

Responsiveness to Change and Construct Validity of the Work Productivity and Activity Impairment Questionnaire for Gastroesophageal Reflux Disease (WPAI:GERD) in Swedish Patients

Peter Wahlqvist¹, Jennie Medin¹, Maria Karlsson¹, Margaret C Reilly²

¹Health Economics & Outcomes Research, AstraZeneca R&D, Mölndal, Sweden; ²Margaret Reilly Associates, Inc., New York, NY, USA

Presented by Katarzyna Kolasa (AstraZeneca R&D, Mölndal, Sweden), on behalf of the authors

CONCLUSIONS

- The Work Productivity and Activity Impairment questionnaire for Gastroesophageal Reflux Disease (WPAI:GERD) measures of presenteeism and impairment during daily activities are responsive to change in Swedish patients with GERD.
- Both cross-sectional and longitudinal construct validity of these WPAI:GERD measures is confirmed.
- Responsiveness and validity for GERD-related absenteeism could not be established in this study.

INTRODUCTION

- Productivity loss is an important measure when considering the burden and cost of chronic diseases such as GERD, which is highly prevalent¹ and impacts on patients' daily lives.²
- The WPAI questionnaire for a Specific Health Problem (WPAI:SHP) is frequently used to evaluate the extent of impaired productivity related to a disease, in terms of absenteeism, presenteeism (productivity at work), and during daily activities.³
- Responsiveness to change and construct validity of a GERD-specific version of the WPAI questionnaire (WPAI:GERD) has recently been demonstrated in Canadian patients.⁴ However, this version was somewhat different from the WPAI:SHP, mainly in that it used a 0 to 100 visual analog response scale for questions related to presenteeism and productivity impairment during daily activities,⁴ while the WPAI:SHP uses a Likert scale ranging from 0 to 10.³

AIM

- To assess responsiveness to change and construct validity of a revised WPAI:GERD questionnaire (a GERD-specific adaptation of the WPAI:SHP) in a Swedish patient population with GERD.

PATIENTS AND METHODS

- Patients (aged 18–65 years) with GERD (defined as heartburn and/or regurgitation) were recruited from primary care centers across Sweden. All patients had experienced episodes of heartburn (of at least mild intensity) on 2 or more days during the previous 7 days. Only patients who were currently employed were included.
- Eligible patients were treated with 4 weeks' acid-suppressive therapy with a proton pump inhibitor (PPI) according to labeled dose recommendations (choice of PPI was at the discretion of the treating physician).

Assessment of productivity, symptoms, and health-related quality of life

- Productivity measures, symptoms, and health-related quality of life (HRQL) were evaluated at baseline and after 4 weeks' acid-suppressive therapy.
- GERD-related productivity measures (WPAI:GERD questionnaire; 1-week recall) included:
 - Percent hours absent from work (absenteeism).
 - Percent reduced productivity at work (presenteeism).
 - Percent reduced productivity during daily activities.

- Heartburn was evaluated by patients (1-week recall) in terms of frequency and intensity (none, mild, moderate, or severe). Patients also completed the Gastrointestinal Symptom Rating Scale (GSRS), which includes reflux (2 questions) and dyspepsia (3 questions) dimensions (7-graded response scale where higher scores = worse discomfort; 1-week recall).⁵
- HRQL was determined using the generic Short Form-36 (SF-36) questionnaire⁶ and the Quality of Life in Reflux and Dyspepsia (QOLRAD) questionnaire⁷ (a 1-week recall was used for both). The SF-36 questionnaire comprises 8 domains (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health), each scored from 0 (lowest well-being) to 100 (highest well-being). The QOLRAD questionnaire evaluates GERD-specific HRQL with 25 items across 5 dimensions: emotional distress, sleep disturbance, food/drink problems, physical/social functioning, and vitality. Items are scored on a 7-grade Likert scale with regard to degree of distress (where 7 = none, 1 = a great deal of distress), and frequency of the problem (where 7 = none of the time, 1 = all of the time). Low QOLRAD scores therefore represent more severe impact on daily functioning.
- After treatment, patients completed the Overall Treatment Evaluation (OTE) questionnaire⁸ with regard to the change in GERD symptoms relative to baseline. The OTE rates the perceived effect of treatment on symptoms on a 15-point scale, ranging from -7 ('a very great deal worse') to +7 ('a very great deal better'). Patients were subsequently classified into 3 main OTE response groups (4 patients experienced deterioration of symptoms and were excluded from the analysis):
 - No or small improvement (0 to +3).
 - Moderate improvement (+4 to +5).
 - Large improvement (+6 to +7).

Construct validity

- Cross-sectional and longitudinal construct validity were assessed by investigating the relationship between WPAI:GERD measures of productivity and symptoms/HRQL, in terms of the Pearson correlation coefficients.^{4,9}
- Longitudinal construct validity was further explored in a descriptive analysis on the relationship between change in heartburn intensity and productivity measures.

Responsiveness to change

- Responsiveness to change was assessed by calculating the effect size (ES) for all patients and by response group according to the OTE questionnaire. An ES between 0.2 and 0.5 was defined as small, between 0.5 and 0.8 as moderate, and ≥0.8 as large.¹⁰

RESULTS

- The study population comprised 205 patients of mean age 46 years (40% men). Most patients (n = 116, 56%) had not sought medical attention for GERD in the previous 12 months. Before treatment, patients experienced heartburn, on average, on 4.4 days/week. Intensity of heartburn was rated as moderate or severe in 75% of patients.
- After 4 weeks' acid-suppressive therapy, patients were typically free from heartburn (35%) or experienced only mild symptoms (46%), and the mean frequency of heartburn had decreased from 4.4 to 1.6 days/week.

Productivity

- Findings for absenteeism showed high variability and relatively low mean change from baseline after 4 weeks' acid-suppressive therapy. Therefore, responsiveness and validity for absenteeism could not be established in this study, and no additional analyses were performed (Table 1). In contrast, statistically significant improvements for both presenteeism (improvement of 15.3%; $P < .001$) and productivity during daily activities (improvement of 18.3%; $P < .001$) were apparent (see Table 1). The improvement in presenteeism translated into a gain of 5.5 hours of work productivity per patient per week.

Table 1. Mean (95% confidence interval) productivity measures at baseline and after 4 weeks' acid-suppressive therapy

	N	Baseline	After treatment	Absolute change from baseline
Absenteeism, %	172	4.3 (2.4, 6.2)	3.9 (1.6, 6.3)	-0.4 (-3.1, 2.4)
Presenteeism (% reduced productivity at work)	187	25.5 (22.2, 28.8)	10.2 (7.9, 12.4)*	-15.3 (-18.7, -12.0)
Work hours lost due to reduced productivity ^a	183	9.1 (7.8, 10.3)	3.6 (2.7, 4.5)*	-5.5 (-4.4, -6.6)
Productivity impairment during daily activities, %	201	31.5 (28.3, 34.8)	13.2 (10.6, 15.9)*	-18.3 (-21.6, -15.0)

^a Number of hours actually worked multiplied by % reduced productivity at work (presenteeism).
* $P < .001$ versus baseline.

Table 2. Pearson correlation coefficients between productivity measures and other study variables: at baseline, after 4 weeks' acid-suppressive therapy, and in relation to change from baseline

	Presenteeism (reduced productivity at work)			Productivity impairment during daily activities		
	Baseline	After treatment	Change from baseline	Baseline	After treatment	Change from baseline
SF-36						
Physical functioning	0.27	0.30	0.33	0.28	0.38	0.33
Role-physical	0.46	0.42	0.41	0.55	0.51	0.50
Bodily pain	0.40	0.46	0.31	0.50	0.53	0.43
General health	0.19	0.27	0.15	0.23	0.34	0.24
Vitality	0.26	0.36	0.31	0.39	0.47	0.36
Social functioning	0.38	0.39	0.17	0.45	0.49	0.23
Role-emotional	0.34	0.48	0.23	0.41	0.54	0.27
Mental health	0.32	0.47	0.33	0.38	0.52	0.28
QOLRAD						
Emotional distress	0.47	0.71	0.42	0.58	0.76	0.53
Sleep disturbance	0.46	0.57	0.41	0.54	0.68	0.52
Food/drink problems	0.39	0.65	0.42	0.47	0.73	0.49
Physical/social functioning	0.58	0.69	0.53	0.68	0.78	0.61
Vitality	0.50	0.73	0.46	0.64	0.79	0.60
Symptoms						
Frequency of heartburn	0.06	0.60	0.21	0.08	0.58	0.23
Intensity of heartburn	0.29	0.56	0.39	0.34	0.52	0.46
GSRS reflux dimension	0.34	0.51	0.40	0.62	0.67	0.55
GSRS dyspepsia dimension	0.42	0.53	0.47	0.52	0.61	0.56

Figures in bold indicate moderate (0.30–0.60) or strong correlation (>0.60). Abbreviations: GSRS = Gastrointestinal Symptom Rating Scale; QOLRAD = Quality of Life in Reflux and Dyspepsia questionnaire; SF-36 = Short Form-36 questionnaire.

Construct validity

- Pearson correlation coefficients between measures of presenteeism and productivity impairment during daily activities and symptoms, as well as HRQL, were in expected directions and generally of expected magnitudes, which supported both cross-sectional and longitudinal construct validity of these measures of the WPAI:GERD questionnaire (see Table 2).
- The descriptive analysis (see Table 3) further supported longitudinal construct validity, in that changes in heartburn intensity were generally associated with improvements in measures of presenteeism and productivity impairment during daily activities.

Table 3. Change from baseline for presenteeism and productivity impairment during daily activities in relation to change in heartburn intensity after 4 weeks' acid-suppressive therapy

Change in heartburn intensity ^a	Presenteeism (reduced productivity at work)		Productivity impairment during daily activities	
	n	Mean change, % (SD)	n	Mean change, % (SD)
-2	45	-24.9 (22.7)	49	-31.6 (22.9)
-1	82	-16.7 (23.2)	87	-19.0 (20.9)
0 (no change)	45	-6.7 (16.9)	48	-8.1 (20.5)

^a Evaluated using a 4-graded severity scale. Abbreviation: SD = standard deviation.

Responsiveness to change

- ES were moderate for the whole study population (presenteeism: 0.67; productivity impairment during daily activities: 0.79), and were high in patients experiencing a large improvement according to the OTE (presenteeism: 0.98; productivity impairment during daily activities: 1.22) (Table 4).

Table 4. Effect size for the WPAI:GERD questionnaire measures of presenteeism and productivity impairment during daily activities

Overall Treatment Evaluation improvement	Presenteeism (reduced productivity at work)		Productivity impairment during daily activities	
	n	Effect size	n	Effect size
Large	79	0.98	85	1.22
Moderate	55	0.60	58	0.72
No/small	49	0.28	54	0.30
All patients ^a	187	0.67	201	0.79

^a Overall Treatment Evaluation findings missing for some patients. Figures in bold indicate moderate (0.5–0.8) or large responsiveness (≥0.8). Abbreviation: WPAI:GERD = Work Productivity and Activity Impairment questionnaire for Gastroesophageal Reflux Disease.

REFERENCES

- Dent J, et al. *Gut* 2005; 54: 710–7
- Wiklund I, et al. *Am J Gastroenterol* 2006; 101: 18–28
- Prasad M, et al. *Pharmacoeconomics* 2004; 22: 225–44
- Wahlqvist P, et al. *Pharmacoeconomics* 2007; 25: 385–96
- Svedlund J, et al. *Dig Dis Sci* 1988; 33: 129–34
- Ware JE, Sherbourne CD. *Med Care* 1992; 30: 473–83
- Wiklund I, et al. *Eur J Surg Suppl* 1998; 583: 41–9
- Jaeschke R, et al. *Control Clin Trials* 1989; 10: 407–15
- Hinkle DE, et al. Applied statistics for the behavioral sciences. Boston, MA: Houghton Mifflin, 1988
- Cohen J. Statistical power analysis for the behavioral sciences. New York, NY: Academy Press, 1977