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Review Article

DEVELOPMENT OF A MEASUREMENT TOOL WITH SPECIAL REFERENCE TO *AVARANA* IN METABOLIC SYNDROME

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ABSTRACT

In many instances the researcher cannot find an adequate or appropriate existing tool to measure an important construct- the theoretical variable that is supposed to measure. In these situations it will become necessary to develop a new instrument for measuring the particular construct. Failure to carefully develop a measurement instrument can result in invalid data. The steps involved in the development of such tools are complex and unknown to many. Hence, the systematic development of a reliable and valid instrument for measuring subjective states is outlined here to assist researchers in devising usable instruments.

According to Ayurveda, the diseases are caused by derangement of *Tridoshas*- the dynamic force (*Vatha*), the transformation factor (*Pitha*) and the anabolic factor (*Kapha*). *Avarana* is the disturbances in the movement of *Vathadosha* by other factors in the body. In the present social scenario, majority of diseases of *Vatha* are the result of *Avarana*. Metabolic syndrome is one such lifestyle disease comprised of obesity, hyperglycemia, hypertension, hyper triglyceridemia and low HDL level. Majority of the symptoms of *Avarana* can be identified in patients presenting with Metabolic syndrome. This article outlines the methodology involved in the development and validation of a measurement tool, taking into consideration of *Avarana* in Metabolic Syndrome.

KEYWORDS: Tool development, Reliability, Validity, Ayurveda, *Avarana*, Metabolic Syndrome.

INTRODUCTION

In research studies different types of instruments are used: (i). standardized instruments, (ii). non-standardized instruments and(iii). instruments constructed by the researcher for the particular study. The standardized instruments have established reliability and validity. For the non-standardized but earlier used instruments, some estimate should be obtained for the reliability of every instrument constructed by the investigator. For validity, the logical estimates are often accepted without a statistical estimate. For the self constructed instrument, the researcher has to develop and validate the tool and must report: (a). the purpose for which it was constructed, (b). the different aspects and total number of statements under each aspect, (c). the nature of the statements, and (d). its reliability and validity coefficients[1]. The steps involved in the development and validation of such tools are difficult and unknown to many researchers. An overview of the tool development and validation are described in this article with special reference to *Avarana* in Metabolic syndrome.

In Ayurveda, the three bioregulatory principles, the *Thridoshas*, the dynamic force (*Vatha*), the transformation factor (*Pitha*) and the anabolic factor (*Kapha*) are responsible for health and disease[2]. Of the three principles, *Vatha* is more important since it is the dynamic force and the vitiation of *Vatha* is occurring by the diminution of body tissues (*Dhathukshaya*) or occlusion of body channels (*Avarana*)[3]. According to *Chakrapanidatta*, in *Avarana* the vitiation of *Vatha* is the result of the obstruction to spontaneous stimulation for movement[4]. Metabolic syndrome is one of the major disorders where *Avarana* pathology can be observed since the etiology, symptomatology and pathogenesis can well be correlated. The etiology of Metabolic syndrome - affluence and lack of exercise are vitiating *Kapha, Pitha* and fatty tissue (*Medodhathu*) and they are obstructing the pathway of *Vatha* hindering its normal function leading to obesity (*Athisthoulyam*), hyperglycemia (*Madhumeham*), dyslipidaemia (*Medo-dosham*) and hypertension (*Vathakopam*) which are the cardinal symptoms of metabolic syndrome[5]. Thus *Avarana* may be considered as the main pathogenic factor for the development of Metabolic syndrome. In the present social scenario, lifestyle diseases are becoming the major health hazards and metabolic syndrome is one such disorder. It is attaining epidemic status and is imparting intense burden to the society in terms of health hazards, expenditure for treatment and the reduction of productivity. Its chronicity and the

development of newer complications are challenging the effectiveness of Allopathic treatment. Ayurveda can put forward a superior management protocol for this chronic lifestyle disorder, by interpreting the condition of Metabolic syndrome with reference to the concept of *Avarana*. Since now, there is lack of an instrument for measuring *Avarana* in metabolic syndrome. The development of a simple tool with good reliability and validity to evaluate the presence of *Avarana* in Metabolic syndrome will help in the early screening of this disorder and formulation of better protocol for prevention and management.

Steps in Development of Tool

1. **Conceptualization**- Tool development process begins with forming a concept and refining it by giving a theoretical definition. In Ayurveda, a better understanding of Metabolic syndrome can be done by interpreting the condition with reference to the concept of *Avarana*. On exploring the concept, the etiological factors, pathophysiology and symptomatology of metabolic syndrome can very well be explained on the basis of *Avarana*. An operational tool may be developed for measuring *Avarana* in Metabolic syndrome with the symptomatology as the items of the tool.
2. **Item generation**- Items in the proposed tool can be generated based on review of relevant literature, signs and symptoms, clinical experience, personal experience, and focus group discussion with respondent population and in-depth interviews with–experts. This process will ensure the various dimensions of the concept and items to capture them. For developing a tool for *Avarana* in metabolic syndrome, items of the proposed tool can be generated by reviewing the signs and symptoms of *Avarana* explained in Charaka Samhitha, Susrutha Samhitha and Ashtanga Hridaya [3,6,7].The significance of the items in metabolic syndrome can be evaluated on the basis of signs and symptoms, on clinical experience, focus group discussion with subjects having metabolic syndrome and in-depth interviews with experts. These processes ensure the inclusion of various dimensions of the concept and appropriate items under specific domains.
3. **Item selection** – Using Microsoft Office Access, overlapping items can be identified and deleted at first. The remaining symptoms can be grouped to make the interview with the respondent population easier. Items can then being selected by administering the draft tool among the patients with metabolic syndrome and selecting items with maximum discriminatory power. Expert paneling can be done by getting the feedback from at least 10 experts, and to select the items most frequently endorsed by them.
4. **Item wording, sequencing and formatting**- Selected items should be worded appropriately to suit the level of comprehension of the respondent population of patients with metabolic syndrome and sequenced from general to specific. The response format has to be structured and the number of response categories fixed, considering the understanding level of the respondent population.
5. **Scoring –**The pattern of scoring has to be decided, usually giving equal weightage to all items if the number of items are more in the tool.
6. **Translation and back translation-** The draft tool has then to be translated to local language and back-translated to English to make sure that the meaning has not been altered on translation. This can be done by independent translators knowing the language as well as the content.
7. **Pre-testing by peer review, respondent review and expert review-** The translated tool has to be given to peers and respondent population to test the wording and comprehensibility. Necessary modifications have to be made based on their feedback. Expert reviews should also be done to ensure the content coverage, clarity and simplicity of items in the tool.
8. **Pilot study-**For the pilot study to measure *Avarana* in metabolic syndrome, the tool has to be administered in 10% of sample size, including patients having Metabolic Syndrome and those not having Metabolic Syndrome and mean score of each item can be calculated. Items with least discriminatory power can be deleted at this stage also.
9. **Reliability**- Reliability refers to the repeatability, stability, and internal consistency of a tool. Before a tool can be used as a measure, it should be established that it measures "something" in a reproducible manner[8]. Repeatability of the tool will be assessed by test retest reliability and inter rater reliability. Test Retest reliability explains whether there is any difference in patient's status in two time points within 10-14 days, when assessed by the same examiner. To assess whether the different raters, assessing the same individual with the draft tool, can obtain similar scores, Inter Rater Reliability test is done. It is done by administering the draft tool by two raters on the same day and to find out whether they can obtain similar scores. It is measured with a coefficient between 0 and 1[9]. Test retest and inter rater reliability can be determined using intra class correlation coefficient (ICC) or kappa statistics depending upon nature of response categories. These tests can be conducted along with pilot study. Item wise intra class correlation can be calculated and any item with poor reliability can be modified and the process may be repeated. Internal consistency needs only single administration and can be determined after main study.
10. **Administration in sample population-** The tool refined through the above processes has to be

administered among the sample population of patients having metabolic syndrome and those not having metabolic syndrome and the data can be collected. The sample size needs to be calculated in advance. A wide range of recommendations regarding sample size have been published in literature. These are usually stated in terms of subject to variable ratio. In clinical settings, for calculating the sample size for the main study, number of subjects selected for the study would be 5 times the number of items in the tool.[10.11]

11. Validity- Validity refers to whether one can draw accurate conclusions about the presence and degree of the attribute for an individual. In other words, validating a tool is a process by which we determine the degree of confidence we can place on the inferences, and we make about people based on their scores from that tool.[12]

1. Face validity and Content validity - Face validity will be ensured during the early stages of development of tool itself by, content review by experts and respondent review. Content validity ensures that all aspects of the construct are represented by an adequate number of items and should not include items that are unrelated to the construct.
2. Criterion validity -Criterion validity refers the correlation of new scale with an external criterion measuring the same construct which is supposed to be the gold standard.
3. Construct validity- Construct validation is heavily relied upon in situations where there is no criterion with which a tool can be compared. One has to generate predictions based on the hypothetical construct (hypothesis generating) which are then tested to determine construct validity. It is an ongoing process of learning more about the construct, making new predictions, and testing them. Construct validity is determined statistically by factor analysis.

12. Analysis

Item analysis is the general term used to clean up the scales, item by item in order to maximize reliability and validity. The data obtained by administering the draft tool on sample population can be analyzed by the steps as follows.

1. Descriptive statistics- Descriptive statistics help us to simplify large amount of data in a sensible way. They are used to describe the basic features of the data in a study. Both numerical and graphical summaries of distribution of each item should be obtained. Items which are highly skewed and do not show variability may be deleted.
2. Inter item correlation, item total correlation and Cronbach's α (for assessing the internal consistency of the tool). For measuring a symptom, the scale must be homogenous, i.e., all of the item should be tapping different aspect of the same attribute and not different parts of different attributes. For a homogenous scale, the items should be moderately correlated with each other (inter item correlation) and each should correlate with the total scale score (item total correlation). An inter-item correlation matrix for each subscale should produce a matrix of positive correlations, ranging from modest values (0.2-0.4) to strong values (0.5-0.8). The item should correlate with the total subscale score above 0.20; items with lower correlations should be discarded. The internal consistency co-efficient (Cronbach's α) tells about similarity in measurement across items within the subscale. Values for the α coefficient ranges between 0.0-1.0; the α coefficient will be larger (closer to 1) when the items are inter-correlated. Cronbach's α of 0.80 is desirable and 0.70 is acceptable (9). Cronbach's α may be calculated by eliminating one item at a time, by discarding any item one by one, where α increases significantly.
3. Exploratory factor analysis for item reduction and construct validity. Factor is an underlying dimension of several related variables. Factor analysis can be applied as an item reduction technique and as a test of construct validity. Kaiser-Mayor-Olkin (KMO) statistic (0.6 or more is acceptable) and Bartlett's test for sphericity has to be done to check the sampling adequacy and factorisability of the data respectively. Construct validation can be done by exploratory factor analysis; extraction of factors done by principal component analysis and factor rotation, using varimax or promax depending on data, for better interpretation of factors. Eigen value is the amount of variance in the data explained by each factor. Usually the factors with Eigen value more than 1 will be retained. Item selection in factor analysis is based on factor loading, which is the correlation of the particular item with factor or domain. Minimum cut off for factor loading may be fixed as 0.35 or 0.4. Ideally the retained factors should account a cumulative variance of at least 60%. Factor analysis will finally give the number of factors with appropriate items loaded under each domain and the maximum variance explained by all the factors in the tool.[12,13]

13. Generation of final instrument after factor analysis- At the end of factor analysis an instrument with acceptable level of reliability and validity can be generated to measure *Avarana* in Metabolic syndrome. Additional measures of construct validity are i). convergent validity- reflects the overlap between alternative measures that tap the same construct ii). divergent validity- a valid tool should also fail to correlate with measures that tap different constructs. Discriminant validity is the ability of the tool to discriminate between different groups of participants and is quite often used interchangeably with divergent validity. Validation hypothesis is a series of hypothesis testing based on the tool will provide additional evidence for construct validity.

Criterion validity of the tool can be assessed by comparing with gold standard. Criterion validity of the *Avarana* tool can be assessed by comparing with metabolic syndrome. This method can be used for correctly identifying those individuals with *Avarana* among the subjects with metabolic syndrome (sensitivity) and the likelihood of correctly identifying people without *Avarana* among the subjects, not having metabolic syndrome (specificity). The receiver operating characteristic (ROC) curve analysis can explore the sensitivity (true positive) and specificity (true negative) of different cut-off points and area under the curve provides the measure of overall performance of the tool. By fixing arbitrary cutoff the tool can be used as a diagnostic tool of *Avarana* in Metabolic syndrome and to classify the subjects for different levels of management for *Avarana* in Metabolic syndrome.

CONCLUSION

A systematically developed and validated measurement tool is highly important in the field of research and clinical practice. The process for tool development and validation as explained above can ensure the quality of research to instill confidence in the results. Poor scale construction questions the reliability and validity of the research results, no matter how careful the study is designed. In contrast, carefully constructed measures help to advance the understanding and ensure that the study will provide accurate and usable data. The various steps outlined in the article would ensure the development of a reliable and valid tool with desirable level of psychometric properties.

Metabolic syndrome is achieving epidemic status all over the world and complications like coronary artery disease are increasing the mortality. On compiling the symptoms of *Avarana*, majority of them can be identified in various conditions of metabolic syndrome. By following various steps explained in the article a scientific tool can be developed for measuring *Avarana* in metabolic syndrome. The development of such a tool to evaluate the presence of *Avarana* in Metabolic syndrome will help in the diagnosis or early screening of Metabolic syndrome and to allocate the patients for different levels of management.

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