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EFFECT OF MINDFULNESS BASED THERAPY USING ANAPANA MEDITATION ON CANCER PATIENTS BEING TREATED WITH RADICAL RADIOTHERAPY: A SINGLE INSTITUTION STUDY

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Abstract
In India, cancer incidence has significantly increased over the last decade with 1.42 million cases in 2022 and with projected rise of 12.8% by 2025. Cancer diagnosis and treatment is associated with stress and anxiety that can adversely impact the quality of life. Stress has also been shown to affect disease progression and development of metastasis. Recently, there has been much interest in alternative methods to improve quality of life in cancer patients. Mindfulness, which has its roots in Buddhist meditation techniques, has been shown to be successful in lowering pain and other symptoms, by enhancing patient's coping mechanisms. Studies have also shown higher levels of mindfulness is associated with improved quality of life. There are several studies testing mindfulness in cancer patients in western literature but they have not included low socioeconomic groups and most are conducted in breast cancer patients undergoing chemotherapy. Ours is a prospective single-arm interventional study conducted in 35 cancer patientsundergoing curative radiotherapy. Patients were subjected to Anapana meditation 30 minutes per day for 15 days. Subjective well-being and Pain scale improvement was assessed by EORTC QLQ C30 questionnaire at baseline and end of Mindfulness Based Intervention (MBI) (Day 15). The mean Global Health Status score was 25.69 before MBI and 22.68 after MBI. Among functional scales, there was an improvement in Physical, Cognitive, and Emotional functioning (p = 0.3751), with Emotional showing maximum improvement by 10 points. Mean scores for Role functioning and Social functioning showed small decrease. Among symptom scales, nausea and vomiting showed improvement with MBI. Fatigue and Pain scores worsened (p = 0.4596). All other symptom scores were static without further decline. These results imply that there is some benefit of MBI in improving perceived symptoms and QoL in patients undergoing RT. Large randomized trials with longer follow up that assess the impact of Mindfulness-based interventions are required to confirm our findings.

Keywords: Mindfulness based intervention, Quality of Life, Stress in cancer patients, Radiotherapy, EORTC Core Quality of Life questionnaire.

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1. INTRODUCTION

Cancer is a leading global health concern accounting for 9.6 million deathsin 2023, which translates toapproximately 26,300 deaths per day. In India, the cancer incidence has increased significantly over the last decade.In 2020, 39 million cases were diagnosed (100.4 per 100,000) which increased to 1.42 million in 2022 and it is predicted to increase by 12.8% in 2025. It is estimated that every ninth person is likely to develop cancer[1].The main treatment modalities for malignancyconsistof surgery, chemotherapy and radiotherapy. Radiotherapy is an integral part of treatment of all solid malignancies and associated with mild to serious adverse effects that can adversely impact the quality of life (QoL), either temporarily or permanently. Advances in oncological treatments have led to improved survival in early-stage cancer and hence QoL is becoming more important in these patients. Also, certain cancers like breast and prostate cancer have a very low mortality rate. Hence, the primary goal of treatment is not only to increase the lifespan but also to provide good QoL. Stress especially chronic stress affects patients' QoL. Research indicates that one of every three cancer patients experience severe psychological problems during cancer treatment.[2]Stress has also been shown to affect disease progression and development of metastasis.[3,4] Research indicates that stress may have an impact on neuroendocrine system as well as increase activity of tumors.Stress alsoresults in poor treatment compliance, and increasedperception of severity of treatment effects.

2. RATIONALE OF THE STUDY

Recently, there has been much interestin alternative non-pharmaceutical methods to manage stress. Mindfulness is one such method. Mindfulness, which has its roots in Buddhist meditation techniques, comprises "the awareness that emerges through paying attention on purpose, in the present moment, and nonjudgmentally to the unfolding of experience moment to moment." It differs from person to person or within the same individual from one moment to another. The ideology of mindfulness is that an attentive person does not think about the past or future; instead, they focus on 'here' and 'now'. He or she thus retains a direct link to reality, as well as to in trapsychic as well as environmental occurrences. Several studies indicate that mindfulness-based interventions (MBI) are successful in lowering cancer patients' psychological distress as well as other symptoms. Studies have also shown that higher levels of mindfulness (as assessed by MASS score) is associated with better quality of life. MBI has been proven to significantly improve psychiatric symptoms, enhance good feelings, enhance coping mechanisms, encourage intentional thought, and lessen emotional tiredness.[5,6] Mindful people are better equipped to adjust to difficult situations and assess potentially fatal events with less anxiety. Although mindfulness practice was originated in India, very few clinical trials have been conducted from Indiaon fewer studies studying its role in cancer patients undergoing radiotherapy. Majority of the published studies are in breast cancer and patients undergoing chemotherapy. Mindfulness studies in western literature have not included patients from low socioeconomic groups. Our study aims to overcome these shortfalls by aiming to have Indian data on mindfulness in cancer patients, evaluate a variety of cancer patients undergoing radiotherapy, to include patients from different socioeconomic groups.Mindfulness based interventions do not involve any financial implications on patients, if found effective, they can be applied as an adjunct to cancer therapies without adding to cost of treatment, and can be a simple and effective way to improve patients' QoL.

3. AIMS AND OBJECTIVE:

To assess the impact of Anapana meditation as a mindfulness intervention on physical, emotional, cognitive and social well-being, pain and symptom control, and the overall QoL in cancer patients undergoing radiotherapy.

Sample size calculation

To determine the sample size, an online tool for sample size calculation (https: //sample-size.net/sample-size-study-paired-t-test/) was utilized. N= Group size/Sample size. $Z\alpha/2$ is the standard normal z-value for significance threshold of $\alpha=0.05$, which is 1.96, or. $Z\beta$ is the standard normal z-value for power of 80 percent, which is 0.84.

The mean difference in pre-test and post-test scores in psychological domain was 2.82, according to reference study. Effect size (E) = 2.82, $S\Delta$ is the standard deviation of the change in outcome= 5.5 B = $(Z\ \alpha\ /2+\ Z\beta\ )2$ =7.8489. C = $(E/S\Delta)2$ =0.2629. N = B/C =29.8562 = 30. The required sample size was estimated as 30. By assuming 5% lost to follow-up, the updated sample size was 32.

4. MATERIALS ANDMETHODS

This is a single institution, single arm study conducted at Harshamitra Cancer Center, Trichy, Tamilnadu. A convenience sampling approach was utilized. 35 consecutive patients undergoing radiotherapy were subjected toAnapana meditation for 30 minutes per day for 15 days and the results were analyzed based on the following:

1. Subjective well-beingas per EORTC questionnaire (on Day 1 and Day 15).
2. Pain scale improvement as per the EORTC questionnaire (on Day 1 and Day 15).

All patients were treated with 3DCRT technique using 6 MV (Varian Unique LINAC).

Inclusion criteria

- Age > 20 years, ≤ 70 years
- Performance status, Eastern Cooperative Oncology Group (ECOG) scores 0 - 1.
- Patients undergoing Radiotherapy with Curative intent

Exclusion Criteria

- Concurrent chemotherapy
- Cognitive deficits or mobility issues
- A serious neurological or psychiatricillness
- Patients not willing for participation

Primary Endpoints

- Subjective well-being EORTC questionnaire on Day 1 and Day 15

- Pain scale improvement as per the EORTC questionnaire on Day 1 and Day 15

Compared to conventional classifications of adverse effects, QoL questionnaires explain changes that an illness or treatment brings about in patient's life in far more comprehensive manner. HandN-35 module is part of EORTC QLQ-C30 (European Organization for Research of Life Questionnaire 30 Items), mostly recognized instrument in evaluating Oncology QoL.

QLQ-C30 version 3.0 was investigated by Aaronson et al. on cancer patients who were taking opioids for pain. And found good reliability for all dimensions, and good validity. Scales commonly used in other studies are Perceived Stress Scale (PSS) to gauge how stressedout people experience andcope with stress, and mindfulness levels using MAAS (Mindfulness Attention and Awareness Scale).The relationship between stress as well as hypothalamic-pituitary-adrenal (HPA) axis has been studied. HPA axis activates via amygdala, hippocampus, and association cortex whenever an individual encounters a stressor that they're unable to handle, raising blood level of cortisol.[7,8,9] However, in our study, we have not opted for serum or salivary cortisol levels as most cancer patients having head and neck cancer and will possess xerostomia post radiation and due to logistics.

6. STATISTICAL ANALYSIS

The study was approved by Institute ethics committee and registered with Clinical Trials Registry of India. The EORTC QLQ C30 scores for all participants before and after MBI was calculated using in-house developed Excel formula. There were no missing values in the questionnaires. The mean scores were calculated for each domain. The differences in scores before and after MBI were compared by paired t-Test. Descriptive statistics used wherever applicable.

7. RESULTS

35 patients undergoing radiotherapy were given Anapana meditation for 30 minutes per day for 15 days. Subjective well-being through RTOG/EORTC QLQ C30 questionnaire on Day 1 and last day of RT.

Patient and Disease characteristics

The mean age was 62.6 years. Majority of patients were female (88.5%) and only 11.42 % (4 patients) male. All had good PS with ECOG 0-1. 37.14 % (13 patients) had breast cancer, 28.57 % (10 patients) cervical cancer, 22.85 % (8 patients) head and neck cancers, 11.42% (4 patients) rectal cancer. All patients received only RT. Reasons for not receiving chemotherapy included age and comorbidities.

RTOG/EORTC QLQ C30 questionnaire

There are four versions of QLQ-C30: version 1.0, version 2.0version 3.0, as well as (+3) intermediate version. Present standard being QLQ-C30 version 3.0. Version3.0 was intended in evaluating cancer patients' QoL through psychological, social, as well as physical functions. It consists of nine single items (pain, fatigue, nausea/vomiting, airway blockage, loss of appetite, sleeplessness, constipation, diarrhea, and financial concerns) and five multi-item measures (role, physical, social, cognitive performance and emotional). Items 29 and 30 are rated on 7-point Likert scale (1=extremely poor,7=excellent), while items 1 through 28 were evaluated on Likert scale with four points. (1= never, 4= too much). Range of scores was 0 - 100.

The better QoL, higher the score in function domains. Severe the symptoms, higher the score in symptoms domains.

Table 1: Distribution of mean scoresat baseline

DOMAIN	MEAN
GLOBAL HEALTH STATUS	25.69
FUNCTIONAL SCALES	
Physical	79.38
Role functioning	90.74
Emotional	74.00
Cognitive	87.04
Social	89.81
SYMPTOM SCALES	
Fatigue	72.53
Nausea and vomiting	82.87
Pain	76.85
Dyspnoea	89.81
Insomnia	80.56
Appetite loss	76.85
Constipation	80.56
Diarrhoea	88.89
Financial difficulties	83.33

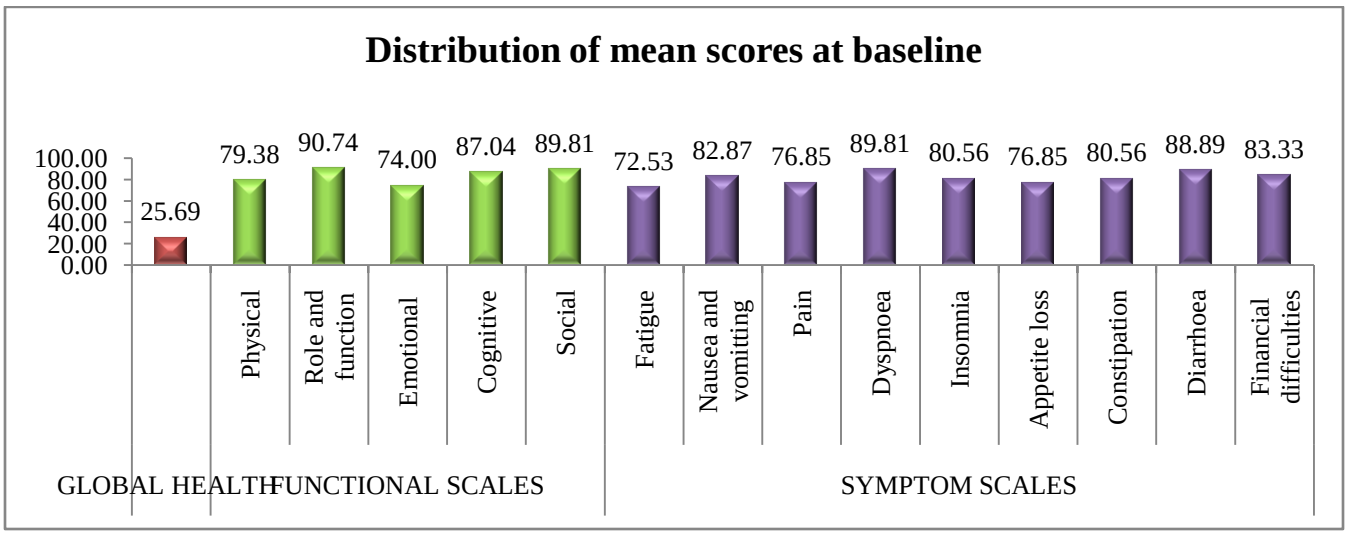

Figure 1: Bar chart showing distribution of mean scores at baseline

Table 2: Distribution of mean scores after MBI

DOMAIN	MEAN
GLOBAL HEALTH STATUS	22.68
FUNCTIONAL SCALES	
Physical	80
Role and function	87.96
Emotional	83.10
Cognitive	88.88
Social	87.03
SYMPTOM SCALES	
Fatigue	74.38
Nausea and vomiting	79.62
Pain	80.55
Dyspnoea	89.81
Insomnia	80.55
Appetite loss	76.85
Constipation	80.55
Diarrhoea	88.88
Financial difficulties	83.33

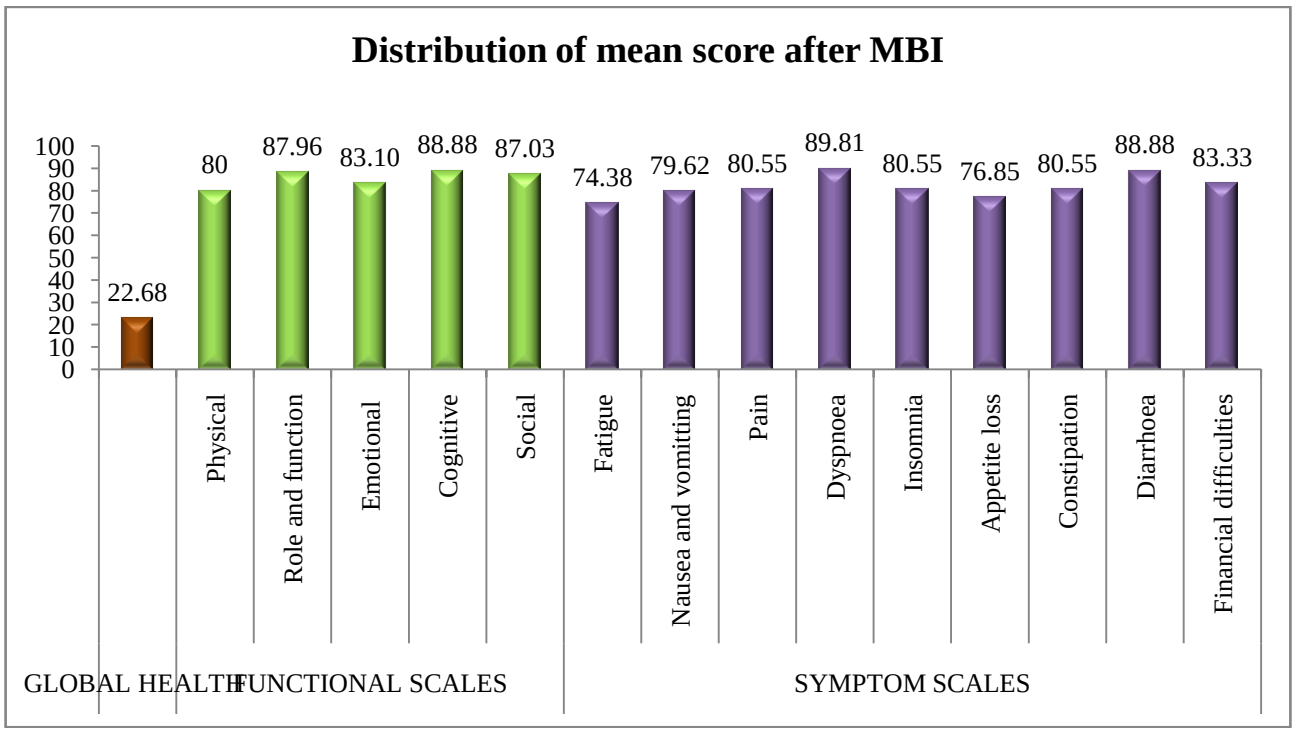

Figure 2: Distribution of mean scores after Mindfulness based intervention

Table 3: Comparison of mean scoresbefore and after MBI.

DOMAIN	Day 1 MEAN SCORE	Day 15 MEAN SCORE	Differences in mean scores	Status	Interpretation
GLOBAL HEALTH STATUS	25.69	22.6851852	3.009259	Decreased score	Worsened
FUNCTIONAL SCALES					
Physical	79.38	80	-0.62	Increased score	Improved
Role functioning	90.74	87.96	2.780741	Decreased score	Worsened
Emotional	74.00	83.1	-9.10309	Increased score	Improved
Cognitive	87.04	88.88	-1.84296	Increased score	Improved
Social	89.81	87.03	2.784815	Decreased score	Worsened
SYMPTOM SCALES					
Fatigue	72.53	74.38	-1.84914	Increased score	Worsened
Nausea and vomiting	82.87	79.69	3.18037	Decreased score	Improved
Pain	76.85	80.55	-3.69815	Increased score	Worsened
Dyspnoea	89.81	89.81	0.004815	No change	
Insomnia	80.56	80.55	0.005556	No change	
Appetite loss	76.85	76.85	0.001852	No change	
Constipation	80.56	80.55	0.005556	No change	
Diarrhoea	88.89	88.88	0.008889	No change	
Financial difficulties	83.33	83.33	0.003333	No change	

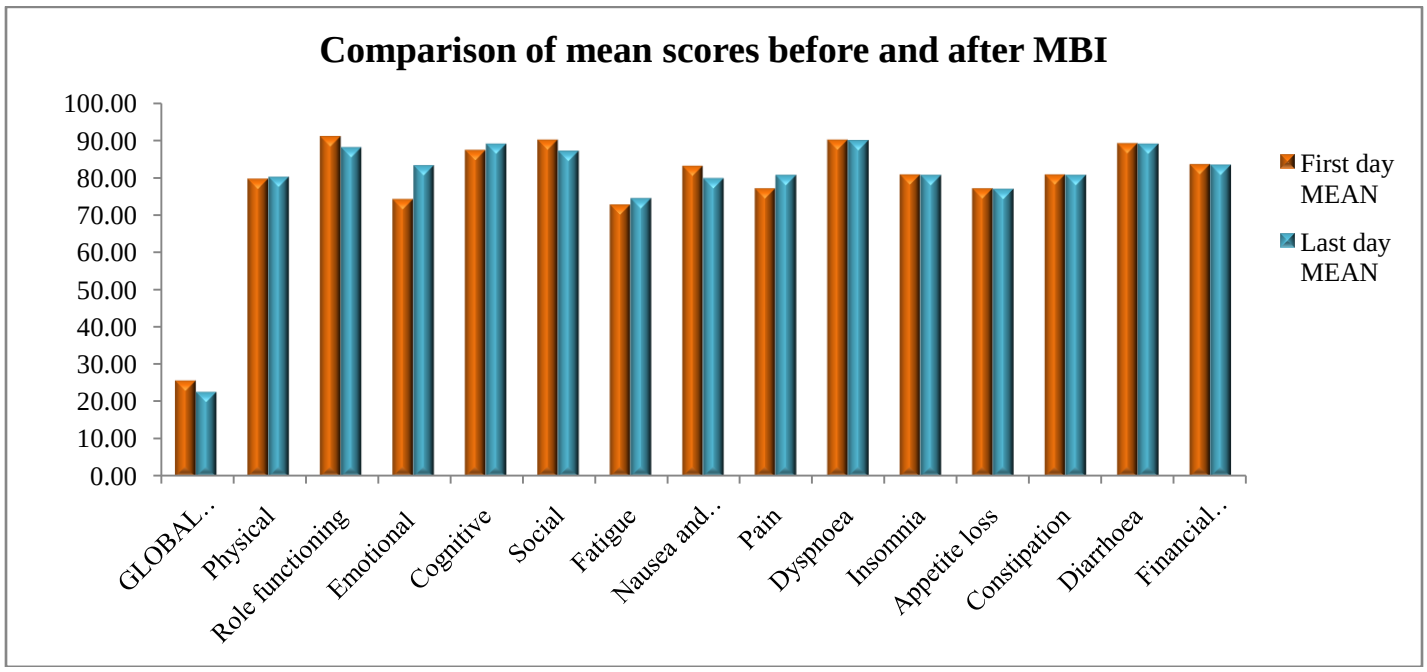

Figure 3: Comparative mean score distribution before and after MBI

The difference in mean scores were not significant in functional scales (p = 0.3751)and symptom scales (p = 0.4596). This is attributed to small sample size (35 patients) and short follow up.

The mean Global Health Status score was 25.69 before MBI and 22.68 after MBI. Among functional scales, there was an improvement in Physical, Cognitive, and Emotional functioning (p = 0.3751), with Emotional showing maximum improvement by 10 points. Mean scores for Role functioning and Social functioning showed small decrease. Among symptom scales, nausea and vomiting showed improvement with MBI. Fatigue and Pain scores worsened (p = 0.4596). All other symptom scores were static without further decline.

8. DISCUSSION

In our study, the mean Global Health Status score was25.69 before MBI and22.68 after MBI. Similar studies on MBI have also shown a slight decline in Global Health status pre and post-treatment, due to Acute Radiation toxicities, which usually improves after 3 months' follow-up. However, note that there was only a small decline in score by -3 points in our study compared to other studies.Among functional scales, there was an improvement in Physical, Cognitive, and Emotional functioning, with Emotional functioning showing maximum improvement by almost 10 points.Mean scores for Role functioning and Social functioning showeda decrease. For factors affecting Social functioning, social stigma unique to India also has to be taken into account. Among symptom scales, nausea and vomiting showed an improvement with MBI. Fatigue and Pain scores were worsened. All other symptom scores (Insomnia, Dyspnoea, Appetite loss, Diarrhoea, Constipation, Perceived Financial challenges) were static without any further decline during RT.Gustav Dobos et al (2014) carried out an extensive randomized control study wherein 117 cancer survivors were randomized to participate in mindfulness-based daycare program for 11 weeks (6 hrs per week).In addition to MBI,cognitive-behavioral techniques, yoga, as well aslifestyle change were incorporated. Majority of patients were females (91.0 %), elderly (53.9±10.7 yrs) breast cancer survivors (65 %) with a mean time since diagnosis of 27.2± 46.5 months.10.3 % had metastatic disease.45.8 % were educated, 47.3 % employed, mean BMI was 25.25±5.21. 85 (72.65 %) had surgery, 57 (48.72 %) chemotherapy, 32 (27.35 %) hormonal therapy and 43 (36.75 %) RT.EORTC QLQ-C30, depression, and anxiety (HADS) were used to measure QoL. Before, during, and at 3 months after the intervention, Fear of Cancer Recurrence (FCR) score, life satisfaction (BMLSS score), adaptive coping styles(AKU), interpretation of illness (IIQ), and spiritual/religious attitudes in dealing with illness(SpREUK), were evaluated. In this study, baseline scores were worse than that seen in our study in all the domains. After MBI, significant improvement was seen in all the domains. Significant improvements were also made in symptom score and psychological symptoms such as despair, pain, anxiety, constipation, sleeplessness, and exhaustion. In this study, there was significant improvement in Mindfulness level, life contentment, health contentment, all coping mechanisms, and all religious/spiritual beliefs. (all $p < 0.05$). The increased levels of mindfulness shown in patient cohort may be cause of improvement in all QoL domains and all symptom scores. This emphasizes the importance of an efficient method and interval/duration of Mindfulness training (11-week program in this study) and the additional incorporation of yoga, meditation and lifestyle changes.[10]Peng et al (2022,China) randomized65 breast cancer survivors to online MBI training for 6 weeks or

to usual care. Five Facet Mindfulness Questionnaire (FFMQ), Short Form of Fear of Cancer Recurrence Inventory (FCRI-SF), and EORTC-QLQ-C30 were assessed at baseline, immediately after MBI, and one month later. The MBI group's emotional as well as cognitive performance dramatically improved in comparison to control group, which is consistent with our findings. Fear of Cancer Recurrence (FCR) decreased considerably. After a month, these effects were still significant. Furthermore, qualitative survey revealed that participants were content with the online MBI format.[11]In a large Indian study (Sandhya et al, Kolkata, 2018 – 2020), 60 patients with head and neck cancer treated withchemoradiation (66 Gy/33 fractions, up to 6 cycles cisplatin) (43 patients chemoradiation, 17 patients RT only). Mean age was 56.3 years, 47 males, and 13 females. Majority were Locally advanced. Symptom scales of EORTC QoL head and neck module (EORTC QLQ-HandN35) and Pain scale (HNPA) (consisting of 4 items), were assessed at baseline, and 6 months post RT. Prior to RT, mean pain score was 51.10; it progressively worsened throughout treatment. Later pain score significantly decreased throughout 3rdand 6th follow-ups, reaching 24.71 in 6th month. At 3 months, mean pain scores were worse in chemoradiation compared to RT alone(P =0.028); At 6 months, there was no significant difference between Rt and CTRT. In our study too, there was worsening in Pain scores with RT.In a recent Iranian study (Mahlagha Dehghan et al, 2020) in 205 cancer patients. Mean age 50.49± 15.27 yrs and mostweremale, welleducated, respiratory, hematological, breast cancers without comorbidities. PSS, MAAS, and EORTC QLQ-C30 were evaluated. QoL was positively correlated with mindfulness (P<0.05). QoLand mindfulness were inversely correlated with perceived stress (P<0.05). This demonstrates that mindfulness can have a direct and indirect impact on cancer patients' QoL.[12]In another Australian study (Mesquita Garcia et al, 2021) 183 patients received online MBI during chemotherapy. Stress and QoL was assessed utilizing Functional Assessment of Cancer Therapy, Self-Compassion Scale, and MAAS.Mean scores were 80.25 for QoL, 69.05 for mindfulness, and4.23for self-compassion. QoL was shown to be positively correlated with both self-compassion (r=0.466,p< 0.001) and mindfulness (r=0.325,p< 0.001). A higher QoL was linked to higher mindfulness levels.[13]The studies along both results of our prospective study underline how crucial mindfulness is in improving quality of life in cancer patients.The limitations of our study are the small sample size and shorter duration of Mindfulness intervention (15 days in contrast to other studies with longer MBI program). Also we assessed the quality of life scores on Day 15 only. Online mode of MBI might help in more effective administration and compliance to MBI training. Also studies have shown in spite of transient worsening in symptoms, most symptoms improve at 6 months in MBI group and improvement is maintained at 1 year. Large randomized trials with longer follow up that assess the impact of Mindfulness based interventions are required to confirm our findings.

9. CONCLUSION

MBIs have emerged as promising methodsto help enhance cancer patients' QoLboth during treatment and in the long term. While many studies showenhancement across all areas of QoL, in our study,there's improvement in functional, emotional, and cognitive functioning. There was no improvement in social and role functioning, which was also the case in Peng et al. Many other factors like social practices and religious belief/spirituality mightplay a role in social and role functioning. Also studies have consistently shown two things. Studies that incorporated yoga, meditation, and CBT along with MBI has shown better improvement in QoL and symptoms in all the domains. A higher QoL has been linked to higher levels of mindfulness after MBI. Thus highlights the need for more effective MBI strategies incorporating yoga, meditation, and CBT.The duration and the effectiveness of mindfulness training are key in deriving benefit. Studies with 10 to 12 week programmes have shown both higher levels of mindfulness and better benefit in improving QoL. The main reason for patients opting not to undergo MBI is logistic issues. The rapid development of information technologies has opened many newer arenas for delivery of MBIs. Time and location restrictions can be overcome with online or app-based MBI, which is simpler and more useful than in-person interactions. Additionally, those with physical and psychological problems that are typical of cancer patients are better suited for online MBIs.In conclusion, MBI is a promising and feasible modality that can be used as an adjunctive to manage cancer-related symptoms. There may be a financial advantage to using online or remote health to implement MBI for existing treatment models and referral networks. Ultimately a multidisciplinary holistic approach to the patient is essential to provide both a longer life and a better quality life.

10. CONFLICT OF INTEREST

Conflict of interest declared none.

11. AUTHORS CONTRIBUTION STATEMENT

All authors are equally contributed.

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