



**CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF  
JATAMANSI OIL SHIRODHARA  
ON CHITTODVEGA (PSYCHOLOGICAL DISTRESS)  
IN TNBC (TRIPLE NEGATIVE BREAST CANCER) PATIENTS**

**A Thesis  
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**Under the Board Of Ayurved Studies**



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## CERTIFICATE OF THE SUPERVISOR

It is certified that work entitled

**Clinical Assessment Of Mind Relaxation Effect Of *Jatamansi* Oil *Shirodhara*  
On *Chittodvega* (Psychological Distress)**

**In TNBC (Triple Negative Breast Cancer) Patients**

is an original research work done by **Vd. Sou. Anaya A. Pathrikar**

Under my supervision for the degree of Doctor of Philosophy in **Ayurved-  
Kayachikitsa** to be awarded by Tilak Maharashtra Vidyapeeth, Pune.

To best of my knowledge this thesis

- embodies the work of candidate herself
- has duly been completed
- fulfils the requirement of the ordinance related to Ph. D. degree of the TMV
- up to the standard in respect of both content and language for being referred to the examiner.

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### UNDERTAKING

I **Vd. Anaya A. Pathrikar**, is the Ph. D Scholar of the Tilak Maharashtra Vidyapeeth in **Ayurved- Kayachikitsa** subject.

Thesis entitled - **Clinical Assessment Of Mind Relaxation Effect Of *Jatamansi* Oil *Shirodhara* On *Chittodvega* (Psychological Distress) In TNBC (Triple Negative Breast Cancer) Patients** under the supervision of **Prof. Dr Abhijit H. Joshi**, Solemnly affirm that the thesis submitted by me is my own work. I have not copied it from any source. I have gone through extensive review of literature of the related published / unpublished research works and the use of such references made has been acknowledged in my thesis. The title and the content of research is original. I understand that, in case of any complaint especially plagiarism, regarding my Ph.D. research from any party, I have to go through the enquiry procedure as decided by the Vidyapeeth at any point of time. I understand that, if my Ph.D. thesis (or part of it) is found duplicate at any point of time, my research degree will be withdrawn and in such circumstances, I will be solely responsible and liable for any consequences arises thereby. I will not hold the TMV, Pune responsible and liable in any case.

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## INDEX

<b>SR. NO.</b>	<b>NAME OF CHAPTER</b>	<b>PAGE NO.</b>
<b>1</b>	<b>INTRODUCTION</b>	<b>1-4</b>
<b>2</b>	<b>LITERATURE REVIEW</b>	<b>5-73</b>
<b>3</b>	<b>RESEARCH METHODOLOGY</b>	<b>74-90</b>
<b>4</b>	<b>ANALYSIS AND INTERPRETATION</b>	<b>91-121</b>
<b>5</b>	<b>CONCLUSION</b>	<b>122-123</b>
<b>6</b>	<b>REFERENCES</b>	<b>124-129</b>
<b>7</b>	<b>BIBLIOGRAPHY</b>	<b>130-131</b>
<b>8</b>	<b>ANNEXURE</b> <ul style="list-style-type: none"><li>• <b>SHLOK OF REFERENCES</b></li><li>• <b>MASTER CHART</b></li><li>• <b>PATIENT INFORMATION SHEET</b></li><li>• <b>INFORMED CONSENT FORM</b></li><li>• <b>SCALES</b></li><li>• <b>CASE RECORD FORM</b></li><li>• <b>CERTIFICATE OF DRUG ANALYSIS</b></li></ul>	

## LIST OF TABLES

TABLE NO.	TITLE OF TABLE
3.1	Classification of <i>Arbuda</i> based on <i>Dosha</i> and <i>Dushya</i> according to different classical texts
3.2	Classification of <i>Arbuda</i> based on <i>Sadhyasadhyata</i> According to <i>Sushruta</i> & <i>Vagbhata</i>
3.3	Samprapti Ghatak of <i>Arbud</i>
3.4	Facets of Test Anxiety and the respective symptoms explained in Ayurvedic Literature
3.5	Factors influencing <i>Chittodvega</i>
5.1	Symptoms of <i>Chittodvega</i> - Psychological Distress
5.2	Treatment and time point assessment of Trial group and Control Group
5.3	Symptom score and grading
5.4	Zung Self-Rating Depression Scale (SDS)
5.5	Zung's self rating anxiety scale
5.6	EORTC QLQ-C30 (version 3)
5.7	EORTC QLQ - BR23
5.8	Karnofsky performance status scale definitions rating (%) criteria
5.9	Overall Assessment Criteria
6.1	Showing Age wise Distribution of 70 patients of TNBC with <i>Chittodvega</i> .
6.2	Showing stagewise Distribution (with AJSC Classification. of 70 patients of TNBC
6.3	Showing Cancer Gradation of 70 patients in Trial
6.4	Showing patient data according to conventional treatment received.
6.5 (A)	Showing assessment as per Karnofsky score at time point B and C

TABLE NO.	TITLE OF TABLE
6.5 ( B)	Showing assessment as per Karnofsky score at time point B and C
6.6	Showing QLQ C30 Functional Score
6.7	Showing scores of QLQ BR23 Scale
6.8	Showing assessment about Restlessness
6.9	showing Efficacy of Jatamansi oil Shirodhra on Irritability.
6.10	showing Efficacy of Jatamansi oil Shirodhra on Difficulty in concentration
6.11	showing Efficacy of Jatamansi oil Shirodhra on Worthlessness
6.12	showing Efficacy of Jatamansi oil Shirodhra on Crying spells.
6.13	showing Efficacy of Jatamansi oil Shirodhra on fearfulness
6.14	showing Efficacy of Jatamansi oil Shirodhra on Tingling and Numbness in limbs
6.15	showing Efficacy of Jatamansi oil Shirodhra on Dryness of mouth
6.16	showing Efficacy of Jatamansi oil Shirodhra on Dyspnoea
6.17	showing Efficacy of Jatamansi oil Shirodhra on Tachycardia
6.18	showing Efficacy of Jatamansi oil Shirodhra on Sleep Disturbance
6.19	showing Efficacy of Jatamansi oil Shirodhra on Suicidal thoughts
6.20	showing Efficacy of Jatamansi oil Shirodhra on Fainting
6.21	showing Efficacy of Jatamansi oil Shirodhra on Increased frequency at Urine & Stool.
6.22	Showing assessment of treatment by Zung's Depression Scale
6.23	Showing assessment of treatment by Zung's Anxiety Scale

## LIST OF GRAPHS

<b>GRAPH NO.</b>	<b>TITLE OF GRAPH</b>
1	Showing Age wise Distribution of 70 patients of TNBC with Chittodvega.
2	Showing stagewise Distribution (with AJSC Classification. of 70 patients of TNBC
3	Showing Cancer Gradation of 70 patients in Trial
4	Showing patient data according to conventional treatment received.
5	Showing assessment as per Karnofsky score at time point B and C
6	QLQ C30 Functional Score
7	Showing scores of QLQ BR23 Scale
8	Showing effect on Restlessness, Anxious feel, Irritability and Difficulty in concentration
9	Showing effect on Worthlessness , Crying spells and Fearfulness
10	Showing effect on Tingling and numbness in limbs, dryness of mouth and Dyspnoea.
11	Showing effect on Tachycardia, sleep disturbances and Easy fatigability
12	Showing effect on Suicidal thoughts, Fainting and increased frequency of passing urine and stools.



## INTRODUCTION

Cancer is one of the most challenging diseases for medical fraternity in 21st century. World Health Organization considers it as the most fatal disease in the world. Cancer is a range of diseases that can involve different organs and any part of the body. It can also spread in different parts of body, a condition called as metastasis. In Metastatic condition, some cells in the body grow in an uncontrolled manner and in some case, spread and attack organs in other parts of the body.<sup>1</sup>This abnormal growth is harmful for the body as because it doesn't just replace healthy cells in organs. It causes changes in our body's biochemistry that can lead to sudden weight loss, compromised immune system, ultimately leading to death.

Cancer is the second leading cause of death worldwide and is estimated to account for 9.6 million deaths in 2018<sup>2</sup>. There are more than 200 different types of cancers. The common types of cancers are lung and breast cancer, colorectal, followed by prostate cancer and stomach cancer, according to the World Cancer Research Fund International Statistics. According to 2018 statistical data, lung and breast cancers were found to be the commonest cancers globally, each contributing nearly 12.3% of the total number of new cases diagnosed in 2018.<sup>3</sup>

There is a considerable rise in the new cases as well as morbidity and mortality in India due to cancer as described in global and Indian studies. According to The National Centre for Disease Informatics and Research of the Indian Council of Medical Research (ICMR) at Bengaluru, India, 1.45 million cases of cancer were estimated to be diagnosed in 2016. This burden is likely to become double in the next 20 years<sup>4</sup>.

Breast cancer is the most common cancer found in females globally representing nearly 25% of all cancers with an approximate 1.67 million new cancer cases diagnosed in 2018.<sup>5</sup> Breast cancer has emerged as one of the leading causes of cancer among women (14.3%) in India, with 144,937 new cases and 70,218 deaths reported.<sup>6</sup> Besides this, young age has been found as a major risk factor for breast cancer in Indian women.<sup>7</sup>

Triple-negative breast cancer (TNBC) is a subtype of breast cancer which is clinically defined as deficient countenance of the Oestrogen receptor, progesterone receptor and HER2. TNBC has been characterized by an insistent natural history and worse disease-specific outcomes compared with other breast cancer subtypes.<sup>8</sup> TNBC are generally unresponsive to

standard receptor-mediated treatments. However, other forms of chemotherapy can still generate positive outcomes. Although, management of TNBC contains mainly chemotherapy, early relapse is common and a preference to visceral metastasis is seen.

TNBC have onset at a younger age, higher mean tumour size, higher-grade tumours, higher rate of node positivity, more aggressive, less responsive to standard treatment, associated with poorer overall patient prognosis. These patients are also known for an early peak of recurrence between the first and third year after diagnosis, and more aggressive metastases which are more likely to occur in viscera particularly in the lungs and brain, and less likely to spread to the bone.<sup>8</sup>

Long term use of Oral contraceptives (OC), multiple childbirth, parous women with absence of breastfeeding, obesity and lack of physical activity were studied as risk factors of TNBC in various studies.<sup>9</sup>

According to major ancient texts of Ayurveda, cancer can be correlated with *Arbuda*. According to Sushrutacharya, the large overgrowth of *Mamsadhatu* which is due to the vitiation of *Mamsadhatu* and *Raktadhatu* by the aggravated *Doshas*, is called an *Arbuda*.<sup>10,11</sup>

The stress plays significant role in aetiology, progression of disease as well as prognosis of disease. So, the stress needs to be treated by pharmacological as well as non-pharmacological therapeutic interventions. The pharmacological intervention consists of medications whereas non-pharmacological interventions consists of lifestyle modifications, and stress reducing programs.<sup>12</sup>

Distress or depression can lead to a poor repair of damaged DNA, an abnormal chromatid exchange, and reduced apoptotic activity. Accordingly, psychological or behavioral factors and stress can influence many physiological and pathological disease outcomes including cancer.<sup>13</sup> Stressful life experiences, depression, and other psychiatric disorders have been shown to disrupt circadian rhythms of the HPA, and these stress-related alterations in hormonal and immunological circadian rhythms was also proposed to play a role in cancer progression (Sephton et al. 2003).

Psychological distress is major risk factors of TNBC, at the same time patients diagnosed with TNBC are under tremendous stress due to aggressive nature of the diseases. These 2 facts underscore the need of mind relaxation treatment for TNBC patients. Stress hormones not only induce significant DNA damage in TNBC cell lines, but that they induce expression of ATR and p21 in such a way as to regulate progression of the cell cycle, an important factor in the efficacy of drug treatment. Stress hormone levels possess the potential to both increase tumorigenicity and decrease the efficacy of therapeutics.<sup>14</sup>

The diagnosis of cancer causes stress on the patient which relates both to symptoms of disease as well as the psychological feeling of the patients on knowing that he or she is suffering from cancer. The level of stress induced by the cancer on patient depends on how the individual is adjustable to emotional ups and downs, the presence of emotional support from family and friends also the symptoms appeared due to cancer, site of cancer and treatment required as well as prognosis. Thus, stress plays significant role in causation of cancer and its progression.

### **Need of the study:**

The increasing incidence as well as mortality of cancer mainly breast cancer in Indian women indicate the urgent need of strengthening and increasing the new treatment modalities than the existing diagnostic and treatment facilities. This can be achieved to some extent by implementing the four components of cancer control: prevention, early detection, diagnosis & treatment and palliative care.<sup>15</sup>

Charakacharya and other Acharyas have mentioned about *Chittodvega* or *Manodvega* and its influence on a body while describing other diseases.<sup>16</sup> Anxiety is a normal response to threat, uncertainty and loss of control. The diagnosis and treatment of cancer is stressful. The Anxiety is considered as '*Chittodvega*' in Ayurveda.

The first line of treatment according to Ayurveda is '*Nidana-Parivarjana*', i. e., avoidance of aetiological factors.<sup>17</sup> Also; Charakacharya has described three types of treatments, namely – *Daivavyapashraya*, *Yuktivyapashraya* and *Sattvavajaya*.<sup>18</sup>

*Shirodhara* with *Jatamansi Taila* is a combination of all above mentioned three types of treatment. *Shirodhara Upakrama* relaxes mind. *Jatamansi* oil used in *Shirodhara* procedure pacifies *Vata Dosha* which governs functions of mind and body. In this trial, *Shirodhara* is done in TNBC patients with *Jatamansi siddha Taila*. Oil is the best drug for pacification of *Vatadosha* and practically usable for external Therapies like *Shirodhara*.<sup>19</sup> *Jatamansi* is well known drug for *Manasa-Doshaharana*. It is also a *Medhya Rasayana*. Charakacharya has mentioned this herb in *Sandnyasthapan Gana*.<sup>20</sup> It calms mind and is also *Nidrajanana*. It is one of the important drugs in treatment of *Unmada* and *Apasmara*.<sup>21</sup> Here, *Jatamansi* was used in view of its *Medhya*, *Manodoshahara* and *Balya* characters.

Thus, two-arm, open-labelled, parallel (add-on design) controlled clinical study was conducted on 70 female patients in the age group of 20 to 70 years who are known cases of TNBC by histology and immune-histo-chemically (Immuno-histo-chemically proven ER,

PR, Her2 Negative) patients; all of whom have completed conventional therapy and opted for Ayurvedic Treatment. These patients were divided into 2 groups. 35 patients of Group A were treated with Ayurvedic oral medicines (*Shamana Chikitsa*) and *Jatamansi Taila Shirodhara*; whereas 35 patients in group B were treated with only Ayurvedic oral medicines (*Shamana Chikitsa*). The data generated through clinical study was subjected to unbiased statistical analysis to draw conclusion.

## 2. LITERATURE REVIEW

This chapter deals with literature which is reviewed and relevant to the present study. Review of literature helps to formulate hypothesis, aims and objectives of the study. It helps how to assess the problem and adopt suitable methodology. A review provides helpful suggestions for significant Investigations. The review of Literature for the present study has been done from Published and unpublished research reviews, articles, text books, cancer Literature and medline search. The literature reviewed to the present dissertation titled, “**Clinical Assessment Of Mind Relaxation Effect Of Jatamansi Oil Shirodhara On Chittodvega ( Psychological Distress) In TNBC (Triple Negative Breast Cancer) Patients**”, is organized and presented in following headings-

- *Stana Sharira &Kriya*
- Anatomy and Physiology of breast
- *Stanroga*
- *Arbuda*
- Cancer
- Ca breast
- TNBC
- Review of *Manas*
- *Chittodvega* and its association with somatic diseases
- Psychological distress- An overview
- Anxiety disorders
- Depression disorders
- Association of anxiety & depression with Cancer
- *Shirodhara*
- *Jatamansi*.
- *Tila Taila*

### **STANA- SHARIR & KRIYA**

*Nirukti & Paryaya of Stana :<sup>22</sup>-*

According to Amarkosha, *Cuchauo* is the synonyme of *Stana*. *Stana*, *Urasija*, *Vakshoj*, *Payodhara*, *Cucha* (Rajnighantu)

*Stana* (Breast) is one of the *pratyanga* (Organ) among 56 *pratyangas*<sup>23</sup>.

There is a difference in male & female breast. In puberty, breasts become well developed in females than males. During pregnancy & after delivery, breasts filled by breast milk.

❖ *STANA SHARIRA* :-

(A) *Bahirmukha Srotasa* (External orifices) -

*Bahirmukha Srotasa* (External orifices) are two in the nose, two in the ears, two in the eyes, one in the rectum, one of the mouth & one of the urethra. In females, there are three more *Srotasa*, two in the breasts & one in the *Raktapatha* (Vaginal tract)<sup>24</sup>.

(B) *Ashaya* -

Females have three more *Ashaya* as compared to male i.e two breasts & one uterus<sup>25</sup>.

(C) *Peshi* (Muscles) -

Females have twenty more muscles. Out of these, ten muscles are found in the breasts each having five muscles which enlarge during youth. Four muscles are found in the genital tract out of which two spread inside & two being circular spread outside as its mouth. Three muscles are situated at the opening of the Uterus & three more muscles are meant to bring together the sperm & Ovum. The Uterus is situated between the gall bladder & the intestine, where the foetus lies<sup>26</sup>.

(D) *Marma* (Vulnerable Areas) -

Below the breasts, on both sides the two "*Stanamula*" *Marmas* having two fingers breadth are situated. Injury to them causes filling up of chest with *Kapha* leading to death from Cough & dyspnea.

Above the nipples, on both sides, the two "*Stanarohita*" *Marmas* having two fingers breadth are situated. Injury to them causes filling up of chest with blood (Haemothorax) leading to death from Cough & dyspnea<sup>27</sup>.

(E) *Avyadha Sira* -

There are forty *Siras* in the thorax & out of these following fourteen *Siras* should be avoided – two in the pericardium, two in each *Stanamula*, eight on the sides of *Stanrohita*, *Apalap* & *Apastambha*<sup>28</sup>.

(F) *Dhamani* (Artery) -

Twenty *Dhamanis* are originated from *Nabhi* (Umbilicus). Out of all these twenty four, ten *Dhamanis* run upwards & ten *Dhamanis* run downwards & four obliquely runs<sup>29</sup>.

Ten *Urdhvaga Dhamanis* after reaching the *Hrudaya* (Heart) divide to three branches each & becomes thirty in total. Out of them, two for the flow of *Stanya* (Breast milk) from the breast in females & the corresponding once carry the semen (internally) from the breasts in males.

❖ *Stana Sampada* (Excellence of breasts)<sup>30</sup> -

The excellence of breasts consists of breasts not too high, too long, or too corpulent; having nipples of appropriate size & easy in sucking.

### • **Anatomy & Physiology Of Breast**

The fundamental knowledge of breast structure and some breast pathologies is essential to understand the importance of breast cancer study.

During the fetal period is created, by epidermis, a depression which forms a mammary pit on the local of mammary gland. The region where the mammary glands appear is located in left and right sides of the upper ventral region of the trunk. The breasts exist in woman and man, but the mammary glands are normally most developed in female, except in some particular circumstances related with hormonal problems. The nipple is a small conical prominence surrounded by a circular area of pigmented skin, the areola, which contains large sebaceous glands that are often invisible to the naked eye. The base of the female breast, roughly circular, extends from the second rib above to the sixth rib below. Medially, it borders the lateral edge of the body of the sternum and laterally it reaches the mid auxiliary line<sup>31</sup>.

At puberty, the female breasts normally grow according to the glandular development and increase of fat deposition; furthermore, also the nipples and areolas grow. The size and shape of breast depends on genetic, racial and dietary factors. During the pregnancy, the areola color becomes dark, and after that keeps the pigmentation. This color diminishes as soon as lactation is over, but is never entirely lost throughout life.

The breast consists of gland tissue, fibrous tissue, connecting its lobes and fatty tissue in the intervals between lobes. The breast contains 15 to 20 lobes of glandular tissue, which constitute the parenchyma of the mammary gland. These lobes give a shape characteristic to the breast due to a considerable amount of fat, and these are composed of lobules, connected together by areolar tissue, blood vessels and ducts. Each lobule is drained by a lactiferous duct, which opens independently on the nipple. Just deep to the areola, each duct has a dilated portion, the lactiferous sinus, which accumulates milk during lactation. The smallest lobules include also the alveoli, which open into the smallest branches of the lactiferous ducts. Many changes happen in the breast tissue during the menstrual cycle and pregnancy, due to hormones progesterone and estrogens. In a woman who is not pregnant or suckling, the alveoli are very small and solid, but during the pregnancy enlarge, and the cells undergo rapid multiplication. The mammary glands only produce milk when the baby is born, despite being prepared for secretion since mid-pregnancy<sup>32</sup>. The first milk, colostrums, eliminates the cells in the center of the alveolus that suffered fatty degeneration. In a woman who has given birth more than twice the breast become large and pendulous, and in elderly women, they usually become small because of the decrease in fat and glandular tissue atrophy. But, normally in young women the breasts are supported and kept in their position by the cooper's ligaments. These ligaments, particularly well developed in the upper part of the gland, help to maintain the lobes of the gland.

Children breast consist principally ducts with dispersed alveoli, being similar in adipose deposition and the growth of the mammary glands, as well as the initial development of lobules and alveoli of the breast. Progesterone and prolactin which cause the final growth are responsible for the function of these structures and cause the external appearance of the mature female breast. During pregnancy, the concentration of estrogen increases. This phenomenon causes expansion and branching of the breast gland ducts and deposition of additional adipose tissue.



- **Breast pathologies**

- i. **Fibroadenoma-** Fibroadenomas are the most common breast tumors in pubertal females, and there are three types of fibroadenoma classified as: common, giant and juvenile. These tumors are characterized by a proliferation of both glandular and stromal elements, have well demarcated borders and are firm, rubbery, freely mobile, solid, usually solitary breast masses. There is no pain or tenderness due to fibroadenomas and their size do not change with the menstrual cycle. Women aged in their 20s and adolescents are the most common people affected with this disease. A rapid growth sometimes occurs but usually that growth is extremely slow. A giant fibroadenoma should measure over 5 cm in diameter but the average is 2.5 cm. These tumors may return (approximately 20% recur), women should be aware of this risk and have periodic examinations.
  
- ii. **Mammary dysplasia -**Mammary dysplasia also can be called as fibrocystic changes (FCC), fibrocystic disease, fibrous mastopathy or fibroadenosis cystic. In reality, these alterations not indicate a disease. This pathology is defined as being a benign alteration of the breast consisting of cystic dilatation of intralobular glands with or without stromal fibrosis. The age distribution of this lesion is between 20 and 50 years. Normally, fibrocystic changes are associated to the cyclic levels of ovarian hormones, because during ovulation and before menstruation, the hormone level changes often lead the breast cells to retain fluid and develop into nodules or cysts, which feel like a lump when touched. The texture of the breast is, in these cases, similar to the breast in premenstrual phase. The signs of fibrocystic changes include increased engorgement and density of the breasts, excessive modularity, rapid change and fluctuation in the size of cystic areas, increased tenderness and occasionally spontaneous nipple discharge. It can be unilateral, bilateral or just affect a part of the breast.
  
- iii. **Mastitis and breast abscess -**Inflammatory conditions of the breast, particularly acute mastitis and breast abscess are rare pathologies. Often these infections can happen in postpartum situations or after a lesion. There are two types of mastitis: acute and chronic. In acute mastitis, it is predominantly composed of neutrophilic granulocytes,

seen mostly in lactating women. Chronic mastitis may be due to reinfection or a relapsed infection; the first case occurs sporadically and commonly is transmitted from the baby and the second case means that eradication of the pathogen failed. Breast abscess arises when mastitis was treated inadequately and milk retention exists. The most common diagnostic techniques used for treatment include ultrasonography of the breast and needle aspiration under local anesthesia with a purpose of identifying collection of fluid or pus.

- iv. Cancer and Breast Cancer- One in eight deaths worldwide is due to cancer. Cancer is the second leading cause of death in developed countries and the third leading cause of death in developing countries.

### **STANAROGA-**

Whatever the types causes of *Gati* & (Sinuses), the same are the types & causes of breast diseases in women.

The openings of the ducts located in the breasts of girls are closed, thus the *Doshas* cannot spread & breast diseases do not occur in them.

They are possible only in those women who have delivered & pregnant as the same ducts open out physiologically in them.

- The Pathogenesis of *Stana Roga* (Diseases of Breast) :-  
The *Doshas* having reached the breasts of women whether lactating or non-lactating & then having vitiated the blood & muscles produce diseases of Breasts<sup>33</sup>.
- Lack of incidence *Stana Roga* (Diseases of Breast) in *Kanya* :-  
The openings of the ducts located in the breasts of girls are closed thus the *Doshas* can not spread & hence breast disease do not occur in them.  
The breast disease is possible only in those women who have delivered & in the pregnant as the ducts open out physiologically.

#### ❖ *Stana Roga* (Breast Diseases According to *Kashyap Samhita*) :-

If lactating mother eats foreign body with food, it does not get digested in

*Pachyamanavashtha* and *Pakavashtha*. Undigested foreign body get converted in *Kled*, and traveled to mammary gland with *Rasa Dhatu* and *Vata Dosha*. This causes obstruction of *Srotasa* and acute disease of breast<sup>34</sup>.

*Stanakilaka*<sup>35</sup> -

Symptoms of '*Pitvajra*' are indigestion, palpitation, giddiness, body ache, anorexia, joint pain, headache, redness of eyes or sneezing, nausea due to *Kapha*, fever, excessive thirst, loose motion, obstruction of urine, stiffness and secretion in breasts, veinulas, inflammation, pain, tenderness and burning sensation of breasts. Clever physician named it as '*Stan Vidradhi*' (mammary abscess) as it causes obstruction in body as nail.

*Stanakilaka* according to *Dosha* dominance<sup>36</sup> -

If *Pitta Dosha* gets aggravated then this Mammary abscess (*stankilak*) gets inflamed and bursts open at an early stage. If *Kapha* is vitiated then instead of proceeding towards inflammation it forms a chronic abscess whereas because of vitiation of *Vata Dosha* the abscess increases in size.

During such circumstances if the child is breastfeed then there is a possibility of the *Stankilak* or in other words the foreign body within the abscess gets excreted through the ducts or lacteals in the form of pus and blood.

- Treatment of *Stanakilaka* :-

The first line of treatment is Internal Oleation with clarified butter (*Ghrutpan*). Due to this treatment the tracts often becomes smooth internally thereby facilitating easy removal of the *Stankilak*. Regular expulsion of breast milk should be done by proper massaging<sup>37</sup>.

Next part of treatment being, application of cold compress and medications over the breast, induction of medicated purgation (*Virechan*) and strict dietary regimen to keep a check over the *Doshas*<sup>38</sup>.

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.

## ARBUDA

- *Nirukti*<sup>39</sup>:

The word “*Arbuda*” is derived from the root word “*Arb*”. When it is suffixed by “*Vic*” pratyaya and suffixed by ‘*Udeti*’ (create *Ua+Ind+DA*), it gives rise to word “*Arbuda*”.

• **Definition:**

1. *Acharya Sushruta*<sup>40</sup>-

The large vegetation of flesh which appears at any part of the body, becomes slightly painful, rounded, immovable and deep seated, and has its root sunk considerably deep in the affected part, and which is due to the vitiation of flesh and blood by the deranged and aggravated *Doshas*, is called an *Arbuda*. It grows slowly and does not suppurate.

2. *Acharya Charaka*<sup>41</sup>-

According to *Charaka Samhita*, there is no much difference between *Granthi* and *Arbuda*. No specific definition and classification is available.

3. *Acharya Vagbhata*<sup>42</sup> :

A large *Granthi* is called as *Arbuda*.

4. *Acharya Madhavahara*<sup>43</sup>:

*Maharishi Agnivesha*<sup>44</sup> :

According to *Anjana Nidana*, if any *Granthi* comes out in any part of the body and which ripen, smear flows out of it frequently then it is treated as *Arbuda Roga*.

5. *Bhavaprakasha*<sup>45</sup>:

He explained definition, and classification of *Arbuda* as same as *Sushruta Samhita*.

Table No. 3.1- Classification of *Arbuda* based on *Dosha* and *Dushya* according to different classical texts

Types	S.S	C.S	A.S/A.H	M.NI	SH.S	B.P	C.T	A.NI	V.M
-------	-----	-----	---------	------	------	-----	-----	------	-----

<i>Vataja</i>	+	-	+	+	+	+	+	+	+
<i>Pittaja</i>	+	-	+	+	+	+	+	+	+
<i>Kaphaja</i>	+	-	+	+	+	+	+	+	+
<i>Raktaja</i>	+	-	+	+	+	+	+	+	+
<i>Mamsaja</i>	+	-	+	+	+	+	+	+	+
<i>Medaja</i>	+	-	+	+	+	+	+	+	+
<i>Agantuja</i>	-	-	-	-	-	-	-	+	-
<i>Adhyarbuda</i>	-	-	-	-	-	-	+	-	-

S.S- *Sushruta Samhita*, C.S- *Charaka Samhita*, A.H- *Ashtanga Hrdayam*,  
A.S- *Ashtanga Sangraha*, M.Ni- *Madhava Nidanam*, Sh.S-*Sharangadhara Samhita*  
B.P.- *Bhava Prakasha*, C.T-*Chakradatta*, A.Ni- *Anjana Nidana*, V.M - *Vrunda Madhava*

- **Classification of Arbuda-**

Table No.3. 2 Classification of Arbuda based on Sadhyasadyata According to  
*Sushruta & Vagbhata*

<b>Types</b>	<b><i>Sushruta</i></b>	<b><i>Vagbhata</i></b>
<i>Vataja</i>	S	S
<i>Pittaja</i>	S	S
<i>Kaphaja</i>	S	S
<i>Raktaja</i>	A	A
<i>Mamsaja</i>	A	A
<i>Medaja</i>	S	S
<i>Adhyarbuda</i>	A	S
<i>DwiArbuda</i>	A	-
<i>Marmaja</i>	A	-
<i>Srotaja</i>	A	-
<i>Sharkra</i>	S	S
<i>Karnarbuda</i>	S	S

<i>Netrarbuda</i>	S	-
<i>Nasarbuda</i>	S	S
<i>Kapalarbuda</i>	-	S
<i>Talvarbuda</i>	A	S
<i>Jalarbuda</i>	-	S
<i>Galarbuda</i>	-	S
<i>Kapharbuda</i>	-	A

S- Sadhya, A- Asadhya

- ***Nidana:***

In the concept of *Mamsarbuda*, *Sushruta* and *Bhavaprakasha* have mentioned few *Nidana* as follows<sup>46</sup> -

- The person who is addicted to meat diet
- Those who are eating meat in his food always
- Those who are assaulted by fist

- ***Rupa*<sup>47</sup>:**

General characteristics of *Arbuda*

- Big swelling , slight painful
- Circular , fixed
- Broad based
- Slow growing
- Seldom suppurates
- Filled with fleshy growth

- ***Samprapti:***

*Samprapti Ghataka*

Table No. 3.3 Samprapti Ghatak of Arbud

<i>Dosha</i>	<i>Tridosha with Kapha predominance</i>
<i>Dushya</i>	<i>Mamsa, Rakta, Meda</i>
<i>Srotas</i>	<i>Mamsavaha, Raktavaha, Medvaha</i>
<i>Srotadusti</i>	<i>Siragranthi</i>
<i>Rogamarga</i>	<i>Bahya<sup>48</sup></i>
<i>Ubhavasthana</i>	<i>Anywhere in the body</i>
<i>Vyaktasthana</i>	<i>Sixth layer of skin- Rohini<sup>49</sup></i>

*Arbuda* by their deep rootedness nature, do not undergo *Paka* because of predominance of *Kapha* and *Medas*. As they are being in more quantity and *Doshas* being stable and the tissue become a hard mass instead.

- ***Sadhyasadhyata<sup>50</sup>***:

*Vataja, Pittaja, Kaphaja* ,and *Medoja* are *Sadhya*, while *Raktaja, Mamsaja* are *Asadhya*.

- ***Chikitsa***:

1. *Aushadha Chikitsa*
2. *Shalya Chikitsa*

*Aushadha Chikitsa* is divided in to two types

1. *Bahya*
2. *Abhyantara*

1. *Aushadha Chikitsa*:

Due to *Kaphapradhananature* of *Arbuda* and involvement of *Mamsa , Meda, Rakta Dushti*, the drugs for it should have following qualities

- *Deepana*
- *Pachana*

- *Srota Vishodhana*
- *Vrana Shodhana* and *Ropana*
- *Rakta Shudhikara*
- *Tridoshashamaka* and *Rasayana*

#### 1. *Bahyachikitsa*<sup>51</sup>:

*Arbuda* should be treated with external application etc. like abscess. Various types of *Arbuda* can be managed with administration of *Kshara*, *Agnikarma*, *Swedana* and *Shastra Karma*.

The treatments include-

##### -*Bandhana*:

Excreta of goat, root of *Shigru*, *Laksha*, *Surasa*, *Lavana* and *Kshara* are cooked in fermented gruel, tied in a cloth and applied warm over the *Arbuda*, covered with thick leaves of *Upodika* and then bandaged.

##### -*Swedana*:

*Swedana* with heated pieces of *Snuhi* and heated salt leads to cures the *Arbuda* .

##### -*Lepana*:

*Haridra*, *Lodra*, *Patranga*, *Grahadhuma*, *Manoshila* are added with honey and made as a paste and applied on *Arbuda*.

##### -*Kshara*<sup>52</sup> :

- Paste of *Shankhabhasma* mixed with ash of radish should be applied on it.
- Paste of the *Kadalikshara*, *Mochaka*, husk and *Shankabhasma* or sulphur, *Yavakshara*, *Vidanga*, *Shunthi* mixed with blood of chameleon .
- *Kshara* prepared with *Mulaka* and *Haridra* mixed with ash of *Shanka* made as a paste and applied externally.

##### -*Agnikarma*:

- Paste of *Nishpava*, *Pinyaka*, *Kulatha*, pasted with curd and an abundant quantity of flesh, should be used in plastering the affected part so that worms and parasites may be produced in the ulcer and flies attracted to it (and so consume



the ulcer). A small portion of the ulcer, left unconsumed (an-eaten) by worms and parasites etc., should be scarified and the ulcer should then be cauterized with fire.

A shallow rooted *Arbuda* should be covered with thin sheets of zinc, copper, lead, or iron and then observing the strength and tolerating capacity of the patient, repeated application of *Kshara*, *Agni* or surgery should be done<sup>53</sup>.

## 2. *Abhyantra chikitsa* :

Some of the drugs prescribed in *Abhyantar Chikitsa* of *Arbuda* have been listed as follows-

- *Lavangadi churna*
- *Khadirarishta*
- *Madhusnuhi Rasayana*
- *Kanchanara Gugglu*
- *Panchatiktaka Ghruta Gugglu*
- *Triphala Ghirta*
- *Mahatriphala Ghirta*
- *Amavatari Vatika*
- *Chandrodaya Varti*
- *Chandraprabha Gutika*
- *Raudra Rasa*
- *Nidyananda Rasa*
- *Shrinrupativallaba Rasa*
- *Pradarantaka Loha*
- *Ramabana Rasa*
- *Vajrabhasma* etc

## **CANCER**<sup>54</sup>

Cancer is not just one disease, but a large group of almost 100 diseases. It is a genetic disease, with two main characteristics of uncontrolled growth of the cells in the human body and the ability of those cells to migrate from the original site and spread to distant sites.

Cancer can attack anyone. Since the occurrence of cancer increases as individual's age, most of the cases are seen in adults, middle-aged or older. Sixty percent of all cancers are diagnosed in people who are older than 65 years of age. The most common cancers are skin cancer, lung cancer, colon cancer, breast cancer (in women), and prostate cancer (in men). In addition, cancer of the kidneys, ovaries, uterus, pancreas, bladder, rectum, and blood and lymph node cancer (leukemias and lymphomas) are also included among the 12 major cancers that affect most of the people.

- **Characters of cancer cells:**

- Anaplastic or undifferentiated cells
- Immortality
- Monoclonal in origin
- Change in the structure of cells
- Decreased adhesiveness
- Invasiveness

- **Causes & Risk Factors:**

The major risk factors for cancer are: tobacco, alcohol, diet, sexual and reproductive behavior, infectious agents, family history, occupation, environment, and pollution.

- *Tobacco-*

Eighty to ninety percent of lung cancer cases occur in smokers. Smoking has also been shown to be a contributory factor in cancers of the upper respiratory tract, esophagus, larynx, bladder, pancreas, and probably liver, stomach, breast, and kidney, as well. Recently, scientists have also shown that second-hand smoke (or passive smoking) can increase one's risk of developing cancer.

- *Alcohol-*

Excessive consumption of alcohol is a risk factor in certain cancers, such as liver cancer. Alcohol, in combination with tobacco, significantly increases the chances that an individual will develop mouth, pharynx, larynx, and esophageal cancers.

- *Diet-*

Thirty five percent of all cancers are estimated to be due to dietary causes. Excessive intake of fat leading to obesity has been associated with cancers of the breast, colon, rectum, pancreas, prostate, gall bladder, ovaries, and uterus.

- *Sexual and reproductive behavior-*

The human papillomavirus, which is sexually transmitted, has been implicated to cause cancer of the cervix. In addition, it has also been shown that women who have not had children or have children late in life have an increased risk for both ovarian and breast cancer.

- *Infectious agents-*

In the last 20 years, scientists have obtained evidence to estimate that 15% of the world's cancer deaths may be traced to viruses, bacteria, or parasites.

- *Family history-*

Certain cancers like breast, colon, ovarian, and uterine cancer, recur generation after generation in some families.

- *Occupational hazards-*

There is evidence to estimate that certain occupational hazards account for 4% of all cancer deaths. For example, asbestos workers have an increased incidence of lung cancer.

- *Environmental radiation-*

Exposure is believed to cause 1–2% of all cancer deaths. Ultra-violet radiation from the sun accounts for a majority of melanoma deaths. Other sources of radiation are x rays, radon gas, and ionizing radiation from nuclear material.

- *Pollution-*

Several studies have shown that there is a well established link between asbestos and cancer. Chlorination of water may account for a small rise in cancer risk.

- **Pathogenesis :**

Cancer results from alterations (mutations) in genes that make up DNA, the master

molecule of the cell. Genes make proteins, which are the ultimate workhorses of the cells, responsible for the many processes that permit humans to breathe, think, and move, among other functions. Some of these proteins control the orderly growth, division, and reproduction of normal tissue cells. Gene mutations can produce faulty proteins, which in turn produce abnormal cells that no longer divide and reproduce in an orderly manner. These abnormal cells divide uncontrollably and eventually form a new growth known as a tumor or neoplasm. A healthy immune system can usually recognize neoplastic cells and destroy them before they divide. However, mutant cells may escape immune detection and become tumors or cancers.

- **Metastasis :**

The first formed malignant structure is called the primary tumour. The majority of cancer are not killed by this. However, cells of the primary tumour can detach and can spread to other sites. Such a spread of cancerous cells is called metastasis.

Tumours spread with the help of enzymes called matrix metalloproteinases (MMPs). These destroy the connective tissues between the cells and organs and allow the tumour cells to break off from the original site. A protein called autocrine motility factor (AMF) secreted by the cells also helps in process of metastasis. After reaching healthy tissues of the body these metastasized cells setup secondary tumours. Such tumors acquire new fine blood vessels (capillaries) to get nutrients to grow. Growth of capillaries called angiogenesis. It is made possible because of tumour angiogenesis factor (TAF) secreted by the tumour cells. They may also secrete hormones that promote their own growth.

Metastasis can occur in two ways:

1. Vascular or Haematogenous spreading.
2. Lymphatic spreading.

- **Types of tumours<sup>55</sup>:**

Tumours can be benign or malignant. A benign tumor is not cancer. It is slow growing, does not invade surrounding tissue, and once removed, does not usually recur. A malignant tumor is cancerous. It invades surrounding tissue and spreads to nearby or distant organs (metastasis).

Some tumours (collection of abnormally growing cells) are benign (not cancerous). In discussing tumours that are malignant (cancerous), however, the term solid tumour is used to distinguish between a localized mass of tissues and leukemia. (Leukemia is actually a type of tumour that takes on the fluid properties of the organ it affects the blood).

- **Different types of cancers :**

- Carcinomas are cancers that arise in the epithelium (the layers of cells covering the body's surface and lining the internal organs and various glands). Ninety percent of human cancers fall into this category. Carcinomas can be subdivided Adenocarcinomas are cancers that develop in an organ or a gland, while squamous cell carcinomas refer to cancers that originate in the skin.
- Melanomas also originate in the skin, usually in the pigment cells (melanocytes).
- Sarcomas are cancers of the supporting tissues of the body, such as bone, muscle and blood vessels.
- Cancers of the blood and lymph glands are called leukemias and lymphomas respectively.
- Gliomas are cancers of the nerve tissue.

- **Symptoms:-**

The classic symptoms of cancer are

- Rapid weight loss;
- A change in a wart or mole;
- A sore that does not heal;
- Difficulty swallowing;
- Chronic hoarseness,
- Blood in phlegm, urine, or stool (a consequence of angiogenesis);
- Chronic abdominal pain;
- A change in size or shape of the testes;
- A change in bowel habits;
- A lump in the breast;

- Unusual vaginal bleeding

The following seven symptoms as possible warning signals of cancer :

1. Changes in the size, color, or shape of a wart or a mole
2. A sore that does not heal
3. Persistent cough, hoarseness, or sore throat
4. A lump or thickening in the breast or elsewhere
5. Unusual bleeding or discharge
6. Chronic indigestion or difficulty in swallowing
7. Any change in bowel or bladder habit

- **Diagnosis:**

Most cancers are initially recognized either because signs or symptoms appear or through screening.

- **Biopsy:**

A cancer may be suspected for a variety of reasons, but the definitive diagnosis of most malignancies must be confirmed by histological examination of the cancerous cells by a pathologist. Tissue can be obtained from a biopsy or surgery. The tissue diagnosis given by the pathologist indicates the type of cell that is proliferating, its histological grade, genetic abnormalities, and other features of the tumor. Together, this information is useful to evaluate the prognosis of the patient and to choose the best treatment. Cytogenetics and Immunohistochemistry are other types of testing that the pathologist may perform on the tissue specimen. These tests may provide information about the molecular changes (such as mutations, fusion genes, and numerical chromosome changes) that has happened in the cancer cells, and may thus also indicate the future behavior of the cancer (prognosis) and best treatment.

- **Treatment:**

The aim of cancer treatment is to remove all or as much of the tumor as possible and to prevent the recurrence or spread of the primary tumor. If the cancer is very aggressive

and a cure is not possible, then the treatment should be aimed at relieving symptoms and controlling the cancer for as long as possible. Cancer treatment can take many different forms, and it is always tailored to the individual patient. The major types of treatment are: surgery, radiation, chemotherapy, immunotherapy, hormone therapy, and bone marrow transplantation.

- **Surgery**

Surgery is the removal of a visible tumor and is the most frequently used cancer treatment. It is most effective when a cancer is small and confined to one area of the body. Surgery can be used for many purposes. Treatment of cancer by surgery involves removal of the tumor to cure the disease. Along with the cancer, some part of the normal surrounding tissue may also be removed to ensure that no cancer cells remain in the area. Since cancer usually spreads via the lymphatic system, adjoining lymph nodes may be examined and sometimes removed, as well.

- **Radiation**

Radiation kills tumor cells. Radiation is used alone in cases where a tumor is unsuitable for surgery. More often, it is used in conjunction with surgery and chemotherapy. Radiation can be either external or internal. In the external form, the radiation is aimed at the tumor from outside the body. In internal radiation (also known as brachytherapy), a radioactive substance in the form of pellets or liquid is placed at the cancerous site by means of a pill, injection, or insertion in a sealed container.

- **Chemotherapy**

Chemotherapy is the use of drugs to kill cancer cells. It destroys the hard-to- detect cancer cells that have spread and are circulating in the body. Chemotherapeutic drugs can be taken either orally or intravenously, and may be given alone or in conjunction with surgery, radiation, or both. The toxic effects of chemotherapy are severe. The more common use of chemotherapy is adjuvant therapy, which is given to enhance the effectiveness of other treatments. For example, after surgery, adjuvant chemotherapy is given to destroy any cancerous cells that still remain in the body.

- **Immunotherapy**

Immunotherapy uses the body's own immune system to destroy cancer cells. This form of treatment is being intensively studied in clinical trials and is not yet widely available to most cancer patients. The various immunological agents being tested include substances produced by the body (such as the interferons, interleukins, and growth factors), monoclonal antibodies, and vaccines. Unlike traditional vaccines, cancer vaccines do not prevent cancer. Instead, they are designed to treat people who already have the disease. Cancer vaccines work by boosting the body's immune system and training the immune cells to specifically destroy cancer cells.

- **Hormone Therapy**

Hormone therapy is standard treatment for some types of cancers that are hormone-dependent and grow faster in the presence of particular hormones. These include cancer of the prostate, breast, and uterus. Hormone therapy involves blocking the production or action of these hormones. As a result, the growth of the tumor slows down and survival may be extended for several months or years.

- **Bone Marrow Transplantation**

The bone marrow is the tissue within the bone cavities that contains blood-forming cells. Healthy bone marrow tissue constantly replenishes the blood supply and is essential to life. Sometimes, the amount of drugs or radiation needed to destroy cancer cells also unfortunately destroys bone marrow. Replacing the bone marrow with healthy cells counteracts this adverse effect. A bone marrow transplant is the removal of marrow from one person and the transplant of the blood-forming cells either to the same person or to someone else. Bone marrow transplantation, while not a therapy in itself, is often used to rescue a patient, by allowing those with cancer to undergo very aggressive therapy.

## **BREAST CANCER**

Breast cancer is a major health burden in women worldwide<sup>56</sup>. It is a leading cause of cancer related death for women aged between 35 and 55 years worldwide. Heterogeneity, aggressive behavior and multi-factorial etiology are some of the important factors that impose a great



clinical challenge in the management of breast cancer. Significant advances in the prevention, diagnosis and management of breast cancer have been made in recent years. However, breast cancer remains a complex disease process and invites attention for further advances in scientific knowledge and clinical care to improve the lives of patients.

- **Epidemiology of breast cancer- a worldwide view**

Breast cancer is the most common malignancy observed in women in both highly developed and developing countries and comprises around 18% of all the female cancers. The incidence rates of breast cancer have tremendously increased in the last two decades. Incidence and mortality rates vary internationally by more than 5-folds<sup>57</sup>. The incidence rates are higher in Western and Northern Europe, Australia/New Zealand and North America; moderate in South America, the Caribbean and Northern Africa; and lower in sub-Saharan Africa and Asia. The age standardized incidence is highest in North America and lowest in central Africa with 99.4 and 16.5 cases per 100,000 cases respectively. However, incidence rates are raising rapidly in most of the low-and middle-income countries (LMCs) compared to the developed countries where incidence rates are already high. The mortality rate due to breast cancer has been estimated to be around 1, 30,000 per year in females. This indicates that a disease once called as ‘a disease of the western world’ has been termed as a ‘global health challenge’. Hence the commitment to cure it should also be a global effort.

- **Etiology of the breast cancer**

Breast cancer has multi-factorial etiology. The most important modifiable and non-modifiable risk factors include age, race, ethnicity, gender, family history as well as environmental, hormonal, dietary, lifestyle and genetic factors. Older age has been linked to the cancer development wherein 1 out of 8 invasive breast cancers are found in women younger than 45, while about 2 out of 3 invasive breast cancers are found in women around 55 years of age or older. Socioeconomic status (SES) has also been found to determine the risk of breast cancer. Unlike other cancers, the risk of breast cancer development has been shown to be positively associated with the higher SES. Around 5-10% of breast cancer cases have been attributed to genetic mutations. For example, inherited mutations in BRCA1 and BRCA2 genes are the most common hereditary cause

of breast cancer. Obesity is also considered to be one of the main risk factors and is positively associated with postmenopausal women as it may raise the estrogen levels<sup>58</sup>.

Exposure to radiations and mutagenic agents, use of oral contraceptives, post-menopausal hormone therapy (PHT), hormone replacement therapy (HRT) and menopausal hormone therapy (MHT) are some of the reasons that may be responsible for the rise in breast cancer incidence rates. Besides these, alcohol consumption and cigarette smoking are other life style factors that may also increase the cancer risk. All these factors may disturb the cellular signaling pathways resulting into altered molecular mechanisms leading to carcinogenesis.

- **Types of breast cancer**

Around 95% of the breast carcinomas begin in the epithelial cells of the breast whereas very rare cases of breast sarcomas are observed in connective tissues such as muscle tissue, fat tissue, or blood vessels. Breast cancer may be invasive or non-invasive depending upon the type and the stage of the disease. It has been divided into ductal carcinoma in situ (DCIS), invasive ductal carcinoma (IDC), non-invasive lobular carcinoma (lobular carcinoma in situ) and invasive lobular carcinoma (ILC). These in situ carcinomas remain confined at a place, with no invasion of the underlying basement membrane into the surrounding breast tissue. Such type of localized and confined malignancy has negligible potential for metastases.

When the ductal or lobular malignancy breaks all the way through the wall of the duct or lobule into the fatty tissue of the breast and invades to other parts of the body, the malignancy is considered as invasive (or infiltrating) ductal or lobular carcinoma. The potential for metastases is very high in invasive disease that ultimately leads to the mortality.

Besides the above, there are additional types that include inflammatory breast cancer (IBC), Phyllodes tumor, angiosarcoma, Paget's disease of the nipple and triple negative breast cancer (TNBC).

- **Breast cancer TNM staging<sup>59</sup> and Grading**

The staging of any cancer describes upon the extent of its spread in the body and helps in better prognosis and treatment, thereby increasing the chances of survival in the patients.

Stages can be decided by the tumor size (less than 2 cm, or between 2-5 cm or more than 5 cm), lymph node involvement as well as by invasive or noninvasiveness of the tumor.

The American Joint Committee on Cancer (AJCC) has designated TNM system ('T' stands for tumor; 'N' for node and 'M' for metastasis) for staging the cancer and has categorized the breast tumors into stage 0, I, IIA, IIB, IIIA, IIIB and IV. Stage 0 is non-invasive whereas I-IV are invasive stages of the breast cancer.

## **BREAST CANCER GRADES**

According to the American Cancer Society (ACS), doctors use the following system to grade

### **Tumor size:**

- **TX:** The doctor is unable to assess the primary tumor.
- **T0:** The doctor has not found evidence of a primary tumor.
- **T1:** The tumor is 2 cm (0.79 inches (in)) or less in diameter.
- **T2:** The tumor is more than 2 cm (0.79 in) but less than 5 cm (1.97 in) across.
- **T3:** The tumor is larger than 5 cm (1.97 in) wide.
- **T4:** The tumor can be of any size, but it is growing into the chest wall or skin. This category includes inflammatory breast cancer.

### **Lymph node status**

When staging a person's breast cancer, doctors will determine whether it has spread to nearby lymph nodes. They do this by removing one or more of the lymph nodes in the armpit and examining them under a microscope.

Doctors categorize lymph node status using the N value of the TNM system, where:

- NX means that the doctor was unable to assess the lymph node status.
- N0 indicates that the doctor did not detect cancer in the nearby lymph nodes.
- N1, N2, and N3 show that the cancer has spread to nearby lymph nodes. Higher values indicate the involvement of more lymph nodes.

### **Metastasis**

Metastasis is when cancer spreads from its original location in the breast to distant parts of the body, such as the liver, lungs, brain, or bones.

The symptoms of metastatic breast cancer depend on which organs the cancer has spread to, and they can vary greatly. Doctors may use additional scans, tests, and exams to diagnose a person with metastatic breast cancer.

Doctors categorize metastasis using the M value of the TNM system, where:

- MX means that the doctor was unable to assess metastasis.
- MO indicates that the doctor did not detect any metastasis.
- M1 means that the breast cancer has spread to other organs.

### **Hormone receptor status**

When staging breast cancers, doctors test the tumor cells for the presence of hormone receptors. The receptors are proteins that respond to the hormones estrogen and progesterone by telling the cancer cells to grow.

Doctors describe breast cancer that has receptors for estrogen as being estrogen receptor-positive, or ER-positive. They refer to breast cancer that has receptors for progesterone as progesterone receptor-positive, or PR-positive.

Breast cancers that have hormone receptors are far more likely to respond to hormone therapy.

### **HER2 status**

HER2 status refers to whether breast cancer cells are producing too much of a protein called human epidermal growth factor receptor 2 (HER2). Doctors test for HER2 status by taking a sample of the cancer and sending it to a laboratory for analysis.

Doctors describe breast cancer with higher than normal levels of HER2 as being HER2-positive. HER2-positive cancers are typically more aggressive than other types of breast cancer, but they are also more likely to respond to targeted therapies.

### **Appearance of cancer cells**

The appearance, or differentiation, of the cancer cells is another factor in cancer staging. Doctors grade cancer cells according to how similar they appear to noncancerous cells under a microscope.

Doctors classify cancer cells that are close to resembling healthy cells as being low grade or well differentiated. These cancers typically grow more slowly.

High grade, or poorly differentiated, cancer cells appear very different than normal cells and tend to grow faster.

## **BREAST CANCER STAGES**

After assessing the different characteristics of the breast cancer, doctors use the information to determine its overall stage from 0 to 4.

Here is an overview of each breast cancer stage:

- **Stage 0:** This cancer is noninvasive and is only present inside the milk duct. This stage includes ductal carcinoma in situ (DCIS).
- **Stage 1:** These are small tumors that either have not spread to the lymph nodes or are only affecting a small area of the sentinel lymph node.
- **Stage 2:** These are larger tumors that have spread to some nearby lymph nodes.
- **Stage 3:** These tumors are large or growing into surrounding tissues, such as breast skin, muscle, and lymph nodes.
- **Stage 4:** These are tumors that started in the breast but have spread to other parts of the body.

- **Signs and symptoms of breast cancer**

There are typically no signs or symptoms observed in breast cancer patients when the tumor is very small at an early stage. Patients with large tumors have painless, hard mass with the irregular edges. Most of the breast cancers can be tender, soft, or rounded and in some cases they may be painful. Other possible less common signs and symptoms of the breast cancer include swelling of all or part of a breast, skin irritation or dimpling, redness, scaliness, or thickening, distortion, tenderness of the breast, nipple pain, nipple retraction, discharge and ulceration. Thus, screening mammography is recommended for every symptomatic or non-symptomatic woman who is at more risk for developing breast cancer.

- **Current methods for early diagnosis, prognosis and therapy**

Early detection has become easy with advances in screening techniques that include routine mammography programs and/or palpation (either self-examination or by physician or nurse), digital mammography, sonogram, thermography, transillumination, xeromammography, CT

scan, magnetic resonance imaging (MRI), ultrasound imaging, radionuclide imaging, positron emission tomography (PET-CT), <sup>99m</sup>Tc-sestamibi scintimammography, electrical impedance tomography (EIT), biopsy as well as genetic testing.

Genetic testing is recommended for women having a strong family history of breast or ovarian cancer. Breast cancers detected by screening mammography have more favourable prognostic characteristics than cancers detected by other methods. These techniques enhance the radiologist's ability to detect cancer and assess the disease extent, which is crucial in treatment planning and staging. Despite the available screening facilities, diagnosis of the breast cancer remains inadequate due to the low sensitivity/specificity, relative complexity and high cost-to-benefit ratio.

During the past few years, biomarkers have gained significant importance in the diagnosis of many diseases. Prognostic and predictive biomarkers such as ER, PR, HER2, p53, BRCA1/2 as well as many others are currently being used for the early diagnosis of breast cancer.

- **Treatment strategy for breast cancer<sup>60</sup>**

There are several treatment options available to cure or improve the survival and quality of the patients diagnosed with breast cancer that includes surgery, chemotherapy, radiation therapy, hormonal therapy and targeted therapies. The most appropriate treatment is given to the patient either alone or in combination depending upon the woman's risk profile and stage of the disease. It is based on the tumor size, location, involvement of lymph nodes and whether or not the tumor has spread to the surrounding tissue or distant organs. Although these treatments are very effective but they are associated with side effects.

### **TRIPLE NEGATIVE BREAST CANCER (TNBC)**

There is an increasing burden of breast cancer worldwide and in India it is also a cause of concern to health providers and is an important area of research. Breast cancer is the most common malignancy worldwide accounting for 21% of all cancers<sup>1</sup> and is the most common cancer among females in urban India.

Introduction of newer technological methods giving insights into tumor biology is also an important area of research solely because of paucity of Indian data and a high prevalence of LABC. It is a heterogeneous disease of different biological subtypes recognized by gene expression study using DNA microarray<sup>61</sup>. These biological subtypes are known to have varied clinico-pathological and molecular features having prognostic and therapeutic

implications. With increasing prevalence of locally advanced breast cancer (LABC) and aggressive tumors it is a good rationale to evaluate hormonal status of breast cancer in central India as there is paucity of hormone receptor data. Triple negative breast cancer (TNBC) is a recent notion for research. It is also associated with aggressive tumors, seen in a younger age group, with shorter disease free survival.

Triple-negative breast cancers are generally unresponsive to standard receptor-mediated treatments. However, other forms of chemotherapy can still generate positive outcomes. Some reports even suggest they are more susceptible to non-receptor mediated therapies than other tumors. Although triple negative breast cancer can be treated with chemotherapy, early relapse is common and a predilection for visceral metastasis is seen. If we see the survival curve in these patients there is a sharp decline in first 3rd to 5th year. Distant metastases are much less common after 5 years. As presented in the comprehensive article by Drs. Anders and Carey, a number of studies have focused on understanding the epidemiology, natural history, biology, and treatment strategies for this subtype. Long-term follow-up of triple negative cohorts has demonstrated a worse prognosis or the triple-negative subgroups than for those that are HR-positive. A number of new strategies are currently being tested in clinical trials.

**Epidemiology:**

The literature review shows TNBC accounts for 15% of all breast cancer. More frequently observed and with worst prognosis in young black women. In the present study this prevalence was 43.5% of all breast cancers and this is consistent with persistently higher prevalence quoted in Indian populations and ethnic groups

**Pathology:**

Triple-negative breast cancers refer to a specific subtype of breast cancer that does not express the genes for estrogen receptor (ER), progesterone receptor (PR) or Her2/neu.

Biologically five distinct breast cancer tumor subsets are-

- Hormone Receptor (HR)-Positive Luminal A
- Hormone Receptor (HR)-Positive Luminal B
- Human Epidermal Growth Receptor 2 (HER2 Positive)
- Normal-Like
- Basal-like

Majority of triple-negative breast cancers carry the “basal-like” molecular profile on gene expression arrays. Although most triple-negative breast tumors do cluster within the basal-like subgroup, these terms are not synonymous; there is up to 30% discordance between the two groups. Triple negative is a term based on clinical assay and basal type is molecular phenotype defined using DNA review assay. Basal epithelial cell markers have higher expression of CK5,CK14,CK17,Smooth muscle marker,P53,P-cadherin,HER1/EGFR and lower expression of ER,PR,HER2,Desmin whereas luminal epithelial cell markers have higher expression of ER,PR,GATA3, Ck3, Ck8, Ck18, Ck19, Epithelial cell adhesion molecules, Alpha 6 integrin and lower expression of HER2,Basal Ck5,Ck14,Ck17. HER1/EGFR is expressed in approximately 60% of basal-like breast tumors. c-Kit expression is higher in basal-like tumors(31%). High p53 IHC expression or p53 gene mutations are common in basal-like breast cancer (82%). Several additional and targetable molecular pathways implicated in the pathogenesis of basal-like breast cancer include the mitogen-activated protein (MAP) kinase pathway, the Akt pathway, and the poly ADP-ribose polymerase 1 (PARP1) pathway. It has been observed that the majority of BRCA1-associated breast cancers are triple-negative and express a high proportion of basal-like cytokeratins (CK5, 14, 17), as well as P-cadherin and HER1/EGFR. As BRCA1 is in part responsible for DNA repair, exploitation of this essential pathway holds therapeutic implications. Majority of triple-negative breast carcinomas are ductal in origin, others being metaplastic, atypical or typical medullary, and adenoid cystic.

**Clinical characteristics** of triple-negative breast cancers are onset at a younger age, higher mean tumor size, higher-grade tumors, higher rate of node positivity, more aggressive, less responsive to standard treatment, associated poorer overall patient prognosis. Visceral and soft-tissue relapse are more common.

**Management:**

Because of the absence of specific treatment guidelines for this subgroup, triple-negative breast cancers are managed with standard treatment; however, such treatment leaves them associated with a high rate of local and systemic relapse. Triple negative breast cancer cells do not express estrogen receptor (ER), progesterone receptor (PR) or Her2/neu receptors. Without these receptors, the cancer growth is not likely to be fueled by estrogen or progesterone, or by growth signals coming from the HER2 protein. Therefore, triple-negative



breast cancer does not respond to hormonal therapy (such as tamoxifen or aromatase inhibitors) or therapies that target HER2 receptors, such as Trastuzumab. There is no standard recommendation that people with triple-negative breast cancer should routinely have more treatment. Research suggests that triple negative breast cancer responds better to chemotherapy than other types of breast cancer . Although triple-negative breast cancer is associated with a generally poor breast cancer– specific outcome, it is not resistant to chemotherapy. They are more susceptible to nonreceptor mediated therapies than other tumors. Triple-negative breast cancer is highly responsive to primary anthracycline and anthracycline /taxane chemotherapy. In a retrospective analysis CMF is suggested to be superior to anthracycline based chemotherapy in basal like breast cancer . While in a meta-analysis in triple negative patients anthracycline containing regimen was found to be superior to CMF. BRCA1 dysfunction harboring deficient double-stranded DNA break repair mechanisms are sensitive to agents that cause DNA damage, such as platinum agents (cisplatin and carboplatin). .Few studies have shown that patients who have responded well to initial neo adjuvant chemotherapy have better outcome than non responders .it has been seen that % of responders is much less of in triple negative patients majority of them remain with residual disease. The newest chemotherapeutic agent available for treatment of metastatic breast cancer is ixabepilone, an epothilone analog. Epothilones bind tubulin, leading to stabilization of microtubules, cell cycle arrest, and subsequent apoptotic cell death.. In a group of 187 patients with triple-negative disease, response rate (RR) increased from 9% to 27% with the addition of ixabepilone to the capecitabine therapy, and progression-free survival (PFS) improved from 2.1 to 4.1 months. EGFR expression is seen in approximately 60% of triple-negative breast tumors, thus providing a rational, targeted treatment approach. Cetuximab a chimeric monoclonal antibody targeting EGFR22-24. The antiangiogenic agent bevacizumab ,a monoclonal antibody targets all forms of vascular endothelial growth factor (VEGF)- Histologic examination of "basal-like" triple-negative tumors has demonstrated the presence of glomeruloid microvascular proliferation. These focal endothelial tufts, which portend a worse prognosis in nodepositive breast cancer may serve as targets for angiogenesis inhibitor therapy. PARP1, a gene that encodes a chromatin-associated enzyme that modifies various nuclear proteins, is involved in the molecular events leading to cell recovery from DNA damage, cells deficient in either BRCA1 or BRCA2 are exquisitely sensitive to PARP1 inhibition, resulting in cell death/apoptosis. Several PARP1 inhibitors are currently in clinical development. Other emerging targets for treatment

incorporate components of cellular proliferative pathways, including the phosphoinositide 3-OH kinase pathway and the mitogen-activated protein kinase pathway, DNA repair and c-kit.

## **CONCEPT OF MANASA**

Human beings possess instinct and intelligence. These things will not happen without presence of *Manasa* (psyche) and *Atma* (soul). *Ayurveda*, has defined *Ayu* (life) as the combined state of *Sarira* (body), *Indriya* (senses), *Sattva* (psyche) and *Atma* (Soul). In this way, *Manasa* is chiefly responsible for perceiving good healthy life.

Signs of good health which are mentioned in *Susruta Samhita* are as followed- *Samdosha*, *Samagni*, *Samdhatumalakriya*, *Prasannatma* *Prasannendriya* and *Prasanna Manas*.

A healthy person is one whose humors (*Dosas*) and metabolic state (*Agni*) are in equilibrium, whose functional activities of the tissues and excretory systems are in balance, and the soul, senses and mind feel well. Therefore, cheerful state of mind is necessary for the good healthy life.

In today's metaphysical society, human life has become speedy, mechanized, less efficacious and more centered, which contribute to more production of *Kama* (Desire), *Krodha* (anger), *Lobha* (greed), *Bhaya* (fear), *Soka* (Grief), *Cinta* (Worry) and *Irsa* (envy) etc. like *Manasa Vikaras*. In this way, accurate knowledge of *Manasa* is necessary to understand about nature of life and health.

### ▪ Etymology of *Manasa*

The word "*Manah*" is derived from root "*Mana*" adding the suffix "*Asuna*", with the following meanings:

- Which perceives
- Which leads to knowledge (*Sabda Kalpadruma*)
- Which analyses by special knowledge (*Maha Bharata*)

### ▪ Definition of *Manasa*

- A substance which is responsible for the presence or absence of the knowledge, is called *Manasa*<sup>62</sup>.
- A substance which establishes the contact between the soul and body and which

regulates the functions of the *Indriyas* is defined as a *Manasa* <sup>63</sup>.

▪ Synonyms of *Manasa*

- *Sattva, Cetah*, (Ca. su. 8/4)
- *Sattvam, Manah* (A. S. Sa. 5/22)
- *Cittam, Cheta, Hridayam, Khantam, Hrat* (*Sabda Ratnavali*)
- *Cittam, Ceth, Hrdyam, Svantam, Hrnmanasama, Manah* (Amarkosa 1/4/3)

▪ Characteristic of *Manasa*

*Anutvam* (atomic dimension) and *Ekatavam* (oneness) are considered to be the two characteristics of the *Manasa*. There are very basic characters of the mind. If it were not so, all kind of perceptions would have occurred at a time.

▪ Subjects of *Manasa*

*Chintya* (things requiring thought), *Vicharya* (consideration), *Uhya* (hypothesis), *Dhyeya* (emotional thinking), *Sankalpya* (determination) or whatever can be known by mind, are regarded as its subjects.

1. ***Cintya***: Thing requiring thought, to think about to do or not to do with purposeful or purposeless manner.
2. ***Vicharya***: It is a distinct analysis, which enough to direct the mind to accept or reject a thing.
3. ***Uhya***: It is a speculation, hypothetical self-discussions and logical thinking about a thing.
4. ***Dhyeya***: It is an emotional thinking about distinct thing.
5. ***Sankalpya***: It is consideration, determination of mind about a thing.

▪ Functions of *Manasa*

*Indriabhigraha* (control of sense organs), *Svasyanigraha* (self restraint), *Uha* (hypothesis) and *Vichara* (consideration) represent the action of mind.

1. *Indriabhigraha*:

*Manasa* is called as the controller of *Indriyas* because it indicates to receive and

send the impulse and impels to cognitive senses for perception of objects.

## 2. *Svasyanigraha*<sup>64</sup>:

Controlling of own function or self control is another function of *Manasa*. It is called *Cancala* so it is necessary to have *Svasyanigraha* to have right orientation towards desired objects and retraction from those after the purpose is fulfilled.

## 3. *Uha*:

*Cakrapani* explained in favor of *Uha* that knowledge of perceived objects, which produced by complete examination by mind is *Uha*.

## 4. *Vichara*:

In *Charaka Samhita Sarirasthana* 1/21, about “*Vichara*” *Cakrapani* has stated that, thinking upon perceived object for its reception (*Upadeya*) or rejection (*Heya*) is *Vichara*.

### ▪ Physiology of *Manasa*

Physiology of *Manasa* can be divided into three stages:

1. Perception (Cognitive or Sensory)
2. Discussion and Determination
3. Stimulation or Initiation (Conation or Motor Reflex)

Though many references regarding this topic are mentioned in *Charaka Samhita*, the prime reference is explained in its *Sarirasthana* 1/22-23, the details of which is as follows:

### 1. Perception (Cognitive or Sensory)

In this stage, *Indriya* receives *Artha* if it is stimulated by *Manasa*. Ca. su. 8/7 also explains that *Manasa* is a key factor of *Indriyas* if it wants to receive *Arthas*. If perception occurs the connection between *Atma*, *Indriya*, *Manasa* and *Arthas* are very essential (Ca. su. 11/20, Ca. Sa. 1/33).

### 2. Discussion and Determination:

After the perception the procedure of actual analysis starts. These processes i.e. *Cintya*,

*Vicarya, Uhya, Dheyaya, Samkalpya* etc. highlight the various objects of mind according to its capacity. It gives the determination to the perception.

### 3. Subjection or Initiation (Conation or Motor reflex):

This part of physiology of *Manasa* is related with *Karmendrya*. *Manasa* is called *Ubhayendriya* because it connects *Jnanendriyas* and *Karmendriyas*. After the determination of knowledge perceived by *Jnanendriyas*, further necessary and desired actions are to be done by *Karmendriyas*.

In this way, beginning from cognitive and sensory perception up to stimulation of motor reflexes, whole process of knowledge is done by *Manasa*.

#### ▪ Seat of *Manasa*

In Ayurvedic literatures, various references are available regarding the seat of *Manasa* which are being discussed as here under:

#### 1. Indefinite:

Mind is continuously active i.e. *Chanchala* (Ca. Sa. 3/21), so it cannot stay at one particular place. Hence, it is very difficult to say about the seat of *Manasa*.

#### 2. *Hridaya*:

Many references are available in Charaka and Sushruta regarding the seat of *Manasa* in *Hridaya*. Both Acharyas have mentioned that only *Hridaya* is the seat of *Chetana* in the body. It indicates that *Hridaya* is the actual seat of *Manasa* (Ca. Sa. 7/8, Su. Sa. 4/34, A.H. Sa. 4/21).

#### 3. *Shira*:

In Caraka (su.17/12), it has been explained that *Prana* and whole *Indriyas* are situated in *Uttamanga* i.e. *Shira*. Among the whole *Indriyas*, *Manasa* is the supreme because it is the controller of them. So it illustrates that *Manasa* is situated in *Uttamanga* i.e. *Shira*.

#### 4. *Sarva Sarira*:

Acarya Caraka states that *Sarva Sarira* is *Adhithana* of *Atindriya* i.e. mind (Ca.Vi. 5/7).

All the references regarding the seat of *Manasa*, which are mentioned above indicate various places, but majority of *Acaryas* believe that the actual seat of *Manasa* is *Hridaya* and its transportation channel is *Sarva Sarira*.

***Manovaha Srotas***<sup>65</sup>

In Charaka, Acarya has mentioned that the channels of the whole body transport the *Tridosha*, similarly *Manasa* is transported through same channels to provide *Chetana* to all the living cells of the body. It is called *Manovaha Srotas* in Ayurvedic texts but separate description regarding this topic is not available in any ancient text.

*Cakrapani* stated that *Manovaha Srotas* are spreaded all over the body but main *Srotas* can be considered as *Hridaya* and ten *Dhamanis* which are related with *Hridaya*. It is also called as a “Manovahi Srotamsi” “*Cetanavahisrota*,” “*Samjnavahisrotasa*” etc. in the particularly with reference to *Unmada*, *Apasmara*, *Mada*, *Murcha* and *Sanyasa* (Ca.su.24/25, Ca. Ni. 7/4, and Ca. Ci. 9/5, Su. Ut. 61/10).

**Emotions and their bodily expressions:**

As a science, psychosomatic medicine aims at discovering the precise nature of the relationship of the emotions and bodily functions. To a certain degree every emotion finds some bodily expressions. The individual will show his emotions in some visible form, perhaps in his posture and attitude, perhaps in his face, perhaps in the trembling of his legs and knees.

Similar changes could be found in the organ themselves, e.g. if he flushes or turns pale, circulation of the blood is affected. In anger, anxiety, sorrow or any other emotion, the body always speaks, and each individual's body speaks in a language of its own. The emotions and their physical expressions tell us how the mind is acting and reacting in a situation, which it interprets as favorable or unfavorable.

**A few emotions are described as follows :**1. *Krodha* (anger):

Anger is generally seen in *Rakshasa*, *Danava* and *Uddhata* personalities and that seems to be one of the causes of fight. The anger influences the organs, mobilizes them for actions or lays an additional stress on them. Some people, when they are angry, have stomach trouble at the same time, or grow red in the face. Their circulation is altered to such a degree that a headache ensues. We shall generally find un-admitted rage and humiliation behind attacks of Urticarial lesions, generalized pruritis etc. and symptoms like the flushing of eyes, sweating and violence.

According to *Ayurveda*, the degree of anger can be measured on the basis of intensity of 'Droha' found in a person. In this emotional disorder the victim can go up to the extent of physical attack and even murder also.

2. *Shoka* (grief) :

*Shoka* is characterized by depressive nature with sorrowful attitude. It may be originated from bad experiences of the past, insult, personnel loss, death of relatives etc.

The degree of *Shoka* can be measured on the basis of intensity of 'Dainya'. The victim of *Shoka* can suffer from diarrhoea, insomnia and pyrexia etc.

3. *Bhaya* (fear) :

Intensity of *Bhaya* is examined by 'Vishada'. This is a specific emotion by which so many diseases are caused. Fear is caused due to injuries of physical and social environment, when one is threatened by some social foe or by some physical threat from the environment, one may attempt to flee from it with accompanying feelings of fear.

Flight and attack are the basis and the primitive activities concomitant with the emotions of fear and rage. Fear in civilization most frequently occurs without physical running away from the situation although as we shall see, psychological running away is quite common.

4. *Chinta* (anxiety):

Sometimes individual suffer from an emotional disorder, which is psychologically just as disabling as the more extreme forms of fear but in which the individual really does not know, of what he is afraid, this is known as *Chinta*.

Neurotic anxiety is perhaps the most important of all the symptoms in the sphere of emotions of psychopathology. The physiological concomitants of tachycardia, of increased respiration, and of sweating of skin surface, which occurs in real fear likewise characterize this anxiety.

By the above emotional disorders and the other than them viz. *Lobha* (greed), *Moha* (narcosis), *Irshya* (jealousy) etc, many diseases are seen. Thus the great importance is given to these psychic factors in respect of their knowledge and necessity of description. Skin disorders fever, insanity, insomnia, diarrhoea, hysteria, *Apatanaka* and so many other diseases are found originated by these emotional factors.

The means by which the body is influenced have never been completely explore, and we shall probably never have a full account of them. A mental tension affects both the voluntary system and the vegetative nerve system. By means of vegetative system the tension is communicated to the whole body, and so, with every emotion. The whole body is itself in a tension. The manifestations of this tension, however, are not as clear at every point, and we speak of symptoms only in those points where the results are discoverable if we examine more closely we shall find that every part of the body is involved in an emotional expression, and the these physical expressions are the consequences of the actions of the mind and the body. It is always necessary to look for these reciprocal actions of the mind on the body, and of the body on the mind, since both of them are parts of whole with which we are concern .

Clinical importance of manovaha srotas In Bhela Samhita Cikitsa Sthana chapter 8 th it has explained as five types of Unmada along with causes and symptoms on Nidana in treatment. Unmada is explained as the diverse or exertions and behaviours of Citta (emotive or the heart element), Buddhi (intellectual or discriminative element) and Indriyas (the senses or the elements of sensory perception). It has mentioned that Unmada is nothing but the dysfunctioning of three bases of emotions, intellection and sensory perception. In Charaka Samhita Nidansthana, chapter 7 th describes the five types of Unmada (insanity), because of the aggravated and vitiated Dosha seriously affects the mind and intellect loses its balance, obstructs the Hridaya and Manovaha Srotas (channels of mind) resulting in insanity. It has described that Unmada (insanity) is characterized by the perversion of mind, intellect, consciousness, knowledge, memory, desire, manners, behaviour and conduct. Apasmara (Epilepsy) is defined by experts as departure of memory associated with entering in to darkness (unconscious) due to derangement of intellect and mind. In those with perverted mind and abundant morbidity due to intake of unwholesome and unclean food, infliction of mind with Rajas and Tamas, masking of heart with Dosha and injury of mind by anxiety, passion, fear, anger, grief, agitation etc. Epilepsy comes forth due to attachment of aggregated Dosha caused as a consequence of Prajnaparadha (Intellectual blasphemy) or literally transgression against the knowledge. In briefly it means acting without common sense. At a more universal level such actions are produced by self centered desires of an individual person, who has lost the memory of universal rhythms of wisdom. This is stated by Acharya Charaka as an unrighteous act done by one who is ignorant and



impaired memory is to be regarded as a volitional transgression. Overruling of Sadvrta has a direct role on Manas Roga. Prajnaparadha give a broad spectrum of Nidana concerned to it. Misconception by the intellect and misconduct are to be considered as volitional transgression. Others are known as non homologous contact of senses (Asatmendriyarthasamyoga) and Parinama. Asatmendriyarthasamyoga means improper actions of Gyanendriya (sense organs). Sense organs are always in contact with the objects of surrounding by acting as a bridge of Atma (soul). Absence, excess, insufficient or troublesome contact with those objects will become the cause for disease. It is well known fact that Manas has the power to control the Indriya or to indulge them in their Artha. Without the involving Manas Indriya are not supposed to perceive their Artha and it is the Manas who gives the order by its knowledge. Vitiating of Guna at the level of Manas indulges Indriya in improper way because of Asatmya Indriyarthasamyoga. Prajnaparadha (volitional transgression) Derangement in the functional faculty of mind (Manas) (known as Dhi, Dhrti, and Smrti) is the state of Prajnaparadha. The power of concentration and making a decision are hampered. The person cannot understand about the whole some and unwhole some things. He falls in such a situation that even knowingly he does successive Prajnaparadha. Parinama (time factor) is an eternal an unavoidable factor. Human being cannot avoid its effect. Its control is not in our hands. According to Parinama variation would be happened of Manasika Dosha as well as Sharirika Dosha. Time factor at the stage of Kala Vaishamyas (different changes of time periods) the Manas which can make the body suitable for the changed situation. But if Manas is not in balanced state then the body cannot change itself. Then disease becomes more susceptible.

Manovaha Srotas is extended all over the body and with the consideration of all physical functions related Manas. After careful screening of references related Manas, it is easy to figure out about Manovaha Srotas and it has been given direct references for Manovaha srotas in Ayurveda. At the level of Manas emotional ups and downs are the most potent causative factors of mental disorders of Manasa Roga in Ayurveda. Sudden elevation or regression in any emotion can directly leads to various mental disorders according to Ayurvedic descriptions. So the proper utilization or excessive utilization, non utilization and wrong utilization of mind or mental faculty are responsible for normal or abnormal mental conditions. That is to say, if mind or mental faculties are

properly utilized, this is conducive to the maintenance of the normal mental conditions; if not, abnormal conditions prevail.

➤ ***Concept of Mind-Modern View***

Mind is the psyche, the faculty, or brain function, by which one is aware of his surroundings and by which one experiences, feelings and desires and is able to attend, reason and make decisions (Dorland's Medical Dictionary).

Though the modern science has a credit of invention of theory of mind, but they could not conclude this. There were several changes even in fundamental, in psychoanalysis by attempt of various eminent scientists.

Sigmund Freud (1856 to 1939), the founder of psychoanalysis was made attempt to illustrate the basic concepts of mind and psychoanalysis:

**I. Topographic Model of the Mind:**

The publication of "The Interpretation of Dreams" in 1900 heralded the arrival of Freud's topographic model of the mind, in which he divided the mind into three regions: the conscious system, preconscious system and the unconscious system. Each system has its own unique characteristics.

**(1) The Conscious:**

The conscious system is the part of the mind in which perceptions coming from the outside world or from within the body or mind are brought into awareness.

Consciousness is a subjective phenomenon whose content can be communicated only by means of language or behavior.

**(2) The Preconscious:**

The preconscious system is composed of those mental events, process and contents capable of being brought into conscious awareness by the act of focusing attention. The preconscious interfaces with both unconscious and conscious region of the mind. To reach conscious awareness, contents of the unconscious must become linked with words and thus become preconscious. The preconscious also serves to maintain the repressive barrier and to censor unacceptable wishes and desires.

### **(3) The Unconscious:**

The Unconscious system is dynamic. Its mental contents and processes are kept from conscious awareness through the force of censorship or repression. The unconscious is closely related to instinctual drives.

The unconscious system is characterized by 'Primary Process Thinking', which has as its principal aim the facilitation of wish fulfillment and instinctual discharged.

The content of the unconscious is limited to wishes seeking fulfillment. These wishes provide the motivation for dream and neurotic symptom formation.

## **II. Instinct Theory:**

After the development of the topographic model, Freud turned his attention to the instinct theory. Instinct is a complex of unlearned responses characteristic of a species.

In Freud view, an instinct has four principal characteristics: source, impetus, aim and object.

**Source** : It refers to the part of the body from which the instinct arises.

**Impetus** : It is the amount of force or intensity associated with the instinct.

**Aim** : It refers to any action directed toward tension discharge or satisfaction.

**Object** : It is the target for this action.

Freud defined some instinct i.e. libido, ego, aggression, life and death instincts.

## **III. Structural Theory of the Mind:**

The structural model of the psychic apparatus made by the three provinces – Id, Ego and Superego – are distinguished by their different function:

### **1. Id:**

Freud used this term to refer to a reservoir of unorganized instinctual drives. Operating under the domination of the primary process, the id lacks the capacity to delay or modify the instinctual drives with which an infant is born.

### **2. Ego:**

The ego spans all three topographic dimensions of conscious, preconscious and unconscious. Logical and abstract thinking and verbal expression are associated with conscious and preconscious function of ego. Defense mechanisms reside in the unconscious

domin of the ego.

The ego is the executive organ of psyche and controls motility, perception, contact with reality and through the mechanisms of defense available to it, the delay and modulation of drive expression.

### 3. Superego:

The third component of the tripartite structural model is the super ego. It established and maintains an individual's moral conscience based on a complex system of ideals and values internalized from parents. It then serves as an agency that provides ongoing scrutiny of a person's behavior, thoughts and feelings; makes comparisons with expected standards of behavior and offers approval or disapproval. These activities occur largely unconsciously.

### IV. Theory of Anxiety:

After the development of structural model, Freud developed a new theory of a second type of anxiety that he referred to as signal anxiety. In this model, anxiety operates at an unconscious level and serves to mobilize the ego's resources to avert danger. Either external or internal sources of danger may produce such a signal that leads the ego to marshal specific defense mechanisms to guard against or reduce the degree of instinctual excitation.

## CHITTODVEGA AND ITS ASSOCIATION WITH SOMATIC DISEASES

The term *Chittodvega* has been considered to represent the Anxiety state for the present study. This term comprises of two components - *Chitta* and *Udvega*.

**Chitta** : It is derived from root "Cit" which denotes the following meanings

To perceive, fix the mind upon, attend to, be attentive, to observe, take notice of, to aim at, intend, to be anxious about, care for, to resolve, to understand, comprehend, know, make attentive, remind of.

The *Vyutpatti* of the word is formed by the addition of "Kta" *Pratyaya* to *Chit* i.e. *Chit + Kta* leads to *Chitta*, which has following meanings according to the Sanskrit - English dictionaries

Thinking, reflecting, imagining, thought, intention, aim, wish, memory, intelligence, “*Chityate sanjnayate Anena Iti chittam*” the one through which perception takes place<sup>66</sup>.

“*Chityate Jnayate Anena iti Chittam*” the one through which understanding takes place<sup>67</sup>.

**Udvega:** It is derived from root “*Ud*” which has following meanings –

Addition of “*Vin*” Pratyaya to “*Ud*” i.e. *Ud + Vin* leads to *Udvega*, which has the following meanings:

Trembling, waving, shaking, agitation, anxiety, regret, fear, distress<sup>68</sup>

Among the above derivations and meaning, *Chittodvega* can be defined as „Anxious status of a mind”. So that *Chittodvega* is a perfect word for highlighting the condition of anxiety state. It is evident from the references in Ayurvedic literatures that different terminologies were used to represent different forms of mental status. Among all these terms, only *Chittakshobha*, *Asvastha Chitta*, *Anavasthita Chitta*, *Tapta Chitta*, *Manvikshobha* and *Chittodvega* are indirectly towards the meaning of anxious status. However, *Chittodvega* is more applicable term to illustrate whole anxious state. Ayurvedic classics has mentioned many words related to mental status, which are as follows:

### References in relation with *Chittodvega*

*Cittavibhramsa* (A.H. Ni. 5/49), *Cittanasa* (Su. Ut. 61/3), *Cittakshobha* (A. H.Ci. 7/78), *Cittaviparyaya* (Su. Ut. 57/3), *Cittavilobhana* (A. H. Ci. 7/79), *Cittopaplava* (A. H. Ni. 6/2), *Asvastha Citta* (Ca. Ci. 9/20), *Anavasthita Citta* (Ch. su. 20/11), *Tapta Citta* (Ch. Ni. 1/35), *Unmat Citta* (Ch. Ni. 7/6), *Bharanta Citta* (Ch. Ci. 24/105), *Uphat Cetas* (Ch. Ni. 8/4), *Vipluta Cetas* (Ch. su. 11/45), *Pranasta Cetas* (Ch. Ci.17/30), *Manovikshobha* (A.H. Ci. 7/46), *Manokshata* (Su. Ut. 62/112), *Manoabhighata* (Ch. Ci. 9/4), *Cittodvega* (Ch. Vi. 6/5).

*Patanjali Yoga Sutra* enumerates nine pathological conditions of mind which includes *Vyadhi*, *Styana*, *Alasya*, *Avirathi*, *Alabdha Bhumikatva* and *Anavasthitatva*. These distractions are accompanied by grief, trembling and dyspnoea. Most of these relates with the facets of Anxiety<sup>69</sup>.

The *Manasa Vikaras* has been defined as an abnormal mental condition characterized by the impairment of *Manasa Karmas* like *Indriyabhigraha* (perception and motor control in the absence of organic problems), *Manonigraha* (mental control), *Uha*

(guess) and *Vichara* (thought) and different aspects like *Buddhi* (decision), *Smruti* (memory), *Samjnajana* (orientation and responsiveness), *Bhakti* (desire), *Shila* (habits and temperaments), *Chesta* (psychomotor activity), *Achara* (conduct) either singly or in combination. According to *Indu*, Commentator of *Ashtanga Sangraha*, mind is vitiated by *Ragadi* i.e. desire etc. *Vikaras* of all human beings and give rise to anxiety, delusion etc.

Table No. 3.4- Facets of Test Anxiety and the respective symptoms explained in Ayurvedic Literature

Facets	Status of Doshas/ Dhatus /Ojas	Respective symptoms Observed	References
Cognitive	<i>Vata Prakopa</i> ( <i>Samanyaja</i> )	<i>Cittopaplava</i> <i>Manobhramsa Soka</i> <i>Samjna Moha</i>	A.H.Ni. 16/24 A.H.Ni.16/23 Ca.Su.12/8 A.S.Su. 17/5
	<i>Vata (Nanatmaja)</i>	<i>Visada</i>	Ca.Su.20/11
	<i>Pitta Prakopa</i>	<i>Bhaya</i> <i>Moha</i> <i>Krodha</i>	Ca.Su.12/11 Ca.Su.12/11 Ca.Su.12/11
	<i>Pitta Nanatmaja</i>	<i>Atripti</i>	Ca.Su.20/14
	<i>Kapha prakopa</i>	<i>Staimitya</i>	Ca.su.20/17
	<i>Oja Kshaya</i>	<i>Abhiksnam</i> <i>Dhyanam, Bibheti</i>	A.H.Su.11
Affective	<i>Vata Prakopa</i> ( <i>Nanatmaja</i> )	<i>Anaha</i> <i>Kampa</i> <i>Nistoda</i> <i>Pumstva Bhramsa</i> <i>Sakrt Graha</i> <i>Hrdrava</i> <i>Mukhasosa</i> <i>Parsvamarda</i> <i>Siroruk</i>	A.H.Su.11/6 A.H.Su.11/6 A.H.Ni.16/24 A.H.Ni.16/24 A.H.Su.11/6 Ca.Su.20/11 Ca.Su.20/11 Ca.Su.20/11 Ca.Su.20/11

		<i>Vepathu</i>	Ca.Su.20/11
		<i>Vaksa Udgarsha</i>	Ca.Su.20/11
	<i>Pitta Nanatmaja</i>	<i>Angamarda,</i> <i>Atisveda, Daha,</i> <i>osha</i>	Ca.Su.20/11 Ca.Su.20/11 Ca.Su.20/11
	<i>Pitta Samanya</i>	<i>Alpanidrata</i>	Su.Su.15/14
	<i>Kapha Nanatmaja</i>	<i>Apakti, Svetabhasata</i>	Ca.Su.20/11
Behavioural	<i>Vata Prakopa</i> <i>(Samanya)</i>	<i>Utsaha Bhramsa</i>	A.H.Ni.16/24
	<i>Kapha Nanatmaja</i>	<i>Alasya</i>	Ca.Su.20/17
	<i>Oja Kshaya</i>	<i>Durmana</i>	A.H.Su.11

**Factors influencing Chittodvega :** *Chittodvega* may result from several causes, most of the times by the combination of more than one factor. These can be studied under the following headings conveniently:

- **Influencing Factors at the Individual Level**

**Hereditary Component :** It is well recorded in the classics that the mental setup of a person corresponds with his parents.

**Intra Uterine Life :** The environment in the Intra Uterine life plays an important role in deciding the vulnerability of the progeny. The attitudes and behaviours of the expectant mother reflects on the emotional states of the offspring. For e.g. if a pregnant woman is an alcoholic the baby that would be born has a likelihood of developing *Anavastita Chittatva* and *Alpa Smrti*, the major features of *Chittodvega*<sup>70</sup>.

**Prakriti :** Prakriti, both physical and mental may have some role in predisposing a person to *Chittodvega*.

**Satva Bala :** The persons possessing excellence of mental faculty called Pravara Satva are not easily prone for *Chittodvega* or any other mental disorder, even under Vyasana (stress). They are Anukula and Kleshasaha. On the other hand, people with Avara Satva are easily vulnerable for mental disorders as they cannot cope up with day to day emotions and stressors.

- **Influencing Factors at the physiological level**

As discussed in the facets of anxiety, *Vata Dosha*, *Pitta Dosha*, *Kapha Dosha* and *Ojas* play an important role in the manifestations of distinctive facets of *Chittodvega*. Apart from that *Manovaha Srotas* being the major one and *Rasavaha*, *Svedavaha* and *Udakavaha Srotas* being the complementary *Srotas* have a major influence on *Chittodvega*.

**Relative Factors :** *Chandogyopanishad*, states that the subtle part of the food nourishes the mind. A reference from *Susruta Samhita* states that *Ahara* has immediate effects on the *Deha Dharana* and *Utsaha*.

**Table No. 3.5 Factors influencing *Chittodvega***

Influencing Factors at the Individual Level	a. Hereditary component b. IntraUterine Life c. <i>Prakruti</i> d. <i>Satva Bala</i>
Influencing Factors at the physiological level	<i>Vata Dosha</i> <i>Pitta Prakopa</i> <i>Kapha Kshaya</i> <i>ManoDoshas</i> <i>Ojo kshaya</i>
Relative Factors	<i>Mithyahara Vihara</i>

- **Coping strategies for *Chittodvega***

In *Mahabharata* it is mentioned that "*Prajnaya Manasam Hanyat*" i.e. Mental disorders can be cured by *Prajna*. *Charaka Samhita* considers that *Jnana* (knowledge of self), *Vijnana* (knowledge of science), *Dhairya* (fortitude), *Smrti* (remembrance of experienced objects) and *Samadhi* (withdrawal from external objects and to fix mind with soul) as the principle line of treatment of mental disorders.

The therapeutic effect is achieved by the restoration of *Dhi*, *Dhairya* and *Atmadi Vijnana*, when the disease is initiated by the two mental *Dosha*. *Dhi* is intellect, it helps in distinguishing the beneficial and harmful regarding the external and internal factors. *Dhairya* is the factor responsible for determination and will, by



which one does not withdraw from the beneficial and does not indulge in prohibited things. *Atma Vijnana* is the insight therapy which is achieved by *Yogabhyasa* and *Samadhi*.

Caraka samhita considers that in the vitiation of *Doshas*, fear, anger, grief are also contributing its share in deterioration of the body. So from a preventive aspect, to check the deterioration of body and mind as well, *Acara Rasayana* or *Nitya Rasayana* which has direct effect on potentiation of *Sattva Guna* of mind has been suggested to overcome the *Vikaras* of *Manas*.

## **PSYCHOLOGICAL DISTRESS-**

Psychological distress covers a wide spectrum, ranging from normal feelings of vulnerability, sadness, and fears to problems that can become disabling, such as depression, anxiety, extensive worries, negative thoughts, or social isolation.<sup>71</sup>

The prevalence of distress, depression, anxiety, and other psychiatric disorders has been studied for many types and stages of cancer. A recent review shows a prevalence of 38.2% of mood disorders in patients with various types of cancer (Mitchell et al., 2011). Significant distress ranges from 20% to 40% in newly diagnosed patients, as well as patients experiencing a recurrence (Holland et al., 2010). Distress is associated with higher rates of non adherence to medical treatment, QoL, or even survival (Shimizu, 2013).

In cancer care, patients' distress levels have been positioned as the sixth vital sign in addition to heart rate, respiration, blood pressure, temperature, and pain (Bultz and Carlson, 2006). Psychological distress may include physical and cognitive dysfunctions resulting from cancer treatment, anxiety and depression, disruptive social and dyadic relationships as well as fatigue and sleep disturbances. Patients experience significant disruptions to normal daily activities, which challenge a person's assumptions about their current and future life trajectory and sense of self. Patients have to cope with role changes and distress provoked by the increase in functional disability and physical side effects associated with cancer and its medical treatment<sup>72</sup>. Some cancer patients blame themselves for the cancer diagnosis (e.g., head and neck cancer patients due to the fact that tobacco and alcohol represent the major risk factors for these cancers (Lang et al., 2013)). Moreover, long-term cancer survivors worry about cancer recurrence or development of new cancers, as well as physical, cognitive, socioeconomic, sexual, and legal issues (Valdivieso et al., 2012).

### **Anxiety and Depression<sup>73</sup>**

Distress in cancer patients can also precede clinical depression and anxiety, with prevalence rates ranging between 5% and 50% (Artherholt and Fann, 2012). A recent meta-analysis found mood symptoms in all patients (men and women) and at all stages of treatment (palliative and nonpalliative; Mitchell et al., 2011). In identifying depression, some symptoms such as low mood, loss of interest in usual activities, feelings of hopelessness or guilt, or suicidal ideations are particularly important to consider whereas physical symptoms such as appetite and weight loss, fatigue, and sleep disturbances may overlap with disease or treatment effects. Depression should carefully be distinguished from sadness or grief. Numerous patients that receive a cancer diagnosis assume that they are close to death and experience anxiety, depression, fear, and anger as the disease progresses.

### **ANXIETY DISORDERS**

Anxiety<sup>74</sup> is commonly experienced by virtually all humans. Anxiety is an alerting signal; it warns of threat, external or internal, and it is probably life saving, more than once in a life time. Anxiety initiates person to take necessary steps to prevent the threat. Since it is beneficial for a person to respond with anxiety in certain threatening situations, one can speak of normal anxiety in contrast pathological anxiety.

Pathological anxiety is an inappropriate response to a given stimulus by virtue of either its intensity or duration. The complete absence of anxiety is just as pathological as excessive anxiety. In Yerkes-Dodson law, it is seen that at very low level of anxiety, the performance is poor. Each increment of anxiety produces equivalent increment in performance. Then there is a phase where performance has reached its maximum and any increase in anxiety does not improve the performance any further. At this stage, the subject may in fact begin having the symptoms of anxiety, although symptoms produced at this stage do not affect performance. Later on, any minor increase in anxiety causes deterioration in performance, which may in turn produce more anxiety. However there are a number of factors, which influence the anxiety response to given stimulus, indicating individual vulnerability in such responses.

#### ➤ Causes of anxiety disorders

A person's genetics, biochemistry, environment and psychologic profile all seem to contribute the development of anxiety disorders.

1. Biochemical Factors: Abnormalities in the brain:

Studies suggest that an imbalance of certain substances called neurotransmitters may contribute to anxiety disorder. Advanced imaging techniques have revealed over-activity in the locus ceruleus, the part of brain important in triggering a response to danger, in people experiencing anxiety, indicating that some people's brain may be more vulnerable to the disorder. Scientists are now beginning to identify different areas of the brain associated with anxiety responses. For example, scans using magnetic resonance imaging techniques of people with OCD, generalized anxiety, and panic disorder have detected abnormalities in the amygdala, a part of the brain that regulates fear, memory, and emotion and coordinates them with heart rate, blood pressure, and other physical responses to stressful events. Abnormalities in a pathway of nerves, referred to as the basal-ganglia thalamocortical pathway, have been linked to OCD, attention deficit disorder, and Tourette's syndrome. The symptoms of the three disorders are similar and they often coexist.

2. Genetic factors:

Researchers have identified a gene associated with people who have personality traits that include anxiety, anger, hostility, impulsiveness, pessimism, and depression. The gene produces reduced amount of a protein that transports serotonin, an important neurotransmitter for maintaining positive emotions. Some experts have identified a genetic defect that affects dopamine, another important neurotransmitter, which appears to cause a syndrome that includes migraine, headache, anxiety and depression.

3. Family Dynamics:

The influence of the family on anxiety is complicated by both genetic and psychologic factors. Many patients with anxiety disorders appear to report parents who were at once overprotective and unaffectionate. One recent study suggested that stressful events, such as disagreements with parents, act upon internalized emotion in young adolescents; eventually these feelings build up and produce full down anxiety or depression disorders in young adulthood.

4. Traumatic Events:

Traumatic events can trigger anxiety disorders, the most obvious being posttraumatic stress syndrome, although there usually needs to be other factors that make one susceptible to

anxiety afterward, specific traumatic events in child hood, however, including abuse-sexual, physical or both can cause anxiety and other emotional disorder later on. Some individuals may even have a biological propensity for specific fears, for instance of spiders or snakes, that can be triggered and perpetuated after a single first exposure.

#### 5. Chemical Hypersensitivity:

Some people have panic attacks after exposure to certain foods or chemicals, such as those contained in perfumes or hair sprays. Some studies have indicated that many children and adults with anxiety disorders may have a hypersensitive response to high level of carbon dioxide, which can occur in crowded spaces.

#### 6. Other Factors:

Anxiety can be chronic symptoms of other psychological or medical problems, such as depression, substance abuse or thyroid disease. A number of studies have reported a strong link between childhood rheumatic fever, which is caused by a streptococcal infection and the development of tic-related disorders, including OCD and Tourett's syndrome the effects of alcohol on the developing fetus now appear to increase the risk for mental disorders as well as birth defects.

## **DEPRESSIVE DISORDERS**

A depressive disorder is an illness that involves the body, mood, and thoughts. It affects the way a person eats and sleeps, the way one feels about oneself.

The clinical features are so varied and individualistic that there may be not be uniformity of symptoms between patients. The illness may have a sudden onset or it may be insidious and gradual over weeks and months.

### **The classical triad of depression is;**

1. Psychomotor retardation
2. Depressed mood
3. Slowed-down thinking

### **DSM-IV-TR Criteria for Major Depressive Episode**

- A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is

either (1) depressed mood or (2) loss of interest or pleasure.  
Note- Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.

1. Depressed mood most of the day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).  
Note- In children and adolescents, can be irritable mood.
  2. Markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
  3. Significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day. Note- In children, consider failure to make expected weight gains.
  4. Insomnia or hypersomnia nearly every day
  5. Psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feelings of restlessness or being slowed down)
  6. Fatigue or loss of energy nearly every day
  7. Feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
  8. Diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
  9. Recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide
- B. The symptoms do not meet criteria for a mixed episode.
- C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).
- E. The symptoms are not better accounted for by bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked

functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms, or psychomotor retardation.

- **Common Signs and Symptoms of Depressive Episode;**

1. **Dysmorphic mood:** The mood is often described by the patient as “sad blue, irritable, hopeless discouraged, down in the dump, inability to feel pleasure. Not caring anymore or depressed.
2. **Loss of interest or pleasure:** It is probably always present to some degree but the individual may not complain of this. It is reflected from withdrawal from friends and family.
3. **Change in psychomotor activity:** There may be agitation in the form of inability to sit still, pacing, hand wringing, pulling or rubbing of hairs.
4. **Retardation:** It may take the form of slowed speech or body movements, a markedly decreased amount of speech or muteness. A decreased level of energy is present.
5. **Changes in appetite and weight:** There is usually loss of appetite and weight. Occasionally there may be increased appetite and weight.
6. **Sleep:** It is also commonly disturbed, more frequently with insomnia but sometimes with hypersomnia. The insomnia may involve difficulty in falling sleep, waking up during sleep and then returning to sleep with difficulty or early morning awakening.
7. **Sexual activity:** There is often lack of interest, characterised by decreased in frequency and enjoyment of sex. Men become impotent while women report an inability to feel aroused or excited.
8. **Sense of worthlessness:** There may be feeling of inadequacy to completely unrealistic negative evaluation of one’s work. Sense of worthlessness, helplessness or excessive guilt.
9. **Cognitive impairment:** Difficulty in concentration, slowed thinking and indecisiveness are common. Patient may complain of memory difficulty and appear easily distracted.

10. Thought of death and suicide: There may be fear of dying, the belief that the individual or other would be better off dead, wishes to die or suicide plans or attempts.

### **ASSOCIATION OF ANXIETY & DEPRESSION WITH CANCER**

➤ Anxiety disorders in Cancer patients<sup>75</sup>-

The diagnosis of cancer causes stress on any individual which relates both to symptoms of disease and to the psychological meaning attached to cancer. The patient's ability to manage these stresses depends on the prior level of emotional adjustment; threat the cancer poses to attainment of age appropriate goals (e.g. career, starting a family, retirement), the presence of emotionally supportive person in the environment and variable determined by the disease itself (disability symptoms, site of cancer, treatment required, presence of pain, and prognosis).

Holland in 1993 has summed up the meaning attached to cancer as five D's as: Death, Disability, Disfigurement, Dependence, and Disruption of relationship.

➤ Depressive disorders in Cancer patients-

Depression in cancer patients results from stress related to cancer diagnosis and treatment, medications, biologically determined depression not related to precipitating events, and recurrence of bipolar mood disorder. A variety of other factors like past history of depression or suicidal attempts, history of alcohol dependence and other substance abuse, presence of neurotic traits, recent loss of events and frequent negative life events could also predispose to depression.

The depressive syndrome is found to influence the participation of medical care, adherence to treatment and return to the premorbid level of functioning. It also affects survival, quality of life and ability to care for one self. These facts make us to realize the necessity of prompt assessment and management of depression in cancer patients. Advanced cancer patients who are depressed may also have physical symptoms which are difficult to palliate and these symptoms improve as their depression is treated. Depressed cancer patients have been found to have higher than normal level of interleukin-6 pro inflammatory cytokine. This could explain the presence of increased physical symptoms in this population.

➤ **Anxiety and Depression in Breast Cancer patients<sup>76</sup>-**

The estimate of the prevalence of major depression among breast cancer patients range from 2 % to 48 %. Breast cancer diagnosis, treatment, and the month following primary therapy are stressful time for most women. While many experience normal distress, there is a subset that experience clinically significant depression that may benefit from specialized psychiatric intervention. Studies that examined both distress and depression have found difference in prevalence. Hegel et al found that while 41 % of newly diagnosed breast cancer patients had high level of distress only 11% had Major Depressive Disorder.

Anxiety is a normal response to threat, uncertainty and loss of control. The diagnosis and treatment of cancer is stressful. After the initial shock of diagnosis, patient typically feels anxious and irritation. They may experience anorexia, insomnia and difficulty in concentration because they are distracted by intrusive thoughts about their prognosis. After that, acute anxiety dissipates as a treatment plan is established and prognosis is classified. A recent cross sectional study on 178 patients with cancer showed that almost half of them had significant anxiety, but anxiety disorder and its subtype was present in 18 % of patients. Breast specific post traumatic stress symptoms were noted in 24 % but only 9 % reported post traumatic stress disorder and majority had co- morbid major depressive disorder.

**SHIRODHARA**

Pouring of a liquid on the forehead or scalp is known as the *Shirodhara*, it can be done by different medicaments like *Taila*, *Takra*, *Kshira*, *Kwatha*, etc. When it is done with medicated Ghee or *Taila*, it is called *Taila Dhara*. This *Taila Dhara* is included in the varieties of *Murdha Taila*, which are *Abhyanga*, *Seka*, *Pichu* and *Basti*. They are told ‘*Uttarottar Gunaprada*’. *Dhara* is not only used in psychic disease but also used in psychosomatic diseases like Insomnia IBS (Irritable Bowel Syndrome), psoriasis etc. Just like the roots of tree nurture and control all the activities and well being of the tree, the head



is the operational center of the entire body. It controls the function of the brain and spinal cord. It has many *Marmas* or vital points and is the house of the master endocrine gland, the pituitary. It is one of the seats of *Vata Dosha* (*Prana Vayu* in particular) and also houses subtypes of *Kapha Dosha* (*Tarpak Kapha*) and *Pitta Dosha* (*Sadhak Pitta*)<sup>77</sup>.

So as the three *Doshas* are represented in the head region, any vitiation in the *Dosha* can cause respective disorders with widespread response in the whole body. Here *shirodhara*, through use of various mediums like oils, ghee and buttermilk, pacifies these *dosha* and works on the entire body indirectly.

- Etymology:

The word *Dhara* is derived from the root 'Dhru' with the suffix 'Nich + Ang + Tap' and is feminine gender.

- Derivation of *Dhara*:

- 1) *Dharyate Yaya*
- 2) *Dharyante Tatra Anaya*
- 3) *Ghatadi Chhidra Santatam Drava, Dravyasya Santatya Patane*

It means a continuous flow of liquid from the hole of the pot.

- Synonyms:

- Dhara*
- Seka*
- Parisheka*
- Avasheka*
- Sechana/Sinchana*
- Prasechana*

- Indications:

*Ardhavabhedaka, Suryavarta, Ardita, Pakshaghata, Hanugraha, Akshishula, Nidranasha, Shirogata Vata, Shirahkampa*

Nowadays, it is indicated in almost all stress and psychosomatic disorders such as IBS, Asthma, Neurological disorders viz. Headache, epilepsy, and psychiatric disorders like psychosis, neurosis, insomnia and also in psoriasis, eczema, H.T. etc.

- Contraindications:

*Kaphaja Vikaras – Shirodhara* further increases *Kapha*, which makes the disease difficult to cure.

➤ ***Taila Dhara and its benefits***<sup>78</sup>:

When medicated Ghee or Taila is poured on the forehead, it is called *Taila Dhara*. It improves speech, stabilizes mind, increases the physical strength, remove anorexia, increases sweetness of voice, softness of skin. It is helpful in *Timira* and *Netra Roga*, *Shukra* etc. *Dhatus* are nourished, increases virility excessive body temperature is reduced and patient can get good sleep.

According to *Acharya Charaka*, one who has his head well oiled daily does not get headache, baldness and grey hair. The strength of his cranial bones is markedly increased and his hair becomes firmly rooted and very black. The sense organs are toned up and the skin of the face becomes beautiful and the person gets good sleep and feels happy (Ch. Su. 5/82-84).

➤ Method of pouring of *Dhara*<sup>79</sup>

The procedure of *Dhara* may be divided into 3 stages for the descriptive purpose.

- Purva Karma*
- Pradhana Karma*
- Pashchat Karma*

▪ *Purva karma*:

*Purva Karma* is related with the preparation of the patient. First it should be confirmed that the patient is fit for *Shirodhara* or not. Following equipments should be prepared.

-*Droni* (Dhara Table)

-*Sharawa* (Dhara Patra)

-Other requirements like cloth piece, cotton, pot etc.

The patient is advised to shave the head or make it short as possible. Shirodhara done after removal of hairs will yields better results than done with hairs intact. The patient should pass stool and urine. Then patients pulse, temperature and blood pressure should be recorded.

- Position of the patient:-

Proper posture of the patient for *Shirodhara* is supine position and *Dhara Patra* should be brought 4 inches above his head. The eyes and ears should be covered with cotton so that liquid may not enter in eyes. His head rests in slightly elevated position, preferably on wooden piece.

- *Droni*:-

For *Shirodhara* a special type of table is used and it is known as *Droni* (vessel). The table is made up of wood with raised edges in all the four side so that the oil may not flow out. In this table arrangement are made at the head end so that the oil poured may be collected in another vessel and may be reused.

- Dimension of *Droni*:-

The construction of *Droni* is explained here by converting the ancient measurements into contemporary one. The length of *Droni* may be 7 feet breadth 2½ feet, the height 2½ feet. On all the sides of the table, 3 inches elevated boundary is constructed towards the side of the head, 2½ feet one horizontal midline strip of wood may be constructed, by which table is divided into 2 parts. This small portion of the table towards the head end is used for *Shirodhara*. In the middle 3 inches from the horizontal line a circular metallic plate of having 6 inches diameter with a central hole may be fixed. This arrangement may be the made to collect the oil in a vessel for its reuse. Above *Shirodhara* portion of the table, the *Dhara Patra* should be suspended with the help of a strong wire to enable liquid to fall from the proper distance.

- *Dhara patra*:-

*Dhara Patra* is a vessel in which liquids used for *Shirodhara* are put in. It is made up of metal or earthen material. The mouth of the vessel should be wide and sides are tapering

gradually to a ventral point in the bottom. At this point a hole may be made approximately of little finger size. The depth of vessel may be 5 to 6 inches. The capacity of the vessel may be 2 *Prastha*. Inside the vessel a small wooden bowl having a central hole should be put inversely so as to both holes of the vessel come in the medial line. In this small vessel a wick should be entered passing through the both holes and hanging down from the big vessel so as to maintain a continuous flow of liquid. The length of the wick outside the vessel should be 4 inches. The upper end of the wick should have knot to prevent slipping from the vessel. The *Dharapatra* should be hanged just above the forehead of the patient. The end of the wick should be 4 fingers (3 inches) above the forehead of the patient. The vessel is kept refilled with the recollected liquid. On the upper edge of the vessel, 3 holes should be made to hang it in a horizontal plane to avoid spillage.

- *Aushadha* (Drug):-

The drug should be selected according to the disease. The quantity required is above 1 to 2 kg. *Sneha* mentioned according to the condition of *Doshas*.

- *Vata Dosha* : *Tila Taila*, *Vataghna* liquid & it should be lukewarm
- *Pitta Dosha* : *Ghrita*, cold water
- *Kapha Dosha* : *Tila Taila*, not very hot, not very cold water
- *Rakta Dosha* : *Ghrita* with cold water
- *Vata + Pitta + Rakta* : *Ghrita + Taila* in equal proportion
- *Vata + Kapha + Rakta* : ½ part *Ghrita* + 1 part *Tila Taila*

- *Pradhana Karma*:

The selected liquid should be kept in the vessel and should be poured continuously and slowly on the forehead of the patient. A mild oscillation may be given, so as to maintain the flow all over the forehead. This liquid gets collected in the vessel, which is kept below the table, when the liquid in the vessel gets emptied and then it is replaced from the lower vessel.

- *Pashchata Karma*:

After completing *Shirodhara* the oil from the head should be removed by a piece of cloth. His eyes should be washed with cold water, he should remove cough. He should rest for some time. The body should not expose to cold & cold measures. If doing so symptoms like headache, cold, etc might be induced. Then remaining oil of the *Dhara* should be massaged on the body. Then he should take bath with hot water.

Then he should take light diet and he should drink water, which is *Siddha* with *Vatanashaka Aushadhi*. He should take the hot meal. He should take *Pathya* up to 7 days or till *shirodhara* is continued. He should not worry about his physical and mental condition.

For drinking purpose warm water boiled with *Dhanyajiraka*, ginger and cumine seeds may be used. For washing and ablating purposes only warm water should be used.

- *Dharakala*:

The patient having dryness and *Pittayukta Vata*, the period is  $2\frac{1}{2}$  *Prahara* or 2 *Prahara* and in *Snigdha Kaphayukta Vata* it is one *Prahara*, or it should be upto perspiration initiate (*Dharakalpa* – 17). The patient has to remain in the laying posture on his back. The treatment may be carried on daily for a period of 7 to 14 days, according to the nature of the disease and the physical condition of the patient. Generally treatment is done in the morning hours preferably between 7 to 10 p.m.

- Period for changing the liquid:

When milk or *takra* is used for *Parisechana* it should be changed every day. When *Dhanyamla* is used, it can be used up to 3 days. Oil also should be changed at 3 days. In the first 3 days; half of the oil used, for next 3 days later half of its used and on the 7th day all the first and second half are mixed together, then it should be discarded (*Dharakalpa* – 21 and 22). But for best results it should be changed on daily basis. As medicated oil is very costly everyone couldn't afford to change oil daily.

- Temperature of the *Sneha*: It should be *Sukhoshna* near about to body temperature. In case of *takra* it should be at room temperature.

- *Pariharyani:*

The patient should abstain from sexual intercourse as well as from any thought or deed that may excite sexual desire, avoid physical exertions, mental excitement such as anger, grief etc. and exposure to cold, sun, dew, wind, smoke or dust should also be avoided. Riding on elephants or horses, walking, speaking too long or too loud and such other acting that may give any strain to the system must be avoided. Sleeping during daytime and standing continuously for long period must also be avoided. It is also advisable to use a pillow which is neither very high nor very low, during sleep at night.

During the course of the treatment, the patient should be cheerful and happy and should avoid wearisome exertions, distasteful diet or excessive indulgence in tasty foods. He should wear clean and dry cloths and may have '*Lepans*' of Sandal wood paste.

- *Pariharakala:*

He should take *Pathya* and remain as *Jitendriya* up to the period which is taken for the completion of *Dharakarma*.

- *Dhara dosha:*

If *Dhara* is done from more height, very early or very slowly then it may produce burning in body, pain in all joints, bleeding tendency, *Jwara*, *Kotha* etc.

For the treatment of *Dhara Dosha*, following measures may be adopted.

1) *Gandusha*

2) *Nasya*

3) *Kashayapana* with Sunthi

4) Light diet at evening, *Yusha* with black pepper.

5) On the third day *Basti* should be given in which Saindhava is mixed.

- Mode of Action of *Shirodhara*:

It is difficult to prove that how *shirodhara* works in a scientific measures but we cannot ignore the magnificent results of the treatment, we can explain it hypothetically as follows-

According to *Ayurveda*:-

*Vata* is a chief controller of the body, *Acharyas* explained *Anidra* as *Vata Nanatmaja Vikara* which is caused due to *vata dosha* as aggravated *Vata* disturbs the sleep and *shirodhara* works as *Samvahana* (gentle massage) on the head which re-establishes the function of *Vata* & *Mana*.

Stress, according to Ayurveda is a state of imbalance of *prana vayu*, *sadaka pitta*, and *tarapaka kapha*. *Shirodhara* through its mechanical effect reestablishes the functional integrity between these 3 doshic subtypes -

1. These will have relaxing effect over the *Vyana vayu*, *Ranjaka Pitta*, *Avalambaka Kapha* & *Udana Vayu* controlling the heart functions & circulation.
2. By controlling the *Kledaka Kapha*, *Bodhaka Kapha*, *Samana Vayu*, *Ranjaka Pitta* & *Pachaka Pitta* will keep the core metabolism under control.
3. By controlling the *Apana Vayu*, it will keep excretory function under control & help in regular detoxification of the body.
4. By controlling the *Bhrajaka Pitta* & *Vyana Vayu* it will improves the color & complexion.
5. By controlling the *Shleshaka Kapaha* function it will maintain the musculoskeletal integrity.

Continuous flow of *Shirodhara* on *Shira* improves the *Dhi* (intellect), *Dhiriti* (restraint) and *Dhyana* (concentration) i.e. there is balance of *Raja* and *Tama Dosha* and improvement of *Satva Guna*. When an individual lies down in a relaxed state for longer time, *Tamasika Guna* overcomes the *Rajasika Guna*. The procedure of *Shirodhara* brings the *Sanjnavaha Srotas* in peaceful state of rest which helps in inducing sleep.

*Dharakalpa* explains the time required for the drug potency to cross through the body elements. the unctuous substances transfers through these hair follicles by a time period of three hundred *matra kala*. These substances cross over through the seven layers of skin by seven days; by six days it reaches upto raktadi six dhatus.

स्नेहोऽत्र त्रिभिरेति रोमविवरं मात्राशतैश्च क्रमात्।

सप्तापि त्वच एति सप्तभिरथो

षडिभस्तथासादिकन्षड्धातू

निषुसिन्धुदिग्ग्रहमिता मात्रामूर्तोभवेत्॥

- धाराकल्प

The process of suffusion explain in detail: The unctuous substances after laying over hair follicles for a period of three hundred *Matra Kalas*, enter skin by four hundred matra kala; similarly, the unctuousness reaches *Rakta, Mansa, Meda, Asthi & Majja* in each successive hundred *Matra Kalas* i.e. it reaches majja by 900 matra *Kalas*. *Bhoja*, in addition, mentioned that unctuousness reaches upto shukra by sixteen hundred *Matra Kalas*.

The medicinal potency during course of successive transference pacifies diseases of *Vata, Pitta & Kapha* located in the respective body elements.

The forehead and head are areas of many vital spots (*Marma*) as mentioned in Ayurvedic classics. *Shirodhara* acts on 7 out of 10 *Marmas* present in *Shiro Pradesh*, mainly *Sringataka, Sthapani, Utkshepa* and *Avarta Marmas* (the vital points in the head) are situated in this region. According to *Acharya Bhela*, the site of *Chitta* (mind) is *Bhrumadhya* (region between two eyebrows) i.e. *Sthapani Marma* and *Buddhi-Vaiseshika Alochaka Pitta* also situated on this region. The *Shirodhara* helps the patient to concentrate on this essential area, which eventually leads to stability in the functions of mind.

According to Yogic Science:-

- *Shirodhara* is believed to act at the level of Yogic *Chakras*. It stimulates the supreme *Chakras* i.e. *Aagya Chakra* and *Sahasrara Chakra* which are situated in the head region. These *Chakras* govern all the vital energies in the body. Due to the stimulation of these *Chakras*, the individual achieves a good mental condition. Hence, conditions like *Anidra* are really benefitted by the *Shirodhara*.
- The method of *Shirodhara* may even produce effects similar to that of “*Yoga nidra*” technique in yogic science. Most of the benefits of meditation and relaxation are seen to be achieved by the procedure of *Shirodhara*.
- In *Shirodhara*, the patient is asked to lie down in supine position as in *Shavasana*. This position in itself is used for relaxation in Yogic science.



According to Modern Science:-

Modern explanation for the therapeutic effect of Shirodhara can be done on the background of following important anatomical and physiological considerations regarding sleep:

The thalamus, basal forebrain and medullary reticular formation are held responsible for sleep. While the brainstem reticular formation, the midbrain, the sub thalamus, the thalamus and the basal forebrain have all been suggested to play a role in the generation of wakefulness.

In the procedure of Shirodhara, when oil is poured upon forehead from a certain height, it generates momentum due to change in the form of energy. This momentum may cause change in voltage and stimulate nerve impulse generation or accentuate its conduction. The magnitude of momentum decides the voltage difference for nerve impulse generation and conduction. If its magnitude is small the energy is absorbed by the skull only. This may be the probable reason why drug should be given for 45 min- 1 hour in *Shirodhara*.

In *Shirodhara* particular pressure and vibration is created over the forehead. The vibration is amplified by the hollow sinus present in the frontal bone. The vibration is then transmitted inwards through the fluid medium of cerebrospinal fluid (CSF). This vibration along with little temperature may activate the functions of thalamus and the basal fore brain which then brings the amount of serotonin and catecholamine to the normal stage inducing the sleep.

Again, it is explained in modern text books of physiology that pressure has an effect on impulse conduction through tactile and thermo receptors. Receptors involved being root hair plexuses, free nerve endings, etc. Warm liquids used in Shirodhara procedure causes increased infiltration of blood in scalp region thus relaxing muscle and nerve endings. If prolonged pressure is applied to a nerve, impulse conduction is interrupted and part of the body may go to rest. In Dhara therapy, prolonged and continuous pressure due to pouring of the medicated liquid may cause tranquility of mind and induce natural sleep.

Continuous flow of lukewarm liquid may dilate the blood vessels and thus increase the blood flow through the brain. It thereafter circulates and warms rest of the body too. It has been proved that higher the body temperature, longer will be the sleep.

According to the modern science, forebrain is the site of behaviour, concentration and intelligence. Shirodhara may stimulate the forebrain and produce improvement in these

qualities.

The space between the two eyebrows is the seat of pituitary and pineal gland. As we know, pituitary gland is one of the main glands of the endocrine system. Shirodhara may stimulate it by its penetrating effect, which decreases the brain cortisone and adrenaline level, synchronizes the brain wave (alpha waves), strengthens the mind and spirit and this continues even after the relaxation.

The concept of percutaneous absorption in the modern physiology is as follows: There are three possible routes of absorption. a) The pilo sebaceous follicles play some part in absorption of many compounds. b) The trans-follicular absorption, the route of penetration is through the follicular pores to the follicles and then to c) The dermis via the sebaceous gland. The permeability of the cells of the sebaceous gland is greater than that of granular layer of the epidermis. In this way the substances which are used in Shirodhara are absorbed and enter in the blood through and remove the pathology.

Shirodhara induces bradycardia & the expired gas analysis showed a decreased tidal volume & CO<sub>2</sub> excretion. During the process subject's sympathetic nervous tone was suppressed. EEG results monitored during the process of shirodhara indicated restful alertness in which the frontal lobe, limbic system & medulla oblongata were activated.

These metabolic, ECG & EEG findings support the reported experience of relaxed & low metabolic states during Shirodhara. Differences in heart rate, CO<sub>2</sub> excretion, sympathetic tone & EEG were indicates a change in function of the frontal lobe, limbic system, brain stem & autonomic nervous system.

### **JATAMANSI**

Latin Name : *Nardostachys Jatamansi DC.*

Family : Valerianaceae

Sanskrit Synonym : Mansi, Jatila, Tamsi, Sulomasha

English : Nardus root, Indian spikenard

Gujarati : Baalchad, Kalichad

Hindi : Balchara

Kannada : Bhootaja

- **History<sup>80</sup>:**

It has been in use from a very remote period among the Indians as a perfume and medicine. It is a nervier tonic and carminative; and aromatic adjunct in the preparation of medicinal oils as well as Ghee. Nardostachys was known in ancient times as “*nard*” and later, as spikenard. It is the Nardin of Dioscorides, which the writer tells us, was also called Gantitis because the Ganges flowed from the foot of the mountains where the plant grew. Nardostachys was recommended in the *Ayurvedic* tradition for nervous and spasmodic symptoms, such as heart palpitations, headache, shaking and convulsions. The active constituents of Nardostachys are similar to those found in valerian. It is being examined for its liver protective effects, ability to increase nerve growth factor and lipid lowering effects.

**Distribution:**

It is commonly distributed in a height ranges from 3500 meter to 4500 meter in the northern aspect of the sub-alpine and alpine pastureland of the Himalayas in Nepal.

The plant is mostly found growing in steep areas. It grows well on open, stony and grassy slopes and on the turf of glacial flats. It is also found growing under the Silver Birch forest, where its growth is good with large leaves and long rootstock.

**Habit:**

Its radical leaves are elongated and spatulate, its cauline leaves are sessile and oblong or sub-ovate; the flowers are rosy, pale pink or blue, in dense cymes. The drug consists of short, thick, dark gray rhizomes crowned with reddish brown tufted fibrous remains crowned with reddish brown tufted fibrous remains of the petioles of the radical leaves.

**Pharmacognosy:**

Dried rhizome is dark brown, 2.5-7.5 cm long, cylindrical, covered with reddish-brown fibres forming a network, which are skeletons of sheathing leaf basis; fracture brittle; internal colour reddish-brown; odour strongly aromatic; taste acrid, slightly bitter and aromatic. Transverse section of rhizome show cork consisting of 2-5 layers of cells filled with oil globules. Cortex is characterized by the presence of schizogenous canals. Phloem is in the form of patches of small cells. Cambium ring is distinct and continuous. Xylem consists of vessels, scattered individually or in rows of 2 or 3 vessels with scalariform thickening. Older

rhizomes show one or more stellate shaped rings or interxylary and medullary cork, completely or incompletely separating the rhizome into 49 vascular strands by joining outer cork. Each separated strand is encircled by a few layers of cork cells consisting of an outer cortex zone followed by two or more functional vascular bundles, tissues in between the strand usually non functional except for the cork cells which act as storage organ for oil globules.

### Chemical Constituents:

Actinidine, carotene, aristolen-1-ol, 1(10)-ariastolen-2-one, calarene, calarenol,  $\alpha$ -carene, 9-dehydroaristolene, 1(10)-dehydroaristolene, elemol, erythro-1-(3,4-dimethoxyphenyl)-2-(2-methoxy-4(E)-prophenyl phenoxy)-propan-1-ol, erythro-1-(4-hydroxy-3-methoxyphenyl)-2-(2-methoxy-4(E)-prophenyl phenoxy)-propan-1-ol,  $\alpha$ -eudesmol, n-hexacosane, n-hexacosanol, nhexacosanylarachidate, isovalerate, 2 $\alpha$ -maleine,  $\alpha$ -maliene,  $\alpha$ -& $\beta$ -pinenes, a C<sub>15</sub> alcohol & its isovaleric ester, (+)-1-hydroxypinoresinol, jatamols<sub>6</sub> A&B, jatmasic acid, jutamansone, nardol, nardostachonol, nardostachone, patchouli alcohol, isovaleric acid,

oil from rhizome);  $\alpha$ -maliene, calarene, nardostachonol, 9-dehydroaristolene, 1(10)-dehydroaristolene, 2 $\alpha$ -maleine, 1,2,9,10-tetrahydroaristolene, an alcohol and its isovaleric ester, sesquiterpene<sup>9</sup> ketonejatamansone<sup>10</sup>, jatmasic acid, terpenoid-jatamansin<sup>11</sup>, oroselol, oroselone, dihydrojatamansin, angelic acid, jutamansinol, seselin, jutamansinone,  $\alpha$ -& $\beta$ -pinene,  $\alpha$ -carene,  $\alpha$ -eudesmol, elemol,  $\alpha$ -sitosterol, angelicin (plant oil)<sup>12</sup>; terpenic coumarins-oroselol, jatamansin (root oil); seychellene, seychalane (plant).

### Pharmacological Activities:

Anti-epileptic, hypotensive, analgesic, anti-implantation, CNS depressant, tranquillizing, hypothermic, antiemetic antiarrhythmic, antispasmodic, antibacterial, antifungal, anthelmintic, diuretic, antiestrogenic, antimicrobial, anticonvulsant, antiulcerogenic, antianxiety, hepatoprotective, bronchodilatory effect.

### Toxicology:

LD<sub>50</sub> of essential oil of *Jatamansi* in mice was found to be 900 mg/Kg *i.p.*

LD<sub>50</sub> of the ethanolic extract (50%) of the rhizomes, in mice was found to be >1000 mg/Kg *i.p.* LD<sub>50</sub> of the Jatamansone in mice is 580 mg/Kg *i.p.*

Lethal doses cause deep narcosis and ultimately death within a few hours.

**Pharmacological Studies:**

- The essential oil obtained from rhizomes of N.J. exerted prolonged and pronounced hypotensive effect in dogs (Arora et al, 1958). However, the oil free aqueous of N.J. showed a transient hypotensive effect and ECG changes in dog's heart (Sheath and Kekre 1956).
- In another study, aqueous, alcoholic volatile oil and alkaloid fraction of N.J. rhizomes and roots were studied for sedative and CNS effects. The alkaloid fraction showed a significant and sustained hypotensive action in dogs. The fraction also produced a marked relaxation of plain muscles and depression of CNS and a mild degree of relaxation of the skeletal muscle (Bose et al, 1957).
  - Jatamansone, the sesquiterpene from N. J. was shown to exert tranquilizing activity in mice and monkeys, hypothermic activity in mice and anti-emetic in dogs (Arora et al, 1962).
  - Various extracts of N. J. Root showed both sedative actions in rats and revealed by physical inactivation and potentiation of phenobarbitone sodium sleeping time in rats and the hypotensive activity in rats (Gupta et al, 1966).
  - The essential oil from the rhizomes had a depressant action on the CNS of guinea pigs and rats (Chopra et al, 1969). The ethanolic extract (50%) of N.J. rhizomes had no effect on the CNS of mice (Bhakuni et al, 1969).
  - A compound herbal preparation with N. J., *Acorus calamus* (Vacha) and *Valeriana Wallichii* (Tagara) as ingredients showed CNS depressant activity in rabbits.
  - N.J. in a dose of 100 mg/kg. I.P. Did not show antiepileptic effect in albino rats. with a higher dose of 200 mg/kg i.p., 60% protection was obtained. With a still higher dose of 400 mg/kg i.p. Better effect was not obtained, on the contrary mortality of the animals increased. Prolonged administration of the drug showed some antiepileptic effect (P. R. U., Lucknow).

In addition to above findings various studies have been carried out which prove that *Nardostachys Jatamansi* has the following properties –

- Aromatic, bitter tonic, stimulant, antispasmodic, useful in intestinal colic, heart palpitation and convulsion, act as substitute for valerian, weak antibacterial, antiprotozoal, hypotensive, hypothermic, potentiation of sleeping time and MAO inhibitor, diuretic, antihistaminic, antiarrhythmic, sedative, antiarthritic, antiepileptic and antiulcerogenic.

- Clinical Study: The oil was tried in cases of neurocirculatory asthenia and related cardiac conditions like functional cardio neurosis, cardiac arrhythmias, menopausal syndrome, hypertensive states etc. showed encouraging results particularly with respect to improvement in subjective parameters (Vakil and Dalal, 1955).

**Rasapanchak:**

*Rasa : Tikta, Kashaya, Madhura*

*Guna : Snigdha, Laghu*

*Virya : Sheeta*

*Vipaka : Katu*

*Prabhava : Bhutaghna.*

**Properties:**

*Vedanasthapaka, Sanjnasthapaka, Nidrajanaka, Medhya, Deepana, Pachana, Anulomana,*

*Yakrituttejaka, Pittasaraka, Hridayaniyamaka, Raktabharashamaka, Kaphanihsaraka,*

*Balavardhaka, Swedajanaka,*

*Brikkauttejaka, Bhutabadhapaha, Kantiprada etc.*

**Part(s) used**

Rhizome

**Dose:** 2-3 gm of the drug in powder form.

5-10 gm of the drug for decoction.

**TILA TAILA<sup>81</sup>:**

Sanskrit - Tila Taila

Hindi - Tila Tel

English - Sesame oil, Gingelly oil

Kannada - Ellenne

Gujarati - Tal nu Tel

The word “*Taila*” is derived from Sanskrit - “*Tilodbhavam*” means, one which is derived from Tila- sesamum. But in general, ‘Taila’ is considered for all oils. Specifically, Tila taila

means oil extracted from the seeds of *Sesamum indicum* (Fam. Pedaliaceae), a herb which is widely cultivated in India, Japan, China and many other tropical countries. This is official oil mentioned in the British Pharmacopoeial codex, British pharmacopoeia and in the European pharmacopoeia.

**Ayurvedic view :**

***Rasa Pancaka :***

*Rasa - Madhura*

*Anurasa - Tikta, Kasaya*

*Guna - Tiktsna, Vyavayi, Suksma, Usna, Visada, Guru, Sara, Vikasi*

*Vipaka - Madhura*

*Dosaghnata - Vatakaphahara*

*Karmukata - Brmhana/Lekhana, Prinana, Vrsya, Twak prasadana, Mardavakara,*

*Sthairyakara, Balya, Garbhasaya sodhaka, Bhagna sandhanakara, Medhavardhaka, Kesya,*

*Sula prasamana, Ropaka*

*Rogaghnata - Vataroga, Bhagna, Yoni-karna-siroroga, Kesapata, Vrana*

**SESAME OIL :**

Sesame oil is the most stable vegetable oil, ever used. The oil is extracted from both the varieties of sesamum seeds Viz., black and white.

It is a light yellow coloured with a pleasant odour of typical character and bland taste. Its density may vary between 0.916-0.920. It solidifies at  $-5^{\circ}\text{C}$  and forms a buttery mass.

The sesame oil is soluble in Ether, Chloroform, Pet-ether and Carbon disulphide solutions. It is partially soluble in alcohol and insoluble in water.

**Chemical composition:**

In experimental studies, it has been observed that sesame oil is the most stable vegetable oil against oxidation.

The stability of Sesame oil against oxidation is due to the lignans such as Sesamol, Sesaminol, Phynoresinol and Sesamolinol. 7- tocopherol is another antioxidant, providing better results in tissue injuries.

Chemical Constituents of Sesame Oil are -

1. Saturated fatty acids - Palmitic acid
2. Non saturated fatty acids- Linoleic acid, Oleic acid
3. Anti oxidant principle -7-Tocopherol
4. Lignans - Sesamolin, Sesamol, Sesamolinal, Sesaminol, Phynoresinol, Sesamin

**Pharmaceutical Uses:**

1. The oils are used as soothing agents or to allay inflammation and pain.
2. In modern pharmacy, it is limited to the preparation of ointments or medicated creams.
3. The conventional medical practitioners use them as demulcent and emollients as protective covering on injured surfaces.

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### 3. RESEARCH METHODOLOGY

#### AIM AND OBJECTIVE

##### AIM

To access mind relaxation effect of Jatamansi oil shirodhara on chittodvega ( psychological distress) in TNBC ( triple negative breast cancer) patients

##### OBJECTIVE

To evaluate efficacy of Jatamansi oil shirodhara for improving Quality Of Life of TNBC patients

#### RESEARCH METHODOLOGY

##### 1) CONCEPTUAL STUDY

All *Ayurvedic* texts with special commentaries including modern text and online updates about diseases, drug and procedure were reviewed and documented for the present study.

##### 2) PHARMACOLOGICAL STUDY

*Jatamansichurna* was collected from local drug vendor. Authentication and identification of drugs were done in .....(Certificates attached in Annexure).  
*Jatamansi-siddha Taila* was prepared in .....by standard methods mentioned in classical texts.

##### a) DRUG STANDARDISATION: -

Drug was standardized in authorized analytical laboratory (Certificates attached in Annexure).

##### b) DRUG MANUFACTURING PROCESS: -

1 Part of *JatamansiBharadwas* taken. It was soaked and mixed with 8 parts of water. Mixture was boiled and reduced till half of its original quantity. Then, this decoction was strained. 4 parts of Decoction was mixed with equal quantity (4 parts) of Sesame oil and heated on mild flame till all moisture was removed. Oil was strained after cooling and was stored in bottles.

### 3) CLINICAL STUDY: -

Type of study: Interventional study

Study design: Two arm, open labeled, Parallel, Randomized Controlled Clinical trial

Duration of study: 30 Days

Centre of study: OPD and IPD of concerned institute

Ethical clearance: From TMV Ethics Committee was taken.

#### a. SELECTION OF PATIENTS-

##### b. A) Grouping of Patients

Total 130TNBC patients *having Chittodvega*; attending OPD were considered for this study. Among them 70 patients undergoing Shamanachikitsa were selected on the basis of inclusion criteria. These 70 patients, eligible for Shirodhara, were paired with identical stage, grade, conventional treatment and duration of Ayurvedic treatment. Paired patients were randomly selected for their enrolment in study (n=35) and control (n=35) group. Study group patients were treated with 7 days course of Jatamansi oil Shirodharaalong-with Shamanachikitsa, whereas control group patients were treated only withShamanachikitsa.

##### c. Shamanachikitsa comprises of Tab. Suvarnamalini Vasant125 mg and Tab.

MauktikyuktaKamadudha 500 mg, with milk, morning, after breakfast –evening, after snacks; Tab. TriphalaGuggulu – 500 mg and Tab. ArogyavardhiniVati – 500 mg with water, after lunch and dinner.

#### d. INCLUSION CRITERIA-

1. Age- 20 to 70 years
2. Known cases of TNBC (Immunohistochemically proven ER, PR, Her2 Negative)
3. Patients who are freely giving Consent for the Trial

#### e. EXCLUSION CRITERIA-

1. Age- Below 20 years and above 70 years
2. Patients with known psychological illness prior to CA Breast
3. Non-complaint patients
4. BREAST CANCER PTS- ER, PR, HER2 –ANY 1 POSITIVE

**f. DIAGNOSTIC CRITERIA-**

Breast cancer patients diagnosed on the basis of immunohistochemistry as ER, PR, Her2 Negative and assessed with help of Zung's self-rating Anxiety scale and Zung's self-rating Depression Scale.

**Criteria for Chittodvega:**

Term 'Chittodvega', basically means instability of mental (psychological) status. It can be either towards Anxiety- *Anavasthitachittatva* or towards Depression-*Manovasaada*. So, common symptoms from both conditions were sorted to finalize clinical symptoms. All these are listed as follows-

Table No. 5.1 Symptoms of Chittodvega- Psychological Distress

Sr. No.	Symptom
1	Restlessness, Anxious
2	Irritability
3	Difficulty in concentrating
4	Worthlessness
5	Crying spells
6	Fearfulness
7	Tingling & Numbness in limbs
8	Dryness of mouth
9	Dyspnea
10	Tachycardia
11	Sleep Disturbances
12	Easy Fatigability
13	Suicidal thoughts
14	Fainting
15	Increased frequency of passing Urine & Stools

All routine examinations like Blood Haemoglobin gm%, total leucocytes count, differential leucocytes count, Liver Function Tests, Renal Function Tests, CA15.3, CRP were carried out to exclude other pathology as well as to keep watch on Progression of Malignancy, if any. While diagnosing patients, careful examination regarding Status of TNBC, Conventional Treatment taken by patient, Ayurvedic Treatment taken and association of Psychological

stress as *Hetu*- cause of CA, *ManovahaSrotodushti* as Symptom and/or consequence of cancer.

**Information Sheet and Consent Form:**

Detail information about the study was given to the patients verbally as well as through specially prepared Patient Information Sheet and a written informed consent of all patients, included in study, in the language best understand to them, was taken before including them in to the study. Both the forms were attached to the CRF herewith.

**Case Record Form (CRF):**

Record of all patients was documented and follow up was mentioned in specially designed case record form (enclosed in annexure)

**4) GROUPING-**

**Sample size:**

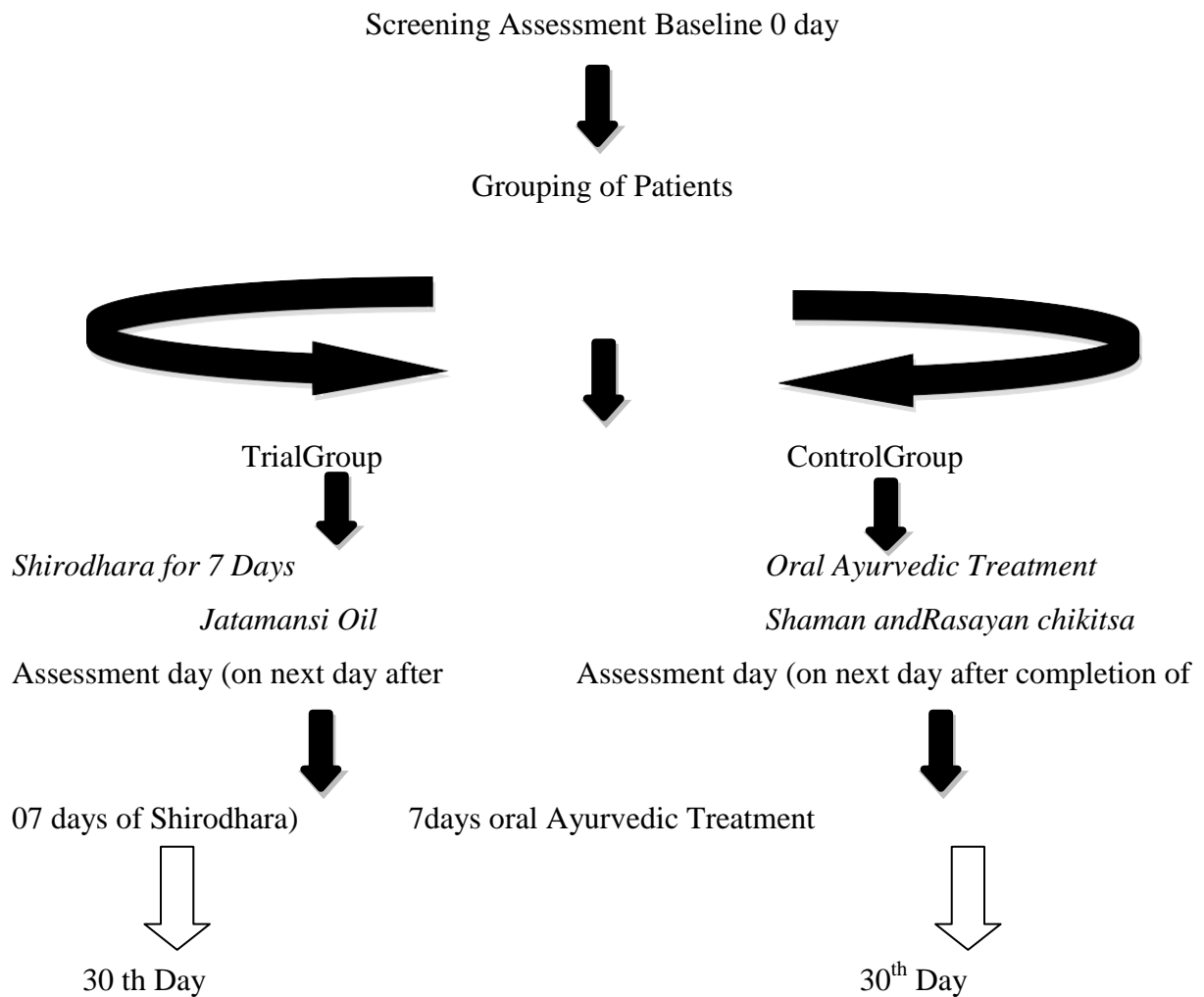
Sample size was calculated as per standard equation and formula.

All patients were divided into two groups called as Trial Group and Control Group with due consideration of matching criteria like Age, Grade and Stage of Cancer, duration of Ayurvedic treatment and other.

Table No. 5.2- Treatment and time point assessment of Trial group and Control Group

<b>Trial Group</b>	<b>Control Group</b>
0 Day assessment (Before treatment)onadmission day	0Dayassessment(Beforetreatment)onadmission day
<i>Shirodhara for 7 days</i>	<i>Ayurvedic Shaman chikitsa for 7 days</i>
Oral Ayurvedic treatment for Shaman and Rasayan chikitsa; continued.	Oral Ayurvedic treatment for Shaman and Rasayan chikitsa; continued.
Assessment after completionoftreatment. Follow up study after 30days	Assessment after completion of Ayurvedic treatment. Follow up study after 30days

## Treatment flow chart (Study Design)



### 5) SHIRODHARA PROCEDURE:

*Jatamansi Siddha* oil was administered through *Shirodhara* procedure.

Quantity – Approximate 500ml

Time of administration- Morning

Duration of Therapy- Approximately 20-30 minutes

*Shirodhara* is one of the allied therapies of *Panchkarma*. It is a titillating form of *Snehana* treatment. Here, *Jatamansi siddha* oil was methodically dripped along a course thread onto the forehead. A metal vessel, the *Dhara Patra*, was suspended directly above the forehead. This treatment involves pouring a stream of oil over patient's forehead. The oil was poured into the pot, and then seeped through a hole in the bottom of the pot and allowed to slide down a 4- inch long thread. The drops of oil from the thread drips directly onto the patient's center of the forehead. Procedure was continued for 20-30 minutes. Approximately 400-500

ml of lukewarm oil was required. This procedure was continued till 7 days. After procedure, patient was advised to avoid contact with cold air, breeze, cold atmosphere, dampness.

**6) FOLLOW UP –**

7<sup>th</sup> day, 30<sup>th</sup> day

**7) CRITERIA FOR ASSESSMENT-**

The assessment of result was based on subjective and clinical improvement which includes the observation of the patient and assessment of physician during the trial.

The criteria for assessment were as follows:

1. ClinicalParameters.
2. Zung’s Anxiety Scale
3. Zung’s Depression Scale
4. QLQ C30 Scale.
5. QLQ BR23 Scale.
6. Karnofsky Scale

**1) Clinical Parameters:**

The symptoms were assessed by adapting suitable method and objective assessment was done by using standard scales for Anxiety and Depression and QLQ Scales. The details are as follows.

Table No. 5.3 SYMPTOM SCORE AND GRADING

SR. NO.	SYMPTOM	GRADE	DESCRIPTION
1	Restlessness, Anxious	0	Absent
		1	Rarely, once in a week
		2	Frequently (2-3 times a week)
		3	Daily
		4	Almost all the time
2	Irritability	0	Absent
		1	Rarely, once in a week as response to stimulus

		2	Frequently ( 2-3 times a week)
		3	Daily
		4	Almost all the time; without stimulus
3	Difficulty in concentrating	0	No
		1	Occasionally
		2	Frequently
		3	In majority of activities
		4	Almost all the time in every task
4	Worthlessness	0	Absent
		1	Rarely, once in a while
		2	Frequently ( once a week)
		3	Daily
		4	All the time
5	Crying spells	0	No
		1	Once a week
		2	2-3 times a week
		3	Daily
		4	2-3 times a day
6	Fearfulness	0	Absent
		1	Rarely
		2	Frequently ( once a week)
		3	Two or more times a week
		4	Daily
7	Tingling & Numbness in limbs	0	No
		1	Very Rarely
		2	Once a week
		3	2-3 times a week
		4	Daily
8	Dryness of mouth	0	No
		1	Mild



		2	Moderate, relieved with liquids
		3	Severe, partially relieved with liquids
		4	Not relieved with liquids also
9	Dyspnoea	0	No
		1	For more than 5 minutes &After Moderate physical activity
		2	For more than 5 minutes &After Mild physical activity
		3	For more than 5 minutes without physical activity
		4	For more than 5 minutes & repeated Sighing
10	Tachycardia	0	Absent
		1	85-90/ min
		2	91-95/min
		3	96-100/ min
		4	More than 100/ min
11	Sleep Disturbances	0	No
		1	Once a week
		2	2-3 times a week
		3	Daily
		4	Difficult to get sleep and continue sleep for continuous 2-3 hours
12	Easy Fatiguability	0	Absent
		1	Mild
		2	Moderate
		3	Severe
		4	Continuous sensation of Tiredness
13	Suicidal thoughts	0	Absent
		1	Only once
		2	More than once
		3	Repeatedly
		4	Thoughts and attempt also

14	Fainting	0	No
		1	Once in a while
		2	2-3 times a week
		3	Daily
		4	Multiple episodes with injury
15	Increased frequency of passing Urine & Stools	0	No
		1	Only with stressful stimulus
		2	Without stimulus
		3	Daily
		4	At night also

### Zung Self-Rating Depression Scale (SDS)

For each item below, please place a check mark (felt or behaved this way during the past several days).

Table No. 5.4 - Zung Self-Rating Depression Scale (SDS)

	A Little of the Time 1	Some of the Time 2	Good part of the Time 3	Most part of the Time 4
1. I Feel down hearted and blue.				
2. Morning is when I feel the best.				
3. I have crying spells or feel like it.				
4. I have trouble sleeping at night.				
5. I eat as much as I used to.				
6. I still enjoy sex.				
7. I notice that I am losing weight.				
8. I have trouble with constipation.				
9. My heart beats faster than usual.				
10. I get tired for no reason.				
11. My mind is as clear as it used to be.				
12. I find it easy to do the things I used to.				
13. I am restless and can't keep still.				
14. I feel hopeful about the future.				
15. I am more irritable than usual.				
16. I find it easy to make decisions.				
17. I feel that I am useful and needed.				
18. My life is pretty full.				
19. I feel that others would be better off if I were dead.				
20. I still enjoy the things I used to do.				

The Zung Self-Rating Depression Scale was designed by Duke University psychiatrist William W.K. Zung MD (1929–1992) to assess the level of depression for patients diagnosed with depressive disorder.

- 20-44 Normal Range
- 45-59 Mildly Depressed
- 60-69 Moderately Depressed
- 70 and above Severely Depressed

ZUNG'S SELF RATING ANXIETY SCALE:

For each item below, please check the column which best describes how often you felt or behaved this way **during the past several days**.

Table No. 5.5 ZUNG'S SELF RATING ANXIETY SCALE

	None or a Little of the Time 1	Some of the Time 2	Good part of the Time 3	Most or all of the Time 4
1. I feel more nervous and anxious than usual.				
2. I feel afraid for no reason at all.				
3. I get upset easily or feel panicky.				
4. I feel like I am falling apart and going to piece.				
5. I feel that everything is all right and nothing bad will happen.				
6. My arms and legs shake and tremble.				
7. I am bothered by headaches, neck and back pains.				
8. I feel weak and get tired easily				
9. I feel calm and can sit still easily.				
10. I can feel my heart beating fast.				
11. I am bothered by dizzy spells.				
12. I have fainting spells or feet faint.				
13. I can breathe in and out easily.				
14. I get feelings of numbness and tingling in my fingers and toes.				
15. I am bothered by stomachaches or indigestion.				
16. I have to empty my bladder often.				
17. My hands are usually dry and warm.				
18. My face gets hot and blushes.				
19. I fall asleep easily and get a good night's rest.				
20. I have nightmares.				

**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):

Table No. 5.6 **EORTC QLQ-C30 (version 3)**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?				
2	Do you have any trouble taking a long walk?				
3	Do you have any trouble taking a short walk outside of the house?				
4	Do you need to stay in bed or a chair during the day?				
5	Do you need help with eating, dressing, washing yourself or using a toilet?				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
6	Were you limited in doing either your work or other daily activities?				
7	Were you limited in pursuing your hobbies or other leisure time activities?				
8	Were you short of breath?				

9	Have you had pain?				
10	Did you need to rest?				
11	Have you had trouble sleeping?				
12	Have you felt weak?				
13	Have you lacked appetite?				
14	Have you felt nauseated?				
15	Have you vomited?				
16	Have you been constipated?				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
17	Have you had diarrhea?				
18	Were you tired?				
19	Did pain interfere with your daily activities?				
20	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?				
21	Did you feel tense?				
22	Did you worry?				
23	Did you feel irritable?				
24	Did you feel depressed?				
25	Have you had difficulty remembering things?				
26	Has your physical condition or medical treatment interfered with your family life?				
27	Has your physical condition or medical treatment interfered with your social activities?				
28	Has your physical condition or medical treatment caused you financial difficulties?				



<b>41</b>	Did you find it difficult to look at yourself naked?				
<b>42</b>	Have you been dissatisfied with your body?				
<b>43</b>	Were you worried about your health in the future?				

**During the past four weeks:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
<b>44</b>	To what extent were you interested in sex?				
<b>45</b>	45. To what extent were you sexually active? (with or without intercourse)				
<b>46</b>	Answer this question only if you have been sexually active: To what extent was sex enjoyable for you				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
<b>47</b>	Did you have any pain in your arm or shoulder?				
<b>48</b>	Did you have a swollen arm or hand?				
<b>49</b>	Was it difficult to raise your arm or to move it sideways?				
<b>50</b>	Have you had any pain in the area of your affected breast? Was the area of your affected breast swollen?				
<b>51</b>	Was the area of your affected breast oversensitive?				
<b>52</b>	Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?				



## KARNOFSKY SCALE

The Karnofsky Performance Scale Index allows patients to be classified as to their functional impairment. This can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses.

Table No. 5.8 KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS

### RATING (%) CRITERIA

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

### 3) WITHDRAWAL CRITERIA:

- Any untoward symptoms seen in patients.
- Any adverse drug reaction seen in patients.

if subject herself wants to withdraw from the study, such subjects will be withdrawn from the study.

### 4) OVERALL ASSESSMENT CRITERIA:

Effect of therapy was assessed as below:

Table No. 5.9 Overall Assessment Criteria

1	Complete Cured	100 % relief from signs and symptoms
2	Marked improvement	76 to 99 % relief from signs and symptoms
3	Moderate improvement	51 to 75 % relief from signs and symptoms
4	Slight improvement	26 to 50% relief from signs and symptoms
5	No improvement	Up to 25% relief from signs and symptoms.

**5) Plan for Statistical Analysis:**

The study data generated and collected was put to statistical analysis to reach to the final results and conclusions. The demographic data were presented in tables and graphs. The data obtained in the studies were subjected to tests of significance.

Chi Square Test and Paired T tests are used for statistical analysis of data.

- **For Subjective parameters:**
- **For Objective parameters:**
- p value < 0.05 was considered significant.
- **Overall assessment of therapy:** Chi-Square Test was applied (Discrete data – Counted facts). p value < 0.05 was considered significant.

## 4. ANALYSIS AND INTERPRETATION

### OBSERVATION AND RESULTS

Total 70 TNBC patients were registered in the clinical trial. Amongst them, 35 patients were treated with Shaman chikitsa along with Shirodhara with Jatamansi oil (Study group) whereas 35 patients were treated with only Shaman Chikitsa (Control group).

Collected data was thoroughly studied and following observations were made. After collection and study of data, this data was subjected to statistical analysis.

In Statistical study,

1. Chi-square Test is used for analysis of data related to Symptoms of Chittodvega
2. Unpaired t test was used for analysis of data related to scores of different scales

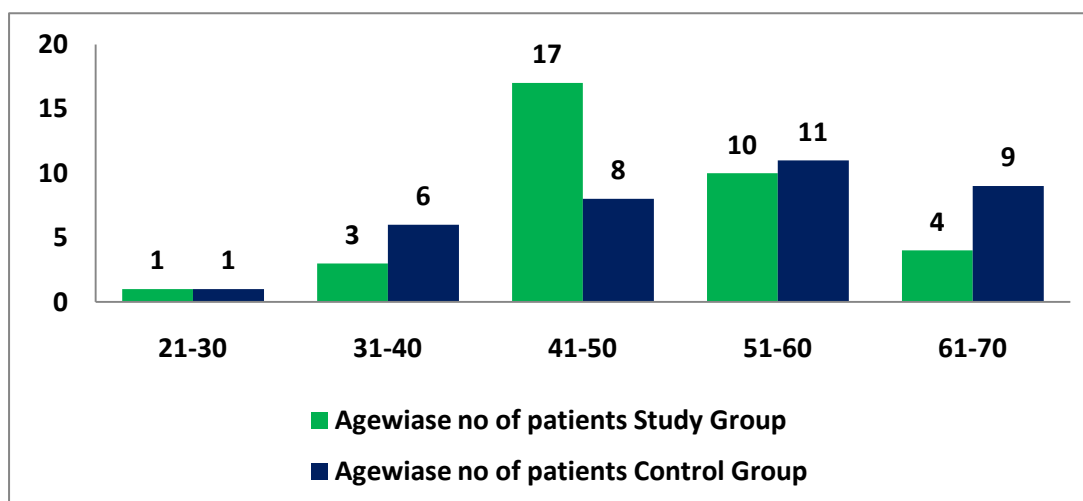
The demographic analysis of these patients is being presented hereafter. Individual group wise distribution is given in tables.

### AGE

Table No. 6.1: Showing Age wise Distribution of 70 patients of TNBC with Chittodvega.

Age Group in Yrs.	Study Group	%	Control Group	%
21-30	1	2.85	1	2.85
31-40	3	8.55	6	17.1
41-50	17	48.45	8	22.8
51-60	10	28.5	11	31.35
61-70	4	11.4	9	25.65
<b>Total no. of patients</b>	<b>35</b>	<b>100</b>	<b>35</b>	<b>100</b>

Graph No. 1 Showing Age wise Distribution of 70 patients of TNBC with Chittodvega.



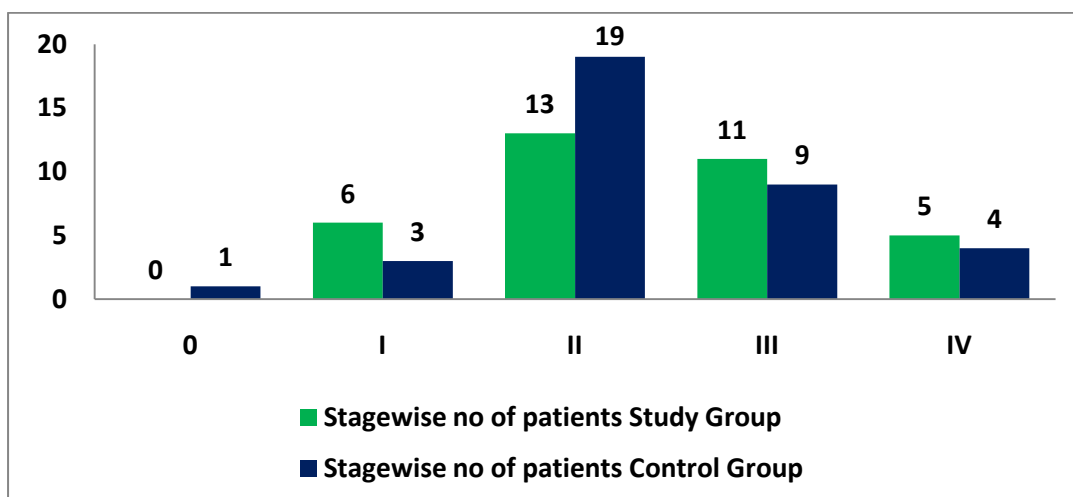
Out of 70 TNBC patients ; 1 patient (2.85%) in Study Group and 1(2.85%) patient in Control Group were in age group of 21-30 years. 3patients(8.55%)in Study group and6patients(17.1%)in Control Group were in age group 31-40 years, whereas 17patients(48.45%) in Study Group and 8patients(22.8%) in Control group were in age group 41-50 years, 10patients(28.5%) in Study Group and 11patients(31.35%) in Control Group were in age group 51-60 . Last age group of 61-70 years had 4patients(11.4%) in Study group and 9patients(25.65%) in control group.

## STAGE OF CANCER

Table No. 6.2 Showing stage-wise Distribution (with AJSC Classification.of 70patients of TNBC

Cancer Stage	Study Group	%	Control Group	%
<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2.85</b>
<b>I</b>	<b>6</b>	<b>17.1</b>	<b>3</b>	<b>8.55</b>
<b>II</b>	<b>13</b>	<b>37.05</b>	<b>19</b>	<b>54.15</b>
<b>III</b>	<b>11</b>	<b>31.35</b>	<b>9</b>	<b>25.65</b>
<b>IV</b>	<b>5</b>	<b>14.25</b>	<b>4</b>	<b>11.4</b>
<b>Total no. of patients</b>	<b>35</b>		<b>35</b>	

Graph No. 2 Showing stage-wise Distribution (with AJSC Classification.of 70patients of TNBC)



## STAGE OF CANCER

AJSC classification of staging was used to confirm stage of cancer of TNBC patients recruited in our clinical trial.

In our study, majority of patients i.e. 32/70 had stage II disease. Among them, 13patients(37.05 %) belong to study group and 19patients( 54.15%) belong to control group.

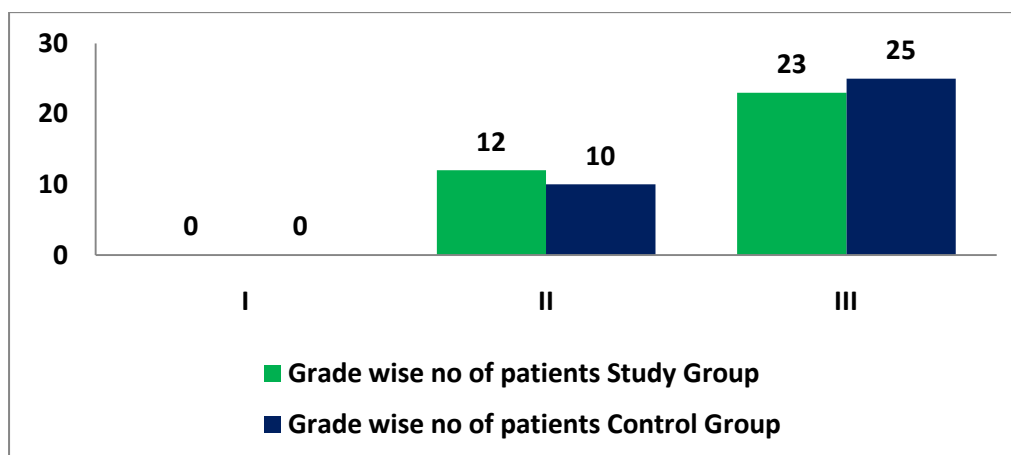
Total 20/70 patients had stage III cancer. 11 patients (31.35%) among them belong to study group, whereas 9 (25.65%) patients belong to control group. 5 patients (14.25%) from study group and 4 patients (11.4%) from control group had stage IV cancer. Total 9/70 TNBC patients had stage I disease. Among them 6 patients (17.1%) were from study group and 3 patients (8.55%) were from control group.

## GRADE OF CANCER

**Table No. 6.3 Showing Cancer Gradation of 70 patients in Clinical Trial**

Cancer Grade	Study Group	%	Control Group	%
I	0	0	0	0
II	12	34.2	10	28.5
III	23	65.55	25	71.25
<b>Total no. of patients</b>	<b>35</b>		<b>35</b>	

**Graph No. 3 Showing Cancer Gradation of 70 patients in Clinical Trial**



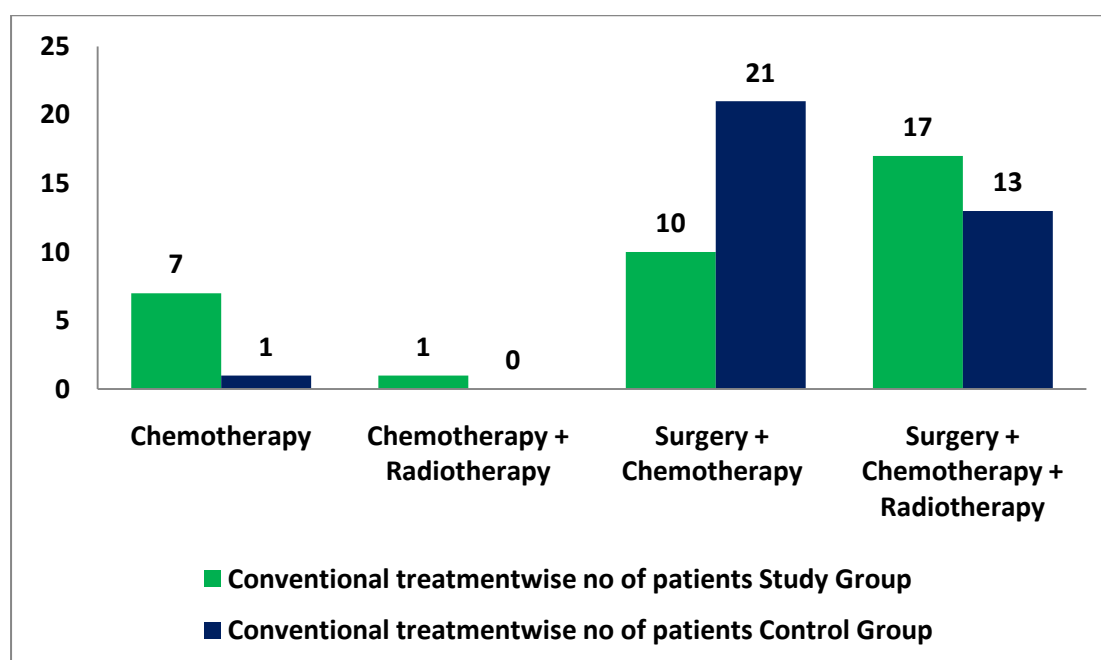
Total 22 patients had Grade II cancer. 12 patients (34.2%) among them belong to study group, whereas 10 patients (28.5%) belong to control group. 23 patients (65.55%) from study group and 25 patients (71.25%) from control group had Grade III cancer. Total 48/70 patients had Grade III cancer.

## CONVENTIONAL THERAPY

Table No. 6.4 Showing patient data according to conventional treatment received.

Conventional Treatment	Study Group	%	Control Group	%
Chemotherapy	7	19.95	1	2.85
Chemotherapy + Radiotherapy	1	2.85	0	0
Surgery + Chemotherapy	10	28.5	21	59.85
Surgery + Chemotherapy + Radiotherapy	17	48.45	13	37.05
<b>Total no. of patients</b>	<b>35</b>		<b>35</b>	

Graph No. 4 Showing patient data according to conventional treatment received.



Observation –

In this clinical trial; out of 35 patients in Study group; 7 patients (19.95%) received Chemotherapy alone and out of 35 patients in control group 1 patient (2.85%) in control group received chemotherapy alone.

1 patient (2.85%) in study group received a combination of Chemotherapy and Radiotherapy, and there was no patient in control group received a combination of chemotherapy and radiotherapy.

In study group 10 patients (28.5%) received a combination of surgery and chemotherapy as conventional treatment and in control group 21 patients (59.85%) underwent combination of surgery and chemotherapy.

17 patients (48.45%) in study group received a combination of surgery, chemotherapy and radiotherapy and 13 patients (37.05%) in control group received a combination of surgery, chemotherapy and radiotherapy.

## **KARNOFSKY SCALE**

Karnofsky performance score is used to assess well-being of patients. It is also used to assess response to treatment.

Score 0 is indicative of Moribund status of patient, whereas score 100 is indicative of complete healthy status of patient.

We measured Karnofsky score of study & control at 3 time points i.e. time point -A - beginning of study / before administration of Shirodhara in study group, time point-B- on 7<sup>th</sup> day after enrolment in study/ last day of Shirodhara & time point 'C' is 30<sup>th</sup> Day after enrolment in study.

Analysis of Karnofsky score was done at time point B& C with reference to Karnofsky score at time point 'A' considering following factors.

1. No. of patients whose Karnofsky score was increased at time point B & C as compared to time point A.
2. No. of patients whose Karnofsky Score was stable at time point B& C as compared to time point A.
3. No. of patients whose Karnofsky Score was decreased at time point B& C as compared to time point A.

Table No. 6.5 (A) showing assessment as per Karnofsky score at time points B and C

	<b>KARNOFSKY SCORE</b>	
	<b>B</b>	<b>C</b>
Study	90.3	93.7
Control	82.9	88.3
SD Study	7.1	6.5
SD Control	6.7	6.2
p Value	<0.0001	0.0006

Graph No. 5- Showing assessment as per Karnofsky score at time points B and C

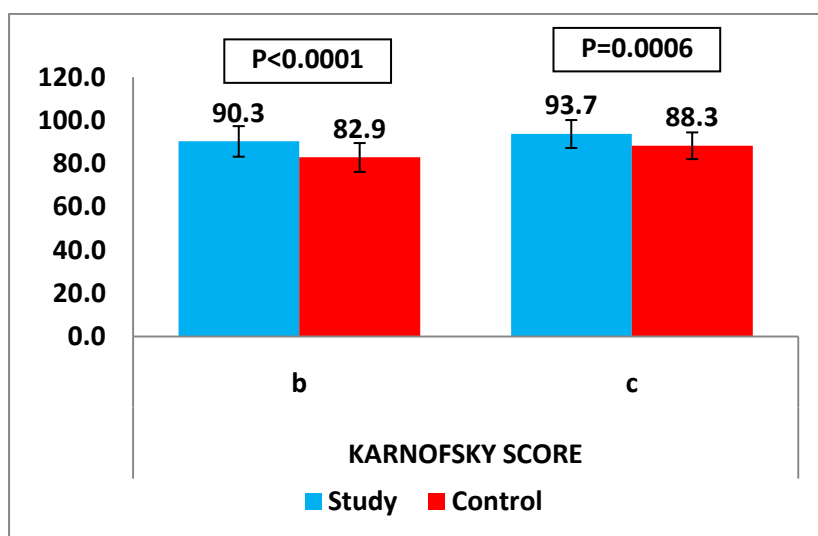


Table No. 6.5 (B) Showing assessment as per Karnofsky score at time points B and C

Karnofsky score	At b time-point		At c time-point	
	Study Group	Control Group	Study Group	Control Group
Karnofsky score increased	14 (39.9%)	14(39.9)	20(57%)	30(85.5%)
Karnofsky score stable	21(59.85%)	21(59.85)	10(28.5%)	5(14.25%)
Karnofsky score decreased	0	0	0	0

### Observations :

It was observed that Karnofsky Score was not decreased in any patient of study group as well as control group; at both time points ( B & C)

Stable & increased Karnofsky Score was observed in equal no. of. patients in study & control groups 21( 59.85%) and 14 (39.9%) respectively at time point 'B'.

At time point C – 10patients(28.5%)from study group presented with stable Karnofsky Score whereas 5patients(14.25%) from control group were presented with stable Karnofsky Score.

20 patients(57%) from study group& 30 patients(85.5%) from control group were presented with increased Karnofsky score at time point 'C'.

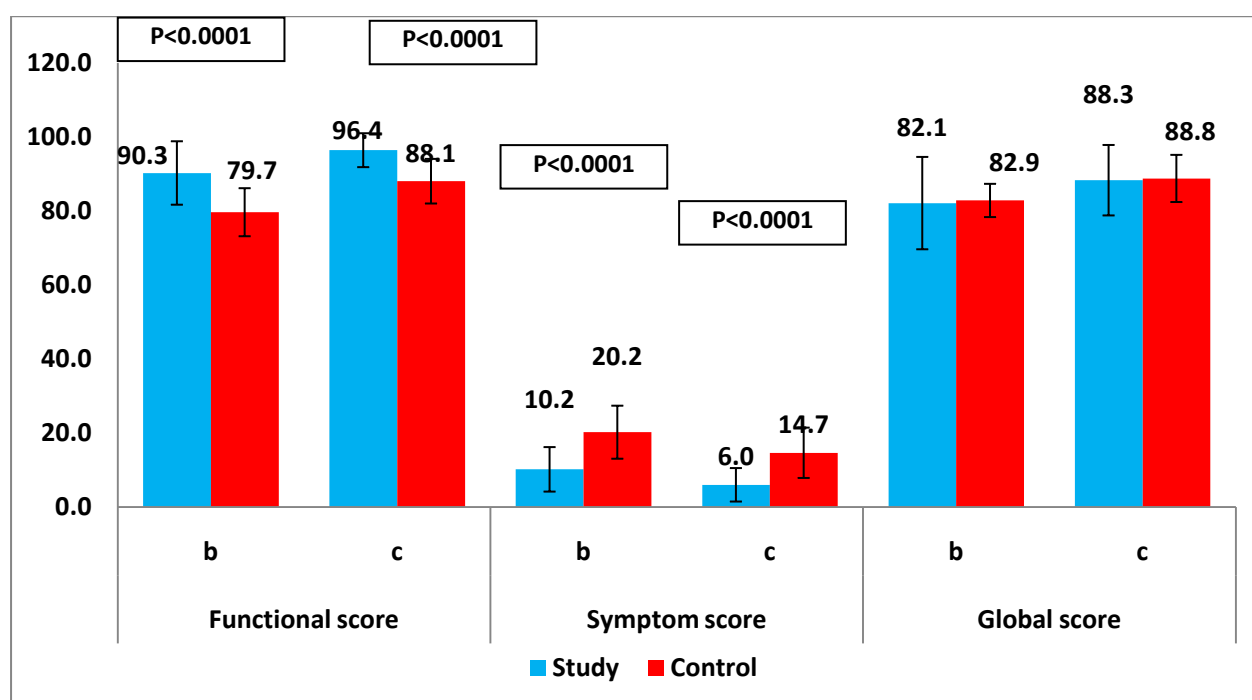


## QLQ C30

Table No. 6.6 Showing mean of Functional Score of QLQ C30 -

	Functional score		Symptom score		Global score	
	B	C	B	C	B	c
Study	90.3	96.4	10.2	6.0	82.1	88.3
Control	79.7	88.1	20.2	14.7	82.9	88.8
SD Study	8.6	4.6	6.0	4.5	12.5	9.5
SD Control	6.5	6.0	7.2	6.8	4.5	6.4
p Value	<0.0001	<0.0001	<0.0001	<0.0001	0.7511	0.8065

Graph No. 6- QLQ C30 Functional Score



### Observation

QLQ C 30 is questionnaire of 30 Questions designed by EORTC for measuring Quality of Life of Cancer patients. Scores of 30 Questions are divided into Functional Score, Symptom Score & Global Score. Functional Score indicates functions / day to day activities whereas Global Score indicates General well-being of the patient.

Symptom Score is an assessment of common symptoms observed in Cancer patients.

Extremely significant results ( $P < 0.001$ ) are obtained for Functional Score & Symptom Score at both time points i.e. B & C.

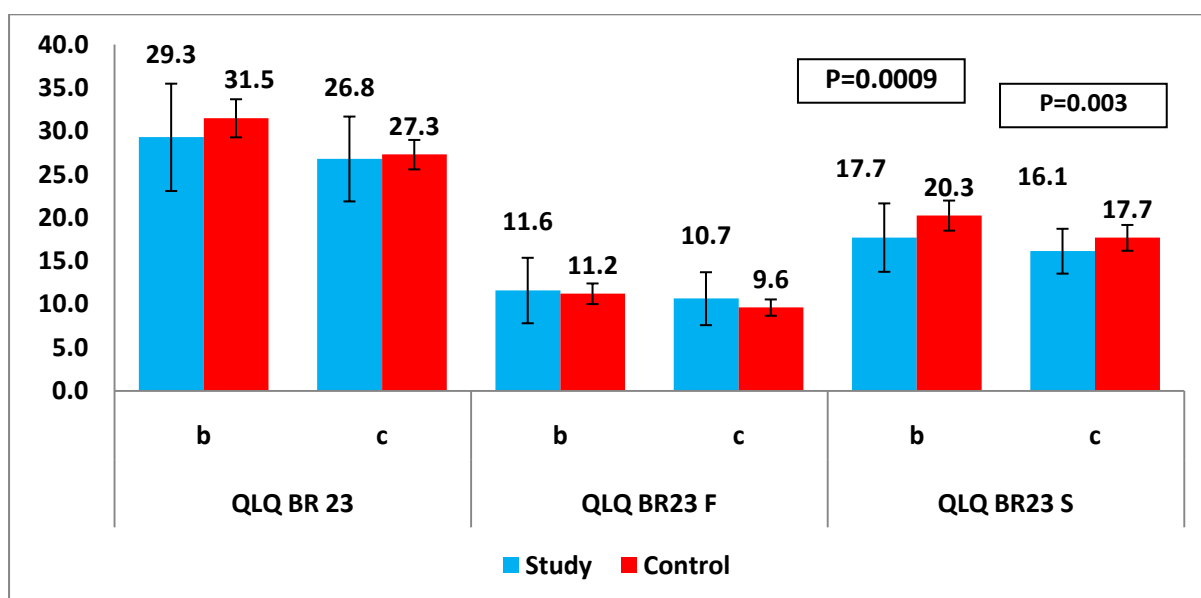
No Significant change in Global Score is obtained at both time points i.e. B & C.

## QLQ BR 23

**Table No. 6.7 Showing mean scores of QLQ BR23 Scale**

	QLQ BR 23		QLQ BR23 F		QLQ BR23 S	
	b	C	b	C	B	C
Study	29.3	26.8	11.6	10.7	17.7	16.1
Control	31.5	27.3	11.2	9.6	20.3	17.7
SD Study	6.2	4.9	3.8	3.1	4.0	2.6
SD Control	2.2	1.7	1.2	0.9	1.7	1.5
p Value	0.0735	0.5608	0.5813	0.0614	0.0009	0.0032

**Graph No. 7 Showing scores of QLQ BR23 Scale**



### Observation

QLQ BR 23 of EORTC is a Questionnaire used for assessing Quality of life & disease status in breast Cancer patients.

QLQ BR 23 is divided into 2 categories namely- FS- Functional Score and SS-Symptom Score.

In our study , extremely significant ( $p = 0.0009$ ) & very significant ( $p = 0.003$ ) results are obtained at time points B& C in Symptom Score of BR 23. No significant difference was observed in study & control group at both time points ( B & C ) in QLQ BR23 Total Score and QLQ BR23 Functional Score.

## OBSERVATIONS ABOUT SYMPTOMS OF CHITTODVEGA

Incidence of breast cancer is raising world-wide. Various risk factors like nuliparity, early menarch, late menopause, genetic predisposition, sedentary lifestyle, consumption of Red Meat, oily food and addiction are associated with breast cancer. According to data of epidemiological study of breast cancer patients recruited in Integrated Cancer Treatment & Research Center Wagholi, Pune, mental stress is found to be evident risk factor in breast cancer patients. Moreover, it is observed as a common risk factor in TNBC patients. Mental stress is responsible for psychological symptoms which are mainly expressed in the form of depression and anxiety. Therefore signs and symptoms of depression and anxiety and depression and anxiety scales are chosen as criteria for evaluating efficiency of Jatamansi oil shirodhara on chittodvega.

### Observation regarding

1. Restlessness, Anxious feel
2. Irritability
3. Difficulty in concentration

Graph No. 8- Showing effect on Restlessness - Anxious feel, Irritability and Difficulty in concentration.

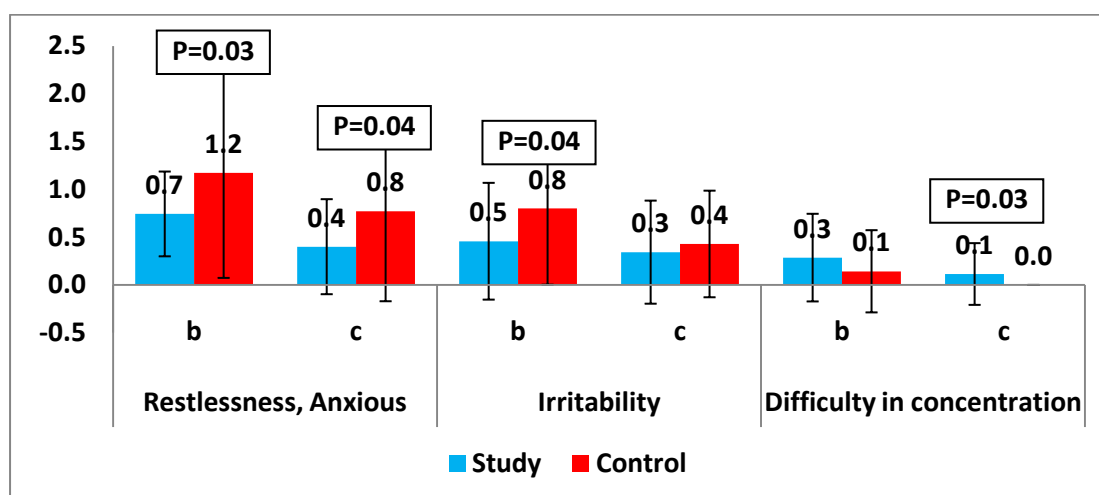


Table showing Efficacy of Jatamansi oil Shirodhara on Restlessness

## RESTLESSNESS

Table No. 6.8 showing Efficacy of Jatamansi oil Shirodhra on Restlessness.

	<b>Restlessness, Anxious feel</b>	
	<b>b</b>	<b>C</b>
Study	0.7	0.4
Control	1.2	0.8
SD Study	0.4	0.5
SD Control	1.1	0.9
p Value	0.0358	0.0429

### Observation

Efficacy of Jatamansi oil Shirodhra on Restlessness is significant at Time point B & C in study group. (p= 0.03)

## **IRRITABILITY :-**

Table No. 6.9 showing Efficacy of Jatamansi oil Shirodhra on Irritability.

	<b>Irritability</b>	
	<b>B</b>	<b>C</b>
Study	0.5	0.3
Control	0.8	0.4
SD Study	0.6	0.5
SD Control	0.8	0.6
p Value	0.0473	0.5155

### Observation-

Efficacy of Jatamansi oil Shirodhra on Irritability is significant at Time point B & C in study group. (p= 0.04).

## **Difficulty in concentration:**

Table No. 6.10 showing Efficacy of Jatamansi oil Shirodhra on Difficulty in concentration

**Observation-**

	Difficulty in concentration	
	B	C
Study	0.3	0.1
Control	0.1	0.0
SD Study	0.5	0.3
SD Control	0.4	0.0
p Value	0.1832	0.0399

Significant improvement in difficulty in concentration was obtained in study group patients at time point 'C' (P=0.03)

**Observation about**

- 2. Worthlessness
- 3. Crying spells and
- 4. Fearfulness

Graph No. 9- Showing effect on Worthlessness, Crying spells and Fearfulness.

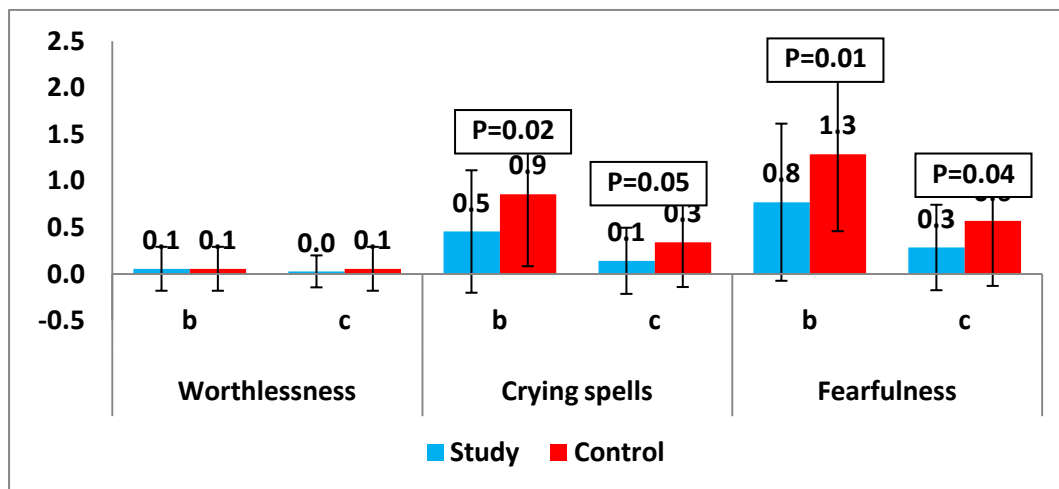


Table no. 6.11 showing Efficacy of Jatamansi oil Shirodhra on Worthlessness.

**Worthlessness-**

	Worthlessness	
	B	C
Study	0.1	0.0
Control	0.1	0.1
SD Study	0.2	0.2
SD Control	0.2	0.2
p Value	1.0000	0.5789

### Observation-

In our study, no significant result was observed in both groups i.e. study & control; at both time points B & C.

### Crying spells

Table No. 6.12 showing Efficacy of Jatamansi oil Shirodhra on Crying spells.

### Observation-

	Crying spells	
	B	C
Study	0.5	0.1
Control	0.9	0.3
SD Study	0.7	0.4
SD Control	0.8	0.5
p Value	0.0226	0.0520

Significant results ( $p=0.02$ ,  $p=0.05$  at time point B and C respectively) on crying spells were obtained with Jatamansi oil Shirodhara at both time point B & C in study group respectively.

### Fearfulness :

Table No. 13 showing Efficacy of Jatamansi oil Shirodhra on fearfulness.

	Fearfulness	
	b	C
Study	0.8	0.3
Control	1.3	0.6
SD Study	0.8	0.5
SD Control	0.8	0.7
p Value	0.0121	0.0469

### Observation-

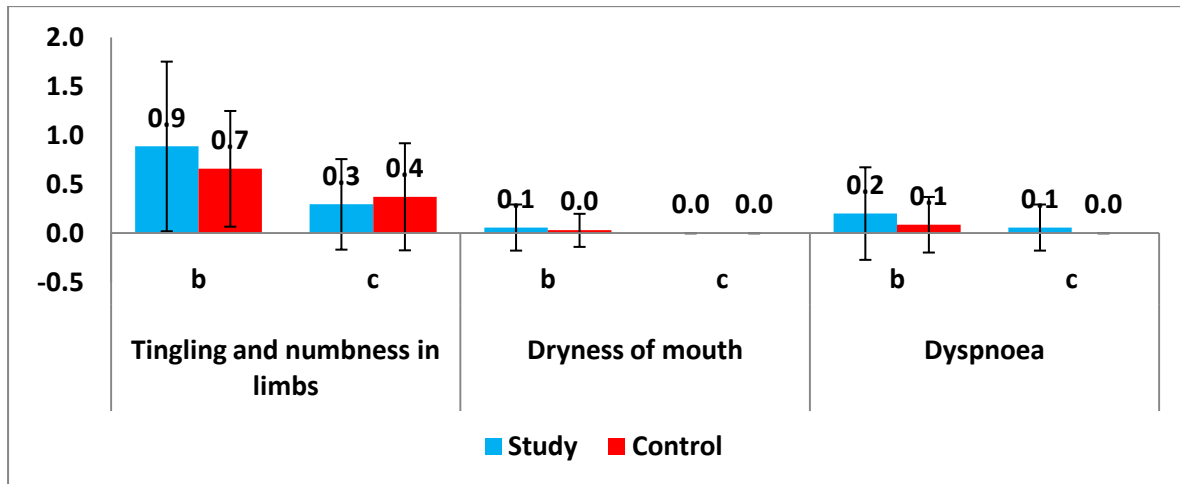
Efficacy of Jatamansi oil shirodhara is found to be significant in relieving fearfulness at both time points “B & C” in study group patients.

Significant results ( $p=0.01$ ,  $p=0.04$  at time points B and C respectively)

## Observation on

5. **Tingling and numbness in limbs**
6. **dryness of mouth and**
7. **Dyspnoea.**

Graph No. 10 Showing effect on Tingling and numbness in limbs, Dryness of mouth and Dyspnoea.



## Tingling & Numbness –

Table No. 6.14 showing Efficacy of Jatamansi oil Shirodhra on Tingling and Numbness in limbs.

	Tingling and numbness in limbs	
	b	C
Study	0.9	0.3
Control	0.7	0.4
SD Study	0.9	0.5
SD Control	0.6	0.5
p Value	0.2018	0.5288

## Observation-

In our study, significant results are not observed in study group patients at both time points B and C.

## Dryness of Mouth

Table No. 6.15 showing Efficacy of Jatamansi oil Shirodhra on Dryness of mouth.

	Dryness of mouth	
	B	C
Study	0.1	0.0
Control	0.0	0.0
SD Study	0.2	0.0
SD Control	0.2	0.0
p Value	0.5618	

### Observation -

In our study, significant results are not obtained in study group at both time points 'B' & 'C'. Still it can be stated that Shirodhara with Jatamansi oil may not give significant results in reducing dryness of mouth in 7 days but, it may relieve this symptom if administered for longer duration of 14 to 21 days or more. Further, dryness of mouth is exacerbated in GAD patients. So, need of Shirodhara course for longer duration is again emphasized as Dohsabala & Vyadibalais Uttam.

## Dyspnoea

Table No. 6.16 showing Efficacy of Jatamansi oil Shirodhra on Dyspnoea

	Dyspnoea	
	B	C
Study	0.2	0.1
Control	0.1	0.0
SD Study	0.5	0.2
SD Control	0.3	0.0
p Value	0.2245	0.1557



In our study, significant results are not obtained in study groups at both time points B & C. The above symptom is found in advanced stages of Anxiety. Thus longer duration or lengthy course of Shirodhara may be required for relief from Dyspnoea.

**Observation on**

**8. Tachycardia,**

**9. Sleep disturbances**

**10. Easy fatigability**

**Graph No. 11-** Showing effect on Tachycardia, sleep disturbances and Easy fatigability

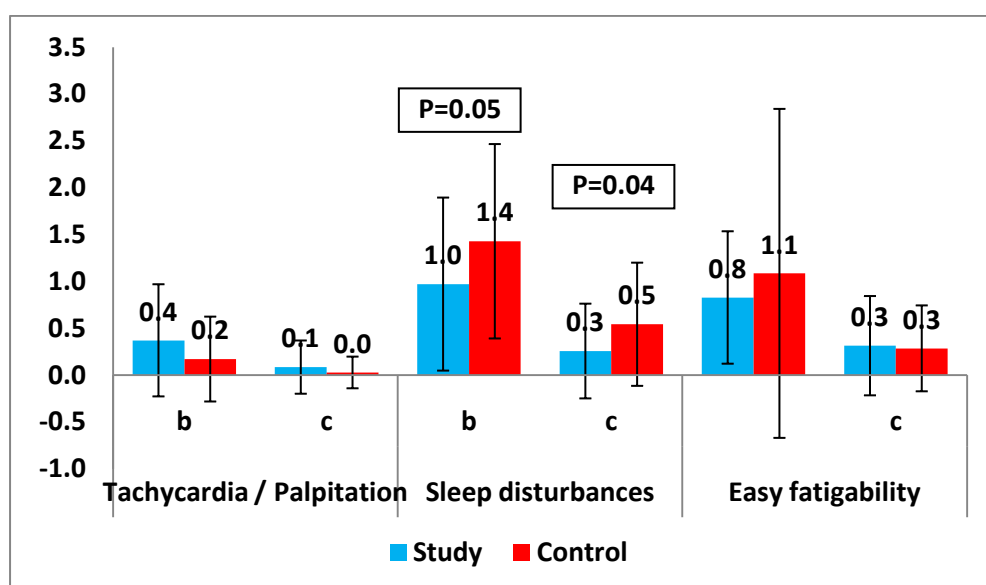


Table No. 6.17 showing Efficacy of Jatamansi oil Shirodhra on Tachycardia.

	Tachycardia / Palpitation	
	B	C
Study	0.4	0.1
Control	0.2	0.0
SD Study	0.6	0.3
SD Control	0.5	0.2
p Value	0.1195	0.3100

## **Tachycardia–**

In our study, no significant result is seen on this symptom at both time points 'B' & 'C' but long term use of Jatamansi oil shirodhara will prove to be fruitful to correct / regulate rhythm of heart.

## **Sleep Disturbance**

Table no. 6.18 showing Efficacy of Jatamansi oil Shirodhra on Sleep Disturbance.

	<b>Sleep disturbance</b>	
	<b>B</b>	<b>C</b>
Study	1.0	0.3
Control	1.4	0.5
SD Study	0.9	0.5
SD Control	1.0	0.7
p Value	0.0556	0.0454

### **Observations on Sleep disturbance (Insomnia)**

Sleep disturbances and Insomnia was observed in majority of patients in our study in both Study and Control group. With Shirodhara treatment, Quality and period of undisturbed sleep was found to be improved significantly. Shirodhara showed quick effect and so improvement was significant at time point 'b'. Similarly, Shirodhara showed significant long lasting results for improving sleep in TNBC patients in our study.

## **Easy fatigability–**

### **Observation-**

In our study, significant results are not observed in study group patients at both time points B and C.

## Observation on

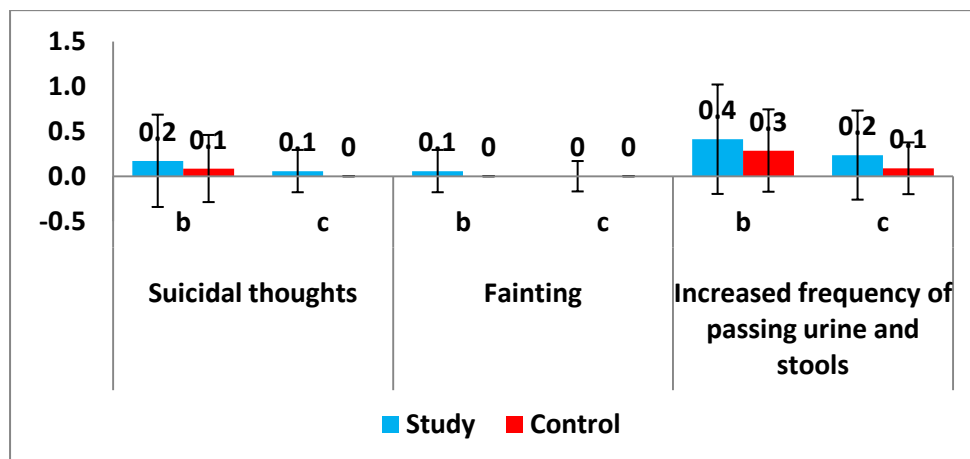
**11.Suicidal thoughts,**

**12.Fainting**

**13.Increased frequency of passing urine and stools**

Graph No. 12 Showing effect on Suicidal thoughts, Fainting and increased frequency of passing urine and stools.

Significant improvement was observed in study group patients at time point B & C.



## Suicidal Thoughts

Table No. 6.19 showing Efficacy of Jatamansi oil Shirodhra on Suicidal thoughts.

	Suicidal thoughts	
	B	C
Study	0.2	0.1
Control	0.1	0
SD Study	0.5	0.2
SD Control	0.4	0.0
p Value	0.4274	0.1618

## Observation

In our study, no significant result is seen on this symptom of depression at both time points B & C.

## Fainting

Table No. 6.20 showing Efficacy of Jatamansi oil Shirodhra on Fainting.

	<b>Fainting</b>	
	<b>B</b>	<b>C</b>
Study	0.1	0
Control	0	0
SD Study	0.2	0.2
SD Control	0.0	0.0
p Value	0.1557	0.3209

### Observation

In our study, no significant result is seen on fainting at both time points b & C. It may be attributed to acute nature of symptom that demands for emergency & immediate intervention.

## Increased frequency at Urine & Stool.

Table No. 6.21 showing Efficacy of Jatamansi oil Shirodhra on increased frequency at Urine & Stool.

	<b>Increased frequency of passing urine and stools</b>	
	<b>B</b>	<b>C</b>
Study	0.4	0.2
Control	0.3	0.1
SD Study	0.6	0.5
SD Control	0.5	0.3
p Value	0.3339	0.1396

### Observation

In our study, no significant result is obtained on this symptom at both time points B and C.

## **ZUNG'S SELF ASSESSMENT SCALES FOR ANXIETY AND DEPRESSION**

The **Zung Self-Rating Depression Scale** was designed by Duke University psychiatrist William W.K. Zung MD (1929–1992) to assess the level of depression for patients diagnosed with depressive disorder.

The Zung Self-Rating Depression Scale is a 20-item self-report questionnaire that is widely used as a screening tool, covering affective, psychological and somatic symptoms associated with depression. The questionnaire takes about 10 minutes to complete, and items are framed in terms of positive and negative statements. It can be effectively used in a variety of settings, including primary care, psychiatric, drug trials and various research situations. Each item is scored on a Likert scale ranging from 1 to 4. A total score is derived by summing the individual item scores, and ranges from 20 to 80. Most people with depression score between 50 and 69, while a score of 70 and above indicates severe depression. The scores provide indicative ranges for depression severity that can be useful for clinical and research purposes. The Zung scale also provides a simple tool for monitoring changes in depression severity over time in research studies.

The rating scale is scored from 1 to 4 points. Most answers go in order of 1 (a little of the time) to 4 (most of the time). However, questions 2,5,6,11,12,14,16,17,18 and 20 are scored in the opposite order, since they represent positive/non-depression statements.

- 20-44 Normal Range
- 45-59 Mildly Depressed
- 60-69 Moderately Depressed
- 70 and above Severely Depressed

Table

Observations on Zung's self-rating Anxiety and Depression Scales in our study

	<b>ZUNG'S SELF RATING ANXIETY SCALE</b>		<b>ZUNG'S SELF RATING DEPRESSION SCALE</b>	
	<b>B</b>	<b>c</b>	<b>B</b>	<b>c</b>
Study	35.5	34.3	34.7	33.1
Control	40.1	34.0	39.3	34.6
SD Study	11.4	10.3	11.6	10.5
SD Control	8.4	8.0	7.2	7.8
p Value	0.0587	0.8873	0.0471	0.4948

Scores of Zung's scales for evaluation of effect on Anxiety and Depression are shown in above table. Shirodhara has shown significant results in improving Anxiety and Depression in TNBC patients in our study.

### **Zung Depression scale**

#### **Reference**

[http://www.mentalhealthministries.net/resources/flyers/zung\\_scale/zung\\_scale.pdf](http://www.mentalhealthministries.net/resources/flyers/zung_scale/zung_scale.pdf)

<https://psychology-tools.com/test/zung-depression-scale>

[https://en.wikipedia.org/wiki/Zung\\_Self-Rating\\_Depression\\_Scale](https://en.wikipedia.org/wiki/Zung_Self-Rating_Depression_Scale)

Table No. 6.22 Showing assessment of treatment by Zung's Depression Scale

Zung Depression scale	At b time-point		At c time-point	
	Study Group	Control Group	Study Group	Control Group
Normal Range	24 (68.4%)	25(71.25%)	29(82.65%)	30(85.5%)
Mildly Depressed	11(31.35%)	10(28.5%)	6(17.1%)	5(14.25%)
Moderately Depressed	0	0	0	0
Severely Depressed	0	0	0	0

### **Zung Anxiety scale**

The **Zung Self-Rating Anxiety Scale (SAS)** was designed by William W. K. Zung M.D, (1929-1992) a professor of Psychiatry from Duke University, to quantify a patient's level of anxiety.

The SAS is a 20-item self-report assessment device built to measure anxiety levels, based on scoring in 4 groups of manifestations: cognitive, autonomic, motor and central nervous system symptoms. Answering the statements a person should indicate how much each statement applies to him or her within a period of one or two weeks prior to taking the test. Each question is scored on a Likert-type scale of 1-4 (based on these replies: "a little of the time," "some of the time," "good part of the time," "most of the time"). Some questions are negatively worded to avoid the problem of set response. Overall assessment is done by total score.

The rating scale is scored from 1 to 4 points. Most answers go in order of 1 (a little of the time) to 4 (most of the time). However, questions 5, 9, 13, 17, and 19 are scored in the opposite order, since they represent positive/non-anxiety statements.

The total raw scores range from 20-80. The raw score then needs to be converted to an "Anxiety Index" score using the chart on the paper version of the test that can be found on the link below. The "Anxiety Index" score can then be used on this scale below to determine the clinical interpretation of one's level of anxiety:

- 20-44 Normal Range
- 45-59 Mild to Moderate Anxiety Levels
- 60-74 Marked to Severe Anxiety Levels
- 75 and above Extreme Anxiety Levels

### **Reference .**

[https://en.wikipedia.org/wiki/Zung\\_Self-Rating\\_Anxiety\\_Scale](https://en.wikipedia.org/wiki/Zung_Self-Rating_Anxiety_Scale)

[https://www.centrahealth.com/sites/default/files/documents/zung\\_self-rating\\_anxiety\\_scale.pdf](https://www.centrahealth.com/sites/default/files/documents/zung_self-rating_anxiety_scale.pdf)

<https://www.mnsu.edu/comdis/isad16/papers/therapy16/sugarmanzunganxiety.pdf>

Table No. 6.23 Showing assessment of treatment by Zung's Anxiety Scale

Zung Anxiety scale	At b time-point		At c time-point	
	Study Group	Control Group	Study Group	Control Group
Normal Range	26(74.1%)	26(74.1%)	31(88.35%)	31(88.35%)
Moderate Anxiety Levels	9(25.65%)	9(25.65%)	4(11.4%)	4(11.4%)
Severe Anxiety Levels	0	0	0	0
Extreme Anxiety Levels	0	0	0	0

Evaluation of data from both scales i.e. ZUNG's Anxiety scale and Depression scale; reveals that statistically, scores of both scales have significant result at time point B. When data is subjected to statistical analysis, it is evident that Scale-wise effect is significant. Results are non-significant for data related to number of patients.



## DISCUSSION

### 1. Discussion on Age-wise distribution of patients of Triple Negative Breast Cancer (TNBC)

Observations reveal that maximum patients in clinical trial are from age group 41-50 yrs i.e. 25 out of 70 and 51-60 years i.e. 21 out of 70; whereas least no. of patients are seen in age group 21-30 years i.e. only 2 out of 70 and age group 31-40 years; 9 out of 70.

Reason behind this is that women in age from 41-50 years are in Peri- Menopausal age and have completed their fertile period. So, whatever hormone therapy has been done till now, will show its effects at this age. Further, hormonal changes in this age, will have physical as well as psychological changes due to hormonal imbalance. Vulnerability to anxiety, depression is also very high in Peri - menopausal period.

Least number of subjects are found in age group 21-30 years i.e. only 2. Reason behind this is, this age group is supposed to be the safest and healthiest period because of young age, more tolerance capacity and less challenges in life. TNBC and Chittodvega will be obviously less in this age group. But because of trauma of TNBC, at such early age, both the patients were prone to depression i.e. Manovasada.

TNBC is common in age group between 40-60 years. Similar observation was seen in our study.

### 2. Discussion on distribution of patients as per Stages of Triple Negative Breast Cancer (TNBC)-

Stage of cancer is defined on the basis of TNM classification. AJCC Classification is used to confirm stage of cancer (Stage I to IV). Staging of cancer is confirmed taking into consideration size of tumour, nodal involvement of tumour and metastasis. Staging is done at initial diagnosis of cancer. Staging of cancer is essential to understand extent of disease and to confirm line of treatment thereafter. It also helps to predict prognosis of patient.

In our study maximum number of patients i.e. 52/70 belong to stage II and III cancer. Distribution of TNBC patients in each stage was almost equal, resulting in assessment of effectiveness of Jatamansi oil Shirodhara in identical data of both study and control groups.

### 3. Discussion on Grade-wise distribution of patients of Triple Negative Breast Cancer (TNBC)-

According to the American Cancer Society (ACS), doctors use the following system to grade **Tumor size**:

- **TX**: The doctor is unable to assess the primary tumor.
- **T0**: The doctor has not found evidence of a primary tumor.
- **T1**: The tumor is 2 cm (0.79 inches (in)) or less in diameter.
- **T2**: The tumor is more than 2 cm (0.79 in) but less than 5 cm (1.97 in) across.
- **T3**: The tumor is larger than 5 cm (1.97 in) wide.
- **T4**: The tumor can be of any size, but it is growing into the chest wall or skin. This category includes inflammatory breast cancer.

#### **Lymph node status**

When staging a person's breast cancer, doctors will determine whether it has spread to nearby lymph nodes. They do this by removing one or more of the lymph nodes in the armpit and examining them under a microscope.

Doctors categorize lymph node status using the N value of the TNM system, where:

- NX means that the doctor was unable to assess the lymph node status.
- N0 indicates that the doctor did not detect cancer in the nearby lymph nodes.
- N1, N2, and N3 show that the cancer has spread to nearby lymph nodes. Higher values indicate the involvement of more lymph nodes.

#### **Metastasis**

Metastasis is when cancer spreads from its original location in the breast to distant parts of the body, such as the liver, lungs, brain, or bones.

The symptoms of metastatic breast cancer depend on which organs the cancer has spread to, and they can vary greatly. Doctors may use additional scans, tests, and exams to diagnose a person with metastatic breast cancer.

Doctors categorize metastasis using the M value of the TNM system, where:

- MX means that the doctor was unable to assess metastasis.
- M0 indicates that the doctor did not detect any metastasis.
- M1 means that the breast cancer has spread to other organs.

Observations reveal that patients in clinical trial in Grade 2 are 12 from study group and 10 from control group. In grade 3 there are 23 patients in study group and 25 in control group.

#### 4. Discussion on scores of Karnofsky scale in Triple Negative Breast Cancer (TNBC) patients-

Karnofsky score is an assessment of well being of patient from physicians perspective. It is used to measure Quality of Life of cancer patients & to assess treatment response.

It is measured on 0-100 scale where 0 indicates moribund stage of patient & 100 indicates healthy state of patient.

In our study, equal no. of patients had stable & increased Karnofsky score in both groups at time point 'B', whereas two times more no. of patients of study group had stable Karnofsky score at time point C (10 patients from study group & 5 patients from control group).

#### 5. Discussion on scores of QLQC30 Questionnaire for evaluating Quality of Life in TNBC patients-

QLQC30 (version 3) of EORTC is a questionnaire of 30 questions to measure quality of life (QOL) of cancer patients from their own perspectives. It is common for all types of cancers.

Question numbers 1 to 28 are answered in 4 options, namely, 1 =not at all; 2=a little; 3=quite a bit; 4=very much.

Question numbers 29 and 30 are to be answered from 1 to 7 scales in which 1 denotes very poor whereas 7 denotes excellent.

QLQ C30 consists of functional, symptom and global scores. Daily activities / functions of patients are measured by functional score which is calculated using questions 1 to 7 and 20 to 27.

A raw mean functional score is converted into final functional score using an equation,

$$\frac{1-(MeanRawScore)}{Range} \times 100$$

High functional score represents high /healthy level of functioning.

Symptom score, which is indicative of symptomatology, is calculated using question numbers 8 to 19 and 28. Final symptom score is calculated using an equation,

$$\frac{(RawScore - 1)}{Range} \times 100$$

High symptom score represent high level of symptomatology.

Global score indicates assessment of overall health and quality of life from patient's own perspectives which is assessed by question numbers 29 and 30. Final global score is calculated by using equation,

$$\frac{(RawScore - 11)}{Range} \times 100$$

High global score indicates healthy status and represent high quality of life.

In our study, extremely significant results in Functional Score at time point B & C are indicative of effectiveness of Jatamansi oil Shirodhara in TNBC patients who were suffering from Chittodvega.

This finding is a reflection of mental relaxation of TNBC patients caused due to administration of a course of Jatamansi Oil Shirodhara and this improvement in day to day activities and well being.

### **Discussion on Symptom Score of QLQ C30 Questionnaire in Triple Negative Breast Cancer (TNBC) patients-**

Similarly, extremely significant reduction in Symptom Score is observed at time point 'B' & C. Symptoms commonly observed in cancer patients are reflected in Symptom Score of Quality of Life Questionnaire. These symptoms are developed due to physical as well as psychological disturbances. Diseases originated from physical & / or psychological disturbances are inter dependent; as per Ayurvedic concepts. Psychological ailment is commonly observed in dreadful & incurable disease like cancer. Moreover, mental stress is an evident cause of breast cancer and especially TNBC. TNBCs are more common in age group between 40-60 years; which is maximum stress-bearing age group. This fact underscores additional benefit of treatment like Shirodhara.

### **6. Discussion on Score of QLQ BR23 Questionnaire in Triple Negative Breast Cancer (TNBC) patients-**

Extremely significant & very significant results at Time point B & C respectively in QLQ B23 Symptom Score can be explained on the basis of same reasoning. QLQ BR 23 is a questionnaire of 23 Questions designed by EORTC especially for Breast Cancer patients.

These 23 Questions assess Quality of life, symptomatology related to disease & conventional Treatment in Breast cancer patients.

Out of 23 Questions, Question No. 9 to 16 are designed for calculating Functional Score of Breast Cancer patients whereas, Question. No. 1 to 8 & 17 to 23 are designed for calculating Symptom Score of breast cancer patients. Increase in BR 23 Functional Score and decrease in BR 23 Symptom Score indicates improvement in Quality of life & regression of disease in breast cancer patients.

## **7. Discussion on Symptoms Of Chittodvega in Triple Negative Breast Cancer ( TNBC) patients-**

Stanya (Breast milk) and Aartava (Menstrual fluid) are described as Upadhatu of Rasa Dhatu in Ayurvedic texts. Chinta (worry) is stated as one of the important causative factors of RasapradoshajaVyadhi. Stanya being Updhatu of Rasa Dhatu, breast cancer is considered as Rasadushtijanya Vyadhi. Therefore, mental stress is considered as major risk factor of breast cancer from Ayurvedic perspective.

### **A. }Restlessness**

Restlessness is a symptom which is commonly observed in Anxiety as well as depression. It is termed as Vyathitendriyata / Adherata in Ayurvedic texts, which is a consequence of Rajovikruti.

Chitta -Sthairya (Steadiness of minds) and Indriya Shuddhi (Proper Functioning of all 11 Indriya) are mentioned as benefits of Shirodhraa with oil. Additionally, Jatamansi oil is beneficial in management of restlessness (a type of Ruja - pain).

### **B. }Irritability**

It is associated with depression & Anxiety both; which can be well managed with Shirdodhara of medicated oil. Shirodharais beneficial for Manasthairya, to establish calmness of mind. Jatamansi being Medhya, Modakrut (Imparting positivity) helps to reduce & eliminate irritability.

### **C. } Difficulty in Concentration**

Difficulty in concentration called as Anavasthitachittatvais a sign of Anxiety & Depression and is caused due to Rajovikruti. Significant improvement in difficulty in concentration was obtained in study group patients at time point 'C' indicating long term beneficial effect of Jatamansi oil Shirodhara in TNBC patients. Jatamansi is Mansthairyakar & Medhya. This effect is observed owing to Medhya & Mansthiryakar properties of Jatamansi.

### **D. } Worthlessness**

Worthlessness is symptom of Depression which is called as Vishannata& caused due to Tamovikruti. In our study, no significant result was observed in both groups i.e. study& control groups; at both time points B & C.

### **E. } Crying Spells**

It is a symptom of Depression which is exacerbation of Shoka&Dainya and caused due to Tamovikruti.

Jatamasni has peculiar property termed as Modkrut (generating happiness), while Shirodhara is effective in reducing mental stress . Thus significant results ( $p= 0.02$ ,  $p=0.05$  at time point B and C respectively) on crying spells were obtained with Jatamansi oil shirodhara at both time point B & C in study group respectively.

### **F. } Fearfulness**

It is a symptom of anxiety caused due to Tamovikruti& called as Vishad or Bhayain Ayurvedic texts. Jatamansi oil Shirodhara is found to be significant in relieving fearfulness at both time points B &C in study group patients. This is associated with Modkrut& stress relieving property of Jatamansi oil Shirodhara in TNBC patients.

### **G. } Tingling and Numbness in Limbs**

Tingling & Numbness in limbs is called as Chimchimayan. It is found due to Rajovikruti. It is generally seen as acute symptom in Anxiety attacks. It is a physical reflection due to vitiation of Vata by its Chala character. (Vata is stimulated due to vitiation of Raja character).

In our study, significant results are not observed in study group patients at both time points B and C.

Reason behind this can be Vikruti in Majjavahasrotas due to effect of Raja. It may require long term treatment with Jatamansi oil Shirodhara.

#### **H. } Dryness of Mouth**

Dryness of mouth is a symptom observed in Anxiety states majorly. It is observed due to Tama & Raja dosh vikruti. It is physical reflection of fear & anxiety. Jatamansi gives strength to Manas of person. It has Rujapahacharacter also.

While Shirodhara increases stability of mind, it reduces heat (Ushanata) in Manovahasrotas and helps in Dhatuposhan also.

#### **I. } Dyspnoea**

This symptom is seen in Anxiety state as Tachypnoea and in Depression as difficulty in breathing as well as shallow breathing which ultimately increases restlessness and dryness of mouth. It is mainly observed in Rajo Vikruti in Mana. It is a reflection of Vishada in Depression and Anavasthitachitta in Anxiety.

Here, Jatamansi is useful as it pacifies increased Raja & Vata. It gives stability to mind by strengthening mind.

Shirodhara is also useful for giving stability to mind (by decreasing Raja & chalaguna) & regulates breathing.

#### **J. } Tachycardia**

This symptom is mainly seen in Anxiety due to Rajovikruti. Continuous exposure to states of psychological disturbance leads to Rajobahulya which leads to Vibhrantcheatas and de – stabilizes the mind. Hridaya is seat of ManovahaSrotas. So instability of mind leads to instability in rhythm of heart leading to either tachycardia or palpitation.

Jatamansi acts to reduce chalaguna of Vata & Raja guna of Manas & stabilizes mind which in turn helps to stabilize and regulate rhythm of heart ultimately leading to regular rhythm of heart.

Shirodhara calms mind and by Medhya virtue of Jatamansi; the combination helps to regulate rhythm of heart.

Effect of Anxiety on heart is seen in 2 ways as strong & acute impact reflected as temporary effect & lingering effect in the form of tachycardia / palpitation intermittently or because of exposure to stimulus.

### **K. }Sleep Disturbance**

Sleep Disturbance (Nidranash) is associated with Rajovikruti & is seen in Anxiety & Depression both. In our study, significant results are obtained at time points B and C for the symptom – Sleep Disturbance.

This effect can be attributed to Nidrajanan effect of Jatamansi oil & Shirodhara procedure.

### **L. }Easy Fatigability**

Easy fatigability is observed in Anxiety as well as Depression. It is a symptom of Tamavikruti. In Anxiety, easy fatigability (Physical symptom) is resultant of over activity (over thinking, worrying) of mind. So, Klama-Easy fatigability/ fatigue without exertion is observed due to Rasa and Majjakshaya.

Easy fatigability in depression is result of Tamapradhanya of mind where Guru guna of Tama and Kapha gives Indriyaavaram and denial for activities. It is observed that fatigue in the body is seen when the mind is tired.

Jatamansi is Indriya and Manasbalya. Shirodhara nullifies fatigue and energizes and strengthens the mind and ultimately body.

In our study, significant results are not obtained for this symptom. This may be because of short duration (7 days) of therapy while this psycho-somatic symptom requires long course of therapy.

### **M. }Suicidal Thoughts**

This symptom is seen mainly in depression and occasionally in Anxiety of acute onset. This is due to Tamavikruti.

Jatamansi decreases 'Tama' by its virtue of Modakrut, Medhya, Balaprada.

Shirodhara is useful to decrease Tama by its virtue of IndriyaShuddhi, Mana SthairyaKaratva and nourishing mind.



Suicidal thoughts are outcome of severe depression. Therefore, use of Jatamansi oil Shirodarafor long duration alongwith other therapies will be required to nullify this symptom of suicidal thoughts.

#### **N. }Fainting**

Fainting is observed in acute &severe attacks of anxiety especially owing to shocking stimulus. Such conditions trigger Vata& Pitta by their virtue of Chala &Teeksha character ultimately leading to Bhramaor fainting. This is extreme &uncontrolled condition of unstable mind reflected as physical symptom. Jatamansi acts by Medhya, Modakrut and Mano- balya characters .

Shirodhara with oil pacifies Vata and achieves Mana - Shanti &Sthairya.

#### **O. }Increased Frequency at Urine & Stool**

This symptom is seen mainly due to Bhayai.e. fear which is commonly seen in Rajovikruti. Jatamansi acts on Bhaya by Medhya character. Shirodhara acts byDhatuposhan and by establishing Sthairya. Even Ojokshya plays an important role in occurrence of these symptoms.

Long term systemic therapy along with Shirodhara may give good results rather than only Shirodhara for such a short time span.

#### **Discussion about ZUNG' Self Rating Anxiety and Depression Scales**

There are 2 different scales for assessment of Anxiety and Depression. Both scales showed significant effect of therapy at time point B. Results at time point C are not significant.

It means; quick effect of therapy was more whereas lingering and long lasting effect was non-significant. This finding may be there because both assessment scales for Anxiety and Depression include more questions related to physical symptoms (due to psychological disturbance as either Anxiety or Depression- psycho-somatic symptoms) than pure psychological symptoms.

## 5. CONCLUSION

In the discussion part of the study entitled

### **‘CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF JATAMANSI OIL SHIRODHARA ON *CHITTODVEGA* (PSYCHOLOGICAL DISTRESS) IN TNBC (TRIPLE NEGATIVE BREAST CANCER) PATIENTS’**

the work is discussed based upon concepts, supported by data and logical reasoning.

**The conclusions drawn from the scientific discussion are as follows**

1. Shirodhara with Jatamansi oil was selected for management of chittodvega in TNBC patients. This emphasizes role of relaxation therapy alongwith Shaman Chikitsa ; for mind and body in psychological distress due to cancer especially TNBC.
2. Overall effect of Jatamansi oil Shirodhara is more effective clinically and statistically ( as add on treatment to Shaman chikitsa) as compared to Shaman chikitsa group in most of the parameters.
3. Jatamansi oil shirodhara was proved to be effective to improve Quality of Life of Triple Negative Breast Cancer ( TNBC) patients.
  - A. Extremely Significant in Functional score and Symptom score of Quality of Life scale i.e. QLQ C30 scale.
  - B. Extremely Significant in Symptom Score in Quality of Life scale i. e. in QLQ BR23 scale at time point B ( assessment on 7<sup>th</sup> Day).
4. Jatamansi oil shirodhara is proved to be Very Significant in Symptom Score in Quality of Life scale i. e. in QLQ BR23 scale at time point C ( assessment on 30<sup>th</sup> Day).
5. Jatamansi oil shirodhara is proved to be Significant in relieving following symptoms of Chittodvega at time point B ( 7<sup>th</sup> Day). These symptoms are- Sleep disturbance, difficulty in concentration, fearfulness.
6. Jatamansi oil shirodhara is proved to be Significant in relieving following symptoms of Chittodvega thus proving to relax mind by decreasing psychological distress at time point C ( 30<sup>th</sup> Day) These symptoms are namely- Restlessness, Irritability, Crying Spells, Fearfulness, Sleep Disturbances.
7. Jatamansi oil shirodhara is proved to be Significant in scores of Zung’s Self Rating Depression scale at time point B- 7<sup>TH</sup> Day.

Zung's Self Rating Anxiety scale at time point C- 30<sup>TH</sup> Day.

8. No complications were observed during and after the study.

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### SHLOK श्लोक

10)

ग्रन्थ्यर्बुदानां च यतोऽविशेषः प्रदेशहेत्वाकृतिदोषदूष्यैः ।  
ततश्चिकित्सेद्भिषगर्बुदानि विधानविद्ग्रन्थिचिकित्सितेन ॥च.चि .12/87

अर्बुदचिकित्सातिदेशार्थमाह- ग्रन्थ्यर्बुदानामित्यादि। अविशेष इव अविशेष इह ज्ञेयः।  
सुश्रुतेऽप्यर्बुदलक्षणमुक्तं- गात्रप्रदेशे क्वचिदेव दोषाः सम्मूर्च्छिता मांसमभिप्रदूष्य। वृत्तं  
स्थिरं मन्दरुजं महान्तमनल्पमूलं चिरवृद्ध्यपाकम्॥ कुर्वन्ति मांसोच्छ्रयमत्यगाधं तदर्बुदं  
शास्त्रविदो वदन्ति (सु. नि. अ. ११) इति; तस्मात् स्तोकविशेषे सत्यपि  
स्रावादयविशेषाद्ग्रन्थिविशेषचिकित्सैवातिदिश्यतेऽर्बुदे॥८७॥

11)

गात्रप्रदेशे क्वचिदेव दोषाः सम्मूर्च्छिता मांसमभिप्रदूष्य ।  
वृत्तं स्थिरं मन्दरुजं महान्तमनल्पमूलं चिरवृद्ध्यपाकम् ॥  
कुर्वन्ति मांसोपचयं तु शोफं तदर्बुदं शास्त्रविदो वदन्ति ।  
वातेन पित्तेन कफेन चापि रक्तेन मांसेन च मेदसा च ॥१४॥  
तज्जायते तस्य च लक्षणानि ग्रन्थेः समानानि सदा भवन्ति ।  
वातेन पित्तेन कफेन चापि रक्तेन मांसेन च मेदसा च ॥१४॥  
तज्जायते तस्य च लक्षणानि ग्रन्थेः समानानि सदा भवन्ति ।  
दोषः प्रदुष्टो रुधिरं सिरास्तु सम्पीड्य सङ्कोच्य गतस्त्वपाकम् ॥१५॥  
सास्रावमुन्नहयति मांसपिण्डं मांसाङ्कुरैराचितमाशुवृद्धिम् ।  
स्रवत्यजस्रं रुधिरं प्रदुष्टमसाध्यमेतद्गुधिरात्मकं स्यात् ॥१६॥  
रक्तक्षयोपद्रवपीडितत्वात् पाण्डुर्भवेत् सोऽर्बुदपीडितस्तु  
सु .नि . 11/13-16

16)

तत्र व्याधयोऽपरिसङ्ख्येया भवन्ति, अतिबहुत्वात् । दोषास्तु खलु परिसङ्ख्येया भवन्ति,  
अनतिबहुत्वात् । तस्माद्यथाचित्रं विकारानुदाहरणार्थम्, अनवशेषेण च दोषान्  
व्याख्यास्यामः । रजस्तमश्च मानसौ दोषौ । तयोर्विकाराः  
कामक्रोधलोभमोहेर्ष्यामानमदशोकचित्तो(न्तो)द्वेगभयहर्षादयः । वातपित्तश्लेष्माणस्तु खलु

शारीरा दोषाः । तेषामपि च विकारा ज्वरातीसारशोफशोषश्वासमेहकुष्ठादयः । इति दोषाः  
केवला व्याख्याता विकारैकदेशश्च ॥५॥

तत्र खल्वेषां द्वयानामपि दोषाणां त्रिविधं प्रकोपणं; तद्यथा- असात्म्येन्द्रियार्थसंयोगः,  
प्रज्ञापराधः, परिणामश्चेति ॥६ च.वि .6/5

17)

सङ्क्षेपतः क्रियायोगो निदानपरिवर्जनम् ।

वातादीनां प्रतीघातः प्रोक्तो विस्तरतः पुनः ॥ सु .3 .1/25

18)

त्रिविधमौषधमिति- दैवव्यपाश्रयं, युक्तव्यपाश्रयं, सत्त्वावजयश्च । तत्र दैवव्यपाश्रयं-  
मन्त्रौषधिमणिमङ्गलबल्युपहारहोमनियमप्रायश्चित्तोपवासस्वस्त्ययनप्रणिपातगमनादि,  
युक्तव्यपाश्रयं- पुनराहारौषधद्रव्याणां योजना, सत्त्वावजयः- पुनरहितेभ्योऽर्थेभ्यो  
मनोनिग्रहः ॥ च. सु.11/54

19)

धीधैर्यात्मादिविज्ञानं मनोदोषौषधं परम्॥२६॥ अ .हु .सू .1/26

20)

मधुमधुकरुधिरमोचरसमृत्कपाललोध्रगैरिकप्रियङ्गुशर्करालाजा इति दशेमानि  
शोणितस्थापनानि भवन्ति शालकटफलकदम्बपद्मकतुम्बमोचरसशिरीषवञ्जुलैलवालुकाशोका  
इति दशेमानि वेदनास्थापनानि भवन्ति  
हिङ्गुकैटर्यारिमेदावचाचोरकवयस्थागोलोमीजटिलापलङ्कषाशोकरोहिण्य इति दशेमानि  
सञ्ज्ञास्थापनानि भवन्ति  
ऐन्द्रीब्राह्मीशतवीर्यासहस्रवीर्याऽमोघाऽव्यथाशिवाऽरिष्टावाट्यपुष्पीविष्वक्सेनकान्ता इति  
दशेमानि प्रजास्थापनानि भवन्ति  
अमृताऽभयाधात्रीमुक्ताश्वेताजीवन्त्यतिरसामण्डूकपर्णीस्थिरापुनर्नवा इति दशेमानि  
वयःस्थापनानि भवन्ति , इति पञ्चकः कषायवर्गः ॥ च.सू .4/18

21)

जटिलां पूतनां केशीं चारटीं मर्कटीं वचाम् ।

त्रायमाणां जयां वीरां चोरकं कटुरोहिणीम् ॥

वयःस्थां शूकरीं छत्रामतिच्छत्रां पलङ्कषाम् ।  
महापुरुषदन्तां च कायस्थां नाकुलीद्वयम् ॥  
कटम्भरां वृश्चिकालीं स्थिरां चाहृत्य तैर्घृतम् ।  
सिद्धं चातुर्थकोन्मादग्रहापस्मारनाशनम् ॥  
महापैशाचिकं नाम घृतमेतद्यथाऽमृतम् ।  
बुद्धिस्मृतिकरं चैव बालानां चाङ्गवर्धनम् ॥  
इति महापैशाचिकं घृतम् । च.चि .9/45-48

22)

अमरकोष, यन्त्रोपारोपितकोशांशः, कल्पद्रुमः

चूचुकम्, क्ली पुं, (चूष्यते पीयते इति । चूष पाने + बाहुलकात् उकः षस्य चत्वञ्च ।)  
चुचुकम् । इत्यमरटीकायां भरतः ॥ (यथा, रामायणे । ६ । २३ । १३ । “स्तनौ च विरलौ  
पीनौ समौ मे मग्नचूचुकौ ॥”) अमरकोशः

चूचुक पुं-नपुं।

स्तनाग्रः - समानार्थकःचूचुक,कुचाग्र 2।6।77।2।1

पिचण्डकुक्षी जठरोदरं तुन्दं स्तनौ कुचौ। चूचुकं तु कुचाग्रं स्यान्न ना क्रोडं भुजान्तरम्।

पदार्थ-विभागः : अवयवः

शब्दसागरः

चूचुक| mn. (-कः-कं) A nipple. E. चूष् to suck, and deriv. irr.; or चूचु imitative  
sound, (in sucking) and क what makes; also चुचुक, &c. चूष्यते चूष वा उकः  
पृषो-षस्य च | कुचाग्रे |

Apte

चूचुकम् [cūcukam] चूचूकम् [cūcūkam], चूचूकम् The nipple of a breast; Śi.7.19.

-a. staggering in speech; मूकचूचुकाः Mb.14.36.3.

Monier-Williams

चूचुक mfn. stammering MBh. xiv , 1016

चूचुक m. pl. N. of a people , xiii , 207 , 42 ( चुच्, C)

चूचुक n. = का-ग्र(also 574720 चुचुकmn. and 574720.1 चुचूकn. L. ) R. vi ,  
23, 13 Sus3r. VarBr2S. lxviii , 27 Katha1s. cxx.

यन्त्रोपारोपितकोशांशः कल्पद्रुमः

स्तन, त् क अभ्रशब्दे । इति कविकल्पद्रुमः ॥ (अदन्तचुरा०-पर०-अक०-सेट् ।) स्तनयति  
मेघः । इति दुर्गादासः ॥

स्तन, मि शब्दे । इति कविकल्पद्रुमः ॥ (म्वा०- पर०-सक०-सेट् ।) मि स्तनयति  
स्तानयति । अतिस्तनत् । इति दुर्गादासः ॥

स्तनः, पुं, (स्तन्यते शब्दयते कामुकैः स्तनयति कथयति वक्षःशोभामिति वा । स्तन शब्दे  
+ घञ् ।) अवयवविशेषः । माइ इति चू ~ची इति च भाषा ॥ तत्पर्यायः । कुचः २ ।  
इत्यमरः । २ । ६ । ७७ ॥ कूचः ३ उरोजः ४ वक्षोजः ५ पयोधरः ६ वक्षोरुहः ७ उरसिजः ८  
। तस्याग्रं चूचुकम् । इति शब्दरत्नावली । तस्य शुभ - लक्षणं यथा, गारुडे । ५६ । ९५ ।  
“अरोमशौ स्तनौ पीनौ घनावविषमौ शुभौ । कठिनावरोममुरो मृदुग्रीवा च कम्बुभा ॥ ” तस्य  
मनोहरत्वकारकौषधं यथा, तत्रैव । १९४ । ४ । “कुष्ठनागबलाचूर्णं नवनीतसमन्वितम् ।  
तल्लेपो युवतीनाञ्च कुर्यान्मनोहरं स्तनम् ॥ ” अधस्तनरोगस्य संप्राप्तिमाह । “सक्षीरौ  
वाप्यदुग्धौ वा दोषः प्राप्य स्तनौ स्त्रियः रक्तं मांसञ्च संदूष्य स्तनरोगाय कल्प्यते ॥ ”  
अदुग्धावपि स्तनौ प्रसू ताया गर्भिण्याश्च स्त्रिया बोद्धव्यौ । यत आह सुश्रुतः “धमन्यः  
संवृतद्वाराः कन्यानां स्तनसंश्रिताः । दोषाविसरणास्तासां न भवन्ति स्तनामयाः ॥ ”  
दोषाविसरणाः संवृतद्वारत्वेन दोषाणाम - विसरणमसञ्चारो यासु ताः । “तासामेव प्रसूतानां  
गर्भिणीनाञ्च ताः पुनः । स्वभावादेव विवृता जायन्ते सम्भवन्त्यतः ॥ ” \* ॥  
स्तनरोगाणामतिदेशेन लक्षणान्याह । “पञ्चानामपि तेषान्तु हित्वा शोणितविद्रधिम् ।  
लक्षणानि समानानि बाह्यविद्रधिलक्षणैः ॥ ” पञ्चानां वातपित्तकफसन्निपातागन्तुजानाम् ।  
आगन्तुजस्तनरोगाभिघातेन शल्येन च बोद्धव्यः ॥ रक्तजस्यासम्भवः । स्वभावात् ॥ \* ॥  
अथ स्तनरोगस्य चिकित्सा । “शोथं स्तनोत्थितमवेक्ष्य भिषग्विदध्यात् यद्विद्रधावभिहितं  
बहुधा विधानम् । आमे विदाहिनि तथैव च तस्य पाके तस्याः स्तनौ सततमेव च  
निर्गृहीतौ ॥ पित्तघ्नानि तु शीताति द्रव्याण्यत्र प्रयोजयेत् । जलौकाभिर्हेरेद्रक्तं न  
स्तनावुपनाहयेत् ॥” उपनाहयेत् स्वेदयेत् । “लेपो विशालामूलेन हन्ति पीडां स्तनो-  
त्थिताम् । निशाकनककल्काभ्यां लेपः प्रोक्तः स्तना - क्षिहा ॥” विशाला इन्द्रवारुणी । कनकस्य  
धत्तूरस्य पत्रं ग्राहयम् । “लेपान्निहन्ति मूलं स्तनरोगं वन्ध्यकर्कोट्याः । निर्वाप्य  
तप्तलोहं सलिले तद्वा पिबेत्तत्र ॥” इति भावप्रकाशः ॥

अमरकोशः

स्तन पुं।

वक्षोजः

समानार्थकःस्तन,कुच 2।6।77।1।6

पिचण्डकुक्षी जठरोदरं तुन्दं स्तनौ कुचौ। चूचुकं तु कुचाग्रं स्यान्न ना क्रोडं भुजान्तरम्।

पदार्थ-विभागः : अवयवः

वाचस्पत्यम्

"स्तनम्"। मेघशब्दे अद. चु. उभ. सक. सेट्। स्तनयति तेअतस्तनत् त। बहवचकत्वान्न षोपदेशः।

"स्तनम्"। पु. स्तन--अच्। (माइ) स्त्रोणामङ्गभेदे पयोधरे अमरः।

"अरोमशौ स्तनौ पोनौ घनाविषमौ शुभौ" स्तनयोःशुभलक्षणं गारुडे ३६ अ.।

शब्दसागरः

स्तनम्। m. (-नः)

1. The female bosom or breast.
2. An udder or dug of any female animal. E. स्तन् to sound, aff. अच् ।

Apte

स्तनः [stanh], [स्तन्-अच्]

The female breast; स्तनौ मांसग्रन्थी कनककलशावित्युपमितौ Bh.3.2; (दरिद्राणां मनोरथाः) हृदयेष्वेव लीयन्ते विधवास्त्रीस्तनाविवं Pt.2.91.

The nipple of the breast.

The breast, udder, or dug of any female animal; अर्धपीतस्तनं मातुरामर्दक्लिष्टकेशरम् §.7.14. -Comp. -अंशुकम् a cloth covering the breasts or bosom, breastmantle. -अग्रः a nipple. -अङ्गरागः a paint or pigment smeared on the breasts of women.

अन्तरम् the heart.

the space between the breasts; (न) मृणालसूत्रं रचितं स्तनान्तरे §.6.17; R.1.62.



a mark on the breast (said to indicate future widowhood). -आभुज a. feeding with the udder (said of cows).

आभोगः fulness or expanding of the breasts.

the circumference or orb of the breast.

a man with large breasts like those of a woman. -आवरणम् a breast-cloth.

-उपपीडम् pressing the breast. -कलशः a jar-like breast. -कुङ्मलम् a woman's

breast. -कोटिः the nipple of the breast.-ग्रहः the sucking or drawing of the

breast. -चूचुकम् the nipple of the breast. -तटः, -टम् the slope or projection

of the breast; cf. तट. -त्यागः weaning. -प, -पा, -पायक, -पायिन् a. sucking the

breast, suckling.-पतनम् flaccidity of the breast. -पानम् sucking of the breast.

भरः the weight or heaviness of breasts; पादाग्रस्थितया मुहुः स्तनभरेणानीतया नम्रताम् Ratn.1.1.

a man having breasts like those of a woman. -भवः a particular position in

sexual union. -मध्यः a nipple. (-ध्यम्) the space between the breasts. -

मुखम्, -वृन्तम्, -शिखा a nipple. -रोहितः, -तम् a particular part of the female

breast. -वेपथुः the having of the breast; अद्यापि स्तनवेपथुं जनयति श्वासः

प्रमाणाधिकः & Sacute.1.29.

Monier-Williams

स्तन m. (or n. g. अर्धर्चा-दि।fc. आor ई; derivation doubtful , but prob.

connected with स्तन्, from the hollow resonance of the human breast) ,

the female breast (either human or animal) , teat , dug , udder RV. etc.

स्तन m. the nipple (of the female or the male breast) Sus3r.

स्तन m. a kind of pin or peg on a vessel shaped like a teat S3Br.

Vedic Rituals Hindi

स्तन न.

उखा का दो से आठ की संख्या में उत्थान-सीमा (रास्ना) से बाहर की ओर उभरा हुआ स्त्री के स्तन के सदृश चिह्न, आप.श्रौ.सू. 12.7.11।

उरस्वत यन्त्रोपारोपितकोशांशः

कल्पद्रुमः

उरस्वान्, [त्] त्रि, (प्रशस्तमतिशयितं वा उरो वक्षःस्थलं यस्य । उरस् + मतुप् + मस्य वः ।) प्रशस्तवक्षोयुक्तः । तत्पर्यायः । उरसिलः २ । इत्यमरः ॥

अमरकोशः

उरस्वत् पुं।

विपुलोरः

समानार्थकः उरस्वत्, उरसिल 2।8।76।1।1।

स्वादुरस्वानुरसिलो रथिरो रथिको रथी। कामङ्गाम्यनुकामीनो ह्यत्यन्तीनस्तथा भृशम्।

पदार्थ-विभागः : , द्रव्यम्, पृथ्वी, चलसजीवः, मनुष्यः

शब्दसागरः

उरस्वत्] mfn. (-स्वान्-स्वती-स्वत्) Broad-chested, full-breasted, strong. E. उरस् and मतुप् poss. aff.

Apte

उरस्वत् [urasvat] उरसिल [urasila], उरसिल a. Broad-chested, full-breasted.

Monier-Williams

उरस्वत्/ उरस्-वत् mfn. broad-chested , full-breasted ,

23)

षट्पञ्चाशत् प्रत्यङ्गानि षट्स्वङ्गेषूपनिबद्धानि , यान्यपरिसङ्ख्यातानि पूर्वमङ्गेषु परिसङ्ख्यायमानेषु, तान्यन्यैः पर्यायैरिह प्र षकाश्यानि भवन्ति । तद्यथा - द्वे जङ्घापिण्डिके, द्वे ऊरुपिण्डिके, द्वौ स्फिचौ, द्वौ वृषणौ, एकं शेफः, द्वे उखे, द्वौ वङ्क्षणौ, द्वौ कुकुन्दरौ, एकं बस्तिशीर्षम्, एकमुदरं, द्वौ स्तनौ, द्वौ श्लेष्मभ्रुवौ, द्वे बाहुपिण्डिके, चिबुकमेकं, द्वावोष्ठौ, द्वे सृक्कण्यौ, द्वौ दन्तवेष्टकौ, एकं तालु, एका गलशुण्डिका, द्वे उपजिह्विके, एका गोजिह्विका, द्वौ गण्डौ, द्वे कर्णशष्कुलिके, द्वौ कर्णपुत्रकौ, द्वे अक्षिकूटे, चत्वार्यक्षिवर्तमानि, द्वे अक्षिकनीनिके, द्वे भ्रुवौ, एकाऽवटुः, चत्वारि पाणिपादहृदयानि ॥ च.शा .7/11

24)

यथादोषोदयं कुर्यात्सन्निपाते चिकित्सितम्।  
नवेऽर्बुदे त्वसंवृद्धे छेदिते प्रतिसारणम्॥७७॥  
स्वर्जिकानागरक्षौद्रैः, क्वाथो गण्डूष इष्यते।  
गुडूचीनिम्बकल्कोत्थो मधुतैलसमन्वितः॥७८॥  
यवान्नभुक् तीक्ष्णतैलनस्याभ्यङ्गांस्तथाऽऽचरेत्।  
वमिते पूतिवदने धूमस्तीक्ष्णः सनावनः॥७९॥  
समङ्गाधातकीरोध्रफलिनीपद्मकैर्जलम्।  
धावनं वदनस्यान्तश्चूर्णितैरवचूर्णितम्॥८०॥  
शीतादोपकुशोक्तं च नावनादि च शीलयेत्। अ .हु .उ .22/77-79

24)

स्रोतांसि नासिके कर्णौ नेत्रे पाय्वास्यमेहनम्॥४०॥  
स्तनौ रक्तपथश्चेति नारीणामधिकं त्रयम्। अ .हु .शा .3/40

25)

श्रवणनयनवदनघ्राणगुदमेढ्राणि नव स्रोतांसि नराणां बहिर्मुखानि, एतान्येव स्त्रीणामपराणि  
च त्रीणि द्वे स्तनयोरधस्ताद्रक्तवहं च ॥१०॥  
सु .शा .5/10

26)

स्त्रीणां तु विंशतिरधिका । दश तासां स्तनयोरेकैकस्मिन् पञ्च पञ्चेति, यौवने तासां  
परिवृद्धिः; अपत्यपथे चतस्रः- तासां प्रसृते अभ्यन्तरतो द्वे, मुखाश्रिते बाहये च वृत्ते द्वे,  
गर्भच्छिद्रसंश्रितास्तिस्रः, शुक्रार्तवप्रवेशिन्यस्तिस्र एव । पित्तपक्वाशययोर्मध्ये गर्भशय्या,  
यत्र गर्भस्तिष्ठति ॥३९॥ सु .शा .5/39

27)

अत ऊर्ध्वं पृष्ठमर्माणि व्याख्यास्यामः - तत्र पृष्ठवं शमुभयतः प्रतिश्रोणिकाण्डमस्थिनी  
कटीकरुणे, तत्र शोणितक्षयात् पाण्डुर्विपर्णो हीनरूपश्च म्रियते ; पार्श्वयोर्जघनबहिर्भागे  
पृष्ठवंशमुभयतो कुकुन्दरे , तत्र स्पर्शाज्ञानमधःकाये चेष्टोपघातश्च ;  
श्रोणीकाण्डयोरुपर्याशयाच्छादनौ पार्श्वान्तरप्रतिबद्धौ नितम्बौ , तत्राधःकायशोषो दौर्बल्याच्च

मरणं; अधःपार्श्वान्तरप्रतिबद्धौ जघनपार्श्वमध्ययोस्तिर्यगूर्ध्वं च जघनात् पार्श्वसन्धी , तत्र लोहितपूर्णकोष्ठतया म्रियते ; स्तनमूलादृजुभयतः पृष्ठवंशस्य बृहती , तत्र शोणितातिप्रवृत्तिनिमित्तैरुपद्रवैर्म्रियते; पृष्ठोपरि पृष्ठवंशमुभयतस्त्रि कसम्बद्धे अंसफलके , तत्र बाहवोः स्वापशोषौ ; बाहुमूर्धग्रीवामध्यैऽसपीठस्कन्धबन्धनावंसौ, तत्र स्तब्धबाहुता ; एवमेतानि चतुर्दश पृष्ठमर्माणि व्याख्यातानि ॥२६॥ सु .शा .6/26

28)

तासां तु खलु नाभिप्रभावाणां धमनीनामूर्ध्वगा दश, दश चाधोगामिन्यः, चतस्रस्तिर्यग्गाः ॥४॥  
सु .शा .9/4

29)

तत्र वातवाहिन्यः सिरा एकस्मिन् सक्थिन् पञ्चविंशतिः ; एतेनेतरसक्थि बाहू च व्याख्यातौ । विशेषतस्तु कोष्ठे चतुस्त्रिंशत् ; तासां गुदमेढ्राश्रिताः श्रोण्यामष्टौ , द्वे द्वे पार्श्वयोः , षट् पृष्ठे, तावत्य एवोदरे , दश वक्षसि । एकचत्वारिंशज्जत्रुण ऊर्ध्वं ; तासां चतुर्दश ग्रीवायां , कर्णयोश्चतस्रः, नव जिहवायां , षण् नासिकायां , अष्टौ नेत्रयोः , एवमेतत् पञ्चसप्ततिशतं वातवाहिनीनां सिराणां व्याख्यातं भवति । एष एव विभागः शेषाणामपि । विशेषतस्तु पित्तवाहिन्यो नेत्रयोर्दश , कर्णयोर्द्वे; एवं रक्तवहाः कफवहाश्च । एवमेतानि सप्त सिराशतानि सविभागानि व्याख्यातानि ॥७॥  
सु .शा .7/7

30)

तत्रेयं स्तनसम्पत्- नात्यूर्ध्वौ नातिलम्बावनतिकृशावनतिपीनौ युक्तपिप्पलकौ सुखप्रपानौ चेति (स्तनसम्पत्) ॥५३॥ च.शा .8/53

33)

अजीर्णासात्म्यविषमविरुद्धात्यर्थभोजनात् ।  
लवणाम्लकटुक्षारप्रक्लिन्नानां च सेवनात् ॥२३२॥  
मनःशरीरसन्तापादस्वप्नान्निशि चिन्तनात् ।  
प्राप्तवेगप्रतीघातादप्राप्तोदीरणेन च ॥२३३॥  
परमान्नं गुडकृतं कृशरां दधि मन्दकम् ।  
अभिष्यन्दीनि मांसानि ग्राम्यान्पौदकानि च ॥२३४॥

भुक्त्वा भुक्त्वा दिवास्वप्नान्मद्यस्यातिनिषेवणात् ।  
अनायासादभीघातात् क्रोधाच्चातङ्ककर्शनैः ॥२३५॥  
दोषाः क्षीरवहाः प्राप्य सिराः स्तन्यं प्रदूष्य च ।  
कुर्युरष्टविधं भूयो दोषतस्तन्निबोध मे ॥२३६॥ च.चि .30

34)

तृणं कीटं तुषं शूकं मक्षिकान्गमलाष्टकम्।  
केशोर्णास्यादिकं विद्याद्वज्रमित्युपचारतः॥ का .सू .19/28

35)

स्तन रोग कारण  
सहान्नपानेन यदा धात्री वज्रम समश्नुते ।  
पच्यमानेन पाकेन ह्यनन्नत्वान्न पच्यते ॥

36)

अपच्यमानम विक्लिन्नं वायुना समुदीरितम् ।  
रसेन सह संपृक्तं याति स्तन्यवहाः सिराः।  
सर्वस्त्रोतांसि हि स्त्रिणां विवृतानि विशेषतः।  
तत् पयोधरमासाद्य क्षिप्रं विकुरुते स्त्रियाः॥

रूपाणि पीतवज्रायाः प्रवक्ष्याम्यत उत्तरम्।  
अजीर्णमरति गर्लानिर निमित्तम व्यथा अरुचिः।  
पर्वभेदोअन्गमर्दश्च शिरोरूग्र क्षवथुग्रहः।  
कफोत्क्लेदो ज्वरस्तृष्णा विगभेदो मूत्रसंग्रहः।  
स्तम्भः स्त्रावश्च कुचयोः सिराजालेन संततः।  
शोथशूलरूजादाहैः स्तनःस्पृष्टं न शक्यते ॥  
स्तनकीलकमित्याहुर्भिषजस्तं विचक्षणाः।  
कीलवत् कठिनोअङ्गेषु बाधमानो हि तिष्ठति ॥

एष पित्तात्मना शीघ्रं पाकं भेदं च गच्छति ।  
कफाच्चिरं क्लेशयति वातादाशु निवर्तते ॥  
शाखाशिरोभिस्तु यदि विमार्गान्न प्रपद्यते ।

आकृष्यमाणं बालेनं क्षिप्रं निर्धावति स्तनात्॥  
निर्दुद्यमानमुत्पिडाद्वज्रं क्षीरशोणितम्॥  
अथवा अभ्येति सहसा प्रत्यक्षं चोपलभ्यते ॥

37)

चिकित्सा

घृतपानं प्रथमतः शस्यते स्तनकीलके ।  
स्त्रोतांसि मार्दवं स्नेहाद्यांति वज्रं च च्याव्यते ॥  
निर्दोहो मर्दनं युक्त्या पायनं च गलेन च।  
इति ताडपत्रक 33 तमं पत्रम्

38)

लालास्त्रवणमत्यर्थं स्तनद्वेषारतिव्यथाः।  
पीतमुद्गिरति क्षीरं नासाश्वासी मुखामये ॥ का .सू .25/8

40)

यस्य वातः प्रकुपितस्त्वङ्मांसान्तरमाश्रितः ।  
शोथं सञ्जनयेत् कुक्षावुदरं तस्य जायते ॥३१॥  
यस्य वातः प्रकुपितः कुक्षिमाश्रित्य तिष्ठति ।  
नाधो व्रजति नाप्यूर्ध्वमानाहस्तस्य जायते ॥३२॥  
रोगाश्चोत्सेधसामान्यदधिमांसार्बुदादयः ।  
विशिष्टा नामरूपाभ्यां निर्देश्याः शोथसङ्ग्रहे ॥३३॥  
वातपित्तकफा यस्य युगपत् कुपितास्त्रयः ।च.सू .18/33

40)

शृणु मांसप्रदोषजान् ॥१३॥  
अधिमांसार्बुदं कीलं गलशालूकशुण्डिके ।  
पूतिमांसालजीगण्डगण्डमालोपजिह्विकाः ॥१४॥  
विद्यान्मांसाश्रयान्, च.सू .28/13

41)

गात्रप्रदेशे क्वचिदेव दोषाः सम्मूर्च्छिता मांसमभिप्रदूष्य ।  
वृत्तं स्थिरं मन्दरुजं महान्तमनल्पमूलं चिरवृद्ध्यपाकम् ॥१३॥  
कुर्वन्ति मांसोपचयं तु शोफं तमर्बुदं शास्त्रविदो वदन्ति । सु .नि .11/13  
दोषः प्रदुष्टो रुधिरं सिरास्तु सम्पीड्य सङ्कोच्य गतस्त्वपाकम् ॥१५॥  
सास्रावमुन्नहयति मांसपिण्डं मांसाङ्कुरैराचितमाशुवृद्धिम् ।  
स्रवत्यजस्रं रुधिरं प्रदुष्टमसाध्यमेतद्रुधिरात्मकं स्यात् ॥१६॥  
रक्तक्षयोपद्रवपीडितत्वात् पाण्डुर्भवेत् सोऽर्बुदपीडितस्तु ।

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मुष्टिप्रहारादिभिरदितेऽङ्गे मांसं प्रदुष्टं प्रकरोति शोफम् ॥१७॥  
अवेदनं स्निग्धमनन्यवर्णमपाकमशमोपममप्रचाल्यम् ।  
प्रदुष्टमांसस्य नरस्य बाढमेतद्भवेन्मांसपरायणस्य ॥१८॥  
मांसार्बुदं त्वेतदसाध्यमुक्तं  
साध्येष्वपीमानि विवर्जयेत्तु ।  
सम्प्रसृतं मर्मणि यच्च जातं स्रोतःसु वा यच्च भवेदचाल्यम् ॥१९॥  
यज्जायतेऽन्यत् खलु पूर्वजाते ज्ञेयं तदध्यर्बुदमर्बुदज्ञैः ।  
यद्द्वन्द्वजातं युगपत् क्रमाद्वा द्विरर्बुदं तच्च भवेदसाध्यम् ॥२०॥  
न पाकमायान्ति कफाधिकत्वान्मेदोबहुत्वाच्च विशेषतस्तु ।  
दोषस्थिरत्वाद्ग्रथनाच्च तेषां सर्वार्बुदान्येव निसर्गतस्तु ॥२१॥ सु .नि .11

41)

तस्य पुनः सङ्ख्यानं - त्वचः कला धातवो मला दोषा यकृत्प्लीहानौ फुफ्फुस उण्डुको  
हृदयमाशया अन्त्राणि वृक्कौ स्रोतांसि कण्डरा जालानि कूर्चा रज्जवः सेवन्यः सङ्घाताः  
सीमन्ता अस्थीनि सन्धयः स्नायवः पेश्यो मर्माणि सिरा धमन्यो योगवहानि स्रोतांसि च  
॥५॥ सु .शा .5/5

41)

गोचन्दना मोहनिका मधुकं माक्षिकं मधु ।  
सुवर्णमिति संयोगः पेयः सौभाग्यमिच्छता ॥२२॥  
पद्मनीलोत्पलकवाथे यष्टीमधुकसंयुते ।  
सर्पिरासादितं गव्यं ससुवर्णं सदा पिबेत् ॥२३॥  
पयश्चानुपिबेत् सिद्धं तेषामेव समुद्भवे ।

अलक्ष्मीघ्नं सदाऽऽयुष्यं राज्याय सुभगाय च ॥२४॥  
 यत्र नोदीरितो मन्त्रो योगेष्वेतेषु साधने ।  
 शब्दिता तत्र सर्वत्र गायत्री त्रिपदा भवेत् ॥२५॥  
 पाप्मानं नाशयन्त्येता दद्युश्चौषधयः श्रियम् ।  
 कुर्युर्नागबलं चापि मनुष्यममरोपमम् ॥२६॥  
 सतताध्ययनं वादः परतन्त्रावलोकनम् ।  
 तद्विद्याचार्यसेवा च बुद्धिमेधाकरो गु(ग)णः ॥२७॥  
 आयुष्यं भोजनं जीर्णं वेगानां चाविधारणम् ।  
 ब्रह्मचर्यमहिंसा च साहसानां च वर्जनम् ॥२८॥  
 इति सुश्रुतसंहितायां चिकित्सास्थाने मेधायुष्कामीयं रसायनं नामाष्टाविंशोऽध्यायः ॥२८॥  
 सु .चि .28/22

42)

महत्तु ग्रन्थितोऽर्बुदम् ॥१४॥  
 तल्लक्षणं च मेदोन्तैः षोढा दोषादिभिस्तु तत् ।  
 प्रायो मेदः कफाढ्यत्वास्थिरत्वाच्च न पच्यते ॥१५॥  
 सिरास्थं शोणितं दोषः सङ्कोच्यान्तः प्रपीड्य च ।  
 पाचयेत तदानद्धं सास्रावं मांसपिण्डितम् ॥१६॥  
 मांसाङ्कुरैश्चितं याति वृद्धिं चाशु स्रवेत्ततः ।  
 अजस्रं दुष्टरुधिरं भूरि तच्छोणितार्बुदम् ॥१७॥  
 तेष्वसृङ्मांसजे वर्ज्ये, चत्वार्यन्यानि साधयेत् ।  
 अ .हु .उ .29/14-18

43)

गात्रप्रदेशे क्वचिदेव दोषाः सम्मूर्छिता मांसमसृक् प्रदूष्य ।  
 वृत्तं स्थिरं मन्दरुजं महान्तमनल्पमूलं चिरवृद्ध्यपाकम् ॥१८॥  
 कुर्वन्ति मांसोच्छ्रयमत्यगाधं तदर्बुदं शास्त्रविदो वदन्ति ।  
 वातेन पित्तेन कफेन चापि रक्तेन मांसेन च मेदसा वा ॥१९॥ मा .नि .38-18,19

49 )

दोषः प्रदुष्टो रुधिरं सिरास्तु सम्पीड्य सङ्कोच्य गतस्त्वपाकम् ॥१५॥  
 सास्रावमुन्नहयति मांसपिण्डं मांसाङ्कुरैराचितमाशुवृद्धिम् ।



स्रवत्यजसं रुधिरं प्रदुष्टमसाध्यमेतद्गुधिरात्मकं स्यात् ॥१६॥  
रक्तक्षयोपद्रवपीडितत्वात् पाण्डुर्भवेत् सोऽर्बुदपीडितस्तु ।

50 )

मुष्टिप्रहारादिभिरदितेऽङ्गे मांसं प्रदुष्टं प्रकरोति शोफम् ॥१७॥  
अवेदनं स्निग्धमनन्यवर्णमपाकमशमोपममप्रचाल्यम् ।  
प्रदुष्टमांसस्य नरस्य बाढमेतद्भवेन्मांसपरायणस्य ॥१८॥  
मांसार्बुदं त्वेतदसाध्यमुक्तं।  
न पाकमायान्ति कफाधिकत्वान्मेदोबहुत्वाच्च विशेषतस्तु ।  
दोषस्थिरत्वाद्ग्रथनाच्च तेषां सर्वार्बुदान्येव निसर्गतस्तु ॥२१॥ सु .नि . 11/15-18

52 )

ग्रन्थीनमर्मप्रभवानपक्वानुद्धृत्य वाअग्निं विदधीत वैद्यः।  
क्षारेण चैतान् प्रतिसारयेत्तु संलिख्य संलिख्य यथोपदेशम् ।  
ग्रन्थार्बुदानाश्च  
यतोअविशेषः प्रदेशहेत्वाकृति दोषदूष्यैः ततश्चिकित्सेद्विषगर्बुदानि विधानविद्  
ग्रन्थिचिकित्सितेन । चक्रदत्त  
वातार्बुदे चात्युपनाहनानि स्निग्धैश्च मांसैरथ वेशवारैः।  
स्वेदं विदध्यात्  
कुशलस्तु नाड्या , शृङ्गेण रक्तं बहुशो हरेत च॥ चक्रदत्त

62)

लक्षणं मनसो ज्ञानस्याभावो भाव एव च ।  
सति ह्यात्मेन्द्रियार्थानां सन्निकर्षे न वर्तते ॥१८॥  
वैवृत्त्यान्मनसो ज्ञानं सान्निध्यात्तच्च वर्तते ।  
अणुत्वमथ चैकत्वं द्वौ गुणौ मनसः स्मृतौ ॥१९॥ च.शा .1/18

63)

अस्ति खलु सत्त्वमौपपादुकं ; यश्ज्जीवं जीवं स्पृशतीति जीवस्पृक् ; जीवस्पृक्शरीरं  
शुक्रशोणितात्मकगर्भशरीरम्; तत्रैव जीवात्मनः प्रथमसम्बन्धो भवतीति तत् जीवस्पृक्  
इत्युच्यते इति योगीन्द्रनाथसेनः ; स्पृक्शरीरेणाभिसम्बन्धनाति, यस्मिन्नपगमनपुरस्कृते  
शीलमस्य व्यावर्तते , भक्तिर्विपर्यस्यते, सर्वेन्द्रियाण्युपतप्यन्ते, बलं हीयते , व्याधय

आप्याय्यन्ते, यस्माद्धीनः प्राणाञ्जहाति , यदिन्द्रियाणामभिग्राहकं च मन इत्यभिधीयते ; तत्रिविधमाख्यायते- शुद्धं, राजसं, तामसमिति । येनास्य खलु मनो भूयिष्ठं, तेन द्विश्तीयायामाजातौ सम्प्रयोगो भवति ; यदा तु तेनैव शुद्धेन संयुज्यते , तदा जातेरतिक्रान्ताया अपि स्मरति । स्मार्तं हि ज्ञानमात्मनस्तस्यैव मनसोऽनुबन्धादनुवर्तते , यस्यानुवृत्तिं पुरस्कृत्य पुरुषो जातिस्मर इत्युच्यते । यानि खल्वस्य गर्भस्य सत्त्वजा नि, यान्यस्य सत्त्वतः सम्भवतः सम्भवन्ति , तान्यनुव्याख्यास्यामः; तद्यथा- भक्तिः शीलं शौचं द्वेषः स्मृतिर्मोहस्त्यागो मात्सर्यं शौर्यं भयं क्रोधस्तन्द्रोत्साहस्तैक्ष्ण्यं मार्दवं गाम्भीर्यमनवस्थितत्वमित्येवमादयश्चान्ये, ते सत्त्वविकारा यानुत्तरकालं सत्त्वभेदमधिकृत्योपदेक्ष्यामः । नानाविधानि खलु सत्त्वानि , तानि सर्वाण्येकपुरुषे भवन्ति, न च भवन्त्येककालम्, एकं तु प्रायोवृत्त्याऽऽह ॥१३॥च.शा .3/13

64)

श्रूयतां षेदमध्यात्ममात्मज्ञानबलं महत् ॥२०॥  
इन्द्रियाणि च सङ्क्षिप्य मनः सङ्क्षिप्य चञ्चलम् ।  
प्रविश्याध्यात्ममात्मज्ञः स्वे ज्ञाने पर्यवस्थितः ॥२१॥  
सर्वत्रावहितज्ञानः सर्वभावान् परीक्षते । च.शा .3/21

65)

तेषां तु खलु स्रोतसां यथास्थूलं कतिचित्प्रकारान्मूलतश्च प्रकोपविज्ञानतश्चानुव्याख्यास्यामः; ये भविष्यन्त्यलमनुक्तार्थज्ञानाय ज्ञानवतां , विज्ञानाय चाज्ञानवताम् । तद्यथा - प्राणोदकान्तरसरुधिरमांसमेदोस्थिमज्जशुक्रमूत्रपुरीषस्वेदवहानीति; वातपित्तश्लेष्मणां पुनः सर्वशरीरचराणां सर्वाणि स्रोतांस्ययनभूतानि , तद्वदतीन्द्रियाणां पुनः सत्त्वादीनां केवलं चेतनावच्छरीरमयनभूतमधिष्ठानभूतं च । तदेतत् स्रोतसां प्रकृतिभूतत्वान्न विकारैरुपसृज्यते शरीरम् ॥६-७॥ च.वि .5/7  
शीताः सेकाः प्रलेपाश्च विरेकः पथ्यभोजनम्॥  
स्त्रावणं चाविदग्धस्य दोषदेहव्यपेक्षया ।  
स्य पाटनं कुर्यान्मृजां विद्रधिवत् च तत्॥ का .सू .19









## PATIENT INFORMATION SHEET

या संशोधन उपक्रमामधे आपण स्वेच्छेने सहभागी होत आहात . तदर्थ या संशोधनाशी व आपल्याशी संबंधित माहिती आपणास विदित करणे,आवश्यक आहे .

### 1. संशोधनाचा उद्देश -

स्तन कर्करोगग्रस्त रुग्णेतील मानसिक अस्वास्थ्य दूर करणे.

### 2. निवड निकष -

स्तन कर्करोगग्रस्त आणि मानसिक तणाव , अस्वास्थ्य , उद्वेग , भय यांनी ग्रस्त रुग्णा.

### 3. सहभाग -

रुग्णाची संपूर्ण संमती आवश्यक . चिकित्सा उपक्रम आवश्यक असताना कोणत्याही क्षणी , कोणत्याही कारणाशिवाय सहभाग रद्द करण्याची मुभा . त्यानंतरही अन्य चिकित्सा चालू राहतील .

### 4. संशोधन उपक्रम माहिती -

संबंधित रुग्णेस सलग सात दिवस सकाळी चिकित्सालयात यावे लागेल. त्यानंतर उपचार कक्षामधे; रुग्णेवर तीस मिनिटपर्यंत आौषधानी सिध्द केलेल्या तेलाने शिरोधारा उपचार केला जाईल . सदर उपचाराचे प्रतिकात्मक छायाचित्र सोबत जोडले आहे .या उपचारानंतर तीस मिनिटांनी आपण घरी जाऊ शकता . आपल्या शरीरातील व मानसिक बदलांची नोंद रुग्णपत्रिकेवर वेळोवेळी

केली जाईल .यानंतर तिसाव्या दिवशी आपणास पुनः परीक्षणार्थ चिकित्सालयात यावे लागेल.

### 5. दुष्परिणामांची शक्यता -

सदर उपचारांदरम्यान अथवा नंतर दुष्परिणाम होण्याची शक्यता दुरापास्त आहे . तरीही कोणत्याही क्षणी ,तुम्ही संबंधित वैद्यांशी संपर्क साधू शकता .

### 6. उपचारामुळेफायदा -

उपचारामुळे फायदा होईलच , याची खात्री नाही . परंतु , सदर संशोधनामुळे ; उपचारांची परिणामकारकता सिद्ध करण्यासाठी पुरेशा सांख्यिक नोंदी निर्माण होतील .

#### 7. उपक्रमातील सहभागाने नुकसान -

उपक्रमातील सहभागाने कोणतेही नुकसान शारीरिक , मानसिक नुकसान होत आहे , असे आढळल्यास , कोणत्याही क्षणी ,तुम्ही संबंधित वैद्यांशी संपर्क साधू शकता.

#### 8. गोपनीयता -

आपली संपूर्ण माहिती गोपनीय व सुरक्षित ठेवली जाईल . केवळ संशोधनकर्ता व वरिष्ठ जबाबदार व्यक्तींनाच त्याबद्दल माहिती असेल .परंतु रुग्णाची ओळख व शारीरिक , मानसिक व्याधींचा तपशील गोपनीयच असेल .

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इस संशोधन उपक्रम में आप स्वेच्छासे सहभागी हो रहे हो । तदर्थ इस संशोधन से और आपसे सम्बंधित जानकारी आपको विदित करना आवश्यक हैं ।

#### 1. संशोधन का उद्देश -

स्तन कर्करोगग्रस्त रुग्णका मानसिक अस्वास्थ्य दूर करना ।

#### 2. निवड निकष -

स्तन कर्करोगग्रस्त और मानसिक तणाव , अस्वास्थ्य , उद्वेग , भय इससे ग्रस्त रुग्ण ।

#### 3. सहभाग -

रुग्ण की संपूर्ण सहमति आवश्यक हैं । चिकित्सा उपक्रम चालू रहते समय किसी भी क्षण , बिना किसी कारन के सहभाग रद्द कर सकते हैं । उसके बाद भी अन्य चिकित्सा चालू रहेगी ।

#### 4. संशोधन उपक्रम जानकारी -



संबंधित रुग्णको सलग सात दिन सुबह चिकित्सालय में आना पडेगा । उसके बाद उपचार कक्ष में ; रुग्णपर तीस मिनिटतक औषध सिध्द तैल से शिरोधारा उपचार किया जाएगा । सदर उपचार के प्रतिकात्मक छायाचित्र उसके साथ जोडा जाएगा । ईस उपचार के तीस मिनिट बाद आप घर जा सकते हो । आपके शारीरिक और मानसिक बदलाव की जानकारी रुग्णपत्रिकापर हर समय की जाएगी । इसके तीस दिन के बाद आपको पुनः परिक्षनार्थ चिकित्सालय में आना होगा ।

#### 5. दुष्परिणामो की शक्यता -

सदर उपचारो के दरम्यान अथवा बादमें दुष्परिणामो की शक्यता दुरापास्त हैं । फिर भी किसी भी क्षण ,आप संबंधित वैद्यसे संपर्क कर सकते हो ।

#### 6. उपचार के फायदे -

उपचार से फायदा होगाही , इसकी शाश्वती नहीं । परंतु , इस संशोधन से ; उपचार की परिणामकारकता सिद्ध करने अल्पशः सांख्यिक नोंद निर्माण होगी ।

#### 7. उपक्रम में सहभाग होनेसे नुकसान -

उपक्रम में सहभागसे कोई भी शारीरिक , मानसिक नुकसान हो रहा हैं ऐसा मिलने पर ,उसकी भरपाई संशोधनकर्ता से की जाएगी ।

#### 8. गोपनीयता -

आपकी पूरी जानकारी गोपनीय और सुरक्षित रखी जाएगी । केवल संशोधनकर्ता और वरिष्ठ जिम्मेदार व्यक्तियोंको ही उसके बारे में जानकारी होगी । परंतु रुग्ण की पहचान और शारीरिक , मानसिक व्याधी की जानकारी गोपनीय ही रहेगी ।

**PATIENT INFORMATION SHEET**

You are willingly participating in this Research clinical trial. So, it is essential that you should be informed the about this trial.

Aim of Research-

To achieve mind relaxation in TNBC patients to relieve their Psychological Stress.

Criteria of patient selection-

Patients who are diagnosed to have TNBC(Triple Negative Breast Cancer) and have psychological Distress in form of Anxiety, Depression

3. Paticipation in Trial

Written Informed Consent of patient is essential. Patient is free to withdraw his participation at any time, without giving reason. Withdrawl of participation wont affect his further medical care.

4. Information about the Treatment-

Patient has to visit the centre daily for consecutive 7 days. Then, patient will made lie down in Therapy room for treatment procedure. During therapy, medicated warm oil will be slowly poured in continuous stream on patient's forehead. Total procedure will take 20-30 minutes. Picture of Therapy is attached herewith. Patient can go home after 30 minutes of the Therapy. Patient will be clinically examined time to time. After 7 days Therapy; patient has to report on 30<sup>th</sup> Day for clinical examination.

5. Possibility of Side effects-

Chances of any side effects, drug reaction or any other trouble; are almost zero. Still, if you notice any change, you can contact anytime.

6. Benefits from the Treatment-

We are not assuring that you will get benefitted. These Ayurvedic Treatments are applied since time immortal. So, chances of benefit are very high. Still, your participation will contribute to generate sufficient clinical and statistical Data for further Research.

7. Loss due to participation-

There are least to no chances of any loss or trouble. Still, if you feel anything related to your health status, you should immediately inform above mentioned.

8. Confidentiality-

Patient's identity, medical record and other information will be kept totally confidential. Only Research scholar and Responsible Authority will have access to records for research purpose. Still, patient identity will not be exposed.

## रुग्ण संमती पत्रक

1.रुग्णनाम

2.अनुक्रमांक

3.मी खात्रीशीरपणे मान्य करते की या संशोधन कामाबद्दल संपूर्ण तपशील मला समजेल अशा भाषेत मला सविस्तरपणे सांगण्यात आला असुन; तो मला समजला आहे . जरूरीप्रमाणे प्रश्न विचारण्याची ही मुभा मला आहे .

4.माझा सहभाग पूर्णतः स्वसंमतीने असुन , मी कोणत्याही क्षणी माझा सहभाग कोणतेही कारण न देता रद्द करू शकतो . तसेच त्याचा माझ्या वैद्यकीय काळजी घेण्यावर परिणाम होणार नाही , याची हमी दिली आहे .

5.माझी वैद्यकीय माहिती व प्रगती नोंद करुन त्याचा अहवाल बनविण्यात येईल व माझी ओळख गुप्त राहील , याची कल्पना दिली आहे .

6.ही माहिती फक्त संशोधन कामासाठीच वापरली जाईल व जरूरीप्रमाणे जबाबदार व्यक्तींनाच फक्त ती उघड केली जाईल , असे मला आश्वासन दिले आहे .

7.सदर संशोधनामध्ये तीस दिवसांसाठी सहभागी होण्यास; मी स्वेच्छेने संमती देत आहे .

## रुग्ण अनुमती पत्रक

1.रुग्णनाम

2.अणुक्रमांक

3. मैं स्वेच्छासे हामी भरता /भरती हूँ की इस संशोधन के बारे में मुझे पूरी जानकारी मेरे समझ में आये इस भाषा में सम्बंधित डॉक्टरोंने मुझे दी हैं। ये जानकारी मुझे समझ में आयी हैं । और जरूरत के हिसाब से मुझे प्रश्न पुछने की इजाजत भी दी गई हैं ।

4.मेरा सहभाग पूर्णतः स्वेच्छासे हैं ,मैं किसी भी क्षण मेरा सहभाग बिना किसी कारन से स्थगित करने का अधिकार मैं रखती हूँ । और उसका ; मेरे भावी इलाज पर कोई असर नहीं होगा ।

5.मेरी वैद्यकीय जानकारी और प्रगती का अहवाल बनाया जायेगा और मेरी पहचान गुप्त रखी जायेगी , इसके बारे में मुझे जानकारी दी गई हैं ।

6. ये जानकारी सिर्फ संशोधन के लिये ही इस्तमाल की जाएगी और जरूरत के हिसाब से जिम्मेदार लोगोंको ही दी जायेगी ऐसा आश्वासन मुझे दिया गया हैं ।

7.इस संशोधन में तीस दिन के लिये सहभाग होने के लिये मैं स्वेच्छासे संमती देती हूँ ।

## INFORMED CONSENT FORM

1. Name of the Patient-
2. Enrollment Code No.-
3. I confidently declare that I have been thoroughly explained about this trial, in the language; that I understand. I have understood it. I can ask questions, whenever I feel.
4. My participation in this particular trial is clearly with my own consent. Si wish to complete trial. Still, I can withdrew from trial at any point in time, without any reason. This wont affect my further care in same center.
5. Total clinical data and medical records will be made during trial and my identity will not be revealed. It will be confidential.
6. I am assured that This clinical information will only be used for Research purpose and Researcher and responsible authorities will only handle this data and information.
7. I am ready to participate in this Research Trial for 30 day. Iam giving consent for the same.

Name of patient

Date

Contact Number

Signature

Name of Witness

Date

Contact Number

Signature

Name of Researcher

Date

Contact Number

Signature

### Zung Self-Rating Depression Scale (SDS )

For each item below, please place a check mark ( felt or behaved this way during the past several days).

	A Little of the Time 1	Some of the Time 2	Good part of the Time 3	Most part of the Time 4
1. I Feel down hearted and blue.				
2. Morning is when I Feel the best.				
3. I have crying spells or feel like it.				
4. I have trouble sleeping at night.				
5. I eat as much as I used to.				
6. I still enjoy sex.				
7. I notice that Iam losing weight.				
8. I have trouble with constipation .				
9. My heart beats faster than usual.				
10. I get tired for no reason.				
11. My mind is as clear as it used to be.				
12. I find it easy to do the things I used to.				
13. I am restless and can't keep still.				
14. I feel hopeful about the future.				
15. I am more irritable than usual.				
16. I find it easy to make decisions.				
17. I feel that I am useful and needed.				
18. My life is pretty full.				
19. I feel that others would be better off if I were dead.				
20. I still enjoy the things I used to do.				

The Zung Self-Rating Depression Scale was designed by Duke University psychiatrist William W.K. Zung MD (1929–1992) to assess the level of depression for patients diagnosed with depressive disorder.

- 20-44 Normal Range
- 45-59 Mildly Depressed
- 60-69 Moderately Depressed
- 70 and above Severely Depressed



## ZUNG'S SELF RATING ANXIETY SCALE

For each item below, please check the column which best describes how often you felt or behaved this way **during the past several days**.

	None or a Little of the Time 1	Some of the Time 2	Good part of the Time 3	Most or all of the Time 4
1. I feel more nervous and anxious than usual.				
2. I feel afraid for no reason at all.				
3. I get upset easily or feel panicky.				
4. I feel like I am falling apart and going to piece.				
5. I feel that everything is all right and nothing bad will happen.				
6. My arms and legs shake and tremble.				
7. I am bothered by headaches, neck and back pains.				
8. I feel weak and get tired easily				
9. I feel calm and can sit still easily.				
10. I can feel my heart beating fast.				
11. I am bothered by dizzy spells.				
12. I have fainting spells or feet faint.				
13. I can breathe in and out easily.				
14. I get feelings of numbness and tingling in my fingers and toes.				
15. I am bothered by stomachaches or indigestion.				
16. I have to empty my bladder often.				
17. My hands are usually dry and warm.				
18. My face gets hot and blushes.				
19. I fall asleep easily and get a good night's rest.				
20. I have nightmares.				

**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):

---

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?				
2	Do you have any trouble taking a long walk?				
3	Do you have any trouble taking a short walk outside of the house?				
4	Do you need to stay in bed or a chair during the day?				
5	Do you need help with eating, dressing, washing yourself or using a toilet?				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
6	Were you limited in doing either your work or other daily activities?				
7	Were you limited in pursuing your hobbies or other leisure time activities?				
8	Were you short of breath?				
9	Have you had pain?				
10	Did you need to rest?				
11	Have you had trouble sleeping?				
12	Have you felt weak?				
13	Have you lacked appetite?				
14	Have you felt nauseated?				
15	Have you vomitted?				
16	Have you been constipated?				



**EORTC QLQ - BR23**

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
31	Did you have a dry mouth?				
32	Did food and drink taste different than usual?				
33	Were your eyes painful, irritated or watery?				
34	Have you lost any hair?				
35	Answer this question only if you had any hair loss: Were you upset by the loss of your hair?				
36	Did you feel ill or unwell?				
37	Did you have hot flushes?				
38	Did you have headaches?				
39	Have you felt physically less attractive as a result of your disease or treatment?				
40	Have you been feeling less feminine as a result of your disease or treatment?				
41	Did you find it difficult to look at yourself naked?				
42	Have you been dissatisfied with your body?				
43	Were you worried about your health in the future?				

**During the past four weeks:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
44	To what extent were you interested in sex?				
45	45. To what extent were you sexually active? (with or without intercourse)				
46	Answer this question only if you have been sexually active: To what extent was sex enjoyable for you				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
47	Did you have any pain in your arm or shoulder?				
48	Did you have a swollen arm or hand?				
49	Was it difficult to raise your arm or to move it sideways?				
50	Have you had any pain in the area of your affected breast? Was the area of your affected breast swollen?				
51	Was the area of your affected breast oversensitive?				
52	Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?				

## KARNOFSKY SCALE

The Karnofsky Performance Scale Index allows patients to be classified as to their functional impairment. This can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses.

### KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS RATING (%) CRITERIA

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

**CASE REPORT FORM I - SCREENING**

**CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF JATAMANSI OIL SHIRODHARA ON CHITTODVEGA ( MENTAL DISTRESS) IN PATIENTS HAVING TNBC ( Triple Negative Breast Cancer)**

**Participant's Name:**

**Group: Group I**

**Group II**

**Date of Induction into the Clinical Trial (Baseline Visit – Day 0)**

**DATES OF SUBSEQUENT VISITS:**

Day 7<sup>th</sup>

Day 30<sup>th</sup>

**STATUS:**

The Participant **completed/** was  
trial

**withdrawn from /**

**Dropped out from** the

**Signature of the Guide**

**Signature of the Researcher**

**CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF JATAMANSI OIL  
SHIRODHARA ON CHITTODVEGA ( MENTAL DISTRESS) IN PATIENTS HAVING TNBC ( Triple Negative Breast Cancer)**

**CASE REPORT FORM I – SCREENING**

**BEFORE TREATMENT**

OPD No: \_\_\_\_\_

Name of the Participant: \_\_\_\_\_

Age: \_\_\_\_\_ years and \_\_\_\_\_ months

Date of birth 

--	--	--	--	--	--	--	--

  
**D    D    M    M    Y    Y    Y    Y**

Address: \_\_\_\_\_

Telephone No: \_\_\_\_\_

Occupation

Marital Status

**INCLUSION CRITERIA**

1. Age- 25 to 70 years
2. Known cases of tnbc by histology and immunohistochemically
3. Known cases of TNBC ( Immunohistochemically proven ER, PR, Her2 Negative) patients
4. Patients who are freely giving Consent for the Trial

**EXCLUSION CRITERIA**

1. Age- Below 25 years and above 70 years
2. Patients with known psychological illness prior to CA Breast
3. Non-complaint patients
4. Breast Cancer Pts- Er, Pr, Her2 –Any 1 Positive

Whether the participant is suitable for enrollment in the study? **Yes** / **No**

**If enrolled:** Subject Enrollment No.:

**Group:** Group I / Group II

**Name of the Researcher**

**Signature**

**Date**

**CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF JATAMANSI OIL SHIRODHARA ON CHITTODVEGA ( MENTAL DISTRESS) IN PATIENTS HAVING TNBC ( Triple Negative Breast Cancer)**

**CASE REPORT FORM II A - HISTORY AT BASELINE  
DEMOGRAPHIC PROFILE**

Marital status:

Educational status:

Past occupation:

Present Occupation

Socio-economic status:

Habitat:

Religion:

**Chief complaints with duration-in days**

SR. NO.	SYMPTOM	NO	IF YES, DURATION	
1	Restlessness, Anxious			
2	Irritability			
3	Difficulty in concentrating			
4	Worthlessness			
5	Crying spells			
6	Fearfulness			
7	Tingling & Numbness in limbs			
8	Dryness of mouth			
9	Dyspnoea			
10	Tachycardia			
11	Sleep Disturbances			
12	Easy Fatiguability			
13	Suicidal thoughts			
14	Fainting			
15	Increased frequency of passing Urine & Stools			





C/O

Diagnosis-

Type

Stage

Grade

Mammography

Histopathology

Treatment Taken

Current Status

Any Emotional Stress:-

Average

Moderate

Too Much

(i) Dietary Habits:

(ii) Sleep:

(iii) Bowel Habits

Stool Consistency:

(iv) Urine Output:

(v) Physical Exercise:

(vi) Allergy to Some Material:

**1. General Physical Examination:**

Sr. No.	Part to be examined	Findings
1	Pulse	
2	Blood Pressure	
3	Respiratory Rate	
4	Temperature	
5	Height	
6	Weight	
7	BMI	
8	Nutrition	
9	Built	

10	Pallor	
11	Oedema	
12	Lymphadenopathy	
13	Tongue	
14	Lips	
15	Eyes	
16	ENT	
17	Thyroid Gland	
18	Nails	

## 2. SYSTEMIC EXAMINATION

(1)Respiratory System:

(2)Gastro-IntestinalSystem:

(3)Cardio-vascularSystem

(4) Nervous System:

(5) Musculo-skeletal System:

(6) Genito-urinary System:

**Name of the Researcher**

**Signature**

**Date**

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**CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF JATAMANSI OIL  
SHIRODHARA ON CHITTODVEGA ( MENTAL DISTRESS) IN PATIENTS HAVING TNBC ( Triple Negative Breast Cancer)**

**CASE REPORT FORM II B**

**AYURVEDIC PARAMETERS**

**Ashtavidh Pareeksha**

Nadi

Mala

Mootra

Jivh

Shabda

Sparsh

Druk

Aakruti

Agni

Koshtha

**Assessment of Prakriti:**

<b>FEATURES</b>	<b>VATA (V)</b>	<b>PITTA (P)</b>	<b>KAPHA(K)</b>	<b>V</b>	<b>P</b>	<b>K</b>
<b>Voice</b>	Low, weak, hoarse, cracks	Medium, clear	Deep, pleasant			
<b>Speech</b>	Quick, talkative	Argumentative, likes debate, convincing	Slow, deliberate			
<b>Sleep pattern</b>	Light, tends towards insomnia	Moderate but sound	Heavy, difficult to wake up, sleeps easily			
<b>Speed of work</b>	Fast, in a hurry	Medium, fast	Steady, slow			
<b>Complexion</b>	Dull, brown, tans without sunburn	Flushed, pigmented, fair, sunburns easily	White, pale, tans evenly with little sunburn			

<b>Consumption of food and drinks</b>	Not fixed	Comparatively more	Comparatively less			
<b>Snacks</b>	Likes crunchy snacks	Likes cold drinks and snacks	Sweets and creamy snacks			
<b>Food preferences</b>	Hot and Wet	Cold and warm	Hot and dry			
<b>Climate preferences</b>	Likes sunny weather	Likes cool weather	Likes warmth, suffers in the cold			
<b>Habits</b>	Likes traveling, fun, entertainment	Likes physical sports, politics, activities	Water sports, gardening, business			
<b>Grasping power</b>	Sometimes grasps quickly	Quick to grasp, very sharp	Grasps late but understands best			
<b>Emotional state</b>	Anxious, nervous, creative	Angry, irritable, jealous	Attached, sentimental, depressed			
<b>Memory</b>	Quick but poor in the long term	Clear	Slow, good in the long term			
<b>Finance management</b>	Spends freely	Tends to budget	Saves, spends emotionally			
<b>When threatened</b>	Fearful, anxious	Angry, irritable, fights	Indifferent, withdraws			
<b>Tackling problems</b>	Worrying constantly, cannot take one stable decision	Takes firm decision quickly	Can take the right and firm decision but takes time			
<b>Cannot tolerate</b>	Cold	Heat, anger, physical or mental exertion, hunger, thirst, physical urges	Can tolerate cold, heat, anger, exertion, physical urges, hunger or thirst			
<b>Nature of dreams</b>	Flying, Moving, Strong Winds, Nightmares	Colorful, passionate, fire, lightning, conflicts	Romantic, uneventful, few dreams, water, gardens, faintly colored			
<b>Thought process</b>	Questions, theorizes	Judgmental, artistic	Stable, logical			

Type of prakriti =

**Assessment of Saara:**

Sr. No.	DHATU	Heena	Madhyam	Uttam
	Rasa / Twak			
	Rakta			
	Mansa			
	Meda			
	Asthi			
	Majja			
	Shukra			
	Sattva			

**Assessment of Samhanana:**

Pravara

Madhyama

Avara

**Assessment of Satmya:**

Sr. No.		Avar	Madhyam	Pravar
1	Aahar			
2	Desha			
3	Kaal			

**Type of Satmya:** Pravara Satmya / Madhyama Satmya / Avara Satmya**Assessment of Satva:**

In the recent past, any event of crisis like

		Was inconsolable AVAR	Could be tolerated with some support from the family and/or friends MADHYAM	Well Tolerated PRAVAR
1	loss of a family member/close friend			
2	loss of money/loss in business			
3	severe deterioration in health of self or a loved one			

**Type of Satva:** Pravara Satva      Madhyama Satva      AvaraSatva**Assessment of Ahara Shakti:**

## Assessment of Vyayama Shakti:

### Srotas Examination

S.No	Srotas	Dushti Hetu	Dushti Lakshan	Dushti Teevrata
1.	Rasavaha			
2	Aartavavaha			
3	Stanyavaha			

Manovaha Srotas Pareekshan

मनोवहस्त्रोतस

Manas Prakruti-

1. सद्यपरीक्षण मन

मानसिकवेग( सम्यकयोग / अयोग / हीनयोग / मिथ्यायोग / अतियोग )

योग्य	अयोग्य
हर्ष - आमोद	मोह - अविज्ञान (ज्ञानस्यअभाव )
प्रीति-तोष	क्रोध - अभिद्रोह (परपीडार्थप्रवृत्ती )
धैर्य	शोक - दैन्य (रोदनादि )
अवस्थान - स्थिरमति	भय - विषाद
श्रद्धा- इच्छा	नैर्लज्य-

हि- लज्जा	द्वेष - प्रतिषेध (व्यावृत्ति )
मेधा - ग्रहणशक्ति	वश्यता
संज्ञा- नामग्रहण	ईर्ष्या
स्मृति - स्मरण	अतिराग( अचितविषयेपुनःपुनः प्रवर्तनेच्छा)
शील - सहजवस्तुपुरागः	अभिध्या (परद्रव्यविषयेस्पृहा )
उपाधि - छद्म	लोभ
धृति - अलौल्य	मान(सत्- असत्गुणअध्यारोपेणआत्मनिउत्कर्षप्रत्यय)
उपस्थितश्रेयस्व- श्रेयस्करमार्गानुष्ठान	
अमलसत्त्व	

मनाचीकार्ये

चिन्त्यं - कर्तव्यतयाअकर्तव्यतयावायन्मनसाचिन्त्यते।

विचार्य- उपपत्त्यनुपपत्तिभ्यांयद्विमृश्यते।

ऊह्यं - यत्सम्भवनयाऊह्यतेएवमेतद्भविष्यति (अथवाएवमेतद्भवतिइतिपाठः !) इति।

ध्येयं - भावनाज्ञानविषयम्।

सङ्कल्प- गुणवत्तयादोषवत्तयावासवधारणाविषयम्।

प्राकृत

विकृत

1. मूळस्वभाव

शांत / चिडचिडा / रागीट / काळजीकरण्याचा / कुढण्याचा /आशावादी / निराशावादी /अंतर्मुख / बहिर्मुख /

भिन्ना / धीट / अतिमहत्वाकांक्षी



2. आजारामूळे स्वभाव परिवर्तन ?होय/ नाही
3. व्याधिनिदानापूर्वी ताण होता का ?होय /नाही

कुठल्या स्वरूपाचा ताण ?

शारीरिक / मानसिक / आर्थिक / व्यावसायिक/ सामाजिक /कौटुंबिक

4. मनोवैचित्य आहे का ?

5. भयातछर्दि / अतिसार आहे का ?

ओज	शारीरिक	मानसिक
क्षयलक्षणे	मलिनकांती, मूर्छा, प्रलाप	मोह, मनोदौर्बल्य, गतोत्साह, चिंता, व्यथितेंद्रिय
ओजोव्यापद	ग्लानि, तंद्रा, निद्रा, स्तब्धगात्रता गुरुगात्रता वर्णभेद	ग्लानि, तंद्रा
ओजोविस्त्रंस	गात्रसाद, संधिविश्लेष, क्रियासान्निरोध, दोषच्यवन	

ANYA DUSHTA SROTAS PAREEKSHAN ( IF ANY)

**Rogapariksha (Examination of stages of disease):**

- a) Nidana (Aetiology):
- b) PurvaRoopa (Prodromal Symptoms):
- c) Rupa (Signs & Symptoms):
- d) Samprapti (Pathogenesis):

Samprapti Ghataka:

**CLINICAL ASSESSMENT OF MIND RELAXATION EFFECT OF JATAMANSI OIL  
SHIRODHARA ON CHITTODVEGA ( MENTAL STRESS) IN PATIENTS HAVING TNBC (**  
**Triple Negative Breast Cancer)**

**DRUG COMPLIANCE REPORT FORM-I**

**(To be filled by the trial participant)**

[To be issued **on Enrollment Day** (Baseline Day 1) and taken back in the next visit]

Participant Enrollment No: \_\_\_\_\_

Please come for next visit on \_\_\_\_\_ (Date and time is to be filled by the Investigator)

<b>Day</b>	<b>Date</b>	<b>Shirodhara with Jatamansi Oil</b> <b>Please put mark after taking the therapy</b>	<b>Any other information</b>
1.			
2.			
3.			
4.			
5.			
6.			
7.			

**Drug Compliance:**

➤ No. of sessions of Shirodhara \_\_\_\_\_ Percentage of Compliance: \_\_\_\_\_

**Signature / Thumb impression of Participant with date:** \_\_\_\_\_

**Signature of the Researcher with date:** \_\_\_\_\_

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## CASE REPORT FORM

**Assessment on Day 7<sup>th</sup>**

DATE

### Clinical Examination

SR. NO.	SYMPTOM	NO	IF YES, DURATION
1	Restlessness, Anxious		
2	Irritability		
3	Difficulty in concentrating		
4	Worthlessness		
5	Crying spells		
6	Fearfulness		
7	Tingling & Numbness in limbs		
8	Dryness of mouth		
9	Dyspnoea		
10	Tachycardia		
11	Sleep Disturbances		
12	Easy Fatiguability		
13	Suicidal thoughts		
14	Fainting		
15	Increased frequency of passing Urine & Stools		

**Concomitant Medication:** Need for any Concomitant Medication: Yes / No

S. No.	Medicine	Dose	Duration	Reason for taking

**Rescue Medication:** Need for any Rescue Medication: Yes / No

S. No.	Medicine	Dose	Duration	Reason for taking

**Adverse Drug Reactions / Adverse Events:** Any adverse effects/other complaints: Yes/ No

Date	Complaint	Treatment given	Remarks

**Did the patient drop out on his / her own? Yes (1)**  **No (0)**

If yes, date & reasons (in detail): \_\_\_\_\_

**Was the patient withdrawn from the trial? Yes (1)**  **No (0)**

If yes, date & reasons (in detail): \_\_\_\_\_

**Drug Compliance:**

- No. of sessions of Shirodhara \_\_\_\_\_
- Percentage of Compliance: \_\_\_\_\_

Remark

**Name of the Researcher**                      **Signature**                      **Date**

---

## **CASE REPORT FORM**

**Assessment on Day 30<sup>th</sup>**

**DATE**

### **Clinical Examination**

SR. NO.	SYMPTOM	NO	IF YES, DURATION	
1	Restlessness, Anxious			
2	Irritability			
3	Difficulty in concentrating			
4	Worthlessness			
5	Crying spells			
6	Fearfulness			
7	Tingling & Numbness in limbs			
8	Dryness of mouth			
9	Dyspnoea			
10	Tachycardia			
11	Sleep Disturbances			
12	Easy Fatiguability			
13	Suicidal thoughts			
14	Fainting			
15	Increased frequency of passing Urine & Stools			

**SCALEWISE ASSESSMENT**

Sr. No.	CRITERIA	Day 0	Day 7	Day 30
1	Subjective- Symptoms			
2	Zung's Self Rating Anxiety Scale			
3	Zung's Self Rating Depression Scale			
4	EORTC QLQ C30 Scale			
	EORTC QLQ BR23 Scale			
	Karnofsky Scale			

**LABORATORY PARAMETERS:**

S.No.	Investigation / Test	0 day	7th	30 <sup>th</sup> day
1.	Haemoglobin		<b>NOT APPL  ICA  BLE</b>	
2.	TLC			
3.	<b>DLC</b>			
	5. N %			
	6. E %			
	7. B %			
	8. L %			
	9. M %			
4.	ESR			
5.	LFT			
6.	KFT			
7.	CRP			
8.	CA 15.3			

**Concomitant Medication:** Need for any Concomitant Medication: Yes / No

S. No.	Medicine	Dose	Duration	Reason for taking

**Rescue Medication:** Need for any Rescue Medication: Yes / No

S. No.	Medicine	Dose	Duration	Reason for taking

**Adverse Drug Reactions / Adverse Events:** Any adverse effects/other complaints: Yes/ No

Date	Complaint	Treatment given	Remarks

**Status of the study subject:**

Completed the study (1)

Drop out (2)

Expired (3)

Reason: \_\_\_\_\_

Cause: \_\_\_\_\_

**Name of the Researcher**

**Signature**

**Date**

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### Zung Self-Rating Depression Scale (SDS )

For each item below, please place a check mark ( felt or behaved this way during the past several days).

	A Little of the Time 1	Some of the Time 2	Good part of the Time 3	Most part of the Time 4
1. I Feel down hearted and blue.				
2. Morning is when I Feel the best.				
3. I have crying spells or feel like it.				
4. I have trouble sleeping at night.				
5. I eat as much as I used to.				
6. I still enjoy sex.				
7. I notice that Iam losing weight.				
8. I have trouble with constipation .				
9. My heart beats faster than usual.				
10. I get tired for no reason.				
11. My mind is as clear as it used to be.				
12. I find it easy to do the things I used to.				
13. I am restless and can't keep still.				
14. I feel hopeful about the future.				
15. I am more irritable than usual.				
16. I find it easy to make decisions.				
17. I feel that I am useful and needed.				
18. My life is pretty full.				
19. I feel that others would be better off if I were dead.				
20. I still enjoy the things I used to do.				



## ZUNG'S SELF RATING ANXIETY SCALE

For each item below, please check the column which best describes how often you felt or behaved this way **during the past several days**.

	None or a Little of the Time 1	Some of the Time 2	Good part of the Time 3	Most or all of the Time 4
1. I feel more nervous and anxious than usual.				
2. I feel afraid for no reason at all.				
3. I get upset easily or feel panicky.				
4. I feel like I am falling apart and going to piece.				
5. I feel that everything is all right and nothing bad will happen.				
6. My arms and legs shake and tremble.				
7. I am bothered by headaches, neck and back pains.				
8. I feel weak and get tired easily				
9. I feel calm and can sit still easily.				
10. I can feel my heart beating fast.				
11. I am bothered by dizzy spells.				
12. I have fainting spells or feet faint.				
13. I can breathe in and out easily.				
14. I get feelings of numbness and tingling in my fingers and toes.				
15. I am bothered by stomachaches or indigestion.				
16. I have to empty my bladder often.				
17. My hands are usually dry and warm.				
18. My face gets hot and blushes.				
19. I fall asleep easily and get a good night's rest.				
20. I have nightmares.				

**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):

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
1	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?				
2	Do you have any trouble taking a long walk?				
3	Do you have any trouble taking a short walk outside of the house?				
4	Do you need to stay in bed or a chair during the day?				
5	Do you need help with eating, dressing, washing yourself or using a toilet?				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
6	Were you limited in doing either your work or other daily activities?				
7	Were you limited in pursuing your hobbies or other leisure time activities?				
8	Were you short of breath?				
9	Have you had pain?				
10	Did you need to rest?				
11	Have you had trouble sleeping?				
12	Have you felt weak?				
13	Have you lacked appetite?				
14	Have you felt nauseated?				
15	Have you vomitted?				
16	Have you been constipated?				



**EORTC QLQ - BR23**

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week.

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
31	Did you have a dry mouth?				
32	Did food and drink taste different than usual?				
33	Were your eyes painful, irritated or watery?				
34	Have you lost any hair?				
35	Answer this question only if you had any hair loss: Were you upset by the loss of your hair?				
36	Did you feel ill or unwell?				
37	Did you have hot flushes?				
38	Did you have headaches?				
39	Have you felt physically less attractive as a result of your disease or treatment?				
40	Have you been feeling less feminine as a result of your disease or treatment?				
41	Did you find it difficult to look at yourself naked?				
42	Have you been dissatisfied with your body?				
43	Were you worried about your health in the future?				

**During the past four weeks:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
44	To what extent were you interested in sex?				
45	45. To what extent were you sexually active? (with or without intercourse)				
46	Answer this question only if you have been sexually active: To what extent was sex enjoyable for you				

**During the past week:**

		NOT AT ALL 1	A LITTLE 2	QUITE A BIT 3	VERY MUCH 4
47	Did you have any pain in your arm or shoulder?				
48	Did you have a swollen arm or hand?				
49	Was it difficult to raise your arm or to move it sideways?				
50	Have you had any pain in the area of your affected breast? Was the area of your affected breast swollen?				
51	Was the area of your affected breast oversensitive?				
52	Have you had skin problems on or in the area of your affected breast (e.g., itchy, dry, flaky)?				

## KARNOFSKY SCALE

The Karnofsky Performance Scale Index allows patients to be classified as to their functional impairment. This can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses.

### KARNOFSKY PERFORMANCE STATUS SCALE DEFINITIONS RATING (%) CRITERIA

Able to carry on normal activity and to work; no special care needed.	100	Normal no complaints; no evidence of disease.
	90	Able to carry on normal activity; minor signs or symptoms of disease.
	80	Normal activity with effort; some signs or symptoms of disease.
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed.	70	Cares for self; unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his personal needs.
	50	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly	40	Disabled; requires special care and assistance.
	30	Severely disabled; hospital admission is indicated although death not imminent.
	20	Very sick; hospital admission necessary; active supportive treatment necessary.
	10	Moribund; fatal processes progressing rapidly.
	0	Dead

# Indian Drugs Research Association & Laboratory



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E-mail : idralpune@gmail.com, Website - www.idra.in

Ref. No. \_\_\_\_\_ Report No. 610.

25-11-2016  
Date \_\_\_\_\_

## CERTIFICATE OF ANALYSIS CONFIDENTIAL

Name of the Party: BSDT'S ICT & RC  
Atharva Nature Health Care Pvt.Ltd.,  
Wagholi-Pune.  
Your Ref No: RD56/16 Letter dt. 25-10-2016.  
Type of the Sample: Jatamansi Taila.  
Date of Receipt: 26-10-2016.  
Batch No: PR10/16R.  
Quantity Received: 1 X 100 ml.  
Sample Drawn by Party.

1. Description: Slightly Yellowish coloured thick viscous  
Liquid (Oil).  
2. Specific gravity: 0.9186.  
3. Refractive Index: 1.546  
4. Acid Value: 2.851  
5. Saponification Value: 134.84  
6. Iodine Value: 92.07  
7. Peroxide Value: 0.5689  
8. Microbial Limits:  
Total Bacterial Counts:  $3 \times 10^3$  CFU/gm.  
9. Total Fungal Count: Nil.  
10. Heavy Metals:-  
Mercury(Hg): Nil  
Lead (Pb): 1.854 PPM  
Cadmium(Cd): Nil  
Arsenic(As): Nil.  
11. Thin Layer Chromatography:  
Adsorbent used: Silica gel G<sub>6</sub>F<sub>254</sub>.  
Mobile Phase: Toluene:Ethyl Acetate(9:1)  
Detection-  
UV 254 nm: Two spots.  
Rf: 0.32, 0.62(Both Blue)  
Iodine Vapours: Four spots.  
Rf: 0.27, 0.32, 0.40, 0.62(All Yellow).  
Anisaldehyde: Four spots.  
Sulphuric Acid Reagent. Rf: 0.27, 0.32, 0.41, 0.87(All Light Blue)

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

*Agf...*