Research Article

TO STUDY THE EFFICACY OF *NISHAKANAK KALKA LEPA* IN *STANPEEDA* W.S.R. TO CYCLIC MASTALGIA

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ABSTRACT

Stanpeeda (Mastalgia) is a commonly occurred breast pain that a female suffers from during her lifetime. Approximately two-thirds of women develop this pain during their reproductive life and may seek medical attention when it adversely affects their daily life. The breast pain may vary from mild to severe, could be intermittent or constant. According to Ayurveda, *Stanpeeda* can be correlated with Mastalgia. The objectives are to study of *Stanpeeda* with reference to cyclic mastalgia and to study the effect of *Nisha kanak kalka lepa* in *Stanpeeda* for 7 days, when cyclic mastalgia occurs. The study was conducted at Stree Rog prasuti tantra department, Hon. Shri. Annasaheb Dange Ayurved Medical College, Post Graduate & Research Center, Sangli, Maharashtra. Total number of 60 patients of 18-35 years age group having *Stanapeeda* were selected and treated with *Nisha Kanak Kalka lepa*. In this study the importance of *Nisha* (Rhizome of *Haridra*) and *Kanak* (*Dhatura patra*) and its possible action on each symptom was explained. Out of 60 patients studied, 21 patients (35%) showed marked improvement, 36 patients (60%) showed moderate improvement while 3 patients (5%) were mildly improved. Hence *Nisha* and *Kanak Kalka lepa* had significant result in *Stana Peeda*.

INTRODUCTION

The main function of the breasts in any female life is the nourishment of a newborn; But in case of *Stanpeeda* which may cause engorgement, pain in the breasts and condition which are very agonizing for the woman. According to modern sciences, *Stanpeeda* can be correlated with Mastalgia.

Mastalgia is a recognized natural condition that is studied less thoroughly than other breast problems. Approximately 70% to 80% of women experience severe breast pain at some time in their lives. Mastalgia accounts for 30% to 47% of breast clinical evaluations. In 15% of the patients, the mastalgia is so severe that it alters lifestyle and requires repeated investigations and treatment. Mastalgia interferes with sexual (48%), physical (37%), social (12%), and work or school activities (8%).

Taking into consideration all the above mentioned factors, I have chosen this subject, to evaluate whether certain Ayurvedic preparations might help the patient get relief from *Stanapeeda* or not. In *Bhavprakash Samhita* a certain *Stanapeedahar lepa* has been described under *Stana Roga Adhikara*. The above mentioned *Lepa* has been described in a *Shloka* for *Stanapeeda*. Day by day with new and sophisticated techniques, modern science is evolving, many drugs prescribed as effective medicines to decrease the severity of various symptoms but these drugs leads to hormonal imbalance which is proven now thus the use of such medicines becomes complicated. Therefore, to avoid the side effects of these drugs and to give effective relief to the patient with *Stanpeeda*, an Ayurvedic preparation called *Nishakanak kalka lepa* is chosen for the study.

Types of Mastalgia

Breast pain is a distressing constellation of symptoms that is classified as
1) Cyclic Mastalgia
2) Non-cyclic or Extra mammary Mastalgia

Cyclic Mastalgia

It is related to exaggerated premenstrual symptoms beginning in the luteal phase of the menstrual cycle, associated with breast engorgement, pain, ache, heaviness and tenderness that is bilateral and can last for more than 7 days in 11% of women. Cyclic mastalgia is more prevalent in women in their third and fourth decades of life and accounts for two thirds of all breast pain symptoms.

Noncyclic Mastalgia

It is independent of menstrual cycles and is described as achy, burning soreness. It may be intermittent or constant, is usually unilateral, occurs in the fourth and fifth decades, and is more difficult to treat than cyclic mastalgia.

Extra mammary pains perceived to be located in the breast but it is related to an extra mammary site. Chest wall muscular pain, costal cartilage symptoms, herpes zoster, radiculopathies, and rib fractures are among some of the more common causes of extra mammary pain.

Pathophysiology of Breast Pain

Inflammatory cytokines were implicated in the etiology of breast pain but in luteal phase painful breast tissue shows lower levels of these cytokines named interleukin 6 and tumor necrosis factor. These levels did not reach upto statistical significance to cause cyclic mastalgia.

Elevated estrogen, low progesterone or an imbalance in the ratio of estrogen and progesterone were suggested as a possible cause for the symptoms of Cyclic Mastalgia.

Stana-Rachana (Anatomy of Breast)

Sushruta has described that in women two *Dhamanis* (Arteries) are present to carry *Stanya* to the breasts, and two *Siras* (veins) situated in root of each breasts not suitable for veinesection. [1]

Women possess twenty extra *Peshi* (muscles)- ten in breasts i.e., five in each one which develop in adolescence.[2]

Doshavastha during *Rutuvyatit Kal*

The present study was concerned with *Rutuvyatit Kal* i.e., luteal or premenstrual phase of menstrual cycle. *Doshavastha* during this phase should be considered.

Rutuvyatit kal is a phase of *Pitta pradhanya* and *Puranraj kal*. As it is *Pitta pradhanya kal Tikshna* and *Ushna guna* of *Pitta* acts for *Sanghatbhedan* as well *Visram* and *Saram guna* affects on *Bahikshapan karm*. During this period, *Ranjak pitta* which will be towards formation of *Ras ranjan* to form *Puran raj* and *Bhrajak pitta* present can be helpful for the study purpose at skin site for entry of drugs into the skin.

Samprapti of *Stanpeeda*

Rutukal (*Navshonit Utpatti kal* or *Sanchaykal* or *Beejotsarga kal*) when forwarded with *Shukra abhav* i.e., absence of sperm, it leads to *Garbhashay Dhatwagni vriddhi* and ultimately to *Agney tatvavriddhi*.

This *Agney tatvavriddhi* i.e., *Pitta pradhanya kal* results into *Sarvadehik Ushma vriddhi* (*Jwarwat purvavastha*) during this phase if patient does not follow *Prakrut ahar* and *Vihar* there will be *Rasdhatu Vikruti*.

As *Ras dhatu vikruti* happened there will be *Sthansanshray* at *Stan pradesh*. Due to *Shukrabhav, Bahikshapan* will about to happen before that there will be *Strotorodh* which leads to *Vata dushti* and due to *Khavaigunya Vata sanchay* at *Stan pradesh. Ras vikrut dhatu sthansanshray* and *Vat sthansanshray* leads to *Stanpeeda*.

Lepa Therapy

Fine powder of drugs mixed with one of the *Dravas* like water, *Swarasa*, *Quath, Hima, Dugdha, Takra*, cow urine, *Kanji*, *Madhya* (alcohol) and oils etc to form *Kalka* for pasting on the body is called *Lepa*.[3]

Lepa is also considered under *Kalka kalpana* in *Panchvidha kashaya kalpna*. And fine powder (*Churna kalpna*) is also a type of *Kalka kalpna*. So according to the preparation of the *Lepa* procedure *Lepa kalpna* is considered in between the *Kalka kalpna* and *Churna kalpna*. In this *Kalpna* fine powder of dry *Dravyas* is made by the powder making machine and *Drava* (hot water) is mixed at the time of the external application. This is called *Lepa kalpana*.[4,5]

The thickness of *Lepa* according to Maharishi Sushruta is equal to the wet leather (wet skin) of the buffalo. [6]

AIMS AND OBJECTIVES

Aim- To study the efficacy of *Nishakanak kalka lepa* in *Stanpeeda* w.s.r. to cyclic mastalgia

Objectives

1. The study of *Stanpeeda* with reference to cyclic mastalgia.
2. To study the effect of *Nisha kanak kalka lepa* in *Stanpeeda* for 7 days, when cyclic mastalgia occurs.

MATERIALS AND METHODS

Study Design

1. Patients were selected by random sampling method.
2. Total number of 60 patients of 18-35 years age group having *Stanapeeda* were selected and treated with *Nisha Kanak Kalka lepa*.
3. Written informed consent of the patient was taken prior to the treatment.
4. Cases were recorded in specially prepared case record form

Inclusive Criteria

1. Patients with cyclic mastalgia with regular menstrual history.
2. Patients with cyclic mastalgia in premenstrual syndrome.
3. Age- 18 to 35 years

Treatment details

Dravya Name	Botanical Name	Family	Parts Used
Kanak	*Dhatura metel*	Solanaceae	Leaf
Nisha	*Curcuma longa*	Zingiberaceae	Bulb

1. Drugs was identified and authenticated by experts,
2. Drug material was prepared under observation of senior experts.

Method of Application

1. 80-l00 mesh *Churna* of *Nisha* and *Kanak patra* was prepared in Ayurvedic pharmacy of the college.

Exclusive Criteria

1. Non cyclical mastalgia
2. Patients suffering from HIV, HbsAg, VDRL, DM, Hypertension, Anemia will be excluded.
3. Patients found with fibrocystic changes, breast lump are excluded.
4. Patients having history of any malignancy or having malignancy are excluded.
5. ANC and lactating mothers.
6. Patients with withdrawals of O.C. Pills.
7. Cyclic mastalgia with nodularity.

Withdrawal Criteria

1) Patient developing any side effects like rash, itching, blisters.
2) If not responding to treatment patient will be withdrawn within 3 days.
3) Patient refuses to continue the treatment.

2. *Nisha Kanak patra Churna* lepa was locally applied twice a day for 7 days.
3. *Kala* ~ Morning at 9:00am and evening at 4:00pm.
4. Thickness of *Lepa* 0.3 to 0.4mm.
5. Application *Lepa* (*Churna* with lukewarm water) was removed after specific signs of drying.
6. Follow up was taken after 7 days.

A) Assessment Criteria

1) Subjective Criteria

a) Pain

b) Breast Engorgement / Heaviness Gradation of Criteria

Criteria	No	Mild	Moderate	Severe
Pain	Absent	Pain during heavy work only	Pain related to movements	Unbearable pain activates Patient cant to regular work Due to continuous
Breast engorgement/ heaviness	Absent	Little heaviness around nipples	Heaviness over half of the breast	Heaviness all over the breast.

2) Objective Criteria

a) Tenderness

b) Swelling– Gradation of Criteria

Criteria	No	Mild	Moderate	Severe
Tenderness	Absent	Elicited by much pressure	Elicited by moderate pressure	Elicited by touch only
Swelling	Absent	Just over 1 quadrant area or 1cm around nipple	Just over 2 quadrant area or 2cm around nipple	All over 4 quadrant area.

Scoring

Grades	Sign
No	0
Mild	1
Moderate	2
Severe	3

Drugs for *Lepa*

The following drugs have been selected for the preparation of *Lepa* in equal parts as per the reference of *Bhavprakash samhita, Chikitsasthan Stana Rogadhikar* (Cha.no.70).

l. *Haridra* (Rhizome of *Curcuma longa*) - 1 part

2. *Dhattura* (Leaf of *Dhatura metel*) - 1 part

Two drugs were taken in equal parts and mixed in each other and made a fine powder of it. Then they were mixed with lukewarm water. Name of the formulation: After making formulation the name is given to the formulation is *Nisha-Kanaka kalka Lepa.*

Application of *Lepa*

Good paste is made mixing hot water in required quantity, so that the water should not flow out from the paste in the pot and kept for 1/2 an hour. Then *Lepa* is applied externally on the abdomen up to 2mm of thickness. *Lepa* should be applied for 1-2 hours at the time of rest and after dryness of the *Lepa* it should be kept for 1/2 an hour more for good skin color and acquiring good results.

RESULTS AND DISCUSSION

1. Incidence of Age

S. No.	Age Group	Count	%
1.	18–20	07	11.67%
2.	21–25	16	26.67%
3.	26–30	26	43.33%
4.	31–35	11	18.33%
Total		**60**	**100%**

Out of 60 patients studied, 7 patients (12%) were from age group 18–20 years, 16 patients (27%) were with age between 21–25 years and 26 patients (43%) were with age between 26–30 years while remaining 11 patients (18%) were having age between 31–35 years.

3. Incidence of Religion

S. No	Religion	Count	%
1	Hindu	58	96.67%
2	Muslim	02	03.33%
Total		**60**	**100.00%**

Out of 60 patients, 58 patients (97%) were Hindu while 2 patients (3%) were Muslim.

4. Incidence of Occupation

Sr. No.	Occupation	No. of patients	
		Count	**%**
1.	Housewife	37	61.67%
2.	Job	05	08.33%
3.	Student	18	30.00%

Out of 60 patients, 37 patients (62%) were housewives, 5 patients (8%) were having job while 18 patients (30%) were student.

5. Incidence of Diet

Sr. No	Diet	Count	%
1	Vegetarian	18	30.00%
2	Mixed	42	70.00%
Total		60	100.00%

Out of 60 patients, 18 patients (30%) were vegetarian while 42 patients (70%) were taking mixed diet.

6. Incidence of *Prakruti*

S. No.	*Prakruti*	No. of patients	
		Count	%
1.	*Vataj*	21	35.00%
2.	*Pittaj*	21	35.00%
3.	*Kaphaj*	18	30.00%

Out of 60 patients, 21 patients (35%) were with *Vataj prakruti*, 21 patients (35%) were with *Pittaj prakruti* while 18 patients (30%) were with *Kaphaj prakruti*.

7. Incidence of *Agni*

S. No.	*Agni*	No. of patients	
		Count	%
1.	Soumya	18	30.00%
2.	Tikshna	21	35.00%
3.	Visham	21	35.00%

Out of 60 patients, 18 patients (30%) were with *Soumya agni*, 21 patients (35%) were with *Tikshna agni* while 21 patients (35%) were with *Visham agni*.

Statistical Analysis of Different Parameters

As grading used for some of the signs and symptoms were ordinal in nature, Wilcoxon Signed Rank test is used for intra-group comparison (i.e., before and after treatment of a group). Findings are presented along with appropriate summary statistics and graphs/diagrams and result is interpreted accordingly. The level of significance is kept at 0.05.

Pain

Pain	Mean score	Median score	Median diff.	IQR (Q3 – Q1)	n	Wicoxon signed rank test (T⁺)	P- Value
B.T.	2.25	2	2	1(2–1)	60	1830	< 0.001
A.T.	0.65	1					

The reduction in pain over treatment period is 2 which is significant (P-value < 0.001) at 5% level of significance. i.e., it can be said that there is significant reduction in pain during study period.

Breast engorgement

Breast engorgement	Mean score	Median score	Median diff.	IQR (Q3–Q1)	n	Wicoxon signed rank test (T⁺)	P- Value
B.T.	2.13	2	1	1(2–1)	60	1653	< 0.001
A.T.	0.7	1					

The reduction in breast engorgement was 1 which was significant (P-value < 0.001) at 5% level of significance i.e., it can be said that there is significant reduction in breast engorgement during study period.

Tenderness

Tenderness	Mean score	Median score	Median diff.	IQR (Q3–Q1)	n	Wicoxon signed rank test (T⁺)	P-Value
B.T.	2.05	2	1	1(2–1)	60	1540	< 0.001
A.T.	0.72	1					

The reduction in tenderness over study period was 1 which was significant (P-value < 0.001) at 5% level of significance i.e., it can be said that there is significant reduction in tenderness during study period.

Swelling

Swelling	Mean score	Median score	Median diff.	IQR (Q3–Q1)	n	Wicoxon signed rank test (T⁺)	P- Value
B.T.	1.97	2	1	0 (1-1)		60	1596
A.T.	0.87	1					

The reduction in swelling over treatment period was 1 which was significant (P-value < 0.001) at 5% level of significance i.e., it can be said that there is significant reduction in swelling during study period.

Effect of Therapy

Parameter	Efficacy	%Relief/improvement
Pain	Significant	73.89%
Breast engorgement	Significant	69.59%
Tenderness	Significant	65.77%
Swelling	Significant	60.82%
Average % relief		67.52%

Distribution of Patients According to Relief

Overall Effect (patient wise)	No. of patients	
	Count	%
Unchanged	00	00.00%
Mild improvement	03	05.00%
Moderate improvement	36	60.00%
Marked improvement	21	35.00%

Out of 60 patients studied, 21 patients (35%) showed marked improvement, 36 patients (60%) showed moderate improvement while 3 patients (5%) were mildly improved.
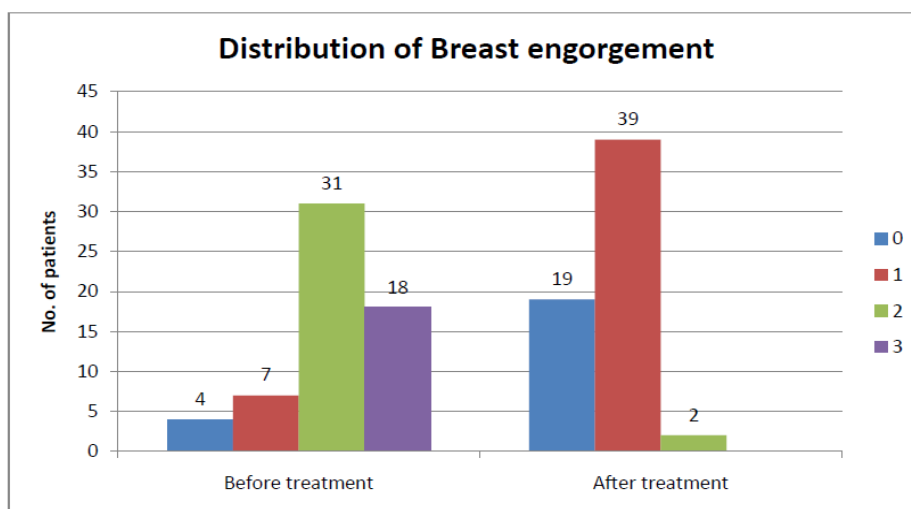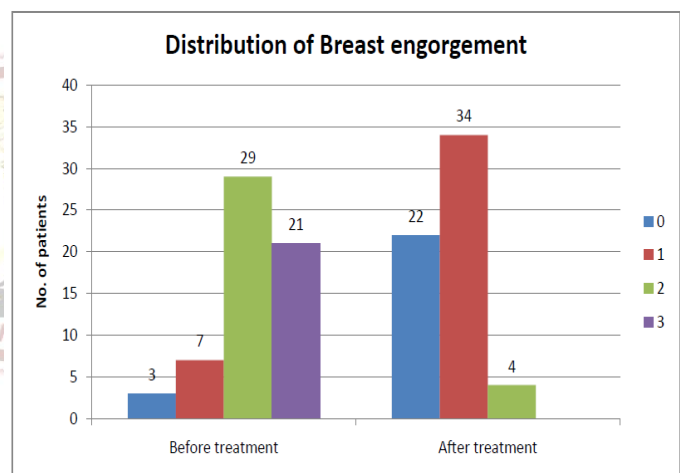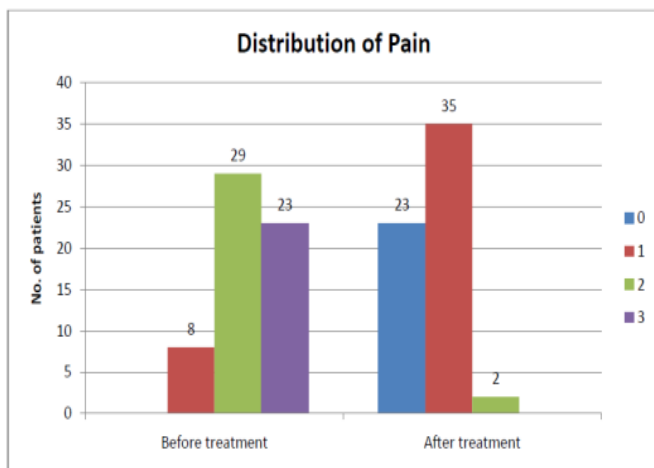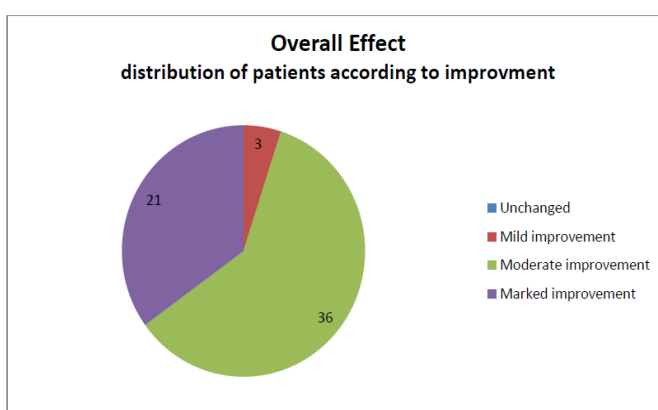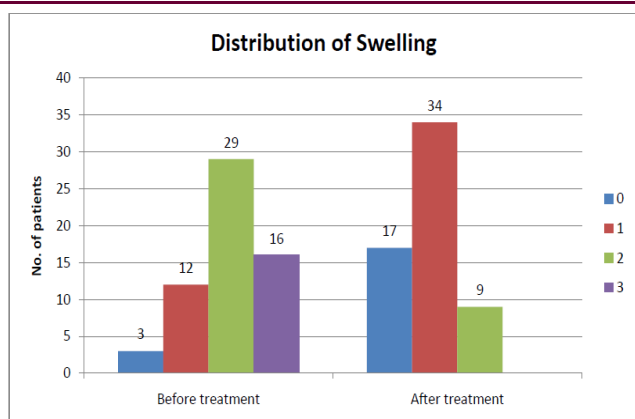
DISCUSSION

Samprapti Bhanga

Guru guna of *Dhatura* leads to *Vishodhan* of *Vat gati*, and acts as a *Shoolaghna* and *Sadyoparinamkar* in *Sthanpeeda*.

Tikta and *Katu ras* of *Haridra* is helpful for *Pachan* of *Rasgat dosh* that will ultimately lead to *Pachan* of *Updhatu*. *Ruksh* and *Ushna guna* will manage *Shoshan* and *Lekhan* of *Vikrut kaph* too.

During the study the following observations were made:

- Patients from the age group 26 to 30, 21 to 25, 31 to 35 years were more prone towards mastalgia and more prevalence rate of mastalgia is seen in 3rd and 4th decade of woman's life.
- Maximum no. of patients i.e. 96% were Hindu.
- Maximum no. of patients i.e., 61% were housewives, 8% were working women and 30% were students but there is no relation of occupation with *Stanapeeda*.
- Maximum no. of patients were having mixed diet (70%) while 30% were vegetarian but there is no relation of diet with *Stanpeeda*.
- No. of patients studied, from them 35% were having *Tikshna agni*, 35% were having *Visham agni* while 30% were of having *Saumya agni* but *Stanpeeda* is irrelevant with *Agni*.

- 35% patients studied were having *Prakruti Vat*, 35% were having *Pitta prakruti* while 30% were having *Kapha prakruti*.

CONCLUSION

Out of 60 patients studied, 21 patients (35%) showed marked improvement, 36 patients (60%) showed moderate improvement while 3 patients (5%) were mildly improved. Hence *Nisha* and *Kanak Kalka lepa* had significant result in *Stana Peeda*.

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