



AN OPEN LABEL -SINGLE ARM SURGICAL TRIAL ON SOOTIKA STANA VIDRADHI W.S.R BREAST ABSCESS

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Submitted on- 23-12-23

Revised on- 22-01-24

Accepted on-29-01-24

ABSTRACT:

Background: Breast abscess usually occurs as a complication of mastitis and is defined as a localized collection of purulent material within the breast parenchyma. Sushrutha, an Ancient Surgeon has described about Breast Abscess in the name of *Stana Vidradhi* (Breast Abscess) with features and treatment that includes both *Abhyantara (Internal)* and *Sthanika Chikitsa (Local Treatment)*. **Design:** This was an open label single arm surgical trial that included 30 *Sootika (Lactating women)* patients diagnosed with *Stana Vidradhi* (Breast abscess). All 30 patients were administered the classical shastra karma explained by Aharya Sushrutha for the management of *Stana Vidradhi* with before and after assessment. **Results:** Significant changes were observed in visual analogue scale, pain, swelling, slough, discharge, granulation tissue, and wound size with ($p \leq 0.005$) after the treatment in post assessment compared to pre assessments. **Conclusion:** This study showed that *Shashtra Karma (Surgical Intervention)* explained in Ayurvedic science is effective in the management of *Sootika Stana Vidradhi (Lactational breast abscess)*.

Keywords: Sootika, Stanavidradhi, Shastrakarma, Bhedana, Visravana, Vranashodhana, Vranaropana

IEC: RGS/IEC/2020-2021/65

INTRODUCTION

Among the many diseases that affect breast, the disease that directly affects the breast feeding and the commonest is breast abscess and is defined as a localized collection of purulent material within the breast parenchyma. Mastitis occurs as a complication of breast abscess and is a relatively common breast condition in which inflammation of breast tissue is caused by infection. In 3-11% of mastitis cases, breast abscesses occur as a complication and in breastfeeding women, incidence of 0.1-3 % is reported. ^[1]

As per Ayurvedic science, Breasts are the sites for all types of *Shothas (Inflammations)*, *Vranas (Ulcers)*, *Granthis (Swellings)* and *Arbudas (Tumours)*. ^[2] Breast abscess can be correlated to *Stana Vidradhi (Breast Abscess)*, or *Stana Shopha Avastha (Aama, Pachyamaana, Pakwa) (Unripe and Ripe stages of Swelling and Inflammation)* based on the explanation given by *Acharya Sushruta (Great Surgeon)*. ^[3] Symptoms, signs and treatment of *Stana Vidradhi (Breast Abscess)* are similar to that of abscess found in the Modern textbooks ^[4] and the treatment is based on the *Pakvata (Ripe Stage)* and *Apakvata (Unripe)* stage of *Vidradhi (Abscess)* which includes both systemic and local treatment. *Mamsa (Muscle tissue)* and *Rakta (Blood)* are the *Dushyas (Causative factors)* mainly involved in the pathogenesis of *Vidradhi (Abscess)* with *Twak (Skin)*, *Medas (Adipose tissue)* and *Doshas (Vitiating factors)* in producing the swelling. ^[1]

The conventional management of abscess includes incision and drainage, the standard of care for

breast abscesses. ^[5,6] In addition to the local intervention, a course of antibiotics may be given before or following drainage of breast abscesses. In breast abscess, it is very important to consider if the patient is breastfeeding and whether the antibiotics given are safe in breastfeeding patients. Cultures should be obtained to guide antibiotic therapy, especially in recurrent breast abscesses. Some of the antibiotics include nafcillin, Augmentin, doxycycline, Trimethoprim, clindamycin, or vancomycin that is administered for 4-7 days. Pain control with NSAIDs and/or prescription narcotics should also be considered. ^[7]

According to *Ayurvedic* system of Medicine, Breast abscess was managed by *Acharya Sushruta* with the *Shastra karma* or the surgical procedures called as *Bhedana (Incision)* and *Visravana (Drainage)* with *Vrana Shodhana (Wound Cleansing)* and *Vrana Ropana (Wound Healing)* treatment methods. *Acharya Sushruta, An Ancient Surgeon*, in his treatise *Sushruta Samhita* has mentioned numerous surgical principles and manoeuvres. All these procedures are of extreme relevance even today. Today's advanced techniques in surgical practice have been developed based on the principles of *Ashtavidha Shastra Karma (Eight Surgical Procedures)*. All surgical procedures performed currently definitely involve one or more of these *Ashtavidha Shastra Karma*. ^[8] Among these *Ashtavidha shastrakarmas*, *Bhedana (Incision)* and *Visravana (Drainage)* have proved to be very effective with the *Vranashodhana (Wound cleansing)* and *Vranaropana (Wound healing)* *Chikitsa*

(Treatment) since the evolution of *Ayurvedic Surgery*. Objectives of the present study was to evaluate the efficacy of shastra karma (Surgical intervention) in the management of Sootika Stana Vidradhi.

OBJECTIVES OF THE STUDY

In the present open label single arm study, an attempt has been made to evaluate and revalidate the concepts of *Ayurvedic Shastra Karma (Bhedana (Incision) and Visravana (Drainage) with Vranashodhana and Vranaropana Chikitsa* in the management of *Pakwa Sootika Stana Vidradhi (Ripe puerperal abscess or Breast abscess)*, according the stages or *Avasthas (Stages)* that is described in *Ayurveda* in association of the current modern management of abscess.

METHODOLOGY

This was an open label single arm surgical trial that included 30 *Sootika (Lactating women)* patients diagnosed with *Stana Vidradhi (Breast abscess)*. Female patients with the features of *Stana Vidradhi (Breast Abscess)* were recruited from the outpatient and in-patient Department of *Prasooti Tantra Evam Stree Roga (Obstetrics and Gynaecology)* at R.G.E.S Ayurvedic Medical College and hospital Ron. Sample size was derived by calculating the effect size based on the mean and standard deviation (SD) of an earlier clinical study conducted on the *Stana Vidradhi* and Shastra Karma. The study was approved by the IRB of Institutional Ethical committee of R.G.E.S Ayurvedic Medical College and hospital Ron.

Signed informed consent was obtained from all the patients. The statistician who did the analysis was blinded to the treatment status of the patients. Statistical analysis was done using appropriate statistical methods and results were interpreted.

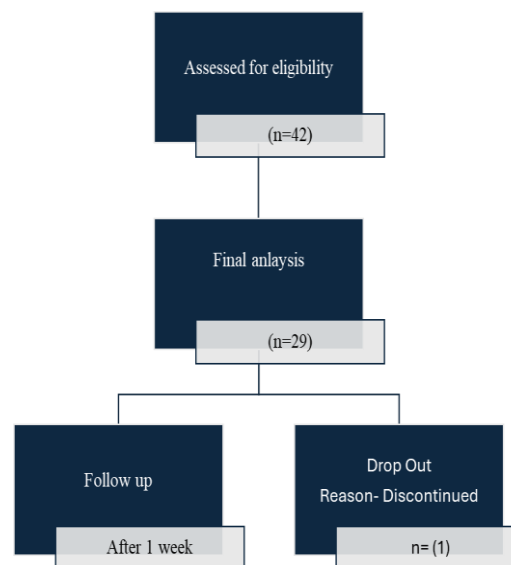


Figure No.1 Flowchart

Inclusion criteria

Sootika (Lactating Women) patients with the features of *Pakwa Stana Vidradhi (Full Ripen Abscess)*, patients with the age group between 20 – 35 years, positive fluctuation test and patient who were fit physically and for anaesthesia and the shastra karma were included for the study

Exclusion criteria

Patients with HIV, HBsAg, VDRL, infection, patients with systemic illness like DM, Hypertension etc, patients with anaemia having Hb less than 8mg/dl, patients with known case of breast malignancy and *Amavastha (Unripe Stage)* of *Stana Vidradhi (Breast abscess)* were excluded for the study.

Intervention

Table No.1 Intervention

Sl.No	Purva Karma	Pradhana Karma	Paschat Karma
1.	Nature of the study was explained to patients	Patient was made to lie in the lateral position on the table	Analgesics (Tab. Paracetamol 650g TID)
2.	Informed consent was obtained from all the patients	Short GA was given	<i>Prakshalana (Cleansing)</i>
3.	Materials kept ready	Operative area was sterilized using Betadine solution	<i>Lepa Chikitsa (Paste application)</i>
4.		Draping was done	
5.		Bhedana was performed with number 11 <i>Vridhipatra Shashtra (Scalpel Blade)</i>	
6.		Visravana was done with <i>Karpasa (gauze piece)</i>	
7.		Vrana <i>Prakshalana (Wound Cleansing)</i>	
8.		Lepana for <i>Vrana ropana (Healing of wound)</i>	
9.		<i>Bandhana (Bandaging)</i>	

Shastra karma procedure that is mentioned in *Susrutha Samhitha* by Acharya Sushruta for the management of *Pakwa Sootika Stana Vidradhi (Fully ripen lactational breast abscess)* including *Bhedana Karma (Incision)*, *Visravana Karma (Drainage)*, *Vrana Shodhana (Wound cleansing)* with *Ksheerivruksha Kashayas* and *Vrana Ropana Karma (Wound healing)* with *Lepa (Paste)* application of *Tila Kalka*, *Yastimadhu*, *Madhu* and *Ghrita* was selected for the present study. The drugs used for the procedure were collected and prepared in the Department of Dravyaguna, RGES Ayurvedic Medical College and hospital, Ron. (TableNo.1)

Purva karma

Nature of the treatment and the study was explained and informed consent was obtained from all the patients. Materials required for the study such as sterile gown, towels, kidney trays, betadine solution, spirit, ribbon gauze, gauze piece, *Kartari (Scissors)*, *Vridhipatra Shashtra (Scalpel and Blade)*, surgical gloves, prophylactic antibiotics (cephalosporins-cefotaxime 1gm, stat before 30 minutes, short GA, *Ksheerivruksha Kwatha (Decoctions of milk yielding trees)* for *Prakshalana (Cleansing)* and *Lepa (Local application)* of *Tila Kalka (Sesamum Paste)*, *Yastimadhu (Glycyrrhiza Glabra)*, *Madhu (Honey)*

and *Ghrita (Ghee)* was kept ready for the procedure.

Pradhana karma

Patient was made to lie in the lateral position on the table and short GA was given. Operative area was sterilized using Betadine solution and the surrounding area was draped with the sterile towel. *Bhedana (Incision)* was done adequately with Number 11 *Vridhipatra Shashtra (Scalpel Blade)* and *Visravana (Drainage)* of pus was carried out using *Karpasa (gauze pad)*. After the removal of pus completely, *Prakshalana (Cleansing)* of abscess was done with *Kshirivruksha Kashaya*

(Decoctions of milk yielding trees) and *Lepa (Local application)* prepared out of *Tila Kalka (Sesamum Paste)*, *Yasti Madhu (Glycyrrhiza Glabra)*, *Madhu (Honey)* and *Ghrita (Ghee)* was applied and was packed with the ribbon gauze. Keeping the gauze pad over it loose bandaging (*Bandhana*) was done.

Paschat karma

Patient was given Analgesics (Tab. Paracetamol 650g TID), *Prakshalana (Cleansing)* and *Lepa Chikitsa (Paste application)* and advised to come for dressing daily for 7 days.

Parameters (Table No.2)

Table No.2 Grading of Parameters

Sl.No	Parameters	Components	Grading
1.	Pain	Pain not relieved with analgesics	3
		Pain relieved with analgesics	2
		Pain relieved without analgesics	1
		No pain	0
2.	Swelling	Swelling > 5cms with tenderness	3
		Moderate swelling with tenderness	2
		Mild swelling with <2cms	1
		No swelling	0
3.	Slough	Slough covered up to 50% - 75% of wound	3
		Slough covered up to 25% - 50% of wound	2
		Slough covered up to 25% of wound	1
		Absent	0
4.	Discharge	Profuse continuous discharge	3
		Often discharge and blood on dressing	2
		Scanty occasional discharge and little wet	1

		dressing	
		No discharge	0
5.	Granulation tissue	No granulation tissue	4
		Unhealthy granulation tissue with slough	3
		50% wound covered with granulation tissue	2
		75% wound covered with granulation tissue	1
		Healthy granulation tissue	0
6.	Wound size	No change	4
		25% reduction	3
		50% reduction	2
		75% reduction	1
		Complete reduction	0

*Footnote: Pain, Swelling, Slough, Discharge, Granulation tissue, Wound size

Duration of the study was 7 days with before and after assessment. Assessments were made on 1st day and on the 8th day after the treatment.

RESULTS

Kolmogorov-Smirnov test for normality was conducted on scores obtained from the difference between baseline and post scores. Wilcoxon signed rank test showed that there was a significant reduction in with Visual analog scale

Assessments were be carried out before the treatment 1st day, and on 7 after the treatment.

($p \leq 0.005$), Pain ($p \leq 0.005$), swelling ($p \leq 0.005$), slough ($p \leq 0.005$), discharge ($p \leq 0.005$), granulation tissue ($p \leq 0.005$), and wound size ($p \leq 0.005$). Post-treatment results showed significant changes compared to Pre-treatment in all the Sootika patients. (Table No.3)

Table No.3 Showing Pre-Post Results

Variable	Pre	Post
VAS	9.86±0.35	0.07±0.26*
Pain	3±0	0±0*
Swelling	2.97±0.19	0.10±0.31*
Slough	3±0	0.07±0.26*
Discharge	3±0	0.07±0.26*
Granulation Tissue	3.9±0.31	0.1±0.31*
Wound Size	3.86±0.35	0.14±0.35*

**Footnote: Scores in Mean±SD of variables of interest before and after intervention. Level of significance fixed at 0.05. Wilcoxon signed rank test was performed to assess the level of significance. VAS – Visual Analogue Scale, Pain, Swelling, Slough, Discharge, Granulation Tissue, Wound Size*

DISCUSSION

Patients usually experience breast pain, erythema, warmth, and oedema etc symptoms in case of Breast abscess with lactation history. In majority of the cases, postpartum mastitis is seen within 6 weeks of breast-feeding. Patient may also present with axillary adenopathy and tachycardia. [9] In Ayurveda Stana is also called as Payodhara and is one among the 56 *Pratyangas (Parts of the body)*. [10] Breast abscess can be correlated with *StanaVidradhi (Breast abscess)*, [11] or *Stana Shopha (Inflammation of Breast)* which is seen in *Aamavastha (Unripe stage)*, *Pachyamaanavastha (Intermediary stage)* or *Pakwavastha (Fully ripen stage)*. Once the breast abscess ruptures, it will be treated as Shuddha or Dushta Vrana based on the Dosha involvement. [12]

The present study was an open label single arm surgical trial that included 30 *Sootika (Lactational)* patients diagnosed with *Stana vidradhi (Breast abscess)*. All 30 patients received the classical shastra karma explained in Ayurvedic science with a Modern aid that included *Bhedana (Incision)*, *Visravana (Drainage)*, *Vrana prakshalana (Wound cleansing)* and *Vrana ropana (Wound Healing)*. Duration of the study was 7 days with before and after assessment. Assessments were made on 1st day and on the 8th day after the treatment. There was 1 drop out in the study.

Repeated measures analysis of variance (RMANOVA) with Bonferroni showed significant

changes in Visual Analogue Scale in the pre assessment (9.86±0.35) compared to Post assessment (0.07±0.26). In pain with pre (3±0) and post (0±0*) swelling with pre (2.97±0.19) and post (0.10±0.31*), slough with pre (3±0) and post (0.07±0.26*), discharge with pre (3±0) and post (0.07±0.26*), granulation tissue with pre (3.9±0.31) and post (0.1±0.31*) and wound size showed significant changes in with pre (3.86±0.35) compared to post assessment (0.14±0.35*) after the treatment with (p≤0.05).

In Modern science, incision that is made only for opening a cavity or tapping of cavity to drain out pus, blood and even to remove calculus etc. Whereas in *Ayurveda*, it is indicated in all *Vidradhis (Abscess)* except *Sannipatika, Stana Vidradhi, Avamanthaka, Kumbhika, Anusayi, Nadivrana, Vrindaroga, Pushkarika, Alaji, Kshudraroga, Talupupputa, Dantapupputa, Vataj Granthi, Pittaja Granthi, Kaphaja Granthi*, Three types of *Visarpa, Vridhiroga, Vidarika, Pramehapidika, Vranshophatundikeri, Gilayu, Ashmari* and *Medajaroga (Different types of diseases)* etc.

Ayurvedic explanation of *Bhedana karma (Incision)* is as follows; it is performed in abscess or *Vidradhi (Abscess)* which is having pus inside but not with an opening, sinuses or pus pockets. Shastra's and *Anushastra's (Accessory Surgical Instruments)* used for *Bhedana karma* include *Vridhipatra, Nakhasastra, Mudrika, Utpalapatra* and *Ardhadhara*. *Anushastra's* are *Twaksara (bamboo)*,

Sphatika (Quartz), Kaca (glass pieces), Kuruvind and Nakha (Nails). These instruments that are used for *bhedana karma* should be held in between the *Vrinta (Handle)* and *Phala (blade)*. In case of *Stana Vidradhi (Breast Abscess)*, *Bhedana Karma (Incision)* should be conducted after suppuration of the *Vidradhi (Abscess)* avoiding the *Dugdharini Nadi (Lactiferous Ducts)* and both *Krishna Chuchuka (Areola and Nipples)*. *Visravana karma (Drainage)* is one of the *Astavidha Shastra Karmas*, that is indicated in five types of *Vidradhi*, *Ekadeshaja Sopha (localized inflammatory swelling)*, *Sleepada*, *Visajusta Vataja Pittaja Kaphaja Granthi*, *Vataja Pittaja Kaphaja Upadamsa*, *Stanaroga*, *Vidarika*, *saushira*, *galashaluka*, *Sonitha*, all kinds of *Arbuda*, all kinds of *Visarpa*, *Kantaka*, tooth caries, pyorrhea, spongy gums, *Upakusha*, *Dantapupputa*, disorders of lips caused by *Pitta*, *Rakta* and *Kapha* etc. *Ksudrarogas*. *Shastra's* and *Anushastra's* used for *Visravana* are *Suci (Needles)*, *Kushapatra*, *Atimukha*, *Sararimukha*, *Antarmukha* and *Trikurcaka* and *Anushastra's* such as *Nakha* and *Jalauka*.^[13]

After the *Bhedana (Incision)* and *Visravana (Drainage)* of *Stana vidradhi (Breast abscess)*, a *Vrana (Wound)* is created which needs *Vrana Shodhana (Wound Cleansing)* and *Vrana Ropana Chikitsa (Wound Healing Treatment)*. For proper care of wound, wound cleaning; as a part of *Vrana-Shodhana and Ropana*, is essential. *Vrana Shodhana Dravyas (Medicinal drugs that does wound cleansing)* mentioned in classical texts of Ayurveda which are used as primarily for cleaning

of wound in form of *Lepa (Paste Application)* or decoction either it for the aim to reduce microbial load or to remove dead, necrotised tissue which are responsible to infection. Acharya Sushruta mentioned 60 different procedures for treating wound in which these seven i.e. *Kashaya (Decoction)*, *Varti*, *Kalka (Paste)*, *Sarpi (Ghee)*, *Taila (Oil)*, *Rasakriya* and *Avachurnana* are specially detailed for proper wound care.^[14] In the present study, the treatment was given under three stages as *Purva*, *Pradhana* and *Paschat Karma*. In *Purva karma*, patient and the materials were made ready. In *Pradhana* patient was given short GA. *Bhedana (Incision)* and *Visravana (Drainage)* was performed with adequate measures with *Prakshalana (Wound Cleansing)* and *Lepa (Paste application)* was applied. Packing with gauze and (*Bandhana*) was done. In *Paschat karma (Post operative procedure)*, Patient was given Analgesics and Antibiotics with *Lepa chikitsa (Paste application)*. The main advantage of *Shalya Chikitsa (Surgical Treatment)* is the non-recurrence of the disease and the immediate relief that it provides. *Stana vidradhi (Breast Abscess)* is one such disease that require *Bhedana (Incision)* and *Visravana Karmas (Drainage)* of *Astavidha Vidha Shastra Karmas (Eight kinds of Surgical procedures)* as it plays a very important role in providing the immediate relief to the *Sootika (Lactational Women)* patients and facilitates the early recovery and early commencement of breast feeding to their infants.

The present study shows that the application of *Ayurvedic Shastra Karma (Surgical Procedures)*

(*Bhedana and Visravana- Incision and Drainage*) with *Vranashodhana (Wound Cleansing)* and *Vranaropana Chikitsa (Wound Healing Treatment)* with the comprehensive approach of Modern Medicine was effective in the management of *Pakwa Sootika Stana Vidradhi (Fully Ripen Lactational Breast Abscess)*. The current study also aids in the revalidation of the concepts of *Shastra Chikitsa (Surgical treatment)* described in *Ayurveda* by *Acharya Sushruta* in the management of *Stana Vidradhi (Breast Abscess)* by providing a broader perspective and direction for the budding researchers.

Limitations of the study

Small sample size, as patients were less aware of Ayurveda treatments, had to create an awareness about the treatments before conducting, Sterilisation of *Lepa (Paste)* was difficult, Storage of *Lepa (Paste)* was difficult, Stress and quality of life of *Sootika (Lactational Women)* patients could have been measured using questionnaires and Healing time could have been recorded.

Strengths of the Study

First study of its kind, only study that has incorporated both *Ayurvedic* and Modern concepts of *Shastra karma* in the management of *Sootika Stana Vidradhi (Lactational Breast Abscess)*, Healing time of the *Vrana (Wound)* was much faster compared to normal conventional treatment, Patients were happy due to early healing and early recovery, Patients were able to breast feed their younger ones much earlier than the normal conventional period.

Scope for further study

Larger sample size, A longer Follow up would be recommended, Parameters that assess healing time of the *Vrana (Wound)* can be included in further studies, Stress assessing questionnaires can be included and Quality of life can be measured.

CONCLUSION

Wilcoxon Signed Rank Test showed that there was a significant reduction in Visual analog scale ($p \leq 0.005$), Pain ($p \leq 0.005$), swelling ($p \leq 0.005$), slough ($p \leq 0.005$), discharge ($p \leq 0.005$), granulation tissue ($p \leq 0.005$), and wound size ($p \leq 0.005$) after the treatment. Post-treatment results showed significant changes compared to Pre-treatment in all the parameters of *Sootika Vidradhi (Breast Abscess)*. *Shastra karma (Surgical intervention)* explained in Ayurvedic science is effective in the management of *Sootika Stana Vidradhi (Lactational Breast Abscess)* that included a comprehensive approach of Modern aid that included *Bhedana (Incision)*, *Visravana (Drainage)*, *Vrana Prakshalana (Wound Cleansing)* And *Vrana Ropana (Wound Healing)*.

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Amruta Mahaveer Bankapure, Shreyes. S, Yogitha Bali M.R. An open label -single arm surgical trial on *sootika stana vidradhi* w.s.r breast abscess. Jour. of Ayurveda & Holistic Medicine, Vol.-XII, Issue-I (Jan. 2024).

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CITE THIS ARTICLE AS

Amruta Mahaveer Bankapure, Shreyes. S, Yogitha Bali M.R. An open label -single arm surgical trial on *sootika stana vidradhi* w.s.r breast abscess. *J of Ayurveda and Hol Med (JAHM)*. 2023;12(1):13-22

Conflict of interest: None

Source of support: None