Research Article

EFFECTIVENESS OF MINDFULNESS BASED STRESS REDUCTION PROGRAM ON QUALITY OF LIFE OF CANCER PATIENTS UNDERGOING RADIOTHERAPY

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A R T I C L E   I N F O

A B S T R A C T

Background: Worldwide cancer is one of the major causes of illness and death. Cancer patients at all stages of their disease need supportive services. Depression occurs in twenty to fifty percent of cancer patients and quality of life decreases. The study was undertaken with the objective to assess the effectiveness of mindfulness based stress reduction program on quality of life of cancer patients undergoing radiotherapy. **Method:** A Randomized control trial was undertaken for the patients with head and neck cancer undergoing radiotherapy treatment. For the intervention group with the pre test 7 weekly sessions of mindfulness based stress reduction program along with routine treatment was given and on the 7th week post test was conducted. For the control group pre test was done on the 1st day and post test was on 7th week who received only the routine treatment. Quality of life was assessed in both intervention and control group in pre test and post test. Pre test-post test control group design was adopted and out of total 221 participants, 112 were in the control group and 109 were in the intervention group. Quality of life of the patients was assessed using the standardized questionnaire "European Organization for the Research and Treatment of Cancer (EORTC) QLQ-C30." **Result:** In the pre test there was no significant difference in the Global health status / QoL and functional scale. After the intervention to the group, the post test depicted significant difference in the Global health status / QoL between the control group and the intervention group with the p value 0.001. In the functional scale, in physical and emotional functioning significant difference was found. In symptom scale for fatigue, nausea and vomiting, insomnia, constipation, and diarrhea significant difference was found between the control group and the intervention group where the p value was <0.05. The overall quality of life scores in all the other areas also were significantly improved in patients of intervention group who received the MBSR intervention compared with those in the control group who received only the routine treatment.

INTRODUCTION

Cancer is one of the major causes of illness and death. After cardiovascular diseases (CVDs) it is the second leading cause of death.[1] About one in six deaths is due to cancer[2] and as per the latest GLOBOCAN 2020 data, the burden of cancer worldwide has risen to 19.3 million and cancer deaths by ten million by 2020.[3] The International Agency for Research on Cancer (IARC) estimates that worldwide, one person in five develops cancer during his or her lifetime and one in eight men and one in eleven women die from this disease.[4] It is predicted that worldwide it will double to nearly twenty to thirty million people with cancer by 2040 with significant increases in low and middle income countries.[5] India is also experiencing a simultaneous increase in cancer cases with more discoveries and advances in cancer care. The projected number of patients with cancer in India is 13,92,179 for the year 2020 and the common 5 leading sites are breast, lung, mouth, cervix uteri and tongue.[6] The North East (NE) regions of India have a much higher incidence of cancer compared to other parts of the country. Trends in cancer incidence rate showed an increase in all sites of cancer in both sexes and were high in Kamrup urban (annual percent change, 3.8%; P< .05).[7]

During cancer treatment, about two-thirds of patients receive radiation therapy (RT) as an integral part of a treatment program aimed at treating the disease, prolonging life or reducing painful symptoms.[8] However, RT often has a strong adverse effect on cancer patients, as it often leads to temporary physical effects (e.g. pain, decreased physical activity) and emotional stress (e.g. anxiety and depression). The need for psychological and social support is an important factor in the treatment of cancer patients receiving RT, which appears to be strongly predicted by Quality of Life (QoL) related to patient health.[9]

The aim of this study was to adopt a randomized controlled trial to investigate whether psychosocial intervention

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Mindfulness Based Stress Reduction (MBSR) during radiation therapy of patients with cancer could reduce emotional stress, strengthen the patient's resilience to treatment and improve treatment outcomes and thus to improve the quality of life. The researcher, who is in nursing profession, felt the need to evaluate the effectiveness of psychosocial intervention for improving the quality of life of cancer patients. For this purpose, this experimental study has been undertaken. The study results may be employed in the nursing practice so as to help the patients in improving the physical health with managing the side effects and improving the health condition and keeping the mental health strong with less stress and anxiety to cope with the disease and treatment effectively.

METHODS

Study design

The study was designed as pre test post test control group design. After the intervention time period of 7 weeks, post test was done for both the groups (on the last day of intervention).

Participants and setting

All the head and neck cancer patients undergoing radiotherapy treatment (both men and women) were the study population. Head and neck radiotherapy patients were used in the study as they are continuously available for more days (usually 7 weeks) for their treatment purpose.

In the present study, the sample consist of 221 cancer patients (both male and female) with radiation therapy treated in cancer hospital who fulfill the inclusion criteria of the study. Out of 221 patients, 109 are in intervention group and 112 in control group. Randomization was done using IBM SPSS software to select the sample of 221 (intervention and control group) from the population comprising of cancer patients undergoing radiation therapy.

Inclusion criteria for the sample were: a) patients having cancer and receiving 7 weeks of radiotherapy treatment b) patients who are between the ages of 20 to 70 years c) patients with 0 - 2 ECOG (Eastern Cooperative Oncology Group) performance scale and d) patients who has an awareness of the diagnosis of cancer. The exclusion criterion was the patients who are not willing to participate in the study were excluded.

Intervention

In addition to routine radiotherapy, patients in the intervention group received a mind fullness based stress reduction (MBSR) program intervention, Mindfulness-based stress reduction (MBSR) is a group program that was developed by Jon Kabat-Zinn in the 1970s to treat patients struggling with life's difficulties and physical and/or mental illness.[10] In the intervention group where the members in the group (maximum 12 numbers) received MBSR meditation of seven session including raisin meditation, body scan, turning toward meditation (meditation for difficult emotions), turning toward meditation (meditation for physical pain) and loving kindness meditation i.e. once a week for one hour session and everyday guided practice along with the usual care and the control group received only the usual care.

Tool for data collection:

Demographic proforma including age, sex, education, occupation, marital status, community and income (per month) was used for colleting the demographic information from the sample.

Quality of life assessment

The Quality of life (QoL) of the patients was assessed using the European Organization for the Research and Treatment of Cancer (EORTC) QLQ-C30. The QLQ-C30 is a 30 item, self reported questionnaire covering functional (Global Health Status, Physical Functioning, Role Functioning, Emotional Functioning, Cognitive Functioning and Social Functioning) and symptom-related aspects (fatigue, nausea and vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties) of QoL in cancer patients.

Content validity and reliability of the tool

The validity and the reliability of the Assamese version of the EORTC QLQ-C30 have been confirmed. The reliability of the tool EORTC QLQ-C30 have been analyzed using Cronbach's Alfa and it was found to be 0.79 which means that the tool is reliable for the use in local language.

Procedures

The study was approved by the Institutional Ethics Committee (Ref. No.: Misc-01/MEC/233/2020).

Written consent was obtained from the participants for participation in the study and if they desire, they can withdraw from the study. All participants were provided written informed consent prior to enrolment. The objectives of the study have been explained to the sample and their consent has been taken and they have been assured of confidentiality of the data obtained.

Statistical analyses

All analyses were conducted using IBM SPSS version 21. Descriptive statistics were used to describe the sample characteristics. 't' test was used depending on fulfillment of normality assumption and ANOVA was used to compare more than two groups for continuous data. A p value less than 0.05 is considered as statistically significant at 5% level of significance.

For assessing the quality of life, linear transformation scale was used. All of the scales and single-item measures range in score from 0 to 100. A higher score represents a higher ("better") level of functioning, or a higher ("worse") level of symptoms.

RESULTS

Findings related to demographic variables

Out of total 221 participants, 112 were in the control group and 109 were in the intervention group. In the frequency and percentage distribution of intervention and control group with respect to age, it was found that in the intervention group majority of patients 52 (46.4%) and in the control group 39 (35.8%) belonged to the age group of 51-60 years. In distribution of patients according to gender, in the intervention group majority 88 (78.6%) and in the control group majority 95 (87.2%) were male. With respect to educational level, in the intervention group majority 52 (46.4%) were with no institutional education and in the control group majority 58 (53.2%) were M. E school pass. In regard to occupation, in the intervention group majority 44 (39.9%) and in the control group majority 35 (32.1%) were cultivator. According to

marital status, in the intervention group majority 91 (81.2%) and in the control group majority 85 (78%) were married. With regard to community, in the intervention group majority 96 (85.7%) and in control group majority 87 (79.8%) were from rural area. In regard to income (per month), in intervention group majority 83 (74.1%) and in the control group majority 66 (60.6%) were with less than 10,000 per month.

Findings related to comparison of quality of life in control and intervention group in the pre test:

In the comparison of quality of life in pre test between control and intervention group, there was no significant difference in the mean functional scale of global health status / QoL, physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning. In comparison of quality of life with regard to the symptom scales/items no significant difference was observed between the two groups in the pre test. There was no significant difference in fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhea and financial difficulties.

and the intervention group (61±7.44) with the *p* value <0.001. For role functioning, cognitive functioning and social functioning no significant difference was found between the control group and the intervention group. But the intervention group had better role functioning, cognitive functioning and social functioning than the control group which is seen in the mean difference.

In the fatigue, significant difference was found between control group (50.5±7.77) and the intervention group (43.83±14.04) with the t value 4.387 and for df 219 *p* value was <0.001 which is less than 0.05. In nausea and vomiting, significant difference was found between control group (23.22±15.06) and the intervention group (12.23±15.65) with the t value 5.318 and for df 219 *p* value was <0.001 which is less than 0.05. For insomnia, significant difference was found between control group (66.4±3.16) and the intervention group (57.2±15.14) with the t value 6.294 and for df 219 *p* value was <0.001 which is less than 0.05. Significant difference was found in appetite loss between control group (57.46±16.29) and the intervention group (51.38±17.32) with the t value

Findings related to comparison of quality of life in control and intervention group after 7 weeks (post test)

Table 1 Comparison of quality of life in post test between control and intervention group

EORTC QLQ C-30 subscale	Control n=112 Mean±SD	Intervention n=109 Mean±SD	t value	df	p value	Inference
Global health status						
Global health status / QoL	46.49±9.85	50.53±6.99	3.509	219	0.001	S
Functional scale						
Physical functioning	62.82±6.8	66.24±8.95	3.203	219	0.002	S
Role functioning	62.05±19.79	62.54±11.6	0.223	219	0.823	NS
Emotional functioning	52.24±11.07	61±7.44	6.895	219	<0.001	S
Cognitive functioning	60.11±20.06	61.03±11.64	0.417	219	0.677	NS
Social functioning	88.98±11.09	89.12±7.99	0.111	219	0.911	NS

S – Significant, NS – Non significant, Significance level <0.05

Table 1 Comparison of quality of life in symptom scale/items in post test between control and intervention group

EORTC QLQ C-30 subscale symptom scales/items	Control n=112	Intervention n=109	t value	df	p value	Inference
Fatigue	50.5±7.77	43.83±14.04	4.387	219	<0.001	S
Nausea and vomiting	23.22±15.06	12.23±15.65	5.318	219	<0.001	S
Pain	33.63±18.31	32.72±14.5	0.409	219	0.683	NS
Dyspnoea	19.92±16.4	19.25±18.85	0.282	219	0.778	NS
Insomnia	66.4±3.16	57.2±15.14	6.294	219	<0.001	S
Appetite loss	57.46±16.29	51.38±17.32	2.687	219	0.008	S
Constipation	42.86±25.1	36.38±22.49	2.02	219	0.045	S
Diarrhoea	19.94±25.89	4.28±11.19	5.809	219	<0.001	S
Financial difficulties	30.66±28	25.67±20.1	1.516	219	0.131	NS

S – Significant, NS – Non significant, Significance level <0.05

In the comparison of quality of life in post test significant difference was found in the Global health status / QoL between the control group (46.49±9.85) and the intervention group (50.53±6.99) with the *p* value 0.001 which was smaller than 0.05, which is due to the MBSR program intervention applied to the intervention group. In the functional scale, significant mean difference was found for physical functioning in control group (62.82±6.8) and the intervention group (66.24±8.95) with the *p* value 0.002 which is less than 0.05. Statistically significant difference in mean was found for emotional functioning between control group (52.24±11.07)

2.687 and for df 219 *p* value was 0.008 which is less than 0.05. In constipation, significant difference was found between control group (42.86±25.1) and the intervention group (36.38±22.49) with the t value 2.02 and for df 219 *p* value was 0.045 which is less than 0.05. For dyarrhoea significant difference was found between the control group (19.94±25.89) and the intervention group (4.28±11.19) with the t value 5.809 for df 219 *p* value was <0.001.

Findings related to the comparison of the quality of life of the cancer patients with their selected demographic variables:

For quality of life significant improvement was noted in the age group of 31 to 40 years in the functional scale ($p=0.021$). In the symptom scale significant difference was found in the age group of 31 to 40 years ($p=0.001$), 41 to 50 years ($p=0.009$), 51 to 60 years ($p=<0.001$) and 61 to 70 years ($p=<0.001$). For male significant difference was found in global health status ($p=0.002$), functional scale ($p=0.002$) and symptom scale ($p=<0.001$). While in female gender significant difference was noted in functional scale ($p=0.045$) and symptom scale ($p=0.001$). For the samples with no institutional education significant difference was found in functional scale ($p=0.002$) and symptom scale ($p=<0.001$). While the samples with M. E school pass shows significant difference in symptom scale ($p=<0.001$). The samples with graduation and above qualification shows significant difference in global health status ($p=0.031$) and the symptom scale ($p=0.024$). For the house wife significant difference was found in symptom scales ($p=0.002$). For the cultivator there was significant difference in functional scale ($p=0.02$) and symptom scales ($p=<0.001$). For the samples with business there was significant difference in global health status ($p=0.002$), functional scale ($p=0.002$), symptom scale ($p=<0.001$). There was significant difference for the sample with service in global health status ($p=0.009$) and symptom scale $p=<0.001$. Significant difference was found for the married in global health status ($p=0.002$), in functional scale ($p=0.005$) and symptom scales ($p=<0.001$). For the unmarried significant difference was found in the functional scale ($p=0.008$). The married but single samples show significant difference in the symptom scales ($p=0.001$). For the samples from urban community significant difference was found in symptom scale ($p=0.003$). For the samples from rural community there was significant difference in global health status ($p=0.003$), in functional scale ($p=0.001$) and symptom scales ($p=<0.001$). For the samples with monthly income less than 10,000 significant difference was found in global health status ($p=0.037$), functional scale ($p=0.001$) and symptom scales ($p=<0.001$). With monthly income 11,000 to 20,000, samples show significant difference in global health status ($p=0.002$) and symptom scales ($p=<0.001$). For the samples with monthly income 21,000 to 30,000 symptom scales shows significant difference ($p=0.046$) and the symptom scales shows significant difference ($p=0.001$) for the samples with monthly income more than 30,000.

DISCUSSION

The present study was conducted to evaluate the effectiveness of psychosocial intervention to improve the quality of life of cancer patients undergoing radiotherapy. The study was conducted in the radiotherapy department. For quality of life significant improvement was noted in the quality of life with significant difference. In the pre test there was no significant difference between the two groups with regard to Global health status / QoL and perceived needs as assessed by independent t test. In the comparison of quality of life in post test significant difference was found in the Global health status / QoL between the control group and the intervention group with the *p* value 0.001 which is due to the psychosocial intervention applied to the intervention group.

In the post test in comparison of quality of life between control and intervention group in symptom scales/items, statistically significant difference was found in fatigue, nausea and vomiting, insomnia, appetite loss, constipation and dyarrhoea between the two groups but no statistically significant difference in mean was found in pain, dyspnoea and financial difficulties.

The results of this study concluded that psychosocial intervention including mindfulness based stress reduction (MBSR) is an effective intervention to improve the quality of life and of cancer patients undergoing radiotherapy. This study was consistent with the study finding of Pollard A, Burchell JL, Castle D, Neilson K, Ftanou M, Corry J et. Al.[11] where they reported that post intervention mindfulness is associated with longer time daily meditation. There was a significant association between higher post-intervention mindfulness and lower psychological distress and higher social and emotional QoL after controlling for pre-intervention mindfulness.

In another study by Liu T, Zhang W, Xiao S, et al[12] reported that patients randomly assigned to the MBSR group showed significantly greater improvements in emotional function, fatigue, global QoL, depression, and anxiety. In a single-group quasi experimental study by Fish JA, Ettridge K, Sharplin GR et al[13] with the cancer patients to explore the impact of a Mindfulness-Based Cancer Stress Management programme on psychological distress and quality of life. The result shows significant improvements on all measures in reducing psychological distress and improving quality of life, including spiritual well-being. The same positive result was found in cohort study conducted by Matousek RH, Dobkin PL. Weathering storms[14] examined whether Mindfulness-Based Stress Reduction (MBSR), an 8 weeks program can bring any improvement or not. The result shows significant changes in depression, stress, emotional coping, and sense of coherence. Speca M, Carlson L, Goodey Eet al[15] conducted an another prospective study with a convenience sample (N = 90) of patients heterogeneous in type and stage of cancer. Participants were randomized into either a 7-week MBSR intervention group or a wait-list control group. The investigators reported significant improvements in mood disturbance and stress symptoms after participation in the MBSR intervention. The positive impact was seen in an another experimental study which was carried out by Carlson LE, Ursuliak Z, Goodey E et al[16] with the goals to assess the effects of participation in a mindfulness meditation-based stress reduction program for 7 weeks. The result shows that patients' scores decreased significantly from before to after the intervention, indicating less mood disturbance and fewer symptoms of stress. Kieviet-Stijnen A, Visser A, Garssen Bet al[17] conducted a study with the objective to explore satisfaction and changes in well-being in cancer patients following mindfulness-based stress reduction training. The result shows that participants were highly satisfied and reported a better quality of life, more joy in life, less tension, and fewer physical symptoms.

In two studies by Witek-Janusek L, Tell D, Mathews HL[18] and another one by Lengacher CA, Reich RR, Paterson CL, et al1[19] who undertook study with the purpose to determine MBSR benefits in women diagnosed with breast cancer. The result shows good improvements mainly in perceived stress, fatigue, sleep disturbance and depressive symptoms and psychological and physical symptoms.

CONCLUSION

Although a physical, psychological, social burden associated with cancer is common, it is not inevitable. The results of this randomized trial demonstrate that a mindfulness based stress reduction program which is a psychosocial intervention significantly improve the quality of life of patients compared to a control group.

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