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Development of Respiratory Objective Assessment Scale for Spinal Cord Injured (Roasci)

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Introduction

Spinal cord injury (SCI) often compromises its major functions in terms of motor, sensory, autonomic and reflex of an individual completely or incompletely (1). Many studies showed that additional to the respiratory complication, which is one of the major cause (3), bowel and bladder dysfunction, pressure ulcers, spasticity, pain and musculoskeletal problems leads to increased mortality and morbidity in them (4).

Although there have been improvements in medical care following spinal cord injury (SCI), mortality rates are still elevated, commonly in the first year and thereafter dupe to pneumonia and other respiratory illnesses, shown in many contemporary studies (5). This shows that impairments in respiration results in medical consequences that are leading cause of morbidity and mortality, and puts economic and emotional burden on the patient and family (6). It has been observed that most of the cases admitted in the acute hospitalization phase belongs to the C1-C4 level of injury (7), majorly effecting pulmonary system, leading to many respiratory difficulties andcomplications, and is a frequent cause of death, both in the acute and chronic phase after injury. Studies have found that 67% of the SCI patients, who are in their acute phase experience severe respiratory complications within the first few days after the injury (8) like atelectasis (36.4%), pneumonia (31.4%), and respiratory failure (22.6%). Injury to the cervical and upper thoracic cord disrupts the function of the inspiratory and expiratory muscles like diaphragm, intercostals muscles, accessory respiratory muscles and abdominal muscles and thereby causing reduction in spirometry and lung volume parameters and static mouth pressure. In higher tetraplegic and paraplegic, expiratory muscle function is more compromised than inspiratory muscle function (9).

Effect of these factors will be difficulty in clearing secretion and ineffective cough along with additional to symptoms like reduced lung and chest wall compliance possibly due to micro-atelectasis, reduced breathing efficiency ribcage stiffness, paradoxical chest wall movements(10). It has been found after studying that more than 80% patients with injuries above C4 and more than 55% patients with injuries from C5 to C8 will suffer from respiratory complications. Similarly, more than 75% of tetraplegia suffering from injury above C4 and more than 50% of the tetraplegia having injury caudal to C4 will need invasive mechanical ventilation to manage their respiratory insufficiencies. Close surveillance of their respiration is important. In addition, a total of 65% of patients with injuries at levels from T-1 to T-12 may have severe respiratory complications. A 30%-50% reduction of vital capacity is described during the first week post injury in patients with injuries at C5-C6. It is recommended that vital capacity and arterial blood gases should be measured until the patient is stable (11). Scales are the reliable and validated methods to assess a particular component or a group of symptoms in a patient. They are economically cheaper as compared to other assessment tools, easily accessible, easy to administer, non-

invasive and widely accepted worldwide. There are many scales that have been used so far for the assessment of the functional component (FIM, QoL), locomotion (BMS, WISCI II), and depression (CESD).

Also, there are many generic scales that have been used to analyze the respiratory system and its components in individuals presenting with or without any respiratory pathology like dyspnea assessed by scales like Borg's scale (RPE), Modified Medical Research Council Dyspnea (MMRC), Cancer Dyspnea Scale,etc; cough and sputum assessed by Leicester Cough Questionnaire (LCQ) and in the patients with COPD like COPD Assessment Scale (CAT) . Also there are number of scales that have been developed specifically for SCI like International Spinal Cord Injury Pain Classification (ISCIP), Multidimensional Pain Inventory SCI version, Functional Tests for Persons who Self Propel a Manual Wheelchair (4FTPSMW) (12) and many more that will help in assessing and measuring different components in SCI like their functional status, degree of functional disability, quality of life, measuring strength, etc. but there is no specific scale developed so far for respiratory system assessment in SCI. Still there is no scale developed so far to assess the respiratory symptoms or respiratory complications of a spinal cord injured patient. There is no such definite tool made till now that will give an overall status of impact of spinal cord injury on respiratory system which needs to be evaluated properly, and therefore the main focus of this study. A study also proved that mortality rates are particularly higher in the first year, and their life expectancy increases if their survival increases in the first year. This concludes about the importance of regular assessment and management of the patient with SCI, especially the respiratory status (8).

There is a dire need for the development of objective scale in particular and we all know that mortality rates are high in spinal cord injured patient because of the respiratory issues, so this study focuses on development of the respiratory objective assessment scale in spinal cord injure patients. As there is no scale developed so far for prospectively examining the respiratory status in SCI, this study focuses on development of that scale.

Methodology

Phase 1: Item Development

Step-1: Domain Identification and Item Generation

• Domain Identification - This is the first step where the identification of the domains, that needs to be focused upon more, were carried out and selected. These items are intended to measure the respiratory status of the patient through the scale which is being developed. This process was entirely based on the data available from various sources like published articles and books.

• Item Generation–In this, the identification and selection of the logical domains was done under which different items of the scale were put and categoried. Items were choosen such that they can be scored,

so as to develop a competent of scale. This was also done with the help of the review of the extensive literature available, taking data from the already existing scales and also from the knowledge and th experience of the researcher. This is usually done by selection a pool of items followed by their evaluation.

Phase 2: Scale Development

Step-2: instrument construction

• This step was done to minimize the misunderstand and the subsequent error in the items. It ensures that the developed items should be meaningful and phrasing was revised in a way which is maximally understood. Cognitive interviews, focused group discussion was dane in such way that it develops the modified items and make them clarified or augmented to fit the study objective. Also helped in testing the appropriateness and strength of the developing items.

• Judgmental evidence: In this, all the panelist members were explained about the study and its objective briefly. The panelist selected consisted of were senior medical doctors, physiotherapist and nursing staff, having more than 10- 15 years of experience their field and were also specialized in the field of cardiopulmonary or neurology.

• Each panelist was asked to score was asked to score each item in the scale through Delphi method and also provide their additional remarks or suggestions, if any, for the scale. The scoring, given by each panelist to each item, reflects the importance and preference of that item in the scale.

• Two separate scales were made, one for the mechanically ventilated patients, named 'For Trachiotomised' and another for non-mechanically ventilated patients named 'For Non-trachiostomised'. There were total of ten panelist members recruited for the first phase and the scale was given to them for the evaluation. With their suggestions and their scoring, some new items in the scale were added like age, BMI, etc and some of them were removed, like measurement of dyspnea and use accessory muscles in mechanically ventilated patients. A new template scale was further developed with these changes and along with few changes and was again given to the panelist for the second round of scoring.

Step-3 : Content Adequacy Assessment/ Validity

• This is an imporatnt step in the development of the scale which is often overlooked by most of the researchers. It deals with the thoeritical analysis of the items and the domains that have been selected. This can be done with help of the expert judges and the target population.

• In order to conduct content validation of the scale, the expert panelist were asked to provide their veiw points on the scale. They were asked to score and evaluate the items of the scale both qualitatively and quantitively. This is conducuted to ensure a functional, internally consistent and parsimonious scale with the deletion and modification of the items.

CONTENT VALIDATION

There are multiple methods for testing the contend validity of the scale and items. This study used one of the methods involving the imperical teqnique to calculate the index of content validity (CVI) and the content validity ratio.

• The content validity form that has been prepared for the panelist making this ensure that it has a clear understanding and expectation about the task. In the imtruction column of the first page of the scale, rating for the relevance score (0-9) of each item was explain which is to be score in the preference column.

• There are two forms of CVI, in which CVI for item (I-CVI) and CVI for scale (S-CVI). Two methods for calculating S-CVI, in which the average of the I-CVI scores for all items on the scale (S-CVI/Ave) and the proportion of items on the scale that achieve a relevance scale of ≥5 score by all experts (S-CVI/UA).(19)

• Both I-CVI (item-level content validity index) and S-CVI I the form of S-CVI/Ave (scale-level content validity index based on the average method) and S-CVI/UA (scale-level content validity index based on the universal agreement method) was calculated.

• Content validity is vital to ensure the overall validity of an assessment, therefore a systematic approach for content validation should be done based on the evidence and best practice. This paper has provided a systematic and evidence-based approach to conduct a proper content validation.

Results

This is a study conducted for the development of a scale that can be used to assess the respiratory status of the spinal cord injured population, in their acute phase of the injury when most of them are either in the ICU or in IPD of the hospital.

Validation of The Scale

In order to finalize the domains and the items of the respiratory scale and to determine the content validity of the scale, 10 expert panels having a minimum of 10 of experience in their field were approached.

Panelists	Qualification	Years of experience
Doctor	MBBS, M.D in medicine	11
Doctor	Senior consultant	12
Nurse	Respiratory nurse	>12
Doctor	Senior consultant, respiratory service	>30
Physiotherapist	Physiotherapist (HOD-C.T.V. S)	>20
Physiotherapist	Physiotherapist	>10
Doctor	Dean	30
Doctor	Senior consultant, head ICU	20
Doctor	Consultant, critical care	14
Nurse	Spine nurse counselor	>15

Table: Demographic details of expert Panel

All the 10-panel member provided their suggestion in the form of qualitative and quantitative review for the first round of assessing relevance of items in both the scale. For later two subsequent rounds, the data of 8 panelist members was obtained and analyzed, as 2 panelist members were unable to participate in the further rounds due to personal reasons.After that the data analyzed for content validity and item reliability using Cronbach's Alpha.(34)

Content Validity

Quantitative values of the scale, represented as numeric values, the CVR values and the CVI values of all items in the scale are presented in the table. For the content validation, a method similar to the Lawshe method, a formula helped calculation of the content validation was used to calculate the content validity ratio (CVR) for each item in the scale and was compared with the minimum value of 0.62 CVR for 10 expert panel and 0.75 for 8 expert panel with 5%level of significance. Also the acceptable value for content validity index is at least 0.78 for 10 experts and is 0.83 for 8 experts.(35)

The CVR and CVI was calculated in each Delphi round and was correlated and compared with the acceptable ranges. Also, this helped in making changes in the items on the basis of the quantitative reviews of the experts and further moved to the next step to get relevance score of each item, until a consensus was achieved between the experts regarding the items of the scale.

In total 17 items were found to be valid, content wise, out of 24 initial items and the remaining 7 items were deleted, i.e., the item number 4, 12, 19, 21, 22, 23 and 24. According to some expert opinion 3 additional items were added in the scale designed for mechanically ventilated patients. In the scale designed for non-mechanically ventilated patients, 23 items were found to be valid, content wise, out of 27 initial items and the remaining 4 items were deleted, i.e., item number 12, 20, 22 and 24. Also there is addition of 4 more items in this case.

The CVI for both the scale came up to be equal to 1 and the S-CVI (scale- content validity index) for both average (S-CVI/Ave) and universal agreement (S-CVI/UA) is also equal to 1. The above values prove that the content is valid and items in the scale have good relevance and universal agreement by all experts.

Descriptive statistics for each item

This procedure is carried out in to describe about the item statistics of each item in the two scales on the basis of the mean and standard deviation, calculated using SPSS software.

Content validity of the scale

These scales have been validated for its content with the most common method for measuring i.e. item level CVI and scale level CVI, which can be calculated using S-CVI/UA or S-CVI/Ave. for this, the panelist in three rounds critically analyzed each item of the scale.

The template was presented to the number of panelists individually, who are expert in the field of assessing respiratory system or have dealt with SCI population, having experience in their field for more than four years. For mechanically ventilated patients (Scale-1), a scale consisting of 24 items divided in five domains- General Assessment, Laboratory Test, Chest Radiograph, Ventilatory status and Suctioning and Examination, was designed to get reviewed. Similarly, for non-mechanically ventilated patients (Scale-2), a scale consisting of 27 items divided in five domains- General Assessment, Laboratory Test, Chest Radiograph, Observation and Examination, was designed to get reviewed. Each item has been scored into three categories where less score indicates no or less affected respiratory system and larger score indicated more of severely affected respiratory system. The panelist was asked to score each item on the basis of their preference and judging the importance of each item to be present in the scale. In this, higher score indicated better fit of that item in the scale whereas lesser score indicates poor fitting. Enough space has been provided in the scale to add remarks for each item and for overall scale, if required.

Based on the data obtained from the panelist after the first round and conducting the statistical procedure for the same, there was removal and addition of items done in each scale. In Scale-1, seven

items with mean less than 6.7, average mean of 5.7 and average SD ±3.34 and I-CVI ≤0.8 was removed. Along with that, further addition of three more items were conducted. The S-CVI/Ave of the scale was 0.90 and S-CVI/UA was 0.58. In Scale-2, four items with mean less than 7.6, average mean of 4.7 and average SD ±2.63 and varied I-CVI (1, 1, 0.4, 0.5) of was removed. Along with that, further addition of four more items were conducted. The S-CVI/Ave of the scale was 0.94 and S-CVI/UA was 0.81.

The revised template of the scale was presented to the panelist for the second round of assessment of the relevance of the items and further modifications. After the second round, there was no further addition or deletion of items were done. Further calculation of the scoring given by the panelist was conducted. In Scale-1, the mean score of all the items was ≥8, SD of each item ≤0.99, average of mean being 8.45, average of SD being 0.66 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of the scale calculated is equal to 1. In Scale-2, the mean score of all the items was ≥8.12, SD of each item ≤0.99, average of mean being 8.5, average of SD being 0.63 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of both the scales calculated was equal to 1.

With these data and non-modified scale further presented to the panelist for the third round. In Scale-1, the mean score of all the items was ≥8.12, SD of each item ≤1.1, average of mean being 8.5, average of SD being 0.62 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of the scale calculated is equal to 1. In Scale-2, the mean score of all the items was ≥8.12, SD of each item ≤0.9, average of mean being 8.5, average of SD being 0.55 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of the scale calculated is equal to 1.

From the data obtained and statistically evaluated, we can determine that both scales showed good content validity, interpreted on the basis of their content valid index and its universal agreement.

Reliability of the Scale

The reliability of any given measurement refers to the extent to which it is a consistent measure of a concept. It depicts the degree to measure of a construct is dependable or consistent, and Cronbach's Alpha is one way of measuring the strength of that consistency.(37)(36)

Cronbach's Alpha is measure that is used to assess the reliability, or internal consistency, of a set of scale or test items. It is considered to be a measure of scale of reliability. This measure helps in interpreting how closely related a set of items as a group. Value of Cronbach's Alpha greater than 0.70 is considered to be an acceptable range of reliability (38) however, having values more than 0.80 is considered good internal consistency (32).

Reliability of items explained by Cronbach's Alpha for the Respiratory Objective Scale (ROASSCI) developed for Mechanically Ventilated patients

Both the scales i.e. the one designed for mechanically ventilated patients and the other designed for non-mechanically ventilated patients, have showed significant results for Cronbach's Alpha with their values more than 0.70.

Discussion

The aim of the study is the development of the Respiratory Objective Assessment Scale for SCI (ROASSCI) suffering respiratory complications in their acute phase (19), who are either admitted in the ICU or in IPD's of the hospitals. The scale has been validated for its content and has been approved for its item reliability using Cronbach's Alpha values. (34)

As we are well aware of the fact that respiratory complications are one of the leading causes of increasing mortality and morbidity in the SCI patients(18)(19)(20). It has been published in studies that majority of the hospitals present in present in developing countries like India, faces lot difficulties while assessing the respiratory system within the healthcare setups. In majority of the hospitals and other healthcare setup's, the evaluation of the respiratory complication for different population was limited to patient's medical history and X-Rays.(13) The chances of respiratory complication increase because of lack of readily available resources like PFT and financial constraints faced by the patients.

To prevent the respiratory complications, like VAP, HAP commonly affecting patients with depressed respiratory system in hospitals (2), a cheap and quick assessment tool like a scale specifically designed for SCI can be used as a substitute for extensive an invasive procedure like ABGA (Arterial Blood Gas Analysis) and PFT (Pulmonary Function Test) to assess their respiratory status routinely by any professional or nursing staff.(19)

The semi-structured scale template was presented to a group of panelist member to obtain their qualitative and quantitative review after which it was thoroughly evaluated by the therapist for their language and scoring using linguistic and numeric review provided by the expert panelists. (33)

The initial draft is then reviewed by the panelists for the linguistic errors. This helped in item reduction and addition to obtain a better modified version of the scale for further evaluation. (33) The scale developed was checked for content adequacy using the formula and the reliability of items using Cronbach's Alpha on the basis of which we conclude that the scale developed for SCI is valid and reliable both.(34)

Content validity of the scale

These scales have been validated for its content with the most common method for measuring i.e. item level CVI and scale level CVI, which can also be further confirmed calculated using S-CVI/UA or S-CVI/Ave. for this, the panelist in three rounds critically analyzed each item of the scale.

The template was presented to the number of panelists individually, who are expert in the field of assessing respiratory system or have dealt with SCI population, having experience in their field for more than four years. For mechanically ventilated patients (Scale-1), a scale consisting of 24 items divided in five domains- General Assessment, Laboratory Test, Chest Radiograph, Ventilatory status and Suctioning and Examination, was designed to get reviewed. Similarly, for non-mechanically ventilated patients (Scale-2), a scale consisting of 27 items divided in five domains- General Assessment, Laboratory Test, Chest Radiograph, Observation and Examination, was designed to get reviewed. Each item has been scored into three categories where less score indicates no or less affected respiratory system and larger score indicated more of severely affected respiratory system. The panelist was asked to score each item on the basis of their preference and judging the importance of each item to be present in the scale. In this, higher score indicated better fit of that item in the scale whereas lesser score indicates poor fitting. Enough space has been provided in the scale to add remarks for each item and for overall scale, if required.

Based on the data obtained from the panelist after the first round and conducting the statistical procedure for the same, there was removal and addition of items done in each scale. In Scale-1, seven items with mean less than 6.7, average mean of 5.7 and average SD ±3.34 and I-CVI ≤0.8 was removed. Along with that, further addition of three more items were conducted. The S-CVI/Ave of the scale was 0.90 and S-CVI/UA was 0.58. In Scale-2, four items with mean less than 7.6, average mean of 4.7 and average SD ±2.63 and varied I-CVI (1, 1, 0.4, 0.5) of was removed. Along with that, further addition of four more items were conducted. The S-CVI/Ave of the scale was 0.94 and S-CVI/UA was 0.81.

Later the revised template of the scale was presented to the panelist for the second round of assessment of the relevance of the items and further modifications. After the second round, there was no further addition or deletion of items were done. Further calculation of the scoring given by the panelist was conducted. In Scale-1, the mean score of all the items was ≥8, SD of each item ≤0.99, average of mean being 8.45, average of SD being 0.66 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of the scale calculated is equal to 1. In Scale-2, the mean score of all the items was ≥8.12, SD of each item ≤0.99, average of mean being 8.5, average of SD being 0.63 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of both the scales calculated was equal to 1.

With these data and non-modified scale further presented to the panelist for the third round. In Scale-1, the mean score of all the items was ≥8.12, SD of each item ≤1.1, average of mean being 8.5, average

of SD being 0.62 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of the scale calculated is equal to 1. In Scale-2, the mean score of all the items was ≥8.12, SD of each item ≤0.9, average of mean being 8.5, average of SD being 0.55 and I-CVI of each item equal to 1. The S-CVI/Ave and S-CVI/UA of the scale calculated is equal to 1.

From the data obtained and statistically evaluated, we can determine that both scales showed good content validity, interpreted on the basis of their content valid index and its universal agreement.

Reliability of the content

Reliability is essential to establish whether a tool is to be used in clinical practice or not. Reliability refers to the degree to which an instrument consistently measures a construct. The steps for the content validity are concluded, then the reliability of the items of the scale was calculated. To make sure that the construct whose content validity calculated is able to measure the right construct in a consistent manner. One of the most common assessments of reliability is Cronbach's Alpha, a statistical index of internal consistency.

The value of Cronbach's Alpha was calculated for each domain designed in both the scales to measure the consistency of items within their domain and in the scale overall. It has been showed in many studies that Cronbach's Alpha>0.7 is considered acceptable reliability of the construct.

In Scale-1, first domain of General Assessment including 9 items showed value of Cronbach's Alpha as 0.73 with the scale mean equal to 76.88 and SD equal to 3.70 for all the 9 items. each item present in the domain was found to be important enough as removal 0r deletion of any item would lead to drop in the value of Cronbach's Alpha along with decreased item mean to <69 and increased SD up to 13.35.

Second domain consisting of 2 items was of laboratory test. Its value for Cronbach's Alpha is 0.84 with scale mean equal to 17.25 and SD equal to 1.16. Third domain consisting of 2 items was for Radiographic Examination. Its value for Cronbach's Alpha is 0.78 with scale mean equal to 16.88 and SD equal to 1.26. Fourth domain of Ventilatory status and Suctioning consisted of 5 items. Its value for Cronbach's Alpha is 0.71 with scale mean equal to 42.38 and SD equal to 2.32. The last fifth domain of the Examination consisting of 2 items showed value for Cronbach's Alpha is 0.75 with scale mean equal to 17.0 and SD equal to 0.92. Overall reliability of the 20 items present in the Scale-1 has been value to 0.82 which depicts that the items are consistent to each other in the domain.

In Scale-2, first domain of General Assessment including 10 items showed value of Cronbach's Alpha as 0.72 with the scale mean equal to 88.25 and SD equal to 2.81 for all the 10 items. each item present in the domain was found to be important enough as removal 0r deletion of any item would lead to drop in the value of Cronbach's Alpha from 0.72 along with decreased item mean to <78 and increased SD up to 7.9.

Second domain consisting of 2 items was of laboratory test. Its value for Cronbach's Alpha is 0.78 with scale mean equal to 17.13 and SD equal to 1.12. Third domain consisting of 2 items was for Radiographic Examination. Its value for Cronbach's Alpha is 0.83 with scale mean equal to 16.88 and SD equal to of each item <0.92. Fourth domain of Observation consisted of 4 items. Its value for Cronbach's Alpha is 0.75 with scale mean equal to 32.88 and SD equal to 2.47. The last fifth domain of the Examination consisting of 8 items showed value for Cronbach's Alpha is 0.72 with scale mean equal to 69.7 and SD equal to 2.25. Overall reliability of the 26 items present in the Scale-2 has been value to 0.84 which depicts that the items are consistent to each other in the domain.

Though some of the items within each scale showed the value of Cronbach's Alpha higher than the overall value of Cronbach's Alpha if that item is deleted from the scale. But the same item was considered relevant for clinical evaluation of respiratory complications therefore, were not removed from the scale. Also, their removal would not have increased the Cronbach's Alpha's overall value of each scale to a great extent.

Since the value of Cronbach's Alpha of Scale-2 is slightly higher than the same value for Scale-1, it can be determined that the Scale-2 has better reliability than Scale-1.

After all the three rounds, finally scale was developed which was supposed to be administered on the patient population, to calcite the construct validity and reliability but due to covid-19 pandemic, this could not be achieved.

Limitations of the current study

The spread of COVID-19 and the steps taken by government, like lockdown and shutdown of institutions, the scale be validated overall by its application on the target population. Also, more detailed review of the literature, including a greater number of panelists coupled with increased group discussion will help in conducting a more validated scale.

Future recommendations

The application of the developed scale on the target population to calculate the overall reliability and internal consistency of the scale. Further researches can be done to calculate the construct and criterion validity of the respiratory objective assessment scale for SCI (ROASSCI). The scale can be translated into other languages for cross-cultural adaptation.

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