

Development and validation of Incontinence - Activity Participation Scale for spinal cord injury

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ABSTRACT

Introduction: We aimed to develop and validate an Incontinence - Activity Participation Scale (I-APS) for measurement of activity limitation and participation restriction due to bladder problems in spinal cord injury (SCI).

Materials and Methods: The process of development was initiated by formation of open-ended questions after thorough review of literature which were then administered to SCI participants, caretakers, and professionals working with SCI. Items were generated based on their responses and initial draft of scale was formulated. This initial draft of the scale containing 77 items was then administered to 56 SCI participants for reduction of items using factor analysis, and a prefinal version of the scale was obtained containing thirty items only. Content validity and face validity was then established.

Results: The I-APS is both health professional and self-administered questionnaire including two domains: Activities of daily living and occupation with 16 items having a content validity of 0.84. The overall internal consistency reliability was 0.86.

Conclusion: The I-APS is a valid, comprehensive instrument that measures the activity limitation and participation restrictions due to bladder problems in SCI.

INTRODUCTION

Participation is defined as “involvement in life situations” and is a core concept in all major models of disability.^[1] Persons with spinal cord injury (SCI) may experience a wide range of activity limitations and participation restrictions.^[2] Previous researches have consistently shown that people with SCI show limited participation across many major life domains such as decreased employment, limited social role, family role and limited access to recreational and leisure activities.^[1] One of the important factors responsible for this limitation is urinary incontinence.^[3]

Incontinence may be due to overactivity of the bladder muscle (detrusor) as seen in spinal cord injuries above the sacral level or following a stroke. It may also be due to detrusor hypocontractility with overflow incontinence, as seen in lower spinal cord lesions.^[4]

Even those who can ambulate may have abnormalities in bladder function, causing social issues such as urinary incontinence.^[5] Nearly 43% of patients report urinary incontinence from less than once a week to daily even after 10–45 years of SCI^[6] with urinary problems ranked as the second leading cause of death in SCI subjects.^[7]

Previous studies have established a cross-sectional association between incontinence and physical activity such that more frequency of urinary leakage is more likely to report low levels of physical activity.^[8]

The level of everyday physical activity is an important outcome measure of the rehabilitation process as well as to improve the physical health, activities of daily living (ADL), psychological wellbeing, and quality of life (QOL).^[3,9]

It has been recommended that all randomized trials evaluating treatment for incontinence should employ

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standardized, validated questionnaires to assess their impact on patient’s outcomes.

Several questionnaires have been used to establish the efficacy of treatment methods for urinary disorders. Some of the reliable and valid tools available for urinary incontinence include incontinence – QOL (I-QOL), King Health Questionnaire (KHQ)^[10-12] but these are used to assess the QOL in subjects with bladder problems. Furthermore, some of the items in the physical limitation in KHQ and I-QOL are not relevant to spinal cord injured subjects and hence, the utility of these generic measures is questionable.^[13] However, only one questionnaire Qualiveen was found in SCI population with urinary difficulties, but it was designed to assess the impact of bladder problems on QOL. As the bladder problems were found to be a barrier to physical activity participation, it becomes necessary to have a tool which can measure the level of participation limitation due to bladder problems. Hence, the aim of the study was to develop a scale which specifically addresses the issues of activity limitation and participation restriction in SCI subjects with bladder problems.

MATERIALS AND METHODS

The study was approved by the Institutional Review Committee. The procedures followed were in accordance with the ethical standards of Helsinki Declaration of 1975, as revised in 2000 The process of scale development was undertaken in the following manner [Figure 1].^[14,15]

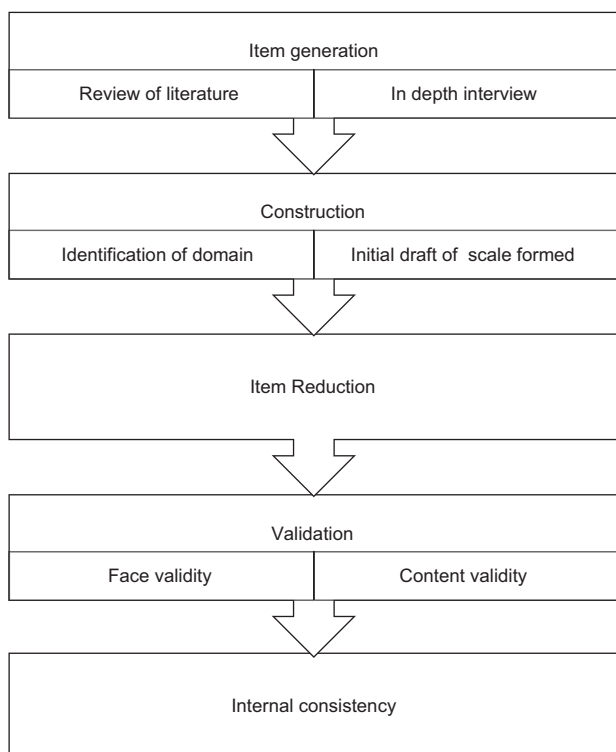


Figure 1: Steps involved in scale development process

Step 1: Item generation

Stating the purpose of the study

The purpose of the scale was specified to understand the impact of bladder problems on activity limitation and participation restriction in SCI subjects.

Identifying the target group

The target group was SCI subjects which were recruited from Indian Spinal Injury Centre and community. Informed consent was obtained from all subjects.

Review of literature

A thorough review literature was done to identify the various domains of activity and participation restrictions due to bladder problems. Primary data resources included PubMed, MEDLINE, CINAHL, and EMBASE database.

In depth interviews

After the identification of domains of activity limitations and participation restrictions due to bladder problems in SCI, open-ended questions were formulated for a one-to-one interview to gain in-depth knowledge of the construct for which the scale was to be developed.

A total of 35 participants were included in the interviews. Among them were twenty subjects with SCI, five caretakers of individuals with SCI and ten health care professionals dealing with SCI individuals (one neurophysiotherapist, one occupational therapist, one peer counselor, one neuro-urologist, one spine surgeon, one urology counselor, one psychologist, one spinal nurse, one urology nurse, one social worker). Open-ended questions were presented in the form of a semi-structured interview which probed into respondent’s feelings and opinions regarding the activity limitation and participation restriction due to bladder problems without imposing any bias. The responses of the interview were noted down as well as audio taped.

Step 2: Construction phase

The domains identified after in-depth interview, and review of literature was self-care, mobility, occupation/education, recreation, social, sexual, and others. The directions and response options for the scale were formed. A five-point Likert scale was used to rate the responses. The scale formatting was then carried out to ensure that the general format, instructions to the patients and individual items are interpretable to patients.

Step 3: Item reduction

Item reduction was done to decide which items should be discarded and which should be retained. For this purpose, a sample of 56 SCI participants was included. Participants were asked to fill the questionnaire in person, through telephone or E-mail. Categorical principal component analysis (CATPCA) was then carried out using SPSS 21.0 for Windows (SPSS Inc., Chicago, Illinois) for reducing the

number of items. The items fulfilling the predetermined criteria of factor loading of 0.6 or more on one factor and <0.3 on other factor were retained. A prefinal version of the scale was hence obtained subject for establishing face and content validity.

Step 4: Validation of scale

Face validity

Face validity was established by experts who reviewed the scale.

Content validation

For establishing content validity,^[16,17] a panel of ten experts was selected for qualitative feedback on title, instructions, content areas covered, response options/scoring of the items and the overall items of the questionnaire. The comments of all the experts were reviewed thoroughly. The experts were then asked to rate the appropriateness of each item of the scale as being: Essential, Useful but not essential, Not necessary and content validity ratio (CVR) was calculated.

$$CVR = (n_e - N/2)/(N/2).$$

Since the number of experts was 10, a minimum CVR of 0.62 was required to satisfy the 5% level. Only those items with CVR values meeting this minimum were retained in the final form of the scale.

Step 5: Pilot testing

The final version of the scale consisting of 16 items and a maximum score of 80 was then administered on 82 SCI subjects of age ≥ 18 years; both male and female, ASIA A–D and the internal consistency was assessed by calculating ordinal alpha using R software.^[18]

“We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during this research.”

RESULTS

Questionnaire development

A total of 156 articles were reviewed. Of these, 81 articles were utilized to identify the domains of activity and participation restrictions and 63 articles were used to formulate an open-ended questionnaire. A total of twenty SCI subjects participated for item generation, out of which ASIA A - 13, ASIA B - 4, ASIA C - 3. Fifteen subjects were married while five were unmarried. The mean age of the subjects was 35.8 ± 11.81 years, median and range 35.5, 37 years and the majority were male (16 subjects) with the mean number of leakages reported per day was 2.3 ± 1.2 .

An exhaustive list of 77 items was generated including the following number in each domain: self-care - 15 items,

mobility - 12 items, occupation/education - 15 items, social - 11, recreation - 12 items, sexual - 7 items, and others - 5 items.

Percentage of activities limitation of various domains revealed during interview phase

Sexual activity (100%), self-care (95%), social activity (95%), and recreational activity (80%) were found to be most limited while mobility (60%) was the least limited domain.

In self-care domain toileting (100%) was the most limited activity. Feeding, grooming, bathing, dressing, putting brace, maintain personal hygiene found to be 32%, 32%, 11%, 58%, 16%, and 89% limited, respectively. In mobility domain, the most limited activity revealed was transfers followed by bed mobility (58%), mobility in wheelchair (50%), standing (42%), and walking (17%).

Those SCI subjects who were employed revealed that getting training/education (47%) and performance at work (47%) were maximally limited while getting to the workplace, contact with colleagues and position at job were 27%, 13%, 33% limited, respectively.

Visiting friends activity was found to be most limited among all the activities in social domain followed by attending social gathering, fulfilling family role, spiritual activities, and home management were found to be 74%, 58%, 63%, and 15%, respectively. In recreational domain, the activity found to be most limited were travelling (81%) and participation in exercise program (81%), whereas other activities that were recreational sports, indoor activities, movies/shopping, and outdoor activities were found to be limited by 31%, 25%, 40%, and 50% of SCI subjects, respectively.

The desire of sex was found to be most affected as reported by 100% of SCI subjects followed by relation with partner (89%), sexual self-confidence (89%), intercourse (89%), and sexual satisfaction (78%).

Item reduction

A total of 98 subjects were recruited for this phase, of which only 56 had participated in the study. The result of the CATPCA analysis identified two factors which were ADL and Occupation/education with Eigenvalues >1 explaining 46% of total variance of the scale. Only 28 items were meeting the predetermined criteria, but two items seem to be important and so retained in the questionnaire with the prefinal version of the questionnaire including 30 items: 25 in ADL and 5 in occupation/education. Table 1 shows Eigen values of the extracted factors.

Content validity

Only 16 items met the criteria of CVR values of more than 0.62 leading to the deletion of rest 14 items with resulting

in CVI of 0.84 with Table 2 showing the CVR values of the final version of Incontinence - Activity Participation Scale.

Pilot testing

The demographic details of the SCI subjects participated in pilot testing phase are shown in Table 3. Out of all the

Table 1: Eigenvalues with percentage of variance of extracted factors for Incontinence - Activity Participation Scale

| Domain | Variance accounted for | |
|----------------------------|------------------------|------------------------|
| | Total (eigenvalue) | Percentage of variance |
| Activities of daily living | 22.371 | 29.053 |
| Occupation/education | 13.052 | 16.951 |
| Total | 35.423 | 46.003 |

Table 2: Content validity ratio of the final version of the Incontinence - Activity Participation Scale

| Domain | Item number | CVR |
|----------------------------|-------------|-------|
| Activities of daily living | 1 | 0.8* |
| | 2 | 0.8* |
| | 3 | 0.8* |
| | 4 | 0.8* |
| | 5 | 1* |
| | 6 | 0.8* |
| | 7 | 0.8* |
| | 8 | 0.8* |
| | 9 | 0.8* |
| | 10 | 1* |
| | 11 | 0.8* |
| | 12 | 1* |
| Occupation/education | 13 | 0.8* |
| | 14 | 0.8* |
| | 15 | 0.8* |
| | 16 | 0.8* |
| Content validity index | | 0.84* |

CVR=Content validity ratio*-significant at ≤0.05

Table 3: Demographic details of spinal cord injury participants during pilot testing phase

| Variables | Values |
|----------------------------|-------------|
| Age (years) | 32.92±11.85 |
| Median | 29.5 |
| Range | 25-46 |
| Gender (n) | |
| Males | 37 |
| Females | 5 |
| Marital status (n) | |
| Married | 20 |
| Single | 22 |
| Cause of injury (n) | |
| Traumatic | 39 |
| Nontraumatic | 3 |
| Severity of injury (n) | |
| AIS-A | 24 |
| AIS-B | 10 |
| AIS-C | 6 |
| AIS-D | 2 |
| Time since injury (years) | 5.059±4.83 |
| Median | 3.5 |
| Range | 19.6 |
| Number of leakages per day | 2.1±1.27 |
| Median | 1.9 |
| Range | 3 |

AIS=Abbreviated Injury Scale

subjects continuous, intermittent catheterization, continuous drainage, self-voiding, and percussion were used by 78%, 16%, 4%, 2%, respectively, for voiding incontinence pads and diapers were used by 40% of subjects. Urinary infection had occurred in 33% of subjects in the past 1 month, and 40% were taking treatment for the bladder problems.

The internal consistency of the scale was calculated using R software. The value of ordinal alpha of the scale found to be 0.86 with all items having an item-total correlation of more than 0.3. The ordinal alpha for ADL domain was 0.85 and for occupation/education was 0.75.

DISCUSSION

Urinary incontinence can certainly have profound impact on patient’s life. Accurate and reproducible methods of measuring outcomes have been a principle challenge.

During open-ended interviews we found in subjects with SCI urinary incontinence is a major barrier to their participation. Subjects reported difficulty in maintaining personal hygiene and restriction in the choice of clothing due to fear of leakage. In the mobility domain, sit to stand, prone lying and turning were reported to be most affected due to bladder problems as according to them these activities put pressure on bladder.

Patients said that they have to plan everything before going out such as to accommodate for clean intermittent catheterization and they have to come back in 4 hours. This was further supported by study done by Hicken *et al.* and Romero-Cullerés *et al.* who concluded that people with incontinence had a fewer social relationship than people with bladder control.^[12,19]

Participation in exercise program was reported to be very difficult for subjects due to their bladder problems. Robberton *et al.* reported in his study that incontinence act as a barrier to exercise in SCI subjects.^[9]

Sexual domain was also revealed to be severely affected with leakages occurring during sexual intercourse hampered the activity; spoiling the mood of the partner.

During the item reduction phase, the initial draft consisting of 77 items was applied to 56 SCI subjects with bladder problems and on CATPCA analysis based on predetermined criteria, only 28 items found to be remaining. However, two items “performance at workplace” and “avoid going to office/classes” were seem to be significant and were retained on authors discussion. On qualitative review during content validation phase, it was suggested that the word “prone” would be difficult to understand and hence it was replaced with “lying on stomach.” Some experts commented that the content area

Table 4: Ordinal alpha values for domains of Incontinence - Activity Participation Scale

| Domains | Standard alpha | Mean±SD |
|----------------------------|----------------|----------|
| Activities of daily living | 0.85* | 2.5±0.88 |
| Occupation/education | 0.75* | 1.9±1.2 |

SD=Standard deviation

is well constructed and covers all the areas that can be affected due to bladder problems. After the quantitative review, 14 items were removed as they did not meet the criteria of CVR value of 0.62 to be retained at 5% level of significance according to Schipper's table. In expert's opinion, some of the items were found to be overlapping and thus were removed. Hence, the final version of the scale contains 16 items with 12 items in ADL and 4 items in occupation/education. Ordinal alpha were 0.86, 0.85, 0.75 for the entire scale, ADL, occupation/education subdomains respectively demonstrating good internal consistency reliability [Table 4].

However, the study had some limitations. It was constructed only for English speaking population and hence the generalizability of the questionnaire was limited. Furthermore, only content validity was established. We are also in the process of establishing other psychometric properties of the questionnaire, in future we suggest that the scale could be used for assessing the impact of bladder problems on activity limitation and participation restrictions in population other than SCI. The scale could be useful as an outcome tool to assess the effect of an intervention to improve bladder dysfunction.

CONCLUSION

The I-APS (Appendix 1) is a valid, comprehensive instrument that measures the activity limitation and participation restrictions due to bladder problems in SCI.

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REFERENCES

1. Magasi SR, Heinemann AW, Whiteneck GG; Quality of Life/Participation Committee. Participation following traumatic spinal cord injury: An evidence-based review for research. *J Spinal Cord Med* 2008;31:145-56.
2. Biering-Sørensen F, Scheuringer M, Baumberger M, Charlifue SW, Post MW, Montero F, *et al.* Developing core sets for persons with spinal

cord injuries based on the international classification of functioning, disability and health as a way to specify functioning. *Spinal Cord* 2006;44:541-6.

3. Noreau L, Fougeyrollas P, Post M, Asano M. Participation after spinal cord injury: The evolution of conceptualization and measurement. *J Neurol Phys Ther* 2005;29:147-56.
4. Wyndaele JJ, Kovindha A, Madersbacher H, Radziszewski P, Ruffion A, Schurch B, *et al.* Neurologic urinary incontinence. *NeuroUrol Urodyn* 2010;29:159-64.
5. Bladder Management for Adults with Spinal Cord Injury: A Clinical Practice Guideline for Health-Care Providers. Consortium for Spinal Cord Medicine; August, 2006.
6. Hansen RB, Biering-Sørensen F, Kristensen JK. Urinary incontinence in spinal cord injured individuals 10-45 years after injury. *Spinal Cord* 2010;48:27-33.
7. Frankel HL, Coll JR, Charlifue SW, Whiteneck GG, Gardner BP, Jamous MA, *et al.* Long-term survival in spinal cord injury: A fifty year investigation. *Spinal Cord* 1998;36:266-74.
8. Lampinen BS. Health Related Quality of Life and Female Urinary Incontinence: Academic Dissertation. Finland: University of Tampere; 2004. Available from: <http://www.acta.uta.fi>.
9. Robberton T, Bucks RS, Skinner TC, Allison GT, Dunlop SA. Barriers to physical activity in individuals with spinal cord injury: A western Australian study. *Aust J Rehabil Couns* 2011;17:74-88.
10. Costa P, Perrouin-Verbe B, Colvez A, Didier J, Marquis P, Marrel A, *et al.* Quality of life in spinal cord injury patients with urinary difficulties. Development and validation of qualiveen. *Eur Urol* 2001;39:107-13.
11. Schurch B, Denys P, Kozma CM, Reese PR, Slaton T, Barron R. Reliability and validity of the incontinence quality of life questionnaire in patients with neurogenic urinary incontinence. *Arch Phys Med Rehabil* 2007;88:646-52.
12. Romero-Cullerés G, Sánchez-Raya J, Conejero-Sugrañes J, González-Viejo MÁ. Validation of the Spanish version of the King's Health questionnaire for evaluating quality of life related to urinary incontinence in patients with spinal cord injury. *Med Clin (Barc)* 2011;137:491-4.
13. Tulsy DS, Kisala PA, Victorson D, Tate D, Heinemann AW, Amtmann D, *et al.* Developing a contemporary patient-reported outcomes measure for spinal cord injury. *Arch Phys Med Rehabil* 2011;92 10 Suppl: S44-51.
14. Benson J, Clark F. A guide for instrument development and validation. *Am J Occup Ther* 1982;36:789-800.
15. Rattray J, Jones MC. Essential elements of questionnaire design and development. *J Clin Nurs* 2007;16:234-43.
16. Lawshe CH. A quantitative approach to content validity. *Pers Psychol* 1975;28:563-75.
17. McKenzie JF, Wood ML, Kotecki JE, Clark JK, Brey RA. Establishing content validity using qualitative and quantitative steps. *Am J Health Behav* 1999;23:311-8.
18. Gadermann AM, Guhn M, Zumbo BD. Estimating ordinal reliability for Likert-type and ordinal item response data: A conceptual, empirical, and practical guide. *Pract Assess Res Eval* 2012;17:1-13.
19. Hicken BL, Putzke JD, Richards JS. Bladder management and quality of life after spinal cord injury. *Am J Phys Med Rehabil* 2001;80:916-22.

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Appendix 1: Incontinence - Activity Participation Scale (I-APS)

Instructions:

The following 16 questions will assess the physical activity - participation limitation due to bladder problems. Please tick in the square box that best describes your physical activity - participation limitation due to bladder problems. If there is any problem in any question please tick the response which is closest to your situation. For questions 12-16 in case not applicable write NA.

Q1-12: Activities of daily living domain

Q13-16: Occupation/education

Scoring: Maximum score - 80

Score ≤16: No limitation.

| Question number | Questions | Never (1) | Rarely (2) | Sometimes (3) | Often (4) | Always (5) |
|-----------------|---|-----------|------------|---------------|-----------|------------|
| 1. | Do your bladder problems restrict your choice of clothing? | | | | | |
| 2. | Do your bladder problems interfere with dressing up of your lower body? | | | | | |
| 3. | Do your bladder problems make it difficult for you to maintain personal hygiene? | | | | | |
| 4. | Does grooming become a time consuming process due to your bladder problems? | | | | | |
| 5. | Do you try to avoid turning in bed due to your bladder problems? | | | | | |
| 6. | Do you avoid prone position due to your bladder problems? | | | | | |
| 7. | Do you have difficulty in changing your position from sitting to standing due to your bladder problems? | | | | | |
| 8. | Do you have to refrain yourself from visiting family/friends due to your bladder problems? | | | | | |
| 9. | Do you avoid going out for shopping due to your bladder problems? | | | | | |
| 10. | Do your bladder problems restrict your participation in exercise program? | | | | | |
| 11. | Do you have to cut on the time duration of your exercise program due to your bladder problems? | | | | | |
| 12. | Do your bladder problems affect your sexual relationship with your partner? | | | | | |
| 13. | Do your bladder problems restrict you to participate/compete at workplace/studies? | | | | | |
| 14. | Do your bladder problems restrict the time spent at workplace/studies? | | | | | |
| 15. | Do your bladder problems affect your performance at workplace/studies? | | | | | |
| 16. | Do you avoid going to office/classes due to your bladder problems? | | | | | |

I-APS score : _____/80

Patient information sheet

Please answer the following:

Patient's name: _____

Age: _____

Gender: _____

(1) Male

(2) Female

Marital status: _____

(1) Single

(2) Married

(3) Widowed

(4) Divorced

Occupational status: _____

(1) Working

(2) Not working

(3) Retired

(4) Others

Cause of SCI: _____

(1) Traumatic

(2) Nontraumatic

Time since injury _____

Do you need someone's assistance to urinate? _____

(1) Yes

(2) No

Bladder sensation: _____

(1) Present

(2) Absent

Mode of micturition: _____

(1) CIC

(2) Continuous drainage

(3) Crede's Maneuvre

(4) Percussion

(5) Self

(6) Others

Do you use any of these as a precaution? _____

(1) Incontinence pad/diapers

(2) Leg bag

Did you had urinary tract infection in the last 30 days? _____

(1) Yes

(2) No

Please answer the following:

Are you taking treatment related to bladder problems? _____

(1) Yes

(2) No

Please specify: _____

Symptoms: _____

Frequency (number of leakages/day): _____

(1) Never

(2) Once or less per week

(3) 2-3 times per week

(4) Once per day

(5) Several times a day

Urgency (the sudden need to urinate): _____

(1) Yes

(2) No

Nocturia (awaken 2 or more times to urinate)

(1) Yes

(2) No

Leakage: _____

(1) Yes

(i) Drops/dribble

(ii) More

(iii) Continuous

(2) No

Bladder spasms: _____

(1) Yes

(2) No

Tick the appropriate complications if you have: _____

(1) Pressure sores

(2) DVT

(3) Bowel problem

(4) Pain

(5) Spasms

(6) Depression

(7) Others

Mode of ambulation: _____

(1) Manual wheelchair

(2) Electric wheelchair

(3) Walk with walker

(4) Walk with cane

(5) Walk without assistance

(6) Others