



## DEVELOPMENT AND VALIDATION OF A TOOL TO ASSESS THE SAMYAK SNIGDHA LAKSANA USING THE PRINCIPLES OF PSYCHOMETRICS IN AYURVEDA

### AUTHORS

1. DR. KADAMBARI P B

MD (AYU), ASSISTANT PROFESSOR, DEPARTMENT OF PANCHAKARMA,  
AMRITA SCHOOL OF AYURVEDA, AMRITAPURI; AMRITA VISHWA  
VIDYAPEETHAM, INDIA [kadambaripb@gmail.com](mailto:kadambaripb@gmail.com)

2. DR. PRATHIBHA C K

M.D (AYU) Ph. D, PROFESSOR, DEPARTMENT OF PANCHAKARMA, GS  
AYURVEDA MEDICAL COLLEGE, PHILKHUWA, UTTAR PRADESH, INDIA  
[drprathibhack@gmail.com](mailto:drprathibhack@gmail.com)

3. DR. VIJAYAPRASAD GOPICHANDRAN MD, Ph. D, ASSISTANT PROFESSOR,  
DEPARTMENT OF COMMUNITY MEDICINE, ESIC MEDICAL COLLEGE & PGIMSR,  
KK NAGAR, CHENNAI, TAMIL NADU, INDIA [vijay.gopichandran@gmail.com](mailto:vijay.gopichandran@gmail.com)

4. Dr. ANANDARAMAN P V

M.D (AYU) Ph.D., PROFESSOR, DEPARTMENT OF PANCHAKARMA, ALL INDIA  
INSTITUTE OF AYURVEDA (A.I.I.A), GAUTAMPURI, SARITA VIHAR, NEW DELHI,  
INDIA [dr.ananthramsharma@gmail.com](mailto:dr.ananthramsharma@gmail.com)

### ABSTRACT

#### Background

To attain the complete benefits in doing a panchakarma procedure, proper purvakarma is essential. Here, the study is on snehapana, the oral administration of plain ghee. In the present study, we are intending to develop an assessment tool for assessing samyak snigdha lakshana. The tool will be validated, and grades will be included based on level of snigdhatata attained.

#### Methods

Stage 1- face validation

The samyak snigdhatata mentioned in ayurvedic texts are reviewed, drafted a model and graded as avara, madhyama, and pravara

Stage 2 - content validation

lakshana was assessed in 60 subjects with the developed model.

Stage 3 – construct validation

Appropriate statistical methods to find the significance.

#### Result

The finalized model was prepared with 9 lakṣaṇa. After analyzing the observed values, we were able to fix an end point to calculate the samyak snigdha lakṣaṇa. The lowest score is made as 6 and the highest score 18. The score between 6-18, was grouped into 3 categories and provided with a reference range and avara snigdhatata as 6 – 8, madhyama snigdhatata as 9 – 13, and pravara snigdhatata as 14 – 18.

## Conclusion

Among the various lakṣaṇa mentioned under samyak snigdha lakṣaṇa by different texts vātānulomana, agni dīpti, snigdha varcha, asamhata varcha, aṅga snigdha and klama plays the deciding role of snigdha. Based on the observed values, it is possible to assess the samyak snigdha lakṣaṇa and the level of snigdha. Using the principles of psychometrics, samyak snigdha lakshana tool developed and validated.

## INTRODUCTION

Panchakarma is a unique and holistic set of therapeutic procedures which are performed depending upon the condition of the person and status of the disease. The Panchakarma procedures are the Vamana, Virecana, Basti, Nasya, Raktamokṣaṇa. To attain the complete benefits of doing a Panchakarma procedure, proper Purvakarma is cardinal. The Purvakarma includes Pacana, Dipana, Snehana, and Swedana. The term Snehana has vast implications in Panchakarma and can be done either externally or internally in different methods.

Sneha is the essence of an individual and his life<sup>1</sup>. Snehana has a cardinal role in Ayurveda treatments in both preventive and curative aspects. It is broadly divided into Bahya Snehana and Abyantara Snehana<sup>2</sup>. Snehapana comes under Abhyantara Snehana and is the internal administration of Sneha dravya. Snehapana is the foremost treatment to be done prior toshoḍana and is one among purvakarma and plays a vital role in the process of shodana karma. The snehapana done prior to shodana procedure for the utkleṣaṇa of the dosha is called as shodanaṅga snehapana. Shodananga snehapana is done in the arohaṇa krama which means the sneha dravya is administered in the multiplying course to avoid the acclimatization of the subject towards the sneha dravya.

Here, the study is on Shodananga Snehapana, the oral administration of sneha dravya in the gradual increase of the dose pattern and to develop and validate a scale to assess the Samyak Snigdha Lakshana. The validation and development process is done step by step with the help of the principles of Psychometrics.

## SAMYAK SNIGDHA LAKSANA

The following table shows the samyak snigdha lakshana mentioned in different texts.

Table 1: samyak snigdha lakshana enlisted.

Vatanulomana	Mrudu gatrata	Twak shaithilya
Agni dipti	Glani	Viṭ shaithilya
Snigdha varcha	Anga laaghava	Snigdhaṅgata
Asamhata varcha	Snehadarshana	Susnigdha
Snehodvega	Vimalendriyatha	Mala pravartanam
Klama	Gṛita vidhwesha	Mardavangata

## PSYCHOMETRICS

Psychometrics<sup>3</sup> developed as a means for measuring psychological abilities and attributes, usually via a standardized psychological test.

## Validation

Validity<sup>4</sup> is the equality or state of being valid, where this can mean anything from being true to, being cogent to being legally accepted. Validity<sup>5</sup> refers to the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure.

### **Reliability**

Reliability<sup>6</sup> is the extent to which an experiment, test, or any measuring procedure yields the same result on repeated trials. Reliability is such an important concept that it has been defined in terms of its application to a wide range of activities.

### **Cronbach's alpha**

Cronbach's alpha is one of the most commonly used indices of the reliability of a scale. Cronbach's Alpha will tell us how closely related a set of items are as a group.

### **AIM AND OBJECTIVES**

- To develop a tool for the assessment of samyak snigdha lakshana
- To validate the developed samyak snigdha lakshana tool and clinically validate the assessment tool.

### **MATERIALS AND METHODS**

- The institutional ethical committee meeting was held on 08-10-2016 at Amrita Institute of Medical Sciences. Institutional ethical clearance number: IEC-AIMS-2016-AYUR-123
- The clinical trial was registered under CTRI- CTRI/2017/05/008538.

### **STAGE 1**

#### **FACE VALIDATION**

Face validation is the first process in developing a scale. Conceptualization of the theory is the first step in scale development. Sometimes a thorough literature review is helpful in identifying the theory. A thorough literature review on Samyak snigdha lakshana was done.

#### **STEP 1**

A model of the samyak snigdha lakshana was drafted to assess the samyak snigdha lakshana in the subjects for conducting the content validation. The samyak snigdha lakshana was tabulated from the different texts and a generalized assessment sheet was drafted comprising of 9 samyak snigdha lakshana. A minimum of 10 subjects was required to assess a lakshana. Since we had 9 lakshana, 90 subjects were required for developing a tool in this study. Lakshana can be classified under the physical and psychological domains. Physical domains includes vatanulomana, agni dipti, snigdha varcha, asamhata varcha, anga snigdha and klama whereas the psychological domains include snehodvega, anga laghuta and anga mardavata

#### **STEP 2**

The lakshana was validated by the internal experts of Amrita School of Ayurveda. The Likert scale pattern was used in the drafted model as Likert rating scale is more powerful in evaluating the traits of the subjects during the days of snehapana and it was graded as proper-0, moderate-1, and mild-2.

### **STAGE 2**

#### **CONTENT VALIDATION**

Content validity is an important research methodology term that refers to how well a test measures the behavior for which it is intended. As a final stage, the questionnaire was corrected and validated by the internal experts of department of Panchakarma. Thereafter, the cases of Snehapana were recorded from the IPD of Amrita Ayurveda hospital satisfying inclusion and exclusion criteria. While doing the study, we could notice that the all the 9 lakshana were not observable in the subjects. Thus, we gave importance to 6 lakshana and

they were Vatanuloma, Agni dipti, Snigdha varcha, Asamhata varcha, Aṅga snigdha, Klama. Thus, to assess these 6 relevant lakshana 60 subjects was required. The subjects who attained Saṃyak Snigdha by 5 days were record and similar 60 cases were recorded for the study. Usually, the saṃyak snigdha will be attained in between the days of 4- 7 and in most of the cases within 5 days. For convenience and proper calculation, the cases of snehapana who attained the saṃyak snigdha within 5 days was documented.

### STAGE 3

#### CONSTRUCT VALIDATION

Construct Validation- Construct validity is the degree to which a test measures what it claims, or purports, to be measuring. This includes factor analysis, reliability statistics, and internal consistency. With the obtained data construct validation was done. Exploratory Factor analysis was done to identify the contribution of each lakshana to the overall diagnosis of cure. The scores on each lakshana were considered on Day 5 of the treatment and entered the EFA model. Exploratory factor analysis (EFA) is a statistical method used to uncover the underlying structure of a relatively large set of variables in multivariate statistics.

#### STAGE II- Clinical Assessment

The developed tool was clinically assessed in 20 healthy volunteers from the IPD of Amrita Ayurveda Hospital satisfying the inclusion and exclusion criteria.

##### The inclusion criteria

- Age group – 15-50
- Snehapana Arha and Virecana Arha as per Ayurveda Texts
- Apparently Healthy without any illness in the past 6 months, without any medication
- Madhyama Koshṭha

##### The exclusion criteria

- Snehapana Anarha and Virecana Anarha as per Ayurveda Text

##### Phase 1-

In 20 healthy volunteers snehapana was done with murcchita ghr̥ta till smyak snigdha

##### Phase 2-

After snehapana, Abyanga with murcchita tila taila followed by baṣpa swedana was done for 3 days

##### Phase 3-

On the 3<sup>rd</sup> day, 25 grams of trivṛt lehyam was given as virecana ouṣadhi before 8:00 am. Depending upon the number of vega, the shuddhi is determined and saṃsarjana was advised.

#### Observation during the days of snehapana

Among the 20 healthy volunteers, 9 attained saṃyak snigdha lakshana within 5 days, 8 subjects attained saṃyak snigdha lakshana in 4 days and 3 attained saṃyak snigdha lakshana within 3 days

#### Vatanulomana-

The term Vatanuloma means the proper direction of vayu. In this context we consider the proper expulsion of flatulence, feces, and urine. The expulsion of the flatulence was noticed in every patient from day 2 till the saṃyak snigdha lakshana attainment. On Day 1, only in 7 cases the lakshana was observed. The expulsion of urine was noticed every day in all the subjects. The expulsion of stool was not seen on day 1 in most of the subjects. The changes in the stool were clearly visible gradually from day 1 onwards. On the last days, that mean the

days about to reach the samyak snigdha, then the frequency of expulsion of the stool also increased. It is noted that they expel flatulence daily even if there is no expulsion of the feces.

#### **Agni dipti-**

The agni bala index is the formulae used for assessing the agni. When the agni bala index decreases, the agni increase and vice-versa. The normal range of the ABI is 3, less than 3 and greater than 3. Among the 20 patients' alteration in agni was observed only in 2 subjects.

ABI was calculated using the formulae "ABI = Test dose X Time taken for digestion / Given dose"

#### **Varcha Snigdha-**

The presence of sneha was observed in all the subjects. 4 subjects remarkably mentioned the presence of sneha from day 2 onwards. Initially the sneha was observed as drops of sneha in stools, eventually the sneha was observed as floated in water during the defecation. In the later days, it was felt in hands while washing after defecation.

#### **Varcha asamhata-**

The consistency of the stool differed from day 1 till the attainment of the samyak snigdha lakshana. Initially, it was observed that there was no expulsion of the stool in the first 2 days in 50 % of the cases. Later on, the frequency of the stool increased in all the subjects.

#### **Snehodvega-**

Snehodvega was not seen remarkably in all the cases. Only in 2 subjects, the lakshana was seen from day 2. In most of the cases, snehodvega was observed very severely from day 4 onwards. As the amount of the sneha increased, the grade of the snehodvega also increased.

#### **Klama-**

Tiredness was seen in all the subjects from day 1 onwards. Even though there were no activities or exercises done during the days of snehapana, remarkable tiredness was observed in all subjects.

#### **Aṅga snigdha-**

Aṅga snigdha was seen in 4 subjects from day 2 onwards. Snigdha was prominently observed in the subjects who was about to attain the samyak snigdha lakshana. The aṅga snigdha was checked with the help of scratch test. Every day while assessing the samyak snigdha lakshana, the scratch was made on the same area to assess the aṅga snigdha. It was also observed that in few subjects, remarkable oiliness was felt on certain body parts like tip of the nose, chin, forehead, and neck. All subjects were asked not to use any cosmetics products like body creams or moisturizers during the days of snehapana to avoid the unnecessary errors.

#### **Aṅga mardavata-**

Aṅga mardavata was observed from day 2 in 6 subjects. Even in the cases where aṅga mardavata was observed, the lakshana was seen only as very mild in certain areas of the body like the calf muscles, biceps, triceps, and thighs. Among 20 subjects, only 15 subjects observed the lakshana on the last day of snehapana.

#### **Aṅga laghuta-**

Aṅga laghuta was not clearly observed in all the subjects. Only in very few cases, the lakshana was noticed as the feeling of mild lightness of the body.

## **RESULTS**

The entire study was conducted in 2 stages. Stage of development - validation and Clinical assessment stage

### **PART I-**

The tool was developed after undergoing various validation processes like Face validation, Content validation and Construct validation. With the data gathered, a model was drafted with lakshana of samyak snigdha. Content validation was conducted by assessing the

samyak snigdha lakshana on the subjects from the IPD of Amrita Ayurveda Hospital. Each lakshana was assessed on 10 patients for producing the adequate data for developing the tool. But while assessing, we could notice only the 6 relevant lakshana, hence the assessment was done on 60 subjects. With the obtained data construct validation was done. Exploratory Factor analysis was done to identify the contribution of each lakshana to the overall diagnosis of cure. The scores on each lakshana were considered on Day 5 of the treatment and entered to the EFA model. To identify the internal consistency, Cronbach's Alpha was done for all 9 items. Cronbach's alpha is a measure of internal consistency, that is, how closely related a set of items are as a group.

### ANALYSIS OUTPUT

This analysis considers all the 5 days readings of all the 60 subjects. It tries to understand the latent variable of samyak snigdha lakshana and assess how much each of the lakshana contributes to it.

Table 2: KMO and Bartlett's Test

KMO and Bartlett's Test	
Kaiser- Meyer- Olkin Measure of sampling adequacy	.867
Approx. chia square	1083.240
Bartlett's Test of sphericity df	36
Significance	.000

With the help of the Kaiser- Meyer- Olkin Test, it's possible to measure the sampling adequacy for each variable in the model and for the complete model. Here, the sampling adequacy is greater than .8 which means that the samples are adequate. The Bartlett test was used to verify that assumption. Here, the significance is less than 0.05, indicating significance.

### RELIABILITY STATISTICS

Here, the Cronbach's Alpha is more than .8 which indicates an excellent internal consistency.

Table 3: Reliability statistics

Cronbach's Alpha	N of items
.881	6

### ITEM-TOTAL STATISTICS

Table 4: Item-Total Statistics

	Scale mean If item deleted	Scale variance If item deleted	Corrected item –total correlation	Cronbach's Alpha If item deleted
Vatanuloma	4.033	7.912	.624	.871
Agni dipti	4.350	6.951	.717	.858
Varcha snigdha	4.860	7.171	.794	.842
Varcha asamhata	4.610	7.048	.810	.839
Anga snigdata	5.100	8.365	.663	.868
Klama	4.663	8.191	.567	.879

Among those 9 lakshana, Vatanulomana, agni dipti, snigdha varcha, asamhata varcha, anḡa snigdha, klama are the important lakshana in assessing the samyak snigdha whereas the snehodvega, anḡa mardhavata, and anḡa laghuta are not much relevant in assessing the samyak snigdha. The developed scale showed statistically high significance and correlation. Predictive validation was done to strengthen the tool by assessing the samyak snigdha with the developed scale.

## PART II- Snehapana

The developed tool was clinically assessed on 20 healthy volunteers satisfying the inclusion and exclusion criteria. Among the 20 subjects, 9 subjects attained samyak snigdha lakshana within 5 days and 8 subjects by 4 days, and 3 subjects within 3 days.

## Abyaḡa- Swedana

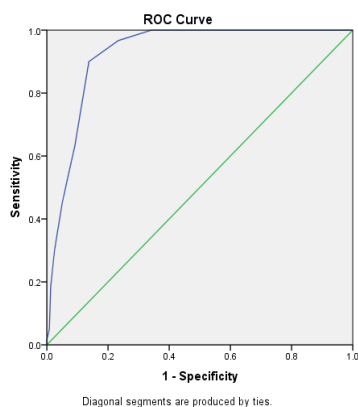
The subjects who attained the samyak snigdha lakshana underwent Abyaḡa for 3 days with murcchita til taila followed by baḡpa swedana.

## Virecana

On the 3<sup>rd</sup> day, 25 grams of trivṛt lehyam was given as Virecana oushadi at 08.00 am for all the 20 subjects. Among the 20 subjects, 18 attained avara śuddhi, 2 attained madhyama shuddhi and nobody attained the pravara shuddhi

## PREDICTIVE VALIDITY

Figure 1: area under curve



## DISCUSSION

### FACE VALIDATION-

The lakshana from various texts were tabulated and a model was drafted with the lakshana. Among all the lakshana, only 9 lakshana were selected for the model. The lakshana which cannot be assessed easily was skipped from the model like vimalendriyatha. The other lakshana were easily assessable with subjective and objective parameters.

### CONTENT VALIDATION-

This process was done by the experts from the Post Graduate department of Panchakarma. The correction was done, and a final model was drafted in a questionnaire form.

## STAGE II- CLINICAL ASSESSMENT

### 1. Vatanuloma-

The assessment was done with the help of a question with the following grade.

- Grade 2- Proper expulsion of adhovayu, urine and stool
- Grade 1- Incomplete expulsion of adhovayu and expulsion of feces and urine
- Grade 0 -Less expulsion of adhovayu, feces and urine

The proper Vatanuloma assessment was really a complex process. Most of the patients void urine from day1 till the samyak snigdhatta whereas the stool and flatus assessment were difficult to assess with the same question. It is always better to assess the Vatanulomana in terms of flatulence and urine.

### 2. Agni dipti-

Agni should be in an increasing pattern from day till the samyak snigdhatta. The alteration in the agni causes the indigestion in the subject which leads to the delayed digestion of the ghee taken. That will result in the next day dose and hamper the entire mechanism of snehapana. The reason for the alteration in agni can be due to many reasons like Sudden climatic changes, emotional stress, less water intake, loss of sleep previous night

### 3. Varcha snigdhatta-

In most of the subjects, the snigdhatta was attained before the anga snigdhatta. The sneha was seen while washing after defecation whereas in few other subjects it was observed that the sneha was seen in stool before on hands while washing. The reason may be because they might not have observed it properly. Many subjects ignore monitoring their own stools. In those conditions the observations will not be proper and the presence of sneha cannot be identified. In subjects who use toilet papers rather than water find it difficult to observe the presence of sneha.

### 4. Varcha asamhata--

In 90 % of subjects, the consistency of the stool will be hard in the initial days because of their regular dry and hard diet intake. In few subjects, semi-solid like stools is seen even in initial days which may be because of the slight indigestion even after pachana and dipana. The normal consistency of the stool of those subjects may be semi solid.

### 5. Snehodvega-

Most of the subjects hesitate to take ghee because of the smell of the ghee which is a strong irritant. The snehapana done with ghee other than murcchita ghṛta did not make such aversions in the subjects. Few subjects did not feel any sort of aversion from day 1 till the samyak snigdhatta. Subjects who had the habit of taking ghee in their daily life had no issues in taking the murcchita ghṛta.

### 6. Klama-

All the subjects noticed the gradual increase in the tiredness during the snehapana days. Few subjects felt giddiness in the last days of their snehapana. The exact reason for their tiredness is not known but we assume that it may be because of the metabolic changes in the body. During snehapana days, the subjects are restricted from all their daily activities like exercises, prolonged reading, mobile usage etc. which makes them too self-conscious and feel clumsy during the daytime of snehapana days.

### 7. Aṅga snigdhatta-

Aṅga snigdhatta is a symptom which was not clearly observed in many subjects. To assess the aṅga snigdhatta scratch test was done. As there was no other test to find the presence of snigdhatta, scratch test was done even though it does not give a relevant assessment. Few subjects were extremely dry in nature, in those conditions scratch test was positive till the samyak snigdhatta. Whereas, in few other subjects, the scratch test was negative from day 1



itself. The reason may be because those subjects have twak snigdha and aṅga snigdha in their normal days.

**8. Aṅga mardavata–**

Similarly, this symptom was also not observed clearly in the subjects. Subjects who had aṅga mardavata were mainly because of the absence of the ama in the body.

**9. Aṅga laghuta–**

Aṅga laghuta was not clearly observed in all the subjects. Those who had aṅga laghuta were because of the absence of the ama in the body.

**GRADING FOR SAMYAK SNIGDHA LAKSHANA**

Based on the findings of the study we tried to grade the samyak snigdha lakshana attained in 20 subjects. After analyzing the observed values, we were able to fix an end point to calculate the samyak snigdha lakshana using the developed samyak snigdha tool. During the content validation among the 60 subjects, the minimum score attained was 6 (by adding the individual scores of the 9 lakshana on daily basis) and the maximum score attained was 15. The lowest score that can be achieved is 0 and the highest score that can be achieved is 18. As 0 can never be a score for attaining samyak snigdha lakshana and as it is the normal state of the patient, the lowest score is made as 6 and the highest score as 18 (which is the maximum score that can be achieved). The score between 6-18, was grouped in to 3 category and provided with a reference range and are follows.

- Avara Samyak Snigdha - 6 - 8
- Madhyama Samyak Snigdha - 9 - 13
- Pravara Samyak Snigdha- 14 – 18

To achieve the samyak snigdha lakshana even if the score is more than 6, among the 6 relevant lakshana any of the lakshana- aṅga snigdha and snigdha varcha should be 1 or more. Aṅga snigdha and snigdha varcha are the 2 factors which evidently show the presence of sneha at Śakha and Koshṭha respectively. And also, these 2 lakshana are the only physical factors which can be easily and directly observed on subjects by monitor/ Doctor from day 1 till the last days.

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