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## Effectiveness of counseling in patients of breast and cervical cancer receiving chemotherapy and radiotherapy - prospective observational study

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### Abstract

Cancer is one of the main problems in the India and world also. From the world health organization report (2022), 10 million deaths in the year of 2022 of the entire world. This reflects one in six deaths. Side effects are very common in the cancer treatment process i.e. chemotherapy, radiotherapy and chemo radiation therapy. Proper knowledge is required in these aspects. Sometimes these side effects lead to life threatening due to lack of knowledge on side effects management while patients are in the home. These patients also need counseling, consultation and about side effects management of their treatment. This counselling leads to not only the patient's quality of life but also improve the patients' psychological conditions during their treatment process. In our prospective observational study, the main objectives are checking the effectiveness of before counselling and after counselling with respect to patient's side effect management and psychological effectiveness. Finally evaluate the outcome with the counselling in both breast and cervical cancer patients. We provide counseling for cancer patients in King George Hospital, Visakhapatnam, India. In our study we used EORTC QLQ – C30 (version 3) scale for comparison of with or without counseling in the areas of side effect management, effectiveness of psychological and nutritional in breast and cervical cancer patients. Finally in our study we noticed that mostly rural area and some urban people were lack of knowledge on side effect management of cancer treatment. By providing better counseling to these patients especially in rural area people for their treatment and create awareness of cancer in group counseling for care givers then automatically better side effect management was possible in cancer patients. Pharmacist counseling is one of the important services that has been associated with improved outcome.

**Keywords:** EORTC QLQ – C30 (version 3) scale, chemotherapy, radiotherapy, prospective observational study, side effect management, cervical cancer, breast cancer, chemoradiation.

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### Introduction

Indian council of medical research (ICMR) stated that 26.7 million people are suffering with cancer until the

year of 2021. But this number increases to 29.8 million in the next four years (2025). In India lung cancer in male and breast cancer in female are the leading Cancer types. After that oesophagus cancer, oral cancer, liver and stomach cancers are more.

### Cancer

Cancer is determined by the conversion of normal cell division uncontrolled cell division and forms the bulky mass/tumour after that spreads to the various parts in the body. Tumour consists number of unregularly growing cells often form a lump [1,2].

### Carcinogens

Cancer causing agents are known as the carcinogens. Carcinogens are divided into the chemical, physical and biological/oncogenes.

Chemical carcinogens.... Asbestos, Vinyl chloride, Cadmium, Benzene and Nickel.

Physical carcinogens..... Ultra violet (UV) rays, X-rays.

Biological carcinogens... Bacteria, Viruses and Parasites.

Epstein-Barr virus, Hepatitis B virus [3,4].

### Risk Factors

Risk factors can increase the occurrence of the disease.

Following are the main risk factors for any cancer.

- Tobacco
- Older age
- Any family history of cancer
- Obesity
- Alcohol consumption
- Some viruses (Human Papilloma Virus HPV)
- Exposure to radiation (X-rays, UV rays)
- Chemical exposure
- Lack of physical activity

Some risk factors are in our hand to control the chance of occurrence, they are avoiding tobacco, alcohol consumption, and unhealthy food. Some risk factors are not in our hand they are age (getting older), cancer causing genes.

### Signs

- Sign is an alert notice for any disease. Following are the main signs in cancer
- Unexpected weight loss or gain.
- Changes related to skin (excessive hair growth, reddened skin, itching).
- Bladder function changes.
- Unusual bleeding or discharge.
- Fatigue.
- Swelling or lumps appears in any part of the body.

### Symptoms

**Most of the cancer symptoms are related to the effected organ in our body.**

For breast cancer... (Lumps, changes in nipple, skin become red, itchy).

For bladder cancer (feeling pain and trouble while urinating).

### Problems related to eating:

- Swallowing
- Nausea and vomiting
- Heartburn
- Indigestion

Sweats in night time

Fever

### Bowel related changes:

- Blood in the stools
- Bowel habits changes
- Cough

### Oral cavity related changes:

- Bleeding
- Red color patches/spots in mouth or tongue
- Pain
- Lip numbness

### Diagnostic Tests for Cancer

Screening of effected organ and along with some specific tests for that cancer.

Breast cancer.... (Mammogram, breast cancer screening).

Lung cancer..... (low dose helical CT scan).

Cervical cancer... (PAP test, Human Papilloma Virus Test).

### Other Tests

- Biopsy tests
- MRI (breast)
- Breast examination
- Prostate Prostate-specific test
- Multi-cancer (MCED) tests
- CA-125 tests
- Alpha fetoprotein test
- Ultrasound
- Colonoscopy

### Types of Cancer Treatment

Cancer treatment varies with the stage of cancer. People are diagnosed in early stages of cancer they have only one treatment, but most of the people are diagnosed in later/advanced stage for those people combination of treatment is necessary that is surgery with chemotherapy/radiotherapy.

### A) SURGERY [5]

Removing of solid tumor and surrounding tissue from the site. Some advanced stages of cancers are not cured with chemotherapy because of the tumors are overweight condition. In that cases surgeon proceeds to surgery. Prior to this surgery somewhat chemotherapy (neo adjuvant chemotherapy) and radio therapy will be performed.

### Side effects

Blood clots, bleeding, pain (especially in removed part), tissue damage (related to removed part area), infections,

fatigue, swelling around the area of surgery, organ dysfunction, numbness, appetite loss.

### B) Radiation Therapy

Radiation therapy performed prior to the surgery, along with chemotherapy, after chemotherapy. In this procedure by using radioactive elements like

Iodine-131..... Widely used for most of the cancer radiotherapy

Strontium-89

Samarium-153.... Metastatic bone cancer

Radium-223..... prostate cancer

These radioactive elements can kill the rapidly dividing cells or alters their DNA that led to slow down their growth.

#### Side effects

Sore throat, Heart burn, Nausea, vomiting and diarrhea, Difficulty in swallowing, Skin problems, Taste changes, Loss of appetite, Low blood cell count.

### C) Chemotherapy:

Chemotherapy is a procedure with injection of highly cytotoxic drugs into the patient's body for killing the rapidly dividing cells. Chemotherapy given in two ways either by alone or combine with radiotherapy/surgery. The main purpose while using combination for reducing the size of the tumor then it will be helpful for surgery. Chemotherapy can kill rapidly dividing cells and normal/healthy cells also during the treatment. Loss of normal healthy cells in the chemotherapy are hair follicular cells, bone marrow cells (depression of bone marrow), cells in the oral cavity followed by digestive tract cells and reproductive system cells. Loss of these cells during the chemotherapy it leads to the side effects. Some times other main organs cells kidney, heart, lungs, nervous system, bladder cells are also damaged.

#### Drugs used for cervical cancer:

##### Single line Therapy

Drug name	Side effects
Bevacizumab	congestive heart failure, hypertension, reduced wound healing, rash
Bleomycin	lure, cardiomyopathy, pulmonary fibrosis.
Topotecan	constipation, abdominal pain.
Pembrolizumab	pain in muscle, rash.
Tisotumab and Taxol	the allergic reactions. rboplatin neurotoxicity.

Gemcitabine and cisplatin ototoxicity, skin rash/dermatitis.

#### Drug combinations for breast cancer [6,7,8]

doxorubicin+cyclophosphamide (AC)

doxorubicin+cyclophosphamide+paclitaxel (AC-T)

cyclophosphamide+ doxorubicin+flurouracil (CAF)

cyclophosphamide+ methotrexate+flurouracil (CMF)

flurouracil+epirubicin+cyclophosphamide (FEC)

paclitaxel+ doxorubicin+cyclophosphamide (TAC)

Drug name	Side effects
Doxorubicin (Adriamycin)	Left ventricular dysfunction
Cyclophosphamide	Congestive heart failure
Paclitaxel	Peripheral neuropathy
Fluorouracil	Anemia
Methotrexate	Bleeding gums, Diarrhoea, Blood in urine
Epirubicin	Congestive heart failure

### D) Chemo radiation Therapy

sometimes doctors give chemotherapy and radiotherapy in the same time is known as chemoradiation therapy. It is mainly useful for unresectable diseases

### What Is Counselling?

The process of interaction between a pharmacist/therapist to the patient is known as counselling. Patient counselling/education is very helpful in the long-time treatment diseases like cancer and HIV. Specifically, during the treatment of cancer side effects management and improvement of patient psychological condition is possible with effective patient counseling.

#### Importance of Patient Counselling In Cancer [9-15]

##### Treatment

Stress, fear about their treatment and health are the main conditions put an impact on patient mental health. By providing effective counselling to the patient, it leads to the drastic changes in the patient's life especially in side effects management and psychological improvement. One of the major drawbacks from the cytotoxic drugs they cause the worse side effects. people who are illiterate have no idea about how to manage side effects. So, providing counselling by pharmacist will help to manage their side effects from chemotherapy and also helpful for health improvement. In India rural area people are having high chance of occurrence and also, they are uneducated so patient

education/awareness is necessary. Sometimes pharmacist will give counselling to care takers along with patients because of patient admitted in hospital care taker role is very important in management of side effects during the treatment

### ROLE OF COUNSELOR?

Create an idea about the treatment and side effect management during their treatment.

Psychological counselling to the patient will help for further treatment procedure

Group counselling to the care takers for the management of side effects and nutritional counselling for hemoglobin percent, WBC count, platelets count in between in the chemo cycles.

Counselor identifying the other chances for improving patients' health condition

Mental support and encouragement to the patient with the counselling

### Outcome of Counselling

Pharmacist evaluate the outcome of counselling by asking some questioner according to the CRONBACHS ALPHA SCORE OF 0.73. This evaluation process is mainly based on the comparison of before counselling and after counselling. Final outcome is evaluated with the patient's response from the questioner, especially in the areas of side effects from treatment and psychological condition after counselling.

### PHARMACIST COUNSELLING FOR:

- Counselling after chemotherapy, radiotherapy and chemo radiation therapy
- Group counselling for care takers
- Individual counselling to the patients about their treatment and try to improve the psychological condition with the counselling
- Group counselling/awareness for patient about their cancer-causing habits like tobacco usage, smoking, alcohol consumption
- Counselling for changing their life style and food habits
- Diet changes and nutritional counseling given by counselor
- Early detection methods and tips were explained during counseling session.
- Specialized counseling for some advanced stage of cancer patients.

### Aim

In this prospective observational study, the main is the evaluation of outcome of effectiveness of counselling in the side effects management and psychological improvement while patient taking chemotherapy, radiotherapy and chemo radiation therapy.

### Objectives

- To find the effectiveness of counselling in patients of breast and cervical cancer receiving chemotherapy and radiotherapy.
- To find out the side effects managements after receiving chemo and radiotherapy in both breast and cervical cancer.
- To find out the improvement of quality of health after receiving the treatment i.e chemotherapy and radiotherapy in both breast and cervical cancer.
- To provide psychological support for breast and cervical cancer during the cancer treatment.
- To educate the care givers and patients about the developing of cancer and early signs and symptoms identification for both cervical and breast cancer.

### Methodology

The study entitled "Effectiveness of counselling in patients of breast and cervical cancer receiving chemotherapy and radiotherapy" was conducted in the Oncology department of King George Hospital (KGH), Visakhapatnam, Andhra Pradesh.

Study Site	KING GEORGE HOSPITAL, Visakhapatnam
Study Design	Prospective Observational Study
Study Duration	5 Months
Study Population	100 Cancer Patients (50 Breast And 50 Cervical)

### Study approval

The approval of the study was obtained from IEC (Andhra university college of pharmaceutical sciences, Visakhapatnam) dated on 5/11/2018.

### Study Criteria

#### Inclusion Criteria:

1. Patients of Breast and Cervical cancer of all age groups receiving chemotherapy, radiotherapy and chemo radiotherapy in the Oncology ward, Department of Oncology, KGH.
2. Patients suffering with Breast and Cervical cancer as per WHO guidelines.
3. Informed consent form was taken from the interesting patients with their signature
4. Patients with presence or absence of any co-morbid conditions.

5. Patient family members (who are care givers to the patients at home).

**Exclusion criteria**

Patients who will deny giving consent i.e. unwilling patients.

Patients who will attend to the Oncology ward but not diagnosed with breast and cervical cancers

Patients who will undergo surgery.

Pregnant women with this type of cancers.

Patient who will be referred to the other ward.

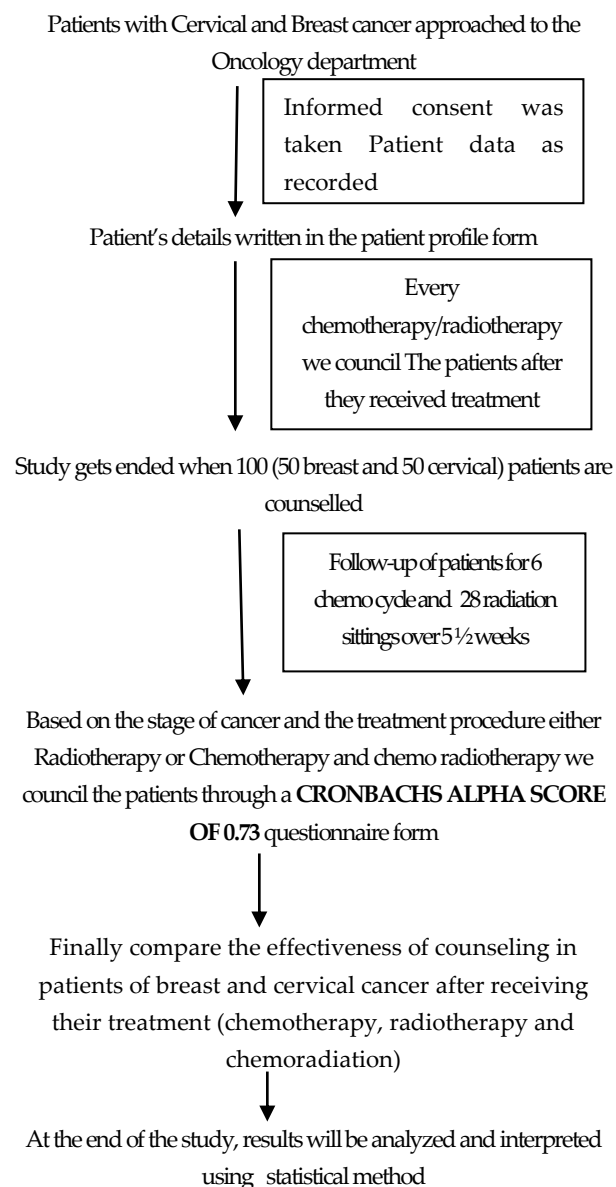
**Study Procedure**

This was a Prospective, questionnaire-based observational study. The study will be conducted on patients attending at Oncology unit, King George Hospital (KGH), Visakhapatnam.

1. Firstly, identify the cervical and breast cancer patients, and then study protocol will be explained after that patient consents will be taken individually.
2. A questionnaire which covers details of patient demographic information will be asked in the language spoken by the patient, mostly Telugu as it is the native language.
3. The data pertaining to the patient including the Patient's name, age, sex, educational level, marital status, place of living, cancer stage, patient past medical history, chemotherapy cycle number, Chemotherapy drug combination, previous history of illness, chemotherapy drug strength/dose will be collected in a well-designed patient data collection and documentation form.
4. Prescription of the patients will be documented in data collection form.
5. Depending up on the stage of cancer and the prescribed drugs we will identify the side effects occurring in the Patient after chemotherapy and radiotherapy.
6. We will council the Patients based up on their side effects with the help of designed questionnaire format.
7. Counseling will be nutritional, psychological, drug related counseling in a comfortable manner to the patient.
8. Leaflet will be provided to each individual; it includes the information regarding the side effects after chemotherapy and radiotherapy.
9. The patients will be followed for period of 5 months.

10. After completion of the counseling results will be analyzed with proper statistical tools.

**Plan of Work**



**Statistical methods**

For measuring of outcomes chi-square test was used. Chi-square test compress the observed values to the expected values. This test is also helpful for determining the difference between observed and expected values are statistically significant or not.

**Description of variables**

Patient Name, Age, Weight, Gender, date of registration, O.P number, Radiotherapy/Chemotherapy number and Address of each individual were recorded in the Patient profile form.

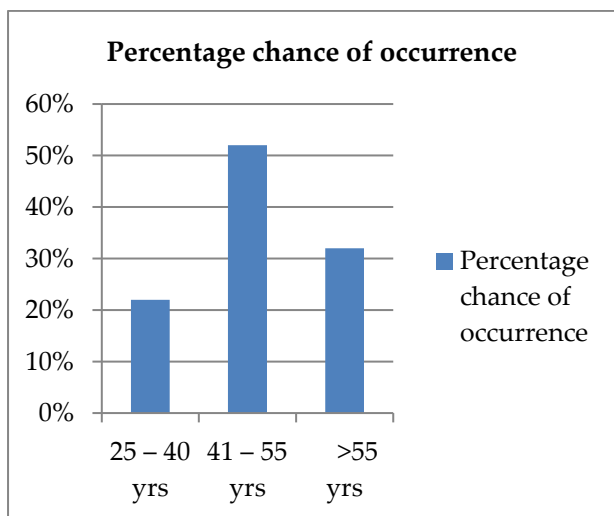
We are taken different stages of Breast and cervical cancer patients randomly. We also taken their literacy status (literate / illiterate) Socioeconomic status (subjects' annual income was considered) Past medical history (for better counselling)

Fruit chart  
 patientnts weekly fruit chart)  
 Menopausal age (for breast cancer we are taken menopausal age)  
 Child birth and breast feeding (for breast cancer patients)  
 Place of residence (based on place divided into (urban, rural, Trible)  
 Smoker, Alcoholism

**Results**

**Table 1: Chances of occurrence of breast and cervical cancers based on Age factor**

Age group in years	Total number of patients	Breast cancer	Cervical cancer	Percentage chance of occurrence
25 – 40	50 breast and 50 cervical	11	7	22%
41 – 55	50 breast and 50 cervical	26	27	52%
>55	50 breast and 50 cervical	13	16	32%



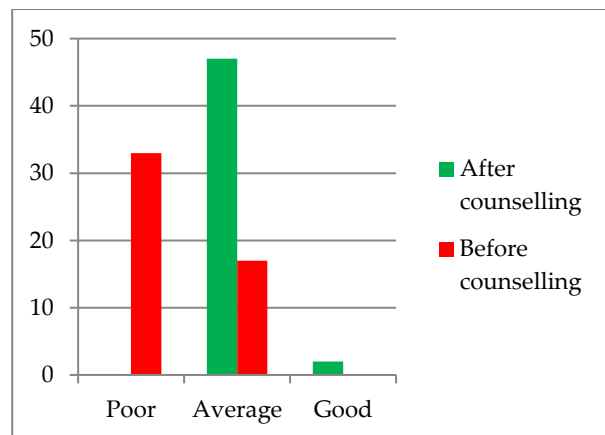
**Figure 1: Percentage chance of occurrence**

**Table 2: Psychological effectiveness of cervical cancer after chemotherapy**

		Outcome Grade			Total
		Poor	Average	Good	
Cervical cancer	Before	33	17	0	50
	After	0	47	3	50
Total		33	64	3	100

Significant value P= 0.000

**Figure 2**



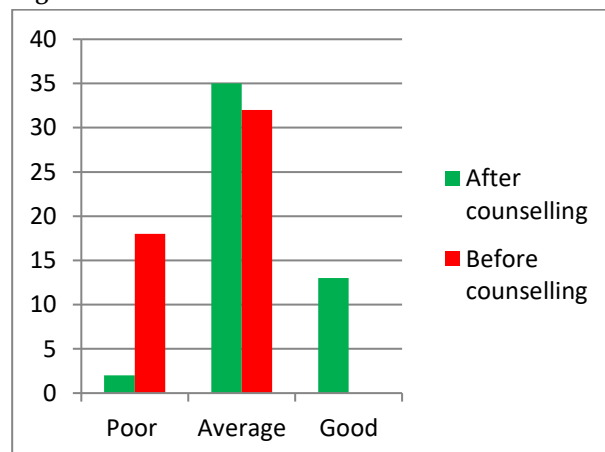
**Figure 2: Psychological effectiveness of cervical cancer after chemotherapy**

**Breast cancer side effects management**

**Table 4: Breast cancer side effects management:**

		Outcome Grade			Total
		Poor	Average	Good	
Breast cancer	Before	18	32	0	50
	After	2	35	13	50
Total		20	67	13	100

Significant value P= 0.000

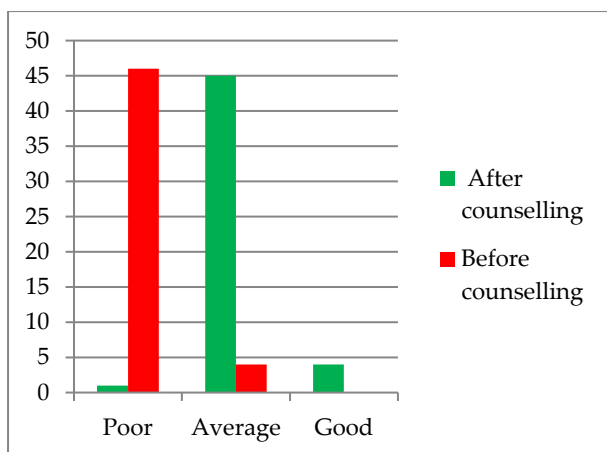


**Figure 4: Breast cancer side effects management Psychological effectiveness of breast cancer after chemotherapy:**

**Table 5: Psychological effectiveness of breast cancer after chemotherapy**

		Outcome Grade			Total
		Poor	Average	Good	
Breast cancer	Before	46	4	0	50
	After	1	45	4	50
Total		47	49	4	100

Significant value P= 0.000



**Figure 5: Psychological effectiveness of breast cancer after chemotherapy**

100 cancer patients included in our study. 50 breast and 50 cervical cancer patients.

**CRONBACHS ALPHA SCORE OF 0.73** questionnaire form was used for our study. This questioner was taken from EORTC QLQ-C30 (version 3) scale was standardized with adding another 10 questions related to nutritional and psychological aspects.

Our scale includes 40 questioners in that we are divided into 4 parts. They are after completion of chemotherapy or radiotherapy, side effects related to the breast or cervical cancer treatment, nutritional counselling and psychological counselling.

Chi-square test was used for assess the improvement of quality of health during their treatment and after the treatment in both the breast and cervical cancer patients.

Our significant value is 0.5

#### **Percentage chance of occurrence**

In our study we noticed that the age group of 41 to 55 had more chance of occurring cervical and breast cancer

#### **Side effect management of both breast and cervical cancer**

Out of 50 breast cancer patients in our study we noticed that 42 patients had average outcome grade. But proper counselling with pharmacist after treatment this outcome grade drastically changes from average (42) to good (31).

Similarly in cervical cancer patients out of 50 cervical cancer patients before counselling the average outcome grade patients are 34 but after counselling the average outcome grade patients have good side effect management.

#### **Psychological effectiveness of breast and cervical cancer patients after counselling**

In our study we found that especially for breast cancer patients they get depressed for loss of breast during their treatment. By providing mental and psychological support and also counselling for patients along with care givers. Finally, we noticed that end of 3 to 4 chemo cycles the outcome grade was raised from one good patient (before counselling) to 19 (after counselling). Similarly in cervical cancer patients the psychological outcome was improved with good counselling.

#### **Discussion**

We found that rural area peoples having more chances to developing cancer compare to urban population. low economic people are also highly effects with cancer. In our study we observed lack of awareness in rural areas about cancer. Signs and symptoms of cancer. So ultimately, they reported to hospital in late phases. So, mortality rate was gradually increasing in rural areas especially in the cancer disease.

In our study we are taking three major aspects in counselling process they are 1) side effect management, 2) psychological conditions and 3) nutritional counselling. We compare the three aspects before and after counselling in both breast and cervical cancer. Side effect managements we included vomiting, diarrhoea, sore throats. Psychological conditions including anxiety, depression, tension, worry. Nutritional counselling including fibre rich food, leafy vegetables, liquid intake. India is developing county majority of the people are living in rural areas we provide better counselling to the cancer patients for their treatment and create awareness of cancer in group counselling for care givers automatically better health care was possible for breast and cervical cancer patients.

Finally patient counselling was very much important in cancer treatment. Because rural area peoples are having no idea about that proper usage of chemo medication and treatment cycles. By providing patient counselling to that patient, we can reduce the side effects, to give psychological support and advices will also useful for maintain better health care during their treatment.

#### **Summary**

The research thesis entitled, "Effectiveness of counselling in patients of breast and cervical cancer after receiving chemotherapy and radiotherapy – prospective

observational study" reported that patient counselling was helpful to improve the quality of health in both breast and cervical cancer patients.

In breast cancer patients both chemotherapy and radiotherapy given to the patient simultaneously. In cervical cancer chemotherapy was given to the patients. In both cases during of treatment process we observed reduction of anxiety, depression, tension and worry after counsel the patient.

We advices the better nutrition and liquid intake supplements that was useful to makes the patient healthy during the chemo and radiotherapy treatment.

Chemotherapy and radiotherapy both are having number of side effects. Throat by providing individual patient counselling in the presence of care givers we reported that diarrhoea, constipation, vomiting, sore throat levels are decreased.

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### Author Contribution

All authors contributed equally.

### Conflict of Interest

The authors declared no conflict of interest.

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