VALIDATION AND PSYCHOMETRIC EVALUATION OF A TRUNCATED VERSION OF THE TOTAL ILLNESS BURDEN INDEX

Kelly McCarrier, PhD, MPH,[1] Donald Bushnell, MA,[1] Mona Martin, RN, MPA,[1] Rosirene Paczkowski, MPH,[2] Don Buesching, PhD[2]

[1]Health Research Associates, Inc. , Seattle, WA USA; [2]Eli Lilly and Company, Indianapolis, IN, USA

ABSTRACT

RESEARCH OBJECTIVE: The Total Illness Burden Index (TIBI; Greenfield, et al, 1995) is a 63-item summary measure assessing patient-reported presence and severity of co-morbid diseases and symptoms, designed as an instrument to characterize case mix in comparative effectiveness research. A 47-item truncated version of the TIBI was recently created. Although the original long-form version has been shown to have adequate measurement properties and to successfully predict new cardiovascular events and all-cause mortality among type 2 diabetic patients, the measurement properties of the truncated version have not yet been formally evaluated. We sought to build on prior validation of the TIBI by evaluating the truncated instrument for evidence of reproducibility, convergent validity and equivalence between paper and electronic administration modes.

STUDY DESIGN: The TIBI and other questionnaire measures were administered to a sample of 258 adults with specific co-morbidities recruited through newspaper and web-based advertisements in 8 U.S. cities. Participants were randomized to complete the TIBI on either a paper or computerized format, with a crossover assessment completed in the alternate format 24 hours later. A one-week retest was completed at home.

Reproducibility and mode equivalence were assessed using the intraclass correlation coefficient (ICC). To assess convergent validity, the correlation of the TIBI and seven other health status measures was assessed. Among these convergent measures were the General Health Item (SF-1) and Physical Component Summary (PCS) of the MOS-SF-36; the BRFS "Illness days" and "Bed days" items; the number of medical encounters in the previous 3 months, the number of prescription medications taken daily, and a generic comorbidity checklist.

POPULATION STUDIED: Adults with a prior diagnosis of clinical depression, plaque psoriasis, type 2 diabetes, rheumatoid arthritis, or chronic kidney disease were recruited for this observational study. Of the 258 participants that completed the baseline assessment, 251 (97%) completed the one-week retest. The mean age of the overall sample at baseline (n=258) was 48.6 years (SD 13.5, range 20-81); 61% of participants were female and 71% were white. The average years of education was 15.0 (SD 2.2, range 8-20); 44% were married or living with a partner, 55% were employed full or part time, while 31% were unemployed.

PRINCIPAL FINDINGS: The mean TIBI score was 3.2(2.8), and the ICC between paper and computerized administration was 0.89. The ICC for the one-week retest was 0.90 for paper and 0.91 for computerized administration. Significant correlations (p<.001) were found between the TIBI and all of the hypothesized convergent validity measures [PCS (r=-0.67), SF-1 (r=-0.42), Illness Days (r=0.37), Bed Days (r=0.23), Number of MD Visits (r=0.24), Number of Prescription Meds (r=0.41) and the comorbidity checklist (r=0.65)].

CONCLUSIONS: The 47-item truncated version of the TIBI was observed to have adequate reproducibility and appropriate convergent validity in this specific population. Equivalence between paper and web-based administration was demonstrated.

IMPLICATIONS for POLICY, DELIVERY, or PRACTICE: The evidence of adequate measurement properties and appropriate convergent and known-groups validity suggests that the shortened version of the TIBI could be a viable option as a patient-reported measure of comorbidity that can be used in assessment and adjustment of case mix in comparative effectiveness studies.

BACKGROUND

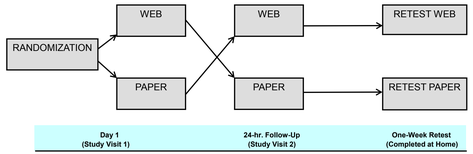
- The Total Illness Burden Index (TIBI; Greenfield, et al, 1995) is a 63-item comprehensive summary measure assessing patient-reported presence and severity of co-morbid diseases and symptoms, designed as an instrument to characterize case mix in comparative effectiveness research.
- The full TIBI is composed of items designed to assess severity and comorbidity across 15 body symptoms, with the resulting summary score intended to be indicative of overall disease burden.
- The convergent validity of the TIBI has been demonstrated against scores from the SF-36 (Greenfield, et al, 1995 ;Carusoa, et. al, 2000; Kerr et al, 2003; Litwin et al, 2007) and the measure has been demonstrated to predict new cardiovascular events and five-year all-cause mortality among type 2 diabetic patients.
- A 47-item truncated version of the TIBI was recently created, which retains 5 of the constituent dimensions from the full version (Lung/CHF, Heart, GI, Arthritis, Feet) and sums to create a total score. While the psychometric performance of the full version has been established, formal assessment of the measurement properties of the truncated TIBI measure have not yet been conducted.
- We sought to evaluate the measurement properties of the truncated TIBI and test equivalence between paper and web-based administration modes in a longitudinal survey.

METHODS

Study Design

- The TIBI-truncated and other questionnaire measures were administered to a large convenience sample of 258 adults with chronic illnesses in a non-interventional study (outside of the clinical trial setting).
- This observational data collection effort used a randomized crossover design to assess equivalence between paper and electronic formats of the TIBI.
- Participants were recruited through newspaper and web-based advertisements in 8 U.S. cities. Individuals responding to study advertisements were screened via telephone for eligibility.
- Individuals between the ages of 18 and 70, who self-reported a diagnosis and treatment of depression, rheumatoid arthritis [RA], chronic kidney disease [CKD], psoriasis, or type 2 diabetes [T2D]; who were able to speak, read, and write in English, and were available to attend both data collection sessions for their location were eligible for participation.
- Recruitment quotas were used to generate subgroups of participants within each of five targeted health conditions.
- After providing informed consent, participants were randomized to complete the TIBI on either paper or computerized format at their first study visit. The alternate format was completed at the second study visit (24 hours later) and the one-week retest was completed from home (Figure 1).

Figure 1: Diagram of Study Data Collection



Measures

- TIBI-truncated, paper and web versions
- SF-36 Physical Component Summary (PCS) and General Health Item (#1)
- Self-report of Number of illness days and bed days in the last month
- Self-report of Number of MD visits in last 3 months.
- Self-report of Number of prescription medications taken each day.
- Comorbidity checklist

Statistical Analyses

- Participant demographic and health variables were characterized with descriptive statistics.
- The intraclass correlation coefficient (ICC) was calculated to assess the one-week reproducibility of the TIBI. An ICC of ≥0.70 was hypothesized as the threshold for reproducibility (Lohr, et al, 1996).
- Measurement equivalence is a function of the comparability of the psychometric properties of the data obtained via the original paper and adapted web administration mode. Equivalence of the paper and web-based TIBI scores were assessed in this study by calculating the ICC between scores from the two modes with values of 0.70 or greater considered indicative of equivalence (Nunnally & Bernstein, 1994) .
- Convergent validity was assessed through Pearson's correlations, with r ≥ 0.30 hypothesized as the threshold for declaring acceptable convergence with each of the following measures:
  - The Physical Component Summary (PCS) and the General Health Item (#1) of the SF-36.
  - Three Self-Reported Health Status Items from BRFSS: Illness Days, Bed Days, and MD Visits
  - The Self-Reported number of daily prescription medications taken
  - The number of self-reported comorbid conditions assessed via a standard comorbidity checklist.
- "Known groups" validity was assessed using ANOVA to examine discriminance in mean TIBI scores between participants grouped by SF-36 PCS score tertile.

RESULTS

Participant Characteristics

- 313 individuals were screened for the study. 258 participants completed the baseline assessment, and 251 (97%) completed the retest.
- Participant demographic characteristics are presented in Table 1.
  - The mean age of participants was 48.6 years; 61% were female, and 71% were Caucasian.
  - Forty-four percent of participants were married or living with a partner; 24% had never been married.
  - Over half (54.6%) of participants were employed either part- or full-time; 31% were unemployed at the time of the study.

Table 1: Demographic Characteristics

Characteristic	Value*
Age, Mean (SD, min-max)	48.6 (13.5, 20-81)
Educational Attainment, Mean (SD, min-max)	15.0 (2.2, 8–20)
Gender	
Male	100 (38.8)
Female	158 (61.2)
Race	
American Indian or Alaskan Native	2 (0.8)
Asian	12 (4.7)
Black/African American	38 (14.7)
Hispanic or Latino	14 (5.4)
Native Hawaiian or other Pacific Islander	3 (1.2)
White	183 (70.9)
Other	6 (2.3)
Marital Status	
Married	89 (34.5)
Widowed	11 (4.3)
Separated	9 (3.5)
Divorced	57 (22.1)
Never married	63 (24.4)
Living with partner	25 (9.7)
Other	4 (1.6)
Employment	
Full time	77 (29.8)
Part time	64 (24.8)
Homemaker	11 (4.3)
Student	8 (3.1)
Retired	18 (7.0)
Not employed	80 (31.0)
Household Income	
$15,999 or LESS	56 (21.7)
$16,000-24,999	24 (9.3)
$25,000-34,999	36 (14.0)
$35,000-49,999	40 (15.5)
$50,000-74,999	47 (18.2)
$75,000-99,999	36 (14.0)
$100,000 AND OVER	13 (5.0)
Missing	6 (2.3)
Living Situation	
Living alone	60 (23.3)
Living with spouse/partner only	68 (26.4)
Living with spouse/partner and children	58 (22.5)
Living with other relative(s)	46 (17.8)
Living with other(s) (not related)	22 (8.5)
Other	4 (1.6)

*reported as N(%) unless otherwise specified

Participant Characteristics (Continued)

- Health Characteristics of participants are presented in Table 2.
  - Approximately 25% of participants rated their general health as "fair" or "poor".
  - Participants averaged approximately 1 medical visit per month, and took over 3 prescription medications each day.

Table 2: Health Characteristics

Characteristic	Value*
General Health	
Excellent	15 (5.8)
Very Good	69 (26.7)
Good	110 (42.6)
Fair	55 (21.3)
Poor	9 (3.5)
Days Physical Health Not Good in Last 30 days	
Mean (SD, min-max)	4.7 (7.9, 0-30)
Days Spent Sick in Bed in Last 30 Days	
Mean (SD, min-max)	1.8 (3.9, 0-27)
Days Mental Health Not Good in Last 30 Days	
Mean (SD, min-max)	6.1 (8.7, 0-30)
Medical Professional Visits in Last 3 Months	
Mean (SD, min-max)	3.2 (5.0, 0-42)
Daily Medications	
Mean (SD, min-max)	3.2 (3.0, 0-15)
SF-36 (Physical Component Summary)	
Mean (SD, min-max)	56.6 (22.0, 4.6-96.7)
SF-36 (Mental Component Summary)	
Mean (SD, min-max)	53.9 (21.2, 6.1-95.6)

*reported as N(%) unless otherwise specified

Measurement Properties of the truncated TIBI

- The mean (SD) TIBI-truncated score among study participants was 3.2(2.8) for both the paper and web-based administration (Table 3)
- The ICC between paper and web-based was 0.89.
- Test-retest reproducibility was observed to be strong (ICC of 0.90 [paper] and 0.91[web]).

Table 3: TIBI Mode Equivalence and Reproducibility

Measurement Characteristic	N	Intraclass correlation coefficient	95% CI	
			Lower	Upper
Equivalence: TIBI Paper to TIBI Web	258	0.887	0.857	0.910
One-week test-retest: TIBI Paper	139	0.896	0.857	0.924
One-week test-retest: TIBI Web	112	0.910	0.872	0.937

Measurement Properties (Continued)

- Convergent Validity (Table 4)
  - The TIBI-truncated was significantly correlated at r>0.30 with the SF-36 PCS and General Health Item, the number of daily prescription medications, and with the overall number of comorbidities endorsed on the self-reported comorbidity checklist. Weaker correlations were observed with the number of illness days, bed days, and provider visits.
- Known Groups Validity (Table 5)
  - The TIBI-truncated significantly discriminated between participants based on tertiles of SF-36 Physical Component Summary scores.

Table 5: Convergent Validity

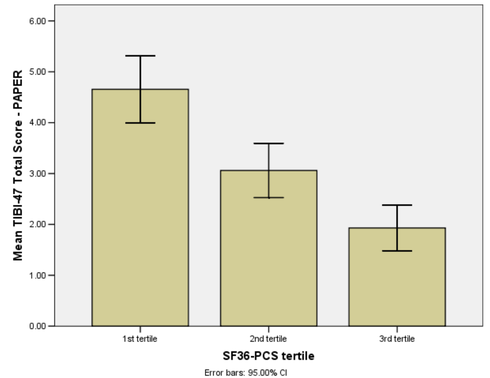
Measures to test Convergent Validity	Pearson Correlation Coefficient	95% CI	
		Lower	Upper
SF-36 PCS Score	-0.670	-0.732	-0.597
SF-36 #1	-0.424	-0.519	-0.318
Number of illness days	0.365 †	0.254	0.466
Number of bed days	0.229 †	0.110	0.342
Number of MD visits	0.236 †	0.117	0.348
Rx Meds.	0.410	0.303	0.507
Comorbidity checklist	0.653	0.577	0.718

Note: † Represents a correlation coefficient whose 95% confidence interval lower bound does not surpass the hypothesized value of 0.30

Table 6: Known Groups Validity

Measures to test Known Groups Validity	Group Categories	N	Mean TIBI Total Score	SD	F-stat	P-value
SF-36 PCS	1st tertile	87	4.66	3.09		
	2nd tertile	83	3.06	2.44	24.304	<0.0001
	3rd tertile	85	1.93	2.08		

Figure 2: TIBI by Physical Component Summary (PCS) Tertile



LIMITATIONS

- The study utilized a convenience sample recruited from newspaper and web-based advertisements. As such, the sample may differ in demographic and or health characteristics from overall US populations with these disease states.
- While potentially limited by the self-report nature of the data, these findings are consistent with previous validation results for the full TIBI instrument.

CONCLUSIONS

- In this randomized crossover validation study, the truncated (47-item) TIBI instrument was observed to have adequate measurement properties.
  - The measure was observed to have high one-week reproducibility.
  - Equivalence between paper and web-based administration mode was demonstrated.
  - The TIBI showed evidence of convergence with 4 of 7 hypothesized validation measures and successfully discriminated between participants by PCS tertile.
- This study provides initial evidence that the truncated version of the TIBI is a valid and psychometrically sound assessment of disease burden. Our findings compliment and extend prior validation of the parent instrument.

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