#### Special Topic for 973 Program

# Evaluation of the reliability and validity of the modified Morisky scale for patient's compliance with moxibustion

### 修改版 Morisky 问卷调查患者艾灸依从性的信度和效度评价

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#### Abstract

**Objective:** A questionnaire for the compliance with moxibustion was designed based on the 4-item Morisky scale, and the reliability and validity of the questionnaire was investigated.

**Methods:** A modified Morisky scale was designed based on the 4-item Morisky scale for the compliance with moxibustion, and 146 patients having received moxibustion for over 2 weeks were investigated using this scale to evaluate their compliance with moxibustion; the internal equity and the construct validity of the scale were statistically analyzed.

**Results:** The analysis of reliability showed that in item of internal consistency, the Cronbach's  $\alpha$  was 0.72 and the split-half coefficient was 0.71, the correlation coefficients between the 4 component scores and the total score ranged 0.67-0.80, and the between-component correlation coefficients ranged 0.24-0.56; the exploratory factor analysis (EFA) totally extracted 1 common factor, and the explicable variation was 55.02%, and the loads of the 4 items were respectively 0.82, 0.81, 0.74 and 0.58.

**Conclusion:** The reliability and validity of the modified Morisky scale for the compliance with moxibustion are acceptable, while several items need further modification and improvement in the expression and content.

**Keywords:** Moxibustion Therapy; Moxa Cone Moxibustion; Moxa Stick Moxibustion; Compliance; Surveys and Questionnaires; Modified Morisky Scale; Reproducibility of Results

【**摘要】目的:**基于 Morisky 依从性量表4个条目设计艾灸依从性调查问卷,探讨该问卷的信度和效度。方法:根据 Morisky 依从性量表4个条目设计用于艾灸依从性评价的修改版 Morisky 问卷,并对146例接受艾灸治疗超过2 星期的患者使用该问卷进行调查,评价艾灸治疗依从性;统计分析该量表的内部一致性及其结构效度。结果:信度分析显示,修改版 Morisky 问卷的内部一致性 Cronbach's a 系数为0.72,折半系数为0.71,4个条目与量表总分之间的相关系数为0.67~0.80,4 个条目之间的相关系数为0.24~0.56,探索性因子分析共提取1个公共因子,可解释的总变异量为55.02%,4条目的载荷值分别为0.82、0.81、0.74和0.58。结论:修改版 Morisky 问卷调查艾灸依从性的信度和效度尚可,但部分条目在语言表述和内容上仍需进一步修订和完善。

【关键词】灸法; 艾炷灸; 艾条灸; 依从性; 调查和问卷调查; 修改版 Morisky量表; 可重复性, 结果

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Moxibustion is a therapy in which a moxa cone or stick with moxa wool as major component is ignited to fumigate or warm superficial meridians and acupoints, and the thermal stimulation or pharmacological effect are adopted to work on human body<sup>[1]</sup>. It's created by ancient working people in China during a long-term fight with diseases. It's mentioned in *Bian Que Xin Shu* (*Precious Writings of Bian Que*) that moxibustion is the first choice for life-sustaining; *Shen Jiu Jing Lun* (*Profound Scholarship of Miraculous Moxibustion*) also

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said that moxibustion can unblock the twelve meridians, enter the liver, spleen and kidney, regulate qi and blood activities, and efficiently treat various diseases. This indicates that moxibustion has a vast range of indications and significant efficacy. Modern research has also proven that moxibustion can modulate the interior environment of body and treat diseases via regulating and improving metabolism, immunity, blood circulation, and neuroendocrine-immune network<sup>[2-6]</sup>.

Despite the vast applications of moxibustion, patients often complain about the thick smoke during the burning of moxa. With the research on the air pollutants inside moxibustion treatment room<sup>[7]</sup> and the increased awareness of environmental protection, it's become a question how are the acceptance and compliance of

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patients with moxibustion therapy. As a crucial factor that directly affects the treatment result and development of diseases<sup>[8]</sup>, compliance is currently investigated especially in terms of administration of drugs, nursing and the act of medical treatment of health care providers in the treatment of chronic conditions and contagious diseases such as hypertension, diabetes, coronary heart disease, chronic heart failure, asthma, cancer, hepatitis B, and human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS)<sup>[9-12]</sup>, while the compliance with moxibustion has never been reported. How to evaluate the clinical compliance with moxibustion? How is the compliance? What are the major factors that influence the patients in choosing and insisting on moxibustion treatment? These questions are left undetermined. In this study, we chose Morisky scale, which has been widely used to test the compliance with drugs<sup>[13]</sup>, to investigate the patient's compliance with moxibustion and reveal the reliability and validity of Morisky scale for the compliance with moxibustion, and further value its applicability, for establishing a practical questionnaire or scale for the compliance with moxibustion.

#### **1** Materials and Methods

#### 1.1 Inclusion criteria

The patients who visited Sichuan Provincial Hospital of Chinese Medicine or Shaanxi Provincial Hospital of Chinese Medicine and received moxibustion treatment during August and October of 2015. They were all required to meet the following criteria: consecutively used moxibustion for over 2 weeks, without hypomnesia, able to express his or her own will, and willing to participate in the study.

#### 1.2 Exclusion criteria

With contraindications for moxibustion; unable to express his or her own will.

#### 1.3 Design of the scale

This study investigated the compliance of patients with moxibustion treatment in a form of questionnaire, modified Morisky scale via referring literatures, interviewing patients, and consulting experts based on the features of moxibustion, and finally developed a scale.

The principles of designing scale: each item has to conform to objective reality; the items should have clear objectives and emphases; in easy-to-understand expressions and avoiding terminologies; able to allow the interviewees to voluntarily and honestly provide answers.

#### **1.4 Investigated contents in the scale**

The modified Morisky scale contained: have you ever disobeyed doctor's advice in moxibustion treatment? have you ever irregularly instead of consecutively received moxibustion treatment? have you ever terminated moxibustion treatment without consulting doctors when feeling symptoms improved? have you ever terminated moxibustion treatment without consulting doctors when feeling symptoms aggravated?

The above items should be answered by 'Yes' or 'No', 0 point for 'Yes', 1 point for 'No'. The higher the score, the better the compliance.

#### 1.5 Investigation methods

The uniformly trained investigator distributed the questionnaire to the eligible patients and let them fill it out voluntarily after careful explanation of the objective, content and instruction. The questionnaire was collected then and there after filled out and kept uniformly by the research group. The input and analysis of data were performed when the investigation work was completely finished.

#### 1.6 Statistical analysis

The SPSS 19.0 statistics software was adopted for data analyses. The internal consistency of the scale was evaluated by Cronbach's  $\alpha$ , and the correlation coefficient between the total score and the components were tested by Spearman's rank correlation coefficient; the exploratory factor analysis was used to examine the construct validity of the scale.

#### 2 Investigation Results

## **2.1** General condition of the interviewees and the scores

A total of 146 questionnaires were distributed and collected, collection rate 100%. The general condition included education level, medical form, disease duration, and time of moxibustion (Table 1 and Table 2).

#### 2.2 Reliability of the scale

The reliability analysis showed that the Cronbach's  $\alpha$  of the scale was 0.72 and the split-half coefficient was 0.71; the correlation coefficients between the 4 component scores and the total score ranged 0.67-0.80, and the between-component correlation coefficients ranged 0.24-0.56, both statistically significant (P<0.01), (Table 3).

#### 2.3 Validity of the scale

The construct validity of the scale was tested using factor analysis, a method that can simplify multiple indicators, find out potential common factors dominating original variables, use the common factors to explain the correlations among the original variables, and finally realize the exploratory analysis of the unpredictable factors. The exploratory factor analysis of the 4 items in the scale showed that the Kaiser-Meyer-Olkin (KMO) was 0.73 and Bartlett's test of sphericity revealed statistical significance ( $\chi^2 = 119.58$ , df=6, P=0.000), indicating that the factor analysis should be applicable for the data. Taking eigenvalue  $\geq 1$ and scree test as the criteria, it's showed on the scree plot of the explicable variations based on the selected

factors that the eigenvalues of the extracted 4 factors were respectively 2.20, 0.79, 0.57 and 0.43. Since the bottom factors of the scree plot were insignificant, only 1 common factor was extracted, and the explicable variation was 55.02%, and the loads of the 4 items were respectively 0.82, 0.81, 0.74 and 0.58 (Table 4 and Figure 1).

	n	Occupation (%)					
Male	40	27.40					
Female	106	72.60					
<30 years	25	17.12					
30-40 years	21	14.39					
40-60 years	73	50.00					
>60 years	27	18.49					
< graduate	100	68.49					
Graduate	34	23.29					
Postgraduate or hig	gher 12	8.22					
Public expense	82	56.16					
Self-paid	43	29.45					
Others	21	14.38					
$\leq 1$ month	49	33.56					
1-3 months	42	28.77					
$\geq$ 3 months	55	36.67					
$\leq 1$ month	91	62.33					
1-3 months	36	24.66					
$\geq$ 3 months	19	13.01					
Table 2. Scale score							
n		Occupation (%)					
8		5.48					
8		5.48					
19	)	13.01					
27	7	18.49					
84	1	57.53					
	MaleFemale $<30$ years $30-40$ years $30-40$ years $40-60$ years $<60$ years $<60$ years $GraduateGraduatePostgraduate or higPublic expenseSelf-paidOthers\leq 1 month1-3 months\geq 3 months\leq 1 month1-3 months\leq 3 monthsscoren88192784$	nMale40Female106 $<30$ years25 $30-40$ years21 $40-60$ years73 $>60$ years27 $<$ graduate100Graduate34Postgraduate or higher12Public expense82Self-paid43Others21 $\leq 1$ month491-3 months42 $\geq 3$ months55 $\leq 1$ month911-3 months19score $n$ $\approx$ 819278484					

Table 1. Combarbon of the Leneral au	Table 1.	Com	parison	of the	general	data
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Table 4. Loads of each item of the scale

Item number	Load
1	0.82
2	0.81
3	0.74
4	0.58



Figure 1. Scree plot of each item of the scale Note: Vertical ordinate for the eigenvalue; horizontal ordinate for the item number

#### **3** Discussion

Currently, the general adherence scale (GAS)<sup>[14]</sup>, Morisky scale<sup>[13]</sup> and self-made questionnaires are commonly used in self-reported compliance research. Morisky scale was brought up by Morisky DE and others in 1986, having good forecasting reliability, and its 4 components were not limited to any specific diseases or treatments. It's later widely used to measure the compliance with drugs in depression, diabetes, heart failure, osteoarthritis, and after renal transplantation. Therefore, it's a generally applicable scale for compliance with medications. According to the features of moxibustion treatment, this study partially modified this scale and developed a new one. So far, there is no such kind of research on the compliance with moxibustion using Morisky scale. Reliability and validity are the first step and also crucial criteria in evaluating the quality of an analysis scale. Thus, the reliability and validity were tested to determine whether this scale is applicable for the compliance with moxibustion.

The reliability refers to the dependability and stability of a scale, and is now most commonly expressed by Cronbach's  $\alpha$ , to reflect the internal equity between the components of the scale. The split-half coefficient also can be used to show the internal consistency between the former and latter parts or odd and even parts. The  $\alpha$  value usually ranges 0-1:  $\alpha > 0.9$  standing for good internal equity;  $0.8 \le \alpha \le 0.9$  for acceptable internal equity;  $0.7 \le \alpha \le 0.8$  indicating that some items require modification but the scale still has some value for

Note:	Comparison	of	the	between-component	correlation
coeffic	vients, 1) P<0.0	)1; co	ompai	rison of the correlation	coefficients
between the total score and component scores, 2) $P < 0.01$					

Table 3. Comparison of the correlation coefficients (r value)

2

1.00

 $0.56^{1)}$ 

0.311)

 $0.79^{2}$ 

1

1.00

 $0.48^{1}$ 

0.431)

0.241)

 $0.69^{2}$ 

3

1.00

0.331)

 $0.80^{2}$ 

4

1.00

0.67<sup>2)</sup>

Total

1.00

Item number

1

2

3

4

Total

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reference;  $\alpha < 0.7$  suggesting that some items need deleting. The validity refers to the effectiveness of a scale, i.e. the correctness of the features examined by the measure, including construct validity, content validity, criterion-related validity, etc. When the KOM of a scale > 0.5 and the test of sphericity reveals significant difference, a factor analysis is applicable. Some scholars once adopted Morisky scale to investigate the compliance with medications for hypertension and severe depression<sup>[13,15-16]</sup>, the Cronbach's  $\alpha$  ranged 0.61-0.76, and the total explicable variation ranged 57.53%-58.36%, indicating that Morisky scale has good reliability and validity and is applicable for the evaluation of the compliance with medications for hypertension and severe depression.

In this study, the modified Morisky scale was used to study the compliance with moxibustion. Its Cronbach's  $\alpha$  was 0.72, split-half coefficient was 0.71, and correlation coefficients between the component scores and total scores ranged 0.67-0.80, presenting a moderate correlation and close to the previous results (0.59-0.84)<sup>[15]</sup>, explicable variation was 55.02%, and the loads of the 4 items were quite high. The internal consistencies among the 4 items and between the former and latter parts were fine, the construct validity was good, and the results were similar to the previous researches. Therefore, the modified Morisky scale should be applicable for the evaluation of compliance with moxibustion. Item No.4 was found to have a low correlation with the rest items and compliance, which possibly was due to the way of expression, the comprehension of patients and explanation, and thus a modification was expected.

Because of the limitations, the test-retest reliability and composite reliability were not measured in this study, so it was impossible to determine the stability of the scale, which requires improvement. Secondly, it's also found that the items in the scale were too simple to completely reflect the compliance. This could be refined by referring the 8-item Morisky medication adherence scale (MMAS-8)<sup>[17]</sup> stipulated in 2008 by Morisky, et al. MMAS-8 adopted items of indeliberate disobeying (majorly refers to forgetting) and deliberate disobeying (reasons including the improvement or aggravation of disease, worry about the adverse reactions of the medication, etc.), and item No.8 takes the format of the 5-level Likert scale: strongly disagree, disagree, neither agree nor disagree, agree, and strongly agree, making the results more abundant and exhaustive. Hence, MMAS-8 could be referred in future studies. Thirdly, the current investigation on the compliance with moxibustion majorly selected the patients who recently had received the treatment for over 2 weeks instead of those who were receiving the treatment, which would exclude a part of patients with poor compliance and affect the investigation results.

Finally, questionnaire is subjective, and possible memory bias could induce bias in the results. Thus, it will enhance the accuracy of the evaluation if objective evaluation methods can be integrated.

In conclusion, there is no unified scale for the compliance with moxibustion yet. This study adopted a generally applicable medication compliance scale to study the compliance with moxibustion, which has certain reference value, but there requires further modification and completion in the expression and content of some items in the scale.

#### **Conflict of Interest**

The authors declared that there was no potential conflict of interest in this article.

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#### Statement of Informed Consent

Informed consent was obtained from all individual participants included in this study.

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