5. SUMMARY AND CONCLUSION

Epidemics of non-communicable diseases are presently emerging among the adult population in both the developed and developing countries. These countries are now warned to take appropriate steps to avoid the “epidemics” likely to come with social, economical and developmental problems. Cancer of breast in women is a major health burden worldwide. Breast cancer accounts for 19 to 34 per cent of all cancer cases among women in India. Life style, genetic, environmental, reproductive and nutritional factors contribute to the risk of breast cancer. Earliest signs or less common symptoms have to be detected early through mammogram or clinical breast examination or breast self-examination methods. The major forms of medical therapy include surgery, radiation and chemo therapy separately or in combination consequently leading to adverse side effects. Experimental studies have shown that dietary antioxidants had been associated with decreased risk of breast cancer.

The higher rates of breast cancer in India especially southern region have created a higher cancer burden in women and are a major societal and familial consequence. Cancer could be prevented if the knowledge of risk factors were successfully implemented. A rational concept to put science into practice has to be formulated to counter this disease.

Hence the present study was undertaken with the broad objectives of understanding the contributory factors towards breast cancer, to identify and implement dietary intervention and with specific objectives to study the type of cancers among women in selected hospitals of Coimbatore, to explore and associate the various risk factors, to formulate and assess Breast Cancer Risk Index and to analyse the impact of dietary intervention on plasma antioxidants and knowledge gained.

In order to fulfil the above mentioned objectives the study was carried out in three phases. A total of five hospitals, four private hospitals and one
Government, Hospital with the Oncology Department in Coimbatore, Tamil Nadu were selected to conduct the study. From these hospitals all the 1200 women with various sites of cancer between 20 and 60 years who visited oncology units over a period of six months were selected. It is identified that 914 women were with breast cancer. Among them 800 case subjects who consented to participate in the study were selected using judgment sampling technique and 500 asymptomatic women as control subjects matching the age of 40-60 years with the case subjects were selected by purposive stratified sampling method to explore the general demographic profile and to identify the association of risk factors.

In Phase I, the details regarding socio-economic background, lifestyle factors, environmental exposure, reproductive, medical history and dietary practices were elicited using a well-framed interview schedule from case subjects and controls. Nutritional status in terms of clinical signs and Body Mass Index was assessed using standard procedures and the association between variables and breast cancer risk factors was found out using factor analysis.

In Phase II, 536 women with breast cancer case subjects between the age group of 40 and 60 years were selected using incidental purposive sampling technique based on certain inclusion criteria. Age matched control group of 500 samples from Coimbatore were selected in order to stratify the highest risk factors. Multiple regression analysis was done using newly detected cancer as the dependent variable and the various risk factors (such as age at menarche, regularity of menstrual cycle, age at first child birth, meat consumption and chemical use) as independent variables to obtain the risk scores. Based on the beta coefficients, a score was created for each parameter. The simplified Breast Cancer Risk Index (BCRI) was then determined by adding the scores for each risk factor. Using the formulated Cancer Risk Index the degree of cancer risk was assessed for control group.
In Phase III, a subsample of 190 case subjects were selected by stratified purposive sampling method and based on the different treatment modality, they were divided into two groups comprising 100 and 90 case subjects as A and B respectively and were given specific dietary intervention.

The group A, received 100 g carrot along with diet counselling whereas group B received only diet counselling for a period of 12 weeks. Diet counselling was given to both groups using booklets, pamphlets and posters through lecture method, individual and group counselling every month fortnightly during their schedule for treatment. The impact of counselling was assessed using scores with the help of formulated check list and software.

Group A was supplied with carrots every week during their visit for follow up or treatments or through attenders. They included the carrots in the form of poriyal or juice. The impact of supplementation was carried out by assessing plasma vitamin antioxidant E and C, β-carotene, and enzyme antioxidants status such as glutathione per oxidase and superoxide dismutase among the six case study subjects using standard procedures of estimation.

Limitation of this phase of the study was drop outs of seven subjects due to recurrence of illness, death and unknown reasons thereby case subjects were restricted to six subjects. Further due to time limitation of study and cost-effectiveness of biochemical parameters impact was not possible among all case subjects of Group A.

The scored PG-SGA tool, a standard for nutrition assessment among breast cancer subjects was adopted before and after intervention among both the group A and B.

**FINDINGS OF THE STUDY**

**PHASE I**

- Among the selected 1200 female cancer subjects breast cancer (76.1 percent) was predominant followed by cervix uterus
Comparing the duration of disease, irrespective of the type of cancer 41 percent suffered for the past six months.

- A majority of 65 per cent of cases and 59 per cent of controls were between the age group of 41 and 60 years and 40 – 50 years respectively.
- Illiteracy was found among 15.2 case subjects and 22.2 per cent of control subjects.
- Only 9.7 per cent of cases were employed as teachers, tailors, sales women and coolies as against 35.4 per cent in high income group among controls working as teachers, lab technicians and press.
- Fifty nine per cent of case subjects were from low income group in comparison with 46.4 per cent controls.
- One per cent controls and 3.7 per cent case subjects were single women.
- The breast cancer case subjects from urban area, was 53.5 per cent and 23.3 per cent controls are from rural area in which 13.6 per cent belonged to LIG.
- Ratio of nuclear and joint family system was 3 : 1 in controls and 89.6 per cent of case subjects were in nuclear family system.
- Chi square test revealed that the demographic factors among case subjects and control subjects showed a significant difference at $P < 0.001$ level.
- Chewing raw tobacco with betel leaves was reported by 11.6 per cent of cases and 25 per cent of controls. Among 54 per cent of case subjects above 60 years and 31.8 per cent of controls between 40 and 50 years of age were sleeping for five to seven hours a day. Twenty six per cent of cases and double that of controls were involved in sedentary life style pattern. Life style pattern of the selected subjects showed a significant difference at $P < 0.001$ level.
- Walking as exercise was performed by 35.6 per cent women of all age group for less than 20 minutes daily only after the diagnosis of illness whereas 12.3 per cent controls walk daily.
The study evinced that 97.3 per cent of cases and 86 per cent of controls used the chemicals like phenol, lizol, dettol, harpic, soap oil and artificial cow dung powder for sanitary purposes both at home and work spot in bare hand. The usage of chemicals by selected subjects was significant at P < 0.05 level.

Mosquito repellents in the form of liquid, cakes, sprays and as ointment were used by 18.8 per cent of cases and 23.8 per cent of controls for more than six years.

Average age of menarche between 10 and 12 years was among 36.3 per cent and 24.8 per cent of cases and controls respectively and it is statistically significant at P < 0.001 level.

Irregular menstruation was noted among 11.6 per cent of cases and 10.2 per cent of controls which is significant at P < 0.01 level.

Seven to eight per cent of both cases and control subjects postponed the menstrual cycle for the purpose of participation in festival occasions, rituals and travelling.

Fifty two per cent of cases and 46.8 per cent of controls were married at the early age of 16 and 20 years.

Age at marriage between cases and control subjects showed a statistical significance of P < 0.001 level.

Three per cent and 3.8 per cent of cases and controls respectively had the habit of using contraceptives.

Abortion and miscarriage were the frequent gynaecological complications encountered by 12.7 and 13.6 per cent of cases and control subjects respectively.

Among parous women 86.4 per cent of case subjects and 87.4 per cent of controls delivered the first child in normal mode.

First child birth above 25 years of age was noted among 12.5 per cent of cases and 28.4 per cent of controls.

A significant difference at P < 0.001 level was noted with regard to age at first child birth among selected women.
With regard to parity, a significant difference at P < 0.001 level was noted among selected women where 14.2 per cent of cases and 11 per cent of controls had single parity as against 10.6 and 3.8 per cent nulliparity.

Among selected women, 17.5 per cent case subjects and 22.2 per cent controls had not fed colostrums owing to their ignorance of understanding its importance.

Breast milk was fed by 1.8 per cent of cases and 19.2 per cent of controls only for three months and the duration of breast feeding showed a significant difference at P < 0.001 level.

Fifteen per cent cases and 30 per cent controls had attained menopause after 50 years of age. The age at menopause showed a significant difference at P < 0.001 level.

Hot flash was the major premenopausal symptoms reported by 39.4 per cent cases and 41.6 per cent controls.

Cancer and obesity was the complications after menopause respectively among cent per cent cases and 23.8 per cent controls.

Nearly five per cent of case subjects had diagnosed breast cancer through the screening tests, 83.5 per cent had breast cancer for a year and five per cent reported of familial tendency of cancer in mother.

Lumps in the breast was the common sign among 89 per cent of women. Chemotherapy was the commonest treatment for 36 per cent women and 34 per cent had been in treatment between 1-6 months duration.

Anaemia was the most common problem encountered by 71.6 per cent women. All selected women below 20 years and 21-40 years were found to be anaemic.

Almost equal per cent of cases and controls had similar type of diet. The ratio of non-vegetarians and vegetarians was 3.4 : 1 indicating the dominance of non-vegetarians.

Consumption of meat by 28.8 per cent and 15 per cent weekly and fortnightly were observed among case subjects respectively and similar trend was noted among control group.
Roasting and deep fat frying were the common cooking methods adopted to cook non-vegetarian foods.

Sunflower oil was the most preferred oil for cooking by 62.2 per cent cases and 59.8 per cent controls, and 81.3 per cent cases and 78.8 per cent controls had the habit of using reheated oil.

Artificial colours were included in the preparation of sweets and savouries by 47.6 per cent and 60 per cent cases and control subjects respectively.

The descending order of usage of carcinogenic agents by case subjects are reheated oil (81.2 per cent), artificial colouring agents (76.1 per cent), pesticides in food (40.7 per cent) and black plastic bags for storage of foods (38.4 per cent), and in controls insecticide in food (100 per cent), reheated oil (78.8 per cent) and black plastic bags (77.4 per cent) ranked the highest order.

Clinical examination revealed that 85.5 per cent and 82.8 per cent of case subjects had dry and scaly skin and difficulty in swallowing respectively.

Chronic energy deficiency of grade III as well as grade II obesity was noted among 3.9 and 4.6 per cent of case subjects respectively whereas 70 per cent of controls were obese.

The Eigen values enlists their relative explanatory powers and factor loading for 15 linear components identified.

Seven factors together explained 59 per cent of the variations in the variables.

Factor 1 age at marriage and age at child birth explained nearly 14 per cent of the variance.

Age of the respondent and menopause age explains 10 per cent of variance, type of diet and meat consumption explained nearly nine per cent of the variance for factor 2 and 3 loading respectively.

Factor 4 and 7 accounted for eight per cent and six per cent respectively had significant loading for only one dimension.

Factor 5 and 6 had significant loadings for three and two dimensions at seven per cent and six per cent of the variance respectively.
Based on factor analysis socio-economic factors viz. – education, locality and marital status; age at menopause; use of chemicals and dietary factors such as meat consumption, use of food colours were the risk factors for breast cancer as stated in Hypothesis H1.

PHASE II

Breast cancer risk index was developed using the data of 536 case subjects recently detected with cancer and 500 control subjects in the age group 40-60 years.

Binary logistic regression analysis revealed several factors were associated with cancer. Multiple logistic regression was undertaken to determine the independent importance of each of the risk factor.

Beta co-efficient for menarche age < 12 years and chemical usage was : 0.61 and for the habit of consumption of meat : 0.42.

Risk score of ≥ 13 had the optimum sensitivity (66.9 per cent) and specificity (51.7 per cent) for determining cancer. The area under the curve for ROC was 0.625 (95% CI : 0.591 – 0.659, P < 0.001).

Based on risk factors such as age at menarche (≤ 12 years); irregular menstrual cycle, age at first child birth (< 23 years), meat consumption and chemical use the individual scores were derived which accounted to total of 25 and a simplified BCRI was formulated.

The degree of risk calculated for 500 samples revealed that the total risk score (≥ 13) was obtained by 47 per cent which depicted a threat of incidence of breast cancer prone among controls.

Among the high risk women 13.2 and 12.2 per cent were found in the age group of 50 – 54 and 45 – 49 years respectively.

Chemical usage was the prominent risk among 86 per cent control subjects followed by meat consumption (65.8 per cent) and age at child birth (55.5 per cent), menarche age (26.8 per cent) and menstrual cycle (10.0 per cent) identified using the formulated breast cancer risk index.
PHASE III

- The impact of diet counselling among 190 subjects of both group A and B were assessed using scores.
- Among group A and B, statistically significant association was observed between literacy level, income status and awareness of breast cancer as disease. No significant association between age and awareness of breast cancer was found.
- Only after counselling 84 and 83 per cent in group A were respectively aware of signs such as orange peel like appearance of skin and change in position of nipple as early warning signs towards incidence of breast cancer.
- Thirty six per cent of subjects in group A were able to identify one or two of the reproductive risk factors as against 27 per cent in group B before diet counselling.
- Before counselling only 4 – 14 per cent of group A and B subjects were aware of consumption of meat alone as a dietary risk factor.
- Ninety four per cent of the subjects in group A before counselling were aware that breast cancer can be detected early. Besides diet counselling imparted, awareness created by health professionals at hospitals also enabled a dramatic gain in knowledge regarding early detection and preventive measures among groups after counselling.
- Both the groups gained a thorough knowledge on foods to be included, antioxidant rich foods, importance of right selection of foods and vegetarian diets only after counselling.
- The mean score for the nutrition and food related knowledge of group A was increased from 25 to 35 after education which is significant at \( P < 0.01 \) level.
- The mean score of group B increased from 20 to 55 after intervention which showed that the diet counselling, enhanced the knowledge and it was statistically significant at \( P < 0.01 \) level and proved the hypothesis \( H_2 \).
According to SGA, out of 190 breast cancer subjects 10.5 per cent were well nourished (SGA-A), 72.6 per cent were malnourished either moderately or suspected of being malnourished (SGA-B), and 16.8 per cent of patients were severely malnourished (SGA-C) before intervention and the outcome of dietary intervention demonstrated six per cent SGA-A and 6.83 per cent of SGA-C.

The major nutrition impact symptom due to treatment such as no appetite, vomiting noted among 14.2 and 13.7 per cent subjects respectively of surgery group reduced to 3.1 and 1.1 per cent after intervention.

A marginal improvement of 0.5 to one per cent in reduction of nutrition impact symptoms was observed among combination treatment groups, who received only diet counselling.

A correlation matrix of the scores obtained from each of the seven items that contribute to overall PG-SGA score showed positive correlation between physical examination and metabolic demand (0.598) in surgery group ; and 0.489 with the food intake in radiation group of experimental group A. The correlation was significant at P < 0.01 level.

The activities performed by cases was positively correlated with symptoms (0.537) and physical examination was correlated (0.489) with activities and there was a significant correlation at P < 0.01 among women who had undergone chemotherapy.

Food intake and weight history showed a positive correlation (0.363) and it is significant at P < 0.01 level among group undergone combination of chemo, radiation and surgery treatment.

There was a negative correlation between food intake and age and it is significant at P < 0.05 in group undergone chemo surgery.

Analysis of variance indicated that weight loss for one month was significantly associated with nutritional status before intervention.

The mean per cent weight loss was reduced from 6.3 to 5.7 after intervention among SGA-C group who were severely malnourished.

There was a significant difference in the PG-SGA scores for each of the SGA classifications (P < 0.05) after intervention.
The analysis proves that there is an association between PG-SGA score and dietary intervention as formulated in hypothesis (H₃).

Among the six case study subjects the mean food intake was less than the recommended dietary allowances before intervention. The improvement was noticed in inclusion of roots and tubers, other vegetables after intervention in the diet regularly.

The mean nutrient intake of the selected case subjects revealed the mean difference of 479.40 ± 139.4 K. cal in the energy intake.

Dietary β-carotene level showed a significant difference at one per cent level among case subjects before and after intervention due to the intake of carrots, which was provided as a supplement.

Hypothesis (H₄) was proved indicating an improvement in the energy and nutrient intake of selected case subjects after counselling.

Plasma β-carotene level was found to be 2.61 mg / l before supplementation and showed an increase of 3.55 mg / l after supplementation. The comparison between the initial and final mean values showed significance at P < 0.05 level.

Similarly a mean increment of 0.96 mg / l and 2.71 mg / dl was found after supplementation in plasma vitamin E and C levels respectively.

Enzymatic antioxidants plasma glutathione peroxidase level and plasma superoxide dismutase level was low with that of normal, even after intervention with the mean increment of 11.15 g / l and 0.12 mg / l respectively which was statistically significant at P < 0.001 level.

This finding proved that the hypothesis (H₅) is positively accepted.

**CONCLUSION**

Continuing increased incidence of breast cancer has added urgency for surveillance interventions and for long term survivors.

Hence in the present study, the major risk factors was identified for 15 linear components through factor analysis among case subjects. Cases along with controls, based on multiple linear regression, easily identifiable five
individualized risk of developing breast cancer such as ≤ 12 years menarche age, irregularity of menstrual cycle, < 23 years at first child birth, meat consumption and use of chemicals were derived.

The Simplified Breast Cancer Risk Index (BCRI) formulated can be used as tool to modify the modifiable risk factors. This index will enable for early detection of warning signs among women population to seek medical support at early stage and promote the quality of life.

Dietary intervention played a significant role in the management of cancer patient, across the spectrum from the advance health care treatment for successful reduction of symptoms leading towards improved health related quality life span.

The knowledge about the possible causes of cancer and easily available tools in general population may promote behavioural changes among masses to bring down the possibility of risk behaviour.

RECOMMENDATION

In the light of findings of present study,

- It is recommended that screening and triage systems be implemented to ensure to those patients, most in need of care receive a level that demonstrates outcomes.
- Policy and intervention programme by Government may be implemented to avail the cost effective screening packages for early detection and treatment for the community.
- Establishment of effective lifestyle model for South Indian women to blitz against the barriers in breast cancer.
- In depth studies, with wider coverage of samples with specific type and stages of breast cancer and with specific assessment tools would enable to understand the deficiencies and consequences among patients.
• Calibration of appropriate biomarkers to examine the association between diet and breast cancer to ascertain the desirable consumption units.

• A package of nutrition intervention programme with innovative, attractive, appealing and acceptable nutraceuticals may be developed to enable the cancer survivors to break the monotony of diet and improve the energy and nutrient intake thus improving the quality of life of women.

• Design educational modules to reinforce and enlighten the society in all walks of life to battle in the war against cancer.