negative effect on the quality of life in prostate cancer patients but it does lead to changes in the general and emotional functional scores, as well as the complaints of pain, insomnia, constipation, and diarrhea.

Key Words: Quality of life, radiotherapy, prostate carcinoma

Introduction

Prostate cancer (Pca), is the second most-frequently encountered cancer in men, after lung cancer. It is of utmost importance in Pca, to know if the disease is localized or not. This is important for the evaluation of therapy options. Before deciding the therapy strategy, it must be known if the cancer is localized or not, and if it has metastasized or not. Currently, 94 % of all Pca are diagnosed during the localized stage (Stages T1 and T2). The availability of testing with the prostate-specific antigen (PSA) has made it possible to detect the disease at an early stage. Approximately 81 % of Pca patients are diagnosed at a clinically localized stage (1). Pca is a heterogenous disease, and is classified as being of low, mild, and high risk. Decisions on the alternatives of active surveillance, radiotherapy (RT), surgery, and hormonal therapy, are made on the basis of the stage of the disease (2). RT and radical prostatectomy are the curative options in the treatment of localized prostate cancer. On the other hand, androgen deprivation therapy (ADT) is another option, and it is used after triaging the patients in accordance with their risk groups. ADT may also be used in patients with disease progression following primary therapy. In the curative option, ADT is not utilized in the low-risk group, while it is administered in association with radiotherapy in the mild and high risk groups. ADT offers the advantage of increased survival in patients whose stages vary between localized disease and localized advanced stage disease, while it gives metastatic disease patients the advantage of relieving the symptoms and increasing the general comfort. The application of ADT prior to RT leads to a volume loss of the prostate, but it may imply a negative effect on the quality of life (3,4,5). ADT may also demonstrate negative effects on life

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Received: 18.05.2018, **Accepted:** 13.07.2018

Table 1. The Properties of the Patients

	N (%)
TNM	
T2A N0 M0	8 (22.9)
T2B N0 M0	9 (25.7)
T2C N0 M0	18(51.4)
Gleason	
6(3+3)	9 (25.7)
7(3+4)	8(22.9)
8(4+4)	13(37.1)
9(4+5)	3(8.6)
10(5+5)	2(5.7)
Risk Groups	
Low risk	9(25.7)
Intermediate risk	12(34.2)
High risk	14(40)
Hormone therapy	
Receiving	9(25.7)
Non-receiving	26 (74.3)

quality, in terms of fatigue, heat stress, depression, cognitive impairment, dementia, osteoporosis, and gynecomastia (6,7). Patients receiving ADT need close follow-up, concerning their life quality.

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ C30) is a methodology developed for the evaluation of the physical and functional scales of cancer patients (8).

The purpose of this prospective study was to compare the life qualities of radiotherapy-receiving early-stage prostate cancer patients during their controls done prior to, at the last week of, and 3 months after, the radiotherapy procedure. In this study, we aimed to evaluate the life quality standards of early stage prostate cancer patients undergoing curative RT, by utilizing the EORTC – QLQ 30 scale.

Materials and Methods

This study was conducted at the Radiation Oncology Department of the Numune Teaching and Research Hospital, Adana, Turkey. 35 patients with early stage prostate cancer who were undergoing radiotherapy were included in the study. The study was done in a prospective manner, between March 2016 and March 2018. Ethical Committee approval was obtained from the University of Cukurova (Decision number and year: 29/2016, 27/2017) Adana, Turkey. All patients gave their informed consents, prior to the study. The mean age of the patients was 66.17 years, while the age range was 54 – 80 years. A total of 35 patients were administered curative radiotherapy. 8 (22.9 %) of these patients were Stage T2A, while 9 (25.7 %) were T2B, and 18 (51.5 %) were T2C. None of the patients were operated. Based on the Gleason scoring system, 9 (25.7 %) patients were labeled as score 6, while 8 (22.9 %) patients were scored as 7, 13 (37.1 %) patients as 8, 3 (8.6 %) patients as 9, and 2 (5.7 %) patients as 10. Based on the risk categorizations, 26 (73.4 %) patients were started on hormone therapy, while the remaining 9 (25.7 %) were excluded from the hormone therapy regimen (Table 1). The patients were evaluated according to the EORT-QLQ 30 life quality test, prior to (RT 0), at the end of (RT 1), and 3 months after (RT2), the RT sessions. During the study period, the weights of the patients were followed closely. The EORTC QLQ-C30 questionnaire comprises 30 questions. Every question is scored as 1, 2, 3, and 4 (8). Global health status, five functional scales (physical, role, cognitive, emotional, social), and nine symptom scales/items (fatigue, nausea/vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, financial difficulties) are the parts of the EORTC QLQ-C30. The sum of these scores (0 – 100) gave the data for the evaluation of the quality of life. A high score on the functional scale represents a high level of functioning but a high score on the symptom scale represents very severe symptoms or financial impact (9).

Radiotherapy: Curative radiotherapy was administered to the patients, using the Intensity Modulated Radiotherapy (IMRT) technique. The patients received a radiation dose changing between 72 and 76 Gy, according to their risk groups.

Statistical Analysis: All statistical analyses were performed using the IBM SPSS Statistics Version 19.0 statistical software package. Categorical variables were expressed as numbers and percentages, whereas continuous variables were summarized as the mean values and standard deviations, and as median, and minimum and maximum, where appropriate. The Mann Whitney U Test was used for the comparison of continuous variables between the two groups, to evaluate the changes in the measurements over the time

Table 2. The evaluation of the hormone-receiving and non-hormone-receiving patients in terms of the EORTC-QLQ 30 measurements performed at the RT 0, RT 1, and RT 2, phases

Hormone treatment n+=26 n-=9		RT 0 Mean ± sd Media (Min,Max)	RT 1 Mean ± sd Media (Min,Max)	RT 2 Mean ± sd Media (Min,Max)	p time
Physical Function Score	-	62.96±17.03 66.67(40.00,86.67)	68.15±20.21 60.00(40.00,93.33)	76.30±11.60 73.33(66.67,93.33)	0,331
	+	57.95±16.95 60.00(20.00,86.67)	68.46±14.79 66.67(46.67,93.33)	83.33±10.37 86.67(66.67,93.33)	<0,001
p time		0,469	0,868	0,197	0,342
The Emotional Function Score	-	85.19±6.95 83.33(75.00,91.67)	76.85±11.62 75.00(50.00,91.67)	93.52±8.10 91.67(75,100)	0,006
	+	69.55±16.99 66.67(41.67,100)	73.08±14.40 75.00(50.00,91.67)	89.74±8.27 91.67(75,100)	<0,001
p time		0,013	0,590	0,224	0,122
Cognitive Function Score	-	81.48±17.57 83.33(50.00,100)	81.48±15.47 83.33(50,100)	83.33±8.33 83.33(67,100)	0,942
	+	63.46±27.09 66.67(16.67,100)	77.33±15.87 83.33(33,100)	89.10±12.42 91.67(67,100)	<0,001
p time		0,093	0,442	0,184	0,068
The Social Function Score	-	79.63±18.21 83.33(50,100)	68.52±13.03 66.67(50,83.33)	77.78±11.78 83.33(67,100)	0,287
	+	60.26±23.61 66.67(16.67,100)	64.75±10.88 66.67(33.33,83.33)	85.90±12.19 83.33(67,100)	<0,001
p time		0,038	0,492	0,119	0,008
Fatigue	-	29.63±13.61 22.22(11.11,55.56)	24.69±9.26 22.22(11.11,44.44)	16.05±11.26 11.11(0,33.33)	0,050
	+	41.45±13.90 44.44(22.22,77.78)	27.78±12.27 27.78(11.11,44.44)	12.82±11.63 11.11(0,44.44)	<0,001
p time		0,038	0,516	0,516	0,079
Nausea and vomiting	-	5.56±11.78 0(0,33)	3.70±7.35 0(0,16.67)	3.70±7.35 0(0,16.67)	0,861
	+	27.56±25.36 25(0,83.33)	7.05±12.63 0(0,50)	1.92±5.43 0(0,16.67)	<0,001
p time		0,023	0,670	0,643	0,016
Pain	-	38.89±16.67 33.33(16.67,66.67)	59.26±14.70 50(50,83.33)	37.04±13.89 33.33(16.67,50)	0,019
	+	50±17 50(16.67,83.33)	67.95±16.95 75(33.33,83.33)	33.97±13.73 33.33(16.67,50)	<0,001
p time		0,128	0,210	0,590	0,184
Loss of appetite	-	22.22±23.57 33.33(0,66.67)	18.52±17.57 33.33(0,33.33)	3.70±11.11) 0(0,0.33)	0,153
	+	17.95±25.35 0(0,33.33)	6.41±13.40 0(0,33.33)	6.41±13.40 0(0,33.33)	0,060
p time		0,540	0,110	0,725	0,371
Weight	-	71.22±7.64 71(63,88)	71.56±6.84 72(64,87)	72.78±7.16 73(65,89)	0,003
	+	66.96±5.92 65(59,81)	67.08±6.45 65(59,80)	67.69±6.50 65.50(59,80)	0,008
p time		0,093	0,073	0,042	0,309

Number of patients receiving hormone therapy= n_+ (+)
Number of patients non-receiving hormone therapy= n_- (-)

interval, the Repeated Measurements Analysis method was applied. The statistical level of significance for all tests was appointed as 0.05.

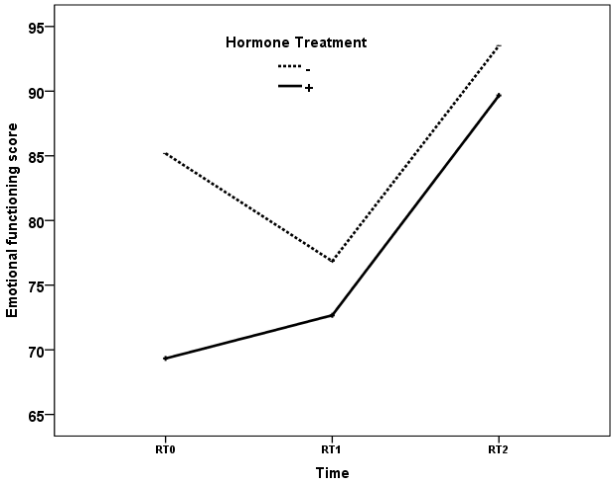
Results

Table 2. Patients who received hormone therapy group, The temporal alterations of the physical function, emotional function, cognitive function, social function, nausea, vomiting, and pain, scores, performed on the basis of the EORT-QLQ 30 system, showed statistically significant changes through time, at the RT 0, RT 1, and RT 2, phases ($p<0.001$). The loss of appetite over time was found to be statistically borderline significant in the hormone - receiving group, during the controls performed at the RT 0, RT 1, and RT 2, phases ($p= 0.06$). Patients who received hormone therapy group, weight change too, observed during the same time period, was found to be

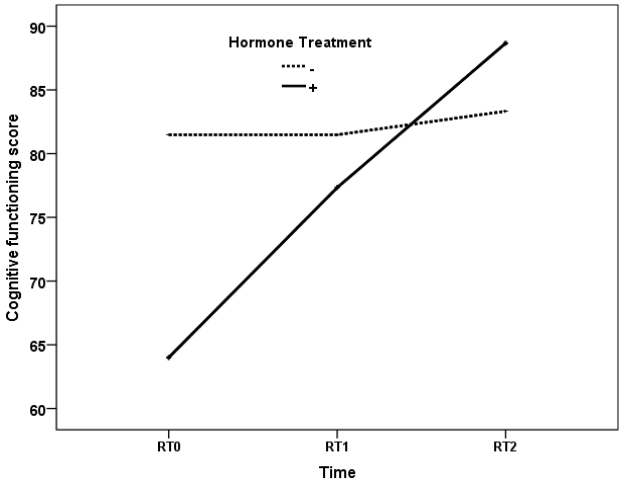
Table 3. The evaluation of the hormone-receiving and non-hormone-receiving patients in terms of the EORTC-QLQ 30 measurements performed at the RT 0, RT 1, and RT 2, phases

Hormone Therapy n+=26 n-=9		RT 0 X ± sd Media (Min,Max)	RT 1 X ± sd Media (Min,Max)	RT 2 X ± sd Media (Min,Max)	p time
General Function Score	-	70.37±18.21 83.33(33.33,83.33)	66.67±8.33 66.67(50,83.33)	72.22±8.33 66.67(66.67,83.33)	0.585
	+	71.67±18.88 66.67(16.67,100)	66.03±9.98 66.67(33.33,83.33)	76.28±8.39 83.33(66.67,83.33)	0.050
p time		0.985	0.985	0.288	0.732
Respiratory Distress	-	11.11±16.67 0(0,33.33)	11.11±16.67 0(0,33.33)	0±0 0(0,0)	0.241
	+	12.82±16.54 0(0,33.33)	7.69±14.32 0(0,33.33)	6.41±13.40 0(0,33.33)	0.227
p time		0.838	0.670	0.403	0.474
Insomnia	-	25.93±27.78 33.33(0,66.67)	33.33±28.87 33.33(0,66.67)	7.41±14.70 0(0,33.33)	0.065
	+	33.33±18.86 33.33(0,66.67)	30.77±28.16 33.33(0,66.67)	6.41±13.40 0(0,33.33)	<0.001
p time		0.424	0.838	0.897	0.721
Constipation	-	11.11±16.67 0(0,33.33)	18.52±17.57 33.33(0,33.33)	7.41±14.70 0(0,33.33)	0.260
	+	14.10±23.43 0(0,66.67)	20.57±21.24 33.33(0,66.67)	6.41±13.40 0(0,33.33)	0.057
p time		0.956	0.926	0.897	0.972
Diarrhea	-	0±0 0(0,0)	3.70±11.11 0(0,33.33)	3.70±11.11 0(0,33.33)	0.390
	+	3.85±14.38 0(0,66.67)	10.26±20.59 0(0,66.67)	1.28±6.54 0(0,33.33)	0.127
p time		0.753	0.590	0.753	0.449
General Life Score	-	66.81±8.10 68.33(58.33,75)	64.81±15.46 66.67(50,83.33)	83.33±5.89 83.33(75,91.67)	0.001
	+	59.61±15.22 58.33(25,100)	66.99±11.42 66.67(50,83.33)	80.77±9.36 83.33(66.67,91.67)	<0.001
p time		0.255	0.670	0.565	0.361
Financial Difficulty	-	33.33±37.27 33.33(0.100)	18.52±24.22 0(0,66.67)	18.52±24.22 0(0,66.67)	0.510
	+	42.17±39.42 33.33(0.100)	19.23±26.95 0(0,66.67)	17.95±28.65 0(0,66.67)	0.016
p time		0.616	0.956	0.781	0.751

statistically borderline significant (p=0.008). Weight change observed in the group not receiving hormone therapy was found to be statistically significant (p=0.003). The changes noted in the physical, cognitive, and social function scores, and the nausea and vomiting and loss of appetite scores, performed according to the EORT-QLQ 30 evaluation system, were found to be statistically insignificant, in the non-hormone-receiving group (p>0.05). The non-hormone-receiving group showed a statistically significant alteration over time, in both the



Graphic 1. Demonstrates the emotional functional variance of the hormone-receiving and non-receiving patients at the RT 0, RT 1, and RT 2, phases



Graphic 2. Demonstrates the cognitive functional variance of the hormone-receiving and non-receiving patients at the RT 0, RT 1, and RT 2, phases

emotional and pain scores, measured at the RT 0, RT 1, and RT 2 phases (p=0.006, p=.019). The fatigue index alteration in the non-hormone-receiving group was also statistically significant (p=0.05). The differences between the hormone-receiving and non-hormone-receiving groups in terms of the following EORT-QLQ 30 criteria were found to be statistically significant (Changes in the groups receiving hormone therapy and not receiving hormone treatment over time, in terms of course over time). Emotional function score, p=0.013; fatigue score, p=0.038, nausea and vomiting score, p=0.023. Apart from the above-mentioned criteria (Changes in the groups receiving hormone therapy and not taking hormone treatment over time, in terms of course over time), there were no statistically significant differences between the two groups in terms of the EORT-QLQ 30 measurements performed at the RT 0, RT 1, and RT 2, phases (p> 0.05). The physical, emotional, cognitive, and social, function scores, showed an increase over time, but these increases were found to be statistically insignificant in the non-hormone-receiving group. On the other hand, the same increases were found to be statistically significant in the hormone-receiving group (p<0.001). The general timelines of both groups (Changes in the groups receiving hormone therapy and not taking hormone treatment over time, in terms of course over time, except for the social function score, p=0.008) were different; although this difference was not statistically significant p>0.05. The fatigue, nausea, and vomiting, scores showed a general decline over time in both groups, and this decline was found to be statistically significant in both groups (p <0.05). Changes in the groups receiving hormone therapy and not receiving hormone treatment over time (in terms of course over time) except p=0.016, excluding nausea and vomiting, was not found statistically significant, and the time course of both groups was different from each other p>0.005.

(Table 3). The alterations that were detected at the RT 0, RT 1, and RT 3, phases, in the parameters of insomnia and general life score, came out to be statistically significant in the hormone-receiving group (p<0.001). The alterations in the general life scores of patients who did not receive hormone therapy that took place at the RT 0, RT 1, and RT 2, phases, were found to be statistically significant (p=0.001). The insomnia score changes detected at the RT 0, RT 1, and RT 2, phases, in the non-hormone-receiving patients, were found to be statistically borderline significant (p=0.065) but The insomnia score changes detected at the RT 0, RT 1, and RT 2, phases, in the hormone-receiving patients, were found to be statistically significant (p<0.001). The temporal difference between the two groups in terms of insomnia was not found to be statistically significant. The insomnia scores of these two groups were different in terms of course over time (p=0.721).

The changes in the respiratory distress, insomnia, constipation, diarrhea, and general function and financial difficulty, scores, measured at the RT 0, RT 1, and RT 2, phases, were not found to be statistically significant, when the two groups were compared with each other. (The insomnia scores of these two groups were different in terms of course over time p> 0.05). The temporal timeline

of these two groups differed. General function score, shortness of breath, constipation, diarrhea change in time in both groups (when viewed in terms of time course) was not statistically significant. Both groups' course is different from each other, in both groups, the changed interaction statistic of these variables was not found significant.

The timeline change of the financial difficulty score was found to be statistically significant in the hormone-receiving group ($p=0.016$). But this same score change did not show any statistically significant alteration in the non-hormone-receiving group. The financial difficulty score demonstrated different alteration courses in the two groups, but this difference was not statistically significant ($p=0.751$). The timeline courses of the general function, respiratory distress, insomnia, constipation, diarrhea, general life, and financial difficulty, scores, demonstrated differences, although these differences were not statistically significant ($p> 0.005$).

(Figure 1). The emotional score showed a decrease at RT 1 in both the hormone-receiving and non-receiving groups; while at RT 2 it demonstrated an increase in both the hormone-receiving and non-receiving groups

(Figure 2). The cognitive functional variance of the hormone-receiving and non-receiving patients at the RT1, was found to be insignificant, whereas the cognitive functional variance at the RT2 was found to be increase in both groups.

Discussion

Surgery or radiotherapy is performed in prostate cancer patients whose disease is limited in the prostate (2). All of our patients were early stage patients, and they had not undergone surgery; instead, all received curative radiotherapy. The patients were triaged according to their risk groups. Hormone therapy was administered as adjuvant and neoadjuvant regimens. The changes in the physical function scores of T2A patients over the time period, who were not administered hormone therapy, were found to be statistically insignificant. But still, this score which was low in RT 0, got higher in RT 1 and RT 2. The same alterations were evaluated in the hormone-receiving group, too, and the differences among the RT 0, RT 1, and RT 2, phases, were found to be statistically significant ($p<0.01$). It was seen that there was a loss of appetite score in patients receiving hormone threapy (a decrease in a loss of appetite score, It shows that there is not much loss of appetite), differences among the RT 0, RT 1, and RT 2 , and this was found to be borderline statistically significant ($p=0.06$). But, in the group of patients not receiving hormone therapy, the change of appetite during the time period was found to be statistically insignificant ($p>0.05$). The RT0, RT1, RT2 weight change statistics in patients with and without hormone therapy were found to be significant ($p<0.05$).

Hiram et al. have found out in their study, that hormone – receiving prostate cancer patients demonstrated a decrease in their physical functions and appetites, during 6 – 12 month controls (10). But our study showed that by time, the physical functional scores increased, and the loss of appetite ceased. In patients receiving hormone therapy, fatigue scores were shown to increase during the RT 1 phase, while they fell at RT 2. Jande et al. have reported results similar to ours, in respect to the fatigue scores in prostate cancer patients (11).

Our study demonstrated statistically significant changes over time, in terms of emotional function scores, in both the hormone-receiving and non-hormone-receiving patient groups ($p<0.05$). The RT 2 values showed an increase following the therapy. Emotional scores demonstrated alterations in both patient groups during the time phases, and these changes were found to be statistically significant ($p<0.05$), Figure 1. The emotional score showed a decrease at RT 1; while at RT 2 it demonstrated an increase in both the hormone-receiving and non-receiving groups. Michael et al. have shown in their study, that the life quality scores of patients who received RT with androgen blockage demonstrated a general rise when compared with the basal values (12). The fall of the emotional score during the last week of radiotherapy which was demonstrated in our study indicates that the patients had been emotionally worn through the therapy period. Nazmiye Kocaman Yılırm et al. have emphasized the importance of supportive care for cancer patients during their therapies (13). Many studies have shown that the physical and emotional alterations of cancer patients have a direct and strong effect on their life qualities and physical energies (14,15,16).

In our study, the change in the cognitive score over time, in the non-hormone-receiving group, was not found to be statistically significant ($p>0.05$). But it was found to be statistically significant in the hormone-receiving group

(p<0.001) Figure 2. Our study showed a tendency to increase in the cognitive scores measured at the RT 2 phase Figure 2. But Irene et al. have demonstrated in their study that the cognitive functions were in a tendency to show a decrease during the course of the follow-up periods, in comparison to the basal values, which were designated as the 1st and 6th months, and the 3rd year after the radiotherapy (17,18,19).

Diarrhea shows an alternating course in patients receiving and not receiving hormone therapy. Similar results were obtained in a study performed by Nora et al. in which the EORTC-QLQ 30 measurements were utilized in prostate cancer patients receiving external radiotherapy. The study emphasizes that the symptoms of diarrhea show variances due to the effects of radiotherapy (20). In a study performed in Toronto in 2006, patients with recurrent prostate cancer following prostatectomy were treated with radiotherapy. In this study, intestinal functions were examined, and it was found that these functions showed an increase by 28 % after RT (21). In our study, the diarrhea and constipation scores of all patients who had undergone curative radiotherapy, showed changes.

The general functional score demonstrated a fall in the RT 1 measurements in our study, but the RT 2 measurements showed an increase instead. The insomnia score showed an increase at the RT 1 phase in the group not receiving hormone therapy, while it demonstrated a decrease at RT 2. We witnessed a general fall of life quality in our patients through the RT period. But we also witnessed that life quality parameters returned to normal following RT. This outcome was in line with the results obtained from various studies (16,22). It was also seen that the insomnia scores of patients receiving hormone therapy showed a tendency to decline at the RT 1 and RT 2 phases (p< 0.001).

A temporal decline in the nausea and vomiting scores was noted in patients receiving RT. It was also noted that the general life score, which was low at the RT 0 phase, showed an increase at RT 2. The financial difficulty score was rather high at the RT 0 phase, while it showed a decline at RT 2. These data of ours are in congruence with the data obtained from the study of Irene et al. which was performed on prostate cancer patients undergoing RT (17). Respiratory distress demonstrated a general tendency to decline through the RT 0, RT 1, and RT 2, phases, in both of the hormone receiving and non-receiving groups. Whereas John W. R et al. In the study conducted by Pca RT patients, after EORTC-QLQ-C30 measurement RT was compared with after RT, There did not appear to be an increase in symptoms. After RT with the exclude of insomnia (23,24).

The alterations in the cognitive functional and fatigue scores of patients through the timeline were found to be statistically bordeline significant in both groups (the interaction of these two groups over time p=0.068, p=0.078). The social function score and the nausea-vomiting score demonstrated statistically significant alterations over time (p<0.05). However, when the other EORTC-QLQ 30 scores in both groups were evaluated from the point of view of the course (the interaction of these two groups over time), they were not statistically significant. Accordingly, both groups course of time is different from each other.

It was observed in our study that the symptoms of diarrhea and constipation did not show a statistically significant change during RT. On the other hand, Michael et al. have drawn attention to the importance of the changes in intestinal functions in RT-receiving prostate cancer patients (24).

Our study has shown that RT, in general, does not affect the quality of life in prostate cancer patients, but it does affect the general function, pain, insomnia, constipation, diarrhea, and emotional, scores, in a temporary manner. It is noteworthy that the emotional and cognitive functional scores were found to be high three months after the end of the RT sessions. It was seen in our study, that life quality scores which were low at the last week of RT, demonstrated an increase during the third month controls following RT. As a conclusion, we would like to point to the importance of supportive management of these patients prior to, and through, their radiotherapy sessions, in order to obtain and sustain high quality standards of life during this difficult period.

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