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Development of *Kostha* Assessment Tool and its Validation in *Katīgraha* (Low Back Ache) Patients with *Sinduvāreranda Taila*

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ABSTRACT

Background: In the field of Ayurveda, scientifically developed and validated assessment tools are less. *Kosthaparikşa* is an important diagnostic tool, for the administration of drugs and to assess the*samyakpravṛthi* of each *Pancakarma* and also has implications in determiningthe line of management of any disease. But a validated assessment tool was not available and the assessments were often subjective. So the current study was planned and conducted in two stages.

Methods: In 1st stage, assessment tool for *koştha* was systematically developed in 11 stages starting from preliminary conceptual decision to item analysis. Content validity, face validity, reliability measures, translation and back translation were done. Factor analysis to state the % of variance of each item and Cronbach's alpha for reliability were performed. In 2nd stage, the developed tool was compared with current clinical practice of*koştha* assessment through a comparative clinical trial for validation. The *sodhana* of 2 groups of 15 *Katigraha*patients each with administration of *Sinduvārerandataila* in *koştha*specific dose was compared. Assessment of *sodhana* was done on frequency, latency, duration, consistency of stool and Visual Analogue Scale (VAS) for pain.

Results: The *kostha* assessment tool with 10 items was developed and validated. On comparing *sodhana* between two groups frequency, latency, watery consistency of bowel evacuation and VAS were more significant in group which is assessed by developed tool and no difference observed for duration and mushy consistency.

Conclusion: A significant difference was there in assessment of *koştha* by developed tool and current clinical practice.

Key Words *Kostha*, Assessment tool, *Sodhana, Sinduvārerandataila, Katigraha*

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INTRODUCTION

The efficacy of *Pancakarma* depends upon the proper time and dose of administration of medicine. *Koṣṭha* is an important factor responsible for determining the *samyakpravṛthi* of each *Pancakarma*. The importance of assessment of *Koṣṭha* is mentioned in the *pūrva* and *pradhāna* stage of *Pancakarma* like *snehapāna,vamana, virecana* and *vasti*. The *Koṣṭha* can be assessed by the duration of *samyak*

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snigdhatha, and through purgation obtained by the administration of milk, *trivṛth, syāma* etc. The *Koṣṭha*s were classified on the basis of *doṣic* predominance indicated by the nature of bowel habit of individuals.

The word *koṣṭha* applies to both physiological and anatomical entities. The physiological entity is the functional nature of bowel habit since birth. The anatomical entity includes all the organs of abdominal and thoracic cavities. *Koṣṭha* is definitely associated with *prakṛti* formed at the time of conception. For the administration of drugs in each stage of Panchakarma, *koṣṭha parīkṣa* plays a key role. Administration of *pūrva karma* and *pradhāna karma* of panchakarma without considering the *koṣṭha* leads to severe complications. So it is obligatory to include *koṣṭha parīkṣa* in the panchakarma practice for better results.

No scientific tools were available for *Koṣṭha* assessment in current practice. It was assessed primarily through one or two parameters like the frequency of bowels and consistency of stool, which were inadequate for the effective assessment and in turn reduce the efficacy of treatment. Available *koṣṭha* assessment tools were not validated, not uniform, not clinically relevant, and did not consider the lifestyle, food habits, digestive strength, straining, satisfaction etc, which play a role in the nature of bowel habits. So a scientific evaluation was necessary for the proper assessment of *koṣṭha*. To be useful, the tool must demonstrate good psychometric properties, such as reliability and validity, and be in a format that is easy to use.

The objectives of the study were-

- To develop a tool for assessment of *koṣṭha.*
- To validate the tool in *Kaṭīgraha* patients with *Sinduvāreraṇda taila*.

MATERIALS AND METHODS

The whole study was planned into 2 stages. Stage 1 was the Development of *Koṣṭha* assessment tool. The methodology adopted was the Descriptive Cross sectional study. Stage 2 was the Validation of tool in *Kaṭīgraha* patients which was done as Comparative clinical trial.

Informed consent

A pamphlet in Malayalam language containing details of the research was given to participants. Consent form in Malayalam language was prepared and prior consent of all participants were obtained on the consent form. A case record form was made to record the details of the case.

Ethical considerations:

The study synopsis was placed before Institutional Ethics Committee of V.P.S.V. Ayurveda College, Kottakkal (IEC/Doc/17/2016 Dated 18/04/2016). After various level of scrutiny and subsequent modification based on their recommendation, the whole plan of study was approved by Institutional Ethics committee (IEC) prior to starting of work (IEC/CI/17/16 Dated 28/04/2016).

Stage 1. Development of *Koṣṭha* assessment tool

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The following steps were performed.

A. Preliminary conceptual decisions.

B. Item generation.

C. Item selection.

D. Expert panelling- Assessment of Face validity, Content validity.

E. Formatting, Sequencing, Wording

F. Translation & Back translation

G. Pre testing

H. Pilot study

I. Generation of refined instrument

J. Administration in main sample

K. Item analysis.

Step A – Conceptual decisions

Here some conceptual decisions were made about the assessment tool. It was decided to develop a physician administered tool for assessment of *Koṣṭha*. *Koṣṭha* should be assessed before the administration of any kind of medicine. In Āyurveda some studies have been carried out related to *Koṣṭha* assessment[1-4]. But these methods were not validated, neither uniform, nor clinically relevant, as they did not consider the lifestyle, food habits, digestive strength, straining during defecation, satisfaction etc. which play a role in the nature of bowel habits. So planned to develop a consistent, reliable and validated assessment tool which is relatively short and simple. Literature review on *koṣṭha* in the available classics were done.

Step B – Item generation

Items in the tool have been selected based on data collected from literature review, opinions of peers and from patients. All available data about concept of *Koṣṭha* was collected from available classical text books, articles etc. An open ended survey was conducted among 65 patients, 10 PG scholars and on 10 UG students for the selection of items in the tool. 65 patients were selected from the IPD of VPSV Ayurveda College Hospital Kottakkal. 10 PG scholars and 10 UG students were selected from VPSV Ayurveda College Kottakkal.

The questions included in the survey were,

1) Frequency of bowel

2) Time of bowel evacuation

3) Factors influencing bowel evacuation,

a) Dietary intake

b) Beverages

c) Travel

d) Place

e) Season

f) Psychological stress

g) Medication

h) Addictions

i) Busy schedule

j) Sleep pattern

k) Appetite

l) Other factors if any

Positive response was obtained from all the participants. Based on the data secured from them preliminary *koṣṭha* assessment tool was prepared. The preliminary *koṣṭha* assessment tool included 6 items. Each item subdivided into four which carried a score of 1/2/3/4 respectively. After summing up of whole response the *koṣṭha* was assessed. The following items were included in preliminary *koṣṭha* assessment tool.

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1. Frequency of bowel
2. Consistency of bowel
3. Changes with dietary intake
4. Effect with psychosocial stress
5. Effect on bowel evacuation by continuous long journey
6. Abdominal feeling.

Step C- Item selection

The preliminary *koṣṭha* assessment tool was submitted to 18 subject matter experts in various department in VPSV Ayurveda College, Kottakkal for their suggestions for refining the tool. Considering the suggestions from all subject matter experts, some modifications were made. 11 items were included for assessment of *koṣṭha*.

1. Frequency of bowel- Number of episodes of bowel evacuation in normal conditions
2. Consistency of bowel- Form of stool
3. Satisfaction on bowel evacuation- Feeling of complete evacuation after defecation
4. Time of defecation- Time of bowel evacuation in normal conditions
5. Colour of stool- Colour of stool in normal conditions
6. Associated symptoms- any effort/symptoms before/after/during bowel evacuation
7. Abdominal feeling- Any feeling of abdominal discomfort after intake of food
8. Effect on bowel evacuation with psycho-social stress
9. Changes with dietary intake
10. Any alteration in bowel evacuation w.r.t. dietary intake, Effect on bowel evacuation by continuous long journey
11. Level of *agni* – Strength of *agni* of individual in normal conditions

Step D- Expert panelling- Assessment of Face validity, Content validity

It is the main component of the tool development. Aim is to obtain the most reliable consensus among a group of subject matter experts by a series of questionnaire and by using content validity index for final selection of items for the tool. The modified *koṣṭha* assessment tool was submitted to 16 subject matter experts. The matter experts included 11 teaching faculties from VPSV Ayurveda College Kottakkal, 5 from outside the campus. Those included one Government medical officer and 4 teaching faculties from different Government Ayurvedic institutions.

Assessment of content validity

For the assessment of content validity the tool was sent to 16 subject experts. They were provided with a content validity assessment sheet. Each item rated as strongly agree, agree, neither agree/ disagree, disagree and strongly disagree. Content validity index of each items were calculated using the formula[5],

$$CVI = \frac{\text{No: of experts rating relevant}}{\text{Total no: of experts}}$$

Here the rating of strongly agree and agree together taken as relevant. The rest of the responses were taken as irrelevant. The Content Validity Index (CVI) of each items were calculated. Among those, the CVI of 10th item was 0.562, was very less when compared to the other ones. So the 10th item was excluded from

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the assessment tool. So the final *koṣṭha* assessment tool contained 10 items. Each item was subdivided into three, and each response carrying a score of 1/2/3 respectively. The *koṣṭha* was subdivided into five categories namely *mṛdu, madhyama mṛdu, madhyama, krūra madhyama* and *krūra koṣṭha.*

Assessment of face validity

For the assessment of face validity a scoring sheet was prepared to evaluate the readability, spelling, grammar, lay out and style, clarity of language, feasibility and overall appearance of tool. It was also subjected to the 16 subject matter experts. Asked them to score those features and give points out of maximum 10 marks. The average of the score was calculated. For readability, 81.25% of SME scored as above 8. For spelling 100% of SME gave a score above 8. For lay out and style, 62.5% recorded a score above 8. For grammar 81.25% of expert scored above 8. For clarity 68.75% recorded a score above 8.

Step E- Formatting, Sequencing, Wording

The developed assessment tool changed into a scientific format and sequence. The main aim of this was to avoid overlapping, discard the synonymous words and arrange the tool in an order[6]. Suggestions from content validity experts were considered. The external features of stool like frequency, consistency and colour were selected as the first three items. Then placed the remaining items.

Step F- Translation and back translation[7]

The aim of the translation process is to achieve Malayālam language versions of the English instrument that are conceptually equivalent in each language. Malayālam is the familiar language of the target population. So the main aim was to convey the tool effectively. Translation was done by two subject matter experts in VPSV Ayurveda College, Kottakkal. One SME from the Dravyaguṇa department and the second from the Śalyatantra department. Then the Malayālam translation of the assessment tool was back translated into English language. It was done to obtain a conceptual equivalence among matter experts. It was done by another two SME in VPSV Ayurveda College, Kottakkal. One SME from the department of Svasthavrutta and the second from the department of Racanāśārīra.

Step G – Pre-test the draft tool

In order to improve the feasibility of tool opinions from experts and target population were considered. 10 target participants were selected from the Pancakarma OPD of VPSV Ayurveda College Hospital. Their *koṣṭha* were assessed by the developed tool. Positive responses were obtained for all items. All questions were easily understandable to them. Opinions from the content validity experts were also considered.

Step H- Pilot study

It was done in a small sample of target population to check the feasibility and reliability of tool. Reliability was assessed by inter rater reliability and test retest reliability.

Test retest reliability

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Koṣṭha of 20 participants with *kaṭīgraha* were assessed by the developed tool. Participants were selected from the Panchakarma OPD of VPSV Ayurveda College Hospital, Kottakkal. *Koṣṭha* of same participants were reassessed after 1 week by the same evaluator.

Inter rater reliability

5 participants with *kaṭīgraha* were selected from Pancakarma OPD of VPSV Ayurveda College Hospital. *Koṣṭha* of these participants were assessed by two different SME from Pancakarma and Śalyatantra department on the same day.

Step I- Generation of refined instrument

The final version of refined instrument was developed. The developed *Koṣṭha* assessment tool consisted of 10 items. Each item was subdivided into three responses. Each response was scored as 1/2/3 respectively. After obtaining responses for all items, total score was calculated by summing up of each score. Based on the final score the *Koṣṭha* of participant could be identified.

Step J- Administration of tool in main sample

The finalised draft tool then administered in main target population with *kaṭīgraha*.

Sample size = No: of items ×10

100 participants were selected from the Pancakarma OPD of VPSV Āyurveda College Kottakkal based on the inclusion, exclusion and diagnostic criteria. Those were consulting in Pancakarma OPD for the first time. Their *koṣṭha* were assessed in the first sitting itself. Among the 100 participants 30 were males and 70 were females.

Step K- Item analysis

Proper statistical tests were done by using SPSS. Factor analysis and Cronbach's alpha were calculated. Factor analysis was performed with 100 participants in main sample, and % of variance of each factor was calculated. Based on the correlation matrix Cronbach's alpha was performed to check the reliability of assessment tool.

Stage 2.Validation of *Koṣṭha* Assessment tool

Validation of *Koṣṭha* Assessment tool in *Kaṭīgraha* patients with *Sinduvāreranda taila* was done.

Objective

To validate the Tool in *Kaṭīgraha* patients with *Sinduvāreranda taila.*

Methodology

Study design – Comparative clinical study

Sample size – 15 in each group ($n=4pq/d^2$, $4\times84\times16/202=13.44$, considering the drop out, n=15)

Sampling method – Convenience sampling

Group A – *Koṣṭha* assessed with *Koṣṭha* Assessment Tool

Group B – *Koṣṭha* assessed with current clinical practice

Study setting – OPD of VPSV Ayurveda College Hospital, Kottakkal

Study period – 18 months

Trial Drug – *Sinduvareranda taila* with batch no: 16A3750 collected from GMP certified company

Dose – 10 – 50 ml

Anupana – Hot water

Diagnostic criteria

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- Pain in *kaṭīdeśa*
- Any one of the following test is positive
  - Genslen's test
  - Pump handle test
  - Schober's test

All of the above tests were used to find out any abnormalities in lumbar and sacroiliac region. So for conformation of LBA those test were performed.

Inclusion criteria

- Patients with *Kaṭīgraha*
- *Śodhanārha*
- Age group 20 – 60 years
- No discrimination of sex
- Participants who have given informed consent

Exclusion criteria

- With known systemic diseases
- With GIT disorder that may change bowel habit
- Known fracture or dislocation of vertebrae
- With Diabetes mellitus
- With known gynaecological disorders which may produce pain in *kateedesha.*

Procedure of *Śodhana*

Participants with *kaṭīgraha* were grouped into two groups, group A and group B. Patient selection was according to convenience sampling. The participants with *kaṭīgraha* attended the Pancakarma OPD were allocated into group A. Those participants attended the Śalyatantra OPD were selected to group B. In group A, *koṣṭha* assessed by developed *koṣṭha* assessment tool and in group B it was done by current clinical practice by expert in Śalyatantra OPD. The dose of *virecana ouṣadha* was selected according to *koṣṭha* which was mentioned in Vangasena samhita[8]. For *mṛdu, madhyama* and *krūrakoṣṭha* it was 1 *karṣa*, ½ *pala* and 1 *pala* respectively. Here 1 *karṣa* was taken as 15 ml, ½ *pala* as 25 ml and 1 *pala* as 50 ml. For *mṛdukoṣṭha*, the dose of *virecana ouṣadha* was 15 ml, for *madhyama* 25 ml, and for *krūrakoṣṭha* 50 ml. The *śodhanaoushadha* was *Sinduvareranda taila*[9,10], which was collected from a GMP certified company. *Śodhana ouṣadha* was administered along with hot water at morning 8 am. Patient was advised to notice the time of 1st bowel evacuation, total number of frequency of evacuation with time, consistency of stool using Bristol stool scale in each evacuation[11], time of last evacuation. Participants were provided with a check list contained all these information. After the completion of *śodhana* advised to take head bath followed by intake of gruel. All features of *śodhana* was evaluated through telephone on next day.

Assessment of *śodhana*

Assessment of *śodhana* was done with:

- Frequency of evacuation
- Latency of evacuation
- Duration of bowel
- Consistency of stool- using Bristol stool scale
- VAS for pain before and after treatment

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OBSERVATIONS AND RESULTS

Distribution of participants according to presenting complaints is given in Table 1. Among the 30 participants in both groups, all were having a localized LBA. 13 participants in group A and 10 participants in group B had complaints of tenderness. 14 participants in group A and 11 participants in group B were having restricted movements. 4 participants in group A and 2 participants in group B had numbness.

Table 1 Distribution of participants according to presenting complaints

Presenting complaints	Group A		Group B	
	No	%	No	%
Localized LBA	15	100	15	100
Tenderness	13	86.6	10	66.6
Restricted movements	14	93.3	11	73.3
Numbness	4	26.6	2	13.3

In group A, *koṣṭha* of patients were assessed by developed *koṣṭha* assessment tool, and in group B it was done by current clinical practice. *Śodhana* was assessed by frequency, duration, latency, consistency of stool and VAS for pain. The data of Group A and Group B were checked for normality by drawing Q-Q plots using Excel worksheet. Since the data were normally distributed, parametric test (unpaired t- test) was used to find out the level of significance between the groups.Comparison of assessment of *śodhana* between two groups using unpaired t-test is given in Table 2. On comparing both groups significant difference was observed in frequency of evacuation, latency of evacuation, consistency of stool (Grade 7) and in VAS for pain at $p<0.05$.

Assessment of *śodhana*	Mean Group A	Mean Group B	p-value
Frequency	5.46	4.0	0.001
Latency	64.33	84.33	0.028
Duration	2.66	2.56	0.34
Consistency of stool (Grade 6)	1.2	1.33	0.54
Consistency of stool (Grade 7)	4.26	2.66	0.00
VAS for pain	2.46	1.33	0.001

Table 2 Comparison of assessment of *śodhana* between two groups (unpaired t-test)

DISCUSSION

***Koṣṭha* assessment tool:** In this study *Koṣṭha* was assessed through the features of bowel evacuation in normal conditions.The factors like frequency, consistency, colour, associated symptoms, time of defecation, satisfaction on bowel evacuation,abdominal feeling, changes with dietary intake, effect on bowel evacuation with stress / anxiety, and level of digestion were considered for the assessment.

Koṣṭha was divided into five types like *mṛdu*, *madhyamamṛdu*, *madhyama*, *krūramadhyama* and *krūra*. The *kapha doṣa* have an important role in determining *Koṣṭha*. *Mṛdu*, *Koṣṭha* was taken as *pitta* predominant, and the *pittakapha* predominant taken as *madhyamamṛdu*. The *kapha* predominant *Koṣṭha* was taken as *madhyamaKoṣṭha*. *Vatakapha* predominant *Koṣṭha* was termed as *krūramadhyama* and the *vāta* predominant as *krūraKoṣṭha*.

Factor analysis: Since there are 10 items in the developed tool, there was no need for further data

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Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	No of Items
0.724	0.703	10

reduction. So the purpose of factor analysis here was to state the percentage of variance which is used to determine which factor is most important. Among the 10 items, item 1 ie. frequency of bowel was found to be most important and least importance given to the 10th item in terms of % of variance.

Cronbach's alpha: Cronbach's alpha score for 50 participants was calculated and was found to be acceptable (A score above 0.6 is considered as acceptable). The score is given in Table 3.

Table 3 Reliability statistics

This result shows that the assessment tool with 10 items have good internal consistency and the tool is reliable. The developed *Koṣṭha* assessment tool is given in Table 4.

Clinical trial: In group A, among 15 participants 13 participants were having *madhyamaKoṣṭha,* and 2 with *krūra Koṣṭha.* In group B, 12 participants were having *madhyamaKoṣṭha,* and 3 of them with *krūraKoṣṭha.*

Table 4 *Koṣṭha* assessment tool

1. Frequency of Bowel movements - number of episodes of bowel evacuation in normal conditions		
a)	More than once daily	1
b)	Daily once	2
c)	Once in 2 or more days / with the aid of purgatives	3
2. Consistency of stool – form of stool		
a)	Mushy consistency/ semi solid/soft/ no firm shape	1
b)	Well formed / firm shape	2
c)	Very hard or fragmented	3
3. Colour of Stool-colour of stool in normal conditions		
a)	Yellow	1
b)	Brownish yellow	2
c)	Dark brown/ blackish	3
4. Associated symptoms– features prior / during / after bowel evacuation		
a)	Large quantity, foul smelling/ hot stool/with burning sensation	1
b)	Easily evacuating , oily stool with no discomfort	2
c)	Less quantity, frothy/ noisy/with flatus	3
5. Time of defecation– time of bowel evacuation in normal conditions		
a)	Early morning , within hours after wakeup	1
b)	Early morning only after intake of hot water/tea/coffee	2
c)	Only after breakfast / no fixed time	3
6. Satisfaction on bowel evacuation– feeling of complete evacuation after defecation		
a)	Attained with more than one bowel evacuation	1
b)	Attained with one evacuation	2
c)	Dissatisfied	3
7. Abdominal feeling- any feeling of abdominal discomfort after intake of spicy/ starchy foods		

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a)	Acid eructation/ burning sensation/ abdominal rumbling	1
b)	Comfortable	2
c)	Abdominal fullness/ tightness/ flatulence	3
8. Changes with dietary intake– any changes in bowel evacuation pattern with dietary intake		
a)	Loose bowel with hot milk/tea/payasam (sweet porridge) /drum stick leaves/wheat/fruits/chicken/ meat dishes/ any unfamiliar food like pizza	1
b)	No change	2
c)	Straining with chicken / meat dishes/ Bengal gram	3
9. Stress or anxiety impact on bowel evacuation		
a)	Loose bowel by stress/ anxiety/ urgency	1
b)	Abdominal discomfort without bowel evacuation	2
c)	No change / constipation	3
10. Level of Digestion– assessed with *jeernahara lakshana* 4 hours after a regular meal		
a)	Digest any amount of food in less time (2-3 hours)	1
b)	Normal digestion- 4 hours	2
c)	Digest with longer time- more than 4 hours	3

Score *Mridukoshta* - <10; *Madhyama Mridukoshta* - 11 to 15, *Madhyamakoshta* - 16 to 21, *Kroora Madhyamakoshta* - 22 to 25, *Kroorakoshta* - 26 to 30

In group A, where *Koṣṭha* of participants assessed by newly developed and validated assessment tool adequate or similar bowel evacuation occurred in different *Koṣṭha*. In group B, inadequate bowel evacuation was observed, as their *Koṣṭha* was assessed by current clinical practice. If they were assessed by the new developed and validated tool they might be included under *madhyamamṛdu*, *madhyama* or *krūramadhyamaKoṣṭha* and could give *Koṣṭha* specific *śodhana* drug to them.

Limitations

- There was a lack of direct evaluation of assessment of *śodhana*, which was done through telephone enquiry
- The tool is not fit for diseases having direct involvement of *koṣṭha* like *atisāra, grahaṇi*, *arśa* etc.

Recommendations for further study

- Likert scale can be used for assessment
- For the administration of tool in main sample, good (300)/ very good (500)/ excellent (1000) sample can be used
- Studies can be conducted to find out association between *koṣṭha* and *prakṛti, agni* etc.

CONCLUSION

Koṣṭha assessment tool was developed and validated. Statistically significant difference was noted between the *koṣṭha* assessed by the developed *koṣṭha* assessment tool and the current clinical practice in parameters like frequency, latency, watery stool consistency of *śodhana* and VAS for pain. No statistical difference was noted between duration and mushy consistency of *śodhana*. The tool is a physician administered tool. So it can be easily administered in illiterate patients also.

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