



PRO FORMA DEVELOPMENT AND VALIDATION OF SAMYAK NASYA LAKSHANA W.S.R. TO KARPASASTHYADI TAILA NASYA IN VISVACHI (CERVICAL RADICULOPATHY)

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ABSTRACT

Introduction: Marsa nasya (nasal instillation of medicine) is the only panchakarma procedure which aims at *uttamaanga sodhana* (cleansing of head). For conducting marsa nasya in a safe and effective manner, an objective tool is necessary. So, it is very high time for a tool development since there is no validated pro forma available for assessing *samyak nasya lakshana* (symptomatology) of a properly conducted marsa nasya so far. **Objective:** To develop and validate a pro forma of *samyak nasya lakshana*. **Materials and Methods:** A pro forma has been developed in a scientific manner by following the steps of compilation of symptomatology, item analysis, literature review, clinical observation and pro forma finalization. An attempt has been made to validate the developed pro forma by passing it through the phases of face validity, content validity, construct validity and criterion validity. **Results:** The pro forma of *samyak nasya lakshana* with *karpasasthyadi taila* in *visvachi* (cervical radiculopathy) was developed and validated following face, content, construct and criterion validity. **Conclusion:** A validated pro forma was not available in the field of nasya karma so far. So, this validated pro forma should be further subjected to intellectual discussions and critical analysis.

KEYWORDS : Marsa nasya, Samyak nasya lakshana, Pro forma development, Validation

INTRODUCTION:

Marsa nasya (nasal instillation of medicine) is the only *panchakarma* (five fold purification therapy) procedure which aims at *uttamaanga sodhana* (cleansing of head and neck) and to alleviate *urdhwa jatru vikara*^[1] (head and neck pathologies). The safety and efficacy of *nasya karma* largely depends on *samyak nasya lakshana*^[2]

(symptomatology obtained for properly conducted *nasya* procedure). Even though, a lot of studies are conducted on *marsa nasya*, most of them are giving prior importance to efficacy. *Ayurvedic* fraternity is many a time, in dilemma how to monitor *marsa nasya* or for stoppage of *marsa nasya*, which *lakshana* (symptomatology) have to be obtained in each pathology. The main challenge before an *Ayurvedic* physician while assessing *samyak nasya lakshana* lies in the fact that most of the *lakshana* are highly subjective. That is, we are severely in need of an objective tool to assess *marsa nasya* each day. There lies the need of a pro forma development for conducting the procedure in the most safe and effective manner. For assessing the strength of any pro forma or objective tool, that is, whether it is measuring what it is intended to measure, the pro forma has to be validated and should be checked for its consistency. So, to satisfy this need, validation of pro forma of *samyak nasya lakshana* in *visvachi* (cervical radiculopathy) with *karpasasthyadi taila* was also conducted.

Aim: Validation of Panchakarma procedures.

Objective: To develop and validate a pro forma of *samyak nasya lakshana*.

Materials and Methods

A pro forma has been developed in a scientific manner by following the steps of compilation of symptomatology, item analysis, literature review, clinical observation and pro forma finalization. An attempt has been made to validate the developed pro forma by passing it through the phases of face validity, content validity, construct validity and criterion validity.

A. Development of pro forma:

The challenge of assessment of *samyak nasya lakshana* lies in the fact that most of the symptoms are highly subjective. So, for the assessment of *samyak nasya lakshana* in the most objective manner, a pro forma was developed through following stages.

1. Compilation
2. Item analysis
3. Literature review
4. Clinical observation
5. Finalization

1. Compilation of *lakshana* (symptomatology):

Samyak nasya lakshana were compiled from all the available *Ayurveda* classics. The references from *Caraka Samhita*, *Susruta Samhita*, *Ashtanga Hridaya*, *Ashtanga Samgraha*, *Saarnagadhara samhitha*, *Kaasyapa Samhita*, *Kalyanakaaraka*, *Cakradatta*, *Vangasena Samhita*, *Bhavaprakasa* are compiled. 28 *lakshana* were collected. This include *urah laghuta* (lightness of chest), *sira laghuta* (lightness of head), *indriyaachayan* (clarity of sensorium), *indriya sudhi* (clarity of sensorium), *akshi laghuta* (lightness of sensorium), *aksha paadavam* (sharpness of sensorium), *srotho visudhi* (clarity of body channels), *swara visudhi* (clarity of voice), *vaktra visudhi* (clarity of throat), *citta prasaada* (clarity of mind), *indriya prasaada* (clarity of sensorium), *sukha uchwasa* (unobstructed exhalation), *sukha niswasa* (unobstructed inhalation), *vikara upasama* (subsidence of diseases), *sukha swapna* (sound sleep), *sukha prabodha* (pleasant awakening), *manaso laaghavam* (easiness of mind), *mana sukham* (pleasant mindset), *siro visudhi* (clarity of head), *vedana upasama* (subsidence of pain), *kheshu vivruthi* (opening of body channels), *na sleshma praseka* (absence of excess salivation), *indriya vimukthatha* (clear sensorium), *swara prasada* (pleasant voice), *varna prasada* (pleasant complexion), *srothasam vimalatha* (clear body channels), *kshavadhu* (sneezing), *vadana visudhi* (clear mouth). The details of these *lakshana* in classics are explained in literary part.

2. Item analysis:

The *lakshana* which were compiled were analysed thoroughly based on *nirukti* (etymology), Sanskrit and English meaning, commentary and available other explanations in classics.

- The *lakshana* mentioned by Vagbhata like *Ghana unnatha prasanna twak* (compact dense skin), *Ghana unnatha greeva*, *skanda*, *vakshas* (compact neck, shoulder and chest), *apalithatha* (un-greying of hair) appears as the delayed benefits of *nasya karma*. So, these *lakshana* are not selected for development of this pro forma for assessment of *samyak nasya lakshana*.
- The *lakshana siro laghuta* (lightness of head) is explained by *Aacarya Caraka*, *Susruta* and *Vangasena* and *siro visudhi* (clarity of head) by *Ashtaanga Samgraha*. Since, both of them carry similar meanings and *siro laghuta* can be better elicited more effectively, *siro laghuta* is selected.
- Out of *vikaara upasama* (subsidence of disease) and *vedana upasama* (subsidence of pain), *vedana upasama* was selected since it is more specific to *visvachi*.
- The *lakshana vaktra visudhi* (clear mouth) mentioned in *Ashtaanga Hridaya* and *vadana visudhi* (clear mouth) mentioned by *Ashtaanga samgraha* carry the same meaning. Hence, *vaktra visudhi* was selected. The *lakshana 'na sleshma praseka'* (absence of excess salivation) mentioned by *Bhela* can occur only if there is *vaktra visudhi*. So, it is filtered out from the pro forma.
- The *lakshana citta prasada* (pleasant mindset), *mana sukham* (pleasant mindset) and *manaso laaghavam* (lightness of mind) were frequently used each other as they carry the same meaning. So,

mana sukham was selected.

- The *lakshana swara prasada* (pleasant voice) was mentioned by *Bhela* and *swara visudhi* (clear voice) by *Vagbhata*. *Swara prasada* can happen only with *swara visudhi*. So, *swara visudhi* was selected.
- The *lakshana indriyaachaayam* (clarity of sensorium) was mentioned by *Caraka*, *indriya vimukthata* (clear sensorium) by *Bhela* and *indriya sudhi* (clear sensorium) by *Susruta*, *Ashtaanga samgraha* and *Vangasena*. Since, all these words carry same meaning, *indriya sudhi* was selected. The *lakshana aksha paadavam* (sharpness of sensorium) and *indriya prasada* (pleasant sensorium) are the result of *indriya sudhi*. So, they are not selected.
- The *lakshana srotho visudhi* (clear body channels) mentioned by *Ashtaanga Samgraha* and *kheshu vivruthi* (opening of body channels) mentioned by *Bhela* have similar meanings. So, *srotho visudhi* was selected.
- After item analysis, 15 *lakshana* were selected, *urah laghuta* (lightness of chest), *s'iro laghuta* (lightness of head), *indriya sudhi* (clarity of sensorium), *akshi laghuta* (lightness of sensorium), *srotho visudhi* (clear body channels), *swara visudhi* (clear voice), *vaktra visudhi* (clear mouth), *mana sukham* (pleasant mindset), *vedana upasama* (subsidence of pain), *sukha swapna* (sound sleep), *sukha prabodha* (pleasant awakening), *kshavadhu* (sneezing), *varna prasada* (pleasant complexion), *sukha uchwasa* and *sukha niswasa* (unobstructed exhalation and inhalation).

3. Literature review:

All the available research works on *marsa nasya* with *karpasasthyadi taila* ^[3] in *visvachi* ^[4] (cervical radiculopathy) were collected. The observations and conclusions made in those works were critically analysed.

- Among them, nature of *kapha sodhana* (expulsion of sputum) mentioned as *samyak nasya lakshana* was selected for clinical observation.
- The *lakshana* like *srotho visudhi* and *indriya sudhi* are splitted with special reference to particular *indriya* like *karna* (ears), *akshi* (eyes), *twak* (skin), *nasa* (nose) and *vaktra* (mouth) and *srothas* involved in *nasya karma* like *nasa*, *netra* (eyes), *karna* and *kanda* (throat). From them, *akshi sudhi* and *vaktra sudhi* are eliminated due to repetition.
- Nasa sudhi* (clear nasal function) can be measured by *sukha uchwasa* and *niswasa* (unobstructed exhalation and inhalation), so it is not selected.
- Varna prasada* (pleasant complexion) is the indicator of *twak sudhi* (clear integumentary function), so it is not included.

4. Clinical observation:

After the completion of conceptual work, with compiled 16 *lakshana* observational study was done. Here, 93 participants diagnosed as *visvachi* (cervical radiculopathy) undergoing *marsa nasya* was selected for clinical observation. The *lakshana* obtained were observed in each day throughout *marsa nasya* procedure and data observed was tabulated and given below.

Here, the grade 1 denotes the feeling of the *lakshana* same as before *nasya*. Grade 2 denotes increased feeling of the *lakshana* after *nasya*.

Table 01: Clinical Observation of selected lakshana (symptomatology)

SI.No	LAKSHANA	Grade 1	Grade 2	Total
1	<i>Sira laghutha</i> (lightness of head)	68	5	73 (78.49%)
2	<i>Akshi laghutha</i> (lightness of eyes/ sensorium)	45	3	(51.61%)
3	<i>Urah laghutha</i> (lightness of chest)	89	0	(95.70%)
4	<i>Sukha uchwasa</i> (Unobstructed exhalation)	93	0	(100%)
5	<i>Sukha niswasa</i> (unobstructed inhalation)	93	0	(100%)
6	<i>Karna sudhi</i> (clarity of hearing)	56	0	(60.22%)
7	<i>Kanda sudhi</i> (clarity of throat)	57	0	(61.29%)

8	<i>Varna prasada</i> (pleasant complexion)	93	0	(78.49%)
9	<i>Vaktra visudhi</i> (clarity of mouth)	93	0	(100%)
10	<i>Swara visudhi</i> (clear voice)	57	0	(61.29%)
11	<i>Kshavadhu</i> (sneezing)	15		(16.13%)
12	<i>Mana sukham</i> (pleasant mindset)	72	0	(77.42%)
13	<i>Sukhaswapna</i> (sound sleep)	77	4	(87.10%)
14	<i>Sukha prabodha</i> (pleasant awakening)	70	11	(87.10%)
15	<i>Vedana upasama</i> (subsidence of pain)	72	0	(77.42%)
16	<i>Kapha sodhana</i> (expulsion of kapha)	48	9	61.29%

1. Finalization of pro forma:

Based on clinical observation, a pro forma was developed by keeping observed cut off as 75%. 11 *lakshana* were coming above this cut –off range. Again, 3 *lakshana*, *ura laghutha*, *manasukham*, *sukha swapna*, *varna prasada* are excluded due to the less observation of grade 2 symptom. Remaining 7 *lakshana* were selected. They were divided into two headings

- For monitoring *marsa nasya*
- For stopping *marsa nasya*.

The 7 *lakshana sira laghuta*, *sukha uchwaasa*, *sukha niswaasa*, *vaktra visudhi*, *sukha prabodha* and *vedana upasama* are mandatory for continuing *marsa nasya*. *Vedana samana* or complete relief of pain was made mandatory to stop *marsa nasya*. The finalized pro forma is given below.

Table 02: Pro forma of samyak nasya lakshana with karpasasthyadi taila nasya in Visvachi

SI.No	LAKSHANA	1 st day	2 nd day	3 rd day	4 th day	5 th day	6 th day	7 th day
For monitoring <i>nasya</i>								
1	<i>S'ira laghuta</i>							
2	<i>Sukha uchwaasa</i>							
3	<i>Sukha niswaasa</i>							
4	<i>Vaktra vis'udhi</i>							
5	<i>Sukhaprabodha</i>							
For stopping <i>nasya</i>								
6	<i>Vedana s`amana</i>							

Duration - upto *vedana samana* or maximum upto 9 days of *nasyakarma*

Validation of pro forma

Here an attempt is made to test the validity and reliability of the pro forma thus generated.

Assessment of validity:

The face validity^[5], content validity^[6], construct validity^[7] and criterion validity^[8] were assessed by following repeated observation of statistical analysis.

1. Face validity:

An evaluation sheet was prepared to check the spelling, grammar, lay out, readability, transliteration, unambiguousness and overall appearance. The average score of each item were separately calculated and based on suggestions received, the necessary modifications were made. The modified pro forma was again checked two more times from the same community and assessment was made. Thus, the draft pro forma was improvised three times.

The face validity rate was estimated as 94.23%

1. Content validity:

The content validity was assessed by experts from inside and outside Kerala. A scoring sheet was prepared with five levels of agreement and was distributed to experts. The levels of agreement were strongly agree, agree, neither agree nor disagree, disagree and strongly disagree. The agreement of each expert more than 80% was taken as excellent and content validity rate (CVR) was calculated.

It is observed that out of 24 experts, 19 selected it as excellent.

Table 03: Number of experts participated on content validity and

the score of excellence

No of experts (N)	Excellent (ne)
24	19

So, the content validity rate CVR calculated with Lawshe formula⁽⁹⁾ as follows.

$$CVR = (Ne - N/2)/N/2$$

$$19 - 12/12 = 7/12 = 0.58$$

The obtained CVR was 0.58 on 24 experts. As per Lawshe formula, the value ranges from +1 to -1. So, when the value becomes 0, it was interpreted as about half of the experts rated the pro forma as excellent. So, the value 0.58 indicates more than 75% of experts rated the pro forma as excellent.

1. Construct validity:

Each constructs of pro forma was developed after passing through a series of discussions, observations and critical analysis. All *samyak nasya lakshana* were compiled from all the available *Ayurvedic* classics. Each item was analysed critically and few of them were filtered out for the pro forma development. All the available current research literature were thoroughly analysed and additions were made in the pro forma. With the constructed pro forma, clinical observation was made on 93 participants diagnosed as *viswachi* undergoing *marsa nasya*. After the stage of clinical observation, 7 *lakshana* were selected for the final pro forma.

The finalized pro forma was again critically analysed and categorized into two headings, for monitoring as well as stopping *marsa nasya*. All finalized *lakshana* were tabulated.

2. Criterion Validity:

The newly developed pro forma was tested for criterion validity by comparing with the gold standard. Since a gold standard for *samyak nasya lakshana* was unavailable, the experience of subject experts who conduct *nasya* was taken as gold standard. Observed and Expected rate of criterion validity was thus calculated as follows

Table 04: Observed and Expected rate of criterion validity:

Observed rate (P _o)	Expected rate (P _e)
0.80	0.50

$$K = [P_0 - P_e] / [1 - P_e]^{(10)}$$

$$= 0.8 - 0.5 / 1 - 0.5$$

$$= 0.3 / 0.5$$

$$= 0.6 \text{ (Moderate agreement)}$$

Reliability:

The validated pro forma was then checked for its consistency by checking inter-observer reliability. In inter – observer agreement, Kappa score was calculated as 0.68.

DISCUSSION:

The pro forma was developed through compilation, item analysis, literature review, clinical observation and finalization. Compilation of *samyak nasya lakshana* was done from all the available classical literature. After item analysis, all the available current classical literature was analyzed and additions were made and gone for clinical observation.

After pro forma development, to check its closeness to reality, an attempt was made to validate it. Face validity rate was estimated as 94.23%. Content Validity Rate was 0.58. The unfamiliarity and non-response of subject experts towards the content validation process was greatly observed during the study. Construct validity was not subjected to more statistical analysis. The gold standard for *samyak nasya lakshana* was not available, so in criterion validity, the clinical experience of subject experts who conduct *nasya* was taken as gold standard and kappa score was calculated as 0.6 which denotes moderate agreement. The validated pro forma was then checked for its inter – observer reliability and Kappa score calculated as 0.68

CONCLUSION:

A validated pro forma was not available in the field of *nasya karma* so far. So, this validated pro forma should be further subjected to intellectual discussions and critical analysis.

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