JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

Assessing *Samyak Snigdha Lakshana* A Critical Review of Clinical Endpoints in *Shodhananga Snehapana*

Author- Anurag Dangi[1], Dr. Yogesh Yadav[2*], Dr. Pushpendra Kumar Pandey[3], Dr. Ashish Choyal[4]

1 Undergraduate student, 2 Assistant Professor, Department of Shalya Tantra, 3 Professor and HOD, Department of Sahita Siddhanta, 4 Associate Professor, Department of Panchkarma. R.N. Kapoor memorial Ayurvedic Medical college and hospital, Dr. A.P.J. Abdul kalam University, Indore, Madhya Pradesh, India

Corresponding author: Dr Yogesh Yadav, email: dryogeshyadav00@gmail.com

Abstract

Samyak Snigdha Lakshana guides assessment during preparatory internal oleation, but research requires explicit definitions of the signs used to continue or stop treatment. This critical narrative review examines two published clinical investigations and measurement reporting principles. The studies demonstrate attempts to record symptom sequence, individualised dosing and accompanying laboratory findings. They do not establish that a fixed cumulative amount of ghee represents adequate oleation for every participant or that a short term laboratory finding validates the clinical endpoint. We distinguish the administered dose, observed endpoint and subsequent procedural outcome. A proposed assessment framework includes item definitions, assessment timing, assessor training, missing observations and reasons for modification. Prospective reliability studies should precede universal scoring thresholds. Adequacy and adverse effects also need separate recording. Better operational definitions would preserve the individualised logic of *Snehapana* while allowing readers to evaluate how consistently the endpoint was assessed.

Keywords

Samyak Snigdha Lakshana; *Snehapana*; oleation; clinical endpoint; reliability; Panchakarma

Introduction

In individualised treatment, the endpoint helps determine the dose. That relationship becomes circular if the endpoint is poorly defined: treatment is called adequate because enough medicine was given, while enough medicine is defined by the appearance of an adequate response. Research needs an observable assessment process that can be examined independently of the final judgement.

Ramteke and colleagues studied *Samyak Snigdha Lakshana* during *Shodhananga Snehapana* in people with psoriasis.[1] Mulay investigated escalating *Sneha* administration in healthy volunteers.[2] These studies offer different clinical contexts for examining endpoint assessment. They should not be combined as though their participants and objectives were identical.

Review approach

Targeted searches of PubMed and PMC indexed records were conducted on 19 and 20 November 2026 using *Snehapana*, *Samyak Snigdha Lakshana*, oleation and escalating ghee administration. Accessible clinical studies were selected for their descriptions of assessment and dosing. COSMIN and GRRAS informed the discussion of measurement and observer agreement. This is a critical narrative review, not a complete inventory of studies or a validation of a new scale.

Sources were organised by the question they could answer: direct clinical evidence, formulation or measurement evidence, and general methodological guidance. Clinical reports were interpreted within their population, comparator and follow up; laboratory findings were used only for the measured property. Proposed explanations and research priorities are identified as interpretation rather than established treatment effects. The synthesis does not claim comprehensive retrieval, duplicate independent screening or a formal risk of bias assessment. Consequently, the examples support a critical argument but cannot determine the frequency of a reporting problem or a pooled estimate of benefit.

Table 1 Selected evidence and its interpretation

Source	Design or material	Direct contribution	Boundary of inference
Ramteke and colleagues[1]	Open study in 30 patients with psoriasis	Records oleation signs through a study specific assessment approach.	Does not establish inter assessor agreement across settings.
Mulay[2]	Before and after study in healthy volunteers	Connects escalating exposure with clinical and biochemical observations.	Selected short term observations cannot establish universal safety.
GRRAS[3]	Reporting guideline	Supports transparent design and analysis of observer agreement studies.	Applying the guideline does not validate a new endpoint instrument.

Dose and endpoint answer different questions

The administered quantity is a treatment exposure. The observed signs are responses assessed during that exposure. A research report should preserve this distinction by presenting the daily quantity, cumulative quantity

and duration separately from the endpoint findings. A participant who reaches a defined endpoint after a smaller quantity should not automatically be classified as undertreated.

Individualisation also needs an explicit decision rule. A statement that dose was determined according to *Agni* and *Koshtha* should identify how those assessments were performed and which observations changed the next dose. TIDieR supports the reporting of planned tailoring and actual modification.[4] This makes clinical reasoning visible rather than replacing it with an identical schedule for everyone.

What the clinical studies contribute

The psoriasis study enrolled 30 patients and used a specific scoring approach to examine the sequence and occurrence of oleation signs.[1] It demonstrates that the traditional endpoint can be broken into observations collected over time. Its single clinical setting and study specific scoring do not establish that another assessor would make the same judgement in another population.

The healthy volunteer study followed escalating administration and measured physical and biochemical variables before and after the treatment sequence.[2] Short term observations in selected volunteers cannot establish safety in all patients. Nor can a laboratory result alone confirm that the intended Ayurvedic clinical endpoint has been measured correctly. The physiological observation and the endpoint judgement are separate pieces of evidence.

Operationalising individual signs

An item should state what is observed, who reports it and how it is graded. A patient reported experience differs from a physical sign examined by a clinician. Combining them can be appropriate, but the basis of the total score needs explanation. The importance assigned to each sign should not be determined only by which signs happen to be common in one small sample.

Assessment timing is equally important. An observation made soon after ingestion may differ from one made before the next dose. If a sign is intermittent, an unspecified once daily assessment can miss it. Recording onset and duration can therefore be more useful than a final present or absent label.

Table 2 Separate elements of the *Snehapana* record

Element	Information required	Interpretation boundary
Baseline assessment	Defined *Agni*, *Koshtha* and clinical suitability	Does not measure later response
Administered exposure	Daily amount, formulation and timing	Does not establish adequacy alone
Clinical signs	Item definitions and observation schedule	Need reproducibility evidence
Stop decision	Criterion reached or other reason	Should distinguish completion from interruption

Element	Information required	Interpretation boundary
Laboratory findings	Method and timing	Do not independently validate the clinical construct
Subsequent outcome	Defined response to the next procedure	Can be influenced by additional treatment

Reliability before a universal threshold

A scoring system can appear precise while remaining dependent on the assessor. Reliability research should examine whether trained assessors identify and grade the same signs consistently. GRRAS provides guidance for reporting agreement studies, including the participants, observers and statistical approach.[3] A high correlation between scores is not automatically sufficient evidence of agreement.

Content validity also needs attention. Expert consensus and patient understanding can help determine whether items represent the intended experience. COSMIN distinguishes content validity from internal consistency and other measurement properties.[5] A reliable but incomplete score could repeatedly omit a clinically important part of the endpoint.

Adequacy and tolerability should be recorded separately

A symptom can influence a stopping decision without being evidence of successful completion. Researchers should specify how they distinguish the intended endpoint from intolerance or an adverse event. An early stop because of a concerning response should not be placed in the same category as completion simply to simplify analysis.

Table 3 Proposed endpoint assessment fields

Field	Purpose
Item and definition	Make each sign reproducible
Reporter and assessor	Separate patient report from clinical examination
Time observed	Relate the sign to dosing and meals
Grade and uncertainty	Avoid forcing ambiguous observations into certainty
Action taken	Connect assessment with dose modification or stopping

Field	Purpose
Adverse-event record	Keep tolerability distinct from adequacy

Prospective harms methods should describe active questioning and the observation window.[6] Laboratory surveillance, where justified by a protocol, complements this record rather than replacing clinical assessment.

The endpoint is part of an adaptive intervention

Shodhananga Snehapana is not adequately represented by a single final quantity. When dose is adjusted according to response, the intervention includes a sequence of assessment and decision. The report should explain what information was available before each adjustment and how it influenced the next step. Otherwise, the same cumulative amount could arise from very different clinical courses. One participant may reach the intended endpoint promptly; another may receive repeated modifications or stop because of intolerance. Describing both as having completed an identical exposure removes the very individualisation that the procedure is intended to preserve.

An adaptive protocol need not eliminate practitioner judgement. It can specify the domains considered, the range of permitted actions and the reasons that must be recorded. TIDieR supports this distinction between planned tailoring and actual modification.[4] Such documentation allows readers to understand how the treatment was delivered without requiring every participant to follow an inflexible schedule. It also permits later evaluation of whether different practitioners implement the same principles similarly. A statement that treatment was given according to *Agni* and *Koshtha* is a rationale; the session record must show how that rationale became a decision.

The intended endpoint should be defined before observing outcomes. If adequacy is assigned retrospectively to those who improve after a subsequent procedure, the definition becomes entangled with the result it is supposed to predict. A prospective endpoint permits a clearer question: does attainment of these specified signs relate to a later meaningful outcome? That question remains open until directly studied. The present review does not validate a particular stopping threshold. It argues that the threshold and its assessment process must be available for independent appraisal before their predictive value can be tested.

Patient reports and clinician observations are different data

Some endpoint features are experiences reported by the participant, while others involve observation or examination. A research form should identify the source of each item. The participant may report a change in appetite or an aversion, whereas a clinician may assess a physical feature. Combining these into a total score can be useful only if the interpretation is clear. The source should remain visible because disagreement may reflect different information rather than error. An assessor should not overwrite a participant's report simply because the expected sequence suggests that a sign ought to be present.

The wording of the enquiry matters. Asking whether a sign has appeared can encourage an affirmative answer when participants believe it indicates progress. Neutral questions followed by a defined grading method can reduce that influence. The study should also state whether participants were taught the expected signs. Education may be necessary for cooperation, but it can change reporting behaviour. This does not invalidate the procedure;

it identifies a feature of measurement that should be described. The reader needs to know whether an endpoint reflects an unsolicited experience, a structured enquiry or an interpretation supplied by the treating team.

Observable features require equally explicit methods. A term such as unctuousness should identify the site, timing and judgement used in the study rather than rely on assumed shared understanding. Research can preserve the traditional label and provide an operational description beside it. If a feature cannot be graded confidently, uncertainty should be recorded rather than forced into a definite category. Missing and indeterminate observations should remain distinct from absent signs. This distinction is essential when a total score or stopping rule depends on the number of features considered present.

Sequence and timing offer more information than a final score

The psoriasis investigation examined the occurrence and sequence of *Samyak Snigdha Lakshana* in a selected clinical population receiving a specified preparation.[1] This temporal approach is informative because an endpoint develops during treatment rather than appearing only at its conclusion. A future record could distinguish the first appearance, persistence and recurrence of each sign. A single final score cannot show whether a feature appeared early and resolved, appeared only briefly or remained throughout the course. Those patterns may have different implications for a decision to continue or stop.

Assessment should be related to ingestion, meals and the next planned dose. An observation made soon after administration addresses a different state from one made the following morning. If timing varies, the same symptom may be captured in one participant and missed in another. Recording actual times is therefore preferable to an unspecified daily assessment. This does not require continuous monitoring of every experience. It requires a schedule justified by the construct and a way to record important observations between scheduled assessments. The feasibility of such a schedule should be tested before it becomes a burdensome trial requirement.

Time to a defined endpoint can be an outcome, but it requires careful handling. Participants who stop for another reason have not necessarily failed to develop the endpoint in the same sense as those observed for the full course. The report should distinguish competing reasons for stopping and avoid treating every incomplete course as equivalent. Daily exposure and assessment data help clarify the clinical trajectory. They also prevent a smaller cumulative amount from being interpreted automatically as insufficient treatment when the intended endpoint was reached earlier under the study's own prespecified criteria.

What the selected studies can and cannot demonstrate

The psoriasis study included 30 participants and selected a common preparation to reduce some sources of variation.[1] That design supports description within the studied clinical setting. It does not isolate the measurement properties of every sign or establish general applicability to other formulations and populations. The reported occurrence of several signs in all participants is an observation within that sample, not proof that those signs are universally necessary. Less frequent signs may be less common, harder to assess or differently related to the selected treatment context. Their role requires further investigation rather than a conclusion based only on frequency.

The healthy volunteer report evaluated escalating *Sneha* administration and physical and biochemical observations in 29 volunteers.[2] Its population differs from patients with active disease. A selected volunteer sample can be useful for exploratory physiology, but it cannot establish that the same course is appropriate for all clinical groups. The study's short term lipid findings should be interpreted within its design and observation

period. They do not validate the endpoint score, identify a universal safe cumulative dose or establish the long term consequences of repeated courses. Each of those claims would require evidence directed to that question.

Laboratory values obtained before and after a treatment sequence may reflect several influences, including accompanying diet and subsequent procedures. The timing of each sample should therefore be explicit. If the paper attributes a change to *Snehapana*, the reader should be able to identify what else occurred between measurements. A before and after difference alone cannot separate those components. This is particularly important when discussing weight change or lipid profiles because a physiological observation can be mistaken for confirmation of a traditional mechanism. The appropriate conclusion remains tied to the measured variables and the actual design.

Developing a defensible assessment instrument

Content development should begin with a clear account of which signs belong to the intended endpoint and why. Classical sources, practitioner expertise and participant experience can contribute different information. Agreement among experts supports relevance but does not establish that patients understand every item. Pilot interviews can identify ambiguous wording and practical difficulty. The aim is an instrument that reflects the construct while remaining usable during clinical care. A long form that is rarely completed accurately may provide less useful evidence than a shorter but well justified assessment with explicit limitations.

The scoring model then needs justification. Adding ordinal grades assumes that the resulting total has an interpretable meaning. Weighting all signs equally is also a choice, not a neutral fact. A total may conceal a concerning symptom behind several favourable observations. Investigators should therefore preserve item level reporting while evaluating any summary score. COSMIN distinguishes content, structural and other measurement properties, helping prevent internal consistency from becoming the only criterion.[5] Endpoint assessment may involve diverse features that do not all behave as interchangeable manifestations of one latent variable.

Reliability testing should match the assessment mode. For clinician observed signs, interrater work can examine whether trained observers agree when assessing the same participant under comparable conditions. For patient reported features, repeated assessment may be appropriate only when the state can reasonably be considered stable. GRRAS encourages clear reporting of the participants, raters, measurement process and analysis.[3] A high correlation does not exclude systematic disagreement between observers. Studies should therefore select agreement methods that answer the intended question and report uncertainty rather than using a single coefficient as proof of universal reproducibility.

Adequacy intolerance and adverse events

A stopping decision can arise because the intended endpoint has been reached, because the participant declines further treatment or because a clinical concern requires interruption. These reasons should not be collapsed. A participant who stops because of an unexpected symptom has provided important tolerability information even if some adequacy signs are present. The report should state the immediate action and subsequent course. It should not relabel the event as successful completion merely to maintain a simple binary outcome. Transparent categories permit readers to judge both the procedure and the decision process.

The relationship between an expected sign and an adverse event may be complex. The solution is not to suppress one category but to define how observations are recorded and assessed. An event can be documented first and its clinical interpretation recorded separately. CONSORT Harms supports explicit methods of collection, severity

assessment and reporting.[6] For *Snehapana*, the observation window should cover the actual course and relevant follow up. A statement that no adverse effects occurred is weak evidence when readers cannot determine whether symptoms were actively sought, spontaneously reported or excluded as expected responses.

Denominators should also be clear. The number of participants experiencing an event differs from the number of doses followed by that event. Both can be informative when repeated dosing is involved. Discontinuations, dose reductions and missed assessments should be reported in relation to the enrolled population. Restricting analysis to those who complete the intended course can remove participants who had the greatest burden. This review does not estimate event rates from the selected reports. It identifies the information needed for a future study to make tolerability interpretable rather than merely assert it.

Testing prediction without creating circular evidence

One possible validation question is whether a defined endpoint predicts a subsequent procedural or clinical outcome. That study would need the endpoint assessed before the later outcome and preferably by assessors unaware of the eventual result. The later outcome must itself be meaningful and reproducibly measured. If the same practitioner judges both adequacy and success using overlapping observations, an apparent association may partly reflect shared judgement. Independence of assessment can reduce that problem. It does not eliminate confounding, but it makes the inferential structure clearer.

Prediction also requires more than a statistically significant association in a small development sample. The model or threshold should be evaluated in new participants, with attention to calibration and practical consequences. A threshold that performs well only after being selected from the same dataset may be overly optimistic. Researchers should state whether the analysis is exploratory or confirmatory and avoid presenting a locally derived cut off as a universal clinical rule. The immediate value of exploratory work is to generate a precise hypothesis and identify which observations deserve testing in a later adequately planned study.

A study should also ask whether the endpoint adds useful information beyond simpler measures already available to the clinician. If a complex score does not improve decision making or reproducibility, its burden may be difficult to justify. Conversely, a structured record may reveal clinically important patterns that an informal final judgement misses. These possibilities should be examined empirically. The goal is a usable assessment that supports transparent individualisation, rather than a numerical instrument developed solely because a total score is easier to place in a results table.

Reporting an individualised course coherently

A complete report should allow the reader to follow baseline assessment, daily exposure, observed signs, modifications and the final reason for stopping. Tables can summarise repeated records, while prose explains decisions that require context. The actual formulation and batch should be identified because findings from one preparation do not automatically transfer to another. Dietary instructions and other care should also be described. These are components of the treatment environment and may influence both symptoms and laboratory observations. Their omission weakens attribution even when the endpoint assessment itself is carefully performed.

Future synthesis will be more useful when studies preserve these distinctions. A pooled cumulative dose cannot resolve inconsistent endpoint definitions, and a pooled endpoint frequency cannot establish that signs were assessed comparably. The first priority is therefore a common descriptive vocabulary with transparent operational methods. The framework in this review is an author proposed starting point, not a consensus

standard. Its value lies in making the unresolved questions explicit: what is observed, how consistently, at what time, and with what consequence for the treatment decision and the participant's subsequent course.

A final methodological safeguard is to retain the actual daily assessment form. A summary stating that signs appeared in sequence cannot show how uncertain or missing observations were handled. Item level records allow later checking of the relationship between dose, assessment time and stopping decision. They also make it possible to distinguish a proposed scoring rule from the rule actually applied. This supports reproducibility without requiring disclosure of identifiable patient information.

Related instruments do not automatically validate an endpoint

The questionnaire development study for *Jatharagni* illustrates that even a familiar Ayurvedic concept requires explicit item definitions when used in research.[7] For *Samyak Snigdha Lakshana*, investigators similarly need to distinguish participant reports from examiner observations and identify the time at which each is assessed. Terwee and colleagues' measurement criteria provide a basis for separating reproducibility from responsiveness and clinical interpretability.[8] Improvement in one property cannot stand in for evidence on the others.

Content validity methodology gives particular attention to the relevance and completeness of items and whether the intended users understand them.[9] A symptom list developed for one oleation regimen may require further work before being used with another formulation or in another patient group. For continuous measurements collected by more than one method, Bland and Altman's work offers a way to think about agreement rather than relying only on correlation.[10] Categorical clinical signs require methods appropriate to their own measurement scale.

Kadus and Vedpathak assessed signs of proper oleation in a comparison of constant and escalating Anuvasana Basti regimens as an alternative approach during Purvakarma.[11] The relevance is that similar endpoint language can appear across distinct routes and treatment schedules. That report does not establish that the resulting scores are interchangeable with those from oral *Snehapana*. The route, preparation and assessment procedure should remain visible whenever endpoint findings are compared.

Discussion

The central methodological challenge is preserving individualisation while making the endpoint testable. This can be achieved through explicit definitions and documented decisions. A universal cumulative dose would remove some variation in administration but would not resolve variation in the interpretation of signs.

This review uses selected studies and does not assess the performance of every proposed scoring tool. Its suggested fields require feasibility testing and validation. Future research should first establish content and observer agreement, then examine whether the endpoint predicts a meaningful subsequent outcome.

Conclusion

Samyak Snigdha Lakshana should be reported through defined observations and a transparent decision process. Dose, adequacy, intolerance and subsequent outcomes must remain distinguishable. Reliable endpoint assessment is necessary before a common scoring threshold can be recommended.

References

1. Ramteke R, Vinodkumar G, Meharjan T. An open clinical trial to analyze Samyak Snigdha Lakshana of Shodhananga Snehapana with Mahatikthakam Ghritam in Psoriasis. Ayu. 2011;32(4):519-525. doi:10.4103/0974-8520.96126.

2. Mulay MS. Short term escalating administration of large amount of sneha does not increase blood lipids. J Ayurveda Integr Med. 2021;12(3):535-539. doi:10.1016/j.jaim.2020.05.004.

3. Kottner J, Audigé L, Brorson S, Donner A, Gajewski BJ, Hróbjartsson A, et al. Guidelines for Reporting Reliability and Agreement Studies (GRRAS) were proposed. J Clin Epidemiol. 2011;64(1):96-106. doi:10.1016/j.jclinepi.2010.03.002.

4. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687. doi:10.1136/bmj.g1687.

5. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res. 2010;19(4):539-549. doi:10.1007/s11136-010-9606-8.

6. Junqueira DR, Zorzela L, Golder S, Loke Y, Gagnier JJ, Julious SA, et al. CONSORT Harms 2022 statement, explanation, and elaboration: updated guideline for the reporting of harms in randomised trials. BMJ. 2023;381:e073725. doi:10.1136/bmj-2022-073725.

7. Eswaran HT, Kavita MB, Tripaty TB, Shivakumar. Formation and validation of questionnaire to assess Jāṭharāgni. Anc Sci Life. 2015;34(4):203-209. doi:10.4103/0257-7941.159829.

8. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol. 2007;60(1):34-42. doi:10.1016/j.jclinepi.2006.03.012.

9. Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res. 2018;27(5):1159-1170. doi:10.1007/s11136-018-1829-0.

10. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet. 1986;1(8476):307-310. doi:10.1016/s0140-6736(86)90837-8.

11. Kadus PA, Vedpathak SM. Comparative study of Anuvasana Basti with constant and escalating dose as an alternative to Snehapana in Purvakarma of Vamana and Virechana. J Ayurveda Integr Med. 2017;8(3):194-199. doi:10.1016/j.jaim.2016.11.001.