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Study Protocol

Development and Validation of Diagnostic Tool for *Janu Sandhigata Vata* with Special Reference to Knee Osteoarthritis- Mixed-Method Diagnostic Validation Study Protocol

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ABSTRACT:

Background: In *Ayurveda,* emphasis is placed on proper diagnosis before giving treatment. A proper diagnosis involves comprehensive assessment of multiple factors like *Dosha, Dhatu etc.* This personalized framework is influenced by physicians' perception there causing variability in clinical judgement. Standardization, reproducibility, and objectivity of diagnostic tools are increasing and contemporary science has well established it. Unlike *Ayurveda* which relies on classical texts and physicians' expertise. This gap creates challenges in ensuring uniformity in diagnosis, especially in clinical research, interdisciplinary practice and evidence-based validation. Development of diagnostic tool is needed to bridge this gap and enhance the credibility of *Ayurvedic* diagnosis. *Sandhigata vata* is a leading disease treated in *Ayurveda* and diagnosed based on *Laxana* due to *vata* vitiation. No standard diagnostic tool is available for it. **Objective:** To diagnose osteoarthritis using Ayurvedic and modern diagnostic approaches and to develop and validate a standardized diagnostic tool/process for *Janu Sandhigata Vata*. **Methodology:** The study will be conducted in four phases. Phase I will identify questionnaire items and response options through literature review, survey, focus group discussions, and in-depth interviews. Phase II will involve pre-testing of the items and response scales among *Ayurveda* physicians and patients with Janu Sandhigata Vata. Phase III will involve domain reduction and expert item revision to retain relevant items and remove unsuitable ones. Phase IV will assess the validity and reliability of the developed diagnostic tool. Both qualitative and quantitative methods will be employed, followed by appropriate statistical analysis. **Results:** In January 2025 present study was initiated. It includes both qualitative and quantitative Methods. All four phases followed by statistical analysis is expected to be completed by June 2027. **Conclusion:** This study protocol is designed to develop and validate a diagnostic tool/ process and develop standard methodology to diagnose diseases in *Ayurveda*.

KEYWORDS: *Ayurveda,* Diagnostic tool, Janu *Sandhigata Vata,* Osteoarthritis, Protocol, validation

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1. INTRODUCTION

Sandhigatavata is mentioned under *Vatavyadhi* (disorders due to vata) by all *Acharyas*. *Acharya Charaka* has mentioned *Nanatmaja Vyadhi* of all three but a separate chapter has been contributed to only *Vatavyadh*i. [1] The OA is often used in *Ayurveda*, roughly translating to '*Vata* is seated in the knee joint' and is characterized by *Vatapurna Dhrutisparsha* (swelling as if filled with vayu on palpation), *Sandhishopha* (swelling in the joints), *Prasarana Akunchana Vedana* **(**flexion and extension of joint with pain), *Sandhi Shula* (joint pain), *Sandhi Karya Hani* (loss of joint mobility). [2] [3] It is most commonly seen in *Vrudha Avastha* (old age) due to the *Vata* predominant phase of life and *Kshya* (depletion) all *Dhatus*. *Sandhivata* (OA) affects all class of people with varying conditions due to their diet, occupation & environmental factors and *Vata* vitiating *Aahara* (food), *Vihara* (regime). *Ayurvedic* diagnosis involves *Laxana Swaroopa*, *Nidana, Samprapti, Avastha,* i.e. external and internal factors that affect the body, mind, and soul. It also involves assessing lifestyle and social well-being, which, together with the above, can lead to imbalance and cause disease. Through proper *Roga- Rogi Pareeksha*, *Ayurvedic* diagnosis comprehensively reaches to identifying the *Dosha-dushya* imbalance. Pathological imbalances in *Ayurveda* differ from concepts of modern medicine. *Ayurveda* understands the pathology in terms of dynamic *ayurveda* principles such as *dosha* (body humors*), Dushya* (tissues), *Srotas* (channels), *Shrotodushti* (abnormality in channels), *Agni* (digestive fire), and *Ama* (toxin). Based on these principles and their understanding, the entire *Samprapti* (pathology) is noted. To understand these *Samprapti* principles, invariably the remaining four components of *Nidanapanchaka* play a significant role and accordingly the treatment is planned. [4]

Diagnosis is believed to be the definition of a snapshot within a constant flow of physiological and pathophysiological factors. This enables the *Ayurvedic* physician to treat a case without giving the disease a name, by dealing with the aforementioned principles. Since *Vata* is the main cause or it's a *Vataj* disease hence *Snehana* (oiliation), *Swedana* (fomentation) and *Mrudu Samshodhana* (detoxification) & *Basti* (enema) is adviced line of treatment. [1] The National Ayurveda Morbidity code for *Sandhigata vata* is AAE-16, has been compared to the signs & symptoms of Osteoarthritis (ICD-11 TM2: bone, joint and muscle disorders (TM2) (SP10-SP1Z). [5] The Modern (allopathic) diagnosis of "osteoarthritis of the knee" doesn't have a direct equivalent in the *Ayurvedic* diagnostic system. It is impossible to generate a precise equation to perfectly translate modern medical nomenclature one to one with *Ayurveda*'s because, there are additional diagnostic components other than symptoms necessary for developing a treatment plan.

Osteoarthritis is the leading cause of pain & disability in older adults worldwide. Globally OA is ranked 8th in all diseases and covers around 17% of musculoskeletal Problems. Osteoarthritis affected nearly 528 million people worldwide in 2019, almost 113% raise since 1990. 60% of people affected by osteoarthritis are female and about 73% are older than 55 years of age**.** [3] [5] Europe and USA reflect highest worldwide frequency of OA. India has higher proliferative rate of OA Almost all persons by age 40 have some pathologic change in weight bearing joint. [6] Since OA is a most commonly disturbing joint disease. Burden of *Sandhigata Vata* is Global prevalence (16·0% [95% CI, 14·3%-17·8%]) and incidence (203 per 10,000 person-years [95% CI, 106–331]) of knee OA. [7] Indian prevalence of knee OA was found to be 28.7%. The associated factors were found to be female gender (prevalence of 31.6%) (P = 0.007), obesity (P = 0.04), age (P = 0.001) and sedentary work (P = 0.001). [8] Prevalence of OA in Karnataka is 10% and in Goa is 13%. [6] Highest diagnostic proportion in the *Ayurveda* hospital is of *Sandhivata* (33.92%) followed by *Katishula* (31.91%) and *Amavata* (22.32%). *Asthi Dhatu Kshaya* and *Greevastambha* were the clinical entities

represented by 9.3% and 5.58% patients respectively. [9] The majority of *Ayurvedic* clinical studies conducted today use generic instruments that are based on references from traditional texts, even if they haven't been properly validated. Additionally, given that the pathological concepts of *Ayurveda* are based on the functional derangements of dosha, there are also no established gold standards like histopathology, for validating these tools. However, diagnostic research remains a relatively underexplored domain in Ayurveda, and there is a lack of well-defined standards for the development and assessment of such diagnostic tools. American College of Rheumatology classification criteria for osteoarthritis knee don't include the *Ayurveda* diagnostic Principles domains, which are essential in establishing diagnosis in *Ayurveda* and also planning the treatment. Hence, diagnosing OA in *Ayurveda* using ACR alone is not sufficient due to differences in diagnostic paradigm. The available tool for diagnosis is through expert diagnosis, which varies, resulting in diagnostic inconsistencies and interrater variability. Therefore, there is a need for developing a comprehensive Ayurvedic diagnostic assessment tool that standardizes these classical Ayurveda diagnostic principles and adds available biomedical diagnostic approaches like laboratory and X-ray for diagnosing OA in *Ayurveda*.

Hypothesis

Ho: the developed tool is not valid and reliable tool for diagnosing *Janu Sandhigata Vata*.

H1: the developed tool is valid and reliable in diagnosing *Janu Sandhigata Vata*

Objective: To design and validate a diagnostic tool for *Janu Sandhigatavata* .

2. METHODS

Protocol version: version 2 and January 2026

Recruitment status: not yet started.

Trial Design: - The present study applies mixed methods design to develop a standardized diagnostic Performa /tool for *Janu Sandhigatavata*. Study will be conducted in 4 phases. The study is a sequential exploratory mixed method carried out in 4 phases first qualitative Phase 1 followed by quantitative validation. The study framework is as below

(Qualitative study): Phase I: -Defining the items of the questionnaire and their response Phase II: - Pre-testing

Phase III: - Domain reduction/Expert item revision

Quantitative study: Phase IV: - Reliability and Validation

Phase I: -Defining the items of questionnaire and their response

Objectives

a) To define the diagnostic criteria: -To List the elements of diagnostic criteria in both Ayurveda and modern diagnostics both laboratory investigations and X-ray imaging and specify standardized case definition, by stating clear operational definitions.
b) To devise item: -To formulate questions for each of the elements & enlist number of questions needed to elicit each element.
c) To select response scales: - To select response scales (Likert scale, Thurstone's method, or Guttman scaling) depending upon the need as well as the factor being assessed.

Methos

a) Literature review – A comprehensive review of classical textbooks, Published articles / online databases, Manual search of available literatures will be done to generate preliminary domains.

b) Survey: - online survey with a validated questionnaire will be conducted among the Expert Ayurvedic practitioners and researchers to understand their perspective in these domains of *sandhivata* in clinical scenarios.

c) Focus group discussion – FGD will be done involving selected experts of *Roganidana, Samhita, Kayachikitsa* and *Panchakarma* departments. Consensus conference, modified Delphi survey, and Nominal group technique will be employed to achieve agreement on diagnostic domains and items. [10]

d) In-depth interviews may be conducted if required, with domain experts to get detailed insights and refine the identified diagnostic themes and items and response.

Proposed conceptual domains: classical presentation, *Sampriti,* Laboratory parameters and imaging(X-Ray) and domain-based scoring or an ordinal scoring system may be employed. Final items, scoring, and operational definitions will emerge through sequential phases.

Phase II- Pilot study

In this phase pre-testing of the items for the questionnaire, along with their response format, will be administered in a small sample.

Objectives

a) To pretest the prepared questionnaire

b) To assess the respondent and interviewer friendliness of certain questions, or the entire questionnaire.

c) To refine the question

Methods

a) Cognitive interview – the tool will be administered to a sample of physician for evaluation of respondent friendliness and literacy level analysis.

b) Face and content validity [12] – Face validity will be assessed if items in the questionnaire are a valid measure of the concept being measured and whether the questions are related to the topic that the researcher wishes to test and for content validity of the tool, will be administered to two experts from the departments of *Kaychikitsa, Roganidana, Samhita*, and *Panchakarma*. To assess content validity, Lynn's process of content validation will be applied, and items with a content validity index of 0.83 or higher will be retained in the tool.

c) Translation review – the tool will be translated to local language (Kannada/Marathi) and back-translated by two different experts and assessed for equivalence between the original and translated version in terms of Content, Concept and Semantic facets. The pre-translated, translated and back-translated tool will be applied to two respondents each to assess equivalence within a gap of two weeks.

Phase III: Domain reduction/Expert item revision

Objective

a) To refine the tool, improve items and their response.

Methods

a) Analyzing the inputs obtained from respondents during the pretesting for relevance and understanding.

b) Item revision: The item found to have a poor face and content validity or low reliability or if there is a poor understanding of the items and response scales by the respondents will be revised.

c) Domain reduction: Overlapping and poor items will be removed, streamlining the tool while retaining its psychometric robustness.

Phase IV: Reliability and Validation

Objective:

a) To assess the Reliability of a tool.

b) To Validate (Construct, criterion, and external) the tool

Methods:

a) Reliability, [11], [12], [13]

Consistency of agreement or extent to which two or more raters agree is called as inter- rater reliability.

The Sample size will be decided depending on no of items in the questionnaire in a item to participant ratio of 1:5 or 1:10 (preferably ≥200) [11] or decided accordingly. Kappa statistics will be employed for assessing the inter-rater reliability, with an acceptance level fixed at kappa score above 0.61.

Internal consistency is the extent to which the questionnaire items are inter-correlated, or whether they are consistent in measurement of the same domain. Internal consistency is commonly estimated using the coefficient alpha also known as Cronbach's alpha.

$$\alpha = \frac{\kappa}{\kappa - 1}\left(1 - \frac{\sum \sigma_i^2}{\sigma_x^2}\right)$$

Given a questionnaire x, with k number of items, alpha can be computed as:

B) Validity:

1. Construct validity:

Objective: to evaluate whether the domains measure the theoretical concept they are intended to measure.

Methods: construct validity of domains will be evaluated by assessing their structural validity, if applicable, by administering to a large sample of patients, preferably ≥200.

Statistical plan: Exploratory factor analysis (EFA)/ Confirmatory Factor Analysis (CFA).

2. Criterion validity/ clinical validity

Objective: Evaluation of the new test's accuracy in discriminating subjects with or without the target condition, in comparison with an existing standard

Methods (panel diagnosis due to lack of gold standard to diagnose *Janu Sandigata Vata*)

The tool will be compared with a panel diagnosis consisting of two experts (blinded), who will simultaneously assess the patients. This assessment will be carried out in 6 patients.

Statistical Plan: - Mc-Nemer Sensitivity and specificity

3. External validity

Objective: Evaluate if the tool can be applied to a larger group of patients with *Janu Sandigata Vata*

Methods: The tool will be administered to a large number of patients.

Statistical plan: - correlation, predictive values and Area under ROC

Trial Duration: Following to Ethics Committee approval, the study will be initiated and completed in next 3 -4 years.

Trial site: The study will be conducted in *Ayurveda* Hospital under department of *Roganidana Evum Vikriti Vijanana.*

Study Population-

Inclusion Criteria: Phase I- Expert Ayurvedic practitioners and researchers, experts of *Roganidana, Samhita, Kayachikitsa* and *Panchakarma* departments and domain experts, all with minimum of more than 5 years of experience in the field.

Phase II- Patients with classic symptoms of *Janu Sandhigata Vata*, treating physician, and experts from the departments of *Kayachikitsa, Roganidana, Samhita*, and *Panchakarma with more than 10 years of experience*.

Phase III- Items with good face and content validity will be retained.

Phase IV- Experts (Ayurveda practitioners with Joint OPD experience of more than 10 years), treating physician and Patients with classical presentation. OA Exclusion criteria

Experts with less-than-expected experience and incomplete responses. Patients Developed as a complication of systemic diseases like Thyroid, Asthma, Malignancies, Liver disorders, Uncontrolled Hypertension, uncontrolled Diabetes mellitus & Chronic renal failure. Trauma, infections and tumors. Patients with classical symptoms of *Amavata* and *Vatarakta* and pregnant and lactating women

Outcome Measures: Primary Outcome is reliability, validity and diagnostic accuracy of the diagnostic tool

Secondary Outcomes are Cronbach's alpha, CVI, Sensitivity and specificity of the tool and Correlation with clinical, laboratory and radiological findings, predictive values and ROC.

Table 1- Timeline: Outcome measurement timepoints.

S.no	Outcomes	Timepoints
1	Devising the items and scaling response format	1-6 Months
2	Pretesting /piloting: Face and content validity	6-12 Months
3	Domain reduction content validity (CVI & correlation)	13-18 Months
4	Expert item revision (correlation)	18-24

		Months
5	Reliability and Validation (criterion & External) : Interrater reliability (kappa)	25-36
	Internal consistency (Cronbach's alpha), criterion validity (McNemar), construct validity (Exploratory factor analysis (EFA) / Confirmatory Factor Analysis (CFA) and external validity (Sensitivity and specificity, predictive values, Area under ROC)	Months

Table 2: Enrolment & assessment schedule

Assessments	Expert	Validation participants	Re-test participants
Informed consent	√	√	√
Demography	√	√	√
Phase1: Item generation	√		
Phase2: Pilot study: Content validation	√		
Face validity			
Phase3: Domain reduction/Expert item revision	√		
Phase 4: Reliability and Validation	√	√	√

Sample Size: The sample size was determined based on standard recommendations for validation studies.

- Qualitative phase: 10–15 Ayurveda experts/ until saturation for content validation in qualitative research the sample size estimation given is as stated above
- Quantitative phase: Approximately ≥200 participants for reliability, as per classical methodological literature 1:5 or 1:10, [11] item to participant ratio i.e for each item, 5 to 10 samples to be taken assuming 20- 30 items the sample size is ≥200 decided but may vary after the final item generation and validity assessment may be adjusted based on statistical requirements
- Recruitment strategy: IPD/OPD screening, cross-referral and camps.

Sampling Technique

- Experts: Purposive sampling
- Patients: Consecutive sampling

Methods: data collection, management, and analysis

Data Collection: p Phase I: Secondary Data will be collected from literature review, primary data (clinical signs & symptoms, laboratory investigations, X-ray imaging etc.) will be directly collected through Survey, FGD, and in-depth interviews

Phase II- questionnaire, Translation Review checklist

Phase IV-, Prepared Structured diagnostic questionnaire a/ Clinical assessment sheets, laboratory data, Scoring system for diagnostic criteria and reference standard, field notes.

Data Analysis Plan: Statistical tests for validating the diagnostic tool for *Janu Sandhigata Vata* are Lynns process of content validation & item content validity index and scale content validity index will be applied for assessing content validity, Kappa statistics will be employed for inter rater reliability, Internal consistency will be estimated using the coefficient alpha also known as Cronbach's alpha, Item total correlation and split half reliability will be assessed along with Cronbach's alpha. Quantifying the diagnostic ability of tool and efficiency in differentiating with and without disease will be assessed using sensitivity and specificity. Evaluation of tool performance when applied to different clinical contexts using Predictive Values. ROC curve will be used to test how much more likely a patient who tests positive is to have the disease compared to one who tests negative, i.e., diagnostic accuracy. McNamar's test to assess agreement and paired diagnostic outcomes obtained from the developed diagnostic tool and the referenced standard (expert physician). Construct validity of domains will be evaluated by assessing their structural validity, using exploratory factor analysis (EFA) / Confirmatory Factor Analysis (CFA).

Data monitoring: An independent data monitoring committee is not constituted as it's a PhD study and will be conducted under university department of academic affairs and institutional doctoral committee. Instead, credibility will be attained through activities like saturation, triangulation, member checking, and maintaining an audit trial ensuring appropriate oversight while safeguarding data integrity. This will be achieved through collaboration between the investigator, the Institutional Medical Research Centre, Ethics Committee (IEC), and the doctrine committee.

Data management: The data will be collected through focus groups and in-depth interviews using a structured focus group and in-depth interview guide, along with video-audio recording of both with participants' consent. The investigator will make field notes/observer notes during both to record the non-verbal and contextual references. The consistency and accuracy of the recording will be reviewed after transcribing them. All the participants' confidentiality will be maintained by giving them a unique identity code. All the data will be securely stored in a separate hard disk accessible only to investigator. Regular internal audits will be done.

Missing data management: missing data will be minimized by probing questions and clarification during data collection, responses that are incomplete will not be included in study.

Dissemination plan (publication/data sharing). The study findings will be disseminated through publication, presentations and conference poster presentations.

Role of trial sponsor and funders: NA

Ethical considerations: Approval of the Ethics Committee: Before initiating the study, all approvals will be obtained from the Institutional Ethics Committee. Such as the study protocol, written informed consent document including participant information sheet, consent form updates and participant recruitment procedures.

IEC NO: Ref.No.KAHER/EC/24-25/378

Informed Consent: Written informed consent will be obtained from each participant (experts, focus group members and patients) in the prescribed format before inclusion in the study. Participants will also be informed of their right to opt out of the study at any time without giving any reasons. Data confidentiality will be maintained and the study will be conducted in accordance with the principles of Good Clinical Practice that has its principles as reported in the Declaration of Helsinki.

3. DISCUSSION

Caraka Samhita described the disease *Sandhigata vata* in the chapter of *Vatavyadhi,* is a degenerative disease caused by the vitiation of *Vata* and has *Pratyamaka laxana* as pain on movement of the joint, joint swelling and crepitus. It is most commonly seen in *Vrudha Avastha* (old age) due to the *Vata* predominant phase of life, and *Kshaya* (depletion) of all Dhatus. [14] Whereas *Acarya Susruta* in *Nidana Sthana* and *Cikitsa Sthana*, has described the disorders and their distinctive *Cikitsa*. He has added a new symptom, "*Hanti Sandhi*" [15], [16] *Aṣṭanga Hṛdaya*, [17] and *Aṣṭanga Sangraha*,[18] have adopted the symptoms as described by *Caraka* and the line of management as described by *Sushruta* . *Madhavanidana* introduces an additional symptom, *Atopa.* [19] The remaining *Laksaṇas* are the same as those found in *Susruta Samhita*. *Sandhivata* (OA) affects all classes of people with varying conditions due to their diet, occupation & environmental factors, and *Vata* vitiates *Aahara* (food) and *Vihara* (regime). Diagnosis of *Sandhigata Vata* is not uniform across *Ayurveda* practice it largely depends on physicians' perception of the symptoms, their experience along with variation in clinical examination. This leads to inter-rater variability and inconsistency in diagnosing as well as grading the disease. Moreover *Sandhigata Vata* shares overlapping *Laxanas* with many other joint diseases explained in *Ayurveda* like *Amavata*, *Vata Rakta*, *Snayaugata Vata*, and all the diseases where the involvement of sandhi is there making diagnosis difficult. Lastly no objective parameter is stated

in classics for diagnosis all are subjective and vary across patients and assessing physicians. [20] A critical appraisal of published studies on the diagnosis of *Sandhigata vata* is not available; most of them are clinical trials in which diagnosis is based mainly on *Ayurvedic* symptomatology and osteoarthritis clinical and radiological findings, revealing considerable inconsistencies in diagnostic approaches. The classical Ayurvedic features are not uniformly defined or graded, while contemporary assessment tools, such as WOMAC, VAS, and other indices, are used inconsistently. Additionally, there were no radiological, biochemical and psychological parameters considered, thus reflecting an incomplete diagnostic framework. [21] There are many subjective parameters in *Ayurveda* and a few objective parameters as well, but the perception varies across all these parameters. There is also variation in their selection, application and interpretation making it non-generalizable. The studies in *Ayurveda* focus more on treatment than diagnosis, neither are they efficiently related the diagnostic aspects with the treatment; if at all it's done, they are mostly theoretical and vary across published literature. Most of the diagnoses in *Ayurveda* rely on modern diagnostic tools like ACR criteria for classification and diagnosis of knee osteoarthritis. ACR criteria are designed for research classification and not for early diagnosis of OA. The 2016 ACR revised criteria for early diagnosis of knee OA is in the form of a proposal and have never been validated. [22] Other available criteria NICE, EULAR and symptomatic X-ray-confirmed OA have varied levels of specificity and sensitivity due to knee OA symptoms fluctuating from time to time and observer variability. [23] All these available criteria have moderate to poor agreement with each other. [24] MRI is proven to be more sensitive than X-ray to diagnose early cartilage damage, but none of these criteria included it. [25] This clearly signifies that there is no standard diagnostic tool available to diagnose OA itself and these available criteria do not include *Ayurveda* diagnostic domains like *Samprapti, Nidana, Dosha Ddushya*, *Laxana* such as *Vatapurna Dhrti Sparsa* etc, hence cannot be used solely to diagnose *Janu Sandhigata Vata* . This clearly signifies the need for appropriate diagnostic criteria/tool/ process for *Ayurveda* diagnosis and based on its own criteria planning and assessing the treatment and also in a research setting. [21] The main causes of lack of uniformity is methodological discrepancies, especially in terms of study designs, study settings and statistical analysis. [26] Diagnosis in *Ayurveda* is significantly influenced by individual perceptions and understanding, which vary across physicians, causing a lot of ambiguity. This approach to disease diagnosis is though negotiating with modern diagnostic technologies. [27] The recent advances in *Ayurveda* education and research very well document the need for using modern diagnostics like imaging and laboratory for advancing *Ayurveda* medicine, education and research. These modern diagnostics can be an aid in prognosis, differential diagnosis and confirming the final diagnosis if used and standardized like it has been in conventional medicine. [28]

Integrating modern diagnostics both investigations and imaging in *Ayurveda* diagnosis will standardize the science and make it evidence-based. For developing a uniform methodology and terminologies accepted universally a holistic methodology combining qualitative and quantitative approaches is needed. [29]

Presently, there is need for a standardized validated diagnostic and assessment tool integrating the ayurveda diagnostics principles and modern diagnostic procedures that can be generalized across the population and minimize differences in diagnosis across *Ayurveda* practitioners, and bring uniformity in disease nomenclature. [30] Hence a standard tool to diagnose OA which is reliable, generalizable and clinically applicable is needed. Further, a similar methodological framework could be effectively utilised to develop a standardised diagnostic tool for other diseases described in *Ayurveda*,

thereby promoting consistency and strengthening evidence- based practice across the discipline.

Strengths and Limitations: The study is first of its kind where perception is also studied by qualitative research, limitation is time-consuming and the availability of experts.

Future Scope: Cross cultural Validation in multicentric and larger populations were conceptually appropriate and can be planned. New diagnostic tools and standardisation of existing diagnostic tool in *Ayurveda* can be done using the same methodology**.**

4. CONCLUSION

The study is taken as PhD study under *Roganidana* which deals with *Ayurveda* diagnosis and diagnostics. The study is designed to generate reliable and reproducible evidence with respect to tool development and validation in *Ayurveda* diagnosis using the classical method and recent diagnostic advances.

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Data collection and literature search: HS

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Reviewing & editing: SKS, SS

Approval of final manuscript: All authors

Declaration of Generative AI

The authors declare this manuscript was written without the use of generative artificial intelligence tools. All the content, including text generation, data analysis and references was developed and reviewed by the author without assistance from AI technologies.

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Additional Information:

Authors can order reprints (print copies) of their articles by visiting: **https://www.akinik.com/products/2281/journal-of-ayurveda-and-holistic-medicine-jahm**

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