

ORIGINAL ARTICLE

Development of Ayurvedic Diagnostic tool for Prameha Roga and its Inter-rater reliability

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ABSTRACT

*Prameha diagnostic Proforma (PDP) is a tool designed to diagnose Prameha disease and its subtypes with an indication of dosha involvement. This study aims to validate and check the reliability of the Ayurvedic Diagnostic tool for Prameha Roga. The intended outcome of this study is to obtain a uniform diagnosis at the dosha level. A cross-sectional study including 96 patients of Prameha was conducted at 10 centres. Patients were screened and enrolled using an Assessed questionnaire (to be filled by the patient) and Physician Screening Format (PSF), which was assessed by the Physician, specifically designed for screening of Prameha patients. Centres participating in this study have followed uniform protocol for Prameha Diagnostic Proforma Inter-rater reliability (kappa and percentage agreement), as well as inter-rater significance (p-value), were reported. The level of agreement was represented by kappa values more than 0.20 and percentage agreement greater than 70%. The GRRAS guideline for reporting of studies of reliability and agreement was followed. Each patient was examined by two Ayurvedic physicians independently. The total no of participants included in the analysis were 95. PDP contains a total of 359 items (PSF-27 and Detailed Proforma-332), Out of total 359 items, all the items of PSF-27 were reported, while out of 332 items of detailed proforma, only 305 were reported. Out of 27 items of PSF, 23 items had good to very good (Almost perfect) agreement having kappa value in between 0.6-1.0 and percentage agreement in between 82.10% -95.80%. All the reported 305 items of detailed proforma had percentage agreement ranging from 57.9% to 99.0% and kappa values ranging from 0.059 to 0.95. In ten items, there was a poor*

level of agreement. There were 213 items with a fair to moderate level of agreement and 82 items with a good to a very good level of agreement. Study findings indicate that PDP is a reliable tool for diagnostic purpose. Removal of unreliable items may produce a shorter more relevant instrument. PDP provides an evidence-based approach to diagnosis and management by which diagnosis of Prameha roga at the level of doshic sub-types may be made accurately.

**Keywords:** Prameha, Inter-rater reliability, Validation, Diagnostic tool

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## INTRODUCTION

The Prameha disease mentioned in the ancient Ayurvedic texts is a group of diseases rather than a single illness that includes clinical symptoms characterized by Prabhuta Avil Mutrata. As per Sushruta, Prameha can be diagnosed by combining features of Prabhuta Avila mutrata with Prameha puravarupa, but for diagnosis at the level of doshas, mutra pariksha is necessary. Due to the interaction of the three Doshas and ten Dushyas, Prameha is divided into 20 subtypes. These twenty types of Prameha have been differentiated based on Mutra parisksha (Urine examination). MutraPariksha examination parameters can be widely divided into two categories i.e. Mutra-ashrita parameters examination which includes Varna, Rasa, Gandha, Varna, sparsha, svarupa, sandrata and Mutra-pravritti jnaya examination parameters which include parameters related to micturition frequency, amount and flow of urine. Apart from urine examination Doshya, Dushya and Srotas pariksha play a significant role in diagnosis at the level of doshas. Prameha has been also classified on an etiological basis into Sahaja/Jata pramehi and Apathya Nimattaja Pramehi. Therefore while defining the diagnostic criteria of Prameha Roga, the above-mentioned points should be kept in mind. This study aims to validate and check the reliability of the Ayurvedic Diagnostic tool for Prameha Roga. The intended outcome of this study is to obtain a uniform diagnosis at the level of Doshya.

Despite the clinical importance of Prameha Roga, no such diagnostic criteria was available which can comprehensively assess this disease. Lack of uniformity in diagnostic methods leads to variation in final diagnosis with dosha involvement. Therefore an attempt is made to develop Prameha disease diagnostic tool entirely based on Ayurvedic principles of diagnosis. The evaluation and interpretation of diagnostic tools used to make uniform diagnoses are frequently not standardised, however, this is important for accurate and reliable testing. We conducted the study to determine the reliability of the Prameha Diagnostic tool that points towards the diagnosis of Prameha and its doshic sub-types. The inter-rater reliability of the Ayurvedic diagnostic proforma of Prameha Rogah has been investigated in this study [1,2]. The inter-rater reliability of diagnostic criteria based on Ayurvedic principles has remained mostly unknown till now. For uniformity in clinical diagnosis and clinical trials, it is necessary to develop validated standard assessment parameters/Ayurvedic diagnostic tools for the disease entirely based on Ayurvedic principles which may provide an evidence-based approach to diagnosis and management.

**Table no 1: Grading of Kappa Value:**

S.N.	Value of Kappa (Altman)	Level of agreement	No of items in Physician Screening Format	No of items in Detailed Diagnostic Proforma
1.	<0.20	Poor	00	12
2.	0.21-0.40	Fair	01	96
3.	0.41-0.60	Moderate	03	115
4.	0.61-0.80	Good	22	72
5.	0.81-1.00	Very good	01	10

A detailed structured diagnostic proforma for Prameha Roga (Prameha Diagnostic Proforma: PDP) has been developed as per principles of diagnostic methods described in Ayurvedic literature by the Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi. A final draft of the proforma has been developed in a sequential phase-wise manner consisting of various phases including literature search, the clinical consensus from experts of the field for face validity and content validity testing and pre-testing of proforma at the OPD level. Prameha Diagnostic Proforma (PDP) is a compilation of the best available evidence for Prameha Roga mentioned in classical Ayurvedic text. PDP consists of two parts, the first is

the screening proforma (physician screening proforma:PSF) and the second is diagnostic proforma. Physician Screening proforma has 27 outcome variables/items related to screening of *Prameha* disease. Diagnostic proforma has seven domains from A to G namely, *Mutra Pariksha, Dosha pariksha, Dushya pariksha, Srotas pariksha, samprapti Nirdharan, upadrava and Nidana vivechan*, consisting of 332 outcome variables/items. Almost all the outcome variables in the proforma were clearly defined and consisted of binary/dichotomous responses (Yes/No or present/absent).

Raters for inter-rater reliability testing were of the same background with post-graduation in the Ayurvedic system of medicine having 5 to 10 years of clinical experience in the desired disease condition. According to McHugh, kappa is the best choice for determining reliability when raters have a strong guessing characteristic in scoring[1]. However, if raters are well-trained and unlikely to make guesses when scoring, percent agreement is the best way to measure the instrument's reliability [1]. The chance agreement can be corrected with Kappa, but the chance agreement cannot be corrected with the percent agreement [1].

Items ( <i>Pradhan Vedana</i> -Presenting complaint)	Percentage Agreement	Kappa value	p-value
<i>Prachura Mutrata</i> (Increase in quantity of urination)	93.7%	0.219	<0.027
<i>Mutra-Abhikshanata</i> (Increase in frequency of urination)	90.6%	0.612	<0.001
<i>Avila Mutrata</i> (Turbidity in urine)	86.3%	0.668	<0.001
<i>Mutra-Vaivarnnyam</i> (Altered colour in urine)	88.4%	0.743	<0.001
<i>Madhur-shukla-Mutrata</i> (Manifestation of abnormalities in urine)	80.0%	0.410	<0.001
<i>Mutra-Daugandhyam</i> (Foul smell from urine)	88.4%	0.756	<0.001
<i>Shatpadpippilikabhii cha Sharir Mutraabhisaranam</i> (Attraction of Ants towards excreted urine)	93.6%	0.785	<0.001
<i>Mukh-Talu-Kantha-Shosha</i> (Dryness of mouth, palate and throat)	86.3%	0.722	<0.001
<i>Pipasa/Trit</i> (Increased Thirst)	85.3%	0.692	<0.001
<i>Karpaaddaha/hastapadataldaha</i> (Burning Sensation in palm/soles)	84.4%	0.767	<0.001
<i>Angeshuparidaha</i> (Burning sensation all over body)	85.3%	0.590	<0.001
<i>Kar-padyo-suptata</i> (Numbness in hands and feet)	84.2%	0.681	<0.001
<i>Angeshu-suptataam</i> (Numbness in body parts)	86.3%	0.667	<0.001
<i>Gatranam Gurata</i> (Feeling of Heaviness in body)	84.2%	0.679	<0.001
<i>Nidra, Tandra cha Sarvakalam</i> (Always feeling sleepy and drowsy)	82.1%	0.637	<0.001
<i>Alasyam</i> (lazyness)	83.2%	0.574	<0.001
<i>Shayya-Asana-Swapna-sukherati</i> (Preference for sleeping, resting and lying down always)	82.1%	0.608	<0.001
<i>Sithilangata/Saad</i> (Laxity of muscles and body in general)	83.2%	0.681	<0.001
<i>Swasa-daugandhyam</i> (Bad breath)	92.6%	0.790	<0.001
<i>Vishra-sharirgandham</i> (Foul Body odour)	91.5%	0.763	<0.001
<i>Sveda</i> (Excessive Sweating)	84.2%	0.675	<0.001
<i>Talu-gal-jihva-danteshu-malotpatti/Kayachhidreshu-updeham</i> (Deposition of grime or dirt over throat-palate-tongue and teeth)	91.6%	0.805	<0.001
<i>Asyamadhuryam</i> (Sweet taste in mouth)	91.5%	0.699	<0.001
<i>Jatilibhava Keshanam</i> (Matted hair)	95.8%	0.833	<0.001
<i>Vridhhi cha Nakhanam</i> (Excessive growth of nails)	92.7%	0.715	<0.001
<i>Vridhhi cha Keshanam</i> (Excessive growth of hairs)	93.7%	0.750	<0.001
<i>Sitapriyatvam</i> (fond of coldness)	85.3%	0.683	<0.001

Internal consistency reliability, test-retest reliability, parallel form's reliability, intra-rater reliability, and inter-rater reliability are some of the ways for determining reliability [2]. Inter-rater reliability is a recommended reliability measurement for the consistency of raters [2]. Recommended reliability measurement for consistency of raters is by using inter-rater reliability. Statistical test for determining inter-rater reliability is the Kappa coefficient combined with percent agreement [3]. Reliability relates to the precision of the measurement or the reproducibility of the scores acquired with the examination, says one definition. Interrater reliability refers to raters' agreement on the same data as a result of scale classification on the same instrument or process. Higher inter-rater reliability means that the results of

the raters are more consistent. The subject to be observed, the raters, the atmosphere at the moment of measurement, and the device are all factors that influence inter-rater reliability.

One of the statistical methods used to assess inter-rater reliability is percentage agreement. Only a value of >70% indicates acceptable percent agreement. In addition to percentage agreement, the kappa statistic can be used to assess inter-rater reliability. Various scholars, such as Landis and Koch, Fleiss, and Altman, have proposed various interpretations of the kappa coefficient. There are three-point of views that defines the unacceptable kappa value. According to Landis and Koch, a kappa value of 0.00 is inappropriate although Altman suggests a value of 0.20. Feinstein, Chiccheti, and Morris, on the other hand, claim that a kappa value of less than 0.41 is unacceptable [1].

**Table no 3 (a): Category A: Mutra Pariksha (Urine Examination)**

Parameters	Items	Percentage Agreement	Kappa value	p-value
Mutra-Varna (Colour of urine)	Samanya Varna(Normal colour i.e.Amber coloured)	78.9	0.352	<0.001
	Udakopam(Colourless)	92.7	0.0719	<0.001
	Kandekshurasa-samkasham(Colour similar to sugarcane juice)	98.9	0.795	<0.001
	Svetam (Whitish)	99	0.662	<0.001
	Shukla-pishtanibham(Dense white)	-	-	-
	Shukrabham (Whitish/ Semen like white)	-	-	-
	Ksharodaka-samkasham(Slight Hazy)	-	-	-
	Kaal (Black)	-	-	-
	Neela (Blue )	-	-	-
	Rakta (Red/ Dark Red Colour)	-	-	-
	Manjisthodaka sadrisham (Pale red)	96.8	0.555	<0.001
	Haridrodaka-samkasham (Colour similar to turmeric water, Yellowish)	95.8	0.833	<0.001
	Vasa-sadrisham(Creamy white)	-	-	-
	Sarpi varnam (Colour similar to Ghrita: Slight yellowish whitish)	-	-	-
	Pandu/kshaudra varnam (Pale yellow/ honey colour)	73.6	0.428	<0.001
Anya(Others)	92.7	0.549	<0.001	
Mutra-Gandha (odour of Urine)	Samanya Gandha(Normal faint odour of urine)	79.5	0.448	<0.001
	Nirgandha (Odourless like water)	65.2	0.327	0.001
	Kshargandha (smell like Alkali-Kshar)	62.1	0.259	0.007
	Amlagandha(Sour smell like vinegar)	65.3	0.324	0.001
	Vishra-gandha(Fleshy smell)	64.2	0.319	0.001
	Madhugandha(Honey like sweet smelling)	71.6	0.441	<0.001
	Anya(Others)	62.1	0.259	0.007
Mutra-Rasa (Taste of Urine)	Samanya (Normal)	65.3	0.299	0.003
	Atyartha Madhuram/ Madhura(Sweet)	81.1	0.483	<0.001
	Amlam (Sour)	68.4	0.39	<0.001
	Lavanam(Salty)	63.1	0.332	<0.001
	Katukam (Pungent)	67.4	0.365	<0.001
	Kshar sadrishha Rasa (Alkaline taste)	62.1	0.27	0.001
	Kashaya-madhuram/Kshaudra Rasam (Astringent-sweet, similar to taste of honey)	65.3	0.324	0.001
	Anya(Others)	63.2	0.28	0.003
Mutra-Sparsha (Temperature of urine during voiding)	Samanya (Normal)	-	-	-
	Ushna (Scalding or hot)	62.1	0.259	0.007
	Shita (Cold)/ Atyartha-shita (Extremely cold)	64.2	0.302	0.001
	Anya (Others)	64.2	0.3	0.002
Swaroop (Physical appearance of)	Samanya (Normal looking without any turbidity)]	76.8	0.434	<0.001

urine)	<i>Achha</i> (Extremely clear)]	60	0.22	0.023
	<i>Aavila</i> (Turbid)]	68.4	0.38	<0.001
	<i>Sikta-anuviddha</i> (Crystal like small sediments in hazy urine)]	68.4	0.399	<0.001
	<i>Tantuyuktam</i> (Thread like components in urine)	65.3	0.341	<0.001
	<i>Mut্রে snigdha padartha/sakapham /salaseekam</i> (Oily or unctuous looking components in urine )	64.2	0.319	<0.001
	<i>Sashukram</i> (Urine mixed with semen)	65.2	0.334	<0.001
	<i>Pichchhila</i> (Sliminess in urine)	63.2	0.299	0.001
	<i>Safena</i> (Frothy urine)	65.2	0.331	<0.001
	<i>Anya</i> (Others)]	64.2	0.327	<0.001
<i>Sandrata Shreni</i> (Grading of Sedimentation)	<i>Samanya</i> (Normal)	70.5	0.319	0.002
	<i>Svalpa-sandra</i> (Slight sedimentation)	68.4	0.238	0.005
	<i>Ghana</i> (More sedimentation)	64.2	0.321	<0.001
	<i>Anya</i> (Others)	68.4	387	<0.001
<i>Mutra-parivartan: Sadyah</i> (Density within minutes after voiding)	<i>Samanya</i> (Normal)	68.5	0.113	0.272
	<i>Svalpa-sandra</i> (Slight sedimentation)	61	0.208	0.02
	<i>Ghana</i> (More sedimentation)	62.1	0.284	0.002
	<i>Anya</i> (Others)	64.2	0.312	0.001
<i>Mutra-parivartan:yaamaat-param</i> (Change in urine after keeping for 3 hours)	<i>Aparivartana</i> (No change)]	90.5	0.42	<0.001
	<i>Upari-achham-adho-ghanam</i> (Sediments settling in the lower part with clear urine in the upper portion )	68.4	0.395	<0.001
	<i>Sandribhavati-bhajane</i> (Upto half or more than half of the urine appear dense with only a small clear part)]	63.2	0.299	0.001
	<i>Anya</i> (Others)]	60	0.246	0.006
Mutra-matra (urine quantity in 24 hours)	<i>Samanya</i> (Normal quantity)]	57.9	0.194	0.039
	<i>Prabhut-mutrata/ Bahu</i> (large quantity) / <i>Bahu-prabhuta</i> (hastivat) (Excessive quantity)]	94.8	0.259	0.011
	<i>Alpa-matra</i> (Less quantity)]	65.3	0.324	0.001
<i>Mutra-Abhikshanata</i> (frequency of urination)	<i>Samanya/Aparivartana</i> (Normal/no alteration in frequency)	70.5	0.412	<0.001
	<i>Bahu-abhikshna-alpa matra</i> ( <i>stokam</i> ) (Frequent urination with low quantity)	71.6	0.39	<0.001
	<i>Bahu-Abhikshna-Bahu-matra</i> (Frequent urination with large quantity)	61.1	0.152	0.108
	<i>Alpa</i> (Decrease frequency of micturition)	63.2	0.293	0.002
	<i>Ratrimutrata</i> (Nocturnal Polyurea)	70.5	0.093	0.263
<i>Mutra-dhara</i> (flow of Urine)	<i>Samanya dhara evam vega</i> सामान्यधारमत्थावेग: (Normal flow and normal stream:)	-	-	-
	<i>Mandam-mandam avegam</i> (Slow stream without force)	61.1	0.235	0.017
	<i>Shighram vega-vivarjitam</i> (Urgency without force)	68.4	0.378	<0.001
	<i>Ajashram</i> (Continuous Flow)	61.1	0.237	0.015
	<i>Anya</i> (Others)	65.2	0.332	<0.001
Others	<i>Savedana-Mutra pravritti</i> (Pain on micturition)	97.9	0.877	<0.001
	<i>Savidaha-Mutra pravritti</i> (Burning on micturition)	78.1	0.595	<0.001
	<i>Mutrakrichhata</i> (Difficulty in urination)	90.5	0.586	<0.001
	<i>Ruksha Mutrata</i> (Absence of unctuous feeling in Urine)	90.5	0.699	<0.001

## MATERIAL AND METHODS

### Development of Prameha Diagnostic proforma:

A detailed structured diagnostic proforma for *Prameha Roga* (Prameha Diagnostic Proforma: PDP) has been developed as per principles of diagnostic methods described in Ayurvedic literature by the Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi. The final draft of the proforma has been developed in a sequential phase-wise manner consisting of various phases including literature search, the

clinical consensus from experts of the field for face validity and content validity testing and pre-testing of proforma at the OPD level. *Prameha* Diagnostic Proforma (PDP) is a compilation of the best available evidence for *Prameha Roga* mentioned in classical Ayurvedic text. The screening proforma (physician screening proforma:PSF) and the detailed diagnostic proforma are the two elements of the PDP. The Physician Screening Proforma has 27 outcome variables/items linked to *Prameha* disease screening. *Mutra Pariksha*, *Dosha pariksha*, *Dushya pariksha*, *Srotas pariksha*, *Samprapti Nirddharan*, *upadrava*, and *Nidana vivechan* are the seven domains of the diagnostic proforma, which contain 332 items. The outcome variable of the proforma was well-defined and consisted of binary/dichotomous responses (Yes/No or present/absent).

**Table no 4: Category B-Dosha Pariksha (Examination of Dosha)**

Variable	Percentage Agreement	Kappa value	p-value
<i>Vak-parushya</i> (Hoarseness of voice)]	93.7	0.634	<0.001
<i>Karshya</i> (Emaciation)]	85.3	0.653	<0.001
<i>Kashnya</i> (Blackish discoloration)]	86.3	0.637	<0.001
<i>Gatra- sphurana</i> (Fasciculation)/]	92.7	0.625	<0.001
<i>Gatra kampa</i> (Tremors)]	88.5	0.29	0.005
<i>Ushna kamta</i> (Liking of hot environment and food articles)]	81.1	0.602	<0.001
<i>Nidra nasha</i> Loss of Sleep)]	82.1	0.623	<0.001
<i>Alpa bala</i> (Decreased strength)]	79.0	0.46	<0.001
<i>Gadha varcha</i> (Hard stool/constipation)]	84.3	0.62	<0.001
<i>Anaha</i> (Flatulence)]	82.1	0.596	<0.001
<i>Bala-indriya-bhransha/ sangya nasha</i> (Loss of consciousness)]	91.6	0.163	0.08
<i>Pralapa/Bhrama</i> (Delirium)(A.H)]	99	0.662	<0.001
<i>Dinata</i> (Depressed)	82.1	0.43	<0.001
<i>Manda Chestata</i> (low activity)]	78.9	0.544	<0.001
<i>Alpa- Vak</i> (talking less)]	83.1	0.47	<0.001
<i>Mudh-Sangyata</i> ( no thoughts)]	97.9	0.657	<0.001
<i>Moha</i> (Delirium)]	-	-	-
<i>Angasada</i> (Body ache) A.H.]	73.7	0.476	<0.001
<i>Apraharsha</i> (Unhappy)	83.1	0.531	<0.001
<i>Pitavabhasata</i> (appearance of yellowish discoloration)]	97.9	0.489	<0.001
<i>Santapa</i> (Rise of body temperature)]	84.2	0.37	<0.001
<i>Sitakamitva</i> (Desire for cold substances)]	81	0.484	<0.001
<i>Alpa nidrata</i> (Decreased Sleep)]	88.4	0.755	<0.001
<i>Murchha</i> (Fainting)]	-	-	-
<i>Bala-hani</i> (Loss of Strength)]	73.6	0.357	<0.001
<i>Indriya -daurbalya</i> (Improper functioning of senses)]	89.4	0.671	<0.001
<i>Pita-Vita-Mutra-netra-Tvaka</i> (Yellowish color of Stool Urine & eyes and skin)]	95.8	0.692	<0.001
<i>Kshudha</i> (Hunger)]	77.9	0.554	<0.001
<i>Daha</i> (Burning Sensation)]	75.8	0.502	<0.001
<i>Santapa</i> (Elevated body temperature)]	86.4	0.059	0.562
<i>Trishna</i> (Thirst)]	81	0.565	<0.001
<i>Mandoshmata /Shita</i> (Feeling of Cold)]	93.7	0.632	<0.001
<i>Mandagnita</i> (Decreased digestive fire)]	85.2	0.502	<0.001
<i>Nishprabhata</i> (loss of luster ]	88.5	0.496	<0.001
<i>Shauklyam</i> (whitishness of body]	95.8	0.581	<0.001
<i>Shaitya</i> (Cold on touch/feeling of cold]	89.5	0.486	<0.001
<i>Sthairya</i> (sturdiness)]	-	-	-
<i>Gaurav</i> (heaviness)	75.8	0.514	<0.001
<i>Avasada</i> (lassitude)]	85.3	0.696	<0.001
<i>Tandra</i> (drowsiness)]	78.9	0.579	<0.001

<i>Nidra</i> (sleepiness)	75.8	0.464	<0.001
<i>Sandhi-Vishlesh</i> (feeling of looseness in joints)	78.9	0.368	<0.001
<i>Slathangatvam</i> (Flaccid body)]	80	0.433	<0.001
<i>Alasyam</i> (Laziness)	72.6	0.354	<0.001
<i>Anutsaaha</i> (less interest in surroundings)	85.3	0.416	<0.001
<i>Praseka</i> (Excess salivation)-]	92.8	0.549	<0.001
<i>Swasa</i> (Breathlessness/shortness of breath)]	93.7	0.733	<0.001
<i>Kasa</i> (Cough)]	96.9	0.65	<0.001
<i>Hrillasa</i> (Nausea)]	91.6	0.29	0.004
<i>Agnisada</i> (Decreased Digestive Fire)]	86.3	0.472	<0.001
<i>Rukshata</i> (dryness)]	94.8	0.808	<0.001
<i>Antardaha</i> (Internal burning sensation)]	87.4	0.386	<0.001
<i>Amashayetara Sleshma Ashaya shunyata</i> (Feeling of emptiness in Sleshna sthana except Amashaya i.e head, neck and thorax )	97.9	0.789	<0.001
<i>Sandhi-Shaithilya</i> (Subluxation of joints)]	86.3	0.183	0.031
<i>Trishna</i> (Thirst)]	71.6	0.4	<0.001
<i>Daurbalya</i> (Weakness)]	72.6	0.382	<0.001
<i>Prajagara</i> (No Sleep at night)]	87.4	0.675	<0.001
<i>Bhrama</i> ( Giddiness)A.H.]	93.7	0.467	<0.001
<i>Angamarda</i> (body ache)]	83.2	0.655	<0.001
<i>Hrid-dravatvam</i> (tachycardia/Palpitation)	93.7	0.692	<0.001

#### Defining the diagnostic criteria/Initial draft of diagnostic criteria:

The initial draft of diagnostic criteria has been developed through an extensive literature search in various classical Ayurvedic texts and focused group discussions. The focused group consists of experts in the concerned subject. In the process of item generation, seven domains have been framed and accordingly, variables of their domain have been categorized. Sanskrit terminologies of the outcome variables were taken up for discussion and an operational definition for each variable has been finalized so that any differences in clinical observations may be minimized. Type of response scale, dichotomous responses (Yes/No or present/absent) was decided for each variable.

#### Face validity and content validity of diagnostic criteria:

For validity testing, a clinical consensus survey has been conducted among ten experts of the field through email by zero draft distribution. For clinical consensus, well experienced Ayurvedic clinicians having >5 years of experience related to the subject were selected. Clinicians were asked to evaluate the items of the proforma and give their consensus by mentioning whether they agree or disagree to retain that item in the proforma. Those variables on which experts did not agree were further evaluated by a focused group. After evaluation items were either modified or discarded. Focused group members who conceptualized the study supervised the entire process.

**Table no 5: Category C-Dushya Pariksha (examination of Dushya)**

Parameter	Percentage Agreement	Kappa value	p-value
<i>Hridyotkleda</i> (Nausea)	95.8	0.644	<0.001
<i>Praseka</i> (excess salivation)	87.7	0.665	<0.001
<i>Hrit-Pida</i> (cardiac pain)	93.7	0.219	0.027
<i>Hrit-kampa</i> (palpitation)	88.4	0.552	<0.001
<i>Hrit-shunyata</i> (Feeling of emptiness in cardiac region)	-	-	-
<i>Trishna</i> (Feeling thirsty)	71.6	0.379	<0.001
<i>Raktangakshita</i> (redness of whole body and eyes)	94.7	0.417	<0.001
<i>Sirapurnatva</i> (fullness of veins)	90.5	0.265	0.005
<i>Tvakparushya</i> (Roughness of skin)	83.1	0.452	<0.001
<i>Amla-shita prarthana</i> (desire of sour and cold substances)	82.1	0.521	<0.001
<i>Sira-Shaithilya</i> (Sluggishness of veins)	-	-	-
<i>Sfig-ganda-ostha-upastha-uru-bahu-janghashu vridhhi</i> (overgrowth of muscular portion of body)	92.6	0.325	0.001

<i>Guru-gatrata</i> (heaviness in body)	76.7	0.541	<0.001
<i>Sfig-ganda-ostha-upastha-uru-vaksha-kaksha-pindika-udar-greeva-shushkta</i> (Emaciation of various muscular parts of body)	89.5	0.387	<0.001
<i>Gatra-Toda</i> (Pricking Pain in whole body)	90.6	0.351	<0.001
<i>Sadana</i> (Generalised weakness)	79	0.428	<0.001
<i>Dhamani-shaithilya</i> (Laxity of Dhamni)	97.9	0.489	<0.001
<i>Snigdhagata</i> (Unctuousness of body)	83.1	0.496	<0.001
<i>Udarparshva vridhhi</i> (Enlargement of lateral side of abdomen)	91.6	0.509	<0.001
<i>Kasa-swasadinam daurgandhyam</i> (bad breath during coughing and breathing)	88.4	0.647	<0.001
<i>Pleeha-abhivridhi</i> (splenomegaly)	-	-	-
<i>Sandhi-shunyata</i> (emptiness/hollowness of joints)	91.6	0.384	<0.001
<i>Raukshaya</i> (Rough skin)	90.5	0.685	<0.001
<i>Medurmamsa Prarthana</i> (desire for unctuous substances)	86.3	0.314	0.001
<i>Adhyasthi evam Adhidanta</i> (additional bone and teeth)	-	-	-
<i>Kesh-nakha ativridhhi</i> (excessive growth of hairs and nails)	94.7	0.817	<0.001
<i>Asthi-shula</i> (Bony pain)	82.1	0.538	<0.001
<i>Danta-nakha bhanga</i> (falling of teeth/nails)	93.7	0.538	<0.001
<i>Ruksha Deha</i> (Dryness in whole body)	89.5	0.629	<0.001
<i>Sarvanga gaurav</i> (generalised heaviness)	85.3	0.704	<0.001
<i>Netra-gaurav</i> (heaviness in eyes)	81.1	0.54	<0.001
<i>Alpa-shukrata</i> (decreased semen quantity)	93.7	0.367	<0.001
<i>Parvabheda</i> (breaking pain of joints)	80	0.268	0.009
<i>Asthinistoda</i> (Pricking pain of bones)	86.3	0.167	0.085
<i>Asthi-shunyata</i> (Hollowness of bones)	-	-	-
<i>Shukrashmari</i> (Shukra-ashmari)	95.8	0.312	0.002
<i>Shukra ati-pradurbhava</i> (Excess semen discharge)	95.8	0.312	0.002
<i>Medhra-vrishan vedana</i> (Pain in Penis and testis)	97.9	0.492	<0.001
<i>Maithuna-ashakti</i> (inability during intercourse)	92.6	0.495	<0.001
<i>Shukra Chira Praseka</i> (Delayed ejaculation)	96.8	0.555	<0.001
<i>Praseke cha alpa-rakta-shukra-darshanam</i> (Less & bloody semen discharge)	-	-	-
<i>Mutra-vridhhi</i> (Increase volume of urination)	82.1	0.219	0.031
<i>Mutra-Muhur-muhur-pravritti</i> (Increased frequency of micturition)	87.3	0.549	<0.001
<i>Basti-toda</i> (Piercing pain in bladder)	90.3	0.475	<0.001
<i>Basti- adhamana</i> (over fullness of bladder)	91.6	0.509	<0.001
<i>Alpa-mutrata</i> (Decrease amount of urine)	-	-	-
<i>Atopa</i> (bloating)	80	0.514	<0.001
<i>Kukshi-shula</i> (Pain in abdomen)	89.5	0.441	<0.001
<i>Hridaya-pida</i> (cardiac pain)	91.6	0.29	0.004
<i>Parshva-pida</i> (lateral side of pain and flank pain)	92.6	0.333	<0.001
<i>Sashabdasya vayo-urdhva gamanam-kukshi sancharanam</i> (Movement of vayu in upward direction producing sound)	93.7	0.716	<0.001
<i>Tvak-daurgandhya</i> (bad smell from skin)	83.1	0.455	<0.001
<i>Kandu</i> (Itching)	85.2	0.599	<0.001
<i>Stabdha-romkupata</i> (Blockage of hair follicles)	97.9	0.657	<0.001
<i>Tvak-shosha</i> (cracking of skin)	96.9	0.384	<0.001
<i>Sparsha-vaigunya</i> (altered sensation of touch)	99	0.662	<0.001
<i>Sveda-nasa</i> (Less perspiration)	96.9	0.652	<0.001

**Method of inter-rater reliability testing:  
Study Design:**



This was a cross sectional study combining qualitative and quantitative methods. A total of 95 cases of *Prameha* were included in this study, screened through assesses questionnaire and physician screening format. At each centre both the raters independently assessed the same ten patients of *Prameha* disease using the same Ayurvedic diagnostic proforma. Entrées participating in this study have followed uniform detailed protocol for PDP. The GRRAS (Guideline for Reporting of Reliability and Agreement Studies) guidelines were followed for reporting. Each patient was examined by two Ayurvedic physicians independently. To reduce the chance of confounding, consultation took place on the same day. Before the study, raters were given a training session to achieve as much uniformity as feasible in the methodology and standardization of test procedures. Written informed consent was obtained from all the participants. Steps for inter-rater reliability are shown in flow diagram 2.

**Table no 6: Category D-*Strotas Pariksha* (Examination of *Strotas*)**

Items	Percentage Agreement	Kappa value	p-value
<i>Ati-srishtam-mutrayantam</i> (passing excess urine with effort)]	86.3	0.633	<0.001
<i>Ati-baddham-mutrayantam</i> (obstructed urination)]	95.8	0.694	<0.001
<i>Alpaalpam mutrayantam</i> (dribbling urination)]	95.8	0.727	<0.001
<i>Abhikshanam mutrayantam</i> (intermittent micturition)]	83.3	0.664	<0.001
<i>Bahalam mutrayantam</i> (excess urination)]	76.8	0.535	<0.001
<i>Sashulam mutrayantam</i> (urination with pain)]	95.8	0.692	<0.001
<i>Chal-sfig-stan-udar</i> (Pendulous buttock-abdomen etc)]	88.4	0.456	<0.001
<i>Anutsaha</i> (Lacking energy/deficient enthusiasm )]	78.9	0.575	<0.001
<i>Javoparodha</i> (Impairment in movement )]	86.3	0.511	<0.001
<i>Krichravyavayata</i> (Difficulty in coitus )]	93.7	0.537	<0.001
<i>Daurbalya</i> (Weakness )]	84.2	0.453	<0.001
<i>Vishra-Sarir-gandha</i> (Foul body odour )]	87.3	0.665	<0.001
<i>Svedabadha</i> (Excessive sweating )]	83.1	0.639	<0.001
<i>Kshuda-ati-matra</i> (Excessive appetite )]	76.8	0.488	<0.001
<i>Pipasa-ati-matra</i> (Excessive thirst )]	76.8	0.518	<0.001
<i>Jhiva-talu-ostha-kantha-kloma-shosham</i> (dryness of tongue,palate,lips,throat)]	89.5	0.783	<0.001
<i>Ati-pravridha Pipasa</i> ( excessive thirst)	82.1	0.618	<0.001
<i>Asvedanam</i> (lack of sweating)]	94.8	0.524	<0.001
<i>Ati-svedanam</i> (excess sweating)]	88.4	0.762	<0.001
<i>Tvak Parushyam</i> (coarse and dry skin)]	87.4	0.634	<0.001
<i>Atislakshana Tvak</i> (waxy skin)]	94.8	0.52	<0.001
<i>Angasya paridaham</i> (burning sensation of body)]	81.1	0.524	<0.001
<i>Loma-harsha</i> (horripilation)]	97.9	0.489	<0.001

### Study Population:

The disease *Prameha* mentioned in Ayurvedic classics is the population of interest. Patients were enrolled and screened using an Assesses questionnaire (to be filled by the patient) and Physician screening format (Assessed by Physician), specifically designed for screening of *Prameha* patients. Inclusion criteria is '*Prabhuta Mutrata*' which is mandatory for the inclusion of patients. This study intended to differentiate the type of *Prameha* among 20 types of *Prameha* so primarily inclusion of *Madhumehi* patients has been avoided. Initially diagnosed cases, uncontrolled Diabetes Mellitus (with medication/without medication) cases, cases with co-morbidity were also considered for enrollment. Cases with controlled diabetes were excluded from the study.

**Study Setting:** The study was conducted in OPD of ten peripheral institutes of CCRAS in India.

Table no 7: Category E-Samprapti

Variable	Percentage Agreement	Kappa value	p-value
Intermittent occurrence of symptoms of <i>kaphaavarana</i>	71.6	0.424	<0.001
Intermittent manifestation of symptoms of <i>Pitta avarana</i>	78.9	0.249	0.015
<i>Kapha- medo-prakopakar-aahara- Vihara</i> (diet and lifestyle exaggerating <i>meda</i> and <i>Kapha</i> )	73.7	0.457	<0.001
<i>Pitta -rakta-prakopakara-ahara-vihara</i> (diet and lifestyle exaggerating <i>Pitta</i> and <i>Rakta</i> )	81.1	0.439	<0.001
<i>Pramehapidaka</i> (	95.8	0.479	<0.001
<i>Sthoola to madhyamasareera</i> (	75.7	0.412	<0.001
<i>Atisnigdha</i>	91.6	0.454	<0.001
<i>Mahashana</i>	91.6	0.553	<0.001
Visible <i>dhatukshayam</i> ( <i>karshyam</i> )	93.7	0.749	<0.001
Very chronic	89.5	0.704	<0.001
Patient following <i>ruksha- laghuahara</i>	92.6	0.765	<0.001
Restricting all types of <i>snigdhaahara-vihara</i>	92.6	0.655	<0.001
<i>Agantunidana</i> such as <i>abhigata</i> , surgery, <i>rogaetc</i> following which disease manifested	94.7	0.426	<0.001
<i>Balakshaya</i>	81	0.543	<0.001
<i>Atiruksha</i>	95.8	0.478	<0.001
<i>Alpashana</i>	97.9	0.822	<0.001

**Inter-rater reliability data collection:**

Data was collected through separate Google forms of PDP, submitted by both the raters independently. Information provided by each centre included data related to PDP along with urine examination (Routine and Microscopic) and blood examination reports, images related to urine examination.

**Assessment Criteria:**

Specifically designed and developed Prameha Diagnostic Proforma (PDP) was used for assessment. The outcome variables in the proforma were clearly defined and consisted of binary/dichotomous responses (Yes/No or present/absent). All the assessments were done as per the instructions given in the manual of the disease proforma. All the raters were trained for the use of proforma, have independently assessed each item for presence or absence of the clinical entity to determine inter-rater reliability.

Table no 8: Category F-Upadrava (observations on Complications)

Items	Percentage Agreement	Kappa value	p-value
<i>Upadrava</i> (Complications)	68.4	0.085	0.402
<i>Makshiko-upsarpanam</i> (Attraction of flies towards excreted Urine)]	95.8	0.795	<0.001
<i>Alasya</i> (Laziness/lethargy)]	77.9	0.39	<0.001
<i>Mamsopchaya</i> ( Growth of flesh)]	92.7	0.188	0.051
<i>Pratishyaya</i> (Rhinitis)]	97.9	0.888	<0.001
<i>Shaithilya</i> (laxity of muscle and body)]	71.6	0.425	<0.001
<i>Arochka</i> (Anorexia/loss of taste)]	88.5	0.295	0.002
<i>Avipaka</i> (Indigestion)]	90.5	0.72	<0.001
<i>Kapha-praseka</i> (excess salivation)]	94.7	0.732	<0.001
<i>Chhardi</i> (Vomiting)]	97.9	0.657	<0.001
<i>Nidra</i> (Sleepiness)]	82.1	0.626	<0.001
<i>Kasa-sa-pinasa</i> (Coughing with sputum)]	94.7	0.417	<0.001
<i>Swasa</i> (Dyspnoea/breathlessness)]	98.9	0.954	<0.001
<i>Tridoshaja Pidika</i> (Presence of Carbuncle)]	97.9	0.492	<0.001
<i>Vrishanyo-avadaranam</i> (breaking type of pain in scrotum)]	-	-	-
<i>Basti-bheda</i> (breaking type of pain over bladder)]	97.9	0.789	<0.001
<i>Medhra-toda</i> (Pain over Penis)]	97.9	0.492	<0.001
<i>Hrid-shula</i> (cardiac Pain)]	95.8	0.314	0.001
<i>Amlika</i> (Sour belching)]	82.1	0.534	<0.001
<i>Jvara</i> (fever)]	97.9	0.489	<0.001
<i>Atisara/vidbheda</i> (Diarrhoea)]	96.9	0.384	<0.001

<i>Arochaka</i> (Anorexia/loss of taste)]	88.5	0.29	0.005
<i>Vamathu</i> (Vomiting)]	97.9	0.657	<0.001
<i>Paridhupana</i> (Feeling of warmth all over body)]	93.7	0.538	<0.001
<i>Daha</i> (burning sensation like burn)]	86.3	0.5	<0.001
<i>Murcha</i> (loss of consciousness)]	95.8	0.321	<0.001
<i>Pipasa</i> (excessive thirst)]	74.8	0.483	<0.001
<i>Nidra-nasa</i> (loss of sleep)]	81.1	0.572	<0.001
<i>Pandu roga</i> (presence of Pallor)]	98.9	0.883	<0.001
<i>Pita-vid-mutra-netra</i> (yellowish discoloration of stool, urine and eyes)]	96.8	0.712	<0.001
<i>Pidaka</i> (Tridoshaja)]	-	-	-
<i>Tridoshaja pidika</i> (Presence of Carbuncle)]	99	0.662	<0.001
<i>Hrid-graha</i> (Feeling of tightness in cardiac region)]	99	0.662	<0.001
<i>Laulya</i> (excess desire to all type of taste of food)]	91.6	0.645	<0.001
<i>Anidra</i> (loss of sleep)]	81	0.576	<0.001
<i>Stambha</i> (Feeling of stiffness in body)]	87.4	0.386	<0.001
<i>Kampa</i> (involuntary movement like tremors)]	95.8	0.645	<0.001
<i>Shula</i> (Any type of pain in body)]	74.7	0.469	<0.001
<i>Baddha purisha</i> (Hard stools)]	87.4	0.682	<0.001
<i>Shosha</i> (Emaciation)]	90.5	0.655	<0.001
<i>Kasa</i> (cough)]	96.8	0.711	<0.001
<i>Svasa</i> (Dyspnoea/breathlessness)]	93.7	0.734	<0.001
<i>Udavarta</i> (upward movement of Vata)]	88.4	0.578	<0.001
<i>Tridoshaja Pidika</i> (Presence of Carbuncle)]	96.9	0.39	<0.001

**Sample Size:** Total sample size of the study is 100, with 10 participants at each centre (10 centres). Assuming that at least 50% ( $p_0$ ) of the raters could correctly identify the Prameha patients without using the questionnaire. By using the questionnaire an improvement of 15% in the diagnosis is expected that is 65% ( $p_1$ ). For achieving 80% power with 95% confidence interval, a sample of 85 will be needed. Adding a non-response rate of 15%, the required sample size for the study is 98 (rounded off to 100).

**Table no 9: Category G-Nidana Analysis**

Variable	Percentage Agreement	Kappa value	p-value
<i>Pituh Kulaja Svabhava</i> (Genetic predisposition from Paternal side)	97.9	0.948	<0.001
<i>Maatuh Kulaja Svabhava</i> (Genetic predisposition from Maternal side)	96.8	0.933	<0.001
<i>Yauvan-Pravyakti bhav</i> (Disease manifested in early age, preferably before 18-20)	95.8	0.314	0.001
<i>Alpashi</i> (Habituated to eating less)	93.7	0.749	<0.001
<i>Bhrisha Pipashu</i> (Excess thirst)	77.9	0.548	<0.001
<i>Parisaranshila</i> (Restless disposition)	84.2	0.479	<0.001
<i>Alpa-hetu</i> (Hardly any evidence of apathyasevan)	84.2	0.463	<0.001
[निदानपरिवर्जनैववाअल्पसुखोत्पत्ति:/Less response to pathya or nidanaparivarjana in symptoms]	84.2	0.551	<0.001
अपथ्यनिमित्तज /Factors supporting Apathyanimittaja [प्रायेणस्थूल: /Predominantly obese or over weight]	88.4	0.734	<0.001
अपथ्यनिमित्तज /Factors supporting Apathyanimittaja [प्रायेणस्निग्ध: /Predominantly unctuous]	76.8	0.457	<0.001
अपथ्यनिमित्तज /Factors supporting Apathyanimittaja [प्रायेणबहुाशी /Habit of overeating]	73.7	0.427	<0.001
अपथ्यनिमित्तज /Factors supporting Apathyanimittaja [शय्यासनस्वप्नशील:/Habit of always resting, sleeping or sitting without any physical activity]	73.7	0.467	<0.001
अपथ्यनिमित्तज /Factors supporting Apathyanimittaja [प्रमेहःहेतुःसेवनः/Indulgence in pramehahetu]	72.7	0.276	0.007
उभयनिमित्तज /Factors pointing to role of both sahaja&	92.7	0.852	<0.001

apathyanimittaja [कुलजस्वभाव:/familial tendency (either paternal or maternal)]			
उभयनिमित्तज /Factors pointing to role of both Sahaja & apathyanimittaja [अपथ्याहारविहार H/o Nidanasevan(Apathyahara-vihara)]	85.3	0.333	0.001
अतिप्रमाणेननवधान्योपयोगः	69.4	0.394	<0.001
सर्पिरुपयोगः	69.5	0.333	0.001
ग्राम्यानूप-औदकमांसातिसेवनं	72.6	0.452	<0.001
इक्षुविकारः	75.8	0.355	<0.001
गुडविकारः	79	0.515	<0.001
पिष्टान्नः	73.7	0.472	<0.001
क्षीरविकारः (क्षीर/दधि:....)	70.5	0.368	<0.001
मधुरद्रव्योपयोगः	69.5	0.355	0.001
नवमद्यः	96.9	0.65	<0.001
उष्णाहारः	77.9	0.516	<0.001
अम्लाहारः	82.1	0.623	<0.001
लवणाहारः	71.6	0.431	<0.001
क्षारभोजनः	92.6	0.774	<0.001
कटुभोजनः	80	0.6	<0.001
अजीर्णभोजनः	83.1	0.237	0.021
विषमाहारसेवनः	82.1	0.536	0.021
कषायभोजनः	-	-	-
कटुभोजनः	66.3	0.324	0.002
तिक्तभोजनः	85.3	0.349	<0.001
रूक्षभोजनः	84.2	0.516	<0.001
लघुभोजनः	82.1	0.27	0.007
शीतभोजनः	81	0.21	0.029
अनशनः	92.6	0.333	<0.001
मृजावर्जनं	85.2	0.379	<0.001
व्यायामवर्जनं	68.4	0.369	<0.001
स्वप्नशय्यासनप्रसङ्गः	76.8	0.471	<0.001
तीक्ष्णातपसेवः	87.4	0.527	<0.001
अग्निसंतापः	88.5	0.29	0.005
श्रमः	75.8	0.391	<0.001
क्रोधः	84.2	0.517	<0.001
व्यवायः	-	-	-
व्यायामः	90.5	0.588	<0.001
पञ्चकर्मातियोगः	-	-	-
संधारणः	87.4	0.437	<0.001
अभिघातः	-	-	-
उद्वेगः	91.6	0.454	<0.001
शोकः	82.1	0.625	<0.001
शोनितातिषेकः	-	-	-
जागरणः	84.2	0.45	<0.001

**Sampling method:**

For inter-rater reliability testing, the same patient was examined by both the raters independently on the same day but the sequence of questioning was changed by the second rater to avoid the chance of getting the same answers. Both the raters examined the urine sample separately on the same day without sharing information.

**Statistical analysis:**

The percentage agreement and kappa coefficient were used to assess the inter-rater reliability of each item in the proforma. The Kappa results were interpreted as no agreement if the value ranges between 0 and 0.20, indicate minimal agreement for values between 0.21–0.39, weak agreement for values ranging between 0.40– 0.59, values between 0.60–0.79 indicate moderate agreement, 0.80–0.90 indicate strong agreement and 0.90–0.90 indicate almost perfect agreement [4]. Items were retained only if percentage agreement was more than 70% [5]. SPSS version 28.0 was used to analyze the data. A p-value of <0.05 has been considered as significant.

**RESULTS AND DISCUSSION**

Two raters were identified at each centre and ten participants were assessed at every nine centres (except 5 participants at one centre) by the two raters independently. Overall, 95 cases were included in the study for statistical analysis.

Raters for inter-rater reliability testing were of the same background with post-graduation in the Ayurvedic system of medicine having 5 to 10 years of clinical experience in the desired disease condition. Before the study initiation, raters were given a training session to achieve as much uniformity as feasible in methodology and standardisation of test procedures, during which each item on the diagnostic criteria list was rated on its presence or absence. The total no of participants included in the study analysis were 95, out of which 34 were female and 61 were male.

PDP contains a total of 359 items (PSF-27 and Detailed Proforma-332), out of which 332 items were reported. Consolidated grading of items according to kappa value has been given in Table no 1(a) and domain wise details of percentage agreement and kappa values were in table no 2 to 9)

**Physician Screening Format (screening for Prameha):** Refer to Table no 1(a) and Table no 2.

This format is used for screening of *Prameha* patients, contains 27 items. All the items were reported, having percentage agreement between 80-95% and kappa value from 0.219 to 0.865 with significant p-values. Out of 27 items, 23 items had good to very good (Almost perfect) agreement having kappa value in between 0.6-1.0 and percentage agreement in between 82.10-95.80%. The variables having good to very good agreement were *Mutra Abhikshanta, Mutra avilata, Mutra Vaivarnya, Mutra daurgandhya, Nidra Tandra cha sarvakalam, Angeshu suptata, Sveda, kar-pada suptata, kar-pada daha, Gatra Gurata, Gatra Daurgandhya, Shithila Angata, Pipasa, Sita Priyatvam, Madhurasyata, kesh and Nakha vridhhi, Mukh-Talu kantha shosha, Vishra Sharira Gandha, Svasa daurgandhya, Talu-gal-jhiva-danta malotpatti and jatilibhava-kesheshu.*

**Detailed Prameha Diagnostic Proforma:**

Detailed proforma contains 332 items. All the reported 305 items (27 items of the proforma were not reported for any case by any rater) had percentage agreement ranging from 57.9% to 99.0% and kappa values ranging from 0.059 to 0.95.

Poor level of agreement was found in 10 items viz. normal findings of urine quantity and urine density (within minutes after voiding), nocturnal polyuria, frequent urination with large quantities, *Santapa, Sangya nasha, Sandhi-shaithilya, Asthi-nistoda, Upadrva* and *Mamsa-upachaya*. A fair to moderate level of agreement was found in 213 items and good to very good level of agreement was found in 82 items of PDP. A very good/almost perfect level of agreement was observed in 10 items.

**Category wise results: (A to G category):** Refer to table no 3 to 9

**Category A: Mutra Pariksha (Urine examination)**

This category contains 74 items, out of which 10 items (8 items in urine colour subgroup i.e. *Shuklapishtanibham, Shukrabham, Ksharodaka sankasham, Kaal, Neela, Rakta, Vasa, Sarpi* and one in temperature subsection i.e. *Sparsha samanya* and one inflow of urine sub group i.e. *samanya Dhara and Samanya Vega*) were not reported from any rater. All the reported items (64) except one item (normal quantity of urine) had percentage agreement >60, kappa ranging from 0.07 to 0.87. All the items had significant to highly significant p-values except 3 items, frequent urination with large quantities, Nocturnal polyuria and urine density (within minutes after voiding).

**Category B: Dosha Pariksha**

This category contains 60 items out of which 3 items (*Moha, Moorchha* and *Sthairya*) were not reported by any rater. All the items had kappa value >0.20 except 3 items namely *Santapa, Sangya nasha* and

*Sandhi shaithilya*. Percentage agreement was found >70% in all the items. All the items had significant to highly significant p-values except *Santapa*.

#### **Category C: Dushya Pariksha**

This category contains 58 items out of which 7 items (*Hrit-shunyata*, *Sira-shaithilya*, *Pleeha-abhivridhi*, *Adhyasthi* and *adhidanta*, *Asthi-shunyata*, *Alpa-rakta shukra darshanam*, *Alpa mutrata*) were not reported by any rater. All items had a kappa value >0.20 except one item, *Asthi-nistoda*. More than 70% inter-rater agreement was observed in all the items.

#### **Category D: Strotas Pariksha**

This category contains 23 items, all the items were reported in this category with highly significant p-values, >0.40 kappa values and more than 76% percentage agreement.

#### **Category E: Samprapti**

All 16 items were reported by the raters having >0.40 kappa values except one item, *Pitta-avaranajanya samprapti* (kappa value, 0.249), >71% agreement and significant to highly significant p-values.

#### **Category F: Upadrava:**

This category contains 44 items out of which 2 items (*Vrishana-Avadaran* and *Pidika*) were not reported by any rater. All items had kappa values >0.20 except one item (*Mamsa-upachaya*), percentage agreement >68% and p-values were significant to highly significant.

#### **Category G: Nidana Analysis**

This category has 54 items, out of which 5 items (*Kashaya Bhojan*, *Vyavaya*, *Panchkarma Atiyoga*, *Abhighata* and *Shonita-atishheka*) were not reported by any rater. All items had >0.20 kappa values, more than 66 % inter-rater agreement and significant to highly significant p values.

## **DISCUSSION**

This study created diagnostic criteria/tools for Prameha Roga that can be used in clinical practice as well as in clinical trials for research purposes. This criterion contains items selected by extensive literature search and clinical consensus survey among well experienced Ayurveda clinicians. While developing the diagnostic criteria seven domains have been identified namely *Mutra Pariksha*, *Dosha pariksha*, *Dushya pariksha*, *Srotas pariksha*, *samprapti Nirdharan*, *upadrava* and *Nidana vivechan*, this categorization made the proforma more comprehensive as well as more precise for evaluating *Prameha* patients. Inclusion of multiple items is necessary because any single item cannot alone sufficiently evaluate *Prameha Roga* and its subtypes. In this study inter-rater reliability of all possible components for diagnosis of *Prameha Roga* was performed. Inter-rater agreement is best measured using Kappa. Kappa has the advantage of being statistically chance-corrected [6].

Based on percentage agreement values most of the observable items of PDP had slight (fair) to very good (almost perfect) reliability estimates.

Physician screening proforma used for screening of *Prameha patients* includes variables related to *Prameha* cardinal features and *purvarupa*. In this proforma, all 27 items have good reliability estimates. *Mutra Abhikshanta* (percentage agreement - 90.6%, kappa -0.612), *Mutra Prachurata* (percentage agreement - 93.7%, kappa -0.219) and *mutra avilata* (percentage agreement - 86.0%, kappa -0.668) were important variable in prameha diagnosis all these were reported good reliability estimates with significant p-values. Good to very good agreement was observed in all the variables related to purvarupa of *Prameha*. These findings were indicating good reliability of physician screening proforma.

Ten (10) items of the proforma had poor inter-rater reliability indicating that these items had less value for clinicians and may be discarded from the proforma once identified. Low kappa value items may indicate that these variables were assessed differently by the raters. In these ten variables having poor reliability, normal findings of urine examination were reported. As these normal findings were not related to the diseased condition, so these items had lower kappa values. *Sangya nasaand mamsopchaya* also have poor reliability indicating that these items need to be modified /more clearly defined/discarded.

Those items having fair to the moderate agreement require more subjective judgement than other signs and symptoms or descriptors of these items that needed to be revised.

In *Dosha pariksha* Moha and Moorcha were not reported because in recent times due to advancement in medical care facilities and increased awareness among patients, these symptoms were not observed frequently, also in these conditions' patient requires hospital admission. *Dushya Pariksha* domain 7 items were not reported indicating less utility for clinicians. All of the items in the *Srotas Pariksha* domain had a moderate to the high level of agreement. Except for non-reported items, all items in the *Samprapti* and *Nidana* domains demonstrated a fair to a very good level of agreement.

Non reported items indicate that either these outcome variables were not reported in recent times when compared with ancient times when medical care facility was low or these items needed to be revised or

these items had less clinical importance. After thorough discussion, these items may be discarded or modified.

## CONCLUSION

As per the observations, it can be concluded that PDP is a reliable tool for the assessment and resulting treatment actions in patients of *Prameha roga*. Findings indicate that the PDP is a reproducible tool for clinical assessment and diagnosis on the level of doshas. Removal of unreliable items may produce a shorter more relevant diagnostic tool. Diagnostic parameter's low reliability severely restricts their predictive validity. PDP provides an evidence-based approach to diagnosis and management by which diagnosis of *Prameha roga* at the level of doshic sub-types may be made accurately.

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