

“CLINICAL TRIALS OF GAURADYA GHRUTA VARTI IN NADIVRANA (SINUS)”**Dr. Vijay Serjerao Dange****Associate Professor, Department of Shalya Tantra, Hon. Shri. Annasaheb Dange Ayurved Medical College Ashta Daist Sangli.****Corresponding Author: Dr. Vijay S. Dange , Contact: 8600600181****ABSTRACT:**

A sinus is a blind-ending tract, usually lined with granulation tissue, that leads from an epithelial surface into the surrounding tissue, often into an abscess cavity. Sinuses may be congenital or acquired. Congenital sinuses arise from the remnants of embryonic ducts that persist instead of being obliterated and disappearing completely during embryonic development. Accurate detection of any associated deep abscess cavity complex deep extensions of the sinus tract is paramount successful treatment. Failure to do this will result in recurrence the sinus either at the same site or an adjacent location.

Key Words: Nadivrana, sinus

CLINICAL TRIALS OF GAURADYA GHRUTA VARTI IN NADIVRANA (SINUS)**INTRODUCTION:**

Nadivrana is a common disorder in tropics due to unhygienic conditions. Clinically Nadivrana forms if abscess is avoided or treated improperly and ineffectively with post-operative complications and complaints of recurrences in most of the cases by the line of treatment adopted by modern surgeons. In spite of tremendous progress in the field of modern surgery, still there are greatly analyzed chances of recurrence are noticed and reduced success rate ^[1].

A sinus is a blind-ending tract, usually lined with granulation tissue, that leads from an epithelial surface into the surrounding tissue, often into an abscess cavity. Sinuses may be congenital or acquired. Congenital sinuses arise from the remnants of embryonic ducts that persist instead of being obliterated and disappearing completely during embryonic development. Acquired sinuses are usually secondary to the presence of foreign or necrotic material (with or without associated sepsis) within the affected tissue or from certain types of microbial infection. It is important to distinguish these from fistulas, which are abnormal communications between two epithelium-lined surfaces ^[2].

Accurate detection of any associated deep abscess cavity complex deep extensions of the sinus tract is paramount successful treatment. Failure to do this will result in recurrence the sinus either at the same site or an adjacent location.

Nadivrana is an ulcer having a tract extending into the deeper tissues. Nadivrana is associated with the presence of a large number of recesses or cavities in an ulcer. When excessive infiltration of pus burrows deeply then it can be called as nadivrana. Nadivrana or sinus comes under a non-healing ulcer so to understand the nature and clinical presentation of nadivrana, the knowledge of an ulcer is needed Ayurvedic classics state-

In our Ayurveda Acharyas have explained in detail about the management of nadivrana with different treatment modalities, Varti application is one among them which does not require anaesthesia and having good curative properties with worth-full results.

The varti is considered to possess an anti-inflammatory and good broad spectrum activity. It must be remembered that nadivrana is a chronic non-healing ulcer (dustavrana) and may occur due to specific organisms also.

Here Gauradya Ghruta Varti^[12] and Lavanottam Varti^[13] are selected for the study, which has got lekhan, shodhana and ropana properties, thus helps in treating the nadivrana effectively.

OBJECTIVES OF THE STUDY

1. To evaluate the efficacy of Gauradya Ghruta varti in Nadivrana.
2. To evaluate the efficacy of Lavanottam varti in Nadivrana.

RESEARCH QUESTION AND HYPOTHESIS

RESEARCH QUESTION:

Which is more effective between Gauradya Ghruta Varti and Lavanottam Varti in the management of Nadivrana?

HYPOTHESIS:-

Primary Hypothesis (H₀):

H₀:Gauradya Ghruta Varti is not significantly effective in the management of Nadivrana.

H₁:Gauradya Ghruta Varti is significantly effective in the management of Nadivrana

Clinical study-

STUDY DESIGN:

A comparative clinical Trial and was designed in the following manner.

- A. The patients were selected by simple randomized sampling procedures.
- B. 32 patients were selected in group „A“ and 32 patients were in group „B“.
- C. Group „A“ patients were treated with „Gauradya Ghruta Varti“ and group „B“ patients were treated with Lavanottam Varti.
- D. Finally the results were assessed.

Type- To determine the efficacy between Group A (Trial Group) and Group B (Control Group).

Place of work (location of study)- Patients attending the OPD and IPD of Shalyatantra

Department with classical symptoms of sinus (Nadivrana) are selected for the study.

Pharmacy attached to the college for the preparation of drug.

OPD, IPD, Laboratory and other provisions of the hospital are availed to do this intended work.

Appropriate sampling technique.

1. Sample size 32 in each group. The patients were selected based on the clinical examination. 64 patients were divided into two groups of 32 patients each.
 2. The total duration of the treatment taken is maximum of 4 weeks.
 3. The length of the tract taken is maximum of 5 cm.
 4. Progress was assessed on Regular followups.
- Group „A“ – Gauradya Ghruta Varti
 - Group „B“ – Lavanottam Varti.

FORMULATION DETAILS:-

Gauradya Ghruta Varti (Trial Group)-

Method of Preparation-

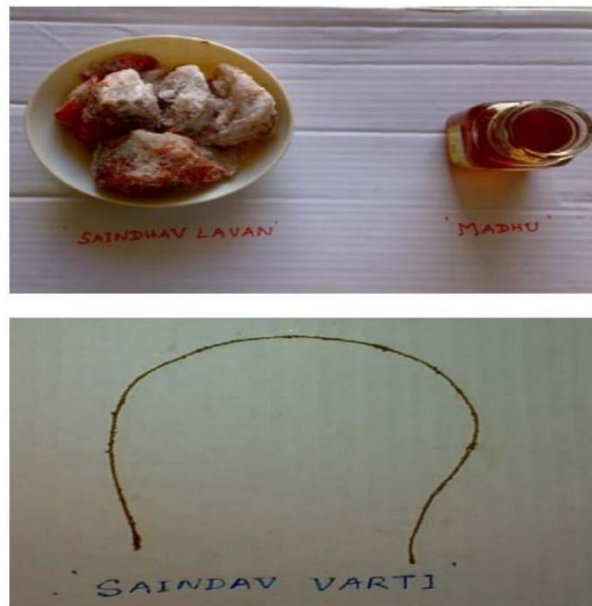


Haridra, Daruharidra, Manjistha, Jatamansi, Madhuk (Yashthimadhu), Prapaoundarik, Hriber, Bhadramustha, Raktachandan, Jatipatra, Nimbapatra, Patolapatra, Karanjbeej, Katurohini, Maduchistha, Madhuk, Mahameda (Abhavvarga- Shatavari) all above contents were taken in equal quantity and then it was grinded to make fine texture. Then water was added to make a kalka (paste like consistency). Panchvalkala was taken in equal quantity to all above contents.

Panchvalkala kwath was prepared and then above kalka and Goghruta was added to it, heated on medium flamed till only Ghruta part remains. Thus in these way Gauradya Ghruta was prepared.

LAVANOTTAM VARTI- (CONTROL GROUP)-Method of preparation

The wick made of Rock salt mixed with honey was applied on plain thread and preserved after dryness is attained and kept inside the sterilized test tube with tight air cork.



Standardization of Gauradya Ghruta Varti was done:

Discription: Colour :

Brown Odour :

Slightly Aromatic

Texture: Smooth,

Greasy

Taste : Slightly Pungent and Astringent

pH Value : 7.84 Specific Gravity: 15.44 g/cm³ Refractive

Index : 7.19

Iodine Value : 34.3506 mg/g

Saponification Value: 198.87 mg/g

Acid Value : 1.521 mg/g

Viscosity : 9.142 PaS

Standardization of Lavanottam Varti was done:

Discription:

Colour : Brown

Odour :Characteristic

Texture: Smooth

Taste : Salty

pH Value : 6.9

Moisture content : 0.26%

Loss on Drying : 2.53%

Total Ash Value (w/w) : 4.71%

Water soluble Ash (w/w) : 1.76%

Acid Insoluble Ash : 0.58%

Water Soluble Extractive : 8.08%

Alcohol Soluble

Extractive : 3.72%

Foreign matter : :0.062%

Friability Test : 24 mins Disintegration Time : 20 mins Total

Hardness : 1.1 kg/cm²

Average weight : 5gm

Administration of drug:

Effect of Gauradya Ghruta Varti and Lavanottam Varti in Nadivranawas assessed by study which is done on 64 patients of Nadivrana.For this purpose clinical study was carried out mainly into followingphase-

Grouping and Randomization of patients:

I.Grouping- Out of 64 patients, 32 patients were included in Group A and 32 patients were included in Group B.

II. Randomization of the patients- By simple randomization procedure 64 patients were equally distributed into two groups.

Inclusion Criteria:

1. Patients presenting with classical signs and Symptoms of Nadivrana with single External opening on the body surfaces will be selected.
2. The age group between 15 to 60 years irrespective to gender.
3. Patients ready to take treatment.
4. Patients who are reluctant for surgery.
5. Length of sinus tract upto 5cm.

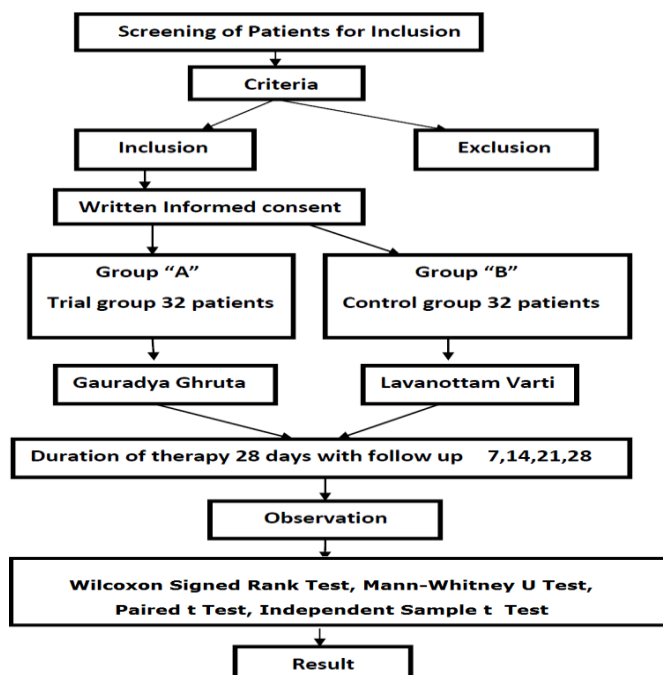
Exclusion Criteria:

1. Patient reluctant to take whole treatment.
2. The age group below 15 years and above 60years.
3. Congenital sinuses.
4. Nadivrana with systemic diseases like uncontrolled DM, Bleeding disorders, AIDS, Tuberculosis and Actinomycosis.
5. Osteomyelitis followed by sinus.
6. Patients having complicated sinus.
7. Patients having Neoplastic Sinus.
8. If the Sinus tract is more than 5cm.

WITHDRAWAL CRITERIA

1. If patient develops any adverse effects due to application of Gauradya Ghruta Varti and Lavanottam Varti.
2. If not responding to treatment and aggravation of symptoms within 15 days.
3. Patient refuses to continue treatment.

METHODOLOGY



Treatment Details-

Gro up	Treatment	Duration	Follow up
A	Gauradya Ghruta aVarti	Taking aseptic precautionsvarti is inserted into Nadivrana giving two daysgap between two applications for 4 weeks	7,14,21,28 days.
B	Lavanottam Varti	Taking aseptic precautionsvarti is inserted into Nadivrana giving two daysgap between two applications for 4 weeks	7,14,21,28 days.

Table No 1: Demographic Variables Distribution

Groups		Group A		Group B		Total	
Sr. No.	Age Group (Years)	Count	Percent	Count	Percent	Count	Percent
Age Group	21-30	4	13%	7	22%	11	17%
	31-40	16	50%	11	34%	27	42%
	41-50	4	13%	8	25%	12	19%
	51-60	8	25%	6	19%	14	22%
Gender	Male	26	81%	23	72%	49	77%
	Female	6	19%	9	28%	15	23%
Weight	51-60	3	9%	5	16%	8	13%
	61-70	13	41%	9	28%	22	34%
	71-80	12	38%	15	47%	27	42%
	81-90	4	13%	3	9%	7	11%
Relegion	Hindu	29	91%	32	100%	61	95%
	Muslim	3	9%	0	0%	3	5%
Marital Status	Married	27	84%	24	75%	51	80%
	Unmarried	5	16%	8	25%	13	20%
Diet	Mixed	18	56%	19	59%	37	58%
	Veg	14	44%	13	41%	27	42%
Prakruti	Kapha-Pitta	8	25%	11	34%	19	30%
	Kapha-Vata	4	13%	1	3%	5	8%
	Pitta Kapha	6	19%	6	19%	12	19%
	Pitta- Vata	6	19%	4	13%	10	16%
	Vata-Pitta	2	6%	3	9%	5	8%
	Vata Kapha	6	19%	7	22%	13	20%
Total		32	100.00%	32	100.00%	64	100.00%

(Source: Primary Data)

Table No 2: IQR Distribution

Parameter	Groups	Mean score			IQR				
					Median diff.	of diff. Q ₃ – Q ₁	Sample size	Wilcoxon signed rank test (T+)	P Value
		B.T	A.T	Diff					
Effect of Treatment on Length of Sinus Tract (cm)	Group A	3.5	0.5625	2.9375	3.5	2.0)	32	528	<0..05
	Group B	3.468	1.218	2.25	3	(3.0	32	465	< 0.05
Pain	Group A	2.1875	0.5312	1.6562	2	1	32	351	<0.05
	Group B	2.4687	1.25	1.2187	2	1	32	290	<0.05
Discharge	Group A	2.5312	0.5312	2	3	0.5	32	528	<0.05
	Group B	2.8437	0.9375	1.9062	2	2	32	435	<0.05

Table no 3: Overall Significance

Parameter	Group A	Group B	Comparative efficacy
Effect of treatment on length Track in Cm	Significant	Significant	Treatment A
Effect of treatment on Pain	Significant	Significant	Treatment A
Effect of treatment on Discharge from sinus tract	Significant	Significant	Equally effective

Table no 4 : Overall Effect

Parameter	Group A	Group B
Effect of treatment on length of tract (cm)	0.8567	0.6635
Effect of treatment on Pain	0.7043	0.4583
Effect of treatment on Discharge from sinus	0.7968	0.677
Mean % improvement	0.7704	0.6033

Table no 5: Overall Effect in counts

Overall Effect (patient wise)	No. of patients			
	Group A		Group B	
	Count	%	Count	%
Marked improvement	18	56%	13	41%
Moderate improvement	10	31%	7	22%
Mild improvement	4	13%	6	19%
Unchanged	0	0%	6	19%
Total	32	100%	32	100%

Gauradya Ghruta varti:

Gauradya Ghruta varti after preparation becomes very sheet (cold),so used for osh, chosha, daha. It has properties as sukshma, Madhur- rasa, sheet eerya, Madhur-vipaka, daha-shamaka. It acts as Vrana- ropaka (wound ealing), jeevanu-rakshak (disinfectant). All the abovepitta-shamaka properties are present in Gauradya Ghruta varti. So it effectively relieves the signs and symptoms of Nadivrana. Additionally, ghruta is a known immune booster and it is the property of Gauradya Ghruta that leads to increase in local cell immunity. This is the causative factor that prevents recurrence of symptoms in patients treated with Gauradya Ghruta varti.

Ghruta contains vitamin A, D, E and K. Vitamin A and E are antioxidant and are helpful in preventing oxidative injury to the body. Vitamin A keeps epithelial tissue of the body intact. It also contains 4-5% linolenic acid as essential fatty acid, which promotes proper growth of human body. Lipophilic action of ghruta facilitates transportation to a target organ and finally delivery inside the cell because cell membrane also contains lipid. This lipophilic nature of ghruta facilitates entry of the formulation into the cell and its delivery to the mitochondria, microsome and nuclear membrane.

Ghruta also reduces the Rukshata of Vayu and maintain the normal tone of muscles. Smoothing effect is achieved due to Ghruta. Goghruta, which itself is having sanskaraanuvarti, analgesic and healing properties. Sanskara-anuvarti property is potentiated by Goghruta which create good medium for absorption, transport and delivers of the Ayurvedic formulation to the proper area of the body. Vit K keeps epithelial tissue of the body instant which is very useful of wound healing. Linolenic acid helps in granulation.

Hence, most of all the contents have Vranashodhana, Vranaropana, Vedanasthapana, Shothahar, Vranashophahara,

Lavanottam varti:

Saindhav Lavan and Madhu (Honey) have sheeta and laghuguna as well as madhu has madhura rasa and kashayaanurasa which will lead for healing of sinus tract.

Also madhu has vranashodhana, ropana and dahahara properties leading to healing of sinus tract.

Discussion on Treatment results obtained:

From the above results it is proved that both the drugs are quiet effective in relieving all the parameters. With regards to Discharge from sinus tract Group A medicine i.e. Gauradya Ghruta varti is equally effective to Group B medicine i.e. Lavanottam varti.

During this clinical study overall assessment noted that cured rate of patient in Group A is 77.04% while cured rate of patient Group B is 60.33% which means that Group A is significantly more effective than Group B. That means Null Hypothesis got rejected and alternative Hypothesis got proved, it means Gauradya Ghruta varti is more effective in Nadivrana as compared to Lavanottam varti.

Conclusion :

- Treatment A and treatment B can be considered as equal efficacious in reducing discharge from sinus tract .
- After the compative statistical analysis of Group „A“ Gavradya Ghruta Varti shown highly significant effect on pain, length of the tract. But Group A and Group B are equally significant on reducing the discharge from sinus.
- Between the Group A and Group B the difference observed in all parameters except discharge from sinus tract parameter is statistically equally significant.

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