



Clinical Research

Evaluation of biophysical parameters of *Amrutapatolaksheeravasti Dravya* and *Karma* - An observational study

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Abstract

The study aims to observe the effects of *Amrutapatolaksheeravasti Dravya* (medicated milk enema) in values of biophysical-chemical parameters. The classical *Vasti* (enema) can be analyzed with the help of biophysical parameters like pH, temperature, and specific gravity (Sp.gr.). Three hundred samples of classically prepared *Amrutapatolaksheeravasti* were analyzed for pH, temp., Sp.gr. with the calibrated instruments before each *Vastikarma*. The clinical symptoms based on proper *Vastikarma* and its complication were recorded and assessed. The parameters – pH, temperature, Sp.gr., and viscosity have shown a significant to highly significant value of correlation coefficient “r” and ‘t’ in relation to successful *Vastikarma* and retention time of *Vasti Dravya* respectively. pH <5.8 and temperature >39°C led to anal irritation in *Ksheera Vasti*. Similarly, pH >6.1 and temperature <32°C resulted in flatulence. The effects of pH and Sp.gr. are due to temperature as both are temperature-based variables.

Key words: Biophysical parameters, standardization, *Vastikarma*

Introduction

Vasti is one of the five special therapeutic procedures (*Panchakarma*) described in Ayurveda medicine. It is similar to conventional enema due to its similarity in procedure and route of administration, but *Vasti* has a wider sphere of action than enema. *Vasti* is considered as the supreme line of treatment by Acharyas. It is said to be a preventive, promotive, and curative therapeutic intervention. In Ayurveda, *Vastikarma* alone is considered as “*Ardhachikitsa*”, i.e., half of the treatment. Due to its long-lasting effects and radical relief from diseases, it is now being considered as an effective treatment globally.

The dosage schedule, procedure patterns, the prepared medicine (*Aushada*) which is one of the four pillars in the practice of medicine are to be standardized so that a uniform system of practice may be developed for treating patients at all centers. Standardization is an important concept for the quality assurance regarding Ayurvedic procedures. Standardization of *Vasti Dravya* can be done on the basis of the following parameters:

1. Biochemical parameters

2. Biophysical parameters.

Biochemical parameters

It is very hard to develop biochemical parameters for Ayurvedic formulations, as they contain large number of drugs with different chemical constituents in different concentrations. Moreover, when medicines are mixed to form an formulation, a number of chemical reactions takes place and lots of new chemical components are generated with different proportion every time.

Biophysical parameters

These parameters have an edge over biochemical parameters for standardizing the Ayurvedic formulation like *Vasti Dravya* because these parameters can be measured within specific limits with minimum variations. Hence, the biophysical parameters available in hand viz., pH temperature, and specific gravity (Sp.gr.) are taken for the analysis of *Vasti Dravya*, which can be applied for all sorts of *Vasti Dravyas*, i.e., *Kashaya*, *Taila*, and *Ksheera*, etc.

This pilot study was undertaken by the P.G. Department of *Panchakarma*, Dr. B.R.K.R Govt. Ayurvedic College, Hyderabad for the standardization of *Vasti Dravya* at random with the help of simple practicable parameters like pH, temperature, and Sp.gr.

pH

It is written in the classical text that when *Vasti Dravya* is sent into the colon, in left lateral position, it may reach the

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Grahani.^[1] The pH of small intestine varies between 7.5 and 8. The pH in the colon varies from 5.5 to 7. It is important to measure the pH of *Vasti Dravya* which is sent into the colon every time because it can alter the pH of gut easily.

The mucosal lining of colon is permeable to the ionized form of a weak acid or weak base. The weakly acidic and basic drugs exist in two forms:

- An unionized component predominantly lipid soluble which is absorbed rapidly
- An ionized and often water-soluble component which is absorbed poorly.

Acidic drugs are rapidly absorbed from the stomach. Basic drugs are not absorbed until they reach the alkaline medium of the small intestine. The alkaline environment in which the major component of the drug exists in an unionized form, facilitates their absorption.^[2]

Chemoreceptor cells in the gut are responsible for the pH regulation and substrate concentration. The pH, viscosity, and enzyme content of the chyme are all optimized for rapid enzymatic breakdown. Once the chyme leaves the initial segment of duodenum, no further adjustment can be done. But if *Vasti Dravya* with desirable pH is sent into the gut, it may create a favorable environment for enzymatic activity in the distal segments of intestine.

Studies *in vitro* and *vivo* have already shown that consumption of carbohydrate substrate and H₂ production by human colonic bacteria are directly related to luminal pH,^[3] which can be easily altered by the pH of *Vasti Dravya* sent into the colon.

It has been observed that low pH of *Vasti Dravya* has some corrosive action on the mucosa, these symptoms are nothing but the complication of *Vasti* like cutting pain in anal region (*Parikartika*), and anal discharge due to inflammation (*Parisrava*) already mentioned in the Charakasamhita.^[4]

Temperature

Temperature is a measure of hotness or coldness. Regarding *Vasti*, some people advocate that the temperature of *Vasti Dravya* should be same as the rectal temperature; some say that it should be 1°C less than the rectal temperature. Rectal temperature is more accurate than the oral or axillary temperature. It averages about 1°F (0.560°C) higher than the oral temperature.

Temperature also plays an important role in absorption of *Vasti Dravyas*. As the temperature increases, the average speed of the molecule in a liquid increases and the amount of the time they spend “in contact” with their neighbor decreases. Thus as temperature increases, the average intermolecular forces decreases, which facilitates the absorption of the concerned molecule.^[5]

Dealing with temperature is like dealing with the fire, as colonic mucosa is very sensitive to the temperature gradient. In the Charakasamhita, it is clearly mentioned that *Vasti Dravya* should not be excessively hot or cold. Excessive hot *Vasti Dravya* causes: Fainting (*Murcha*), burning sensation in anal region (*Daha*), diarrhea (*Atisara*), and increases *Pitta Dosha* in the body. Excessive cold *Vasti Dravya* causes constipation (*Vibandha*) and flatulence (*Adhmana*) increase *Vata Dosha*.^[6,7]

Owing to these probable effects of *Vasti Dravya*, all the safety procedures and precautions were taken. To maintain the safety of the patient, all the material for combating any type of complication of *Vasti* were procured.

Specific gravity (Sp.gr.)

Weight of a substance compared with an equal volume of water is called its Sp.gr. It denotes how tightly particles are packed in a particular volume. The particle size of sparingly soluble drug can affect their absorption. Thus, *Vasti Dravya* that contains large aggregates of active compound does not disintegrate easily, even on prolonged contact with the mucosa of colon, hence it is poorly absorbed. Small size of particle is important for absorption. Thus, the dosage of the active drug can be reduced without losing efficacy, simply by reducing the particle size.

Materials and Methods

Drug

Amruta (Latin name – *Tinospora cordifolia*, Family - *Menispermaceae*).

Patola (Latin name – *Tricosanthem diocius*, Family - *Cucurbitaceae*).

Milk (Standardized homogenized toned milk with 3% fat content).

Distilled water.

Materials and Methods

Procedure given in the Sharangadharasamhita (Ayurvedic text) is taken as authority for the preparation of milk enema (*Ksheera Vasti*). 10 g each of dry stem *Kashaya* powder of *Amruta* and *Patola* were taken and mixed with eight times milk, i.e. 160 ml and 32 times water, i.e. 640 ml (1:8:32). The mixture was heated and reduced to only milk, i.e., 160 ml. The mixture was then filtered using cotton cloth and used as a *Vasti Dravya* in *Ksheera Vasti*. Three hundred samples of *Amrutapatolaksheeravasti* were taken for the study. [Table 1]

Patients

Ten persons of age group 30-45 years with five men and five women were selected for the study. All the selected patients were suffering from *Asthidhatukshaya* (Osteoporosis).

A course of 30 *Vasti* was given to each patient with the gap of 4 days after every 10 *Vasti*. In this way, 300 *Vasti* procedures were recorded. Informed consent was taken from all the patients. Ethical clearance was also obtained from the institutional ethics committee.

Instrument used

A calibrated pH meter (range 0-14), thermometer (0-100°C), lactometer (range 1.000-1.040) were the instruments used in the research work.

Table 1: Preparation of *Ksheera Vasti*

Ingredient	Quantity
<i>Amruta</i> (<i>Tinospora cordifolia</i>)	10 g
<i>Patola</i> (<i>Tricosanthem diocius</i>)	10 g
Milk (homogenized toned milk)	160 ml
Water	640 ml

The readings were taken with the help of these instruments and their effects were assessed on the basis of criteria for the symptoms of proper *Vasti Karma* mentioned in the classical text.

Results and Discussion

pH

The pH of *Amrutapatolaksheeravasti* varied between the range of 5.6 to 6.3. In 84% of the cases, the pH range was 5.8-6.1 which resulted in proper *Vasti Karma*, without causing any discomfort to the patients. In 7.33% of the cases, where pH was below 5.8, i.e., 5.6 or 5.7, anal irritation-like complaints were reported by the patient. This might have happened because of the corrosive action of *Vasti Dravya* in such conditions. In other 8.66% of the cases where the pH was above 6.1, the patients have complaint of flatulence. Although the retention time was maximum in these cases, the symptoms of proper *Vasti Karma* were not seen. This might have happened because of temperature dependence of pH. In all these cases, the temperature was 30°C-31°C which is much below the normal body temperature [Tables 2 and 3 and Figure 1].

Table 2: Relation between pH and retention time

pH	No. of samples	Average retention time (min)	Remarks
5.6-5.7	22	160	Anal irritation*
5.8-5.9	104	300	No complications
6.0-6.1	148	360	No complications
6.2-6.3	26	400	Insufficiency (<i>Ayoga</i>) and flatulence (<i>Adhamana</i>) [†]
Total	300	328	

*Out of 22 procedures with pH 5.6-5.7, 15 times patients have reported anal irritation. [†]Out of 26 procedures with pH 6.2-6.3, 16 times patients have complained of flatulence

Table 3: Statistical significance-pH versus retention time

Statistical test	Observation	Result
r value	0.9586	Highly significant
t value	4.764	Highly significant

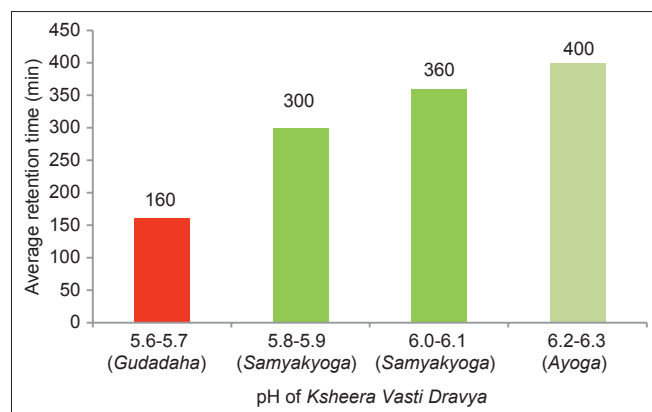


Figure 1: Effect of pH on Vasti retention time

Temperature

Temperature range between 32°C and 37°C resulted in proper *Vasti Karma* with maximum retention time. Temperature above 39°C was not comfortable for the patients regarding procedure point of view as well as in getting proper result of *Vasti Karma*. Increase in temperature above 39°C has a sclerosing action on colonic mucosa which can be the reason of anal irritation in the patients. This also stimulates the sensory nerve endings which results in early evacuation and less retention time [Tables 4 and 5 and Figure 2].

Table 4: Relation between temperature and retention time

Temperature (°C)	No. of samples	Average retention time (min)	Remarks
30-31	32	380	Flatulence*
32-33	18	330	No complication
34-35	24	340	No complication
36-37	140	365	No complication
38-39	48	370	No complication
40-41	18	120	Anal irritation [†]
42-43	16	70	Anal irritation [‡]
Total	300	328	

*Flatulence appeared 16 times out of 32 during which the temperature was 30-31°C. [†]Anal irritation appeared five times out of 18 during which the temperature was 40-41°C. [‡]Anal irritation appeared 10 times out of 16 during which the temperature was 41-42°C

Table 5: Statistical significance temperature versus retention time

Statistical test	Observation	Result
r value	-0.7846 [§]	Highly significant
t value	-2.829 [§]	Significant

[§]Negative value of r and t indicate that temperature is inversely related to retention time, as temperature increases, retention time decreases

Table 6: Relation between specific gravity and retention time

Specific gravity	No. of samples	Average retention time (min)	Remarks
1.015-1.018	26	80	Anal irritation*
1.019-1.022	120	335	No complication
1.023-1.026	130	360	No complication
1.027-1.030	24	388.3	Flatulence [†]
Total	300	328	

*Anal irritation appeared 15 times out of 26 during which the specific gravity was 1.015-1.018. [†]Flatulence appeared 16 times out of 24 during which the specific gravity was 1.015-1.018

Table 7: Statistical significance specific gravity versus retention time

Statistical test	Observation	Result
r value	0.8455	Significant
t value	2.239	Significant

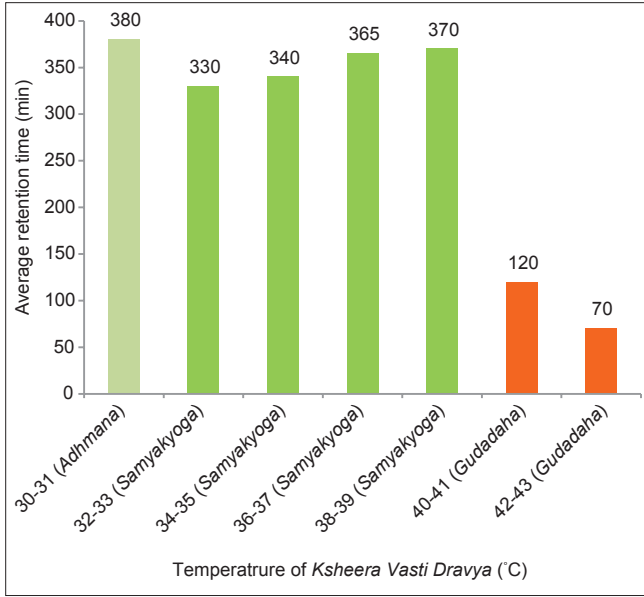


Figure 2: Effect of temperature on Vasti retention time

Specific gravity (Sp.gr.)

Sp.gr. range 1.019-1.026 was proved to be the most appropriate for proper Vasti Karma and maximum retention time. Sp.gr. decreased with the increase in temperature. Sp.gr. below 1.019 is less viscous, velocity with which it comes out is more (velocity of fluid is inversely proportional to the viscosity). Hence, the retention time was less. Similarly, Sp.gr. more than 1.026 resulted in increased retention time and flatulence [Tables 6 and 7 and Figure 3].

Conclusion

All the parameters – pH, temperature, S.g., and viscosity have shown the significant and highly significant value of correlation coefficient “r” and value of “t”. pH <5.8 and temperature >39°C led to anal irritation in Ksheera Vasti. Similarly, pH >6.1 and temperature <32°C resulted in flatulence. The effects of pH and Sp.gr. are due to temperature as both are temperature-based

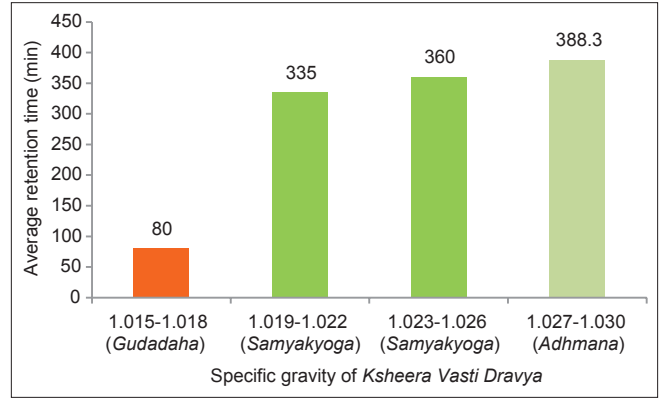


Figure 3: Effect of specific gravity on Vasti retention time

variables. In the present era of evidence-based medicine, there is urgent need for standardization of the classical Panchakarma procedure and it is important to generate such data that will support decisions to use Ayurveda in the mainstream of healthcare.

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हिन्दी सारांश

जैवभौतिकी मापदण्डों पर अमृता-पटोल क्षीरवस्तिद्रव्य एवं कर्म का प्रारम्भिक अध्ययन

संदिप कुमार, एम. श्रीनिवासुलु, वी. क्रिष्णमूर्ति

आयुर्वेद में वस्ति के चमत्कारी प्रभाव के कारण ही इसको अर्धचिकित्सा भी कहा जाता है। इसीलिये वस्ति जैसी आयुर्वेदिक चिकित्सा का मानकीकरण वर्तमान समय की मांग बन गया है। इस अध्ययन में अमृता-पटोल क्षीर वस्ति द्रव्य के 300 नमूनों का भौतिक और रासायनिक गुणों के अनुसार वस्ति के सम्यक् योग, अयोग तथा अतियोग के शास्त्रोक्त लक्षणों के आधार पर निरीक्षण किया गया। प्रत्येक वस्ति देने से पहले वस्ति द्रव्य के पी. एच., तापमान तथा विशिष्ट गुरुत्व का माप लिया गया और यह पाया गया कि इन मानकों की विशिष्ट सीमा में ही वस्ति का सम्यक् योग मिलता है। तापमान के बढ़ने तथा पी.एच. व विशिष्ट गुरुत्व के घटने पर वस्ति के अतियोग के समान लक्षण पाये गये। इसके विपरीत तापमान के घटने तथा पी.एच. व विशिष्ट गुरुत्व के बढ़ने पर वस्ति अयोग के समान लक्षण पाये गये।