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AN EFFECT OF DANTYADI LEPA IN THE MANAGEMENT OF FIBROADENOMA OF BREAST

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ABSTRACT

Fibroadenoma are one of the main benign diseases of breast. They account for 77.6% of benign disease. Early diagnosis and treatment can relieve anxiety associated with non-malignant conditions of breast. Though, it is known to regress by its own and can be managed conservatively, but anxiousness of patient owes for surgical intervention. *Mamsaja granthi* with the lakshana of *Snigdha, Katina, Niruja, Ghana* is explained by *Acharaya vridha Vagbhata*, can be considered as fibroadenoma of breast. As there is higher chance of reoccurrence even after the surgery, to avoid repeated surgical intervention on aesthetic part of breast, *Dantyadi lepa* as external application could be considered as Conservative line of treatment in the management of fibroadenoma which also aids beneficiary in Alling population. So, the study Dantyadi lepa has been taken.

KEYWORDS: *Mamsaja Stana granthi; Fibroadenoma; Dantyadi Lepa; Vridha vagabhata.*

INTRODUCTION

The female body is revered as she is three times more responsible than male in procreation. Through-out the life women undergo series of physical changes of body that include attaining of puberty, menstruation, pregnancy and menopause. These changes initially start with the development of reproductive organ and also breast changes. Breast forms a part of accessory reproductive organ, that symbolizes the feminity. Its significance also revolves as a symbol of

fertility and sexual pleasure. Women, in general are concerned with their appearance, their weight, and their body image. Any abnormal changes or disturbances in their body image can lead to discomfort and low-esteem. This may further take a psychological toll and affect their relationships and quality of life.

With the advancement of technology and adaptation to western diet, sedentary life style and stress, the most common disease encountered along with hormonal imbalance and menstrual irregularities are benign disease of the breast. Though it seems to be common, it affects the psychologyof the woman. Among them fibroadenoma of breast (77.6%) are one of the common benign diseases of breast. Though considered as a risk factor for development of breast cancer its reporting has been over shadowed by that of breast cancer.

Fibroadenoma is the most common benign breast tumour found in age group between 15 to 45 years. They usually present as solitary or multiple, mobile and hard masses varying in size of less than 1 cm to 10 cm, which is noted accidently during physical examination. It is believed to be hormone dependent especially estrogen. Fibroadenomas which is small, single, and age less than 30 years can be left alone with regular follow up of USG at 6 months interval. Surgery will not be effective as fibroadenoma is having recurrence associated with hormonal changes and life style modification. In order to avoid repeated surgery of fibroadenoma on the aesthetic part of breast, the conservative line of treatment has to be taken up.

In this regard, an Ayurvedic approach using classical medicines in the management of fibroadenoma of breast is required. Mamsaja Granthi in Stana has a close resemblance with fibroadenoma of breast in its signs and symptoms and a number of drugs are described which can be used in the management of Granthi. Among them the Dantyadi lepa having tikshna, ushna gunaatamaka dravyas as contents is explained as treatment for mamsaja granthi. If the conservative approach like external application of Dantyadi lepa on fibroadenoma of breast could be established in the management of fibroadenoma, it would be beneficiary to the allied population. Hence this study was taken up to understand the action and efficacy of Dantyadi lepa application as conservative management of fibroadenoma of breast.

Objectives of the study

To assess the effect of Dantyadi lepa in the management of Stana Granthi (fibroadenoma of breast).

MATERIALS AND METHODS

Study design

- This was an open label clinical study with pre-test and post-test design.

Where 20 patients diagnosed with fibroadenoma were selected based on diagnostic and inclusion criteria.

Source of data

- Minimum 20 patients of fibroadenoma of breast were selected from the out- patient department of S.D.M. College of Ayurveda and Hospital, Udupi.

Methods of collection

1. Patient having features like soft, firm, freely mobile masses between 1 cm to 5cm were taken for the study
2. Data were collected based on investigation like sonography showing fibroadenoma of breast
3. A detailed proforma was prepared of all the points of history taking, USG as mentioned and patients were analyzed and selected
4. At the end of the treatment changes in size, consistency of mass, shape of mass and echo-texture were noted with the help of USG and signs of patient.

Intervention

In the selected patient Dantyadi Lepa with Gomutra Arka for external application with thickness of 0.5cm two times a day for 40 days was given at normal temperature.

RESULTS

Following results were obtained within the group and the data observed in BT, after 10^{th} day,20^{th} day,30^{th} day and 40^{th} day (AT) were compared by using Wilcoxon signed rank test. Effect of treatment were analyzed by using paired 't' test and Wilcoxon signed rank test.

Table no. 1: Shows the statistical analysis of dantyadi lepa on consistency of mass.

Parameter	Negative Rank			Positive Rank			Ties	Total	Z Value	p value	Remar ks
	N	MR	SR	N	MR	SR					
BT-10D	1	1.00	1.00	0	0	0	19	20	-1.000	0.317	NS
BT -20D	11	6.00	66.00	0	0	0	9	20	-3.317	0.001	HS
BT -30D	16	8.50	136.00	0	0	0	4	20	-3.589	0.000	HS
BT-AT	16	8.50	136.00	0	0	0	4	20	-3.589	0.000	HS

- When Consistency of mass was compared from Before Treatment to 10th day, 1 patient showed change in consistency of mass, in 19 patients no changes were noted. On 20th day 11 patient showed change in consistency and 9 patients there was no changes. On 30th day and after treatment that is on 40th day, 16 patients showed changes in consistency of mass and 4 patients showed no changes when compared to before treatment. So, in first 10 days of follow up the change in consistency of mass was not significant at p=.317, z=-1.000(p<0.016). On 20th day of treatment change in consistency of mass was seen to be statistically significant p=0.00, z=-3.317(p<0.016); Within 40 days of treatment change in consistency of mass was seen to be highly significant at p=0.000, z-3.589.

Table no. 2: Shows the statistical analysis of dantyadi lepa on Shape of mass.

Parameter	Negative Rank			Positive Rank			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-AT				0	0	0	14	20	-	.014	S
			21.								
	6	3.50							2.44		
			00								
									9		

- Changes in the shape of the mass before treatment was compared to after treatment 6 patients showed changes in shape and 14 patients showed no changes in shape with p value of 0.014 z=-2.449 (p<0.016). The treatment showed statistically significant.

Table no. 3: Shows the statistical analysis of dantyadi lepa on echo texture of mass.

Parameter	Negative Rank			Positive Rank			Ties	Total	Z value	P value	Remarks
	N	MR	SR	N	MR	SR					
BT-AT				0	0	0	14	20	-	.014	
			21.								
	6	3.50							2.44		S
			00								
									9		

- Changes in the echo texture of nodule before treatment was compared to after treatment, 6 patients showed changes in echotexture of nodule and 14 patients showed no changes with p value of 0.014 z=-2.449 (p<0.016). The treatment showed statistically significant.

Table no. 4: Showing the effect of treatment on size of mass of breast.

N	BT Mean	AT Mean	Diff(d)	%	Paired t test				Significant
					SD	SEM	t value	P value	
20	2.7685	2.1095	.65900	23.8	.76182	.17035	3.869	.001	S

- Statistical analysis reveals that, the mean of size of mass, between BT & AT (at 40 Day) shows changes from 2.7685 to 2.1095, showing reduction of 0.6590 i.e., 23.8% which is statistically significant with p=0.001(p <0.05).

DISCUSSION

In Ayurvedic classics there are many formulations which are told for *granthi chikista*. Among them *Dantyadi Lepa* is quoted in *granthi chikista* by *Chakradutta* in *granthi chikista adhyaya*. In *ama avasta* of *granthi* after *shodhana* karma, lepa application has been advised. Since *Kapha* and *vata dosha* along with *mamsa dhatu* is responsible for formation of *stana granthi,* this yoga can be considered appropriate for stana granthi. *Acharyas* have emphasized the importance of lepa for therapeutic and cosmetic purpose for best result. Lepa application is one of the routes of drug administration for localized action and better absorption which reaches the target cells quickly. The studies have proved that the Transdermal absorption of drug administration yield better result, quick action and reaches the target cells faster than oral route. This is due to the fact that transdermal route avoids first pass effect metabolism.

Dantyadi lepa having a property of *katu-tikta rasa, tikshna guna, usna virya, katu vipaka* and *kapha vata samaka.* To understand the target action of the drug it is of prime importance to know the pharmacodynamics and pharmacokinetics of each and every drugs.

The *katu* rasa is formed by the combination *of vayu and agni mahabhuta*, which has properties like *ruksha, ushna, laghu, tikshna, vishada* helps in the penetration of drug. *Marga vivranotti* is feature of *katu rasa* according to *charaka*, it clears and dilate the passage and alleviates the kapha. *Vagbhata Acharya* states that *lekhana* as *guna* of *katu rasa* which help in *vighatana of granthi* and *katu rasa* does the *kapha dosha vilayana* which is involved in *samprapti of stana granthi.*

The *Tikta rasa* is formed by combination *of vayu and prthvi mahabhuta, it* has ruksha, *sheeta,* and *laghu guna*. It is *Vishagna, krimighna, pachana, lekhana, kleda, meda, puya, kapha soshana.* It is valuable to use drug having *tikta rasa in sotha chikista.* According *to acharya*

charaka granthi chikista follows *sotha chikista*, *tikta rasa* present in *lepa* acts as *sothaghna*. *Tikshna guna* literally means sharpness. It is *teja mahabhuta pradana*, it is *vata kapha samaka* and penetrates inside the body at faster action than any other guna. It has *lekhana guna*. The drugs like *Bhallataka, snuhi ksheera and arka ksheera* in yoga has this guna.

According to the research works done, most of the ingredients of Dantyadi lepa have phytoconstituents as flavonoids and phenolic compounds. All the drugs are having the properties of anti-oxidants, immuno-modulatory, anti-cancerous, anti-inflammatory and wound healing property. The active components present in *danti* moola is diaphoretic and rubefacient, this property of drug initiates perspiration (*swedana)* and produces redness by causing dilation of the capillaries and an increase in blood circulation respectively. *Chitraka* major phytoconstituent i.e., Plumbagin which is known as modulator of cellular proliferation and carcinogenesis, these reactions are regulated by activation of transcription factor NF-Kappa B activation pathway.

The mode of drug administration was in the form of lepa mixed in *Gomutra arka* of thickness 0.5cm approximately at room temperature (i.e., one-fourth of *Dosaghna lepa* by *Sharangadhara for sotha).* The rationality behind selecting Gomutra arka was because the karma of *gomutra is kushtagnha, kandughna* and can be used as *Alepana.* Gomutra as *sukshma guna* which makes it more permeable to penetrate through the skin. Research works have shown that Gomutra arka is having anti-oxidant and immuno-modulatory properties. Physio-chemical analysis of drug where pH was assessed. When 0.1 % solution of Dantyadi lepa mixed in water and pH estimated showed 4.2 at routine room temperature and solubility was of 70 %. When same was assessed with 1 % solution, pH estimated to be 3.6 at routine room temperature with 80% solubility. When the same 1% solution was mixed with go-mutra arka pH was found to be 9.6 at routine room temperature with 100% solubility. With this aim Gomutra arka was selected as a base for application. The studies have shown that Transdermal Absorption of Drug is better with weak base than weak acid with higher solubility and Lipophilicity. When Dantyadi lepa was mixed with Gomutra arka, Probably it contains a factor that dissolves lipophilic content present in bhallataka and substantially influenced solubilty. This active principle of Gomutra arka helped for better transdermal absorption (Surber C, Abels C et al).

The drug Dantyadi lepa along with Gomutra arka acts through the properties of anti-oxidant and immune-modulatory action. The Bio-active compound of the drug inhibits activation by

TNF, and Plumbagin supresses the constitutive NF-Kappa B activation which inhibits the oxidation of lipid-Peroxidase leading to cell Proliferation in Tumour. Flavonoids and Phenolic Compound present in Formulation acts as anti-oxidant and Free-radical scavenging.

The animal study by Suman Paul et al has shown that Dantaydi lepa act anti-oxidant. The anti-oxidant study was analysed with protein estimation, catalase activity and Glutathione peroxidase changes. The experimental study shown that there was decrease in catalase activity and glutathione peroxidase.

We can conclude that on application of *Dantyadi lepa* with *Gomutra arka* for 40 days on Fibroadenoma of breast were statistically significant. Therefore, Data collected from Clinical study proves that there is definite activity of Dantyadi lepa in the treatment of Fibroadenoma of breast or Stana Granthi.

Further studies can be Carried out by intervention through shodhana, followed by oral medication and external application along with estimation of Estradiol hormonal essay and Ca 15-3 tumour marker and USG followed by FNAC to be more specific. Estradiol hormonal Essay is advised because of the cause that estrogen influence the growth of the tumour and the animal study done by Suman Paul et al has shown that estradiol in test group was decreased but was not statistically significant. With this it can be concluded that Dantyadi lepa not only act locally on granthi but also on the hormonal level.

CONCLUSION

The complied result obtained from clinical study carried out on 20 patients showed reduction in size,

- Masses less than 0.5-1.5 cm^2 found in 3 patients out of 20 were completely regressed.
- The size of mass more than 1.5-2.5 cm^2 showed considerable reduction in size.
- There was change in the consistency of mass was noted from hard to soft in all the 20 patients after constant application for 40 days.

The study showed both clinically and statistically significant results in changing the consistency of mass and reduction in size of breast mass, being a kapha vatahara Dantyadi lepa has effect on stana granthi.

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