A Study to evaluate the effectiveness of patient tailored nutritional intervention on fatigue & nutritional status among cancer patients at OPD of selected Hospital, Ambala, Haryana.

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Abstract- Design: True experimental i.e: “Randomized controlled Trail: pretest posttest design”

Setting: Cancer OPD of Maharishi markandeshwar institute of medical sciences and research hospital Mullana, Haryana.

Sample size and sampling technique: Total 60 patients were selected by convenience sampling technique and randomized into two groups experimental (n=30) and control (n=30) by computer generated code method.

Intervention: Patient tailored nutritional intervention was administered in experimental group.

Results: The post intervention mean score of nutritional status in experimental group was 5.00 which was significantly higher than mean score of control group 6.70 (t=3.90, p=0.001). The computed pearson's correlation between posttest fatigue and nutritional status was 0.63 & correlation between fatigue and nutritional status was 0.67 which is highly significant (p=0.01**)

Conclusion: The use of Patient tailored nutritional intervention was effective in improving nutritional status among cancer patients. There is no effect of patient tailored nutritional intervention on fatigue among cancer patients. There was a positive moderate relationship between fatigue and nutritional status among cancer patients. As the level of fatigue increase, the nutritional status decrease in cancer patients. Therefore, it is recommended that the 'patient tailored nutritional intervention’ can be used in case of patients suffering from side effects of patients undergoing chemotherapy and radiation therapy treatment.

Index Terms- Fatigue, Nutritional status, Patient tailored nutritional status, Cancer

I. INTRODUCTION

Cancer arises from the transformation of normal cells into tumour cells in a multistage process that generally progresses from a pre-cancerous lesion to a malignant tumour.¹

Chemotherapy is an important treatment modality in oncology which can prolong life of cancer patients. These drugs are chemically designed to target cancer cells that are dividing and growing rapidly. However most chemotherapy drugs have some side-effects such as nausea and vomiting, mouth sores and ulcers and increased susceptibility to infection that can profoundly affect the nutritional status. Patients who have lost a significant amount of weight before cancer treatment are at increased risk of becoming further malnourished during treatment.²

The prevalence of malnutrition in cancer patients ranges from 40-80%. This varied prevalence is due to the elevated basal energy requirements due to the inherent illness and decreased oral intake. Whereas in simple starvation, re-feeding restores normal nutritional states, cancer related weight loss is different, in that abnormalities associated with tumour frequently prevent restoration of muscle mass by provision of nutrient. Loss of weight can be attributed to increased cytokines associated with tumour, including- malabsorption, obstruction, diarrhoea and vomiting, host response to the tumour (causing anorexia and altered metabolism) and the side effects of anti-cancer treatment.³

Malnutrition can influence the effectiveness and success of chemotherapy, radiotherapy, and cancer-related surgery due to changes in metabolism, pharmacokinetics and healing dynamics. Moreover, malnutrition seems to be responsible for changes in absorption, protein binding, hepatic metabolism and renal elimination of drugs and their metabolites.

Fatigue is the most frequent side effect of cancer and its treatment that is subjective in nature and experienced as a feeling of tiredness that varies in degree, frequency and duration. Cancer associated fatigue is reported in 14% to 96% of patients undergoing cancer treatment & in 19% to 82% of patients post management.⁴
65% to 95% of patients experience fatigue during chemotherapy. Such fatigue is mostly encountered in the late afternoon and perceived as reasonable during chemotherapy by patients. It is also ignored or left untreated by 80% of healthcare professionals. Lack of attention to treatment can allow the fatigue to worsen in intensity and prolong patients’ recovery process.\textsuperscript{5}

II. NEED OF THE STUDY:

It is known that fatigue is the commonest side-effect of chemotherapy and radiotherapy: it has been shown that 65–100% of patients undergoing radiotherapy and up to 82–96% of those receiving chemotherapy suffers from fatigue during their treatment. As could be imagined, fatigue is correlated to the intensity of treatment, and becomes a relevant toxic effect the more the treatment intensity is increased. This correlation could be predictive of the fatigue observed at some time after treatment.\textsuperscript{vi}

Cancer patients undergo metabolic alterations, which render them to have protein energy malnutrition throughout all stages of the disease. Malnutrition globally impacts all cancer patients by increasing the risk of infection, delaying wound healing, increasing treatment toxicity, prolonging hospital stay and increasing health related costs. While malnutrition is already very prevalent among cancer patients, nutrition supportive intervention should always be part of the global oncology strategy.\textsuperscript{vii} Nutrition plays an important role in maintaining better quality of life among cancer patients, and it is an instinct for every human being to value food intake in order to maintain social structure, self esteem and enjoyment.\textsuperscript{viii} A study by Gupta et al showed that well-nourished (a good SGA-subjective global assessment score) cancer patients were associated with better survival outcomes.\textsuperscript{ix}

Malnutrition has been observed to negatively impact patients reaction to treatment, elevate treatment side effects, disrupt consecutive treatment regimens, increase hospital stay, weaken functionality and immunity of patient hence affecting survival rates of the patients.\textsuperscript{x} Malnutrition and weight loss are prevalent in 20–80% of cancer patients.\textsuperscript{xi} Early recognition and detection of risk for malnutrition through nutrition screening followed by comprehensive nutrition assessment and timely interventions should be considered a valuable measure within the overall oncology strategy.\textsuperscript{xii}

III. OBJECTIVE:

This study was conducted with an objective to assess the effectiveness of patient tailored nutritional intervention on fatigue and nutritional status among cancer patient at OPD of selected hospital.

IV. METHODOLOGY:

A randomized control trial was taken up and 60 patients were selected by convenience sampling technique and randomized into two groups experimental (n=30) and control (n=30) by computer generated code method. The inter-rater reliability of Patient generated subjective global assessment scale was determined by using Pearson Correlation. Two raters independently assessed the patients for muscle strength examination. The inter-rater reliability was calculated by Pearson Correlation and found to be 0.80. The internal consistency was also calculated by using Cronbach’s Alpha and found to be 0.86. Patient tailored nutritional intervention was administered in experimental group. The pre and post interventional fatigue and nutritional status score were assessed in both the group by using a scale i.e. brief fatigue inventory (BFI) and patient generated subjective global assessment scale (PG-SGA). The data was collected by self reported, record review and anthropometric measurement.

Ethical approval to conduct study was obtained from institutional ethical committee of M.M (Deemed to be University), Mullana. Consent form was taken from the patients regarding their willingness to participate in the research project. The purpose for carrying out research project was explained to the subjects and assurance of confidentiality was given.

V. RESULTS:

Section- I

Sample characteristics and clinical variables of patients:

Half of the patients in experimental group (50.0%) were in the age group of 40-60years and more than half of the patients in control group (53.3%) were in the age group of 60-80years. Majority of the patients in both the experimental group (66.7%) and control group (60.0%) were males. More than 1/3rdof the patients in both the experimental group (40.0%) and control group (36.7%) were having no formal education. 1/3rdof the patients in both the experimental group (36.7%) and control group (30.0%) were self employed. More than half of the patients in both the experimental group (53.3%) and control group (56.7%) were having the BMI between 18.5 - 24.99. Majority of the patients in both the experimental group (66.7%) and control group (63.3%) were having the 2nd stage of cancer. More than half of the patients in experimental group (36.7%) and control group (36.7%) were having protein energy malnutrition throughout all stages of the disease. Malnutrition globally impacts all cancer patients by increasing the risk of infection, delaying wound healing, increasing treatment toxicity, prolonging hospital stay and increasing health related costs. While malnutrition is already very prevalent among cancer patients, nutrition supportive intervention should always be part of the global oncology strategy. Nutrition plays an important role in maintaining better quality of life among cancer patients, and it is an instinct for every human being to value food intake in order to maintain social structure, self esteem and enjoyment. Early recognition and detection of risk for malnutrition through nutrition screening followed by comprehensive nutrition assessment and timely interventions should be considered a valuable measure within the overall oncology strategy.
**Section – II**

**Table- 1**

Mean, Mean difference, Standard Error of Mean difference and ‘t’ value of fatigue score of Experimental and Control Group before & after administration of patient tailored nutritional intervention.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>M_D</th>
<th>SE_MD</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>25.40</td>
<td>2.96</td>
<td>4.51</td>
<td>3.60</td>
<td>0.001***</td>
</tr>
<tr>
<td></td>
<td>22.43</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>23.90</td>
<td>1.33</td>
<td>2.39</td>
<td>3.04</td>
<td>0.005***</td>
</tr>
<tr>
<td></td>
<td>25.23</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*** very highly significant (p<0.01)

T Table 1 & fig 1 shows a comparison of fatigue score in experimental and control group using paired ‘t’ test.

In the experimental group, the mean pretest fatigue score was 25.40 and mean posttest fatigue score was 22.43 with the mean difference of 2.96 which was found statistically significant (t=3.60, p= 0.001**) at 0.05 level of significance. The mean posttest fatigue score of patients in experimental group was significantly lower than the mean pretest fatigue score. Therefore, it can be inferred that patient tailored nutritional intervention was effective in reducing fatigue among patients in experimental group.

In control group, the mean pretest fatigue score was 23.90 and mean posttest fatigue score was 25.23 with a mean difference of 1.33 which was found to be statistically significant (t= 3.04, p=0.005**). The mean posttest fatigue score of patients in control group was significantly higher than their mean pretest fatigue score. Therefore, it can be inferred that in absence of patient tailored nutritional intervention, the fatigue score of patients in control group increased significantly.

![Bar graph showing mean fatigue score before and after administration of patient tailored nutritional intervention in experimental and control group](image-url)

**Figure: 1 Bar graph showing mean fatigue score before and after administration of patient tailored nutritional intervention in experimental and control group**

**TABLE: 2**

Mean, Mean difference, Standard Error of Mean difference and ‘t’ value of nutritional status score of Experimental and Control Group before & after administration of patient tailored nutritional intervention.

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean</th>
<th>M_D</th>
<th>SE_MD</th>
<th>T Value</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>6.80</td>
<td>1.80</td>
<td>0.26</td>
<td>8.75</td>
<td>0.001***</td>
</tr>
<tr>
<td></td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2 & fig 2 shows a comparison of nutritional status score in experimental and control group using paired ‘t’ test.

In the experimental group, the mean pretest nutritional status score was 6.80 and mean posttest nutritional status score was 5.00 with the mean difference of 1.80 which was found to be significant (t=8.75, p= 0.001) at 0.05 level of significance. It shows that the posttest nutritional status score was significantly lower than the pretest score in experimental group which indicates that the nutritional status of patients improved in experimental group after the administration of patient tailored nutritional intervention.

In the control group, the mean pretest nutritional status score was 7.17 and mean posttest nutritional status score was 6.70 with the mean difference of 0.47 which was found to be statistically non significant (t=1.99, p= 0.06NS) at 0.05 level of significance. It can be inferred that in absence of patient tailored nutritional intervention, there was no change in nutritional status of patients in control group.

Therefore, it can be concluded that patient tailored nutritional intervention is effective in improving nutritional status among cancer patients.

Figure 2: Bar graph showing comparison of mean nutritional status score before and after administration of patient tailored nutritional intervention in experimental and control group

Section – III

TABLE 3
Pearson’s correlation showing relationship of posttest fatigue and nutritional status in Experimental & Control Group

<table>
<thead>
<tr>
<th>Correlation</th>
<th>Nutritional status ‘r’ value</th>
<th>Fatigue ‘r’ Value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>0.63</td>
<td>xx</td>
<td>0.01**</td>
</tr>
<tr>
<td>Nutritional status</td>
<td>Control group</td>
<td>0.67</td>
<td>0.01**</td>
</tr>
<tr>
<td>** * highly significant (p&lt;0.01)</td>
<td>r(58)= 0.250</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The finding in Table 3 reveals that the computed Pearson’s correlation between posttest Fatigue and Nutritional status after administration of patient tailored nutritional intervention in experimental & control group. The computed Pearson’s correlation between posttest Fatigue and Nutritional status score was 0.63, which is statistically significant at 0.05 level suggesting a moderate degree positive relationship between posttest Fatigue and Nutritional status scores of experimental group. This indicates that as the fatigue score decrease the nutritional status score also decrease lower score of nutritional status indicates good nutritional status. Therefore, it can be
inferred that as fatigue level of patients decrease, the nutritional status improves and vice versa.

In control group, the computed Pearson’s correlation between posttest Fatigue and Nutritional status score was 0.67 which is statistically significant at 0.05 level suggesting a moderate degree positive relationship between posttest Fatigue and Nutritional status scores. This indicates that as fatigue score decrease, nutritional status score also decrease. Therefore, it can be inferred that as fatigue level of patients decrease, the nutritional status improves.

Hence, null hypotheses ($H_0$) was rejected and research hypotheses($H_3$) was accepted.

VI. DISCUSSION:

The present study shows that 50% patient were in the age group of 60-80 year which is consistent with the findings of the study conducted by Wen-Hao Su et al (2011) who reported that the 73% patients were more than 65 year.

The present study shows that 66.7% of cancer patients were male and rest 33.3% were female which is consistent with the findings of the study conducted by Kavyaparasa et al (2016) which shows that 71.5% were male and rest 28.5% were female.

The present study shows that 26.7% were underweight, 60.0% were normal weight and 6.7% were overweight, 6.7% were obese which is consistent with the findings of the study conducted by Bincy R et al (2014) in which 23.3% patients were underweight 43.3% normal weight and 23.3% overweight 6.6% obese.

The present study shows the mean nutritional status score of patients in experimental & control group before intervention was 6.80 & 7.13 respectively before administering patient tailored nutritional intervention. These findings are consistent with the study conducted by Opanga Y et al (2017) who reported mean PG-SGA score of cancer patients as 6.76±5.17.

In the present study, the mean posttest fatigue score of experimental group (22.43) was significantly lower than control group (25.23) after administering patient tailored nutritional intervention.

In the present study, the mean posttest nutritional status score of experimental group (5.0) was significantly higher than control group (6.70) after administering patient tailored nutritional intervention. It indicates better nutritional status in experimental group as compared to control group. This finding is consistent with the study conducted by Langius JAE et. Al(2013) systematic review to assess the effect of nutritional intervention on nutritional status in which four out of 10 studies showed significant benefits of nutritional counseling on nutritional status.

The present study shows that there was a significant relationship between nutritional status score and fatigue score ($r=0.63$, $p=0.01$). The findings were consistent with the study conducted by Young Heet. Al(2003) to assess the relationship between fatigue and nutritional status in patients with cancer undergoing radiotherapy which shows that there is significant correlation between the fatigue scores with Body weight ($r=0.38$, $p<0.01$) and BMI ($r=0.34$, $p<0.01$).

VII. CONCLUSION:

Patient tailored nutritional intervention was effective in improving nutritional status among cancer patients. There is no effect of patient tailored nutritional intervention on fatigue among cancer patients. There was a positive moderate relationship between fatigue and nutritional status among cancer patients. As the level of fatigue increase the nutritional status decrease in cancer patients.

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