Digestive Diseases and Sciences, Vol. 50, No. 11 (November 2005), pp. 2025–2033 (© 2005)
DOI: 10.1007/s10620-005-3002-1

Development and Validation of the Gastroesophageal Reflux Disease Treatment Satisfaction Questionnaire

RICHARD SHIKIAR, PhD,* EMUELLA FLOOD, BA,* RESHMI SIDDIQUE, PhD,†
JAMIE HOWELL, PHARMD, MS,†‡ and SHERI L. DODD, MSc†

There is growing recognition of the importance of assessing patient perceptions of treatment, especially patient satisfaction. The Gastroesophageal Reflux Disease (GERD) Treatment Satisfaction Questionnaire (GTSQ) was developed to assess satisfaction with GERD medication. A web-based survey, which included the GTSQ and the GERD Symptom Assessment Scale (GSAS), was administered in September 2003 to 2511 subjects taking prescription GERD medication, identified as H_2-receptor antagonists (H2RAs) and proton pump inhibitors (PPIs). Results showed excellent reliability of the GTSQ subscales (from 0.82–0.95) and validity with respect to two GSAS subscales. Rabeprazole (Aciphex) subjects taking 1 pill per day were statistically more satisfied than those taking 2 pills per day for all subscales except "Daytime Relief" and "Quick and Long-Lasting." Those who stayed on rabeprazole therapy longer showed statistically significant greater satisfaction on the "Daytime Relief" and "Health-Related Quality of Life" scales. The GTSQ has high reliability and can be used to assess aspects of satisfaction with GERD medication.

KEY WORDS: GERD; patient satisfaction; validation; proton pump inhibitors, H_2-receptor antagonists; questionnaire.

Gastroesophageal reflux disease (GERD) is a common, chronic condition typically characterized by the symptom of heartburn. GERD is widely prevalent in the United States; an estimated 18% of the adult population reported having heartburn at least once a week and almost half of these people reported having their symptoms for 10 years or longer (1). A national random sample conducted in the United States in 1998 found the prevalence of frequent GERD (responding positively to having at least 1 key GERD symptom at least once per week) to be 14%, and of nocturnal GERD to be 10% (2).

Prescription medications for GERD include H_2-receptor antagonists (H2RAs) and proton pump inhibitors (PPIs). PPIs have been shown to be more effective than H2RAs (3); however, these medications are costly to patients and insurers. GERD also negatively impacts the psychosocial well-being of patients. The presence of GERD is associated with impaired functioning and quality of life, even with treatment (4).

With the large variety of alternative pharmacologic treatments available for GERD, insights into the patient's evaluation of their medication can be instructive. Patient satisfaction with medication has been defined as the evaluation of the process of taking one's medication and the outcomes associated with the medication (5). Patient satisfaction with specific treatment regimens is important for several reasons. First, it is related to patient adherence to the regimen—other things being equal, patients who are more satisfied with their medication should be more likely to continue taking the medication as prescribed by

Manuscript received December 23, 2004; accepted February 25, 2005.
From *MEDTAP International, Inc., Center for Health Outcomes Research, Seattle, Washington, and †Janssen Medical Affairs, LLC, Titusville, New Jersey; and ‡Currently with Ortho Biotech, Bridgewater, New Jersey.

Address for reprint requests: Richard Shikiar, PhD, MEDTAP International, 2601 Fourth Avenue, Suite 200, Seattle, WA 98121; Shikiar@MEDTAP.com.

their physician. There is little information addressing this question, likely due in large part because of the lack of systematic research on patient satisfaction with treatment. Nonetheless, there is some empirical support for this supposition (6). Second, patient satisfaction can influence a patient's and/or a physician's choice of medications. When confronted with a choice between two or more equally efficacious drugs, the patient will more likely select the one with which he or she is more satisfied. Third, the drive toward quality assessment within managed care organizations has resulted in greater interest in patient satisfaction (7), with positive satisfaction having the potential to influence formulary decisions. Fourth, in a changing healthcare environment where consumerism has affected physician–patient decision making and the impact of consumer satisfaction can play an important role in both payor and consumer willingness to pay for drug therapy, a greater understanding of satisfaction in therapeutic categories is critical to future health care decisions. Finally, feedback about specific aspects of patient satisfaction with the medication can help to inform a pharmaceutical company's product improvement programs, for example, by focusing resources on more convenient drug dosing schedules or delivery systems.

Most studies assessing patient satisfaction with specific treatments do so in only a very general way; few satisfaction instruments have been developed in a rigorous manner based on patient concerns (8). Among other things, satisfaction questionnaires should include questions pertaining to treatment, such as extent of and time to symptom relief, side effects, ease and convenience of treatment, as well as overall satisfaction (5, 9). In addition, given the impact of GERD on patient functioning and quality of life, measures of satisfaction with GERD treatment should also take into account satisfaction with the outcomes of treatment vis à vis these important attributes as well. Ideally, questionnaires assessing patient satisfaction with treatment should be specific to the disease entity and treatment of interest. At the time this study was undertaken, no GERD-specific treatment satisfaction questionnaire had been published and available that captured multiple aspects of satisfaction that are or potential importance to patients. Hence, the objective of this study was to develop and validate the GERD Treatment Satisfaction Questionnaire (GTSQ), which was developed specifically to assess satisfaction along several potentially salient domains.

METHODS

Development of the GERD Treatment Satisfaction Questionnaire (GTSQ). An initial pool of 25 items was developed based on a review of the literature regarding aspects of GERD and its treatment. Based on this review, items were developed for 7 different aspects of GERD treatment, using prior patient satisfaction items and the symptoms themselves as the basis for constructing the items: Specific Symptom Relief (e.g., "Gets rid of the burning or acid feeling inside your chest"), Nighttime Relief, Daytime Relief, Quick and Long-Lasting Relief, Ease and Convenience, Health-Related Quality of Life (HRQL), and Overall Satisfaction. The initial pool of items was subjected to a "cognitive debriefing" with 11 subjects. These subjects completed the items and were asked questions concerning the meaning of items to them, preferred alternatives to wording and response formats, and whether or not the instrument had any important omissions of any key areas. As a result of this process, 1 item was added and several items were altered in line with the suggestions of the subjects; no items were deleted. The final version of the GTSQ contains 25 items (Appendix A).

The GTSQ items are rated on a 5-point Likert scale with responses ranging from 1 (very satisfied/strongly agree) to 5 (very dissatisfied/strongly disagree). For some questions, there is an additional choice of "never had this symptom/never had this problem." There are 7 subscale scores for the GTSQ and an additional total score (derived by calculating the mean across subscale scores). Subscale and total scores range from 1–5, with lower scores indicating greater satisfaction. For purposes of this study only, a fourth part was added to the GTSQ to include items on GERD prescription medication use, including dosing frequency and duration on the medication(s). A copy of the self-administered GTSQ, excluding this fourth portion, is included in Appendix A.

Sample/data collection. A company specializing in web-based medical surveys identified eligible subjects through its nationally representative online panel. The panel was made up of a statistically valid sample of U.S. consumers. Subjects were randomly recruited by telephone; members without access to the Internet were provided access.

Subjects meeting the following criteria were eligible to participate in the study:

1. current heartburn and/or acid reflux as diagnosed by a physician;
2. $\geq$18 years of age; and
3. currently taking a prescription medication to treat heartburn and/or acid reflux.

Note that responses to these criteria were determined completely on the basis of self-report; given the web-based nature of the survey, independent confirmation of these criteria was deemed impractical. Eligible and interested subjects accessed and completed the questionnaire online. The electronic data sets were used for analysis. Although the survey did ask patients to identify if they were specifically taking rabeprazole (Aciphex), no other specific drug information was collected.

The Online Survey. The survey consisted of two parts, the GTSQ (including the fourth part, described above) and the Gastroesophageal Reflux Disease Symptom Assessment Survey (GSAS) (4). The GSAS, a validated GERD symptom measure, was used to validate the GTSQ and included items on symptom frequency and bother/distress. In particular, the bother/distress subscale of the GSAS was used to validate the GTSQ. Bother/distress is indicated on a 4-point scale ranging from 0 "not at all" to 3 "very much." The distress scale is scored by summing responses across items and dividing by the total

number of nonmissing items ($n_{symptoms}$ = 15) and is scored in this manner as long as 12 or more symptoms are nonmissing, or present. Patients with 4 or more missing symptom scores were assigned a missing GSAS score. Additionally, the Regurgitation/Heartburn (RHB) subscale of the distress score (10) was calculated and used in the validation. The RHB subscale includes 8 items related to heartburn and regurgitation and is computed as the average of the 8 distress scores. If more than 4 of the individual distress scores were missing, the RHB score was considered missing.

Statistical Analysis. The key criterion for deciding if an item belonged to a predefined scale was if its inclusion in the scale resulted in a marked decrement to the internal consistency reliability of the scale, as assessed by changes in Cronbach's coefficient α (11) with the item included versus with the item excluded. The key criterion for assessing whether the scales were well defined was through assessment of the overall reliability of the scale, again assessed by coefficient α. Measures of reliability, including coefficient α, provide an index of the precision of an instrument.

Researchers have developed standards for minimally desired values; coefficient $\alpha \geq 0.70$ are generally considered acceptable for instruments used in group-level comparisons (12). However, the number of items comprising the instrument must be considered. Given the few number of items for several of the subscales, an α of 0.60–0.69 was considered acceptable, an α of 0.70–0.79 good, an α of 0.80–0.89 very good, and an α of 0.90 or higher outstanding. The study design did not allow for evaluation of test–retest reliability.

The following steps were employed in the reliability analyses:

1. Subscale analysis: developed descriptive statistics for each of the subscales corresponding to the dimensions of satisfaction, as well as for the total score.
2. Calculated item to subscale correlations and item to total score correlations (Pearson product moment).
3. Examined whether exclusion of each item from the subscale resulted in a marked increase in Cronbach's α.
4. Calculated Cronbach's α for each finalized subscale (i.e., after elimination of noncontributing items, if applicable) and for the total score.

Validity of the GTSQ scales consisted of assessing the degree to which the constructs measured by this instrument correlated with other indicators of similar/related constructs, with a particular focus on symptom bother/distress, as measured by the bother/distress scale of the GSAS and the RHB distress subscale. Assuming that patients who are more satisfied with their medication may be so because their medication results in fewer symptoms and/or less distress as a result of these symptoms, we compared the satisfaction subscales and total scores with scores of symptom distress obtained from the GSAS. In addition, we would expect the GTSQ scales dealing with symptom relief to be more highly related to the GSAS scores than would be the case for GTSQ scales dealing with other aspects of satisfaction (e.g., ease and convenience).

In this study, the magnitude of correlation coefficients used to assess validity was interpreted in light of guidelines proposed by Cohen (13). Cohen suggested a correlation of 0.10 is small; correlations of 0.30 are moderate (9% common variance) and comparable to a medium effect size in differences between 2 means. A correlation of 0.50 is considered "large" (r^2 = 0.25). In the behavioral sciences, validity coefficients can be as large as 0.60 or higher, with most indices below 0.40 (12).

Subgroup analyses were also performed to see if differences existed between those subjects on rabeprazole and those not on rabeprazole. Item and subscale distributional characteristics of the rabeprazole population were examined and t-tests comparing rabeprazole and non-rabeprazole populations were performed. For the rabeprazole sample, t-tests comparing those taking 1 pill and those taking 2 pills per day were conducted. Additionally, ANOVAs were run comparing people who had been on rabeprazole 1–6 months, 7–12 months, or longer than 12 months. Those who were on rabeprazole less than 1 month were not included in the analyses under the presumption that this was insufficient time to form definitive opinions concerning satisfaction with various aspects of the medication.

RESULTS

Sample Characteristics

The questionnaire was administered to the online panel from September 12–30, 2003. A total of 2511 subjects who reported having a diagnosis of GERD and taking prescription medications for GERD completed surveys. Demographic characteristics of the sample are provided in Table 1. The majority of subjects were women (58.2%), Caucasian (87.4%), married (66.2%), and had at least some college (67.3%). The mean age of the sample was 55.7 years.

Item and Scale Reliability Analyses

There were very few missing data on the GTSQ ($\leq$1.1% for each item, 0.7% for all items). Mean scores across items ranged from 1.44 ($SD = 0.59$) for item O5, "easy to take," to 2.27 ($SD = 1.05$) for item R6, "relieves bloating," on the 1 (Very Satisfied/Strongly Agree) to 5 (Very Dissatisfied/Strongly Disagree) scale (data not shown). Only 3 of the 25 items had a mean score of 2.0 or greater.

Reliability was assessed by examining the descriptive characteristics and Cronbach's α for the subscale and total scores. Descriptive characteristics of the GTSQ scales and total score for the total sample are provided in Table 2. Mean subscale scores ranged from 1.52 ($SD = 0.61$) for "Ease and Convenience" to 1.93 ($SD = 0.80$) for "Specific Symptom Relief." The range of scores for all subscales was 1 to 5. The mean total score for the total sample was 1.80 ($SD = 0.71$) and the range was 1.0 to 4.68 (data for range not shown for scale or total scores).

As shown in Table 2, Cronbach's α for all subscales were at or above 0.90 with the exception of "Ease and Convenience," which had a value of 0.82. Cronbach's α for the total score was 0.98. The exclusion of each item from the subscale was examined to determine if it would result in an increase in Cronbach's α. Results demonstrated that, for all subscales except "Quick and Long-Lasting,"

TABLE 1. SAMPLE DEMOGRAPHIC CHARACTERISTICS

Characteristic (patient-reported)	N *(%) or Mean (SD)*
Sample size	2511
Age (y)	
18–24	24 (0.96)
25–34	117 (4.7)
35–44	389 (15.5)
45–54	671 (26.7)
55–64	636 (25.3)
65–74	432 (17.2)
≥75	242 (9.6)
Mean (SD)	55.7 (13.6)
Gender	
Female	1461 (58.2)
Male	1050 (41.8)
Race	
White, non-Hispanic	2195 (87.4)
Black, non-Hispanic	165 (6.6)
Other, non-Hispanic	73 (2.9)
Hispanic	78 (3.1)
Education	
Less than high school	174 (6.9)
High school	648 (25.8)
Some college	1049 (41.8)
Bachelor's degree or higher	640 (25.5)
Marital status	
Married	1661 (66.2)
Single (never married)	228 (9.1)
Divorced	389 (15.5)
Widowed	193 (7.7)
Separated	40 (1.6)
Dual income household	
Yes	1430 (57.0)
No	1081 (43.1)
Head of household	
Yes	2271 (90.4)
No	240 (9.6)
Household size	
1	457 (18.2)
2	1224 (48.8)
3	403 (16.1)
4	263 (10.5)
5	103 (4.1)
≥6	61 (2.4)
Housing type	
Single-family house detached	1816 (72.3)
Single-family house attached	142 (5.7)
Apartment	224 (8.9)
Condominium or co-op	82 (3.3)
College dormitory	2 (.1)
Manufactured or mobile home	197 (7.9)
Other	48 (1.9)
Region of residence	
Northeast	359 (14.3)
Midwest	733 (29.2)
South	871 (34.7)
West	548 (21.8)
Ownership status of living quarters	
Own	2009 (80.0)
Rent	441 (17.6)
Do not pay for housing	61 (2.4)
Employment status	
Employed	1138 (45.3)
Homemaker	197 (7.9)
Unemployed, seeking work	74 (3.0)
Retired	699 (27.8)
Disabled	313 (12.5)
Other	90 (3.6)
Household income ($)	
0–24,999	609 (24.3)
25,000–49,999	818 (32.6)
50,000–74,999	591 (23.5)
75,000–99,999	278 (11.1)
≥100,000	215 (8.6)

eliminating each item resulted in a decrease in Cronbach's α for the subscale. Item O8, "Important to Provide Fast Relief," from the "Quick and Long-Lasting" subscale was the only item that when eliminated, resulted in an increase in Cronbach's α for a subscale. The Cronbach's α went from 0.904 to 0.927, a difference of 0.023. This improvement in α was deemed to be minimal; therefore, the item was not eliminated as a result of this analysis.

Validity Analyses

Validity was assessed by comparing the GTSQ subscale and total scores with the RHB subscale and distress scores of the GSAS. These correlations are presented in the last 2 columns of Table 2. Correlations with the RHB scale ranged from 0.25 ("Ease and Convenience") to 0.42 ("Specific Symptom Relief"). The correlation of the RHB with the total score was 0.43. Correlations with the distress score of the GSAS ranged from 0.28 ("Ease and Convenience") to 0.47 ("Specific Symptom Relief"). The correlation of the distress score with the total score was 0.47.

Relation Among GTSQ Subscales

The correlations among the 7 subscales of the GTSQ are shown in Table 3. The subscales are all significantly and highly intercorrelated, with the Ease and Convenience subscale generally having the lowest level of correlations with other scales. The highest correlation with the Overall Satisfaction subscale was for the Quick and Long Lasting subscale.

Subgroup Analyses

As mentioned in the Methods section, a fourth section of the GTSQ was added to determine if the subject was currently taking rabeprazole as opposed to another prescription medication to treat their GERD, and if so, how many pills they were taking daily and how long they had been taking the drug. Differences in mean GTSQ scores for the rabeprazole and non-rabeprazol subgroups were examined. Subscale and total scores for those on rabeprazole were lower (there was greater satisfaction)

TABLE 2. DESCRIPTIVE CHARACTERISTICS OF GTSQ SUBSCALES AND TOTAL SCORE AND CORRELATIONS WITH GSAS RHB AND DISTRESS SCALES

GTSQ Subscale/Total Score	*Nonmissing*	N *(%) missing*	*Mean* (SD)*	*Cronbach's α*	*Correlation† with RHB*	*Correlation† with distress*
Specific symptom relief scale (R1–R6)	2152	359 (14.3)	1.93 (0.80)	0.92	0.41988	0.466
Night-time relief scale (R8, R10, Q4)	2434	77 (3.1)	1.76 (0.84)	0.92	0.41304	0.427
Daytime relief scale (R9)	2462	49 (2.0)	1.68 (0.79)	N/A	0.33304	0.355
Quick and long-lasting scale (R7, R11–R13, O1, O8)	2488	23 (0.9)	1.86 (0.76)	0.90	0.38965	0.405
HRQL (Q1, Q2, Q3)	2283	228 (9.1)	1.86 (0.84)	0.92	0.40145	0.434
Ease and convenience (O5, O6)	2486	25 (1.0)	1.52 (0.61)	0.82	0.25206	0.277
Overall satisfaction (O2, O3, O4, O7)	2500	11 (0.4)	1.72 (0.81)	0.95	0.39552	0.420
Total score	2449	62 (2.5)	1.80 (0.71)	0.98	0.43193	0.465

*Lower scores indicate greater satisfaction with medication (1 = Very satisfied/Strongly agree, 2 = Satisfied/Agree, 3 = Neither satisfied nor dissatisfied/Neither agree nor disagree, 4 = Dissatisfied/Disagree, 5 = Very dissatisfied/Strongly disagree).
†All correlations significant at $P < .0001$.
Abbreviations: HRQOL, health-related quality of life; RHB, Regurgitation/Heartburn.

for all subscales except HRQL (Table 4). The differences in means ranged from 0.077 for "Specific Symptom Relief" to −0.044 for "HRQL." However, none of these differences were found to be statistically significant. The mean total score for the rabeprazole group was 1.765 and for the non-rabeprazole group was 1.804, a difference of 0.039. This same pattern was found for the GSAS distress and RHB scores; rabeprazole patients reported less severe symptoms, but the differences were not statistically significant.

For the rabeprazole population, scores were lower (there was greater satisfaction) for those taking 1 pill versus those taking 2 pills per day for all subscale scores and the total score. These differences were significant ($P < .05$) for all scores except "Daytime Relief" and "Quick and Long-Lasting" (Table 5).

Last, analyses were done within the rabeprazole subgroup to compare people who had been on rabeprazole for different periods of time. Specifically, ANOVAs were run comparing people who had been on rabeprazole 1–6 months, 7–12 months, or longer than 12 months. These results, shown in Table 6, indicate a trend for greater satisfaction with more time on the drug. This difference was significant for two of the scales: "Daytime Relief" and "HRQL." A similar analysis was performed on the GSAS distress scores; no significant difference was found between groups on this measure.

DISCUSSION

The current study assessed the psychometric properties of the newly developed GTSQ in a representative U.S. sample of 2511 subjects with GERD taking prescription medications. Approximately 11% of the sample was taking rabeprazole at the time of the interview. The study found the GTSQ to have good reliability and validity.

The reliability analyses showed that the reliability of the GTSQ was very good, with Cronbach's α for the subscales ranging from 0.82 for "Ease and Convenience" to 0.95 for "Overall Satisfaction." The Cronbach's α for the total score was outstanding (0.98). The examination of Cronbach's α after eliminating each item showed that inclusion of all items except 1 increased the overall Cronbach's α of the subscales. Eliminating item O8, "Important to Provide Fast Relief," resulted in an increase in Cronbach's α of 0.023. Because this increase was relatively small, it was decided to maintain this item for purposes of the analyses performed in this manuscript. However, in future applications of the GTSQ, we would recommend eliminating this item both because of the small decrease in α

TABLE 3. CORRELATIONS* AMONG GTSQ SUBSCALES

GTSQ Subscale/Total Score	*Night-time relief*	*Daytime relief*	*Quick and long lasting*	*HRQL*	*Ease and convenience*	*Overall*
Specific symptom relief scale	0.83	0.79	0.86	0.80	0.61	0.81
Night-time relief scale		0.75	0.82	0.80	0.59	0.82
Daytime relief scale			0.80	0.74	0.58	0.77
Quick and long-lasting scale				0.80	0.66	0.85
HRQL					0.60	0.79
Ease and convenience						0.71

*All correlations significant at $P < .0001$.

TABLE 4. DIFFERENCES BETWEEN SUBGROUPS IN GTSQ SUBSCALE AND TOTAL SCORES AND GSAS DISTRESS AND RHB SCALE SCORES

Subscale	*Rabeprazole Mean* (n = *266)*	*Non-rabeprazole Mean* (n = *2245)*	*Difference*	P-*Value*
GTSQ Specific Symptom Relief Scale (R1–R6)	1.860	1.937	0.077	.173
GTSQ Night-time Relief Scale (R8 R10 Q4)	1.726	1.765	0.040	.474
GTSQ Daytime Relief Scale (R9)	1.627	1.685	0.058	.261
GTSQ Quick and Long-Lasting Scale (R7 R11–R13 O1 O8)	1.799	1.873	0.074	.136
GTSQ HRQL (Q1 Q2 Q3)	1.899	1.855	−0.044	.440
GTSQ Ease and Convenience (O5 O6)	1.474	1.524	0.051	.202
GTSQ Overall Satisfaction (O2 O3 O4 O7)	1.708	1.720	0.012	.818
Total score	1.765	1.804	0.039	
GSAS Distress Score*	0.380	0.397	−0.017	.571
GSAS RHB Score*	0.371	0.385	−0.014	.678

*Higher scores on GSAS correspond to more distress caused by symptoms.

and because the item itself does not assess the evaluative aspects of taking the medication, but instead focuses on the underlying belief system concerning impacts of taking the medication (1).

Validity analyses indicated that the GTSQ subscale and total score were moderately correlated with the RHB and distress scores of the GSAS. As expected, given that all 3 scores assess aspects of symptom relief, correlations were highest with the "Specific Symptom Relief" subscale of the GTSQ and these two GSAS measures. Similarly, it is not surprising that correlations were lowest for the "Ease and Convenience" subscale of the GTSQ and these 2 GSAS measures, because ease and convenience of taking GERD medication would not be expected to be closely related to the bother and distress that subjects experience from GERD symptoms.

GTSQ item responses (data not shown) indicated that patients were generally very satisfied or satisfied with various aspects of their GERD medication, with the majority of subjects giving each item a score of 1 (very satisfied/strongly agree) or 2 (satisfied/agree). "Easy to Take" was endorsed most frequently and "Relieves Bloating" was endorsed least frequently.

The mean total GTSQ score was 1.80 ($SD = 0.71$) for the total sample, which suggests that, overall, subjects were satisfied with their GERD medication. Mean subscale scores for the total sample indicated that subjects were most satisfied with the "Ease and Convenience" (1.52; $SD = 0.61$) of their medication, followed by "Daytime Relief" (1.68; $SD = 0.79$), "Overall Satisfaction" (1.72; $SD = 0.81$), "Nighttime Relief" (1.76; $SD = 0.84$), "Quick and Long-Lasting" (1.86; $SD = 0.76$), "HRQL" (1.86; $SD = 0.84$), and "Specific Symptom Relief" (1.93; $SD = 0.80$). The fact that the items and the resulting subscale and total scores were skewed in the direction of being satisfied with medication is not unusual with satisfaction with medication instruments (e.g., 6, 8, 14, 15). In addition, the subscales themselves were highly intercorrelated among themselves. Again, this is not unusual with satisfaction with medication measures (14). It is important to keep in mind the conceptual differences among the scales. For example, quick and long lasting relief likely leads to overall satisfaction, and hence a high correlation between the 2 respective subscales, but this does not mean they are measuring the same concept. Finally, the assessment of satisfaction essentially involves the subject's evaluation of the particular aspect of the medication being covered by the item (5), and hence all satisfaction items share this evaluative component, and therefore are likely to be correlated with one another.

TABLE 5. RABEPRAZOLE 1 PILL VERSUS 2 PILLS

Subscale	*1-Pill mean* (n = *191)*	*2-Pill mean* (n = *29)*	*Difference*	P-*value*
GTSQ Specific Symptom Relief Scale (R1–R6)	1.7813	2.1868	−0.405	.0207
GTSQ Night-time Relief Scale (R8 R10 Q4)	1.6667	2.0575	−0.391	.0191
GTSQ Daytime Relief Scale (R9)	1.5632	1.7931	−0.23	.1488
GTSQ Quick and Long-Lasting Scale (R7 R11–R13 O1 O8)	1.7365	2.023	−0.286	.0596
GTSQ HRQL (Q1 Q2 Q3)	1.839	2.2436	−0.405	.0319
GTSQ Ease and Convenience (O5 O6)	1.4179	1.7241	−0.306	.0089
GTSQ Overall Satisfaction (O2 O3 O4 O7)	1.641	2.0345	−0.393	.0146
Total score	1.7046	2.0562	−0.352	.0207

Abbreviations: GTSQ, Gastroesophageal Reflux Disease Treatment Satisfaction Questionnaire; HRQOL, health-related quality of life.

TABLE 6. GTSQ SCALES BY LENGTH OF TIME ON RABEPRAZOLE

GTSQ Scales	*Duration on Rabeprazole*				
	1–6 months, mean (SD)	*7 months–1 year, mean (SD)*	*More than 1 year, mean (SD)*	*Overall* F *value*	*Significant post hoc tests*
GTSQ Specific Symptom Relief Scale (R1–R6)	2.00 (0.80)	1.84 (0.83)	1.78 (0.70)	1.5	
GTSQ Night-time Relief Scale (R8 R10 Q4)	1.89 (0.88)	1.69 (0.81)	1.64 (0.76)	1.9	
GTSQ Daytime Relief Scale (R9)	1.84 (0.89)	1.64 (0.81)	1.50 (0.72)	3.7*	2*
GTSQ Quick and Long-Lasting Scale (R7 R11–R13 O1 O8)	1.91 (0.76)	1.80 (0.80)	1.74 (0.72)	1.0	
GTSQ HRQL (Q1 Q2 Q3)	2.18 (0.93)	1.79 (0.77)	1.79 (0.85)	4.1*	2*
GTSQ Ease and Convenience (O5 O6)	1.62 (0.65)	1.43 (0.57)	1.42 (0.58)	2.2	
GTSQ Overall Satisfaction (O2 O3 O4 O7)	1.88 (0.90)	1.68 (0.76)	1.62 (0.73)	2.2	
Total score	1.93 (0.76)	1.74 (0.71)	1.68 (0.68)	2.4	

Pairwise comparisons between means were performed using Scheffe's test of multiple comparisons.
1* = (1–6 months vs. 7 months–1 year), 2* = (1–6 months vs. More than 1 year), 3* = (7 months–1 year vs. More than 1 year).
***<0.001;l **<0.01, *<0.05.
Abbreviations: GTSQ, Gastroesophageal Reflux Disease Treatment Satisfaction Questionnaire; HRQOL, health-related quality of life.

The rabeprazole population was slightly more satisfied with their medication, as indicated by the slightly lower GTSQ total score, than the population of patients taking other prescription medications; however; this difference was of small magnitude and not found to be statistically significant. Similarly, subscale scores for the rabeprazole group tended to be slightly lower than the non-rabeprazole group, although not at significant levels. Those on rabeprazole for a longer period of time tended to be more satisfied with their treatment. This difference was found to be significant for both the "Daytime Relief" and "HRQL" subscales.

Another treatment satisfaction questionnaire was recently described in the literature (16). There is some overlap in the scales described in that instrument and the GTSQ. Specifically, the Treatment Satisfaction Questionnaire for GERD (TSQ-G) contains scales assessing symptom relief, satisfaction, provider relationships, cost, treatment expectations, bother associated with medication, and flexibility with dosing. The TSQ-G assesses both medication and treatment satisfaction, whereas the GTSQ is focused specifically on satisfaction with the medication (see Shikiar and Rentz [5] for a distinction among satisfaction concepts). As such, the GTSQ "drills deeper" into aspects of symptom relief by assessing different types of symptom relief, as well as having scales corresponding to the TSQ-G's satisfaction scale (i.e., the overall satisfaction scale of the GTSQ). However, even though at the surface, the "Ease and Convenience" scale of the GTSQ appears to be similar to the flexibility with dosing and the bother scales of the TSQ-G, the reference point for the GTSQ's items is always the respondent's own medication (e.g., "Taking this medication is convenient"). For the TSQ-G, the items sometimes reference the patient's own medication (e.g., "I worry about the side effects I have with my medication") and sometimes reference GERD medications in general (e.g., "I don't like taking medications every day"). Hence, although each measure has its own distinct value, having been designed specifically with the goal in mind, we believe the GTSQ is appropriate for assessing satisfaction with the specific GERD medication that the patient is taking.

There are several limitations to this study, some of which are inherent in a web-based survey of the type undertaken for this manuscript. Specifically, we relied on self-reports without independent confirmation for determining whether the subjects indeed met the inclusion criteria to participate in the study. In addition, we cannot assess the extent to which the sample completing the GTSQ is truly representative of all GERD patients taking prescription medications. In addition, the GTSQ was developed and validated on the same sample of subjects. Ideally, one would like to have a separate validation sample for the purpose of selecting and eliminating items; however, in the present case none of the items appreciably detracted from the reliability of the scale for which it was designed, and all of the scales had more than adequate reliability coefficients; hence, it appears that the present study did not suffer from lack of an independent validation sample.

In conclusion, the GTSQ was found to have good internal consistency reliability and adequate validity, supporting its use to assess satisfaction with medication in patients with GERD. Overall, the sample was found to be satisfied with their GERD medication. The rabeprazole sample tended to be more satisfied with their GERD treatment compared to the rest of the sample, but the differences found were small and not statistically significant. Those receiving rabeprazole for a longer period of time tended to be more satisfied with their medication than those who had been on rabeprazole for a shorter duration.

APPENDIX A: GERD TREATMENT SATISFACTION QUESTIONNAIRE (GTSQ)

Instructions: We would like to ask you some questions about how satisfied or dissatisfied you are with the prescription medication you are using to treat your heartburn or acid reflux symptoms. Please circle the answer that best describes your satisfaction with the following.

Part 1. Symptom Relief

For this first set of questions, please circle the answer that best describes how satisfied or dissatisfied you are with how well your *prescription* medication helps to relieve your heartburn or acid reflux symptoms. *If you did not have the specific symptom, please circle number 9 (never had).*

How satisfied are you with how well your prescription medication . . .		*Very satisfied*	*satisfied*	*Neither satisfied nor dissatisfied*	*Dissatisfied*	*Very dissatisfied*	*Never had this symptom*
R-1.	. . . gets rid of the burning or acid feeling inside your chest	1	2	3	4	5	9
R-2.	. . . relieves the feeling that you have to burp or belch frequently	1	2	3	4	5	9
R-3.	. . . gets rid of the sour taste in your mouth	1	2	3	4	5	9
R-4.	. . . relieves the feeling of pain or pressure inside your stomach or chest	1	2	3	4	5	9
R-5.	. . . gets rid of the fluid or food that comes back into your throat or mouth	1	2	3	4	5	9
R-6.	. . . relieves bloating	1	2	3	4	5	9
R-7.	. . . provides fast relief	1	2	3	4	5	9
R-8.	. . . prevents your symptoms from waking you during the night	1	2	3	4	5	9
R-9.	. . . relieves your symptoms during the day	1	2	3	4	5	9
R-10.	. . . relieves your symptoms at night	1	2	3	4	5	9
R-11.	. . . provides relief following the first dose of the day	1	2	3	4	5	
R-12.	. . . provides 24 hour relief of symptoms	1	2	3	4	5	
R-13.	. . . provides both relief following the first dose of the day and 24 hour relief of symptoms	1	2	3	4	5	

Part 2. Other Impacts of Medication

Now, please circle the answer that best describes how satisfied or dissatisfied you are with the impact of your *prescription* medication on your ability to engage in some activities of your daily life. *If this had not been a problem for you, circle number 9 (Never had this problem).*

How satisfied are you with how your prescription medication . . .		*Very satisfied*	*Satisfied*	*Neither satisfied nor dissatisfied*	*Dissatisfied*	*Very dissatisfied*	*Never had this problem*
Q-1.	. . . has allowed you to have freedom to do what you want	1	2	3	4	5	9
Q-2.	. . . has allowed you to enjoy social activities with family and friends	1	2	3	4	5	9
Q-3.	. . . has allowed you to enjoy food and drinks that you like	1	2	3	4	5	9
Q-4.	. . . has allowed you to sleep better	1	2	3	4	5	9

Part 3. Overall Satisfaction

Please tell us *how you feel overall* about your heartburn or acid reflux *prescription* medication by circling the answer that best describes how much you *agree or disagree* with each of the following statements.

		Strongly agree	*Agree*	*Neither agree nor disagree*	*Disagree*	*Strongly disagree*
O-1.	I am *satisfied* with how quickly my medication works.	1	2	3	4	5
O-2.	Overall, I am *satisfied* with how well this medication has controlled my heartburn or acid reflux.	1	2	3	4	5
O-3.	I am *confident* that this medication will make me feel better.	1	2	3	4	5
O-4.	I am *confident* that this medication will continue to work.	1	2	3	4	5
O-5.	This medication is *easy to take*.	1	2	3	4	5
O-6.	Taking this medication is *convenient.*	1	2	3	4	5
O-7	I *will continue to use* this medication for controlling my heartburn or acid reflux.	1	2	3	4	5
O-8.	It is important to me that my medication provides fast relief.	1	2	3	4	5

REFERENCES

1. Locke GR 3rd, Talley NJ, Fett SL, Zinsmeister AR, Melton LJ 3rd: Prevalence and clinical spectrum of gastroesophageal reflux: a population-based study in Olmsted County, Minnesota. Gastroenterology 112:1448–1456, 1997
2. Farup C, Kleinman L, Sloan S, *et al.*: The impact of nocturnal symptoms associated with gastroesophageal reflux disease on health-related quality of life. Arch Intern Med 161:45–52, 2001
3. Vigneri S, Termini R, Leandro G, *et al.*: A comparison of five maintenance therapies for reflux esophagitis. N Engl J Med 333:1106–1110, 1995
4. Rothman M, Farup C, Stewart W, Helbers L, Zeldis J: Symptoms associated with gastroesophageal reflux disease: Development of a questionnaire for use in clinical trials. Dig Dis Sci 46:1540–1549, 2001
5. Shikiar R, Rentz AM: Satisfaction with medication: an overview of conceptual, methodological, and regulatory issues. Value in Health 7:204–215, 2004
6. Shikiar R, Rentz AM, Barone J, Duncanson F, Katz E: Patient satisfaction with ofloxacin (F) and polymyxin B/Neomycin/Hydrocortisone in the treatment of otitis externa: results from two randomized clinical trials. Journal of Managed Care Medicine 6:24–27, 2002
7. Thompson JW, Bost J, Ahmed F, Ingalls CE, Sennett C: The NCQA's quality compass: evaluating managed care in the United States. Health Aff (Millwood) 17:152–158, 1998
8. Weaver M, Patrick DL, Markson LE, Martin D, Frederic I, Berger M: Issues in the measurement of satisfaction with treatment. Am J Manag Care 3:579–594, 1997
9. Atkinson MJ, Sinha A, Hass SL, *et al.*: Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication, using a national panel study of chronic disease. Health and Qual Life Outcomes 2:12, 2004
10. Damiano A, Siddique R, Xiao X, Johanson J, Sloan S: Reductions in symptom distress reported by patients with moderately severe, nonerosive gastroesophageal reflux disease treated with rabeprazole. Dig Dis Sci 2003:657–662, 2003
11. Cronbach L: Coefficient alpha and the internal structure of tests. Psychometrika 16:297–334, 1951
12. Nunnally JC, Bernstein IH: Psychometric Theory, 3rd ed. New York, McGraw-Hill, 1994
13. Cohen J: Statistical Power Analysis for the Behavioral Sciences, 2nd ed. Hillsdale, NJ, Lawrence Erlbaum Associates, 1988
14. Atkinson MJ, Sinha A, Hass SL, *et al.*: Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease. Health and Quality of Life Outcomes 2:1–13, 2004
15. Revicki DA: Patient assessment of treatment satisfaction: methods and practical issues. Gut 53(Suppl 4):iv4–44, 2004
16. Coyne KS, Wiklund I, Schmier J, Halling K, Degl' Innocenti A, Revicki D. Development and validation of a disease-specific treatment satisfaction questionnaire for gastroesophageal reflux disease. Aliment Pharmacol Ther 18:907–915, 2003