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Design and psychometric properties of Iranian pre-hospital stroke scale

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Abstract

Background: The studies have shown that stroke morbidity and mortality could be decreased if early diagnosis and treatment is delivered faster for patients. This tool is designed based on all Pre-hospital stroke scales across the world as well as experiences of the emergency medicine specialists and pre-hospital emergency technicians to improve the diagnostic accuracy of the stroke scale in Iran.

Methods: This study used mixed methods and was carried out in two main phases. In the first phase (items generating), concept elicitation was conducted based on the review of the literature related to stroke diagnosis and usual instruments in pre-hospital emergency stroke centers, and a series of semi- structured individual interviews with 35 neurologists, emergency medicine practitioners, and physicians working in hospitals and emergency technicians in the pre-hospital field participated. In the second phase (items reduction), the face and content validity, and reliability of the procedure were checked.

Results: According to results from the first phase of this study (items generation), three domains were introduced as the most important factors influence to detection of early signs and symptoms of stroke. In the second phase (items reduction), the face validity of this tool was based on the comments received from participants (the experts and EMS technicians), and changes were made for clarity of items. The content validity based on Lawshe index was identified. The S-CVI/Ave for Iranian Pre-Hospital stroke scale was calculated (89%). To determine the criterion validity of the instrument, he Iranian pre-hospital stroke scale scores were compared with the final diagnosis based on Brain CT scan result in hospital.

Conclusion: This study made an Iranian pre hospital stroke scale for emergency technicians in pre-hospital field which is dichotomous items, simple and very easy to use. For future this tool could be recommended and employed by emergency dispatch units as well as using it in the triage procedure in the hospital.

Keywords: Psychometric properties, Pre-hospital emergency, Stroke Scale and Iran.

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Introduction

Stroke is the most common neurological disease and an important cause of death and disability worldwide (1). The incidence of stroke is 15 million worldwide annually; over 5.7 million of these patients will die (2, 3) .The cost of the dis ease in 2010, is an estimated 73.7 billion (4). The statistics show stroke on the Asian continent is increasing (5,6). In Iran, sporadic studies conducted in accordance with the incidence of stroke in all age groups of 33 to 372 cas-

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es per 100 thousand, and in people older than 45 years are estimated at 500 cases per 100 thousand people (7, 8) The incidence of stroke in Western countries, is estimate with approximately 100 to 300 cases per 100 thousand people (8). Today, by improving the care and treatment for stroke patients, the stroke mortality rate has decreased in developed countries (3), although the 87% mortality in these patients is observed in middle and low income countries (9). Stroke complications effect the roles and responsibilities of the individual patient's daily activities as well as the quality of life of patients and caregivers (1,4).

In Iran, the mortality rate due to stroke is approximately between 15.3 -31.5%, which is far higher than the global rate of about 12.6% for all stroke types (2, 10, 11). Using multiple methods for assessment of signs and diagnosis of stroke patients at pre-hospital field by emergency technicians has caused increasing delay in transferring patients to medical centers and also increasing misdiagnosis of stroke in the pre-hospital phase (12).

In Iran, the assessment of stroke patients in the pre-hospital phase is implemented in two ways: 1- In some of the pre-hospital emergency centers with a doctor, the Neurological examinations conducted by the emergency technicians and the information gathering will be provided for the final decision by a doctor (general practitioner based in Pre-hospital Emergency Center). 2- In some of the Pre-hospital emergency centers without a doctor, the Neurological examinations and the final decision are based on emergency medical technicians.

These methods are often learned through experience and knowledge in the basic training of personnel so due to these causes treatment is not the same for different technicians (13). Therefore, the American Heart Association, American Stroke Association and other organizations which are involved in the prevention and treatment of stroke, recommend the using of diagnostic tools for improving diagnosis in patients at the pre-hospital phase, by emergency medical technicians (14). Using these tools can help pre-hospital emergency technicians with minimal information to do neurologic examinations, and provide patient care for the best results. At present, in Iran, none of these tools which are designed and recommended for stroke diagnosis is employed.

In other words, a good tool for diagnosis of stroke by pre-hospital emergency technicians is one that is easy to learn and use, and it has reliability and validity, as well as the methods used to diagnose stroke by pre-hospital emergency medical technicians (15). The aim of this study is to design and assess the psychometric of a suitable tool for diagnosis of stroke by pre-hospital emergency technicians.

Methods

This study used mixed methods and was carried out in two main phases.

Generating of Items

The first phase (generating of items), concept elicitation was conducted. After a review of the literature related to stroke diagnosis and usual instruments in pre-hospital emergency stroke centers including NIHSS, LAPSS, CPSS, FAST, OPSS, KPSS, were detected around the world, a series of semi- structured individual interviews with 35 neurologists, emergency medicine practitioners, and physicians who working in hospitals and emergency technicians regarding the pre-hospital phase. Data was conducted for concept elicitation in order to identify those concepts relevant to participants' experience, to explore variability of symptoms .Qualitative analysis of transcripts obtained from concept elicitation interviews was used to support the items generation process and resulted in a preliminary draft of the measure.

Finally, the most important elements for pre-hospital diagnosis of stroke in a panel of experts were identified. After that the primary tool comprising 17 items was developed. In the last phase of the process, weighting and ranking items of the instru-

ment was performed using the Delphi technique.

In end of first phase, we have a pool items which were drafted for each concept based on qualitative data from experts' input and support from the literature.

Item Reduction

The second phase (Item Reduction): This phase was to determine the psychometric properties and the cutoff point of the instrument. In the first stage, for validity of this instrument three methods were examined including; face validity, content validity and criterion validity.

Face validity: To this step, 10 emergency technicians were interviewed by face to face technique and the level of difficulty (difficulty of understanding words and phrases), the fit (fit and proper communication with the statements of the questionnaire) and uncertainty (probability of false impressions despite the failure of the meanings of words or phrases) were studied (16).

Content Validity: Quantitative determination of content validity was done for scale utilization, and research issues discussed by the 15 faculty members who were oriented in this subject from Social Welfare and Rehabilitation Sciences, Tehran University of Medical Sciences, Arak University of Medical Sciences and University of Khorasan Razavi Medical Sciences, gave their opinion about the necessity, fitness, clarity and relevance of items to assess Content Validity Ratio (CVR) and Content Validity Index (CVI) provider (16).

At the end of this phase, we calculate S-CVI/Ave. S-CVI/Ave definite Average of the I-CVIs (Content Validity of individual items) for all items on the scale.

Criterion validity: Criterion validity primary scale was used for 96 suspected stroke patients and results compared with discharge diagnosis by brain CT scan, (as standard clinical criteria for stroke diagnosis) (17).

Internal consistency: To determine the reliability used internal consistency coefficient Iranian pre-hospital stroke scale the Kuder Richardson method, was calculated to determine the objectivity of instrument, and also the reliability between observers, was used.

In this stage, for determining the rate of reliability, the tool was given to emergency pre-hospital technicians and based on tool guidelines they fulfill them for the patients who had the inclusion criteria. Finally about 140 tools were taken, 20 of them due to uncompleted information and 24 of them due to no registered name of patient by emergency pre-hospital technicians and not having a final diagnosis, were excluded. It should be noted that the final diagnosis of stroke or TIA was proved by the neurologist based on the gold standard of brain CT scan.

In this study the elimination of one non-harmonic question contributed to the improvement of the overall reliability of the instrument.

Inter-rater Reliability: In this study, due to the nature of the tool, the response to some items depended on the user of the tool; also there was no possibility to implement a unique test because of the changing in patients' conditions over time, therefore, the reliability between observers was used. For this, three questionnaires were completed for 10 patients, simultaneously, by different persons. As there was only one technician for each urgency mission, one tool by emergency technician and two other instruments were completed by nurses at the hospital triage units. Then, scores of these three questionnaires using interclass correlation coefficient (ICC) were compared.

Determination of the cutoff point: After entering the data of 96 suspected stroke patients according to convenience sampling were chosen from medical centers of Arak University of Medical Sciences, University of Khorasan Razavi Medical Sciences. Patients into the computer software SPSS16, using receiver operation characteristic curve (ROC), the best cut-off point, the sensitivity, specificity, and area under the curve were calculated.

Regarding ethical considerations, the permission of the University of Social Welfare and Rehabilitation Sciences, Arak University of Medical Sciences, University of Khorasan Razavi Medical Sciences was taken; also anonymity of the participants and informed consent was obtained for all participants, and names of all patients who meeting the inclusion criteria removed and numeric codes assigned to them.

Results

According to results from the first phase of this study, three domains were introduced as the most important factors influence to detection of early signs and symptoms of stroke including: the signs and symptoms of stroke, the distinguished factors between acute stroke and mimics and the main risk factors of stroke (Table 1). Following this phase, the Iranian pre-hospital stroke scale with 17 primary items, which made by with yes and no answers being identified.

Finally, the weighting and ranking of items performed by the experts who have assigned to each items; the first 4 items were scored 3, the score of 2 was given to the next 5 items and other items were scored 1.

In the second phase, for the face validity of the Iranian pre-hospital diagnosis tool based on the comments received from participants (the experts and EMS technicians), changes were made for clarity of items.

For the content validity, the two items which having less than 0.49 (minimum of acceptable level for 15 experts based on Lawshe table) were excluded (18). Also, according to the results of the calculation of index of content validity, some of the instrument items were corrected. The S-CVI/Ave for Iranian Pre-Hospital stroke scale was calculated (89%).

To determine the criterion validity of the instrument, the Iranian pre-hospital stroke scale scores were compared with the final diagnosis based on brain CT scan result in hospital (Table 2). As in Table 2, 14 patients had other diagnosis (false positive) and 6 patients had lower scores of cutoff point index despite having a stroke; the tool did not find them as a suspected stroke (false negative).

Also, the comparison of Iranian pre-hospital stroke scale scores with a final diagnosis of stroke patients by discharge records in hospital, made it possible to estimate the positive predictive value (PPV), negative predictive value (NPV), Positive Likelihood Ratio (PLR), and Negative Likelihood Ratio (NLR) that is presented in Table 3.

The positive predictive value of 81% was in compliance with the final diagnosis in the hospital, when patients are detected as stroke or TIA, with 81% probability of Iranian pre-hospital stroke scale indicating suspected stroke or TIA patients. The negative predictive value of 71% means that compliance with the final diagnosis in the

Table 1. The results extracted from the first phase of first stage

Signs and symptoms of stroke	Common risk factors	differentiate the conditions mimicking stroke
• Unilateral Weakness or paralysis • Speech disorders • Face paralysis • Sudden onset • Decline in strong gripping • Imbalance • Impaired vision • Headache • Loss of consciousness • Urinary incontinence • Nausea and vomiting	○ TIA ○ MI ○ CVA ○ DM ○ HLP ○ HTN ○ Age greater than 45 years ○ Patient's blood pressure is higher than usual, or 200/120 mmHg	• Having history of seizures or loss of consciousness • altered level of consciousness or motor symptoms compared to the Previous status • glucose 60 to 400 mg / dl •

Table 2. Comparison of the results of tool pre-hospital diagnosis of stroke patients in the hospital with a cut to the final diagnosis results in a total of 11 patients having criteria

`	The final diagnosis in hospital	
Results Patient Tool	Patients Number (%)	Healthy Number (%)
Above cut-off (patient)	61(81.3%)	14(18.8%)
Below cut-off (non-patient)	6(28.6%)	15(71.4%)

Table 3. Numerical values of the validity criterion of pre-hospital diagnosis tool in Iran

The criterion validity of utility values	The presented value	Confidence Interval 95%
Sensitivity	92%	81.51 to 96.62%
Specificity	51%	32.54 to 70.54%
Positive Predictive Value (PPV)	81%	70.67 to 89.39%
Negative predictive value (NPV)	71%	47.83 to 88.65%
Positive Likelihood Ratio (PLR)	1.89	1.28 to 2.77
Negative Likelihood Ratio (NLR)	0.17	0.07 to 0.40

hospital, when a patient is not diagnosed with stroke or TIA. The Iranian pre-hospital stroke scale confirmed the probability of 71% with stroke or TIA in patients. Positive Likelihood Ratio and Negative Likelihood Ratio also computed 1.89 and 0.17, respectively.

For the remaining 15 items of instrument the internal consistency reliability, the coefficient Kuder Richardson was 0.68.

After this step, one item due to low coefficient correlation internal consistency of the instrument was removed and finally, the coefficient Kuder Richardson for Iranian pre-hospital stroke scale, (total of 14 items) 0.7 was calculated.

To determine the inter-rater reliability, among the scores assigned to patients by three different observers the coefficient correlation was calculated and the ICC of total scores for patients 0.96 was calculated, and that was significant (p< 0.001). Then, based on the result of ROC curve, the cutoff point for sensitivity (92%) and specificity (51%) was calculated (10.5) respectively (Fig. 1). That means that in coordination with the final diagnosis of patients, in those who earned the score less than 11 as healthy (no stroke) and in those who earned the score 11 and upper, suspected stroke or TIA are considered.

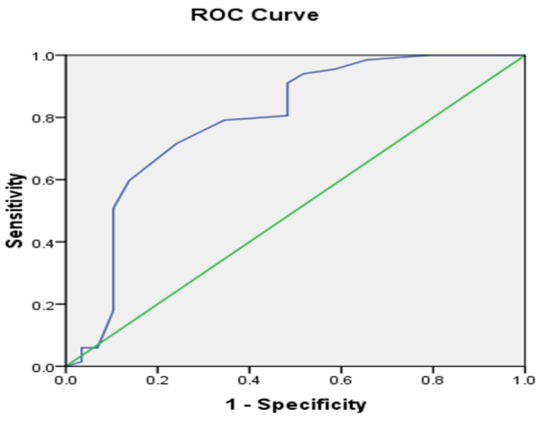

Fig. 1. ROC curve

Accuracy of the results is based on the area under the curve ROC 0.79 (CI 95%, 0.68-0.90) and was calculated (p< 0.001), indicating that about 79 percent of cases have been diagnosed correctly.

Discussion

Extending the fast and accurate methods for the assessment of stroke patients by emergency medical technicians in the pre-hospital or hospital triage personnel can reduce the delay in the evaluation and treatment by a physician. Now, different tools are used for different purposes of identifying stroke to predict the consequences of stroke, in different settings. In order to minimize any delay in the start of treatment, the designing and using of pre-hospital stroke tools for recognition, is a current focus in the pre-hospital phase. However, there is no definitive diagnostic tool for the pre-hospital phase of stroke in whole the world. Researchers have done several studies about designing a most perfect and appropriate tool for detecting stroke in the pre-hospital setting.

Consistent with the changes in the treatment of stroke, the design of an Iranian pre-hospital stroke scale, for the first time in Iran, has been conducted based on psychometric process and used in a considerable number and variety of experts' opinions.

A unique innovation in this study is the benefit of clinical experience of pre-hospital emergency technicians and other doctors associated with the diagnosis and treatment of stroke patients.

Because studies shown in designing and making other tools for pre-hospital diagnosis of stroke in the world, researchers were used of literatures review and research experiences or common signs of stroke patients in the database.

Since, the signs and symptoms of stroke involved a wide range of neurological signs and symptoms this is demonstrated, in other central nervous system diseases and disorders such as epilepsy, diabetes, dementia and brain tumors and abscesses are seen (19). Therefore, the taking of a history and clinical examination (performed by technicians in the pre-hospital emergency and not too time consuming) can help to distinguish stroke from mimics.

Brott et al, in 1989 studied previous stroke scales and neurological symptoms that created by the most common brain areas involved in the stroke .This research has led to the design of NIHSS (19). Nowadays the NIHSS is introduced as a basis for further design pre-hospital stroke recognition tools such as ETSS, CPSS and KPSS (15, 20, 21)

This scale has 15 items with 3 to 4 parts for response range, and requires the user to spend a lot of time in pre-hospital emergency care. However, samples containing 5 to 8 items of these tools are designed for ease of use in pre-hospital emergency care (22).

CPSS and LAPSS are the most popular diagnostic tools in the pre-hospital setting that are recommended by the American Heart Association (AHA), American Stroke Association (ASA) and The European Stroke Organization (ESO) (23).

Despite this, none of them cover vision problems and impaired balance in the posterior circulation problems (24).

Hence, we have designed the Iranian pre-hospital stroke scale based on clinical experience of personnel who are involved in the care and treatment of stroke patients, a broad overview of relevant resources and previous tools. Our tool consists of 14 items; each item has 2 answers, yes or no. At all stages of the study, we tried to design a simple and brief scale. Short and simple tools help avoid fatigue in technicians and prevent delay of patient transfer. Furthermore, it has tried, addition to briefly, scale covers common signs and symptoms base on the brain areas involved.

Clinical tools for stroke diagnosis in the acute care setting should be simple, valid and reliable; so widespread use of some of these tools is limited, due to problems such as the lack of clarity in reliability and validity (25).

In this study, content validity index of Iranian pre-hospital stroke scale was calculated at 89%. Review of previous studies did not provide clear results of the content validity of previous instruments (26-28).

In 2013, Studnek et al, reported sensitivity and specificity values of 79% and 24% respectively for the CPSS and 74 and 33 percent respectively in Med PACS tool (29). These values are less than 92 and 51 percent of our tools for sensitivity and specificity respectively. Although the specificity of Iranian pre-hospital stroke scale compared with the ROSIER tool, at 83% is less, but ROSIER sensitivity of 90% is below our tool (30). However, since Iranian pre-hospital stroke scale is a screening tool, the higher sensitivity is more important (31).

In this study the internal consistency reliability was indicated with coefficient Kuder Richardson 0.7. This result shows that domains have positive correlation and are significant with each other, as well as with total scores. It demonstrated that 30% of variances of total scores of the instrument depend on probability error .The internal

consistency value (α> 0.9) is good and when (α> 0.8) is at low levels may be indicative of the notion that there is more than one good internal consistency value in the α hardware tools. High values indicate good internal consistency α, but must be repeated. Repeated expressions cause unnecessary prolongation of the tools and due to measure of the same concepts, it indicates a good internal consistency (17).

We need different items, which cover stroke symptoms in different parts of the brain. It seems to be one of the reasons of the low coefficient Kuder Richardson in this study. For example, items such as headaches, despite the high frequency in patients with acute cerebral stroke, particularly hemorrhagic stroke, lead to a decrease in internal consistency of the instrument; But we maintain it due to its importance in stroke diagnosis.

Also in order to check reliability of the NIHSS, researchers were used from test-retest and inter-rater reliability. The finding was reported as correlation in test-retest method of 0.66-0.77 and agreement between observer of 0.69 (19).

Inter-rater reliability in our study was 0.96. This outcome suggests the present scale has excellent agreement among the participants, including nurses and pre-hospital emergency technicians.

In this study, one reason for the high level of agreement between observers can be induced from objective responses tools and the other can be by having two options for items .Therefore there is a need to time out to select various options and personal judgment involved in selecting the response, will be reduced.

In addition, to using this tool, reliability process is not given any training to pre-hospital emergency technicians. Only research purposes described and asked them use the tools via the attached tool guide, for completing a scale. We believe one reason for deficit in sensitivity and specificity ratio in some scales was lack of pre-hospital emergency medical technicians' knowledge about importance of rapid transport and treatment of stroke patients. It is recommended that in future studies; pre-hospital emergency technicians' take an appropriate training course about the importance of immediate action in the treatment of stroke and emphasizing the role of pre-hospital emergency care in the treatment of these patients.

Also, Gur et al. used to ROC curve in order to determine their scale cutoff point (32).

Another finding of this study is accuracy of the instruments that indicated 79% in which according to table 4 is set at a good level. Accuracy of the instruments is determined by the area under the curve (AUC) (33).

However, our research limitations can be lack of access to national studies, evaluation of other diagnostic and treatment professional groups (for example emergency medical dispatch, Triage nurses etc.) in order to ensure generalizability capacity and lack of checking for timeout in completing the tool. Also positive points of this tool are considered as preserving the simplicity, eloquence, brevity and logical sequence of items.

This study attempted to create a tool for emergency medical technicians based on good pre-hospital stroke tool definition. After the above procedures, the Iranian Pre-hospital Stroke Scale consists of 14 items; with responses of the two options (yes or no), with cut-off point of 11 and psychometric properties, was designed.

Conclusion

This study made an Iranian pre hospital stroke scale for emergency technicians in pre-hospital field which is dichotomous items, simple and very easy to use. For future this tool could be recommended and employed by emergency dispatch units as well as using it in the triage procedure in the hospital.

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