Original Article

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Development and Validation of Stroke-specific Shoulder Disability Index: A Cross-sectional Study

Physiotherapy Section

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ABSTRACT

Introduction: Shoulder difficulties are the most prevalent secondary musculoskeletal dysfunction after stroke, accounting for 34-85% of patients. To resolve these issues, a comprehensive evaluation is necessary. Currently, there is no evaluation instrument, that includes all shoulder problems.

Aim: To develop and evaluate the content validity of stroke-specific shoulder disability index, unique to stroke patients.

Materials and Methods: The present study was a cross-sectional content validation study, conducted at a tertiary care hospital from August 2020 to March 2021. Domains included in the scale were muscle tone, pain, subluxation, synergy pattern, active (within synergy, mixed synergy, away from synergy), and passive range of motion, sensation, and Activity of Daily Livings (ADLs) by an exhaustive literature search and direct patient interview. Prior to the construction of the scale, two physiotherapists with relevant field experience were interviewed, to identify domains and items. Then, 10 stroke patients were interviewed to generate new items depending on the challenges they experienced. The scale was subsequently sent to a panel of eight experts for content evaluation.

Results: Initial production yielded 49 items over 10 domains. On the advice of the reviewers, one item was added to the pain domain after the original Delphi survey round. The first-round I-Content Validity Index (CVI)/Average (Ave) score was 0.97, which was a good content validity score; nevertheless, the second round of the Delphi survey was conducted since reviewers suggested modifying the scoring criteria for some domains. Following any required revisions, the scale was resubmitted to a panel of eight experts for final approval. In the second round, the proposed stroke-specific shoulder disability index achieved an I-CVI/Ave score of 0.98, therefore, no extra survey was required.

Conclusion: Stroke-specific shoulder disability index was developed and earned a strong validation score. Therefore, the items collected under various domains, may be utilised to develop a shoulder impairment index, unique to stroke patients.

Keywords: Content validity, Delphi survey, Domain, Item generation, Shoulder assessment

INTRODUCTION

Stroke is a significant public health concern across the globe. It is the second leading cause of death and a major contributor to future disability [1]. The widely accepted definition of stroke comes from the World Health Organisation (WHO) [2] and dates back to 1980. It states that, rapidly evolving clinical signs of focal (sometimes global) disorders of brain function, 24 lasting hours or fatal for no apparent reason other than vascular origin. It is the second greatest cause of mortality and the fourth major cause of disability in the world [3]. Approximately, 20 million people experience a stroke each year, with death of 5 million people [4]. Shoulder problems are common secondary musculoskeletal complications after a stroke, with an occurrence rate ranging from 34-85% [5-9]. The onset of shoulder problems after a stroke starts at 14 days and is most evident after 2-4 months [10]. Common poststroke shoulder problems include altered muscle tone, pain (85%), subluxation (84%), impingement, frozen shoulder, reflex sympathetic dystrophy, spastic shoulder, etc., [11]. For researchers, to assess the success of various treatment approaches based on the hemiplegic shoulder, they must be able to quantify shoulder dysfunctions after a stroke in a cost-effective, valid, reliable, and freely accessible way. There is currently no scale that can assess the hemiplegic shoulder and its related deficits. Various functional scales, such as Fugl-Meyer [12], ABILHAND Questionnaire [13], Disabilities of Arm, Shoulder and Hand (DASH) Questionnaire [14] etc., are available in the literature. The most significant issue with evaluating hemiplegic shoulder impairments with these questionnaires is that they do not cover all areas pertinent to hemiplegic shoulder impairments [15]. The primary challenge comes when researchers evaluate the effectiveness of a shoulder-based intervention, by adopting the complete upper extremity scale and the need of various outcome testing instruments, which is arduous and time-consuming. Another drawback of evaluating the shoulder using the full upper extremity scale is the typical recovery pattern of stroke patients. The actual evaluation score at the postprocedure level may be impacted, if the proximal section of the limb recovers more than the distal component of the limb [15].

Therefore, it is necessary to develop a shoulder-specific scale for hemiplegics that includes all relevant domains and items so that researchers can use this scale effectively. Consequently, the primary objective of the present study was to create and validate a stroke-specific shoulder disability index, including all relevant domains and components.

MATERIALS AND METHODS

This cross-sectional, content validation study, was conducted at a tertiary care hospital. from August 2020 to March 2021. Ethical clearance from the Institution's Ethics Committee (IEC) (IEC-1825) was obtained. The study consisted of two parts. Initial item production pertaining to muscle tone, pain, subluxation, synergy component, active Range of Motion (ROM) (within synergy, mixed synergy and against synergy), sensation, and ADLs derived from an exhaustive literature search and direct patient interview. Secondly, material is validated using the Delphi approach. Before participating in the research, all 10 interview participants completed a written informed consent form. Experts who participated in the Delphi poll, signed the electronic permission form.

Phase 1: Domain and item development: During this phase, items were developed for the domains of muscle tone, discomfort, subluxation, synergy component, active ROM, passive ROM, sensation, and ADLs. This phase was divided into subphases.

1a. In-depth direct interview from experts: Two physiotherapists with a decade of experience working with stroke patients were interviewed in-depth to identify domains associated with hemiplegic shoulder impairment and to produce related items.

1b. Extensive literature search: From 1980 to 2021, the English-language databases google scholar, Pubmed, ProQuest, Scopus, and Cochrane library were used to search for relevant material. Literature search terms included hemiplegic shoulder, shoulder disability, stroke outcome measure, upper extremity scale, shoulder ADL, and shoulder disability questionnaire. From a total of 48 papers, 17 pre-existing scales [12-14,16-29] were employed in the construction of stroke-specific shoulder disability index.

1c. Direct patient interview: In this phase of the research, 10 people with stroke were interviewed directly. Individuals with an ischaemic stroke, being between the ages of 40-70, of both sexes, able to comply with simple orders and having an Mini Mental Status Examination (MMSE) greater than or equal to 23 were included. Participants who had haemorrhagic stroke and multiple strokes were excluded from this interview process. All participants were told to produce a list of elements, they deemed essential to include on the scale. They were also instructed to add items under various domains, that were generated from the literature search.

Phase 2: Content validation via Delphi method: Specialists and professionals with atleast eight years of experience treating stroke patients were contacted to validate the scale using the Delphi method [30]. Ten experts were invited to participate in the content validation Delphi survey through email and eight responded and agreed for content validation. From the eight professionals, six were physical therapists and two were neurologists. The experts were directed to assess the items' relevance using a four-point rating scale. 1=Not relevant, 2=Item need adjustment, 3=Item is significant but only requires minor change, and 4=Very relevant. During content validity analysis score 1 was assigned to the items got 3 or 4 on a relevance rating scale from experts, score 0 was assigned to the items got 1 and 2 on a relevance rating scale from experts.

Although the scale received good I-CVI and I-CVI/Ave scores (0.97) in this round, every expert proposed modifying the scoring criteria for certain domains. Accordingly, authors updated the scoring criteria based on the ideas of experts and resent the scale to another eight experts who did not participate in the first Delphi poll. According to the Lynn MR criteria [31], authors obtained an appropriate content validity index (0.98) in the second round, hence, a third round of Delphi survey was unnecessary.

Draft of scale after Delphi survey: The final draft of the scale is attached in [Appendix].

STATISTICAL ANALYSIS

Analysis of the data consisted of tabulating the results of a comprehensive literature search and in-person interviews, and removing any duplicates that were detected. Each produced item was checked and reported in accordance with I-CVI nomenclature. At the conclusion of each Delphi survey, S-CVI was used to reveal the overall validation of the suggested scale with the desired item pool. S-CVI was calculated using both the universal agreement technique and the average approach. In the process of content validation, Lynn MR [31] advised an S-CVI of 0.78 for 6-10 experts, and an S-CVI/Ave of 0.90 was regarded as outstanding content validity [32].

RESULTS

The first-round S-CVI/Ave score was 0.97, which was a good content validity score; In the second round, the proposed stroke-specific shoulder disability index achieved an S-CVI/Ave score of 0.98 [Table/Fig-1].

Domain	Delphi round 1		Delphi round 2	
	S-CVI/Ave	S-CVI/UA	S-CVI/Ave	S-CVI/UA
D-1 Muscle tone around shoulder muscles	0.97	0.8	1	1
D-2 Pain	1	1	0.97	0.8
D-3 Subluxation	0.95	0.75	0.96	0.75
D-4 Synergy component appeared	1	1	1	1
D-5 Active movement pattern, within synergy pattern	1	1	1	1
D-6 Active movement pattern mixed synergy	1	1	1	1
D-7 Active movement pattern, against synergy	1	1	1	1
D-8 Passive range of motion of affected shoulder	0.93	0.83	1	1
D-9 Sensation	0.93	0.6	1	1
D-10 Activity of Daily Living (ADL)	0.96	0.8	0.96	0.8
Total	0.97	0.87	0.98	0.93

[Table/Fig-1]: Content validity index scores in each round of Delphi survey.
CVI/Ave: Scale level content validity index/Average, S-CVI/UA: Scale level content validity index/Universal acceptance

DISCUSSION

According to the best of authors knowledge, the present study, was the first research to construct a shoulder impairment scale, after a stroke. In all rounds of the Delphi poll, a total of eight panelists were involved. According to the criteria established by Lynn MR [31], 8-10 experts are adequate for content validation. Larger sample sizes are likely to cause issues with data processing and analysis [33]. In the Delphi survey, a panel of acknowledged experts in a certain subject was asked to respond to a series of questions, in order to discover the panel's consensus on a specific topic [34]. Delphi survey was used to verify the domains and items, since it offers benefits over focus groups. It is more efficient than other methods, since members are not required to engage. The agreement is reached without any contact among respondents, which might remove the possibility of a dominating expert influencing the opinions of other experts [35].

Content validation results were shown as I-CVI for each individual item, S-CVI/Ave and S-CVI/UA for each domain, and S-CVI/Ave and S-CVI/UA for the whole scale [Table/Fig-1]. Lynn MR [31] considers an S-CVI/Ave score of 0.83 for six to eight experts to be a good score for content validation. In the present research, even though S-CVI/Ave was 0.97 in the first round of content validation, a second round Delphi survey was done, since in the first round, one expert advised the inclusion of a pain-related item which is pain during overpressure , under domain 2. Authors deemed it appropriate to include this question, and six experts advised modifying the scale's scoring standards. Initially, authors utilised separate point scales for different domains, but a panel of experts recommended that, we use the same point scale for all domains and offer an explanation of the scoring criteria. After implementing these modifications, another Delphi survey was conducted for content confirmation. In the last round, the S-CVI/Ave score was determined to be 0.98, and no more Delphi surveys were necessary.

In both rounds, the suggested scale received a high I-CVI/Ave and I-CVI/UA, score for content validity, indicating that its content validity was outstanding. In addition, to include all categories linked to hemiplegic shoulder impairment, this scale also includes items that can assess ADL, which contributes to its high rating among specialists. By using a single outcome measure, physicians and researchers will be able to get a full and comprehensive result, eliminating the need for a thorough upper extremity examination. The scale has achieved a high content validity score, and future studies may be conducted to examine its reliability, criterion validity,

and psychometric properties for improved application in clinical and research contexts.

Limitation(s)

The research has various drawbacks, such as the absence of confirmatory factor analysis, to determine, if a certain item is suitable for a specific domain. As a result of the small sample size, and the use of convenience sampling to choose participants for direct patient interviews, there was a potential of selection bias.

CONCLUSION(S)

The scale was developed and earned a strong validation score. Therefore, the items collected under various domains, may be utilised to develop a shoulder impairment index, unique to stroke patients.

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APPENDIX

STROKE-SPECIFIC SHOULDER DISABILITY INDEX

Demographic profile of patient

Patient code:

Trial no:

Age:

Sex:

Duration of stroke:

Side of involvement (Paretic side):

Total score obtained:

1. Muscle tone around shoulder muscles:

Therapist should move the affected shoulder passively five times with sufficient speed and record the resistance to passive motion they feel. Internal Rotation (IR)/External Rotation (ER) with arm by side and arm abducted at 90°.

	Normal (4)	Slight ↑ in muscle tone. Mild resistance felt during passive ROM (3)	Moderate ↑ in muscle tone, passive movement difficult (2)	Severe ↑ in muscle tone, passive movement not possible (1)	Flaccid (0)
Flexion					
Extension					
Abduction					
Adduction					
Internal Rotation (IR)					
External Rotation (ER)					

Total score:……/24

2. Pain

	No pain (4)	Mild pain (3)	Moderate pain (2)	Severe pain (1)	Not testable (0)
Resting pain:					
Pain during Passive ROM:					
Pain during Passive ROM with over pressure:					
Pain during Active ROM:					
Pain during ADLs:					

Total score:……/20

3. **Subluxation on digital vernier caliper:** Patient is seated in a chair or wheelchair with both feet flat on the ground or on a footrest. The physical therapist will first assess the unaffected side to palpate the gap between the acromion and the head of the humerus, and this assessment will be repeated on the affected shoulder. Shoulders will be positioned in neutral rotation, with the arm hanging by the side. Tip of acromion process and the head of humerus is marked with marker. This two marked point will be measured by digital vernier caliper in millimeter.

Subluxation	Scores
No subluxation	4
Grade 1 (0.1-5 mm)	3
Grade 2 (5.1-10 mm)	2
Grade 3 (10.1-15 mm)	1
Grade 4 (15.1 mm or more)	0

Total score:……/04

4. **Synergy component appeared:** Score will be given only to those components which have appeared as synergy, other components will be marked as not applicable (NA). Maximum four component can appear as flexor/extensor/mixed synergy (two from scapula, two from shoulder). So maximum score under this domain will be 16.

Joint	Movement	Active movement possible against synergy (4)	Some active movement is initiated against synergy (3)	Some active movement possible within the synergy (2)	All components of synergy developed fully, no active movement possible (1)	No synergy or synergy component just starts appearing. No active movement possible (0)
Scapula	Elevation					
	Depression					
	Protraction					
	Retraction					

Shoulder	Flexion					
	Extension					
	Abduction					
	Adduction					
	Internal rotation					
	External rotation					

Total score:……./16

5. Active movement pattern, within synergy pattern:

Umbilical level will be considered as 1/2 distance of total available range.

Movement	Pt is able to complete full movement as instructed (4)	Pt is able to complete more than 1/2 of ROM but not able to complete full (3)	Pt is able to complete 1/2 of ROM (2)	Pt is able to perform only some degree of movement but less than 1/2 of ROM (1)	Pt is not able to do any movement (0)
Take your hand from opposite knee to paretic side ear					
Take your hand from paretic side ear to non paretic side knee					

Total score:……./08

6. Active movement pattern: Mixed synergy:

For hand to sacrum, up to ASIS level will be considered as 1/2 distance of total available range.

Movement	Pt is able to complete full movement as instructed (4)	Pt is able to complete more than 1/2 of ROM but not able to complete full (3)	Pt is able to complete 1/2 of ROM (2)	Pt able to perform only some degree of movement but less than 1/2 of ROM (1)	Pt is not able to do any movement (0)
Hand to sacrum					
Shoulder flexion up-to 90°					

Total score:……./08

7. Active movement pattern: No synergy:

Movement	Pt is able to complete full movement as instructed (4)	Pt is able to complete more than 1/2 of ROM but not able to complete full (3)	Pt is able to complete 1/2 of ROM (2)	Pt is able to perform only some degree of movement but less than 1/2 of ROM (1)	Pt is not able to do any movement (0)
Shoulder flexion 90-180°					
Shoulder abduction 0-90° with elbow extension					

Total score:……./08

8. Passive range of motion of affected shoulder:

Passive ROM should be measured by therapist with the help of goniometry and based on response score should be given.

Movements	Full ROM (4)	3/4th ROM (3)	1/2 ROM (2)	1/4th ROM (1)	None (0)
Flexion					
Extension					
Abduction					
Adduction					
Internal rotation					
External rotation					

Total score:……./24

9 Sensation: Standard sensory assessment should be followed. For joint position sense and movement sense patient will be blindfolded and rehearsal should be given on sound limb.

Test		Normal (3)	Impaired (2)	Absent (0)
Superficial (pain and touch)				
Deep	Joint position sense			
	Movement sense (Affected shoulder should be move in all directions)			

Total score:……./06

10 Activity of Daily living (ADLs)

Activity	Pt is able to complete without any difficulty (4)	Pt is able to complete with mild difficulty (3)	Pt is able to complete with minimal support from caregiver (2)	Pt is able to complete with maximum support from caregiver (1)	Pt is unable to perform the activity (0)
Can raise shoulder less than 90° in supine					
Can raise and hold shoulder at 90° in supine					
Can take a jar from shelf above head height					
Can take purse from back pocket					
Can wash head with help of affected upper limb					
Can close button with help of affected upper limb					
Turn on a light on the switchboard					
Move an object from one end to another of the table					
Put on t-shirt					
Putting affected arm through coat sleeves					

Total score:...../40

Total score:...../