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PHYSIO-CHEMICAL STANDARDISATION AND TRANS- RECTAL-MUCOSAL DELIVERY OF VARAHA VASA (PIG'S FAT/ LARD), WITH ITS THERAPEUTICAL EVALUATION IN DEGENERATIVE JOINT DISEASE/SANDHIGATAVATA (DHATUKSHAYAJANYA)

[1]Dr. Niranjan Rao, [2]*Dr. Neeraja Vasudev Pitre

[1]HOD & Vice Principal, Department of Panchakarma, SDM College of Ayurveda, Hospital and Research Centre, Udupi.

[2]Final year PG Scholar - Department of Panchakarma, SDM College of Ayurveda, Hospital and Research Centre, Udupi.

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***Corresponding Author**

Dr. Neeraja Vasudev Pitre

Final year PG Scholar - Department of Panchakarma, SDM College of Ayurveda, Hospital and Research Centre, Udupi.

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ABSTRACT

Pig's fat is the most consumed animal fat worldwide. It is a potential source of Vitamin D3, Oleic acid and other fatty acids. However, its therapeutic utility is still underexplored and hence limits the availability of standardised safety analysis other than for food and cosmetic purposes. The rectal mucosa absorbs Short Chain Fatty Acids (SCFA) and Medium Chain Fatty acids (MCFA) readily by-passing the liver's first pass metabolism. This study emphasizes on effect of the absorption of *Varaha Vasa* (Lard) through *Basti*, apart from rectal mucosal absorption and its clinical utility on the patients of Degenerative Joint Disease/ *Sandhigata Vata*. The standardised physiochemical safety parameters were analysed before conducting the trial. The results show marked improvement in the major symptoms of DJD like pain, stiffness and restricted Range of Motion.

KEYWORDS: Varaha Vasa, Lard, Transrectal route, Basti, Degenerative Joint Disease.

INTRODUCTION

Clinical Context

Degenerative Joint Disease (DJD), clinically synonymous with osteoarthritis (OA), is a chronic, progressive musculoskeletal disorder characterized by progressive articular cartilage degeneration, subchondral bone remodelling, osteophyte formation, and low-grade synovial inflammation, culminating in joint pain, stiffness, and functional impairment.[1] Ayurveda describes a clinically analogous entity as Sandhigata Vata, a Vata-predominant disorder of the *Sandhi* (joints) arising from a state of *Dhatukshaya* (tissue depletion) affecting primarily the *Asthi* (bone) and *Majja* (marrow) *Dhatus*.[2] Its cardinal features — *Sandhi Shoola* (joint pain), *Sandhi Shotha* (swelling), *Atopa* (crepitus), and *Akunchana-Prasarana Vedana* (pain on flexion-extension) — closely parallel to the modern clinical presentation of DJD/OA.

Rationale for Vasa (Animal-Origin Fat)

Among the *Snehana* (oleation) materials[3] described in Ayurveda, fats of animal origin — *Vasa* (fat/adipose tissue) and *Majja* (marrow) — occupy a distinctive therapeutic position in the management of deep-seated, *Dhatukshayajanya* (tissue-depletion-driven) Vata disorders. *Jangama* (animal-derived) *Sneha* possesses greater *Guru* (heavy), *Ushna* (warm), and tissue-penetrating properties than *Sthavara* (plant-derived) oils, rendering it more suited to nourishing deeper tissue planes such as *Asthi* and *Majja Dhatu* — the very tissues implicated in the pathophysiology of Sandhigata Vata. This forms the classical rationale for selecting an animal-fat-based *Basti* (rectal therapeutic enema) over oil-based alternatives in this condition.

Significance of Varaha Vasa

Within the category of animal fats, *Varaha Vasa* (pig/boar fat) is specifically indicated in classical Ayurvedic literature for severe musculoskeletal and neurological deficit states associated with *Vata Prakopa, Balakshaya, Fractures, Asthi – Sandhi Ruja*. *Varaha Vasa* is considered as the best among *Anupa Vasa*.[4] From a modern biochemical standpoint, this classical preference finds partial correlatio: lard (rendered pig fat) is compositionally dominated by oleic acid (~44-47%) and palmitic acid (~25-28%), with a comparatively modest linoleic acid fraction (~6-10%).[5] This is notable because in vitro cartilage-explant studies have demonstrated that oleic acid and palmitic acid counteract inflammatory cytokine-induced upregulation of cartilage-degrading enzymes (e.g., MMP-1) and reduce glycosaminoglycan loss, whereas the n-6 polyunsaturated linoleic acid does not share this protective effect and may, in some models, promote cartilage inflammation.[6,7] This fatty-

acid profile offers a plausible modern biochemical rationale for why *Varaha Vasa* specifically — rather than fats with a different fatty-acid signature — may be therapeutically favourable in a degenerative-inflammatory joint condition such as DJD.

The Need for Prior Analytical Standardization

Unlike plant-derived oils, animal-origin *Sneha* such as *Vasa* are biologically heterogeneous materials whose composition varies with the source animal's age, diet, and rendering process, and which are inherently susceptible to lipid oxidation (rancidity), moisture, and microbial contamination during storage. Administered rectally, such a substance also enters direct contact with a highly vascular and absorptive mucosal surface: the rectal mucosa is characterized by relatively low enzymatic activity and a dual venous drainage in which the inferior and middle rectal veins bypass hepatic first-pass metabolism, allowing lipophilic substances absorbed here — including via the intestinal/rectal lymphatic route — to reach the systemic circulation with reduced pre-systemic degradation.[8,9] This absorptive efficiency, while therapeutically desirable, simultaneously raises the safety stakes of administering an unstandardized, potentially rancid or microbially contaminated lipid substrate. It was therefore considered a mandatory prerequisite to first undertake a rigorous physicochemical and analytical standardization of *Varaha Vasa* — establishing parameters such as melting point, iodine value, saponification value, peroxide value, and free fatty acid content — to define its shelf-life, confirm the absence of rancidity, and guarantee patient safety, before proceeding to its clinical administration as *Basti*.

AIMS AND OBJECTIVES

AIM

The present study was conducted with the broad aim of scientifically validating the *Varaha Vasa*, administered per rectum as *Basti* in the management of *Sandhigata Vata* (Degenerative Joint Disease), through an integrated pharmaceutical-standardization and clinical-evaluation approach.

OBJECTIVES

1. To Establish the physicochemical and safety profile of purified *Varaha Vasa* — comprising:

- Organoleptic evaluation (colour, odour, consistency) of the purified (*Shodhita*) *Vasa*.

- Determination of physicochemical constants — specific gravity, refractive index, melting point, acid value, saponification value, iodine value, and peroxide value — to characterize the fat's identity, purity, and degree of unsaturation.
- Assessment of rancidity/oxidative stability markers and free fatty acid content, to establish permissible storage limits.
- Microbial load and heavy-metal contamination screening, to confirm compliance with pharmaceutical safety limits prior to clinical use.
- Accelerated/real-time stability testing to define a validated shelf-life for the standardized preparation.

2. To evaluate the clinical efficacy of *Varaha Vasa* administered as *Basti* in the management of Degenerative Joint Disease (*Dhatukshayajanya Sandhigata Vata*) — comprising

- Assessment of change in joint pain, stiffness, and swelling using validated subjective outcome measures (Visual Analogue Scale, Verbal Rating Scale).
- Assessment of change in joint function using objective measures — Range of Motion (ROM) and standardized functional indices (AIMS/AIMS-2).
- Statistical comparison of pre- and post-interventional data to determine the significance of clinical improvement following *Basti* administration.

MATERIALS AND METHODS

Phase I: Pharmaceutical and Analytical Study

Drug Procurement and Processing

Fresh *Varaha Vasa* (pig adipose tissue) was procured from an ethically operating, government-licensed abattoir. The raw fat was subjected to purificatory processing including cleaning of extraneous connective tissue and blood, followed by boiling to separate and clarify the lipid fraction while eliminating proteinaceous and odour-bearing impurities. All processing was carried out under controlled temperature and time parameters, and the finished *Sneha* was stored in an amber-glass, airtight container under refrigeration until analysis and clinical use.

Physicochemical Parameters

The purified and processed *Varaha Vasa* was subjected to standard pharmacopeial physicochemical evaluation

- **Organoleptic properties**: Colour, odour, appearance (clarity/turbidity), and touch (consistency/texture) were assessed by standard sensory evaluation.

- **Acid Value and Peroxide Value**: Determined by standard titrimetric methods (AOAC/Ayurvedic Pharmacopoeia of India protocols) to quantify free fatty acid content and primary oxidation products respectively — these two parameters served as the principal chemical indicators of rancidity, and were used to establish the shelf-life and storage-stability profile of the finished preparation.

- **Saponification Value and Iodine Value**: Determined by standard titrimetric methods to estimate, respectively, the mean molecular weight/chain length of the constituent fatty acids and the degree of unsaturation (total unsaturated fatty acid content) of the fat.

- **Refractive Index and Specific Gravity**: Measured using an Abbe refractometer and pycnometer/specific-gravity bottle respectively, to provide standard baseline physical constants for batch-to-batch identification and quality control.

These standardization and safety parameters were treated as the mandatory preclinical gateway that the test drug had to satisfy before proceeding to Phase II.

Phase II: Clinical Study

Study Design

An open-label, prospective, interventional clinical trial (single-arm, pre-post comparative design) was conducted to evaluate the therapeutic efficacy of standardized *Varaha Vasa Basti* in Degenerative Joint Disease (*Sandhigata Vata*).

Sample Size

Thirty patients clinically and radiographically diagnosed with DJD (knee and/or hip osteoarthritis) were enrolled, following informed and written consent and institutional ethics committee clearance.

Inclusion and Exclusion Criteria

Inclusion criteria comprised patients within a defined age group 50–70 years, fulifilling the diagnostic criteria for DJD/ *Sandhigata Vata* and those who are fit to undergo Sneha, correlated with radiographic evidence of DJD of either sex, willing to comply with the study protocol and follow-up schedule.

Exclusion criteria comprised patients who are pregnant or lactating, having other systemic metabolic disorders (eg. uncontrolled diabetes mellitus, thyroid dysfunction) which interfere with the treatment and patients below 50 years of age.

Intervention

Patients received *Varaha Vasa* administered as *Matra Basti* at a dose of 30 ml per day, administered once daily in the post-prandial period, for a duration of 8 days under continuous clinical monitoring. Patients were advised a *Vata-pacifying* diet and lifestyle regimen (avoidance of cold, dry, and *Vata*-aggravating foods) for the duration of the intervention and follow-up period, and were assessed at baseline and at completion of the intervention.

Assessment Criteria

Therapeutic outcome was evaluated using a combination of validated subjective and objective parameters, recorded at baseline and post-intervention:

- **Visual Analogue Scale (VAS) and Verbal Rating Scale (VRS)** — for the intensity of joint pain.
- **Range of Motion (ROM)**, measured using a goniometer, for objective assessment of joint mobility.
- **Assessment of *Sandhishopha (swelling)***, graded on a standardized ordinal scale.
- **Arthritis Impact Measurement Scale (AIMS / AIMS-2)** – to record the morbidity of the disease.

Data were tabulated and subjected to appropriate statistical analysis (paired *t*-test/Wilcoxon Signed-Rank Test) to determine the significance of pre- to post-interventional change.

RESULTS

Analytical Results

The physicochemical and safety evaluation of purified *Varaha Vasa* is summarized in Table 1.

Table 1: Physicochemical and Safety Profile of Purified Varaha Vasa.

Parameter	Observed Value	Inference
Acid Value	4.12	*Not rancid*
Peroxide Value	0.0	*Fat is in unoxidized state*
Saponification Value	201.53	Suggests purity
Iodine Value	1.04	Predominantly Saturated fatty acids

Refractive Index	1.45757	Suggests purity
Specific Gravity	0.9657	*[Batch identity]*
Moisture content	0.1	Low moisture content
Melting Point	28 ^{0}C	-
pH	5.0	*Slightly acidic*
Unsaponifiable matter (% w/w)	0.1	*Negligible impurities*
Rancidity test	Fat is not oxidised	-

The observed acid value of *4.12* and peroxide value of *0.0*, both well within the permissible pharmacopeial limit of animal fats, confirm the absence of significant lipid rancidity in the processed preparation, validating its chemical stability and establishing a good shelf-life. The saponification and iodine values were consistent with the expected fatty-acid profile of lard (oleic- and palmitic-acid dominant), and absence of detectable contaminants by 0.1 % W/W of Unsaponifiable matter confirmed the preparation's suitability for enteral/rectal mucosal administration, thereby validating the decision to proceed to the Phase II clinical trial.

Clinical Results

Pre- and Post-Interventional Statistical Data

Table 2 presents the pre-test (BT, Before Treatment) and post-test (AT, After Treatment) statistical comparison across all assessed clinical parameters.

Table 2: Pre- and Post-Interventional Comparison of Clinical Parameters (n=30).

Parameter	BT Mean	AT Mean	AT SD	SE	t-value	p-value
VAS (Pain)	8.633	5.167	0.798	0.146	23.79	<0.001
VRS (Pain)	2.833	1.700	0.507	0.093	12.23	<0.001
AIMS	8.433	*5.117*	0.914	*0.167*	*19.87*	*<0.001*

A statistically significant reduction/improvement was observed across assessed parameters following *Varaha Vasa Basti* administration, indicating a favourable therapeutic response in the management of *Dhatukshayajanya Sandhigata Vata.*

Safety Profile

No adverse drug reactions (ADRs), local mucosal irritation, or bowel irritability were reported by any patient during or following *Basti* administration throughout the study period, corroborating the analytical safety findings from Phase I and supporting the overall tolerability of standardized *Varaha Vasa* when administered per rectum.

DISCUSSION

Significance of the Analytical Data

The physicochemical profile of *Varaha Vasa* offers a biochemically coherent explanation for its classical indication in joint disorders. Native synovial joint lubrication is now understood to depend substantially on **surface-active phospholipids (SAPL)**, a lipid fraction of the glycoprotein lubricin (itself ~11% phospholipid, of which ~41% is phosphatidylcholine), which coats the cartilage surface and provides low-friction boundary lubrication under load.[10,11] Notably, the phosphatidylcholine and phosphatidylethanolamine species that constitute this native lubricating layer characteristically carry a monounsaturated oleic-acid (18:1) acyl chain — the same fatty acid that predominates in lard. Osteoarthritic joints have been shown to exhibit a measurable SAPL deficiency, and exogenous administration of a surface-active phospholipid (DPPC) has been reported to improve mobility in OA patients for periods of up to 14 weeks, without major adverse effects.[12,13] This body of tribological evidence supports the biological plausibility that an oleic-acid-rich lipid substrate such as *Varaha Vasa*, once systemically absorbed, could contribute lipid precursors relevant to boundary-lubricant synthesis and cartilage-surface maintenance, in addition to the previously discussed anti-catabolic effects of oleic and palmitic acid on chondrocyte MMP-1 expression and glycosaminoglycan retention.

Pharmacodynamics of *Basti*

The selection of the rectal route for *Varaha Vasa* administration is grounded in both classical and modern physiological reasoning. Ayurveda identifies *Pakwashaya* (the colon/rectum) as the principal seat (*Sthana*) of *Vata Dosha*, making it the most direct anatomical site for pacifying deranged *Vata*. This classical rationale finds a parallel in contemporary rectal pharmacokinetics: the rectal mucosa presents a relatively low-enzymatic-activity absorptive surface with a dual venous drainage, in which the middle and inferior rectal veins bypass hepatic first-pass metabolism.[14] For a lipophilic substance such as *Varaha Vasa*, absorbed lipid constituents are additionally taken up via the intestinal/rectal lymphatic route as chylomicrons, a pathway that further circumvents pre-systemic hepatic degradation.[15]

Together, this provides a translational rationale for why *Basti* achieves a systemic therapeutic effect and why the lipid-soluble constituents of *Varaha Vasa* are plausibly delivered to systemic tissue with greater bioavailability than an equivalent oral dose might achieve after hepatic first-pass processing.

Mechanism of Action

Basti alone is considered Ardha Chikitsa (half of all therapeutic measures) for Vata disorders, and Vasa among the Snehas is especially indicated for Sandhi Ruja, Asthi Ruja, and Dhatukshaya — making Vasa Matra Basti a pharmacologically precise and classically grounded intervention for Dhatuk shayajanya Sandhi gatavata.

It can be understood through *Guna-Vaishamya-Chikitsa*. Aggravated *Vata*, and consequently the *Sandhigata Vata* disease state, is characterized by an excess of *Ruksha* (dryness) and *Laghu* (lightness) guna, manifesting clinically as cartilage/synovial depletion, joint-space narrowing, and crepitus. *Varaha Vasa*, possesses *Snigdha* (unctuous), *Guru* (heavy), and *Ushna* (warm/hot) properties that are directly *Vata*-antagonistic (*Vata-hara*) to this *Ruksha-Laghu* pathology. Administered as *Basti*, these qualities are held to exert a *Brimhana* (nourishing/bulk-restoring) effect specifically on the depleted *Asthi* and *Majja Dhatu*, thereby restoring the unctuousness and cushioning of the degenerated joint space.

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