



Research Article

VALIDATION OF SAMYAKVIRIKTALAKSHANA (IDEAL PURIFICATORY SYMPTOMS) WITH RESPECT TO GAMBHEERAVAATARAKTA (CHRONIC ARTHRITIS)

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ABSTRACT

Samyaklakshana (ideal symptoms) is the goal in any type of *Shodhanachikitsa* (purificatory treatment) and the type of *Shudhi* (purification) will decide the *Samsarjanakarma* (dietary regimen after purification). Assessment of *Samyakviriktalakshana* (ideal purificatory symptoms) is a key element in making *Virechana* (purgation) a *Samyakprayoga* (ideal practice). An attempt was made to develop and validate a proforma to assess *Samyakviriktalakshana* (Ideal purificatory symptoms). *Samyakviriktalakshana* (ideal purificatory symptoms) from all texts were compiled and analyzed for root word, meaning and explanation. One representative *Lakshana* (symptom) was taken for those conveying the same meaning. Classical references for *Vaigikee* (urge), *Maanikee* (volume) and *Aantikee* (last output) of *Shudhi* (elimination) were taken and a preliminary proforma was prepared. The clinical study was carried out in 20 participants having *Gambheeravatarakta* (chronic Arthritis). Conclusions were drawn from statistical work and the pro forma was finalized which determines *Shuddhi* (purification) based on all four criteria for *Samyakviriktalakshana* (Ideal purificatory symptoms). Face validity of pro forma was checked in terms of spelling, grammar, layout, readability, transliteration, unambiguousness and overall appearance and was found to be 90%. Content Validity Ratio (CVR) was calculated as 0.44 on 32 experts. The pro forma had good Construct validity. Criterion validity was calculated by comparing the pro forma with the gold standard in 10 observations. The *Lakshana* found observable at the end of the pilot study, and classical references for *Vaigikee* (urge), *Maanikee* (volume) and *Aantikee* (last output) of *Shuddhi* (purification) were together taken as gold standard. Criterion validity was found as 80%. *Kapha* was significant and the confidence interval was moderate. The proforma can be used as a tool to determine *Pravara*, (finest) *Madhyama* (moderate) or *Avara* (least) *Shudhi* (purification) in a *Virechana* (purgation).

KEYWORDS: *Samyakviriktalaksana* (ideal purificatory symptoms), *Virechana* (purgation), Validation, Proforma.

INTRODUCTION

The best treatment for *Pitta dosha*, *Pitta-anubandhadosha* (like *Vaatapitta*, *Kaphapitta*) and *Pittasthaana-anugata dosha* (like Blood, Eyes etc.) is *Virechana*.^[1] *Pitta dosha* and *Raktadhaatu* share *Aashraya-aashrayibhaava*,^[2] (dependent relation) and for this reason, *Virechana* is an ideal treatment modality for *Raktajavyaadhi* (Blood related disorders) as well. The success of all the treatments depends on their *Samyakprayoga* (ideal practice). It is vital to decide the correct *Samsarjanakrama* (diet regimen after purification) based on *Shuddhi* (purification).^[3]

Panchakarma (fivefold purificatory therapy) procedures become successful only when *Samyakprayoga* (ideal practice) is done.^[4] In case of *Virechana* (purgation), *Samyakprayoga* (ideal practice) is evaluated through *Samyakviriktalakshana* (ideal purificatory symptoms).^[5] Validated tool for assessment of *Samyakviriktalakshana* (ideal purificatory symptoms) was unavailable. Therefore, an attempt was made to develop and validate a pro forma to assess *Samyakviriktalakshana* (ideal purificatory symptoms).

The objectives of the study were

- To develop a proforma to assess *Samyakvirikta lakshana* (ideal purificatory symptoms).
- To validate the proforma to assess *Samyakvirikta lakshana* (ideal purificatory symptoms).

Prior to the commencement of the study the research proposal was submitted to the Institutional Ethics Committee and approval was obtained (IEC No:IEC/CI/012/11 dated 07/04/11).

Materials & Methods

i) Pro forma development

The proforma was developed in the following steps:

1. Compilation
2. Item analysis
3. Clinical observation
4. finalization

Samyakvirikta lakshana (ideal purificatory symptoms) from all classics were collected and analyzed for root word, meaning, explanation etc. For a few *Lakshana* (symptoms) conveying the same meaning, only one representative *Lakshana* (symptom) was kept. Classical references for *Vaigikee* (urge), *Maanikee*

(volume) and *Aantikee* (last output) of *Shuddhi* (purification) were taken and in a pilot study, preliminary pro forma was tested in 50 participants. *Lakshana* (symptoms) which were not observable were deleted.

Clinical study was carried out in 20 participants having *Gambheera vaatarakta* (Chronic Arthritis) admitted in the IPD of Vaidyaratnam P.S. Varier Ayurveda College hospital, Kottakkal, Kerala. *Virechana* (purgation) was administered by the same protocol for all and *Samyakvirikta lakshana* (ideal purificatory symptoms) were noted by all 4 criteria.

Diagnostic criteria

- Multiple joint pain
- MCP joint involvement
- Swelling of the joints
- Tenderness of the joints
- Restriction of movements

Inclusion criteria:

- Diagnosed cases of *Gambheeravaatarakta* (Chronic Arthritis) who are *Virechanaarha* (fit for purgation).
- Age 20- 60 years
- Chronicity upto 5 years
- Sex & religion – no discrimination

Exclusion criteria

- *Avarabala* (poor endurance)
- Rectal pathologies
- Other major systemic diseases

The participants selected were put through the same protocol of intervention.

Rooksana (internal demoiurising)

Panchakolachoorna 5 gm tds with hot water as *Anupana* (adjuvant) before food upto *Samyakrukshalakshana* (ideal demoiurisation symptoms) or 7 days maximum.

Snehapana (internal oleation): plain ghee in *Arohanakrama* (ascending order) depending on *Koshta* (bowel) & *Agni* (appetite) upto *Samyaknigdhalakshana* (ideal internal oleation symptoms) or 9 days maximum *Abhyanga* (Oil massage) with *Pindataila* (AVS kottakkal, GMP certified company) and *Ooshmasweda* (sweating from vapour) for 3 days following *Snehapana* (Internal oleation).

Virechana (purgation) with *Erandataila* (Castor oil) (Mangalodayam pharmaceuticals, GMP certified company) 50 to 100 ml between 8.30 am and 9.30 am with *Ksheera* (Milk), double the quantity of the drug.

The participants were advised to take *Pitta Utkleshanaahara* (food which increase *Pitta dosha*) on the previous day of *Virechana* (purgation), which consisted of *Tamarind Rasam* (a curry) with rice, sour fruit juice and hot water with lemon juice. On the day of *Virechana*, (purgation) *Erandataila* (Castor oil) was administered in empty stomach. A special chair was made available to pass stools and instructed to mark the level of stool contents. They were also provided with pen and a sheet of paper to note the exact time of each sitting, along with the number of *Vega* (urge) in each sitting and the contents of the stool. The participants were asked to take a sample of stool

when they observed yellow colour of the stool contents or burning sensation in the anal region. They were allowed to take 2 to 3 teaspoons of hot water only if they had unbearable thirst in the intervening time. In the event of stoppage of *Vega* (urge), they were advised to do mild sudation by keeping hot water bag over the abdomen. After the complete stoppage of *Vega* (urge), they were advised to take hot water bath, and have *Manda* (rice water) when they felt appetite and the subsequent pattern of food was explained to the participants.

Assessment criteria

1. *Samyakviriktalakshana* (ideal purificatory symptoms) Assessed in terms of *Vaigikee* (urge), *Maanikee* (volume), *Aantikee* (last output) and *Laingikee* (symptoms) criteria immediately after *Virechana* (purgation).

- *Vaigikeeshuddhi* (urge wise purification) was assessed as number of evacuations through anal orifice followed by a pause, which was counted by the self administered note provided to the participants prior to *Virechana* (purgation). It was counted as 10, 20 and 30 *Vega* (urge) for *Avara* (least), *Madhyama* (moderate) and *Pravara* (finest) *Shuddhi* (purification) respectively.^[7]

- *Maanikeeshuddhi* (volume wise purification) was assessed by excluding a few initial *Vega* (urge) containing formed stool. The vessel which was provided to the participants was taken, water was added to the level of each mark and the quantity was measured in ml. It was taken as 2, 3 and 4 *Prastha* (a measure, 1 *Prastha* is approx. 672ml) for *Avara* (least) *Madhyama* (moderate) and *Pravara* (finest) *Shuddhi* (purification) respectively.^[7]

- *Aantikeeshuddhi* (last output wise purification) was assessed as the contents of the last *Vega* (urge) which was made out by the self administered note. It was taken as *Kaphanta* (*Kapha Dosha* at the end).^[7]

- *Laingikeeshuddhi* (symptom wise purification) was assessed by interrogating with the participants after *Virechana* (purgation).

2. Visual Analogue Scale (VAS) for pain before and after treatment.

3. Goniometer for joint mobility before and after treatment.

4. Vernier calipers for swelling before and after treatment.

5. Activities of daily living (ADL) before and after treatment.

Investigations

Stercobilinogen estimation was done before treatment and during *Virechana* (purgation) using N. F. Maclagan's method.^[6]

Statistical analysis was done with the help of Microsoft Office Excel. Based on the findings, the pro forma was finalized.

Total 42 *Lakshanas* (symptoms) were collected from classics and other texts and at the end of item analysis, 20 remained. After the pilot study, 14 *Lakshanas* (symptoms) were observable and others were deleted. In total, 75% participants had *Shareeralaghava*, (lightness of body)

Agnideepti (good appetite) *Kukshishuddhi* (clear bowels) *Dourbalya* (weakness) and *Vyaadhiupashama* (relief from disease) after *Virechana* (purgation). All the participants passed *Vega* (urge) in the ranges 5 - 15, 15 - 25 and 25 -

35. All the participants passed *Kapha*, *Pitta* or clear fluid in the last *Vega* (urge). *Vaatarakta* (Arthritis) participants passed stool in ranges < 1000 ml, 1000-2000 ml and > 2000 ml.

Table 1: Laingikeeshuddhi (symptom wise purification) in 70 observations

Lakshana (symptoms)	No: of observations	%
<i>Shareeralaghava</i> (lightness of body)	62	88.57
<i>Agnideepthi</i> (good appetite)	59	84.28
<i>Kukshishuddhi</i> (clearness of bowels)	54	77.14
<i>Dourbalya</i> (weakness)	53	75.71
<i>Vyadhiupasama</i> (relief from disease)	58	82.85
<i>Mutrapureesha pitta oushadhakaphakramenagachanti</i> (orderly evacuation of feaces, <i>Pitta Dosha</i> , medicine & <i>Kapha Dosha</i>)	45	64.28
<i>Vatanulomana</i> (gaseous clearness)	45	64.28
<i>Manastushti</i> (pleasant mind)	44	62.85
<i>Trishna</i> (thirst)	25	35.71
<i>Gatramardava</i> (softness of body)	21	30
<i>Vaktravaishadya</i> (clearness of mouth)	20	28.57
<i>Hridayashuddhi</i> (clearness of chest)	10	14.28
<i>Angaanamasnigdhatta</i> (dryness of skin)	6	8.57
<i>Varna shuddhi</i> (lustre of skin)	2	2.85

The first five *Lakshana* (symptoms) which were present in more than 75% of the participants were selected for the proforma.

Table 2: Vaigikeeshudhi (urge wise purification) in 70 observations

No of Vega (urge)	No: of observations	%
5 - 15	36	51.42
15 - 25	21	30
25 - 35	13	18.57

From the pilot study and the clinical study, it was found that all the participants passed *Vega* (urge) in the ranges 5 -15, 15 - 25 and 25 - 35. Hence these ranges were kept in the proforma for the evaluation of *Vaigikeeshudhi* (urge wise purification)

Table 3: Aantikeeshudhi (last output wise purification) in 70 observations

Contents of last Vega (Urge)	No: of observations	%
Clear fluid	13	18.57
<i>Pitta</i>	24	34.28
<i>Kapha</i>	33	47.14

All the participants passed *Kapha*, *Pitta* or clear fluid in the last *Vega*. So they were kept in the proforma

Table 4: Maanikeeshudhi (volume wise purification) in 20 observations

Maana (Volume)	No: of observations	%
<1000 ml	7	35
1000 - 2000 ml	12	60
>2000 ml	1	5

In preference to 2, 3 and 4 *Prastha*, ranges <1000ml, 1000 - 2000 ml and > 2000 ml were selected for the proforma. The finalised proforma is given below.

Table 5: Assessment proforma Samyakoviriktalakshana (Ideal Purificatory Symptoms)

Criterion {Immediately after Virechana (Purgation)}	
I. Laingikee	✓ / X
• <i>Shareeralaghava</i> (significant lightness of body)	
• <i>Annaabhilaasha</i> (desire to take food)	
• <i>Dourbalya</i> (complete exhaustion)	
• <i>Kukshishuddhi</i> (complete evacuation)	
• <i>Vyaadhiupashama</i> (relief from symptoms)	
II. Maanikee	Score
• Less than 1000 ml	1
• 1000 to 2000 ml	2
• More than 2000 ml	3
III. Aantikee	

• Clear fluid	1
• Pitta / Yellow fluid	2
• Kapha / Mucoïd discharge	3
IV. Vaigikee*	
• 5 to 15	1
• 15 to 25	2
• 25 to 35	3

Pravarashuddhi (Finest purification) → 4 or 5 *Lakshana* + score 8 or 9

Madhyamashuddhi (Moderate purification) → 4 or 5 *Lakshana* + score 5 to 7 or 3 *Lakshana* + score 6 to 9

Avarashuddhi (Least purification) → 4 or 5 *Lakshana* + score less than 5
or
3 *Lakshana* + score less than 6
or
Less than 3 *Lakshana*

*Vega (Urge) to be counted as number of evacuations through anal orifice followed by a pause.

ii) Pro forma validation

After developing the proforma, its validity was tested by the following validation methods:

1. Face validity
2. Content validity
3. Construct validity

4. Criterion validity

Face validity was checked in terms of spelling, grammar, layout, readability, transliteration, unambiguousness and overall appearance. Content validity was checked among subject experts. Construct validity was evaluated. Criterion validity was calculated by comparing the pro forma with the gold standard in 10 observations. All the *Lakshanas* (symptoms) mentioned in the classics and other texts were taken as gold standard. Statistical significance and confidence level of kappa were calculated.

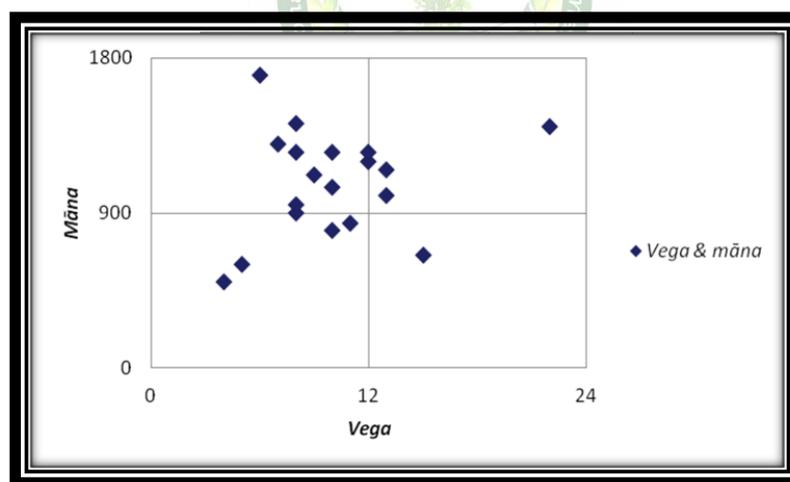
Table 6. Observed and Expected rate for kappa statistic

Observed rate (P ₀)	Expected rate (P _e)
0.8	0.58

$$K = [P_0 \cdot P_e] / [1 - P_e]$$

On face validation average score of 63 out of 70 was found. For content validity, out of 32 experts 23 agreed 80% or more. The validity of developed pro forma against the gold standard was estimated as 80%. Kappa was calculated as 0.52.

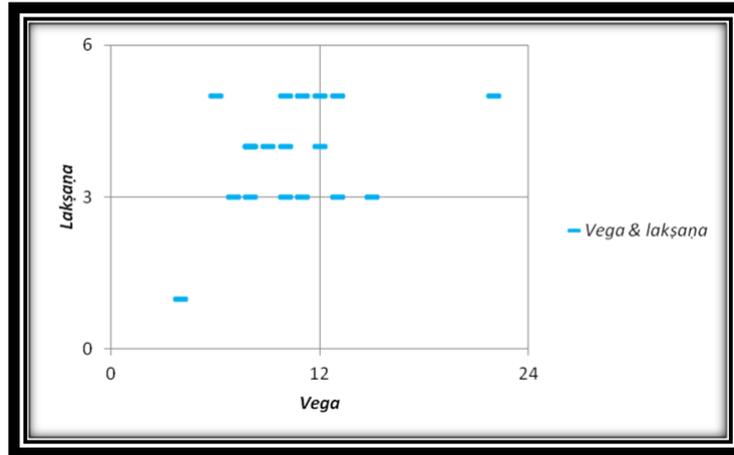
Scatter diagram showing Vega (Urge) and Maana (Volume) (No correlation)



Kaphanta (Kapha dosha) and Vega (urge) association

Criterion	Kaphānta present	Kaphānta absent	P value
Vega < 10	4	5	P* = 1.00
Vega > 10	4	7	

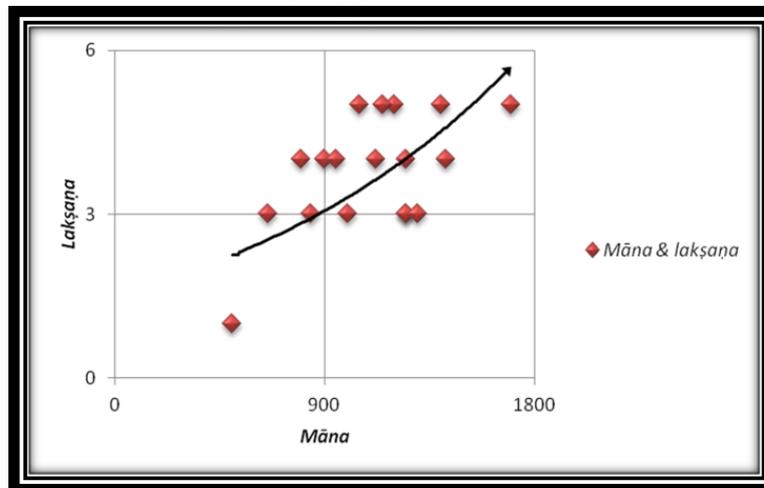
Scatter diagram showing Vega (urge) and Lakshana (symptom) (No correlation)



Kaphaanta (Kaphadosha) and Maana (Volume) association

Criterion	Kaphānta present	Kaphānta absent	P value
Māna < mean	4	7	P* = 1.00
Māna > mean	4	5	

Correlation graph of Maana (Volume) and Lakshana (Symptoms) (Positive correlation)



Kaphaanta (Kapha Dosha) and Lakshana (Symptoms) association

Criterion	Kaphānta present	Kaphānta absent	P value
4 or 5 lakṣaṇa	5	7	P* = 1.00
Less than 4 lakṣaṇa	3	5	

RESULTS

The four criteria for assessment of *Samyavirikta lakshana* (ideal purificatory symptoms) are independent. They have to be evaluated separately, and for the determination of *Shuddhi* (purification) they have to be considered together. *Maana* (Volume) was found to be having direct relation with *Lakshana* (symptoms) but was not excluded from the pro forma due to limited number of observations on *Maanikeeshuddhi*. (Volume wise purification) The pro forma had face validity of 90%. Content Validity Ratio (CVR) was calculated as 0.44 on 32 experts. The pro forma had good Construct validity. Kappa statistic for Criterion validity was statistically significant

(>0), and Confidence interval was Moderate agreement (0.52).

CONCLUSION

It was not possible to imply *Maana* (Volume) by number of *Vega* (urges) or vice versa. This finding showed that while determining the *Shuddhi* (purification) the criteria *Vega* (urge) and *Maana* (Volume) had to be evaluated separately. Strength of association between *Vega* (Urge) and *Lakshana* (symptoms) as well as *Maana* (Volume) and *Lakshana* (symptoms) showed that number of *Vega* (urge) could not affect *Lakshana* (symptoms) but *Maana* (Volume) could do so. The study showed that *Maana* can be implied by the number of *Lakshana*

(symptoms) attained. Testing of association between *Kaphanta* (last output as *Kapha Dosha*) with *Vega* (urge), *Maana* (volume) and *Lakshana* (symptoms) showed that *Kaphaanta* (*Kapha* as the last output) was not dependent on *Vega* (urge), *Maana* (Volume) or *Lakshana* (symptoms) and therefore *Aantikeeshuddhi* (last output wise purification) needed to be evaluated separately. Attainment of *Kaphaanta* (*Kapha* as the last output) may depend on various factors like *Prakruti* (Body Constitution) *Dosha* dominance, *Kaala* (Season, time of the day etc.), Drug (Purgative medicine) etc.

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