



Research Article

STANDARDIZATION OF PHALA VARTHI AN AYURVEDIC RECTAL SUPPOSITORY

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ABSTRACT

Suppositories are solid dosage forms intended for insertion into body cavities or orifices, where they melt or dissolved to exert either local or systemic effect. *Phalavarti* is an Ayurvedic way of application of suppositories in rectal ailments as discussed in Samhitas. *Phalavarthi* is one of *Vati Kalpana*, It is a simple homemade medicament which can be prepared with easily available ingredients, It can be used in various types of GIT disorders like *Udavarta*, *Anaha*, *Adhmana*, *Arsas*, *Gulma*, *Udara*, *Vibanda*, which are some of the very common problems faced by general population due to irregular dietary habits and sedentary life style leading to *Mandagni*. The impaired digestion is main cause for various types of systemic and metabolic disorders. In such conditions *Vatanulomana* is main line of management. Apart from above specified conditions, *Phalavarthi* preparations can also be used in *Panchakarma ayoga* conditions like *Virechana*, *Niruha*, *Anuvasana* and *Uttara vasthi*. Despite the fact that various types of *Phalavarthi* preparations have been mentioned in *Ayurveda* texts, they are not in regular use due to less attention and focus received on this subject. Therefore the present scientific study has been taken up to overcome the practical difficulties in both preparation and application of *Phala vartis* with a scientific approach. *Phalavarthi* is a very unique concept which is far superior to modern concept of rectal suppositories, it can be administered to children, old persons and all those who cannot swallow drugs easily. Hence keeping this advantage in mind, an attempt has been made to prepare and administer *Phalavarthi* in GIT disorders following the guidelines of *Acharya Charaka* and also keeping in view of modern principles of preparation of suppositories.

INTRODUCTION

Nirukti- *Vartayateeti Varti*^[1]


Definition- *Vartiriva svarupatvata Vartih namna Prakrititah*^[2]

Varthi kalpana is derivative of *Vati kalpana*. The method and preparation is similar to that of *Vati* preparation. But, both of them differ in their shape, use and indications. For making *Varthi* medicine is modified into *Yavakuthi* (elongated with tapering ends) form.

Varthi kalpana is mentioned by *brhatrayees* and almost all other Ayurvedic treatises, with a view of treating various disorders. *Varthis* are commonly used for local administration through the following routes viz. *Guda* (anus), *Yoni* (vagina), *Sisna* (penis), and *Netra* (eye). According to specific route of administration, length and diameter of the *Varthi* will be modified. It acts rapidly and in a better way to remove the imbalanced state of *Doshas* and *Malas*. These *Varthis* are solid at room temperature but melt/dissolve at body temperature.

AIMS AND OBJECTIVES

1. Conceptual study of various types of *Phala varti's* with a special emphasis on *Gudavarti* mentioned in *Ayurveda*.
2. Standardization of preparation of *Madanaphala varti* based on principles of Pharmaceutics.

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Literary Review**Types**

- Depending upon the size.
- Depending upon its indication at the particular site.
- Depending upon its composition.
- Depending on its action.

a) Depending upon the size

- Yoni varthi: Pippalyadhi varthi- Pradeshini angulivat pramana*
- Guda varthi: Shyamaphaladi varti- Angushta pramana*
- Guda varthi: Pippalyadhi varti- Puspanetravat*
- Vrana varthi: Sodhana varthi varti- Sukshma to Sthula as per size and depth of Vrana*
- Dhumra varthi: Venvadhi varthi- Yavakara*
- Netra varthi (Lekhana karma): Sindavadhi varthi- Harenuka pramana*

b) Depending upon its indication at the particular site

- Guda Varti*, 2.*Yoni Varti*, 3.*Vrana Varti*, 4.*Sishna Varti*, 5.*Dhuma Varti*, 6.*Netra Varti*.

c) Based on composition

Ex; *Phala Varti* where *Madhana phala* is the main ingredient.

d) Based on the action

Varti can be *Saumya* and *Tikshna*. *Saumya Varti* is for the purpose of attaining *Snehana*, *Poshana* and *Ropana* actions. The drugs used for the *Saumya Karma*, possess qualities like *Mandaguna* and *Sita Virya*. *Tikshna Varti* is used for *Virechana* and *Lekhana Karma*. The drugs of *Tikshna Varti* are *Ushna* in *Virya* and *Tikshna guna yukta*.

Gudavarthi (Anal suppositories of Ayurveda): *Guda Vartis* are meant for insertion into the anus (*Guda*). It helps in *Apana vayu anulomana*, thereby aiding in easy expulsion of *Sancita dosha* (*Mala, Mutra, Pureesha* etc) from the body. Rectal suppositories are the modified form of *Guda (Anus) vartis*, meant for introduction into the rectum for their systemic and local effect. These are particularly useful when the drug cannot be administered orally. They are tapered at one or both ends and usually weigh about 2 gms. They are in an acceptable form, safe and easier for administration with a higher rate of bioavailability, faster onset in shorter peak and less wastage.

Table 1: Showing the different Guda Vartis mentioned in Ayurvedic Samhitas

S. No	Name	Indication	Reference	Size
1.	<i>Hingwadi varti</i> ^[3]	<i>Udavarta</i>	<i>Bhaishya ratnavali</i>	<i>Angushta pramana</i>
2.	<i>Madanaphala varthi</i> ^[4]	<i>Udavarta</i>	<i>Bhaishya ratnavali</i>	<i>Angushta pramana</i>
3.	<i>Aagaradhumadi varti</i> ^[5]	<i>Udavarta</i>	<i>Bhaishya ratnavali</i>	<i>Kanista anguli pramana</i>
4.	<i>Trikatwadi varti</i> ^[6]	<i>Udavarta</i>	<i>Charaka</i>	<i>Angushta pramana</i>
5.	<i>Shyamadi varti</i> ^[7]	<i>Udavarta</i>	<i>Charaka</i>	<i>Angushta pramana</i>
6.	<i>Pinyakadi varti</i> ^[8]	<i>Udavarta</i>	<i>Charaka</i>	<i>Angushta pramana</i>
7.	<i>Pippalyadi varti</i> ^[9]	<i>Udavarta</i>	<i>Charaka</i>	<i>Pushpanetravat</i>
8.	<i>Haridradhi varti</i> ^[10]	<i>Arshas</i>	<i>Charaka</i>	<i>Angushta pramana</i>
9.	<i>Nikumbakampilladi varti</i> ^[11]	<i>Udavarta</i>	<i>Susrutha samhita</i>	<i>Angushta pramana</i>
10.	<i>Samudraka sarshapa marichadi varti</i> ^[12]	<i>Vata varcha nirodha</i>	<i>Susrutha samhita</i>	<i>Angushta pramana</i>
11.	<i>Shodana gana varti</i> ^[13]	<i>Aprathyagamana vasti</i>	<i>Susrutha samhita</i>	<i>Angushta pramana</i>
12.	<i>Phala varthi</i> ^[14]	<i>Udavarta of vata mutra pureesha</i>	<i>Susrutha samhita</i>	<i>Angushta pramana</i>
13.	<i>Rataadi varti</i> ^[15]	<i>Shula</i>	<i>Chakradatta</i>	<i>Angushta pramana</i>
14.	<i>Ghosaphaladi varti</i> ^[16]	<i>Arshas</i>	<i>Chakradatta</i>	<i>Angushta pramana</i>
15.	<i>Thumbi bijadhi varti</i> ^[17]	<i>Arshas</i>	<i>Chakradatta</i>	<i>Angushta pramana</i>

Table 2: Showing the specific sizes of Guda Varti told in Ayurvedic Samhita

Example	Size
<i>Shyamaphaladi varti</i> ^[18]	<i>Angushta pramana</i>
<i>Pippalyadi varti</i> ^[9]	<i>Pushpa netra vat</i>
<i>Aagaradhumadi varti</i> ^[5]	<i>Kanista anguli pramana</i>
<i>Kanakamuladi varti</i> ^[19]	<i>Valla pramana</i>

Table 3: Showing the different methods of preparation of Guda Varti with an example

Example	Size
Paka method	Pippalyadi varti ⁹
With the help of Guda	Shyamaphaladi varti ¹⁸
Paka in Gomutra	Nikumbakampilladi varti ¹¹
Bhavana in Tila taila	Aagaradhumadi varti ⁵

Material & Method adopted in the present study

Evaluation of the formulation of *Madhanaphala varti* and its preparation has been taken up in the present study. The following table provides information of the ingredients and their individual properties of the *Madanaphala Varthi*.

Madana phalavarti:

मदनं पिप्पली कुष्ठं गौराश्च सर्षपः । गड़क्षार समायुक्तः फलवर्ति रिहोच्यते ॥ भै. र.31/10

Table 4: Showing Properties of Madanaphala varti

S.no	Name of drug	Latin name	Rasa	Guna	Vipaka	Virya	Action on Dosha	Karma
1	Madanaphala	<i>Randia dumetorum</i>	Madhura, Tikta	Laghu Sukshma Ruksha	Ushna	Katu	Kapha vata hara	Lekhana gulmahara
2	Pippali	<i>Piper longum</i>	Katu Tikta	Laghu Tikshna	Madhura	Ushna	Kapha vata hara	Deepani Rechani Gulmahara Udarahara Arshahara
3	Kushta	<i>Saussurea lappa</i>	Tikta Katu Madhura	Laghu Ruksha teekshna	Katu	Ushna	Kapha vata hara	
4	Vacha	<i>Acorus calamus</i>	Katu Tikta	Laghu Tikshna	Katu	Ushna	Kapha vata hara Pittakara	Pachana Vibandhahara Adhmanahara Shakrutmutra vishodini
5	Sweta sarshapa	<i>Brassica campestris</i>	Katu Tikta	Snigdha Ruksha	Katu	Ushna	Kapha vata hara Pittakara	Deepana
7	Guda	<i>Saccharum officinarum</i>	Madhura	Snigdha	Madhura	Ushna	Vata Pitta hara	Balya, Vrushya Krumikara
8	Yava kshara	<i>Hordeum vulgare</i>	Katu	Rukshna Sara Laghu	Katu	Ushna	Kapha vata hara	Anaha Arshas Asmari

General method of preparation of Phalvarti's

In general there is a common practice to prepare *Madana phala varti* by taking equal quantity of each of eight ingredients as mentioned in the above table. *Bhavana* method, used to be adopted, where a fine powder of the medicinal drugs of the said eight ingredients were mixed together and triturated along with the liquid media mentioned in the preparation. All the prepared *Vartis* were made to dry sufficiently so that a solid form is gained. The prepared *Vartis* were used for therapy purpose in patients suffering from chronic constipation as per the classical indications.

However despite following a standard method of preparation certain difficulties were observed from time to time in the clinical use of rectal suppositories with regards to its size, problems in its insertion, absorption etc.

The preparation of *Guda Varti* is same that of *varti*. Classically two methods are employed here,

Method-1 (Paka method): Jaggery along with water boiled together over a mild fire until *Paka* of 2 to 3 thread consistency. Later the fine powder of medicinal

drugs are added little by little and stirred well to attain a homogenous mixture and desired sized *Varti* are prepared^[20].

Fig 1: Showing preparation of *Phala varti* by *Paka* method



Observation: penetration of *Phala varti* is not possible because of loose consistency. So, we made another attempt to prepare *Phala varti* by *Bhavana* method.

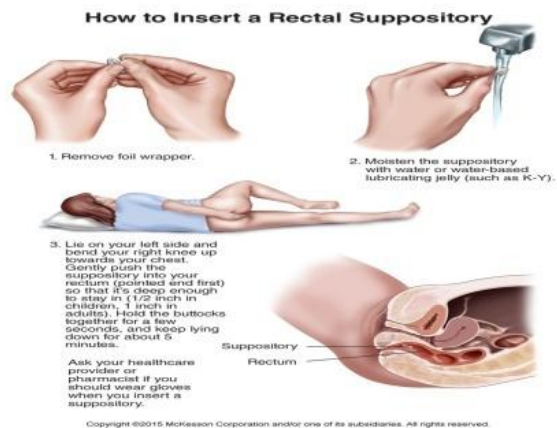
Method-2 (*Bhavana* method): fine powder of the medicinal drugs are mixed together and triturated along with the liquid media mentioned in the preparation. Later desired sized *Varti* are prepared^[21].

Fig 2: Showing preparation of *Phala varti* by *Bhavana* method



Mode of Administration of Ayurveda rectal suppositories

Patient is asked to lie down in left lateral position. The anal verge is applied with ghee and the *Varti* immersed in ghee is slowly administered into the rectum. The patient is allowed to be in supine position until the urge of defecation begins. The drug may kick-start its action within 30 minutes of administration^[22].



Qualities of an Ideal *Phalavarthi* (Rectal suppositories)

1. *Phala varti* should be easily inserted
2. Liquefaction of the *Varthi* should happen at appropriate time
3. Should Melt at Rectal mucosa

Practical difficulties observed in the clinical application of the *Varti* prepared from a standard Textual method.

1. The size and form of the *Varthi* was not uniform as they were prepared manually.
2. Resistance observed in the insertion of the *Varti*, despite the *Vartis* were well lubricated. Either they are too hard or they were breaking and not difficult to insert.
3. There was practically nil or little purgative effect observed in 9 out of ten subjects. All the nine could not get bowel evacuation even after a period of ten hours, which was indicative of ineffectiveness either in the method of preparation.
4. It was observed that the entire *Phala varti* or parts and pieces of it came out in the same form

without getting dissolved in the rectal mucosa as reported by many.

5. So therefore, we approached pharmaceutical department, under their guidance melting point and liquefaction time all are adjusted to that *Phalavarti* gets absorbed and melts at proper time.

Scientific Methodology adopted for the preparation

In order to overcome the above difficulties some changes were made related to ingredients of *Madanaphala varti* with a collaborative study from Modern Pharmaceutics

1. Some base ingredients were added to the standard herbal ingredients.
2. To bring uniform shape to the *Vartis*, standard suppository molds were used.
3. To make a homogenous mixture, sodium stearate was added.
4. A uniform Melting point of the *Varti* has been observed and noted.
5. Solubility, absorption and diffusion studies have been taken up in the following manner.

1: Base ingredients

S.no	Ingredient name	Weight
1	Cocoa butter	7.6g
2	Yellow wax	0.8g
3	Petroleum jelly	0.6g
4	Sodium stearate	0.4g

2: Herbal ingredients

S.no	Ingredient name	Weight
1	<i>Madhanaphala</i>	1.56g
2	<i>Pippali</i>	1.56g
3	<i>Sarshapa</i>	1.56g
4	<i>Kushta</i>	1.56g
5	<i>Vacha</i>	1.56g
6	<i>Yavakshar</i>	1.56g

Procedure adopted for preparation: Following procedure is adopted for the preparation of *Varti*.

Specified quantities of base ingredients were weighed and taken in a glass beaker. The beaker is then placed on a hot plate and allowed to melt. Once all the ingredients were melted the beaker was removed from hot plate and checked for it to reach a temperature of 60°. Simultaneously in a separate dish or beaker all the herbal ingredients were weighed according to the specified quantities and grinded till fine powder is attained then kept aside.

Once the base ingredients reached the required temperature, the mixture of herbal ingredients which was kept aside was now added into the base formulation and mixed until homogenous mixture is obtained. Once homogenous mixture was obtained sodium stearate was added and checked for the required pH.

This mixture was poured into the suppository moulds placed on an ice bath which were previously greased.

Fig 3: Showing pharmaceutical preparation of *Phala varti*

Procedure for evaluation: following evaluation methods have been taken up

1. Standard plot

- Preparation of Stock 1: (1000 µg concentration)
20 mg drug was taken and dissolved in 20 ml acetone.
- Dilutions from stock 1: (100µg concentration)
1ml of stock 1 in 9ml of acetone – 100µg conc.
2ml of stock 1 in 8ml of acetone – 200µg conc.
3ml of stock 1 in 7ml of acetone – 300µg conc.
4ml of stock 1 in 6ml of acetone – 400µg conc.
5ml of stock 1 in 5ml of acetone – 500µg conc.

Spectral scan for stock 1 showed maximum absorbance at 334.7 nm with absorbance of 0.794.

Melting point: - Studied by melting point apparatus. The melting point of prepared suppository was observed as 36°C.

Solubility:- The suppositories are soluble in acetone

Absorption value of dilutions

S.no	Dilution	Concentration	Absorption value
1	1ml of stock 1 in 9ml of acetone	100µg	0.121
2	2ml of stock 1 in 8ml of acetone	200µg	0.207
3	3ml of stock 1 in 7ml of acetone	300µg	0.269
4	4ml of stock 1 in 6ml of acetone	400µg	0.323
5	5ml of stock 1 in 5ml of acetone	500µg	0.435

When standard plot was plotted using the above concentration and absorbance values:

The plot showed $R^2 = 0.983$ and slope = 0.081.

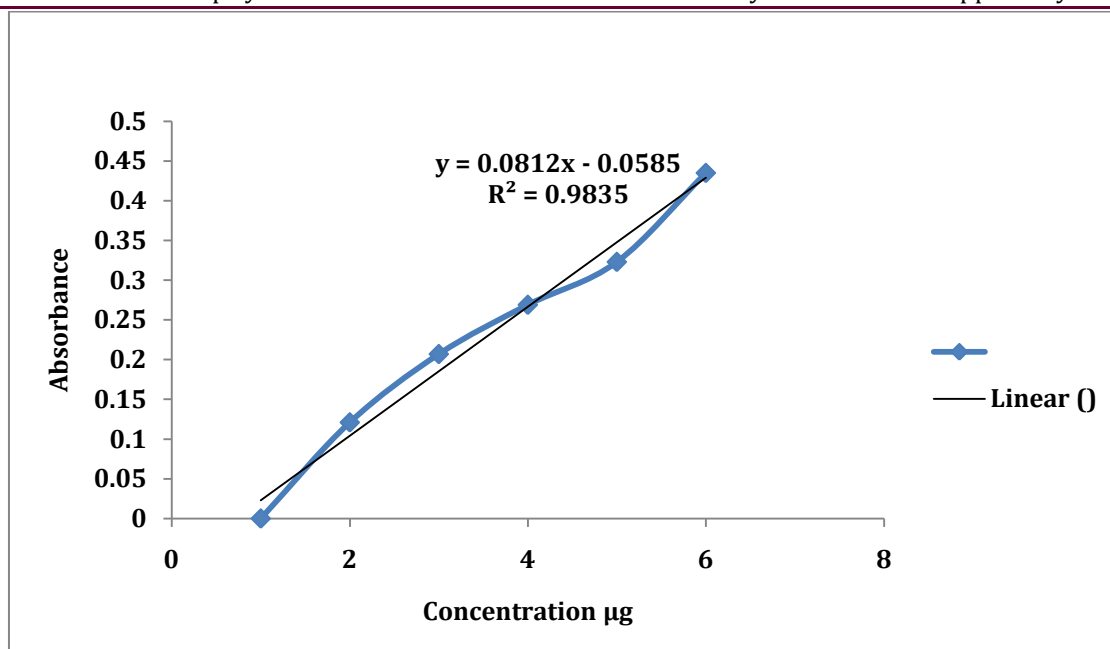


Fig: Standard plot of the *Madanaphalavarti*

2. Diffusion studies:

Dialysis membrane was soaked in pH 7.4 overnight. 7.4 pH phosphate buffer was prepared and kept aside. Diffusions cells were taken and receptor compartment was filled with buffer. The overnight soaked dialysis membrane was placed and checked for diameter. on top of dialysis membrane donor compartment was placed such that it will be intact. The suppository liquid was prepared and poured into the donor compartment. Samples were taken every half an hour for 2 hours.

Preparation of suppository liquid: Take 5ml water and one whole suppository was added then kept for sonication for about 15 mins.

Absorption values

S.no	Sample time	Absorbance	% drug release
1	½ hr	0.030	3 %
2	1 ½ hr	0.578	57.8 %
3	2 hr	0.775	77.5 %
4	2 ½ hr	1.134	113.4 %

MODE OF ACTION:

Rectal suppositories are used to produce local action at the site of application but many of them are used to produce systemic actions. Drug absorption through rectal route is different from that of oral administration. In rectal absorption of drug, portal circulation is bypassed giving an advantage of preventing the biotransformation of drugs in the liver. The lower haemorrhoidal veins surrounding the colon receive the absorbed drugs and initiate its circulation throughout the body bypassing the liver. Lymphatic circulation also assists drug absorption rectally^[23]. The pH of the rectal fluids is 7 to 8 and has no buffering capacity. Thus the form of administered drug is not changed chemically in the rectal environment^[24].

DISCUSSION

The topic of *Varti Kalpana* has been dealt in almost all the Ayurvedic treatises viz. *Charakasamhita*, *Sushruta Samhita*, *Ashtanga hridaya*, *Bhaishajya ratnavali*, *Chakradatta* and *Rasarathnasamucchaya* etc. *Bhaishajyaratnavali* widely contributes different *Guda Varti's* in different diseases like *Udavarta*, *Atisara* and *Arshas*. *Chakradatta* also explains in detail about *Guda Varti* for the treatment of *Shula*, *Arshas* and *Udavarta*. The method of preparation also has been dealt as per the purpose and site of application.

Suppositories are particularly useful when the drug cannot be administered orally, or the drug is likely to get destroyed in the stomach due to the acidity of gastric juices. The lower portion of the rectum affords a large absorption surface area from which the soluble substance can bypass quickly and

reach the venous circulation directly and rapid action of the drug is produced. It also provides neutral pH which is very helpful to maintain the stability of the drugs.

The standard method of *Varthi* preparation has revealed some great practical difficulties which were observed its insertion, liquefaction and there by over all efficacy. Majority of the patients didn't experienced the desired therapeutic effect despite repeated applications. It was observed that the manually prepared *Vartis* were not uniform and they have some roughness which interfered with the overall process of insertion and efficacy. Also there were very few scientific studies done with respect to the melting of the *Varti* at rectal musosa. In order to over come the above difficulties a collaborative study has been taken up with Dept of Pharmaceutics, RBVRR Women's college of pharmacy to eliminate the Procedural inadequacies of *Phalavarthi* by adding some base ingredients like coca butter, petroleum wax, yellow jelly and sodium stearate to the standard herbal ingredients of *Madanaphalavarthi*. Also solubility, diffusion and assimilation studies have been taken up in the present study. From the diffusion studies it was observed that the *Vhalavarthi* was diffused completely in a time period of two hours and thirty minutes. The formulation was showing greater efficacy when administered in few subjects suffering from Constipation.

CONCLUSION

Rectal suppository is an age old concept of Ayurveda, which is popularly known as *Phalavarthi*, has some difficulties at method of preparation, application aspect, which intern affect its overall effectiveness. Therefore some standardization studies are needed to make it more effective. The effectiveness of the rectal suppository depends on hardness (for proper handling and delivery), shape (for comfortable insertion and retention), solubilization of drug in suppository matrix, and a timely melting after application. The diffusion studies conducted for *Madanaphalavarti* in this study have shown timely diffusion after making necessary changes in the base ingredients. This is the first of its kind study on Ayurveda suppositories using recent pharmaceutical techniques. However a thorough clinical study is needed to evaluate the efficacy of the standardized models of *Phalavarti*.

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