

ORIGINAL REPORT

CLINICAL OUTCOME VARIABLES SCALE: A RETROSPECTIVE VALIDATION STUDY IN PATIENTS AFTER STROKE

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Objective: The construct, predictive and longitudinal validity of the Clinical Outcome Variables Scale (COVS), an assessment of functional mobility, was examined in relation to measures of functional disability (Functional Independence Measure (FIM™)), balance (Berg Balance Scale (BBS)) and length of stay in inpatient stroke rehabilitation.

Methods: Associations between admission and discharge scores on each measure were examined retrospectively for 134 patients admitted for inpatient stroke rehabilitation. The association between admission scores and length of stay was tested using a simple linear regression. Paired *t*-tests and standardized response means were calculated to examine longitudinal validity.

Results: COVS scores were correlated with FIM™ and BBS scores at admission ($\rho=0.823$ and 0.895 , respectively) and discharge ($\rho=0.771$ and 0.895 , respectively). Admission COVS, FIM™ and BBS scores were correlated with length of stay ($\rho=-0.61$, -0.69 and -0.61 , respectively; $p<0.01$). A significant ($p<0.01$) linear association was demonstrated between admission scores and length of stay. All measures demonstrated significant change over time. Standardized response means were 1.23, 1.16 and 1.36 for the COVS, BBS and FIM™, respectively.

Conclusion: Within a subset of rehabilitation patients with stroke, the COVS demonstrated construct, predictive and longitudinal validity. The COVS provides a comprehensive assessment of functional mobility and should be evaluated further for its usefulness in stroke rehabilitation.

Key words: stroke; mobility; assessment; validity; outcome measures.

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INTRODUCTION

Of those individuals who survive stroke, it has been estimated that 35% are not functionally independent one year after the stroke event (1). Costs associated with stroke are very high, particularly when one considers the impact of residual, ongoing,

stroke-related disability. However, there is strong evidence in the published literature that specialized stroke rehabilitation can significantly improve functional outcome significantly, particularly among patients with moderately severe stroke (2).

In stroke rehabilitation, functional mobility and postural control are the two areas of intervention most frequently targeted by physiotherapists (3). Given the importance of functional mobility as a rehabilitation outcome, the selection of an appropriate assessment tool is crucial. The Clinical Outcome Variables Scale (COVS) was designed for use by physiotherapists in the assessment of functional mobility status in order to identify treatment goals and initiate treatment protocols (4–6), where mobility is defined as “the movement of persons from one postural position to another (e.g. lying to sitting) or from one location to another within walking or wheeling distance” (4: p. 266). Unlike general measures of function, which may include a limited assessment of certain aspects of mobility, the COVS provides assessment of a broad range of mobility tasks, including the negotiation of environmental barriers, multiple transfers (to and from both the bed and floor) and wheelchair skill.

While it has been demonstrated that the COVS is a reliable instrument, the validity of the COVS has not been rigorously assessed (7, 8). It was the purpose of the present study to provide further evaluation of the construct, predictive and longitudinal validity of the COVS when used to assess patients with stroke as follows:

- **Construct validity.** On the basis of previously reported associations between mobility, balance and functional abilities (5, 9–11), it was hypothesized that the scores obtained via the COVS would be strongly and positively associated with scores from a general measure of functional disability (Functional Independence Measure; FIM™) and a measure of functional balance (Berg Balance Scale; BBS).
- **Predictive validity.** Given that impairments in mobility have been associated with increased lengths of stay in inpatient rehabilitation following stroke (12), it was hypothesized that COVS scores obtained at admission to inpatient rehabilitation would be a significant predictor of length of stay.
- **Longitudinal validity.** Given the accepted time course of functional recovery following stroke (13) and the established benefits of specialized stroke rehabilitation (2, 14), it was hypothesized that COVS scores should, if the instrument is longitudinally valid, reflect the significant improvement expected over the course of inpatient rehabilitation.

METHODS

A retrospective review was conducted of patient charts from 292 consecutive admissions to a specialized inpatient stroke rehabilitation program at a regional rehabilitation facility in Ontario, Canada. COVS, total-FIM™ and BBS scores at admission and discharge were recorded, along with each patient's length of stay, patient characteristics (age, sex, stroke type and location), and days from stroke onset to rehabilitation admission. A data abstraction form was developed by the research coordinator (NF). Trained research associates, who were familiar with the process of chart review, extracted information from charts using the form provided.

Charts containing scores on all 3 measures at both assessment times were selected for inclusion. Differences in patient characteristics for those with complete assessment data vs incomplete assessment data were examined using either the Pearson's χ^2 statistic for categorical variables or *t*-tests for continuous variables.

For patient data included in the validation study, score distributions for the COVS, FIM and BBS were examined. Percentages of patients achieving minimum and maximum scores on each measure were recorded. Assessment of floor and ceiling effects provide information regarding limits to the range of detectable change beyond which improvement or deterioration cannot be noted. In general, the presence of floor and ceiling effects in $\leq 20\%$ of patients is considered adequate (15).

Spearman's correlation (2-tailed) statistics were calculated to examine the strength of association between COVS, FIM™ and BBS scores at admission and discharge and between admission scores and length of stay. Linear associations between admission scores and length of stay were tested using a simple linear regression equation for each measure in turn.

Given the presence of a known, successful therapeutic intervention (i.e. specialized stroke rehabilitation), significance of change over time was examined via paired *t*-tests and internal responsiveness to change was estimated using the standardized response mean (SRM). The SRM is an effect size that provides an estimate of change relative to between-patient variability in change scores (16). The SRM is calculated as follows (16, 17):

$$\text{SRM} = \frac{\text{mean change score}}{\text{standard deviation of change scores}}$$

A value of 0.80 or greater may be interpreted as a large effect size, while values of 0.50 and 0.20 represent moderate and small effect sizes, respectively (16, 18).

With the exception of the SRM, SPSS for Windows® version 15.0 was used for all calculations. A *p*-value < 0.05 was considered statistically significant.

Assessment instruments

COVS. The COVS provides an assessment of functional mobility on 13 items selected to be representative of outcomes associated with a regular physiotherapy caseload within the general rehabilitation population (4). Each item or functional task has its own 7-point rating scale (Appendix I). Items can be considered individually or summed to provide a composite score ranging from 13 to 91. While reported reliability and validity of the COVS appears adequate, the validity of the COVS, when used to assess patients with stroke, has not been rigorously evaluated (7).

BBS. The BBS provides a quantitative assessment of balance in older adults (19). The scale consists of 14 items requiring subjects to maintain positions or complete movement tasks of varying levels of difficulty. Items receive a score of 0 (unable to complete) to 4 (completed independently). Total scores range from 0 to 56. The BBS has been reported to be both reliable and valid when used in populations of individuals with stroke (20).

FIM™. The FIM™ provides an assessment of physical and cognitive disability in terms of burden of care (21). The FIM™ is a composite measure consisting of 18 items assessing 6 areas of function (self-care, sphincter control, mobility, locomotion, communication and social cognition). Each item receives a rating of 0 (total assistance required) to 7 (total independence). Total scores range from 18 to 126.

The FIM™ has been reported to be both reliable and valid when used in populations of individuals with stroke (20).

Assessments using both the COVS and the BBS were conducted by staff physiotherapists, trained and experienced in the administration of both tools. FIM™ assessments were completed by trained, certified members of the multidisciplinary stroke rehabilitation team.

RESULTS

A total of 134 charts with complete test scores at both assessment times were identified and included in the study. A summary of sample characteristics is provided in Table I. Patients whose charts were included did not differ significantly ($p > 0.05$) from those who were excluded in terms of age, gender, length of stay, length of time between stroke onset and admission to inpatient rehabilitation or initial severity of deficits as represented by admission FIM™ scores.

Examination of scores from all 3 measures at both assessment points revealed no substantial floor or ceiling effects associated with any of the measurement tools used (Table II).

Admission COVS scores were significantly correlated with both admission FIM™ scores and admission BBS scores. At discharge, correlations were similarly strong. The FIM™ and BBS were also highly correlated at both assessment points. In addition, admission scores for each measure were strongly associated with all discharge measures (Table III).

Admission COVS, FIM™ and BBS scores were significantly correlated with length of stay ($\rho = -0.61, -0.69, -0.61$, respectively; $p < 0.01$) such that higher admission test scores were associated with shorter stays in rehabilitation. On regression analysis, a significant ($p < 0.01$) linear association was demonstrated between admission scores and length of stay in rehabilitation (COVS $R^2 = 0.323$; FIM™ $R^2 = 0.38$; BBS $R^2 = 0.345$).

Table I. Patient characteristics

Characteristics	Complete data available (<i>n</i> = 134)	Incomplete data available (<i>n</i> = 158)
Age on admission, years mean (SD)	68.64 (14.2)	71.34 (12.5)
Gender, <i>n</i>		
Male	73	81
Female	61	77
Stroke type, <i>n</i>		
Infarct	120	136
Haemorrhage	14	22
Stroke location, <i>n</i>		
Right	69	78
Left	47	56
Brainstem	11	20
Bilateral	7	4
Days from stroke event to rehabilitation admission, mean (SD)	31.84 (59.2)	67.31 (238.9)
FIM™ score on admission, mean (SD)	73.86 (24.1)	70.66 (24.2)
Length of stay, mean (SD)	50.36 (29.4)	44.58 (25.9)

SD: standard deviation.

Table II. Mean scores, standard deviations and the percentage of patients achieving minimum/maximum scores at admission and discharge

	COVS		FIM TM		BBS	
	Mean (SD)	Min/max (%)	Mean (SD)	Min/max (%)	Mean (SD)	Min/max (%)
Admission	51.90 (18.78)	0.7/0.7	73.86 (24.13)	0.7/0	26.28 17.49)	1.5/0.7
Discharge	67.58 (17.5)	0/4.5	95.70 24.65)	0/1.5	38.00 16.98)	0.7/9.7

SD: standard deviation; COVS: Clinical Outcome Variables Scale; FIMTM: Functional Independence Measure; BBS: Berg Balance Scale.

As expected, patients demonstrated improvement over the course of inpatient rehabilitation, on all 3 measures (see Table II). In all cases, this change in scores was significant on all paired *t*-tests (COVS *t*=-14.2, *df*=1.133, *p*<0.001; BBS *t*=-13.3, *df*=1.133, *p*<0.001; FIMTM=-15.7, *df*=1.133, *p*<0.001). In all, 125 of 134 patients demonstrated improvement on the COVS. SRMs for the COVS, BBS and FIMTM were 1.23, 1.16 and 1.36, respectively.

DISCUSSION

The COVS is an assessment scale used to quantify functional mobility status. As hypothesized, COVS scores at admission and discharge were strongly and positively correlated with both FIMTM and BBS scores at both administration times. This relationship provides support for the construct validity of the COVS, in that it confirms previously documented relationships between functional mobility, overall functional ability and balance (5, 9-11).

In the examination of construct validity, correlations in excess of 0.6 are considered excellent (22); however, the strength of association between measures demonstrated here might also be indicative of a certain amount of overlap in assessment content. The FIMTM, for instance, contains items that constitute a brief assessment of locomotion and transfers, and the BBS contains items designed to assess sitting balance and transfers. However, the COVS provides a more comprehensive assessment of functional mobility (6, 7, 23) than either of the other 2 measures employed in the present study. The strong association between the FIMTM and the COVS may reflect, not only the overlap in items between the 2 scales, but also the emphasis within the FIMTM on items that assess physical independence (5).

Table III. Correlation matrix for Clinical Outcome Variables Scale (COVS), Functional Independence Measure (FIMTM) and Berg Balance Scale (BBS) scores at admission and discharge

	Admission		Discharge			
	COVS	BBS	FIM TM	COVS	BBS	FIM TM
Admission						
COVS	1.00					
BBS	0.895	1.00				
FIM TM	0.823	0.817	1.00			
Discharge						
COVS	0.783	0.802	0.737	1.00		
BBS	0.750	0.818	0.697	0.895	1.00	
FIM	0.629	0.656	0.796	0.771	0.772	1.00

* All correlations significant at the *p*<0.01 level.

Both functional ability and balance, assessed using the FIMTM and BBS, have been evaluated previously as predictors of length of stay (10, 11, 24, 25). In addition, it has been reported that mobility status post-stroke can account for a significant amount of variance in length of stay in stroke rehabilitation (12). Our analysis determined that, like the FIMTM and BBS, admission COVS scores were a significant predictor of length of stay in stroke rehabilitation, thereby providing support for the predictive validity of the COVS. In addition to construct and predictive validity, the present study provides support for the longitudinal validity or internal responsiveness of the COVS assessment tool. Over the course of inpatient stroke rehabilitation, during which significant improvement was expected, COVS scores demonstrated significant positive change. Calculated effect sizes for all measures included in this study were large (>0.80), suggesting that each measure demonstrated excellent internal responsiveness.

When selecting an assessment instrument to evaluate functional mobility from among those with acceptable psychometric properties, one's decision may rest with the appropriateness and practical feasibility of the tool within a given setting (20). None of the measures evaluated in the present study demonstrated substantial floor or ceiling effects when administered at either admission to or discharge from stroke rehabilitation. The COVS, like the FIMTM or BBS, appears to be an appropriate tool to evaluate the range of function experienced by persons with stroke in an inpatient rehabilitation setting. However, unlike the FIMTM or BBS, the COVS provides a comprehensive assessment of functional mobility based on the evaluation of a broad range of mobility tasks. In addition, assessment of functional mobility with the COVS incorporates negotiation of environmental barriers and the use of assistive devices; a feature which distinguishes it from other validated measures of functional mobility, such as the Rivermead Mobility Index (RMI) (26). The RMI reflects only the individual's ability to move his or her own body but does not take environmental modifications, use of assistive devices or help from another person into consideration (20).

From a practical standpoint, administration of the COVS is somewhat lengthy (15-45 min) and requires a relatively long list of equipment (stopwatch, plastic mug, penny and slotted can, exercise mat, ramp with a 1-12-inch (30 cm) rise and a 6-inch (15 cm) platform). However, the COVS was designed so that it could be incorporated into a routine physiotherapy assessment (4), thereby reducing patient burden associated with a long assessment process. With the exception of equipment used to simulate outdoor settings, the items listed are easily obtainable.

Limitations

This study included patient data from a single, specialized stroke rehabilitation program in Ontario, Canada. This may raise concerns with regard to the generalizability of results; however, the program is operated within a tertiary care facility, which receives referrals from a wide catchment area that includes both rural and urban settings. Length of stay, and therefore predictors of length of stay, may be dependent upon the policies and resources associated with a given institution, healthcare region or authority.

In addition, examination of construct validity was restricted to retrospective data available in patient charts. The identification of testable hypotheses to support the various forms of validity evaluated here was constrained by the types and completeness of existing information. Unfortunately, complete admission and discharge data for all 3 assessment tools were available for only 134 of 292 patients. Although these 2 groups (complete vs incomplete data) did not differ significantly in terms of demographic data, nature of stroke or functional ability at admission, it is not possible to ascertain the details of individual physiotherapist practice that could account for the decision to use the COVS or the BBS. Use of the FIM™ to assess all patients is required. In addition, available data included only total scale scores from 2 assessment points. Therefore, we were unable to perform evaluations dependent on item-level data or examine strength of association between COVS scores and FIM™ subscales or dimensions.

In conclusion, the items comprising the Clinical Outcome Variables Scale represent a wide range of skills from bed mobility to ambulation and wheelchair mobility and can provide detail on areas of mobility not assessed by either the FIM™ or the BBS. Scale items reflect tasks retrained by physiotherapists, and administration can therefore be incorporated effectively into a routine assessment. Our findings provide support for the validity of the scale. It is recommended that further, prospective, validation of the COVS be carried out in order to compare it directly with other, concurrent measures of functional mobility.

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APPENDIX I. Clinical Outcome Variables Scale (COVS)*

Item	Score/rating
1. Roll in bed from supine to lying (to affected side)	1 Dependent
	2 One person assist (with/without assistive device)
	4 Rolls by self; needs assistance for getting comfortable in final position
	5 Independent (with use of assistive device)
	6 Independent (no device) but is slow/awkward, required more effort
	7 Normal
	2. Roll in bed from supine to lying (to unaffected side)
2 One person assist (with/without assistive device)	
4 Rolls by self; needs assistance for getting comfortable in final position	
5 Independent (with use of assistive device)	
6 Independent (no device) but is slow/awkward, required more effort	
7 Normal	
3. Gets to a sitting position from supine lying in bed	
	2 One person assist (with/without assistive device)
	4 Supervision/instruction for safety, or verbal cueing
	5 Independent (with use of assistive device)
	6 Independent (no device) but is slow/awkward, required more effort
	7 Normal
	4. Sitting balance: edge of bed, thighs supported, hands on lap, feet flat on floor
2 No discrepancies tolerated	
3 Move within base	
5 Move beyond base and return	
6 Tolerates quick push beyond base	
7 Normal	
5. Horizontal transfer: from chair or wheelchair to bed/plinth	
	2 One person assist (with use of assistive device)
	3 One person assist (no device)
	4 Supervision (with/without assistive device)
	5 Independent (with use of assistive device)
	6 Independent (no device) but is slow/awkward, required more effort
	7 Normal
6. Vertical transfer from supine on floor to chair or to standing	1 Dependent
	2 One person assist (with use of assistive device)
	3 One person assist (no device)
	4 Supervision (with/without assistive device)
	5 Independent (with/without assistive device) in home, but slow/awkward, requires more effort
	6 Independent in community
	7 Normal

7. Ambulation	1 No functional ambulation	
	2 One person continuous physical assist	
	3 One person intermittent physical assist	
	4 Supervision	
	5 Independent level surfaces only; assist with environmental barriers, stairs with railing	
	6 Independent including environmental barriers, stairs with no railing	
	7 Normal	
8. Ambulation (aids)	1 Not walking	
	2 Parallel bars/2-person continuous assist	
	3 Walker (rollator, walk-canes)	
	4 Two aids	
	5 One aid (except straight cane)	
	6 Straight cane	
	7 No aids	
9. Ambulation (endurance)	1 Not walking	
	2 ≤ 10 m (6 m = parallel bars)	
	3 ≤ 50 m	
	4 ≤ 100 m (86 m = 2 min timed walk)	
	5 ≤ 500 m (300 m = park walk)	
	7 > 500 m (park walk and gym loop)	
	10 m/s	
10. Ambulation (velocity)	2 ≤ 0.1 m/s	
	4 ≤ 0.3 m/s	
	5 ≤ 0.6 m/s	
	6 ≤ 0.9 m/s	
	7 > 0.9 m/s	
	11. Wheelchair mobility	1 Dependent
		2 Assistance
3 Intermittent assist for distances > 30 m		
4 Supervision		
5 Independent indoors		
6 Independent outdoors except curbs and grass		
7 Independent operation of wheelchair		
12. Arm function (affected)	Starting position: sitting at a table in a wheelchair or chair	
	1 Unable to actively move any part of the arm	
	2 Some active movement – nothing useful	
	4 Able to use arm as a stabilizer or as an assist	
	5 Able to bring cup to the mouth	
	6 Functional including fine movements (pick up penny)	
	7 Normal	
13. Arm function (unaffected)	Starting position: sitting at a table in a wheelchair or chair	
	1 Unable to actively move any part of the arm	
	2 Some active movement – nothing useful	
	4 Able to use arm as a stabilizer or as an assist	
	5 Able to bring cup to the mouth	
	6 Functional including fine movements (pick up penny)	
	7 Normal	

*The COVS scale, guideline booklets, video and data management software are available from The Institute for Rehabilitation Research and Development, Ottawa, Ontario, Canada (<http://www.irrd.ca/covs/>). Reproduced with permission (27).