Development and study of self-efficacy scale in medication adherence among Iranian patients with hypertension

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Abstract:
BACKGROUND: This study was aimed at developing and studying the scale of self-efficacy in adherence to treatment in Iranian patients with hypertension.

METHODS: A mix-method study was conducted on the two stages: in the first phase, a qualitative study was done using content analysis through deep and semi-structured interviews. After data analysis, the draft of tool was prepared. Items in the draft were selected based on the extracted concepts. In the second phase, validity and reliability of the instrument were implemented using a quantitative study. The prepared instrument in the first phase was studied among 612 participants. To test the construct validity and internal consistency, exploratory factor analysis and Cronbach’s alpha were used, respectively. To study the validity of the final scale, the average score of self-efficacy in patients with controlled hypertension were compared with patients with uncontrolled hypertension.

RESULTS: In overall, 16 patients were interviewed. Twenty-six items were developed to assess different concepts of self-efficacy. Concept-related items were extracted from interviews to study the face validity of the tool from patient’s point of view. Four items were deleted because scored 0.79 in content validity. The mean of questionnaire content validity was 0.85. Items were collected in two factors with an eigenvalue >1. Four items were deleted with load factor <0.4. Reliability was 0.84 for the entire instrument.

CONCLUSION: Self-efficacy scale in patients with hypertension is a valid and reliable instrument that can effectively evaluate the self-efficacy in medication adherence in the management of hypertension.

Keywords: Hypertension, medication adherence, mix-method study, reliability, self-efficacy, validity

Introduction

Diagnosis and treatment of high blood pressure plays an important role in reducing deaths due to coronary heart disease and stroke, however, controlling high blood pressure has basically dropped in many of countries in the recent years. From hundreds of Iranian adults, 26 person involved in hypertension whereas 13 are only aware of their condition. Moreover, only 24% of patients with hypertension are treated in Iran that 8% are controlled.

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be consequently decreased to $20\%$–$25\%$ and $35\%$–$40\%$, respectively.\[^{[5,6]}\]

Despite the availability of a variety of different drugs in the treatment of hypertension with approved effects, the control rate of hypertension is completely disappointing that formed a big public health challenge all around the world. It is estimated that about $50\%$ of patients who are prescribed blood pressure medication, interrupted their treatment within 1 year.\[^{[9]}\] The low number of patients consuming blood pressure medications, as well as not well-controlled patients with blood pressure, has persuaded researcher to focus on medication adherence in hypertension. Accordingly, in many studies, nonadherence to treatment is one of the key factors in the failure to achieve goal blood pressure, refractory hypertension to treatment, and sudden loss of control has emphasized.\[^{[8]}\]

In the past decade, different theories have been applied to explain treatment adherence in patients with hypertension.\[^{[9,10]}\] Self-efficacy theory is known in the field of health behavior researches. According to Albert Bandura, self-efficacy is defined as “belief in one’s capabilities to organize and execute actions required to manage prospective situations.” In other words, self-efficacy is described as “ a person’s belief in their ability to succeed in a particular situation.” Bandura described these beliefs as determinants of how people think, behave, and feel.\[^{[11,12]}\] Self-efficacy has been shown to be a predictor of a wide range of health-related behaviors such as adherence to treatment behavior. Self-efficacy is designed for the adherence to treatment in chronic diseases in different populations, as yet.\[^{[13-15]}\] Despite the importance of adherence to treatment self-efficacy in patients with hypertension, the current study showed that the role of this theory has rarely been noted in improving adherence to treatment in Iranian society that might be caused by lack of tools tailored to the demographic characteristics of Iranian society. Besides, the self-efficacy is heavily influenced by the culture of each country, and then the tools used in other countries with different context cannot be generalized in Iranian society. Therefore, this investigation was aimed to develop and compare the scale of self-efficacy in adherence to treatment in Iranian patients with hypertension in the form of a mix-method study.

**Methods**

The mix-method study was conducted in the two phases including developing items in a qualitative study (phase I) and testing validity and reliability of the instrument in a quantitative study (phase II).

**Phase I: Developing items**

**Participants**

Participants were recruited from patients with hypertension serviced by the health centers of Isfahan city (Isfahan, as the capital of Isfahan Province, is one of the central cities in Iran). Two centers were randomly selected from ten control centers of chronic diseases. To select participants, purposeful sampling was started and continued until data saturation. Inclusion criteria were as follow: (1) patients diagnosed definitely as hypertension, (2) a 1-year period of treatment at least, (3) aged over 18 years and $<60$ years, (4) being literate, and (5) consuming a blood pressure medicine at least. Exclusion criteria were also considered as: (1) approval of specific mental illnesses and (2) disinterest and noncooperation to participate properly in the study.

**Interviews with patients**

The main method of data collection was deep and semi-structured interviewing with open-ended questions. This type of interviewing is one of the most common methods of data collection in qualitative research that known as an approach of the general interviewing guide.\[^{[16]}\] Interviewing guide was pretested using a researcher-made preliminary interviewing, also some of questions were rewritten and some others were added in the interviewing content. Semi-structured interviewing of patients was developed based on open-ended questions and the following structure:

- What problems are you facing in consuming blood pressure drugs?
- What conditions of receiving antihypertensive drugs make its consumption easy or difficult to you?
- What do you think of the skills which can help people to consume a blood pressure drugs?

**Data analysis**

All interviews were conducted by an interviewer. To analyze, continuous comparative analysis was implemented that is a method to increase the validity of data. All statements and expressions of the participants were completely written and content analysis and coding process was also performed. To analyze and coding, software of qualitative data analysis (Multilingual MAXQDA Plus 2010 v10.4.16.1) was run. The validity and reliability of the instrument were evaluated during the study.

**Self-efficacy questionnaire**

The draft tool was developed after completing the process of analyzing the data. Items in the draft were developed based on the extracted concepts, in the other words; developed items were the same meaning as the extracted concepts. All items were developed as phrases and based on standard version of self-efficacy
questionnaire. Phrases were developed fluently and with appropriate wording; to achieve this, comments of an expert in Persian literature field was considered. Items were developed based on the 1st year of high-school education level, as well.

**Phase II: Validity and reliability of the instrument**

Participants in this phase were the same as the participants in the first phase. A multi-stage sampling method was conducted in the way that four health centers were randomly selected. A list of patients with hypertension was provided those had a file in the centers. Samples with equal volume were selected using systematic random sampling method from each center. The same inclusion and exclusion criteria were considered as the first phase of the study.

**Face validity**

Face validity was assessed in the two qualitative and quantitative stages. In the qualitative stage, items relevancy, ambiguous perceptions, and difficulty of concepts perception were explored by eight specialists. In this phase, researcher was used the experts comments to correct items. In the second stage (quantitative stage), impact score was evaluated. Specialists were asked to categorize all items based on a 5-point Likert scale with regards to the being important from completely important (score = 5) to completely not important (score = 1); afterward, impact score was evaluated for all items according to a formula. Items were suitable for further analysis and were retained if the impact score was more than 1.5 for each question.

**Content validity**

To test content validity, some of the necessary criteria were as follows: (1) all items include the main and basic aspects of concept, (2) all items reflect the population’s characteristics, and (3) all items reflect the goal of measurement. Content validity was tested using qualitative and quantitative methods. In the quantitative phase, content validity ratio and content validity index (CVI) were conducted to select the most important and correct content and the best method to measure items, respectively. Some of specialists were interviewed to check the qualitative content and were also asked to declare their comments toward compliance with grammar, use of appropriate and understandable words, proper scoring, completion time of the tool, consistency, and placement of items in their proper place. The final version of the questionnaire was prepared and developed after collecting specialists’ comments.

**Construts validity**

In the current survey, exploratory factor analysis with principal components analysis and varimax rotation was used to assess construct validity. Kaiser-Meyer-Olkin (KMO) index and Bartlett’s test of sphericity were used to assess the adequacy of the sample size and the correlation between variables. The turning point of 0.4 was considered as the required minimum load factor to keep all the factors extracted from factor analysis.

**Reliability**

To test reliability, internal consistency was conducted; also alpha coefficient was used for measuring internal consistency. Cronbach’s alpha represents the fitness of a group of items to measure a structure. Acceptable internal consistency was considered more than 0.7.

**Criterion validity of final self-efficacy**

To test criterion validity in final tool, the mean score of self-efficacy in patients with controlled blood pressure was compared to patients with uncontrolled blood pressure with an assumption the high score of self-efficacy in patients with controlled blood pressure.

Given the previous studies, blood pressure control in patients was directly associated with medication adherence, this study examined blood pressure directly and medication adherence was not investigated. To achieve this, the past 6-month average blood pressure of the patients was extracted from medical records. According to the Joint National Committee, a systolic blood pressure of 140 and higher or diastolic blood pressure of 90 and higher was classified as people with uncontrolled blood pressure.

**Data analysis**

Data were analyzed using SPSS version 21 (SPSS Inc., Chicago, IL), descriptive methods and statistical tests including Cronbach’s alpha coefficients, Pearson’s correlation, KMO index, sphericity of Bartlett, and varimax rotation.

**Results**

**Phase I**

In overall, 16 patients were interviewed and analyzed. Demographic characteristics of these patients are shown in Table 1. The mean age of participants was 42.31 ± 9.81 years with a range of 23–60 years. Blood pressure of 44% of patients was not controlled. The mean duration of blood pressure was 9.19 ± 3.53 years and duration of consuming antihypertensive drug was 4.15 ± 2.68 years.

Extracted codes were categorized into 6 subscale including self-efficacy against negative beliefs of subjective norms, forgetfulness, access, financial problems, regular follow-up, and access to medicines.
In total, 26 items were developed to test the various levels of self-efficacy scale in medication adherence. Concepts-related items were extracted from patients interviewing till explore the face validity from patient’s point of view. In this instrument, patients were announced their confidence about taking blood pressure drugs in different situations as well as their confidence about the activities associated with medication adherence. All items were replied as 3-point Likert scale (1 = low, 2 = somewhat, and 3 = high). Higher scores indicated higher self-efficacy.

Phase II
In this phase of study, 612 patients were analyzed. The mean age of participants was 44.08 ± 10.38 years. In total, 314 were women, 10% were single, and 52% had high-school education. Blood pressure of 53% of patients was not controlled [Table 1].

Face validity assessed by impact score showed that all items had impact score more than 1.5. From 26 tested items by content validity based on expert comments, four items were deleted because scored 0.79. The mean of CVI for the questionnaire was 0.85.

To ensure adequate sample size, KMO index was tested before conducting the exploratory factor analysis. KMO index was 0.81 that revealed that the main items are suitable for data analysis. Furthermore, Bartlett’s test of sphericity was significant (4494.15, \( P < 0.001 \)) that representing the adequate correlation to analyze variables. Exploratory factor analysis was conducted on 22 items. Items were collected for two factors with eigenvalue higher than one. Four items with load factor <0.4 were excluded from the scale. KMO index was run after deleting aforementioned items, again which showed a value of 0.92. The results of the factor analysis reported in Table 2 in the form of two factors with 18 items. Factor loads were in the range of 0.53–0.82. Two factors explained 50.12% of variance, in overall. Factor 1 and 2 entitled “self-efficacy in different situations” and “self-efficacy to overcome barriers” with 13 items and 5 items that explained 31.73% and 18.39% of variance, respectively [Table 2].

Reliability was evaluated after conducting factor analysis using of Cronbach’s alpha for the total scale and for each factor. Total reliability was 0.84 and for two factors were 0.89 and 0.82. In Table 3, the internal consistency coefficient of each factor with the whole questions was shown.

In this study, researchers compared the mean score of self-efficacy of patients with controlled blood pressure to patients with uncontrolled blood pressure. The mean score of self-efficacy was 2.18 ± 0.75 in all patients. Given the findings, patients with controlled blood pressure had higher average score of self-efficacy compared with patients without controlled pressure. The comparison of all items between the two groups declared that patients with good blood pressure control had higher mean score for 83% of items which reflects the inverse relationship between blood pressure and self-efficacy among patients [Table 4].
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Table 4: Mean scores±standard deviation on the self-efficacy scale in patients with controlled and uncontrolled blood pressure

| Self-efficacy (IN) | Blood pressure (mean±SD) |
|-------------------|--------------------------|
|                   | Controlled                | Uncontrolled              |
| 1                 | 2.30±0.62                | 2.08±0.59                |
| 2                 | 2.05±0.71                | 2.17±0.48                |
| 3                 | 2.44±0.59                | 2.18±0.52                |
| 4                 | 2.52±0.53                | 1.95±0.49                |
| 5                 | 1.92±0.32                | 2.01±0.31                |
| 6                 | 2.44±0.65                | 1.93±0.70                |
| 7                 | 2.85±0.60                | 2.01±0.62                |
| 8                 | 2.23±0.72                | 1.82±0.69                |
| 9                 | 2.20±0.52                | 1.82±0.50                |
| 10                | 2.89±0.60                | 2.59±0.63                |
| 11                | 2.07±0.49                | 1.97±0.53                |
| 12                | 2.22±0.51                | 2.11±0.60                |
| 13                | 2.21±0.61                | 2.06±0.82                |
| 14                | 2.60±0.59                | 2.43±0.68                |
| 15                | 2.82±0.73                | 2.33±0.81                |
| 16                | 2.09±0.51                | 1.51±0.52                |
| 17                | 2.11±0.91                | 2.23±0.71                |
| 18                | 2.59±0.51                | 2.01±0.50                |

IN=Item number, SD=Standard deviation

Discussion

The current study presented development and study of self-efficacy scale for medication adherence among Iranian patients with hypertension. To the best of our knowledge, this questionnaire is one the first standardized one in terms of self-efficacy of medication adherence among patients with hypertension in Iran. Self-efficacy of medication adherence included 18 items that completed using interviewing with patients in the form of self-report. Results found that the aforementioned tool is reliable to study the self-efficacy of medication adherence in Iranian society. In addition, internal consistency reported the constant score of the mentioned questionnaire by spending the time. Two level of self-efficacy were observed after conducting explanatory factor analysis in self-efficacy of medication adherence as follows: (1) self-efficacy of in different situations such as party, workplace, traveling, and when a person is not existed to remind drug consumption and (2) self-efficacy to overcome the obstacles including providing the hypertension drugs with every cost, having drugs in access for preventing of forgetfulness, and treat as a routine habit for consuming drugs.

Hypertension has usually not a specific symptom and its treatment continues throughout life, thus the most of patients leave treatment.[18,19] Several studies have shown that low self-efficacy is significantly in line with uncontrolled hypertension, also self-efficacy has been known as the strongest predictor of medication adherence.[20-22] Therefore, this tool can effectively apply in medication centers and future researches. For example, it is potentially able to determine the specific situation named commonly problems in medication adherence among patients with hypertension that support physicians to implement the likely beneficial interventions to improve medication adherence. This tool can be used for evaluating the effectiveness of behavioral interventions to promote the self-efficacy or medication adherence among patients. Moreover, other studies can benefit from the current tool for exploring and diagnosing of patient’s problems. This tool can also be applied for studying the self-efficacy of patients in cognitive, behavioral, and medicine researches.

Criterion validity showed that this tool has a high discrimination power in diagnosing and discriminating patients with hypertension. Despite the studies such as Ogedegbe et al. and Risser et al. that developed the self-efficacy scale and studied its association with medication adherence, our survey was also represented the self-efficacy discrimination power regarding the final outcome of health (control hypertension).[23,24] Then, the power of tool is confirmed toward relation of self-efficacy, medication adherence, and hypertension control in exposure to other modification factors.

The strongest point of the tool is goal-based of that and its development from patients. In every context, patients are usually used of context-tailored approaches; then, the patients might be faced by different sociocultural situations in Iranian society. As mentioned above, it was necessitate us to study qualitatively the self-efficacy of medication adherence tool. A study conducted by Como revealed that understanding the differences between populations and ethnical history is important in behavior adherence that might be likely useful to meet requirements of people. They accentuated that tools and interventions must be noticed in accordance with culture and self-efficacy of medication adherence.[25]

Conclusion

In final, the current tool is a valid and reliable questionnaire among Iranian patients with hypertension. These findings can be used for developing and implementing the effective health interventions in the field of medication adherence and hypertension control.

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Conflicts of interest
There are no conflicts of interest.

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