Effect of Integrated Approach of Yoga Therapy for Premenopausal Women with Mastalgia, a Randomized Controlled Study with 6 months follow up

Thesis submitted by

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Towards the partial fulfillment of the degree of

DOCTOR OF PHILOSOPHY (YOGA)

Under the guidance of

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&

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To

SWAMY VIVEKANANDA YOGA ANUSANDHANA SAMSTHANA

(A yoga University established under Section 3 of the UGC Act, 1956 vide Notification No. F.9-45/2001-U.3 dated 08-05-2001 of the Government of India)

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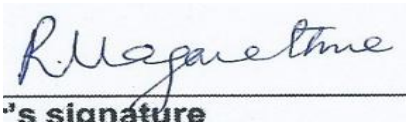

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DECLARATION

I hereby declare that this study was conducted by me at Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA), Bangalore, under the guidance of Dr Raghruam Nagarathna, Dean, Division of Yoga and Life Sciences, Swami Vivekananda Yoga Anusandhana Samsthana, Deemed University and Dr. Sandhya Ravi, Consultant Surgeon, Research Scientist, Norwich Clinical Services, Bengaluru, India.

I also declare that the subject matter of my thesis entitled "**The Effect of Integrated Approach of Yoga Therapy in Premenopausal Women with Mastalgia, a Randomised Controlled Study with 6 months follow up",** has not formed the basis of the award of any degree, diploma, associate-ship, fellowship or similar titles previously.

Sukanya. R

Date: 10-11-2015 SUKANYA RAGHUNATH

Place: Bengaluru (Candidate)

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STANDARD INTERNATIONAL TRANSLITERATION CODE USED TO TRANSLITERATE SANSKRIT WORDS

a	=	अ	ṅa	=	ङ	pa	=	प
ā	=	आ	ca	=	च	pha	=	फ
i	=	इ	cha	=	छ	ba	=	ब
ī	=	ई	ja	=	ज	bha	=	भ
u	=	उ	jha	=	झ	ma	=	म
ū	=	ऊ	ñ	=	ञ	ya	=	य
ṛ	=	ऋ	ṭa	=	ट	ra	=	र
ṝ	=	ॠ	ṭha	=	ठ	la	=	ल
e	=	ए	ḍa	=	ड	va	=	व
ai	=	ऐ	ḍha	=	ढ	śa	=	श
o	=	ओ	ṇa	=	ण	ṣa	=	ष

au	=	औ	ta	=	त	sa	=	स
ṁ	=	अं	tha	=	थ	ha	=	ह
ḥ	=	अः	da	=	द	kṣa	=	क्ष
ka	=	क	dha	=	ध	tra	=	त्र
kha	=	ख	na	=	न	jña	=	ज्ञ
ga	=	ग	gha	=	घ			

SUBJECT INDEX AND COMMON ABBREVIATIONS USED

ACM	**A-cyclical mastalgia**
ANOVA	**Analysis of Variance**
BDI	**Beck Depression Index**
BMI	**Body Mass Index**
BP	**Breast Pain**
BSc	**Bachelor of Science**
CAM therapy	**Complementary and Alternative therapy**
EPO	**Evening Prim Rose Oil**
GNM	**General Nursing Midwifery**
IAYT	**Integrated Approach of Yoga Therapy**
HP	**Hypothalamus-Pituitary**
HPA Axis	**Hypothalamus-Pituitary-Adrenal Axis**
HPO	**Hypothalamus-Pituitary-Ovarian**
NCD	**Non Communicable Disease**
RCT	**Randomized Controlled Trial**
RM-ANOVA	**Repeated measures analysis of Variance**
TRH	**thyrotrophic-releasing hormone**
VAS	**Visual Analogue Scale**
QOL	**Quality of life**
WHOQOL-BREF	**World Health Organisation quality of life-bref**
US SCANNING	**Ultra sound scanning**
TSH	**Thyroid stimulating Hormone**

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ABSTRACT

Background

Mastalgia is a common breast disorder with highly variable prevalence estimates ranging from 41% to 79%. It is important to study its high prevalence and its potential to become benign to malignant.

The prevalence in young women is unknown, but it is more than 50% of women of reproductive age. Therefore, identifying and treating young women with mastalgia is of prime importance. To the best of our knowledge, there are no published studies on the prevalence of mastalgia with or without fibrocystic disease in young Indian women.. Hence the present study was undertaken to estimate the prevalence of mastalgia among young Indian women.

Usage of drugs has shown to have several side effects. Yoga being one of the mind, body interventions have shown beneficial effects in reducing pain, stress and depression, thereby improving quality of life in many other conditions but there are no studies on yoga in Indian adults with mastalgia.

Objectives: (1) to look at the prevalence of mastalgia among nursing students,(2) to assess the benefits of integrated yoga in nursing students with mastalgia through an RCT.

Methods: The prevalence study was carried out on 748 young females between 18 to 29 years of age in residential nursing colleges of Bengaluru rural and Ramanagaram district, South India, by administering a specific breast history checklist prepared for the purpose.

For the interventional study, 80 young female nursing students from 2 residential nursing colleges of Bengaluru rural and Ramanagaram district, South India, who satisfied the selection criteria and consented to participate in the study were randomized into yoga or control groups(40 each).yoga group practiced specific integrated yoga one hour in daily classes supervised by a post graduate yoga therapist, and the control(6 days/week) in their hostel, for three months ; control group practiced supervised walking for one hour daily for 3 months. They all continued the same practices on their own for the next three months with weekly follow up classes (one hour) and reporting through diary. All outcome measures were documented at 0, 3months and 6 months of the study. Data were analyzed using suitable statistical tests for significance of results on ‘R’ 3.1.0 software.

Results

The Prevalence of mastalgia was 47.33% (354 out of 748), of which 88.70% (314) had cyclical mastalgia and 9.89% (35) had acyclic mastalgia. Students who had Low BMI had a higher risk for mastalgia as compared to those with normal BMI (RR of 1.063) or high BMI (RR = 1.685). Moderately stressed students were at higher (RR of 0.771) risk of mastalgia compared to those with low stress. Students with high stress levels were also at a higher risk (RR=0.787) as compared to those with low stress.

In the RCT, there was a significant reduction in weight and BMI from baseline to 3rd month with no further reduction in the 6th month. The pain scores on numerical Pain Analogue Scale (0-10), RM-ANOVA showed a significant reduction in mastalgia from the baseline to the end of 3 months ($p<0.001$). After 6 months follow up the time*group effect was also significant ($p<0.001$). Depression as measured by beck's depression Inventory (BDI) showed significant differences between groups ($p <0.001$, RM-ANOVA) with a better reduction in yoga ($p<0.001$ Post hoc paired sample t test) than the control group.

Quality of life as measured by WHOQOL-BREF also showed significant differences between groups ($p<0.001$) with better improvement in all domains of QoL in the yoga than the control group.

Premenstrual symptoms as secondary variables which showed a significant reduction in menstrual pain in the yoga group from 38 (100%) to 2 (5.26%) and also between group significance ($p<0.0001$) from the baseline to 3rd month. Menstrual cycle also got regularized in the yoga group from baseline 28 (73.68%) to 3rd month 38(100%) compared to control group.

Conclusion: The prevalence of mastalgia was 47.33% among 748 young females from 4 nursing colleges in India.

There was significantly better improvement in yoga than the control group in pain, depression, quality of life and other premenstrual symptoms at 3 and 6 months after the intervention. Pain due to mastalgia, depression scores, QOL improved significantly after yoga in nursing students with mastalgia. Yoga Therapy is an effective alternative therapy compared with physical activity may be recommended as a mind body intervention to alleviate mastalgia.

Keywords: Depression, Mastalgia, Nursing students, Quality of life, Yoga

CHAPTER -1

INTRODUCTION

1.0 INTRODUCTION

1.1. Background

Mastalgia or breast pain is a common problem (Nasreen, 2010; Saeed, 2012) with the prevalence of 41% to79.(D N Ader, South-Paul, Adera, & Deuster, 2001) To rule out the fear of cancer women seek further clinical evaluation although it is benign.(Murshid, 2011) Mastalgia in young women is associated with anxiety; depression thereby brings down her quality of life (QOL).We get the description of Mastalgia (breast pain) in medical history from 1829.

Most of the women suffer from various breast symptoms, i e., swelling and tenderness, nodularity, pain, palpable lumps, nipple discharge, or breast infections and inflammation, most of the cases will be benign.

Cyclical mastalgia (CM) or mastodynia typically occurs every month before the start of the menstrual period and is relieved within 7 days of the onset of menses (Afsheen Zafar, 2013). Approximately 40 to 70% of breast pain is due to cyclical/hormonal imbalance (estrogen, progestin and prolactin). Acyclic mastalgia (ACM) would be from moderate to severe, disturbs the day to day activities often, will account up to 30% of breast pain (BP) (American Cancer Society, 2012). Little is known about the cause of Acyclical mastalgia. BP with or without a tender palpable swelling and nodularity (fibrocystic disease) seeks greater attention because of the anxiety and fear about the risk of getting breast cancer (American Cancer Society, 2012). It is important to study its high prevalence and its potential to become benign to malignant.(American Cancer Society, 2012)

1.2. Prevalence of Mastalgia and Fibrocystic Disease of the Breast: India and Global.

The prevalence seems to vary widely in different countries. In the US, two studies on adult population documented prevalence rates of 68% (D N Ader ., 2001) and 11% for cyclical mastalgia(Deborah N. Ader & Browne, 1997), while in and UK it is reported to be 51.5% and 32% respectively (Brown, White, Brasher, & Scurr, 2014).The prevelnace in India appears to be similar with a reported prevelance of 51% (J. V. Joshi & Galvankar, 2010) to 54 % (Uma, 2003) in adult urban population.

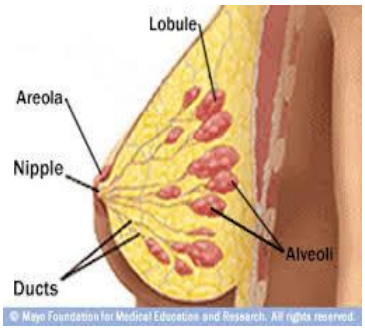
1.3. Aetiology

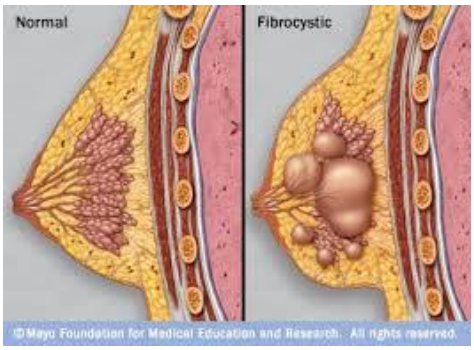
Although the aetiology of mastalgia is not clearly understood, several contributory factors have been reported. Imbalance in oestrogen and progesterone hormones, Prolactin,(Peters, Pickardt, & Breckwoldt, 1985)thyroid stimulating hormone,(Bhargav ., 2009) abnormalities of lipid metabolism,(Rosolowich ., 2006) ageing,(Murshid, 2011) premenstrual syndrome,(D N Ader ., 2001) stress (anxiety, depression, childhood abuse),(S Colegrave, Holcombe, & Salmon, 2001) duct ecstasies,(Morrow, 2000) smoking,(Kaiser ., 2003) caffeine (Allen & Froberg, 1987) have all been implicated.

1.4. Pathophysiology of Mastalgia

Fig 1:

<table>
<tr>
<td>Mastalgia may be associated with nodular lumps with pain. These benign lumps are free-moving with defined edges and are usually found in the upper, outer sections of the breast .(nearest to the armpit).

Normal breast</td>
<td> 

Fibrcystic disease with cysts</td>
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The exact mechanism of fibrocystic disease is not fully understood. It is a psycho-neuro-endocrine disorder that is known to be related to the hormone levels, as the condition usually subsides after menopause and is also related to the menstrual cycle.

It is caused by the normal variations that occur in the hormonal levels (estrogen, progesterone and prolactin) during the monthly cycle; these are responsible for the cells in the breast tissues to grow and multiply. Many other hormones such as TSH,

insulin, growth hormone factors such as TGF-beta exert direct and indirect effects amplifying or regulating cell growth. Increased sensitivity to catecholamine and pituitary hyperprolactinemia due to inappropriate dopaminergic tone [decreased baseline dopamine levels in blood found in studies] results in breast pain. Decreased baseline dopamine estrogen increases dopaminergic tone.

Mastalgia may be related to an upward shift in the circadian prolactin profile, a possible downward shift in menstrual profiles, and loss of seasonal variations. Patients with mastalgia also show a heightened prolactin secretion in response to thyrotrophic-releasing hormone (TRH) anti-dopaminergic drugs and may actively sequester iodine within their breast tissue as a result of an alteration in prolactin control (Fig 1). There is preliminary evidence that iodine deficiency contributes to fibrocystic breast changes by enhancing the sensitivity of breast tissue to estrogen. (Joseph E, 2012). In addition, stress can cause a rise in prolactin response. (Klimberg VS, 1998)

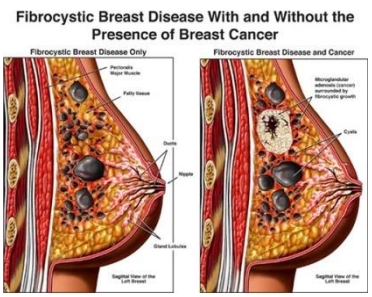


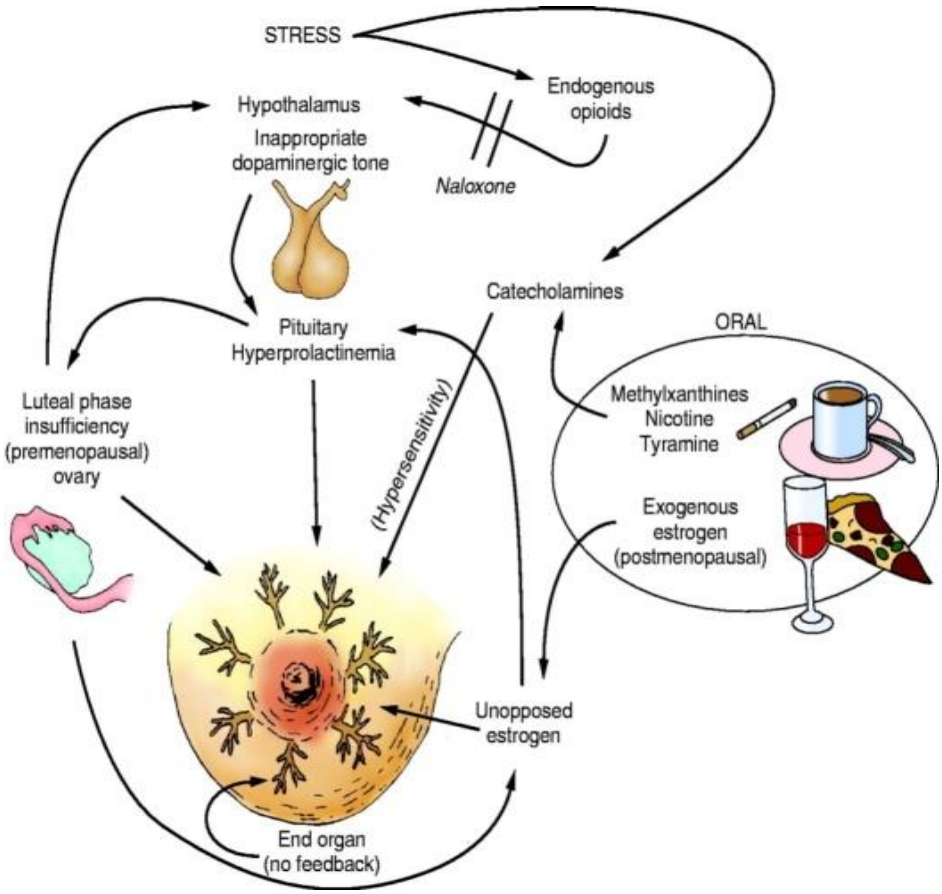
Fig 2:

Years of such fluctuations eventually produce small cysts and/or areas of dense or fibrotic tissue. Over time, due to abnormal growth signals, such lesions may accumulate genetic and epigenetic changes such as modified expression of hormone receptors that may result in atypical changes that may precede development of cancer.

Breast pain without lumps does not carry any risk of cancer. The risk of developing breast cancer in cases of mastalgia with nodules due to fibrocystic disease depends mainly on the family history. If there is a family history of breast cancer the risk is doubled in those whose biopsy shows atypical changes in the breast tissue. (Marshall ., 1997)

1.5. Stress and mastalgia

Fig 3:Stress and mastalgia



Picture Ref:(Klimberg VS, 1998)

It is well recognized that psychological stress is a major factor in the cause of mastalgia.(Poe, 1966; Yilmaz, 2014) Severe mastalgia is caused with high levels of psychological distress(Ramirez, A. J. S. R. Jarett, H. Hamed, 1993) which consecutively affects the patients' quality of life negatively. Depression and anxiety are the other important psychological disturbances in patients with mastalgia.(Yilmaz, 2014) Stressors induce cognitive and affective responses triggering the sympathetic nervous system and endocrine changes (Corticotrophin releasing hormone, epinephrine, nor-epinephrine, adrenaline amongst other) which could result in disturbed physiological functions through the Hypothalamic-Pituitary-Adrenal, Sympatho-Adrenal-Medullary and HP- gonadal axes.(Andersen, Kiecolt-Glaser, & Glaser, 1994; Chrousos, George P. Gold, 1992; Michalsen A , 2005) breast function is a balance between estrogen and progesterone, which is a part of the neuro-endocrine control exerted by the Hypothalamo Pituitary- gonadal axis. Normally, estrogen induces prolactin release by increasing the dopaminergic tone centrally. It has been postulated that this tone is impaired in patients with mastalgia. Decreased baseline dopamine levels and increased catecholamines have been seen in studies in patients with cyclic and non cyclic mastalgia. Catecholamine may be released due to dietary factors or stress resulting in altered abnormal sensitivity of the breast tissue. Recent studies point to a PRL secretory hypersensitivity for estradiol in patients with cyclical mastalgia.

1.6. Management of mastalgia

Treatment strategies have varied from hormonal to non hormonal, from reassurance,(Rosolowich, 2006) or relaxation therapies to other non-drug therapies

like vitamin E, vitamin B6, evening prim rose oil (EPO),(Saeed, 2012) phytoestrogens, herbs.

Drug therapies such as progesterone creams, NSAIDs, Tamoxifen(Jain, Bansal, Choudhary, Garg, & Mohanty, 2015), Danazol (Tejwani 2010), Bromocriptine (Goyal, 2011)and Centchroman(18-22), Goserelin, Gonadotropin-releasing-hormone agonists, (BeLieu, 1994)Centchroman (Dhar, 2007; Saeed, 2012; Tejwani ., 2010) have all been tried. Usage of all these drugs have shown to have minor or major side effects.

1.7. Mind body interventions for Mastalgia

As there is no known organic aetiology for mastalgia and the main cause appears to be psychosomatic, it appears that mind body interventions would play an important role. It is reported that cognitive behavioural therapy notably reduces the complaints of more than half of the mastalgia patients (Susan Colegrave, Holcombe, & Salmon, 2001).

1.8. **Need for the study**

Yoga has been extensively used as one of the mind body interventions and has shown beneficial effects in reducing pain,(Wren, Wright, Carson, & Keefe, 2011) anxiety (Nidhi, Padmalatha, Nagarathna, & Amritanshu, 2012) and depression(Kinser, Bourguignon, Whaley, Hauenstein, & Taylor, 2013). It can be hypothesized that it would lead to a reduction/normalization of sympathetic nervous system/hypothalamo-pituitary axis (HPA) activation. In a systematic review that looked at the role of yoga in pain management, nine randomised control trials (RCT) have shown yoga intervention has beneficial effects in reducing pain in any

part of the body as compared to the control interventions.(Posadzki, Ernst, Terry, & Lee, 2011)Yoga is also found to reduce back pain, (C & Jagannathan, 2014; P Tekur, Nagarathna, Chametcha, Hankey, & Nagendra, 2012; Padmini Tekur, Chametcha, Hongasandra, & Raghuram, 2010a) head ache, abdominal pain during menstruation and other pre menstrual symptoms (Rani, Tiwari, Singh, Agrawal, & Srivastava, 2011) and different gynaecological problems.(Nidhi, Padmalatha, Nagarathna, & Amritanshu, 2013; Sarita kanojia , 2013; Satyapriya, Nagendra, Nagarathna, & Padmalatha, 2009) Pointing to the benefits achieved by mind management techniques of yoga, it has been found to be useful in decreasing stress,(Kiecolt-Glaser., 2010; Rao., 2008; Rocha., 2012; Ruchika Rani, 2013) stress and inflammation(Kiecolt-Glaser., 2010) and also in increasing self esteem(Woodyard, 2011), positive affect and wellness.(Nagarathana. & Nagendra, 2001)

Yoga which is known to be an effective mind body intervention for stress management, has not been tried in women with mastalgia. Hence, the present study was planned to evaluate the efficacy of yoga in nursing students with mastalgia.

CHAPTER – 2

LITERATURE REVIEW

2.0 LITERATURE REVIEW

2.1 Literature review of published works related to management of mastalgia

Summary of studies done in the past decade on different complementary and alternative therapies including supplements, herbal, diet, acupuncture and psycho-education in treating mastalgia, is tabulated below.

Table 1: Summary of Scientific studies related to Complimentary and Alternative (CAM) therapies in mastalgia

	Citation details	Subjects, design	Intervention, assessments	Conclusion, critical analysis
A	**Studies on Supplements for Mastalgia**			
1	Breast pain. Amit Goyal. BMJ Publ Gr;2011(1):812.	24 systematic reviews, and RCTs	Evening primrose oil	Less Efficacy Licence banned in USA
			low-fat, high-carbohydrate diet, lisuride, or vitamin E	Do not know the efficacy Very few studies
2	A.R.Carmichael. Evidence-based complementary and alternative medicine: eCAM. Review article 2008	ReviewRCTs, Non-RCTs, cohort, N=1992 (total)	.Agnus Castus Questionnaire, visual analogue scale, HAM-D DSR CGI-SI, DMS III-R	Effective in cyclical mastalgia. safe side effect profile and can be used
3	Romualdo C, Gama B, . International Journal of Clinical	91 subjects with cyclic mastalgia,	900 mg borage oil capsules) Assessed by Visual Analogue scale	The scores of both the mean mastalgia and most severe mastalgia showed significant ($p < 0.0001$) reduction

	Medicine2015			
4	Nadia Saeed, ISRA Medical Journal 2012.	quasi-experimental, purposive N= 50 25 Danazol; 25 primrose	Evening primrose Oil Assessment - Cardiff Breast pain scale 8^{th}, 12^{th} , 24^{th} weeks	Danazol more effective than Evening primrose Oil
5	Vaziri F, ., International journal of family medicine. 2014.	3 armed RCT 61 -flax seed as bread, 60-omega-3 fatty acids as pearl 60- wheat bread women	Visual analogue scale after two menstrual cycles.	Flax seed was more effective than omega 3 fatty acids ($p<0.001$)
6	Allen SS, Froberg DG, surgery, 1987	3 armed RCT, single blind N= 56 with mastalgia. exptal-caffeine- free diet Control -no dietary restriction Placebo -cholesterol-free diet	Caffeine- free diet	Decreased caffeine consumption did not result in a significant reduction of palpable breast nodules or in a lessening of breast pain/tenderness
B	**Studies on Non pharmacological CAM studies**			
7	Lori A. Pilot Study The American Journal of Chinese Medicine, A (2011)	N=37. A pilot study, acupuncture. Treatment consisted of four acupuncture sessions over two weeks, with three months of follow-up.	Reduction in pain intensity and pain interference was demonstrated within one cycle through acupuncture	a randomized controlled trial may be warranted to evaluate the effect of acupuncture on noncyclic breast pain, as well as the optimal frequency of acupuncture treatments
8	Yarkın Ozenli.	N=98 Mastalgia	SF36 Health-	psycho-education

	Applied Research in Quality of Life. 2013.	without organic etioligy. 66= Psycho-Education PEG.32=no Psycho-Education	Related Quality of life scale Visual Analogue scalescale Baseline and 2months later	effective in reducing pain and increasing the quality of life

The effects of yoga on psychological aspects, (anxiety, depression, stress and quality of life) have been studied from past several years. Summary of a few recent studies has been given in the table below.

Table 2: A few published articles in Yoga and Stress

Sl. No	Author, Year	Design, Subjects intervention	Results	Conclusion
1.	(Vedamurthachar et a2006	Subjects -60 alcoholics 30- Sudarshan Kriya Yoga 30- control 60 minutes sessions, alternate days;2weeks	SKY group reduced depression (BDI) plasma cortisol & ACTH more than control. Depression correlated with cortisol in SKY group.	SKY Reduces depression and stress-hormone levels (cortisol and ACTH) in alcoholics
2.	(Jiang, Li,&Zhang 2009)	yoga [3 times weekly] (n=30), Yoga [once weekly] (n=30, control (n=30) female college students 8 week intervention lgG level measured	Yoga increases IgG levels More Prominent in 3 times/week group	Yoga influence the immunity (IgG levels)
3.	(Gopal, Mondal, Gandhi, Arora, & Bhattacharjee, 2011)	Yoga (n=30), control (n=30) 1st –year medical students 12 weeks Heart rate, respiratory rate, blood pressure,	Physiological measures increased in control but did not in yoga group. Psychological	Yoga resists autonomic changes and impairment of cellular immunity seen during exam Stress

		Stress, anxiety, Serum cortisol, IL-4, IFN-y measured	stress was very high in control but moderately high in yoga group. rum cortisol increased & IFN-γ decreased less in yoga group than in the control Both groups increased IL-4	
4.	Kariya, Yook, yang & Lee, 2010	Yoga (n=255 16 weeks, symptoms check list, physical self perception, serum immunoglobulin measured	Somatisation, personal relationship, hostility decreased compulsion, anxiety, depression, fear, psychosis decreased, serum IgM decreased	Yoga improves social health and promotes immune changes
5.	Kumar & Pandya2012,	Yoga (n=80), Control(n=30) PG students 30 min/day for 6 monthsESR measured	ESR was lower in yoga group for both males and females	yoga nidra non-specific inflammation
6.	Ram Nidhi, 2012	RCT, N=90, 12 weeks of yoga and	Trait anxiety was	Anxiety reduced in yoga group

		physical exercise for control. Anxiety level measured	significantly lower	.P=0.002
7.	Kinser PA, 2013	N=12, 8 weeks of gentle yoga. Interpretive phenomenological study. RCT mixed method study.	MDD came down. The main reason was stress.	Yoga served as a self care technique in MDD (major depressive disorder)
8.	Ruchika Rani. 2013	N=50, enumeration sampling technique	Modified stress assessment scale	
9.	Janice K. Kiecolt-Glaser 2010	N=50, hatha yoga and tread mill walk, to measure potential stress reduction benefits and inflammatory and endocrine response	Novices' average serum IL-6 levels were 41% higher than those of experts	Yoga significantly reduces cortisol and inflammation
10.	Janice K. Kiecolt-Glaser 2014	Patients from 0 to III stage BC. Yoga N=53, Stretching, n=54	Improved qol. Depression, sleep quality and fatigue measured in 1, 3 & 6 months later.	YG improved QOL and physiological changes associated with XRT beyond the benefits of simple ST exercises,
11.	H. S. Vadiraja . 2009	N=88. 44=yoga, 44=supportive therapy. Stage II & II BC patients undergoing radiotherapy	Reduction in anxiety, depression and stress level in the yoga group	Yoga helps in reducing stress in BC patients
12.	(S Telles,			Yoga changes the

	Nagarathna, & Nagendra, 1994)			physiological responses to stressors by improving autonomic stability with better parasympathetic tone in normal adults

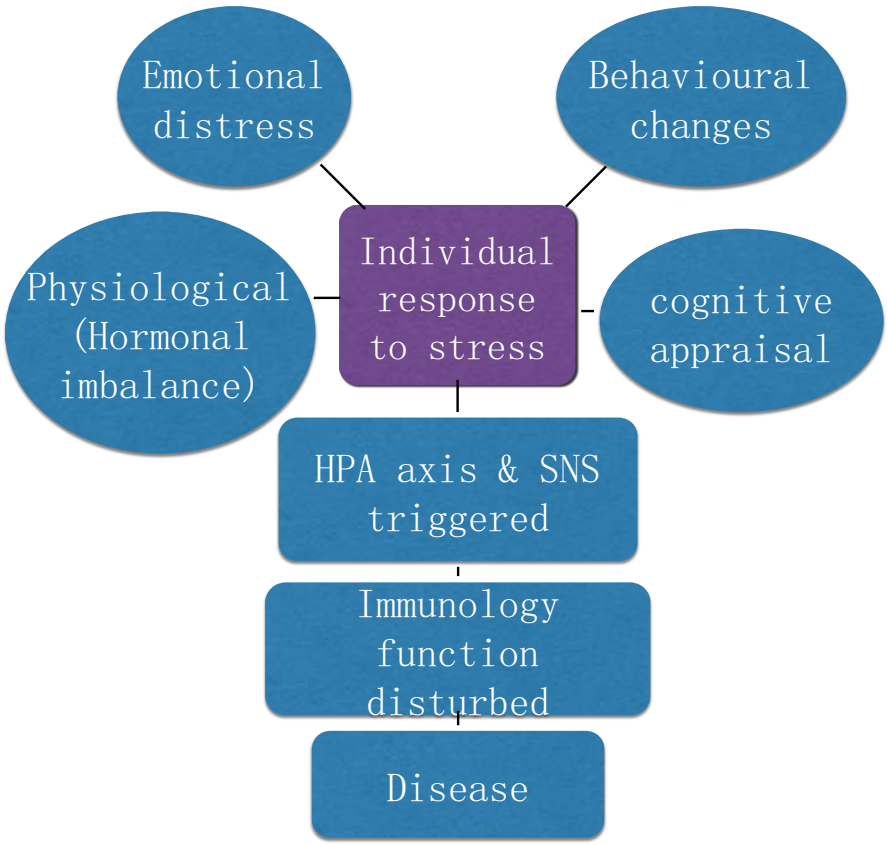
These studies, including several other RCTs over the past decade have shown yoga practices have brought about improvement in psychological aspects, lowering the anxiety, depression, stress level and improving quality of life which may be traced to lowering the sympathetic with increased parasympathetic tone and reduced pro-inflammatory activity. These publications offer a strong evidence that yoga helps in the management of stress.

There is evidence to suggest that cyclical mastalgia is caused by a latent stress-induced hormonal imbalance as indicated by hyper Prolactinemia.(Carmichael, 2008) It is observed that patients with cyclic and non-cyclic mastalgia have increased catecholamine and decreased baseline dopamine level which suggests that catecholamine may be released due to stress resulting in abnormal sensitivity of the breast tissue.(Kirby, 2009)Yoga may improve the quality of life by promoting voluntary reduction in violence and aggressiveness.(Deshpande, Nagendra, & Raghuram, 2008) Mastery over the emotional reactions of anxiety(Miller, Fletcher, & Kabat-Zinn, 1995)or depression(Sharma, Das, Mondal, Goswampi, & Gandhi)is achieved through restful awareness during all the practices in general and meditation in particular(Telles S, Nagarathna R, 1995). Kundalini Yoga is found to be beneficial

in cases of depression It stimulates the various autonomic nerve plexus (Chakras) and activates pineal organ which in turn brings homeostasis between sympathetic and parasympathetic activities.(Devi, Chansauria, & Udupa, 1986) This mastery over emotional surges leads to controlled and need based physiological responses that may reduce the overtones of Hypothalamus-Pituitary-Adrenalin (HPA)

axis(Leonard, 2006) during chronic pain. Yoga has an influence on the HPA axis as evidenced by a reduction in cortisol levels in normal(Kamei ., 2000) and sick individuals.(Curtis ., 2011; H. S. Vadiraja ., 2009)

Fig 4: Pathophysiology of Stress



CHAPTER – 3

LITERARY REVIEW OF YOGA

3.0 LITERARY REVIEW OF YOGA TEXTS

3.1 Integrated Approach of Yoga Therapy (Iayt) for Mastalgia

Ancient Indian texts dating back to about 5000 years (Rig Veda, Patañjali Yoga Sutra. Upanishads, Bhagavad Gita and ayurveda) provide a highly evolved conceptual basis for the aetiopathogenesis of disease and its management. This chapter highlights the definition of yoga, five aspects of human existence, stress according to yoga, an analysis of happiness and unhappiness (Sukha dukha pariksa), Role of happiness analysis for cognitive change in women with mastalgia.

3.1.1 The origin and scope of yoga

Yoga is a rich traditional contribution from India to the entire globe which starts with physical activity, instructed relaxation and introspection. (Nagarathana. & Nagendra, 2001) Yoga includes diverse practices, such as physical postures (asanas), regulated breathing (prāṇa yama), meditation and lectures on philosophical aspects of yoga.(Nagarathana. & Nagendra, 2001) Yoga and Prāṇayama are today recognised as techniques that can improve muscle strength, flexibility, blood circulation and oxygen intake as well as hormone functions (Woodyard, 2011) at the gross level. Meditation (intrinsic yoga techniques called Dhāraṇa, Dhyāna and Samādhi) has been described as training in awareness the produces definite changes in perception, attention and cognition (Parshad, 2004) and thus help in reducing stress (Kiecolt-Glaser ., 2010) depression (Kinser, Bourguignon, Taylor, & Steeves, 2013) and anxiety (Nidhi ., 2012)

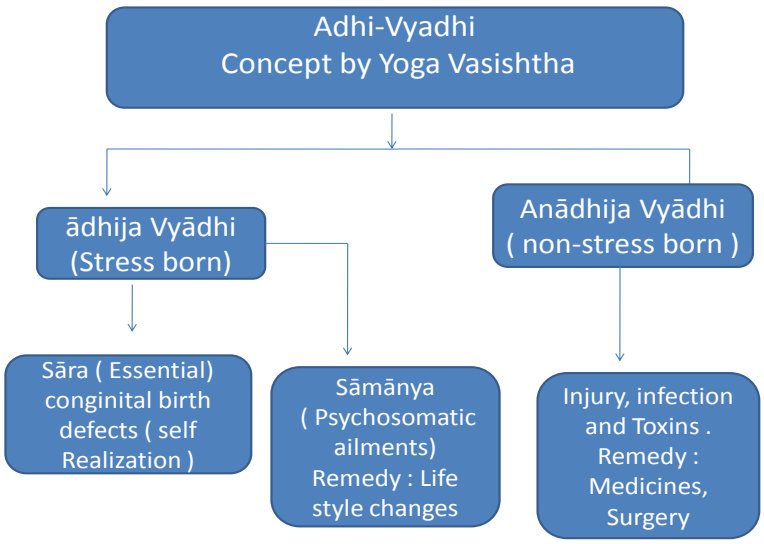
Yoga is the need of the hour in all the fields and for non-communicable diseases (NCDs) Yoga is a way of life. The scope of yoga in India and abroad is extended to

bring about changes in the life style which is at the base of these NCDs. People are slowly accepting yoga, as a complimentary system of medicine, especially for stress borne diseases. Promotion of positive health is being nurtured by many who do not want to be the victims of modern ailments.

The term 'Yoga' comes from a Sanskrit word 'Yuj' meaning 'to join'. Yoga is a method of joining the individual consciousness with Universal consciousness.(Nagarathna, 2004)

Yogic understanding of mastalgia as a mind body disease – Ādhija Vyādhi

Fig 5:



According to the yoga text, Yoga Vāsiṣtha, all diseases can be classified as ādhija or anādhija. imbalance caused by disturbances at the mind level. On the other hand, anādhijah vyādhis are not Ādhija Vyādhi (stress born disease) is due to ādhi (stress); it begins as an internal

due to ādhi (stress); they are caused by external causes such as infections, toxins, injuries etc.

Though the aetiology of mastalgia is unclear, it is clear that this is not due to any infection, injury or toxins (not andhija vyādhi) and hence can be considered to be ādhija vyādhi (non – communicable life style disease).

Fig 6:I**mbalance is disease**

Balance is Health

The root cause, the wrong life style, results in stress that begins in the Manomaya kośa (instinctual mental layer of human system).The persistent uncontrolled repetitive thoughts in the mind during these chronic emotional surges of stress activates the physiological responses at the body level. The texts say that prāṇa is the mediator that transfers the imbalances from the mind to the body. This speed of the mind activates the vital energy(prāṇa) that controls all physiological functions, that results in hightened neurochemical activity in the body as stress responses. The speed of the prāṇa is directly correlated with the speed of the mind.

prāṇa is defined in chāndogya upaniṣat as that energy that controls all activites of the body .

प्राणं क्षक्षुः प्राणं श्रोत्रं प्राणं मनः प्राणोह्येवैतान् सर्वान् संवऋङ्क इति। स यदा स्वपिति प्राणमेव वागप्येति।

चन्दोग्य उपनिषद् ।४-३-३

prāṇaṁ kṣakṣuḥ prāṇaṁ śrotraṁ prāṇaṁ manaḥ

prāṇohyevaitān sarvān saṁvaṛṅkta iti।

All physical and psychological activity is closely connected with prāṇa.

sa yadā svapiti prāṇameva vāgapyeti।

"When a person is in deep sleep his speech gets merged into general prāṇic activity.

Likewise, when he is awake, all his prāṇa merges in the single activity".

Chāndogya upaniṣad 4-3-3 (Shankaracharya, 1850)

Prāṇa is the vital energy (vital force/ Bioenergy/ subtle energy/ life energy/ chi) that carries out all activities in the physical body (annamaya kosha). When the mind picks up enormous speed (vega –udvega- the uncontrolled speed in upward direction), more prāṇa is activated to promote heightened activity in all organs. Persistent excessive prāṇa flow to an organ causes tissue damage which could be inflammation or early degenerative. Inflammation without any external onslaught by a germ or a toxin is ādhija Vyādhi. The text goes on to describe two factors that decide where the ādhija vyādhi manifests. These are: (a) a genetic predisposition to a particular disease and/or (b) an inherent weakness or vulnerability of the organ in the particular individual. (Nagarathana. & Nagendra, 2001)

Let us look at mastalgia as ādhija Vyādhi - mind body disease: the problem begins as responses which are persistent long standing emotions (recognizable or unrecognizable/ suppressed or expressed) which could be anxiety or depression; this invariably draws too much prāṇa to carry out the stress responses; over a period of

time the habituated excessive prāṇa activity localizes to the breast as pain; pain is uncontrolled excessive activity in the sensory nervous system which is the result of hormonal (estrogen, progesterone, prolactin etc) imbalance.

In summary, the yogic model proposes that the entire problem is due to repetitive onslaught by uncontrolled thoughts (suppressed emotions) at the mind level (Manomaya kośa) which causes excessive prāṇa activity and manifests as violence (inflammation) that results in an imbalance (endocrine/nervous) at annamaya kośa to show up as breast pain.

3.1.2 Five aspects of mind body complex

The integrated approach of yoga therapy **(IAYT)** repairs and restores the system into balance at all five levels of one's existence. The pancakośa concept given in the Taittirīya Upaniṣad, forms a model of the total structure of a human being. It brings a deep understanding of the relationship between a human being and all aspects of his or her experience. This theme of relationship is fitting as we glimpse into the fifth layer of the five bodies, Änandamaya Koça, to gain an understanding of its properties in relation to health. Understanding the mechanisms behind such reversal by yoga, requires considering the subject in the terminology specified in the field of study.

Fig 7:

Yoga therapy techniques are based on the principle of mind-body medicine that includes: (a) The concept of five aspects of one's personality, called the Pañcakośa viveka (Taitriya Upaniçad), (b) Yogic definition of

stress (Bhagavadgita) as kleṣas (patanjali yoga sutras) and (c) Progression of a mind body illness from mind to the

body as vyādhi or disease through intermediation of prāṇa(Yoga Vāsiśtha)

अन्नं ब्रह्मेति व्यजानात्। अन्नाद्येव खल्विमानि भुतानि जायन्ते।

अन्नेन जातानि जीवन्ति। अन्नं प्रयन्त्यभिसम्विषन्तीति। तै उप।३।२।

annaṁ brahmeti vyajānāt। annādyeva khalvimāni bhutāni jāyante।

annena jātāni jīvanti। annaṁ prayantyabhisamviśantīti। tai upa।3।2।

I have come to realize that the physical is the ultimate truth. It is the physical that is responsible for all the elements of the universe to be born; the world is sustained because of the physical and finally it is into the physical that the entire world dissolves and is destroyed thereby.

प्रानो ब्रह्मेतिव्यजानात्। प्रानाध्येव खल्विमानि भूतानि ज़ायन्ते।

प्रानेन जातानि जीवन्ति। प्रानं प्रयन्त्यभिसम्विषन्तीति। तै उप।३।३।

prāno brahmetivyajānāt। prānādhyeva khalvimāni bhūtāni zāyante।

prānena jātāni jīvanti। prāṇa ṁ prayantyabhisamviśantīti। tai upa।3।3।

I have realised that vital energy is the truth. The vital energy is the cause for the birth of all the elements in the Universe; the vital energy is what sustains the universe and the same vital energy is responsible for the dissolution of the Universe.

मनो ब्रह्मेति व्यजानात्। मनसोह्येव खल्विमानि भूतानि ज़ायन्ते।

मनसा जातानि जीवन्ति। मनः प्रयन्त्यभिसम्विषन्तीति। तै उप। ।३।४।

Mano brahmeti vyajānāt। Manasohyeva khalvimāni bhūtāni jāyante।

Manasā jātāni jīvanti। Manaḥ prayantyabhisamviśantīti। tai upa।3।4।

I have realised that mind is the truth. The mind is the reason for the origin of the Universe; the mind is what sustains the Universe and the same mind is responsible for the dissolution of the Universe.Yoga vasiṣtha

विज्ञानम् ब्रह्मेति व्यजानात्। विज्ञानाध्येव खल्विमानि भूतानि ज़ायन्ते।

विज्ञानेन जातानि जीवन्ति। विज्ञानम् प्रयन्त्यभिसम्विषन्तीति। तै उप। ।३।५।

vijñānam brahmeti vyajānāt। vijñānādhyeva khalvimāni bhūtāni jāyante।

viñānena jātāni jīvanti। vijñānam prayantyabhisamviśantīti। tai upa।3।5

I have realised that the intellect is the supreme truth. The intellect is the reason for the creation of the Universe; the intellect is what sustains the universe and the same intellect can destroy the Universe.

आनन्दम् ब्रह्मेति व्यजानात्। आनन्दाध्येव खल्विमानि भूतानि ज़ायन्ते।

आनन्देन जातानि जीवन्ति। आनन्दम् प्रयन्त्यभिसम्विषन्तीति। तै उप ।३।६।

ānandam brahmeti vyajānāt। ānandadhyeva khalvimāni bhūtāni jāyante।

ānandena jātāni jīvanti। ānandam prayantyabhisamviśantīti। tai upa।3।6।

I have realised that the bliss is the supreme truth. The bliss is the reason for the creation of the Universe; the bliss is what sustains the universe and the same bliss can destroy the Universe.(Gambhirananda, 2010) (chap 3 verse 2-6)

The Pañca Kośa viveka explains the anatomy and physiology of the subtle aspects of human mind-body system that helps us to understand the imbalances that lead to evolution of chronic lifestyle related diseases and their pathophysiology in a totally different perspective which can help modern science to unravel some of the mysteries behind life style problems. These five aspects are:

(a) Annamaya Kośa (Sheath of physical body that is composed of all the molecules of gross elements) (b) Prānamaya Kośa (the subtle energy that is at the base of all cellular activities), (c) Manomaya Kośa (Sheath of Mind / Emotion),

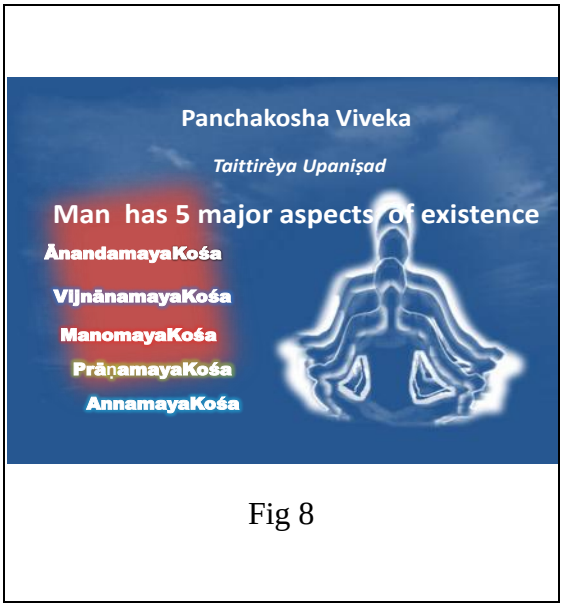


Fig 8

(d) Vigñānamaya Kośa (Sheath of Intellect) and (e) Ānandamaya Kośa (Sheath of Bliss).

3.1.3 Reversal of stress induced mastalgia by yoga techniques at five layers of the system

Yoga is defined as 'mastery over the modifications of the mind' by sage Patanjali (Swami Prabhavanada, 2002) which is the goal of the integrated yoga program. The module of integrated approach of yoga therapy used in this study [IAYT] are techniques that help to repair and restore the system into balance at all five levels of one's existence.

The practices used at annamaya Kośa include yogic diet, kriyas (cleansing techniques) and asanas and relaxation practices. Annamaya Kośa may be regarded as the focus of modern medicine.

IAYT recommends sātvik diet, and moderation in eating habits, sleep, and behaviour. Asana gives therapeutic benefits and may give relief from pain by improving lymphatic flow through different stretches in the thoracic region. Kriyās such as kapālabhati also helps in clearing the endo-toxins which may be considered to be the accumulated free radicals in the breast area (Reuter, 2010) This is referred to as āma in āyurveda due to the blockages and constriction of prāṇa (yoga) or obstructed meridians (srotas or nādis) in Chinese medicine. Different relaxation techniques like alertful rest, deep relaxation, help to remove the muscle spasm and reduce the tone of the muscles all over the body.(Vivekananda 1999)

Prāṇayama is a very useful tool to calm down the mind through voluntary slowing down of the breathing rate.(Taimini, 1999)

तस्मिन् सति श्वास प्रश्वासयोः गति विच्चेदः प्राणायामः।२।४९।प।यो।सू।

Tasmin sati śvāsa praśvāsayoḥ gati viccedaḥ prāṇāyāmaḥ।2।49 pa।yo।sū।

Slowing down the rate of inhalation and exhalation is prāṇa yama.

Meditation

Dhāraṇa and dhyāna are the two components of meditation described by patanjali.

देश बन्ध चित्तस्य धारण।३।१प।यो।सू।

deśa bandha cittasya dhāraṇa।3।1pa।yo।sū।

Concentration (dhāraṇa) is the process of holding or fixing the attention of mind onto one object or place, and is the sixth of the eight rungs.

dhāraṇa (focussing) helps remove the restlessness in the mind, reduces the number of destructible thoughts and helps in channelizing them to one single thought.

तत्र प्रत्यय एकतानता ध्यानम्।३।२। प।यो।सू।

tatra pratyaya ekatānatā dhyāna m।3।2। pa।yo।sū।

The repeated continuation or uninterrupted stream of that one point of focus is called absorption in meditation (dhyāna), and is the seventh of the eight steps.

dhyāna (meditation), helps to defocus through effortless flow of a single thought and promotes the inner calmness and bliss that is the goal of yoga i.e. gain mastery over the mind.

योगश्चित्त व्रित्ति निरोधः।२।१।प।यो।सू।

yogaścitta vritti nirodhaḥ।2।1pa।yo।sū।

Yoga is the technique to stop the modifications of the mind.(Taimini, 1999)

3.1.4 Jnāna Yoga, Karma Yoga and Bhakti Yoga

The theory lectures that explain the unique concepts from scriptures on mind body disease (ādhi, vyādhi), happiness analysis, yama, niyama, working without building stresses (karma yoga), emotion culture through devotional practices (bhakti yoga) help in changing the loop of stress responses such as anxiety or depression and promote positive feeling by unfolding the divinity within.

3.1.5 Notional correction by happiness analysis

Yogic counselling in which the therapist goes into the life problems of the individual and helps the participant to change the perception of the problem goes a long way to bring about the required cognitive change.

शोकम् तरति आत्मवित् इति

śokam tarati ātmavit iti।7-1-3 । Yo।Va।

"The one who has realised self overcomes grief".

This change is brought about by recognizing the psychological freedom 'to react, not to react or change the usual pattern of reaction to situations' highlighted in yoga texts(Nagarathana. & Nagendra, 2001) called Upaniṣats a part of the Vedas, that form the base for all self knowledge which is the aim of any spiritual wisdom, and not restricted to one religion/sect/creed. (Prof. Satyanarayana shastri, 2014) The happiness analysis (jnana yoga) described in these Upaniṣats and other yoga texts that was used in this study to bring about cognitive change by understanding the mental processes that happen during stress(dukha) and non-stressed blissful state of health is reviewed below. The aim is to use the intellect (logical mind) for self analysis to reach the ānadamaya kosa. Establishing in ānadamaya kosa needs correction of all imbalances

created in the three kosas (manomaya, pranamaya and annamaya) by irregularities in life style. This life style change is a major component in which the basic notions in the vijnānamaya kosa (seat of knowledge), about one's understanding of happiness the meaning and purpose of life and are by notional correction using the wherein they are restructured through this upaniṣadic knowledge.

3.1.6 Why happiness analysis?

One engages in any form of activity because it gives happiness (freedom from discomfort); it may be the simple day to day activites for survival such as eating , washing etc, or involvement in a life mission through strenous (physical), stressful (emotionally challenging) jobs or entertainments. The only goal of lfie is to be happy (freedom from distress).

यदा वै सुखं लभतेऽथ करोथि। चन्दोग्य उपनिषद् ७-२२

yadā vai sukhaṁ labhate'tha karoti। chāndogya upaniṣat 7-22

"One will involve oneself only in that activity which gives happiness (sukha)".

सुखमेव लब्ध्व करोति।

sukhameva labdhva karoti।

"One will do an activity only if it gives happiness".

सुखं त्वेव विजिज्ञासितव्यमिति।

sukhaṁ tveva vijijjñāsitavyamiti।

Hence, we should examine the happiness

सुखं भगवो विजिज्ञास इति।

sukhaṁ bhagavo vijijñāsasva iti।

Oh my Lord, let me know the secrets of sukha .

सैषानन्दस्य मीमांसा भवति। तैत्तिरीय उपनिस्षद् २-८

saīṣānandasya mīmāṁsā bhavati

this is happiness analysis ।

taittirīya upanisṣad8(Gambhirananda, 2010)

3.1.7 What is happiness?

A famous thinker Gaudapāda, Shankarāchārya's teacher, in his commentary to māndukya Upaniṣat says, (Shankaracharya, 2004)

निगृहीतस्य मनसो निर्विकल्पस्य धीमतः। मान्दूक्य उपनिषद्। ३-का। ३४

Nigṛhītasya manaso nirvikalpasya dhīmataḥ। Māndūkya Upaniṣad। 3-kā। 34

"Once the mind is purified, there remains peace, which is called happiness (ānanda, or Brahman)".

निगृहीतं मनः एव निर्भयं ब्रह्म।

Nigṛhītaṁ manaḥ eva nirbhayaṁ brahma।

भिद्यते हृदयग्रन्थिः चिद्यन्ते सर्वसम्शयाः।

"The fully conquered mind is the seat of fearless self (happiness/ānanda)".

yo.vaa

In kathopaniṣat, the nine year old boy nachiketa asks the master yama, the god of death, 'o lord yama, is it not that all these objects of enjoyment of the

external world make the mind go out and prevent it from turning towards discovering the inner core which is the everlasting ānanda / happiness?'

पराञ्चि खानि व्यतृणत्स्वयम्भूस्तस्मात् पराञ्पश्यति नान्तरत्मन्।

कश्चिद्धीरः प्रत्यगात्मानमैक्षत् आवृत्तचक्षुरमृतत्वमिच्चन्॥ कठोपनिषद् २-४-१

Parāñci khāni vyatṛṇat svayambūstasmāt parāñpaśyati nāntaratman।

kaściddhīraḥ pratyagātmānamaikṣat

āvṛttacakṣuramṛtatvamiccan।।kaṭhopaniṣad 2-4-1

Mind is programmed to go out through the doors of percetion , the sensory organs (jnanendryas)or motor (karmendriyas) organs. It is only a courageous seeker who can close his eyes , and look inside to recognize his own **self** as the source of all happiness. (Prof. Satyanarayana shastri, 2014)

3.1.8 Analysis of happiness

Two methods are suggested for achieving freedom from distress(happiness analysis) (Prof. Satyanarayana shastri, 2014)

1. Self examination –Ātmaparikṣa
2. Investigating happiness and sorrow- Sukha dhukha parikṣa

Ātmaparikṣa (self examination) is described in Brhadaranyakopaniṣad. Yājnavalkya who is the hero here, when he decides to take sanyāsa (renunciation), one of his wives, Kātyāyini, permits him, as she is provided with enough wealth to sustain her for her future. He then goes to other wife Maitreyi to offer her enough wealth so that he can take renunciation. She asks him 'can all this wealth give me that permanent happiness?' Then he replies:

अमृतत्वस्य न आशा अस्ति वित्तेन।

amṛtatvasya na āśā asti vittena | Brha.Upa.2-4-2

"Money/wealth cannot give permanent everlasting bliss", which makes Maitreyi accompany him to the forest as a seeker. Yājnavalkya continues, and says there are three processes involved in the practice to achieve this permanent bliss (ānanda) .

आत्मा वारे द्रष्टव्यः शोतव्यो मन्तव्यः निदिध्यासितव्यः। बृह उप २-४-५

ātmā vāre draṣṭavyaḥ śotavyo mantavyo nididhyāsitavyaḥ | bṛha upa 2-4-5

"The process of realsing the self involves studying the scriptures, meditating upon the concepts portrayed thereof and dwelling in that experience of bliss".

3.1.9 What is unhappiness (definition of stress)?

The analysis begins by watching one's own mind during moments of happiness and unhappiness. All stress responses begin in the mind as intense negative emotions such as tension, fear, anger or depression etc ; these emotions (unhappiness, anxiety, fear, tension, depression, Raga- attraction, dvesa-repulsion, dullness, laziness, jealousy, inferiority), are nothing but ***uncontrolled speeeded up rewiding of thoughts in the mind*** . this is described in several yoga texts as follows.

When there is disturbance, tension, fear, anxiety, raga(attraction), kama (desire), krodha (anger), uncertainty, impatience etc., the mind is in violent uncontrollable speed

शोक्नोतीहैव यः सोढुं राक्शरीरविमोक्षणात्।

कामक्रोधोद्भवं वेगम् स युक्तः स सुखी नरः।भगवद्गीत ५-२३

śoknotīhaiva yaḥ soḍhuṁ prākśarīravimokṣaṇāt।
kāmakrodhodbhavaṁ vegam sa yuktaḥ sa sukhī naraḥ। Bhagavadgīta 5-23
"One who is able to withstand the impulse of lust and anger before death is a yogi, and a happy man. Man can be happy when he is able to control or drop the speed arising out of kama krodha bhaya etc., which are the moments of dukha".

duḥkheṣvanudvignamanāḥ. Gīta2-56 (Tapasyānanda, 2000)

dukha is udvigna manah- unhappiness is a mind which is stuck in uncontrolled

speed.Yogi is one who is ***un****udvigna manah*– one who has no uncontrolled speed of the

mind i.e. has mastery over the speed of the mind.

Hence the remedy for moving from unhappiness to happiness is to reduce the speed of the mind and move towards complete mastery

मनः प्रशमन उपायः योगः। यो वा

Manaḥ praśamana upāyaḥ yogaḥ। yo vā.3.9.132
Mind slowing down technique is yoga

खेष्वनुद्विग्नमनाः सुकेहेषु विगतस्पृहः।

।वीतरागभयज्क्रोधः स्थितधीमुनिरुच्यते॥ गीत २-५६

duḥkheṣvanudvignamanāḥ sukheṣu vigataspṛhaḥ।

।vītarāgabhayajkrodhaḥ sthitadhīrmunirucyate।।Gīta2-56

“A person whose mind is unperturbed by sorrow, who does not crave for pleasures and who is completely free from attachments fear and anger is called sthitaprajna, a sage established in wisdom’.

अनास्थैव हि निर्वाणं दुःखमास्था परिग्रहः।योग वासिष्ठ ३-९-३९

anāsthaiva hi nirvāṇaṁ duḥkhamāsthā parigrahaḥ।yoga vāsiṣṭha 3-9-39

“While attachment is suffering, detachment alone leads to liberation”.

Focussing, pinpointedness, or uncontrolled excessive concentration(e.g. OCD, brooding) result in untold suffering or Duhkha. Whereas, vistarata or diffusion or expansive state of mind gives sukha or happiness or deliverance from duhkha. Therefore drop the burdensome focussing and adopt a ‘let go’ attitude.

द्वित्वैकत्वदृशौ चित्तं तदेवाज्ञानमुच्यते।

एतयोर्यो लयो दृष्टयोः तज्झअनं सा परा गतिः।

dvitvaikatvadṛśtau cittaṁ tadevājñānamucyate।

etayoryo layo dṛṣṭayoḥ tajjhaanaṁ parā gatiḥ।

“mind in either of the two phases is ajnana(ignorence or dukha)- cognizes several objects at a time (random mind) or concentration on one object ; when both these modes of the mind dissolves then that is the highest exalted state of happiness”.

Thus, **speed and focussing** are the two aspects of dukha. If agitation is replaced by slowness of the rate of flow of thoughts in the mind (naidhānya-slowing down) gradually and consciously it will result in less and less of suffering/unhappiness (dukha). whenever focussing becomes burdensome, replace the same by de-focussing or diffusion. The pracitce is to develop “**Let go”** attitude.

If disturbance of mind (cancalya) is one form of bondage (Bandhana), concentration or focusing (Ekagrata) is also a form of bondage (bandhana). When both these are put to an end, then that is liberation.

Introspective examination of the mind during any happiness reveals that we get joy when the sense organs come in contact with objects of enjoment. E.g.when we enjoy a sweet dish the taste buds are excited by the touch of the dish placed on the tongue. If one observes the state of mind at that moment, it becomes clear that momentarily the mind had become quiet/silent / no thought state. The mind would have touched the blissful inner quietitude ; this is the real state of ānandamaya kosa the self (ātma swarupa or the Brahma swarupa). Thoght free state, true state.(Shankaracharya, 2004)

लौकिकोऽपि आनन्दो ब्रह्मानन्दस्यैव मात्रा। टैत्तिरीय ऊपनिषद्। शङ्कराभाष्य २-८-१९७

laukikoau'pi ānando brhmānandasyaiva mātrā | ṭaittirīya Upaniṣad | śaṅākarabhāṣya 2-8-197

in This happiness obtained by any common man during the worldly enjoyment is nothing but a fraction of the total bliss of a self realised person .

Shankaracharya in his commentary on Brhadarnayaka Upanishad (4-3-32) says that nay one can achieve this untimate state of eternal bliss devoid of unhappiness by practice.

आत्मसत्यानुबोधेन न सङ्कल्पयते यदा।

अमनस्तं तदा याति ग्राह्याभावे तदग्रहम्॥ मन्दुक्य ऊपनिशद्। ३क३२

ātmasatyānubodhena na saṅkalpayate yadā |
amanastaṁ tadā yāti grāhyābhāve tadagraham | | mandukya ūpaniśad | 3ka32

"While modifications of the mind stop, having realised the Self, no mind state is
attained due to the absence of graspable phenomenal world".

यद पञ्चा व तिष्ठन्ते ज्नाननि मनस सह।

बुद्धिष्ःच तमहुः परमां गतिम्॥ कथ २-६-१०

yada pañcā va tiṣṭhante jnānani manasa saha | buddhiṣḥca tamahuḥ paramāṁ gatim | | katha 2-6-10

"When the five sense organs, the mind and the intellect are not functioning, that is your true nature".

3.2 Summary

According to Modern Science, Stress is defined as 'a phylogenetic, nonspecific, conventional basic response pattern to any demanding situation'.(Francisco J. Karkow, Wilson P. Spiandorello, Rossane F. Godoy & Faintuch, 2004) Several physiological changes occur when exposed to life threatening physically demanding situations that help the system for fight or flight. Although this does cause a temporary imbalance in the metabolic processes that may drain out the useful chemicals and generate many endotoxins, the system has enormous capacity to restore the balance by detoxification, repair and rejuvenation. The responses are similar when the demanding situations are physical or emotional and the system can restore to normalcy over a period of time. But when the situations become chronic and does not give time for restoring normalcy before taking up the next challenge, the system is forced to reset itself at a different level, the imbalance continues and normalcy is lost; this long standing imbalance leads to an illness. Thus disease is a habituated disturbed pattern of response. (N., 1982)

Yoga, a science of introspection / internal awareness / mindfulness, that promotes self analysis of the mental processes during stress response. All stress responses begin in the mind as intense emotional responses (fear, anger or depression); these intense surges of brain activity; in all these emotional surges the thoughts in the mind go on rewinding at uncontrolled speed; this gathers enough energy to bring about all the physiological changes. Thus stress according to yoga is ***persistent uncontrolled repetitive thoughts in the mind (ut-vegam)***. ***Yoga teaches the process of slowing***

down the flow of thoughts which is the technique to manage stress and reach a state of self realised blissful state of silence.

CHAPTER – 4

AIMS AND OBJECTIVES

4.0 AIM AND OBJECTIVES

4.1 Aim of the research

1. To find the prevalence of mastalgia in young Indian females

2. To assess the effect of yoga on alleviation of symptoms of pain and discomfort associated with mastalgia through a randomised control trial

3. To determine the impact of yoga on quality of life in women with mastalgia

4. Effect of yoga on women with mastalgia with depression

4.2 Objectives

To estimate the prevalence of mastalgia in young Indian females

To determine the effect of 12 weeks of yoga therapy in alleviating the pain in nursing students with mastalgia with 6 months follow up.

To determine the effect of 12 weeks of yoga therapy on quality of life in nursing students with mastalgia with 6 months follow up.

To determine the effect of 12 weeks of yoga therapy on reduction of depression scores in nursing students with mastalgia with 6 months follow up.

4.3 Research Questions: PART 1: Is the prevalence of mastalgia in young Indian women similar to the other countries?

Is there any correlation between stress and BMI in young Indian women with mastalgia?

PART 2: Is IAYT as/more effective than brisk walk practice in alleviating pain, bringing down the depression thereby improving quality of life in nursing students with mastalgia?

4.4 Hypothesis

PART 1: There will be significant prevalence of mastalgia in young Indian women.

Part 2: Yoga therapy will significantly reduce the pain and discomfort associated with mastalgia; lower depression scores thereby improve the quality of life.

4.4.1 Null hypothesis: The yoga group will show changes similar to control group in reducing the pain and discomfort associated with mastalgia.

CHAPTER - 5

METHODS

5.0 METHODS

Part I: Prevalence of Mastalgia in Young Indian Females

The study was carried out on young women between 18 to 29 years of age from 4 residential private nursing colleges and one State Government Nursing & Degree College in south Karnataka, India. All subjects included in the survey were volunteers hailing from semi urban and rural areas. After obtaining signed informed consent from the students, they were given a lecture about the need of the study, importance of breast self examination and breast health.

They were asked to fill up the checklist for mastalgia suitable to Indian population developed as part of the study. The checklist included a numerical pain analogue scale (PAS) marked from 0 to 10, based on Cleeland's Breast Pain Inventory (BPI), Clinical and demographic features of subjects including age, marital and educational status, history of hypothyroidism, their stress level, shifts at work, lifestyle pattern along with anthropometric and demographic data was obtained.

Weight was measured using a research grade electronic weighing scale and Height using a simple tape measure. Body Mass Index (BMI) was calculated as weight in kilograms divided by the square of height in meters.

Data analysis: Data analysis was done using 'R' software version=3.1.0. Mean and standard deviations are reported for continuous variables and frequencies and percentages are reported for categorical variables. Relative risk was calculated as a ratio between the proportion of cases with to cases without mastalgia for BMI and Stress categories.

Part II: Integrated Approach of Yoga Therapy for Women with Breast Pain

5.2 Design: This was a prospective, randomized, active controlled trial wherein concealed envelope procedure was followed for randomization. Participants (n=80) were randomly divided into two groups. The randomization was done using a computer generated random number table (www.randomizer.org) with a pre-labeled, sealed envelope. The intervention group (n=40) practiced yoga and the control group (n=40) did brisk walking for the same duration without any conventional treatment.

5.3 Subjects: Pre-menopausal young female participants in the age range of 18 to 25 years with breast pain (cyclical or acyclical) for more than 3 months comprised the subjects for this study. Female students of first and fourth year B.Sc. (Bachelor of Science) Nursing and GNM (General Nursing Midwifery) courses from two residential nursing colleges from Rural Bengaluru, India were recruited. Students belonged to urban, semi-urban and rural areas from 5 different states of India (Karnataka, Andhra Pradesh, Tamil Nadu, Maharashtra, and Kashmir) and Nepal.

5.4 Sample size: To ascertain the optimum sample size for the study, a pilot study including 10 women with breast pain was conducted. They went through 12 weeks of yoga therapy. Pain, quality of life (QOL), anxiety and depression were assessed for baseline as well as post-treatment. Results of 7 subjects who completed 12 weeks of yoga therapy indicated a reduction in pain (ES=3.09), anxiety (ES=1.59) and depression (ES=2.21) and an increase in mean QOL (ES=0.80) with the two tailed analyses powered at 0.95.

Taking into consideration the effect size of QOL a sample size of n=23 was obtained and anticipating a higher attrition of 70% due to the forthcoming academic year a total of 40 subjects in each arm were recruited for the study. Although the effect sizes of the

pilot study indicated the optimum sample size of 12, a sample size of 80 was chosen to ensure that the study is adequately powered (alpha=0.8) to meet its objectives.

5.5 Criteria for selection of subjects: (i) Pre-menopausal women between 18 and 25 years, (ii) those with breast pain for more than 3 months (cyclical or acyclical, uni or bilateral) requiring reassurance and/ or non drug therapy, (iii)those who had a pain score ≥2 on Cleeland's Breast Pain Inventory (BPI),(47)(iv) those with or without fibrocystic disease of the breast and (v) women not on any hormonal treatment or oral contraceptive pills (OCP), were included in the study. Post-menopausal women, women with any malignancy, pregnant women and those already practicing yoga were excluded from the study.

5.6 Consent and ethical clearance

Written informed consent from all the students was sought before the commencement of recruitment for the study. The study started after the approval from the Institutional Ethical Committee of Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA) University (RES/IEC-SVYASA/16/201). This study was registered with Clinical Trial Registry of India (CTRI/2014/08/004911).

5.7 Methodology

After giving an introductory lecture about the study, 314 students from two nursing colleges were screened for this study using a screening checklist based on the inclusion/exclusion criteria. After obtaining the signed informed consent they were asked to fill up a short symptom check list which included questions regarding their breast health and the demographic data.

A breast surgeon along with 4 female gynecologists from the state government conducted a detailed physical/clinical examination on all the 80 students who consented, in a hygienic biology lab of the college providing them the privacy and comfort. Uniformity was maintained by all the medical officers during the screening. Educating along with counseling with regard to breast care, breast self examination (BSE) and the pathology of the breast was also done during clinical examination.

Baseline clinical breast examination done on all the 80 students who consented and satisfied the selection criteria and randomised determined the necessity for further breast imaging. Breast ultrasonography was therefore done on 28 students. Of the 28, only 4 students had repeat ultrasonography at the end of study. All the 80 students underwent blood test for clinical and subclinical hypothyroidism. Students who had elevated or close to upper limit of normal thyroid stimulating hormone levels (TSH) had a repeat blood test at the end of the study.

5.8 Breast examination (clinical/physical) procedure

Breast examination involved inspection of the breasts with the subject in a seated position and then with both arms raised above the head, to see the abnormalities in terms of the shape, difference in the skin color, rashes, visible lumps or swelling, inverted nipple. With the subject in the seated and supine position, all quadrants of the breast were palpated using the flat of the hand. The nipples were examined to check any abnormal discharge. The axillae were examined.

5.9 Blinding and masking: Double blinding was not possible as this was an interventional study. The research medical officer, the breast surgeon, 4 gynecologists, Ultrasonologists and the laboratory staff were blind to the groups. Also, the statistician

who did the randomization and the final analysis was blind to the source of the data. The coded answer sheets were analyzed only after completion of the study.

5.10 Intervention: All the 80 students were allocated to one of the two arms: yoga or brisk walk. The interventional group underwent Integrated Approach of Yoga Therapy (IAYT) module. IAYT included breathing practices, warm up stretches, Surya namaskara (Sun Salutation), asanas (postures), prāṇa yama practices (altered breathing), and dhyana(meditation). It also included lectures on the conceptual basis of yoga from the traditional scriptures of yoga (Patanjali Yoga Sutras, Upanishads, and Yoga Vasishtha) which helps in overall development of a personality (physical, vital, mental, emotional, intellectual and spiritual) and yogic counseling for emotion culture, deep relaxation practices for stress management. Control group subjects did brisk walking for half an hour followed by warm up stretches and supine rest. Both the groups practiced for six days a week up to twelve weeks under supervision by the therapist. Both the groups were given conventional lecture classes about breast disease, its causes and the role of stress etc. Attendance was taken for both the groups. The duration of practice along with lecture was one hour and fifteen minutes/ day for both the groups.

5.11 Assessments

Demographic and anthropometric details including age, height, weight, BMI, home town were obtained. A check list included the age of menarche, menstrual history, breast pain (mild, moderate or severe), breast pain before/during/ after menstrual cycle (cyclical), breast pain throughout the month (acyclical), breast pain duration, history of fibroadenoma, fibrocystic disease, previous history of breast cancer, history of other previous illnesses, treatment, scanning or surgery, Secondary Variables: Pre menstrual

symptom checklist was obtained which included menstrual history, back pain, migraine headache, anger, mood swings, stress levels etc., life style details like shifts in work, sleep and appetite, diet pattern, alcohol and smoking, happiness scores were collected. Clinical examination of the breast was documented in all cases.

5.11.1Cleeland brief pain inventory (BPI): Cleeland's BPI(Cleeland CS, 1994) was used after obtaining written permission from the author. Numerical Pain Analogue Scale (PAS) is a valid and reliable measure of pain intensity. BPI is a validated tool(Keller ., 2004) with a Cronbach's alpha between 0.77 to 0.91. The 5th question of BPI is a numerical PAS from 0 (no pain) to 10 (pain as bad as you imagine) to measure the pain intensity. The PAS from Cleeland's BPI has been vastly used for mastalgia studies.

5.11.2 Ultra sound scanning (US scanning): US Scanning was done to look for fibroadenoma/cysts and blood test for thyroid profile was done in cases recommended by the clinician. Post data were collected after 12 weeks of intervention.

5.11.3 Psychological assessments: QOL and BDI questionnaires were administered at baseline, after 3 months and 6 months after the intervention.

Beck depression inventory: BDI, developed by Dr Beck in 1961, (BECK, WARD, MENDELSON, MOCK, & ERBAUGH, 1961) aims to evaluate the risk of depression and level of depressive symptoms objectively. The inventory consists of 21 questions, each with 4 possible answers scored between 0 and 3, with the total score ranging from 0 to 63. The total score demonstrates the level of depression. The score for each item ranges from 0-3 and the range of total score is 0-63. A score between; $0 \leq 9$: No depression, 10-19: Mild depression, 20-25: Moderate depression, 26 and above: Severe depression. BDI has been used widely and has Cronbach's alpha coefficient of

0.80 and r: 0.74. This instrument has a reliability of 0.48–0.86 and validity of 0.67 with the Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnostic criteria for depression. (Hisli N, 1988)

BDI questionnaire attempts to measure the intensity, severity and depth of depression. It is commonly used in clinical setting as a novel way of diagnosing and categorizing depression in psychiatric settings.

WHOQOL-BREF questionnaire

Quality of Life reflects the psychological imbalances that result from amplified responses to incorrectly perceived environmental situations. The WHO QOL-Bref which is the short version of the WHOQOL-100 is widely used. WHO QOL-Bref consists of 26 items assessing the QOL in four domains (Physical health, Psychological health, Social relationships and Environment) and a general evaluative facet (Overall QOL and general health). The psychometric properties of the WHOQOL- Bref is considered good for assessment of QOL in women with benign breast disease.(Lotje Van Esch ., 2011) Higher the scores in WHO QOL-Bref, higher is the quality of life. Cronbachis alpha being >0.70.

5.12 Statistical analysis: Data was analyzed using 'R' software (ver. 3.1.0). The data was analyzed using a repeated measures ANOVA to investigate changes in mean scores over three time points (baseline, 3rd month & 6th month). Post-hoc tests were done using Bonferroni correction for changes at different time points between groups. Chi-square test was done for secondary variables. Statistical significance was set at Alpha =0.05.

Chapter – 6

RESULTS

6.0 RESULTS

The present Randomised Controlled trial tested the effect of yoga intervention compared to a control group (brisk walk) in nursing students with mastalgia. As a prelude to this RCT, prevalence of mastalgia was studied in 748 students from 5 different nursing colleges.

6.1: Prevalence of mastalgia in nursing students Seven hundred and fifty four students attended the introductory lecture. Of these 748 girls (99.2%) responded and agreed to participate. Their age ranged between 18 and 29 years with a mean age of 19.96 years. Average BMI was 20.8 Kg/m^2 and the average age of menarche was 12.5 years. Out of these 748 girls, 711 were unmarried while 34 were married. Most of these girls reported low stress levels (73.73%) and had regular menstrual cycles (85.2%). The socio-demographic details are shown in table 3.

Table 3: Socio demographic data (Mean ± SD)

S.No	Characteristics	Units/ Scale	Whole gp (n=748)	With Mastalgia (n=354)	Mastalgia Cyclical (n=314)	Mastalgia Acyclical (n=35)
1.	Age	Years	19.96 ± 1.89	19.89 ±1.69	19.82 ±1.64	20.40 ± 2.03
2.	Height	Centimeters	153.07 ± 10.37	153.16±11.05	153.04±11.44	154.6 ± 7.66
3.	Weight	K.gs	48.35 ± 8.91	46.92 ± 7.47	46.8 ± 7.46	47.5 ± 7.87
4.	BMI	Kg/m^2	20.8 ± 4.04	20.18 ± 3.66	20.18 ± 3.76	19.86 ± 2.8
	Low BMI	<18.5	236 (31.6%)	130 (36.7%)	118 (37.6%)	12 (34.3%)
	Normal BMI	18.5 to ≤23	304 (40.6 %)	156 (44.1%)	135 (43.0%)	18 (51.4%)
	High BMI	>23	207 (27.7%)	67 (18.9%)	60(19.1%)	5 (14.3%)
5.	Marital Status	Married	34 (4.5%)	14 (4%)	12 (3.82)	2 (5.71%)

		Unmarried	711 (95.1%)	340 (96%)	302 (96.18%)	33 (94.29%)
6.	Age of Menarche	Years	12.5 ± 0.99	12.45 ± .98	12.43 ± 0.97	12.66 ± 1.03
7.	Menstrual Pattern	Regular	637 (85.2%)	298 (84.2%)	269 (85.67%)	25 (71.43%)
		Irregular	111(14.8%)	56 (15.8%)	45 (14.33%)	10 (28.57%)
8.	Pain Duration	Months	4.74 ± 7.87	9.8 ± 8.83	9.6 ± 8.8	12.06 ± 9.31
9.	Pain Score	Numerical	1.55 ± 1.85	3.08 ± 1.57	3.03 ± 1.57	3.71 ± 1.45
10.	Stress	Low	551(73.73%)	238 (67.2%)	222 (70.70%)	14 (40%)
		Medium	164(21.9%)	92 (26%)	73 (23.25%)	16 (45.71%)
		High	20 (2.7%)	11 (3.1%)	9 (2.87%)	2 (5.7%)
			66.15 ±15.8	63.45±15.78	63.7±15.95	60.16 ±14.17

Of the 354 (47.33%) who were diagnosed with mastalgia, 314 (88.70%) had cyclical (CM) and 35 (9.89%) had acyclical (ACM) mastalgia. Five girls (1.41%) who had mastalgia missed reporting whether they had cyclical pain or acyclical pain. Out of 354 women with mastalgia, 13 (3.67%) missed reporting their stress levels, of which 10 girls were in CM group while 3 were in ACM group. One woman with CM (0.28%) missed her height assessment. The average pain score for CM group was 3.03 ± 1.57 while it was 3.71 ± 1.45 for the ACM group. Average pain duration was more than 9.6 ± 8.8 months for mastalgia group, on the other hand it was12.06 ± 9.31 for the ACM group. Majority of the CM girls reported low stress levels (70.70%) while ACM girls reported moderate stress levels (45.71%).

Association between mastalgia and other variables was estimated by relative risk (RR) and is shown in table 3. Women who had low BMI had higher risk (RR of

1.685) for mastalgia as compared to those with normal BMI (RR =1.063) or high BMI (RR=1.685). Moderately stressed students had a higher risk (RR of 0.771) for mastalgia compared to those with low stress (RR of 0.771). Women with high stress (RR of 0.787) levels had a higher risk for mastalgia as compared to those with low stress (RR=0.787).

Thus, those with medium and high stress levels and low BMI had higher risk of developing mastalgia than those with low stress and normal or high BMI.

Table 4: RELATIONSHIP BETWEEN MASTALGIA , BMI AND STRESS

VARIABLE	GROUPS (N)	RR	95% CI Lower Bound	95% CI Upper Bound
BMI	Low BMI(126) : Normal BMI (156)	1.063	0.905	1.248
	Low BMI (126) : Overweight BMI(67)	1.685	1.34	2.12
STRESS	Low Stress(238) : Medium Stress(92)	0.771	0.654	0.91
	Low Stress(238) : High Stress(92)	0.787	0.523	1.183

6.2: Results of RCT

INTEGRATED APPROACH OF YOGA THERAPY FOR WOMEN WITH BREAST PAIN

Out of 314 nursing college students who enrolled for the study, 154 fulfilled the eligibility criteria, 74 were excluded as they did not satisfy the inclusion criteria; 80

students who consented to participate in the RCT were randomized into two groups, yoga (n=40) and control (n=40) for a period of 3 months. In the yoga group 38 students completed the study, and 2 dropped out, one due to back pain (slipped down the stairs in the hostel) and one discontinued the study course and left the city. In the control group 36 students completed the study, 4 dropped out as they discontinued the academic course.(Fig 9) None of the participants reported adverse events during the intervention, which were specifically checked after each session.

Fig 9:

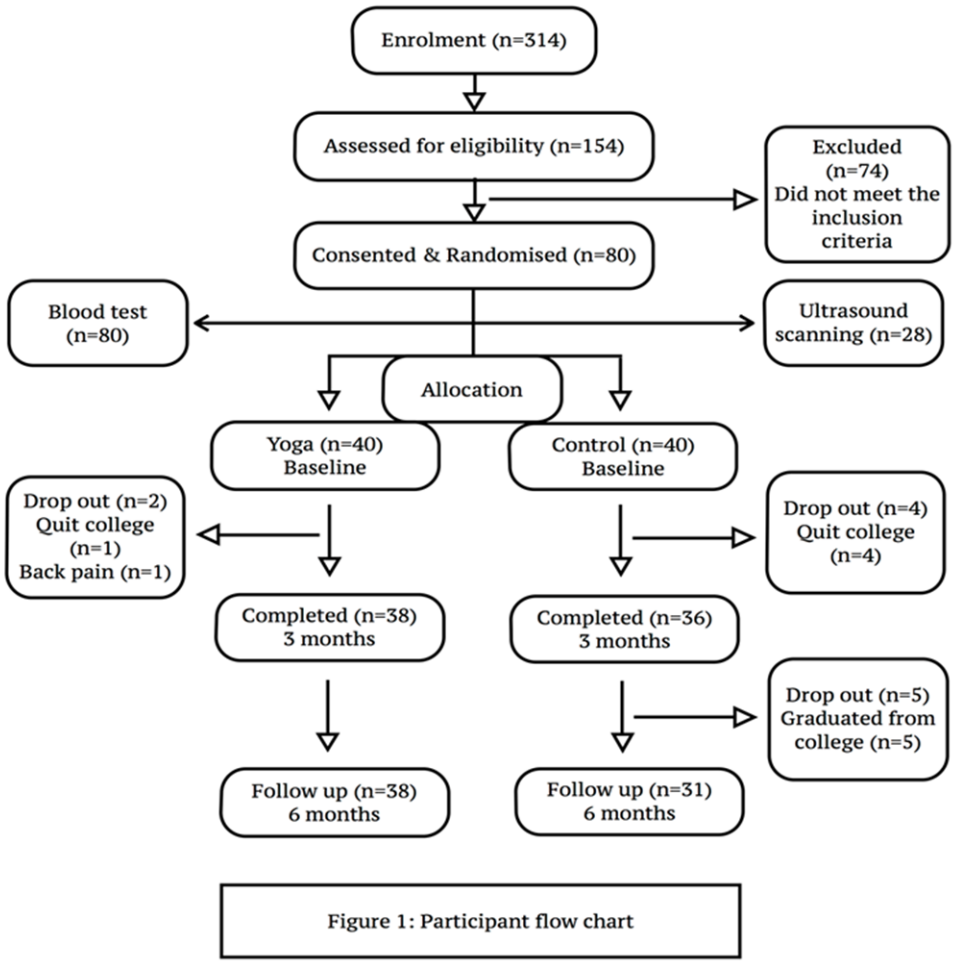


Figure 1: Participant flow chart

6.2.1: Socio-demography of students randomized for RCT

All the eighty residential students from 1st to 4th BSc Nursing and GNM course were unmarried, had mean age of 19.84 ± **1.15** years, the onset of menarche was at the age between 11-15 years (12.66±0.97), the duration of breast pain varied from 4-60 months (M=13.13, SD=10.06), the BMI was 20.61±3.23 and the baseline mean of the breast pain score on Pain Analogue Scale was 3.67±1.11. Majority of the students 58 (72.5%) had cyclical mastalgia while 22 (27%) students had acyclical mastalgia. Most students, 61 (76.25%) had regular menstrual cycle while 19(23.75%) had irregular menstrual cycle; 32(40%) of them had menstrual (abdominal) pain. Out of 72 practice sessions within the first three months, the attendance was 56.89 ±4.29 in yoga group and 54.83 ±4.4 **in the control group.** Baseline scores of QOL was 87.28 ± 6.16 in yoga group and 86.88 ± 7.07 in control group; BDI was 15.28 ± **6.75** in yoga and 14.48 ± **4.67** in control group. (Table 5)

Table 5: Socio-Demographic, breast and menstrual cycle characteristics:

Characteristics		Yoga (n=40)		Control (n=40)		Total (n=80)	
		Mean	SD & %	Mean	SD & %	Mean	SD & %
Age (Years)		20.10	1.28	19.58	0.96	19.84	1.15
Height (Centimetres)		155.08	7.35	155.95	4.50	155.51	6.07
Weight (Kilos)		48.90	6.86	50.85	9.72	49.88	8.42
BMI		20.33	2.43	20.90	3.88	20.61	3.23
Education	I BSc	3	7.5%	3	7.5%	6	7.5 %
	II BSc	13	16.25%	11	27.5%	24	30%
	III BSc	13	16.25%	12	30%	25	31.25%
	I GNM	8	20%	8	20%	16	20%
	II GNM	3	7.5%	6	15%	9	11.25%
Age of Menarche		12.48	1.06	12.85	0.83	12.66	0.97
Menstrual Cycle-Regular		28	70%	33	82.5%	61	76.25%
Menstrual Cycle-Irregular		12	30%	7	17.5%	19	23.75%
Menstrual pain		2	5%	30	75%	32	40%
Menstrual pain nil		38	95%	10	25%	48	60%
Cyclical Mastalgia		30	75%	28	70%	58	72.5%
Acyclical Mastalgia		10	25%	12	30%	22	27.5%
Breast Pain Duration (in Months)		13.78	11.05	12.38	8.97	13.13	10.06
Breast Pain Score		3.85	1.17	3.63	1.10	3.67	1.11
Family History (Breast Cancer)		2	5%	0	0	2	.5%
T3 (ng/dL)		1.30	0.15	1.26	0.23	1.30	0.16
T4 (mcg/dL)		8.90	1.39	8.62	1.74	2.2 1	1.80
TSH (U/mL)		1.96	1.05	1.80	0.74	1.94	1.05
Anger (1-3)	Rarely lose temper	5	12.5%	19	47.5%	24	30%
	Easily disturbed	22	55%	15	37%	37	46.25%
	High temper	13	32.5%	6	15%	19	23.75%

6.*2.2*: Primary variables: Results after the Intervention

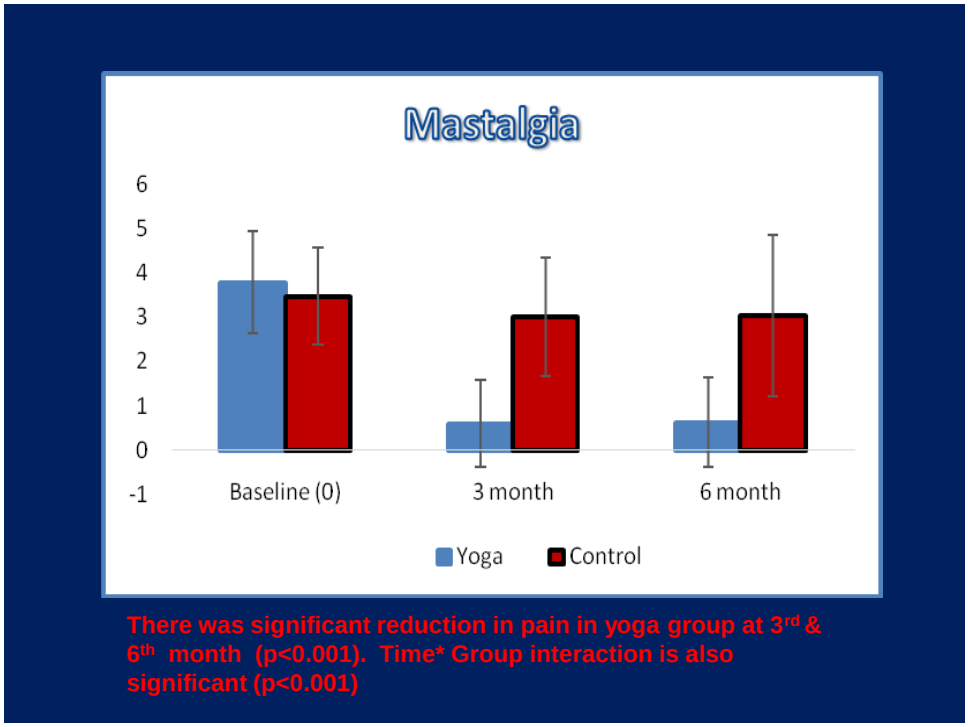
Pain Analogue Scale (PAS)

Pain reduced significantly over time ($p<0.001$) from baseline to 3rd month and also from baseline to 6th month. There was significant difference between groups ($p<0.001$). Groups * time interaction was significant for pain ($p<0.001$). (Table 6)

Table 6: Results of Pain (Mastalgia)

Group	Descriptive Statistics			Time Effect		Sig Group Effects	Sig Group *Time
	Baseline	3rd month	6th month	0-3 months(p-value)	0-6 months(p-value)		
Yoga	3.79 ± 1.16	0.60 ± 0.97	0.63 1.02	<0.001	<0.001	<0.001	<0.001
Control	3.48 ± 1.09	3.00 ± 1.34	3.03±1.83				
There was significant reduction in pain in yoga group at 3rd & 6th month ($p<0.001$). Time* Group interaction is also significant ($p<0.001$)							

Figure10: Pain (PAS)



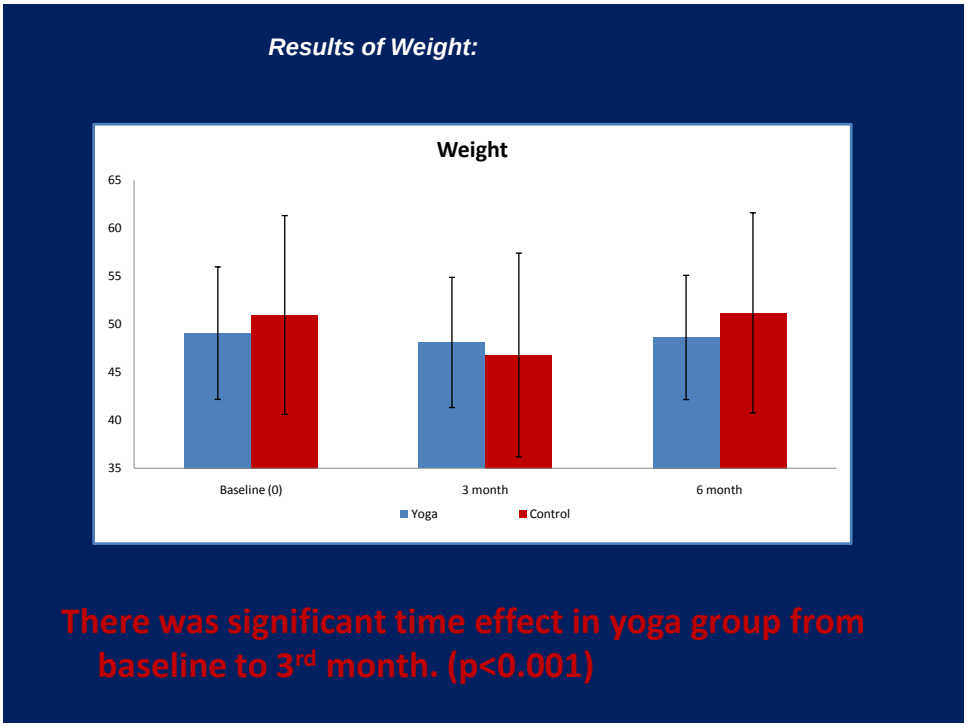
6.2.3: Results of Weight: There was significant time effect in yoga group from baseline to 3rd month. (p<0.001).(Table 8)

Table 7: Results of Weight

Groups	Descriptive Statistics			Time Effect		Group Effects	Group *Time
	Baseline	3rd month	6th month	0-3 months (p-value)	0-6 months (p-value)		
Yoga	49.08 ± 6.65	48.11 ± 6.90	48.63 ± 6.47	<0.001	0.100	0.265	0.100
Control	50.97 ± 10.35	50.65 ± 10.61	51.19 ± 10.42	1.00	0.21		

Adjustment for multiple comparison: Bonferroni (α=0.05). There was significant reduction in weight in yoga group at 3rd month (p<0.001).

Figure 11: Weight

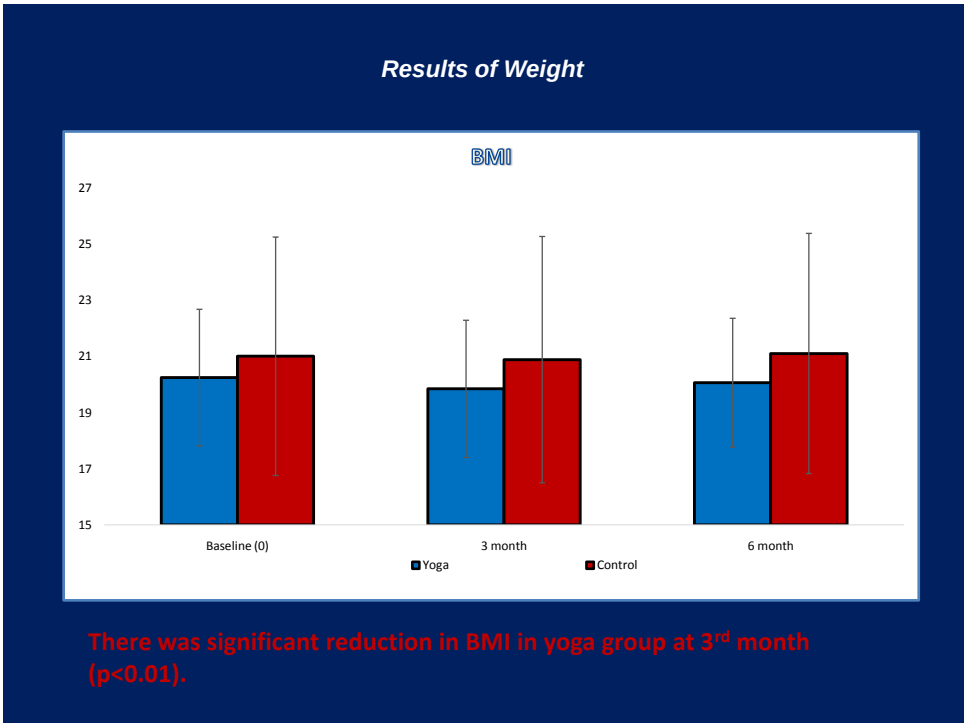


6.2.4: Results of BMI: BMI was significant in yoga group from base line to 3rd month. (p<0.001)

Table :9 Results of BMI

Group	Descriptive Statistics			Time Effect		Group Effects	Group *Time
	Baseline	3rd month	6th month	0-3 months (p-value)	0-6 months (p-value)		
Yoga	20.24 ± 2.43	19.84 ± 2.43	21.10 ± 4.26	<0.001	1.000	0.250	0.083
Control	21.00 ± 4.23	20.88 ± 4.38	21.10 ± 4.26				
There was significant reduction in BMI in yoga group at 3rd month (p<0.001).							

Figure 12: BMI: There was significant reduction in BMI in yoga group at 3rd month (p<0.001).



6.2.5: Results of Quality of life

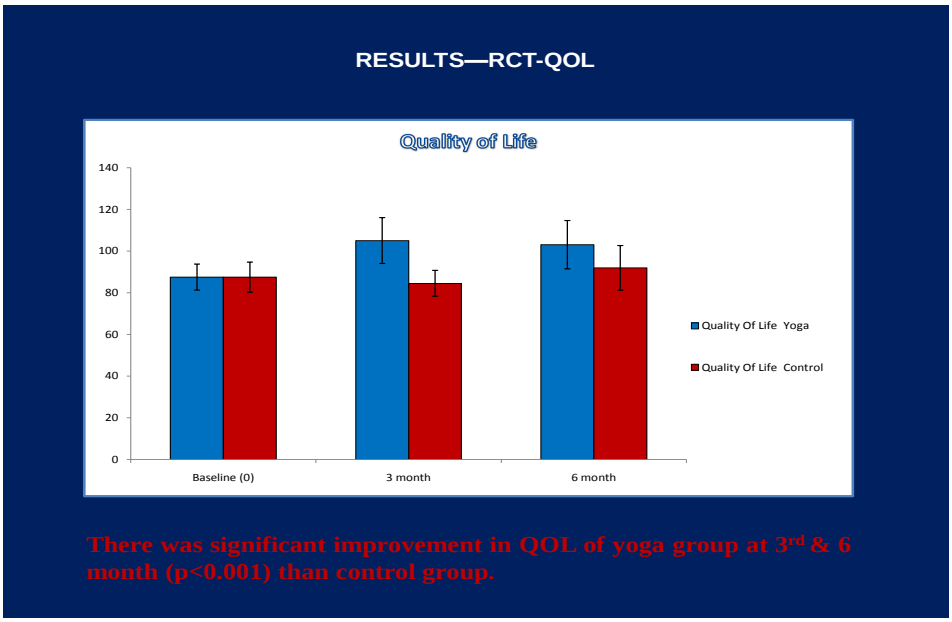
Comparison of means of the two groups by repeated measures ANOVA showed highly significant difference in the group effect with better improvement in yoga than control group on all 4 domains and the total score of QOL ($p < 0.001$). Further, the post hoc analysis using paired samples T test showed significantly better improvement at 3 months ($p<0.001$) and 6 months($p<0.001$) in the yoga group as compared to control group (table 10) .

Table 10 : Results of Quality of life four domains and total QOL

Variable	Group	Baseline		3 Months		Sig within groups (0-3 Months)	6 Months		Sig within groups (0-6 months)	RM ANOVA between groups
		Mean	SD	Mean	SD	T (p)	Mean	SD	T (p)	
QOL D1*	Yoga	26.45	2.82	30.84	3.96	7.08 (<0.01)	30.39	3.07	5.71 (<0.001)	f-1045.01 p<0.001
	Control	25.61	3.21	24.4	2.45	2.92 (=0.01)	27.2	3.61	2.28 (0.02)	
QOL D2*	Yoga	21.16	2.15	25.6	2.55	-7.88 (<0.001)	25.6	3.42	6.3 (<0.001)	f-471.58 p<0.001
	Control	20.55	1.8	20.4	2.06	0.31 (=0.75)	22.9	3.25	3.77 (0.001)	
QOL D3*	Yoga	11.5	1.43	13.4	1.64	-5.68 (<0.001)	12.7	2.42	2.79 (0.008)	f-167.96 p<0.001
	Control	12.16	1.0	11.6	0.99	2.53 (=0.01)	11.8	1.24	1.07 (0.29)	

Table 10 : Results of Quality of life four domains and total QOL										
QOL D4*	Yoga	28.37	3.16	34.7	3.79	-8.06 (<0.001)	34.2	4.71	6.91 (<0.001)	f-1087.42 p<0.001
	Control	29.13	3.03	28.1	2.65	1.87 (=0.07)	30	3.94	1.05 (0.30)	
QOL* overall	Yoga	87.47	6.25	105	11.0	-9.08 (<0.001)	103	11.6	7.34 (<0.001)	f-6881.41 p<0.001
	Control	87.45	7.22	84.5	6.19	2.60 (=0.01)	91.9	10.7	2.19 (0.03)	

Figure: 13 Overall Quality of Life



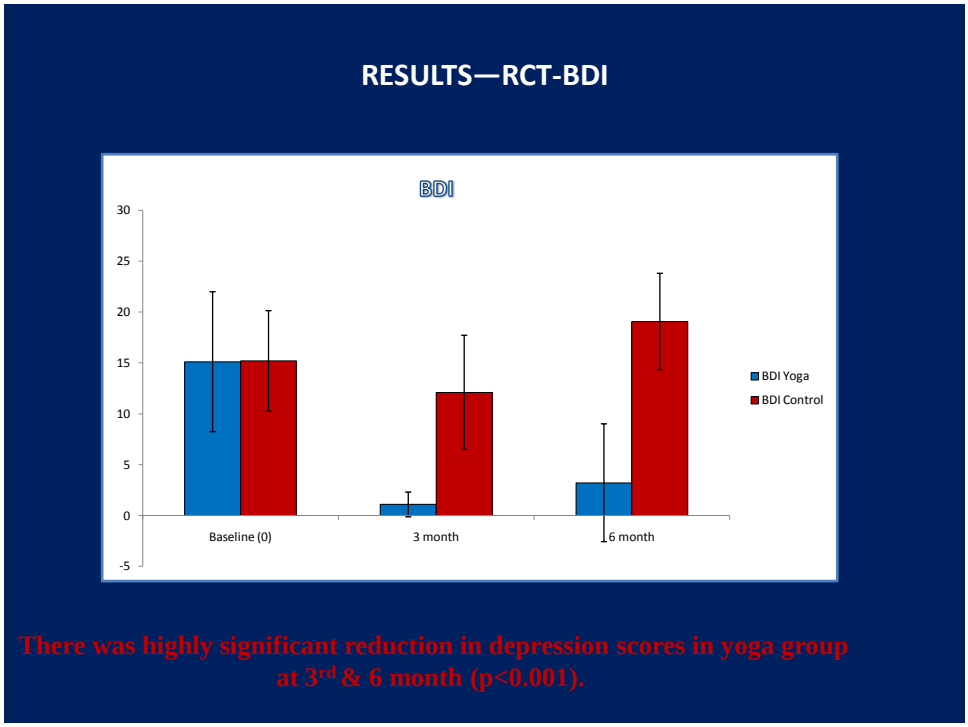
6.2.6: *Beck's Depression Inventory*

There was significantly better reduction ($p<0.001$) in depression in yoga than the control group as seen in the 'between group effect' on repeated measures ANOVA. Further, the Post hoc analysis using paired samples T test showed that there was significantly better reduction at both 3 and 6 months in yoga intervention group as compared to control group. (table 11)

Table 11: Depression BDI scores before and after intervention in both the groups (Repeated Measures ANOVA)

Group	Baseline		3 Months		Sig within groups (0-3 Months)	6 Months		Sig within groups (0-6 months)	RM ANOVA between groups (p)
	Mean	SD	Mean	SD	T (p)	Mean	SD	T (p)	
Yoga	15.11	6.88	1.08	1.22	12.96 (<0.001)	3.21	5.79	8.90 (<0.001)	p<0.001
Control	15.19	4.94	12.1	5.61	2.60 (=0.01)	19.1	4.74	3.72 (=0.001)	
There was highly significant reduction in depression scores in yoga group at 3rd & 6th month ($p<0.001$).									

Figure 14: Results of BDI



6.2.7: severity of depression before and after intervention in both the groups

Table 12: BDI –Number of subjects in different degrees of depression before and after intervention (Yoga n = 38; Control n = 31)

I Scores	Depression	Baseline				3 months				6 months			
		Y		C		Y		C		Y		C	
		n	%	n	%	n	%	N	%	N	%	N	%
(0-9)	Nil	7	18.42	0	0	38	100	16	51.61	32	84.21	0	0
10-19	Mild	22	57.89	27	71.05	0	0	9	29.03	5	13.16	14	45.16
20-25	Moderate	9	23.68	4	10.53	0	0	6	19.35	1	2.63	17	54.84
>26	Severe	0	0	0	0	0	0	0	0	0	0	0	0

None were severely depressed at base line. Although there were more number who had mild and mod depression at base line, all moved to nil after yoga; the number with mild and mod depression increased in control group.

6.2.8 Secondary variables

PMS

This study also looked at pre menstrual symptoms as which showed a significant reduction in menstrual pain in yoga group from 38 (100%) to 2(5.26%) and also between group significance ($p<0.0001$) from the baseline to 3rd month. Menstrual cycle also got regularized in yoga group from base line 28(73.68%) to 3rd month 38(100%) compared to control group.

Looking at the psychological aspects**,** although significantly higher number of students in yoga group had reported greater scores of anger at baseline (35 yoga vs. 17 control) than the control group, the changes reversed after 3 months of yoga practices with none reporting grade 2 or 3 anger scores (0 yoga vs. 17 control). Similar changes are seen in mood swings and stress levels with significantly better improvement in yoga than the physical activity group.

Table 13: Result: secondary variables: chi-square test for PMS symptoms

S.N	Variables		yoga baseline	yoga 3rd month	control baseline	control 3rd month	P value (between)
1	Menstrual Cycle	Regular	28(73.68%)	38(100%)	33(91.67%)	34(94.44%)	p<0.001
		Irregular	10(26.32)	0	3(8.33%)	2(5.55%)	
2	Menstrual Pain	yes	38(100%)	2(5.26%)	30(83.33%)	24(66.67%)	p<0.001
		No	0	36(94.74%)	6(16.67%)	12(33.33%)	
3	Back pain	yes	35(92.11%)	2(5.26%)	36(100%)	18(50%)	p<0.05
		Nil	3(7.89%)	36(94.74%)	0	18(50%)	
4	Head ache	Yes	38(100%)	2(5.26%)	36(100%)	24(66.67%)	p<0.000
		Nil	0	36(94.74%)	0	12(33.33%)	
5	Anger 0-3	1	3(7.89%)	38(100%)	19(52.78%)	19(52.78%)	p<0.05
		2	22(57.89%)	0	15(41.67%)	17(42.22%)	p<0.001
		3	13(34.21%)	0	2(5.55%)	0	
6	Mood Swing 0-3	1	7(18.42%)	37(97.37%)	0	4(11.11%)	p<0.000
		2	20(52.63%)	1	23(63.89%)	31(86.11%)	
		3	11(28.95%)	0	13(36.11%)	1	
7	Stress 0-3	1	0	36(94.74%)	8(22.22%)	11(30.56%)	p<0.001
		2	10(26.32)	2(5.26%)	23(63.89%)	20(55.56%)	
		3	28(73.68%)	0	5(13.89%)	5(13.89%)	

6.2.9: Ultrasound scanning

Of the 80 subjects, 28 were recommended ultrasound scanning of the breast based on nodularity or lumps detected during clinical breast examination. Only 4 (2 in yoga and 2 in control) of them had ultrasound findings of simple cyst and fibroadenoma. We repeated Post intervention, there were a better improvement in yoga group but showed no significant differences in either of the groups. No statistical test was applied due to the small sample size.

6.3 Summary of RCT

This is the first randomized controlled trial comparing the effect of integrated approach of yoga therapy with physical activity such as walking on mastalgia and other premenstrual symptoms in nursing students. Breast Pain reduced significantly over 6 months while significant weight reduction occurred during first 3 months of supervised training which did not persist after the follow up. The present RCT on 80 nursing students in age range of 18 to 25 with non organic breast pain looked at the effect of yoga on QOL and depression in a six month period. Results of repeated measures ANOVA showed significant group time interaction ($p<0.001$). Post hoc tests revealed significant improvement within the yoga group at third and sixth month follow up on all 4 domains of QOL and BDI.

CHAPTER – 7

DISCUSSIONS

7.0 Discussion

This is the first randomized controlled trial comparing the effect of integrated approach of yoga therapy with physical activity [walking] on mastalgia and other premenstrual symptoms in nursing students. Breast Pain reduced significantly within 3 months that continued to be stable after 6 months. Significant weight reduction occurred during first 3 months of supervised training with no further reduction at 6th months.

7.1 Comparisons

7.1.1 Pain

Our study reported a reduction of mean scores (3.19) on pain (breast) scale from baseline (3.79±1.16) to 3rd month (0.60±0.97), which persisted until the end of 6th month (0.63±1.02)'this reduction observed in our study is greater than the reduction of 0.8 mean score from baseline (3.5±3.6) to 3rd month (2.7±2.4) of a acupuncture intervention by Lori . (Lori A Thicke, 2011)

7.1.2. BMI

Also, our study reported a reduction of 0.4 mean scores for BMI from baseline (20.24±2.43) to3rd month (19.84±2.43), which was similar to the non-significant reduction of 0.07 mean score from baseline (23.75±2.40) to 3rd month (23.68±2.42) after administration of Borago officinalis (900 mg borage oil capsules) in the study by Gama B .(Gama et al., 2015) A growing body of literature suggests U-curved link between psychological state and weight change (de Wit, van Straten, Lamers, Cuijpers, & Penninx, 2015; Gaysina et al., 2011) underlining the need for homeostasis at sympathetic nervous system level and body weight level.

7.1.3 PMS

Our study also looked at pre menstrual symptoms which showed a significant reduction in menstrual pain in the yoga group from 38 (100%) to 2(5.26%) with significant difference between groups ($p<0.001$) from the baseline to 3rd month. Menstrual cycle also got regularized in yoga group from base line 28 (73.68%) to 3rd month 38(100%) compared to control group.

7.1.4 Psychological- Anger, mood swings and stress

Looking at the psychological aspects**,** although significantly higher number of students in yoga group had reported greater scores of anger at baseline (35 yoga vs. 17 control) than the control group, the changes reversed after 3 months of yoga practices with none reporting grade 2 or 3 anger scores (0 yoga vs. 17 control). Similar changes are seen in mood swings and stress levels with significantly better improvement in yoga than physical activity group.

7.1.5 Depression (BDI)

In the survey on 105 Turkish women with mastalgia with a mean score of 5 on Visual Analogue Scale (1-10) 58% were depressive, 30% were anxious and 4% were depressive and anxious.(þ ý O R et al., 2014) Yilmaz, Enver Demirel showed that anxiety, depression, harm avoidance and self-transcendence scores were significantly higher in premenopausal women with mastalgia in comparison with age matched healthy control group of premenopausal women.(Yilmaz, 2014)

BDI score (table 4) less than 9 indicates no depression and that between10-19 indicates mild, 20-29 moderate and 30-40 severe depression. The mean baseline scores in our sample (around 15) showed that majority in yoga group were in this

range of mild to moderate depression with lesser numbers in control group. None were severely depressed in either of the groups. The yoga group moved to normal values (<9) at 3 months. In the control group, there were a good number (16) of subjects with reduced depression scores at 3rd month, who reverted back to depression in 6th month although they had the same instructions, monitoring and counseling by the therapists at regular intervals.

Looking at BDI scores of IAYT study in chronic low back pain[27], the BDI scores in the back pain study also showed similar trends with significant reduction in mean scores moving from mild depression zone (12.13) to no depression zone (6.43).

BDI scores in the back pain study also showed similar trends with significant reduction in mean scores moving from mild depression zone (12.13) to no depression zone (6.43) .(Padmini Tekur, Chametcha, Hongasandra, & Raghuram, 2010b)

Mastery over the emotional reactions of anxiety(Miller et al., 1995)or depression(Sharma .)is achieved through restful awareness during all the practices in general and meditation in particular.(S Telles, Nagarathna, & Nagendra, 1995)

7.1.6. Quality of life

The present study also looked at the effect of yoga on QOL. Results of repeated measures ANOVA showed significant group time interaction ($p<0.001$). Post hoc tests revealed significant improvement within the yoga group at third and sixth month follow up on all 4 domains of QOL.

Although some studies point to a negative association of pain and depression with quality of life in women with non-organic mastalgia,(Carmichael, 2008) very few interventional studies have measured QOL. Those that did look at QOL after

pharmacotherapy did not show significant change in QOL as many of them were associated with adverse effects.(Rosolowich ., 2006)Looking at non pharmacological therapies, a pilot study of acupuncture on 37 women with non-cyclic breast pain were given four acupuncture sessions over two weeks, showed no significant improvement in any of the domains (mental, physical, emotional, social, or spiritual well-being) of QOL after three months follow-up, although there was a significant reduction ($p<0.05$) in the pain scores by about 67% and pain interference by about 56%.(Lori A Thicke, 2011)

A randomized pre–post intervention study on 98 (66 experimental and 32 control) Turkish patients with non- organic mastalgia looked at the effect of a session of Psycho-education on QOL and pain (Visual Analogue Scale). While the baseline QOL in both groups was poorer than the normative values for Turkish women, the QOL of those who had psycho-education was significantly better (SF-36) after two months as compared to the control group.(Eryılmaz1, 2014)

As there are no published studies on yoga in patients with mastalgia, we have made an attempt to compare the effect of integrated yoga (similar yoga module in a similar setting) with that of other non organic pain conditions. In patients with mechanical chronic low back pain admitted for yoga therapy(Padmini Tekur ., 2010a), the baseline mean QOL (12 to 13) was much lower in all domains of WHOQOL-Bref in patients with low back pain than our study (22 to 29) except the social domain in which it was 11.5 in our study. This could be because of the age difference between the two groups (ours were young students); also the degree of psychological disturbance/frustrations in patients of chronic low back pain would be much higher as compared to functional students with mastalgia.

The improvement observed was highly significant in both studies (16 t0 28 % in back pain study and 10 to 20 % in present study) although the groups were different in their demography (higher age in back pain study). A similar work by Deshpande on normal volunteers also looked at the QOL which showed similar improvements after three months intervention on all domains of WHOQOL100.(Deshpande, 2008)

Results of integrated yoga in elderly patients with osteoarthritis of the knee showed about 20-30 % increase in QOL(SF36).(Ebnezar, Nagarathna, Bali, & Nagendra, 2011)The various domains of the WHOQOL –Bref assessed in this study is discussed below.

7.2.Physical health

This domain of WHOQOL-Bref deals with features such as mobility, fatigue, pain, sleep, work capacity etc. The observed improvement can be attributed to better physical stamina that occurs after maintained stretches followed by deep rest (*sthiram sukham āsanam*-definition by Patañjali)(Swami Prabhavanada, 2002)to musculoskeletal system during the āsana practices. Other studies on integrated yoga in healthy children and adults have shown significant improvements in their physical stamina. (Raghuraj & Telles, 1997)Better quality and duration of sleep after yoga has been reported in the elderly too.(Bankar, Chaudhari, & Chaudhari, 2013)

7.2.1 Psychological health

The improvement seen in this domain that deals with questions relating to feelings, self esteem, spirituality, thinking, learning, memory etc., may be attributed to reduction in depression. Yoga is defined as ‘mastery over the modifications of the mind’(Patañjali)(Swami Prabhavanada, 2002)which is the goal of the integrated yoga

program; Several studies have shown the effect of yoga in reducing anxiety, (Michalsen ., 2012)depression,(Sharma .) and stress(Carmody & Baer, 2008) with enhanced mental health as observed by improved perceptual sharpness, (Telles S, Nagarathna R, 1995) and memory.(Naveen, Nagarathna, Nagendra, & Telles, 1997)

7.2.2.Social health

This domain has questions relating to problems with interpersonal relationships, social support etc which could be the main source of stress contributing to mastalgia. In this domain the baseline scores (table 3) were lesser than the other three domains in both groups of students which improved significantly after the intervention. These were addressed during lectures and at a personal level in yoga counseling sessions. They were aimed at achieving an introspective cognitive change by recognising the psychological freedom 'to react, not to react or change the usual pattern of reaction to situations' highlighted in yoga texts.(Tapasyānanda, 2000)

The students reported that the analysis of happiness (highlighted in chapter 3) that was discussed in the interactive lecture sessions made a big difference for them to recognize their freedom and remain joyful under all circumstances.

7.2.3. Environmental health

This domain has questions that deal with problems relating to financial resources, physical safety, adaptability to physical environment such as pollution, noise, climate etc. One of the definitions of yoga (*Bhagavad*-Gīta) says that yoga results in equanimity and balance (*samatvam*) that can help in better tolerance to environmental changes.(Tapasyānanda, 2000)

Studies have shown that yoga changes the physiological responses to stressors by improving autonomic stability with better parasympathetic tone in normal adults.(Shirley Telles ., 2013)

7.3. Mechanism

Stress reduction .

Normal breast function is a balance between estrogen and progesterone, which is a part of the neuroendocrine control exerted by the HP- gonadal axis. There is evidence to suggest that cyclical mastalgia is caused by a latent stress-induced hormonal imbalance as indicated by hyper Prolactinemia.(Carmichael, 2008) Studies point to a prolactin secretory hypersensitivity for estradiol in patients with cyclical mastalgia. Normally, estrogen induces prolactin release by increasing the dopaminergic tone centrally- but this is postulated to be impaired in patients with mastalgia. It is observed that patients with cyclic and non-cyclic mastalgia have increased catecholamine and decreased baseline dopamine level which suggests that catecholamine may be released due to stress resulting in altered abnormal sensitivity of the breast tissue.(Kirby, 2009) Catecholamines may be released due to dietary factors or stress resulting in altered abnormal sensitivity of the breast tissue.

Yoga may improve the quality of life by promoting voluntary reduction in violence and aggressiveness.(Deshpande ., 2008) Mastery over the emotional reactions of anxiety(Miller ., 1995)or depression (Sharma) is achieved through restful awareness during all the practices in general and meditation in particular.(S Telles ., 1995) Kundalini Yoga is found to be beneficial in cases of depression; it stimulates various autonomic nerve plexus (Chakras) and may activate pineal organ which in turn brings homeostasis between sympathetic and parasympathetic activities.(Devi ., 1986) This

mastery over emotional surges leads to controlled and need based physiological responses that may reduce the overtones of Hypothalamus-Pituitary-Adrenalin (HPA) axis(Leonard, 2006) during chronic pain. Yoga has an influence on the HPA axis as evidenced by a reduction in cortisol levels in normal(Kamei ., 2000) and sick individuals.(Curtis ., 2011; S. H. Vadiraja ., 2009) Pointing to its effect on the HPA Axis, furthermore, a study by Nidhi Ram has shown the beneficial effects of yoga in correcting the imbalances in reproductive hormones such as prolactin, FSH, LH and AMH in PCOS. Thus, yoga may help in restoring the normal biorhythm of reproductive hormones in these students resulting in reducing mastalgia.

Hence, it appears that the beneficial effects of yoga in mastalgia could be mediated through HPA axis by stabilizing the hypothalamic–pituitary–adrenal axis and promoting autonomic balance. We may hypothesize that yoga helps in restoring the normal biorhythm of reproductive hormones in cases of cyclical or non cyclical mastalgia and thus improve the quality of life.

Lymphatic drainage

Āsanas helps overcome lethargy and builds physical stamina. Studies suggest that the practice of yoga poses in standing, sitting, supine and prone positions offer good stretches of upper limbs along with twisting and bending of the thoracic spine which may help in clearing the lymphatic channels to promote better circulation and lymphatic drainage in the breast area that would help in clearing the congestion and fluid retention.(Clennell, 2014)

Kriyās designed as cleansing techniques of yoga, may help to clear the accumulated endotoxins (āma in Ayurveda) and free radicals induced by stress. (Tripathi, 1999). IAYT recommends sātvik diet, and moderation in eating habits,

sleep, and behavior. This may help in reducing the altered abnormal sensitivity of the breast tissue to catecholamine.

Prāṇayama practices help to remove the blockages and imbalance of prāṇa all over the body by altering and slowing down the breath.(Vivekananda S, 1999)

Meditation and relaxation

Deep relaxation technique and meditation that was a part of the module offers deep rest at cellular level, reduces speed, violence and inflammation; dhāraṇa (focussing) helps remove the restlessness in the mind, reduces the number of thoughts, Dhyāna(meditation), helps to defocus and promotes the feeling of inner silence and bliss. This deeply rested silent state of mind helps to gain mastery over the mind.(I.K. Taimini, 1999; Vivekananda S, 1999) With the **yogic counselling,** the theory lectures from scriptures on mind body disease (Adhi, vyādhi), happiness analysis, etc., prepared the participant to change the perception of the problematic situations that were disturbing. This helped them to gain mastery over emotions, increases the will power and erases the loop of depression and anxiety.

The lectures from the scriptures (Bhagavad Gita and Yoga Vasistha) helped them in improving social life and interpersonal relationships, adjusting to environmental changes and ups and downs of life. They were aimed at achieving an introspective cognitive change by recognizing the psychological freedom ‘to react, not to react or change the usual pattern of reaction to situations’ highlighted in yoga texts.(Tapasyānanda, 2000)

7.4 Model of IAYT for mastalgia **Fig 15.**

Annamaya kosa

Modern science has unraveled the psycho-neuro endocrine model of stress related mastalgia. This is understood as an imbalance between the hormonal levels that results in hypersenesitization of the breast tissue to these stress related hormones.

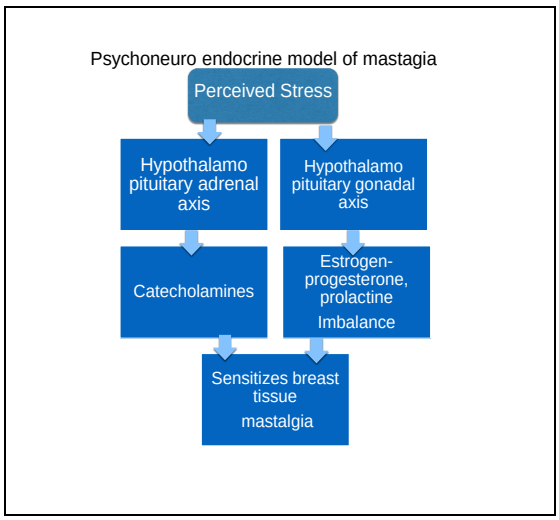


Fig 15 Depicts more details of many factors that have been detected over the past decade.

This model that depicts the pathogenesis as a psycho-neuro-endocrine imbalance shows the role of several factors involved in the genesis of mastalgia .

A. central factors include: (a) inappropriate dopaminergic tone at the hypothalamus, (b) endogenous opioids released during stress responses at the cortical level, (c) hyper-prolactinemia at the pituitary level.

B. External factors include: (a) smoking that releases catecholamine due to nicotine, methyl xanthenes and tyramine , (b) alcohol, (c)iatrogenic by exogenous estrogen

C. End organ factors include: (a) hypersensitization of breast tissue and (b) luteal phase insufficiency in the ovaries.

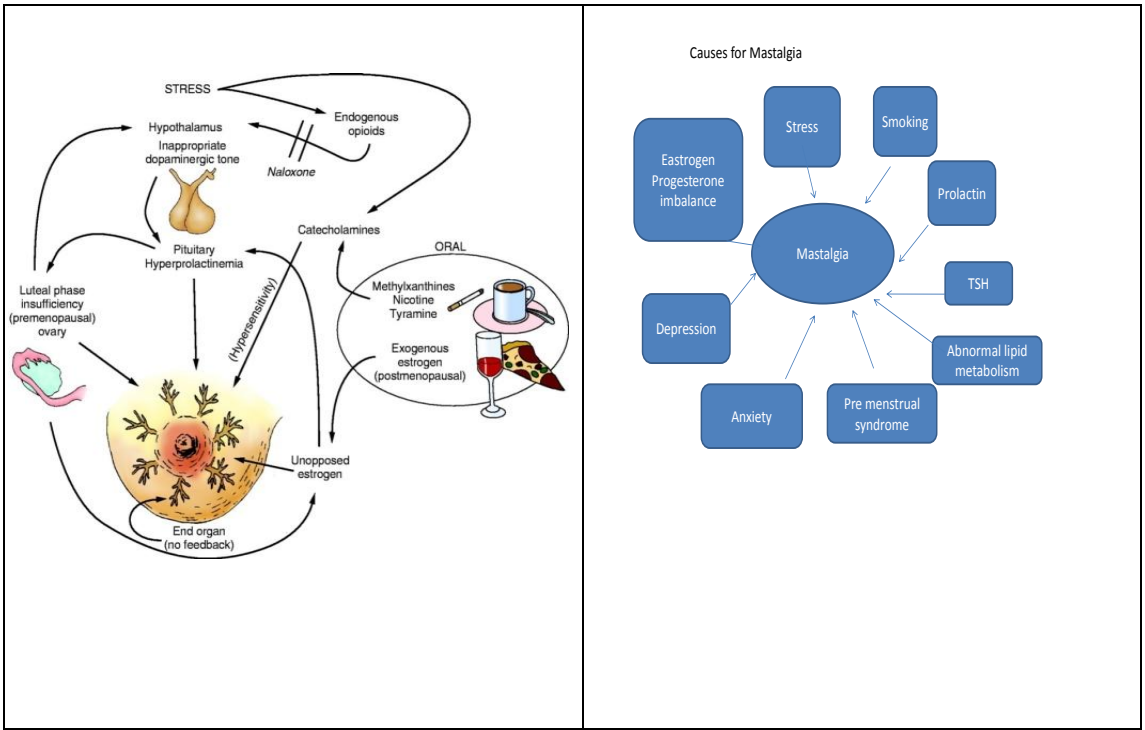


Fig 16: Psychoneuro endocrine model of mastalgia depicting the role of internal and external factors

Yoga texts go further to elaborate the processes that happen in the psyche in response to situations of life perceived as stressful. These changes occur at a subtler aspect of the personality i.e the manomaya kosa much before the actual manifestation of the disease occurs a t the physical level , the annamaya kosa. What translates the excessive uncontrolled speed of the mind to the

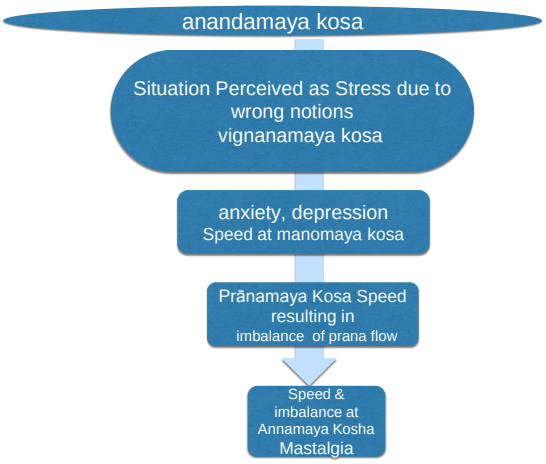


Fig17

body to cause the observed changes in the hormonal profile or the tissue disturbance is the präna. This process described elaborately in chapter 3 is depicted in the figure.

7.4.1.Similar models are available for many similar endocrinal disorders. Nidhi developed a yogic model of PCOS by incorporating the concepts from yogic texts and the modern medical understanding of the hormonal imbalances.

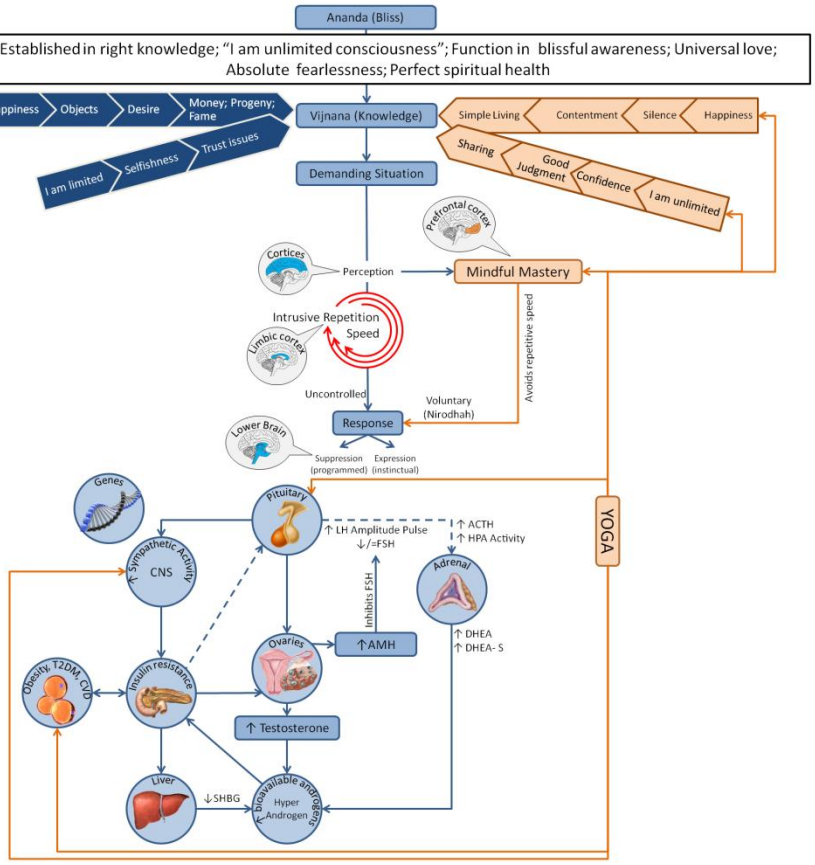


Fig 18: Etiology of PCOS and mechanisms by which yoga reverses it.

Pratiprasava (reversibility model of PCOS).

Dr Nidhi Chaudhury

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Dr Amrit Ram proposed a similar yogic model of breast cancer that shows the intrusive nature of the mind that gathers enormous power to produce violent changes in the genetic programming to produce mutation that results in inflammation; the model proposes that all these changes are reversible by using the specific yoga modules designed for the purpose.

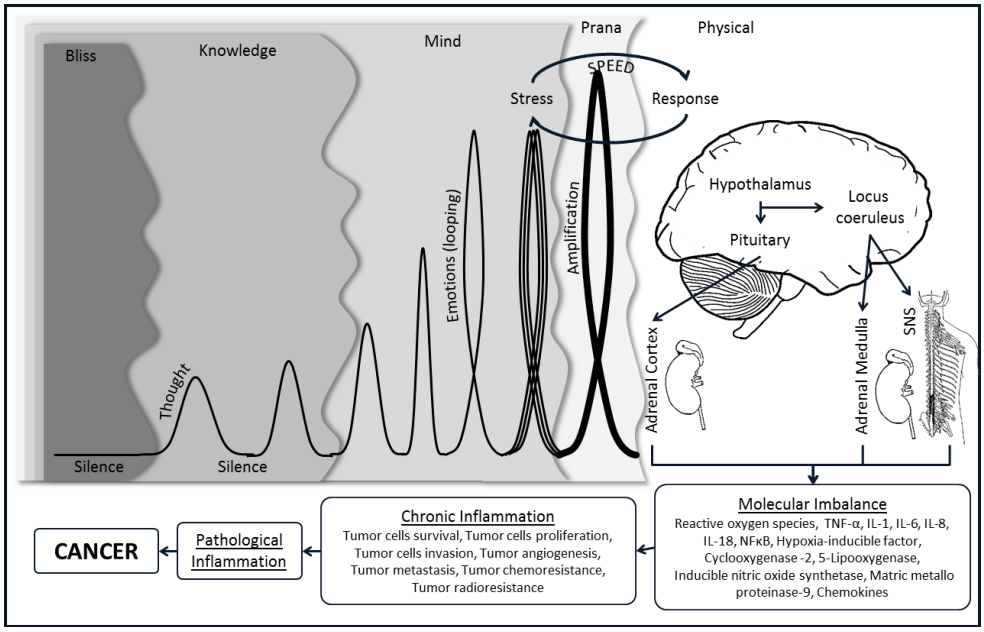

Fig 19: yoga based Biobehavioural model of cancer

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Based on these models and the review of literature (chapter 2 and 3) a hypothetical psychoneuro endocrinal model of mastalgia is presented in the figure 20

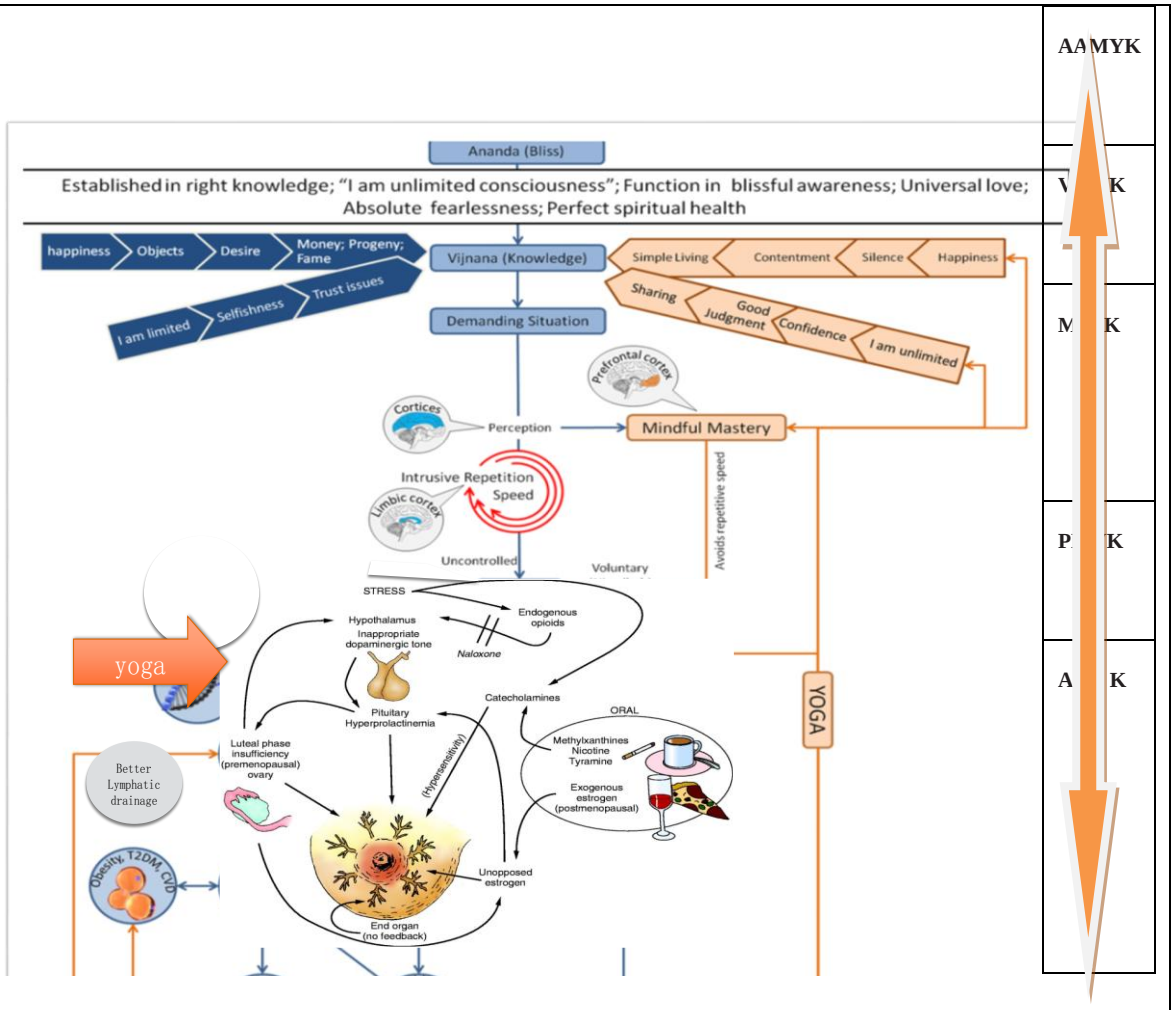

Fig 20: A hypothetical yogic reversibility model of mastalgia

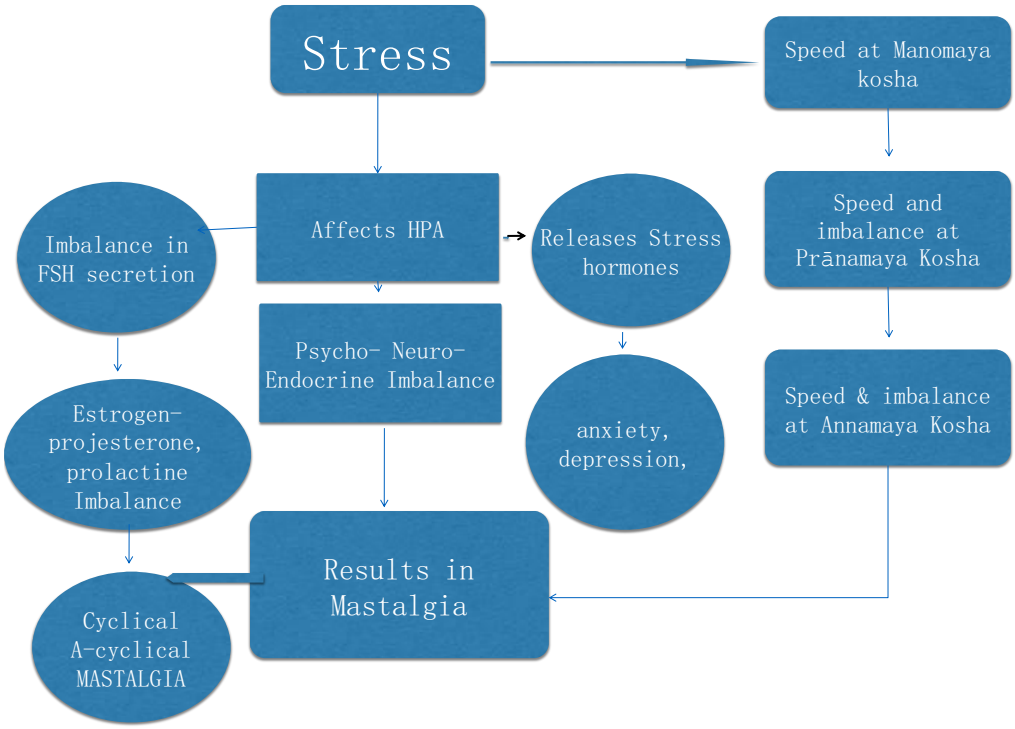

Fig 21: Imbalance Manifesting as Hormonal Imbalance And Immune Imbalance

This also prepares the participant to face any stressfully demanding situation that may trigger the uncontrolled surges of emotions such as anxiety or depression or tension or fear. The improved confidence and will power helps in improving the feeling of wellness and thus the quality of life. Thus, the lectures from the scriptures and yogic counselling helped them in improving their interpersonal relationships (Abbas, Maharana Satyapriya, Raghuram, Nagendra, & Venkatram, 2010; Deshpande, 2008) and adaptation to the ups and downs of life.

CHAPTER – 8

APPRAISAL

8.0 APPRAISAL

8.1 Summary

This is the first study that documented the prevalence of mastalgia in young women in a nursing college in south India and its association with stress and BMI. There is a need for early recognition and treatment. The estimated prevalence of mastalgia is 47.33%.

This is also the first prospective randomized controlled study on integrated yoga in nursing students with mastalgia. The result has shown significantly better improvement in the yoga than the control group (walking) in pain, depression, PMS and all four domains of QoL.

8.2 Details of published and accepted papers followed by summary of results.

1.Raghunath Sukanya, Raghuram Nagarathna, Ravi Sandhya, Ram Nidhi, Ram Amritanshu, (2015) Prevalence of Mastalgia in Young Indian Females, ***Journal of Health Research Reviews, 2/3/108/168368.***

2. Effect of Integrated Yoga in Measures of Pain in Premenopausal Women with Mastalgia, a Randomized Controlled Study: *Effect of Integrated Yoga in Measures of Pain in Premenopausal Women with Mastalgia, a Randomized Controlled Study:* ***Journal of Midlife Health.*** *Peer Review.*

3**.** Raghunath Sukanya, Raghuram Nagarathna, Ravi Sandhya, Ram Nidhi, Ram Amritanshu, (2015) *Effect of Yoga Therapy on Quality Of Life and Depression in*

Pre-menopausal Nursing Students with Mastalgia: an RCT with 6 month Follow up. Journal of Health Research and Reviews | January - April 2016 | Volume 3 | Issue 1

4.Raghunath Sukanya, Raghuram Nagarathna, Ravi Sandhya, H. R. Nagendra, "Integrated Yoga Therapy for Mastalgia": A Review article, ***International Journal of Medical Science and Public Health:*** | 2016 | Vol 5 | Issue 02

1.The prevalence of mastalgia was 47.33% among 748 young females from 4 nursing colleges in Karnataka, India.

2.Repeated Measures-ANOVA showed a significant reduction in mastalgia from the baseline to the end of 3 months ($p<0.001$). After 6 months follow up the time*group effect was also significant ($p<0.001$). There was a significant reduction in weight and Body Mass Index from baseline to 3rd month but not at 6th month.

3. RM-ANOVA group effect was significant in BDI, $F(1, 67) = 2632.72$, $p(<0.001)$ and in overall Qol, $F(1, 67) = 6881.41$, $(p<0.001)$. Post hoc test (paired sample t test) showed better improvement in yoga group (0-3, 0-6 month) in both Qol ($p<0.001$) (in all the four domains) and depression scores ($p<0.001$) compared to control group.

4. This is an effort to give a brief synthesis of the rich traditional knowledge of yoga which has explained a problem and a solution to mastalgia through the Indian scriptures and yogic life style, which is been implemented in our Randomized Controlled Trial with six month follow up (CTRI/2014/08/004911),

8.3 Limitations of the study:

Nursing students constitute a much selected group of the "Universe of population of young women in India". Hence, this conclusion may not be extrapolated to or generalized to all the young women. The association of stress level and BMI may simply be a chance finding and needs to be confirmed in other population-based studies.

Though changes in PMS symptoms and psychological variables were not the primary objective of the study, it could have brought more light to the conclusion, if follow up data was collected for these variables.

The age group was heterogeneous and there were not enough of students in all age groups.

Integrated yoga module that was used was not validated by experts from other yoga institutions. This was developed based on inputs from seniors (clinicians and yoga experts) who validated the module based on their experience.

Although the classes were conducted by therapists other than the researcher, the data analysis and scoring of the coded questionnaires were done by the researcher and not by uninvolved third person.

8.4 Strengths of the study

The present study is the first to explore the prevalence of mastalgia in young women and its association with stress and BMI. There is a need for early recognition and treatment to rule out the fear of cancer.

To the best of our knowledge this is the first randomized controlled study on the role of yoga in mastalgia. The strength of the study was mainly the design: the adequate sample size, supervised practice sessions, randomization and the six months follow up with very few drop outs.

The uniqueness of the results was the highly significant reduction with significant differences between groups in pain intensity with no side effects and improvement in other physical symptoms and the psychological status.

8.5 Suggestions for future work

a. Association of mastalgia with benign breast conditions such as fibroadenosis, adenomas, and cysts can been explored by ultrasound scanning of the breast.

b. Data related to endocrine abnormalities such as hypothyroidism and polycystic ovarian disease, which is commonly seen in this age group, could be done.

c. Future studies on adolescent and young women can be planned for different ethnic groups.

d. Assessments may include psychological scales to measure stresses specific to nursing professionals and ultrasound scanning can also be documented to explore the association of mastalgia with benign breast conditions.

e. Assessments may include more objective measurements to understand the mechanism at the molecular and biochemical level.

f. Assessments may include measurements of prana and triguna to understand the mechanism as explained in yoga.

g. Assessments may include measurements of agni, ama, dosa, mala, dathu etc to understand the mechanism as explained in ayurveda.\

h. Studies could be designed to understand the holistic model of yoga by looking at correlations between the central and peripheral level changes: at central level using brain imaging, brain blood flow, neuro-chemical, hormonal assessments, psychological changes and at peripheral level using biochemical, molecular and gene expression markers.

8.6 Conclusion

Three months of integrated yoga therapy program in women with mastalgia is significantly better than a brisk walk practice program in decreasing pain depression thereby improving Quality of Life which continues to persist after six months of practice.

8.7 Implications and recommendations

a. This offers the first evidence to recommend yoga as a non invasive and cost effective therapy in all cases of mastalgia before embarking on any drug therapy. There is an urgent need to educate and train young women to bring awareness about the importance of self examination of breast.

b. Yoga is cost effective and hence lessens the financial burden compared to that of conventional medical management related to mastalgia.

c. Yogic intervention also takes care of the psychological components like depression, anxiety and stress which contribute to better attitude and functioning.

d. Yogic intervention improves quality of life which helps in coping skills and fostering a better sense of wellbeing.

e. Since yoga based lifestyle change has other benefits for the young growing population we recommend that the education authorities make it a part of the syllabus in all schools and colleges.

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