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

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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 snigdhata attained.

Methods
Stage 1 - face validation
The samyak snigdha lakshana 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 snigdhā 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 snigdhata as 6 – 8, madhya snigdhata as 9 – 13, and pravara snigdhata as 14 – 18.
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Section A - Research paper

Conclusion
Among the various lakṣaṇa mentioned under samyak snigdha lakṣaṇa by different texts vātānulomana, agni dipti, snigdha varcha, asamhata varcha, anga snigdhata and klama plays the deciding role of snigdhata. Based on the observed values, it is possible to assess the samyak snigdha lakṣaṇa and the level of snigdhata. Using the principles of psychometrics, samyak snigdhā lakṣaṇa 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 life¹. Snehana has a cardinal role in Ayurveda treatments in both preventive and curative aspects. It is broadly divided into Bahya Snehana and Abyantara Snehana². Snehapanas comes under Abhyantara Snehana and is the internal administration of Sneha dravya. Snehapanas is the foremost treatment to be done prior toṣhoḍana and is one among purvakarma and plays a vital role in the process of shodana karma. The snehapanas done prior to shodana procedure for the utklesha of the dosha is called as shodanaṅga snehapanas. Shodananga snehapanas 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 Shodananag Snehapanas, the oral administration of sneha dravya in the gradual increase of the dose pattern and to develop and validate a scale to assess the Saṃyak 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 saṃyak snigdha lakṣaṇa mentioned in different texts.

<table>
<thead>
<tr>
<th>Vātānulomana</th>
<th>Mrudu gatrata</th>
<th>Twak shaithilya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agni dipti</td>
<td>Glani</td>
<td>Viṭṭ shaithilya</td>
</tr>
<tr>
<td>Snigdha varcha</td>
<td>Anga laaghava</td>
<td>Snigdhagata</td>
</tr>
<tr>
<td>Asamhata varcha</td>
<td>Snehadarshana</td>
<td>Susnigdha</td>
</tr>
<tr>
<td>Snehodvēga</td>
<td>Vimalendriyatha</td>
<td>Mala pravartanaṃ</td>
</tr>
<tr>
<td>Klama</td>
<td>Grita vidhwesha</td>
<td>Mardavangata</td>
</tr>
</tbody>
</table>

PSYCHOMETRICS
Psychometrics³ developed as a means for measuring psychological abilities and attributes, usually via a standardized psychological test.

Validation
Validity⁴ is the equality or state of being valid, where this can mean anything from being true to, being cogent to being legally accepted. Validity⁵ refers to the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure.
Reliability
Reliability 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 laksha, 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,snugda varcha, asamhata varcha, anga snigdhata and klama whereas the psychological domains include snehodvega, anga laghu 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 Snehapan 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 laksha and
they were Vatanuloma, Agni dipti, Snigdha varcha, Asaṃhata varcha, Anga snigdhata, Klama. Thus, to assess these 6 relevant lakṣaṇa 60 subjects was required. The subjects who attained Saṃyak Snigdhata by 5 days were record and similar 60 cases were recorded for the study. Usually, the saṃyak snigdhata 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 snehapanas who attained the saṃyak snigdhata 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 lakṣaṇa to the overall diagnosis of cure. The scores on each lakṣaṇa 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
- Snehapanas Arha and Virecana Arha as per Ayurveda Texts
- Apparently Healthy without any illness in the past 6 months, without any medication
- Madhyama Kosṭha

The exclusion criteria
- Snehapanas Anarha and Virecana Anarha as per Ayurveda Text

Phase 1-
In 20 healthy volunteers snehapanas was done with murcchita ghṛta till smyak snigdhatha

Phase 2-
After snehapanas, Abyanga with murcchita tila taila followed by baṣpa swedana was done for 3 days

Phase 3-
On the 3rd 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 saṃsārjana was advised.

Observation during the days of snehapanas
Among the 20 healthy volunteers, 9 attained saṃyak snigdha lakṣaṇa within 5 days, 8 subjects attained saṃyak snigdha lakṣaṇa in 4 days and 3 attained saṃyak snigdha lakṣaṇa 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 snigdhata lakṣaṇa attainment. On Day 1, only in 7 cases the lakṣaṇa 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 saṃyak snigdhata, 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 formulæ “ABI = Test dose X Time taken for digestion / Given dose”

**Varsha Snigdhatha-**
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.

**Varsha asamhata-**
The consistency of the stool differed from day 1 till the attainment of the saṃyak 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.

**Aṇga snigdhata-**
Aṇga snigdhata was seen in 4 subjects from day 2 onwards. Snigdha was prominently observed in the subjects who was about to attain the saṃyak snigdha lakshana. The anga snigdhata was checked with the help of scratch test. Every day while assessing the saṃyak snigda lakshana, the scratch was made on the same area to assess the anga snigdhata. 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.

**Aṇga mardavata-**
Aṇga mardavata was observed from day 2 in 6 subjects. Even in the cases where anga 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.

**Aṇga laghuta-**
Aṇga 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 saṃyak snigdhata. 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

<table>
<thead>
<tr>
<th>KMO and Bartlett’s Test</th>
<th>Kaiser- Meyer- Olkin Measure of sampling adequacy</th>
<th>.867</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approx. chia square</td>
<td></td>
<td>1083.240</td>
</tr>
<tr>
<td>Bartlett’s Test of sphericity df</td>
<td></td>
<td>36</td>
</tr>
<tr>
<td>Significance</td>
<td></td>
<td>.000</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Cronbach’s Alpha</th>
<th>N of items</th>
</tr>
</thead>
<tbody>
<tr>
<td>.881</td>
<td>6</td>
</tr>
</tbody>
</table>

ITEM-TOTAL STATISTICS
Table 4: Item-Total Statistics

<table>
<thead>
<tr>
<th>Item</th>
<th>Scale mean If item deleted</th>
<th>Scale variance If item deleted</th>
<th>Corrected item–total correlation</th>
<th>Cronbach’s Alpha If item deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vatanuloma</td>
<td>4.033</td>
<td>7.912</td>
<td>.624</td>
<td>.871</td>
</tr>
<tr>
<td>Agni dipti</td>
<td>4.350</td>
<td>6.951</td>
<td>.717</td>
<td>.858</td>
</tr>
<tr>
<td>Varcha snigdha</td>
<td>4.860</td>
<td>7.171</td>
<td>.794</td>
<td>.842</td>
</tr>
<tr>
<td>Varcha asaṃhata</td>
<td>4.610</td>
<td>7.048</td>
<td>.810</td>
<td>.839</td>
</tr>
<tr>
<td>Anga snigdata</td>
<td>5.100</td>
<td>8.365</td>
<td>.663</td>
<td>.868</td>
</tr>
<tr>
<td>Klama</td>
<td>4.663</td>
<td>8.191</td>
<td>.567</td>
<td>.879</td>
</tr>
</tbody>
</table>
Among those 9 lakshana, Vatanulomana, agni dipti, snigdha varcha, asaṃhata varcha, anga snigdhata, klama are the important lakshana in assessing the saṃyak snigdhata whereas the snehodvega, anga mardhavata, and anga laghuta are not much relevant in assessing the saṃyak snigdhata. The developed scale showed statistically high significance and correlation. Predictive validation was done to strengthen the tool by assessing the saṃyak snigdhata 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 saṃyak snigdhata lakshana within 5 days and 8 subjects by 4 days, and 3 subjects within 3 days.

Abyanga- Śwedana
The subjects who attained the saṃyak snigdha lakshana underwent Abyaṅga for 3 days with murcchita til taila followed by baṣpa swedana.

Virecana
On the 3rd 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

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 adhohayu, urine and stool
- Grade 1: Incomplete expulsion of adhohayu and expulsion of feces and urine
- Grade 0: Less expulsion of adhohayu, feces and urine

The proper Vatanuloma assessment was really a complex process. Most of the patients void urine from day 1 till the samyak snigdhata 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 snigdhata. 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 snigdha-
In most of the subjects, the snigdha was attained before the anga snigdha. 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 asamphata--
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 murchita ghṛta did not make such aversions in the subjects. Few subjects did not feel any sort of aversion from day 1 till the samyak snigdhata. Subjects who had the habit of taking ghee in their daily life had no issues in taking the murchita ghrita.

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. Anga snigdhata-
Anga snigdha is a symptom which was not clearly observed in many subjects. To assess the anga snigdhata scratch test was done. As there was no other test to find the presence of snigdha, 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 snigdhata. Whereas, in few other subjects, the scratch test was negative from day 1.
itself. The reason may be because those subjects have twak snigdhata and aṅga snigdhata 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 SĀMYAK SNIGDHA LAKSHANA**

Based on the findings of the study we tried to grade the sāmyak snigdha lakshana attained in 20 subjects. After analyzing the observed values, we were able to fix an end point to calculate the sāmyak snigdha lakshana using the developed sāmyak snigdhata 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 sāmyak 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 into 3 categories and provided with a reference range and are follows.

- **Avara Samyak Snigdhata** - 6 - 8
- **Madhyama Samyak Snigdhata** - 9 - 13
- **Pravara Samyak Snigdhata** - 14 - 18

To achieve the sāmyak snigdha lakshana even if the score is more than 6, among the 6 relevant lakshana any of the lakshana- aṅga snigdhata and snigdha varcha should be 1 or more. Aṅga snigdhata and snigdha varcha are the 2 factors which evidently show the presence of sneha at Ṣakha 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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