

Use of Ayurvedic Diagnostic Criteria in Ayurvedic Clinical trials: A Literature Review focused on Research Methods



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Presenter Disclosures

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- (1) The following personal financial relationships with commercial interests relevant to this presentation existed during the past 12 months:

“No relationships to disclose”

What is Ayurveda?



- An ancient Indian medical science, originated over 3,000 years ago.
- Ayurveda is a Sanskrit word, made up of two words: ‘*Ayur*’ means life, and ‘*Veda*’ means science or knowledge.
- Thus, the word Ayurveda means “the science of life”.

History of Ayurveda

Box 1.1

Historical Timetable of Ayurveda

1500BCE Vedic religion *Rg, Yajur, Sama & Atharva Vedas*:

125 herbal medicines mentioned in *Atharva Veda*

c.600BCE Rise of heterodox traditions of Jainism, Buddhism. Also growth of what is now called Hinduism

150BCE–100CE *Caraka Samhitā*: The earliest complete ayurvedic treatise. Herbs are here classified by action and morphology. Again reformatted by *Dṛḍhabala* circa 400CE

c.100–500 *Suśruta Samhitā*: detailed surgical text
Bhela Samhitā

500 *Dhanvantari Nighaṅṭu*: an early compilation of herbs into certain functional groups based on the property of the herbs

c.600 *Aṣṭāṅgahṛdaya Samhitā* by *Vāgbhaṭa*: a collated work on the essence of Ayurveda

c.650–950 *Madhava Nidana* (aka *Rogavinīśaya*): the first text committed solely to pathology

c.875 *Siddhayoga* by *Vṛnda*. Early ayurvedic text of the same type as *Cakradatta*

900–1400 *Gorakṣa Samhitā*: early *haṭhayoga* text where many ayurvedic concepts are fused with tantric yogic practice

1075 *Cikitsāsaṃgraha/Cakradatta* by *Cakrapāṇi*: professional ayurvedic handbook of the medieval era

1100 *Dravyaguṇasaṃgraha*: the first *Nighaṅṭu* written by *Cakrapāṇi*

c.1300 *Ānandakanda*: an early alchemical treatise

1374 *Madanaphala Nighaṅṭu*: a further compilation of herbs and minerals

1300–1400 *Śārṅgadhara Samhitā*: collected work on ayurvedic formulas and preparations. First record of pulse-taking as a diagnostic method. A pivotal

work linking early ayurvedic thought with new tantric alchemical techniques

1449/50 *Lakṣmaṇotsava*: a text describing pulse-taking

1474–1538 *Jvaratimirabhāskara* of *Cāmūṅḍa*. The first mention of *aṣṭasthānaparikṣā*, the eight methods of diagnosis (pulse, tongue, urine, eyes, face, faeces, voice and skin)

1596 *Bhāvaprakāśa Nighaṅṭu* by *Bhāvarnīśra*: the most important ayurvedic *materia medica* treatise

c.1600 *Ayurvedasūtra*: a text mixing ayurvedic, yogic and tantric thought
Rasarātsamuccaya: a pivotal alchemical text compiling much earlier thought and theory

1676 *Yogarātnākara*: a pivotal work reflecting the assimilative trait of Unani and European influences on Ayurveda

1760 *Rajavallabha Nighaṅṭu*: progressive *materia medica*

1815 *Samgraha Nighaṅṭu*

1893 *Bhāṣajya Ratnāvalī*: *Govindadāsa*'s work listing numerous medical preparations and introducing different European diseases

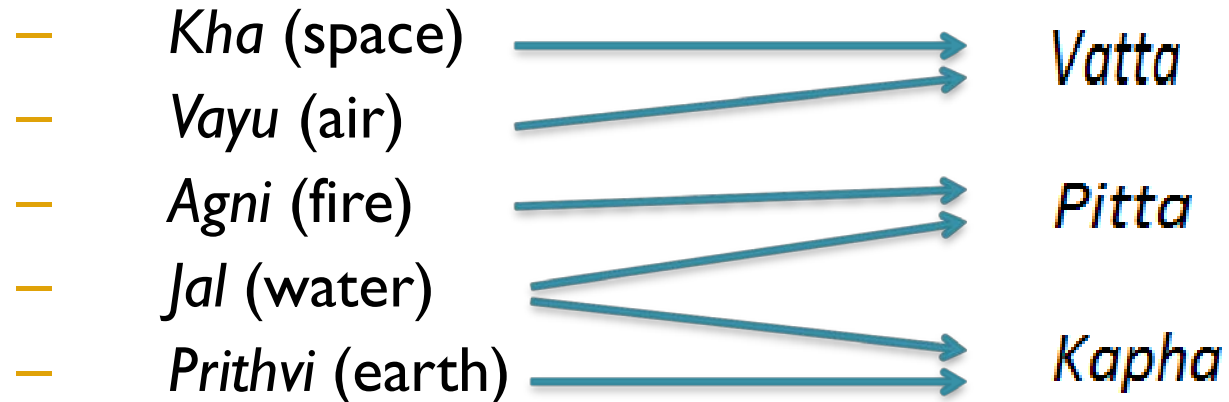
c.1900 *Nāḍīprakāśana*: *Śāṅkara Sen*

1924 *Nighaṅṭu Ratnākara*

Note: I have relied heavily on Jan Meulenbeld's works for categorising dates, notably 'A History of Indian Medical Literature' (1999–2002). While the dates that I have given are the commonly-decreed historical dates of authorship, Indian Indologists often place the dates of the early ayurvedic texts significantly earlier (c.4000–1000BCE). This is a contentious issue and reflects some of the different perspectives on history, origins and tradition that exist between certain European and Indian medical historians.

Basic principles of Ayurveda

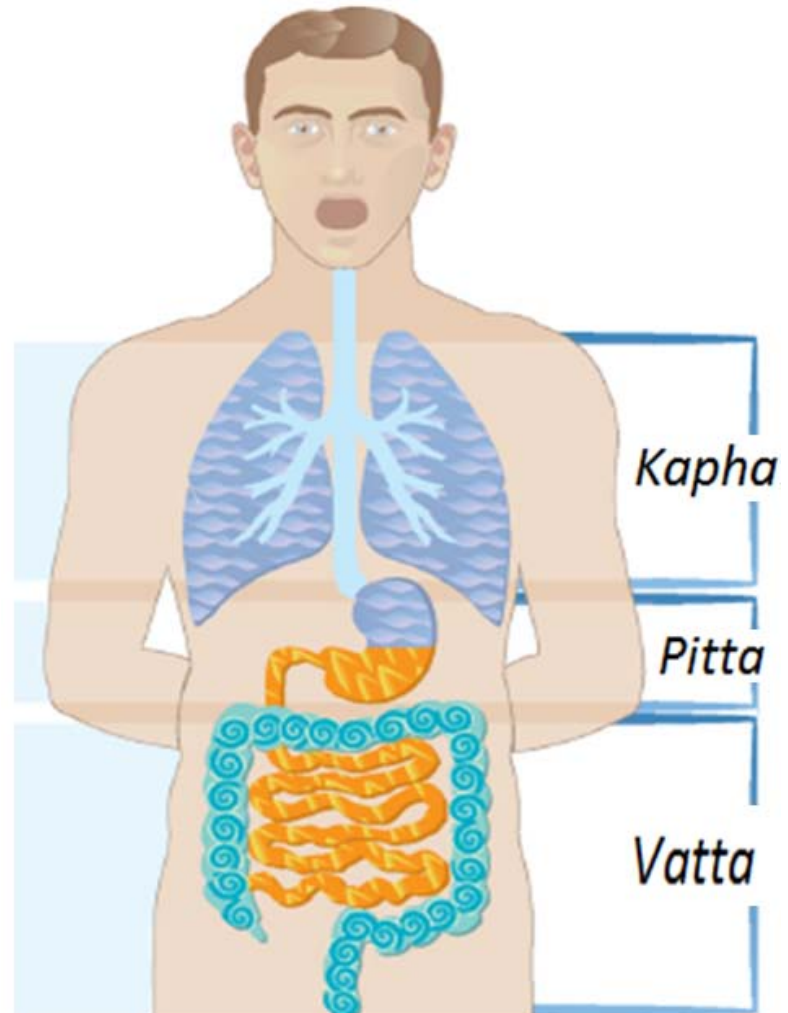
- All the living and non-living things are made up of five basic elements:



- These five elements combine and manifest in human body as three humors (*Doshas*), known as *Vatta*, *Pitta* and *Kapha* (collectively known as *Tridosha*).

Basic principles of Ayurveda...

- *Tridosha* control : all the biological, psychological and patho-physiological functions.
- Any imbalance in these *doshas* will result in illness.
- The three seats of the *doshas*: *vatta*, *pitta*, and *kapha*



Basic principles of Ayurveda...

Signs of *doshas*: Balanced state, increased state, and decreased state.

TABLE 2.3 Signs of the *doṣa* balance and excess Reference: *Aṣṭāṅgahṛdaya Saṃhita*

Doṣa	Balanced state (<i>sāmya</i>)	Increased state (<i>vṛddhi</i>)	Decreased state (<i>kaṣṭya</i>)	Colour
Vāta	Conveys movement, inspiration, expiration, enthusiasm, desire, excretion of wastes	Promotes wasting, thinness, weight loss, weakness, aversion to cold, desire for heat, softness and comfort, experience of piercing pain, mobile pain, numbness, erratic digestion, bloating, constipation, incontinence, urinary tenesmus, cracking joints, contraction, dry skin, dehydration, astringent taste in the mouth, spasms, rigidity, dark complexion, dark discolorations, dizziness, fear, anxiety, nervousness, loneliness, insomnia, depression. Symptoms worse for changes in the seasons, dry and cold climates, early in the morning, early in the afternoon and later in life	<i>Kapha</i> -like symptoms: sluggish, sloth, lack of enthusiasm, no desire to speak, confusion, delirious, loss of consciousness	Blue, black, brown, orange, clear
Pitta	Oversees metabolism, digestion, regulation of appetite and thirst, hormones and enzymes, intelligence, courage, flexibility, the quality of the complexion and eyesight	Causes burning, fever, inflammation, redness, bleeding, sweating, septic conditions, necrosis, putrid smells, fainting, aversion to heat, sour or bitter taste in the mouth, acidity, heartburn, loose stools, dark red urine, burning urine, yellow, green and red discolorations, aversion to heat, desire for cold, impatience, anger, frustration, critical, judgemental. Aggravated by hot and humid weather, middle of the day and night and mid life	Increased signs of <i>vāta</i> and <i>kapha</i> , poor digestion, pallor, coldness	Red, yellow, green, red
Kapha	Gives strength, solidity, structure, endurance, lubrication	Causes mucus, sticky phlegm, excess salivation, wet cough, itching, coldness, heaviness, stagnation, congestion, growths, cysts, tumours, dull pain, obesity, oedema, sluggish digestion, cloudy urine, excessive desire to sleep, sweet and salty tastes in the mouth, thick and white discharges, aversion to wet and cold, greed, apathy, attachment, depression. Worse for cold and damp weather, childhood and mid-morning and mid-evening	Signs of <i>vāta</i> increase; emaciation, dizzy, cracking joints, dryness and anxiety	White

A Biostatistical Approach to Ayurveda: Quantifying the *Tridosha*

RAJANI R. JOSHI, Ph.D.

ABSTRACT

Objective: To compute quantitative estimates of the *tridosha*—the qualitative characterization that constitutes the core of diagnosis and treatment in Ayurveda—to provide a basis for biostatistical analysis of this ancient Indian science, which is a promising field of alternative medicine.

Subjects: The data sources were 280 persons from among the residents and visitors/training students at the Brahmvarchas Research Centre and Shantikuj, Hardwar, India.

Design/methodology: A quantitative measure of the *tridosha* level (for *vata*, *pitta*, and *kapha*) is obtained by applying an algorithmic heuristic approach to the exhaustive list of qualitative features/factors that are commonly used by Ayurvedic doctors. A knowledge-based concept of worth coefficients and fuzzy multiattribute decision functions are used here for regression modeling.

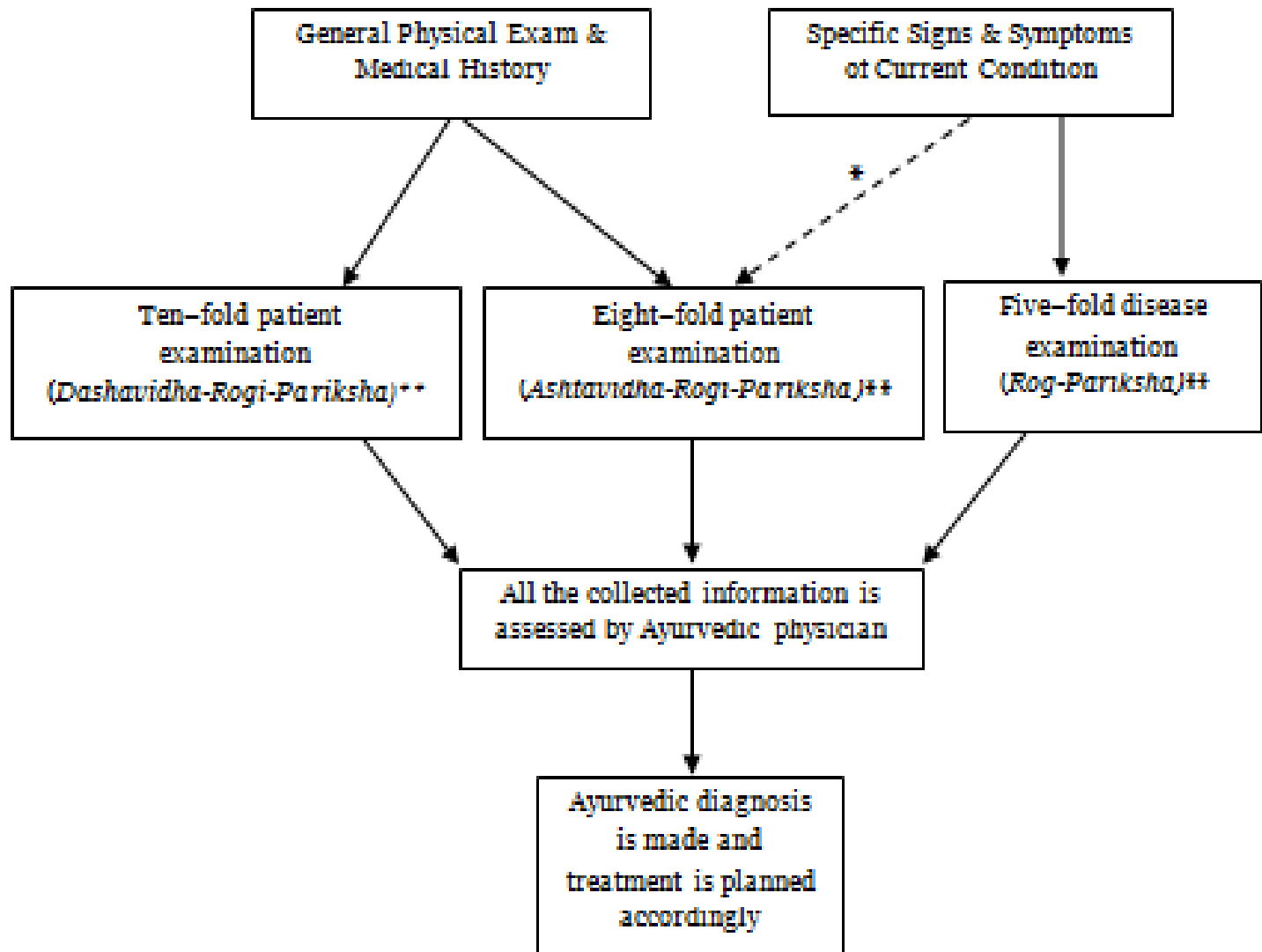
Validation and applications: Statistical validation on a large sample shows the accuracy of this study's estimates with statistical confidence level above 90%. The estimates are also suited for diagnostic and prognostic applications and systematic drug-response analysis of Ayurvedic (herbal and *rasayanam*) medicines. An application with regard to the former is elucidated, extensions of which might also be of use in investigating the role of *nadis* in Ayurvedic healing vis-à-vis acupuncture and acupressure techniques. The importance and scope of this novel approach are discussed.

Conclusions: This pioneering study shows that the concept of *tridosha* has a sound empirical basis that could be used for the scientific establishment of Ayurveda in a new light.

Basic principles of Ayurveda...

- ‘*Prakirti*’ is thought to be a unique combination of physical and psychological characteristics which governs the way the body functions.
- There are seven types of ‘*Prakirti*’, depending upon which ‘*Dosha*’, or combination of ‘*Doshas*’, dominate.

Ayurvedic diagnosis and treatment planning: Flow chart



*weakly evaluated by 'Eight-fold' examination (primarily evaluated by 'Five-fold' examination).

Brief definitions of the Ten-fold patient examination (Dashavidha Rogi Pariksha)

- **Prakirti** (Body Constitution) - The *prakriti* is thought to be a unique combination of physical and psychological characteristics and the way the body functions.
- **Vikriti** (Doshic vitiation) - This refers to the degree to which an individual has deviated from the original proportion of the three *doshas*.
- **Sara** (Quality of the tissues) - This aspect of the patient examination assesses the quality of the seven *dhatus* (tissues) and the mind (brightness of the intellect, mental capacity for discrimination)
- **Samhana** (Compactness of body) - This is the solidity and overall physique of the body frame. A more compact body usually indicates better immunity and healing capacity than a very soft and flaccid body.
- **Pramana** (General structure and physical proportionality) - This term really refers to the ratio of the height to the outstretched arms, and several other scriptural measurements.
- **Vyayam Shakti** (Physical Strength) - This factor means the capacity of the individual to be physically exerted and is measured by assessing the powers of endurance.
- **Satmya** (Adaptability) - This is a measure of the capacity of an individual to adjust to both physically and mentally unsettling conditions and to maintain homeostasis in the face of these factors.
- **Satava** (Emotional Balance) - This factor specifically refers to the mental steadfastness. The ability to tolerate and withstand distractions such as pain and physical or mental discomfort.
- **Ahar Shakti** (Digestive capacity) - This is an assessment of the capacity to ingest, digest, and assimilate food. One way of assessing this is by virtue of the appetite and how strong and sharp it is.
- **Vaya** (Age) - This is the comparison of the person's actual chronological age with one's apparent age.

Brief descriptions of the 'Eight-fold' patient examination and 'Five-fold' disease examination

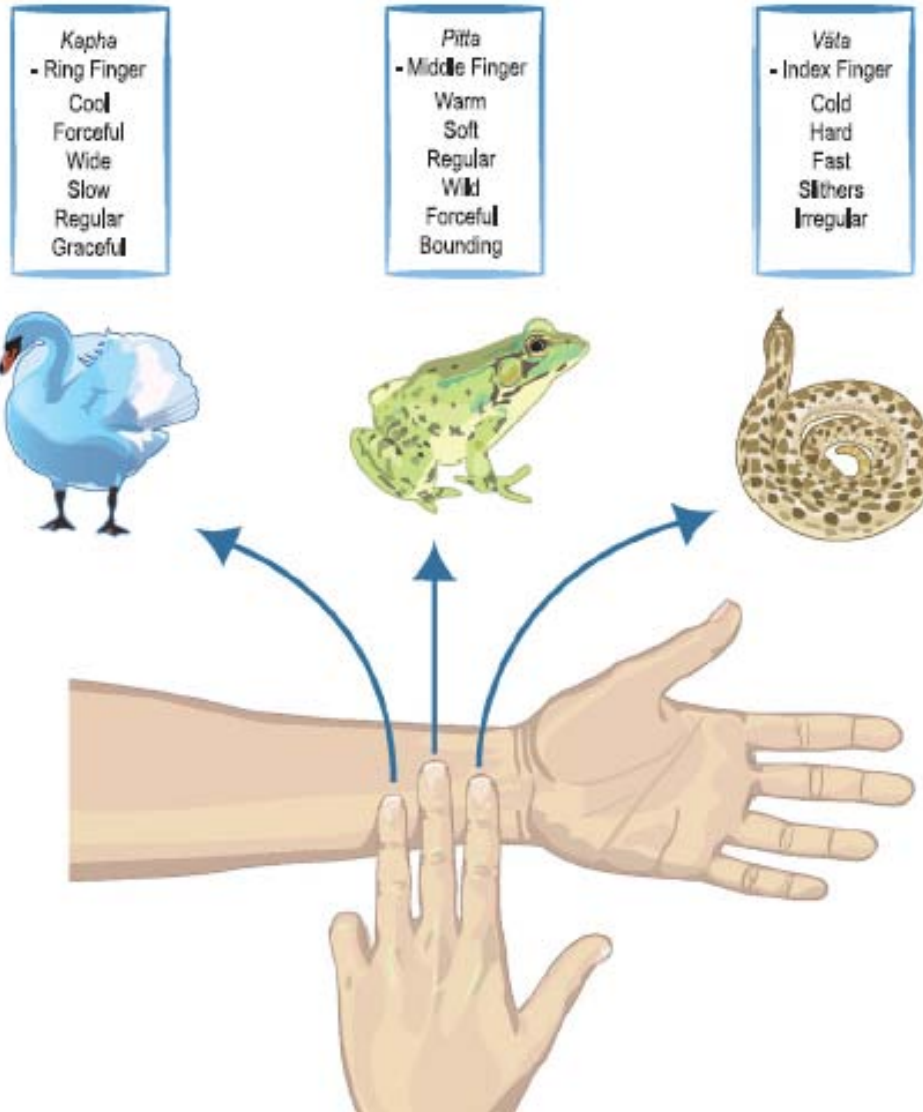
Eight Fold Exam

1. **Akar pariksha** (Examination of complexion and Body shape)
2. **Drika pariksha** (Examination of eyes)
3. **Shabada pariksha** (Examination of speech/voice)
4. **Jhiva pariksha** (Examination of tongue)
5. **Sparsha pariksha** (Examination of skin)
6. **Mala pariksha** (Examination of stool)
7. **Mutra pariksha** (Examination of urine)
8. **Nadi pariksha** (Examination of pulse)

Five Fold Exam

1. **Nidana** (cause/s of the disease).
2. **Samprapti** (stage of progression of the disease or pathogenesis).
3. **Purvarupa** (the very early signs of disease).
4. **Rupa** (the overt symptoms of the manifest disease condition).
5. **Upashaya-anupshya** (how the disease responds to the therapeutic interventions)

Pulse examination in Ayurveda



Objective

- To evaluate whether Ayurvedic diagnostic criteria or western medicine diagnostic criteria have been used in published clinical trials testing an Ayurvedic intervention/treatment.

Rationale of this literature review

- The use of “western medicine diagnostic criteria” in Ayurvedic CTs would raise:
 - methodological concerns about the possible - if not likely - misclassification of subjects as regards the appropriateness of the treatments provided.
 - and hence, draw into question the validity of the findings of the clinical studies.

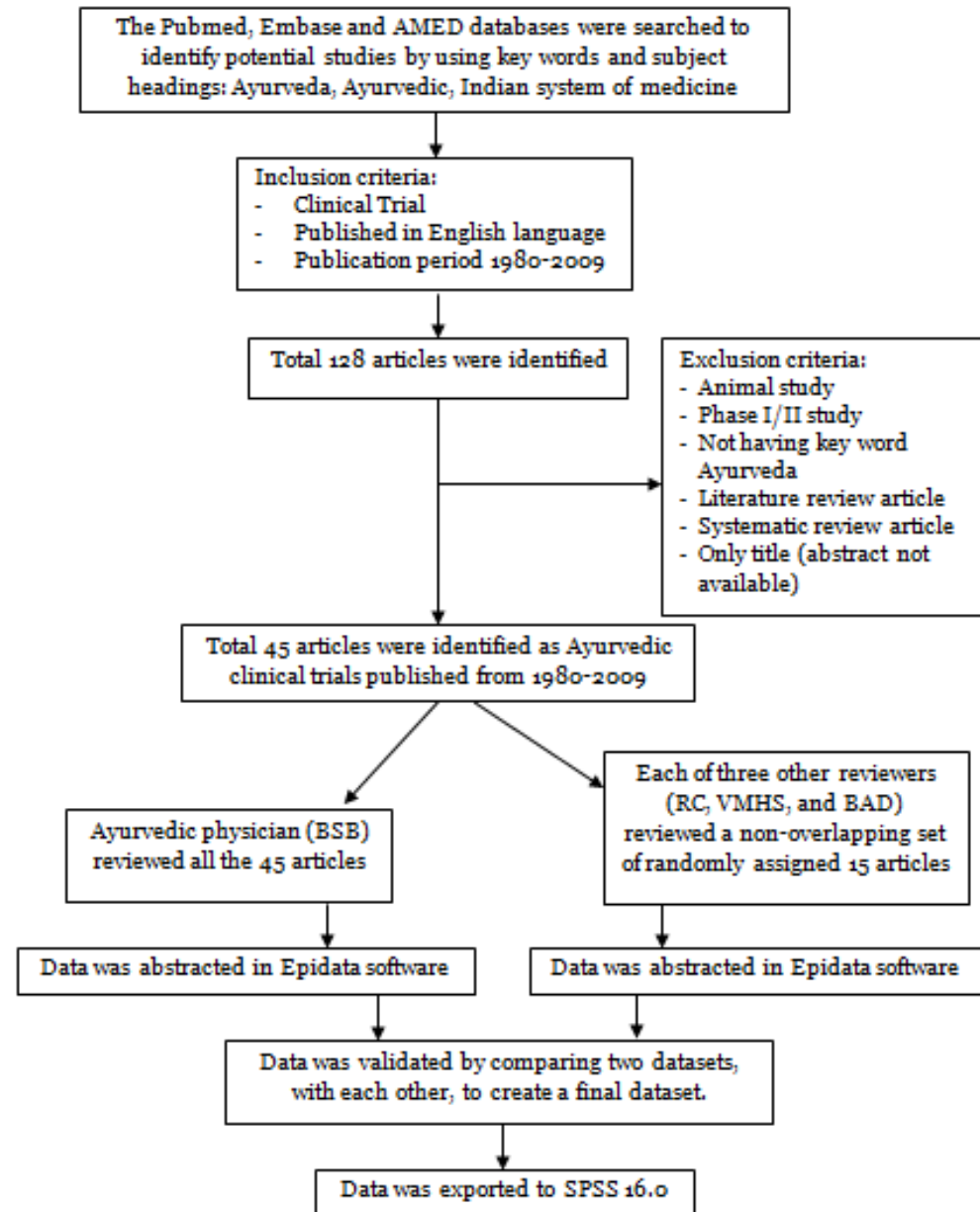
Rationale of this literature review...

- If diagnostic misclassification occurred routinely,
 - it would raise serious questions about the validity of the collective findings from this growing body of clinical trials on Ayurvedic interventions/treatments.

Materials and Methods

- Literature search
 - 1980 -2009
 - 128 abstract and titles
 - 45 clinical trails testing Ayurvedic intervention/treatment were identified.
- Review of articles:
 - BSB: 45 articles
 - Each of the other three reviewers (RC, VM, and BD) reviewed randomly assigned non-overlapping set of 15 articles.

Literature search and data retrieval: Flow chart



Materials and Methods...

- Data collection and management
 - Data retrieval document was created
 - A database was designed in Epidata software
 - 8 general questions:
 - 1) the title
 - 2) the author names
 - 3) publication date of the article
 - 4) the length of the follow-up observation period
 - 5) number of subjects in the study
 - 6) confirmation that the study was a clinical trial
 - 7) whether random assignment of subjects to study groups is used in the clinical trial
 - 8) a judgment of whether the diagnostic criteria were clearly described.

Materials and Methods...

- 23 specific Ayurvedic diagnostic terms
 - 10-fold (10 diagnostic terms)
 - 8-fold (8 diagnostic terms)
 - 5-fold (5 diagnostic terms)
- *Tridosha*
- Western diagnostic terms:
 - ECG, Laboratory test, CT scan, Ultrasonography, Liver functions test , Renal function test etc.

Materials and Methods...

- Data collection strategy:
 - 10-Fold examination and Tridosha
 - Diagnostic terms were purely Ayurvedic
 - Data was collected in responses:
 - Yes/Mentioned
 - No/Not-mentioned

Materials and Methods...

- 8-Fold and 5-Fold examinations
 - The diagnostic terms can be correlated to western medicine, for example:
 - *Nadi pariksha* - (pulse examination)
 - *Mutra pariksha* - (urine examination)
 - *Rupa* - (signs and symptoms of disease)

Materials and Methods...

- 8-Fold and 5-Fold examinations
 - Responses were collected with four options:
 - Term clearly reported in Ayurvedic term
 - Term clearly reported in Western term
 - Term reported but not clearly specified whether the term was mentioned in Ayurvedic or western terms
 - Not reported at all.

Materials and Methods...

- Data analysis:
 - Data exported from Epidata to SPSS software
 - Frequencies
 - Descriptive analysis
 - Cross-tabulations

Results

- The number of published Ayurvedic clinical trials over the 30 years observation period:

- 2 in the 1980's
 - 16 in the 1990's
 - 27 in the 2000's
-
- The diagram consists of three blue arrows pointing to the right. The top two arrows originate from the text '2 in the 1980's' and '16 in the 1990's' and converge towards the text 'Pre-2000'. The bottom arrow originates from '27 in the 2000's' and points towards 'Post-2000'.
- | Decade | Number of Trials | Period |
|--------|------------------|-----------|
| 1980's | 2 | Pre-2000 |
| 1990's | 16 | |
| 2000's | 27 | Post-2000 |

- 50% increase in the number of the trials using Ayurvedic interventions in the post-2000 decade period (n=27) as compared to the pre-2000 two-decade period (n=18).

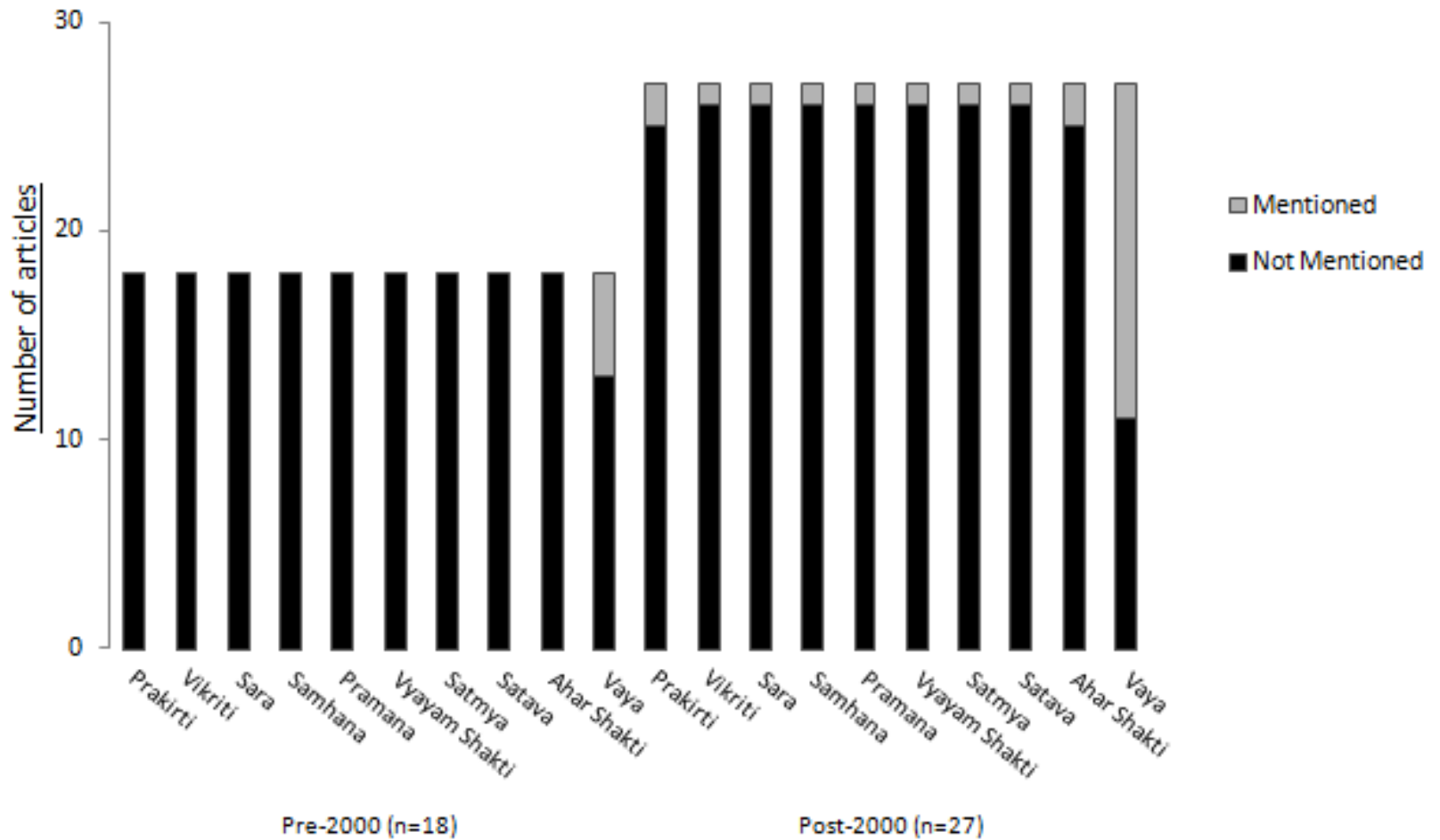
Results...

- None of these articles reported use of all the Ayurvedic diagnostic criteria.
 - Only 3 articles reported Ayurvedic term “*Tridosha*”
 - Pre-2000: only 2 articles reported.
 - Post-2000: only 1 article reported.
 - Only 2 articles reported Ayurvedic term “*Prakirti*”
 - Pre-2000: none of articles reported.
 - Post-2000: only 2 articles reported.

Results...

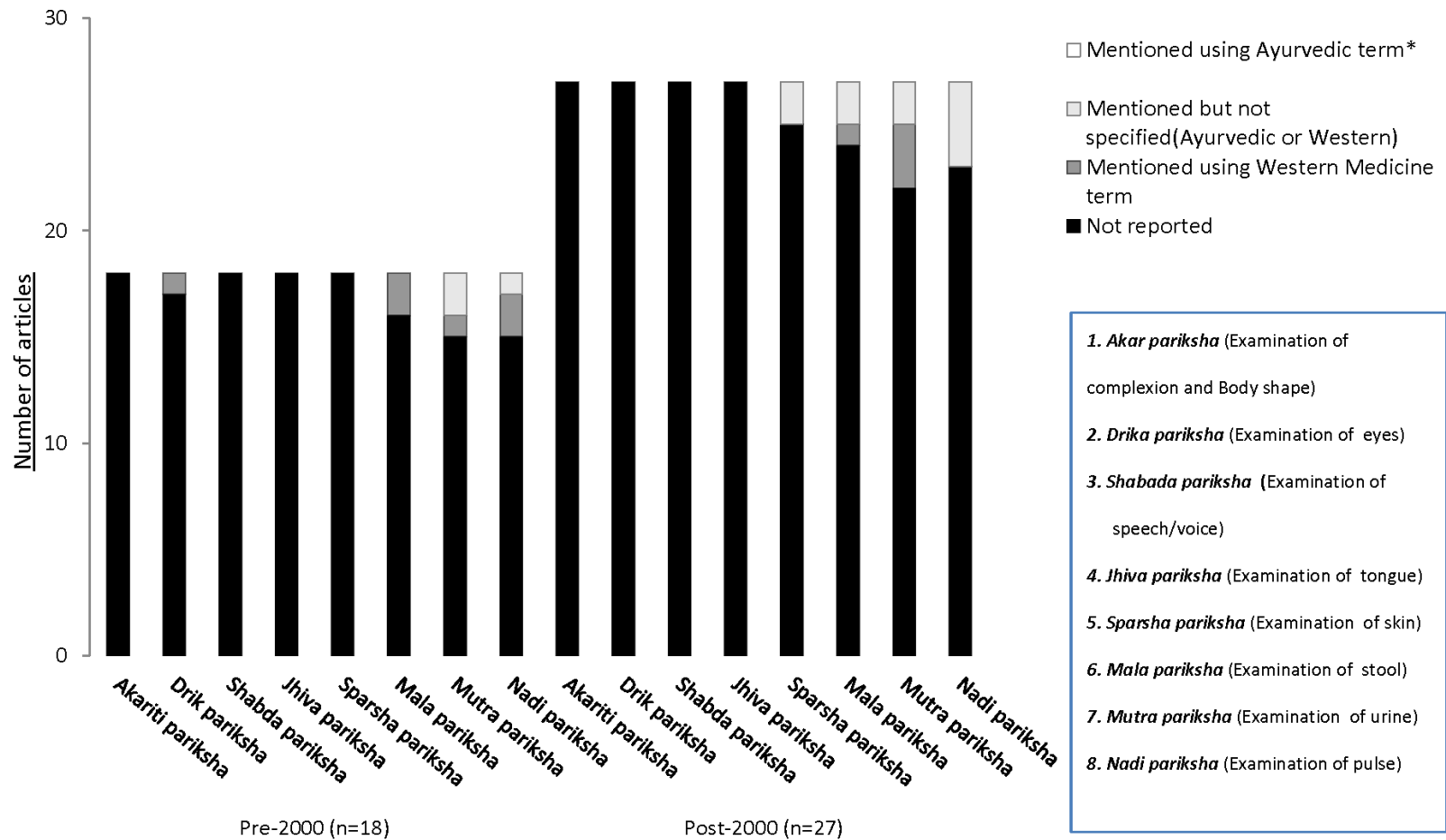
	Pre-2000 (n=18)	Post-2000 (n=27)
% of articles (n=45)	41%	59%
% of randomized controlled trial	66.6%	74%
study duration in days (Mean \pm SD)	61.8 \pm 53.9	94.4 \pm 88.2
number of subjects (Mean \pm SD)	49 \pm 23.8	55.9 \pm 37.2

Ten-fold patient examination: pre-2000 Vs post-2000.



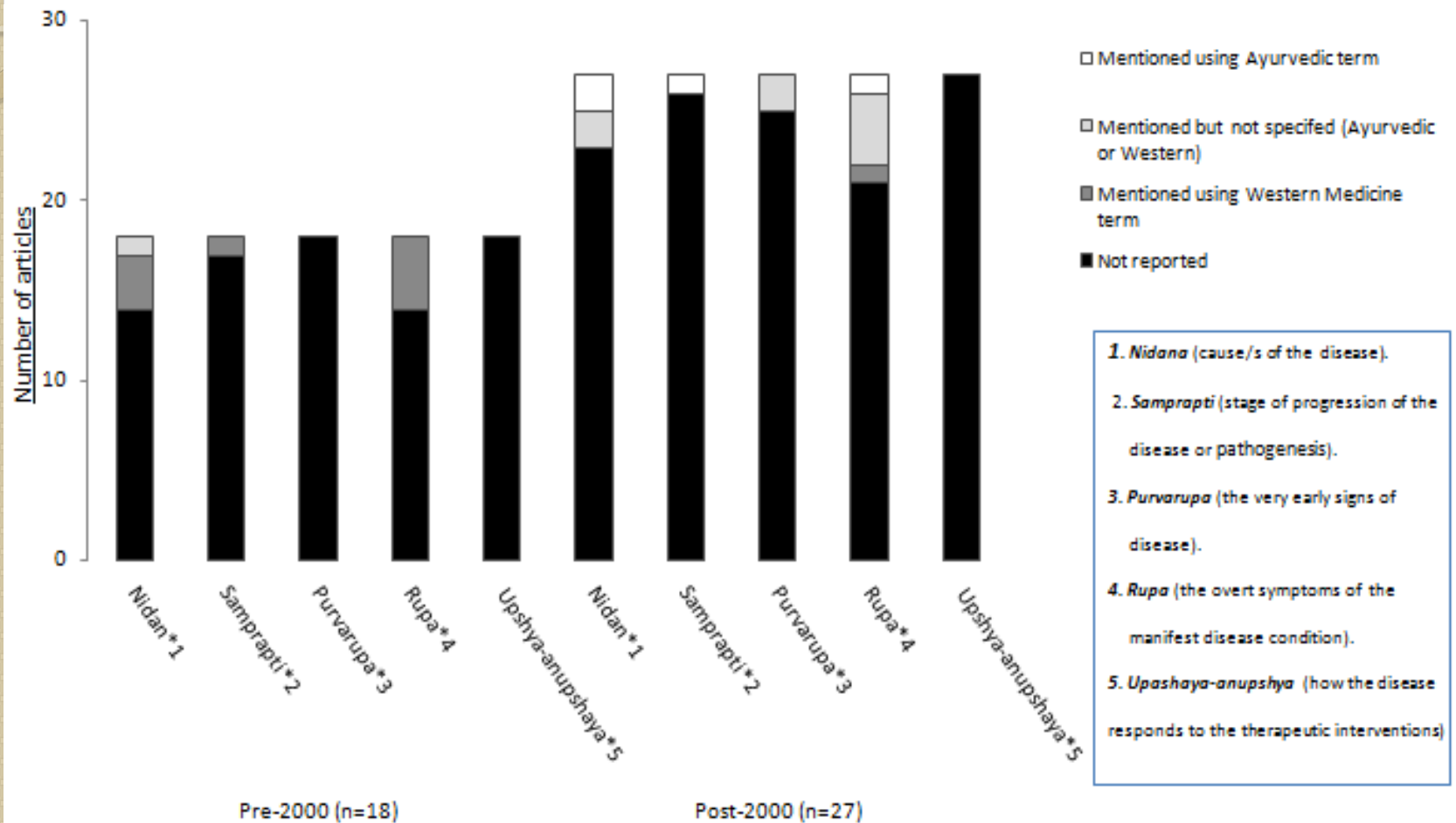
* Definitions of these terms of ten-fold patient examination are reported in table 2.

Eight-fold patient examination: Use of Ayurvedic Vs Western medical terminology

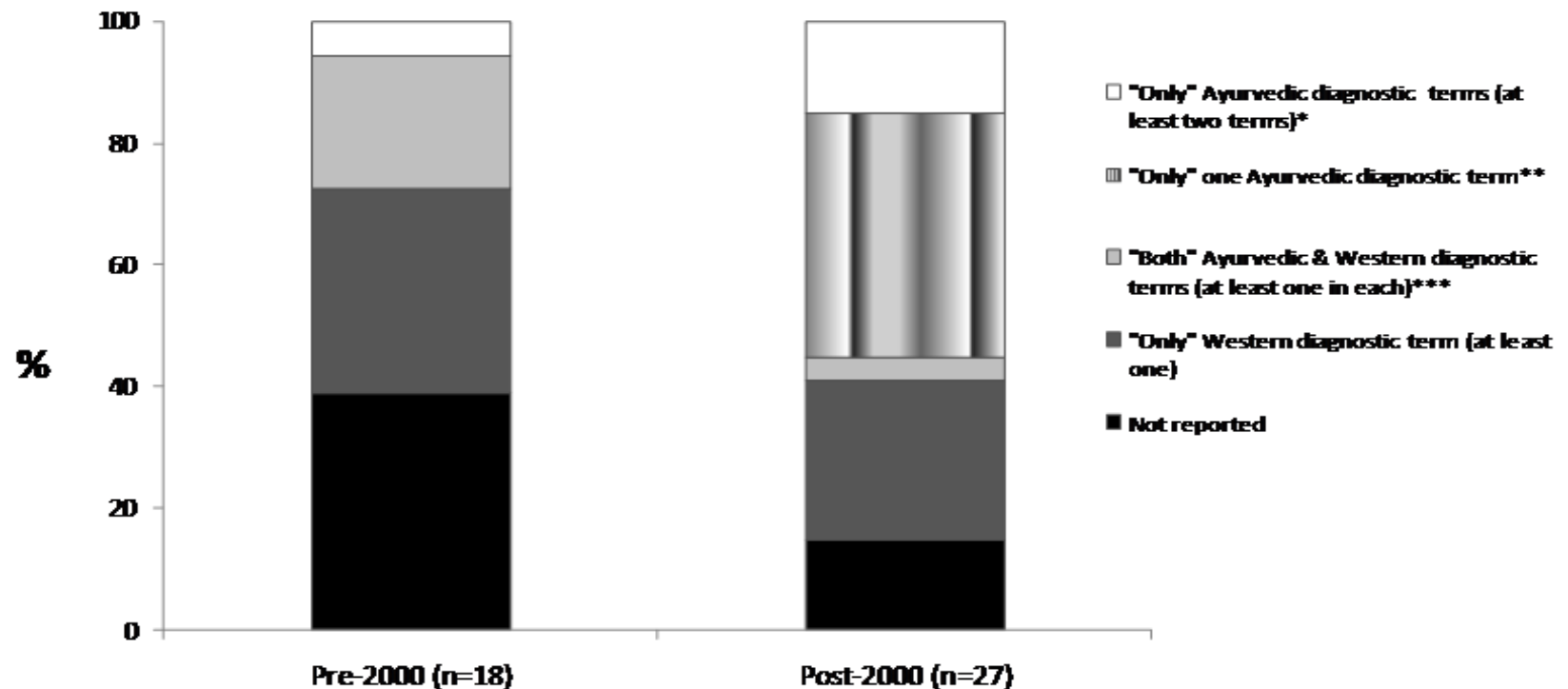


* None of the articles reported any of the eight diagnostic criteria in Ayurvedic terms

Five-fold disease examination: Use of Ayurvedic Vs Western medical terminology



Comparison of 'Ayurvedic' versus 'Western' diagnostic criteria in pre- and post-2000



* "Only" Ayurvedic diagnostic terms (at least two terms); only one reported 10 and all other less than five out of 23 Ayurvedic diagnostic terms, that should have been used.

** "Only" Ayurvedic diagnostic term (only one term); only single term was reported out of 23 Ayurvedic diagnostic terms.

*** Articles that reported both Ayurvedic and western diagnostic terms (at least one term); not more than two Ayurvedic terms have been reported out of 23 Ayurvedic diagnostic terms.

Discussion

- Ayurvedic treatment is very individualized i.e., a specific Ayurvedic treatment for a specific disease will ‘only’ be beneficial to a specific group of people who share same ‘*Prakirti*’ (Body constitution)

Discussion...

Example: Ayurvedic treatment for arthritis

- *Commiphora wightii* (Guggal) is effective in the arthritis treatment
- But it is used in specific formulations for patients with various *Prakirtis* i.e., *Vatta*, *Pitta*, and *Kapha*....

Discussion...

Use of Commiphora wightii (Guggal) in Vatta, Pitta, and Kapha Prakirti patients

- *Vatta Prakirti* ➤ Panchatiktaghruta Guggal' and 'Maharasandiquath'
- *Pitta Prakirti* ➤ 'Sinhanad Guggal' and 'Castor oil'
- *Kapha Prakirti* ➤ 'Yograj Guggal', 'Hingwashtak churan', and 'Dashmool'

Conclusion

- Future studies should overtly strive to correct this inappropriate underuse of Ayurvedic diagnostic criteria in the designing of clinical studies which aim to rigorously test the effectiveness of Ayurvedic treatments.

***THANK
YOU***

