



“PROCEDURAL REQUIREMENTS AND IMPORTANCE OF STANDARDIZATION OF PANCHAKARMA THERAPY”

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Abstract:

Purpose: The present study aimed to highlighting key-aspects of procedural requirements and importance of standardization of *Panchakarma* therapy. **Methods:** *Panchakarma* is an important therapeutic approach of Ayurveda, it act as preventive measure and resist disease. Improper use of *Panchakarma* therapy may results hazardous effects therefore Ayurveda recommended various parameters to be followed during *Panchakarma*. These parameters should be standardized to achieve maximum benefits without any adverse effects of therapy. As per Ayurveda standardization is very essential to prevent *Atiyoga*, *Ayoga* and to get optimum effects in a systematic manner of predetermined protocol. The development of medical science seeks standardization of traditional therapeutic approaches to establish uniformity of procedural practice. **Result:** The standardization of *Panchakarma* considered dosage schedule, procedural protocol, dose of medicaments and assessment of effects of therapy, etc. All the procedures of *Panchakarma* should be performed by the same person till the clinical trial. The medicine used for standardization setup should not be change during the trial period. Protocol should be designed by field experts. Fixation of dose, duration and *Anupana* uniformly is required. Standardization of *Purva karma*, Standardization of *Pradhan karma* and Standardization of *Pashat Karma* need to be performed stage wise to acquire maximum health benefits of therapy.

Conclusion: Standardization of *Panchakarma* offer effective and safe procedural protocol. The Standardization of *Panchakarma* after clinical study may be considered as standard for further utilization and uniform application.

Key-Words: *Ayurveda, Panchakarma, Standardization, Parameters, Protocol*

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Introduction:

Ayurveda is the traditional medical system of India and, according to the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health, is understudied in Western contexts¹. Although there are numerous pilot studies that indicate the effectiveness of *Ayurveda* in the treatment of specific diseases^{2,3}, this is the first published scientific study of the *Ayurvedic* treatment of *Panchakarma* in a Western country. *Panchakarma* is believed to help cleanse the body of impurities that can lead to disease.

Ayurveda is a holistic, comprehensive medical system. In order to effectively study complex, multidimensional, or traditional medical systems, research must first begin with descriptive or observational studies. Without such work, even the best science can yield confusing results^{4,5,6}. Initial descriptive work can clarify the theoretical frameworks and elementary constructs that need to be understood in order to formulate controlled studies. Only after such descriptive work and using the observations gathered there can we proceed to observational studies and, if warranted, to controlled clinical trials.

Panchakarma, a complex and integral part of *Ayurvedic* treatment and has a role in each therapeutic condition. Thanks to its long-term and radical relief from chronic diseases, it is now developing globally. If *Panchakarma* therapy is not used in the right dose, in the recommended indications and in a suitable environment, it can lead to dangerous effects like bleeding, organ prolapse, shock, etc. To avoid these effects, scientists have advocated many subjective parameters and few objective parameters. However, they need to be standardized for effective application in current practice.

During the post-independence era, no attempts were made to revive the practice of *Panchakarma* at the institutional level. Very few centers have established clinical units for *Panchakarma*

practice. Gujarat Ayurveda University, Jamnagar, Gujarat, India is one of the centers where classical *Panchakarma* therapy is performed. *Panchakarma* therapy should be done only by a specialist to ensure better therapeutic efficacy and to avoid complications. Here is the urgent need to standardize the classical *Panchakarma* procedure keeping in view the needs of today. The dosing schedule, precise procedures, drugs, effects and side effects need to be standardized so that a uniform practice procedure can be developed to be practiced in all centers. According to the Oxford dictionary, the verb "to standardize" means to average, equalize, homogenize, systematize, or conform to a "standard", where the noun "standard" represents a meaning such as degree, measurement, model, pattern, mean, mean, level, or norm".

Need for standardization:

Doctors can be divided into two categories i.e. *Vikalpavid* and *Avikalpavid*. *Vikalpavid* is one who is able to judge *Agni* (bio-fire), *Koshtha* (intestinal nature) and weigh all the variations, determine the dose and duration. But on the contrary, *Avikalpavid* is not capable of this. Standardization is the need of the hour for second-category practitioners to avoid *Atiyoga* (excessive activity), *Yoga* (less or no activity) and to achieve adequate effects in a systematic and sophisticated manner in the required period of time.

Limitations for standardization:

- Standardization becomes difficult due to the following factors:
- *Dosha*, *Dhatu* and mala are unstable due to daily variations, seasonal variations etc.
- Differences in the effect of therapy due to different *Agni*, *Koshtha*, *Prakriti*, *Desha*, *Kala*, *Bala*, *Vaya* etc.
- Reference normalization in the classics.
- Many references are available in the classic *Madanaphala* dose - *Antarnakhamushthi Pramana* (measurement of a straight clenched fist) of a patient undergoing *Vamana*².
- The dose of *Snehana* described by *Vangasena*³
- Dose of *Vamana Dravya*⁴
- Dose of *Niruha Basti* according to age⁵

General instructions

- All *Panchakarma* procedures should be performed by the same therapist/physician until the clinical trial is complete.

- The medicine used in the study for the participants should not be changed.
- Participants who belong to the same region should be considered for the clinical trial.
- *Shodhana Karma* (bio-purification therapy) should be done in the appropriate season. eg – vomiting (*Vamana*) in *Vasant Ritu* (spring season).

Protocol for standardization of *Panchakarma* procedures:

Standardization steps⁶

Literature review

- Drafting of the protocol by an expert team consisting of an *Ayurvedic* researcher, a clinical pharmacologist and a biostatistician.
- Selection of participants/patients - *Madhyama Kosta/ Madhyama Agni/ Madhyama Bala/ Madhyama Vaya*.
- Dose, duration and *Anupana* should be fixed.
- Pilot study on at least 20-50 healthy volunteers.
- Phase 1 and Phase 2 clinical trials – Specific area of the procedure in different geographies of India and abroad – In different population (gender, age, race, constitution, *Dhatu* nature etc.)
- Phase 3: multicenter clinical trial.

Methodology:⁷

Preoperative procedure:

1. Required materials with quantities and specifications.
2. Therapist's request.
3. Medicines needed for therapy - number, quantity.
4. Taking the right medicines
5. In case of unavailability of genuine drugs, the best possible alternatives should be used.
6. Formulation/method of drug preparation.
7. Selection of medicines on the basis of biohumors, tissues, constitution, bio-fire, nature of intestines.
8. For the external treatment process, the oil temperature, the amount of oil used,
9. Oil change frequency.

Operating procedure:

1. Standard operating procedure of *Panchakarma* therapy

2. Appropriate time
3. Frequency of therapy
4. Duration of proceedings
5. Course of therapy

Postoperative procedure:

1. Rest period
2. Medicinal or non-medicinal baths
3. Eating - quantity, quality, frequency
4. Dietary restrictions and behavioral restrictions



Figure 1: Panchakarma dosing which may considered for standardization.

Example :

Standardization of Bindu for Nasya karma

Nasya is one of the important practices of *Panchakarma* which involves the administration of medicines through the nostril. Dose fixation is an important factor in all *Panchakarma* procedures to achieve optimum efficacy and also to prevent possible side effects due to

overdosage. Similarly, *Nasya* also requires fixation of dose and *Bindu* is the unit of measurement used for dosing in *Nasya*. Single unite *Bindu* resembles one drop (0.05 ml); however, single unite *Bindu* as 01 Shana is also mentioned, which is more than the commonly practiced dose. A clinical study standardizes the classical concept of *Bindu* for *Nasya*. The study presented a standardization of the single *Bindu* dose measurement process. Clinical examination included application of *Tila Taila* fixed drops from *Anguli* and dropper. The study observed variations in literature methods and commonly prescribed methods for dosing *Nasya*. The traditional method of *Bindu* offers to administer a larger amount for *Nasya* as compared to the modern method. The method of standardization recommended that the drops counted from the dropper administered with the wrong amount of medicine for *Nasya* and should consider *Ayoga* for *Nasya Karma* and it can only offer the effect of *Dosha Utkleshana* but get rid of the effect of *Dosha Nirharana*. However, Acharya Charaka recommended the exact amount for *Nasya* which is half a *Pala*⁸⁻¹⁰. Standardization of two methods for *Nasya*; The results of the dropper and *Bindu* methods are as follows

- *Bindu* is not equivalent to one drop.
- The commonly practiced dose is smaller than the recommended classical dose.
- Study the recommended use of *Bindu* for *Nasya* and the measurement of *Bindu* in milliliters.
- The ancient recommended amount for *Nasya* which is half a *Pala* can also be followed.

Scope of *Panchakarma* Clinic:

Panchakarma Clinic is an independent outpatient healthcare organization that provides. *Panchakarma* treatment services (consultation, medicines and procedures) provided by Vaidya registered with the State Council/Council of Practitioners of AYUSH systems.

Panchakarma Clinic includes the following types of facilities:

S. No.	Health care facility	Definition
1	Consultation	The action or process of formally consulting or discussing.
2	Ayurveda Pharmacy	Medicines from the Ayurvedic Pharmacopeia
3	<i>Panchakarma</i> Procedure	<i>Panchakarma</i> (" <i>Pancha</i> " means five and " <i>Karma</i> " means treatment) is done to detoxify the body according to Ayurveda. These procedures are claimed

		to eliminate the vitiated <i>Doshas</i> from the body.
4	Post procedure Observation	<i>Panchakarma</i> procedures requires Post procedure observation. If this observation period extends and requires overnight stay, then patient need to be transfer to Ayurveda hospital.

A *Panchakarma* clinic should provide such services that do not require an overnight stay either for the procedure or for observation. Leaving the clinic after treatment should not cause any harm to the individual. It may be noted that the standards for accreditation of an Ayurvedic hospital include services related to *Panchakarma* procedures that require an overnight stay under medical supervision.

Conclusion:

Standardization is not a new topic in Ayurveda, although the references are from BC, but the researchers came to the conclusion only after repeated clinical evaluation. Standardization is essential to perform effective and safe *Panchakarma*. Data obtained after a phase 3 clinical trial can be considered standard. Standards of practice should only be applied to the geographic area where the clinical trial is conducted. The above standard operator Guidelines for Procedures (SOPs) can be adopted for all standardization of *Panchakarma* therapy.

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