Assessment of Effect of CG4 (An Ayurvedic Formulation) in The Management of Side Effects of Chemotherapy in Breast Cancer

A thesis submitted to

TILAK MAHARASHTRA VIDYAPEETH, PUNE

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Subject	**:**	**Kayachikitsa**
Under Faculty of	**:**	**Ayurved**
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Month & Year	**:**	**December 2016**

DECLARATION

I hereby declare that the thesis entitled **"Assessment of Effect of CG4 (An Ayurvedic Formulation) In the Management of Side Effect of Chemotherapy in Breast Cancer"** completed and written by me has not previously formed the basis for the award of any degree or other similar title or any other university or examining body.

Place - Pune

Date –20/12/2016

Vd.Mrs. Anjali A. Deshpande

CERTIFICATE

This is to certify that the thesis entitled, **"Assessment of Effect of CG4 (An Ayurvedic Formulation) in the Management of Side Effect of Chemotherapy in Breast Cancer"** which is being submitted herewith for the award of the Degree of Vidyavachaspati (Ph. D.) in Ayurveda of Tilak Maharashtra Vidyapeeth, Pune is the result of original research work completed by **Vd. Mrs. Anjali A. Deshpande** under my supervision and guidance. To the best of my knowledge and belief the work incorporated in this thesis has not formed the basis for the award of any degree or similar title of this or any other University or examining body.

Place - Pune
Date : 20/12/2016

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Vd. Mrs. Anjali A. Deshpande
Research Scholar

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LIST OF ABBREVIATIONS

Texts

च.सं	Charak Samhita	(चरक संहिता)
सु.स	Sushrut Samhita	(सुश्रुत संहिता)
अ.ह्व	Ashtang Hrudaya	(अष्टांग ह्रदय)
अ.सं	Ashtang Sangraha	(अष्टांग संग्रह)
का.सं	Kashyap Samhita	(काश्यप संहिता)
भा.प्र	Bhav Prakash	(भाव प्रकाश)
यो.र	Yoga Ratnakar	(योग रत्नाकर)
मा.नि	Madhav Nidan	(माधव निदान)
रा.नि	Raj Nighantu	(राज निघण्टु)
कै.नि	Kaiyyadev Nighantu	(कैय्यदेव निघण्टु)
ध.नि	Dhanvantari Nighantu	(धन्वन्तरी निघण्टु)

Sections

सू.स्था	Su.	Sutrasthana	(सूत्र स्थान)
नि.स्था	Ni	Nidansthana	(निदान स्थान)
वि.स्था	Vi	Vimansthana	(विमानस्थान)
शा.स्था	Sha	Sharirsthana	(शारीर स्थान)
चि.स्था	Chi.	Chikitsa Sthana	(चिकित्सा स्थान)

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INTRODUCTION

An uncontrolled growth of cells leads to malignant tumours (cancer), which have a tendency to invade nearby parts of the body. [1]

Cancer statistics including prevalence, mortality and morbidity dreadfulness of the disease.Global burden of cancer rises to 14.1 million new cases and 8.2 million cancer deaths in 2012.A 1.7 million women were diagnosed with breast cancer.It is also the most common diagnosed malignancy in India. In India it is estimated that there are nearly 2 to 2.5 million cancer cases.Over 7 to 9 lakh new cases and 3 lakh deaths occur annually in India due to breast cancer. [2]

Conventional treatment modalities for breast cancer are surgery, chemotherapy, radiation therapy and hormonal treatment in some cases. Adjuvant or neo-adjuvant chemotherapy in breast cancer patients helps to control cancer growth[3]. However many patients suffer from the side effects of chemotherapy, hampering their Quality of life, immune system and sometimes postponing schedule of Chemotherapy. Side-effects of chemotherapy are exhibited on the various systems of the body i.e. nausea, loss of appetite, stomatitis, vomiting, diarrhea, constipation, pile are the GI related side-effects. Joint pain, bone pain, weakness are the side-effects related to musculoskeletal system. Myelosupression leading to low hemoglobin, low WBCs and low platelets are also very common toxicities during the course of chemotherapy.[4]

Many drugs like Mesna with Ifosfamide and cytoprotector like Amifostine have been tried to prevent or control chemotherapy related toxicities, but these agents have their own side-effects.[5]

1. Cancer fact sheet N297 WHO Feb 2014 retrieved 10 June 2014.
2. Parkin DM. Global cancer statistics in the year 2000. Lancet Oncol. 2001;2:533., http://seer.cancer.gov.in
3. Cancer Principal and Practice of oncology, Vincent T. Devita, Jr. , Samuel Hellman , Steven A. Rosenberg, 7th edition,Chapter26.2,pp681
4. Perry MC. Principles of cancer therapy. In: Goldman L, Ausiello D, eds. Cecil Medicine. 23rd ed. Philadelphia, Pa: Saunders Elsevier;2007:chap 192.
5. Lima MV, Ferreira FV, Macedo FY, de Castro Brito GA, Ribeiro RA "Histological changes in bladders of patients submitted to ifosfamide chemotherapy even with mesna prophylaxis." Cancer Chemother Pharmacol 59 (2007): 643-50

Thus there is a need to explore an adjunct treatment that helps to minimize toxicities of chemotherapy and thus improves Quality of life of cancer patients.

In our Cancer Research Center, we had clinically assessed efficacy of Ayurvedic medicines in management of side-effects of chemotherapy in all types of cancers at different stages and grades. The assessment of side-effects would be difficult to understand as the chemotherapy regimen differs according to organ and type of cancer. Thus specific organ i.e. breast, the breast cancer has been chosen to assess role of Ayurvedic treatment on toxicities of chemotherapy. Drugs used for chemotherapy are mainly disturbing functions of Jatharagni, Annavaha, Purishavaha, Rasavaha and Raktavahasrotasa and are causing Pitta and Vatadushti exhibiting symptoms like Anannabhilasha (nausea), Agnimandya (loss of appetite), Chhardi (vomiting), Mukhapaka (stomatitis), Atisara (diarrhea), Malavibandha (constipation), Sraviarsha (bleeding piles), Jwara (fever), Twakvaivarnya (skin and nail discolouration). Ayurvedic medicines chosen for the study are Deepana – Pachana (digestive), Pitta shamak (anti-inflammatory) and Rasayan (immunomodulatory). Due to these actions the medicines improve Quality of Life and thus impart feeling of well-being.

.

Hence this study was undertaken to assess the role of Ayurvedic medicines (CG4 - which is a combination of four Ayurvedic formulations) in management of side effects of chemotherapy in breast cancer.

AIM AND OBJECTIVES

Aim :

To assess the effect of CG4 (an Ayurvedic formulation) in the management of side effects of chemotherapy in breast cancer.

Objectives:

- To evaluate the role of CG4 on side-effects of chemotherapy in breast cancer.
- To evaluate the role of CG4 on Karnofsky score and QoL (Quality of life).
- To evaluate the role of CG4 on pathological investigations.

LITERATURE REVIEW

3 A. Cancer from Ayurvedic Perspective

Ayurveda has clearly mentioned the guild lines for the diagnosis and treatment of the diseases, about the diseases which are not mention in Ayurvedic samhitas. In Trishothiya Adhyaya, the Eighteenth chapter of Sutrasthana of Charak samhita Acharya charaka explains.[8]

त एव अपरिसंख्येया भिद्यमाना भवन्ति हि ।
रूजावर्णसमुत्थानस्थानसंस्थाननामभिः ।।
व्यवस्थाकरणं तेषां यथास्थूलेषु संग्रहः ।
तथा प्रकृतिसामान्यं विकारेषु उपदिश्यते ।। च. सू. १८ । ४२ - ४३

References indicate that there are numerous diseases exists on the basis of Ruja (pain), Varna (colour), samutthana (causative factor), sthana (site of origin) and sansthana (signs and symptoms). The physician can understand and treat the disease by the knowledge of Vikarprakruti (state of vitiated dosha, dhatu and mala causing disease), Adhishthantarani (Site of vitiated dosha) and Samutthan Vishesha (cause of the vitiated dosha) and achieve success in the treatment.

विकारनामाकुशलो न जिह्रीयात् कदाचन।
न हि सर्वविकाराणां नामतोस्ति ध्रुवा स्थितिः।।४४।।
स एव कुपितो दोषः समुत्थानविशेषतः।
स्थानान्तरगतश्चैव जनयत्यामयान् बहून्।।४५।।
तस्माद्विकारप्रकृतीरधिष्ठानान्तराणि च।
समुत्थानविशेषांश्च बुद्ध्वा कर्म समाचरेत् ।।४६।।
यो ह्येतत्त्रितयं ज्ञात्वा कर्माण्यारभते भिषक् ।
ज्ञानपूर्वं यथान्यायं स कर्मसु न मुह्यति।।४७।। च. सू. - १८/४४-४७

8. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi ,Charak Sutrasthan 28/9 pp 108

In the above mentioned, shloka Acharya charaka[9] describe that one should not bother to know the name of the disease, on the contrary physician should understand thoroughly the vitiated dosha, dhatu and mala causing disease, causes and site of origin of disease.

In Ayurveda cancer is not directly mentioned as one disease, but under the umbrella of cancer, many diseases are described in Ayurvedic samhita. The diseases showing signs and symptoms (lakshanas) similar to cancer, similar causative factors (nidan), similar process of formation of disease (samprapti) to cancer, are included under the cancer disease. The diseases explained in Ayurveda like Dushta Arbuda, Dushta Granthi, Dushta Vranashotha, Dushta Nadivrana, Dushtavisarpa can be correlated with Cancer.

रोगाश्चोत्सेधसामान्यदधिमांसार्बुदादयः ।

विशिष्टा नामरुपाभ्यां निर्देश्याः शोथसङ्ग्रहे ।। च. सू. १८/३३

ग्रंथादिभ्यो विलक्षणः पृथुर्ग्रथितः समो विषमो वा त्वङ्मांसस्थायी

दोषसंघातः शरीरैकदेशोत्थितः शोफ इत्युच्यते । सु.सू. १७-३

Acharya Charaka explains in 18th chapter that Shotha developed at different sites forms various diseases like adhimansa, arbud, [10]etc. According to Modern science the malignant tomours are divided in two types, solid tumours and non solid tumours. [11] Solid tumours resemble to the diseases like Dushta shotha – malignant oedema, Dushta Vrana-Maliganant Wounds or ulcers, Dushta Granthi-Malignanat Nodes, Dushta Arbud-Malignant tumors, Dushta Visarpa-Malignanat Spreading Cellulitis, Dushta Nadivrana-Malignanat Fistula or Sinus, Dusht Mansapradoshja Vikara-Malignanat diseases cause due to vitiation of mansa dhatu. Non solid tumor are similar to diseases like Rasa-Rakta Dhatugata Jwara-fever pertaining to Rasdhatu & Raktadhatu, Raktapitta-Bleeding Disorder, Pandu-Anemia, Raktja Krumi-Worms's causing skin disorders.

9. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi ,Charak Sutrasthan 28/9 pp 108
10. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi ,Charak Sutrasthan 28/9 pp 107
11. Cancer Principal and Practice of oncology, Vincent T. Devita, Jr. , Samuel Hellman , Steven A. Rosenberg, 7th edition, chapter 17

Usteda (growth/swelling) is the predominant and common symptom in these diseases. The shotha (swelling) or usteda progreses in various stages (Avastha) like Amamvashtah, Pacchamanavashta, and Pakwa avstha (acute stage). It also passes through Dhatugatavastha and Dhatupakavastha. These stages are observed in solid tumors (arbud etc.) which resembles to the stages of cancer in breast.

मांसदोषेण जानीयात् अर्बुदं मांससंभवम् ।

शीर्यन्ते यस्य मांसानि यत्र सर्वाः च वेदना ।।

विद्यात् तं मांसपाकं तु सर्वदोषकृतं भिषक् । सु. नि. १४ । १५

In Ayurveicd texts, Arbuda is mentioned as disease caused by vitiation of Mansavaha strotas[12]a. So the consideration of vitiation of Mansavaha strotasa is essential in Samprapti (Pathogenesis) of breast cancer.

शृणु मांसप्रकोपजान् ।

अधिमांसार्बृदं कीलं गलाशालूकशुण्डिका ।।

पूतिमांसालजीगण्ड गण्डमालोपजिव्हिकाः ।

विद्यान्मांसाश्रयात् ।। च. सू. २८/१३-१४

मांसजानान्तु संशुध्दिः शस्त्रज्ञाराग्निकर्म्म च । च. सू. २८/२६

Dushta arbud is mentioned as one of the mansapradoshja[13] vyadhi in Charak Samhita. The line of treatment in this condition is shastrakrma, agnikarma and ksharakarma[14]**.**

According to physiology of Ayurved Stana (breast) is the site of Stanya (Breast Milk), which is mentioned as upadhtu of Rasa dhatu.

The state of vitiated Dosha, Dhatu, Mala causing breast cancer: -

- Vitiated Dosha –Vata, Pitta, Kapha
- Vitiated Dhatu-Rasa and Mansa
- Vitiated Strotasa- Rasavaha and Mansavaha

12. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2005), Sutrasthan 17/11pp 72
13. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrasthan 28 , pp 179
14. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrasthan 28 , pp 180

Causes of Dushta sthanarbuda (cause of breast cancer):-

Its causes are dietary, behavior and psychological disturbances causing vitiation of Kapha dosha, Rasa dhatu and Mansa dhatu; external causes like Aghat (trauma) and Pradhanik hetu like Vyasana (Addiction), Manas hetu (Mental stress), Rajovikruti (Menstrual disorders).

3 A. i) Literature review of Stana and Stanya

Stana Sharir Rachana

- **Synonyms for Stana**

Kuchauo is the synonym of Stana mentioned in Amarkosha[15].

स्तनौ कुचौ । चुचुकम् कुचाग्रं इति स्तनाग्रस्य । उरः वत्सम् वक्षः इति ।

अमरकोष व्दितीय काण्ड १२२७,१२२८,१२२९

Stana, Urasija, Vakshoj, Payodhara, Cucha are names mentioned in Rajnighantu. Stanagra (Nipple of the breast) is also referred as Chucukam or Kuchagra.Stanamukh, Vrutta, Shikha are also mentioned as synonyms for stanagra (nipple).

स्तनोरसिजवक्षोज पयोधर कुचस्तथा।। स्तनाग्रं चूचुकं वृत्तं शिखा स्तनमुखञ्च तत्।। राज.नि.मनुष्यादि वर्ग६०, ६१[16]

- **Stana Sharir**

Stana is one of the 56 pratyangas. Stana are formed in both males and females but the functions differ. In males it remains in rudimentary form while in females after attaining puberty, stana attain fullness. In garbhini and sootika (pregnancy and lactation) it is filled with stanya (breast milk).

षट्पञ्चाशत्प्रत्यांगेषु एकम् । व्दौ स्तनौ ।। च.शा.७/११[17]

- **Stana Sampat**

Stana should not be too high, too small or too big. It should not be sagging. Nipple should be well formed by which the infant is able to suckle breast milk with ease[18].

स्तनसम्पद् - नात्यूध्वौ नातिलम्बावनतिकृशावनतिपीनौ युक्तपिप्पलकौ सुखप्रपानौ स्तनौ ।। च.शा.८/५३

15. Amarkosha:-By Maheshwari samlamkruta with a short commentary & Footneotes by Narayan ram Acharya "Kavyatritha" 9 th edition , Niranaya Sagar Press , Bombay,1950,Ref,=Amarosha Dwitiya kanda 1227,1228,1229
16. Raj Nighantu - Commentary by Dr. Indradev tripathi, published by choukhamba, Krishnadas Acadamy , Varanasi. Ref: Raj Nighnatu, Manushyadi Varga 60,61
17. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sharirsthan 7/11 , pp 338
18. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sharirsthan 8/53 , pp 351

❖ **Stana Nirmiti(formation)** – Matruj Avayava

❖ **Sthana** – Urah(Chest)

चतुर्थमङ्गं वक्षस्तु तदुपाङ्गान्यथ ब्रूवे।

स्तनौ पुंसस्तथा नार्याविशेष उभयोरयम्।। भा.प्र. पूर्वखण्डगर्भ प्रकरणम् ३ – ७३[19]

❖ **Stana Vaishishta (Characteristic feature of Stana Breasts)**

When a female attains puberty, stana are enlarged and during pregnancy and lactation period they are filled with breast milk[20].

स्तनौ पुंसस्तथा नार्याविशेष उभयोरयम्।।

यौवनागमे नार्याः पीवरौ भवतः स्तनौ।

गर्भावत्याः प्रसूतायास्तावेव क्षीरपूरितौ।। भा.प्र. पूर्वखण्ड गर्भ प्रकरणम् ३–७३, ७४

❖ **Srotasa** –

Bahirmukha Srotasa. In males there are nine bahirmukha srotasas while in females three more have been described. Two in the stana and one in the yonimarga 'Rajovaha srotasa'. [21]

स्त्रोंतासि नासिके कर्णौ नेत्रे पाय्वास्यमेहनम् । स्तनौ रक्तपथश्चेति नारीणामधिकं त्रयम् ।। अष्टांगह्रदय शा.३/४०

श्रवणनयनवदनघ्राणगुदमेढ्राणि नव स्त्रोतांसि नराणां बर्हिमुखानि एतान्येव स्त्रीणामपराणि च त्रीणि द्वे स्तनयोरधस्ताद्रक्तवहं च ।। सु.शा.५/१०[22]

Acharya Sushrut has mentioned Stana as moolasthana of Shukravaha srotasa[23].

शुक्रवहे द्वे तर्योमूलं स्तनौवृषणौ च , तत्र विध्दस्य क्लीबता चिरात् प्रसेको रक्तशुक्रता च ।। सु.शा.९/१२

19. Bhavprakash Nighantu by Bhavmishra with Vidyodini Hindi Commentary by Shree Bramha Shankar Mishra and Shree Ruplalji Vaishya, Chaukhamba Sanskrit Samsthan, (2005), 10th Eddition, Nighantu Bhag,Purva khanda grabha prakarana 3/73 pg32
20. Bhavprakash Nighantu by Bhavmishra with Vidyodini Hindi Commentary by Shree Bramha Shankar Mishra and Shree Ruplalji Vaishya, Chaukhamba Sanskrit Samsthan, (2002), 10th Eddition, Nighantu Bhag, Purva khanda grabha prakarana 3/73/74.pg32
21. Ashtanghridya, Vagbhat with Sarvasunder commentary of Arundatta and Ayurved Rasayan commentary of Hemadry, Chaukhamba Surbharati Prakashan, Varanasi (2010) , Uttarsthan, 22-77-79, Sharirsthan 3/40
22. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sharirsthan – 5/10 pg364,
23. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sharirsthan – 9/12 , pp 298

❖ **Peshi –**

Overall there are 500 peshi (muscles) in the body. In females there are 20 more. 5 peshi in each stana. These peshi develop during puberty[24].

स्त्रियां तु विंशतिरधिका।दश तासां स्तनयोरेकैकस्मिन् पश्च पश्चेति यौवने तासां परिवृद्धिः। सु.शा. ५/५०

❖ **Marma**

Table No. 1 :- 9 marmas reside in the ura (Chest region). Hridaya, Stanamula, Stanarohit, Apalapa and Apastambha.[25]

Marma	**Type of Marma as per effect of its' injury**	**Sthana**	**Type of Marma as per its' constitution**	**Consequences of injury to Marma**
Stanamula	Kalantara pranahara (gradual detoriation)	Situated two fingers below the stana on either side.	sira marma	Injury to this marma causes kasa (cough) and shwasa(dyspnoea) resulting in death
Stanarohita	Kalantara pranahara	situated at both the breasts , two fingers above the nipple or stanachuchuka	mansa marma	Injury to this marma causes lohitapurna koshtha (congestion in the lungs), Kasa (cough), shwasa (dyspnoea) and gradual detoriation resulting in death.
Apastambha	Kalantar pranahara	situated in the thorax bilaterally	sira marma	Injury to this marma causes vatapurnakoshthata (pneumothorax), kasa (cough) and shwasa (dyspnoea) and gradual detoriation resulting in death

24. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sharirsthan – 5/39 pg368
25. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sharirsthan – 6/26 pg 373,374

स्तनयोरधस्ताद् द्वयगुलमुभयतः स्तनमूले तत्र कफपूर्णकोष्ठतया (कासश्वासाभ्यां) म्रियते ।

स्तनचूचुकयोरूर्ध्व द्वयगुलमुभयतः स्तनरोहितौ , तत्र लोहितपूर्णकोष्ठतया कासश्वासाभ्यां च म्रियते ।

उभयत्रोरसो नाड्यौ वातवहे अपस्तम्भौ नाम, तत्रवातपूर्णकोष्ठतया कासश्वासाभ्यां च मरणम्।। सु.शा.६/२६

❖ **Dhamani**– Twenty-four dhamani originate from the nabhi. 10 dhamani nourish the upper part of the body. These 10 dhamani after reaching the heart subdivide into three branches thus forming 30. Of these 30, 2 Dhamani reside in the breast to secrete breast milk. [26]

तासां तु खलु नाभिप्रवणानां धमनीनामूर्ध्वगा दश, दश चाधोगामिन्यः चतस्त्रस्तिर्यगाः। सु.शा.९/४

❖ **Sira**– There are forty sira in the thorax & out of these following fourteen sira should be avoided – two in the pericardium, two in each Stanamula, eight on the sides of Stanrohita, Apalap & Apastambha[27].

चत्वारिंशद्वक्षसि, तासां चतुदर्शाशस्त्रकृत्याः द्वे द्वे स्तनमूले स्तनरोहितापलापस्तम्भेषूभयताऽष्टौ। सु.शा.७/२४

Stana roga

In childhood the dhamanis residing in the breast are very constricted due to which vitiated doshas cannot penetrate to cause imbalance. In childbearing age (pregnancy or lactation period) these dhamanis get enlarged, thus can be vitiated and cause stana roga (breast disease)[28].

यावत्यो गतयो यैश्च कारणैः संभवन्ति हि । तावन्तः स्तनरोगाः स्युः स्त्रीणां तरेव हेतुभिः ।।धमन्यः संवृत्तव्दारा कन्यानां स्तनसंश्रिताः। दोषाविसरणात्तासां न भवन्ति स्तनामया :।

तासामेव प्रजातानां गर्भिणीनां च ताः पुन : । स्वभावादेव विवृत्ता जायन्ते संभवन्त्यतः ।। सु.नि.१०/१५ – १७

26. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sharirsthan – 9/4 ,Pg384
27. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sharirsthan – 7/7,pg377
28. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Nidansthan – 10/15-17pg308,309

Samprapti of Stana Vidradhi Roga:

Vitiation of Doshas cause dushti in the stana (breast) of a lactating or non-lactating female, vitiate rakta and mansa dhatu thus cause 'Stana-Roga (Vidradhi)'.[29]

Types: Vata, Pitta, Kapha, Sannipatika, Aagantuja

सक्षीरौ वाऽप्यदुग्धौ वा प्राप्य दोषः स्तनौ स्त्रिया :।

रक्तं मांसं च संदूष्य स्तनरोगाय कल्पते । सु.नि.१०/२६

Stana Kriya Sharir – Physiology

Stanya

- **Stanyashaya**

Organ where stanya (breast milk) gets collected and is secreted through the stanachuchuka

- **Nirmiti (formation)** – Matruj Avayava
- **Sthana** – Urah (Chest)
- **Dosha** – Kapha
- **Dhatu** – Rasa
- **Upadhatu** – Stanya
- **Definition of Stanya**–

Stanya – that which is secreted through Stana.

Stanya is one of upadhatu of Rasa[30].

रसात् स्तन्यं ततो रक्तमसृजःकण्डरासिरा । च.चि.१५/१७

29. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Nidansthan – 10/26,310
30. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Chikitsarsthan 15/17 , pp 514

◆ **Lakshan (Properties)-**

The cream part of Rasa formed from the digestion of food, which is Madhur (sweet) gets accumulated in the stana and termed as 'Stanya'. Just as Shukra (semen) is present in the whole body but gets secreted by the thought or sight of a beautiful woman, in the same way stanya is formed from aahar rasa in a female but is secreted by the touch, sight or thought of child[31].

रसप्रसादो मधुरः पक्वाहारनिमित्तजः। कृत्स्नदेहात् स्तनौ प्राप्तः स्तन्यमित्यभीधियते।।

विशस्तेष्वपि गात्रेषु यथा शुक्रं न दृश्यते। सर्वदेहाश्रितत्वाच्च शुक्रलक्षणमुच्यते।। सु. नि. १०/१८-१९

- ✓ Pandur (White)
- ✓ Madhur (sweet)
- ✓ Nirdosha (Without any imperfections)
- ✓ Sheeta (cool)
- ✓ Snigdha (unctuous)
- ✓ Dissolves in water
- ✓ Avivarna(clear)

अदुष्टं चाम्बुनिक्षिप्तमेकीभवति पाण्डुरम्।मधुरं चाविवर्णं च प्रसन्नं तत् प्रशस्यते।। मा.नि.स्तन्यदुष्टी निदानम्४[32]

◆ **Karya (Functions)** –

Nourishment of the organ stana.

Nourishment of the infant[33]

स्तनयोरापीनत्वजननं जीवनं चेति।। सु.सू.१५/९

Causes of Dysfunction :

Dietary causes: [34]

- Intake of Lavan (Salt), Katu (hot and spicy), Kshara (alkali) in excess.
- Praklinna bhojana (Food which is decomposed), Abhishyandi (Diet aggrevating Kapha dosha)

31. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Nidansthan – 10/18-19 pg309
32. Madhava Nidananm by Shri Madhavkara:- With Madhukosha commentary by Shri Vijay rakshita & Shrikanthadatta, Vidyotini Hindi Commentary by Shri Sudarshan Shastri and revised and edited by Vaidya Yadunanadan Upadhyay, Publisher, -Chaukhamba Sanskrit Sansthan, 26 th edition 1996,Stanya dushti nidanam 4
33. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Sutrasthan – 15/5 pg68
34. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Chikitsarsthan 30/232-236 , pp 644

- Excessive intake of Paramanna (porridge or various sweets prepared in oil or ghee), Guda (jaggery), Mandak (curds which is not well formed), Dadhi (curds), intake of Mansa (chicken, pork, fish etc)
- Excessive intake of Madya (Alcohol)
- Asatmya bhojan (food which is not used to the body)
- Vishamashana (food taken at irregular time and in irregular proportion)
- Viruddhashana (incompatible diet)
- Atyashana (excessive eating)

Habitual Causes:

- Withholding or forcefully eliminating natural urges
- Daytime sleep immediately after having meals
- Keeping awkae till late night
- Over exertion

External causes:

- Due to abhighata (accident due to physical trauma)
- Chronic disease
- Emaciation

Psychological causes:

- Mental irritation (Sudden mental shock or stress)
- Chinta (over-anxiety or worry)
- Krodha (Anger)

अजीर्णासात्म्यविषमविरुद्धात्यर्थभोजनात्। लवणअम्लकटुक्षारप्रक्लिन्नानां च सेवनात्। ।२३२।।

मनःशरीरसन्तपादस्वप्नान्निशि चिन्तनात्। प्रप्तवेगप्रतीघातादप्राप्तोदीरणेन च।।२३३।।

परमान्नं गुडकृशरां दधि मन्दकम्। अभिष्यन्दीनि मांसानि ग्राम्यानूपौदकानि च।।२३४।।

भुक्त्वाभुक्त्वादिवास्वप्नान्मद्ट्टयस्यातिनिषेवणात्। अनायासादभीघातात् क्रोधाच्चातङ्कर्शनैः।।२३५।।

च.चि.३०– २३२ – २३६

Samprapti of Stanya Dushti :

Due to improper diet or mental stress

Dosha Dushti (vitiation of dosha)[35]

35. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Chikitsarsthan 30/236 , pp 644

Stanyavah Sira Dushti (vitiation of Stanyavaha sira)

Stanya Dushti (vitiation of Breast milk)

दोषाः क्षीरवहाः प्राप्य सिराः स्तन्यं प्रदूष्य च। कुर्युरष्टविधं भूयो दोषतस्तन्निबोध मे।।२३६।। च.चि.३०

Stana Keelaka :

If lactating mother eats foreign body with food, it does not get digested in pachyamanavashtha and pakavashtha. Undigested foreign body gets converted in kleda, circulates with Rasa dhatu and Vata dosha and reaches stanyavaha sira (the mammary gland). This causes obstruction of srotasa and acute disease of breast[36]. (Ka.su.19)

सहान्नपानेन यदा धात्री वज्रं समश्नुते ।पच्यमानेन पाकेन ह्यनन्नत्वान्न पच्यते।।अपच्यमानं विक्लिन्नं वायुना समुदीरितम्।रसेन सह संपृक्तं याति स्तन्यवहाः सिराः ।। सर्वस्त्रोतांसि हि स्त्रीणां विवृतानि विशेषतः ।तत् पयोधरमासाद्य क्षिप्रं विकुरुते स्त्रियाः ।। काश्यपसंहिता सू.१९

Stana Keelaka Roopa (signs & symptoms) :

Signs : Stiffness and secretion in breasts, Veinulas, Inflammation, Pain, Tenderness

Symptoms : Indigestion, Palpitation, Giddiness, Body ache, Anorexia, Joint pain, Headache, Redness of eyes or Sneezing, Nausea due to Kapha, Fever, Excessive thirst, Loose motions, Obstruction of urine and Burning sensation of breasts.

Clever physician named it as ‘stan Keelaka’ (mammary abscess) as it causes obstruction in body as nail[37].

रूपाणि पीतवज्रायाः प्रवक्षाम्यत उत्तरम् । अजिर्णमरतिग्लानिरनिमित्तं व्यथाऽरुचिः ।।पर्वभेदोऽङ्गमर्दश्च शिरोरुग् द(क्ष)वथुग्रहः ।कफोत्क्लेदो ज्वरस्तृष्णा विड्भेदो मूत्रसंग्रहः ।।स्तम्भः स्त्रावश्च कुचयोः सिराजालेन संततः । शोथशूलरुजादाहैः स्तनः स्प्रष्टुं न शक्यते ।। स्तनकीलकमित्याहुर्भिषजस्तं विचक्षणाः । कीलवत् कठिनोऽङ्गेषु बाधमानो हि तिष्ठति ।। काश्यपसंहिता सू.१९

36. Kashyap Samhita by Vruddha Jivak, Revised by Vatsya with Sanskrit introduction by Pandit Hemraj Sharma with vidyodini hindi commentary, Chaukhamba Sanskrit Samsthan,(2010), Sutrasthan , 19.
37. Kashyap Samhita by Vruddha Jivak, Revised by Vatsya with Sanskrit introduction by Pandit Hemraj Sharma with vidyodini hindi commentary, Chaukhamba Sanskrit Samsthan,(2010), Sutrasthan 19

Stanakeelaka according to Dosha dominance –

Vata Dominance - the abscess increases in size.

Pitta Dominance –accelerates inflammation and suppuration of Stanakeelaka (Mammary abscess) at an early stage.

Kapha Dominance –Slows process of pathology causing a chronic abscess[38].

एष पित्तात्मना शीघ्रं पाकं भेदं च गच्छति ।कफाच्चिरं क्लेशयति वातादाशु निवर्तते (विवर्धते) ।।शाखाशिरोभिस्तु यदि विमार्गान्न प्रपद्यते । काश्यपसंहिता सू.१९

Treatment of Stanakeelaka :-

1. Ghruta paana (Internal Oleation with clarified butter). Due to this, the tracts often becomes smooth internally thereby facilitating easy removal of the stankilak. Regular expulsion of breast milk is advised by proper massaging.
2. Sheetaseka (Application of cold compress)
3. Pralepa (external application of medications over the breast)
4. Virechana (Purgation treatment with medication)
5. Pathya Bhojana (dietary regimen) to keep a check over the doshas.

With the help of this treatment if the abscess is in primary stage then it gets healed or else it has to be treated with Incision and drainage.

घृतपानं प्रथमतः शस्यते स्तनकीलके ।स्त्रोतांसि मार्दवं स्नेहाद्यान्ति वज्रं च च्याव्यते ।।निर्दोहो मर्दनं युक्त्या पायनं च गलेन च । (इति ताडपत्रपुस्तके ३३ तमं पत्रम्)[39]

शीताः सेकाः प्रलेपाश्च विरेकः पथ्यभोजनम् ।। काश्यपसंहिता सू.१९[40]

38. Kashyap Samhita by Vruddha Jivak, Revised by Vatsya with Sanskrit introduction by Pandit Hemraj Sharma with vidyodini hindi commentary, Chaukhamba Sanskrit Samsthan,(2010), Sutrasthan , 19
39. Tadapatra Pustake 33 Tamra Patram
40. Kashyap Samhita by Vruddha Jivak, Revised by Vatsya with Sanskrit introduction by Pandit Hemraj Sharma with vidyodini hindi commentary, Chaukhamba Sanskrit Samsthan,(2010), Sutrasthan , 25-8, pp 19

3. A. ii) Anatomy of Breast

The breasts are paired structures located on the anterior thoracic wall, in the pectoral region. They are present in both males and females, yet are more prominent in females following puberty.

In females, the breasts contain the mammary glands – an accessory gland of the female reproductive system. The mammary glands are the key structures involved in lactation.

Surface Anatomy

The breast is located on the anterior thoracic wall. It extends horizontally from the lateral border of the sternum to the **mid-axillary line**. Vertically, it spans between the 2nd and 6th**intercostal cartilages**. It lies superficially to the pectoralis major and serratus anterior muscles[41].

The breast can be considered to be composed of two regions:

- **Circular body** – largest and most prominent part of the breast.
- **Axillary tail** – smaller part, runs along the inferior lateral edge of the pectoralis major towards the axillary fossa.

At the centre of the breast is the **nipple**, composed mostly of smooth muscle fibres. Surrounding the nipple is a pigmented area of skin termed the **areolae**. There are numerous **sebaceous glands** within the areolae – these enlarge during pregnancy, secreting an oily substance that acts as a protective lubricant for the nipple.

Anatomical Structure

The breast is composed of mammary glands surrounded by a connective tissue stroma.

41. Basic Human Anatomy – A regional Study of Human Structure, Ronan O'Rahilly, Fabiola Müller, Stanley Carpenter, Rand Swenson, Chapter 07: The Breast. https://www.dartmouth.edu/~humananatomy/

Mammary Glands

The mammary glands are modified sweat glands. They consist of a series of ducts and secretory lobules (15-20). Each lobule consists of many alveoli drained by a single **lactiferous duct**. Each duct contains a dilated section, (the lactiferous sinus) which is located just behind the **areola**. In the nursing mother, droplets of milk accumulate in this sinus, and is then expressed when the baby begins to suckle. The lactiferous ducts converge at the **nipple** like spokes of a wheel.

Connective Tissue Stroma

The connective tissue stroma is a supporting structure which surrounds the mammary glands. It has a fibrous and a fatty component.The **fibrous stroma** condenses to form suspensory ligaments (of Cooper). These ligaments have two main functions:

1. Attach and secure the breast to the dermis and underlying pectoral fascia.
2. Separate the secretory lobules of the breast.

Pectoral Fascia

The base of the breast lies on the **pectoral fascia** – a flat sheet of connective tissue associated with the pectoralis major muscle. It acts as an attachment point for the suspensory ligaments.There is a layer of loose connective tissue between the breast and pectoral fascia – known as the **retromammary space**. This is a potential space, often used in reconstructive plastic surgery.

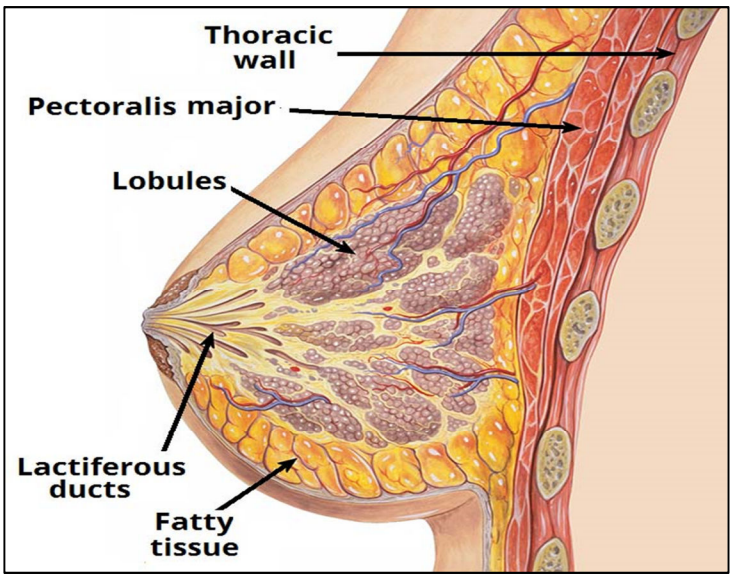


Fig 1 – The internal structure of the breast

Vasculature

Arterial supply to the medial aspect of the breast is via the **internal thoracic artery**, a branch of the subclavian artery.The lateral part of the breast receives blood from four vessels:

1. **Lateral thoracic and thoracoacromial branches** – originate from the axillary artery.
2. **Lateral mammary branches** – originate from the posterior intercostal arteries (derived from the aorta). They supply the lateral aspect of the breast in the 2nd 3rd and 4th intercostal spaces.
3. **Mammary branch** – originates from the anterior intercostal artery.
4. The veins of the breast correspond with the arteries, draining into the **axillary** and **internal thoracic veins**.

Lymphatics

The lymphatic drainage of the breast is of great clinical importance due to its role in the **metastasis** of breast cancer cells[42].

There are three groups of lymph nodes that receive lymph from breast tissue – the axillary nodes (75%), parasternal nodes (20%) and posterior intercostal nodes (5%).
The skin of the breast also receives lymphatic drainage:

Skin – drains to the axillary, inferior deep cervical and infraclavicular nodes.
Nipple and areola – drains to the subareolar lymphatic plexus.

42. http://teachmeanatomy.info/lower-limb/vessels/lymphatics/

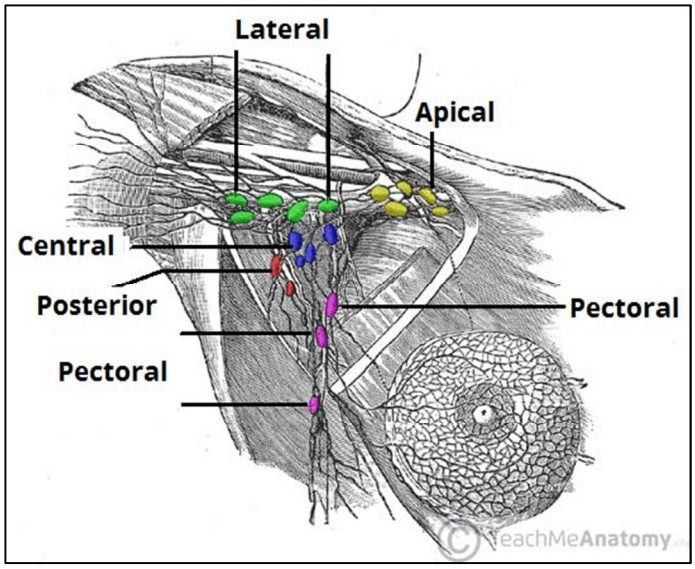


Fig 2 – The five groups of axillary lymphatic nodes. All groups drain into the apical nodes.

Nerve Supply

The breast is innervated by the **anterior** and **lateral cutaneous branches** of the 4th to 6th intercostal nerves. These nerves contain both sensory and autonomic nerve fibres (the autonomic fibres regulate smooth muscle and blood vessel tone)[43].

It should be noted that the nerves do not control the secretion of milk. This is regulated by the hormone prolactin, which is secreted from the **anterior pituitary gland**.

Physiology

The function of producing milk is regulated by hormones. Stimulation of the female sex hormone, estrogen, causes the development of glandular tissue in the female breast during puberty. Increase estrogen levels during pregnancy causes the breast size to increase in size through the accumulation of adipose tissues[44].

43. Human Anatomy, Regional and Applied:-By B.D.Chaurasia, volume 1,3rd edition, Publisher-CBS Publisher and distributors,4596/1A,11 Daryaganj, New Delhi-110002(India)
44. Text Book Of Medical Physiology:- By Arthur C. Guyton, prism India Printers and 10 th edition 2002

Presence of progesterone stimulates the growth and maturation of the duct system. During pregnancy levels of estrogen and progesterone rises (levels are needed to sustain pregnancy) that further enhances the development of the mammary glands. This is the main reason why pregnant women has larger and more enhanced breast.

Another hormone important for the implementation of mammary gland function is the presence of prolactin and oxytocin. Without these hormones, milk will not be produced and ejected out of the breast. Prolactin from the anterior pituitary gland stimulates the production of milk in the glandular tissues while oxytocin causes the ejection of milk from the glands.

3 B. i) Literature Review of Arbuda

Literature review from ancient Sanskrit literature & Ayurvedic samhitas

Vedic Period –

The disease arbud was prevalent during the Vedic period. In Rugveda, it has been mentioned that arbuda is just like a danava & is destroyed by Indra. Rugved tikakar Sayan has mentioned arbuda as ambu (water) which needs to be destroyed by use of Agni (agnikarma).

References from Atharvaveda

In the ancient classics, direct reference of Arbuda has not mentioned but diseases like Apachi, Gulma, Granthi & Gandamala which resembles the clinical features of Arbuda have been mentioned.

- Just as the physician treat the diseases like Gandamala (Cervical lymphadenopathy) by the rays of the sun & moon along with medicines, in same way human being by acquiring knowledge destroy the innocence[45].

  अपचितः प्रपतत सुपर्णो वसतेरिव । सूयै : कृणोतु भेषजं चन्द्रमा वोऽपोंच्छतु ।। अथर्ववेद षष्ठ काण्ड / नवम अनुवाक सूक्त ८३/१

- A human being should overcome his drawbacks in the same way as good physician treat the diseases like Gandamala (Cervical lymphadenopathy)[46],

  पत्र्च्च च यः पत्र्च्चाशच्च संयन्ति मन्या अभि । इतस्तः सर्वा नश्यन्तु वाका अपचितामिव ।।

  अथर्ववेद षष्ठ काण्ड /तृतीय अनुवाक सूक्त २५/१

- Gandamalas (Cervical lymphadenopathy) become dry or green some times, just as bad feelings become weak & strong sometimes[47]

  आ सृस्त्रसः सृस्त्रसो असतीभ्यो असत्तरा :। सेहोरंरसतरा लवणाद् विक्लेदीयसी ।।.

  अथर्ववेद सप्तम काण्ड / सप्तम अनुवाक सूक्त ७६/१

  Atharvaveda has mentioned some charm for curing tumours called gayanya.

45. Atharvaveada:- Maharshi Dayananda Saraswati kryaa(Aryabhasha Bhashya), Published By Sarvadeshika Arya Pratinidhi Sabha, Maharshi Dayananda Bhavan, ram Leela maidna ,New Delhi-1 Year Vikramabda 2045, Shahsthakanda Navam Anuvaka Sukta 83/1
46. Atharvaveada:- Maharshi Dayananda Saraswati kryaa(Aryabhasha Bhashya), Published By Sarvadeshika Arya Pratinidhi Sabha, Maharshi Dayananda Bhavan, ram Leela maidna ,New Delhi-1 Year Vikramabda 2045, Shahsthakanda Tritiya Anuvaka Sukta 25/1
47. Atharvaveada:- Maharshi Dayananda Saraswati kryaa(Aryabhasha Bhashya), Published By Sarvadeshika Arya Pratinidhi Sabha, Maharshi Dayananda Bhavan, ram Leela maidna ,New Delhi-1 Year Vikramabda 2045, Saptamakanda Saptama Anuvaka Sukta 76/1

Vyutpatti –

अर्बुद नपुसक । अर्ब (र्बु) विच् तस्मै उदेति उद् - इण् - ड ।

"Arbuda" is constituted of the root word "**Arba "** and the verb "**Udeti"**The word arbuda has been derived from the root "Arb" with suffix "Ena" along with augmentation of "Nd," which means "to destroy", "to kill" or to "hurt". The verb "**Udeti"** means to elevate, to rise. Grammatically, it denotes the fleshy outgrowths.

Synonyms for Arbuda -

1)	Mansapindakara Rogabhede	(a fleshy mass)
2)	Asurabhede	(a demon)
3)	Kadrabhede Sarpabhede	a demon(i.e., a serpent)
4)	Megha	(Clouds)
5)	Mansapindabhide	(a swelling)

At the time of Vedic period, arbuda was considered as a serpent like demon that was conquered by "Lord Indra".

Definition of Arbud

When the three doshas (Vata, Pitta Kapha dosha) get aggravated in any part of the body and affect the Mansa dhatu, they produce a circular, fixed, slightly painful, big, broad based slow growing non-suppurating and dense elevation (swelling) of mansa. This elevation is called as "arbuda" by the learned[48].

Aggravation of the tridoshas and vitiation of rasa-rakta-mansa-meda dhatus in stana can lead to causation of dushta stanarbuda[49, 50].

गात्रप्रदशे क्वचिदेव दोषाः संमूर्च्छिता मांसमभिप्रदूष्य। वृत्तं स्थिरं मन्दरुजं महान्तमनल्पमूलं चिरवृध्यपाकम्।।कुर्वन्ति मांसोपचयं तु शोफं तदर्बुदं शास्त्रविदो वदन्ति। सुश्रुत निदानस्थान अ.११

48. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2005), Nidansthan – 11
49. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2005), Sutrasthan – 25/13 pg312
50. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2005), Sutrasthan – 25/13 pg312

Nidan Panchak

- **Dosha –** Vata,Pitta, Kapha
- **Dushya –**Rasa-Rakta, Mansa, Meda
- **Agni –** Dhatvagni dushti
- **Srotasa –** Rasavaha,Raktavaha, Mansavaha srotasa, Medovaha
- **Marg –**Bahya roga marga
- **Sthana –** Anywhere in the body

कुष्ठविसर्पपिडकामशकनीलिकातिलकालकन्यच्छव्यङ्गेन्द्रलुप्तप्लीह -

विद्रधिगुल्मवातशोणितार्शोऽर्बुदाङ्गमर्दासृग्दररक्तपित्तप्रभृतयो रक्तदोषजा गुदमुखमेढ्रपाकाश्च ।। सु.सू २५/११

अधिमांसार्बुदार्शोऽधिजिह्वोपकुशगलशुण्डिकाऽलजीमांससङ्घातौष्ठप्रकोपगलगण्डगण्डमालाप्रभृतयोमांसप्रदोषजाः ।। सु.सू २५/१२

ग्रन्थिवृद्धिगलगण्डार्बुदमेदोजौष्ठप्रकारपमधुमेहातिस्थौल्यातिस्वेदप्रभृतयो मेदोदोषजाः ।। सु.सू२५/१३

.. श्रुणु मांसप्रदोषजान्। अधिमांसार्बुदं कीलं गलशालूकशुण्डिके। पूतिमांसालजीगण्डगण्डमालेपजिव्हिका।।च.सू.२८/१४[51]

शाखा रक्तादयस्त्वक् च बाह्यरोगायनं हि तत् । तदाश्रया मषव्यंग्डगण्डालज्यर्बुदादय : ।।बहिर्भागाश्च दुर्नामगुल्फशोकादयो गदाः ।। अष्टांगह्रदय सू. १२/४४-४५[52]

Characteristics of Arbud –

Arbud has been mentioned as an elevated swelling by acharya Charak[53].

रोगश्चोत्सेधससामान्यादधिमांसार्बुदादयः । च.सू.१८/३३

Arbud is bigger than granthi.

- ✓ Since arbud has the predominance of Kapha dosha and Meda dhatu it is sthira (fixed/hard) and does not suppurate[54].

.....महत्तु ग्रन्थितोऽर्बुदम्।ऽ१४।। प्रायो मेदः कफाढ्यत्वात्थिरत्वाच्च न पच्यते।। अ.ह्रु.उ.२९/१४-१५

51. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 28/14 , pp 616
52. Ashtanghridya, Vagbhat with Sarvasunder commentary of Arundatta and Ayurved Rasayan commentary of Hemadry, Chaukhamba Surbharati Prakashan, Varanasi (2010) , Uttarsthan, 22-77-79, Sutrasthan 12/44-45
53. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 18/33 , pp 107
54. Ashtanghridya, Vagbhat with Sarvasunder commentary of Arundatta and Ayurved Rasayan commentary of Hemadry, Chaukhamba Surbharati Prakashan, Varanasi (2010) , Uttarsthan, 22-77-79, Uttartantra 29/14-15

Purvarupa of Arbuda –

No mention of purvarupa of arbud has been seen in the ancient texts.

Rupa of Arbuda (signs and symptoms)

Six types of arbud have been mentioned in the texts[55].

वातेन पित्तेन कफेन चापि रक्तेन मांसेन च मेदसा च । तज्जायते तस्य च लक्षणानि ग्रन्थे : समानानि सदा भवन्ति । सु.नि.११/ १४

Vataja Arbud –

Characteristics

- ✓ Pain - pricking or splitting sensation
- ✓ Black discolouration
- ✓ Feels hard on touch,
- ✓ Feels like distended bladder
- ✓ Secretes clear fluid if it bursts open

Pittaj Arbud –

Characteristics

- ✓ Burning sensation severe irritation similar to that caused by burns
- ✓ Hot to touch
- ✓ Red or yellow discolouration
- ✓ When burst discharges hot & excessive amount of blood.

आयम्यते व्यथत एति तोदं प्रत्यस्यते कृत्यत एति भेदम् ।कृष्णोऽमृदू बस्तिरिवाततश्च भिन्न :स्त्रवेच्चाविलजोस्त्रमच्छम् ।।

दन्दह्यते धूप्यति चोषवांश्च पापच्यते प्रज्वलतीव चापि । रक्त : सपीतोऽप्यथवाऽपि पित्ताद्भिन्नः स्त्रवेदुष्णमतीव चास्त्रम । सु.नि.११/ ४-५

55. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Nidansthan – 11/14pg313

Kaphaja Arbud –

Characteristics

- ✓ Cold to touch
- ✓ Minimal discolouration or no discolouration
- ✓ Slight pain
- ✓ Severe itching
- ✓ Secretes white, thick pus when it bursts open.

Raktarbuda –

Characteristics

- ✓ Elevated swelling (lump of muscle)
- ✓ Contration in rakta (blood) & sira (blood vessels) caused due to vitiated q doshas thus creating muscular lump which is covered with fleshy buds.
- ✓ Very less or no suppuration
- ✓ Grows very fast.
- ✓ Continuous discharge of blood

It is considered incurable and the person suffers from complication like anaemia[56]. [57]

दोषः प्रदुष्टो रूधिरं सिरास्तु सम्पीडय संकोच्य गतस्त्वपाकम् । सास्त्रावमुन्नह्यति मांसपिण्डं मांसाकुरैराचितमाशुवृद्धिम् । स्त्रवत्यजस्त्रं रूधिरं प्रदुष्टमसाध्यमेतद्रुधिरात्मकं स्यात् । रक्तक्षयोपद्रवपीडितत्वात् पाण्डभर्वेत् सोऽर्बुदपीडितस्तु ।। सु.नि.११/१५-१६

दोषः प्रदुष्टो रूधिरं सिरास्तु सम्पीडय संकोच्य गतस्त्वपाकम् । सास्त्रावमुन्नह्यति मांसपिण्डं मांसाकुरैराचितमाशुवृद्धिम् । स्त्रवत्यजस्त्रं रूधिरं प्रदुष्टमसाध्यमेतद्रुधिरात्मकं स्यात् । रक्तक्षयोपद्रवपीडितत्वात् पाण्डभर्वेत् सोऽर्बुदपीडितस्तु ।। माधवनिदान व्दितीय खंड ३८/२०- २१

Mansarbud –

This arbud is caused due to trauma of a fist or any type of blow. This causes injury to the muscles which get vitiated and swollen.

56. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Nidansthan – 11/15-16pg313
57. Madhava Nidananm by Shri Madhavkara:- With Madhukosha commentary by Shri Vijay rakshita & Shrikanthadatta, Vidyotini Hindi Commentary by Shri Sudarshan Shastri and revised and edited by Vaidya Yadunanadan Upadhyay, Publisher, -Chaukhamba Sanskrit Sansthan, 26 th edition 1996,Dwitiya Khanda 38/30-21

Characteristics

- ✓ Non-suppurating
- ✓ Stony hard and fixed.

A person who has excessive intake of mansa (non-veg food) is prone to this type of arbud due to further vitiation of the mansa dhatu.

मुष्टिप्रहारादिभिरर्दितेऽ ङ्गे; मांसं प्रदुष्टं प्रकरोति शोफम् । अवेदनं स्निग्धमनन्यवर्णमपाकमश्मोपममप्रचाल्यम् ।। प्रदुष्ट मांसस्य नरस्य बाढमेतद्भवेन्मांसपरायणस्य ।

Medoja Arbud –

Characteristics

- ✓ Smooth –having no cotours
- ✓ Big in size
- ✓ Increases and decreases according to the body fat.
- ✓ Doesn't cause much pain
- ✓ When it bursts open discharges secretion like pinyak (oil-cake) or sarpi (ghee)[58].

शरीरवृद्धिक्षयवृद्धिहानिः स्निग्धो महानल्परूजोऽतिकण्डूः । मेदःकृतो गच्छति चात्र भिन्ने पिण्याकसर्पिः प्रतिमं तु मेदः ।। सु.नि.११/ ६

Characteristic features of Arbud :

- ➢ Gatra Pradesh (anywhere in the body)
- ➢ Vrutta (round)
- ➢ Sthir (fixed)
- ➢ Mandruja (Slightly painful)
- ➢ Mahant (big)
- ➢ Analpamoola (which is deep seated)
- ➢ Chirvruddhi (which grows slowly)
- ➢ Apaka (which does not suppurate)

58. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2005), Nidansthan – 11/6 4-7pg 311

This characteristic is seen because of the dominance of Kapha dosha & meda dhatu & also because of the immobilization & binding of doshas in them. Tumours do not undergo suppuration because predominance of Kapha dosha & meda dhatu.

Upadrava –

When there is occurrence of arbud at the same site of prevailing arbud or after the excision of earlier arbud it is called Adhyarbud[59].

Dwirarbud can be defined as arbud occurring at the same or other site, at the same time or after sometime of occurrence of the earlier arbud[60].

यज्जायते ऽन्यत् खलु पूर्वजाते ज्ञेयं तदध्यर्बुदमर्बुदज्ञैः । यद् द्वन्द्वजातं युगपत् क्रमादा व्दिरर्बुदं तच्च भवेदसाध्यम् ।।२०।। सु.नि.११/ २१, मा. निदान व्दितीय खंड ३८/२५

Sadhyasadhyata of Arbud – (curability of Arbud)[61]

तेषासृड्.गमांसजे वर्ज्ये चत्वार्यन्यानि साधयेत् ।। अष्टांगह्रदय उत्तरस्थान २९/ १८

Kashtasadhya Arbud (Difficult to cure)

Vataja arbud, Pittaja arbud, Kaphaja arbud and Medoja arbud have been mentioned as kashtarbud (difficult to cure).

Asadhya Arbud(incurable)

Raktarbud, Mansarbud, Adhyarbud, Dwirarbud have been considered as asadhya.

Arbud becomes asadhya …

- ✓ if there is oozing of secretions from the arbud
- ✓ if it is affecting marmsthana(vital points)
- ✓ if the arbud is affecting the srotasa
- ✓ if it is fixed
- ✓ if it develops adhyarbud or dwirarbud.

59. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2012), Nidansthan – 11/20 pg313
60. Madhava Nidananm by Shri Madhavkara:- With Madhukosha commentary by Shri Vijay rakshita & Shrikanthadatta, Vidyotini Hindi Commentary by Shri Sudarshan Shastri and revised and edited by Vaidya Yadunanadan Upadhyay, Publisher, -Chaukhamba Sanskrit Sansthan, 26 th edition 1996,Dwitiya Khanda 38/25
61. Ashtanghridya, Vagbhat with Sarvasunder commentary of Arundatta and Ayurved Rasayan commentary of Hemadry, Chaukhamba Surbharati Prakashan, Varanasi (2010) , Uttarsthan, 29/18

- **Chikitsa - Sutra of Arbuda :-**

ग्रन्थ्यार्बुदानां च यतोऽविशेषः प्रदेहहेत्वाकृतिदोषदूष्यैः। ततश्चिकित्सेद्विषग -र्बुदानि विधानवद् ग्रन्थिचिकित्सितेन।।

संशोधिते स्वेदितमश्मकाष्ठैः साङ्गुष्ठदण्डैर्विलयेदपक्वम्। विपाट्य चोद्धृत्य भिषक् सकोशं शस्त्रेण दग्धवा व्रणवच्चिकित्सेत्।।

अदग्ध ईषत् परिशेषितश्च प्रयाति भूयोऽपि शनैर्विवृद्धिम्। तस्मादशेषः कुशलैः समन्ताच्छेद्यो भवेद्वीक्ष्य शरीरदेशान्।।

च.चि.१२/८२,८३,८७

There is similarity between Granthi and Arbuda with respect to Pradesha (site), akruti, Dosha and Dushya. Hence, the physician should apply the treatment mentioned for granthi[62].

- **Shodhana** – Vaman and Virechana
- **Swedana** – Hot fomentation at the site of Arbuda
- **Vilayana** – Causing ripening in the apakva granthi using ashma,wood, thumb pressing etc.
- **Agni Karma** – If the Granthi is ripe or fully matured it should be cauterized.
- **Vrana Karma** –Performing the treatment advised in wounds
- **Shastrkarma**- If the Granthi cannot be cauterized or if it is cauterized partially i.e. if it is deep rooted it can grow again. Hence, it is advisable to excise it totally.

62. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 12/82,83,87 , pp 489

3 B. ii) BREAST CANCER

Breast cancer is a malignant (cancerous) growth that begins in the tissues of the **breast**. **Cancer** is a disease in which abnormal cells grow in an uncontrolled way. **Breast cancer** is the most common **cancer** in women, but it can also appear in men.

Breast cancer usually starts off in the inner lining of milk ducts or the lobules that supply them with milk. A malignant **tumor** can spread to other parts of the body. A breast cancer that started off in the lobules is known as *lobular carcinoma*, while one that developed from the ducts is called *ductal carcinoma*.

ANATOMY OF BREAST CANCER

The breasts are the main accessory organs of the female reproductive system . It provides nutrition to the newborn in the form of milk. It is a modified sweat gland. breast lies on top of the pectoralis major muscle.It extends from second rib to sixth rib vertically. It extends from the lateral border of the sternum to the mid axillary line horizontally[63].

The skin, parenchyma and stroma are the structures of the breast. The skin covers the gland. A nipple is a conical projection.It is pierced by 15 -20 lactiferous ducts.It contains circular and longitudinal smooth muscle fibres which can make the nipple stiff or flatten respectively.The skin surrounding the base of the nipple is pigmented and forms a circular area called the Areola. This region is rich in modified sebaceous glands. These become enlarged during pregnancy and lactation. Fibrous stroma provides the background architecture of the breast. Cooper's ligaments are attached to both the fascia of the skin and the pectoralis major muscle. Carcinoma invading these ligaments may result in skin dimpling which could be subtle or obvious during visual inspection (Figure 1).

63. http://www.cancercenter.com/skin-cancer/symptoms/

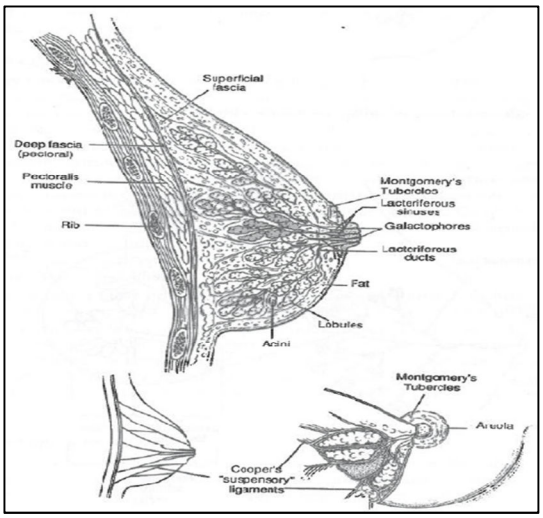


Figure 1. Carcinoma may result in skin dimpling.

Internal Anatomy

The breast is composed of glandular ducts and lobules, connective tissue, and fat, with most of the benign and malignant pathology arising in the duct and lobular network (Figure 2). Specifically, most breast cancer is thought to originate in the terminal ductal lobular unit (TDLU).

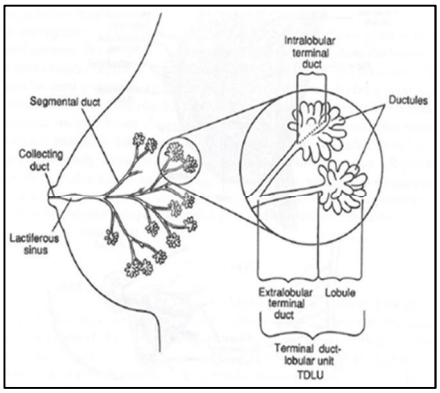


Figure 2. The breast is composed of glandular ducts and lobules, connective tissue, and fat.

The parenchyma is made up of glandular tissue which secrets milk. The gland consists of 15 to 20 sections called lobes. Each lobe is made up of mainly smaller sections called lobules. Lobules have group of tiny glands which make milk. A breast also contains lymph vessels. These vessles are connected to small round masses of tissues called lymph nodes. These lymph nodes are ingroup near axilla. The stroma forms the supporting framework of the gland. It is partly fibrous and partly fatty. The fibrous

stroma forms suspensory ligament (of copper) which anchor the skin and gland to the pectoral facia. The fatty stroma forms the main bulk of the gland.

Lymphatic drainage of the breast:

The carcinoma of the breast spreads mostly along lymphatics to the regional lymph nodes. Lymphatic drainage is of great importance to the surgeon. Lymph from the breast drains into the axillary lymph nodes mainly the antirior group. The other group of nodes posterior, lateral, central and apical also receive lymph directly or indirectly supraclavicular nodes, the cephalic nodes, the posterior intercostals nodes and subdiphragmatic and subperitonial lymph plexuses. The internal mammary nodes also receive lymph. Some lymph from the brast reaches t

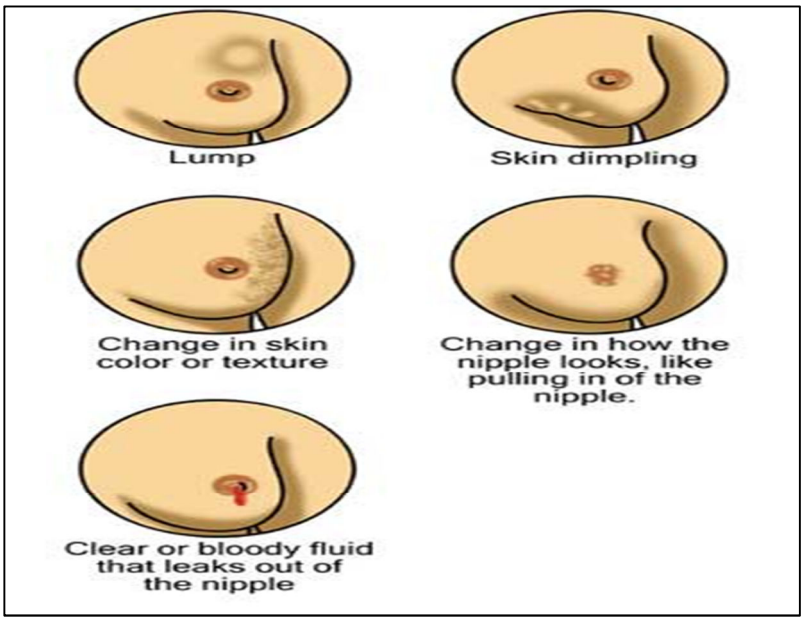
Half of this glandular tissue is located in the upper outer quadrant; therefore, nearly one half of all breast cancers occur in this area.

Symptoms of breast cancer

The first symptoms of breast cancer are usually an area of thickened tissue in the woman's breast, or a lump. The majority of lumps are not cancerous[64]

- A lump in a breast
- A pain in the armpits or breast that does not seem to be related to the woman's menstrual period
- Pitting or redness of the skin of the breast; like the skin of an orange
- A rash around (or on) one of the nipples
- A swelling (lump) in one of the armpits
- An area of thickened tissue in a breast
- One of the nipples has a discharge; sometimes it may contain blood
- The nipple changes in appearance; it may become sunken or inverted
- The size or the shape of the breast changes
- The nipple-skin or breast-skin may have started to peel, scale or flake.

64. Cancer Principal and Practice of oncology, Vincent T. Devita, Jr. , Samuel Hellman , Steven A. Rosenberg, 7th edition, chapter 17



Some of the early signs of breast cancer

Causes of breast cancer

It is hard to say why one person develops the disease while another does not. We know that some risk factors can impact on a woman's likelihood of developing breast cancer. These are:

1) Getting older

The older a woman gets, the higher is her risk of developing breast cancer; age is a risk factor. Over 80% of all female breast cancers occur among women aged 50+ years (after the menopause).

2) Genetics

Women who have a close relative who has/had breast or ovarian cancer are more likely to develop breast cancer. If two close family members develop the disease, it does not necessarily mean they shared the genes that make them more vulnerable, because breast cancer is a relatively common cancer.

The majority of breast cancers are not hereditary.

Women who carry the BRCA1 and BRCA2 genes have a considerably higher risk of developing breast and/or ovarian cancer. These genes can be inherited. TP53, another gene, is also linked to greater breast cancer risk.

3) A history of breast cancer

Women who have had breast cancer, even non-invasive cancer, are more likely to develop the disease again, compared to women who have no history of the disease.

4) Having had certain types of breast lumps

Women who have had some types of benign (non-cancerous) breast lumps are more likely to develop cancer later on. Examples include atypical ductal hyperplasia or lobular carcinoma in situ.

5) Dense breast tissue

Women with denser breast tissue have a greater chance of developing breast cancer.

6) Estrogen exposure

Women who started having period's earlier or entered menopause later than usual have a higher risk of developing breast cancer. This is because their bodies have been exposed to estrogen for longer. Estrogen exposure begins when periods start, and drops dramatically during the menopause.

7) Obesity

Post-menopausal obese and overweight women may have a higher risk of developing breast cancer. Experts say that there are higher levels of estrogen in obese menopausal women, which may be the cause of the higher risk.

8) Height

Taller-than-average women have a slightly greater likelihood of developing breast cancer than shorter-than-average women. Experts are not sure why.

9) Alcohol consumption

The more alcohol a woman regularly drinks, the higher her risk of developing breast cancer is.

10) Radiation exposure

Undergoing X-rays and CT scans may raise a woman's risk of developing breast cancer slightly. Women who had been treated with radiation to the chest for a childhood cancer have a higher risk of developing breast cancer.

11) HRT (hormone replacement therapy)

Both forms, combined and estrogen-only HRT therapies may increase a woman's risk of developing breast cancer slightly. Combined HRT causes a higher risk.

Types of Breast Cancer:-

Invasive and non-invasive breast cancer

Invasive breast cancer - the cancer cells break out from inside the lobules or ducts and invade nearby tissue. With this type of cancer, the abnormal cells can reach the lymph nodes, and eventually make their way to other organs (metastasis), such as the bones, liver or lungs. The abnormal (cancer) cells can travel through the bloodstream or the lymphatic system to other parts of the body; either early on in the disease, or later[65].

Non-invasive breast cancer - this is when the cancer is still inside its place of origin and has not broken out. Lobular carcinoma in situ is when the cancer is still inside the lobules, while ductal carcinoma in situ is when they are still inside the milk ducts. Sometimes, this type of breast cancer is called "pre-cancerous"; this means that although the abnormal cells have not spread outside their place of origin, they can eventually develop into invasive breast cancer.

Types of breast cancer

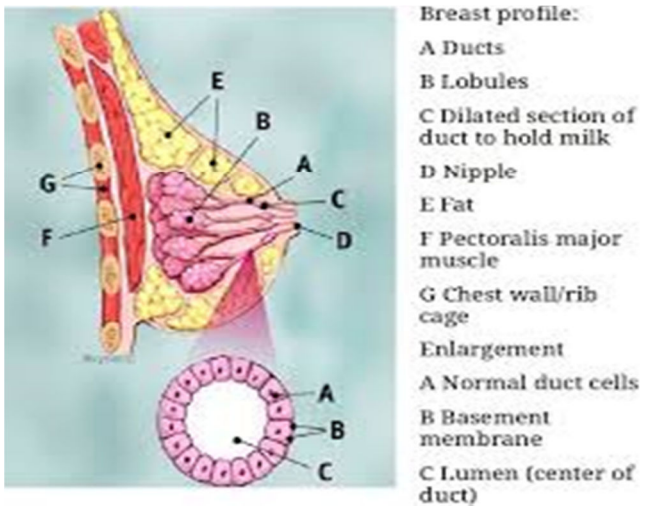
Breast cancer can begin in different areas of the breast — the ducts, the lobules, or in some cases, the tissue in between. The different types of breast cancer are non-invasive, invasive, recurrent, and metastatic breast cancers, as well as the intrinsic or molecular subtypes of breast cancer and breast cancer in men.

65. Cancer Principal and Practice of oncology, Vincent T. Devita, Jr. , Samuel Hellman , Steven A. Rosenberg, 7th edition, chapter 17

- DCIS — Ductal Carcinoma In Situ
- IDC — Invasive Ductal Carcinoma
- IDC Type: Tubular Carcinoma of the Breast
- IDC Type: Medullary Carcinoma of the Breast
- IDC Type: Mucinous Carcinoma of the Breast
- IDC Type: Papillary Carcinoma of the Breast
- IDC Type: Cribriform Carcinoma of the Breast
- ILC — Invasive Lobular Carcinoma
- Inflammatory Breast Cancer
- LCIS — Lobular Carcinoma In Situ
- Male Breast Cancer
- Molecular Subtypes of Breast Cancer
- Paget's Disease of the Nipple
- Phyllodes Tumors of the Breast
- Recurrent & Metastatic Breast Cancer

Ductal carcinoma in situ (DCIS)

Ductal carcinoma in situ (DCIS) is the most common type of non-invasive breast cancer. Ductal means that the cancer starts inside the milk ducts, carcinoma refers to any cancer that begins in the skin or other tissues (including breast tissue) that cover or line the internal organs, and in situ means "in its original place." DCIS is called "non-invasive" because it hasn't spread beyond the milk duct into any normal surrounding breast tissue. DCIS isn't life-threatening, but having DCIS can increase the risk of developing an invasive breast cancer later on.

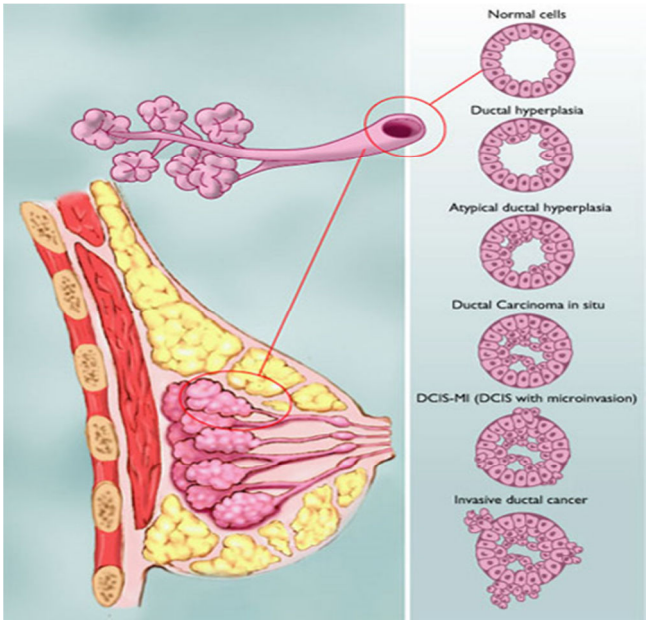


When you have had DCIS, you are at higher risk for the cancer coming back or for developing a new breast cancer than a person who has never had breast cancer before. Most recurrences happen within the 5 to 10 years after initial diagnosis. The chances of a recurrence are under 30%.According to the American Cancer Society; about 60,000 cases of DCIS are diagnosed in the United States each year, accounting for about 1 out of every 5 new breast cancer cases.

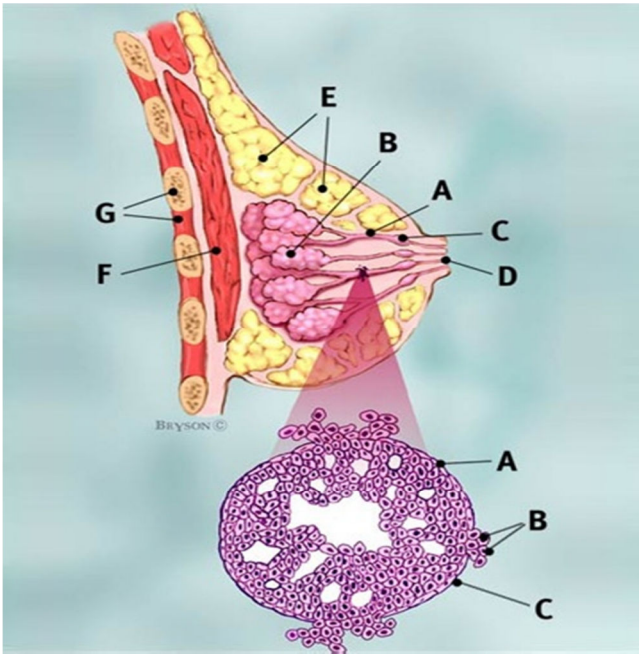
Invasive ductal carcinoma (IDC)

Invasive ductal carcinoma (IDC), sometimes called infiltrating ductal carcinoma, is the most common type of breast cancer. About 80% of all breast cancers are invasive ductal carcinomas.*Invasive* means that the cancer has "invaded" or spread to the surrounding breast tissues. *Ductal* means that the cancer began in the milk ducts, which are the "pipes" that carry milk from the milk-producing lobules to the nipple. *Carcinoma* refers to any cancer that begins in the skin or other tissues that cover internal organs — such as breast tissue. All together, "invasive ductal carcinoma" refers to cancer that has broken through the wall of the milk duct and begun to invade the tissues of the breast. Over time, invasive ductal carcinoma can spread to the lymph nodes and possibly to other areas of the body.

According to the American Cancer Society, more than 180,000 women in the United States find out them have invasive breast cancer each year. Most of them are diagnosed with invasive ductal carcinoma.



Although invasive ductal carcinoma can affect women at any age, it is more common as women grow older. According to the American Cancer Society, about two-thirds of women are 55 or older when they are diagnosed with an invasive breast cancer. Invasive ductal carcinoma also affects men.



Tubular carcinoma

Tubular carcinoma of the breast is a subtype of invasive ductal carcinoma (cancer that begins inside the breast's milk duct and spreads beyond it into healthy tissue). Tubular carcinomas are usually small (about 1 cm or less) and made up of tube-shaped structures called "tubules." These tumors tend to be low-grade, meaning that their cells look somewhat similar to normal, healthy cells and tend to grow slowly.

At one time, tubular carcinomas accounted for about 1-4% of all breast cancers.Studies also suggest that the average age of diagnosis for tubular carcinoma is the early 50s, although women can be diagnosed with it at any age. This type of cancer is rare in men.

Even though tubular carcinoma is an invasive breast cancer, it tends to be a less aggressive type that responds well to treatment. It isn't likely to spread outside the breast and is considered to have a very good prognosis.

Medullary carcinoma

Medullary carcinoma of the breast is a rare subtype of invasive ductal carcinoma (cancer that begins in the milk duct and spreads beyond it), accounting for about 3-5% of all cases of breast cancer. It is called "medullary" carcinoma because the tumor is a soft, fleshy mass that resembles a part of the brain called the medulla.

Medullary carcinoma can occur at any age, but it usually affects women in their late 40s and early 50s. Medullary carcinoma is more common in women who have a *BRCA1* mutation. Studies have shown that medullary carcinoma is also more common in Japan than in the United States.

Medullary carcinoma cells are usually high-grade in their appearance and low-grade in their behavior. In other words, they look like aggressive, highly abnormal cancer cells, but they don't act like them. Medullary carcinoma doesn't grow quickly and usually doesn't spread outside the breast to the lymph nodes. For this reason, it's typically easier to treat than other types of breast cancer.

Mucinous carcinoma

Mucinous carcinoma of the breast — sometimes called colloid carcinoma — is a rare form of invasive ductal carcinoma (cancer that begins in the milk duct and spreads beyond it into nearby healthy tissue). In this type of cancer, the tumor is made up of abnormal cells that "float" in pools of mucin, a key ingredient in the slimy, slippery substance known as mucus.

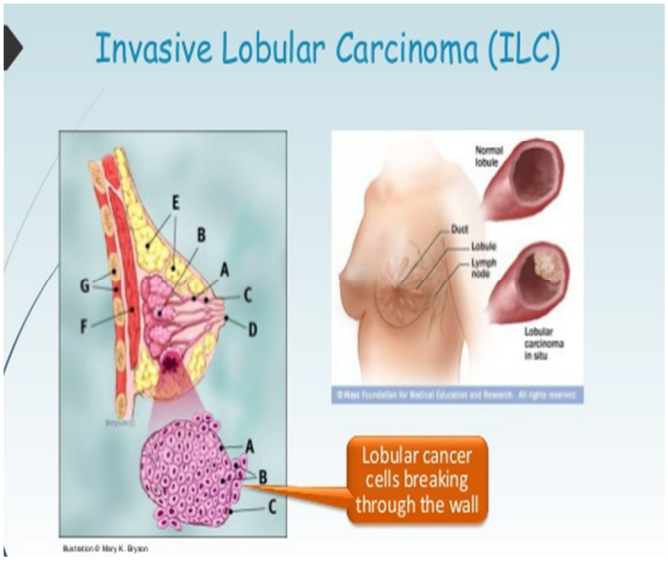
Normally, mucus lines most of the inner surface of our bodies, such as our digestive tract, lungs, liver, and other vital organs. Many types of cancer cells — including most breast cancer cells — produce some mucus. In mucinous carcinoma, however, mucin becomes part of the tumor and surrounds the breast cancer cells. Under a microscope, it looks like the cancer cells are scattered throughout pools of mucus.

Research suggests that only about 2-3% of invasive breast cancers are "pure" mucinous carcinomas — meaning that this is the only type of cancer present within the tumor. About 5% of invasive breast cancers appear to have a mucinous component within them, with other types of cancer cells present as well. Mucinous carcinoma is

extremely rare in men.Although mucinous carcinoma can be diagnosed at any age, it tends to affect women after they've gone through menopause. Some studies have found that the average age at diagnosis is in the 60s or early 70s.Even though mucinous carcinoma is an invasive breast cancer, it tends to be a less aggressive type that responds well to treatment. Mucinous carcinoma is less likely to spread to the lymph nodes than other types of breast cancer.

Invasive papillary carcinomas

Invasive papillary carcinomas of the breast are rare, accounting for less than 1-2% of invasive breast cancers. In most cases, these types of tumors are diagnosed in older women who have already been through menopause. An invasive papillary carcinoma usually has a well-defined border and is made up of small, finger-like projections. Often it is grade 2, or moderate grade, on a scale of 1 to 3 — with grade 1 describing cancer cells that look and behave somewhat like normal, healthy breast cells, and grade 3 describing very abnormal, fast-growing cancer cells. In most cases of invasive papillary carcinoma, ductal carcinoma in situ (DCIS) is also present. (DCIS is a type of cancer in which the carcinoma cells are confined to the breast duct.)



Invasive cribriform carcinoma

In invasive cribriform carcinoma, the cancer cells invade the stroma (connective tissues of the breast) in nestlike formations between the ducts and lobules. Within the tumor, there are distinctive holes in between the cancer cells, making it look something like Swiss cheese. Invasive cribriform carcinoma is usually low grade, meaning that its cells look and behave somewhat like normal, healthy breast cells. In

about 5-6% of invasive breast cancers, some portion of the tumor can be considered cribriform. Usually, some ductal carcinoma in situ (DCIS) of the cribriform type is present as well.

Invasive lobular carcinoma (ILC)

Invasive lobular carcinoma (ILC), sometimes called infiltrating lobular carcinoma, is the second most common type of breast cancer after invasive ductal carcinoma (cancer that begins in the milk-carrying ducts and spreads beyond it). According to the American Cancer Society, more than 180,000 women in the United States find out they have invasive breast cancer each year. About 10% of all invasive breast cancers are invasive lobular carcinomas. (About 80% are invasive ductal carcinomas.)

Invasive means that the cancer has "invaded" or spread to the surrounding breast tissues. *Lobular* means that the cancer began in the milk-producing lobules, which empty out into the ducts that carry milk to the nipple. *Carcinoma* refers to any cancer that begins in the skin or other tissues that cover internal organs — such as breast tissue. All together, "invasive lobular carcinoma" refers to cancer that has broken through the wall of the lobule and begun to invade the tissues of the breast. Over time, invasive lobular carcinoma can spread to the lymph nodes and possibly to other areas of the body.

Although invasive lobular carcinoma can affect women at any age, it is more common as women grow older. According to the American Cancer Society, about two-thirds of women are 55 or older when they are diagnosed with an invasive breast cancer. ILC tends to occur later in life than invasive ductal carcinoma — the early 60s as opposed to the mid- to late 50s.

Inflammatory breast cancer (IBC)

Inflammatory breast cancer (IBC) is a rare and aggressive form of breast cancer. According to the American Cancer Society, about 1% of all breast cancer cases in the United States are inflammatory breast cancers.

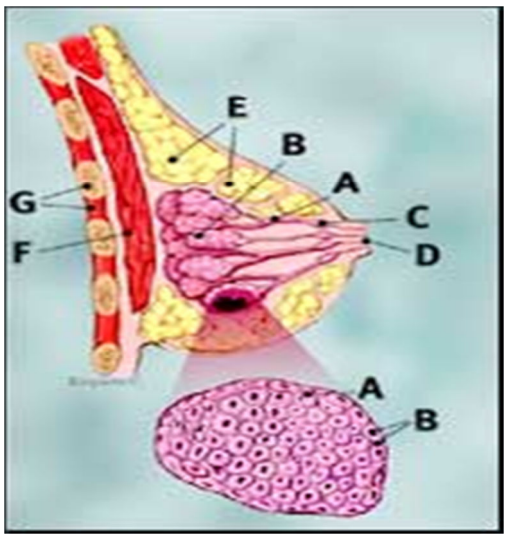
Inflammatory breast cancer usually starts with the reddening and swelling of the breast instead of a distinct lump. IBC tends to grow and spread quickly, with

symptoms worsening within days or even hours. It's important to recognize symptoms and seek prompt treatment. Although inflammatory breast cancer is a serious diagnosis, keep in mind that treatments today are better at controlling the disease than they used to be.

The average age at diagnosis for inflammatory breast cancer in the United States is 57 for white women and 52 for African American women. These ages are about 5 years younger than the average ages at diagnosis for other forms of breast cancer. According to the American Cancer Society[66], inflammatory breast cancer is more common in African American women. A 2008 study found that being overweight makes a person more likely to develop IBC. Like other forms of breast cancer, IBC can also affect men.

Lobular carcinoma in situ (LCIS)

Lobular carcinoma in situ (LCIS) is an area (or areas) of abnormal cell growth that increases a person's risk of developing invasive breast cancer later on in life. Lobular means that the abnormal cells start growing in the lobules, the milk-producing glands at the end of breast ducts. Carcinoma refers to any cancer that begins in the skin or other tissues that cover internal organs — such as breast tissue. In situ or "in its original place" means that the abnormal growth remains inside the lobule and does not spread to surrounding tissues. People diagnosed with LCIS tend to have more than one lobule affected.



66. http://www.cancer.org/cancer/breastcancer/

Despite the fact that its name includes the term “carcinoma,” LCIS is not a true breast cancer. Rather, LCIS is an indication that a person is at higher-than-average risk for getting breast cancer at some point in the future. For this reason, some experts prefer the term “lobular neoplasia” instead of “lobular carcinoma.” A neoplasia is a collection of abnormal cells.LCIS is usually diagnosed before menopause, most often between the ages of 40 and 50. Less than 10% of women diagnosed with LCIS have already gone through menopause. LCIS is extremely uncommon in men.

Paget's disease of the nipple

Paget's disease of the nipple is a rare form of breast cancer in which cancer cells collect in or around the nipple. The cancer usually affects the ducts of the nipple first (small milk-carrying tubes), then spreads to the nipple surface and the areola (the dark circle of skin around the nipple). The nipple and areola often become scaly, red, itchy, and irritated.

According to the National Cancer Institute[67], Paget's disease of the nipple accounts for less than 5% of all breast cancer cases in the United States. Being aware of the symptoms is important, given that more than 97% of people with Paget's disease also have cancer, either DCIS or invasive cancer, somewhere else in the breast. The unusual changes in the nipple and areola are often the first indication that breast cancer is present.Paget's disease of the nipple is more common in women, but like other forms of breast cancer, it can also affect men. The disease usually develops after age 50. According to the National Cancer Institute, the average age of diagnosis in women is 62, and in men, 69.

Phyllodes tumors

Phyllodes tumors of the breast are rare, accounting for less than 1% of all breast tumors. The name "phyllodes," which is taken from the Greek language and means "leaflike," refers to that fact that the tumor cells grow in a leaflike pattern. Other names for these tumors are phylloides tumor and cystosarcoma phyllodes. Phyllodes tumors tend to grow quickly, but they rarely spread outside the breast.

67. https://www.cancer.gov/types/breast/paget-breast-fact-sheet

Although most phyllodes tumors are benign (not cancerous), some are malignant (cancerous) and some are borderline (in between noncancerous and cancerous). All three kinds of phyllodes tumors tend to grow quickly, and they require surgery to reduce the risk of a phyllodes tumor coming back in the breast (local recurrence).

Phyllodes tumors can occur at any age, but they tend to develop when a woman is in her 40s. Benign phyllodes tumors are usually diagnosed at a younger age than malignant phyllodes tumors. Phyllodes tumors are extremely rare in men.

Recurrent breast cancer is cancer that has come back in the same or opposite breast or chest wall after a period of time when the cancer couldn't be detected.

Metastatic breast cancer is breast cancer that has spread to other parts of your body. Both are considered advanced-stage cancer.

Grade (The Bloom–Richardson grading system) :-

The grading of a cancer in the breast depends on the microscopic similarity of breast cancer cells to normal breast tissue, and classifies the cancer as well differentiated (low grade), moderately differentiated (intermediate grade), and poorly differentiated (high grade), reflecting progressively less normal appearing cells that have a worsening prognosis. Although grading is fundamentally based on how biopsied, cultured cells behave, in practice the grading of a given cancer is derived by assessing the cellular appearance of the tumor. The closer the appearance of the cancer cells to normal cells, the slower their growth and the better the prognosis. If cells are not well differentiated, they will appear immature, will divide more rapidly, and will tend to spread. Well differentiated is given a grade of 1, moderate is grade 2, while poor or undifferentiated is given a higher grade of 3 or 4 (depending upon the scale used)[68].

68. American Joint Committee on Cancer. Lip and Oral Cavity. In: AJCC Cancer Staging Manual, 7th ed. New York, Springer: 2010; 29–35.

The Nottingham (also called Elston-Ellis) modification of the Scarff-Bloom-Richardson grading system is recommended, which grades breast carcinomas by adding up scores for tubule formation, nuclear pleomorphism, and mitotic count, each of which is given 1 to 3 points. The scores for each of these three criteria and then added together to give an overall final score and corresponding grade.

3 C) Conventional treatment for Breast Cancer[69]

1. Surgery :

Surgery is the first option in breast cancer. It is often needed to remove a breast tumor. Surgical options include Breast-conserving surgery (partial or segmental mastectomy) or Entire Breast Removal (Mastectomy) whereby all of the breast tissue is removed, sometimes along with other nearby tissues .Lymph nodes are also excised during the surgery (to determine if the breast cancer has spread to axillary lymph nodes, one or more of these lymph nodes may be removed).Reconstructive surgery can be done to restore the breast's appearance after surgery. This surgery can be done at the same time as the mastectomy (immediate reconstruction) or at a later time (delayed reconstruction).

2. Radiation: Radiation therapy can be given in 2 main ways.

External beam radiation

This is the most common type of radiation therapy for women with breast cancer. The radiation is focused from a machine outside the body on the area affected by the cancer. The extent of radiation depends on surgical procedure done and involvement of lymph nodes. In mastectomy no lymph nodes, radiation is targeted at the chest wall and the places where any drains exited the body. In Breast Conservation Surgery, most often the entire breast gets radiation, and an extra boost of radiation is given to the area in the breast where the cancer was removed to prevent recurrecne. The boost is often given after the treatments to whole breast end.

Internal Radiation (Brachytherapy)

Instead of aiming radiation beams from outside the body, radioactive seeds or pellets are placed into the breast tissue next to the cancer. It is often used in patients who had BCS as a way to add an extra boost of radiation to the tumor site (along with external radiation to the whole breast). It may also be used by itself (instead of radiation to the whole breast). Tumor size, location, and other factors may limit who can get brachytherapy.

69. Cancer Principal and Practice of oncology, Vincent T. Devita, Jr. , Samuel Hellman , Steven A. Rosenberg, 7th edition, Chapter 26.2,pp 665.

3. Chemotherapy:

Chemotherapy is the use of anti-cancer (cytotoxic) drugs to treat cancer. It is usually a systemic therapy that circulates throughout the body and destroys cancer cells, including those that may have broken away from the primary tumour.

It may be used in following conditions:

- **Adjuvant chemotherapy (After surgery)**

  To destroy residual cancer cells and to reduce the risk of recuurrence of cancer recurring

- **Neoadjuvant chemotherapy (Before surgery).**

  To reduce the size of breast tumour if it is large

  To treat a breast cancer recurrence

- **Palliative Chemotherapy**

  To relieve pain or to control the symptoms of advanced breast cancer

4. Hormonal therapy

Estrogen and progesterone are 2 female hormones made mainly by a woman's ovaries until menopause. Estrogen and progesterone can stimulate the growth of some breast cancers. After menopause, the ovaries stop making estrogen, but the body continues to make a small amount of estrogen with an enzyme called aromatase.

Hormonal therapy is a systemic therapy that slows the growth and spread of breast cancer cells by changing hormone levels in the body, or by stopping breast cancer cells from using estrogen.

Hormonal therapy is used only in women who have breast cancer that is estrogen receptor positive (ER positive or ER+) and progesterone receptor positive (PR positive or PR+).

Hormonal therapy is not used in women who have hormone receptor–negative tumours.

Hormonal therapy may be used:

- **After surgery and radiation therapy**

  To stop cancer cells that may have been left behind from growing and to reduce the risk of the cancer recurring (adjuvant hormonal therapy)

- **Before surgery**To shrink the primary tumour, especially in older women with breast cancer that is ER+, PR+ or both
- **In Locally advanced cancer**
  As part of a combined treatment approach for locally advanced breast cancer
- **As Prevention**
  To decrease the chance of cancer developing in the opposite breast
- **In Recurrence**
  To treat breast cancer that has recurred

Most common hormonal therapies used to treat breast cancer:

Anti-estrogens: Work by stopping breast cancer cells from getting estrogen. Anti-estrogens bind directly to and block the estrogen receptors.e.g Tamoxifen

Aromatase inhibitors: Aromatase is an enzyme involved in the production of estrogen in the body. Aromatase inhibitors are drugs that stop the production or block the actions of aromatase, which in turn lowers the level of estrogen in the body. E.g letrozole (Femara), anastrozole (Arimidex)

5. Ovarian ablation: Ovarian ablation (or ovarian suppression) refers to treatments that stop the ovaries from making estrogen. Reducing the level of estrogen made in the body helps prevent and stop breast cancer cells from growing. Ovarian ablation can be done in one of 3 ways: surgery, drugs (luteinizing hormone–releasing hormone agonists) or radiation therapy.

3 D.i) Types of of Chemotherapy Drugs[70]

Alkylating agents

Special Features :

✓ Most active in the resting phase of the cell.

✓ Drugs are cell-cycle non-specific.

Types of alkylating agents used in chemotherapy treatments:e.g-

- Mustard gas derivatives: Mechlorethamine, Cyclophosphamide, Chlorambucil, Melphalan, and Ifosfamide.
- Ethylenimines: Thiotepa and Hexamethylmelamine.
- Alkylsulfonates: Busulfan.
- Hydrazines and Triazines: Altretamine, Procarbazine, Dacarbazine and Temozolomide.
- Nitrosureas: Carmustine, Lomustine and Streptozocin. Nitrosureas are unique because, unlike most types of chemo treatments, they can cross the blood-brain barrier. They can be useful in treating brain tumors.
- Metal salts: Carboplatin, Cisplatin, and Oxaliplatin.

Plant Alkaloids

Special Features:

✓ Chemotherapy treatments derived made from certain types of plants.

✓ The plant alkaloids are cell-cycle specific. This means they attack the cells during various phases of division.

Vinca alkaloids are made from the periwinkle plant (catharanthus rosea). The taxanes are made from the bark of the Pacific Yew tree (taxus). The vinca alkaloids and taxanes are also known as antimicrotubule agents.

Podophyllotoxins are derived from the May apple plant. Camptothecan analogs are derived from the Asian "Happy Tree" (Camptotheca acuminata). Podophyllotoxins and camptothecan analogs are also known as topoisomerase inhibitors, which are used in certain types of chemotherapy. Vinca alkaloids: Vincristine, Vinblastine and Vinorelbine.

70. BC Cancer Agency Cancer Drug Manual developed 1 May 2012,Revised 1 April 2013, 1 July 2014, 1 January 2015

- Taxanes: Paclitaxel and Docetaxel.
- Podophyllotoxins: Etoposide and Tenisopide.
- Camptothecan analogs: Irinotecan and Topotecan.

Antitumor Antibiotics

Special Features:

- ✓ Made from natural products produced by species of the soil fungus Streptomyces.
- ✓ Act during multiple phases of the cell cycle and are considered cell-cycle specific.

Types of antitumor antibiotics:

- Anthracyclines: Doxorubicin, Daunorubicin, Epirubicin, Mitoxantrone, and Idarubicin.
- Chromomycins: Dactinomycin and Plicamycin.
- Miscellaneous: Mitomycin and Bleomycin.

Antimetabolites

Special features:

- ✓ Types of chemotherapy treatments that are very similar to normal substances within the cell.
- ✓ When the cells incorporate these substances into the cellular metabolism, they are unable to divide.
- ✓ These chemotherapy agents are cell-cycle specific. They attack cells at very specific phases in the cycle.

  Antimetabolites are classified according to the substances with which they interfere.

- Folic acid antagonist: Methotrexate.
- Pyrimidine antagonist: 5-Fluorouracil, Foxuridine, Cytarabine, Capecitabine, and Gemcitabine.
- Purine antagonist: 6-Mercaptopurine and 6-Thioguanine.
- Adenosine deaminase inhibitor: Cladribine, Fludarabine, Nelarabine and Pentostatin.

Topoisomerase inhibitors

Special Features:

- ✓ Types of chemotherapy drugs interfere with the action of topoisomerase enzymes (topoisomerase I and II).
- ✓ Control the manipulation of the structure of DNA necessary for replication.
- Topoisomerase I inhibitors: Ironotecan, topotecan
- Topoisomerase II inhibitors: Amsacrine, etoposide, etoposide phosphate, teniposide

3 D. ii) Chemo Therapy Drugs[71]

1. Cyclophosphamide

Synonyms: Cyclo, CPA, CTX, CYC, CPM, CYT

Trade Names: Cytoxam, 1 Procytox, Neosar

Type: Alkylating agent of the nitrogen mustard type from the oxazophosphorine group.

Mode of Action: Its cytotoxic effect is mainly due to cross-linking of strands of DNA and RNA, and to inhibition of protein synthesis. These actions do not appear to be cell-cycle specific.

The Compounds are crosslink DNA by adding an alkyl group (c H) to the guanine base of DNA, at the number seven nitrogen atom of the imidazole ring. This induces inhibition of DNA replication, leading to cell death. CYC exerts its cytotoxic effect on both resting and dividing lymphocytes. It is one of the most potent immunosuppressive drugs available.

2. Doxorubicin

Synonyms: ADR, 1 Adria, 2 Dox, 2 hydroxyl, daunorubicin, Adriamycin

Trade Names: Adriacin, Adrimedac, DOXO-CELL, Doxorubin, Farmiblastina

Type: Anthracycline Antineoplastic antibiotic.The hydrochloride salt of doxorubicin, an anthracycline antibiotic with antineoplastic activity. Doxorubicin, isolated from the bacterium Streptomyces peucetius var. Caesius, is the hydroxylated congener of daunorubicin.

Mode of Action: Doxorubicin intercalates between base pairs in the DNA helix, thereby preventing DNA replication and ultimately inhibiting protein synthesis. It also inhibits topoisomerase II which results in an increased and stabilized cleavable enzyme- DNA linked complex during DNA replication and subsequently prevents the ligation of the nucleotide strand after double strand breakage. Doxorubicin also forms oxygen free radicals resulting in cytotoxicity secondary to lipid peroxidation of cell membrane lipids; the formation of oxygen free radicals also contributes to the toxicity of the anthracycline antibiotics, namely the cardiac and cutaneous vascular effects.

9. https://www.cancercare.on.ca/toolbox/drugs/drugformulary/

3. Fluorouracil

Synonyms: 5-FU, 5-Fluorouracil

Trade Names: Adrucil, Efudes Cream

Type: Antimetabolite.Fluorouracil is an analog of the pyrimidine uracil and thus acts as a pyrimidine Antagonist.

Mode of Action: There are three possible mechanisms of action.

- First, the fluorouracil metabolite fluorodeoxyuridine monophosphate (FdUMP) competes with uracil to bind with thymidylatesynthetase (TS) and the folate cofactor. This results in decreased thymidine production and therefore deceased DNA synthesis and repair, and ultimately decreased cell proliferation. Leucovorin (formyltetrahydrofolate, formyl-FH4) enhances fluorouracil by stabilizing the binding of FdUMP to Ts.
- Second, the fluorouracil metabolite fluorodeoxyuridine triphosphate (FdUPT) is incorporated into DNA thus interfering with DNA replication.
- Finally, the fluorouracil metabolite fluorouridine-5-triphosphate (FUTP) is incorporated into RNA in place of uridine triphosphate (UTP), prodiucing a fraudulent RNA and interfering with RNA processing and protein synthesis.Flurouraciliscell_cycle specific (S-phase).

4. Methotrexate

Synonyms: Amethopterin, MTX

Type: Antimetabolite. Methotrexate is folateantagonist.Tetrahydrofolate is the active form of folic acid required for purine and thymidylate synthesis. Folic acid is reduced to tetrahydrofolate by dihydrofolatereductase (DHFR).

Mode of Action: Methotrexate is most active against rapidly multiplying cells because the cytotoxic effects occur primarily during the S phase of the cell cycle. Methotrexate also has immunosuppressive activity, possibly due to inhibition of lymphocyte multiplication.

The cytotoxicity of methotrexate results from three actions:

- Inhibition of DHFR
- Inhibition of thymidylate

- Alteration of the transport of reduced folates,

Inhibition of DHFR results in a deficiency of thymidylate and purines and therefore a decrease in DNA synthesis, repair and cellular replication. The affinity of DHFR to methotrexate is far greater than its affinity for folic acid or dihydrofolic acid, therefore large doses of folic acid given simultaneously will not reverse the effects of methotrexate. However, leucovorin calcium, a derivative of tetrahydrofolicacid,may block the effects of methotrexate if given shortly after the methotrexate since it does not require DHFR for activation, Moderate 100mg/m) to high –does methotraxate (100mg/m) plus leucovorin rescue is routinely used therapeutically in cancer treatment.

5. Gemcitabine

Synonyms: Gemcitabine hydrochloride, difluorodeoxycytidine, 2-difluorodeoxycytidine,

Trade Names: GEMZAR

Type: Antimetabolite.

Mode of Action: Gemcitabine, a pyrimidine anolog, is structurally similar to cytarabine, but has a wider spectrum of antitumour activity due to its different cellular pharmacology and mechanism of action. 1 Femcitabine is metabolized intracellulary to two active metabolites, gemcitabine diphosphate (dFdCDP) and gemcitabine triphosphate (dFdCTP).

The cytotoxic effects of gemcitabine are exerted through incorporation of DfdCTP into DNA with the assistance of dFdCDP, resulting in inhibition of DNA synthesis and induction of apoptosis.

6. Docetaxel

Synonym: RP56976

Trade Names: Taxotere, Docefrez

Type : Mitotic inhibitor.Docetaxel is a taxane derivative similar to paclitaxel.

Mode of Action: Docetaxel is cell cycle phasespecific for the G2/M phase. Docetaxel is a radiation-sensitizing agent and an immunosuppressant.

Docetaxel binds to tubulin, the protein component of microtubules, and simultaneously promotes assembly and inhibits disassembly of them. Stabilization of microtubules leads to inhibition of cell division (mitosis) and tumour proliferation, resulting in cell death. Both docetaxel and paclitaxel bind to the same microtubule site. Docetaxel is approximately 2 times as potent as paxlitaxel and at least 5 times more potent against paclitaxel-resistant cell.

7. Paclitaxel

Synonym: Benzenepropanoic acid

Trade Names: Taxol, Onxol

Type: Antimicrotubule agent.Paclitaxel is a taxane

Mode of Action: Paclitaxel binds to tubulin.The protein component of microtubules, simultaneously promoting their assembly and disassembly to form stable, non-functional microtubules.

Stabilixation of microtubules blocks cells in the M phase of the cell cycle, inhibiting cell division and causing cell death. Paclitaxel acts as a radiosensitizing agent by blocking cells in the G2phase, Paclitaxel is an immunosuppressant.

8. Epirubicin

Synonym: 4-epiDOXOrubicin, 1 IMI-28, 1 NSC-2569421 is the synonym.

Trade Names: Pharomorubicin, 2 Ellence3

Type: Anthracycline antineoplastic antibiotic.

Mode of Action: Epirubicin appears to be related to its ability to bind to nucleic acids. It forms a complex with DNA by intercalation between base pairs, resulting in inhibition of DNA and RNA synthesis. Intercalation also triggers DNA cleavage by topoisomerase, resulting in cytocidal activity. Binding to cell membranes and plasma proteins may also be involved. Epirubicin also generates cytotoxic free radicals. Epirubicin is the 4, - epimer of DOXOrubicin; i.e; there is a different spatial orientation of the hydroxyl group at the 4, carbon of the sugar moiety. This difference may account for faster elimination and reduced toxicity.

9. Carboplatin

Synonyms: CBDCA, JM8, NSC 241240

Trade Names: Paraplatin, Paraplatin-AQ

Type: Alkylating agent.Carboplatin is an analoglike cisplatin.

Mode of Action: It contains a platinum atom surrounded in a plane by two ammonia groups and two other ligands in the cis position. The other two ligands in carboplatin are present in a ring structure rather than as two chloride atoms in cisplatin. This difference makes carboplatin more stable and has less nephrotoxicity, neurotoxicity, ototoxicity and emotogenesis. The exact mechanism of action of carboplatin is not known. Carboplatin undergoes intracellular activation to form reactive platinum complexes which are beli are believed to inhibit DNA synthesis by forming interstrand and intrastrand cross-linking of DNA molecules. Carboplatin is a radiation- sensitizing agent. It is cell cycle- phase nonspecific.

Side –effects of Chemotherapy[72]

Commonly observed side effects of chemotherapy

Table No.:-2 Haematological Manifestations

Myelosuppression	Grade 1	Grade 2	Grade 3	Grade 4
Neutropenia	< LLN – 3000/mm^3; < LLN – 3.0 x10e9/L	< 2000-1000/mm^3; < 3.0 – 2.0 x10e9/L	< 2000-1000/mm^3;< 2.0-1.0 x 10e9/L	<1000/mm^3; < 1.0x 10e9/L
Thrombocytopenia	< LLN - 75000/mm^3	< 75000-50000/mm^3	< 50000-25000/mm^3; < 50.0-25.0 x 10e9/L	< 25000/mm^3;<25.0 x 10e9/L
Anaemia	Haemoglobin (Hgb) < LLN - 10.0g.dL; < LLL - 6.2 mmol/L; < LLN – 100 g/L	Hgb<10.0 – 8.0 g/dl; < 6.2 – 4.9 mmol; < 100- 80 g/L	Hgb< 8.0 g/dL; 4.9 mmol/L; < 80 g/L; transfusion indicated	

Table No:-3 Gastrointestinal symptoms

	Grade 1	Grade 2	Grade 3	Grade 4
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	Associated with significant weight loss or malnutrition(e.g., inadequate oral intake); IV fluids, tube feeding or TPN indicated	Life-threatening consequences
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-
Vomiting	1 - 2 episodes (separated by 5 minutes) in 24 hrs	3 - 5 episodes (separated by 5 minutes) in 24 hrs	>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated
Taste abnormality	Altered taste but no change in diet	Altered taste with change in diet (oral suppliment) noxious or unpleasant taste,loss of taste.	---	-----
Mucositis/ stomatitis(clinical exam) - Oral cavity - Larynx - Pharynx -Trachea - Oesophagus --Stomach -Small bowel -Large bowel -Rectum - Anus	Erythma of mucosa	Patchy ulceration or pseudomembranes	Confluent ulceration or pseudomembranes bleeding with minor trauma	Tissue necrosis, significant spontaneous bleeding, Life threatening consequence
Mucositis/stomatitis (functional or symptomatic)	Upper_aerodigrstive tract sites: Minimal symptoms, normal diet, minimal	Upper aerodigestive tract sites: Symptomatic but can eat and swallow modified diet, respiratory	Upper aerodigestive tract: Symptomatic and unable to adequate aliment or hydrate oraly,	Symptoms associated with life-threatning consequence.

- Oral cavity - Larynx - Pharynx -Trachea - Oesophagus --Stomach -Small bowel -Large bowel -Rectum - Anus	respiratory symptoms but not interfering with function	symptoms interfering with function but not interfering with ADL Lower GI sites: Symptomatic, medical intervention indicated but not interfering with ADL	respiratory symptoms interfering with ADL. Lower GI sites: Stool incontinence or other symptoms interfering with ADL	
Diarrhoea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline	Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL	Life-threatening consequences; urgent intervention indicated
GI bleed --- Heamorrhaige	Asymptomatic,mild, intervention,(other	Symptomatic and medical intervention or minor cautarization indicated	Interfering with ADL,interventional radiology,endoscopic or operative intervention indicated	Life-threatening Consequences
Constipation	Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL	Constipation with manual evacuation indicated; limiting self care ADL	Life-threatening consequences; urgent intervention indicated

72. Common Terminology Criteria for Adverse Events (CTCAE)Version 4.0,May 2009 (updated June 2010) U.S. Department Of Health and Human Services NIH, NCI http://www.eortc.be/ services/doc/ctc/CTCAE_4.03_2010-06 14_QuickReference_5x7.pdf

Table No:-4 Dermatological Symptoms:

	Grade 1	Grade 2	Grade 3	Grade 4
Alopecia	Normal	Mild hair loss	Pronounced hair loss	-
Skin rash	None	Macular or popular eruption or erythema without associated symptoms	Macular or popular eruption or erythema with pruritus or other associated symptoms covering < 50% of body surface area	Symptomatic generalised erythroderma or macular, popular or vesicular eruption or desquamation covering 50% of body surface area.
Nail discoloration	Normal	Discolouration or ridging (koilonchia) or pitting	Partial or complete loss of nail(s) or pain in nailbeds.	-
Photosensitivity	Painless erythema and erythema covering <10% BSA	Tender erythema covering 10- 30% BSA	Erythema covering >30% BSA and erythema with blistering; photosensitivity; oral corticosteroid therapy indicated; pain control indicated (e.g., narcotics or NSAIDs)	Life-threatening consequences; urgent intervention indicated

Rarely observed side effects of chemotherapy

- Allergic Reactions – Anaphylaxis, Urticarial reactions
- Cardiovascular symptoms - Arrhythmias, chestpain, CHF, hypotension, myocardial infarction, oedema/peripheral oedema
- Hepatic Dysfunction - elevated alkaline phosphatase, elevated SGOT/SGPT,elevated bilirubin
- Neurological – Optic Neuropathy, visual disturbances, peripheral neuropathy.

The chemotherapy side effects as per Ayurvedic perspective

The chemotherapy side effects namely anorexia, nausea, vomiting, taste abnormality, diarrhea, GI bleeding, stomatitis, constipation are correlated with the diseases having similar signs and symptoms. The symptoms and treatments explained for these diseases forms the basis of correlation with the side effects of chemotherapy and its treatment.

Anorexia, Nausea, Taste abnormality :-

रस प्रदोषज विकार :-

अश्रद्धा चारुचिश्चास्यवैरस्यमरसज्ञता ।
हृल्लासो गौरवं तन्द्रा साङ्गमर्दो ज्वरस्तमः।।
पाण्डुत्वं स्त्रोतसां रोधः क्लैब्यं सादः कृशाङ्गता।
नाशोऽग्नेरयथाकालं वलयः पलितानि च।।
रस प्रदोषजा रोगा ।। च. सू. २८ / ९ -१०.

Following diseases are caused by the vitiation of Rasadhatu[73] -Ashraddha (Disclinition of food), Aruchi (Anorexia), Asyavairasya (Tastelessness of Mouth), Hrullas (Nausia), Gaurava (Heaviness), Tandra (drowsiness), Jwara with Angamarda (fever with generalised bodyache), Tama (fainting), Pandutwa (Anemia), Strotorodha (Obstruction of the channels), Klaibya (impotency), Sada (Asthenia), Krushangata (emaciation), Agni Nasha (diminished digestive power), Akal Vali and Palita (premature appearence of wrinkles and gray hairs).

Treatment - रजसजानां विकाराणां सर्वम् लङ्घनमौषधम् । च. सू. २८/२५

The treatment described in this condition is Langhan[74]

73. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 28/9-10 , pp 489
74. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 28/25 , pp 489

Skin rash, Hyperpimentation, Photosensitivity:-

रक्त प्रदोषज विकार -

वक्ष्यन्ते रक्तप्रदोषजाः।

कुष्ठविसर्पपिडका रक्तपित्तमसृग्दरः।।११।।

गुदमेढ्रास्यपाकश्च प्लीहा गुल्मोऽथ विद्रधिः।

नीलिका कामला व्यङ्गः पिप्लवस्तिलकालकाः।।१२।।

दद्रुश्चर्मदलं श्वित्रं पामा कोठास्त्रमण्डलम्।

रक्तप्रदोषाज्जायन्ते, ।। च. सू. २८ / ११ - १२.

चिकित्सा- विधिशोणितिके ध्याये रक्तजानां भिषग्जितम् ।।

चि. सु.चि. २८।२५

कुर्याच्छोणितरोगेषु रक्तपित्तहरीं क्रियाम्।

विरेकमुपवासं च स्त्रावणं शोणितस्य च ।।१८।।

चि. सु.चि. २४।१८

Following are the diseases caused by vitiation of Rakta Dhatu[75] -Kushtha (All types of Skin diseases), Visarpa (Erysipelas), Pidaka (Papules,macules etc.), Raktapitta (Bleeding Disorders), Raktapradar (Menorrhagia), Gudapaka (Inflamation of the Rectum and Anus), Medhrapaka , Asyapaka (Stomatitis), Pliha (splenic Disorders), Gulma (Abdominal Tumers), Vidradhi (Abscesses), Nilika (Blue moles), Kamala (Jaundice), Vyanga (Freckles), Piplava (portwin Marks), Tilakalaka (black moles), Dadru (a type of Skin Diseas), Charmadala (Charmadala), Shwitra (Leucoderma), Pama (papules), Kotha (Urticaria), Raktamandal (red patches on skin).

अतिसार- Diarrhoea:-

पित्तज अतिसार

पित्तलस्य पुनरम्ललवणकटुकक्षारोष्णातिमात्रनिषेविणः प्रतताग्निसूर्यसंतापोष्ण मारुतोपहतगात्रस्य क्रोधेर्ष्याबहुलस्य पित्तं प्रकोपमापद्यते।

If a Pittal person exposes to following factors Pitta gets vitiated - excessive intake of sour, salty, pungent, alkaline, hot and sharp ingredients; Afliction of the body by excessive exposure to heat of Fire, Sunlight, hot air; excessively wrathful and jealous disposition.

तत प्रकुपितं द्रवत्वादूष्माणमुपहत्य पुरीषाशयविसृतमौष्ण्याद् द्रवत्वात् सरत्वाच्च भित्वा पुरीषमतिसाराय कल्पते।

75. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 28/11-12 , pp 489

Vitiated Pitta because of Drava Guna decreases the digestive power, coming down to the intestines it disintegrates the stool because of its Drva, Ushna, Sara Gunas and causes Pittaj Atisar.

तस्य रुपाणि - हारिद्रं हरितं नीलं कृष्णं रक्तपित्तोपहितमतिदुर्गन्धमतिसार्यते पुरीषं, तृष्णा दाहस्वेदमूर्च्छाशूलब्रध्नसंतापपाकपरीत इति पित्तातिसारः।

Frequent loose motions, which is green, yellowish, bluish or blackish in appearance; stool is mixed with blood, Pitta, and having excessive foul smell. Patient suffers from thirst, burning sensation, sweating, fainting, abdominal pain, and suppuration of anus[76].

सामान्य संप्राप्ती- संशम्यापां धातुरन्तः कृशानुं वर्चोमिश्रो मारुतेन प्रणुन्नः ।
वृद्धोऽतीबाधः सरत्येष यस्माव्याधिं घोरं तं त्वतीसारमाहुः ।। सु.उ.४०/६

चिकित्सा- तत्रादौ लङ्घनं कार्यमतिसारेषु देहिनाम् । ततः पाचनसंयुक्तो यवाग्वादिक्रमो हितः ।। सु.उ.४०/२५
आमान्वयमतीसार पैत्तिकं लंघनैर्जयेत् । लंघितस्य यथासात्म्यं यवागूमण्डतर्पणैः ।।
शृतचन्दनमुस्ताभ्यां पटोलोदीच्यनागरैः। पेयामम्लामतक्रां वा पाचनी ग्राहिणी पिबेत् ।। यो.र.२/१-

रक्तातिसार चिकित्सा- तत्र च्छागं पयः शस्तं शीतं समधुशर्करम् । पानार्थं भोजनार्थं च गुदप्रक्षालने तथा ।।
ओदनं रक्तशालीनां पयसा तेन भोजयेत्। रसैः पारावतादीनां घृतभृष्टैः सशर्करैः ।
शशपक्षिमृगाणां च शीतानां धन्वचारिणाम् । रसैरनम्लैः सघृतैर्भोजयेत्तं सशर्करैः ।।
रुधिरं मार्गमाजं वा घृतभृष्टं प्रशस्यते । काश्मर्यफलयूषो वा किंचिदम्लः सशर्करः ।। च.चि.१९/७१-७४

in the treatment of Atisara(diarrhoea) Langhana and Laghu ahara like Yavagu, manda for tarpana, use of medicated drinks with chandana, musta, patol, shunthi, takra(butter milk) are advised. In case of bleeding through GI tract the use of goat milk with sugar,mansa rasa, raktashali should be included in ahara is advised. Ghruta should be used in diet[77].

76. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 19 , pp 548
77. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 19/71-74 , pp 553

छर्दि - Vomiting:-

वातज छर्दि - व्यायामतीक्ष्णौषधशोकरोग भयोपवासाद्यतिकर्शितस्य।
वायुर्महास्त्रोतासि संप्रवृद्ध उत्क्लेश्य दोषांस्तत ऊर्ध्वमस्यन् ।।
आमाशयोत्क्लेशकृतां च मर्म प्रपीडयंश्छर्दिमुदीरयेत्तु।
हृत्पार्श्वपीडामुखशोषमूर्धानाभ्यर्तिकासस्वरभेदतोदैः।।
उद्गारशब्दप्रबलं सफेनं विच्छिन्नकृष्णं तनुकं कषायम्।
कृच्छ्रेण चाल्पं महता च वेगेनार्तिऽनिलाच्छर्दयतीह दःखम्।। च. चि. २० / ७ -९.

In a person emaciated due to physical exercise, irritant drugs, grief, illness, fear, fasting etc. Vayu aggregated in Maha strotas (gastrointestinal tract) excite and throw the doshas upwards and thus cause vomiting due to gastric irritation also producing discomfort pressing the cardiac region[78].

In Vataj Chardi (vomiting) the patient suffers from pain cardiac region and dryness of mouth, pain in head and navel, cough, hoarseness of voice and pricking pain. he vomites with loud sound of eructation, frothy, having broken up black colour, thin and astringent materrial with difficulty, in the little quantity but with severe impulse and great distress.

पित्तज छर्दि -

अजीर्णकट्वाम्लविदाह्यशीतैरामाशये पित्तमुदिर्णवेगम्।
रसायनीभिर्विसृतं प्रपीड्य मर्मोर्ध्वमागम्य वमिं करोति।।
मूर्च्छापिपासामुखशोषमूर्धातालवक्षिसंतापतमोभ्रमार्तः।
पीतं भृशोष्णं हरितं सतिक्तं धूम्रं च पित्तेन वमेत् सदाहम्।। च. चि. २० / १० -११.

78. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 20/7-9 , pp 555

Pitta aggravated in stomach due to intake of food during indigestion and ingestion of pungent, sour, burning hot food spread through Rasayanis (vessels) and pressing heart comes upwards and causes vomiting.

By this the patient is affected with fainting, thirst, dryness of mouth, burning in head, palate and eyes, feeling of darkness and gidiness. he vomits yellow, green, too hot, bitter and smoky material with burning sensation.

अर्श - **(GI bleeding)**: -

संप्राप्ति -

तत्रानात्मवतां यतोक्तैः प्रकोपणैर्विरुद्धाध्यशनस्त्रीप्रसङ्गोत्कटासनपृष्ठयानवेगविधारणदिभिर्विशेषैः प्रकुपिता दोषा एकशो द्विशः समस्ताः शोणितसहिता वा यथोक्तं प्रसृताः प्रधानधमनीरनुप्रपद्याधो गत्वा गुदमागम्य प्रदूष्य गुदवली मांसप्ररोहान् जनयन्ति विशेषतो मन्दाग्नेः; तथा तृणकाष्ठोपललोष्ठवस्त्रादिभिः शीतोदकसंस्पर्शनाद्वा कन्दाः परिवृद्धिमासादयन्ति, तान्यर्शांसीत्याचक्षते। सु. नि. २ / ४

In uncertain persons, by aforesaid exciting factors particularly incompatible food, eating before previous food is digested, sexual intercourse, squatting poison, riding, suppression of natural urges, etc. doshas singly, dually, all or associated with blood are aggravated and spreading to chief passages moves downwards, reach anal folds and after vitiating them produce fleshy growths particularly in those having diminished digestive power; these tuber like growths by rubbing with grass, wood, stone, cloth, etc. or by the excessive contact of cold water develope further which are known as hemorrhoids[79].

पित्तज अर्श -

पित्तान्निलाग्राणि तनूनि विसर्पाणि पीतावभासानि यकृत्प्रकाशानि शुकजिव्हासंस्थानानि यवमध्यानि जलौकावक्रसदृशानि प्रक्लिन्नानि च भवन्ति; तैरुपद्रुतं सदाहं सरुधिरमतिसार्यते, ज्वरदाहपिपासामूर्च्छाश्चास्योपद्रावा भवन्ति, पीतत्वङ्नखनयनदशनवदनमूत्रपुरीषश्च पुरुषो भवति।। सु. नि. २/१०.

79. Sushrut Samhita with commentary Ayurveda Tatvasandipika by Kaviraj Ambikadatta Shastri, Chaukhamba Sanskitti Sansthan, Varanasi (2005), Nidansthan – 2/10 pg 271

Hemorrhoids caused by Pitta are blue typed, thin, spreading, yellowish, liver-like, similar to parrots tongue or leech's mouth, spindle shaped and oozing. Afflicted with these the patient passes blood with burning sensation, thirst and fainting as complications and has yellow skin, nails, teeth, face, urine and stool.

मलावष्टंभ – (Constipation):-

It is not explained as a disease or process of formation of a disease in Ayurvedic texts. It is manifested as a symptom in another diseases.

> वर्चसोऽतिविबन्धोऽधः स्वे स्थाने परिकृन्तति। व्रजत्याशु जरां स्नेहो भूक्ते चानह्यते नरः।।
> चिरात् पीडितमन्नेन दुःखं शुष्कं शकृत् सृजेत् । श्रोणी वंक्षणपृष्ठेशु रुग्विलोमश्च मारुतः।।
> अस्वस्थं हृदयं चैव वर्चसा त्वावृतेऽनिले।। च. चि. २८ / ७० - ७१.

when vayu is covered with faeces stool is constipated[80] too much, there is cutting pain downwards in anorectum, uncuting substance gets digested quickly, the patient suffers from hardness in bowels after meals, due to pressure with food the patient passes hard stool with difficulty and delay, there is pain in hip, groins and back Vayu moves in reverse direction and heart is ill.

Mukhapaka – (Stomatitis):

तिक्तवक्त्रता । क्षारोक्षितक्षतसमा व्रणाः वा.उ. २१-५८, ५९

Pittaj Mukha Paka – (Acute Stomatitis). In this, vitiated pitta dosha causes inflammation and ulceration of oral mucosa. Smaller reddish yellow papules develop throughout the mouth and causes severe burning, altered taste, difficulty in mastication and deglutition[81].

80. Charak Samhita, Vol.1, Tripathi B (2003) Chaukambha Subharati Prakashan, Varanasi, Sutrarsthan 28/70-71 , pp 619
81. Ashtanghridya, Vagbhat with Sarvasunder commentary of Arundatta and Ayurved Rasayan commentary of Hemadry, Chaukhamba Surbharati Prakashan, Varanasi (2010) , Uttarsthan, 21-58,59, pp850

Treatment – Nidan Parivarjan (avoiding causative factors), Snehan, swedana (oleation and fomentation). Shodhana Karma (Vaman, Virechan, Nasya, Rakta mokshan),Kavalgraha / Gandush with Panch valkal Kashaya, Pancha Tikta Kashaya, Yashtimadhu Kashaya, milk, sugarcane juice and ghee. Shaman Dhoomapana (Medicated Smoking). Nasya with Sheeta virya, Pittahara Taila or Ghrita or Kashaya. Lekhana and Pratisaran**.**

Allopathic management of chemotherapy induced side effects

Management of chemotherapy induced side effects described above is a perpetual problem in giving chemotherapy in breast cancers. The allopathic modalities of management of side effects are rather peripheral, which include nutritional support to minimize the weakness, pain control to reduce the painful sufferings, control of bleeding to counteract the blood loss by administering the blood clotting factors, correcting the blood loss by blood transfusion, iron suppliments, intake of heamatinic. Allopathic management of side effects include the following types of medicines-

Anti emetics, antihistaminic, antacids, purgatives, antidiarrhoeal, antibiotics, steroids. Injections of filgreestin to increase the leucocytic counts and to counteract the myelossupretion caused due to chemotherapy. Still with this managent the cancer patients suffer from the severe clinical manifestation of the symptoms like anorexia, nausea, vomiting, taste abnormality, constipation, GI bleeding, diarrhea, stomatitise, alopecia skin and nail discoloration, hyperpigmentaton and severe myelossupretion.

The fact remains that there is a symptomatic allopathic management and patient's quality of life remains poor. Most of patients are not in condition to tolerate chemotherapy or to complete the recommended cycles of chemotherapy. Some times patients drop out chemotherapy, and they also suffer under depressed state of mind. Thus there is a lack of supportive care for the complications of chemotherapy and lack of comprehensive holistic treatment under one roof and under the expert guidance of multidisciplinary team[82]. (Ref; ICMR – consensus document for management of breast cancer.)

82. ICMR-Consensus Documents for Management of Breast Cancer

Drug Review

3 E) Literature review of medicines used to reduce side effects of chemotherapy

A) Mouktikayukta Kamdudha[83]

मौक्तिकस्य प्रवालस्य मुक्ताशुक्ति भवस्थ च ।

वराटिकायाः शंखस्य भस्मानि गैरिकं तथा ।।

गुडुचिकोभ्दवं सत्वं समभागानि कारयेत् ।

अजानिकासिताभ्याञ्च गृठीयाद्राक्तिकाव्दयम् ।।

जीर्णज्वरभ्रमोन्मादपित्तरोगेषु शस्यते ।

अम्लपित्ते सोमरोगे योज्यः कामदुधारसः । र.यो.सा. २६०

Table No:- 5 Details of contents of Mouktikayukta Kamdudha and it's useful action :-

Sr. No	Dravya Name	English Name	Rasa (Taste)	Veerya (Potency)	Vipaka (Post-digestive test)	Doshghnata (Action on doshas)	Karya (Action)
1	Praval	Coral	Madhur (Sweet), Amla (sour), Kashay (Astringent)	Sheeta (Cold)	Madhur (Sweet)	Pittashamak, Kaphaghna	Rasayan , Jwaraghna, Raktapittahar, Vishbadhahar
2	Mouktika	Pearl	Madhur (Sweet), Kashay (Astringent)	Sheeta (Cold)	Madhur (Sweet)	Tridoshshamak	Daha shamak , Balya
3	Shankha	Conch shell	Tikta (Bitter)	Ushana (Hot)	Madhur (Sweet)	Kaph pitta shamak	Chhradighna
4	Shauktika	Peral Shell	Katu (Pungent)	Sheeta (Cold)	Madhur (Sweet)	Vat Pittaghna	Arochakahar, Chhardighna
5	Kapardika	Cowrie shell	Katu (Pungent)	Sheetoshna	Madhur (Sweet)	Vat Kaphaghna	
6	Guduchi	Tinospora cordifolia	Tikta, Kashay	Ushna	Madhura	Tridoshshamak	Deepan, pachak, Pittasarak, Balya, Raktashodhak, Jwaraghna, Dahaprashaman
7	Gairik	Red Lumber Stone	Madhur Kashay	Sheet	Madhur	Pittashamak	Pittashamak , Vishhara

82. Sharma HP Rasa Yoga Sagar Part -1, Krishnadas Ayurved Series, pp 260

B) Mouktik yukta praval Panchamrut[84]

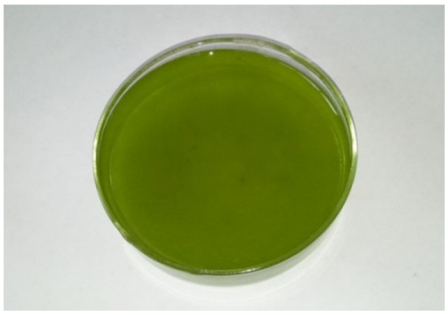
प्रवालमुक्ता फलशंखशुक्ति कपर्दिकानाञ्च समांशभागम् ।
प्रवालमात्रं व्दिगुणं प्रयोज्यं सर्वैः समांशं रविदुग्धामेव ।।
एकीकृतं तव्खलु भाण्डमध्ये क्षिपवा मुखे बन्धनमंत्र योज्यम् ।
गुल्मोदरप्लीहविबध्दकासश्वासाऽग्निमान्द्यान्कफमारुतोत्थान् ।।
अजीर्णमुग्दारह्रदमायघ्नं बालग्रहार्तो परमं प्रशस्तम् ।
मेहामयं मूत्ररोगं मूत्रकृच्छ्र तथाऽश्मरीम् ।योगोत्तमः सर्वगदाऽपहारी ।। (र.यो.सा. ९३)

Table No:-6 Details of contents of Mouktikayukta Praval Panchamrut and it's useful action on chemotherapy side-effects

Sr. No	Dravya Name	EnglishName	Rasa (Taste)	Veerya (Potency)	Vipaka (Post-digestive test)	Doshghnata (Actionon doshas)	Karya (Action)
1	Praval	Coral	Madhur (Sweet), Amla (sour), Kashay (Astringent)	Sheeta (Cold)	Madhur (Sweet),	Pittashak, Kaphaghna	Rasayan , Jwaraghna Raktapittahar, Vishbadhahar
2	Mouktika	Pearl	Madhur (Sweet), Kashay (Astringent)	Sheeta (Cold)	Madhur (Sweet),	Tridoshshamak	Dahashamak, Balya
3	Shankha	Conch shell	Tikta (Bitter)	Ushana (Hot)	Madhur (Sweet),	Kaph pitta shamak	Chhradighna
4	Shauktika	Pearl Shell	Katu (Pungent)	Sheeta (Cold)	Madhur (Sweet),	Vat Pittaghna	Arochakhar, Chhardighna
5	Kapardika	Cowrie shell	Katu (Pungent)	Ushna (Hot)	Madhur (Sweet),	Vatshamak Kaphaghna	Dahshamak, deepan, Raktavikarhar, Pittahar
6	Arka kshira	Calotrophis giganticum	Tikta (Bitter) Lavan (salty)	Ushna (Hot)	Katu	Kaphashamak	Virechaka, Gulmahara

84. Sharma HP Rasa Yoga Sagar Part -2, KrishnadasAyurved Series, pp 93.

C) Padmakadi Ghruta :-



स्मृतिबुध्दयग्निशुक्रौजःकफमेदोविवर्धनम् ।
वातपित्तविषोन्मादशोषालक्ष्मीज्वरापहम् ।।
सर्वस्नेहोत्तमं शीतं मधुरं रसपाकयोः ।
सहस्त्रतीर्यं विधिभिर्घृतं कर्मसहस्त्रकृत् ।।
मदापस्मारमूर्च्छाय शोषोन्मादगरज्वरान् ।
योनिकर्णशिरःशूलं घृतं जीर्णमपदोहति ।।
च.सू. २७/२३१ - २३३ पा. नं. ९६६

Table No:-7 Details of Contents of Padmakadi Ghrut and its useful action on chemotherapy side-effects

Sr. No.	Dravya Name	Botanical Name	Rasa (Taste)	Veerya Potency	Vipaka (Post digestive taste)	Doshaghnata (Action on doshas)	Rogaghnata (Action on Roga)	Karya (Action)
1	Padmak (Kamal) Swaras	Nelumbo Nucifera	Madhur Kashaya	Sheet	Madhur	Pitta _ Kapha nashak	Trushna (Thirst), Daha (Burning all over body), Visphot (Boils), Visha (Toxicity), Visarpa (Herpes), Raktapitaa (Bleeding through openings of body)	Dahaprashaman, varnya,Chhardighna, trushnanigrahan,stambhan, mutravirajaniya, mutravirechaniya,vishghana, Balya
2	Durva[85] Swaras	Cynodon dactylon Pers	Madhur, [86]Tikta, Kashaya	Sheet	Madhur	Pitta nashak Kapha nashak	Trushna (Thirst), Arochak (Loss of taste), Vanti (Vomiting), Visarpa(Herpes), Daha(Burning sensation), Twak Rog (Skin disease)	Prajashtapana, varnya, ropana, dahprashman, stambhan
3	Anantaol	Hemidesmos Indicus	Madhur,	Sheet	Madhur	Tridosha shamak	Agnimandya (Loss of appetite), Aruchi (Loss of taste), Kasa (Cough), Visha (Toxicity), Jwar (Fever), Atisar (Loose motion), Raktapitta (Bleeding through openings of body)	Pittashamak, Rakatprasadak, Sthanya shodhan, Vishghna, Dahaprashaman, jwarhar, purishsangrahaniya.
4	Goghrut		Madhur,	Sheet	Madhur	Vatshamak, Pittashamak	Vishanashak (Toxicy), Rasayan (Rejuvinator), Visarpa (Herpes), Daha (Burning all over body), Agnimandya (Loss of appetite)	Balvardhan Agnidipan

दुर्वा

दुर्वाः कषायः मधुराश्च शीताः पित्ततृषारोचकवान्तिहन्त्र्यः ।
सदाहमूर्च्छाग्रहभूतशान्तिश्लेष्मश्रमध्वंसनतृप्तिदाश्च ।। रा.नि.
दुर्वा स्वाव्दी हिमा तिवता कषाया जीवनी जयेत् ।
कफपित्तास्त्रवीसर्प तृष्णादाहत्वगामयान् ।। (कै. नि.)
दुर्वा शीता कषाया च रवतपित्ताकफापहा । ध. नि.
वृक्षादनी पयस्या च लता चोत्पलसारिवा ।
यथासंख्यं प्रयोवतव्याः गर्भस्त्रावे पयोयुतः ।। सु.शा.१०

पदम – कमल [87]

कमलं शितलं वर्ण्यमधुरं कफापित्तजित्।
तृष्णदाहास्त्राविस्फोटमविषवीसर्पनाशनम् ।।
पद्मबीजं हिम स्वादु कषायं तिक्तकं गुरुः । भा.प्र.
कुमुदं पिच्छिलं स्निग्धं मधुरं हृदि शितलम् ।
पद्मिन्या ये गुणाः प्रोवता कुमुदिन्याश्च ते स्मृताः । भा. प्र.
उत्पलकुमुदपदम्किंजल्कःसंग्राहिकरवतिपत्तप्रशमनानाम्। (च.सू.२५)

अनन्ता [88, 89]

सारिवायुगलं स्वादु स्निग्ध शुक्रकरं गुरु ।
अग्निमाद्यारुचिश्श्वासकासामविषनाशनम् ।।
दोषत्रयास्त्रप्रदरज्वरातीसारनाशनम् । (भा.प्र.)
सारिवे व्दे तु मधुरे पित्तवातास्त्रनाशने ।
कण्डूकुष्ठज्वरहरे मेहदुर्गन्धनाशने ।। (ध.नि.)
अनन्ता संग्राहकरक्तिपत्तप्रशमनानां श्रेष्ठ । (च.सू.२५)

87. Bhavprakash Nighantu by Bhavmishra with Vidyodini Hindi Commentary by Shree Bramha Shankar Mishra and Shree Ruplalji Vaishya, Chaukhamba Sanskrit Samsthan, (2005), 9th Eddition, Nighantu Bhag, Purva khanda grabha prakarana pp. 483
88. Bhavprakash Nighantu by Bhavmishra with Vidyodini Hindi Commentary by Shree Bramha Shankar Mishra and Shree Ruplalji Vaishya, Chaukhamba Sanskrit Samsthan, (2005), 10th Eddition, Nighantu Bhag, Purva khanda grabha prakarana pp.426
89. Dhanvantaari Nighantu :-Hindi commentaryby Dr. Jharkhande jha & Dr.Umapati Mishra, Publisher-chauhamba sanskrit sansthan, Re -edited -2004 ,3 rd edition 1941

D) शतावरी कल्प (Shatavari Kalpa)

शतावरी [90]

शतावरी गुरुः शीता तिक्ता स्वाव्दी रसायनी । मेघाग्निपुष्दि स्निग्धा नेञ्या गुल्मातिसारजित्।

शुक्रस्तन्यकरी बल्या वातपित्तास्ञशोथजित् ।महाशतावरी मेध्या हद्या वृष्या रसायनी ।।

शीतवीर्या निहन्त्यर्शोग्रहणीनयनामयान् ।तदंकुरस्ञिदोषघ्नो लघुरर्शःक्षयापहा ।। (भा.प्र.)

वातपित्तहरी वृष्या स्वादुतिक्ता शतावरी । महती चैव हद्या च मेध्याग्निबलवर्धिनी ।।

ग्रहण्यर्शोविकारघ्नी वृष्या शीता रसायनी ।कफपित्तहरास्तिक्तातस्या एवांकुराः स्मृताः ।। (सु. सू.४६)

शतावरी हिमा तिक्ता रसे स्वादुः क्षयास्ञ जित् । वातपित्तहरी वृष्या रसायनवरा स्मृता ।। (घ.नि.)

भुक्त्वा वरी क्षीतयुतां विलासी भुंक्ते शतं सुन्दरी । सुन्दरीणाम् । (वै.जी.) (अतिवृष्य)

90. Bhavprakash Nighantu by Bhavmishra with Vidyodini Hindi Commentary by Shree Bramha Shankar Mishra and Shree Ruplalji Vaishya, Chaukhamba Sanskrit Samsthan, (2005), 10th Eddition, Nighantu Bhag, Purva khanda grabha prakarana 392

Table No:-8

Details of Contents of Shatavari Kalpa and its useful action on chemotherapy side-effects

Sr. No	Dravya Name	Botanical Name	Rasa (Taste)	Veerya Potency	Vipaka (Post digestive taste)	Doshaghnata (Action on doshas)	Rogaghnata (Action on Roga)	Karya (Action)
1	Shatavari	Asparagus racemosus	Madhur tikta	Sheet	Madhur	Vat - pittashamak	Grahani (Iritabale bovel) Arsha, (Pilse)Kshay (Tubarculosis) Gulm, Atisar(Diarrhoea)	Balya, Vayasthapan, Pittashamak, rasayan. Netrya, Sthanyakar, shothhar, medhya, rudhya, brushya, agnivardhan
2	Sugar		Madhur	Sheet	Madhur	Pitta shamak	Tarpan ,Balya	

REVIEW OF PREVIOUS WORK DONE

1) ICMR - Clinical trials of Guduchi & Ashwagandha by Dr.U. Thatte. CTRI Number CTRI/2008/091/000052 [91]

Title -- A clinical trial to study the effects of Ayurvedic formulation containing Ashwagandha and Guduchi in improving the quality of life in patients of breast cancer receiving chemotherapy as treatment. Study group - Tablet PHP-Cancer containing hydro500 mg BD for 6 months -alcoholic extracts of Withania somnifera 150mg and Tinospora cordifolia 200 mg. Tablet Placebo 500 mg BD for 6 months. Sample size 60.

Primary outcome - The primary outcome measures will be 20% improvement in the QOL score over and above that obtained in the group receiving placebo and less than 10% difference in adverse events (including laboratory variables) between placebo and active treatment groups.

2) Indian journal of Medicinal & Pediatric oncology, vol.29, no.2, 2008.Original article II[92]

Title - An Ayurvedic Herbal Compound to reduce Toxicity to cancer Chemotherapy - A randomized controlled trial.by Saxena, Dixit etc. MAK – Maharshi Amrit Kalash is an Ayurvedic compound containing many herbs rich in antioxidants. Evaluated its role in reduction of chemotherapy toxicities among woman with breast cancer.214 patients of Ca breast receiving chemotherapy. There was significant reduction in toxicities in MAK group. Vomiting – 95%,Anorexia – 95% reduced. No improvement in stomatitis, diarrhea, alopecia and leucopenia.

91. ICMR - Clinical trials of Guduchi & Ashwagandha by Dr. U. Thatte. CTRI Number CTRI/2008/091/000052
92. Indian journal of Medicinal & Pediatric oncology, vol.29, no.2, 2008.Original article II

Conclusion - MAK reduces chemotherapy induced vomiting, anorexia and improving general well being of patients.

3) RAV,6-7 Feb 16 New Delhi. Selected Research papers from National seminar on Management of cancer through Ayurveda.RAV publication - Feb.2012. Page no.276[93]

Title - Management of side effects of cancer chemotherapy with Ananta Kalpa - A sugar based Ayurvedic preparation of Ananta (Hemidesmus indicus) by Dr S.P.Sardeshmukh.

Title-Atharva anantakalpa is found to be effective in the minimizing of toxicities of chemotherapy. 59 patients had completed course of chemotherapy in expected time. Toxicities of chemotherapy like nausea, loss of appetite, vomiting, diarrhea were remarkably reduced in more than 60% of patients.

4) Support Care Cancer.2014 Nov, 22(11):3007-15.doi:10.1007/s00520-014-2294-0.EPUB2014 Jun7 [94]

Title - Efficacy of combinations of Ayurvedic drugs in alleviating drug toxicity and improving quality of life of cancer patients treated with chemotherapy by Vineeta Deshmukh, Kulkarni A et al.

Random patients with malignancies of different tissues, grade, and stage were divided into two groups according to their treatment modality. 15 patients treated with 6 cycles of chemotherapy, and other group divided in 3 arms who received Ayurvedic drugs and chemotherapy.

93. 6-7 Feb 16 New Delhi. Selected Research papers from National seminar on Management of cancer through Ayurveda. RAV publication - Feb.2012. Page no.276
94. Support Care Cancer.2014 Nov, 22(11):3007-15.doi:10.1007/s00520-014-2294-0.EPUB2014 Jun7

Nineteen patients in arm 1 received Moutikyukta Kamdudha; Mouktikyukta Praval Panchamrut from the beginning of chemotherapy, 15 patients of arm 2 received Moutikyukta Kamdudha and Moutikyukta Praval Panchamruta after completing chemotherapy. 18 patients of arm 3 received additional Suvarnra bhasmadi formulation after completing chemotherapy.

Results: There was significant improvement in all 3 arms compared with control groups in nausea, loss of appetite, constipation and fatigue. There was significant improvement in Karnofsky score and global score of QLQ. Haemogram did not show significant difference between control group and study group.

5) Ashwasan, ICAC, 6-7 Dec. 1997, pg 142[95]

Title-Efficacy of Kamdudha and Praval in counter acting side effects of chemotherapy and radiothaerapy.

Kamdudha- Praval pishti are found to be effective in counteracting side effects of chemotherapy and radiation which are related to Annavaha, Purishvaha, Rasavaha, and Raktavahasrotasa. These medicine are highly effective on side effects of chemotherapy namely burning, loose motions, pain, acidity, altered bowel habit, pigmentation of skin.

6) Dr. S. P. Sardeshmukh. Proceeding of 2nd International conference on "Ayurved for Cancer Research Paper presented at 2nd International Conference on Ayurved for Cancer Year 2002.[96]

Title - Efficacy of Padmakadi Ghrut in counteracting side reactions of Chemotherapy and Radiotherapy.

95. Ashwasan, ICAC , 6-7 Dec. 1997, pg 142
96. Dr. S.P.Sirdeshmukh. Proceeding of 2nd International conference on "Ayurved for Cancer Research Paper presented at 2nd International Conference on Ayurved for Cancer Year2002.

Padmakadi Ghrut is found to be effective in counter acting side effects of chemotherapy namely burning, vomiting, bleeding, pigmentation, loose motion, acidity.

7) www.ncbi.nlm.gov/pmc/articlespmc3203371, journal-Ayu 20100u-Dec 31(4) 417- 423[97].

Title - Efficacy of Rasayana Avaleha as adjuvant to radiotherapy & chemotherapy in reducing Adverse effects. By Purvi Vyas, A. B. Thakar, M. S. Baghel, Arvind Sisodia, Yogesh Deole.

Thirty-six patients fulfilling the diagnostic criteria of carcinoma (under treatment of radiotherapy and Chemotherapy) were randomly selected .*Rasayana Avaleha* an Ayurvedic preparation — as adjuvant to allopathic chemotherapy. The herbal preparation comprises of *Emblica officinalis, Ashwagandha- Withania somnifera, Guduchi Tinospora cordifolia, Glycirrhiza glabra, Leptadenia reticulat), Tulasi Ocimum sanctum*, and *Piper longum Rasayana Avaleha* showed significant results on nausea and vomiting (86%), mucocitis (72.14%), and fatigue (58.93%). Also, other symptoms like xerostomia (48.17%), alopecia (45.24%), and tastelessness (33.59%) were decreased. Administration of *Rasayana Avaleha* along with chemotherapy and radiotherapy can improve the quality of life of cancer patients.

8) HHS Public Access, PMC3188425- 2011 Oct 6, www.ncbi.nlm.nih.gov/ pubmed/[98]

Title - Treatment of chemotherapy induced nausea in cancer patients. Julie L. Ryan.
Ginger supplementation and acupressure are used to aid in the reduction of nausea and improve quality of life in cancer patients receiving chemotherapy.

97. www.ncbi.nlm.gov/pmc/articlespmc3203371, journal-Ayu 20100u-Dec 31(4) 417- 423.
98. HHS Public Access, PMC3188425- 2011 Oct 6,www.ncbi.nlm.nih.gov/pubmed/

9) DARU journal of pharmaceutical sciences 2014, jan 6,doi; 10.1186/2008-2231-22-7[99]

Title - The extracts of cuscuta reflexa Roxb. in treatment of cyclophosphamide induced alopecia, S. Patel, V. Sharma. In this work it was be concluded that the petroleum ether extract and ethanolic extract of cuscuta reflexa were used to prevent hair loss or to treat alopecia during chemotherapy.

99. DARU journal of pharmaceutical sciences 2014, jan 6,doi; 10.1186/2008-2231-22-7

MATERIALS AND METHODOLOGY

Plan of work done -

- Diagnosed breast cancer patients receiving chemotherapy were selected for the study from the integrated cancer research centre of BSDT Wagholi.
- The diagnosis of breast cancer was confirming on the basis of histopathological examination reports.
- References of arbuda, stana, stanya, dyavya etc. were taken from Bruhattrayee and Laghutrayee
- References of breast cancer and chemotherapy were collected from modern science.
- CG4 - Standardized Ayurvedic medicines (group of 4 medicines- Mauktikyuktakamadudha, Mauktikyuktapravalpanchamrut, Padmakadi Ghruta, Shatavari Kalpa) from Atharva Ayurved Pharmacy were used for the study.
- Clinical trial design is open labelled controlled clinical trial.
- 100 Patients were divided in 2 groups of 50 patients each. Study group (Group A) of 50 patients receiving Ayurvedic formulation along with chemotherapy and control group of 50 patients (Group B) receiving only chemotherapy.
- Specially designed informed written consent was taken.
- Detail case was taken on specially designed CRF.
- Criteria for assessment like Karnofsky scoring for performance status[100] and QLQ were noted at three time points – After 1st chemotherapy (time point a), middle of the chemotherapy (time point b),15 days after last chemotherapy (time point c).
- Side effects were noted as per Common Toxicity Criteria (CTC) derived by Cancer Therapy Evaluation Program (CTEP).[101] Symptoms were noted after each chemotherapy and15 days after last chemotherapy.
- Follow ups were taken after every chemotherapy and 15 days after last chemotherapy.
- Investigations were done before and after each chemotherapy.

- Statistical analysis was done using Man Whitney test for symptoms, paired t Test for laboratorial investigations, Karnofsky score for performance status and Quality life Questionnaire[102].

Materials and Methods

Diagnosed Breast Cancer patients receiving chemotherapy were selected for the study from the cancer research centre of BSDT Wagholi.

All the patients were subjected to the screening test of random blood sugar levels to rule out diabetes as one of the medicines given to study group patients was containing Shatavari Kalpa, a sugar based medicine.

.

Type of cancer selected for study – Breast cancer.

Sample size - 100 histopathologically diagnosed breast cancer patients were selected for the study. 50 patients were incorporated in each group.

Medicine –

Ayurvedic Medicines - CG4 (combination of 4 Ayurvedic medicines).

<u>Ingredients of CG4</u> :-

- Moukticyuktakamdudha
- Moukticyuktapravalpanchamruta
- Shatavari Kalpa
- Padmakadi Ghruta

All ingredients in CG4 formulation used were from Atharva Nature Healthcare Pvt. Ltd., Wagholi, and Pune.

102. The European organization for research and treatment of cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology (1993), Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, Filiberti A, http://www.ncbi.nlm.nih.gov/pubmed/8433390

Chemotherapy regimen used in breast cancer treatment.[103]

Patients receiving Chemotherapy regime according to standard chemo protocols used in Breast cancer like CAF,CMF, AC-T,FEC etc. were enrolled.

CAF - Cyclophosphamide, Doxorubicin, 5 flurouracil

CMF – Cyclophosphamide, Methotrexate, 5 flurouracil

CG -Carbopatin, Gemcitabine

FEC - 5flurouracil, Epirubicin, Cyclophosphamide

AC-T – Doxorubicin, Cyclophosphamide, Paclitaxel

TAC – Docetaxel, Doxorubicin, Cyclophosphamide

This contains medicines- Cyclophosphamide, 5 flurouracil, Doxorubicin, Epirubicin, Carbopatin, Gemcitabine, Paclitaxel, Docetaxel, Methotrexate.

Method

Clinical trial was carried in two groups

1. **Group A (Study group)** – Patients undergoing chemotherapy and simultaneously taking Ayurvedic treatment CG4.
2. **Group B (Control group)** – Patients undergoing chemotherapy.

Screening Blood sugar – BSL - Randomwas done to rule out diabetes mellitus.

Clinical Trial Design -

Open labelled controlled clinical trial.

Inclusion criteria-

1. Breast cancer patients scheduled to receive intravenous chemotherapy.
2. Patients of age group 25-75 years.

103. Protocol in Chemotherapy Your Companion In Cancer Treatments, Dr.Vikram Sanghavi

Exclusion criteria-

1. Patients with not confirmed diagnosis of breast cancer.
2. Patients suffering from diabetes mellitus as one of the ingredient of CG4 is sugar based
3. Patients likely to receive radiation therapy in combination with chemotherapy.
4. Male patients of breast cancer

Assessment criteria –

- Side effects of chemotherapy like anorexia, nausea, vomiting, diarrhoea, taste abnormality, stomatitis, constipation, GI bleeding, alopecia, nail discoloration, skin rash, hyperpigmentation, photosensitivity were assessed as per Common Toxicity Criteria (CTC) derived by Cancer Therapy Evaluation Program (CTEP) (CTCAE v4.03 Pub: 14/06/2010,ref:http://ctep.cancer.gov)
- Karnofsky scoring for performance status
- QLQ – Questionnaire to assess quality of life
- Complete blood count (CBC) was noted after each chemotherapy. Liver function test (LFT) and Renal function test (RFT) were noted at three time points.

Side effects of chemotherapy were assessed according to Ayurveda by correlating these side effects to effects of chemotherapy with Dosha, Dhatu, Mala and Strotas.

Table No:-9 Dose Design of CG4 :-

Sr. No.	Name of medicine	Matra	Kala	Anupana
1	Moukticyuktakamdudha	250 mg	Vyanodan (Morning – Evening after breakfast and snacks)	Milk
2	Moukticyukta Praval Panchamrut	250 mg	Vyanodan (Morning – Evening after breakfast and snacks)	Milk
3	Shatavari Kalpa	5 grams	Vyanodan (Morning – Evening after breakfast and snacks)	Milk
4	Padmakadi Ghruta	5 grams	Apankal (Before lunch and dinner)	Water

- Dosages of the study medicines were decided as per the reference from Ayurveda Sar Sangraha[104], Rasa Yoga Sagar .The dose of Ghruta was decided as per the reference from Sharangdhar Samhitatrutiyakhanda 1/6 Snehapana Vidhi Adhyay.
- Aushada sevana Kala - Vyanodankala (After morning breakfast and after evening snacks) and Apanakala (before lunch and dinner)

Duration of treatment -

Simultaneously with chemotherapy and 15 days after completion of last chemotherapy in study group patients.

Side effects of chemotherapy -

Commonly observed side effects of chemotherapy regimens were selected as assessment criteria.

Table No:-10 Showing gradation of commonly observed Side effects of Chemotherapy

Haematologicalside effects

Myelosuppression	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**
Leucocytopenia	< LLN – 3000/mm^3; < LLN – 3.0 x10e9/L	< 2000-1000/mm^3; < 3.0 – 2.0 x10e9/L	< 2000-1000/mm^3;< 2.0-1.0 x 10e9/L	<1000/mm^3; < 1.0x 10e9/L
Thrombocytopenia	< LLN - 75000/mm^3	< 75000-50000/mm^3	< 50000-25000/mm^3; < 50.0-25.0 x 10e9/L	< 25000/mm^3;<25.0 x 10e9/L
Anaemia	Haemoglobin (Hgb) < LLN - 10.0g.dL; <	Hgb<10.0 – 8.0 g/dl; < 6.2 – 4.9	Hgb< 8.0 g/dL; 4.9 mmol/L; < 80 g/L;	<6.5g/dl <4.0mmol <65g/L

	LLN -6.2 mmol/L; < LLN – 100 g/L	mmol; < 100- 80 g/L	transfusion indicated	

Gastrointestinal side effects.				
	Grade 1	Grade 2	Grade 3	Grade 4
Anorexia	Loss of appetite without alteration in eating habits	Oral intake altered without significant weight loss or malnutrition; oral nutritional supplements indicated	Associated with significant weight loss or malnutrition(e.g., inadequate oral intake); IV fluids, tube feeding or TPN indicated	Life-threatening consequences
Nausea	Loss of appetite without alteration in eating habits	Oral intake decreased without significant weight loss, dehydration or malnutrition	Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated	-
Vomiting	1 - 2 episodes (separated by 5 minutes) in 24 hrs	3 - 5 episodes (separated by 5 minutes) in 24 hrs	>=6 episodes (separated by 5 minutes) in 24 hrs; tube feeding, TPN or hospitalization indicated	Life-threatening consequences; urgent intervention indicated
Taste abnormality	Altered taste but no change in diet	Altered taste with change in diet (oral supplement) noxious or unpleasant taste, loss of taste.	---	-----

Mucositis/ stomatitis(clinical exam) - Oral cavity - Larynx - Pharynx -Trachea - Oesophagus --Stomach -Small bowel -Large bowel -Rectum - Anus	Erythema of mucosa	Patchy ulceration or pseudomembranes	Confluent ulceration or pseudomembranes bleeding with minor trauma	Tissue necrosis, significant spontaneous bleeding, Life threatening consequence
Mucositis/stomatitis (functional or symptomatic) - Oral cavity - Larynx - Pharynx -Trachea - Oesophagus --Stomach -Small bowel -Large bowel -Rectum - Anus	Upperaerodigrstivetract sites: Minimal symptoms, normal diet, minimal respiratory symptoms but not interfering with function	Upper aerodigestive tract sites: Symptomatic but can eat and swallow modified diet, respiratory symptoms interfering with function but not interfering with ADL Lower GI sites: Symptomatic, medical intervention indicated but not interfering with ADL	Upper aerodigestive tract: Symptomaticand unable to adequate aliment or hydrate orally, respiratory symptoms interfering with ADL. <u>Lower GI sites:</u> Stool incontinence or other symptoms interfering with ADL	Symptoms associated with life-threatening consequence.
Diarrhoea	Increase of <4 stools per day over baseline; mild increase in ostomy output compared to	Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output	Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated;	Life-threatening consequences; urgent intervention indicated

	baseline	compared to baseline	severe increase in ostomy output compared to baseline; limiting self-care ADL	
GI bleed --- Haemorrhagic	Asymptomatic, mild, intervention,(other	Symptomatic and medical intervention or minor cauterization indicated	Interfering with ADL, interventional radiology, endoscopic or operative intervention indicated	Life-threatening Consequences
Constipation	Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL	Constipation with manual evacuation indicated; limiting self-care ADL	Life-threatening consequences; urgent intervention indicated

Dermatological Side effects:

	Grade 1	Grade 2	Grade 3	Grade 4
Alopecia	Normal	Mild hair loss	Pronounced hair loss	-
Skin rash	None	Macular or popular eruption or erythema without	Macular or popular eruption or erythema with pruritus or other associated	Symptomatic generalised erythroderma or macular, popular or

		associated symptoms	symptoms covering < 50% of body surface area	vesicular eruption or desquamation covering 50% of body surface area.
Nail discoloration	Normal	Discolouration or ridging (koilonchia) or pitting	Partial or complete loss of nail(s) or pain in nailbeds.	-
Photosensitivity	Painless erythema and erythema covering <10% BSA	Tender erythema covering 10-30% BSA	Erythema covering >30% BSA and erythema with blistering; photosensitivity; oral corticosteroid therapy indicated; pain control indicated (e.g., narcotics or NSAIDs)	Life-threatening consequences; urgent intervention indicated
Hyper pigmentation	Hyper pigmentation covering <10% BSA; no psychosocial Impact	Patchy ulceration or pseudo membranes Hyper pigmentation covering >10% BSA; associated		-

		psychosocial impact		

Karnofsky scoring for performance status

General well-being and activities of daily life were assessed from patients own point of view by using Karnofsky score to compare effectiveness of therapies. Ascending order of Karnofsky score shows improvement in well-being of patients. The assessment of these scores was as per the formulae described by Crooks et al**.**

Table No:-11 showing particulars regarding status of Karnofsky score

Patient do not need special care and able to carry normal day to day activity.	100	Patient is normal without complaints and evidence of disease.
	90	Patient is able to carry normal activity with minor signs and symptoms of the disease.
	80	Patient can do normal activity with minimum effort with some signs and symptoms of the disease.
Patient cannot work, only live at home and can take care for personal needs. Rarely assistance needed.	70	Patient has to take self-care and cannot perform normal activity.
	60	Patient has to take self-care and occasionally need assistance, but can able to care for most of his personal needs.
	50	Patient requires considerable assistance with medical care.
Patient can not take care for self. Require hospital care. Disease is progressing rapidly.	40	Patient is disabled and needs hospital admission, special care and assistance.
	30	Patient is severely disabled; hospital admission is needed although not on the verge of death.
	20	Patient is very ill, hospitalized and active treatment intervention is necessary.
	10	Patient is declining state, fatal process

		progressing rapidly.
	0	Death.

The use of the Karnofsky Performance Scale in determining outcomes and risk in geriatric outpatients (1991), Crooks, V, Waller S, et al ,J Gerontol46, pp 139-144

EORTC Quality of Life Questionnaire

QLQ C – 30 – General Questionnaire for all types of cancer

QLQ-C30 questionnaire is designed by European Organization for Research and Treatment of Cancer (EORTC), which consists of functional, symptom and global scores, recorded in patient's own perspective. High functional score represents high level of functioning. High symptom score represents a high level of symptomatology while overall QoL was assessed in terms of global score, the high score representing healthy status**.**

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:
Your birthdate (Day, Month, Year):
Today's date (Day, Month, Year): 31

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4
16.	Have you been constipated?	1	2	3	4

Please go on to the next page

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Ver Mu**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

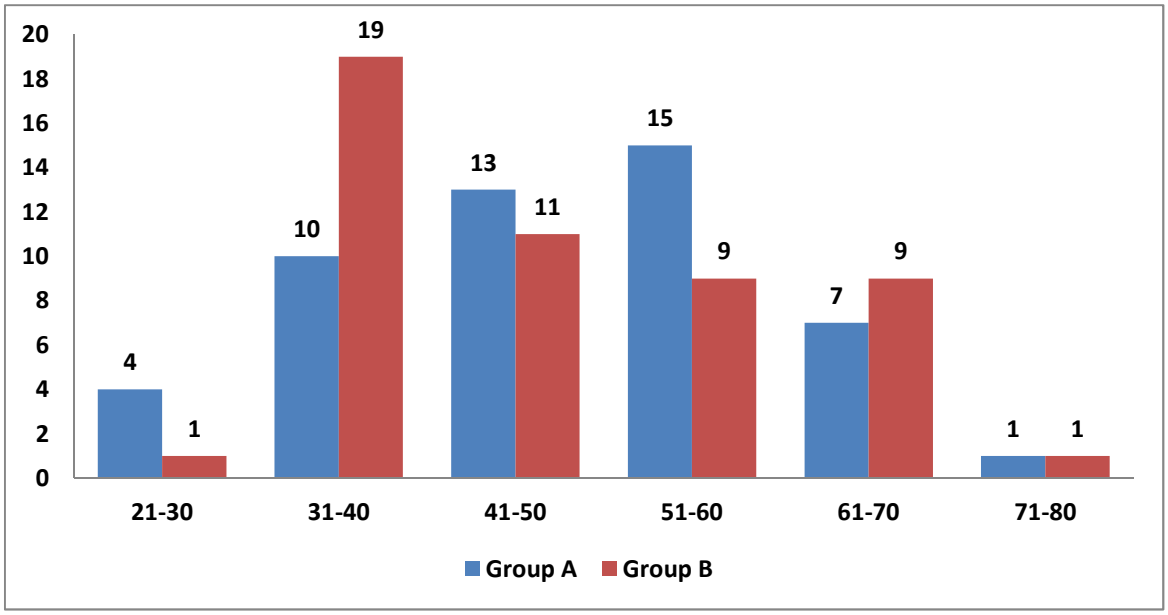
OBSERVATIONS AND RESULTS

1) Observation of demographic data

Table12 :- showing age wise distribution of Breast cancer patients

Sr.No.	Age	Group A	Group B
1	21-30	4	01
2	31-40	10	19
3	41-50	13	11
4	51-60	15	09
5	61-70	7	09
6	71-80	1	01
TOTAL		50	50

Graph 1 – Graphical representation of age wise distribution of breast cancer patients

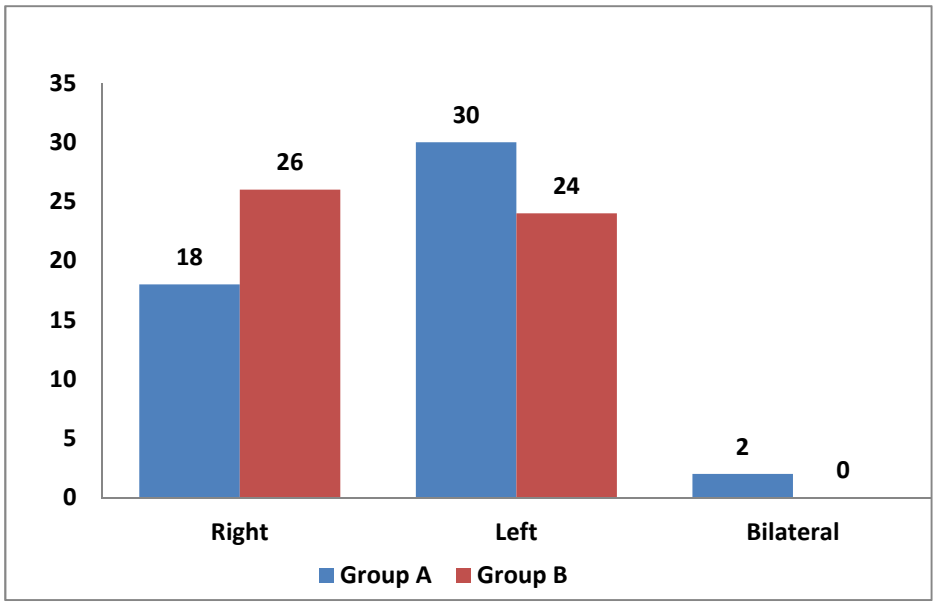


In this study, patients were divided into 6 age groups. Maximum numbers of patients (77%) were between the age group 31 to 70 years.

Table: 13 -showing distribution of Breast cancer patients as per side of the affected organ

Sr. No.	Side	Group A	Group B
1	Right	18	26
2	Left	30	24
3.	Bilateral	2	0
TOTAL		50	50

Graph 2. – Graphical representation of distribution of breast cancer patients as per side of the affected organ

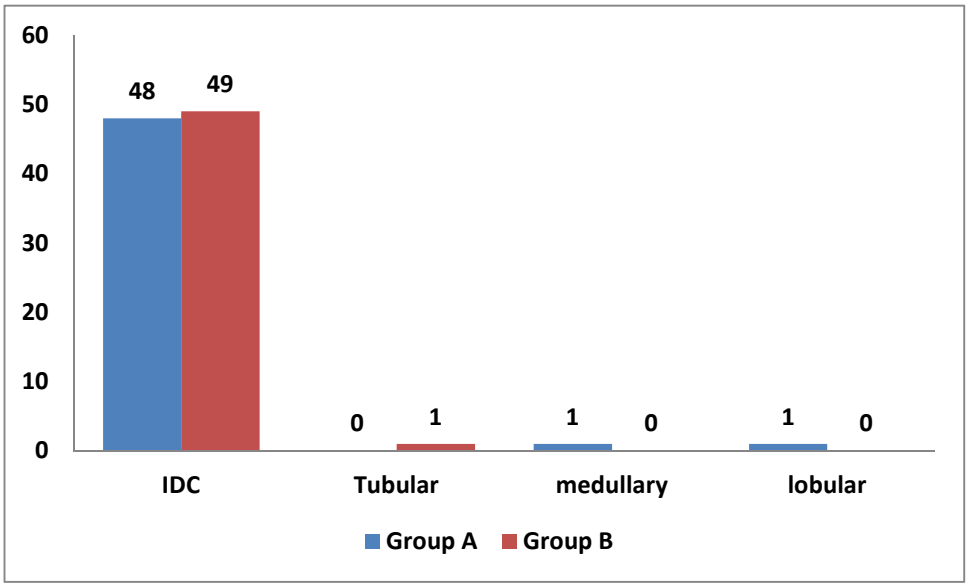


Out of 50 patients in Group A maximum no. of patients were diagnosed with Right sided breast cancer, where in group B maximum number of patients (26) were diagnosed with left side breast cancer.

Table 14:- Table showing the Histopathological type wise distribution of Breast cancer patients

Sr. No.	Histopathological type	Group A	Group B
1	IDC	48	49
2	Tubular	0	01
3	Medullary	01	0
4	Lobular	01	0
TOTAL		50	50

Graph 3 : – Graphical representation of Histopathological type wise distribution of breast cancer patients.

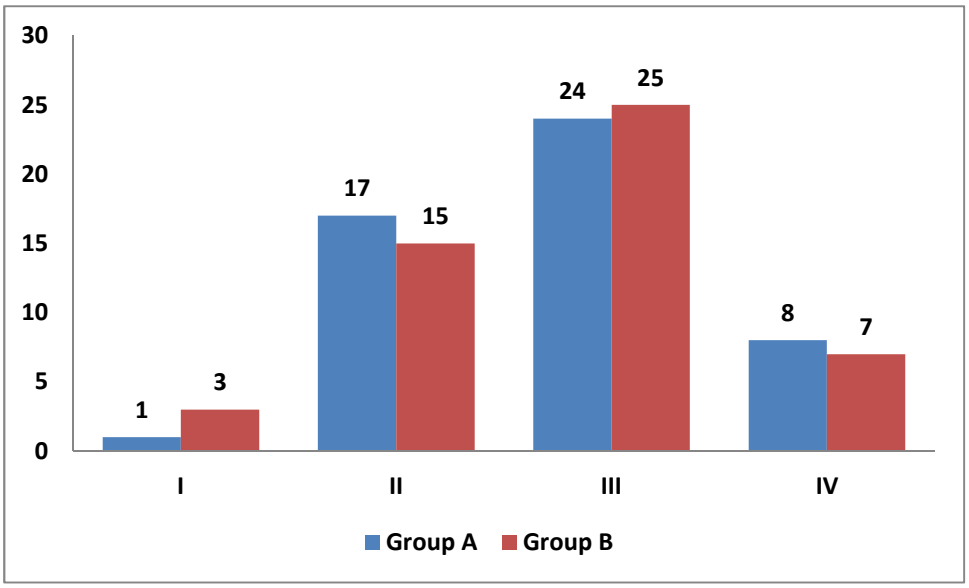


Out of 50 patients in group A, 48 patients were of Infiltrating Duct Carcinoma, 1 patient was diagnosed as Tubular carcinoma, 1 patient of medullary carcinoma and 1 of lobular carcinoma. Out of 50 patients of Group B 49 patients were of Infiltrating Duct Carcinoma, 1 patient was diagnosed as Tubular carcinoma. 97% patients were of IDC.

Table15:- Table showing the stage wise distribution of Breast cancer patients

Sr. No.	Stage	Group A	Group B
1	I	1	03
2	II	17	15
3	III	24	25
4	IV	8	07
TOTAL		50	50

Graph 4. – Graphical representation of stage wise distribution of breast cancer patients

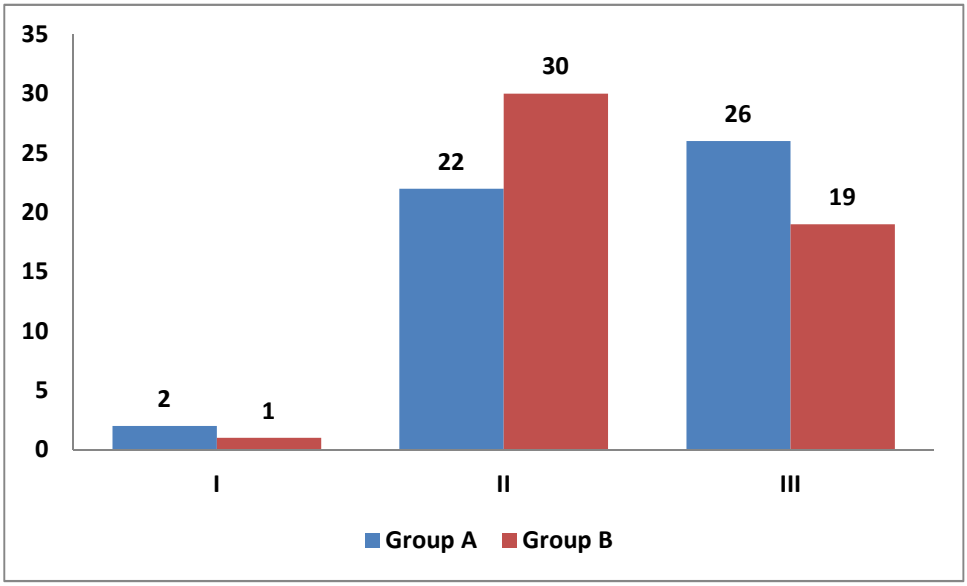


In stage wise distribution of Breast cancer patients maximum number of patients were of stage II and stage III (32% & 49% respectively) in both the groups.

Table 16:- Table showing the Histopathological grade wise distribution of Breast cancer patients.

Sr. No.	Histopathological grade	Group A	Group B
1	I	02	01
2	II	22	30
3	III	26	19
TOTAL		50	50

Graph 5. – Graphical representation of the Histopahological grade wise distribution of breast cancer patients

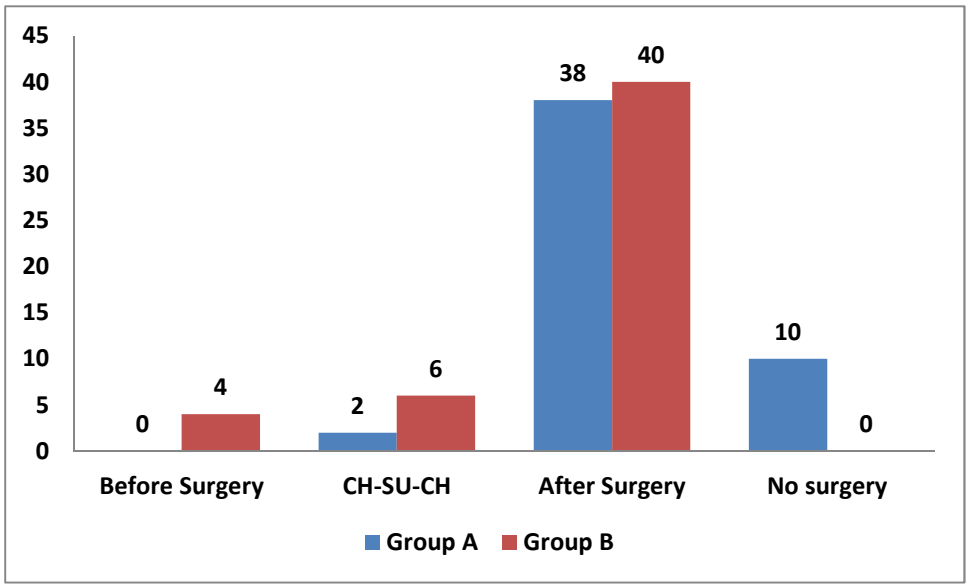


In histopathological grade wise distribution of Breast cancer patients, 2 from Group A and 1 patient from Group B were of Grade I, 22 patients from Group A and 30 patients from Group B were of Grade II and 26 patients of Group A and 19 patients of Group B were of Stage III. Maximum numbers of patients were from Grade II and III in both the groups (52% & 45% respectively)

Table17:-Table showing the distribution of Breast cancer patients with respect to prior treatment

Sr. No.	Chemo	Group A	Group B
1	Before Surgery	0	04
2	Chemo – Surgery - Chemo	2	06
3	After Surgery	38	40
4	No surgery	10	0
TOTAL		50	50

Graph 6:- Graphical representation of distribution of Breast cancer patients with respect to prior treatment

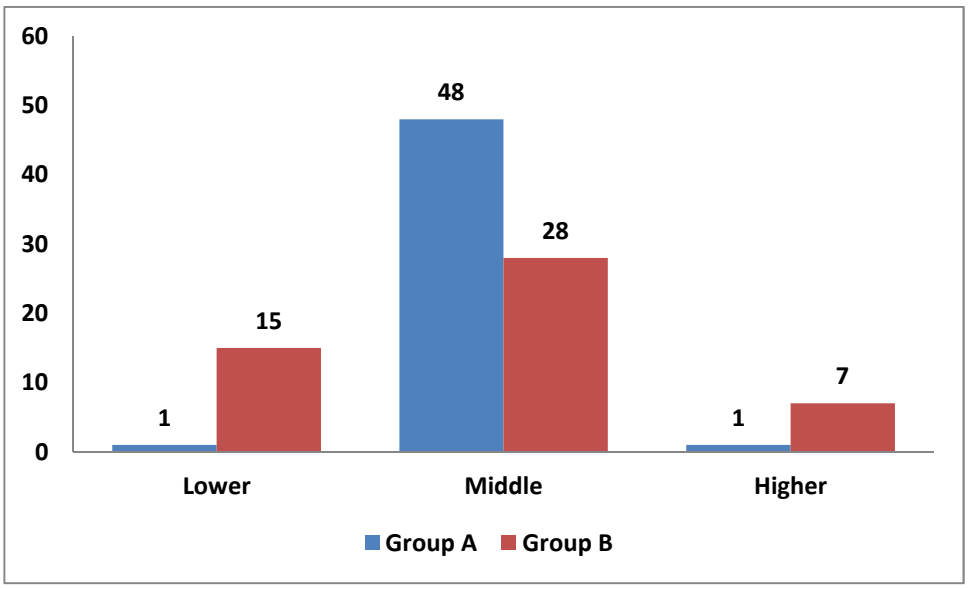


In this study, maximum number of patients took chemotherapy after surgery in both the groups. (78%).

Table18: Table showing the Socio-economic status wise distribution of Breast cancer patients

Sr. No.	Economical status	Group A	Group B
1	Lower	1	15
2	Middle	48	28
3	Higher	1	07
TOTAL		50	50

Graph 7:- Graphical representation of Socio-economic distribution of breast cancer patients

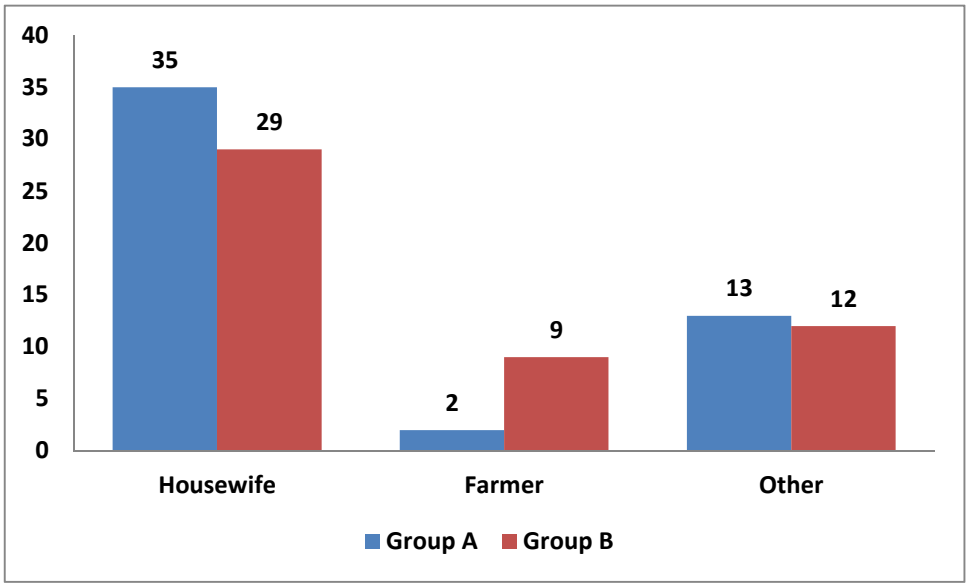


Out of 50 patients of Group A, maximum 48 patients were of Middle income group, 1 patient was of higher income group, while in Group B 15 patients were of Lower income group, 28 patients of Middle income group and 7 patients were of Higher income group. 76% patients were from middle income group.

Table19: Table showing the occupation wise distribution of Breast cancer patients

Sr. No.	Occupation	Group A	Group B
1	Housewife	35	29
2	Farmer	2	09
3	Other	13	12
TOTAL		50	50

Graph 8:- Graphical representation of occupation wise distribution of breast cancer patients.

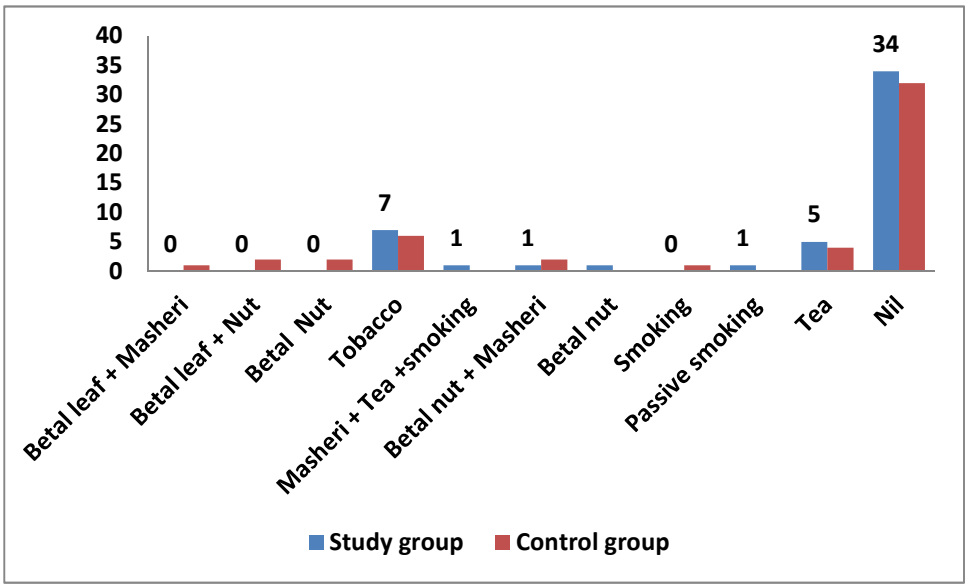


Out of 50 patients in Group A 35 patients were housewives, 2 patients were in farming, 13 patients were other than the above mentioned occupations. In Group B 29 patients were housewives, 9 patients were in farming, 12 patients were other than the above mentioned occupations.

Table20: Table showing the addiction wise distribution of Breast cancer patients.

Sr. No.	Type of Addiction	Group A	Group B
1	Betel leaf + Masheri	0	1
2	Betel leaf + Nut	0	2
3	Betel Nut	1	2
4	Tobacco	7	6
5	Masheri + Tea +smoking	1	0
6	Betel nut + Masheri	1	2
7	Smoking	0	1
	Passive smoking	1	0
8	Tea	5	4
9	Nil	34	32
TOTAL		50	50

Graph 9:- Graphical representation of addiction wise distribution of breast cancer patients.



Out of 50 patients of Group A, 7 patients were having addiction of tobacco, 1 patient had addiction of masheri, smoking and excess of tea,1 patient had addiction of betel nut and masheri,1 patient had addiction of only betel nut,1 patient gave history of passive smoking, 5 patients had habit of excessive tea intake.

Observations on side – effects (Toxicities) of Chemotherapy in Breast Cancer patients.

All toxicities of chemotherapy are graded as per Common Toxicity Criteria (CTC) described by NCI, which is a worldwide accepted gradation system for side-effects of cancer. They are graded from 0 to 2 to 0 to 3 as described in CTC.

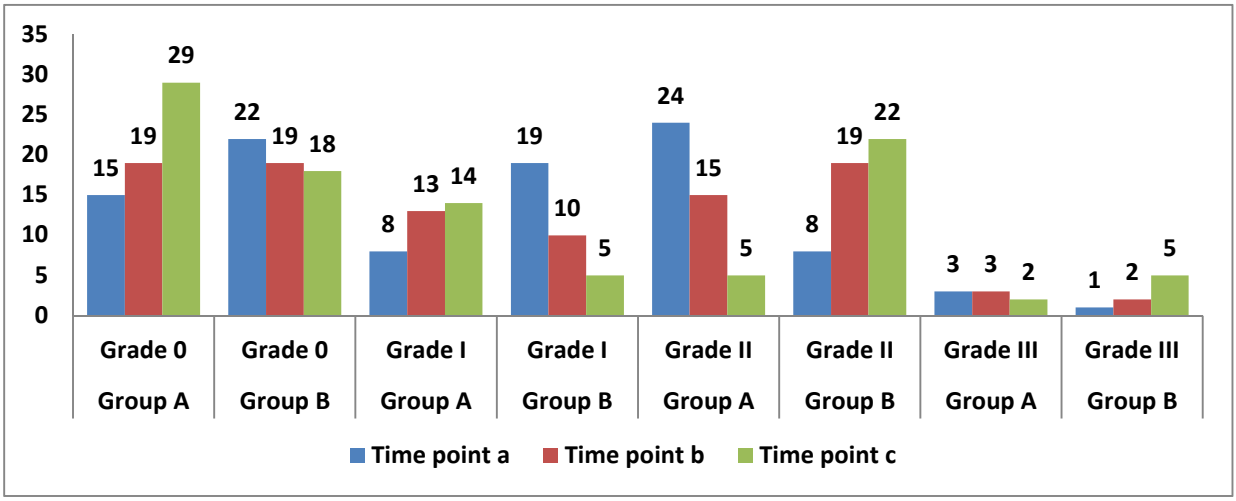
Gradation of symptoms is noted at 3 times–points i.e. after the 1st chemotherapy (a), in the middle of chemotherapy (b) and 15 days after the last chemotherapy (c).

Table21: Table showing grade wise distribution of patients suffering from Anorexia at three time points in both groups.

1. Anorexia

1. Anorexia								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	15	22	8	19	24	8	3	1
Time point b	19	19	13	10	15	19	3	2
Time point c	29	18	14	5	5	22	2	5

Graph 10:- Graphical representation of grade wise distribution of patients suffering from Anorexia at three time points in both groups.



It is observed as per the graph that, at time point a 15 patients of A group & 22 patients of B Group didn't complaint of Anorexia (i.e. Grade 0).While at time point b 19 patients of A group & 19 patients of B Group didn't complaint of Anorexia (ie. Grade 0). It is observed at time point c 29 patients of A group & 18 patients of B Group didn't complaint of Anorexia (i.e. Grade 0)

At time point a, 8 patients of A group A & 19 patients of B Group complaint of Anorexia (i.e. Grade I). While at time point b, 13 patients of A group & 10 patients of B Group complaint of Anorexia (i.e. Grade I). It is observed at time point c 14 patients of A group & 5 patients of B Group complaint of Anorexia (i.e. Grade I)

At time point a 24 patients of A group A & 8 patients of B Group complaint of Anorexia (i.e. Grade II). While at time point b 15 patients of A group & 19 patients of B Group complaint of Anorexia (i.e. Grade II). It is observed at time point c 5 patients of A group & 22 patients of B Group complaint of Anorexia (i.e. Grade II)

At time point a -3 patients of group A & 1 patients of B Group complaint of Anorexia (i.e. Grade III). While at time point b 3 patients of A group & 2 patients of B Group complaint of Anorexia (i.e. Grade III). It is observed at time point c 2 patients of A group & 5 patients of B Group complaint of Anorexia (i.e. Grade III)

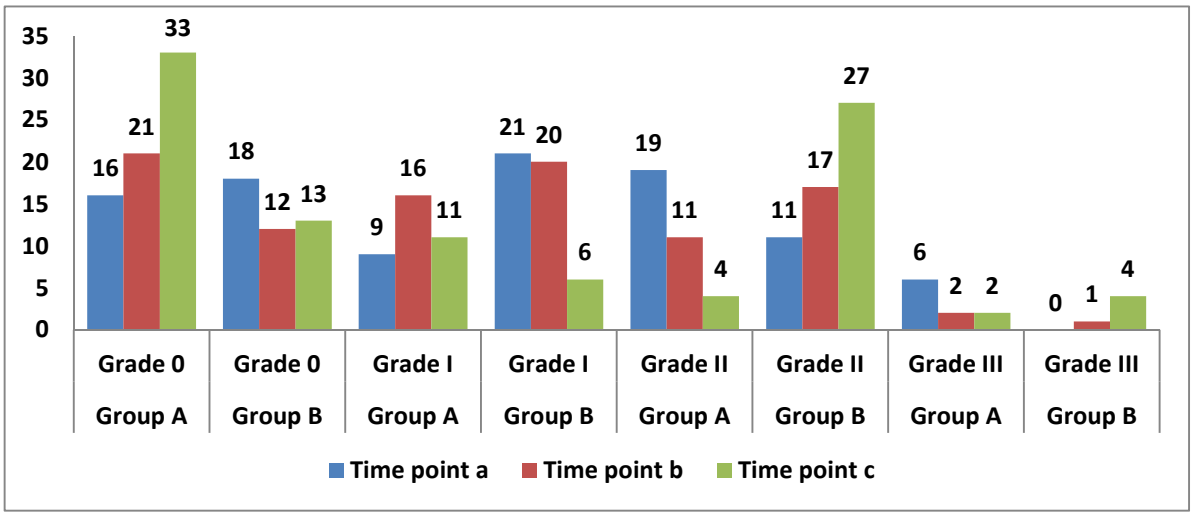
Statistically Anorexia was found to be very significant ($p = 0.0011$) at time point b (middle of chemotherapy) and extremely significant ($p < 0.0001$) at time point c (at the end of chemotherapy) in group A patients (study group).

2. Nausea

Table 22: Table showing grade wise distribution of patients suffering from Nausea at three time points in both groups.

2. Nausea								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	16	18	9	21	19	11	6	0
Time point b	21	12	16	20	11	17	2	1
Time point c	33	13	11	6	4	27	2	4

Graph 11:- Graphical representation of grade wise distribution of patients suffering from Nausea at three time points in both groups.



It is observed as per the graph that, at time point a, 16 patients of A group & 18 patients of B Group didn't complaint of Nausea (i.e. Grade 0). While at time point b 21 patients of A group & 12 patients of B Group didn't complaint of Nausea (i.e. Grade 0). It is observed at time point c 33 patients of A group & 13 patients of B Group didn't complaint of Nausea (i.e. Grade 0)

At time point a 9 patients of A group A & 21 patients of B Group complaint of Nausea (i.e. Grade I). While at time point b 16 patients of A group & 20 patients of B Group complaint of Nausea (i.e. Grade I). It is observed at time point c 11 patients of A group & 6 patients of B Group complaint of Nausea (i.e. Grade I)

At time point a, 19 patients of A group A & 11 patients of B Group complaint of Nausea (i.e. Grade II). While at time point b 11 patients of A group & 17 patients of B Group complaint of Nausea (i.e. Grade II). It is observed at time point c 4 patients of A group & 27 patients of B Group complaint of nausea (i.e. Grade II).

At time point a, 6 patients of group A & 0 patients of B Group complaint of nausea (i.e. Grade III). While at time point b 2 patients of A group & 1 patients of B Group complaint of Nausea (i.e. Grade III). It is observed at time point c 2 patients of A group & 4 patients of B Group complaint of nausea (i.e. Grade III)

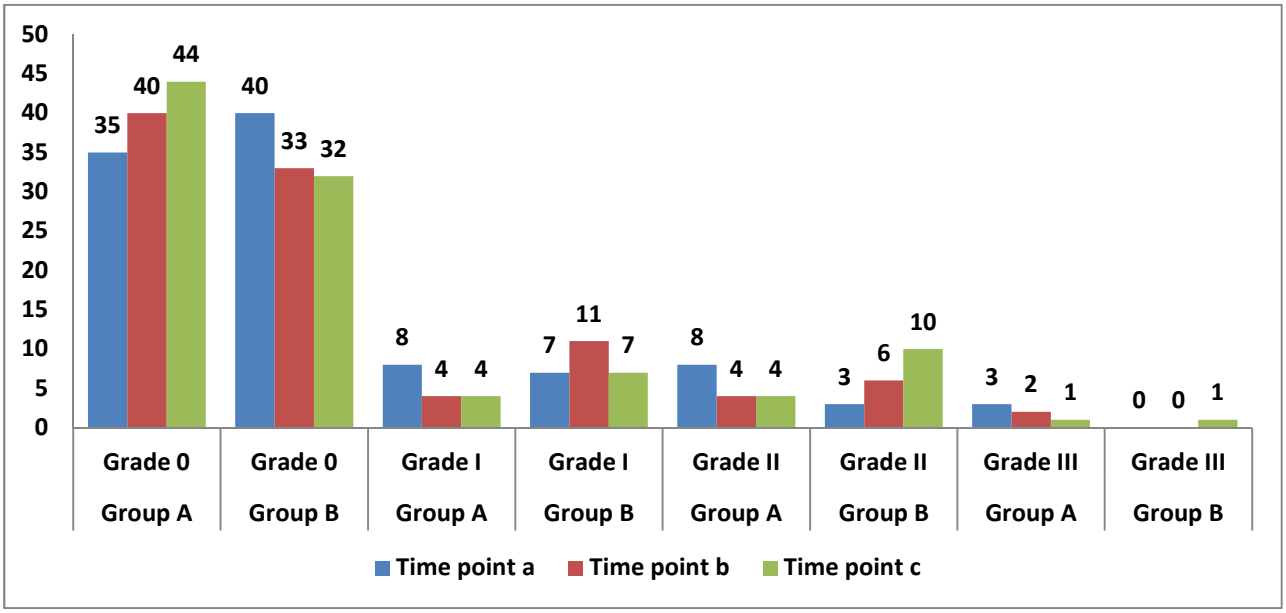
Statistically Nausea was found to be extremely significant ($p = 0.0001$) at time point b (middle of chemotherapy) and extremely significant ($p < 0.0001$) at time point c (15 days after the last chemotherapy).

3. Vomiting

Table 23: Table showing the grade wise distribution of patients suffering from Vomiting at three time points in both groups

3. Vomiting								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	35	40	8	7	8	3	3	0
Time point b	40	33	4	11	4	6	2	0
Time point c	44	32	4	7	4	10	1	1

Graph 12:-Graphical representation of the grade wise distribution of patients suffering from Vomiting at three time points in both groups.



It is observed as per the graph that, 35 patients of A group & 40 patients of B Group didn't complaint of Vomiting (i.e. Grade 0) at time point a. At time point b 40 patients of A group &33 patients of B Group didn't complaint of Vomiting (i.e. Grade 0).and at time point c it is observed that 44 patients of A group &32 patients of B Group didn't complaint of Vomiting (i.e. Grade 0).

At time point a, 8 patients of A group & 7 patients of B group suffered from Grade I Vomiting. While at time point b 4 patients of A group &11 patients of B group suffered from Grade I Vomiting. 4 patients of A group &7 patients of B group suffered from Grade I Vomiting at time point c

At time point a, 8 patients of A group &3 patients of B group suffered from Grade II Vomiting. While at time point b 4 patients of A group & 6 patients of B group suffered from Grade II Vomiting. 4 patients of A group & 10 patients of B group suffered from Grade II Vomiting at time point c

At time point a, 3 patients of A group & 0 patient of B group suffered from Grade III Vomiting. While at Time point b 2 patients of A group &0 patient of B group suffered from Grade III Vomiting. At time point c 1 patient of A group & 1 patient of B group suffered from Grade III Vomiting.

Statistically Vomiting was found to be very significant ($p = 0.0091$) at time point b (middle of chemotherapy) and extremely significant ($p < 0.0001$) at time point c (15 days after the last Chemotherapy)

4. Taste Abnormality

Table24: Table showing the grade wise distribution of patients suffering from Taste abnormality at three time points in both groups

4. Taste Abnormality								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	40	47	1	1	8	2	1	0
Time point b	39	44	6	4	4	2	1	0
Time point c	41	43	4	5	4	1	1	1

Graph 13:- Graphical representation of the grade wise distribution of patients suffering from Taste abnormality at three time points in both groups

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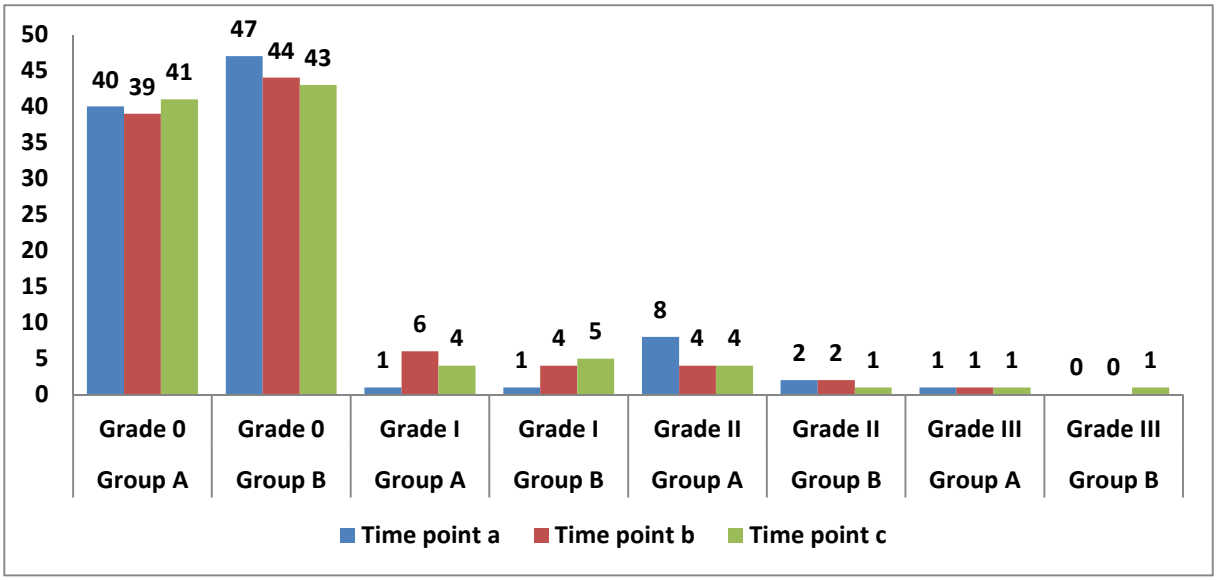


It is observed as per the graph that, In the beginning 40 patients of A group &47 patients of B Group didn't complaint of Taste Abnormality (i.e. Grade 0).In the mid of the chemo 39 patients of A group & 44 patients of B Group didn't complaint of Taste Abnormality (i.e. Grade 0). At the end of chemo 41 patients

of A group & 43 patients of B Group didn't complaint of Taste Abnormality (i.e. Grade 0).

In the beginning of chemo 1 patient of A group &1 patient of B group suffered from Grade I Taste Abnormality. In the mid of chemo 6 patients of A group &4 patients of B group suffered from Grade I Taste Abnormality. 15 days after the last chemo 4 patients of A group & 5 patients of B group suffered from Grade I Taste Abnormality.

In the beginning of chemo 8 patient of A group & 2 patient of B group suffered from Grade II Taste Abnormality. In the mid of chemo 4 patients of A group & 2 patients of B group suffered from Grade II Taste Abnormality. 15 days after the chemo 4 patients of A group &1 patients of B group suffered from Grade II Taste Abnormality.

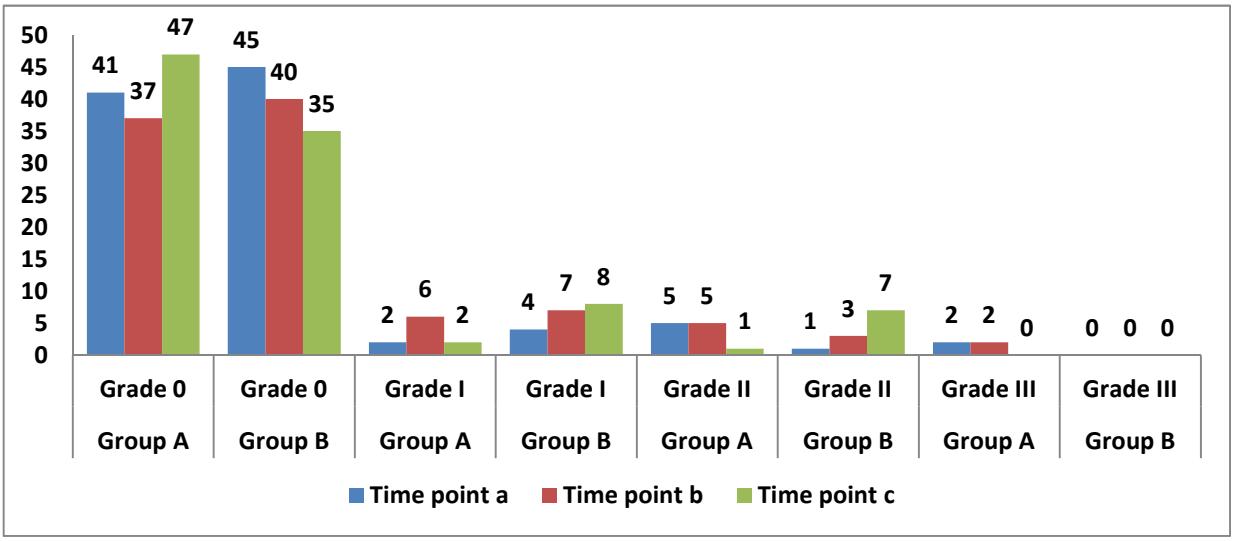
In the beginning of chemo1 patient of A group &0patient of B group suffered from Grade III Taste Abnormality. At the mid1 patients of A group &0patient of B group suffered from Grade III Taste Abnormality. At the end 1 patient of A group &1 patient of B group suffered from Grade III Taste Abnormality. Statistically no significance was observed in both the groups.

5. Diarrhoea

Table 25:Table showing the grade wise distribution of patients suffering from Diarrhoea at three time points in both groups.

6. Diarrhoea								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	41	45	2	4	5	1	2	0
Time point b	37	40	6	7	5	3	2	0
Time point c	47	35	2	8	1	7	0	0

Graph 14:- Graphical representation of the grade wise distribution of patients suffering from Diarrhoea at three time points in both groups.



It is observed as per the graph that, In Time point a 41 patients of A group &45 patients of B Group didn't complaint of Diarrhoea (i.e. Grade 0).37 patients of A group & 40 patients of B Group didn't complaint of Diarrhoea (i.e. Grade 0) at time point b. 47 patients of A group &35 patients of B Group didn't complaint of Diarrhoea (i.e. Grade 0) at time point c.

- At time point a, 2 patients of A group &4 patients of B group suffered from Grade I Diarrhoea. In Time point b 6 patients of A group & 7 patients of B group suffered from Grade I Diarrhoea. At time point c 2 patients of A group & 8 patients of B group suffered from Grade I diarrhoea.
- At time point a 5patients of A group &1 patients of B group suffered from Grade II Diarrhoea .At time point b 5 patients of A group &3 patients of B group suffered from Grade II diarrhoea. At time point c1 patients of A group &7 patients of B group suffered from Grade II diarrhoea.
- At time point a, 2 patients of A group & 0 patient of B group suffered from Grade III Diarrhoea. At time point b 2 patients of A group &0 patient of B group suffered from Grade III diarrhoea. At time point c 0patient of A group &0patient of B group suffered from Grade III diarrhoea.

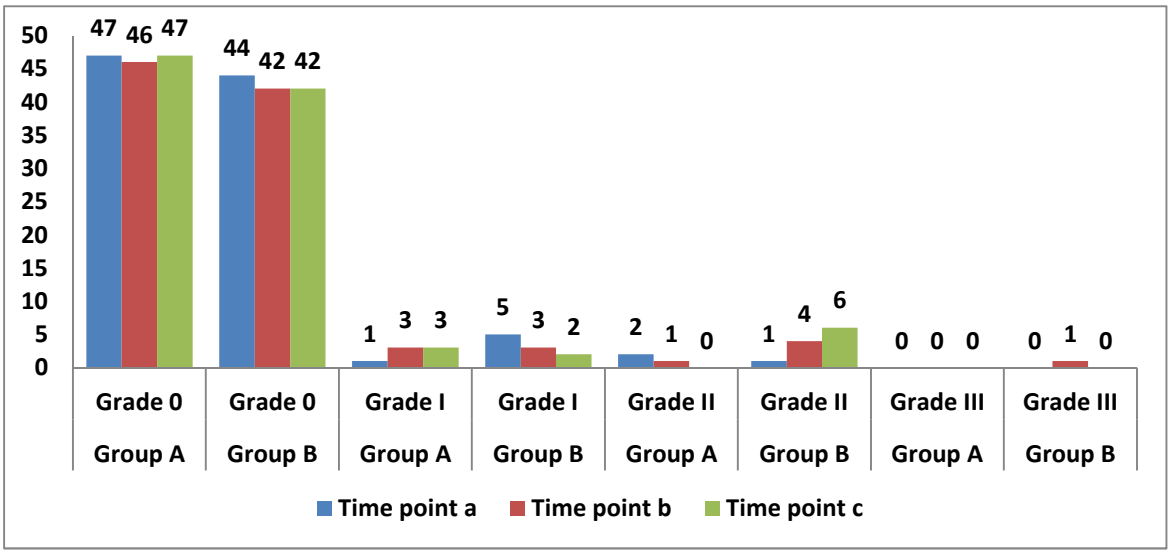
Statistically Diarrhoea was found extremely significant ($p< 0.0001$) at time point c 15 days after the last chemotherapy).

6. GI bleeding

Table26: Table showing the grade wise distribution of patients suffering from GI bleeding at three time points in both groups.

6. GI Bleed								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	47	44	1	5	2	1	0	0
Time point b	46	42	3	3	1	4	0	1
Time point c	47	42	3	2	0	6	0	0

Graph 15:- Graphical representation of the grade wise distribution of patients suffering from GI bleeding at three time points in both groups.



It is observed as per the graph that, In Time point a 47 patients of A group & 44 patients of B Group didn't complaint of GI bleeding (i.e. Grade 0). At time point b 46 patients of A group & 42 patients of B Group didn't complaint of GI bleeding (i.e. Grade 0). And at the time point c 47 patients of A group & 42 patients of B Group didn't complaint of GI bleeding (i.e. Grade 0).

At a time point1 patients of A group & 5 patients of B group suffered from Grade I GI bleeding. At time point b3 patients of A group &3 patients of B group suffered from Grade I GI bleeding. And at time point c 3 patients of A group & 2 patients of B group suffered from Grade I GI bleeding.

At time-point a, 2 patients of A group & no patient of B group suffered from Grade II GI bleeding. At Time point b 1 patients of A group &4 patients of B group suffered from Grade II GI bleeding. At c 0 patient of A group &6patients of B group suffered from Grade II GI bleeding

At time point a, no patient of A group &1 patients of B group suffered from Grade III GI bleeding. At c, none of the patient of A group and B group suffered from Grade III GI bleeding.

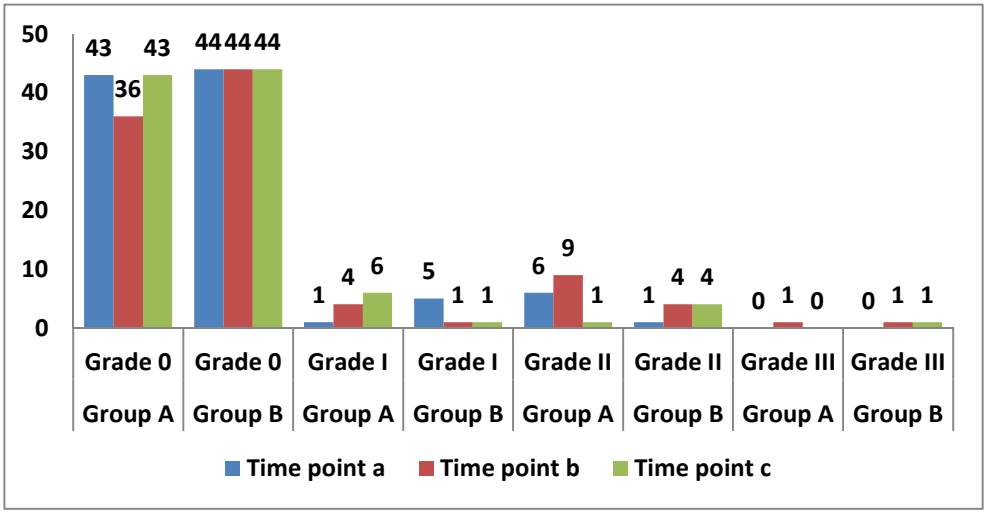
Statistically GI bleeding was found to be significant ($p = 0.03$) at time point b (middle of chemotherapy) and considerably significant ($p = 0.00488$) at time point c (at the end of chemotherapy) in group A patients (study group).

7. Stomatitis

Table27: Table showing the grade wise distribution of patients suffering from Stomatitis at three time points in both groups.

7. Stomatitis								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	43	44	1	5	6	1	0	0
Time point b	36	44	4	1	9	4	1	1
Time point c	43	44	6	1	1	4	0	1

Graph 16:- Graphical representation of the grade wise distribution of patients suffering from Stomatitis at three time points in both groups.



Stomatitis is presented as per 4 gradations. It is observed as per the graph that,

In Time point a, 43 patients of A group & 44 patients of B Group didn't complaint of Stomatitis (i.e. Grade 0).1 patient of A group &5 patients of B group suffered from Grade I Stomatitis.6 patients of A group &1patients of B group suffered from Grade II Stomatitis.

In Time point b, 36 patients of A group &44 patients of B Group didn't complaint of Stomatitis (i.e. Grade 0). 4 patients of A group &1 patient of B group suffered from Grade I Stomatitis.9 patients of A group &4 patients of B group suffered from Grade Stomatitis.1 patient of A group &1 patient of B group suffered from Grade III Stomatitis

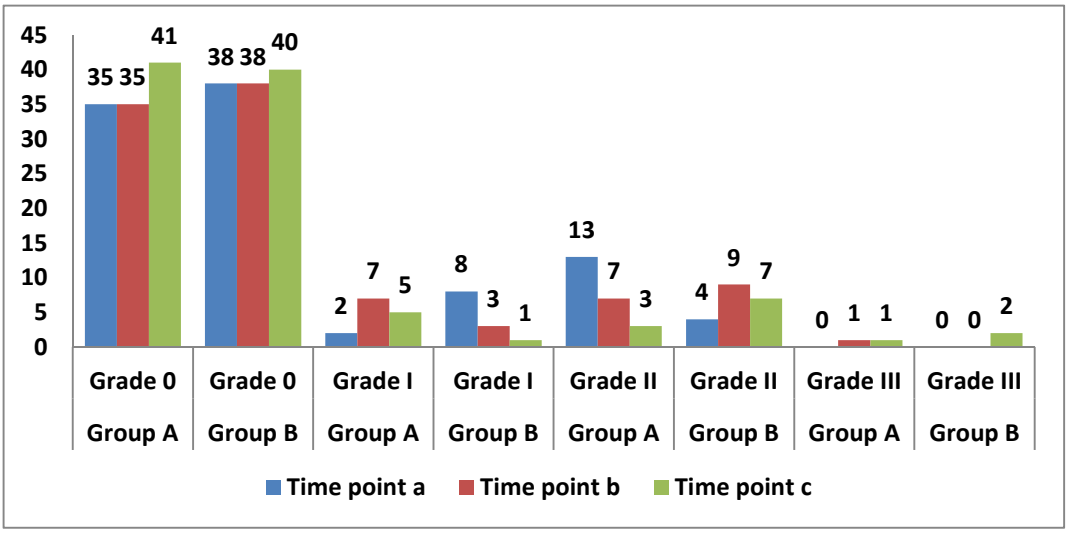
In Time point c, 43 patients of A group &44 patients of B Group didn't complaint of Stomatitis (i.e. Grade 0).6 patients of A group & 1 patient of B group suffered from Grade I Stomatitis. 1 patient of A group & 4 patients of B group suffered from Grade II Stomatitis. None of the patient of A group & 1 patient of B group suffered from Grade III Stomatitis

8. Constipation

Table 28:Table showing the grade wise distribution of patients suffering from Constipation at three time points in both groups.

8.Constipation								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	35	38	2	8	13	4	0	0
Time point b	35	38	7	3	7	9	1	0
Time point c	41	40	5	1	3	7	1	2

Graph 17:- Graphical representation of the grade wise distribution of patients suffering from Constipation at three time points in both groups.



Constipation is presented as per 4 gradations. It is observed as per the graph that, In Time point a – 35 patients of A group &38 patients of B Group didn't complaint of Constipation (i.e. Grade 0).In Time point b 35 patients of A group &38 patients of B Group didn't complaint of Constipation (i.e. Grade 0).In Time point c 41 patients of A group & 40 patients of B Group didn't complaint of Constipation (i.e. Grade 0).

At a time point 2 patients of A group & 8 patients of B group suffered from Grade I Constipation.13 patients of A group &4 patients of B group suffered from Grade II Constipation. and at time point b 7 patients of A group & 3 patients of B group suffered from Grade I Constipation patients of A group & patients of B group suffered from Grade II Constipation.1 patient of A group &0 patient of B group suffered from Grade III Constipation

At time point a, 5 patients of A group &1 patients of B group suffered from Grade I Constipation3 patients of A group & 7 patients of B group suffered from Grade II Constipation1 patient of A group &2 patients of B group suffered from Grade III Constipation.

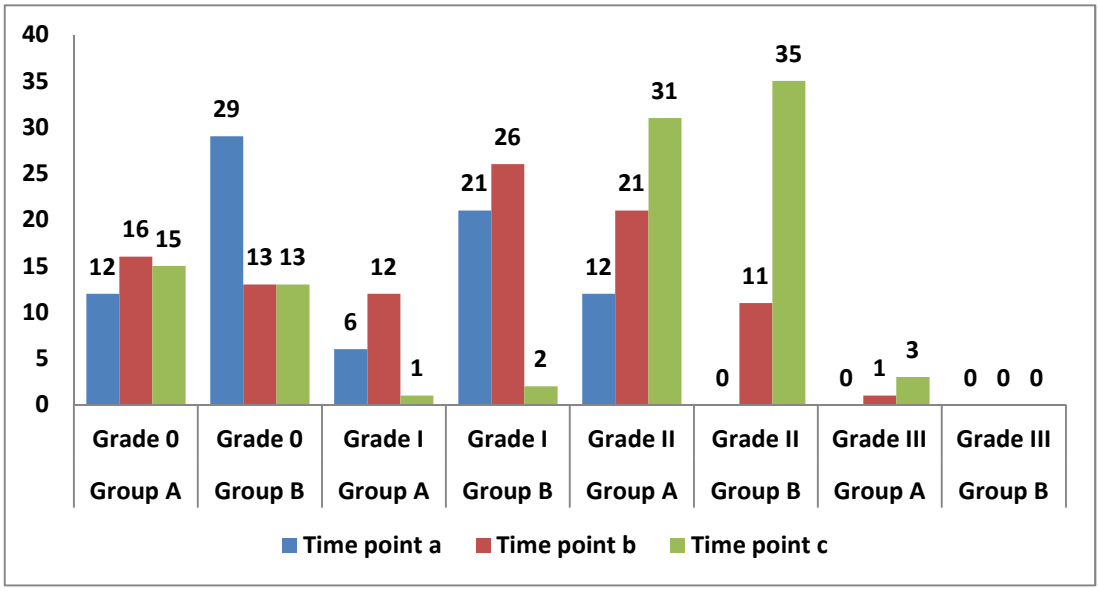
Statistically Constipation was found to be significant ($p = 0.0141$) at time point c (at the end of chemotherapy) in group A patients (study group).

9. Alopecia

Table 29: Table showing the grade wise distribution of the patients suffering from Alopecia at three time points.

9. Alopecia								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	12	29	6	21	12	0	0	0
Time point b	16	13	12	26	21	11	1	0
Time point c	15	13	1	2	31	35	3	0

Graph 18:- Graphical representation of the grade wise distribution of the patients suffering from Alopecia at three time points.



Alopecia is presented as per 3 gradations .It is observed as per the graph that,

- At Time point a –
  - 12 patients of A group & 29 patients of B Group didn't complaint of Alopecia (i.e. Grade 0) .6 patients of A group &21 patients of B group suffered from

Grade I Alopecia. 12 patients of A group &0 patients of B group suffered from Grade II Alopecia

At Time point b, 16 patients of A group & 13 patients of B Group didn't complaint of Alopecia (i.e. Grade 0). 12 patients of A group & 26 patients of B group suffered from Grade I Alopecia. 21 patients of A group & 11 patients of B group suffered from Grade II Alopecia. 1 patient of A group & 0 patients of B group suffered from Grade III Alopecia.

At Time point c, 15 patients of A group &13 patients of B Group didn't complaint of Alopecia (i.e. Grade 0) 1 patient of A group &2 patients of B group suffered from Grade I Alopecia. 31 patients of A group & 35 patients of B group suffered from Grade II Alopecia. 3 patients of A group & none of the patient of B group suffered from Grade III Alopecia.

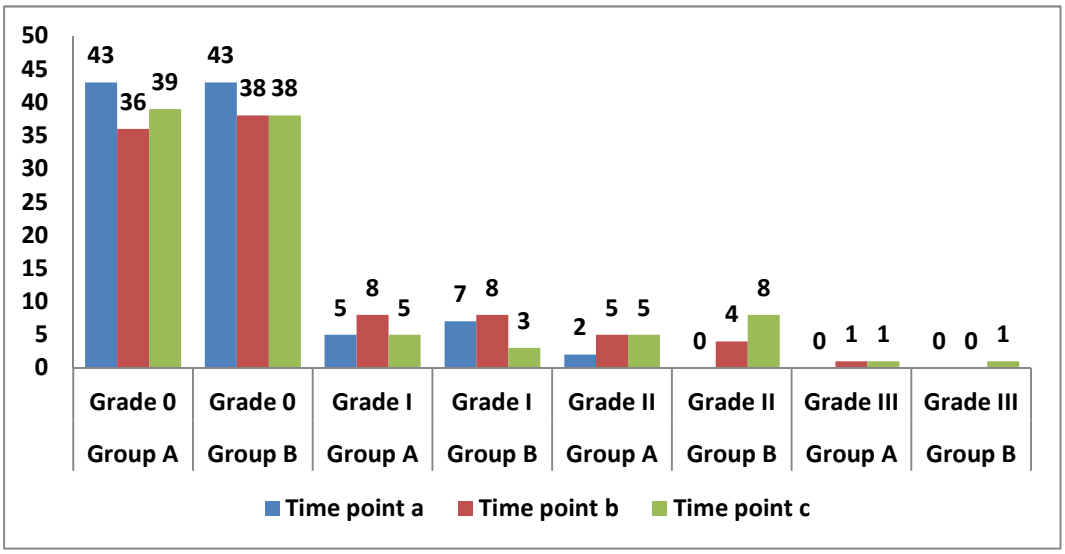
Statistically Alopecia was found to be very significant ($p = 0.0086$) at time point b (middle of chemotherapy) and extremely significant ($p = 0.001$) at time point c (at the end of chemotherapy) in group A patients (study group) as compare to control group.

10. Skin Rash

Table 30: Table showing the grade wise distribution of the patients suffering from Skin rash at three time points.

10. Skin Rash								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	49	47	0	2	0	0	1	1
Time point b	48	47	1	2	0	1	1	0
Time point c	48	45	1	4	1	1	0	0

Graph 19:- Graphical representation of the grade wise distribution of the patients suffering from Skin rash at three time points.



Skin rash is presented as per 4 gradations.

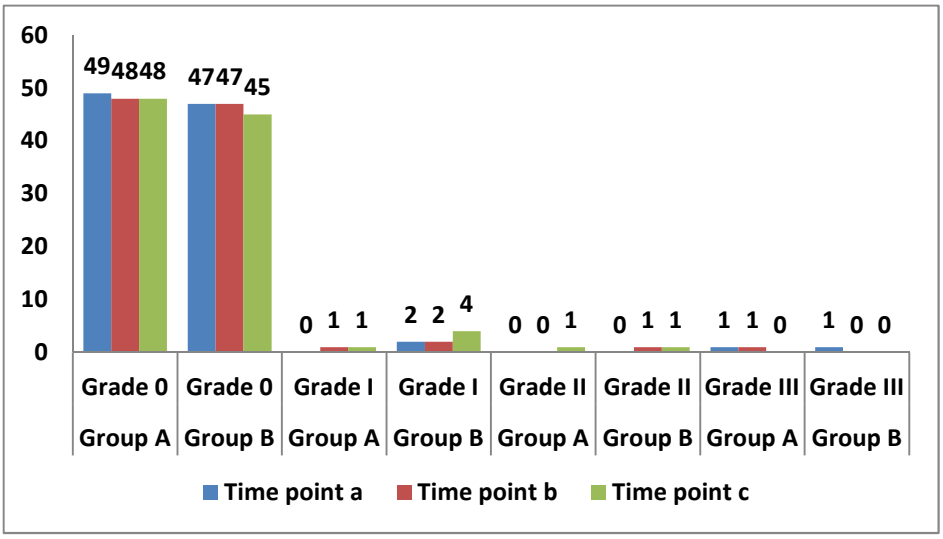
It is observed as per the graph that, very few patients (2) of grade II and 1 of grade III had suffered from this symptom. Statistically this symptom was not assessed as the number was very less.

11. Nail Discolouration

Table 31:Table showing the grade wise distribution of the patients suffering from Nail Discoloration at three time points.

11. Nail Discolouration								
Nail discoloration	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	43	43	5	7	2	0	0	0
Time point b	36	38	8	8	5	4	1	0
Time point c	39	38	5	3	5	8	1	1

Graph 20:- Graphical representation of the grade wise distribution of the patients suffering from Nail Discoloration at three time points.



Nail discoloration is presented as per 4 gradations.

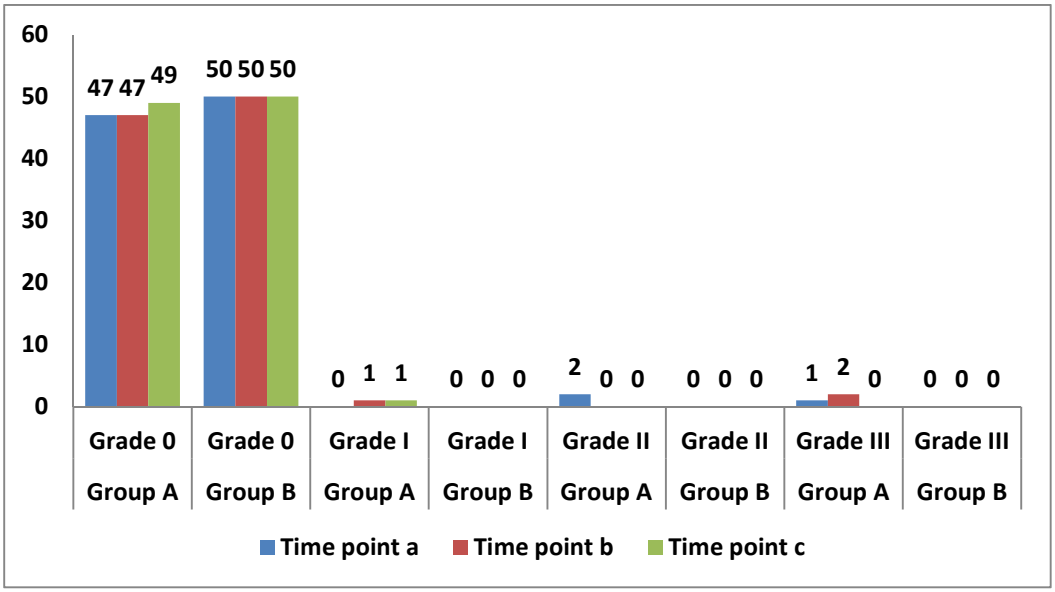
It is observed as per the graph that, very few patients (2) of grade II and 1 of grade III of Group-A had suffered from this symptom. Statistically this symptom was not assessed as the number was very less.

12. Hyperpigmentation

Table 32: Table showing the grade wise distribution of the patients suffering from Hyperpigmentation at three time points

12. Hyperpi-gmentation								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	47	50	0	0	2	0	1	0
Time point b	47	50	1	0	0	0	2	0
Time point c	49	50	1	0	0	0	0	0

Graph 21:- Graphical representation of the grade wise distribution of the patients suffering from Hyperpigmentation at three time points



Hyperpigmentation is presented as per 4 gradations.

It is observed as per the graph that, very few patients had suffered from this symptom.

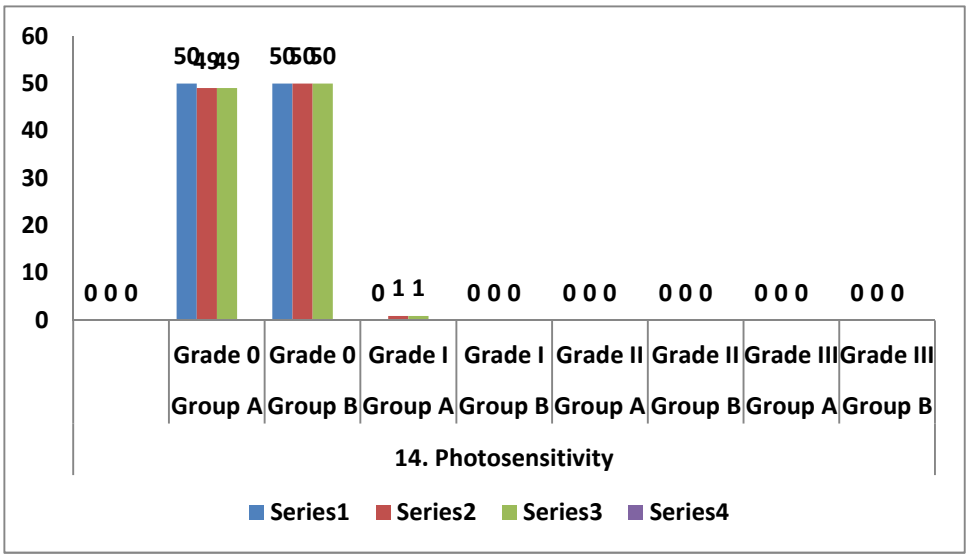
Statistically this symptom was not assessed as the number was very less.

13. Photosensitivity

Table 33:Table showing the grade wise distribution of patients suffering from Photosensitivity at three time points.

13. Photosensitivity								
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	Grade 0	Grade 0	Grade I	Grade I	Grade II	Grade II	Grade III	Grade III
Time point a	50	50	0	0	0	0	0	0
Time point b	49	50	1	0	0	0	0	0
Time point c	49	50	1	0	0	0	0	0

Graph 22 –Graphical representation of the grade wise distribution of patients suffering from Photosensitivity at three time points



Photosensitivity is presented as per 4 gradations. It is observed as per the graph that, only 1 patient of group A was having this symptom. Hence not subjected to statistical analysis.

Table No 34 - Statistics of side – effects of Chemotherapy

Symptom Assessment- Group A -- Group B (b - a)							
Sr. No	**Symptom**	**Mean of Group A**	**Mean of Group B**	**SD GR A**	**SD GR B**	**P value**	**Significance**
1	**Anorexia**	-0.26	0.32	1.1	0.5	0.0011	Very Significant
2	**Nausea**	-0.42	0.28	1	0.5	0.0001	Extremely Significant
3	**Vomiting**	-0.14	0.2	0.8	0.4	0.0091	Very Significant
4	**Taste abnormality**	-0.06	0.06	0.9	0.2	0.3396	Not significant
5	**Diarrhoea**	0.08	0.14	0.7	0.5	0.6297	Not significant
6	**GI Bleeding**	0.0	0.14	0.2	0.4	0.03	Significant
7	**Stomatitis**	0.24	0.11	0.12	0.05	0.3074	Not significant
8	**Constipation**	-0.08	0.91	0.98	0.46	0.2456	Not significant
9	**Alopecia**	0.14	0.54	0.9	0.5	0.0086	Very Significant
10	**Skin Rash**	0.02	-0.02	0.1	0.5	0.5683	Not significant
11	**Nail Discoloration**	0.24	0.18	0.7	0.4	0.592	Not significant
12	**Hyper pigmentation**	_	_	_	_	_	_
13	**Photosensitivity**	_	_	_	_	_	_

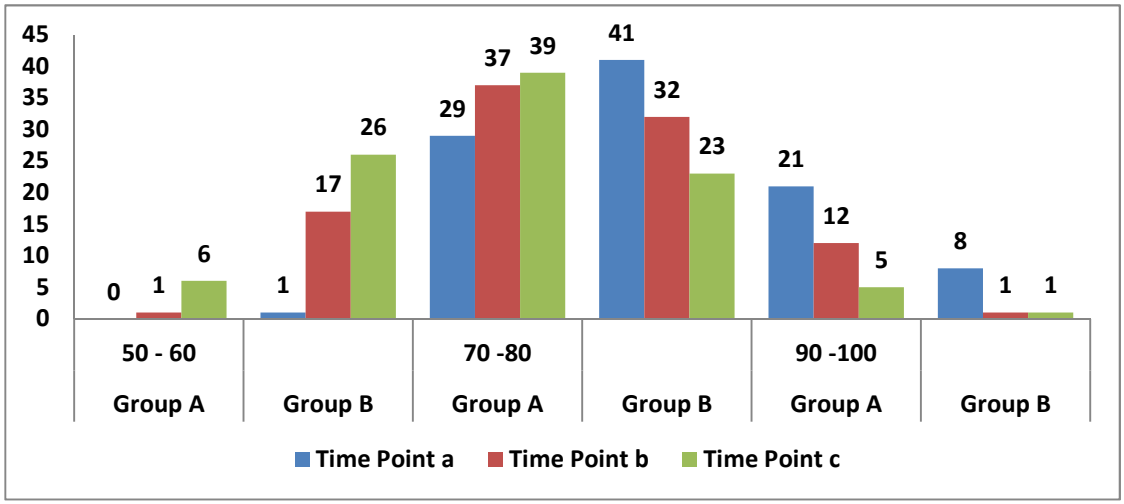
Table No 35 - Statistics of side –effects of chemotherapy

Symptom Assessment- Group A -- Group B (c - a)							
Sr. No	**Symptom**	**Mean of Group A**	**Mean of Group B**	**SD GR A**	**SD GR B**	**P value**	**Significance**
1	**Anorexia**	-0.7	0.5	1.1	0.6	<0.0001	Extremely Significant
2	**Nausea**	-0.8	0.6	0.98	0.75	<0.0001	Extremely Significant
3	**Vomiting**	-0.3	0.34	0.97	0.65	0.0001	Extremely Significant
4	**Taste abnormality**	-0.1	0.1	0.83	0.5	0.1519	Not significant
5	**Diarrhoea**	-0.3	0.3	0.7	0.6	<0.0001	Extremely Significant
6	**GI Bleeding**	0.0	0.14	0.4	0.5	0.00488	Considerably significant
7	**Stomatitis**	-0.1	0.1	0.7	0.4	0.088	Not quite significant
8	**Constipation**	-0.28	0.1	0.9	0.6	0.0141	Significance
9	**Alopecia**	0.44	1.02	0.9	0.8	0.001	Extremely Significant
10	**Skin Rash**	0	0.02	0.5	0.5	0.8492	-
11	**Nail Discolouration**	0.18	0.3	0.8	0.6	0.4024	-
12	**Hyper pigmentation**	_	_	_	_	_	_
13	**Photosensitivity**	_	_	_	_	_	_

Karnofsky

Table36: Table showing Karnofsky score of Breast cancer patients

	Number of patients					
	Group A	Group B	Group A	Group B	Group A	Group B
	50 – 60		70 -80		90 -100	
Time Point a	0	1	29	41	21	8
Time Point b	1	17	37	32	12	1
Time Point c	6	26	39	23	5	1



Observations regarding Karnofsky score recorded at various time points :

- At time-point a - Karnofsky score between 50 – 60 was recorded in 1 patient of group B. Karnofsky between score 70 – 80 was recorded in 29 patients of Group A and 41 patients of Group B. Karnofsky score between 90 – 100 was recorded in 21 patients of Group A and 8 patients of Group B.
- At time point b - Karnofsky score between 50– 60 was recorded in 1 patient of Group A and 17 patients of Group B. Karnofsky score between 70 – 80 was recorded in 37 patients of Group A and 32 patients of Group B. Karnofsky score between 90-100 was recorded in 12 patients of Group A and 1 patients of Group B.

- At time-point c - Karnofsky score between 50 – 60 was recorded in 6 patient of Group A and 26 patient of Group B. Karnofsky score between 70 – 80 was recorded in 39 patients of Group A and 23 patients of Group B. Karnofsky score between 90 – 100 was recorded in 5 patients of Group A and 1 patients of Group B. Statistical analysis of Karnofsky score at time points b and c is extremely significant ($p<0.0001$) and ($p=0.0006$) for group A patients.

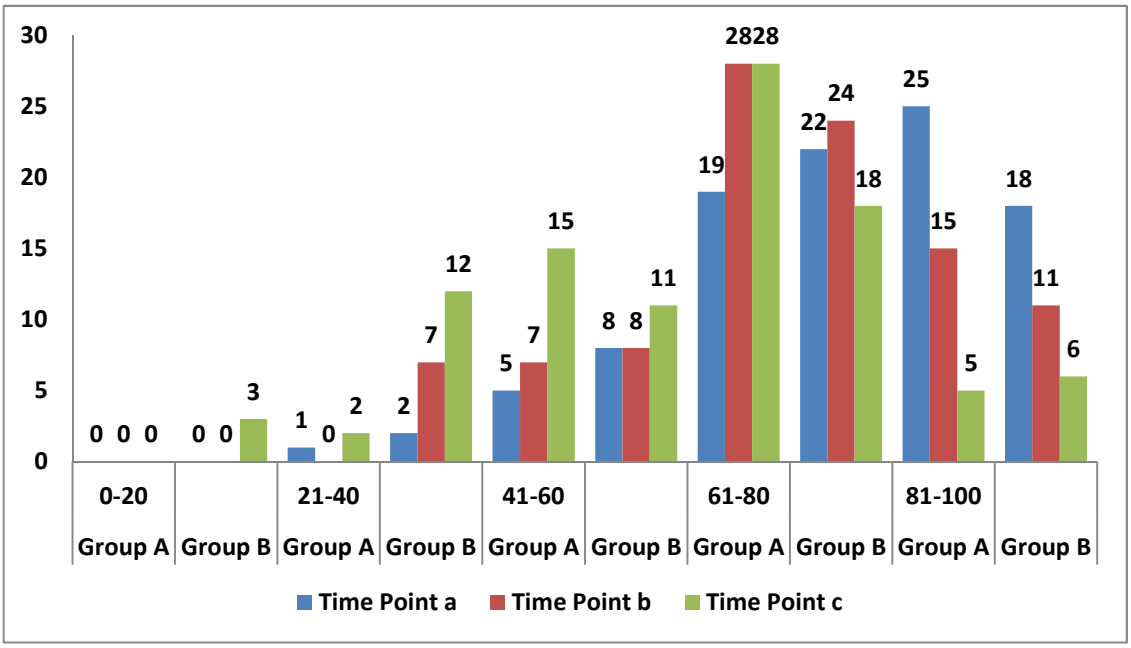
Quality Life Questionnaire (QLQ)

Table 37:- Showing Functional score of QLQ of Breast cancer patients

Functional score	**Number of patients**									
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
	0-20		**21-40**		**41-60**		**61-80**		**81-100**	
Time Point a	**0**	**0**	**1**	**2**	**5**	**8**	**19**	**22**	**25**	**18**
Time Point b	**0**	**0**	**0**	**7**	**7**	**8**	**28**	**24**	**15**	**11**
Time Point c	**0**	**3**	**2**	**12**	**15**	**11**	**28**	**18**	**5**	**6**

The functional score - The number of patients in group A were showing increasing trend and also the functional score shows increasing score values in group A (study group).The same trend is observed in control group. Thus there is no significant improvement in functional score in Study group patients as compare to control group patients.

Graph 23 - Graphical representation of the Functional score of QLQ of Breast cancer patients



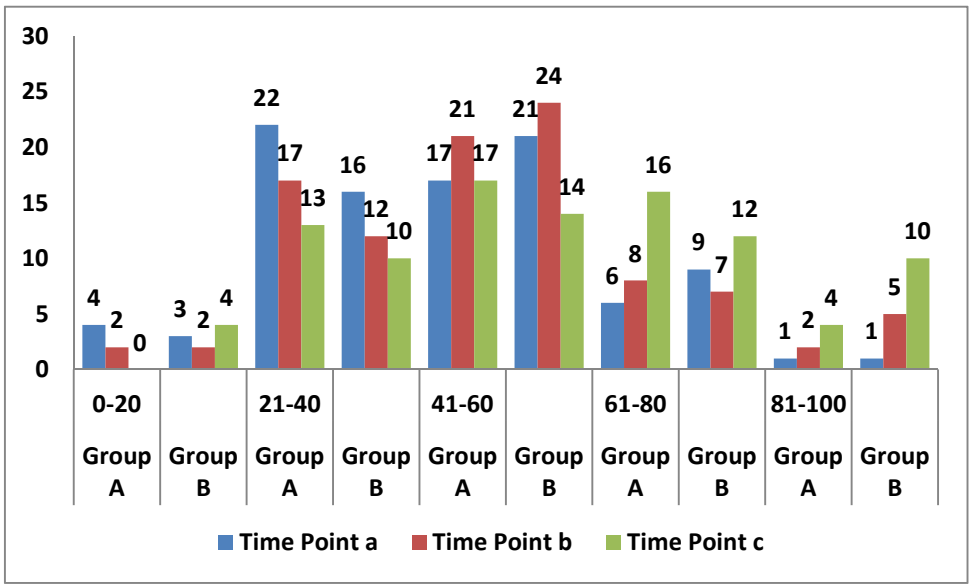
Functional score of both the group has not shown any significant difference.

Table38–showing Symptom score of QLQ of Breast cancer patients

Symptom Score	Number of patients									
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	0-20		21-40		41-60		61-80		81-100	
Time Point a	4	3	22	16	17	21	6	9	1	1
Time Point b	2	2	17	12	21	24	8	7	2	5
Time Point c	0	4	13	10	17	14	16	12	4	10

The symptom score - The number of patients in group A were showing increasing trend in middle of treatment and again decreasing pattern at the end. Also the symptom score shows increasing score values in group A (study group). The same trend is observed in control group. Thus there is no improvement in symptom score in Study group as compared to control group.

Graph 24 – Graphical representation of the Symptom score of QLQ of Breast cancer patients



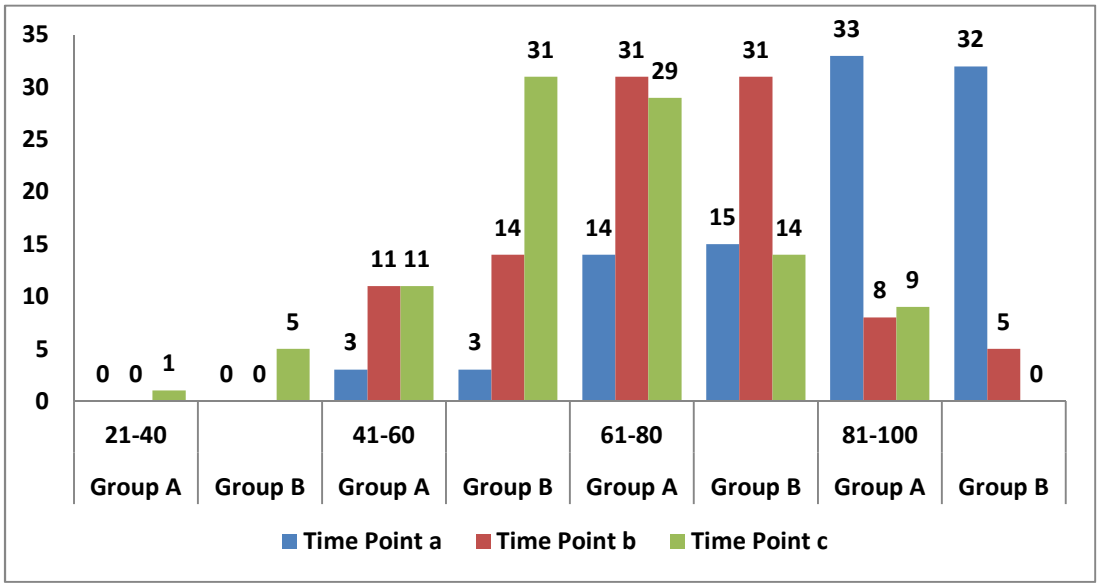
Symptom score of both the groups has not shown any significant difference.

Table 39 –showing Global score of QLQ of Breast cancer patients

Global score	Number of patients							
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	21-40		41-60		61-80		81-100	
Time Point a	0	0	3	3	14	15	33	32
Time Point b	0	0	11	14	31	31	8	5
Time Point c	1	5	11	31	29	14	9	0

The Global score - The number of patients showing the increased score value is maximum in study group as compared to the control group. While the less number of patients reported the increase in score value in control group. Thus there is a remarkable improvement in Global score as compared to control group.

Graph 25 – Representation of the Global score of QLQ of Breast cancer patients



The global score of the both the groups has shown statistically significant difference in both the groups.

Statistics – Clinical assessment

Table 40 – Showing Clinical Assessment Group A -- Group B (b - a)

Clinical Assessment Group A -- Group B (b - a)							
Sr. No	**Parameters**	**Mean of Group A**	**Mean of Group B**	**SD GR A**	**SD GR B**	**P value**	**Significance**
1	**Karnofsky score**	**-4.4**	**-11.6**	**6.4**	**7.9**	**<0.0001**	**Extremely significant**
2	**QLQ-Functional score**	**-6**	**-6**	**7.8**	**12.4**	**0.9**	**Not significant**
3	**QLQ-Symptom score**	**8**	**4**	**7.4**	**14.6**	**0.17**	**Not significant**
4	**QLQ-Global score**	**4**	**-11.2**	**7.6**	**6.3**	**0.008**	**Very significant**
5	**Weight**	**2.7**	**1.7**	**19.6**	**6.6**	**0.1273**	

Table 41 – showing Clinical Assessment Group A -- Group B (c - a)

Clinical Assessment Group A -- Group B (c - a)							
Sr. No	**Parameters**	**Mean of Group A**	**Mean of Group B**	**SD GR A**	**SD GR B**	**P value**	**Significance**
1	**Karnofsky score**	**-7.8**	**-13.4**	**8.1**	**7.7**	**0.0006**	**Extremely significant**
2	**QLQ-Functional score**	**-14.4**	**-15.8**	**11.4**	**15.6**	**0.61**	**Not significant**
3	**QLQ-Symptom score**	**16.6**	**11.3**	**9.6**	**19.4**	**0.08**	**Not significant**
4	**QLQ-Global score**	**-11.5**	**-24.5**	**9.8**	**8.6**	**<0.0001**	**Extremely significant**
5	**Weight**	**4.9**	**-1.5**	**17**	**3.5**	**0.0097**	**Very Significant**

Investigations

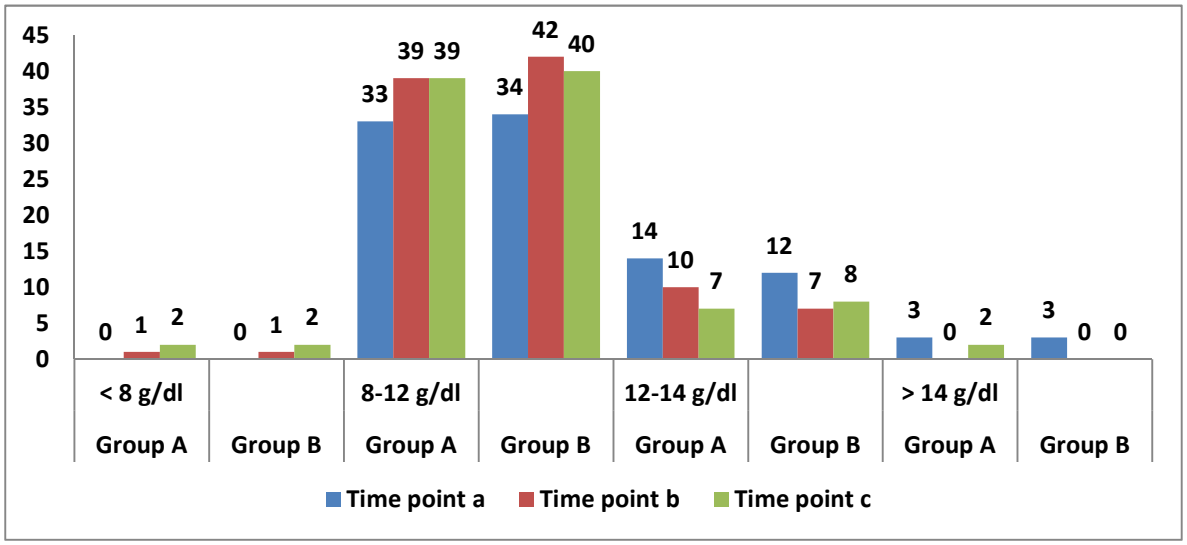
Haemoglobin

Table 42 –Table showing values of Haemoglobin of Breast cancer patients

Haemoglobin	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	< 8 g/dl		8-12 g/dl		12-14 g/dl		> 14 g/dl	
Time point a	0	0	33	34	14	12	3	3
Time point b	1	1	39	42	10	7	0	0
Time point c	2	2	39	40	7	8	2	0

Observations regarding Haemoglobin values recorded at various time points dis not show any significant different in both the groups.

Graph 26 – Representation of the of HB of Breast cancer patients



No statistically significant difference is observed in Haemoglobin value in the both the groups.

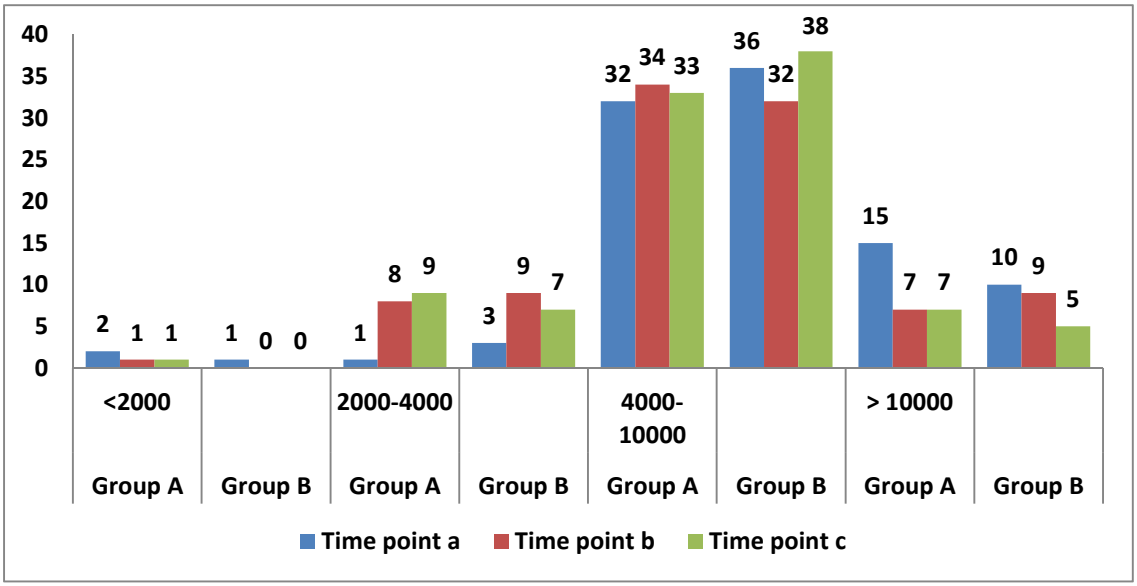
WBC Count

Table 43 –Table showing values of WBC of Breast cancer patients

WBC	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	<2000		2000-4000		4000-10000		> 10000	
Time point a	2	1	1	3	32	36	15	10
Time point b	1	0	8	9	34	32	7	9
Time point c	1	0	9	7	33	38	7	5

Observations regarding WBC values recorded at various time points shown no significant different in both the group. The values of WBC are equally low throughout the chemotherapy in both the groups.

Graph 27 – Representation of the values of WBC of Breast cancer patients



No statistically significant difference is observed in WBC count in the both the groups during the course and at the end of chemotherapy.

Platelet count

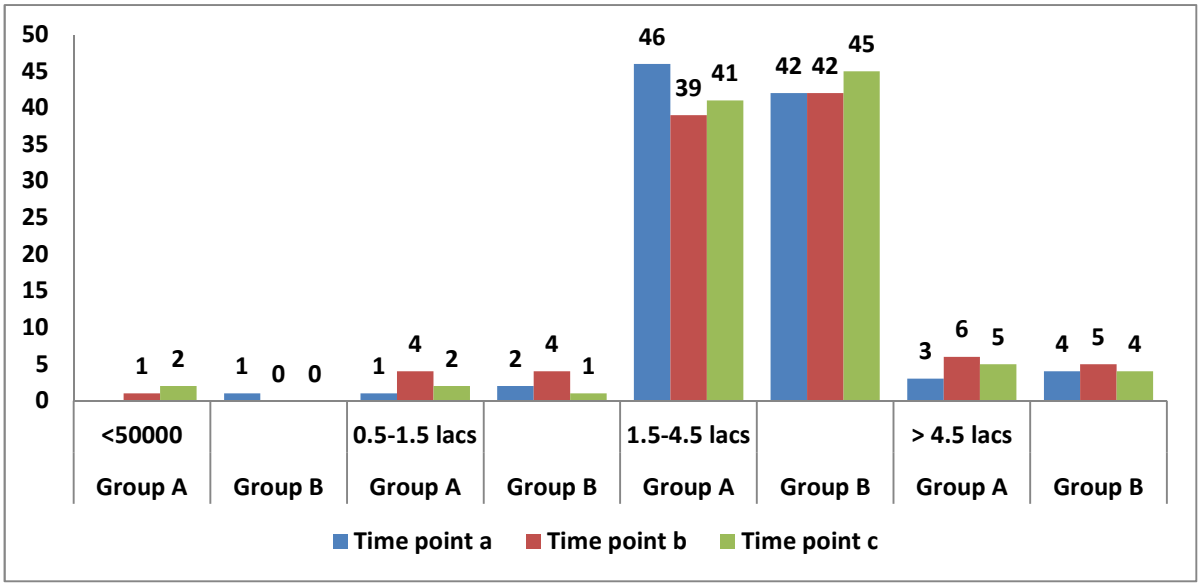
Table 44 –Table showing values of Platelet count of Breast cancer patients

Platelet	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	<50000		**0.5-1.5 lacs**		**1.5-4.5 lacs**		**> 4.5 lacs**	
Time point a		**1**	**1**	**2**	**46**	**42**	**3**	**4**
Time point b	**1**	**0**	**4**	**4**	**39**	**42**	**6**	**5**
Time point c	**2**	**0**	**2**	**1**	**41**	**45**	**5**	**4**

Observations regarding Platelets values recorded at various time points,

- At time-point a, none of the patient of Group A and 1 patient of Group B recorded Platelets values < 50000. 1 patient of Group A and 2 patients of Group B recorded Platelets values between 50000 – 1.5 lacs. 46 patient of Group A and 42 patients of Group B recorded Platelet counts between 1.5 lacs – 4.5 lacs. 3 patients of Group A and 4 patients of Group B recorded Platelets values > 4.5 lacs.
- At time point b. 1 patient of Group A and 0 patient of Group B recorded Platelets values < 50000. 4 patients of Group A and 4 patients of Group B recorded Platelets values between 50000 – 1.5 lacs. 39 patient of Group A and 42 patients of Group B recorded Platelets values between 1.5 lacs – 4.5 lacs. 6 patients of Group A and 5 patients of Group B recorded Platelets values > 4.5 lacs.
- At time-point c, 2 patients of Group A and no patient of Group B recorded Platelets values < 50000. 2 patients of Group A and 1 patient of Group B recorded Platelets values between 50000 – 1.5 lacs. 41 patients of Group A and 45 patients of Group B recorded Platelets values between 1.5 lacs – 4.5 lacs. 5 patients of Group A and 4 patients of Group B recorded Platelets values > 4.5 lacs. Statistically platelet count has shown extremely significance in study group at time point b.

Graph 28- Representation of the values of Platelet of Breast cancer patients



The Platelet Count has shown statistically significant difference at time point b.

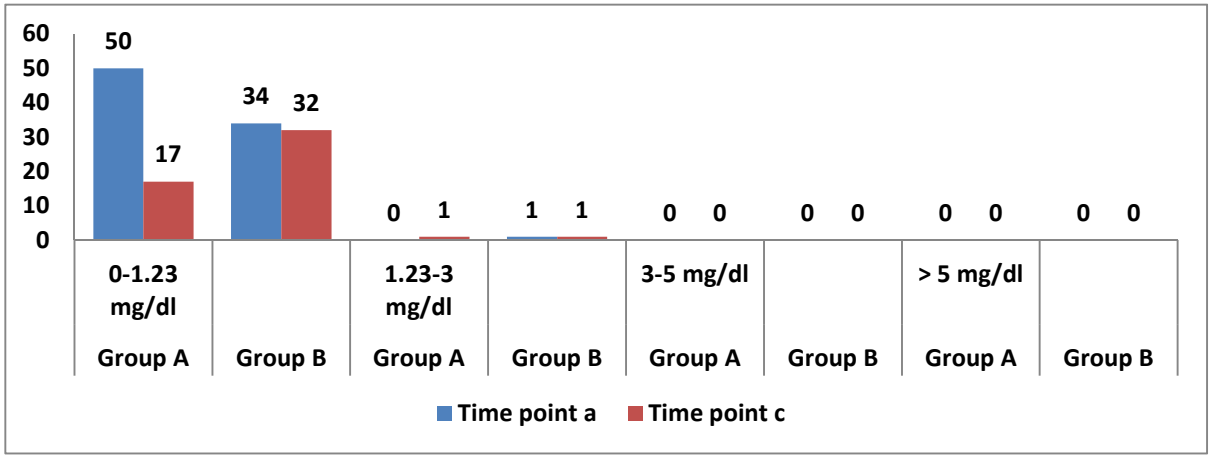
Bilirubin

Table 45 –Table showing values of Total Bilirubin of Breast cancer patients

Total Bilirubin-	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	0-1.23 mg/dl		1.23-3 mg/dl		3-5 mg/dl		> 5 mg/dl	
Time point a	50	34	0	1	0	0	0	0
Time point c	17	32	1	1	0	0	0	0

Total Bilirubin value was maintained within normal limit in both the groups.

Graph 29- Representation of the values of Total Bilirubin of Breast cancer patients



No significant difference was observed in the total Bilirubin value in the both the groups.

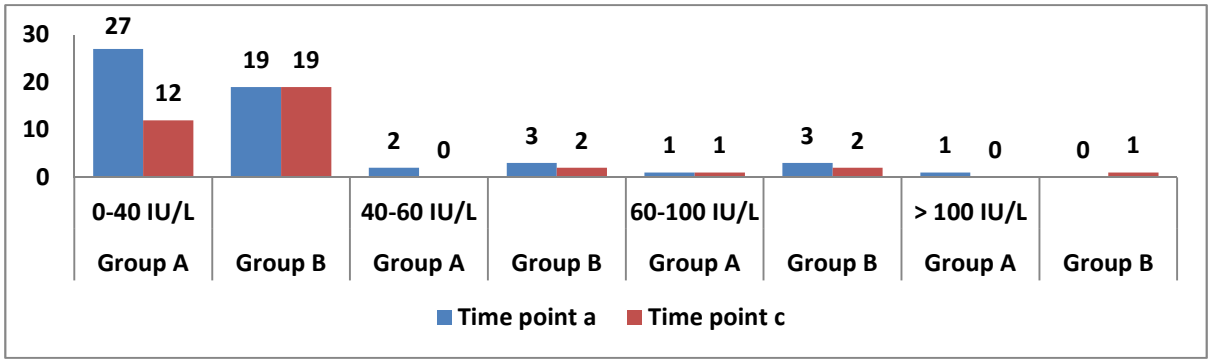
SGOT

Table 46 –Table showing values of SGOT of Breast cancer patients

SGOT	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	0-40 IU/L		40-60 IU/L		60-100 IU/L		> 100 IU/L	
Time point a	27	19	2	3	1	3	1	0
Time point c	12	19	0	2	1	2	0	1

Nearly in both the groups the SGOT value was maintained and was within normal limits.

Graph 30- Representation of the values of SGOT of Breast cancer patients



There was no statistically significant difference observed in value of SGOT .

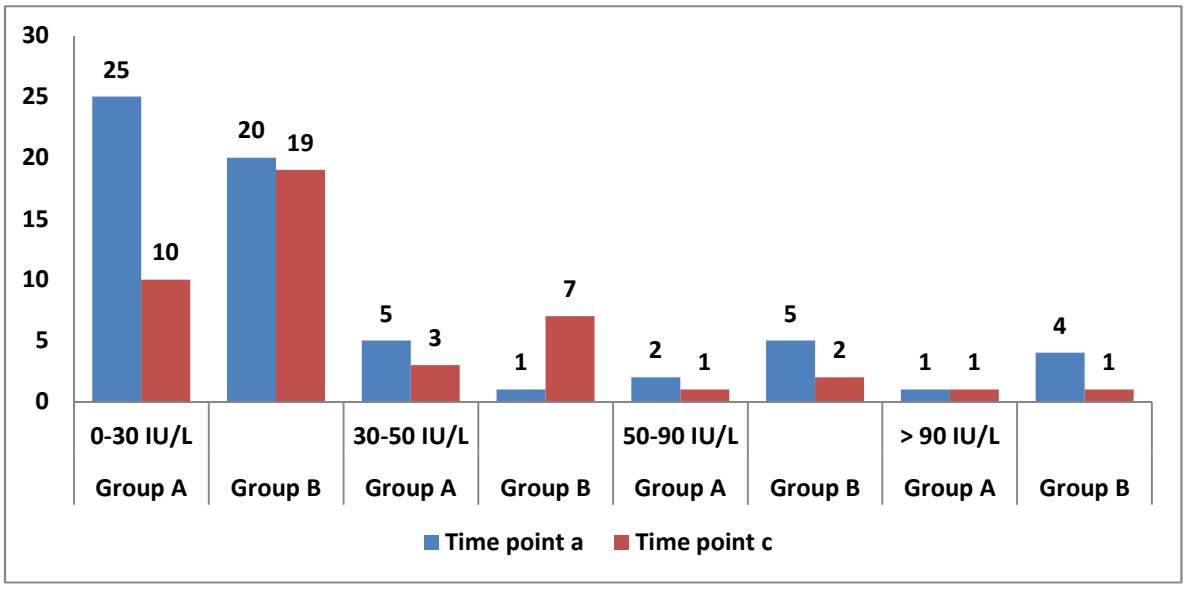
SGPT

Table 47 –Table showing values of SGPT of Breast cancer patients

SGPT	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	0-30 IU/L		30-50 IU/L		50-90 IU/L		> 90 IU/L	
Time point a	25	20	5	1	2	5	1	4
Time point c	10	19	3	7	1	2	1	1

No significant difference in SGPT value is observed in both the groups.

Graph 31- Representation of the values of SGPT of Breast cancer patients



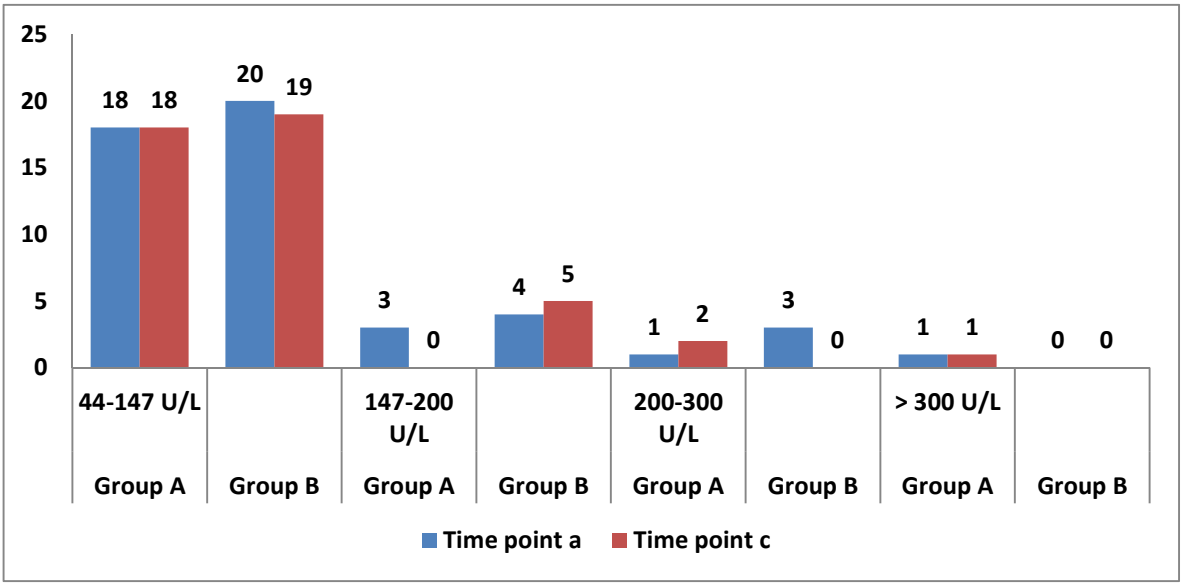
There was no significant difference observed in value of SGPT .

Alkaline Phosphates

Table 48 –Table showing values of Alkaline Phosphates of Breast cancer patients

Alkaline Phosphates	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
	44-147 U/L		147-200 U/L		200-300 U/L		> 300 U/L	
Time point a	18	20	3	4	1	3	1	0
Time point c	18	19	0	5	2	0	1	0

Graph 32- Representation of the values of Alkaline Phosphate of Breast cancer patients



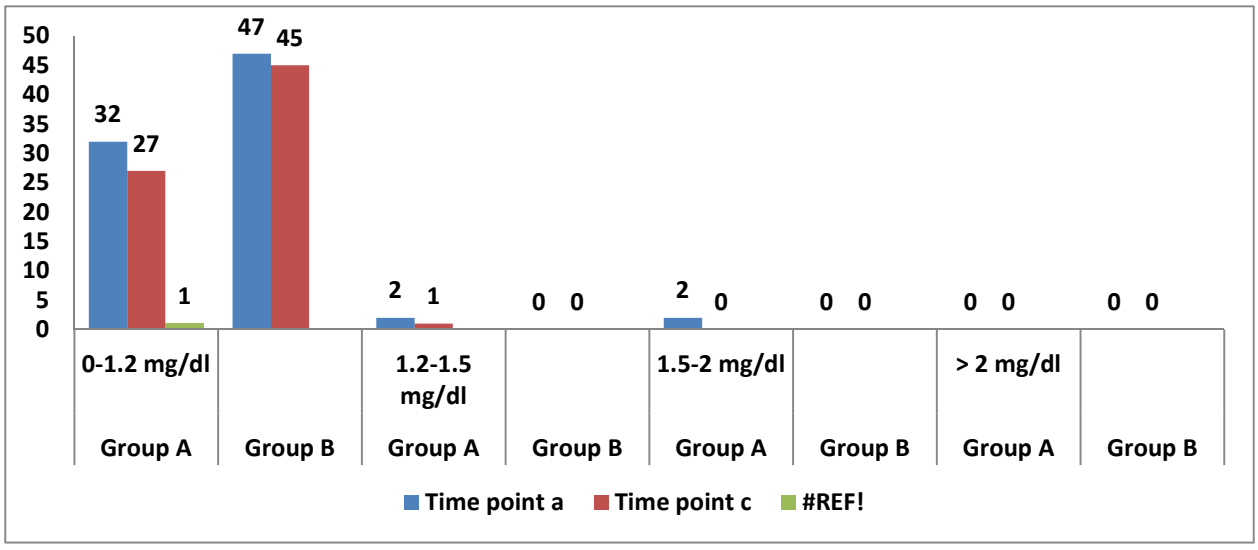
Statistically no significant difference is observed in both the groups.

Creatinine

Table 49 –Table showing values of Creatinine Phosphates of Breast cancer patients

Creatinine								
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**
	0-1.2 mg/dl		**1.2-1.5 mg/dl**		**1.5-2 mg/dl**		**> 2 mg/dl**	
Time point a	**32**	**47**	**2**	**0**	**2**	**0**	**0**	**0**
Time point c	**27**	**45**	**1**	**0**	**0**	**0**	**0**	**0**

Graph 33- Representation of the values of Creatinine Phosphate of Breast cancer patients



Statistically no significant difference is observed in both the groups.

Statistics of Investigations

Table 50 -Investigations Assessment Group A -- Group B (b - a)

Investigations Assessment Group A -- Group B (b - a)							
Sr. No		**Mean of Group A**	**Mean of Group B**	**SD GR A**	**SD GR B**	**P value**	**Significance**
1	**HB**	**-0.98**	**-0.084**	**1.15**	**1.125**	**0.55**	**Not significant**
2	**WBC**	**-1506**	**-874**	**4779**	**4054**	**0.49**	**Not significant**
3	**PLATELET**	**5977**	**303902**	**91360**	**120375**	**<0.0001**	**Extremely significant**

Table 51 - Investigations Assessment Group A -- Group B (c - a)

Investigations Assessment Group A -- Group B (c - a)							
Sr. No	**Symptom**	**Mean of Group A**	**Mean of Group B**	**SD GR A**	**SD GR B**	**P value**	**Significance**
1	**HB**	**-1**	**-0.9**	**1.26**	**1.46**	**0.6**	**Not significant**
2	**WBC**	**-1456**	**-1364**	**5734**	**3271**	**0.92**	**Not significant**
3	**PLATELET**	**-20930**	**-19388**	**121568**	**136052**	**0.95**	**Not significant**
4	**S.BILIRUBIN**	**0.009**	**-0.04**	**0.16**	**0.4**	**0.41**	**Not significant**
5	**SGOT**	**0.2**	**1.15**	**5.66**	**25.6**	**0.81**	**Not significant**
6	**SGPT**	**1.8**	**-6.55**	**8.5**	**43.8**	**0.22**	**Not significant**
7	**Alkaline Phosphates**	**0.3**	**-0.04**	**2.16**	**0.24**	**0.27**	**Not significant**
8	**Creatinine**	**0.28**	**-0.64**	**2.16**	**0.25**	**0.28**	**Not significant**

DISCUSSION

A) Discussion on need of management of chemotherapy side-effects with Ayurvedic medicines

Management of chemotherapy induced side effects described above is a perpetual problem in giving chemotherapy in breast cancers. The allopathic modalities of management of side effects are rather peripheral, which include nutritional support to minimize the weakness, pain control to reduce the sufferings, control of bleeding to counteract the blood loss by administering the blood clotting factors, correcting the blood loss by blood transfusion, iron supplements, intake of heamatinic. Allopathic management of side effects includes anti emetics, antihistaminic, antacids, purgatives, antidiarrhoeal, antibiotics, steroids, injections of filgrastin to increase the leucocytes counts and to counteract the myelosuprssion caused due to chemotherapy. Still with this management the cancer patients suffer from the severe clinical manifestation of the symptoms like anorexia, nausea, vomiting, taste abnormality, constipation, diarrhea, alopecia skin and nail discoloration, hyperpigmentaton and severe myelosuprssion. The general condition of patients worsens due to these side-effects. The quality of life is not well maintained during the course of chemotherapy. Due to this fact most of the patients are not in condition to tolerate chemotherapy or to complete the recommended cycle of chemotherapy in expected time limit. In this scenario, Ayurvedic medicines could help to minimize the side effects, enhance the immunity, and increase the strength physically as well as mentally. Patients could complete chemotherapy protocols in the due course of time. In this respect, the study conducted and data presented here is very useful. The Ayurvedic drugs used are non-toxic, easily palatable and not very expensive, and the effect appears to be very significant. The study was carried out in 2 groups. Group A was study group of 50 patients who had received Ayurvedic treatment (CG4 – combination of four Ayurvedic medicine ie Mautikyukta Kamdudha, Maukticyukta Pravalpanchamrut, Pandmakadi ghruta, Shatavari Kalpa) during chemotherapy and thereafter. Group B was the control group of 50 patients who had received chemotherapy as described earlier.

B) Discussion on Demographic data

Patients diagnosed with breast cancer and underwent chemotherapy are mostly in between the age group of 31 to 70 yrs. in both the groups. This group comprises of perimenopausal and menopausal stage in which the hormonal changes occur frequently. 40% patients were in the 50 years onwards age group. This age is considered as older & it seems that the occurrence of cancer progresses as per the age. 53% patients are from hormonally active age group. 80% patients of breast cancer underwent chemotherapy after surgery. It is because; the chemotherapy is the most recommended conventional treatment available for breast cancer after surgery. 97% patients were diagnosed as infiltrating ductal carcinoma. This type of breast cancer shows maximum prevalence in this study. Infiltrating ductal cancer or Invasive ductal cancer is the most common type of breast cancer. In stage wise distribution of breast cancer 50% patients are of stage III and 30% patients are of stage II. 80% of the patients were receiving chemotherapy after surgery that is adjuvant chemotherapy. 76% patients were from middle socio economic group. In occupation-wise distribution 65% patients were the housewives. In 65% of patients no any specific type of addiction was found. In this study patients who underwent chemotherapy before surgery are less than those who underwent chemotherapy after surgery which is dependent upon the decisive factors namely the stage of the disease and age of the patient.

C) Discussion on mode of action of combination of Ayurvedic medicines on side-effects of chemotherapy –

Side-effects exhibited by chemotherapy drugs like vomiting, loss of appetite, nausea, diarrhea, constipation, GI bleeding, stomatitis, weakness, skin rash are mainly seen by dushti of Vata and Pitta dosha. These drugs have direct effect on Rasa, Rakta, Asthi, Majja and Shukra dhatus. Chemo drugs also vitiate Rasavaha, Raktavaha, Annavaha Strotas. The Jatharagnidushti and Ojakshaya are also caused due to the toxic effects of chemotherapy drugs. Pitta dushti causes Rakta dushti, as Rakta and Pitta being interdependent. Toxins produced are circulating with Rakta dhatu throughout the body causing the systemic side effects. The side effects of chemotherapy thus produced are systemic as well as generalized like Chhardi (vomiting), Raktapitta

(bleeding through openings of the body), Sarvanga Daha (burning in the body), Twakdushti (skin pigmentation), Malavashtambha (constipation), Khalitya (alopecia), Khushdhamandya, Anannabhilasha (anorexia), Dourbalya (weakness) etc.

Patients from Group A received combination of oral Ayurvedic medicines (CG4 combination of 4 Ayurvedic drugs) from the beginning of the chemotherapy and continued for 15 days after completion of chemotherapy. CG4 is a formulation which contains a combination of 4 Ayurvedic medicines namely Mouktikayukta Kamdudha**,** Mauktikyukta Pravalpanchamrut, Shatavari Kalpa and Padmakadi ghruta.

Mouktikayukta Kamdudha –

An Ayurvedic Rasa Kalpa (herbo – mineral formulation) medicine which contains Guduchi (Tinospora cordifolia) satva as a herbal content and Shankh bhasma (Conches), Shauktik bhasma (Pearls), Kapardika bhasma (Cowries), Praval bhasma (Corals), Mouktik bhasma (Mukta) and Gairik (Red Lumber Stone) as the mineral contents.

Guduchi is having Tikta, Kashay Rasa and Madhur Vipak. It is Tridoshashamaka, pacifies three doshas. Guduchisatva is Rasayan, Agni deepan, Balya, Dahshamaka, Jwaraghna and Raktashodhak. Guduchi satva is sheeta in nature, which is the starch based preparation of Guduchi. It has cooling action. These properties of Guduchi are useful in counteracting the Pitta dominant, Raktadushtikar and Agnimandya induced symptoms as side effects of chemotherapy. It boosts the suppressed immune status with its Rasayana action.

Gairik having Madhur Ras, Madhur vipak and Sheeta virya which is beneficial in pacifying Pitta dosha. It possesses the property of Vishanashana. Thus it is beneficial in Pitta pradhan (dominant) side effects of chemotherapy such as GI bleeding, stomatitis, skin rash, hyperpigmentation, vomiting, loose motions, anorexia, nausea in breast cancer patients and eliminates toxins accumulated in the process of disease development and chemotherapy.

Praval is having Madhur, Amla, Kashay Ras, Madhur vipak and Sheet veerya. It is Pittanashak and Kaphanashak and possesses Rasayan, Jwarhar, Raktapittanashak and

Vishghna action which counteracts the chemotherapy induced side effects like anorexia, nausea, taste abnormality, vomiting stomatitis, skin rash, myelosupression. It is Raktaprasadak and helps in maintaining hemoglobin levels and other blood counts during the course of chemotherapy.

Mouktik bhasma possesses Madhur Kashay Ras, Madhur vipak, and Sheet virya. With these properties it is Balya, Tridoshshamak and Dahashamak. The chemotherapy induced side effects like anorexia, nausea, GI bleeding, vomiting, stomatitis, are thus well controlled by intake of Mouktik Bhasma.

Combination of Shankh bhasma, Shauktika bhasma and Kapardika bhasma is mainly Pachak, Tridoshshamak, Agnideepak and thus it alleviates anorexia (annanabhilasha) and vomiting (chhardi) by improving digestion. Nausea and taste abnormality developed during the course of chemotherapy are well controlled with this combination. The mineral contents of this combination are Praval, Shankha, Shauktika and Kapardika. The mineral contents of this combination are basically aquatic in nature thus having Jalamahabhuta dominance. Prithvi and Jalamahabhuta dominant contents reduce the heat (Ushna guna of vitiated Pitta Dosha) and toxicity in the body produced due to chemotherapy. Gairik, is a mineral which is Prithvi mahabhut dominant. Thus this combination is useful in counteracting the Tejamahabhut dominant side effects of chemotherapy according to one of the Ayurvedic concept ie Vishesh siddhanta.

Mouktikayukta Pravalpanchamrut is a combination of Shankh bhasma (Conches), Shauktik bhasma (Pearls), Kapardika bhasma (Cowries), Praval bhasma (Coral), and Mouktik bhasma (Mukta). The mode of action of these minerals in chemotherapy side effect is previously discussed. Godugdha is the bhavana dravya (used for trituration) used in the preparation of Praval Panchamrut which imparts the additional cooling effect to the formulation. It enhances the Pittashamaka activity and counteracts the side effects of chemotherapy.

Padmakadi Ghrut contents Padmaka (Kamal), Durva (Harali), Ananta (Sariva) and Goghruta. Padmaka, Durva, Ananta and Ghruta are having Madhur, Kashaya, Tikta Rasa, Sheeta Veerya, Madhur Vipaka due to which it is having action on doshas as

Pittanashaka, Kaphanashaka and Tridoshashamaka. It is also useful in Trushna (thirst), Mukhapaka (stomatitis), Amlapitta (Acidity) and Daha (burning).

Tikta rasa, Kashaya rasa and Madhur vipaka of Durva is useful in –Agnimandya (Loss of appetite) and Arochak (Loss of appetite). It has beneficial effects on Chhardi (vomiting), Dravamalpravrutti (loose motions), Swedadhikya (excessive sweat), Raktapitta (bleeding through openings of body). Snigdha Guna of Sariva and Ghruta is useful In Agnimandya (loss of appetite), Daha (burning all over body), Malavastambha (constipation), Raktapitta (bleeding though openings of body). Varnya and ropana guna of Padmak are supposed to be useful in Twak dushti (Hyperpigmentation of skin), skin rash. Vishaghna guna of Anantomool, Padmaka and Ghruta are useful in the management of the severe toxic, side effect of chemotherapy. Deepan Karma of Anantmool and Ghruta, Raktasangrahi Karma of Padmak and Anantmool, Rasayan karma of ghruta are useful in management of Daurbalya (weakness), Bharkshaya (loss of weight).

Shatavari Kalpa contents Shatavari and sugar. Shatavari is having Madhur rasa, Madhur vipaka and sheet (cold) guna, thus possesses action as Vata-Pittashamaka, Balya, Vayasthapan, Rasayan. Netrya, Sthanyakar, Shothhar, Medhya, Hrudhya, Vrushya, Agnivardhan, With these properties it counteracts the side effects of chemotherapy.

Overall role of CG4 on chemotherapy induced side-effects is explained on the basis of Ayurvedic principles is as follows –

1. Improving digestion (Pachan)
2. Improving appetite (Deepan)
3. Anti-inflammatory (Shothaghna)
4. Pacifying vitiated Vata and Pitta Dosha
5. Detoxifies blood (Raktaprasadak)
6. Enhancing immune system (Rasayana)
7. Detoxifying (Vishaghna)

D) Discussion on management of adverse effects of chemotherapy with CG4 in breast cancer patients undergoing chemotherapy -

Anorexia - It is the significant side effects of chemotherapy in breast cancer. As per Ayurvedic principles, it is mainly Rasapradoshaja vikara and caused due to vitiation of Kapha and Pitta doshas. Chemotherapy hampers the function of agni. It also affects the metabolism of pachaka pitta and causes angnidushti which leads to Rasa dushti, Rakta dushsti and Rasa - Rakta kshaya. These are the precipitating factors of chemotherapy induced anorexia.

Anorexia - It can be seen that in Group A (Study group) 8 & 24 patients had Grade I and II anorexia respectively immediately after the 1st chemotherapy. While 19 & 8 patients from group B (Control group) had grade I and II anorexia. It implies grade I and II anorexia was evident in the patients of both the groups. At the end time-point (time point c) that is 15 days after the last chemotherapy, 29 patients of study group (A group) got complete relief, 14 patients shows moderate relief in anorexia. While In group B (Control group), only 18 patients got complete relief while rest of the patients were having grade II & grade III anorexia. It implies grade II and III anorexia was evident in control group patients while complete relief in anorexia or grade I anorexia were seen in patients treated with adjunct Ayurvedic treatment. This observation was statistically supported with significant p value ie $p < 0.0001$. These observations established the significant efficacy of Ayurvedic treatment in management of anorexia (annanabhilasha) which is caused due to agnidushti. Agnidushti is a consequence of chemotherapy induced Pittavrudhi and Raktadushti.

Nausea (hrullas) – It is due to the Pittaprakopa, Agnidushti (hampered digestion) and Rasadushti. It is the significant side effect of chemotherapy drugs. Pachaka pitta gets vitiated causing agnidushti and produces nausea.

16 patients from group A and 18 patients from group B were not suffering from nausea when assessed after 1st cycle of chemotherapy. At this time point, 9 patients from group A and 21 patients from group B had grade I nausea, 19 patients from group A and 11 patients from group B were having grade II nausea, 6 patients from group A had grade III nausea. At the time point c (15 days after last chemotherapy.) nausea reduced significantly in patients of group A. 33 patients were having complete

relief in nausea. 11, 4 and 2 patients remain in grade I, II and III respectively in group A at the end of treatment. Number of patients suffering from nausea increased to 27 and 4 respectively in Grade II and III in group B.

p value of nausea 15 days after the last chemo is also significant ie $p < 0.0001$ indicating effectiveness of selected Ayurvedic medicines in minimizing usha guna, pacifying Pachaka pitta and Kapha dosha and thus subsiding nausea.

Loss of taste - Chemotherapy induced loss of taste is developed due to Rasa dusti and Annavaha srotas dushti. According to Ayurvedic principles, Bodhaka Kapha, whose site is Jivha, is responsible for knowledge of tastes. Chemotherapy which hampers functions of bodhaka Kapha, causes loss of taste. In our study, selected Ayurvedic medicines were not found to be effective in study group. Perhaps it may be due to physiological irreversible changes in taste buds after chemotherapy.

Vomiting – Chemotherapy drugs mainly hamper digestion, leading to Pachaka Pitta dushti. Vomiting is induced due Pachaka Pitta dushti. Vomiting leads to severe Rasakshyaya and Agnimandya. At time point a (after 1st chemo) 8,8,3 patients of grade I, II and III respectively from group A were suffering vomiting, while 35 patients did not suffer from vomiting. However at time point c (15 days after last chemotherapy) 4, 4 and 1 patients respectively had grade I, II, III vomiting and 44 patients did not suffer from vomiting from group A. This indicates extremely significant effect of study medicines on vomiting (p value < 0.0001). Shankhs, Shautik, Kapardic bhasmas from Mauktikyukta Kamdudha and Mauktikyukta Praval Panchamrut are Agnideepak and Pachak. Durva Ananata, Padmaka are chhardighna Pitta shamak, and having sheeta virya, Madhur and Kashsya Rasa, Madhur vipaka which pacifies Pitta and subsides vomiting.

Diarrhoea - It is another severe side effect of chemotherapy that causes severe Rasa Kshaya, Agnimandhya which leads to sever weakness and giddiness. In our study, at time point a (after 1st chemotherapy) 2, 5 and 2 patients were having grade III, II and I diarrhoea from study group and 1 and 4 patients were having grade II and I diarrhoea from group B. At time point c (15 days after last chemo) 0, 1, 2 patients were having grade III, II, I diarrhoea respectively, which indicates efficacy of Ayurvedic treatment

in management of diarrhoea. On the other hand, in group B, 7 and 8 patients of grade II, I respectively were suffering diarrhoea. Among Ayurvedic medicines Kamdhudha and Pravalpanchamrut are Grahi and Stambhak in nature. Kashaya rasa and Madhur vipaka of Durva (One of the content of Padmakadi Ghruta) is useful in relieving diarrhoea. The p value <0.0001 which is extremely significant. Indicates usefulness of study medicine in management of diarrhoea.

Gastro intestinal (GI) bleeding – It is an another commonly observed side effect of chemotherapy. The toxicities of chemotherapy medicines increase Ushna and Tikshna guna in body, which causes severe irritation and ulceration in the GI tract. Padmaka, Ananta, Durva and Shatavari possess Sheeta virya, Madhur vipaka and Madhur, Kashaya Rasa which helps to control bleeding. These medicines are also Vranaropak (possess healing property) in nature. Study group patients responded well to GI bleeding (p=0.00488).

Stomatitis – Not quite significant results of Ayurvedic medicines were found for stomatitis in our study.

Constipation is relieved significantly as compare to control group. Mauktikyukta Kamadudha and Mauktikyukta Pravalpanchamrut, Padmakadi ghruta pacify Pitta and Vata dosha. These drugs also possess Deepana and Pachana property. Thus constipation caused due to excessive ushna and ruksha guna, was well controlled with these medicines.

Alopecia – Extremely significant results were observed in alopecia. This is due to the fact that maximum number of patients from group A received Paclitaxel, Carboplatin regimen, which is not likely to cause Alopecia.

Skin rash, hyperpigmentation, photosensitivity and nail discoloration – Very less number of patients in both the groups presented with these symptoms. Thus statistical analysis was not possible for these symptoms.

E) Discussion on clinical parameters (Karnofsky score and QLQ) assessed in breast cancer patients treated with chemotherapy

In this study, we assessed the patient's response to treatment in terms of functional ability and global status with the help of QLQ of EORTC and Karnofsky scores which are well - accepted methods of analysis of outcome measures.

Karnofsky score for performance status was recorded for assessment of general wellbeing and ability to conduct activities of daily life. The higher score of Karnofsky denotes better ability to carry on normal activity which was recorded in Oxford Textbook of Palliative Medicine.

As Karnofsky score indicates feeling of wellbeing. It commonly shows decreasing trend during the course of chemotherapy. As per this trend Karnofsky score of most of the patients in control group was remarkably declined after 1st chemotherapy, in the middle of chemotherapy and 15 days after completing chemotherapy (80, 69, and 67 respectively). On the other hand Karnofsky score was not significantly reduced at the three time points in study group (84, 80, 76 respectively), indicative of beneficial effects of adjunct oral Ayurvedic medicines. Karnofsky score shows $p<0.0001$ (extremely significant), $p= 0.0006$ (extremely significant) when tested in middle of the chemotherapy and 15 days after completion of chemotherapy.

The Quality of Life (QLQ) is assessed on the basis of 3 parameters ie functional score, global score and symptom score as per EORTC QLQ - C30. Functional score is the sum total of improvement in all side effects of chemotherapy leading to achieving normal levels of functional ability of the patient, which is end point of assessment of well – being of the patient. It is a numerical score. Increase in the score denotes improvement in general functional activity of the patient.

The Global score denotes status of QLQ as judged by the patient himself. Improvement in global score indicates improvement in QoL. Symptom score indicates sufferings orr symptoms. Higher symptom score indicates severe symptom gradations. Functional score and Global score of QoL (quality of life) are normally hampered after completion of chemotherapy. In our study decreased functional and symptom scores were observed in almost all patients in control group, while these

parameters were improved or maintained in nearly 42 patients of study group. This indicates effectiveness of selective Ayurvedic medicines in boosting immunity due to their Rasayana action, decreasing symptomatology and ultimately improving functional ability of patients during and after chemotherapy. Global score of QLQ is very significant at time point b ($p=0.0008$) and extremely significant at time point c ($p < 0.0001$). There is no statistical improvement seen in functional and symptom score as the functional improvement after chemotherapy is rather slow and in symptom score the discrepancy could be due to less improvement in disease related symptoms.

F) Discussion on pathological investigations assessed in breast cancer patients treated with chemotherapy

Myelossupression is the known side effect of chemotherapy. The heamoglobin percentage and the WBC count show no change in both the groups. Platelet count is extremely significant at time point b ($p < 0.0001$). A set of Ayurvedic medicines used in the study was not effective in treating chemotherapy induced myelosupression, though its efficacy is proved in management of major side-effects of chemotherapy.

CONCLUSION

a. CG4 was highly effective in the management of gastrointestinal side effects of chemotherapy.
b. CG4 was not effective in management of dermatological side effects of chemotherapy.
c. CG4 Ayurvedic treatment was highly significant in management of Karnofsky score and Global score of quality of life questionnaire.
d. CG4 was not effective in the management of heamatological side effects of chemotherapy.

SCOPE FOR FURTHER STUDY

Role of Ayurvedic treatment in management of side effects of Chemotherapy in CA Breast is studied in this research work on the basis of clinical examinaltion (CTC ,QLQ, Kernofsky) and clinical bio chemistry(Haemogram, Liver Function Test, Kidney Function Test).

Ayurvedic treatment is found to be effective in management of side effects of Chemotherapy.The exact mechanism of action of ayurvedic medicines on chemotherapy side effects has to be understood on the basis of inflammatory cytokines(Immunological markers like IL levels & Reactive oxidative stress.)in view of immunomodulatory and anti inflammatory action of selected ayuvedic medicines.

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1) Control Group-Master Chart(a=after first chemotherapy,b=mid of the chemotherapy, c=fifteen days after last cycle of chemotherapy.)

Sr No	Name	Age	Side	HPR	Grade	Stage	Chemotherapy Protocol	Status	Occupation	Soscioeconomis	Addiction	weight					kernofsky score					Actual QLQ-Functional					Actual QLQ-Symptom					Actual QLQ-Global					QLQ-Functional			QLQ-Symptom			QLQ-Global		
												a	b-a	c-a	b	c	a	b-a	c-a	b	c	a	b-a	c-a	b	c	a	b-a	c-a	b	c	a	b-a	c-a	b	c	a	b	c	a	b	c	a	b	c
1	SB	37	Lt	IDC	II	II	TAC	post surgery	House Wife	Middle	Nil	62	-4	-6	58	56	80	-10	-10	70	70	44	18	27	62	71	74	-18	-5	56	69	100	-17	-33	83	67	40	32	28	42	35	40	14	12	10
2	MB	54	Lt	IDC	III	II	TAC	post surgery	House Wife	Middle	Nil	58	-3	-4	55	54	80	-10	-20	70	60	67	-24	-47	42	20	49	36	51	85	100	83	-17	-33	67	50	30	41	51	32	46	52	12	10	8
3	VR	48	Rt	IDC	II	I	FEC	post surgery	House Wife	Middle	Nil	51	-2	-3	49	48	80	-10	-20	70	60	67	-4	-20	62	47	54	-10	15	44	69	67	-8	-25	58	42	30	32	39	34	30	40	10	9	7
4	KG	38	Lt	IDC	III	III	AC-T	post surgery	House Wife	Middle	Nil	76.5	-2.5	-3	74	74	80	-10	-20	70	60	62	-9	-22	53	40	59	10	23	69	82	83	-17	-17	67	67	32	36	42	36	40	45	12	10	10
5	VP	64	Rt	IDC	III	III	AC-T	post surgery	House Wife	Higher	Nil	55	-1	-1	54	54	80	-10	-20	70	60	44	-4	-9	40	36	74	-18	-5	56	69	100	-17	-33	83	67	40	42	44	42	35	40	14	12	10
6	ST	41	Lt	IDC	III	III	TAC	post surgery	Farmer	Lower	Nil	64.5	-0.5	-2	64	63	90	-30	-20	60	70	89	-27	-27	62	62	28	31	31	59	59	83	-8	-25	75	58	20	32	32	24	36	36	12	11	9
7	SJ	51	Rt	IDC	III	IV	FEC	Chemo-surg-Chemo	House Wife	Lower	Nil	73	-2	-4	71	69	70	-10	-10	60	60	62	4	0	67	62	56	3	15	59	72	67	0	0	67	67	32	30	32	35	36	41	10	10	10
8	GG	50	Lt	IDC	III	II	FEC	post surgery	labour	Lower	Masheri	51	0	-1	51	50	80	0	-10	80	70	89	-13	-27	76	62	28	15	28	44	56	83	-8	-25	75	58	20	26	32	24	30	35	12	11	9
9	VM	38	Lt	IDC	II	II	FEC	post surgery	Teacher	Middle	tea	69	1	1.4	70	70	80	-20	-10	60	70	84	-18	-27	67	58	38	18	31	56	69	83	-17	-17	67	67	22	30	34	28	35	40	12	10	10
10	SM	78	Rt	IDC	II	IV	FEC	before surgery	Farmer	Lower	mashery,nut chewing	43	-1	-1	42	43	90	-10	-30	80	60	98	-24	-31	73	67	18	28	31	46	49	83	-17	-17	67	67	16	27	30	20	31	32	12	10	10
11	AG	33	Rt	IDC	II	II	TAC	post surgery	Teacher	Middle	Nil	39.3	0.7	1.2	40	41	80	-20	0	60	80	78	-7	-2	71	76	44	-15	-26	28	18	92	-8	-25	83	67	25	28	26	30	24	20	13	12	10
12	MV	48	Rt	IDC	II	II	CAF	post surgery	House Wife	Middle	Nil	59	0.5	0.9	60	60	90	-20	-20	70	70	89	-4	-4	84	84	28	0	-10	28	18	100	-33	-50	67	50	20	22	22	24	24	20	14	10	8
13	SK	40	Rt	IDC	III	III	CAF	post surgery	House Wife	Middle	Nil	62.4	0.6	1.2	63	64	90	-30	-20	60	70	87	-16	-24	71	62	33	10	15	44	49	83	-8	-17	75	67	21	28	32	26	30	32	12	11	10
14	HM	31	Rt	IDC	II	III	AC	post surgery	House Wife	Lower	Betel nut	53	0	1	53	54	80	-10	-10	70	70	87	-2	-7	84	80	33	0	-5	33	28	67	-17	-25	50	42	21	22	24	26	26	24	10	8	7
15	SB	50	Lt	IDC	II	III	CAF	post surgery	Farmer	Lower	Masheri	49	0	0	49	49	90	-10	-10	80	80	89	4	4	93	93	28	-10	-15	18	13	83	-8	-25	75	58	20	18	18	24	20	18	12	11	9
16	PV	48	Rt	IDC	II	III	TA	Chemo-surg-Chemo	Farmer	Middle	Masheri	79	0	0.4	79	79	80	-10	-20	70	60	64	24	2	89	67	54	-26	-15	28	38	83	-17	-33	67	50	31	20	30	34	24	28	12	10	8
17	VK	60	Rt	IDC	II	III	CA	post surgery	House Wife	Lower		74.5	-0.5	-1	74	73	80	-20	-20	60	60	53	9	0	62	53	69	-13	-10	56	59	100	-8	-25	92	75	36	32	36	40	35	36	14	13	11
18	PD	40	Lt	IDC	III	III	AC-T	post surgery	Business	Middle	Nil	66	-1	-1	65	65	80	-20	-10	60	70	40	0	-4	40	36	74	-21	-5	54	69	83	-17	-33	67	50	42	42	44	42	34	40	12	10	8
19	RP	32	Rt	IDC	III	III	CE	post surgery	Service	Higher	Nil	74	-1	-1	73	73	80	-10	-10	70	70	44	-4	-18	40	27	79	10	5	90	85	67	-8	-17	58	50	40	42	48	44	48	46	10	9	8
20	UJ	57	Lt	IDC	II	IV	CE	post surgery	House Wife	Lower	Nil	51	-1	-1	50	50	80	-20	-20	60	60	62	-9	-22	53	40	54	15	15	69	69	75	-17	-33	58	42	32	36	42	34	40	40	11	9	7
21	PS	30	Lt	IDC	III	III	C-CG	post surgery	software Engg.	Higher	Nil	68.7	2.3	5.1	71	74	80	-10	0	70	80	89	-4	4	84	93	28	5	-15	33	13	83	-8	-25	75	58	20	22	18	24	26	18	12	11	9
22	RP	64	Rt	IDC	II	III	FEC	post surgery	House Wife	Middle	Nil	60.3	0.1	-3	60	58	90	-20	-30	70	60	93	-18	-49	76	44	18	26	56	44	74	83	-17	-25	67	58	18	26	40	20	30	42	12	10	9
23	NK	45	Rt	IDC	III	IV	FEC	Before surgery	House Wife	Higher		72.9	-0.5	-0	72	73	80	-20	-20	60	60	64	-24	-38	40	27	56	23	33	79	90	67	-8	-17	58	50	31	42	48	35	44	48	10	9	8
24	SP	65	Rt	IDC	II	I	FEC	post surgery	House Wife	Middle	Nil	67	-1	-1	66	66	80	-20	-20	60	60	84	4	-4	89	80	28	0	5	28	33	75	0	-17	75	58	22	20	24	24	24	26	11	11	9
25	SG	47	Rt	Tubular ca	I	I	FEC	post surgery	House Wife	Lower	Nil	55.7	0.3	1.4	56	57	80	-20	-20	60	60	58	-27	-36	31	22	64	15	41	79	105	83	-8	-25	75	58	34	46	50	38	44	54	12	11	9
26	SJ	46	Rt	IDC	III	II	CAF	post surgery	House Wife	Higher	Nil	72	-3	-2	69	70	80	-20	-10	60	70	67	13	0	80	67	54	-15	-15	38	38	75	-8	-25	67	50	30	24	30	34	28	28	11	10	8
27	ST	45	Lt	IDC	III	III	CAF	post surgery	Business	Higher	Nil	52.9	0.9	1.1	54	54	70	-10	-10	60	60	62	22	-24	84	38	49	-10	31	38	79	50	0	0	50	50	32	22	43	32	28	44	8	8	8
28	VG	52	Lt	IDC	II	III	ACT	post surgery	Nurse	Middle	Masheri	46	-46	-1		45	90	-10	0	80	90	98	-4	-11	93	87	18	0	5	18	23	83	-8	-25	75	58	16	18	21	20	20	22	12	11	9
29	MC	40	Lt	IDC	II	III	ACT	post surgery	House Wife	Lower	Masheri	55	-0.3	-2	55	53	70	-10	-10	60	60	67	-24	-47	42	20	49	36	51	85	100	83	-17	-33	67	50	30	41	51	32	46	52	12	10	8
30	AK	40	Lt	IDC	II	III	ACT	post surgery	House Wife	Middle	Nil	61.5	-0.6	-6	61	56	70	-10	-10	60	60	87	2	0	89	87	28	-5	-8	23	21	67	-8	-25	58	42	21	20	21	24	22	21	10	9	7
31	SD	61	Rt	IDC	II	III	ACT	post surgery	House Wife	Middle	Nil	53.1	0.9	0.7	54	54	60	0	-10	60	50	27	0	-24	27	2	##	-3	13	###	121	50	-8	-25	42	25	48	48	59	55	54	60	8	7	5
32	RS	49	Lt	IDC	II	II	ACT	post surgery	House Wife	Middle	Nil	46.5	1.7	2.9	48	49	70	0	-10	70	60	58	-4	-24	53	33	64	5	26	69	90	67	-17	-33	50	33	34	36	45	38	40	48	10	8	6
33	ST	63	Rt	IDC	II	IV	FEC	post surgery	House Wife	Middle	Tea	65.4	-0.4	-1	65	64	80	-10	-20	70	60	91	-29	-24	62	67	21	28	33	49	54	83	-8	-25	75	58	19	32	30	21	32	34	12	11	9
34	VK	65	lt	IDC	II	III	CEF	Sandwich	House Wife	Middle	supari	60	-2	-5	58	55	70	0	-10	70	60	44	-4	-18	40	27	79	10	5	90	85	67	-8	-17	58	50	40	42	48	44	48	46	10	9	8
35	GD	41	Lt	IDC	II	IV	CAF	post surgery	Farmer	Lower	Masheri	77	-0.8	-2	76	76	80	-10	-20	70	60	62	-4	-16	58	47	54	15	15	69	69	67	-8	-25	58	42	32	34	39	34	40	40	10	9	7
36	VB	36	Lt	IDC	II	III	CE	Before surgery	House Wife	Middle	Nil	75	1	2	76	77	80	-10	-10	70	70	84	-13	-18	71	67	28	5	10	33	38	67	-17	-33	50	33	22	28	30	24	26	28	10	8	6
37	SC	38	Rt	IDC	II	II	FEC	post surgery	House Wife	Middle	Nil	85	-5	-15	80	70	80	-10	-10	70	70	58	-4	-24	53	33	64	5	26	69	90	67	-17	-33	50	33	34	36	45	38	40	48	10	8	6
38	RT	36	Rt	IDC	II	III	ACT	post surgery	Professor	Higher	Tea	74	-1	-1	73	73	90	-20	-20	70	70	76	-9	-16	67	60	38	10	15	49	54	50	-8	-25	42	25	26	30	33	28	32	34	8	7	5
39	AN	34	Rt	IDC	III	III	Gemcitamine 70mg	post surgery	House Wife	Middle	Nil	48.5	0.2	0.3	49	49	80	-10	-10	70	70	67	-4	-11	62	56	49	5	10	54	59	83	-17	-33	67	50	30	32	35	32	34	36	12	10	8
40	MK	65	Lt	IDC	III	IV	CAF	post surgery	House Wife	Middle	betel leaf & nut	65	1	3.7	66	69	70	0	-10	70	60	80	-9	-2	71	78	44	0	-10	44	33	67	0	-17	67	50	24	28	25	30	30	26	10	10	8
41	MS	60	Rt	IDC	II	II	ACT	post surgery	House Wife	Lower	Nil	62.7	-1.7	-2	61	61	80	-10	0	70	80	80	-16	-20	64	60	44	13	10	56	54	83	-8	-17	75	67	24	31	33	30	35	34	12	11	10
42	JG	44	Rt	IDC	II	II	CAF	Chemo-surg-Chemo	Farmer	Middle	Nil	74	-0.7	-2	73	72	80	-10	-10	70	70	76	9	4	84	80	38	-10	-10	28	28	83	-17	-33	67	50	26	22	24	28	24	24	12	10	8
43	ND	40	Rt	IDC	III	III	FEC	post surgery	House Wife	Middle	Nil	57	-0.5	-1	57	56	80	-20	-20	60	60	71	0	-7	71	64	44	5	5	49	49	83	-8	-17	75	67	28	28	31	30	32	32	12	11	10
44	KK	57	Lt	IDC	III	II	AC	Before surgery	Nurse	Middle	betel leaf & masheri	82	0	1	82	83	80	-10	-10	70	70	84	-27	-36	58	49	44	10	21	54	64	83	-8	-25	75	58	22	34	38	30	34	38	12	11	9
45	PR	55	Lt	IDC	II	II	FEC	post surgery	House Wife	Middle	Nil	70	-4	-6	66	64	80	-10	-20	70	60	67	-4	-11	62	56	49	5	10	54	59	83	-17	-33	67	50	30	32	35	32	34	36	12	10	8
46	AR	39	Rt	IDC	II	II	CA	post surgery	software Engg.	Middle	tea	60	0	0.4	60	60	80	10	0	90	80	84	2	0	87	84	38	-10	-15	28	23	83	0	-17	83	67	22	21	22	28	24	22	12	12	10
47	CD	34	Lt	IDC	II	III	FEC	Chemo-surg-Chemo	Farmer	Lower	Nil	49	1	3	50	52	80	0	0	80	80	80	-4	-18	76	62	44	5	3	49	46	83	-8	-25	75	58	24	26	32	30	32	31	12	11	9
48	SN	40	Rt	IDC	III	III	CA	Chemo-surg-Chemo	Business	Middle	Nil	46	0	-8	46	38	80	-10	-20	70	60	84	-13	-44	71	40	38	15	36	54	74	83	-8	-17	75	67	22	28	42	28	34	42	12	11	10
49	SB	52	Lt	IDC	II	II	FEC +	post surgery	Farmer	Lower	Nil	76	-6	-8	70	68	80	0	0	80	80	67	-4	-11	62	56	49	5	10	54	59	83	-17	-33	67	50	30	32	35	32	34	36	12	10	8
50	SB	65	Lt	IDC	III	III	FEC	post surgery	Farmer	Lower	Smoking	55	-5	-10	50	45	80	-10	-20	70	60	71	0	-7	71	64	44	5	5	49	49	83	-8	-17	75	67	28	28	31	30	32	32	12	11	10

2) Control Group-Master Chart(a=after first chemotherapy,b=mid of the chemotherapy, c=fifteen days after last cycle of chemotherapy.)

Sr No	Name	1. Anorexia			2. Nausea			3. Vomiting			4. Taste Abnormality			5. Diarrhoea			6. GI Bleed			7. Stomatitis			8. Constipation			9. Alopecia			10. Skin Rash			11. Nail Discolouration			12. Hyperpigmentatio			13. Photosensitivity		
		a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
1	SB	0	0	0	1	1	2	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
2	MB	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
3	VR	0	0	0	1	2	2	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	0	1	2	0	0	0	0	1	2	0	0	0	0	0	0
4	KG	0	0	0	0	1	1	0	0	1	0	0	0	1	2	2	2	3	2	0	0	0	0	0	0	0	0	0	1	2	1	0	0	0	0	0	0	0	0	0
5	VP	1	2	2	0	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	ST	0	0	0	1	1	2	0	1	2	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	1	2	3	0	0	0	0	0	0	0	0	0	0	0
7	SJ	0	1	1	1	1	2	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	1	2	1	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
8	GG	3	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9	VM	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	SM	1	1	1	1	2	2	0	1	2	0	0	0	0	2	2	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
11	AG	1	1	1	0	1	1	0	0	0	1	1	1	0	1	2	0	0	0	0	1	1	1	0	0	0	1	2	0	1	1	0	0	0	0	0	0	0	0	0
12	MV	0	1	2	2	2	3	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
13	SK	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	0	0	0	1	2	3	0	0	0	0	0	0
14	HM	0	0	2	2	3	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	2	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	SB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	PV	0	0	0	1	1	2	0	1	1	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
17	VK	2	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	2	1	1	2	0	0	0	0	0	0
18	PD	1	2	2	2	2	2	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
19	RP	1	1	2	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	UJ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0
21	PS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
22	RP	1	2	2	1	1	1	0	0	0	0	0	0	0	0	0	1	2	1	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	NK	2	2	2	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
24	SP	1	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
25	SG	2	2	3	2	2	2	0	0	0	2	2	2	0	0	0	0	1	2	1	0	0	2	2	3	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
26	SJ	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
27	ST	1	2	2	2	2	2	0	0	0	0	0	0	1	1	2	0	0	0	1	2	2	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
28	VG	2	2	3	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	1	2	2	0	0	1	0	1	2	0	0	0	0	0	0
29	MC	2	2	3	2	2	3	2	2	1	0	0	1	0	1	1	0	1	2	0	0	0	1	1	0	1	2	2	0	0	0	0	2	2	0	0	0	0	0	0
30	AK	1	1	2	2	2	2	0	0	0	0	1	3	0	0	1	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	1	1	2	0	0	0	0	0	0
31	SD	0	2	2	0	1	2	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	1	2	0	0	1	0	1	1	0	0	0	0	0	0
32	RS	1	2	2	1	1	2	0	0	0	2	2	1	0	1	2	0	0	0	0	0	0	2	1	0	0	1	2	0	0	0	1	1	2	0	0	0	0	0	0
33	ST	1	2	2	1	1	2	0	1	1	0	1	1	0	0	0	0	0	0	0	0	0	1	2	2	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
34	VK	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	3	3	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
35	GD	0	0	0	1	2	1	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
36	VB	1	1	1	1	1	2	1	1	2	0	1	1	0	1	1	0	1	1	0	0	0	0	0	0	1	1	2	0	0	0	0	1	1	0	0	0	0	0	0
37	SC	0	0	0	2	2	1	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	RT	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
39	AN	1	2	2	1	1	2	1	2	2	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
40	MK	0	0	0	2	2	3	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
41	MS	2	2	2	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	JG	1	1	2	2	2	3	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	ND	1	2	2	1	1	2	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
44	KK	1	1	1	0	1	2	1	1	1	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	1	2	2	0	0	0	0	0	0
45	PR	2	3	2	1	1	2	2	2	2	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	1	1	2	0	0	0	1	1	1	0	0	0	0	0	0
46	AR	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
47	CD	1	2	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	SN	2	2	2	1	1	2	0	0	0	0	0	0	2	1	2	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	0	0
49	SB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	1	2	2	0	0	0	0	0	0
50	SB	0	0	0	1	1	2	1	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

3) Control Group-Master Chart(a=after first chemotherapy,b=mid of the chemotherapy, c=fifteen days after last cycle of chemotherapy.)																				
Sr No	**Name**	**Hb**			**WBC**			**Platelets**			**Bilirubin-Total**		**SGOT**		**SGPT**	**Alkaline Phosphatase**			**Creatinine**	
		a	**b**	**c**	**a**	**b**	**c**	**a**	**b**	**c**	**a**	**c**	**a**	**c**	**a**	**c**	**a**	**c**	**a**	**c**
1	SB	12.9	12.6	12.1	7200	4500	4800	215000	234000	165000	0.7	1.2	23.5	19.2	26.8	15	76.5	86.2	0.6	0.8
2	MB	11.8	11.8	13	10200	5200	6500	136000	246000	215000									0.8	0.7
3	VR	11.5	10.1	10.8	7100	4200	7800	336000	276000	236000									0.8	0.8
4	KG	10.6	10.4	10.9	11500	12500	7300	466000	631000	431000	0.8	0.4		20.4		19.2		190.9	0.47	0.7
5	VP	9.9	5.5	6.6	10350	2300	2950	359000	52000	79000		0.9		77.1		47.6		155.6	0.92	1
6	ST	12.4	12.9	10.4	9100	10200	9000	240000	393000	277000	0.9	0.72	29	27	24	22.28	94	77	1	1.01
7	SJ	12.7	10.8	11.6	5300	7200	6500	408000	245000	347000	0.3	0.3							1	1.1
8	GG	11.9	11.3	11.2	7700	3800	4900	299000	421000	409000					59.1	25.2			0.95	0.67
9	VM	10.8	11.4	11.1	4200	7480	6950	339000	475000	278000	0.63	0.6	16	22	21	20	198	139	0.46	0.8
10	SM	11	9.3	9.6	7700	2900	5200	235000	167000	263000	0.68	0.7	44.49	19.89	28.75	10.3	53.84	57.81	0.97	0.85
11	AG	11.8	10.9	10.5	7800	5100	5300	312000	353000	255000	0.62	0.57			25	35			0.57	0.53
12	MV	9.8	8.6	9.2	9500	3400	6000	344000	325000	313000	1.5		23		21		157		1.2	
13	SK	13.3	11.8	11.8	10300	5900	2600	276000	269000	173000	0.9		14		25				0.6	0.7
14	HM	9.8	10.7	11.3	7100	7900	8500	183000	190000	198000	0.81		99		265		149		0.61	
15	SB	13.1	12.9	12.9	7900	8500	5350	373000	297000	327000	0.5	0.26							0.8	0.7
16	PV	12.4	12.1	9.9	10400	6700	8000	10800	250000	185000									0.8	0.45
17	VK	10,5	9.8	10.1	8100	6400	8700	536000	486000	563000									0.69	0.71
18	PD	13.4	10	12.1	5300	6500	3700	424000	569000	347000									0.7	0.6
19	RP	12	10.1	11.6	3600	4680	4910	240000	267000	277000	0.61	0.64	21.1	21.2	19	24.3	76.6	81.4	0.65	0.6
20	UJ	11.8	10.7	11.9	7700	6600	5000	328000	389000	340000	0.88	0.87	18.4	20	21.1	18.7	96.4	88.1	0.96	0.75
21	PS	11	10.3	9.6	6800	6100	4500	298000	261000	182000	0.7	0.4							0.8	0.7
22	RP	11.7	9.6	9.6	6800	6800	8000	197000	267000	185000	0.4	0.6	9	13	13	18	76	85	0.7	0.5
23	NK	14.3	12.7	11.8	9650	8100	7300	212000	229000	155000	0.3		37		56		107			
24	SP	11.6	11.8	11	8300	5400	5400	398000	363000	276000	0.9	0.94		31		28		169	1.2	1.01
25	SG	12.4	11.6	10.3	8100	12700	7000	278000	324000	297000	0.7	0.2							0.79	0.8
26	SJ	11.1	10.6	10.2	9800	6100	5000	372000	410000	291000			64		79	32	203		0.69	0.83
27	ST	10.7	10.4	11	6600	3600	5200	414000	260000	213000		0.6			137	45			0.9	0.78
28	VG	8.6	8.7	9.1	6900	4600	6100	291000	267000	315000	0.69	0.68	18.77	34.74	11.98	24.12	90.19	80.02	0.86	0.75
29	MC	11.9	11.9	9.1	4500	3000	4600	343000	202000	228000	0.7		21.96		23.56		95.6		0.74	0.95
30	AK	10.3	9.4	8.4	7800	4500	6100	335000	279000	387000	0.71	0.62	19.09	23.58	20.37	24.36	102	69.1	0.7	1.08
31	SD	12	12.5	11	7800	7400	7500	343000	381000	217000	0.65	0.7	16.45	27	13.5	11.34	94.59	47.27	0.78	0.72
32	RS	14.3	11.6	12.3	3100	4900	3300	276000	296000	218000	0.65	0.69	33	91.61	27.48	59.11	68	81.88	0.59	0.71
33	ST	10.7	10.1	10.8	6300	5100	6500	303000	110000	239000	0.4	0.5					85	72	0.6	0.5
34	VK	12.55	11	8.9	1081	8180	4950	334000	409000	219000									0.7	0.9
35	GD	11.2	11.5	11.5	7500	5000	4400	365000	320000	212000	1	0.8	52	52	78	54	178		0.8	0.9
36	VB	15.2	12.3	13	11340	6590	11190	313000	443000	315000	1.19	0.68	20	23	14	19	110	102	0.9	0.8
37	SC	13	11.7	10.1	11200	26800	6980	368000	221000	408000	0.42	0.5							0.64	0.8
38	RT	9.3	9.3	8.5	8600	7300	6500	306000	150000	539000									0.91	0.66
39	AN	11.1	9.4	7.9	4300	3300	5650	107000	165000	800000										
40	MK	10.4	10.5	12.2	12700	13200	12900	283000	424000	253000		0.44		22		11		110	0.84	0.72
41	MS	9.7	9.6	10.6	15700	3900	11200	565000	184000	396000	0.27	0.79	14	26	14	27.8	87	161	0.81	0.9
42	JG	10.7	10.8	11.2	10100	10900	2340	268000	306000	243000	0.61	0.43	29	19	55	29	60	57	0.7	0.7
43	ND	13.5	10.6	10.9	9490	6090	4660	238000	140000	155000	0.5	0.52	17	34	15	44			1.05	1.04
44	KK	12.3	11.8	10.2	5700	5600	3800	310000	413000	334000	0.36	1.4	64	118	96	140	67	70	0.72	0.7
45	PR	10.5	9	9.9	4800	6100	4900	243000	288000	263000	0.8	0.74	28	21	33	14	263	84	0.8	1
46	AR	9.5	9.5	9.5	5700	3500	4200	265000	261000	298000	0.47	0.51			13	38			0.61	0.61
47	CD	11.7	11.3	9.1	3500	4800	2400	253000	299000	163000					11.2	39.4	0.7	0.8		
48	SN	9.3	8.7	12	9100	13600	22600	240000	400000	160000									1	0.5
49	SB	10.8	9.74	8.8	11580	10470	7380	475000	609000	556000	0.3	0.4					106	99	0.6	0.57
50	SB	10.1	11.1	12.1	9600	13200	10400	398000	302000	267000	0.54	0.55		27.88		16.85	123	161.8	0.7	0.83

1)Study Group=(a=after first chemotherapy,b=mid of the chemotherapy, c=fifteen days after last cycle of chemotherapy.)

Sr No	Reg No	Age	Side	HPR	Grade	Stage	Protocol	Status	Occupation	Socio-economic	Addiction	Weight			Kernofsky			Functional			Symptom			Global		
												a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
1	101117	50	Left	IDC	III	III	CE	Post surgery	Clerk	Middle	Nil				90	90	90	53.33	48.89	37.78	66.67	74.36	82.05	100.00	91.67	83.33
2	2013,0,397	40	Left	IDC	II	III	FC	Post surgery	Farmer	Lower	Masheri	44.8	49	50	90	80	90	75.56	71.11	62.22	41.03	58.97	69.23	83.33	66.67	75.00
3	2012,0,054	53	Right	IDC	II	III	CAF	Post surgery	House wife	Middle	Nil	62	65	66	80	70	70	66.67	66.67	53.33	46.15	48.72	53.85	83.33	75.00	66.67
4	2012,0,126	68	Right	IDC	II	III	FEC	Post surgery	House wife	Middle	Nil	49	52	52	80	80	80	62.22	66.67	75.56	51.28	51.28	64.10	83.33	75.00	66.67
5	2012,0,247	59	Left	IDC	II	III	FEC	Post surgery	Clerk	Upper	Tea	62	60	65	90	80	80	55.56	57.78	55.56	66.67	69.23	79.49	100.00	83.33	75.00
6	2011,0,064	68	Bilatera	IDC	I	III	AC-T	Post surgery	House wife	Middle	Nil	54	55	55	80	80	70	95.56	91.11	84.44	20.51	33.33	38.46	83.33	75.00	66.67
7	111289	59	Left	IDC	III	III	CAF	Post surgery	House wife	Middle	Masheri, Tea				90	90	80	73.33	66.67	62.22	48.72	58.97	58.97	66.67	58.33	50.00
8	2016,0,202	45	Right	IDC	II	III	CA	Post surgery	House wife	Middle	Nil				100	90	80	88.89	88.89	88.89	20.51	20.51	30.77	83.33	58.33	66.67
9	2014,0,174	45	Left	IDC	III	III	CAF	Post surgery	House wife	Middle	Nil				80	80	70	95.56	71.11	66.67	30.77	58.97	69.23	83.33	75.00	66.67
10	2013,0,143	73	Right	IDC	III	II	FEC	Post surgery	House wife	Middle	Masheri	70.3	49	49	80	70	70	97.78	93.33	93.33	10.26	30.77	38.46	83.33	75.00	66.67
11	2013,0,226	54	Left	IDC	II	IV	ACT	Post surgery	House wife	Middle	Nil	56.5	46	71	90	80	70	84.44	88.89	80.00	35.90	38.46	48.72	91.67	100.00	100.00
12	2013,0,247	43	Right	IDC	II	II	CAF-T	Post surgery	House wife	Middle	nil	54	68	55	100	90	80	97.78	84.44	77.78	20.51	28.21	38.46	100.00	91.67	91.67
13	2013,0,283	37	Left	IDC	II	III	TAC	Post surgery	Teacher	Middle	Nil	56	56	59	90	90	80	93.33	88.89	84.44	25.64	33.33	43.59	83.33	66.67	66.67
14	2013,0,301	42	Left	IDC	III	III	CAT	Post surgery	House wife	Middle	Nil	64	59	59	80	80	70	97.78	77.78	75.56	25.64	28.21	35.90	66.67	50.00	58.33
15	2013,0,027	67	Left	IDC	III	III	FEC-T	Post surgery	House wife	Middle	Masheri , Tea	62	57	57	90	90	80	93.33	84.44	75.56	20.51	23.08	33.33	83.33	75.00	66.67
16	2013,0,209	36	Left	IDC	III	III	ACT	Post surgery	House wife	Middle	Nil	54.2	61	57	90	80	90	75.56	80.00	75.56	46.15	58.97	66.67	83.33	83.33	83.33
17	121306	26	Left	IDC	III	III	FEC	Post surgery	software service	Middle	Nil		60	60	100	90	90	60.00	55.56	44.44	61.54	66.67	74.36	100.00	91.67	83.33
18	2013,0,003	28	Left	IDC	III	III	AC-T	Post surgery	House wife	Middle	Tea	54	57	58	90	90	80	51.11	55.56	60.00	66.67	82.05	89.74	83.33	66.67	66.67
19	2014,0,280	65	Right	IDC	II	II	CG	post surgery	House wife	Middle	Nil		61	62	80	80	80	62.22	66.67	64.44	71.79	74.36	79.49	66.67	58.33	41.67
20	2015,0,027	35	Right	IDC	III	II	ACT	Post surgery	House wife	Middle	Nil	64.1	57	58	90	90	80	73.33	66.67	53.33	46.15	58.97	66.67	75.00	58.33	58.33
21	91019	39	Left	IDC	III	IV	CP	Post surgery	House wife	Middle	Nil	58	63	64	90	80	80	97.78	93.33	55.56	20.51	33.33	43.59	83.33	75.00	58.33
22	2012,0,478	50	Left	IDC	II	IV	Pacletaxel 100 mg	Post surgery	House wife	Middle	Tea Masheri		60	60	80	80	80	97.78	84.44	75.56	10.26	12.82	20.51	83.33	66.67	66.67
23	2012,0,445	58	Left	IDC	II	II	P	Post surger	House wife	Middle	Masheri tea	54.4	55	55	80	70	80	75.56	66.67	62.22	48.72	58.97	66.67	66.67	58.33	50.00
24	2012,0,420	60	Right	IDC	III	II	FEC	Post surgery	House wife	Middle	Nil				80	70	60	95.56	88.89	80.00	20.51	53.85	71.79	75.00	66.67	58.33
25	71034	63	Right	IDC	III	IV	FEC	Post surgery	Tailoring	Middle	Nil				70	70	80	68.89	66.67	62.22	56.41	66.67	74.36	83.33	75.00	66.67
26	2012,0,326	60	Left	Medullary	III	III	ACT	Post surgery	House wife	Middle	passive smoking				80	70	70	77.78	66.67	53.33	46.15	64.10	89.74	75.00	66.67	66.67
27	2012,0,140	48	Left	IDC	II	IV	ACT	Post surgery	House wife	Middle	Tobacco				70	70	70	73.33	66.67	62.22	41.03	48.72	56.41	50.00	50.00	50.00
28	2012,0,192	53	Left	IDC	III	III	ACT	Post surgery	House wife	Middle	Tobacco Masheri	65.2	66	65	80	70	70	97.78	91.11	73.33	10.26	15.38	20.51	83.33	75.00	66.67
29	2012,0,196	45	Right	IDC	III	III	FEC-T	Post surgery	House wife	Middle	Nil	74.4	69	70	80	80	80	77.78	75.56	55.56	41.03	46.15	51.28	83.33	75.00	66.67
30	2011,0,393	60	Left	IDC	III	I	CEF,Tubetere 150mg	Post surgery	Headclerk	Middle	Nil	49	48	48	80	80	70	97.78	93.33	84.44	20.51	33.33	41.03	66.67	83.33	83.33
31	2011,0,023	60	Left	IDC	II	II	PC	Post surgery	Teacher	Middle	Nil	75	74	77	70	70	70	37.78	44.44	33.33	82.05	84.62	92.31	50.00	41.67	33.33
32	2014,0,102	32	Left	IDC	III	II	PC	No Surgery	House wife	Middle	Nil	56	53	55	70	80	60	68.89	66.67	53.33	56.41	66.67	74.36	66.67	83.33	83.33
33	81160	60	Left	infiltreting	III	III	FEC	Post surgery	Nurse	Middle	Nil	40	44	44	80	80	60	97.78	93.33	75.56	12.82	23.08	38.46	83.33	75.00	66.67
34	2014,0,424	24	Left	IDC	II	II	CA	No Surgery	House wife	Middle	Nil	53.6	52	52	70	70	80	55.56	66.67	55.56	71.79	74.36	79.49	66.67	66.67	66.67
35	2015,0,117	25	Left	IDC	II	IV	AC	Post surgery	computer networking	Middle	Coffee				80	70	80	73.33	71.11	68.89	46.15	48.72	56.41	66.67	58.33	50.00
36	2015,0,281	46	Right	IDC	II	III	AC	Chemo-Surgery	Housewife + Buiness	Middle	Nil	56.5	58	59	90	90	80	95.56	77.78	73.33	20.51	23.08	41.03	66.67	66.67	66.67
37	2015,0,304	35	Right	IDC	II	II	CAF	No surgery	Teacher	Middle	Nil		52	54	80	80	80	68.89	62.22	53.33	56.41	58.97	66.67	66.67	58.33	50.00
38	2015,0,233	36	Left	IDC	III	III	CAF+PC+T	Post surgery	Housewife + admin job	Middle	Nil	62.1		62	80	70	70	86.67	77.78	57.78	30.77	41.03	51.28	50.00	50.00	50.00
39	2015,0,404	46	Right	IDC	III	IV	PC	No surgery	House wife	Middle	Nil				70	80	60	77.78	68.89	62.22	41.03	43.59	43.59	83.33	75.00	66.67
40	2015,0,458	50	Left	IDC	I	III	CA	No surgery	House wife	Middle	Nut chewing	74.3	73	73	90	80	90	88.89	80.00	71.11	35.90	46.15	53.85	66.67	75.00	75.00
41	2015,0,460	39	Right	IDC	II	II	D	Post surgery	accountant	Middle	Nil	62	62	65	90	90	70	88.89	75.56	62.22	35.90	43.59	58.97	83.33	75.00	66.67
42	2015,0,491	60	Right	IDC	II	III	AC	Post surger	House wife	Middle	tea	82	80	80	90	80	80	86.67	80.00	53.33	30.77	30.77	38.46	83.33	75.00	66.67
43	2016,0,137	41	Right	IDC	III	IV	AC	Post surgery	Farmer	Middle	Masheri Tobacco	63.5	50	66	90	80	80	80.00	68.89	62.22	35.90	38.46	38.46	83.33	75.00	66.67
44	2016,0,006	60	Left	IDC	II	II	AC	No Surgery	House wife	Middle	Nil	55	55	52	80	80	60	95.56	73.33	53.33	35.90	38.46	46.15	83.33	75.00	75.00
45	2016,0,008	50	Right	IDC	II	II	CG	No Surgery	House wife	Middle	Nil	58	52	55	80	90	80	77.78	53.33	80.00	41.03	43.59	51.28	83.33	75.00	66.67
46	2016,0,055	39	Left	IDC	II	II	CA	No Surgery	House wife	Middle	Nil	51	61	53	80	70	80	84.44	84.44	71.11	30.77	28.21	35.90	83.33	75.00	75.00
47	2016,0,043	57	Left	IDC	III	II	D	No Surgery	House wife	Middle	Nil	62	56	60	80	70	80	91.11	91.11	68.89	35.90	41.03	48.72	83.33	75.00	83.33
48	2016,0,063	70	Bilatera	IDC	III	II	P	No Surgery	House wife	Middle	Nil	54	54	56	80	60	50	95.56	77.78	75.56	30.77	30.77	38.46	83.33	75.00	83.33
49	mumbai	63	Right	IDC	III	III	FEC	Chemo-Surgery	House wife	Middle	Nil	58	58	54	90	80	80	66.67	53.33	57.78	41.03	58.97	66.67	83.33	75.00	66.67
50	81139	59	Left	IDC	III	II	CA	post surgery	House wife	Middle	coffee	48	51	52	90	80	80	82.22	77.78	68.89	35.90	53.85	61.54	83.33	75.00	66.67

2)Study Group=(a=after first chemotherapy,b=mid of the chemotherapy, c=fifteen days after last cycle of chemotherapy.)

Sr No	Name	1. Anorexia			2. Nausea			3. Vomiting			Taste Abnormalit			5. Diarrhoea			6. GI Bleed			7. Stomatitis			8. Constipation			9. Alopecia			10. Skin Rash			Nail Discoloura			Hyperpigmentat			3. Photosensitivit		
		a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
1	SK	0	0	0	1	2	2	0	0	2	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0
2	SK	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	MK	3	0	0	3	2	1	1	0	0	0	0	0	3	0	0	0	0	0	0	2	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4	BK	0	2	0	0	2	0	0	0	0	0	2	0	0	0	0	0	0	0	2	2	0	0	0	0	0	2	0	0	0	0	0	2	0	0	0	0	0	0	0
5	SJ	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2	2	0	0	0	1	2	0	0	0	0	0	0	0
6	MD	1	2	0	3	2	3	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	2	2	2	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0
7	PN	2	2	2	3	0	2	3	0	1	2	0	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	0	0
8	PS	2	0	2	2	0	1	0	0	0	0	2	0	0	2	0	0	0	0	0	2	1	2	0	2	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
9	HS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	SK	3	3	2	0	0	0	0	0	0	2	3	2	2	2	0	0	0	0	2	0	0	0	2	3	2	0	3	0	0	0	0	0	2	0	0	0	0	0	0
11	MB	0	3	0	2	2	1	0	0	0	0	0	0	2	3	0	0	0	0	0	2	1	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	AD	0	2	0	2	0	0	2	0	0	0	2	3	2	3	2	0	0	0	0	0	0	0	2	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	VG	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	2	0	0	0	0	0	0	0	0	0
14	SS	2	0	0	3	2	0	2	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	3	3	0	0	0	0	3	3	0	0	0	0
15	VM	2	2	3	2	2	3	0	2	3	2	2	0	0	2	0	0	0	0	0	2	0	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	VS	3	1	0	3	2	0	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	JJ	2	0	3	3	0	0	0	0	0	3	0	2	0	0	0	0	0	0	0	2	2	2	3	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	SK	0	0	2	2	3	2	3	3	1	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	2	2	3	0	0	0	0	2	0	0	0	0	0	0	0
19	SJ	0	0	0	1	1	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	UP	2	3	0	2	3	1	2	3	0	0	0	0	0	0	0	0	0	0	2	3	1	0	0	0	2	3	3	0	0	0	2	3	0	2	3	0	0	0	0
21	SD	2	2	1	2	1	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
22	VS	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
23	PV	2	1	1	0	0	0	1	2	1	0	0	0	0	0	0	0	0	0	2	1	1	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
24	SA	2	1	2	2	2	2	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	1	1	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
25	SK	2	2	1	2	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0
26	DJ	1	1	0	1	1	0	0	0	0	0	0	1	0	0	0	0	1	1	0	0	0	0	0	1	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
27	SB	0	0	0	2	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
28	SG	1	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	1	2	1	0	0	0	0	0	0
29	SK	2	1	0	1	0	0	0	0	0	2	1	1	2	2	1	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
30	AD	2	2	1	1	2	0	0	1	0	2	1	1	0	0	0	0	0	0	0	0	0	0	1	1	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
31	MD	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
32	VP	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
33	SJ	0	2	1	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	2	2	0	0	0	0	1	1	0	0	0	0	0	0
34	RK	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	1	1	0	0	0	0	0	0
35	AK	0	0	1	0	0	0	1	0	0	0	0	0	3	2	1	0	0	1	0	0	0	2	1	1	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
36	SK	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	2	2	2	0	0	0	0	1	1	0	0	0	0	0	0
37	SG	2	1	0	2	1	0	1	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0
38	GM	0	0	0	2	1	1	0	0	0	0	1	0	0	0	0	2	2	1	2	1	0	2	2	1	1	2	2	0	1	1	0	0	0	0	0	0	0	0	0
39	UR	2	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
40	AS	1	0	0	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
41	DT	2	2	1	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	2	0	0	1	1	1	0	0	0	1	1	2	0	0	0	0	0	0
42	JD	2	2	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	1	1	2	0	0	0	0	0	0
43	LR	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	2	1	0	0	0	0	2	1	0	1	1	2	0	0	0	0	0	0	0	0	0	0	0	0
44	GY	1	1	1	0	2	1	2	1	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	1	1	2	0	0	0	0	1	2	0	1	1	0	0	0
45	SD	1	0	0	1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	1	1	2	0	0	0	0	0	0	0	0	0	1	1	1
46	RM	2	2	1	2	1	1	1	2	1	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	1	2	2	0	0	0	0	0	0	0	0	0	0	0	0
47	RB	1	1	0	1	0	0	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	PS	2	1	0	2	1	1	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	2	2	2	0	0	0	0	0	0	0	0	0	0	0	0
49	MR	2	2	1	2	1	0	0	0	0	1	1	0	0	0	0	0	0	0	1	0	0	2	1	1	1	2	2	0	0	0	1	1	2	0	0	0	0	0	0
50	SK	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	1	1	0	0	0	0	0	0

3)Study Group=(a=after first chemotherapy,b=mid of the chemotherapy, c=fifteen days after last cycle of chemotherapy.)

Sr No	Name	Hb			WBC			Platelets			Bilirubin-Total		SGOT		SGPT		Alkaline Phosphatase		Creatinine	
		A	B	C	A	B	C	A	B	C	A	B	A	B	A	B	A	B	A	B
1	SK	12.8	10.9	10.1	7400	3610	4100	227000	273000	456000										
2	SK	11.4	11.4	11.5	10900	10200	8200	487000	434 000	400 000	0.5						91.4		0.7	0.7
3	MK	10.5	9.3	11.5	10500	4700	7400	287000	162000	205000	0.32		34		34		101			
4	BK	11.6	10.1		6600	5100		287000	316000											
5	SJ	11.9	11		9430	5500	6800	262000	244000	300000	0.5		19		21		76		0.8	0.7
6	MD	9.5	9.3		13700			406000												
7	PN	9	9.4	9.5	6200	4000	4400	191000	163000	207000	0.91	1.6	32.8		17.3				0.7	1.04
8	PS	11.7	10.9	10.9	9600	5200	8100	288000	336000	229000	0.3	0.67	27	36.74	31	33.15	105	77.66	0.6	0.88
9	HS	10.6	10.4		7400	4900		422000	476000							22				0.84
10	SK	12.1	10.5	9.2	12700	17100	22900	344000	392000	278000	0.71	0.5	36.2	26.3	13	18.2	118	209.9	1.7	1.4
11	MB	11.6	8.2	9.9	8600	2600	3800	144000	61000	43000	0.68		29.39		13.74		114.9		0.85	
12	AD	12.2	11.5	11.9	6100	5500	6500	399000	310000	186000	0.72	0.9	25.4	36	24	40	76	106	0.7	0.8
13	VG	11	10.8	10.4	5600	21300	9100	335000	234000	525000	0.4	0.65	37	19	30	18	243	309	1	0.68
14	SS	13.2	10.7	11.1	7000	3000	9200	337000	268000	272000	0.5	0.58	16.8	33.46	16.9	24.98	171.9	98.19		0.69
15	VM	12.1	9.5		8200	8300		240000	331000		0.44	0.48	21		10		218		0.8	0.8
16	VS	11.2	10.2		7300	5400		281000	32000		0.9		22		17.5				0.8	
17	JJ	12.2	10.8	10.3	8200	3600	2000	413000	418000	172000	0.8				110					
18	SK	13.2	12.5	11.7	12900	10400	14400	505000	446000	376000	0.58		19.8		13		71		1.398	16.48
19	SJ	10.4	8.2	8.4	22720	9410	6120		237000	266000										
20	UP	13.3	12.4	13.4	5600	9500	8600	375000	373000	343000	0.7		24		23		301		0.8	0.8
21	SD	13	13.1	12.1	5200	4200	5600	229000	374000	238000	0.86	0.4	20.4	22	14.9	17	56.9	84	0.9	
22	VS	9.1	11	10.2	8700	8200	8500	293000	308000	359000									1	0.72
23	PV	11.6	11.3	11.5	7200	4300	14700	276000	338000	178000									0.7	
24	SA	12		11.8	10080		5440	276000		237000										
25	SK	11.2	10.6	9.4	5300	3950	3500	220000	210000	250000									0.6	0.9
26	DJ	12.4	11.2	11	11000	9400	13600	350000	476000	469000		0.9				28				
27	SB	10.5	10.3	10	13700	9700	3700	503000	432000	214000		0.6		19.7		14.5		280.7	0.9	0.5
28	SG	13.5	13.4	11.4	7700	9000	2100	417000	580000	416000	1.2		27.8		10.3		181		1	
29	SK	14.5	11.2	14	8600	3400	6400	283000	216000	350000	0.42	0.43	28	21.3	41.5	17.8	30	68	1.14	1.02
30	AD	12	10.7	10.2	7070	11230	5290	320000	422000	486000	0.7	0.4	23		23		278		0.73	0.78
31	MD	10.8	11.4	10.1	4000	5200	4100	201000	164000	186100										0.7
32	VP	12	9.5	10.2	7700	7000	4700	240000	184000	232000	0.5		71.6		87.68				1.1	1
33	SJ	14.6	13	11	11800	8900	7400	253000	273000	359000										
34	RK	13	11.1	10.1	1600	10600	22400	277000	336000	293000										
35	AK	11.9	8.9	8.8	8060	4850	3530	284000	160000	184000	0.5	0.52							0.75	0.78
36	SK	13.8	11.7	10.8	9200	10700	6400	351000	314000	335000	0.5	0.2		17	67	95	67	6.5	1.2	0.8
37	SG	8.9	9.8	9.7	21500	8390	12930	162000	297000	152000	0.71	0.56	22.36	26.6	15.89	27.8	113.6	87.22	0.87	0.81
38	GM	14	12.3	12.4	6000	5400	3200	166000	205000	195000	0.6	0.73	29	25.33	21	15.02	209	68.61	0.8	0.72
39	UR	10	9.9	8.7	11000	7200	4500	411000	414000	247000									1.74	
40	AS	12.8	12.3	11.2	10300	7900	5800	317000	269000	380000	0.8		33		27		98		1	
41	DT	10.9	10.4	10.2	10100	8900	7000	339000	313000	393000	0.7		27.88		14.06		81.15		0.81	0.97
42	JD	11	10.5	10.8	10300	9000	7000	206000	265000	210000	0.61	0.75	48.56	63.9	41.69	70.32	86.1	52.73	0.89	0.93
43	LR	11.8	10.2		4400	5700		301000	406000		0.5		23		28		182		0.7	
44	GY	9.9	7.6	10.8	7100	8900	7600	372000	491000	368000	0.7		34.74		28.12				0.81	0.77
45	SD	11.3	9.8	9.4	5900	2170	4360	238000	193000	140000	0.62		92		30				0.54	
46	RM	13.8		11.9	9500		4300	254000		314000	0.73		23		16		80			
47	RB	10.1	10	11.5	8300	5900	5800	392000	459000	242000	0.7	0.63	39	27.72	20.36	38.74	149.3	140	1.22	0.96
48	PS	11.1	11.3	9.9	6900	5600	12400	312000	276000	229000										
49	MR	11.8	10.4	11.4	10330	6200	6300	221000	228000	222000	0.25		12.26		9.07		71.1		0.58	0.6
50	SK	13	12.8	13.1	8570	7000	5000	259000	350000	221000									0.6	0.73

Indian Drugs Research Association & Laboratory

561-B, Shivajinagar, Behind Congress Bhavan Lane, Pune - 411 005.
☎ : (020) 25534018 / 25537875 • E-mail : idralpune@gmail.com

Ref. No. _____ Date _____

Report No. 153 21-11-2013

CERTIFICATE OF ANALYSIS
CONFIDENTIAL

Name of the Party	B.S.D.T's Integrated Cancer Treatment and Research Centre, Wagholi.Pune.
Your Ref.No.	Your Letter dt.12-11-2013.
Type of the Sample.	Praval Panchamrit. (Mouktik Yukta).
Date of Receipt.	13-11-2013.
Batch No.	-
Quantity Received.	1 X 10 Tab.

Sample Drawn by Party.

Description:	Grey coloured round cylindrical Tablet.
Ca % (As is)	42.22 %

ADesai

For I.D.R.A.& L. Pune.

Indian Drugs Research Association & Laboratory

561-B, Shivajinagar, Behind Congress Bhavan Lane, Pune - 411 005.
☎ : (020) 25534018 / 25537875 • E-mail : idralpune@gmail.com

Ref. No. _____ Date _____

21-11-2013

Report No. 152

CERTIFICATE OF ANALYSIS
CONFIDENTIAL

Name of the Party	B.S.D.T's Integrated Cancer Treatment and Research Centre, Wagholi.Pune.
Your Ref.No.	Your Letter dt.12-11-2013.
Type of the Sample.	Kamdudha Rasa.. (Mouktik Yukta).
Date of Receipt.	13-11-2013.
Batch No.	-
Quantity Received.	1 X 10 Tab.

Sample Drawn by Party.

Description:	Brown coloured round cylindrical Tablet.
Ca % (As is)	24.39 %
Fe % (As is)	0.64 %

AeDesai

For I.D.R.A.& L. Pune.

Atharva Praval Panchamrut Ras (Mouktik Yukta)

Sr. No.	Test Applied	Remark/ Parameter
1	Description	Grey colored, circular, compressed, flat, uncoated tablet.
2	Loss on drying	Not More Than 5 %w/w
3	Average Weight	0.275 – 0.325 gm
4	Diameter	8-9 mm
5	Thickness	3-4 mm
6	Hardness	2-5 Kg/Sq.cm
7	Disintegration Time	Not More Than 30 %w/w
8	Friability	Not More Than 1 % w/w

Atharva Kamdudha Vati (Mouktik Yukta)

Sr. No.	Test Applied	Remark/ Parameter
1	Description	Light pink colored, circular, compressed, flat, uncoated tablet.
2	Loss on drying	Not More Than 5 %w/w
3	Average Weight	0.275 – 0.325 gm
4	Diameter	8-9 mm
5	Thickness	3-4 mm
6	Hardness	2-5 Kg/Sq.cm
7	Disintegration Time	Not More Than 30 min
8	Friability	Nor More Than 1 % w/w

BHARATIYA SANSKRITI DARSHAN TRUST

Regd. under B.P. Trust Act of 1950 No. 29, Bombay R. No. E 626 (Pune) 27-3-1979

HEAD OFFICE :
1170/31, Revenue Colony,
Opp. Hotel Span Executive,
Shivajinagar, Pune - 411005. MS India.
Website : www.ayurved-for-cancer.org

CENTRE :
'Vishwa Shanti Dham', Keshnand Road,
Wagholi, Tal. Haveli, Pune-412207, MS India.
Ph. : +91-20-67346000 / +91 9545508890
E-mail : ictrcpune@gmail.com

CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product : Atharva Padmakadi Ghrut
Batch no. : 01/13 **Batch Quantity** : 14 Kg
In- Date : 25-05-2013 **Best before Dt** : 04-2015
Sampled Qty : 140 gms **Sampling date** : 25/05/13
Analysis date : 25/05/13 **Reporting date** : 25/05/13

S.N.	Test	Result	Specification
1.	Description	Green coloured Ghruta with characteristic odour	Green coloured Ghruta with characteristic odour
2.	Agni Pariksha (Flame Test)	Positive	Kalka burn without crackling sound when exposed to flame
3.	Varti Pariksha (Wick Test)	Positive	Kalka becomes harder and rolls in to varti (wick)
4.	Fena Pariksha (Foam Test)	Positive	Foam should be disappear over the ghrut

Remark: The above sample complies/~~Not complies~~ as per IHS

Analyzed & Approved by:

SRF
Integrated Cancer Treatment
& Research Centre

BHARATIYA SANSKRITI DARSHAN TRUST

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Wagholi, Tal. Haveli, Pune-412207, MS India.
Ph. : +91-20-67346000 / +91 9545508890
E-mail : ictrcpune@gmail.com

CERTIFICATE OF ANALYSIS

(Finished Product)

Name of Product : Atharva Shatavari Kalpa
Batch no. : 05/13 **Batch Quantity** : 10 Kg
In- Date : 09-05-2013 **Best before Dt** : 04-2015
Sampled Qty : 100 gms **Sampling date** : 09/05/13
Analysis date : 09/05/13 **Reporting date** : 09/05/13

S.N.	Test	Result	Specification
1.	Description	Cream coloured granules with sweet taste	Cream coloured granules with sweet taste
2.	Loss on drying	0.3564 % w/w	Not More Than 10% w/w
3.	pH	7.10	7.00- 7.50

Remark: The above sample complies/~~Not complies~~ as per IHS

Analyzed & Approved by:

Bhavan

SRF
Integrated Cancer Treatment
& Research Centre

PATIENT CONSENT FORM

Title of the Study: 'Assessment of Effect of CG4 (An Ayurvedic Formulation) in the Management of Side Effect of Chemotherapy in Breast Cancer.'

Name of the Participant:

Documentation of the informed consent:

I, ……. have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered.

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. My rights and responsibilities have been explained to me by the researcher.
5. I have been explained the researcher of all the treatments I am taking or have taken in the past ……. months including any desi (alternative) treatments.
6. I hereby give permission to the investigator to release the information obtained from me as result of participation in this study ethics committee. I understand that they may inspect my original records.
7. My identity will be kept confidential if my data is published or presented.
8. I have had my questions answered to my satisfaction.
9. I have decided to be in the research study.

I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent form, I attest that the information given in this document is true.

Name and signature / thumb impression of the participant (or legal representative if participant incompetent) :

Name :

Address :

Contact No. :

Date : Sign of the Participant :

रुग्ण संमतीपत्रक

अभ्यासक्रमाचे शीर्षक : 'Assessment of Effect of CG4 (An Ayurvedic Formulation) in the Management of Side Effect of Chemotherapy in Breast Cancer'

रुग्णाचे नाव :

रुग्ण संमतीपत्रक नियम :

मी रुग्ण पत्रकातील सर्व माहिती वाचून किंवा मला वाचून दाखविले आहे.

मी विचारल्या जाणाऱ्या प्रश्नांची उत्तरे देण्यास संमती दर्शवित आहे.

१. मी रुग्ण पत्रकात नमूद केलेली सर्व माहिती वाचली आहे.

२. मला रुग्ण संमती पत्रक समजवून सांगण्यात आले आहे.

३. मला माझे हक्क अभ्यासकाने माहिती करुन दिले आहे.

४. मला अभ्यासाबद्दल माहिती देण्यात आली आहे.

५. मी सध्या घेत असलेल्या सर्व औषधोपचाराची माहिती अभ्यासकाला देत आहे.

६. मी ओळख (Identity) माहिती (Publish) करताना गोपनीय ठेवण्यात यावी.

७. मी माझी उत्तरे समाधानकारकरीत्या देत आहे.

८. मी स्वतः अभ्यासाचा एक भाग होण्यास तयारी दर्शवित आहे.

प्रौढ व्यक्तीसाठी :

रुग्णाचे नाव :

नाव :

सही / अंगठा :

दिनांक :

Tilak Maharashtra Vidyapeeth, Pune

The Late Vaidya P.G.Nanal Department of Ayurveda

CASE RECORD FORM

Title - Role of CG4 (an Ayurvedic formulation) in the management of side-effects of chemotherapy of Breast cancer

Date:

Name of patient: **OPD No. :**

Address:

Contact No. :

Sex: **Occupation:**

Qualification:

Type of Work: **Work Duration:**

VartamanVyadhivrutta:

Purvavyadhi

Kulajaitihas - Swakula/Pitrukula/matrukula

Vyasan

Supari / Tambakhu / Vidi / Sigaret / Gutakha / Madhyapan / Others

Praman :

Purva Chikitsa / Purva shastrakarma

Indriyaparikshan

Dnyanendriya -

Karmendriya –

- **Strotas Parikshana-**

1. Pranavaha strotas-

2. Udakvaha strotas-

3. Annavahastrotas

4. Rasavahastrotas

5. Raktavahastrotas

6. Mansavahastrotas

7. Medovahastrotas

8. Asthivahastrotas

9. Majjavahastrotas

10. Sukravahastrotas

11. Aartavahastrotas

12. Purisavahastrotas

13. Mutravahastrotas

14. Swadevahastrotas

- **Nidanpanchak**

1. Hetu

   Aaharaja -

   Viharaja

   Manasik

2. Purvarupa

3. Rupa

4. Upashaya / Anupshaya

5. Samprapti

Chikitsa - Group –A/ Group B

Primary Examination -

B.P. - Pulse - Weight –

Mala – Mutra -

JivhaParikshan -

Mukha Parikshan -

Ura Parikshan -

Udara Parikshan –

CRF

CONTROL / EXPERIMENTAL GROUP - Date –

Reg. No. -

Name –

Age (At enrollment) -

Diagnosis –

HPR -

Status

Chemotherapy details –

No	Cycle No & Date	Drug with Dose	Side effects	Management
1				
2				
3				

SIDE EFFECTS AND GRADATION ---

STATUS ---	B	A C1	A C2	A C3	A C4	A C5	A C 6
SYMPTOMS							
Gastrointestinal							
1.Anorexia							
2.Nausea							
3.Vomiting							
4.Taste abnormality							
5.Diarrhea							
6.GI bleed							
7.Stomatitis							
8. Constipation							
Dermatological							
1.Alopecia							
2.Skin rash							
3.Nail discoloration							
4.Hyperpigmentation							
5.Photosensitivity							
Hematological							
1.Heamoglobin							
2.WBC							
3.Lymphocytes							
4.Neutrophil							

5.Platelet							
LFT							
T Bilirubin							
I D Bilirubin							
D Bilirubin							
SGOT							
SGPT							
ALK Phos							
T Protien							
T Albumin							
T Globulin							
KFT							
Sr. Creatinine							
Bl. Urea							
Kornofsky score							
QLQ							
Functional							
Symptomatic							
Global							

Signature of Guide **Signature of Student**