

Research Article

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A DESCRIPTIVE STUDY TO DEVELOP A TOOL FOR THE CLINICAL EVALUATION OF THE STATUS OF OJAS

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ABSTRACT

Introduction: Developing valid and reliable tools for fundamental concepts is the need of the hour. The present study aims to develop a valid and reliable tool for measuring the status of Ojas. Methodology: In the conceptualisation part of the study, lakshanas of vitiation of Ojas explained by different Acharyas were identified as variables. By operationalisation, these variables were grouped under three domains and items were generated as questions. The study fulfilled all necessary steps of validated tool making, such as wording and sequencing of items, translation, back translation, and pre-testing. A pilot study was done on 30 individuals in 4 groups as per the inclusion criteria. Test-retest reliability was checked along with the pilot study. The tool was administered to 200 subjects in 4 groups as per the inclusion criteria. Face validity, content validity and construct validity of the tool were checked. Validation of the tool was done along with steps of tool development, and reliability was computed using Cronbach's alpha. Item selection and reduction were carried out with statistical analysis. Results: The tool for clinical evaluation of the status of Ojas developed through this research has 37 items. The tool is reliable, with a Cronbach's alpha value of 0.963 (N=200). Based on scores, the population was divided into Pravaraojas, Madhyamaojas and Avaraojas. After statistical analysis, the variables were placed under seven subdomains. Discussion: The tool developed for clinical evaluation of the status of Ojas through this study is a validated and reliable tool to measure Ojas.

Keywords: Ojas, Tool development, Validation

INTRODUCTION

Questionnaires help attain information on how people feel about the experience of a given research concept. Ojas is an entity that signifies excellence in functioning both body and mind ¹. Its identification in individuals remains ambiguous. Ojas can be inferred only through the lakshanas of its derangement. Many causes result in the derangement of Ojas. Marked derangement of Ojas seen in carcinoma, chronic anaemia, renal failure, depression, etc. By assessing the status of Ojas in a person, the prognosis and severity of the disease could be elicited. So, in the current scenario, developing a tool for assessing the status of Ojas is essential.

Objective

1) To develop a tool for the clinical evaluation of the status of Ojas

2) To categorise the status of Ojas into Pravara, Madhyama and Avara based on scores obtained

MATERIALS AND METHODS

Study design - Descriptive study Study area – Kannur, Kerala, India Study setting - Government Ayurveda College, Kannur, Kerala, India Period of study - 18 months Sample size - 200

Inclusion Criteria Individuals of the age group 20-50 years Literate subjects Patients with chronic diseases (more than two years) and healthy bystanders and hospital staff.

Exclusion Criteria

Pregnant and lactating women Subjects with mental illness Subjects who have alcohol and tobacco addictions

Tool Development Process

Conceptualisation and Operationalisation

The constructs defined were, Bhaya- fear Abheekshnamdhyaanam - excessive worrying Sandhi vislesham - flaccidity in joints Gatrasadanam - fatigue of the body Stabdhagatrata - difficulty in the movements of the body Guru gatrata - heaviness in the body Varna bhedam - discolouration Glani - sudden loss of body strength even at the beginning of heavy work Tandra - laziness Atinidra - excessive sleep Moorcha - fainting Mamsa Kshayam - loss in muscle mass Pralapam - gibberish talks Durmana - negative mental state Rooksham - dryness Vatasopham - oedema of vatika nature Balam- Swaraprasadam - clarity in speech Varna prasadam - lustre Sthiropachitamamsata - firmness of body

Kriyasannirodham

Sareerakriyasannirodham - physical insufficiency Vakpravrithisannirodham - verbal insufficiency Manasakriyasannirodham - mental insufficiency ²⁻⁵

Operationalisation: In this step, a transition from theory to measurement was made. The variables to be used were theoretical. To operationalise, the variables were grouped under different domains. The domain was identified based on literary review and expert opinion from a panel in the Department of Kriya Sareera, Government Ayurveda College, Kannur, Kerala, India.

Physical domain	Intellectual domain	Attitude domain
Sandhi vislesham	Tandra	Bhaya
Gatrasadanam	Durmana	Abheekshnamdhyaana
Gurugatrada	Manasakriyasannirodha	
Stabdhagatrada	Pralapam	
Varnabhedam	Vakpravrithi	
Glani		
Mamsakshayam		
Rooksham		
Balam		
Sareerakriyasannirodha		
Atinidra		
Moorcha		
Vatasopham		

Item generation: Item generation was done based on clinical experience, personal experience and discussions in the Department of Kriya Sareera, Government Ayurveda College, Kannur, Kerala, India. Available questionnaires regarding each variable were referred to avoid bias and discourage the process of guessing. A total of 110 questions were prepared and subjected to discussion in the Department of Kriya Sareera, Government Ayurveda College, Kannur, Kerala, India.

Item selection: This was done through a series of pilot steps. Overlapping, the most common and frequently quoted questions were deleted. Out of 110 statements that were analysed for relevance, clarity and suitability, 70 statements were selected. These 70 statements were submitted to the content adequacy assessment panel. The Content adequacy assessment panel consisted of 10 subject experts working in different Ayurveda Colleges in Kerala, 5 established Ayurveda medical practitioners and 10 BAMS students from Government Ayurveda College, Kannur. Item selection was done using the 'in-depth" interview technique, which involved extensive probing with open-ended questions. Respondents were asked to evaluate each statement's **face validity** and **content validity** by matching each item with its construct definitions.

Item wording: For item wording, familiar words were framed in uncomplicated sentence structures. The number of words made as few as possible. Care was taken to ask about only one concept at a time and to avoid double negatives. It was ensured that response categories were exhaustive and mutually exclusive.

Item sequencing: This was done to make the order of questions relevant and exciting. Thus, the variety of response sets was increased.

Formatting the response

Levels of measurement - Ordinal scale

Scoring pattern - Single construct with single cut-off Scale of measurement - 3-point Likert scales

The scoring pattern included 0, 1 and 2 for each question. The scores of negatively worded items were reversed so that higher scores indicated a higher level of status of Ojas.

Translation and back translation: This step was done by two bilingual translators. Two back-translations were done. The translators were blinded to the original version

Pre-testing: It was done in three groups through informal, openended interviews. Five academicians from Government Ayurveda College, Kannur, did an expert review. The peer review was done by five PG scholars in Government Ayurveda College, Kannur, and the Respondent's review was done by ten individuals almost similar to the target group, which satisfies the inclusion criteria. A rough evaluation of content validity was done. Nine unsatisfactory statements were deleted after pre-testing.

Pilot study

It was conducted in 30 subjects under four categories from 2/5/2017 for over one month.

The first group had five subjects having a history of Diabetes Mellitus over the past six years and having FBS >110mg/dl, PPBS >180mg/dl, HbA1C >6.5%

The second group had five subjects having anaemia with Hb <10g%.

The third group had five subjects with third-degree haemorrhoids. $^{6\cdot8}$

The fourth group had 15 healthy volunteers among hospital staff and healthy volunteers.

Test-retest reliability: This shows a measure of how consistent the results of tests are over time. This was done using Intra class correlation coefficient in the data received from 10 selected individuals who participated in the pilot study. Reliability was found to be 0.944. Since reliability greater than 0.7 is considered acceptable reliability.

Administration of instrument

Preparation of Research Proforma: The proforma prepared had three parts - Informed Consent form, Basic information and Tool for analysis of Ojas. Forty-two items were present in the tool developed for assessing the status of Ojas. The final administration was carried out in and around GAVC, Kannur. Out-patients, in-patients, hospital staff, and bystanders were included as samples per the inclusion criteria. It took two months for the completion of the final administration of the tool.

Informed Consent: The study was done as per ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Informed consent was obtained from the participants.

RESULTS AND DISCUSSION

Validation of tool Arbitrary cut-off

A nonparametric Chi-squared test was performed for validation. The null hypothesis was - 'There is no difference in response to the tool in different populations'

An alternate hypothesis was - 'There is a difference in response to the tool in different populations'.

Statistical analysis showed a significant difference in the scoring pattern in different tool settings, thus rejecting the null hypothesis. In the distribution of each item, three items showed skewness. These items were deleted because they would not have discriminative power to measure the particular problem if skewed.

Descriptive statistics

Minimum score - 13 Maximum score - 82 Mean score - 58.3 Median - 66 Mode - 75. 44 Range of item mean - 1.045 Item variance - 0.602 Inter-item covariance - 0.514 Inter-item correlation - 0.985.

Reliability statistics were done using Cronbach's alpha, of which the score obtained was .965.

Kmo and Bartlett's test was done to prove the adequacy of the sampling. Communality with questions had been found. Two items had deficient communality values of 0.2 and 0.177.

Items having a value below 0.4 are considered to be insignificant. These items are considered to not fit with the other items. Those two items were deleted. A scree plot was made. A rotated component matrix was used to achieve subdomains. Seven subdomains were thus achieved. At the end of the study, five items were deleted, and 37 items were retained.

The reliability statistics for the tool were 0.965 (N=200). So, it could be concluded that the tool is reliable. The tool satisfied content validity, face validity and construct validity. This also increases the validity of the tool. Using this tool, the population can be effectively divided into pravara, madhyamana, and avara status of Ojas. So, the tool is feasible. The intra-class correlation

showed a highly significant correlation with a value of 0.944. The chi-squared test showed a significant difference between the four groups that participated in the study: sampling adequacy and relevance of factor analysis done by KMO and Bartlett's test. Communalities with questions were conducted, and all retained items had loadings of more than 0.50 with no cross-loadings. The tool contains 37 items in a three-choice Likert scale format with the scores ranging from zero to two. There were 35 positive and 2 negative questions. No strong correlations exist between different variables of the same domain; hence, the variables differ. Any score less than 30 is likely to cause severe Ojakshaya.

Limitations of the study

Some of the variables used in the study contain only a minimum number of questions. Methods other than questionnaires were not employed for measuring the activity and intellectual domains. Important dimensions with more emphasis on measurable variables were only included in the study.

Tool for the clinical evaluation of status of Ojas (English)

Instructions: You are expected to indicate to what extent each statement is true in your case. Three answers are given along with each statement. Please mark the appropriate answer with a '/'. You have to respond to all the statements. As the statements relate to individual characteristics, there are no right or wrong answers to any of them. Hence, you may mark the first response that comes to your mind after reading each statement. Your responses will be kept confidential and used only for research purposes.

1)	Are you afraid to have a visit to a hospital?	
	a) Always afraid b) Sometimes afraid c) Never afraid	
2)	Do you have the feeling of fear when you are being watched by someone else?	
	a) Always fears b) Sometimes fears c) Never fears	
3)	Do you feel any anxiety about misfortunes that will befall on you?	
	a) Always anxious b) Sometimes anxious c) Never anxious	
4)	Do you get tensed about travelling outside alone?	
	a) Always get tensed b) Sometimes get tensed c) Never get tensed	
5)	5) Do you have the feel of easy dislocation of joints?	
	a) Always feel b) Sometimes feel c) Never feel	
6)	Do you feel weary?	
	a) Always feel b) Sometimes feel c) Never feel	
7)	Do you find any difficulty in moving your body?	
	a) Always feel b) Sometimes feel c) Never feel	
8)	Do you feel heaviness in your body?	
	a) Always feel b) Sometimes feel c) Never feel	
9)	Do you feel any change in complexion during the last six months?	
	a) Always feel b) Sometimes feel c) Never feel	
10)	Do you feel exhausted even in the beginning of a heavy work?	
	a) Always feel b) Sometimes feel c) Never feel	
11)	Do you feel lazy always?	
	a) Always feel b) Sometimes feel c) Never feel	
12)	Do you feel drowsy while doing things?	
	a) Always feel b) Sometimes feel c) Never feel	
13)	Do you often yawn?	
	a) Always yawn b) Sometimes yawn c) Never yawn so much	
14)	Do you feel sleepy even after having a sound sleep?	
	a) Always feel b) Sometimes feel c) Never feel	
15)	Have you been losing consciousness frequently during the last six months?	
	a) Always lose b) Sometimes lose c) Never lose	
16)	Do you feel that your body is getting slim during the last six months?	
	a) Always feel b) Sometimes feel c) Never feel	
17)	Are you not able to enjoy even joyful moments?	
	a) Never able to enjoy b) Sometimes able to enjoy c) Always able to enjoy	
18)	Do you feel that your body is dry?	
	a) Always feel b) Sometimes feel c) Never feel	
19)	19) Do you feel that your lips are always dry?	
	a) Always feel b) Sometimes feel c) Never feel	

20)	Do you feel thirsty even after drinking enough water?
	a) Always feel b) Sometimes feel c) Never feel
21)	Do your nails break easily?
	a) Always break easily b) Sometimes break easily c) Never break easily
22)	Do you have hair loss?
	a) Always have b) Sometimes have c) Never have
23)	Do you have constipation?
	a) Always have b) Sometimes have c) Never have
24)	Does your body have inflammation that appears and disappears abruptly?
	a) Always have b) Sometimes have c) Never have
25)	Do you feel you don't have the required firmness in your body?
	a) Always feel b) Sometimes feel c) Never feel
26)	Do you feel difficulty in doing daily chores?
	a) Always feel b) Sometimes feel c) Never feel
27)	Can you bend down and straighten up with ease?
	a) Can always bend b) Can sometimes bend c) Can never bend
28)	Do you feel any difficulty in lifting even one kilogram weight?
	a) Always feel b) Sometimes feel c) Never feel
29)	Do you have any difficulty while getting up from armless chair?
	a) Always have b) Sometimes have c) Never have
30)	Do you have any difficulty in getting up from bed?
	a) Always have b) Sometimes have c) Never have
31)	During the last six months have you felt having reduced voice while talking?
	a) Always feel b) Sometimes feel c) Never feel
32)	In the past six months have you felt any strain in talking?
	a) Always feel b) Sometimes feel c) Never feel
33)	Is your daily routine disturbed due to lack of memory?
	a) Always disturbed b) Sometimes disturbed c) Never disturbed
34)	Do you find any difficulty in taking decisions regarding day today matters?
	a) Always feel difficulty b) Sometimes feel difficulty c) Never feel difficulty
35)	Do you find situations in which you don't remember the tasks to be done one after another?
	a) Always find b) Sometimes find c) Never find
36)	Are you able to pray with concentration?
	a) Always able to b) Sometimes able to c) Never able to
37)	Are you able to do things with concentration?
	a) Always able to b) Sometimes able to c) Never able to

CONCLUSION

The present study, titled a descriptive study to develop a tool for the clinical evaluation of the status of Ojas, aimed at creating a validated and reliable tool for assessing the status of Ojas. The tool was developed in the form of a structured, close-ended questionnaire. The questionnaire has 37 questions measuring 18 variables under three domains and seven subdomains. The 18 variables represent the status of Ojas in an individual in a diseased condition and health. The tool was administered to 200 individuals residing in Kannur district of Kerala. 200 individuals who participated in the study were in 4 groups – healthy subjects, subjects with anaemia, subjects with bleeding haemorrhoids and subjects with diabetes mellitus.

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