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Guided imagery- Effectiveness in cancer fatigue in patients undergoing chemotherapy: A clinical trial

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Abstract
Background: Cancer fatigue is a detrimental factor in the prognosis and overall quality of life in cancer patients. Estimates show that more than 50 percent of people with cancer experience cancer-related fatigue(CRF) which is often said to be the most common and distressing symptom reported by people living with cancer which is attributed either to the disease process or the treatments undertaken.
Objective: The objective of the present study was to evaluate the effects of guided imagery on cancer related fatigue, anxiety and quality of life in patients undergoing chemotherapy treatment.
Settings and design: the study was undertaken in a tertiary health care centre for a period of (six) 6 months
Methodology: Fifteen (15) patients undergoing chemotherapy treatment were recruited in the clinical trial based on the inclusion and exclusion criteria. The outcome measures were Fatigue symptom inventory scale, Hamilton anxiety questionnaire and EORTC QLQ C-30 scale which were computed at baseline and after the end of the treatment and the scores were recorded. Guided imagery in the form of an audio was given to the patients and they had to listen to it thrice a week for a period of three weeks.
Results: Guided Imagery was effective in decreasing fatigue, anxiety and improving quality of life scores (p<0.01).
Conclusion: Guided Imagery may be used as a strategic tool to reduce the levels of fatigue, anxiety and improve quality of life for patients undergoing chemotherapy treatment in the clinical setup of the Indian Scenario.

Keywords: Guided imagery, cancer, chemotherapy, cancer related fatigue, anxiety, quality of life

Introduction
Cancer rates are growing exponentially with cancer being one of the leading cause of death worldwide [1]. In India, although the prevalence of cancer is lower compared to other countries, cancer ranks as the sixth leading cause of death in India. A total of 1.1 million new cases of cancer are projected to have been diagnosed in India each year, of which breast and cervical rank among the top two cancers in terms of both incidence and mortality [2]. The treatment options for cancer comprise of chemotherapy, radiotherapy, surgery, immunotherapy, targeted therapy, stem cell therapy, genetic therapy and hormone therapy which can either be taken individually or as a combination of two or more treatment options [3]. Chemotherapy works by stopping or slowing the growth of cancer cells, which grow and divide rapidly. The commonly used chemotherapeutic drugs in practise are cyclophosphamide, cytosar-U, cisplatin, vincristine sulphate, vectibix, gemcitabine-oxaliplatin etc. [4] Cancer is associated with a variety of side effects due to chemotherapy which may be caused due to the disease itself or may arise during the course of cancer treatment. These side effects include anemia, appetite loss, fatigue, headaches, infection, nausea and vomiting, dyspnoea, insomnia, weight gain or loss, anxiety, depression etc. [5]
It has been estimated that more than half of the people diagnosed with cancer experience cancer-related fatigue (CRF), which is characterized by excessive and persistent exhaustion that adversely interferes with the person's daily activities, functions and overall quality of life. Signs of CRF may include physical weakness, changes in mood or motivation, withdrawal from social activities, irritability and impaired ability to perform daily activities, concentrate or make decisions [6]. Guided imagery is a technique used to harness the power of the mind to form mental representations of objects, places or situations, which are perceived through the senses. Guided imagery interventions in oncology have focused on four areas:

efficacy in pain management, influence on surgical outcomes, improvement in quality of life and changes in immunity [7].

There are several studies showing the efficacy of guided imagery on cancer induced side effects like cancer pain, nausea and vomitting for a span of 3-12 weeks. However, there is limited literature on the effects of guided imagery in cancer related fatigue with a short intervention span. Therefore the present study explored the short-term effects of guided imagery on fatigue, anxiety and quality of life in patients with chemotherapy induced cancer fatigue.

Materials and Methods

Design

The present study was a single centre, clinical trial conducted at a tertiary healthcare hospital in Belagavi-Karnataka, India, which evaluated the effects of guided imagery on cancer fatigue in patients undergoing chemotherapy. An ethical clearance was obtained from the Institutional Review Committee (IRC) prior to the commencement of the study. Fifteen (15) patients were recruited from Tertiary Care Hospital and KLE Cancer Hospital, Belagavi-Karnataka, India. A written informed consent was obtained from the patients wherein they were given detailed information pertaining to the study and the risks and benefits associated.

Study participants

The patients were recruited into the study if they were in the age group of 18- 60 years, diagnosed with Stage 1, 2 or 3 cancer, currently undergoing chemotherapy treatment and experiencing fatigue which was assessed according to the Fatigue Symptom Inventory scale(FSI). The patients were excluded if an intravenous dose of analgesic medication was injected within the last thirty (30) minutes or an oral analgesic dose was administered sixty (60) minutes before the treatment, presence of any hearing deficits, any form of imagery techniques administered in the past, brain metastasis and/or any other illness which would impair their ability to comprehend and follow commands.

Intervention

The patients were administered the guided imagery in the form of an audio which was in English and was translated into the vernacular language of Hindi, Marathi and Kannada. This audio tape was played for a duration of ten (10) minutes. The patient was asked to sit comfortably and instructed to close his/her eyes whilst listening to the audio which was given through headphones. All the patients were instructed to concentrate his/her mind on different body parts and to slowly feel each part relaxing. It also instructed all patients to let go of all tension, stress and negativity to be at peace. Furthermore it instructed the subject to visualize a place that the subject has good memories of and that that puts the subject at ease and to imagine all the smells, sounds and visual cues present in the surroundings. The first session was carried out under the supervision of the therapist/ investigator and subsequently the patients had to listen to the audio thrice a week for a period of three (3) weeks. The patients were constantly monitored by motivational calls by the therapist/investigator.

Outcome measures

Chemotherapy induced cancer fatigue was quantified by the fatigue symptom inventory (FSI) scale and quality of life was measured by the EORTC-QLQ C30 scale and anxiety that was measured by the Hamilton Anxiety Rating Scale(Ham- A). All the three (3) scales were administered at baseline and after completion of the stipulated intervention period i.e. three (3) weeks.

Fatigue symptom inventory (FSI) [8]

FSI is a 14- item self report measure designed to assess the severity, frequency and daily pattern of fatigue as well as its perceived interference along with quality of life. Severity was quantified with questions 1-4, the disruption index was computed by summing items 5-11 which reflected perceived interference and frequency was measured as the number of days the in the past week(0-7) that respondents felt fatigued.

European organisation for research and treatment of cancer scale (EORTC QLQ C-30) version 3.0 [9]

The QLQ C-30 is composed of both single item measures and multi-item scales. This scales is further subdivided into global health status, functional scales and symptom scales wherein a high score for a functional scale represents a high/ healthy level of functioning, a high score for global health status represents a high quality of life but a high score for a symptom scale represents a high level of symptomatology.

Hamilton Anxiety Rating scale [10]

The HAM-A scale consists of 14 items, each defined by a series of symptoms and measure both psychic anxiety and somatic anxiety. Each item is scored on a scale of 0(not present) to 4(severe), with a total score range of 0-56, where <17 indicates mild severity, 18-24 mild to moderate severity and 25-30 moderate to severe.

Statistical analysis

Statistical analysis for the present study was done manually as well as using statistical package of social sciences (SPSS) version 21so as to verify the results obtained. Various statistical measures such as mean, median, standard error, standard deviation were used. Nominal data such as subject's demographic data i.e. age, BMI (kg/m^2), height (metres), weight (kgs) distribution were analysed. Normality of all the parameters was determined by Kolmogorov Smirnov test and as the data followed a normal distribution, dependent t-test was used for analysis of the Fatigue Symptom Inventory scale, European Organisation For Research And Treatment of Cancer Scale (EORTC QLQ C-30) and Hamilton Anxiety Rating scale. With a power of 80%, probability values of less than 0.05 were considered statistically significant.

Results

The baseline data demonstrated a homogenous sample with a mean age of 43.87years. There were no drop outs in the study and all the fifteen (15) patients completed the three (3) weeks of intervention. Most of the patients were diagnosed with stage 2 or 3 cancer. The distribution of type of cancer of the patients show that there were five (5) patients with breast cancer, two (2) patients with small cell lung cancer and prostrate cancer and one (1) patient each with buccal mucosa, esophagus, laryngeal, lung, ovarian, and tongue cancers respectively. Fatigue scores according to the Fatigue Symptom Inventory scale shows a statistically highly significant reduction in pre and post fatigue scores in terms of overall fatigue, fatigue severity, disruption index and frequency of fatigue with a p value of <0.01. Significant improvement in quality of life was noted in all the patients by the (EORTC QLQ C-30) scores with p-value of <0.01for

all the domains i.e. overall quality of life, functional quality of life and symptom severity. The Hamilton Anxiety Rating scale also showed a statistically highly significant reduction in anxiety in all patients with p-value of <0.01.

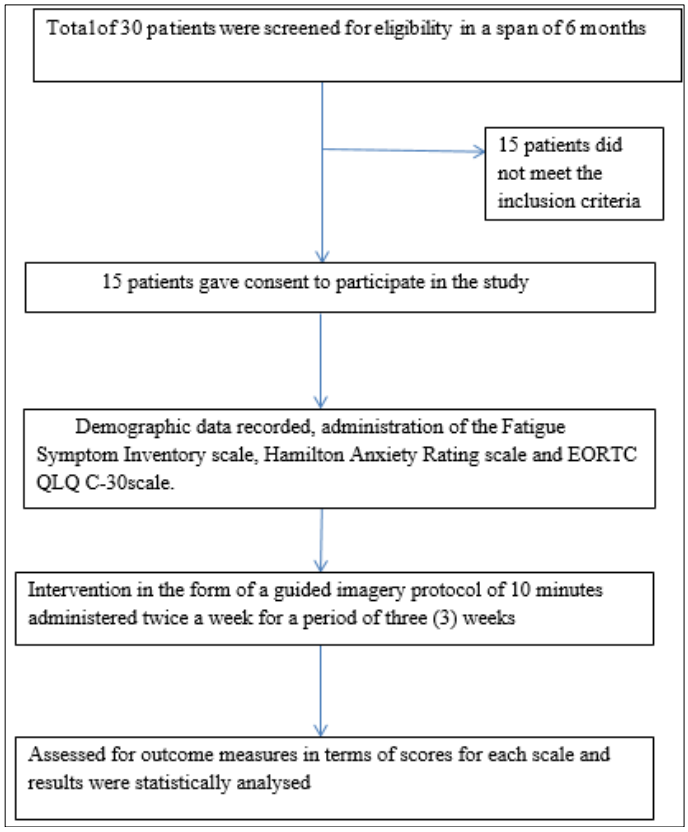

Fig 1: Flow chart of patient recruitment process for the study

Table 1: Distribution of baseline characteristics of all the patients in the study

Variable	N	Mean±SD	Median	SE	Range	%
Age(years)	15	43.87±9.33	44	2.41	32	
Weight (kgs)	15	52.80±9.72	50	2.51	31	
Height(metres)	15	1.52±0.08	1.52	0.02	0.27	
BMI(kg/m^2)	15	22.81±3.14	22.22	0.81	10.04	
Chemotherapy cycles received	15	3.07±1.39	3	0.36	4	
Diagnosis						
Buccal mucosa cancer stage III	1					6.67
Esophagus cancer stage II	1					6.67
Breast cancer stage I	1					6.67
Breast cancer stage II	3					20.00
Breast cancer stage III	1					6.67
Laryngeal cancer stage II	1					6.67
Lung cancer stage III	1					6.67
Lung cancer stage III	1					6.67
Ovarian cancer stage II	1					6.67
Prostrate cancer stage II	1					6.67
Prostrate cancer stage III	1					6.67
Small cell lung cancer stage II	2					13.33
Tongue cancer stage III	1					6.67

Table 2: Comparison of pretest and posttest Fatigue scores (and its components) of all the patients in the study

Variables	Time	Mean ±Std. Dv.	% of change	Paired t	P-value
Fatigue	Pretest	73.27 ±14.46	48.59	10.5053	0.0001*
	Posttest	37.67 ±6.92			
Severity	Pretest	24.00 ±6.44	46.67	9.4273	0.0001*
	Posttest	12.80 ±3.97			
Disruption index	Pretest	43.87 ±7.86	49.70	9.6922	0.0001*
	Posttest	22.07 ±3.77			
Frequency	Pretest	5.40 ±0.83	48.15	11.0625	0.0001*
	Posttest	2.80 ±0.56			

* Level Of Significance -p<0.05

Table 3: Comparison of pretest and posttest European organisation for research and treatment of cancer scale (EORTC) and its components of all the patients in the study Level of Significance -*p*<0.05

Variables	Time	Mean ±Std. Dv.	% of change	Paired t	P-value
EORTC-QLQ	Pretest	124.20 ±15.12	-45.06	-8.0811	0.0001*
	Posttest	180.16 ±24.68			
Functional	Pretest	23.87 ±11.50	-218.07	-13.7513	0.0001*
	Posttest	75.91 ±10.39			
Symptom	Pretest	68.16 ±12.88	63.57	7.8477	0.0001*
	Posttest	24.83 ±13.49			
QOL	Pretest	32.18 ±14.35	-146.82	-9.6576	0.0001*
	Posttest	79.42 ±11.28			

Table 4: Comparison of pretest and posttest Hamilton Anxiety Rating Scale (HAM-A) of all the patients in the study

Time	Mean ± Std. Dv.	% of change	Paired t	P-value
Pretest	37.07 ±10.34			
Posttest	13.80 ±4.97	62.77	10.4604	0.0001*

*Level Of Significance -*p*<0.05

Discussion

The study evaluated the effects of a three week guided imagery program on fatigue, quality of life and anxiety in fifteen (15) cancer patients undergoing chemotherapy treatment with an average of three (3) cycles. The results of the present study indicate that guided imagery has beneficial psychological, physical and functional effects.

Cognitive behavioural strategies encourage people to feel a connection between their mind and body and can aid in facilitating feelings of empowerment which aid in combatting various difficulties in life. Various strategies. relaxation training, progressive muscle relaxation, hypnosis, imagery i.e. guided imagery, mental imagery and positive images with audio-visual aids or solely imagination and supportive therapy have been inculcated to reduce the side effects of cancer including cancer pain, cancer related fatigue, depression, anxiety, nausea, vomiting and to help improve the overall functioning and quality of life of the patient [11]. Guided imagery when administered as a twelve (12) minute protocol proved to be a beneficial tool in the reduction of cancer pain in a pilot study conducted by Kristine *et al* [12]. However, relaxation training proved to be effective in the reduction of depression, anxiety and hostility but had no effect on patients levels of vigor, fatigue and confusion in patients undergoing acute non-surgical cancer treatment [13].

Cancer related fatigue is a detrimental factor in the prognosis of the patients with a direct impact on psychological and physical functioning. The present study demonstrated a significant reduction in overall fatigue scores including the severity and frequency of fatigue with guided imagery which may be attributed to the effects of relaxation as well as the immune responses via guided imagery. Guided imagery has been found to show positive immunological effects including enhanced lymphokine-activated killer cell cytotoxity, higher numbers of activated t-cells and reduced blood levels of tumour necrosis factor α. [14]. Another study showed that guided imagery also helped in reversing the increased levels of peripheral cortisol associated with fatigue and anxiety which have immunosuppressive effects thus aiding in alleviating fatigue [15].

When comparing imagery with support, imagery patients tend to have less stress, increased vigor and improved functional and social quality of life [16] which correlate with the findings of the present study wherein quality of life significantly improved along with increments in functional capacity and alleviation of symptoms. The clinical effects of relaxation, stress and quality of life may in part be explained by release of potent factors such as neuropeptides and glucocorticoids into the circulation where they act as immunomodulators both directly and indirectly. Results from a clinical trial showed that the patients who were given guided imagery were more relaxed and easy going and had fewer psychological symptoms with higher self-rated quality of life with relaxation training and guided imagery than the patients who did not undergo any form of psychotherapy [14].

Psychological distress in patients with breast cancer often includes depression, poor coping and anxiety related symptoms which play a vital role in the overall function of the patient as well as with coping with the disease and treatment process [17]. This is supported in a study by Shu-Fen Chen *et al* wherein a 20 minute program of guided imagery with relaxation proved to be an effective tool in the reduction of anxiety and depression in breast cancer patients undergoing chemotherapy [18]. A study conducted to demonstrate the effects of relaxation training and guided imagery on psychological and quality of life indices in patients showed that these therapies were effective in reducing anxiety and depression as well as body discomfort in cancer breast patients undergoing brachytherapy [19].

The findings of the present study illustrate that guided imagery interventions can aid health professionals in developing and taking responsibility for clinically managing the distressing symptoms associated with chemotherapy. Guided imagery can be used in conjuction with conventional physiotherapy to aid in the rehabilitation process.

Guided imagery is a relatively inexpensive protocol which is easy and feasible to administer in a tertiary healthcare setup. However, the results of the present study may not be generalised due to a relatively small sample size. The future scope will include multicentric trials on a larger population.

Guided Imagery may be used as a strategic tool to reduce the levels of fatigue, anxiety and improve quality of life for patients undergoing chemotherapy treatment in the clinical setup of the Indian Scenario.

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